Europe Economics

The Economic, Social and Innovation Value Novartis Brings to the UK

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Executive Summary

This report, commissioned from Europe Economics by Novartis UK, is about the range of economic, social and innovation impacts Novartis has upon the UK. This covers the activities and investment of Novartis UK entities, such as Novartis Pharmaceuticals and Oncology, Sandoz (the generics arm), Novartis Technical Operations (manufacturing) and recent acquisitions Advanced Accelerator Applications (AAA) and Novartis Gene Therapies (formally AveXis). It also includes the extensive role which other Novartis entities based outside the UK have through their spending on and investment in UK suppliers.

A traditional economic impact study will assess a firm's economic footprint by measuring its total spending in the UK economy, then applying what economists call "multipliers" to allow for the ripple effects as purchases from suppliers, salaries paid to workers and returns paid to investors allow those suppliers, workers and investors to make their own additional purchases. Such models have value and provide important insights, and in Chapter 1 we report the results of such modelling for Novartis in the UK in 2019. These impacts are estimated at £1.7bn in GDP contribution, generating £0.64bn of tax for public spending, and supporting jobs for 22 thousand workers, as well as an estimated £0.7bn dividend to UK shareholders in 2019.

However, for a pharmaceuticals company, and for Novartis in particular, analysis of its economic footprint provides only part of the story — partly because behind these aggregated economic figures there are all kinds of qualitative and quantitative impacts that the aggregate numbers do not fully communicate or quantify, but also because Novartis generates many forms of value to the economy that are not captured either by the firm itself or its suppliers. In this report we have sought to identify, explore and vivify these other "channels of value".

The most important such impact any pharmaceuticals company has upon an economy is the ways its medicines have an impact on patients' lives. This generates value in a number of ways – the huge gains for human welfare such improved health outcomes represent; cost efficiencies for healthcare systems; and wider gains to society for example through interrupting the spread of infectious diseases. There are also measurable impacts on economic activity, contributing to the evidence that healthcare expenditure generates wealth on both the demand side as well as the supplier side. Good health outcomes are likely to deliver a higher economic output, if treatments can enable more people to engage in economic activity. In Chapters 2 and 3 we report the results of the model of the economic impacts of such potential effects, which are estimated at just below £9bn in 2019 across Novartis and innovative medicines and generics portfolios. This estimate, based on just a sample of Novartis and Sandoz medicines, serves to illustrate the tremendous potential social impact of Novartis UK. The extensive Novartis pipeline – ranked number 1 in terms of value creation and with more than 160 products in clinical development – offers some promise that this type of impact will continue to be realised long into the future.

As well as its research and development of new patented medicines, Novartis has a generics arm Sandoz which is devoted to the production and supply of off-patent medicines: generics and biosimilars. Sandoz is the largest supplier of generic medicines in Europe with a market share of around 11.5 per cent.[1] As the firm that launched the first biosimilar in Europe (in 2006) Sandoz is a market-leader in the production of alternative versions of these more complex medicines. Off-patent medicines supply bids down prices: for generics, a typical price reduction is around 80 per cent relative to when the medicine was still on-patent. Such price reductions save money for the NHS. In Chapter 3 we estimate that generics medicines as a whole saved

[1] Source: IQVIA PADDS Apr'19 Value: @TGT'19.

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some £23.8bn for the NHS in 2019 when compared to innovator prices. If we consider the medicines Sandoz itself supplied to the NHS in 2019, the saving is estimated at around £1.12bn.

Novartis invests in technology and equipment needed for the development and manufacture of medicines, and in its research and development pipeline, in both cases boosting the level of economic output. In 2019 Novartis spent around £169m on R&D activities and infrastructure in the UK through its various suppliers. But, in addition, certain classes of investment by Novartis tend to stimulate not merely the *level* of output, but also accelerate the rate at which knowledge diffuses across the economy in the future, enhancing the *rate* of economic growth. We explore these investments in Chapter 4, including those by the Novartis Venture Fund and in NHS data capabilities and access. As part of its commitment to innovation and future value creation we also explore Novartis investment in Advanced Therapy Platforms (ATPs), including its acquisitions of companies such as AAA and AveXis (now Novartis Gene Therapies).

In Chapter 5 we explore ways in which the nature of firms in the life sciences sector means their activities permeate other sectors of the economy. As the leading industry sponsor of clinical trials in the UK over the past 10 years (in 2019 Novartis sponsored 146 clinical trials) it is likely that Novartis creates amongst the largest such spillovers for the UK, helping to push the frontiers of what is possible in the provision of treatments to patients. The COVID-19 pandemic and lockdowns in the UK however created significant disruption for clinical trials and patients in 2020, with less than a third of Novartis trial sites open to patient recruitment by September 2020. These delays impact global perceptions of the attractiveness of the UK health system as a location for clinical trials, and will have affected the economic impact from clinical trials in 2020.

Trial transparency allows data collected from studies to be re-analysed by other researchers, which could lead to new insights that may not be gained otherwise. Novartis is in the process of increasing its potential spillovers by sharing its clinical trial data with innovative research institutions dedicated to using machine learning that can help to identify novel medical insights from the data. Its use of digital trials involving remote follow-ups have addressed some of the disruption caused by COVID-19, and its partnership with Genomics England seeks to further the understanding of the disease through clinical study of the genes of COVID-19 patients.

Aggregate economic footprint data can disguise the extent to which certain firms facilitate and contribute to adding economic value by collaborating with other firms. In Chapter 6 we explore Novartis' contribution to a broad collaborative ecosystem. This network fosters a dynamic multi-disciplinary knowledge-sharing environment, comprised of the NHS, innovative medical technology start-ups, research institutions, and life sciences firms. The joint ventures into big data analytics – such as with the Oxford Big Data Institute and the AI Innovation Lab with Microsoft – promise to uncover information hidden in pre-existing datasets and ones yet to be created. Novartis is particularly active in joint working partnerships with the NHS, contributing more than 12 times the industry average number of JWPs. Through these partnerships and other collaborations, there are opportunities for knowledge transfer between partners, both directly through learning different components of the life sciences field, and tacitly through interaction with partners that builds understanding and trust. A key example of this is Novartis collaboration for population health management strategies with NHS England aligned to the NHS Long Term Plan.

In Chapter 7 we explore how Novartis is committed to advancing environmental and social goals and the benefits of ESG (environmental, social and governance) accountability across firms. This includes a €1.85bn sustainability-linked bond based on targets related to improving access to medicines and addressing global health challenges. In particular Novartis recognises and is transparent about its environmental impact and has taken steps to calculate and reduce its use of water, energy and materials. In 2019 it measured its environmental impact on the UK at -£54m, covering direct, indirect and induced impacts across the economy. It has set ambitious targets and is progressing towards them, such as being carbon neutral across its value chain (Scope 1,2 and 3 emission) by 2030; reducing waste disposal by half by 2025 and being fully plastics

neutral by 2030; and being water neutral in all areas by 2030. This is consistent with the pace of the UK's (including the NHS') move to reduce carbon emissions. It is also embracing a much wider vision of environmental responsibility that includes projects, goals and targets across a range of areas such as renewable energy, green manufacturing, single-plastics use and leadership across its supply chain. For example, the recent announcement of six virtual power purchase agreements (VPPAs) expected to add more than 275 megawatts of clean power to the electrical grid, and the launch of more environmentally sustainable dry powder inhalers producing 25 times less CO2 a day than pressure metered dose inhalers.

In Chapter 8 we consider Novartis human capital. As a high-skill sector with high pay productivity, pharmaceuticals and life sciences firms make a comparatively larger contribution to gross domestic product than other sectors. In 2019 Novartis supported just over 22,000 jobs across the economy, with 1,284 direct employees. The wide variety of labour requirements in the sector offers a multitude of opportunities for human capital attainment, through apprenticeships and graduate training, to on-the-job training. Novartis had over 30 students in various internships and 32 apprentice positions in 2019, and implemented a number of other training initiatives for its employees such as the "Learn 100 Campaign" to support employees in investing 100 hours (5 per cent) of their working time in learning, and providing 260 hours of personal one-to-one coaching during the pandemic. It is estimated that in 2019 the accumulated training hours during tenure at Novartis created an incremental contribution to future salaries for Novartis employees of around £1.6m. Novartis also demonstrates its commitment to developing human capital through hosting speaker events, supporting youth leadership and through its collaboration with universities. Between 2014 and 2019 Novartis published 869 studies jointly with UK academics at 288 institutions, and invested around £15m across 67 universities and institutions. Novartis is committed to equality and diversity in the workplace – in 2020 42 per cent of management roles at Novartis UK were filled by women, and there was a median pay gap of over 11 per cent in favour of women in 2019.

Whilst this report focuses on the impact Novartis had in the UK in 2019, we cannot ignore the extraordinary changes that have occurred during 2020 as a result of the COVID-19 pandemic. The impacts of the disease and containment measures have been felt at a global, national and individual level. Our report highlights the role of the life sciences industry in managing the pandemic and supporting the economy, and the specific contributions Novartis continues to make in the context of COVID-19 across all areas of its business. In particular is Novartis support for the NHS, for example through maintaining medicines supply and developing digital solutions in a variety of areas. At the beginning of 2020 the UK also left the EU, and as the UK prepares for the end of the transition period in December 2020, Novartis is again working with the Department of Health and Social Care and other stakeholders to minimise disruption to the supply of medicines.

Introduction

Novartis is a leading pharmaceuticals company harnessing advanced therapy platforms and data science that strives to discover new ways to improve health outcomes for our populations. The company uses innovation to help address some of society's most challenging healthcare needs by discovering new ways to fight diseases and deliver treatments for patients. Headquartered in Switzerland and with a significant presence in the UK, Novartis has a material impact on the economy and society of the UK.

This report presents Europe Economics' analysis of the economic, social and innovation value that Novartis brings to the UK. We examine Novartis activities in 2019 – updating from our 2018 report – and also look further into 2020 and beyond at Novartis contributions during the COVID-19 pandemic and its continuing work in that area, its environmental sustainability and its pipeline. We consider the wide range of Novartis activities, and assess how these add value to the UK and the magnitude of this value using the following approaches:

- Identifying forms of value from published literature. We researched the economic theory underpinning the various forms of value that Novartis brings by reviewing economic journal articles, government and industry reports and emerging (grey) literature. We analysed the relevance of the sources according to our own knowledge of economic theory and the nature of the source, placing the most weight on journal articles.
- Quantifying Novartis value by linking facts and figures with economic theory. One approach to quantification entailed linking information and statistics about Novartis activities to the economic theory. We gathered this information through a series of interviews with Novartis personnel across the various areas of activity, and through reviewing company reports and corporate documents.
- Quantifying value by developing models. The second approach to quantification entailed developing numerical models to apply estimates of value from the literature to Novartis data.

The report analyses Novartis value across eight key channels:

1. Creating economic activity across the UK economy.
2. Impacting lives through health outcomes.
3. Generating value for the NHS through its generics and biosimilars activity.
4. Investing in the future of life sciences.
5. Innovating across a range of areas.
6. Creating a collaborative ecosystem.
7. Advancing environmental and social goals.
8. Generating a skilled UK workforce.

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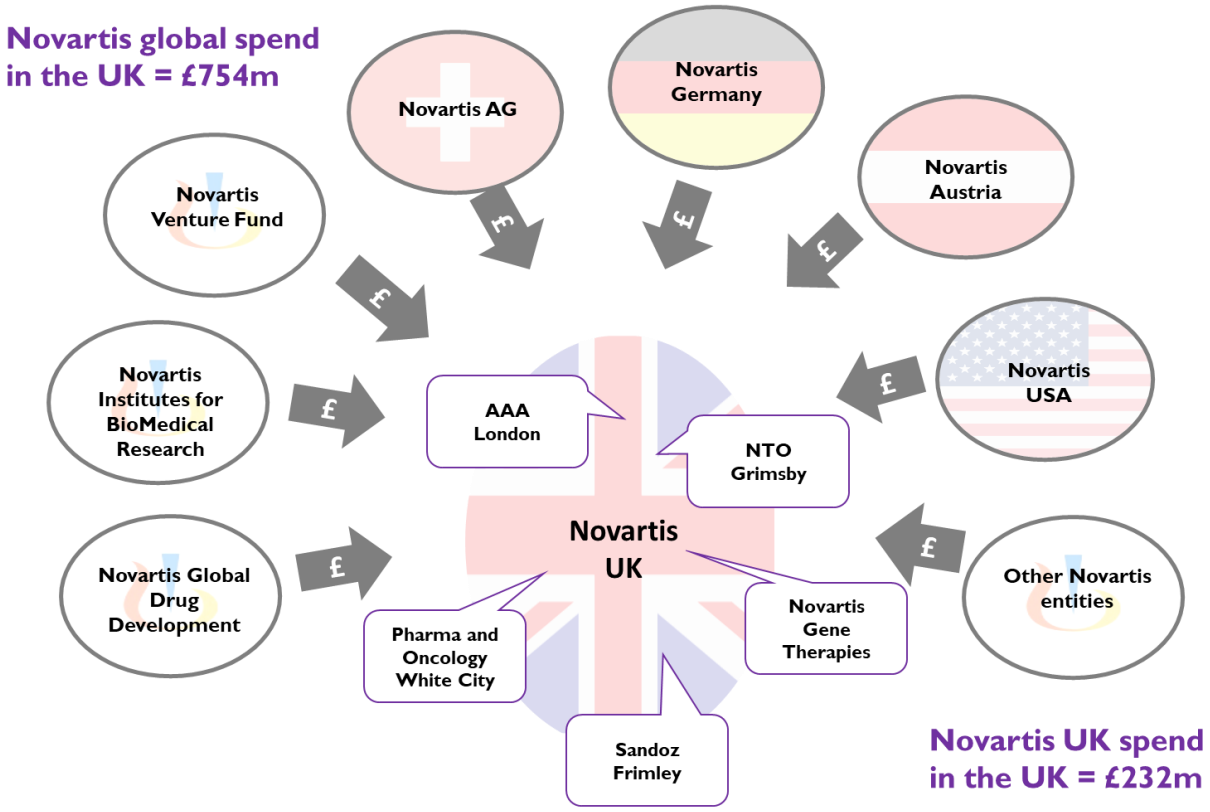
1 Creating Economic Activity

1.1 Novartis UK

Novartis is a multinational life sciences and pharmaceutical company with headquarters in Basel, Switzerland. Novartis has a strong presence in the UK, developing, manufacturing and marketing a broad range of healthcare products. It provides treatments and solutions to improve health outcomes within multiple disease areas including oncology, cardiology, respiratory, neuroscience, immunology and ophthalmology, as well as a wide range of generic and biosimilar medicines across many disease areas. In 2019 Novartis UK had a turnover of approximately £0.97bn[2], employed 1,284 people across four sites in England,[3] and paid out an estimated £0.7bn in dividends to UK shareholders.[4] Novartis UK consists of a number of sites, namely pharmaceuticals and oncology headquartered at White City; its generics arm Sandoz in Frimley; its manufacturing site Novartis Technical Operations (NTO) at Grimsby; and its recent acquisitions AAA (Advanced Accelerator Applications) and Novartis Gene Therapies (formally AveXis). Novartis entities based outside the UK (e.g. Novartis AG in Switzerland, Novartis Institutes for BioMedical Research (NIBR), Novartis Venture Fund, and national Novartis firms based in other countries) also have a large spending footprint in the UK: around 76 per cent of Novartis expenditure in the UK stems from such non-UK Novartis entities, with these entities accounting for all of the third party manufacturing expenditure in the UK (the largest expenditure category).[5] The diagram below illustrates the structure of Novartis UK and the expenditure inflows from abroad.

[2] Novartis "Data on File. Ref 001".
[3] Novartis (2020) "2019 FES impact valuation results UK".
[4] Europe Economics analysis of Novartis share ownership and dividend values based on Novartis "Data on File. Ref 011".
[5] Contract manufacturing refers to suppliers contracted by Novartis to manufacture Novartis medicines.

Figure 1: Novartis UK and external spending inflows



Novartis works in partnership with the NHS, academic institutions and other organisations and suppliers to optimise patient outcomes and support future development within the Life Sciences sector. It invests hundreds of millions of pounds in research and development in the UK, and has been the leading industry sponsor of clinical trials in the UK over the last 10 years, supporting trials in around a quarter of all trial site organisations in the UK.[6,7] The company also supports the use and development of artificial intelligence and big data technologies, for example developing technologies to better harness clinical trial data, and contributing to genome databases. Through its Venture Capital Fund, Novartis invests in innovative UK start-ups, supporting the development of sectors integral to the future development of Life Sciences.

The COVID-19 pandemic and related containment measures have had a significant impact on the global economy. The OECD estimates that in 2020 global GDP will have contracted by three per cent, and that output and consumer spending will drop by around 25 and 30 per cent respectively in many countries. The life science sector has arguably been an essential component in all countries to respond to the crisis. It has been a source of diagnostics, treatments, and other healthcare supplies and is continuously developing innovative solutions to support the health workforce at tackling this pandemic. The lessons from the pandemic could induce countries to increase their investments in health and life science infrastructure to develop resilience in the scenario of a similar situation in the future. More specifically, the UK Government, in its COVID-19 recovery strategy, has identified the life sciences as an area of competitive strength and the importance of continuing to build on the previous commitments to make the UK a global life science hub.[8] Novartis has made a number of specific contributions to tackling the pandemic, which we describe throughout the report. These include working with the Department of Health and Social Care and other stakeholders

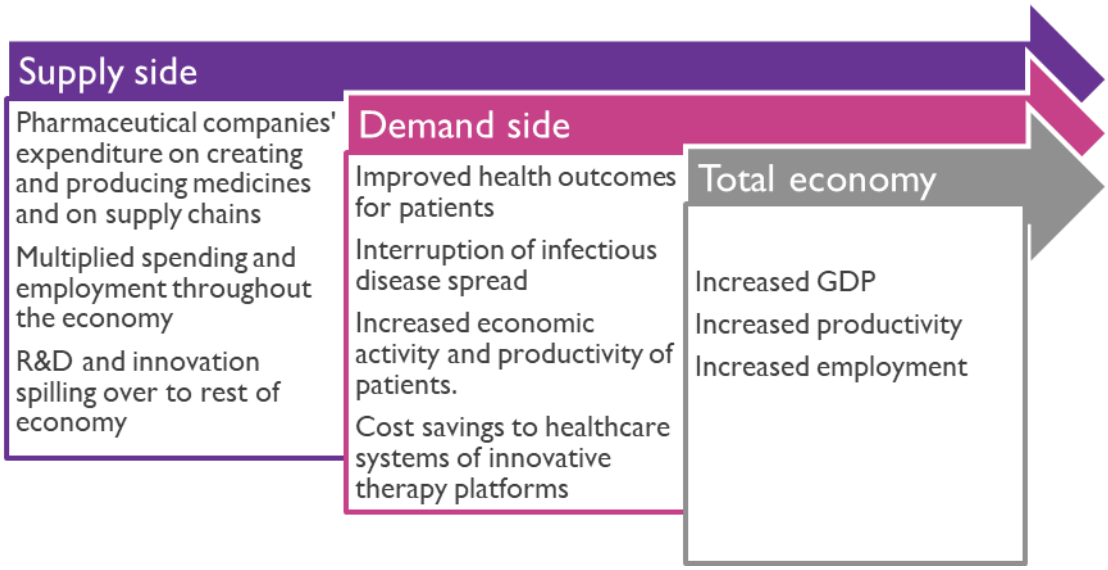
[6] Novartis (2020) "Novartis in the UK" [online] [last accessed 18/09/2020].
[7] Novartis "Trial Trove Data on File 1" (2020). Sitetrove® | Informa, 2020. Accessed September 2020.
[8] HM Government (2020) "OUR PLAN TO REBUILD: The UK Government's COVID-19 recovery strategy" [online] [last accessed 03/11/2020].

to ensure continuity of medicines supply; keeping prices stable for certain generic medicines which may be used to deal with the pandemic;[9] implementing flexible approaches to testing and clinical trials which enable patients to stay at home; investing in companies and initiatives instrumental in responding to and recovering from the pandemic; and implementing internal structures and support to manage the impact among its employees.

Novartis also continues to play a key role in preparing for the end of the Brexit transition period, again collaborating with the government and NHS to ensure medicine continuity through maintaining extended inventories of Novartis and Sandoz medicines.

Contrary to the view that healthcare expenditure is simply a drain on public finances, it is in fact a key driver of economic growth, productivity and employment. This is true both on the "supply-side" e.g. through the pharmaceutical industry and its supply chains, and the "demand side" through buyers and users of medicines. This relationship between "health and wealth" is reflected for example in academic analysis and integral to the Novartis view of how sustainable and equal access to healthcare can reduce inequalities and generate wealth.[10]

Figure 2: The healthcare value of medicines



In this report we demonstrate the Novartis contribution to both the supply-side and demand-side drivers of value, starting with its direct creation of economic activity.

1.2 Supporting a complex supply chain

Novartis activities in the UK lead to the creation of extensive economic activity through its purchasing from and investment in suppliers and partner organisations. The Novartis supply chain[11] is complex and far-

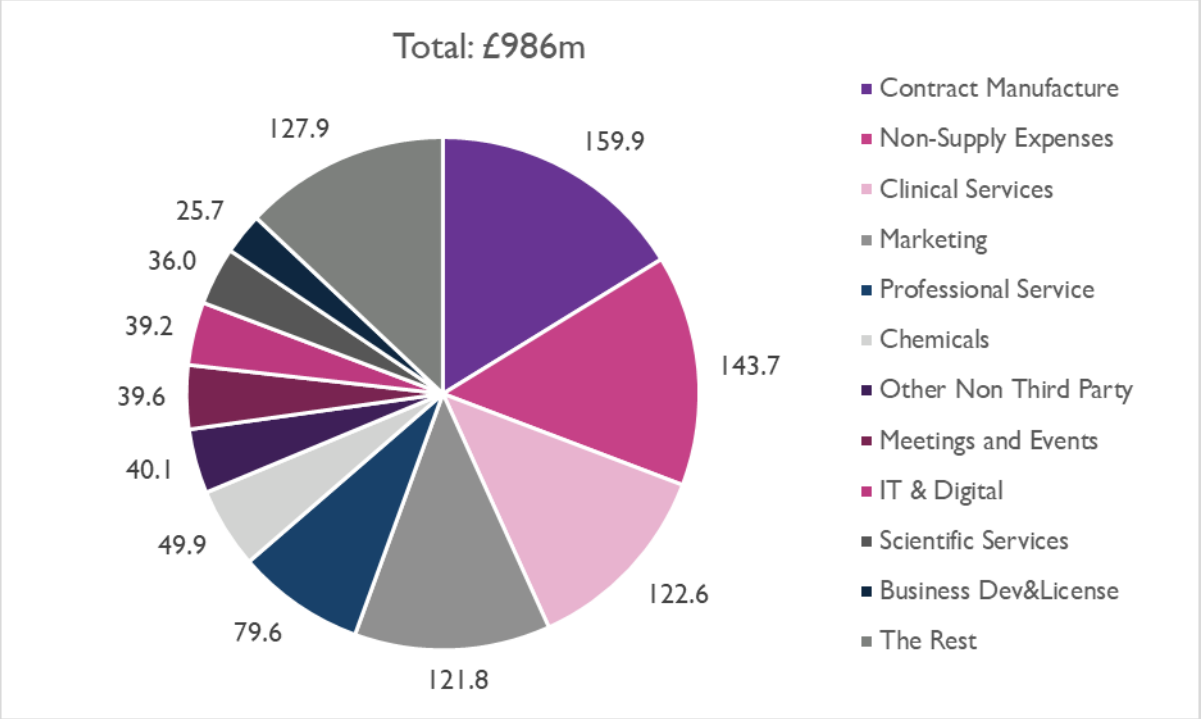
[9] Sandoz (2020) "Sandoz commits to keep prices stable for basket of essential COVID-19 medicines; Novartis responds to COVID-19 with broad range of initiatives" [online] [last accessed 04/12/2020]

[10] See for example Value Balancing Alliance (2020) "Health is wealth – interview with Patrice Matchaba, M.D. of Novartis South Africa" [online] [last accessed 16/10/2020]

[11] The supply chain refers to the network of all suppliers used by an organisation to produce and distribute its goods and services to the final buyers. This includes the transformation of raw materials, research and development, operational activities such as finance and administration, and customer facing activities such as marketing and customer services.

reaching. In 2019 Novartis expenditure in the UK was just under £1 billion (from Novartis UK and Novartis entities globally)[12] across over 3,000 UK suppliers for a wide range of services, as illustrated in the diagram below.[13] The largest three areas of expenditure are contract manufacturing (the manufacture of Novartis medicines), non-supply related expenses (patents, taxes and royalties to partner organisations) and clinical services (research and development and clinical trials).

Figure 3: Novartis Total Expenditure in the UK in 2019 (£m)

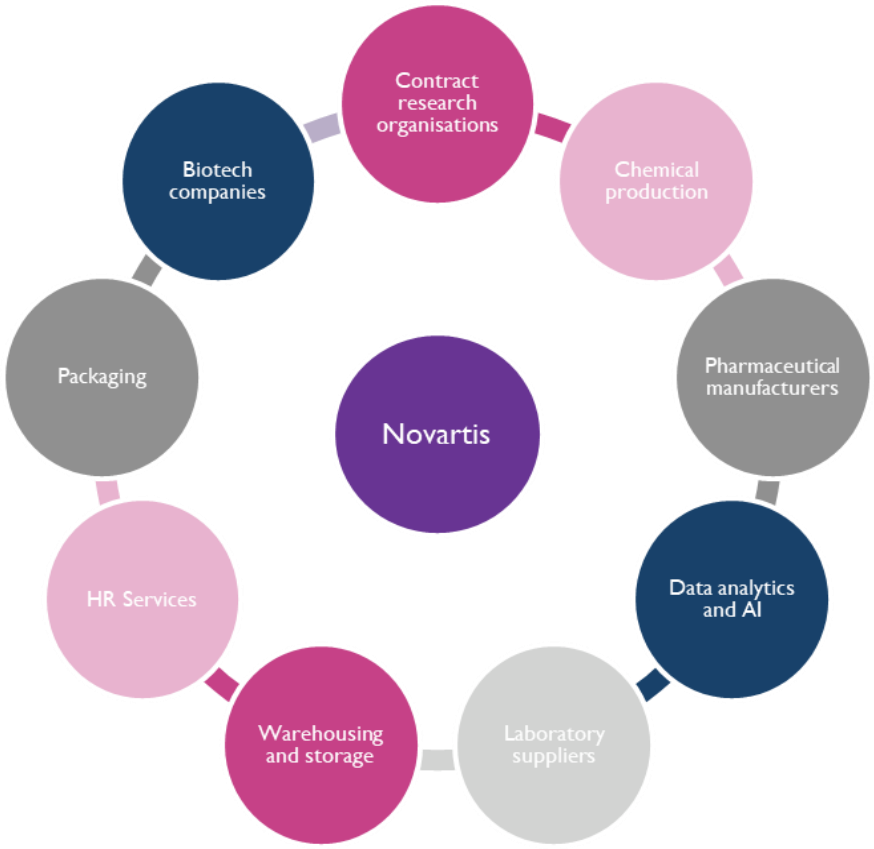


Source: Novartis (2019) "Novartis Third Party Spend data". "The Rest" includes expenditure on, *inter alia*, production equipment, warehousing and transport, and utilities

Through this expenditure Novartis supports a host of other sectors, including digital and health sectors, engaging collaboratively with many of its suppliers. There are a number of UK suppliers which are almost entirely supported by Novartis. The figure below illustrates the range of companies Novartis engages with in its supply chain.

[12] Novartis (2019) "Novartis Third Party Spend data".
[13] This refers to direct expenditure by Novartis and does not include investments e.g. through its Venture Fund.

Figure 4: The range of UK companies in the Novartis supply chain



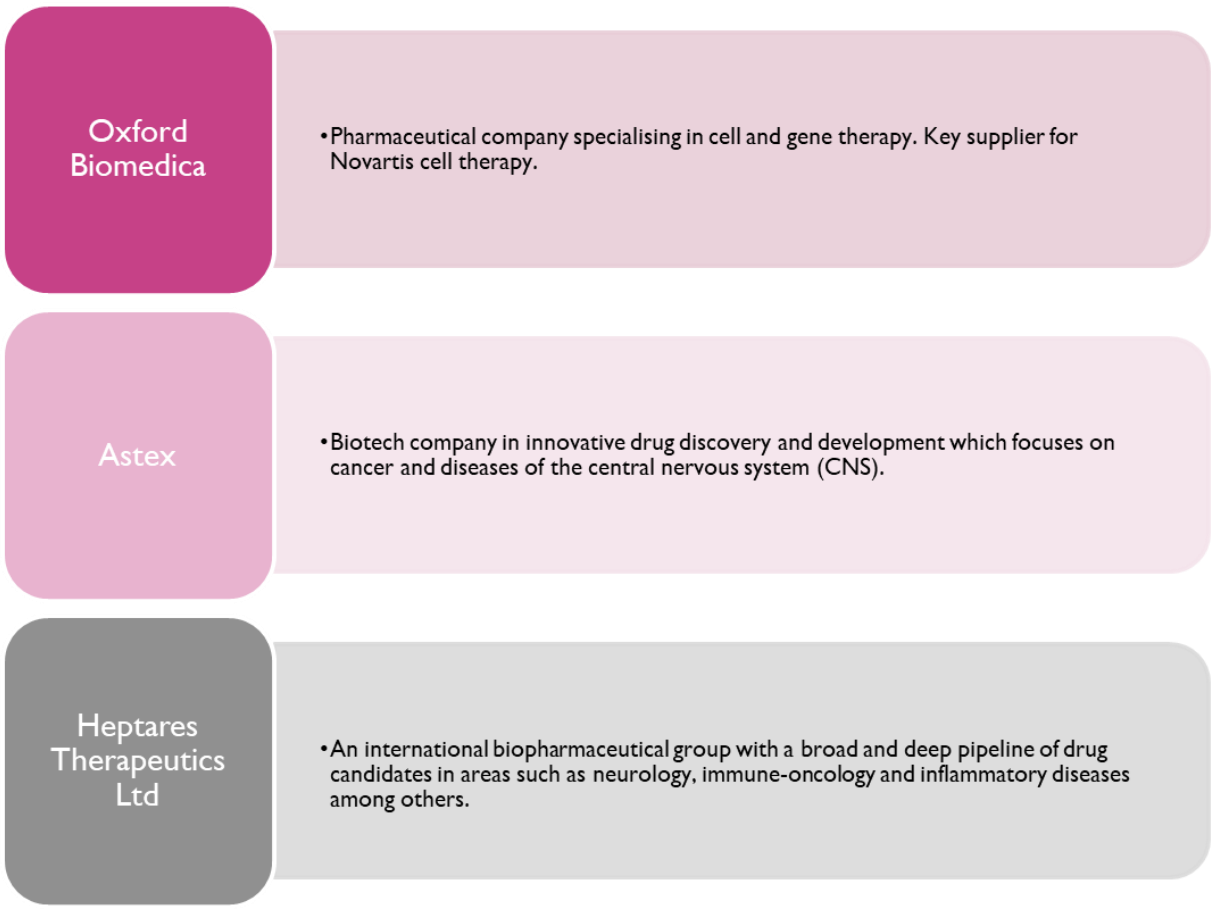
Source: Novartis (2019) "Novartis Third Party Spend data".

Examples of Novartis UK suppliers, illustrating the range of its supply chain, are described in Figure 5 and Figure 6 below. Together, Novartis spent £135m on these UK suppliers in 2019, representing nearly 14 per cent of its total 2019 UK supply chain expenditure.

In particular, Novartis collaborates with a range of innovative biotechnology companies (the development of treatments using living organisms, such as cutting edge gene and cell therapies) and SMEs, which are core to the growth and stimulation of the life sciences economy in the UK.[14]

[14] UK Government (2017) "Life Sciences Industrial Strategy" [online] [last accessed 08/12/2020]

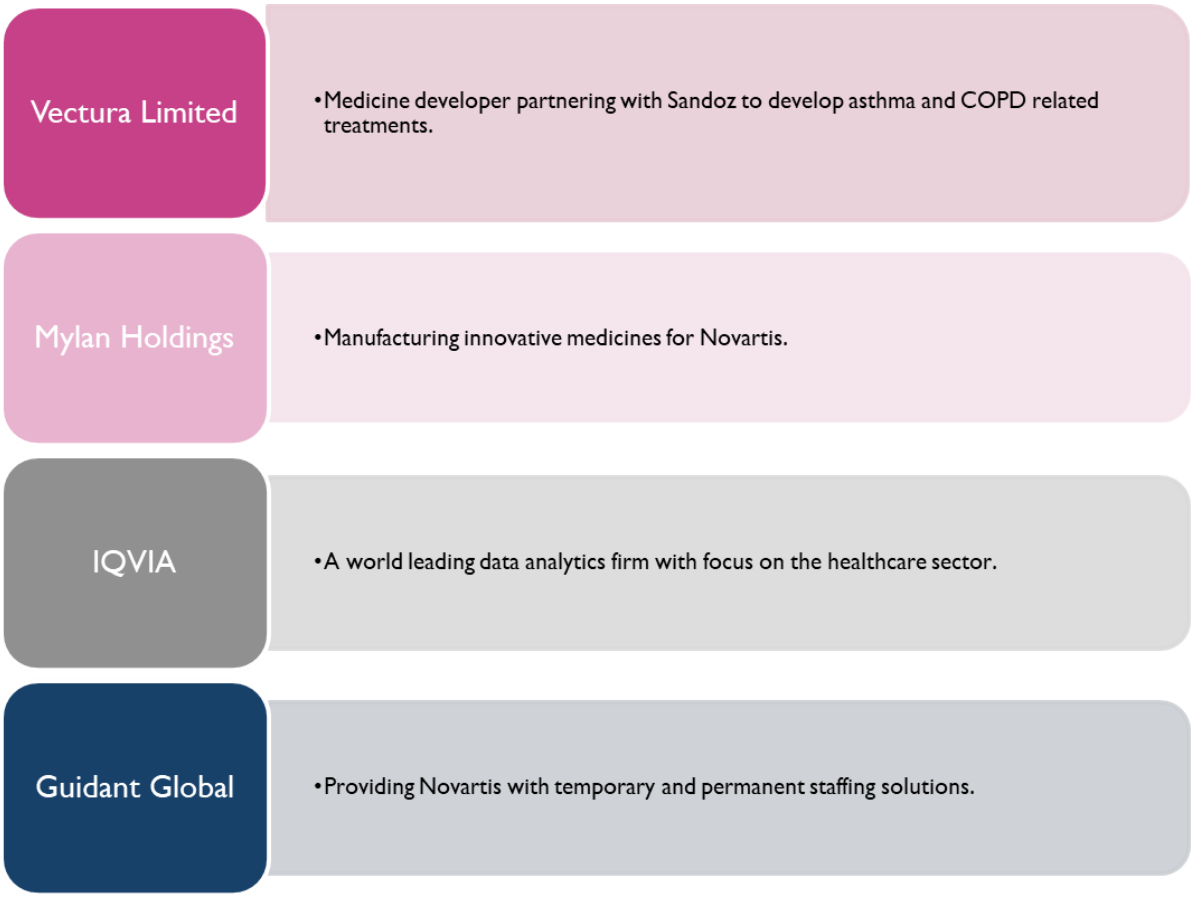
Figure 5: Examples of Novartis Biotech suppliers



Sources: Oxford Biomedica,[15] Astex,[16] Heptares Therapeutics Ltd. [17]

[15] Oxford Biomedica (2019) "Oxford Biomedica" [online] [last accessed 04/11/2020].
[16] Astex Pharmaceuticals (n.d.) "Astex Pharmaceutical" [online] [last accessed 04/11/2020].
[17] Sosei Heptares (2020) "Sosei Heptares" [online] [last accessed 04/11/2020].

Figure 6: Examples of Novartis other UK suppliers



Sources: Vectura Limited[18, 19], Mylan Holdings,[20] IQVIA,[21] Guidant Global (part of legal entity Carlisle Staffing PLC),[22] ISS Facilities.[23]

In 2019 Novartis acquired three innovative medicines companies, Advanced Accelerator Applications (AAA), AveXis (now Novartis Gene Therapies) and The Medicines Company, which have their own unique contribution to Novartis' medicines pipeline as described in Chapter 4 "Investing in the Future". The box below illustrates the footprint that AAA alone has in the UK.

Advanced Accelerator Applications

AAA is an innovative medicines company focused on the development of products designed to treat complex forms of cancer. It was acquired by Novartis in 2019 for USD3.9bn and in 2019 generated a revenue of £30.5m. In 2019 AAA employed 35 people and spent £4.9m on UK suppliers and an additional £4.8m on R&D activities in the UK.

Mirroring the Novartis commitment to building a diverse workforce (covered in Chapter 8) around 47 percent of leadership roles at AAA are held by women. AAA also demonstrates the Novartis collaborative culture (described in Chapter 6) through its Joint Working Partnership with Queen Elizabeth University Hospital Birmingham (UHB). The project aims to improve the access to new cancer therapies, improve the

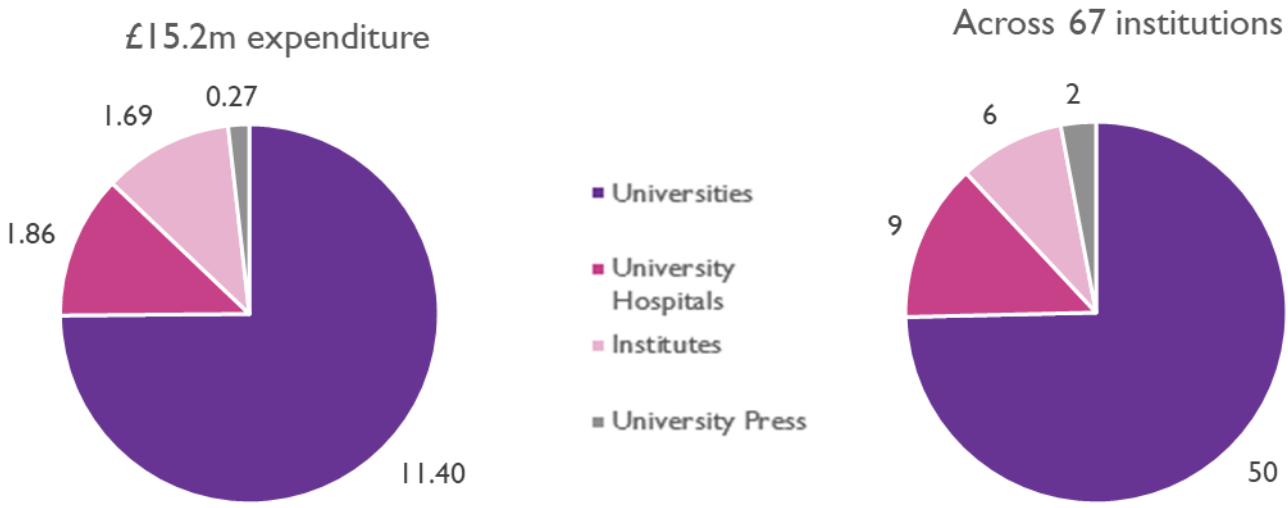
18 Vectura Limited (2020) "Vectura" [online] [last accessed 04/11/2020].
19 Vectura developed the device and is managing the commercial supply of the device only. McKee, S (June 2017) "Vectura links with Novartis for inhaled asthma / COPD generic" Pharma Times [online] [last accessed 04/11/2020].
20 Mylan (2019) "Mylan" [online] [last accessed 04/11/2020].
21 Iqvia (2020) "Iqvia" [online] [last accessed 04/11/2020].
22 Novartis "Data on File. Ref 002"
23 ISS (2020) "ISS" [online] [last accessed 04/11/2020].

patient experience in the service and reduce the waiting time from treatment decision and start of the treatment. AAA also upskills clinicians and encourages best practice through training sessions at the Royal Free Hospital, which cover areas such as patient diagnosis, patient selection and treatment of complex forms of cancer.

AAA has joined the efforts to address the impacts of the COVID-19 pandemic, by setting up a home service to support patients receiving its medicine without them having to visit hospital when NHS facilities were being used for COVID treatment.[24] It has extended its support by working in partnership with independent centres such as The Wellington Hospital in an effort to alleviate capacity constraints faced by NHS hospitals and ensure that patients can continue to receive treatment throughout the pandemic.

Novartis also invests in and collaborates with universities. Novartis globally has partnered with academic institutions to produce a total of 4,016 publications since 2014, 869 of which were with UK institutions.[25] In 2019, Novartis spent £15.2m across approximately 67 UK universities, university hospitals, institutes and university press to promote research and development and the development of human capital.[26] Novartis' contributions to a skilled UK workforce and its commitment to collaborations in the life sciences and digital sectors is analysed in Chapters 6 and 5.

Figure 7: Novartis UK Expenditure - Academic Institutions, 2019 *(£m)*

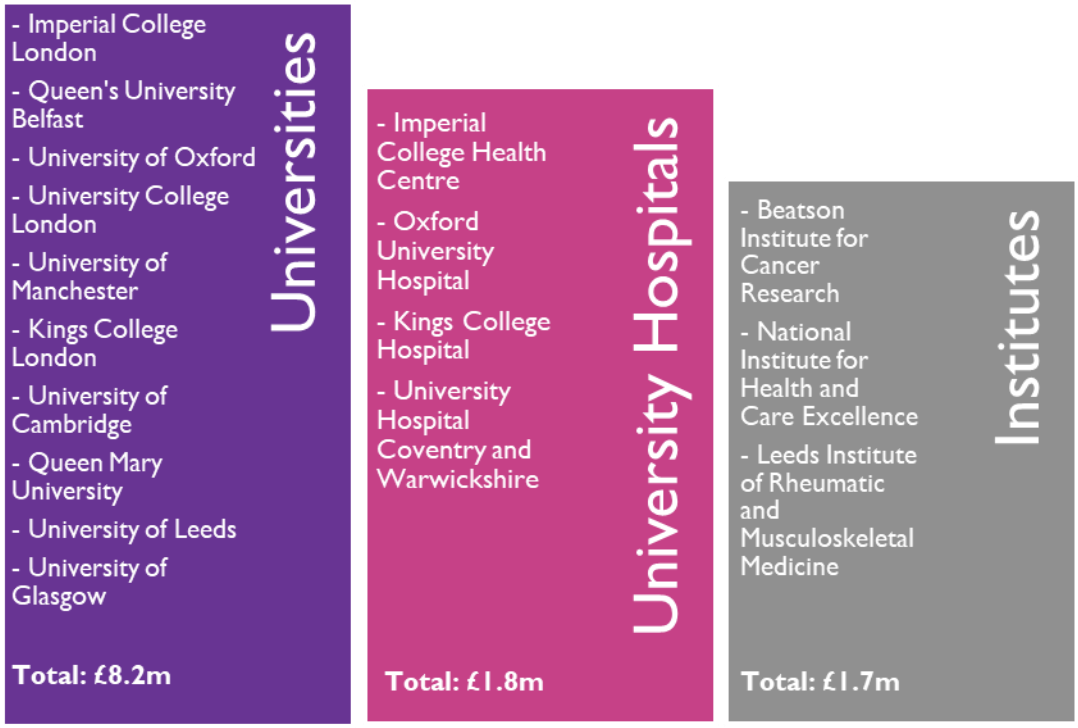


Source: Novartis (2019) "Novartis Third Party Spend data".

Novartis expenditure on universities and research institutes covers a broad range of institutions across the UK, as illustrated below.

[24] AAA (2020) "The time to solve the cancer care crisis in the NHS is now".
[25] Deloitte Innovation Dashboard source data Pub-Med publications 2014-2019.
[26] Note that some of this expenditure (on university hospitals) is part of Novartis spending on the NHS.

Figure 8: Sample of top academic institutions for Novartis UK expenditure



Source: Novartis (2019) "Third Party Spend data".

In addition to its spending across academic institutions, Novartis works closely with the NHS more broadly, sharing and gaining expertise. Subsequent chapters describe Novartis activities and expenditure on NHS research and development (clinical services), joint working partnerships, research, meetings and events and various other collaborations.

As a pharmaceutical company, Novartis investment in medicines is the core element of its innovative activities, exemplified by its pipeline being ranked number one in terms of value creation in 2018.[27] Novartis spends millions of pounds in research and development (R&D) in the UK, and has been the leading commercial clinical trial sponsor in the UK over the last 10 years.[28] Novartis uses key developments in data analytics and artificial intelligence to enhance its innovative activities, such as contributing to data troves and genome projects and extending the value of its clinical trials. Chapters 4, 5 and 6 describe Novartis' added value through innovation, data analytics and investment.

As a listed company Novartis also returns value to its shareholders in the form of dividend payments. We estimate that in 2019 Novartis paid a dividend of approximately £0.7bn to UK holders of registered shares.[29] Whilst some proportion of these shares will not be beneficially owned by UK domiciled owners (i.e. where the UK registered shareholder includes beneficial owners based in other jurisdictions), this is nevertheless a significant value stream into the UK.

1.3 Creating activity throughout the economy

Novartis activities in the UK create economic impact far beyond its own expenditure. One component of that additional contribution (though, as we shall see throughout this report, by no means the only one) is the

[27] EvaluatePharma (2018) "World Preview 2018, Outlook to 2024" [online] [last accessed 30/09/2020].
[28] Novartis "Trial Trove Data on File 1" (2020). Sitetrove® | Informa, 2020. Accessed September 2020.
[29] Novartis "Data on File. Ref 011".

way its direct expenditures ripple out across the economy, creating extra value as they do so. This "ripples" form of economic contribution of Novartis to the UK can be estimated using what economists term an "input-output" framework. There are three types of impact modelled in an input-output framework:[30]

- Direct impacts. This represents the direct gross value added (GVA) generated by the organisation itself, for example, the salaries Novartis pays to employees or its expenditure on its suppliers.
- Indirect impacts. This is the wider supply chain impact generated by the direct activity of Novartis. For instance, demand generated through Novartis expenditure on its suppliers.
- Induced impacts. This is the impact from employees of, and investors in, Novartis and its supply chain, spending the associated income and thereby increasing demand across a wider range of sectors in the economy.

Novartis has developed a method to estimate the aforementioned direct impacts and build a picture of its total Financial, Environmental and Social (FES) contribution.[31] The calculations for the indirect and induced GDP contribution, indirect and induced employment effects, indirect and induced environmental effects were performed by WifOR to produce the figures reported in this report.[32]

From these calculations, in 2019, Novartis contributed a total of £1,702m gross domestic product through direct, indirect and induced impacts in the UK.[33] These estimates are based on Novartis financial accounts and UK input-output databases. They do not include all areas of Novartis expenditure (e.g. investment through its Venture Fund, described in Chapter 3, or all its dividend payments described earlier).

Figure 9: Novartis GDP Contribution in the UK in 2019 *(£m)*

Source: Novartis (2019) "FES Impact Valuation Results UK". Indirect and induced supply chain effects by WifOR (2020).

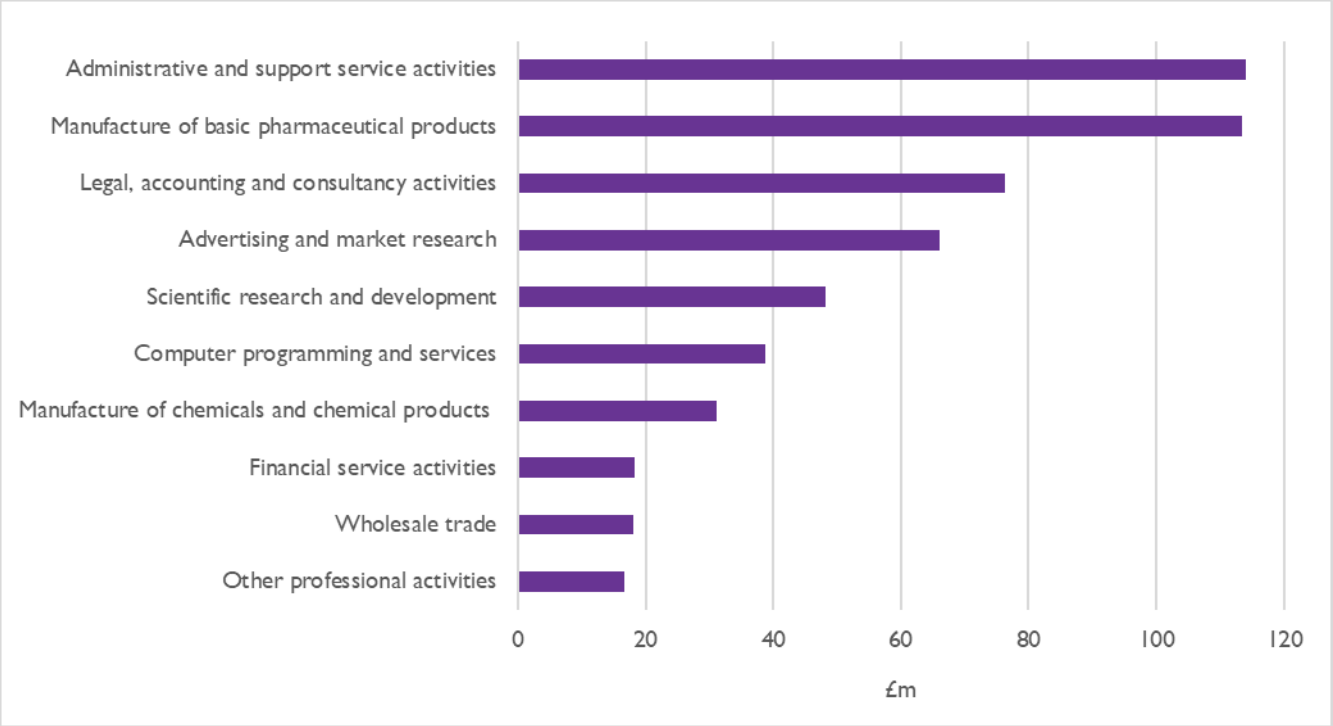
The sectors on which Novartis had the largest indirect impacts in terms of GDP in 2019 were administration and support services, manufacture of basic pharmaceutical products, and legal and accounting services (see

[30] ONS (2017) "Input-output analytical tables: methods and application to UK National Accounts" [online] [last accessed 18/09/2020]
[31] Novartis (2017) "Corporate Responsibility Report".
[32] We have converted the FES calculation results from US dollars to pound sterling using the exchange rate $1 = £0.783652. 1 USD = 0.783652 GBP from OFX (2020) "Yearly average exchange rate" [online] [last accessed 01/09/2020].
[33] Novartis (2019) "FES Impact Valuation Results UK".

Figure 10, below). This breakdown offers a top-down estimate of the broad sectors on which Novartis has an economic impact based on input-output data. It reflects the specific elements of the Novartis supply chain described in section 1.2 and illustrated in Figure 4. For example, the Novartis-specific supply chain elements "Data Analytics and AI" and "contract research organisations" would be categorised under the broad sector "Scientific research and development" and is explored in Chapter 6. The top ten sectors account for nearly 72 per cent of the total GDP impact created by Novartis.

The Novartis impact on the supply chain also reflects that of the wider pharmaceuticals sector in the UK, where nearly 54 per cent of inputs into the production process are pharmaceutical products and preparations made by the sector itself.[34] The remaining inputs are dominated by service-related sectors, such as computer programming, financial services, and advertising.

Figure 10: Top 10 UK sectors supported by Novartis in 2019, GDP impact (£m)



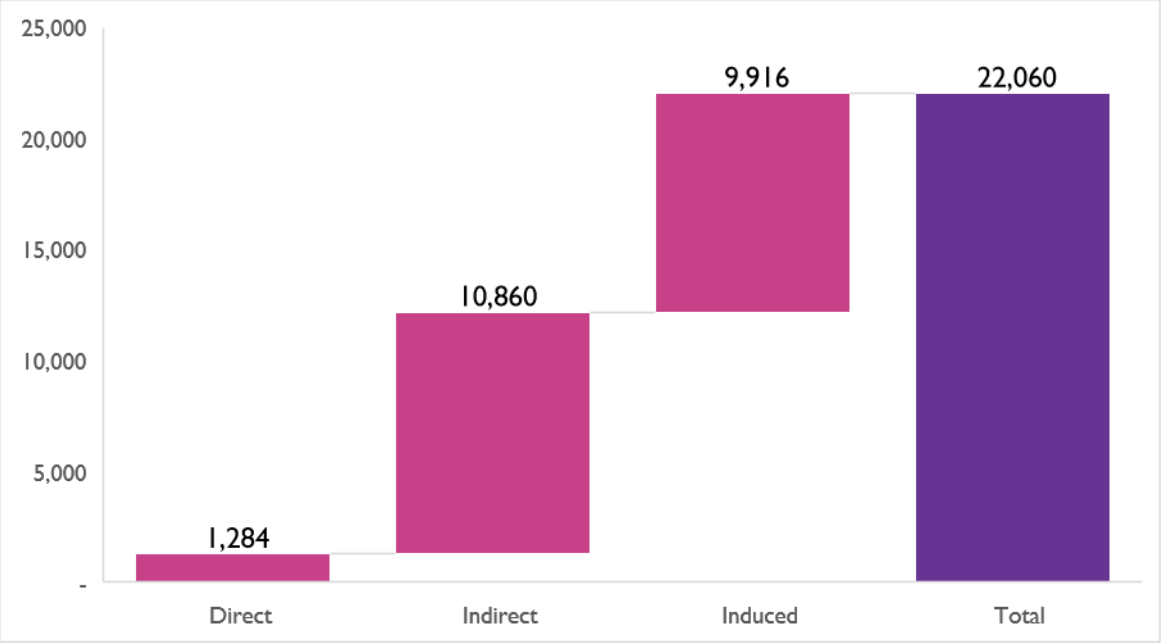
Source: WifOR (2020) "Novartis UK Economic and Environmental Footprint: top 10 sectors in 2019"

1.3.1 Employment

Novartis also contributes significantly to the UK labour force through direct, indirect and induced effects. In 2019, Novartis supported a total of 22,060 jobs in the UK, of which it directly employed 1,284 full time equivalent workers. Through indirect spillover effects Novartis also supported 10,860 jobs due to its purchases of goods and services within its supply chain. Novartis had a further impact on employment through induced spillover effects, contributing 9,916 jobs. This stemmed from the spending of wages of employees of Novartis and its supply chain. Novartis' contributions to employment and the workforce are covered in more detail in Chapter 8.

[34] EEF The Manufacturers' Organisation (2018) "Sector bulletin: Pharmaceuticals", p5 [online] [last accessed 18/09/2020].

Figure 11: Novartis Employment Contribution in the UK 2019



Source: Novartis (2019) "FES Impact Valuation Results UK". Indirect and induced supply chain effects by WifOR (2020).

1.3.2 Tax contribution

This added GDP creates a tax contribution, reflecting the taxes paid by suppliers and consumers across the economy. We can estimate tax contributions by applying a taxation multiplier to the total economic contribution. We apply the national tax-as-a-share-of-GDP from the public finances databank, which for 2019/2020 was approximately 38 per cent, to the total GDP contribution of Novartis.[35] Hence the implied tax impact on GDP of Novartis in the UK in 2019 is estimated to be £641.7m across its direct, indirect and induced impacts.

1.4 Summary

Novartis UK supports a large number of companies through its diverse supply chain. This stimulates economic activity within a wide range of industries. This means Novartis makes a material contribution to the UK economy not only through its direct expenditure but also through the "ripple" effects it creates across its supply chain and via the spending of its employees and shareholders and those of its suppliers. The combined GDP contribution in 2019 was £1.7bn and the tax contribution was £0.64bn.

[35] Public Finances Databank (2019/20) "Public sector current receipts as a percentage of GDP – 2019/20" [online] [last accessed 18/09/2020].

2 Impacting Lives

2.1 The Economic Impact of Medicines

Pharmaceutical innovations can prevent disease, modify and alter disease progression and treat disabling symptoms with the ultimate aim of treating patients and improving their health outcomes. As well as being valuable to patients themselves, this has a broader social value, in that those treated are potentially enabled to continue to be productive in their working lives. Furthermore, although caring for those that are ill or facing the challenge of ongoing disorders has its own value, the release of carers from such duties potentially creates economic resources that can be used in more conventional economic activities (in work, consumption and leisure) that tends to boost output as normally measured.

This chapter illustrates and models such contributions Novartis makes to the society of the UK through its medicines. We set out illustrative economic impacts in GDP terms to reflect the broad span of economic and social benefits.[36]

2.1.1 Estimating the economic value of medicines

The healthcare sector is a key driver for economic growth and employment through its impact on buyers and users of medicines (the "demand side"). This is arguably a less recognised channel of value compared to its impact on the economy through its supply chain, as outlined in Chapter 1, but no less important.

According to the Office of Health Economics (OHE), empirical evidence shows that healthcare interventions have many important effects outside of the healthcare system.[37] If these effects are not recognised – perhaps because evaluations are restricted to a healthcare perspective – then there may be underinvestment in healthcare interventions as well as suboptimal outcomes for society.[38] The OHE states that although there are practical difficulties in capturing societal benefits and costs in health technology appraisals (HTAs) and that there is not yet consensus on the methodologies to use in a societal perspective, some elements such as productivity and carers' quality of life effects can and are being incorporated into HTAs in other markets.

Novartis recognises the value that medicines can bring in its articulation of its 'pillars of value':

- Clinical value: The effectiveness of a medicine in treating or curing a disease and its symptoms.
- Patient value: This includes the quality of life a medicine brings a patient, but also other factors such as side effects or methods of administration.
- Healthcare system value: Healthcare system value includes benefits for the healthcare system from patients requiring less intervention as a result of the treatment, but is also linked to the burden that a medicine will impose to the healthcare system. For example, a medicine will have a greater healthcare system value than a comparator which is identical save for the fact that the comparator requires the patient to visit the hospital whereas the first medicine can be administered at home.
- Societal value: Lastly, the societal value is determined by how much better off the society as a whole is when a patient uses the medicine in question compared to a comparator medicine (or no treatment). For example, the value of interrupting the spread of an infectious disease. This also includes the ability of

[36] Note, however, that our methodology is intended to be illustrative and display value in a new way. It is not an official economic assessment of health outcomes or cost-effectiveness.

[37] As an example the OHE cites that the direct healthcare costs of treating cancer in the UK amounted to €6.68 billion in 2015, but the total burden on the economy amounted to €19.10 billion, €7.90 billion of which was due to production losses from individuals unable to undertake paid work because of their condition.

[38] OHE (2020) "Note on a societal perspective post-COVID-19: In healthcare resource allocation in the UK".

the patient to return to work and engage in other economic activity, resulting both from the clinical effectiveness of the medicine and also from the means of administration and the likelihood of side effects.

The following sections demonstrate the use of a value-based approach when estimating a medicine's economic benefit.

2.1.2 Approach to estimating the GDP impacts of medicines

One approach to measuring the societal value of medicines has been developed by a German economic consultancy WifOR. This methodology is intended to model and estimate the value of medicines by focusing on their wider economic impacts.[39] This method assumes healthier people have more capacity for economic activity (both work and non-work) and, therefore, are able to make greater economic contributions. In turn, the health benefits offered by Novartis medicines can be translated into quantifiable potential socioeconomic benefits.

The startpoint for this calculation is the health benefits of medicines. This is calculated as the additional number of Quality-Adjusted Life Years (QALYs) that a medicine generates. One QALY represents a year lived in perfect health. The health benefit of a medicine can therefore be computed as the *incremental* gain in health outcomes between a given medicine and a suitable comparator (either the next best standard of care, or best supportive care), measured in QALYs. The total health footprint derives from the number of patients reached in a year and the average number of QALYs gained per patient per year. Medicines can have different impacts here – for example some may be associated with high QALYs but only reach a limited number of patients in a year, whilst others may have relatively low QALY values with respect to a comparator but may reach thousands of patients.

The estimated QALY gains serve to identify the wider economic and social benefits resulting from improved health. A single QALY equates to one additional year of full working capability. Both paid and unpaid work activities are included in order to obtain the full socioeconomic benefit. These might imply longer lifespans, greater productivity at work and in the home, and greater spending potential. Importantly, QALY estimates vary with the modelling assumptions and the comparator standard of care. Given these limitations, within this methodology the QALY gains are intended to estimate the economic impact of a medicine, rather than provide definitive conclusions on the health impacts of the medicines.

The footprint for paid economic activity is calculated by considering the time gained from health benefits for patients of working age. Unpaid work activities encompass the working and non-working population as both contribute to national wealth through household production and voluntary work. Every productive activity has direct, indirect and induced effects. Direct effects are measured by gross value added and represent immediate economic impact. Indirect effects describe intermediate consumption of goods and services from suppliers. Induced effects capture the impact of spending by households receiving income based on direct and indirect effects. The socioeconomic footprint is the sum of paid and unpaid activities.

The WifOR approach to estimating economic impact has been used in a number of studies:

- WifOR published a study in the *Expert Review of Pharmacoeconomics & Outcomes Research,* estimating the social impact of a treatment in psoriatic arthritis using this method to allocate gains in productive time in paid and unpaid activities.[40]

[39] WifOR (2020) "The Social Impact of Novartis Innovative Medicines and Sandoz Products in United Kingdom in 2019". The WifOR method is explained in greater detail in the Appendix.

[40] Himmler, S et al. (2019) "A case study applying a novel approach to estimate the social impact of a medical innovation - the use of secukinumab for psoriatic arthritis in Germany" *Expert Review of Pharmacoeconomics & Outcomes Research*, (July).

- PWC used a similar methodology of assigning GDP impacts to QALY gains when the European Federation of Pharmaceutical Industries (EFPIA) asked it to identify the direct and indirect contributions of Europe's pharmaceutical sector.[41]
- WifOR has used this methodology in estimating the social impact of Novartis in other contexts, such as the impact of Novartis medicines in Africa.[42]

The methodology has some limitations and assumptions. While a QALY is an aggregate metric of survival and quality of life, the methodology assumes one QALY is equivalent to one year of a person being fully capable of performing paid and unpaid activities. As the focus is on the economic gains from improved health, only the working-age patient population (20 to 60 years old) is considered for paid activity, and the non-working population over 20 years for unpaid activity. Thus the estimates do not capture economic health benefits to children or teenagers. The inputs used by WifOR are also not necessarily tailored to the UK – for example QALY estimates for some medicines are generated from international studies whereas the specific impacts for the UK population may differ due to patient characteristics and the availability of different standards of care. Further, as the methodology focuses on the economic contributions of individuals, it does not capture wider economic benefits of medicines in reducing societal costs e.g. in relieving burdens on healthcare systems.

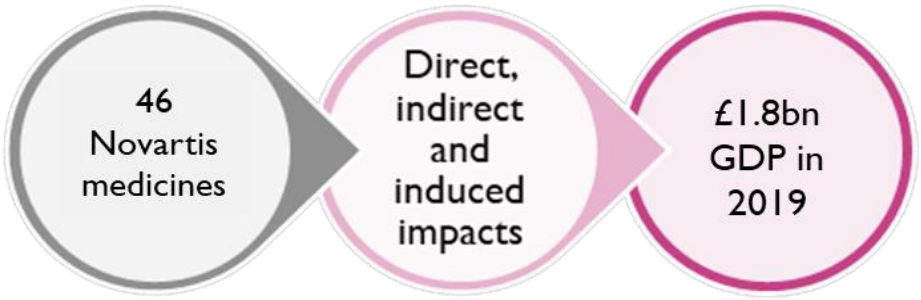
However, these limitations do not prevent this approach from being a valuable new way of describing the economic value of medicines. The results are not intended to generate precise conclusions on the incremental health benefits across the whole UK patient population or the cost-effectiveness of specific medicines. Rather, they are intended to estimate the potential scale of the economic contributions arising from improvements in patients' quality of life.

2.1.3 The economic impact of Novartis medicines

Using the above methodology and a basket of 46 medicines produced by Novartis across its Innovative Medicines and Oncology portfolios (thus, excluding Sandoz medicines), WifOR estimates that Novartis contributed approximately £1.8bn to UK GDP in 2019 through the improved economic contributions of a healthier population. This captures the direct economic activity undertaken by those receiving the medicines, and the indirect and induced economic value generated by the consumption of goods and services from intermediate suppliers.

[41] PWC, EFPIA (2019) "Economic and societal footprint of the pharmaceutical industry in Europe. A report for EFPIA" [online] [last accessed 25/09/2020].
[42] WifOR, EFPIA (2016) "The social impact of Novartis medicines: Two case studies from South Africa and Kenya" [online] [last accessed 18/10/2020].

Figure 12: The social impact of Novartis medicines in the UK in 2019



Note: This figure reflects WifOR's updated methodology on calculating drugs' impacts. See the Appendix for details.

This demonstrates the wide impact of Novartis beyond just the health benefits that accrue to patients. This figure is illustrative in that it does not capture the impact of the full Novartis innovative medicines portfolio nor that of the generics arm Sandoz, and is based on a wide range of sources of health benefits that are not always directly linked to the UK population. (International sources are typically used, and we note that in any case only around half of the medicines have been reviewed by the NICE, the UK National Institute for Health and Clinical Excellence.)

The results serve to illustrate a fuller view of the benefits of medicines over and above health gains. As stated they are not intended to generate precise conclusions on the incremental health benefits or cost-effectiveness of specific medicines.

In the case studies below, we present a sample of disease areas where Novartis is active and apply the WifOR methodology using UK-generated inputs of health gains (QALYs) from NICE appraisals in order to tailor these specifically to the UK patient population. The aim is to demonstrate the potential economic impact of a range of treatments, highlighting different sources of economic value (some treatments reach a large number of patients; others have high incremental QALY gains; others treat a wider age demographic). The case studies use incremental QALY gains and patient numbers associated with specific medicines relevant to the various disease areas, but we do not include details of the specific health benefits of treatments, as the focus is on demonstrating the economic value in a single year rather than describing their precise health benefits.

2.2 Demonstrating the Economic Impact of Novartis Various Medicines

2.2.1 Heart failure

Heart failure is a chronic and progressive condition arising when the heart cannot pump blood around the body to deliver oxygen and nutrients to cells. In 2013 it was estimated to affect 60m people worldwide,[43] and 900,000 people in the UK in 2017.[44] It is more common among the elderly but can manifest at any age and has various causes.

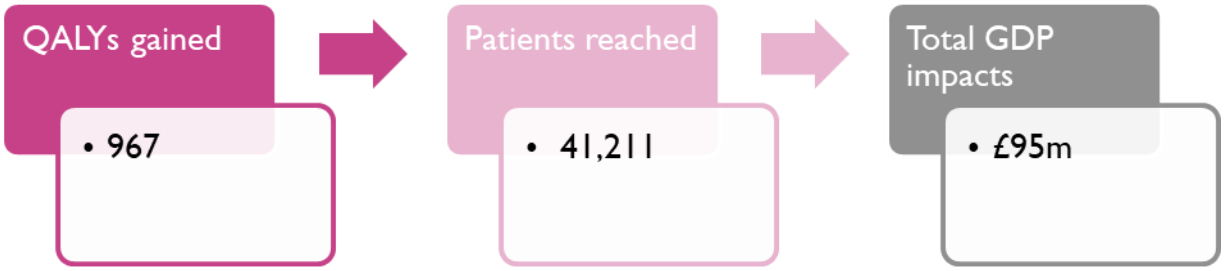
Economic and social impact of treating heart failure

A Novartis medicine was prescribed in around 41,000 patients in 2019, with an estimated 967 QALYs gained over this population.[45] In addition to the welfare gains for patients, the treatment will have reduced the

[43] Elsevier Ltd (2015) "Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study" *Systematic Analysis for the Global Burden of Disease Study,* Vol 386, No 9995, p743.
[44] O'Donovan, K (2017) "Entresto in heart failure" *Journal of Prescribing Practice,* Vol 15, No 12 (Dec).
[45] Europe Economics calculations based on WifOR methodology.

number of days lost to illness and created other related economic gains. The total economic gain from this treatment is estimated at around £95m in the UK in 2019, including direct, indirect and induced impacts of greater economic activity.

Figure 13: Summary of annual social and economic impacts of treating heart failure in 2019 in the UK



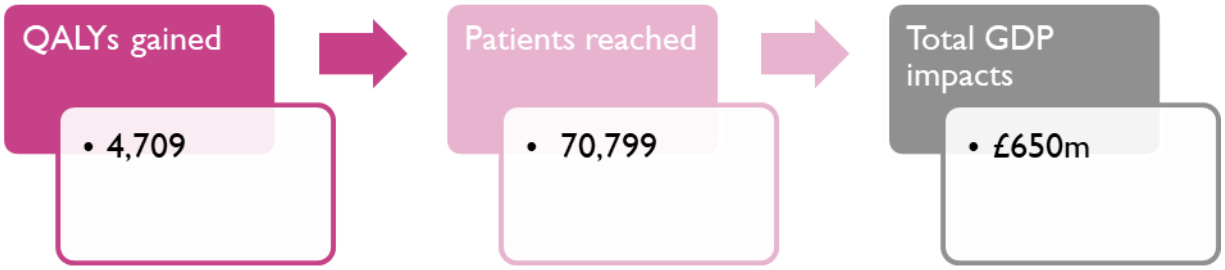
2.2.2 Macular Degeneration

Age-Related Macular Degeneration (AMD) is a medical condition that damages the macula, the retina's most sensitive part, and is the leading cause of blindness in adults.[46] The retina is responsible for central vision as well as colour and detail. AMD is the most common form of macular degeneration, affecting more than 600,000 people in the UK.[47]

Economic and social impact of treating wet AMD

A Novartis medicine was prescribed in just under 71,000 patients in the UK in 2019, resulting in a gain of 4,709 QALYs over this population.[48] This is estimated to have generated over £650m in the UK in GDP impacts.

Figure 14: Summary of annual social and economic impact of treating wet AMD in 2019 in the UK



2.2.3 Multiple Sclerosis

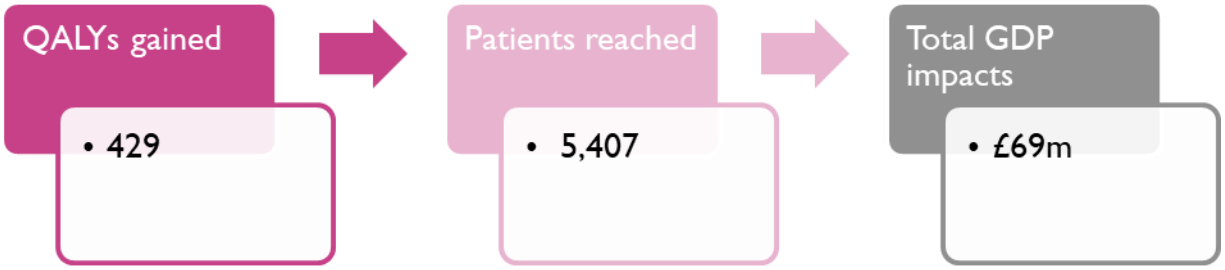
Multiple Sclerosis (MS) is a chronic disease affecting the brain and spinal cord. MS is a lifelong condition with symptoms limiting vision, bodily movement, sensation and balance.[49] The most common symptom is severe fatigue, making it difficult for people to carry out basic activities. This coincides with vision problems, such as colour blindness and eye pain, as well as speech and swallowing problems. MS also interferes with mental wellbeing, affecting an individual's thinking, learning and planning.

[46] RNIB (2019) "Key information and statistics on sight loss in the UK" [online] [last accessed 25/09/2020].
[47] Macular Society (2017) "Your guide to age-related macular degeneration" [online] [last accessed 25/09/2020].
[48] Europe Economics calculations based on WifOR methodology.
[49] NHS (n.d.) "Multiple sclerosis" [online] [last accessed 25/09/2020].

Economic and social impacts from treating MS

A Novartis treatment was prescribed in just over 5,400 patients in 2019 with an aggregate 429 QALY gains across this population.[50] This is estimated to have generated over £69m in additional GDP in the UK in 2019, taking into account direct, indirect and induced impacts.[51]

Figure 15: Summary of annual economic and social impacts of treating MS in 2019 in the UK



2.2.4 Acute lymphoblastic leukaemia

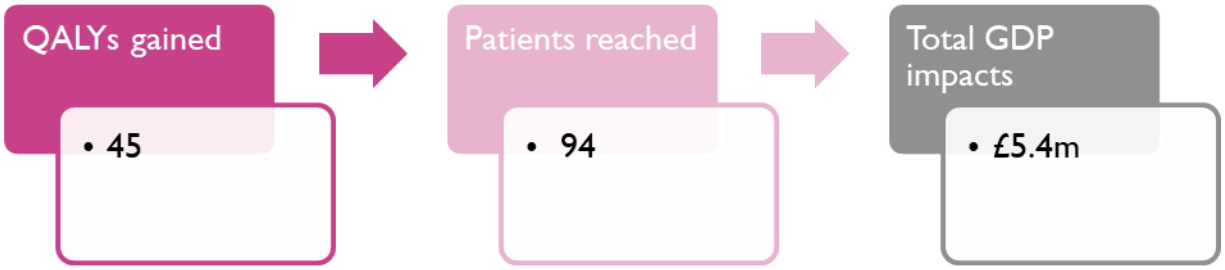
Acute lymphoblastic leukaemia (ALL) is a type of blood cancer, starting from young white blood cells called lymphocytes in the bone marrow. Although rare, it is the most common type of leukaemia to affect children but can also affect adults. Around 800 people are diagnosed with ALL in the UK each year.[52] It can require patients to endure multiple rounds of chemotherapy for several years. Their hospital visits are disruptive and treatment carries adverse symptoms, such as tiredness and nausea.

Economic impact of Treating ALL

A Novartis therapy was prescribed in 94 patients since late 2019 in England, generating around 45 QALYs across this group in one year and an estimated £5.4m GDP.[53] This is an example of a treatment that has a relatively large GDP impact despite the small population affected – a sizeable proportion of whom are below working age – and a very significant impact per patient in terms of health gains. Reflecting this, this therapy has an estimated GDP impact of approximately £58,000 per patient.

[50] Novartis data on file, Europe Economics analysis.
[51] Novartis data on file, Europe Economics analysis.
[52] Cancer Research UK (n.d.) "What is acute lymphoblastic leukaemia (ALL)?" [online] [last accessed 28/09/2020].
[53] Europe Economics calculations based on WifOR methodology. Patient numbers apply to England only, NHS England. Novartis "Data on File. Ref 013".

Figure 16: Summary of annual economic and social impacts of treating ALL, between 2019 and 2020



2.2.5 Melanoma

Melanoma is the fifth most common form of skin cancer in the UK.[54] Doctors diagnose almost 15,400 new cases of melanoma in the UK annually. The symptoms from advanced melanoma can be severely debilitating and the disease often returns.

Economic impact of Treating Melanoma

A Novartis treatment has been prescribed in around 850 patients in England in the past year, generating around 367 QALYs and an estimated GDP impact of £51m. [55]

Figure 17: Summary of annual economic and social impacts of treating Melanoma in England between 2019 and 2020

2.2.6 Neuroendocrine Tumours

Neuroendocrine tumours (NETs) are a group of rare, life-threatening tumours that can be found almost anywhere in the body. The prevalence of NETs has been estimated as 35/100,000 in the UK.[56]

[54] Cancer Research UK (n.d.), "Melanoma skin cancer statistics", [online] [last accessed 28/09/2020].
[55] Europe Economics calculations based on WifOR methodology. Patient numbers and QALYs for oncology cases. Patient numbers apply to England only, NHS England, January – December 2019. Novartis "Data on File. Ref 013".
[56] Varley-Campbell, J, Mujica Mota, R, et al. (2016) "Everolimus, lutetium-177 DOTATATE and sunitinib for treating unresectable or metastatic neuroendocrine tumours with disease progression" *Peninsula Technology Assessment Group (PenTAG), University of Exeter Medical School (Report to NICE)*.

Economic impact of treating neuroendocrine tumours

A Novartis' treatment has been prescribed in 404 patients in England in 2019[57] generating approximately 36 QALYs and an estimated GDP impact of £5.1m.

Figure 18: Summary of annual economic and social impacts of treating neuroendocrine tumours in England in 2019

2.3 Further economic value of Novartis medicines

The examples above demonstrate how Novartis brings economic value by improving people's health outcomes through its medicines. The economic value of Novartis will continue in the future, given its pipeline and work in areas such as population health approaches. As described in section 2.1.1 this will bring not just potential clinical and patient value, but also potential value to healthcare systems and society at large.

Population Health Approaches

Novartis' focus on population health also has the potential to realise economic value, through exploring whether population health approaches offer the potential for cost-effective outcomes to be achieved across the healthcare system. Aligning goals with those of the NHS Long Term Plan enables Novartis to build pioneering partnerships aimed at tackling national healthcare challenges. This has the potential for significant gains for patients, healthcare systems and the economy.

2.4 Summary

Novartis treatments directly contribute to the health of individuals in the UK, and generate potentially many wider forms of value to healthcare systems and the economy. This chapter aims to provide an estimate of the social value of this contribution by taking into account direct, indirect and induced effects of the time gained by the UK workforce that fuels paid and unpaid economic activity. This chapter demonstrates the potential social value of Novartis innovative medicines and treatments in 2019. The method is illustrative and describes this value in a novel way. It is not an economic appraisal of the health outcomes or cost-effectiveness of specific medicines. Under this method, it is estimated that that the social impact of Novartis medicines in the UK was £1.8bn in 2019.

The value that Novartis brings to society will continue over time as it develops more medicines, often involving cutting edge therapies which could offer significant health outcomes and benefits to patients and the economy. The Novartis medicines pipeline has been ranked number one in terms of value creation in 2018, based on an independent evaluation of 7,000 of the world's leading pharmaceutical and biotech companies.[58] Up to now, more than 160 projects are in clinical development and there are more than 500 ongoing clinical trials.[59] Until 2022, more than 80 major submissions are planned in the US, Europe, Japan and China.

[57] Novartis "Data on File. Ref 003"
[58] EvaluatePharma (2018) "World Preview 2018, Outlook to 2024" [online] [last accessed 30/09/2020].
[59] Novartis (2019) "Novartis R&D Day" [online] [last accessed 30/09/2020].

3 Enhancing Value for the NHS

3.1 Overview

When the patent on an innovative medicine expires, other manufacturers are free to introduce their own version. These medicines can be manufactured as generic medicines that have identical molecular structures to the innovative medicine.[60] An entrant making its version of more complex medicines that are made or derived from a biological source requires more complex manufacturing to develop what are known as biosimilars. Biosimilars have no clinically meaningful differences in safety, efficacy, quality, structural characteristics, and biological activity in comparison with the innovator biologic medicine.[61] Both generics and biosimilars are typically priced well below the cost of the innovative medicine at patent expiry,[62] and the consequent emergence of competition in the prescriptions market means that the innovator product no longer enjoys exclusivity and, possibly, significant price-setting power.[63]

The lower costs of generics and biosimilars enhances the value of medicines available to national health authorities and provides the NHS with significant savings on its medicine expenditure. Novartis, through its generic and biosimilars division Sandoz, is a crucial source of such savings given its leading role in the UK market. Box 1 provides a brief description of key terms used in this chapter.

[60] NHS (2019) "What is a biosimilar medicine" [online] [last accessed 14/09/2020].

[61] British Biosimilars Association (n.d.) "Facts about Biosimilars" [online] [last accessed 14/09/2020]. The European Commission produces guidelines for each biosimilar medicine, specifying the procedures to be performed in order to gain regulatory approval. This includes a thorough demonstration of the biosimilar's similarity to the reference product that, if successful, eliminates the need for further proof of safety and efficacy of the biosimilar.

[62] For example, see Figure 20.

[63] We recognise that having a patent on an innovator medicine does not necessarily imply significant market power on the part of the innovator manufacturer. Indeed, the innovator medicine could be one of a number of alternative treatments for the same type of disease or condition, and may therefore be exposed to competition before generic entry. Conversely, in principle, even post-patent-expiry some medicines might hold such a high market share, with some form of limits to new entry by competitors, that they could still have significant market power.

Box 1: Glossary of terms used in this chapter

Generic medicine
Generic medicines can be supplied by other manufacturers after the patent expires on the original incumbent medicine, which is referred to as the "reference" or "innovator" medicine. Depending on the product, generics can be brought to market at a lower cost in comparison with the expenditure that goes in to bringing the original innovator medicine to market.

A "generic" competitor is the standard general term across sectors — pharmaceuticals, information technology, the automotive sector, defence (etc.). In the medicines sector the term "generic" has an additional narrower meaning — specifically the new entrants for pharmaceutical medicines as opposed to biologic medicines (the latter being referred to as "biosimilars"). However, perhaps confusingly, both generic medicines and biosimilars are termed "generics" in the economic literature on patenting.

Biological medicine
Biological medicines are derived from living cells or organisms and consist of large, highly complex molecular entities which may be difficult to characterise. Due to the variability of the biological system and the manufacturing process, biological medicines may show a certain degree of variation, even between batches of the same product.

Biosimilar medicine
A biosimilar medicine is a biological medicine that is developed to be highly similar and clinically equivalent to an existing biologic medicine. A biosimilar contains a version of an active substance of an already approved biological reference medicine. Similarity to the reference medicine must be established based on a comprehensive biosimilar comparability exercise to demonstrate that they do not have any clinically meaningful differences from the reference medicine in terms of quality, biological activity, safety, efficacy and immunogenicity. Comparability is a well-established concept, used to evaluate manufacturing changes in biological medicines.

If a biosimilar is highly similar to the reference medicine and has comparable safety and efficacy in one indication, safety and efficacy data may be extrapolated to other indications already approved for the reference medicine, if scientifically justified. This avoids unnecessary repetition of clinical trials. Biosimilar medicines are not the same as generic medicines, which contain simpler chemical structures and are identical, in terms of molecular structure, to their reference drug.

Source: NHS (2019), 'What is a Biosimilar Medicine?'; Europe Economics' explanation.

3.2 Economic theory

3.2.1 Theory of generics markets

A patent provides the patent-holder with a period in which that firm is uniquely able to sell and use the patented product (or process — hereafter we shall restrict the discussion to the case of product patents). If that product is sufficiently different from other products, if consumers want that product and are prepared to pay for it, and if consumers themselves are not combined such that they have monopsony buying power, the result can be that during the period of the patent the patent-holding firm has significant market power, meaning that it is able to sell the product at what economists call a "monopoly price".

When the patent expires[64] (either because its term expires or the patent-holder decides not to renew it), other firms are able to enter the market to supply their own version of the product. Such competitors might apply their own branding[65] (which may be required by regulation, depending on the medicine) or they may supply an unbranded version. In either case, these new entrant products, post-patent-expiry, are referred to as "generics".

When there are many suppliers of a product, as opposed to just one, and that product has limited other substitutes the market will be more competitive. In a more competitive market, prices are bid down because a buyer has the option of purchasing from the cheapest supplier and suppliers will therefore gain custom, and hence profits, by cutting prices below those of their rivals until the point at which further price cuts would make supplying the product unprofitable (the price at which this occurs is called the "marginal cost").

Since patent expiry can be associated with a change from a situation of monopoly pricing to competitive pricing, we should expect post-patent-expiry, or "generics", markets to exhibit lower prices than was the case when the patent was still in force.[66] Whilst the overall volume of medicine in any given generic market may remain the same – or even increase[67] – the market value of the medicine is often expected to fall as a consequence of this price reduction.[68]

3.2.2 Application in the pharmaceuticals sector

Generic and biosimilar medicines offer significant savings for the cost of prescribing medicines to the UK taxpayer. This is because, once a patent on an innovative medicine expires, other manufacturers are free to introduce their own highly similar and clinically-equivalent medicines at a lower price (subject to appropriate standards regulation). All suppliers (including the original post-patent-expiry product — often referred to as the originator or innovator product) can now compete, bidding down prices.[69] And the mere possibility of a manufacturer to put its own, lower priced generic, on the market (even if it never does so) will also put downward pressure on the price of that medicine. In the economics jargon, this is referred to as the "threat" of market entry.

Prescribing authorities may choose to prescribe the new lower-cost medicines as they become available, observing that the new alternatives are more cost-effective than the innovator medicine.[70] This can reduce

[64] Note that we use the concept of a "patent expiring" here to include the expiration of any supplementary protection period, such as that provided via a Supplementary Protection Certificate.

[65] These are referred to as "branded generics".

[66] We note that the above is subject to a number of strong qualifications. Many patents are not renewed up to their maximum term precisely because demand for the product has fallen away over the lifetime of the patent. That might happen, for example, if the patented product is superseded by a superior alternative innovation or if demand for the product stops arising in the first place (e.g. medicines to treat smallpox victims have much less value since smallpox became extinct). In such cases we should not expect that the patent-holder had significant market power at the point the patent expired, so we should not expect that generic competition will materially reduce prices.

[67] Having a higher volume of medicines post-generic entry might be possible because, with access to the cheaper generics, prescribing authorities might prescribe more of the medicine for the same, or even lower overall cost.

[68] See for example Pharmaletter (1997) "Antihypertensive Sales "Set To Decline"" [online] [last accessed 0810/2020].

[69] In the UK, the Department of Health and Social Care (DHSC) is the primary purchaser of medicines. Such a sole buyer or "monopsony" position is often said to provide a form of "buyer power" in negotiating with manufacturers, allowing the buyer's purchase prices to be bid down.

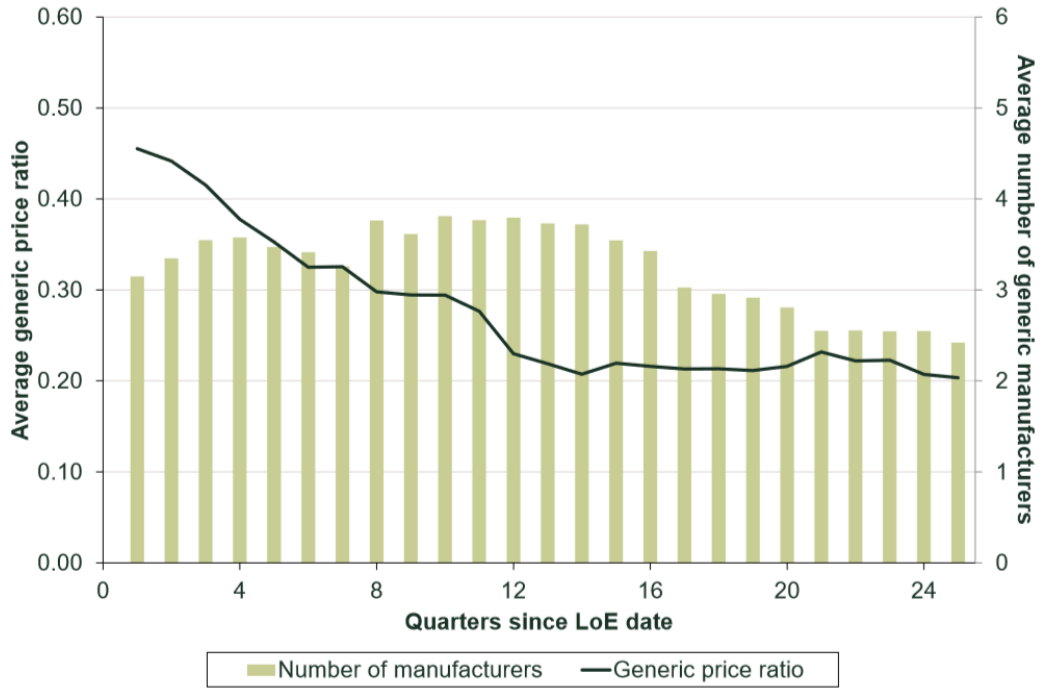
[70] Some research suggests the drive of prescribing authorities to prescribe generic alternatives is strongest for the first generic 'entrant' but tails off thereafter. Prescribing authorities must consider all the effects of switching medicines, so constantly switching to the cheapest available medicines is not always possible. For example, certain costs can be associated with switching patients to different medicins, such as clinical appointments, education of patients on why their medicine in changing, education on a new device, managing perceived or real side effects and the potential of switching back if the treatment goal is not reached. The difference in price between the original medicine and the first generic is typically much larger than that between subsequent generic entrants, thus further reducing incentives

pressure on their budgets and reduce the share of prescriptions of the innovator product through price competition. This process puts downward pressure on the costs of medicines as a whole.

Figure 19: Stylised timeline of generic entry in a given condition area

The evidence across a range of medicines offers strong support for the theory. Across 163 molecules, Oxera, a UK-based economics consultancy, finds that the price of generic medicines is just 10-30 per cent of the pre-patent expiry price of the innovator medicine after 2-4 years.[71] The average ratio of the generic price to the incumbent price before patent expiry is shown in Figure 20. After 3 years, the generic price is some 20 per cent of the original innovator price. We use this 20 per cent figure later in the chapter to estimate the cost-savings enabled by generic medicines produced by Sandoz.

Figure 20: ratio of generic to incumbent innovator price following patent expiry



Source: Oxera (2019) "The supply of generic medicines in the UK" [online] [last accessed 14/09/2020].

The reduction in the average price of medicines in a given therapy area post-patent expiry can significantly reduce the overall value of the associated market, even if medicine volumes in the market remain the same or increase (as long as demand does not increase so much as to offset the reduction in price). This reduction in market value illustrates the potential large savings to health authorities' medicines budgets.

for further switching. See, for example, Yu, Y and Gupta, S (2014) "Pioneering advantage in generic drug competition" *International Journal of Pharmaceutical and Healthcare Marketing,* p1750-6123 [online] [last accessed 3/11/2020].

[71] Oxera (2019) "The supply of generic medicines in the UK" [online] [last accessed 14/09/2020].

Box 2: Example of impact of generics on market value

The global market for antihypertensive medicines (for treating high blood pressure), which was worth $24.7bn in 1997, was expected to decline from 2000 despite a growing patient population and increasing market volume.[72] It was envisaged that this would occur due to patent expiries on most calcium channel blockers and ACE inhibitors, which together accounted for more than 75 per cent of the market at the time. This is indeed what happened: by 2018, the market for antihypertensives was valued at approximately $13.8bn and it is currently expected to continue declining to $9.7bn in 2022.[73]

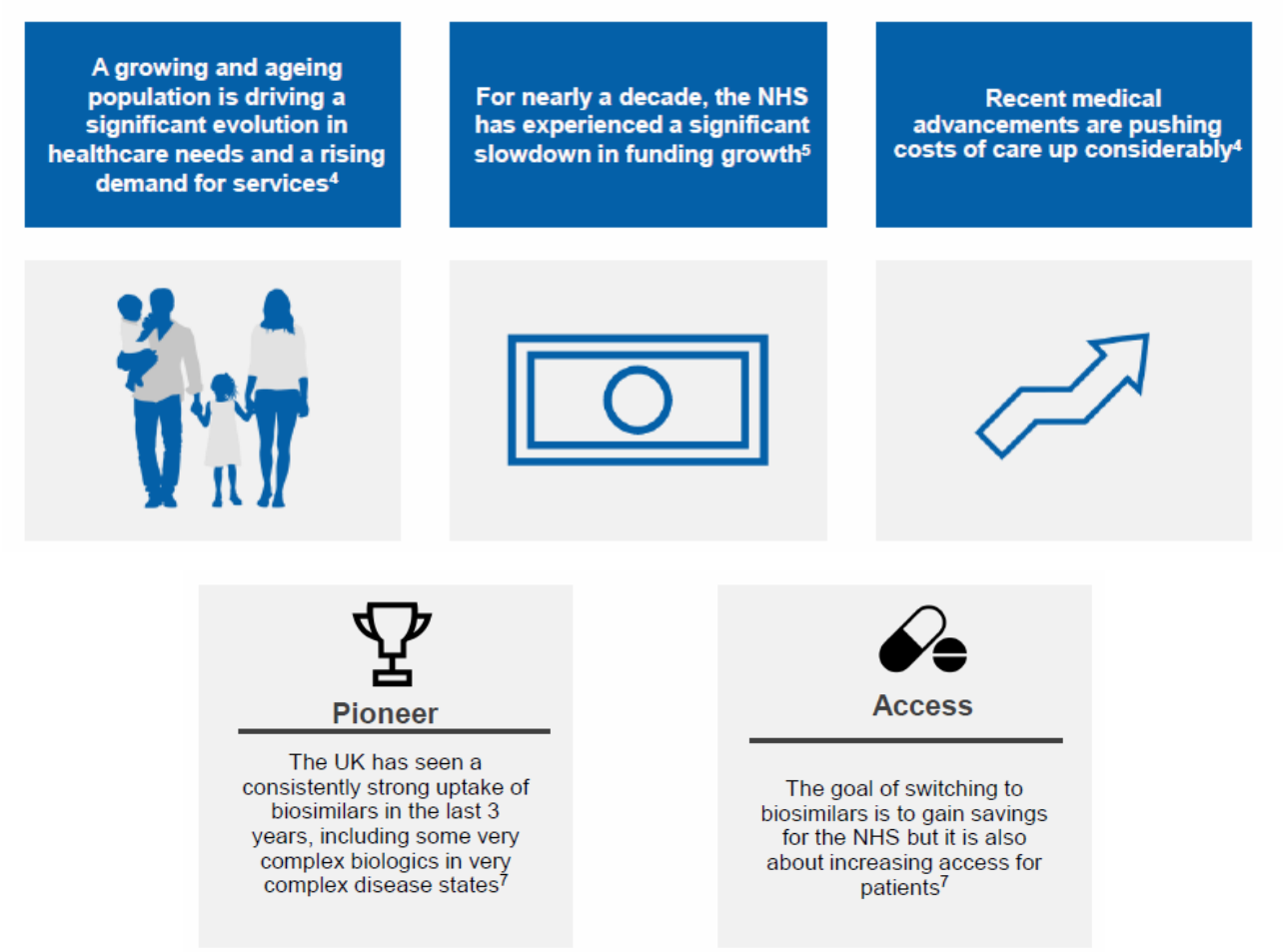
The UK is a pioneer in the use of generic and biosimilar medicines. Compared with other European countries, the UK has the largest share of generics in the total pharmaceutical market measured by volume at 85.2 per cent.[74]

Recent published data on NHS expenditure on generics is limited. The National Audit Office (NAO) estimated that 28 per cent of all NHS medicine expenditure was on generics in the year 2016/17 (accounting for both primary and secondary care medicine expenditure), equating to approximately £4.3bn in the same year.[75] Applying this proportion to an estimate of UK expenditure on prescribed medicines for 2019/20 suggests that the NHS may have spent as much as £5.96bn on generics in 2019/20.[76]

Despite accounting for the smaller share of total medicine expenditure, generics account for the majority of medicine *volume* in the UK. Approximately 75 per cent of medicines in the UK are dispensed as generics,[77] estimated at over a billion items prescribed by the NHS every year.[78] Consequently, the production of generics is vital for ensuring that patients receive affordable medicine. The British Generic Manufacturers Association estimates that savings to the NHS from generics spending (compared to on-patent prices) have "passed more than £13bn annually".[79]

[72] Pharmaletter (1997) "Antihypertensive Sales "Set To Decline"" [online] [last accessed 0810/2020].
[73] Global Newswire (2019) "Anti-Hypertensive Drugs Market Report | Global Market Set to Decline to $9.72 Billion by 2022" [online] [last accessed 15/09/2020]
[74] Data for latest available year: 2017. OECD (2019) "State of Health in the EU. United Kingdom Country Health Profile 2019" [online] [last accessed 08/10/2020].
[75] National Audit Office (2018) "Investigation into NHS spending on generic medicines in primary care" [online] [last accessed 14/09/2020].
[76] This applies the NAO's findings (that generics account for 28% of medicine expenditure) to a baseline figure of expenditure on medicines across primary and secondary care in 2019/20 – £21.3bn – which is estimated by the Nuffield Trust. Nuffield Trust: Dayan, M (2018) "Calculating the costs of a no deal Brexit for the NHS: Methodological assumptions" [online] [last accessed 25/09/2020].
[77] Kelly, P. (2020) "UK Generic Medicine Price Flux? The real data behind the headlines", Accord UK White Paper [online] [last accessed 2/11/2020].
[78] British Generic Manufacturers Association (2019) "About generics – Industry overview" [online] [last accessed 14/09/2020].
[79] British Generic Manufacturers Association (2019) "About generics – Industry overview" [online] [last accessed 14/09/2020].

Figure 21: The importance of generics in the UK



Note: References in the figures (4) – The Rising Cost of Medicines to the NHS, accessed at: https://www.kingsfund.org.uk/sites/default/files/2018-04/Rising-cost-of-medicines.pdf, on 14/09/20; (5) - The NHS Long Term Plan Explained, accessed at: https://www.kingsfund.org.uk/publications/nhs-long-term-plan-explained, on 14/09/20; (7) - The future of biosimilars in the UK, accessed at: https://www.kingsfund.org.uk/sites/default/files/2018-04/Rising-cost-of-medicines.pdf/, on 14/09/20.
Source: Sandoz (2019): 'Making access happen', presentation October 2019.

With its generic- and biosimilar-producing arm Sandoz (one of the largest suppliers of generic medicines in the UK and the largest in Europe as a whole[80]), the Novartis Group contributes to making medicines more accessible after their patents expire. That is true for the generic medicines it actually supplies, and because its *potential* to supply in generics markets in which it is not currently a supplier is a competition stimulant in those markets.

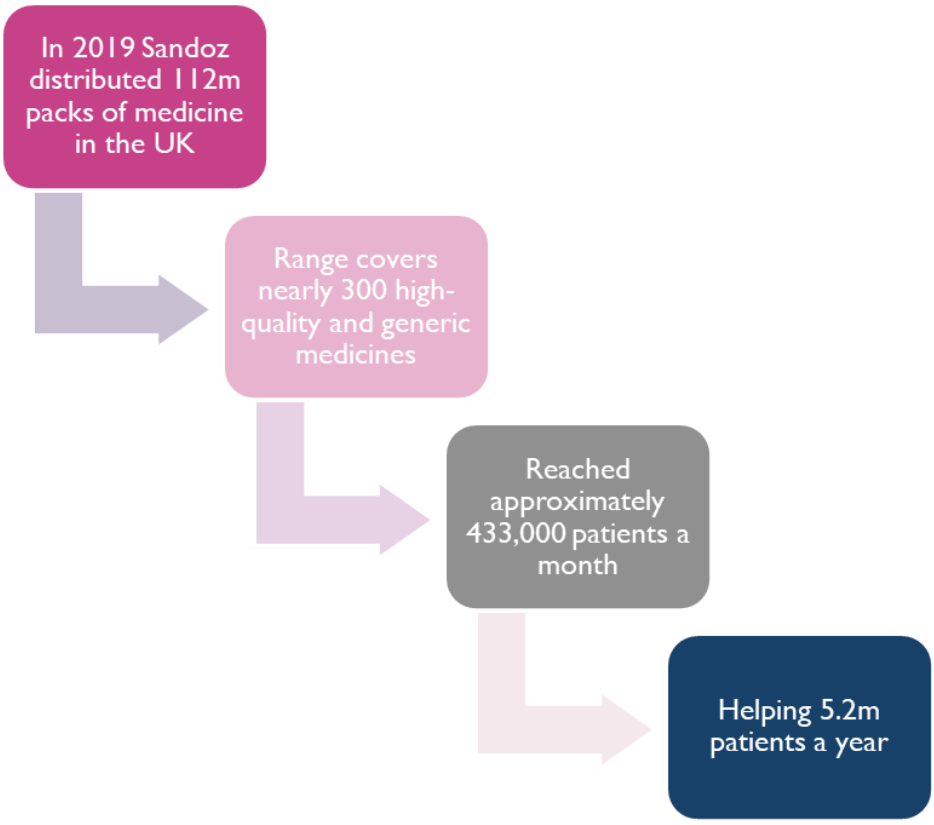
3.3 Examples of how Novartis adds value in the UK: Sandoz

As part of the UK generics market, Sandoz makes a significant contribution to the affordability of medicines in the NHS. In 2019, Sandoz distributed 112m packs of medicines in the UK[81] from a product range that

[80] Based on 11.5 per cent market share YTD April 2019 USD. Source: IQVIA PADDS Apr'19 Value: @TGT'19.
[81] Sandoz (2020) "Sandoz Fast Facts".

covers nearly 300 high-quality and generic medicines. It reached at least 433,000 patients a month, helping approximately 5.2m patients over the course of the year.[82]

Figure 22: Sandoz presence in the UK 2019



Source: Europe Economics' illustration of Sandoz (2020) "Fast Facts"

The savings to which Sandoz contributes are generated from its production of both generic and biosimilar medicines. Through manufacturing these medicines upon the expiry of patents on innovative products, Sandoz is one of the many suppliers whose role is outlined in the theory above: its supply of highly similar and clinically equivalent products at a lower price than the innovator medicine helps to exert downward pressure on the market price of that medicine, and the generic medicines market as a whole.

3.3.1 Generics

As noted above, as a large player across the generics and biosimilars sector, Novartis contributes through Sandoz to price reductions even in markets where it does not itself supply medicines, through the potential that it might enter. Indeed, given that large volumes of medicines are imported into the UK in addition to those manufactured here, that point applies to Sandoz's global contribution to generics, not simply to its UK supply. If we apply the Oxera price ratio (20 per cent of the patented price)[83] to the estimated £5.96bn spent by the NHS on generic medicines in 2019/20, we estimate implied savings to the NHS of around £24bn

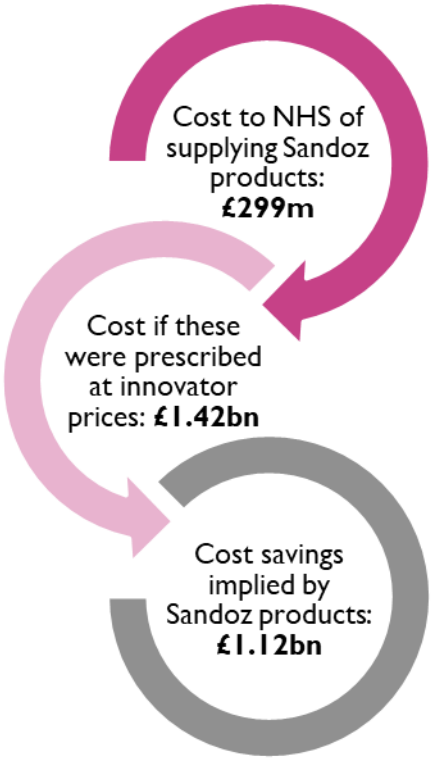
[82] Sandoz (2020) "Sandoz Fast Facts". Number of prescriptions filled with Sandoz product divided by the average number of prescriptions per person per year (set at 20 based on findings published in NHS Digital (2017) "Prescriptions dispensed in the community - statistics for England 2006-2016", p5 [online] [last accessed 12/01/2020]).

[83] Oxera (2019) "The supply of generic medicines in the UK" [online] [last accessed 14/09/2020].

generated by having access to generic medicines.[84] As one of the largest generics companies in the UK and Europe, Sandoz would be responsible for a significant proportion of these savings, both through the supply of generic medicines in markets where it is active, as well as its *potential* to supply in others via the competition dynamics discussed earlier in this chapter. Applying the Novartis European market share to this figure[85] gives a sense of the scale of the potential Novartis impact on NHS savings through this competitive dynamic – around £2.7bn.

Turning to the generic products Sandoz actually supplies, the direct savings to the NHS which Sandoz influences can be estimated.[86] In 2019, the cost to the NHS of prescribing Sandoz generics was £299m.[87] If these medicines were prescribed at the price of the original innovative products before their respective patent expiry, the cost would have been £1.42bn.[88] Therefore, it is estimated that Sandoz contributed to a total implied savings of approximately £1.12bn for the NHS in 2019 in relation to the medicines it supplies, a saving of just under 80 per cent. This is illustrated in the figure below.

Figure 23: Sandoz's impact on cost savings for the in NHS in 2019 from the medicines it supplies



Source: Sandoz (2020) "Sandoz Fast Facts"

[84] 5.96 / 0.2 – 5.96 = 23.84. We note that this figure is a broad estimate, intended to illustrate the implied savings enabled by generics versus on-patent drugs. It does not take into account dynamic effects, e.g. changes in prescribing volumes and patterns adopted by the NHS if the generics were not available.

[85] 11.5% in 2019. IQVIA PADDS Apr'19 Value: @TGT'19.

[86] We note that this concept of savings uses a different methodology to the previous concept of the general competition dynamic.

[87] Sandoz (2020) "Sandoz Fast Facts". Sold quantity multiplied by average reimbursement rate for the year, except for primary care products where the calculation is sold quantity multiplied by Sandoz brand list price. As agreed with Sandoz UK business, figures taken from Sandoz UK Business Intelligence Sales Report 2019.

[88] Sandoz (2020) "Sandoz Fast Facts". Most recent originator list price used. We note that this is a high-level estimate intended to illustrate the scale of cost savings to the NHS.

3.3.2 Biosimilars

The importance of biosimilars in the UK

Biosimilars are competitive alternatives of more complex medicines. Whereas generic medicines offer alternatives of relatively simple (and small) molecules, biosimilars are based on naturally-occurring proteins and produced using living cells, so they have more complex molecular structures. This makes the production process of biosimilars more demanding. NICE's recommendation regarding the biologic is often extended to its biosimilars in recognition of their highly similar features.[89] Biosimilars are expected to play an increasing role in the future of affordable healthcare. Five of the top seven innovator biologics will have lost their patents by 2020[90] and there are currently 15 reference biological medicines with biosimilars approved for use in the UK as well as many in development.[91] As the biosimilar market develops, it is estimated that increased competition between biological medicines has the potential to deliver significant annual savings to the NHS of £400m to £500m by 2020/21 through increased uptake of the best value biologic medicines, including biosimilars.[92]

Biosimilars, which do not require research to identify drug targets or to undergo lengthy clinical trials to the extent of the reference biologic, may be brought to the market at a lower cost than the innovator medicine. In turn, this means that they can be brought to market faster, and their subsequent uptake can entail cost savings to healthcare authorities and better patient access to costly biologic therapies.[93] In addition, biosimilars are sometimes licenced for more health conditions than the originator medicine, generating value to patients and healthcare systems.

Box 3: Biosimilars for broad range of conditions

In the UK, biosimilars of one key originator medicine – originally licensed for the treatment of particular blood cancers and inflammatory condition – have been licensed for as many as 10 different health conditions.[1]

Like all medicines, these biosimilars bring value through improving health outcomes, increasing people's GDP contributions and reducing systems costs through the mechanisms described in Chapters 1 and 2. With the advent of biosimilars of this originator medicine across a number of health conditions, the NHS has been able to buy an effective medicine for a lower price. NHS England reports that it saved £45m in 2018-19 from encouraging prescribers to use the best value biosimilar for these various health conditions.[2] Sandoz has actively contributed to realising such savings as it produces a biosimilar for these indications too.

Sources: 1 Technology appraisal recommendations (Excel document) downloaded from NICE (Source: Sandoz (2020) "Sandoz input v1.1"); 2 NHS (2019) "NHS cuts medicines costs by three quarters of a billion pounds" [online] [last accessed 15/09/2020].

Increasing the uptake of biosimilars is regarded as one of the cost-effective policy solutions to the growing and ageing population that is causing significant changes in healthcare needs in the UK.[94] Indeed, the UK has experienced consistently strong switching to biosimilars over the past three years.[95] For example, NHS Trusts in England had achieved more than a 90 per cent uptake of two particular biosimilars for particular indications

89 NHS England (n.d.) "Biosimilar medicines" [online] [last accessed 15/09/2020].
90 British Biosimilars Association (n.d.) "Introduction" [online] [last accessed 15/09/2020].
91 NHS (2019) "What is a biosimilar medicine" [online] [last accessed 14/09/2020].
92 NHS (2019) "What is a biosimilar medicine" [online] [last accessed 14/09/2020].
93 Sarnola, K et al. (2020) "Physicians' perceptions of the uptake of biosimilars: a systematic review" *BMJ Open*, Vol. 10 [online] [last accessed 15/09/2020]
94 Ewbank, L et al. (2018) "The rising cost of medicines to the NHS – what's the story?" [online] [last accessed 15/09/2020].
95 Green, Claire (2019) "The future of biosimilars in the UK" [online] [last accessed 15/09/2020].

by March 2019.[96] Generally, biosimilars have exceeded cost-reduction targets across a range of expensive medicines. In 2017/2018, the NHS set a savings target of £250m for NHS trusts that use 10 expensive medicines. By July 2018, the trusts had already exceeded the target by £74m.[97]

The NHS has published official guidance stating that the majority of patients for whom biosimilars are available should be prescribed them.[98] Such a drive is especially important for reducing the cost burden of certain complex medicines. For example, a biologic (of which Sandoz is one producer), which treats a number of inflammatory conditions was the individual medicine on which hospitals spent the most[99] before the patent expired on the innovator medicine in October 2018.[100] Over the following year the switch to the best value biosimilar led to an overall saving of £98m – which was expected to rise to £308m by the end of 2020,[101] rather than by 2021 as originally estimated.[102]

In some countries, such as the UK, there is an active effort to encourage the switching to biosimilars from originator biologics with incentive programmes that share the benefits of the savings from biosimilar uptake with the prescribing clinic.[103] For example, the savings from a gain-share agreement between University Hospital Southampton NHS Foundation Trust and local clinical commissioning groups to encourage the uptake of particular biosimilars were able to fund a new specialist nurse post and proportions of other whole time equivalent positions. This demonstrates that the cost savings made possible by access to biosimilars (and generics) can make scarce resources available for other important uses. By 2018, switching to biosimilars (of which Sandoz is one producer) more widely across England had delivered savings of approximately £99m to NHS England.[104]

Sandoz: a pioneer in the use of biosimilar medicines in the UK

Having launched the first biosimilar in Europe in 2006,[105] Sandoz is a market-leader in the production of highly similar and clinically equivalent versions of these more complex biological medicines. Novartis' experience on both sides of the patent divide gives it insights into the quality production of more complex medicines that a producer of only generics may not possess.

Sandoz has worked closely with the NHS in the past to facilitate the appropriate use of biosimilars and thus bring about the savings described above. Box 4 provides an example of a joint working partnership between Sandoz and the NHS in relation to biosimilars for the treatment of cancer in London. As we shall see in the chapter 'Creating a Collaborative Ecosystem', Novartis works extensively with partners in the NHS and further afield.

[96] NHS Business Services Authority (n.d.) "NHS medicines optimisation dashboard" [online] [last accessed 22/10/2019].
[97] NHS (2018) "The NHS saves £324 million in a year by switching to better value medicines" [online] [last accessed 15/09/2020].
[98] NHS England (2017) "Commissioning framework for biological medicines (including biosimilar medicines)" [online] [last accessed 15/09/2020]
[99] NHS (2019) "NHS cuts medicines costs by three quarters of a billion pounds" [online] [last accessed 15/09/2020]
[100] NHS (2018) "The NHS saves £324 million in a year by switching to better value medicines" [online] [last accessed 15/09/2020].
[101] NHS (2019) "Regional Medicines Optimisation Committee Briefing Best Value Biologicals: Adalimumab Update 6" [online] [last accessed 15/09/2020]
[102] "NHS savings from adalimumab biologic switching hit earlier than expected" *The Pharmaceutical Journal,* Vol 302, No 7926. [online] [last accessed 15/09/2020]
[103] Razanskaite V et al. (2017) "Biosimilar Infliximab in Inflammatory Bowel Disease: Outcomes of a Managed Switching Programme" *Journal of Crohn's and Colitis*, 690-696 [online] [last accessed 15/09/2020]
[104] NHS (2018) "The NHS saves £324 million in a year by switching to better value medicines" [online] [last accessed 15/09/2020].
[105] Sandoz (2019) "Making access happen".

Box 4: Collaboration between industry and the NHS to educate on biosimilars

The Joint Working Partnership (JWP)

Joint working partnerships (JWPs) are collaborative arrangements for the benefit of patients in which the NHS and industry pool skills, experience, and / or resources for the joint development and implementation of patient-centred projects.[1]

Back in 2017, Sandoz partnered with Cancer Vanguard – a partnership of hospitals across Greater Manchester and London. Cancer Vanguard was established in response to the National Cancer Strategy to test and fast-track innovative and new models of cancer care. The objective of the JWP was to ensure biosimilars are used safely, and it combined skills and resources from The Royal Marsden and Sandoz to develop a targeted biosimilar education programme applicable to any biosimilar to ensure their use is optimised in the NHS.[2]

Recognised benefits of the JWP

As part of the project, the partners assessed the impact of the education and received very positive feedback. The Royal Marsden is generating savings of around £60,000 a month for the NHS by using biosimilars in place of branded medicines.[3]

Jatinder Harchowal, the Chief Pharmacist at the Royal Marsden Hospital and involved in the JWP, suggested that the pace of delivery of the Cancer Vanguard approach would not have been possible without the collaboration of the pharmaceutical industry.[3] In recognition of the success of the JWP, the project won Highly Commended in the Health Service Journal's Partnership Awards in 2018.[4]

Sources: (1) ABPI (n.d.) "Joint Working", presentation; (2) Sandoz (2018) "Cancer Vanguard" [online] [last accessed 3/11/2020]; (3) Harchowal J, NHS Commissioning Chemotherapy Services (n.d.): "The introduction of biosimilars into clinical practices" pages 30 and 33 [online] [last accessed 3/11/2020]; (4) Health Service Journal SJ (2018) "HSJ partnership awards 2018: best pharmaceutical partnership with the NHS" [online] [last accessed 21/09/2020].

Whilst innovation on the medicine itself is not needed in the production of biosimilars, this does not mean that no innovation takes place. In 2019, Sandoz invested 8.2 per cent of its global net sales into research and development.[106] This has led to innovation on, for example, the delivery side of a biological medicine in order to ease its administration to patients.[107]

Sandoz is also able to leverage its size and extensive distribution networks to bring innovations to market. For example, Sandoz will be responsible for marketing and distributing the Novartis innovative "green" dry powder inhalers (described further in Chapters 5 and 7) using its capabilities in respiratory primary care and local access focus.

Box 5: Helping to reduce the extraordinary pressure on supplies during the COVID-19 pandemic

Sandoz's manufacturing capacity and willingness to cooperate with other players have been important in keeping the supply of medicines flowing in the UK throughout the COVID-19 pandemic. The pandemic has put unparalleled pressure on the generic medicines supply chain. Up to ten times the normal quantities of some medicines were needed and at short notice.[108] There have been large surges in demand for medicines used in Intensive Care Units, particularly for patients who needed mechanical ventilation.

Despite the extraordinary circumstances, the supply chain has held up well. Cooperation and coordination between the pharmaceutical and life sciences sector, government and the NHS has ensured that patients continue to receive the medicines they need. This was achieved through the considerable effort of all

[106] Sandoz (2020) "Sandoz Fast Facts".
[107] Sandoz (2019) "Medical device information".
[108] BGMA (2020) "Generic Industry Supply Chain Resilience Post Covid-19".

parties. One of Sandoz's contributions to this effort was the identification of an urgently-needed anaesthetic that was not marketed in the UK but was in short supply.[109] Working closely with the Medicines and Healthcare products Regulatory Agency, Sandoz was able to identify the product in its supply chain outside the UK and bring this to UK patients through a degree of regulatory flexibility that is inconceivable in normal times.

In February 2020, Sandoz committed to keeping prices stable for a basket of medicines which may be used to deal with the pandemic.[110] In addition, Novartis and Sandoz UK put the following measures in place:

- As part of its business continuity plans and in line with requests from the Department of Health and Social Care, Novartis and Sandoz maintained increased inventories across their medicines portfolios.
- They monitored orders carefully and considered demand management plans in the event of unusual ordering patterns.
- They continue to work together with partners at the DHSC to keep them informed of supply chain risk assessments, which currently have adequate supply to meet usual levels of demand. [111]

3.4 Demonstrating the Social and Economic Impact of Various Generic Medicines

Generic and biosimilar medicines help treat a variety of debilitating health conditions. In what follows, the economic and social impact of a small selection of such conditions is demonstrated.

The value of generics is not limited to savings they bring to patients and healthcare providers. The medicines themselves can have significant health impacts on patients, which in turn translate into economic benefits to society as a whole. Given the impact that cost savings have on the number of patients then able to access the medicines, these societal gains can be extensive indeed.

In the previous chapter, we explored a way of quantifying the social impact of medicines developed by WifOR, which translates QALY gains across patients into the GDP impacts. To illustrate the economic value of Sandoz medicines, this methodology was applied to a subset of 14 of Sandoz medicines. Together these medicines reached 3.1m patients in the UK in 2019, generating just under 58,000 QALYs and a total GDP impact of £7.1bn.[112] This subset of medicines represents approximately 22 per cent of total Sandoz sales,[113] so it is clear that the total impacts of Sandoz would be in considerable excess of the figure estimated by WifOR.

We present below case studies illustrating the cost savings and social impacts of a range of generic medicines, of which Sandoz is one producer.

3.4.1 Generics for antihypertension

Sandoz illustrates the market value-reducing effect of generic medicines entering after the patent expires on an innovator medicine. Its generic in hypertension, for example, has been a contributor to the diminishing

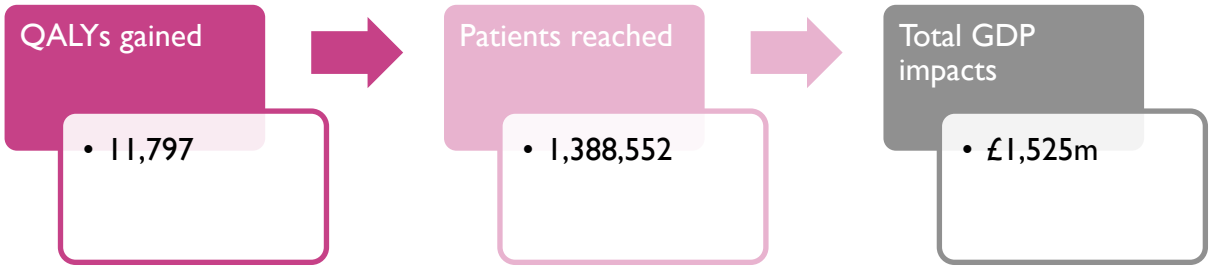
[109] Sandoz (2020) "Sandoz input v1.1"
[110] Sandoz (February 2020) "Sandoz commits to keep prices stable for basket of essential COVID-19 medicines; Novartis responds to COVID-19 with broad range of initiatives" [online] [last accessed 16/11/2020].
[111] Sandoz (2020) "Sandoz input v1.1"
[112] WifOR (2020) "The Social Impact of Novartis Innovative Medicines and Sandoz Products in United Kingdom in 2019". GDP impact of $9,099,346,530 converted to GBP using 1 USD = 0.783652 GBP from OFX (2020) "Yearly average exchange rate" [online] [last accessed 01/09/2020].
[113] WifOR basket as proportion of Sandoz sales (2020). £20,124,000 / £91,099,000 = 22.09%.

monetary size of the global antihypertensive market.[114] The global sales of the innovator medicine were anticipated to peak at $1.9bn in 2005 – two years before its patent expired – before falling to $495m by 2010.[115] This is despite the number of sufferers of hypertension (high blood pressure) climbing to over 210m globally by 2015.[116] Not only does this mean health authorities have been able to benefit from the reduced costs of this medicine, it also demonstrates the ability of a generic medicine to increase the accessibility of the treatment to those who need them.

Economic and social impact of treatment of hypertension

In 2019, Sandoz's generic reached approximately 1.4m individuals in the UK, generating a social impact of around £1.53bn due to improved quality of life and economic activity of these patients.[117]

Figure 24: Summary of annual social and economic impact of treating hypertension in 2019 in the UK



3.4.2 Generic medicines for transplant rejection

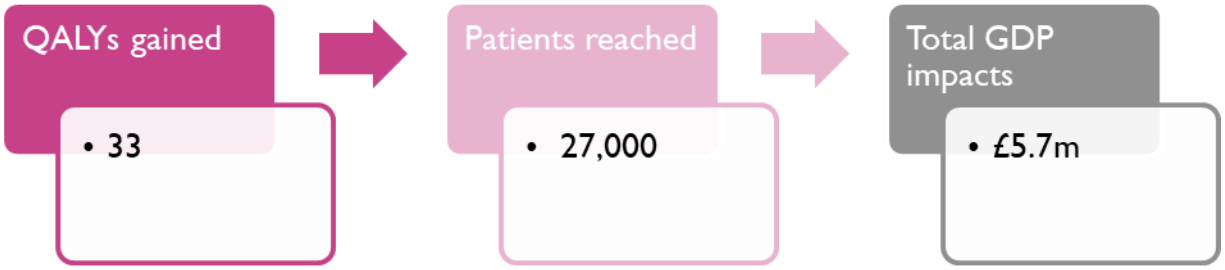
People who undergo a procedure for organ transplant must be put on a regimen of immunosuppressive medicines to prevent disease and ensure the new organ's survival.[118] Naturally, the survival of the organ is crucial for the sustained health and survival of the individual receiving it.

Economic and social impact of treatment of transplant rejection

A Sandoz generic drug for treating transplant rejections has been prescribed in around 27,000 patients in England in the past year, generating around 33 QALYs and an estimated GDP impact of £5.7m.[119]

[114] The originator medicine is licenced to treat high blood pressure as well as chronic stable angina pectoris and vasospastic (Prinzmetal's) angina. See for example EMC (2020) "ISTIN 10mcg tablets" [online] [last accessed 08/10/2020].
[115] Pharmaletter (1997) "Antihypertensive Sales "Set To Decline"" [online] [last accessed 08/10/2020]
[116] Pharmaletter (2006) "Generics "striking at the heart of the antihypertensives market," Datamonitor" [online] [last accessed 08/10/2020].
[117] WifOR (2020) "The Social Impact of Novartis Innovative Medicines and Sandoz Products in United Kingdom in 2019". Total GDP impact converted from using 1 USD = 0.783652 GBP from OFX (2020) "Yearly average exchange rate" [online] [last accessed 01/09/2020]
[118] Sanders, M and Langone, A (2015), "Drugs in development for prophylaxis of rejection in kidney-transplant recipients", *Transplant Research and Risk Management*, 2015(7), pp.59-69 [online] [last accessed 25/09/2020].
[119] Europe Economics calculations based on WifOR methodology. Patient numbers: Sandoz (2020) "Sandoz input v1.1".

Figure 25: Summary of annual economic and social impacts of treating transplant rejection in England between 2019 and 2020



3.5 Summary and conclusion

When the patent of an innovator medicine expires, other medicine manufacturers are able to provide similar versions at lower prices. The supply of lower priced alternative medicines to patients is beneficial for both public health and the Department of Health and Social Care's medicine expenditure budgets. Sandoz, the division of the Novartis Group responsible for generics and biosimilars production, is a key player in their provision, having produced the first biosimilar medicine and continuing to innovate in the market after the patent expires on the original innovative medicines. In 2019 Sandoz contributed a total cost savings of approximately £1.12bn for the NHS on medicines it sold, and an estimated £7.1bn in GDP contribution.

4 Investing in the Future

Novartis brings value to the UK through a multitude of investments in different forms. In Chapter 1, the model of the economic impact of Novartis included its purchases across its supply chain, covering both repeat purchases and one-off investments. That includes investments in capital equipment, IT and the other standard forms of business infrastructure required by any major multinational operation. Novartis globally invested $2.2bn in 2019, including investments in breakthrough technologies, as for example the acquisition of AAA and AveXis, now Novartis Gene Therapies UK.[120]

The most important form of investment for a patented pharmaceuticals firm is investment in its R&D pipeline of new medicines. In Chapter 2 we discuss the value such investments provide to the economy beyond Novartis itself, from the way they improve patients' lives and bring value to healthcare systems.

In addition to the standard financial and medical effects of investment, certain forms of investment can provide particular benefits that are captured neither by the seller nor the purchasers and patients of medicines. Certain such "spillover effects", and how Novartis contributes to them, are discussed in Chapter 5.

In this chapter, however, we focus upon ways in which particular classes of investment by Novartis tend to stimulate not merely the *level* of output, but also accelerate the rate at which knowledge diffuses across the economy, enhancing the *rate* of economic growth and supporting innovation and medical developments into the future.

One particular forum for such investment is the Novartis Venture Fund. That Fund acts as an investment vehicle funnelling capital into promising companies and valuable areas of medical research. Novartis also directly funds initiatives such as the UK Biobank, and provides in-kind support to initiatives such as the NHS Health Data Research Hubs. These initiatives, and the gains they deliver to the frontier of medical knowledge, are described in this section.

4.1 Novartis Venture Fund

Venture capital is a specific category of high-risk private equity fund, suited both for investors seeking to acquire stakes in start-ups and small and medium sized firms (SMEs) with high growth potential. Angel investors provide funds for launching or growing start-ups, usually against convertible debt or ownership equity.

Venture capital and angel investors are important for fostering pharmaceutical innovations. Pharmaceuticals start-ups often require high levels of technology to commence operations, in turn requiring a significant capital injection — typically external.[121] However, conventional sources of financing often require collateral, and much of the value of pharmaceuticals start-ups is typically intangible (e.g. the intellectual property of some innovation or idea, or the personal skills of some group of researchers), and pay-back periods, if the start-up does not fail in the first place, can run to decades.[122]

Novartis Venture Fund (NVF) is a corporate life science venture fund wholly-owned by Novartis. It provides capital and guidance to start-ups creating novel therapeutics and platforms, especially where this provides

[120] Novartis (2019) "Novartis annual report 2019", pF-5 [online] [last accessed 15/09/2020].
[121] Morales, R and Radoniqi, F (2018) "Intangibles and the market value of biopharmaceutical start-ups" *The Journal of Business Inquiry,* Vol 18, No 2, p82-99.
[122] Berger, A and Udell, G (1998) "The economics of small business finance: The roles of private equity and debt markets in the financial growth cycle" *Journal of Banking & Finance,* Vol 22, No 6-8.

solutions for unmet needs. In doing so, NVF seeks to improve clinical impact and creates a sustainable financial model. It currently manages approximately US$800m in committed investments across North America, Europe and Israel, allocating up to US$30m per company.[123] Approximately £64m has been invested in the UK since 2009.[124] This investment strategy and its influence on company boards has created more than 1,000 jobs, 18 Phase 1 programs and 2 clinical programs over 20 years.[125]

4.1.1 Added-Value of Investments

Venture capital firms collect resources from investors and distribute them to start-ups and SMEs. This reduces the cost of capital for investees who develop a track-record of attracting money. Targeted investments are vital for technically niche areas which may not receive further funding. They struggle to obtain loans due to their inconsistent profits, inadequate collateral, information asymmetries, limited access to bank credit and high failure rates.[126] Venture capital funds like NVF can have a meaningful impact.

Investors monitoring start-ups motivate them to increase their performance. The rise in competition, in turn, spurs any incumbents to innovate in order to retain their market share.[127] The start-ups receiving funding tend to see greater total-factor productivity.[128] In this way, the use of targeted investments may boost growth.

Financial development and access to financing opportunities lead to economic growth. Endogenous growth theory suggests that where the engine of growth is technological progress, this derives from innovations developing products, processes and sectors. For example, the expanding variety model of Romer (1990) and the Schumpeterian growth model of Aghion and Howitt (2005) highlight the impact finance or financial constraints have on an economy's long-run growth rate.[129]

Growth stems from technological progress partly as a consequence of purposeful innovation investments (R&D) by firms and individuals. Moreover, R&D is costly and monopoly profits via patents provide incentives for companies to pursue discoveries. The patents ensure idea-creators undertaking R&D enjoy a degree of monopoly power because they exclude anyone from employing their idea. This theory about financial system and endogenous growth emphasises that financial constraints prevent entrepreneurs and innovators from pursuing R&D, which is essential for technological progress. This would cause growth to decline below its level in perfect credit markets.

Angel investing and venture capital is suited for this purpose because, as mentioned, start-ups may lack access to financing opportunities. Thus, as in other sectors, entrepreneurial financing of pharmaceutical start-ups may help them to increase their R&D investment, their success in obtaining patents, total factor productivity and eventually economic growth.

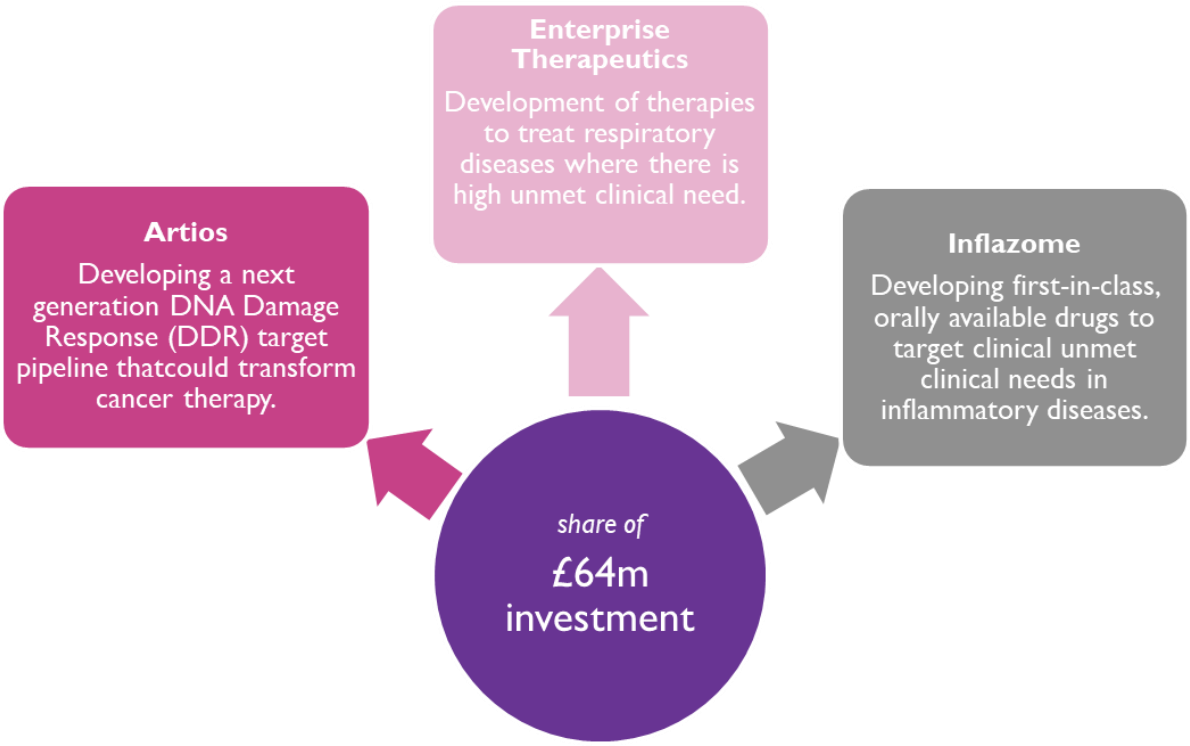
[123] Novartis Venture Fund (n.d.) "Our fund" [online] [last accessed 15/09/2020].
[124] Novartis "Data on File. Ref 012".
[125] Novartis Venture Fund (n.d.) "Our fund" [online] [last accessed 15/09/2020].
[126] Europe Economics for European Parliament (2009) "Directorate-general for internal policies, ex-ante evaluation of the proposed alternative investment managers directive", p42 [online] [last accessed 03/10/2020].
[127] Europe Economics for European Parliament (2009) "Directorate-general for internal policies, ex-ante evaluation of the proposed alternative investment managers directive", p42 [online] [last accessed 03/10/2020].
[128] Chemmanur, T, Krishnan, K, Nandy, D, Centre for Economic Studies (2009) "How does venture capital financing improve efficiency in private firms? A look beneath the surface" Unpublished working paper.
[129] Romer, P (1987) "Growth based on increasing returns due to specialization" *American Economic Association,* Vol 77, No 2, p56-62; Aghion and Howitt (2005) "Growth with quality-improving innovations: An integrated framework" *Handbook of Economic Growth,* Vol 1, No 1, Ch 2, p67-110.

4.1.2 Examples of NVF's value

Current investments

NVF has invested approximately £64m in a range of companies organized in the UK or with UK operations since 2009. Below, we describe a selection of companies that have benefited from continued NVF investment.

Figure 26: Selection of NVF UK investments



Artios Pharma

Artios Pharma Ltd was established in May 2016 to develop a next generation DNA Damage Response (DDR) target pipeline that has the potential to transform cancer therapy. Artios has in-licensed its lead DDR programme, PolΘ, from Cancer Research UK (CRUK). Artios had raised £25m prior to its launch in 2016.[130] The company has continued to attract investments, with Novartis having committed £5m. In recognition of its funding success, Artios won the 2018 Lifestars EU Private Finance Raise of the Year Award.[131]

[130] Artios (2016) "Strengthened management team with the appointment of Dr Simon Boulton as vice president science strategy" [online] [last accessed 15/09/2020].
[131] Artios (2018) "Artios pharma wins 2018 lifestars EU private finance raise of the year award" [online] [last accessed 15/09/2020].

Enterprise Therapeutics

Enterprise Therapeutics, with offices at the University of Sussex Innovation Centre, is a drug discovery company with focus on respiratory diseases.[132] The focus of the company is on researching and developing novel therapies in order to help treat mucus congestion arising with diseases such as asthma and COPD.[133]

In a Series B funding round, co-led by NVF and Versant Ventures, the company has raised £29m in investments.[134] The investment will be crucial in assisting the company develop therapies to treat patients suffering from respiratory diseases, currently with high unmet medical need. The success of the company has been demonstrated by the acquisition by Roche of its portfolio in October 2020, with an initial payment of £75m to its shareholders.[135]

Inflazome

Inflazome is a biotech company founded in 2016 with headquarters in Ireland and Cambridge, UK. It is developing first-in-class, orally available drugs to target clinical unmet needs in inflammatory diseases. The scope of this need is wide, incorporating for example Parkinson's and Alzheimer's, asthma, inflammatory bowel disease, chronic kidney disease, cardiovascular disease, and arthritis.

In 2018, Inflazome completed a Series B financing led by Forbion, with Novartis Venture Fund participating alongside Longitude Capital and Fountain Healthcare Partners, where it raised €40bn (approximately £35bn) to develop NLRP3 Inflammasome Inhibitors to Clinical Proof-of-Concept.[136] The success of the company has been demonstrated by its acquisition by Roche in September 2020, with an initial payment of €380m (approximately £334m) to Inflazome shareholders.[137]

Success stories

NVF identifies innovative firms in the UK and supports them at crucial times. The fund cultivates these start-ups with financial and technical support. This ensures the firms overcome the difficult conditions of the market and bring new medicines to a wide audience.

Heptares Therapeutics

Heptares Therapeutics, a clinical-stage biotechnology company, was founded in 2007 based on the pioneering work of its founding scientists Richard Henderson and Christopher Tate at the MRC Laboratory of Molecular Biology (Cambridge, UK). With venture funding from NVF and other leading investors, Heptares developed its unique StaR® technology platform that enables it to design drugs precisely based on a detailed understanding of the structure of the drug target – an approach known as structure-based drug design (SBDD). By this method, Heptares aims to design and develop medicines that are effective, selective and with fewer side effects. The potential of the Heptares platform for both discovery of novel, differentiated small molecules and biologics, is therefore expected to be especially high.

Heptares has leveraged the capabilities of its proprietary StaR® technology to sign partnership agreements with a number of the world's leading pharmaceutical and biologics companies, including AstraZeneca, Cubist

[132] Enterprise Therapeutics (2020) "About us" [online] [last accessed 15/09/2020].
[133] COPD stands for Chronic Obstructive Pulmonary Disease. Is the name of a group of lung illnesses which cause breathing difficulties.
[134] Businesswire (2018) "Enterprise Therapeutics Raises £29 Million ($41 Million USD) Funding" [online] [last accessed 16/09/2020].
[135] Businesswire (2020) "Enterprise Therapeutics' First-in-Class TMEM16A potentiator program for treatment of cystic fibrosis and other respiratory diseases acquired by Roche" [online] [last accessed 13/10/2020].
[136] Businesswire (2018) "Inflazome Completes €40m ($46m) Series B Financing to Develop NLRP3 Inflammasome Inhibitors to Clinical Proof-of-Concept " [online] [last accessed 03/09/2020].
[137] Pharmaceutical Technology (2020) "Roche acquires biotech firm Inflazome" [online] [last accessed 29/09/2020].

(Merck), Takeda Pharmaceutical, MorphoSys, MedImmune and Novartis. These existing partnerships have provided more than USD 30 million in upfront and milestone payments to-date and are expected to continue generating revenues through milestone payments and royalties over the coming years. The success of the company has been demonstrated by its acquisition by the Sosei Group in February 2015, with payment of up to $400m (approximately £306m) to be paid to Heptares' shareholders.[138]

Silence Therapeutics

Silence Therapeutics is a biotechnology company formed in 1994 to develop gene therapeutic technology from RNA. NVF was an early investor in Silence which is now listed on the London Stock Exchange.

It is notable that Silence is developing orphan medicines, i.e. medicine for diseases so rare they are unlikely to be developed under usual market conditions. This achieves the NVF's ambition of satisfying the unmet need of patients.

In the past yet, Silence established a research and collaboration agreement with Mallinckrodt Pharmaceuticals with an exclusive worldwide licence an early pre-clinical candidate drug for immune and inflammatory disorders, through which it received a $20m upfront payment and another $5m equity investment. Moreover, in March 2020, Silence Therapeutics announced a collaboration with AstraZeneca which aims at the discovery and development of siRNA therapeutics for cardiovascular, renal, metabolic and respiratory diseases.[139]

KuDOS Pharmaceuticals Limited

KuDOS was a biotechnology company formed in 1997 to develop oncology therapies involving DNA repair inhibitors. KuDOS developed medicines which treat a range of cancers.[140] NVF was one of the initial investors in KuDOS, providing investment capital, support and credibility.

AstraZeneca bought KuDOS for £120m in 2005 (approximately £180m in real terms today). This equipped AstraZeneca with an innovative technology platform and a team of 75 employees. The move demonstrated commitment to innovative therapies, signalling how KuDOS had become a worthy investment.[141]

Binx Health (Atlas Genetics)

Binx Health (previously named Atlas Genetics) is a spin-out company of the University of Bath and a pioneer in near-patient testing solutions. It creates new categories of healthcare solutions offering on-demand testing where people need it most. In 2011, the company received an investment of £16.9m from a syndicate of investors led by NVF to further develop its systems, including a test for sexually transmitted diseases.[142] Binx has recently developed the first FDA-cleared point-of-care test which produces lab-quality results in approximately 30 minutes.[143] NVF has invested a further £10.3m in Binx since 2014, expecting the company to transform near-patient testing through novel delivery models. Since then, Binx has attracted significant funding, announcing in January 2017 its receipt of $35m.[144] In 2019, the company received 510(k) clearance from the FDA to market its point-of-care chlamydia and gonorrhoea tests.[145]

[138] Businesswire (2015) "Sosei Acquires Heptares Therapeutics for up to USD 400 million" [online] [last accessed: 13/10/2020].
[139] Silence Therapeutics (2020) "Final results for the year ended 31 December 2019" [online] [last accessed 21/09/2020].
[140] Cancer Research (2019) "Olaparib (Lynparza)" [online] [last accessed 17/09/2020].
[141] Muspratt, C (2005) "AstraZeneca buys biotech company for £120m" *The Telegraph* [online] [last accessed 17/09/2020].
[142] Research Excellence Framework (2014) "Atlas Genetics Limited: a University of Bath spin-out company providing novel technology for rapid diagnosis of infectious diseases" [online] [last accessed 17/09/2020].
[143] Binx (2020) "Revolutionary point-of-care STI testing. That's binx io" [online] [last accessed 13/10/2020]
[144] Binx (2017) "Atlas Genetics raises $35m in Series D fundraising" [online] [last accessed 17/09/2020].
[145] PR Newswire (Aug 2019) "Binx health receives FDA 510(k) clearance for rapid point of care platform for women's health" [online] [last accessed 17/09/2020].

In June 2020, Binx Health announced an international partnership with UPS to offer at-home "Contactless" COVID-19 sample collection, starting with the UK.[146] In July 2020, it also announced its plan to develop a rapid test for COVID-19 in collaboration with Sherlock Biosciences. They will use leading technology to develop a rapid, point-of-case diagnostic test which will be able to yield results within the an hour.[147]

Bicycle Therapeutics

Bicycle Therapeutics is a Cambridge-based clinical-stage biopharmaceutical company. It was founded in 2009 to create transformative medicines for life-altering diseases. Their proprietary bacteriophage (phage) display screening platform derives from the work of Sir Greg Winter, winner of the Nobel Prize in Chemistry in 2018 for his pioneering work in phage display. NVF has invested £11.3m since 2009 when it was a founding investor together with Atlas Ventures.[148] Since the company's inception, the number of targets to which its 'Bicycle' modality is applied has grown from a single target to over 90 in 2019.[149] Bicycle Therapeutics had an initial public offering on NASDAQ in May 2019 during which it raised over $60m. [150] The company has sites in Cambridge, UK and Cambridge, Mass.

4.2 Investment in advanced therapy platforms

Advanced therapy platforms (ATPs) describe treatments targeting diseases in novel and disruptive ways, for example through delivering cell and gene therapies. The potential of such platforms is still being discovered, and they represent a powerful future opportunity for the development of healthcare. Novartis investment in ATPs is in part exemplified by its recent acquisition of Advanced Accelerator Applications (AAA) and Novartis Gene Therapies (NGTx).

AAA

AAA has developed a platform called radioligand therapy. This platform combines a therapeutic radioactive particle (the 'medicine') with a targeting compound (ligand) which targets and binds to specific receptors in target cells. The radioactive medicine is delivered directly to the target cells, triggering cell death. Novartis acquired AAA in 2019 for US$3.9bn.

Novartis Gene Therapies (NGTx)

NGTx is developing therapies to address the underlying genetic root cause of diseases by delivering genes directly to relevant targets. This gene therapy approach has the potential to deliver new or working copies of a missing or non-working gene to human cells to restore normal gene function. NGTx's research and policy work is crucial in the development and roll-out of transformative gene therapy platforms. Novartis acquired AveXis – now NGTx – for US$8.7bn in 2018.

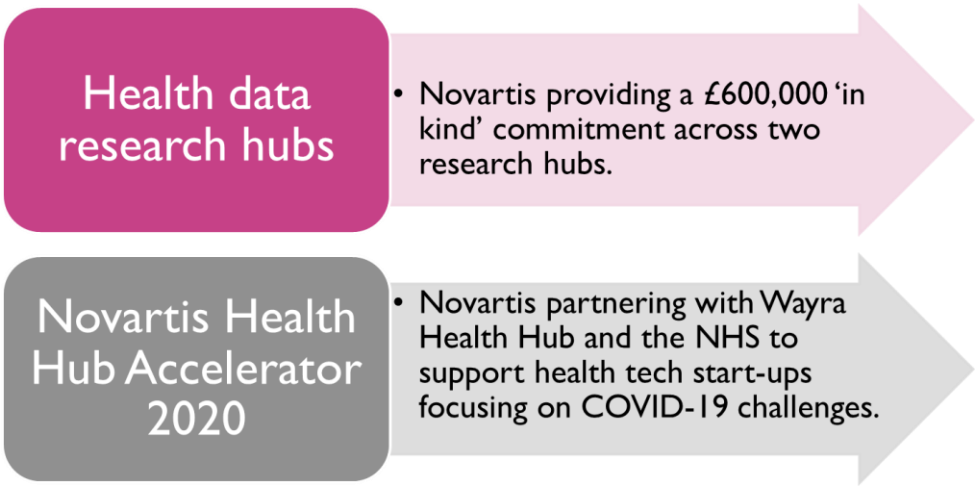
4.3 Investments in NHS data capabilities and access

The UK's 2017 Industrial Strategy identified the life sciences sector as a "priority business sector", in which the UK holds a clear advantage, for continued development over the coming years.[151] In particular, it highlighted the role that leveraging the powerful healthcare datasets could have in fostering innovative

[146] Binx (2020) "binx health and UPS Jointly Announce International Partnership for At-home "Contactless" COVID-19 Sample Collection" [online] [last accessed 18/09/2020].
[147] Binx (2020) "Sherlock Biosciences and binx health Announce Global Partnership to Develop First CRISPR-based Point-of-care Test for COVID-19" [online] [last accessed 18/09/2020].
[148] Bicycle Therapeutics Ltd (2014) "Bicycle Therapeutics announces £20M ($32M) million financing for drug development" [online] [last accessed 18/09/2020].
[149] Bicycle Therapeutics Ltd (2019) "Bicycle Therapeutics awarded contract" [online] [last accessed 06/11/2020].
[150] Goodwin Law (2019) "Bicycle closes $60 million IPO" [online] [last accessed 18/09/2020].
[151] HM Government (2017) "Industrial Strategy" [online] [last accessed 09/11/2020].

research. Novartis has demonstrated its firm commitment to the government's target of strengthening UK leadership in the life sciences.

Figure 27: Selected Novartis investments in UK data and digital programmes



Health Data Research Hubs

Health Data Research Hubs use recent technology to analyse health data in partnership with the NHS. The British government funds Health Data Research Hubs via the Industrial Strategy Fund whereby industry matches its funding. The work focuses on addressing interoperability, quality data and access. Its reach is expanding and eight data hubs were introduced across the UK in 2019 to foster research for new medicines providing quicker diagnoses.[152, 153]

Novartis is collaborating in two of the Health Data Research Hubs with a £300,000 'in kind' commitment for each. The work is collaborative and includes 'Breathe', a consortium of Imperial, Leicester, Edinburgh, Nottingham, Queen Mary and Swansea dedicated to consolidating the disparate data held on respiratory conditions.[154] Another winning project, 'Discover-NOW', involves research into improving patient care and identifying disease patterns. It is led by the Imperial College Health Partners. The project has collected significant data, making it one of the largest datasets of depersonalised data in Europe, with an initial population of 2.3m people and scaling to nearly 9m over time.[155] We expand on the nature of this collaboration in Chapter 6.

The Novartis Health Hub 2020 Accelerator

The Health Hub is a nine-month accelerator programme offered in collaboration between Novartis and Wayra, under the umbrella of Novartis Biome UK. This year is the second time the Accelerator has been implemented with the general focus on addressing COVID-19 challenges faced by the NHS. To do so, it invests in three health tech start-ups and assists them by providing investment, mentoring, networking, office space and access to masterclasses to a select group of start-ups.

[152] HDRUK (n.d.) "Pioneering data research centres to enable cutting-edge research and innovation to benefit UK patients" [online] [last accessed 14/10/2020].
[153] BHF (2019) "Millions to benefit from £10M national cardiovascular data science centre" [online] [last accessed 14/10/2020].
[154] HDRUK (n.d.) "BREATHE - The health data Research Hub for Respiratory Health" [online] [last accessed 14/10/2020].
[155] HDRUK (n.d.) "Discover-NOW - The Health Data Research Hub for Real World Evidence" [online] [last accessed 14/10/2020]

This investment is intended to help develop health-tech solutions in the NHS, collaboration between the NHS and pharmaceutical companies, and Novartis' ability to deliver digital transformation. Health tech start-ups were invited to apply to the programme, after which three were chosen: Albert Health, Vinehealth and Medwise.ai.[156] In Chapter 6, we expand on the value of nature of the collaboration embodied by the Novartis Biome Health Hub.

4.4 Summary

Many models of economic growth and development highlight the catalytic role played by investment in technology. Novartis investments represent its leadership in the pharmaceutical industry. The company uses its expertise to scout opportunities for innovation and foster smaller firms in the UK. This provides firms with the financial and professional guidance to succeed. Such collaborations give start-ups with high-potential platforms a strong opportunity to deliver new technologies to patients.

[156] Novartis "Data on File. Ref 004"

5 Incubating Innovation

5.1 Overview

5.1.1 Novartis innovation in medicines

New medicines serving unmet medical needs are one of the key value drivers of research-based pharmaceutical companies.[157] As one of these companies, Novartis investment in medicines is the core element of its innovative activities. A large proportion of the value added by Novartis to the UK economy identified in Chapter 1 is likely to stem directly or indirectly from the development of medicines in its pipeline. The Novartis medicines pipeline has been ranked number one in terms of value creation in 2018 with more than 160 projects in clinical development and more than 500 ongoing clinical trials globally.[158] As mentioned in Chapter 1, Novartis also purchased three medicine development companies AAA, Novartis Gene Therapies UK (formerly AveXis) and The Medicines Company, which are contributing significantly to the Novartis innovative pipeline.

Novartis spent around £169m on R&D activities and infrastructure in the UK in 2019 through its various suppliers.[159] The global team of 23,000 Novartis researchers were tackling diseases in neuroscience, oncology, and ophthalmology, among others.[160] An important component of any pharmaceutical company's innovative pipeline is the imagination that goes in to applying new and emerging technologies to health issues. The Novartis Annual Review reports that it encourages its people to challenge the status quo and explore new ways of working to ensure that it continues to push the frontiers in biomedical research.[161,162] With "new ways of working" having become a common requirement throughout 2020, Novartis has adjusted its approaches to treatment discovery through its clinical trials to mitigate the risks to patient safety and trial integrity posed by the COVID-19 pandemic.

5.1.2 Novartis and knowledge spillovers

The activities of Novartis have significant benefits for the UK's stock of knowledge beyond those directly accounted for by its expenditure on innovative medicines and other developments. In the economic jargon, Novartis can be said to be the source of "knowledge spillovers".[163] The other side of knowledge spillovers occurs when others (including Novartis) seize and exploit (or "garner") the knowledge spillovers that have been created by other sectors in the economy.

[157] Schuhmacher, A et al. (2016) "Changing R&D models in research-based pharmaceutical companies" [online] [last accessed 29/09/2020].
[158] EvaluatePharma (2018) "World Preview 2018, Outlook to 2024" [online] [last accessed 30/09/2020].
[159] Novartis (2020) R&D metrics. The figure includes expenditure coded as laboratory supply & equipment, clinical services and scientific services in Novartis spending data. $215m (2019) converted to GBP using 1 USD = 0.783652 GBP from OFX (2020) "Yearly average exchange rate" [online] [last accessed 01/09/2020].
[160] Novartis Annual Review (2018) "Deliver transformative innovation" [online] [last accessed 29/09/2020].
[161] Novartis Annual Review (2019) "Unleash the power of our people" [online] [last accessed 29/09/2020]. In Chapter 7.1 we discuss further features of Novartis human capital management.
[162] The firm at large, including Novartis UK, also pursued and promoted data science and digital technology, as we discuss in Chapter 7.
[163] As descried below, a "spillover" is where knowledge and innovation developed in one sector for a specific set of purposes spills over and is useful for other purposes, either within that sector or in other sectors.

The spillovers generated by Novartis include the benefits of clinical trials over and above those of the eventual introduction of a Novartis innovative medicine, its contribution to the evaluation tools at the disposal of researchers in multiple disciplines, and the potential of its activities to produce the next game-changing innovation. This chapter explains how Novartis is a prime component of the UK life sciences sector through its role as a generator of spillovers and, therefore, an incubator of innovation.

Novartis reports to us that it is aware of the information value of its clinical trials for other researchers and healthcare providers, and it actively promotes the diffusion of knowledge created in the process. This includes making its clinical trial results publicly available online to health professionals and researchers. Novartis has fostered a culture of transparency to strengthen the diffusion of knowledge and enable others to learn. Novartis is committed to "being open and clearly disclosing what we do, how we work, where we are successful".[164]

5.2 Economic theory

5.2.1 Theory of innovation spillovers

Innovations in one sector or country often build on knowledge that was created in another sector or country.[165] The most revolutionary innovations that have transformed household life and businesses, such as steam[166], electricity, and information technology, spillover into multiple sectors and are called general purpose technologies (GPTs).[167] GPTs embody new knowledge and cause profound changes to the direction of technological advancement, introducing new avenues of research as well as enhancing existing ones. More generally, the spillovers from transparent sharing of knowledge benefit society and the economy through their:[168]

- Pervasiveness — the spillover increases the stock of knowledge in other sectors and locations.
- Continuous improvement — the spillover is improved by both the originator sector and other sectors.
- Innovation incubation — access to the new knowledge makes it easier to spawn new innovations.

The cumulative value of these benefits is not accounted for in the level of expenditure on research and development (R&D) that fuels the original innovation. When the benefits fall on other sectors, the R&D is said to generate positive externalities. These positive externalities extend beyond the private value of the innovation enjoyed by the original investor to the benefits for society as a whole.

5.2.2 Application to the life sciences sector: clinical trials

In the life sciences sector, research and development is a major component of the activity of pharmaceutical firms. Arguably the most pervasive innovation of the sector is the clinical trial. Over the decade to 2019, an

[164] Novartis (n.d.) "Transparency & Disclosure" [online] [last accessed 30/09/2020].
[165] Aghion, P and Jaravel, X (2015) "Knowledge spillovers, innovation and growth" *The Economic Journal,* Vol 125, No 583, p533-573 [online] [last accessed 29/9/2020].
[166] Steam power is an interesting example of spillovers between sectors. It was first exploited commercially in pumping water from mines, with the Savery and Newcomen engines developing techniques subsequently used extensively by James Watt, in combination with his own advances allowing the driving of a fly-wheel, outside mines in mills for manufacturing, which in turn were used and developed further, outside manufacturing, for steam-powered locomotives and steamboats for transport.
[167] Jovanovic, B and Rousseau, P (2005) "General purpose technologies" NBER working paper series no 11093, National Bureau of Economic Research Inc [online] [last accessed 29/9/2020].
[168] Bresnahan, T and Trajtenberg, M (1995) "General purpose technologies: 'engines of growth'?" NBER working paper series no 4148, National Bureau of Economic Research Inc. [online] [last accessed 29/9/2020].

average of 28 per cent of EU clinical trial applications have come from the UK, and the UK ranks first in Europe for the number of early clinical trials.[169]

Figures from the Association of the British Pharmaceutical Industry (ABPI) in 2019 show that clinical research is worth £2.7bn annually, with £1.5bn of this funded by commercial sources, and supports 47,000 jobs across the UK.[170] In 2018/19, the National Institute for Health Research centres and facilities supported over 3,500 commercial studies, with over £100m in funding leveraged from industry.[171] Furthermore, for every patient recruited onto a commercial clinical trial between 2016 and 2018, the NHS in England received £9,189 from life sciences companies.

New treatments and medicines are subject to rigorous testing before their commercialisation through clinical trials. While a new treatment or medicine will improve outcomes for patients once it becomes available, both patients and clinicians who participate in clinical trials could benefit from participation in trials, as well as the wider life sciences industry, in ways that are not envisaged. These can be considered the spillover effects of clinical trials. Potential benefits include:

- Therapeutic benefits to patients from participating in trials
- Faster uptake and use of new treatments where these are being tested.
- Increases in the human capital of clinicians who participate in the trials, and of those who do not.

A direct form of benefit to patients directly involved in the trials is the aptly-named 'trial effect'. This is the direct potential benefit of receiving new research treatments before they become widely available, which may have a positive impact on their health. Further benefits could result from the combination of the way the treatments are delivered in a trial setting (the 'protocol effect') and differences in care in a trial setting in comparison to non-trial treatment, for example extra nursing cover or follow-up under the trial (the 'care effect').[172]

There may also be psychological effects on trial participants that could lead to improved outcomes. For example, the 'Hawthorne effect' describes changes in doctor or patient behaviour due to the fact that the trial is an area of interest for them, any additional information they have as a result of the trial, or even due to the knowledge they are under observation. Furthermore, psychological factors could influence a patient's outcomes through awareness of participating in a trial — the placebo effect.

Beyond the participants of the clinical trial, there may be faster uptake and use of new medicines generally, and sometimes in the location of the clinical trials and the trial participants. In the UK, a study into the factors influencing new medicine uptake in secondary care found that clinical trial investigators and physicians who sit on decision-making bodies are more likely to prescribe new medicines due to their proximity to their research and understanding of the evidence base.[173]

Spillovers for clinicians and researchers can exist as involvement in trials keeps them up to date with cutting edge research. Pharmaceutical companies in the UK routinely provide additional training to clinicians on an *ad hoc* basis to enhance specific clinical skills during the course of a trial. Participating clinicians, therefore, benefit directly from clinical trials by increasing their human capital. Clinicians and researchers *not* participating in a trial also stand to benefit from the positive externalities of a trial. A clinical trial produces information and data that can be anonymised and re-analysed by researchers in other settings. Even clinical trials that do not yield immediate commercial value or provide large-scale benefits to the population produce

[169] ABPI (2019) "Clinical trials: How the UK is researching medicines of the future" [online] [last accessed 01/10/2020].
[170] ABPI (2019) "Clinical trials: How the UK is researching medicines of the future" [online] [last accessed 01/10/2020].
[171] ABPI (2020) "Clinical trials: How the UK can transform the clinical research environment" [online] [last accessed 14/10/2020].
[172] Europe Economics (2012): 'Economic Research into the Environment for Clinical Research and Development in the UK', A Report Prepared for Novartis.
[173] Chauhan, D and Mason, A (2008) "Factors affecting the uptake of new medicines in secondary care – a literature review" *Journal of Clinical Pharmacy and Therapeutics,* Vol 33, No 4 (Aug), p339-48 [online] [last accessed 29/9/2020].

spillovers. Trials that fail are signals that encourage researchers to follow alternative development strategies, and those that work stimulate further research in the underlying mechanisms.

5.2.3 Application to the life sciences sector: RCTs

The central concept of the methodological tool used to test the efficacy of medicines in a clinical trial — the randomised controlled trial (RCT) — was first developed and perfected in the life sciences sector. This tool has subsequently been applied in numerous other academic disciplines to test interventions ranging from the provision of textbooks in rural Kenyan schools to the Universal Credit programme in the UK. Some researchers go as far as saying that the RCT of the life sciences sector has provided the 'gold standard' of quantified research in these varied disciplines.[174] As a pervasive and continuously-improved evaluation tool, the RCT method is an innovation that has influenced research across the social sciences. For example, in 2015, 333 papers listed by the International Initiative for Impact Evaluation were RCTs — approximately the same number as the total number of papers (in all fields) published annually in the top four economic journals combined.[175]

Continuous innovation in the clinical trials sphere

Whilst the RCT sets a high standard for identifying effectiveness, it is nevertheless important to continuously improve upon its techniques and methods. This is what the pioneering innovation of the life sciences sector is currently doing. In 2020, the UK government published its National Genomic Healthcare Strategy that describes its approach to exploiting the technological advances made in recent years to tackle the combining forces of rising healthcare costs and the increasing prevalence of complex conditions.[176] The technological advancements made in genomics has significantly reduced the cost of genome sequencing, thus allowing effective diagnosis of conditions (pillar 1 of the Strategy), making possible the development of predictive interventions (pillar 2) and encouraging a "seamless interface" between research and healthcare.

The Strategy clearly recognises the value brought by genomic advancements to the conduct of RCTs. Genomics has already proven its usefulness here by increasing the speed and efficiency of recruitment to clinical trials with the NIHR BioResource for Translational Research in Common and Rare Diseases, a national resource of around 100,000 volunteers who have consented to be recalled for research based on their genotype and/or phenotype. Going forward, the Strategy aims to rollout gene sequencing more widely to the benefit of clinical trials. For example, increasing routine genomic testing in the NHS may enable the treatment or eligibility for clinical trials in cancer to be allocated to patients on the basis of genomic sequencing. Cancer patients are expected to participate in greater numbers than ever in such genomic-enabled clinical trials. The Life Sciences Industrial Strategy has already set a goal increase the number of clinical trials carried out with the pharmaceutical sector by 50 per cent, and to increase the proportion of trials with novel methodology, over the next five years.[177]

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[174] Of course, RCTs have their downsides for certain applications, and we are aware of the critique provided by academic economists. See, for example, Deaton, A and Cartwright, N (2018) "Understanding and misunderstanding randomized controlled trials" *Social Science & Medicine,* Vol 210, (Aug), p2-21 [online] [last accessed 29/9/2020], Barrett, C and Carter, M (2010) "The power and pitfalls of experiments in development economics: Some non-random reflections" *Applied Economic Perspectives and Policy,* Vol 32, No 4, p515-548 [online] [last accessed 29/9/2020], Gelman, A and Hennig, C (2017) "Beyond subjective and objective in statistics" [online] [last accessed 29/9/2020].

[175] These journals are: American Economic Review, Journal of Political Economy, Quarterly Journal of Economics, Econometrica, and the Review of Economic Studies.
Ravallion, M (2018) "Should the randomistas (continue to) rule?" Center for Global Development working paper no 492 [online] [last accessed 29/9/2020].

[176] UK Government (2020) "Genome UK: the future of healthcare" [online] [last accessed 30/09/2020].

[177] UK Government (2017) "Life sciences: industrial strategy" [online] [last accessed 3/11/2020].

These goals are more likely to be reached with the additional support for R&D promised by the government to keep pace with growing international competition. The commitment to increasing R&D investment to 2.4 per cent of GDP and industry investment is key to achieving a supportive environment for the continued innovation through clinical trials in the UK.[178]

5.3 Examples of how Novartis adds value in the UK

Novartis generates knowledge spillovers from its R&D efforts in the UK. It has spent around £169m on R&D activities in the UK in 2019 alone.[179] The UK is the location of a significant body of other research activity, so there are natural synergies across disciplines. Research in other medical areas, or even in other sectors of the economy, cross-fertilises innovative ideas, methods and adaptation to events in trials, benefitting the quality of those trials themselves but also benefitting research in other areas at the same time. The long history of R&D in the UK, and the NHS specifically, therefore offers significant scope for spillovers through R&D.

Information spillovers occur most efficiently when information is readily available and dispersed. Novartis has fostered a culture of transparency to strengthen the diffusion of knowledge and enable others to learn. Novartis is committed to "being open and clearly disclosing what we do, how we work, where we are successful".[180] In order to facilitate this, Novartis publishes several key pieces of information including its 'Novartis in Society Report', funding of healthcare professionals, living wage details, and, primarily, clinical trials results disclosure in which Novartis has made details of its performance in clinical trials public since 2005.[181]

5.3.1 Clinical trials

As leading commercial sponsor of clinical trials in the UK with 622 trials conducted over the last 10 years,[182] Novartis has, over several years, placed itself as a key creator of knowledge spillovers in the UK, despite not being a UK head-quartered company. In 2019 over 4,200 patients in the UK benefited from a Novartis medicine through a clinical trial.[183] Novartis has implemented innovative approaches to continue with many of its existing clinical trials despite the COVID-19 pandemic taking hold throughout 2020, although the UK lockdowns have impacted its ability to recruit patients and run trials in 2020, as described later in this section.

In 2019, Novartis sponsored 146 clinical trials, conducting studies in a quarter of all trial site organisations in the UK, 86 per cent of which were Phase I to Phase III, reaching a total of 4,252 patients. A total of 324 UK organisations hosted ongoing Novartis trials.[184] The many participants in the trials of these medicines are likely to have benefitted from the 'trial effect' described above. They may also experience the protocol and care effects, since patients participating in a clinical trial visit their health care professional more often than they would in routine clinical practice.[185] This allows them to benefit from increased contact accompanied by the best possible care, as well as additional assessments using the latest technologies.

[178] ABPI (2019) "Clinical trials: How the UK is researching medicines of the future" [online] [last accessed 01/10/2020].
[179] Novartis (2020) R&D metrics. The figure includes expenditure coded as laboratory supply & equipment, clinical services and scientific services in Novartis spending data. $215m (2019) converted to GBP using 1 USD = 0.783652 GBP from OFX (2020) "Yearly average exchange rate" [online] [last accessed 01/09/2020].
[180] Novartis (n.d.) "Transparency & Disclosure" [online] [last accessed 30/09/2020].
[181] See Novartis (n.d.) Trials disclosure webpage [online] [last accessed 3/11/2020]. More on this below.
[182] Novartis "Trial Trove Data on File 1" (2020). Trialtrove® | Informa, 2020. Accessed September 2020. Ongoing trials in the past 10 years (ongoing between 01/01/2010 to 31/12/2019).
[183] Novartis "Trial Trove Data on File 1" (2020). Sitetrove® | Informa, 2020. Accessed September 2020.
[184] Novartis "Trial Trove Data on File 1" (2020). Sitetrove® | Informa, 2020. Accessed September 2020.
[185] Novartis Medical Narrative (2017) "Core messages project LIGHT".

Novartis clinical trial work produces further indirect benefits to the NHS by providing the opportunity to trial high-cost late-phase medicines. Novartis clinical trials in new treatments also contribute to the knowledge advancements of healthcare professionals as described in section 5.2.2, for example through their exposure to novel research and specific clinical skills related to the treatments. In recognition of the ground-breaking new treatments, such as the targeted nature of cell and gene therapies and the specialised nature of personalised medicines, Novartis is committed to supporting the development of workforce skills and capabilities that will facilitate their rollout across the healthcare system.

With 146 trials taking place across the UK in 2019, successful Novartis trials support the understanding and adoption of life-changing medicines across the UK as a whole (as opposed to the spillover being confined to a few locations), in line with the effect described above.

Novartis is committed to working together with the NHS and academic networks to understand how to evolve clinical trial approaches. Through broader partnership agreements and the increasing use of electronic health data, the potential to develop and deliver large-scale investigational trials in the UK, with the associated indirect benefits described above, will continue to evolve.

Moving into 2020, as the COVID-19 pandemic took hold in the UK, social distancing and restricted access to healthcare settings created challenges to the maintaining of trials in the UK and elsewhere.[186] The following box describes the flexible and responsible approach Novartis took to mitigating the risks to participant safety and trial efficacy.

Box 6: Clinical trials during the COVID-19 pandemic: remote follow-ups and harnessing the power of genome sequencing with Genomics England

Disruption to ongoing clinical trials from the global COVID-19 pandemic not only compromise the usefulness of research data but also pose risks to patient care. Novartis has been able to continue with many of its existing trials by developing pragmatic solutions in partnership with regulators.[187] One of these solutions was to introduce remote follow-ups.

Remote follow-ups offer an easier method of participating in trials and may continue to influence the ways in which clinical trials evolve once the pandemic has abated.[188] They protect the most at-risk patients who do not have to venture into a hospital waiting room to participate in a clinical trial since it can be done remotely at safe distances. A part of the Novartis broader response to lockdown, the company rolled out guidelines to allow for clinical trials to be conducted safely at patient homes when this was unavoidable, including the use of home delivery of investigational medical products and domiciliary care visits.

Despite the contemporary difficulties of conducting a clinical trial, Novartis has been an active player in helping the discovery of COVID-19 therapeutics globally through clinical trials. It has supported the evaluation of existing products as candidates for the potential treatment of COVID-19. Some of these treatments were rapidly progressed into clinical trials, and UK sites were included in these global programmes. The shared determination of UK authorities and sites to work with industry to get COVID-19 trials underway was a critical factor in beginning trials.

Novartis has also partnered with Genomics England in a collaboration to leverage the power of genetics research in clinical trials and the fight against COVID-19. The clinical trials will involve 20,000 people currently or previously in an intensive care unit with COVID-19 as well as 15,000 individuals who have

[186] Novartis (2020) "Relevant Novartis content submitted to recent PPP Coalition on Clinical Trials".
[187] Public Policy Projects (2020) "Clinical Research Coalition: Evidence Summary and Recommendations".
[188] Toms, M (2020) "How do we make the UK world leading for COVID-19 clinical trials?", Health Data Research UK conference briefing pack.

mild or moderate symptoms.[189] With the individuals' consent, their genetic code will be studied to help scientists understand whether a person's genes may influence their susceptibility to the virus. Novartis scientists will have access to the collected data to gather novel insights that will assist in developing new medications for COVID-19 patients as well as repurposing existing ones.[190]

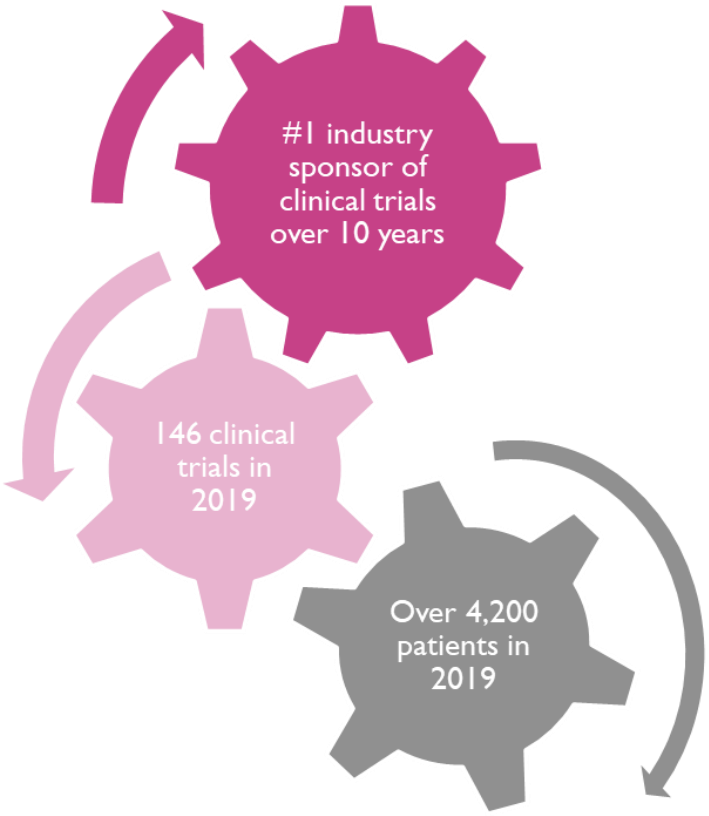
Despite Novartis flexible approaches, the COVID-19 lockdowns in the UK and the need to prioritise NHS care and research on COVID-19 interventions have created significant disruption for other trials. In the course of 2020 clinical trial recruitment targets were reduced by nearly 40 per cent, while as of mid-September only 30 per cent of Novartis trial sites were re-open to patient recruitment and some sites withdrew from trials altogether. The ABPI has reported that the UK's strong international position in global clinical research is at risk because of the delays in restarting clinical research, which lags behind some other nations.[191] This impacts global perceptions of the UK ecosystem, and also creates short term risk to NHS income linked to commercial trials.

The positive externalities of Novartis R&D stem from both the successes and failures of its trials. The Novartis pipeline of new medicines provides a unique opportunity for researchers to work on some of the most innovative avenues of medical research, enabling the UK to remain a global leader in life sciences. But, as a responsible pharmaceutical innovator, Novartis also takes responsibility for its clinical trials and is transparent about failures to ensure future success.[192]

Novartis has, since 2005, published the outcome of every study online for healthcare professionals and researchers, and qualified external researchers are able to request access to anonymised patient-level data and redacted clinical study results.[193] Not only does this send signals of 'what works' to other researchers, it helps individuals make informed decisions about treatment options. The trial data that Novartis makes available can be exploited as pre-existing datasets, thus eliminating the need for researchers to collect their own primary data. Therefore, through this commitment to transparency, Novartis ensures that the learning process 'spills' into other research areas in which researchers can continuously build upon the past experience of Novartis and others.

[189] Genomics England (2020) "New partnership to sequence human genomes in the fight against coronavirus" [online] [last accessed 14/10/2020].
[190] Novartis "Data on File. Ref 006"
[191] Research Professional News (October 2020) "UK's restart of clinical trials 'lags behind other nations'" [online] [last accessed 16.11.2020].
[192] Novartis "Data on File. Ref 010".
[193] Novartis (n.d.) "Clinical trial information disclosure" [online] [last accessed 18.11.2020].

Figure 28: Summary of Novartis clinical trial impact and spillovers in the UK



Source: Novartis "Trial Trove Data on File 1" (2020). Sitetrove® | Informa, 2020. Accessed September 2020.

Novartis commitment to innovation is reflected by its acquisition of leading development companies, such as AAA, which demonstrates a strong clinical trial presence. AAA currently has nine ongoing clinical trial studies in the UK at 14 trial sites, recruiting 434 patients.[194]

5.3.2 Incubating the next innovation promising to spill into other realms

Large innovative pharmaceuticals firms such as Novartis have long pipelines of medicines and other innovations under research and development. One or more of these could potentially be a revolutionary innovation, akin to a general purpose technology. In Novartis' case its more than 160 innovative pipeline projects, such as its contribution to the advancement of gene therapy and data analytics, have sought to exploit recent technological developments that are rapidly permeating multiple sectors. Progress Novartis makes in these areas, or that is made by users of Novartis products, could potentially spill back into feedback developments in other fields. It is in the nature of GPTs that it is nigh-impossible to predict with any reliability which they will be. Nonetheless, we offer below an illustrative selection of contenders from the Novartis pipeline.

- Leveraging AI to help build the post-COVID environment of predictive healthcare – Novartis and Microsoft recently reported on the importance of sustained investment in data and AI to achieve the

[194] AAA (2020) Clinical trials metrics. Note that these trials are included in the overall number of Novartis clinical trials.

health system improvements needed to respond to and recover from the COVID-19 pandemic.[195] The research finds that the specific challenges of rich and poor countries are ripe for disruption through AI. For instance, underserved individuals in low-income countries can use AI to predict risks of certain health conditions before they present, whilst health worker shortages in richer countries could be met with AI-powered tools to augment the current health workforce.

- Gene therapy — As mentioned above, the National Genomic Healthcare Strategy represents the UK Government's formal recognition of the profound importance of genomics for furthering our understanding of health conditions and therapies. Novartis has positioned itself at the forefront of this knowledge frontier. Novartis is also partnering with Oxford BioMedica to build a global infrastructure for delivering this type of therapy.

  Novartis contribution to the development of gene therapies could help to accelerate the learning process of this new technology, and expand the range of health problems to which gene therapy can be applied beyond cancer. Indeed, these innovative therapies offer treatments for conditions that previously had limited remedy options available, from leukaemia to blindness, and have been described as the "future of the healthcare system".[196]

- Leveraging the 100,000 Genomes Project data trove – Novartis is collaborating with Genomics England, the organisation steering the UK's genome sequencing project, to access one thousand anonymised genomes from the project for the purposes of patient recall, access to biological samples, and health records.[197] This is expected to generate benefits for data modelling technology development, medicine discovery, and disease understanding. The level of understanding that may be gleaned from the study of genomes could allow more precision in designing treatments to combat rare diseases. More generally, the study of the human recipe promises to shed greater light on the internal makeup that makes each human unique. Since gene large-scale sequencing began, 95 per cent of a human genome that was previously disregarded as 'junk DNA' has become open to analysis.[198]

  The global genomic industry was valued at over £8bn in 2015, of which the UK's contribution is approximately 10 per cent.[199] The multiple stages of the genomics value chain (sampling, sequencing, analysis, interpretation and application) means that its rapid growth in the UK has a marked multiplier effect on economic activity in these stages, including the promotion of associated industrial jobs.

Novartis has also partnered with NHS professionals to promote the up-take of digital methods of conducting clinical trials. The box below describes an example of a recent partnership in this area with DigiTrials, the Health data Research Hub for clinical trials.

Box 7: Supporting NHS data capabilities to make the most of clinical trial data through digital means

The NHS DigiTrials is a Health Data Research Hub aiming to provide national platform services (data and infrastructure) to enable efficient, high quality clinical trials that meet the standards required by international regulatory agencies, funders, clinicians and patients. [200]

[195] Novartis (2020) "New report shows how AI in health is critical for COVID-19 response and recovery" [online] [last accessed 14/10/2020].
[196] Innovate UK (2017) "Cell and gene therapies set to revolutionise the healthcare system" [online] [last accessed 01/10/2020].
[197] Novartis (2019) "Summary of Novartis 'Innovation Board' Initiatives as of April 2019".
[198] Genomic England (n.d.) "What is a genome?" [online] [last accessed 01/10/2020].
[199] Deloitte (2015) "Genomics in the UK: An industry study for the office of life sciences" [online] [last accessed 01/10/2020].
[200] NHS Digital (2019) "NHS DigiTrials - Service User Research Briefing", ABPI Event December 2019.

Novartis has recently participated in research with NHS DigiTrials to support the evaluation and service design of the national platform services. In collaboration with NHS Digital, Novartis piloted two trials looking at the 'feasibility' stage of the NHS DigiTrials capability by comparing two of its own internal (traditional method) feasibility study results with the NHS DigiTrials feasibility method for identifying appropriate trial sites.[201] Both pilots showed a strong correlation between the Novartis trial sites identified through traditional feasibility and DigiTrials sites, and DigiTrials identified some outliers worth further consideration. Based on trial eligibility criteria, three new regions were identified for a new study This collaboration is an example of how existing trial information can be used to ensure that innovative approaches to conducting clinical trials with digital capabilities are as effective as their more traditional counterparts. In the long-term, these innovative approaches may promote more efficient clinical trials.

More efficient clinical trials may enable medicines to be brought to patients more rapidly and boost the treatment of medical problems. Furthermore, it will increase the likelihood of spillover effects such as the trial, protocol, and care effects which together may improve participant health outcomes for a greater number of participants.

5.4 Summary

The nature of firms in the life sciences sector means that their activities permeate other sectors of the economy. As the leading industry sponsor of clinical trials in the UK, it is likely that Novartis creates amongst the largest such spillovers for the UK amongst firms operating in the sector. Its prominent contribution to the clinical trials environment in the UK means that it likely to be the catalyst for a considerable proportion of the knowledge emanating from the life sciences sector, helping to push the frontiers of what is possible in the provision of treatments to patients.

While Novartis is the leading sponsor of clinical trials in the UK in terms of the number of trials, the UK is only the 11th ranking market for Novartis in Europe in terms of recruiting patients onto trials, suggesting that there is a great opportunity for the NHS and UK patients to benefit further from clinical trials in the UK.[202] Trial transparency (to which we understand Novartis is committed) means that the data collected from a study can be re-analysed by other researchers, which could lead to new insights that may not be gained otherwise. Novartis is in the process of increasing its potential spillovers by sharing its clinical trial data with innovative research institutions dedicated to using machine learning that can help to identify novel medical insights from the data.

[201] Novartis (2020) "NHS DigiTrials"
[202] Novartis internal data.

6 Creating a Collaborative Ecosystem

6.1 Overview

Besides the positive externalities that it produces for other sectors indirectly, Novartis actively collaborates with a variety of UK organisations. Since 2014, Novartis has collaborated globally with academic researchers in 4,016 publications – a significant proportion of which has been with UK institutions.[203] Novartis' geographic proximity to centres of research is important for direct knowledge transfer.[204] This channel of value aligns with the UK government's Life Sciences Industrial Strategy to enhance collaboration in the sector to strengthen the UK's role as a global leader in research and innovation in the life sciences. Novartis is particularly enthusiastic about this UK government programme, given the importance of collaboration in Novartis relationships with its partners in the NHS, academia, and innovative businesses. Such collaborations, as well as their value in their own terms, also allow for the transfer and spread of knowledge.

Adding to its longstanding collaborations with the NHS and academia, Novartis has also become active in seeking to found a digital community promoting close collaboration in the field of big data and artificial intelligence (AI) with both research institutions and innovative start-ups. This has been a crucial development for ensuring the continuation of health care services during the COVID-19 pandemic. These new collaborative programmes aim to glean insights from the troves of informative clinical and biological data that exist in the life sciences sector, only the surfaces of which may have hitherto been explored. Providing resources and its expertise, Novartis is an integral part of the synergies in the life sciences sector. This has positive effects for the economy at large as such R&D synergies increase growth, productivity and research quality.[205]

6.2 Economic theory

6.2.1 Theory of the value of collaboration

Scientific and technological knowledge is scattered across multiple people and organisations. Cooperation and collaboration between these agents could potentially yield greater benefits than if knowledge is exploited individually. Agents do not possess the same level or type of information, so combining resources and knowledge can produce outcomes that would not otherwise be possible, which may be referred to as a process of 'knowledge synergies'. As well as learning from each other, the sum of knowledge created is more than simply the addition of the individual separate pieces.

Learning, or knowledge transfer, through collaboration can be direct or tacit. "Direct knowledge transfers" is the term used when information is explicitly transferred between agents — e.g. providing instructions for the operation of a new machine. "Tacit knowledge transfers" are situations in which collaboration fosters the diffusion of understandings of processes and experiences, and "knowledge that exists in an intuitive realm".[206] Collaboration between two agents of different sectors can lead to some of the understanding of

[203] Deloitte Innovation Dashboard source data Pub-Med publications 2014-2019.
[204] Abramovsky, L and Simpson, H (2008) "Geographic proximity and firm-university innovation linkages: evidence from Great Britain" *The Centre for Market and Public Organisation* [online] [last accessed 01/10/2020].
[205] Dowling, A (2015) "The Dowling review of business-university research collaborations" [online] [last accessed 02/10/2020].
[206] Foos, T et al. (2010) "Tacit knowledge transfer and the knowledge disconnect" *Journal of Knowledge Management,* Vol 10, No 1, p6-18 online] [last accessed 1/10/2020].

the idiosyncrasies of one sector passing on to the other, as well as the building of trust between them, which help in their future trading with those and other sectors. Indeed, creativity often consists of applying insights or lessons from one context (e.g. one sector) to a new context. Both types of knowledge transfer are likely to exist when agents are in close proximity. Agglomeration through proximity allows agents to find business partners, friends, and to exchange ideas and generate new ones.

6.2.2 Application to the life sciences sector

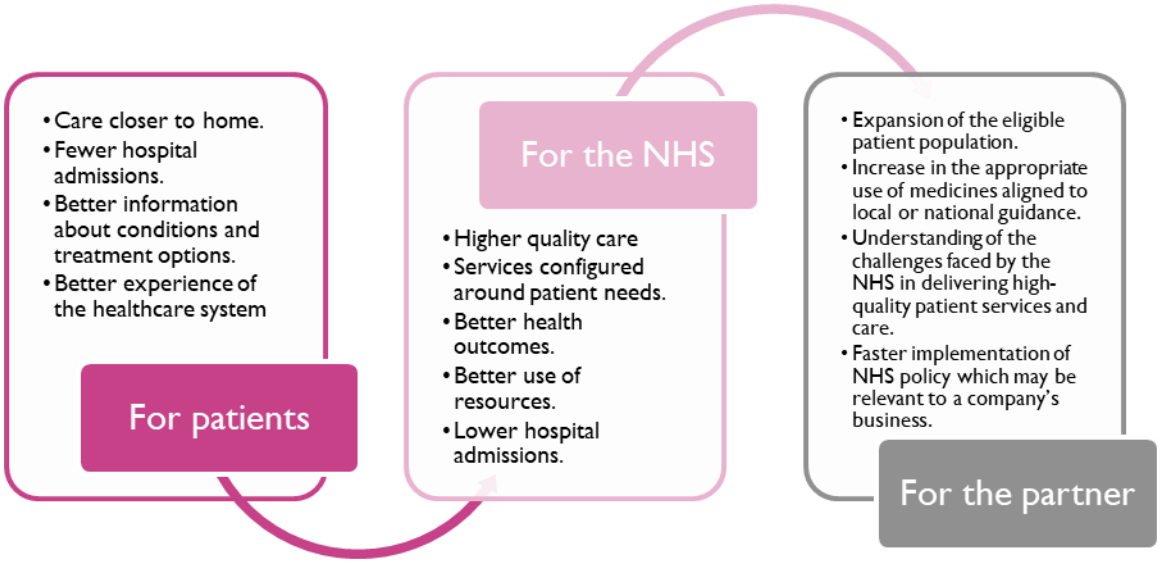
In the life sciences sector, collaborations and the knowledge transfer they facilitate form a routine component of the development of new medicines. Life sciences firms provide resources in forms ranging from clinical trials data to financial investment, whilst the contributions of academic researchers and the NHS include expertise and contacts. Firms can be said to operate R&D "listening posts" to capture and make productive use of the output of research clusters, such as universities and science parks.[207] Indeed, in the UK, more than two fifths of all academic articles are published in the field of clinical sciences.[208] The joint scientific endeavours between life sciences firms, academia, and healthcare professionals collectively generate their own ecosystem of collaboration in the advancement of medical care.

As the main purchaser of medicines in the UK, collaboration between the NHS and the life sciences sector is as important as it is inevitable. The NHS Long Term Plan recognises the importance of research and innovation to drive future medical advance, specifically through multi-stakeholder engagement.[209] The government has set a target of trebling contracting with the life sciences sector and R&D collaboration in the NHS over the next ten years, so collaboration with the sector will only increase into the future. Joint Working Partnerships (JWPs) are the best-established form of collaboration. JWPs are purely collaborative arrangements between NHS Trusts and pharmaceutical companies in which focus is turned to specific healthcare issues within a clear timeframe. Both parties contribute, either financially or through the provision of skills and knowledge. Pharmaceutical companies have disclosed at least £4.4m to date in contribution to JWPs started in 2019.[210]

The ABPI notes that JWPs can offer "triple wins" in the form of benefits to the three main stakeholders involved – patients, the NHS and the life sciences industry partner. The figure below summarises the range of benefits to each.

[207] Cooke, P (2009) *Interactive Learning for Innovation,* Macmillan (Palgrave).
[208] BEIS (2017) "International comparative performance of the UK research base 2016" [online] [last accessed 01/10/2020].
[209] NHS (2019) "The NHS long term plan" [online] [last accessed 01/10/2020].
[210] Europe Economics analysis of companies' published individual methodological notes submitted to ABPI for the 2019 Disclosure UK summaries. This total is not complete for all companies. These are available at ABPI (2020) "Disclosure UK: Methodological Notes by Year / Company" [online] [last accessed 13/10/2020].

Figure 29: Potential benefits of JWPs to the stakeholders involved



Source: ABPI (2019) "Joint Working" [online] [last accessed 01/10/2020]

One potentially significant area of collaboration between life sciences firms and other sectors is big data and AI. Economists have predicted that the economic contribution of big data may be as much as £630bn of the UK economy by 2035, increasing the annual growth of gross value added from 2.5 to 3.9 per cent.[211] The progress in this field is rapidly shaping the ways we go about our daily lives, influencing markets from lightbulbs to cars, and the technologies are permeating the healthcare sector too. Indeed, the value of big data in the healthcare sector was estimated to reach £10bn in 2020.[212] The previous chapter has explored how progress made in one sector can 'spill over' into another, in which the contribution of Novartis and the life sciences sector has the potential to shape technological development in other fields. Below, we show that Novartis collaborations with innovative technology firms is likely to accelerate the progress being made in the field of big data and AI through the fusion with unique sector knowledge.

Collaboration with cutting-edge data analytics harbours the potential to dramatically improve the quality, and reduce the cost, of care. The rise of wearable health-tech, able to capture data in real time, is helping to improve patient care 'beyond the pill' and at far lower costs.[213] And medicine products may be tailored for the precise needs of patients. This personalisation of healthcare is supported by cost reductions elsewhere such as genome sequencing which has seen significant reductions in the cost of sequencing an individual genome.[214] In pharmaceutical research, big data has the potential to further enable a data-driven approach to the life sciences. Big data techniques make it easier to work with large datasets, link disparate datasets, identify

[211] Hall, W and Presenti, J (2017) "Growing the artificial intelligence industry in the UK" *BEIS* [online] [last accessed 01/10/2020].
[212] CEBR (2016) "The value of big data and the internet of things to the UK economy" [online] [last accessed 01/10/2020].
[213] Examples of this technology include not only well-known products like the Fitbit or smartwatches, but also wearable biosensors (e.g. that produced by Philips) wearable ECG monitors (such as the Move ECG), Omron Healthcare's Heartguide blood pressure monitor.
[214] Deloitte (2014) "Healthcare and life sciences predictions 2020: A bold future?" [online] [last accessed 01/10/2020].

patterns in real time, make predictions, and test hypotheses.[215] The combined impact can be to enable more efficient and less-costly development of medicines and a more rapid process of bringing them to patients.

A recent trend in business-academic collaboration involves 'open innovation'. This refers to collaborative environments in which research and development is conducted without the level of secrecy traditionally associated with corporate research. 'Precompetitive research' is especially useful as organisations can identify and resolve challenges that are significant across the sector. Pharmaceutical companies have been among the earliest and most enthusiastic adopters of the open innovation approach.[216]

6.3 Examples of how Novartis adds value in the UK

Novartis UK has repeatedly demonstrated its commitment to bolstering the transfer of knowledge between different members of society, and in doing so it supports the continuous building of the stock of knowledge. This section describes samples of Novartis involvement in Joint Working Partnerships and other collaborations with colleagues in NHS organisations, in joint academic pursuits with researchers at UK institutions, and in collaborations with organisations at the height of the technological frontier in big data and artificial intelligence. It also draws out the potential value of collaboration that the new Novartis headquarters in White City Place, London may catalyse.

The Novartis approach to population health also represents a significant contribution in this area. The group of partners involved in this broad-based approach, including NHS England, the National Institute for Health Research (NIHR), the University of Oxford, and Novartis, is exemplary of bringing innovative approaches to healthcare through a collaboration that cuts across the boundaries of frontline care, academia and industry. The partners also committed to the creation of an industry and academic consortium to improve the efficiency with which the UK can manufacture oligonucleotide based medicines.[217] Furthermore, the Government believes that in in the shadow of Brexit the Population Health Collaboration will showcase the UK as an attractive destination for life sciences investment over the following years.[218]

Investment in collaborative projects in the UK is integral to the Novartis approach to contributing to the next generation of healthcare research and delivery. It is routinely sought in the programmes of the Novartis Institutes for BioMedical Research (NIBR), which is dubbed the "innovation engine of Novartis",[219] as the next figure shows.

[215] ABPI (2013) "Big data roadmap" [online] [last accessed 01/10/2020].
[216] Dowling, A (2015) "The Dowling review of business-university research collaborations" [online] [last accessed 02/10/2020].
[217] UK Government (2020) "New heart disease drug to be made available for NHS patients" [online] [last accessed 01/10/2020].
[218] World Healthcare Journal (2020) "The UK's Global Leadership of the Genomics Revolution: 38th Annual JP Morgan Conference" [online] [last accessed 02/10/2020].
[219] Novartis (n.d.) NIBR webpage [online] [last accessed 01/10/2020].

Figure 30: Selection of recent NIBR partnerships in the UK

Sources: Cancer Research UK and Beatson Institute (2019) "Joining forces with Novartis to advance novel cancer therapeutics" [online] [last accessed 01/10/2020]. Novartis (n.d.) "NIBR Global Scholars Program" [online] [last accessed 01/10/2020]. Start Codon (2019) "Start Codon: The Life Sciences Accelerator" [online] [last accessed 01/10/2020].

6.3.1 Joint Working Partnerships

Participating in more than 12 times the average number of pharmaceutical industry JWPs jointly funded with the NHS in 2018,[220] in 2019 Novartis invested in 48 JWPs with NHS partners, of which 37 were initiated during the year.[221] Novartis contribution to JWPs consists of funds (£1.79m in 2019)[222] as well as resources and knowledge. In particular Novartis financial contributions may also provide key core capital commitments enabling these projects to secure further financial investment. The JWPs are spread across a wide range of therapy areas spanning oncology to rheumatology through migraine services and ophthalmology.[223]

One example is the Public Health Wales NHS Trust. This JWP consists of an in-depth diagnostic of the heart failure and lung cancer patients' experience, from diagnosis through to treatment. The collected data are being used to identify ways to improve parts of the services for patients needing care and treatment for these conditions. It is a concrete example of direct knowledge transfers between the NHS and the pharma sector, the objective being 'to leverage Novartis expertise and the skills and experience within NHS Wales'.

Oncology JWPs

Given its long history of researching and developing transformational cancer medicines,[224] Novartis has focused support for JWPs aimed at improving patient access to cancer care. By offering the opportunity to

[220] ABPI Disclosure UK [online] [last accessed 01/10/2020]. 2018 data used because 2019 disclosures have not all been made public. Industry total for JWP declared in 2018 (£5.2m) divided by the number of ABPI members (64) which gives an average JWP spend per member of £81,250. Novartis 2018 spend of £1,006,139 is 12x this figure.
[221] Novartis (n.d.) "Joint Working' [online] [last accessed 01/10/2020].
[222] ABPI Disclosure UK [online] [last accessed 01/10/2020].
[223] Novartis (2020) JWA Projects listed on website.
[224] Novartis (2018) "Defining New Models of Care".

pool its resources and expertise, JWPs can help to tackle the challenges the NHS faces and ensure that patients have access to innovative medicines and are given the best possible care.

Having partnered on more than 50 since 2014, Novartis Oncology supports knowledge sharing through JWPs. Recognising that the UK typically has a poorer record in cancer patient outcomes than comparable European countries, Novartis hopes that the JWP model may support significant improvement in NHS cancer services and patient-reported outcomes. Independent evaluations of Novartis JWPs by Insight2Implement have found that Novartis employees involved in JWPs are helpful and motivated and appear willing to initiate JWPs when the typical industry partner will not. Novartis Oncology JWPs address many of the NHS top priorities to improve the healthcare system, as demonstrated by 80 per cent of JWPs digitally enabling the NHS, 92 per cent improving patient satisfaction, and 100 per cent reducing variation in care.[225]

Figure 31: a sample of recently concluded Novartis Oncology JWPs

Sources: Novartis (n.d.) "Investigating the inequalities of access to sBC treatment in Greater Manchester - a Joint Working Project (JWP) with Novartis"; Novartis (2020) "UCLH Cancer Collaborative: Novartis Joint Working Agreement"; Novartis (n.d.) "The NHS Greater Glasgow & Clyde (GGC) molecular diagnostic pathway development joint working project (JWP) and industry engagement with the Scottish genetics laboratories".

[225] Novartis (2020) "Novartis Oncology partnering with the NHS".

Box 8: JWP in-depth: Introducing a second renal nurse at Christie NHS Foundation Trust

The expansion of therapeutic options for patients with metastatic renal cell carcinoma (mRCC) led to a significant increase in outpatient appointments required to sustain the service for patients of Christie NHS Foundation Trust in Manchester (approximately 200 additions per year).[226] Novartis and the hospital worked together to set up the Christie mRCC Service Development JWP. The JWP funded a Clinical Nurse Specialist (CNS) to work part-time for two years to work alongside the existing multidisciplinary team (MDT). The JWP provided the evidence needed to secure long-term funding for this second CNS post, ensuring patients will continue to benefit well beyond the two-year duration of the project. Indeed, the CNS role has now been made permanent.

The JWP created new opportunities for efficiency gains

The impact of the JWP was closely monitored to ensure that added value of the second CNS appointment aligned with expectations. An unanticipated benefit was that a telephone clinic, established in the JWP, enabled the mRCC team to adapt quickly during changes to NHS working practices during COVID-19.

"Having the project with Novartis which provided a CNS to work alongside myself for 27 hours per week, has enabled the nurse specialist service to expand to ensure patients are better supported." — Clinical Nurse Specialist mRCC Christie Hospital.

"The temporary funding of a second renal CNS post has ensured that our patients are currently receiving a higher level of support than ever before". — Consultant Medical Oncologist Christie Hospital.

Sources: Christie NHS Foundation Trust (2019); Europe Economics analysis.

Figure 32: Novartis contribution to JWPs (jointly funded with NHS) in 2019

6.3.2 Academic collaborations

Of all Novartis academic collaborations globally, 25 per cent have been with UK academic and scientific institutions, meaning the UK ranks second overall for total Novartis collaborations by country, based on Pub Med publications between 2014 and 2018.[227] This demonstrates the commitment of Novartis to academic institutions in the UK.

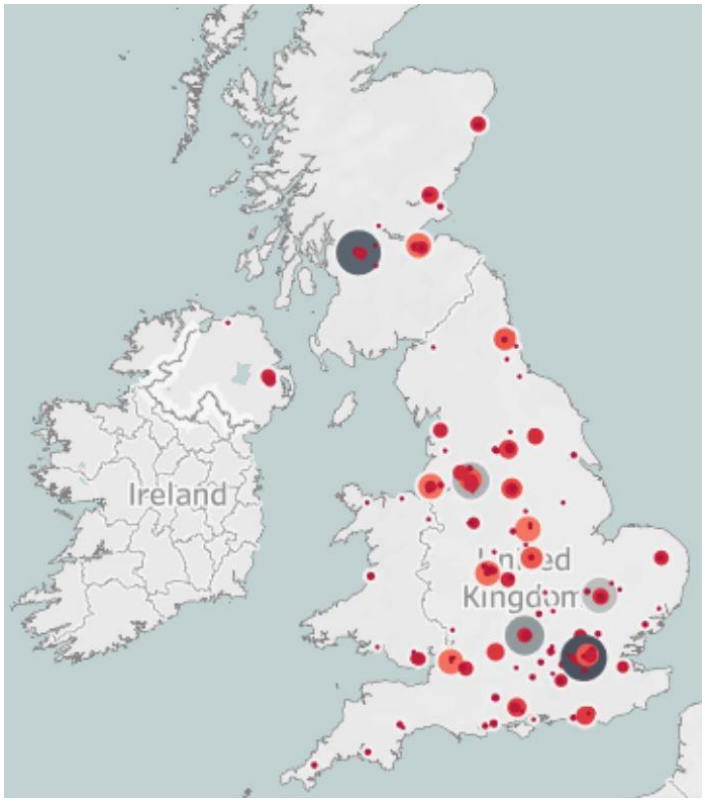
[226] Christie NHS Foundation Trust (2019), "Final Report from the Metastatic Renal Cell Carcinoma Service Development Joint Working Project (JWP) Between Novartis Pharmaceuticals and The Christie NHS Foundation Trust – Renal CNS".

[227] Deloitte Innovation Dashboard source data Pub-Med publications 2014-2019.

The Research Excellence Framework impact case study in 2015 ranked Novartis as the seventh most cited company in the UK in terms of collaborations with universities.[228] In the period from 2014 to October 2019, Novartis collaborated through publications with a total of 288 UK institutions (producing 869 publications).[229]

Figure 33 below shows that Novartis actively collaborates with academic institutions across all four countries of the UK. For instance, 141 of its publications since 2014 have been produced jointly with researchers in Scotland and 161 with researchers in the North West of England.[230] The top five institutions are Imperial College London (with which Novartis has published 86 studies since 2014[231]), University of Glasgow, University College London, University of Oxford, and University of Manchester. Novartis has collaborations with UK academic institutions in more than 17 therapy areas to confront the healthcare challenges faced by a variety of people, the top two therapy areas being oncology and cardiovascular.

Figure 33: Diversity of Novartis collaborations across UK academic institutions 2014-2019



Source: Deloitte Innovation Dashboard source data Pub-Med publications 2014-2019.

Its collaboration with academic institutions extends beyond joint publications and the NIBR programmes: in 2019, Novartis worked with 67 UK universities and research institutes as suppliers, spending a total of £15.2m (see Table 1 below). Of this figure, £11.4m went towards the universities for activities such as clinical services and grants, £1.86 towards university hospitals, £1.69m to academic institutes and a further £0.27m to academic publishers.

[228] Dowling, A (2015) "The Dowling review of business-university research collaborations" [online] [last accessed 02/10/2020].
[229] Deloitte Innovation Dashboard source data Pub-Med publications 2014-2019.
[230] Novartis data on file, joint publications across the UK.
[231] Novartis data on file, joint publications across the UK.

Table 1: Novartis university expenditure, 2019

Expenditure on	Total (£m)
Universities	11.4
University Hospitals	1.86
Institutes	1.69
University Press	0.27
Total	**15.2**

Source: Europe Economics analysis of Novartis Third Party Spend data, 2019. Figures may not add due to rounding.

6.3.3 The collaborative community: local ecosystems of knowledge

Clustering is a well-known economic phenomenon referring to the economic tendency for similar firms to be located geographically close to one another, the competitiveness gains from such clustering and the spillover benefits such clusters create.[232] Indeed, geographic proximity and the collaboration it could garner have been cited as the key anticipated benefits of the Novartis recent relocation.[233]

In November 2019, Novartis relocated its UK headquarters to White City Place, London. The promotion of the White City innovation cluster was a cornerstone of the London Borough of Hammersmith and Fulham (H&F) 2017 industrial strategy. The industrial strategy's ambition is to make 'West Tech', as the site was dubbed, a 'global beacon for innovation and growth and a leading place for tech and creative businesses'.[234] A further aim is for the dense agglomeration of research, creative, and innovative firms in White City to support the residential and commercial environment in West London.

The move was described as an "unprecedented opportunity" for life sciences when the new headquarters were opened in February 2020.[235] The anticipated clustering and spillover effects of the move was kickstarted with NIBR's hosting of a scientific symposium of around 200 scientists from across the UK at Imperial's Molecular Sciences Research Hub.

> "What we set out to do at White City is all about synergy - of having strong corporate, international and academic partners, having our doors open to these partners and having the ability to collaborate freely in close proximity."
>
> Professor Alice Gast
> President, Imperial College London

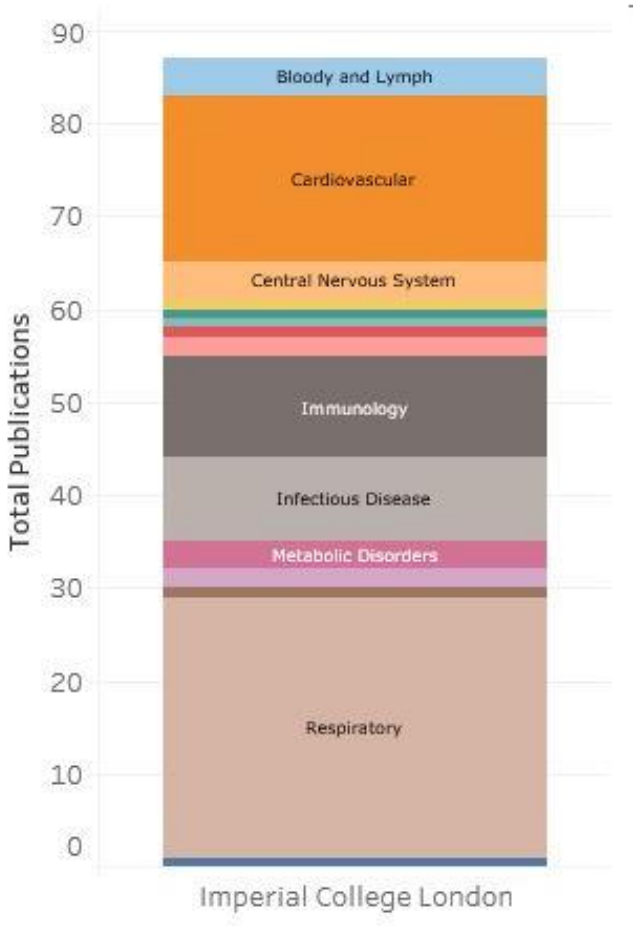
Source: Imperial College London (2020) "Novartis move spurs "unprecedented opportunity" for life sciences at White City" [online] [last accessed 01/10/2020].

White City Place is already home to pioneering research centres, innovative life sciences companies, bio- and health-tech companies, and start-ups. This includes the Imperial College Molecular Sciences Research Hub, which is the home of Imperial's Department of Chemistry. Imperial College London is the highest ranking university in terms of Novartis collaborations on publications, with 86 Novartis collaborations between 2014 and 2019, which reinforces the collaboration benefits of the move.[236] As can be seen in Figure 34, below, the majority of joint publications between Novartis and Imperial College London are in the therapy areas of

[232] The best-known theorist in this area is Michael Porter. A particularly well-known example of his thinking appears in the following Harvard Business Review article: Porter, Michael E (1998) "Clusters and the new economics of competition" [online] [last accessed 02/10/2020].
[233] Imperial College London (2020) "Novartis move spurs "unprecedented opportunity" for life sciences at White City" [online] [last accessed 01/10/2020].
[234] London Borough of Hammersmith and Fulham (2017) "Economic growth for everyone" [online] [last accessed 01/10/2020].
[235] Imperial College London (2020) "Novartis move spurs "unprecedented opportunity" for life sciences at White City" [online] [last accessed 01/10/2020].
[236] Deloitte Innovation Dashboard source data Pub-Med publications 2014-2019.

respiratory, cardiovascular, immunology, and infectious diseases. But as an 'anchor firm', Novartis (being an internationally-recognised innovative life sciences company) is set to be one of a host of innovative firms that H&F expect to support the thriving West London economy as well as create new opportunities for the deprived areas that also exist. The aspiration is that Novartis might act as a magnet for further innovative global companies to establish themselves there. To add to this, with the current COVID-19 pandemic negatively affecting the economy, high-growth firms, such as Novartis, have the potential to revive and stimulate the economic activity in the region.[237]

Figure 34: Imperial College London collaborations broken down by therapy area



Source: Deloitte Innovation Dashboard source data Pub-Med publications 2014-2019.

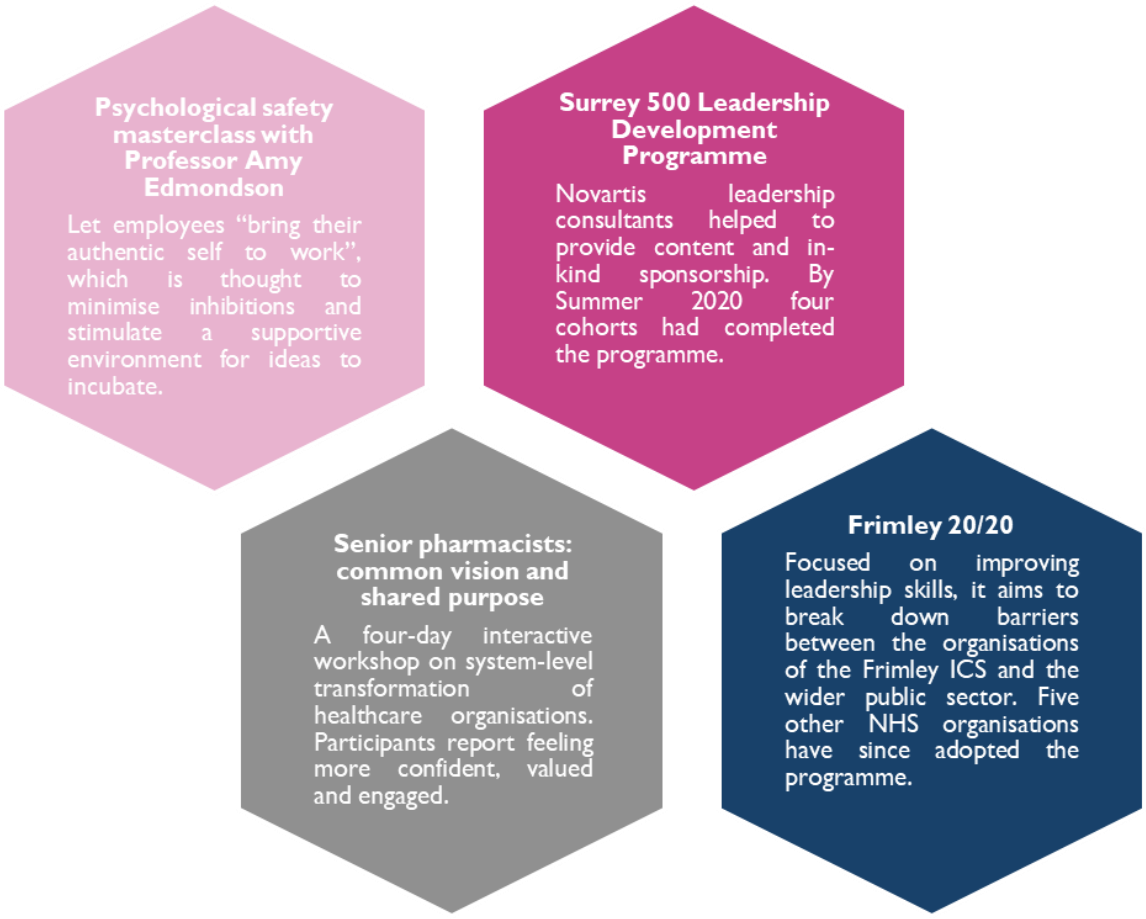
6.3.4 Developing people-power to enhance the effectiveness of collaboration

As well as working directly on patient-level services through JWPs, Novartis works with leaders of NHS organisations at all levels. It sponsors leadership skills programmes, such as the Surrey 500 and Frimley 20/20 (see Figure 35) and helps organisations 'tap the people power' of their staff through the various workshops and masterclasses it regularly hosts. These events demonstrate Novartis commitment to the NHS People Plan 2020/21, which states that "the NHS needs more people, working differently, in a compassionate and inclusive culture."[238]

[237] West London Alliance (2020) "Build and Recover: An Economic Recovery Strategy for West London" [online] [last accessed at 16/10/2020]
[238] Public Policy Project (2020) "Workforce and Talent Development: Interim report".

For example, an interactive collaboration masterclass with the NHS Leadership Academy was developed to support those leading the development of Integrated Care Systems (ICS) across England with practical skills training on uniting teams of people. Attendees were brought together with Professor Amy Edmondson to review "real-life" examples of work related to developing ICS in England and to foster collaboration and experience sharing between them. The workshop focused on "teaming", which aims to eliminate the rigid divisions that can exist between teams, organisations and even sectors. This approach is fundamental to creating a culture of excellence and an environment in which teams can unlock creativity to solve our most pressing challenges.[239] We describe other aspects of the partnership with Professor Edmondson in Chapter 8.

Figure 35: Some of the NHS leadership and system transformation programmes supported by Novartis



Sources: Novartis (2020) "Patient safety masterclass in psychological safety with Professor Amy Edmondson" [online] [last accessed 01/10/2020]; Public Policy Project (2020) "Workforce and Talent Development: Interim report".

6.3.5 Digital innovation through collaboration

The COVID-19 pandemic has both revealed the limitations of existing healthcare systems and put "rocket boosters" on the digital transformation of them.[240] Digitised healthcare offers the opportunity to transform frontline services for the benefit of patients and provide powerful new tools to improve prevention as well as the quality of life for those in receipt of care. A shift to person-centred health and care will involve greater use of new and emerging technology, whilst self-management and remote monitoring will exploit the greater use of shared data. One need only look to the national track-and-trace systems being rolled out in various

[239] Public Policy Project (2020) "Workforce and Talent Development: Interim report".
[240] Public Policy Project (2020) "State of the Nation: Digitisation and Medical Technologies".

countries to see this in action, but there are myriad other forms of this digitisation: from remote monitoring and virtual clinics to apps that help patients with their medication doses. Even before the pandemic, Novartis has been a key player helping to fuel the transformation, but it recently demonstrated its leadership on this front at a strategic round table with participants such as NHSX, Treasury, King's Fund, Leeds Institute for Data Analytics, Greater Manchester Future for Health Digital Accelerator and other health research institutions.[241]

Digital platforms to reduce inequality and improve patient experience

This section has already touched upon the identification of the travel burden as a key driver of patient access inequality. But travel to clinics is not necessary for every form of patient care. Recognising these, and developing digital platforms to address them, is a promising step in reducing inequality and improving patient experience. Novartis has helped to develop two such platforms in Reading and Bath. These developments have proved to be particularly valuable given the implications of the COVID-19 pandemic.

One of the digital platforms facilitates the collection and monitoring of PROMs in prostate-specific antigen clinics.[242] This platform helps to abate the problems of inconsistent collection of patient reported outcome measures (PROMs), manual data re-entry, as well as the more general issue of an increasing population putting pressures on capacity. With this platform, patients can now enter their PROMs remotely and in their own time. Regular virtual clinics are also now in place, freeing up space for new or more complex patients. The other digital platform aims to reduce the issue of diagnostic delay for people with chronic inflammatory back pain, which can otherwise be undiagnosed and lead to ankylosing spondylitis (AS). Reducing referral time is crucial in this process. The platform acts as an aide memoir for GPs to consider when referring a patient for AS diagnosis. This enables healthcare professionals to make a confident, informed decision about a patient's treatment plan based on their outcomes. The earlier diagnosis of AS patients reduces the occurrence of long term irreversible structural changes.

Health Data Research Hubs

As a pioneering firm in the sphere of medical healthcare, Novartis harnesses the strides made in data analytics to enhance its activities and generate valuable resources, such as data troves. In doing so, these troves can be exploited to foster and generate developments that can be used more widely. The Health Data Research Hubs aim to enable a UK life sciences ecosystem that provides responsible and safe access to health data, technology and science, research and innovation services to ask and answer important health and care questions. As previously mentioned in Chapter 3, Novartis is part of two consortia contributing resources and building on the health data available: Discover-NOW and BREATHE. Earlier, we focused attention on the Novartis investments in these projects (£300,000 in kind for each bid).[243] Now, we turn attention to the collaborative dynamic embodied by them.

Discover-NOW is a programme that grants access to NHS health data in London and Manchester to support research into finding new ways to diagnose and treat disease and improve the quality and safety of patient care.[244] Recently, this Hub's partnership with NorthWest EHealth involves 50 organisations participating together in the COVID-19 Diagnostics Evidence Accelerator, a collaboration to advance the worldwide development of diagnostics into COVID-19 through real-world data.[245] The collaboration sees the sharing of

[241] Novartis (2020) Novartis Collaborations on Digital Healthcare.
[242] Novartis (2020) Patient Access Managers.
[243] In this context, by "in kind" we refer to human expertise resources.
[244] HDRUK (n.d.) "Discover-NOW - The health data research hub for real world evidence" [online] [last accessed 01/10/2020].
[245] HDRUK (n.d.) "Discover-NOW - The health data research hub for real world evidence" [online] [last accessed 01/10/2020].

insights from the North West London COVID-19 data repository of de-identified cases to organisations outside the Discover-NOW consortium.[246]

BREATHE involves connecting the currently disparate data of a vast number of people suffering from respiratory conditions such as asthma.[247] Over the COVID-19 pandemic, the BREATHE consortium has joined with King's College London and ZOE, a health science company, to enable the ethical and safe use of the national Symptom Study app data by other researchers and decision-making bodies to tackle the pandemic in the UK.[248] The BREATHE data infrastructure is also being shared with the International COVID-19 Data Research Alliance and Workbench to promote access to global health data for research at scale.

The Novartis Biome and the Health Hub 2020

Novartis has also engaged with start-ups with innovative solutions to address current healthcare challenges. In 2018, Novartis partnered with Wayra Digital Health Accelerator and the NHS, which together aim to fuel a sharing of knowledge and expertise between creative start-ups and global players with access to resources. This collaboration has since evolved into the Novartis Biome and the Health Hub 2020.

- Novartis Biome – The move to White City coincided with the announcement that Novartis would expand its Biome programme to the UK.[249] The Novartis Biome is a digital innovation lab that aims to empower and engender health tech companies and people passionate about disrupting healthcare through the use of data and digital technologies. It is intended to open up access to key Novartis resources, including relevant datasets, mentorship and customised curriculums. Fundamentally, the Biome brings together Novartis' deep scientific experience with the expertise of the tech ecosystem to develop and scale digital solutions that improve and extend people's lives.[250]
- Health Hub 2020 – This is a nine-month health-tech accelerator programme delivered in partnership with Wayra UK, Telefonica's open innovation facility. It has been specifically designed to address COVID-19 challenges facing the NHS by investing into three start-ups and providing them with access to cash investment, mentoring/coaching and NHS market access.[251] This year three companies were selected by an expert panel of judges to be recipients of support: Albert Health (voice-based health assistant app that helps patients "take the right dose at the right time"), Vinehealth (an artificial intelligence [AI] platform that provides instant answers to clinical queries) and Medwise.ai (an app that combines behavioural science and AI to support patients during their cancer treatment and optimise care).[252]

UK Biobank

The UK Biobank contains a vast trove of information that may be used to identify health patterns and expose hitherto unnoticed risks. It follows the health and well-being of 500,000 volunteer participants and, with the unidentifiable health information they provide, aims to improve the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses.[253]

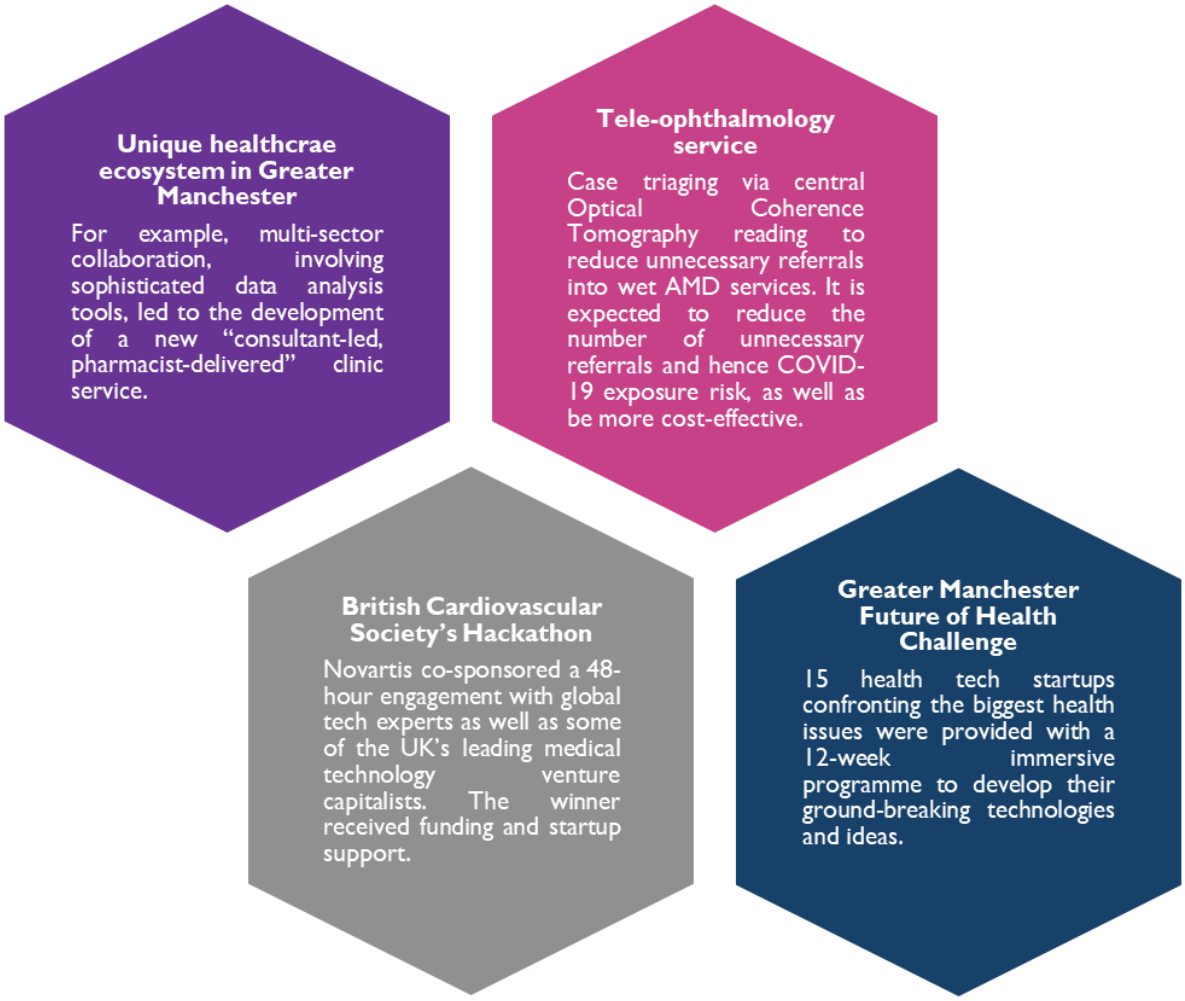
A Novartis initiative is currently underway at the UK Biobank, the Phenome-Wide Association Study. This study uses the UK Biobank resources to identify disorders that may benefit from existing pharmacotherapies, prioritize complementary targets for existing indications, and evaluate unanticipated adverse effects of target

[246] Imperial College Health Partners (2020) "Joining the global conversation of real-world evidence supporting the COVID-19 response" [online] [last accessed 14/10/2020].
[247] HDRUK (n.d.) "BREATHE - The health data research hub for respiratory health" [online] [last accessed 01/10/2020].
[248] University of Edinburgh Usher Institute (2020) "Our response to COVID-19" [online] [last accessed 14/10/2020].
[249] Novartis (2020) "UK announced as global centre of major cardiovascular trial as Novartis opens new HQ in White City, London" [online] [last accessed 02/10/2020]
[250] Novartis (2020) "Introducing the Novartis Biome".
[251] Novartis (2020) Health Hub and IHD and GM.
[252] Novartis (2020) "Health Hub Accelerator 2020 finalists announced" [online] [last accessed 14/10/2020].
[253] UK Biobank (n.d.) home webpage [online] [last accessed 3/11/2020].

modulation.[254] This study seeks to increase the number and range of disorders being tested in clinical trials with pharmacotherapies under development at Novartis Institutes for Biomedical Research. The ultimate goal is to increase the number of people who can be treated effectively with pharmacotherapies.[255]

Two further Novartis projects with the UK Biobank are to focus on several heart related diseases. The results of these projects will be used as input into clinical trials and will help to determine which patients stand to benefit the most from targeted therapies. This information can then be used to inform the population level strategy for reducing heart disease in the UK – where it is currently the second biggest cause of death.

Figure 36: Further example of Novartis digital collaboration with healthcare and NHS partners



Sources: Novartis (2020) "Reflecting on 2019 – highlights from Novartis UK partnerships" [online] [last accessed 01/10/2020]; Health Innovation Manchester (2020) "Impact Report 2019/2020" [online] [last accessed 01/10/2020]; Novartis (2020) Tele-ophthalmology service.

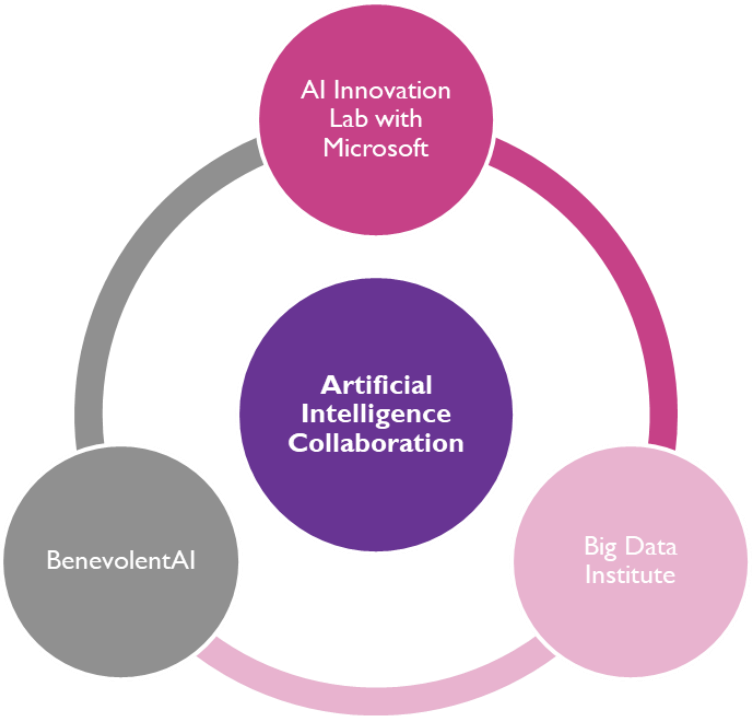
6.3.6 Artificial intelligence in healthcare

During 2020 it was estimated that the amount of health data doubles every 73 days.[256] This vast sum of data necessitates the integration of artificial intelligence (AI) and machine learning in healthcare and medicine discovery. Building upon recent technological advances in AI, Novartis has collaborated with partners at the

[254] UK Biobank (2018) "Phenome-Wide Association Studies to inform therapeutic development at Novartis Institutes for Biomedical Research" [online] [last accessed 01/10/2020].
[255] UK Biobank (2018) "Phenome-Wide Association Studies to inform therapeutic development at Novartis Institutes for Biomedical Research" [online] [last accessed 01/10/2020].
[256] PMLive (2020) "AI: the smart money is on the smart thinking" [online] [last accessed 02/10/2020].

forefront of knowledge in that area, engaging with both established technology organisations and innovative start-ups.

Figure 37: Selected Novartis AI collaborations 2018-20



AI Innovation Lab with Microsoft

Novartis has announced the AI Innovation Lab with Microsoft. The combination of advanced analytical systems developed by Microsoft and Novartis's extensive chemical knowledge has the potential to foster the development of molecules that work more precisely and efficiently in the body. Furthermore, this partnership aims to empower Novartis associates across its businesses with AI capability by making it accessible to all, regardless of their knowledge of data science. This direct knowledge transfer of the expertise of Microsoft and Novartis is also an illustration of improving workforce skills — including some skills that are transferrable or communicable to others. By creating a 'crop of citizen data scientists' capable of using AI to unlock valuable insights from Novartis' rich and diverse store of data, new AI models and applications can be designed to increase the human capital of Novartis associates. This could in turn make them more productive in addressing future challenges in medicine.[257,258]

Big Data Institute

Another Novartis collaboration in the area of data science is with Big Data Institute at the University of Oxford. In January 2019, Novartis announced a five-year collaboration with the Institute with the aim of extracting the value offered by the UK's expertise in data science and new digital technology such as artificial intelligence.[259] The collaboration involves Novartis sharing with the Institute the anonymised data it has collected from running clinical trials over multiple years in areas such as dermatology, rheumatology, and Multiple Sclerosis imaging. The collaboration draws on further data from UK Biobank, Genomics England and

[257] Novartis (n.d.) "AI innovation lab" [online] [last accessed 01/10/2020].
[258] This project will be run in part from Microsoft Research Lab in Cambridge, UK, as well as global Novartis campuses.
[259] Novartis (2019) "Novartis and the University of Oxford's Big Data Institute to establish world-leading research alliance using artificial intelligence to understand complex diseases and improve drug development" [online] [last accessed 01/10/2020].

China Kadoorie Biobank.[260] This will help to develop new machine learning algorithms and identify patterns across ultra large datasets in an effort to better understand disease and predict how patients respond to existing and new medicines.

To understand how this form of collaboration differs from the use of data produced in the normal course of clinical trials, it may be helpful to note that information collected during a clinical trial is shared most commonly with other researchers only via the publication of studies in peer-reviewed journals. But these publications typically report on only a small subset of the data collected and analysed in a clinical trial.[261] The raw data underlying the results of a trial can provide a wide range of medical statistics on the patients that is not ultimately central to the results and goals of the trial itself. For example, it can involve participant characteristics such as weight, blood pressure, heart rate, clinical laboratory results, and self-reported data. As such, the raw data provides a potential treasure trove from which new insights not necessarily related to the research objectives of the initial trial can be gleamed.

BenevolentAI

In recognition of the synergy already existing between medicine development and advanced analytics, Novartis has teamed up with established UK AI company BenevolentAI. BenevolentAI was founded to bridge the gap between data and medicine, and combines the power of computational medicine with the principles of open systems and cloud computing to transform the way medicines are designed, developed, tested, and brought to market.[262] BenevolentAI's analytics platform ingests molecular, clinical, pharmacological data and scientific literature to identify relationships in the data between genes, diseases, medicines, and biological pathways, which can eventually lead to the proposal of optimum medicine targets. From this collaboration, Novartis is able to leverage its clinical trial and experimental data using BenevolentAI's unique analytics platform, whilst BenevolentAI gains access to a data trove compiled by the UK's leading sponsor of clinical trials.[263] Indeed, Anne Phelan, the Chief Scientific Officer of BenevolentAI, notes that such a collaboration, over time, can amount to saved lives:

> "Working with Novartis Global Drug Development, we are investigating new indications for and patient responders to Novartis' clinical oncology programs. By working together, we can develop more targeted cancer therapies with a greater understanding of which patients they will help, and we hope one day soon more patients will survive because of it."
>
> Anne Phelan
> Chief Scientific Officer, BenevolentAI

Source: Novartis (2020) "A Powerful Pairing" [online] [last accessed 14/10/2020].

6.4 Summary

Novartis is part of an extensive network of collaboration in the UK. This network fosters a dynamic knowledge-sharing environment. Comprised of the NHS, innovative medical technology start-ups, research institutions, and life sciences firms, it is a multi-disciplinary ecosystem of collaboration. This network contributes to the growth and dynamism of the UK economy and helps it to confront emerging healthcare challenges. The joint ventures into big data analytics promise to uncover information hidden in pre-existing datasets and ones yet to be created, and they are supporting advanced, high-growth sectors in the UK.

[260] Novartis (2020) "Annual Review 2019" (full) [online] [last accessed 14/10/2020].
[261] Committee on Strategies for Responsible Sharing of Clinical Trial Data; Board on Health Sciences Policy; Institute of Medicine (2015) "Sharing clinical trial data: Maximizing benefits, minimizing risk" *National Academies Press (US),* Vol 4, (Apr), Ch 4 [online] [last accessed 3/10/2020]..
[262] Benevolent AI (n.d.) "Benevolent AI" [online] [last accessed 01/10/2020].
[263] Based on Novartis being the UK being the leading sponsor of clinical trials. Source: Novartis "Trial Trove Data on File 1" (2020). Trialtrove® | Informa, 2020. Accessed September 2020. Ongoing trials in the past 10 years (ongoing between 01/01/2010 to 31/12/2019).

Novartis support of Joint Working Partnerships with the NHS has led to participation in more than 12 times the pharmaceutical industry average number of JWPs. Through these partnerships, there are opportunities for knowledge transfer between partners, both directly through learning different components of the life sciences field, and tacitly through interaction with partners that builds understanding and trust. Over the long term, this learning process is a powerful force in maximising productivity and economic growth, and the Novartis contribution to it is clearly industry-leading.

7 Advancing Environmental and Social Goals

7.1 Overview

In recent decades, major corporates across the world have become particularly conscious of their environmental impacts. Responsible firms seek to recognise and (to the extent feasible and proportionate, and consistent with still achieving their positive goals) to minimise environmental impacts as well as foster positive targets and ambitions.

Within this context, the reporting of Environmental, Social and Governance (ESG) targets and achievements is increasingly prioritised among corporates, including in the UK, and may be seen as a means of holding companies accountable for their environmental commitments among others. ESG has been a key priority for Novartis with its ESG strategy focused on 4 key pillars namely Ethical Standards, Pricing and Access, Global Health Challenges and Responsible Citizenship.[264] Through its objectives and actions Novartis is not only leading the way in ESG targets and reporting, but is also contributing to the wider benefits achieved by the pharmaceutical and life sciences sectors through encouraging businesses to set similarly ambitious objectives in the fields of environment, sustainability and ethical business practices. For example, Novartis has recently announced a new €1.85bn sustainability-linked bond which for the first time includes social targets. This means that bondholders could receive higher interest if Novartis fails to meet targets relating to improving access to medicines and addressing global health challenges.[265] In addition, Novartis has also announced ambitious ESG targets which include reaching full carbon neutrality across its value chain by 2030 as well as improving patient access to its innovative medicines in low- and middle-income countries.[266] Novartis is equally committed to good corporate governance based on a framework supporting sustainable financial performance and long-term value creation reflecting the company's broader values and behaviours. Through these actions Novartis has taken further steps to embed ESG into the core of its business and deliver benefits to patients, healthcare professionals, investors and society.

This chapter focuses on the environmental aspect of ESG, and presents the economic theory around environmental impacts and the Novartis goals and achievements in advancing environmental sustainability. Although the pharmaceuticals sector is not amongst the most carbon-emitting sectors,[267] it does have a range of impacts across emissions, waste and water, with certain therapeutic areas contributing more than others (for example, the environmental impact associated with metered dose inhalers can be significant).[268] It also generates impacts through its extensive supply chain: emissions from pharmaceutical supply chains are some ten times higher than those of their direct operations, and their water consumption is three times higher.[269]

[264] Novartis (n.d.) "Environmental, Social and Governance" [online] [last accessed: 09/10/2020].
[265] Novartis (September 2020) "Novartis reinforces commitment to patient access, pricing a EUR 1.85 billion sustainability-linked bond" [online] [last accessed: 09/10/2020].
[266] Novartis (September 2020) "Novartis announces ambitious ESG targets to increase access to medicines and achieve full carbon neutrality" [online] [last accessed: 09/10/2020].
[267] WifOR (2018) "The environmental impact of Novartis along global supply chains", p3 [online] [last accessed 06/10/2020].
[268] For example, see: Green Inhaler (n.d.) "The Problem with Inhalers" [online] [last accessed: 03/11/2020].
[269] WifOR (2018) "The environmental impact of Novartis along global supply chains", p3 [online] [last accessed 06/10/2020].

There are further indirect environmental impacts related to the import and export of medicines, e.g. emissions from air transport.

7.2 Economic theory

7.2.1 Theory of externalities

Externalities arise when the actions of an economic agent (e.g. a firm) affect other agents and wider society, yet the firm does not consider the full costs and benefits of its actions on others and society as a whole. Externalities are a key theoretical concept in the context of environmental impacts as the actions taken by firms to reach their environmental objectives often 'spill over' to the rest of the economy. Depending on whether the impact on others and society is adverse or beneficial, economic theory makes a distinction between negative and positive externalities.

Box 9: Illustrating the concept of externalities

The classic illustration economists use to explain the concept of an externality is an unregulated factory from some centuries ago that produces chemicals as a by-product of its production process. Suppose that the factory were to simply dump those chemicals, e.g. through a waste pipe into a river. These chemicals might cause environmental damage of various sorts (e.g. killing wildlife; damaging buildings; harming the health of pedestrians) that would not necessarily be experienced by either those supplying goods and services to the factory, the factory-owners themselves or those buying the factory's products.

Because the effects are external to the web of economic relationships around the factory itself, they are called "externalities".

As well as negative externalities, there can also be positive ones. The purchase of a vaccine for an infectious disease will not only lead to a gain for the vaccine-seller (the money paid for the medicine) and for the vaccine-buyer (a reduced risk of getting the disease), but also for those that vaccine-buyers might have infected had they contracted the disease. These positive externalities are in part embodied in the social impact of medicines described in Chapters 2 and 3.

As firms do not take account of the full impacts of their decisions on others, these give rise to inefficient market outcomes, meaning that the total benefit to society is not maximised. The polluting factory does not experience all the negative impacts of its pollution, so does not seek to keep it down to the socially-optimal level. The vaccine-buyer does not experience all the disease benefits of its purchase of the vaccine, so may choose not to buy it in cases when it would be socially optimal to do so.

Box 10: Impacts of taking account of externalities

Externalities can lead to socially-suboptimal choices by firms regarding their innovations and investments. Suppose a firm faces an investment choice between:

- improving an existing product (or service); or
- a process improvement that reduces energy consumption.

When the environmental impacts of the investment are not taken into account, the firm may marginally prefer investing in improving the existing product.

However, once the environmental impacts associated with each option are explicitly included in the firm's decision function (e.g. through the firm adopting a policy of seeking environmental improvements in its

processes), the firm may become more likely to invest in the process improvement. In this way, the firm can improve its environmental impact as part of its internal efficiency improvement processes.

7.2.2 Application to the life sciences sector

Within the life sciences sector externalities – both positive and negative – manifest themselves in many different forms. Over recent years, pharmaceutical companies and the wider life sciences sector have been taking various steps to mitigate and reduce the impact of negative externalities associated with the sector. For example:

- The carbon footprint, energy and water usage and waste generation of pharmaceutical companies as part of their core activities focusing on the development and manufacturing of medicines can generate significant negative environmental impacts. Opportunities to reduce emissions include the increased use of renewable energy (e.g. wind power) while reducing the use of plastics used in packaging can lower the waste generated.
- In addition, corporate functions of companies can also add to this footprint, for example through the use of company cars, single-use plastics in canteens and cafeterias or printing in offices. Low emissions vehicles used for transport and reducing or eliminating the use of single use plastics can contribute to reducing this footprint.
- Further, greenhouse gas emissions across the supply chain (e.g. through transportation or energy use) also increase the negative environmental impact of the industry. Encouraging suppliers to embed environmental sustainability goals within their own processes can help tackle the impact of emissions in companies' supply chains.
- Molecules and chemicals used as part of the drug manufacturing process can also lead to negative impacts when released to the environment (e.g. oil-derived solvents are toxic, flammable and difficult to degrade). "Green chemistry"[270] can contribute to developing more environmentally sustainable alternatives used to produce active pharmaceutical ingredients (APIs).
- Medicines, including inhalers (in particular metered dose inhalers) to treat conditions such as asthma and anaesthetic gases used in surgeries release a significant amount of greenhouse gases to the environment, and thus increase the carbon footprint of patients and the health care system alike. The environmental impact of these medicines may be reduced through replacing these with low carbon alternatives, such dry powder inhalers.
- Finally, the wider supply chain of pharmaceutical companies could also add to the environmental footprint of the sector through emissions, energy and water usage, waste generation or corporate functions. Setting ambitious environmental sustainability requirements for companies along the supply chain can help reduce the negative externalities associated with the actions taken by suppliers.

At the same time, pharmaceutical companies play an important role in bringing about positive externalities through their medicines. For example, this includes interrupting communicable diseases (such as the coronavirus at the heart of the current COVID-19 pandemic). Vaccines, treatments that lead to more rapid recovery or devices such as virus testing kits that generate information that helps interrupt transmission not only benefit the direct users of these products but also deliver further benefits through reducing the likelihood of spreading the disease around to others.

[270] Green chemistry can be described as "the utilisation of a set of principles that reduces or eliminates the use or generation of hazardous substances in the design, manufacture and application of chemical products". Advancing Green Chemistry (n.d.) "Definition & Principles" [online] [last accessed: 03/11/2020].

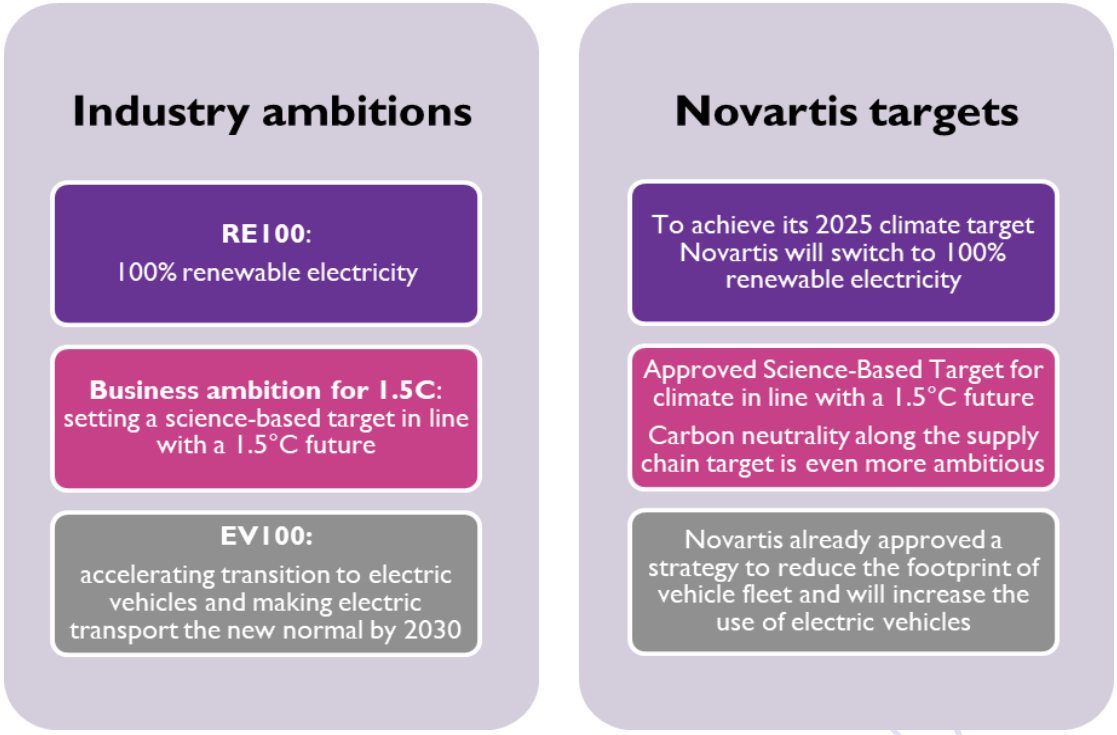
7.2.3 Government action in the UK health and life sciences sectors

To reduce the impact of negative externalities generated by the life sciences sector, governments, health care systems and pharmaceutical companies have been setting ambitious objectives associated with environmental sustainability. This includes a pledge by the UK government to bring all greenhouse gas emissions to net zero by 2050, making it the first major economy to pass such a law.[271] Further, the Climate Change Act of 2008 requires government institutions in the UK, including the NHS to reduce greenhouse gas emissions by 80 per cent by 2050 compared to a 1990 baseline.[272] At the EU level the European Union Strategic Approach to Pharmaceuticals in the Environment reflects EU priorities in terms of reducing the environmental impact of pharmaceuticals.[273]

The 26th UN Climate Change Conference of the Parties (COP26) will be hosted by the UK in Glasgow in November 2021.[274] Ahead of the conference, the UK government is actively seeking to gain companies' commitment to various environmental and climate change targets. These include initiatives around renewable electricity (RE100 global initiative); climate change (business ambition for 1.5°C) and the use of electric vehicles (EV100 commitment).

Novartis targets are already aligned with these initiatives – as shown in the figure below – and Novartis is also committed to joining the RE100 industry initiative. Section 7.3 offers further details around Novartis ambitions in these areas and how it compares with other companies.

Figure 38: Benchmarking Novartis targets with industry ambitions



Source: RE100 (n.d.) "We are committed to 100% renewable power" [online] [last accessed 23/10/2020], United Nations Global Compact (n.d.) "Business Leaders Taking Action" [online] [last accessed 23/10/2020], and Climate Group (n.d.) "EV100" [online] [last accessed 23/10/2020].

[271] Department for Business, Energy & Industrial Strategy (2019) "UK becomes first major economy to pass net zero emissions law" [online] [last accessed 01/10/2020].
[272] NHS (n.d.) "Climate Change Act (CCA)" [online] [last accessed 22/10/2020].
[273] European Commission (2019) "European Union Strategic Approach To Pharmaceuticals In The Environment" [online] [last accessed 12/10/2020].
[274] UK Government Department for Business, Energy & Industrial Strategy (n.d.) "COP26" [online] [last accessed 23/10/2020].

7.2.4 Achieving Net Zero NHS targets

In the UK, the NHS alone accounts for 5.4 per cent of total carbon emissions.[275] Moreover, climate change and air pollution are both linked with putting pressure on the health care system through increased patient numbers and hospitalisations. For example, air pollution is associated with conditions such as heart disease, stroke and lung cancer and can contribute to as many as 36,000 deaths annually.[276] To address this climate "health emergency" in the UK, the NHS has committed to reaching net zero by 2040 in terms of the NHS Carbon Footprint (including emissions directly controlled by the NHS) and by 2045 with regards to the NHS Carbon Footprint Plus (also including emissions the NHS can influence).[277]

Box 11: Achieving Net Zero NHS targets

Despite the progress achieved so far, the challenge faced by the NHS to reach its net zero targets is considerable. Within the NHS' Carbon Footprint Plus, medicines & chemicals is estimated to account for approx. 25 per cent of emissions (including a 5 per cent contribution by anaesthetic gases and metered dose inhalers), while the wider supplier chain is considered to account for about 24 per cent of emissions. Therefore, the NHS has set out a range of steps to decarbonise the health and care system across various dimensions, including medicines, hospitals, transport and the supply chain.

For example, in the area of medicines actions to reduce the emissions associated with inhalers (e.g. propellant in metered dose inhalers) include: (i) increasing the use of clinically equivalent low carbon inhalers (such as dry powder inhalers); (ii) supporting innovation linked with lower carbon propellants and alternatives; and (iii) supporting the greener disposal of used inhalers.

As part of the NHS Long Term Plan, the model around outpatient services will also be redesigned, building on the advances brought about by digital services to access advice and care. Over the next five years this will remove the need for as much as 30 million outpatient appointments a year, saving patients time and convenience, while also significantly reducing the environmental impact through fewer road miles (it is estimated that 6.7 billion road miles each year are from patients and their visitors travelling to the NHS). Joint Working Partnerships in which Novartis is involved (discussed in Chapter 6) using digital technologies can also contribute to reducing the need for outpatient appointments.

Source: NHS (October 2020) "Delivering a 'Net Zero' National Health Service" [online] [last accessed 01/10/2020] and NHS (January 2019) "The NHS Long Term Plan" [online] [last accessed 01/10/2020].

The remainder of this chapter focuses on the Novartis ambitions regarding environmental sustainability and its contribution to a greener sector both in the UK and globally.

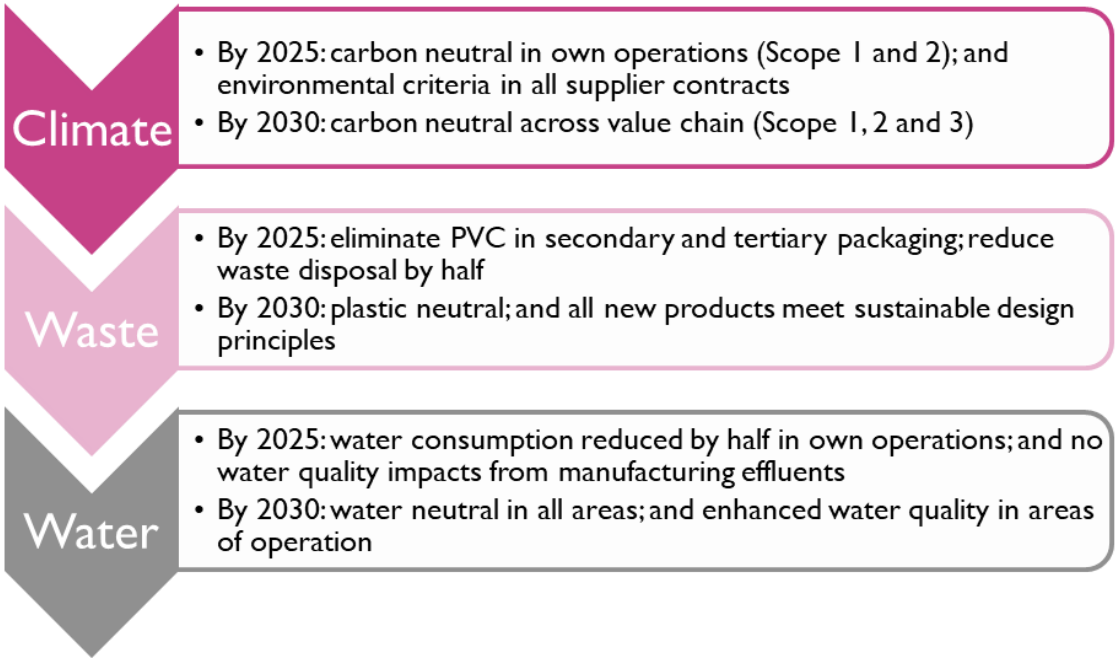
7.3 Examples of how Novartis contributes to a greener sector

In light of the commitments set by the UK government and the NHS with regards to emissions and net zero targets, Novartis has committed to reducing its environmental footprint and ensuring that the benefits generated through positive externalities are shared across the wider society. In particular, Novartis aims to be a leader in environmental sustainability and a catalyst for positive change through its own operations as well as through encouraging suppliers to include environmental sustainability goals in their own policies and processes.

[275] Bawden, A (2019) "The NHS produces 5.4% of the UK's greenhouse gases. How can hospitals cut their emissions?" *The Guardian* [online] [last accessed 01/10/2020].
[276] NHS (2020) "Greener NHS campaign to tackle climate 'health emergency'" [online] [last accessed 01/10/2020].
[277] NHS (2020) "A Net Zero NHS" [online] [last accessed 01/10/2020].

Figure 39 below summarises the environmental targets Novartis aims to achieve by 2025 and 2030, in the areas of climate, waste and water, across its global operations.

Figure 39: Summary of Novartis environmental targets



Note : *Scope 1* (or direct) emissions : emissions from sources that are owned or controlled by Novartis.
Scope 2 (or indirect) emissions: emissions from the consumption of purchased electricity, steam, or other sources of energy (e.g., chilled water) generated upstream from Novartis.
Scope 3 (or other indirect) emissions: emissions that are a consequence of the operations of an organization, but are not directly owned or controlled by Novartis, e.g. including the supply chain, business travel, employee commuting, and use of products.
Source: Novartis (n.d.) "Novartis sustainability strategy changing tomorrow with actions today".

Novartis targets are challenging both in their own right and in comparison to the goals of other companies. This is supported by the results of a recent benchmarking exercise assessing the environmental ambitions of 20 large, prominent companies across a range of sectors in the areas of carbon emissions, waste disposal, and water quality and consumption.

Box 12: Benchmarking Novartis environmental targets

- In terms of Scope 1 and 2 carbon emissions, the Novartis target of carbon neutrality by 2025 is matched by few of the pharmaceutical companies assessed.
- The Novartis ambition to reach carbon neutrality by 2030 with regards to Scope 1,2 and 3 carbon emissions represents a more ambitious target than set by most companies included in the benchmarking exercise, e.g. AstraZeneca and Microsoft currently have a target of becoming carbon negative by 2030.
- In the area of waste disposal, most of the 20 companies assessed stated a less ambitious target than the Novartis commitment to reduce waste disposal by 50 per cent by 2025.

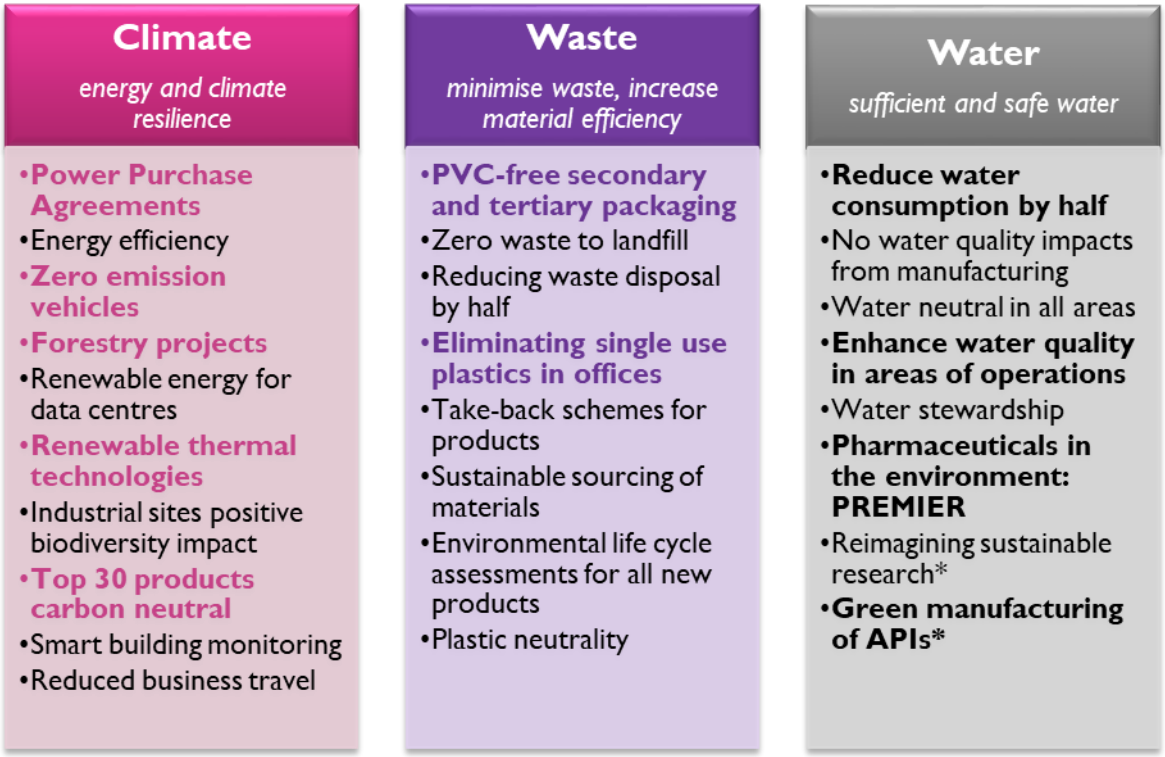
Source: Novartis (September 2020) "Build our future together! Environmental Sustainability @ Novartis".

Driven by these global and UK targets across emissions, water and waste, Novartis has embarked on an ambitious environmental sustainability journey focusing on a range of action plans to reduce its environmental footprint. These targets also contribute to and are aligned with achieving the 17 sustainable development goals set by the United Nations. This includes the goals on climate action; clean water and sanitation; affordable and clean energy; and responsible consumption and production.[278]

[278] United Nations Department of Economic and Social Affairs (n.d.) "The 17 goals" [online] last accessed [23/10/2020].

Figure 40 below summarises the various action plans Novartis is focusing on as part of this journey. Section 7.3.2 provides further details on selected (emboldened) action plans such as forestry projects, the green manufacturing of APIs, zero emission vehicles or PVC-free secondary and tertiary product packaging.

Figure 40: Novartis environmental sustainability action plans



Note: (*) These action plans cut across all three areas.
Source: Novartis (n.d.) "Novartis Framework to be the Leader in Environmental Sustainability".

Section 7.3.1 below presents the Novartis estimated measurable environmental impact in the UK in terms of emissions, water and waste. Section 7.3.2 explores other ways in which Novartis seeks to be environmentally sustainable both globally and in the UK, picking up on the highlighted action plans presented in the figure above. As a leading importer of medicines to the UK and due to the global nature of pharmaceutical supply chain, these global initiatives are also expected to positively affect the Novartis environmental footprint in the UK.

7.3.1 Measurable environmental impacts in the UK

As part of its ESG ambitions to measure and report targets and achievements in a transparent manner, Novartis estimates its environmental impact in the UK at -£54.4m. This includes a direct negative impact to the environment of £4.2m, an indirect negative impact of £18.1m and an induced impact of £31m through ripple effects through the economy.[279] In addition, it includes downstream impacts of £1m corresponding to the environmental impact of the consumption of medicines using the "pharmaceuticals in the environment" approach.[280] The various types of impact are explained in the box below, and illustrated in the figure.

Box 13: Articulation of impacts

Direct impacts include the environmental impact arising from Novartis (global and UK) own business activities in the UK.

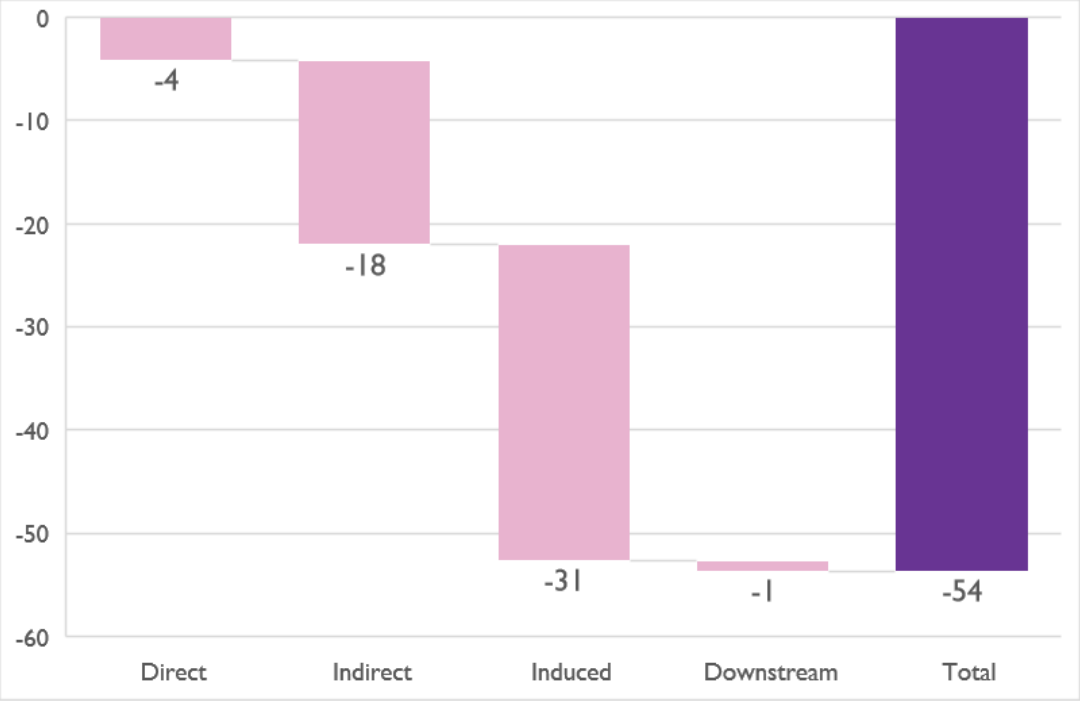
[279] Novartis (2019) "FES Impact Valuation Results UK".
[280] Novartis (2019) "FES Impact Valuation Results UK".

Indirect impacts cover the environmental impacts coming from Novartis global and UK buying goods and services from vendors in the UK as well as the purchases by vendors in the UK along the supply chain.

Induced impacts include the environmental impacts coming from the consumption of goods and services by Novartis employees and from the employees of firms along the supply chain in the UK. These include, for example, the environmental impacts associated with air emissions, water and waste.

These impacts are estimated by measuring direct air emissions, water and waste (or spending volumes to represent indirect and induced impacts) and multiplying by a cost which represents environmental damage. The impact calculations would capture some of the Novartis externalities – and reductions through its mitigating efforts for 2019 – through the damage cost. Mitigation strategies that do not directly affect air emissions, water usage or waste would not be captured.

Figure 41: Novartis environmental impact in the UK, 2019 (£m)



Source: Novartis (2019) "FES Impact Valuation Results UK".

Novartis takes account of the carbon price in its investment decisions, setting an internal carbon price of $100 per ton of carbon dioxide equivalents. This provides internal incentives to Novartis operations to pursue projects with low climate impacts. The company's energy management programme scouts energy saving opportunities for new projects and audits major sites to find energy efficiency improvements. This is part of the Novartis global goal to use renewable energy wherever it is feasible.[281] Where renewable sources are not yet viable, Novartis implements policies to offset its carbon footprint. For example, as part its agroforestry projects (discussed in more detail in section 7.3.2 below), the company has developed carbon sequestration projects or 'carbon sinks' in Argentina, Mali, Columbia and China that compensate for its emissions.[282]

The ongoing COVID-19 pandemic has also contributed to a rise in the share of renewable sources (such as wind and solar) in electricity across the globe. While the longer-term effect of the pandemic remains unknown

[281] Novartis (n.d.) "Climate" [online] [last accessed 02/10/2020].
[282] Novartis (n.d.) "Climate" [online] [last accessed 02/10/2020].

for a while, governments, businesses and investors can all play a role in a greener post-COVID environment for example through supporting low-carbon supply chains and investment and innovation in batteries, storage or smarter grids.[283]

In addition to the GDP impacts above, in the UK Novartis also measures its direct environmental impact against its specific water, emissions and waste targets.

Water

Novartis has reduced site effluents (liquid waste) in the UK to one order of magnitude below the predicted no-effect limits. Since 2010 it has reduced its water usage by 42 per cent at its Grimsby site,[284] and enhanced the water quality in places where it operates. Novartis achieved this by tracking water streams into and out of its sites. Looking ahead, Novartis targets reducing its water consumption by half versus its 2016 level, aiming to be water neutral in all areas by 2030.

Emissions

Novartis has reduced its greenhouse gas emissions in the UK by 25 per cent since 2010 and has set a target to become carbon neutral in its own operations by 2025 and carbon neutral across the supply chain by 2030.[285] This overlaps with other goals; e.g. its selective use of water sources conserves energy.[286] The target is more challenging to achieve because Novartis cannot always access feasible sources of renewable energy. That is part of the reason Novartis has made its own investments in greener energy, such as investing in solar PV capacity or virtual power purchase agreements through wind farms in the US and Europe (discussed in more detail in section 7.3.2 below).

Waste

Novartis has increased the recycling of hazardous waste in the UK by 58 per cent and non-hazardous waste by over 1,000 per cent since 2010.[287] It has achieved this by working closely with 3rd party waste partners to proactively identify waste improvement opportunities, having an annual waste plan and following the waste hierarchy as well as quarterly reporting and auditing. Novartis has prohibited its operations from disposing of organic hazardous waste in landfills since 2007, even where local regulations permit this.[288] Its waste efficiency has improved, decreasing waste by 41 per cent from 2010 to 2019.[289] The pace of change is accelerating as Novartis seeks to remove polyvinyl chloride in secondary and tertiary packaging and halve waste disposal by 2025, relative to 2016 levels. The company seeks to be plastic neutral by 2030.[290]

[283] World Economic Forum (June 2020) "COVID-19 is a game-changer for renewable energy. Here's why" [online] [last accessed: 06/10/2020].
[284] Novartis Data on File: Environmental Statistics
[285] Novartis Data on File: Environmental Statistics
[286] Novartis (n.d.) "Becoming an environmentally sustainable business" [online] [last accessed 02/10/2020].
[287] Novartis Data on File: Environmental Statistics
[288] Novartis (n.d.) "Becoming an environmentally sustainable business" [online] [last accessed 02/10/2020].
[289] Novartis Data on File: Environmental Statistics
[290] Novartis (n.d.) "Waste" [online] [last accessed: 02/10/2020].

Figure 42: Summary of Novartis environmental improvements in the UK 2019 from 2010

Note: (*) Between 2010 and 2019, Novartis has increased the recycling of hazardous waste in the UK by 58 per cent and the recycling of non-hazardous waste by around 1,200 per cent.
Source: Novartis Data on File: Environmental Statistics.

7.3.2 Other ways in which Novartis seeks to be environmentally sustainable

We now explore how Novartis is implementing some of the action plans set out in Figure 40 above.

Environmental sustainability and supply chain

Novartis is partnering globally with external organisations to seek ways to reduce its footprint inside the company as well as that of its supply chain partners. This also contributes to the Novartis goal to become carbon neutral across the supply chain by 2030. For example, in 2019 Novartis hosted a conference in India with the aim of assisting its partners and suppliers in including environmental sustainability goals in their own policies and processes.

Encouraging environmental sustainability initiatives across the supply chain is particularly relevant for Novartis as its suppliers account for around 80 per cent of total emissions. The main drivers of emissions in the supply chain include the energy use of suppliers, transportation of good and materials, and the production and use of chemicals.[291]

Environmental objectives that are internal to Novartis – including eliminating single use plastics in offices

The Novartis move to White City Place reflects the local authority's aim to create an innovation cluster of innovative healthcare start-ups and research outposts, in which Novartis is seen as a key anchor firm. Beyond the knowledge spillovers that this move is expected to create, this move was also used by Novartis as an opportunity to spur further its environmental ambitions, including 'Green Team' initiatives.

Novartis adopted and delivered various targets relating to its environmental ambitions when it moved to the new White City headquarters.[292] This includes the following:

- Novartis has made its White City operations more sustainable by running 100 per cent on renewable energy (by March 2021) and using 100 per cent recycled paper.
- Novartis uses no single-use plastic on site and no chemicals in office cleaning.
- Novartis had adopted an electronic signature system with DocuSign to further reduce paper use.
- Novartis uses smart meters[293] that provide objective tracking of utility energy consumption giving greater intelligence, measurement, monitoring and control.

[291] Novartis (August 2020) "Going with the wind" [online] [last accessed: 03/11/2020].
[292] Novartis (2020) "Sustainable / Green Energy @ White City".
[293] Novartis (2020) "Sustainable / Green Energy @ White City".

Moreover, prior to moving to White City, as part of the Frimley / Watchmoor Park green achievements by 2019 Novartis reduced its energy consumption by 40 per cent, increased recycling by 40 per cent and introduced eco hybrid and electric vehicles into its fleet compared to the 2018 baseline.[294] As with the White City headquarters, Novartis also has made its Watchmoor Park operations more sustainable by running 100 per cent on renewable energy and recycled paper.[295]

In addition to the environmental objectives for White City, Novartis has also committed to reducing the footprint of its Grimsby site, as shown by the case study below.

Box 14: Waste recycling and disposal at Grimsby

Novartis Grimsby has also been seeking to improve its waste recycling and reduce the costs of waste disposal.

Facilitated by a collaborative approach and a culture of speaking up, in 2017 the Site Waste Team at Grimsby identified and implemented various waste saving opportunities, delivering positive outcomes for business and environment alike. This included a shift to filling road tankers close to maximum capacity (safely and following all legal requirements), leading to 64 less road tanker collections each year, reducing CO_2 emissions and saving £45,000 annually.

Moreover, instead of paying to dispose of empty kegs containing raw materials and buying new containers for waste collection, Novartis Grimsby has also started re-using selected empty raw material containers for the disposal of plant general waste. This is estimated to generate cost savings of over £50,000 per year through fewer empty containers purchased, and additional savings of £10-20,000 per year through reducing the costs associated with the disposal of empty raw material kegs. The changes implemented also mean less work for the warehouse responsible for delivering the kegs purchased for waste disposal and collecting the empty raw material containers.

Source: Novartis (2020) "Grimsby case studies".

Forestry projects

The projects undertaken by Novartis to establish sustainable forestry plantations in order to remove carbon dioxide from the atmosphere in locations such as Argentina, Colombia, Mali and China support its dual strategy on energy and climate. First, they contribute to reducing GHG emissions which is then supported by a subsequent "energy and renewables" programme and second, they facilitate achieving carbon neutrality by balancing the remaining emissions with carbon sinks from natural climate solutions. Novartis anticipates that these four programmes will enable the company to offset over 4.5 million tons of CO_2 emissions over the next 30 years.[296]

Power purchase agreements

Through a virtual power purchase agreement with Invenergy for 100 megawatts of wind power from the Santa Rita East windfarm in Texas, Novartis neutralises the carbon footprint for all the electricity bought for its operations in the US and Canada. This results in 220,000 tons of carbon being displaced from the electrical grid each year, equivalent to taking over 60,000 cars off the road. Novartis is also concluding six contract negotiations to ensure the procurement of clean and renewable energy for its European operations, expecting to install over 275 megawatts of generation via wind turbines and solar panels. With the agreements anticipated to be online over the next three years, these are expected to address greenhouse gas emissions across its European operations. This represents a major milestone for the environmental sustainability journey Novartis has embarked on, including meeting its 2025 and 2030 climate targets.[297]

[294] Novartis (2020) "Green Team".
[295] Novartis (2020) "Sustainable / Green Energy @ White City".
[296] Novartis (2017) "Novartis carbon-sink forestry projects" [online] [last accessed: 03/11/2020].
[297] Novartis (2020) "Novartis set to achieve 100% renewable energy in its European operations ".

Secondary and tertiary product packaging

As part of aiming to eliminate polyvinyl chloride (PVC) in secondary and tertiary packaging by 2025 and to become plastic neutral by 2030, Novartis is seeking to find new ways of sustainable packaging for its medicines. Novel ways to replace PVC in secondary packaging, for example, include exchanging a PVC foil for newly launched biologics that holds the product together in the box with bio-thermoplastic based on renewable raw materials. Novartis aims to eliminate all PVC from secondary packaging for biologic drugs.[298]

Green manufacturing of APIs

Novartis seeks ways to make molecules more sustainable and environmentally friendly, for example through organic solvents or using enzymes to improve drug substance production. As an example, Novartis has been embracing new chemical processes and created a new vitamin-E derived surfactant which can contribute to reducing the use and impacts of toxic chemicals such as dimethylformamide (or DMF) on the environment and human health. Other advantages to transitioning to the new surfactant include saving both water and energy, as well as less decomposition and waste. In addition, the new process typically costs 20 to 30 per cent less than the previous process without requiring additional capital investment.[299]

Green inhalers

In response to evidence regarding the carbon footprint of metered dose inhalers typically used by patients with asthma and the NHS' targets to reduce emissions associated with medicines, with the launch of a new inhaler Novartis seeks to provide a greener, more environmentally sustainable dry powder inhaler (DPI) alternative to traditional pressurised metered dose inhalers (pMDIs), reflecting both company and NHS targets to reduce CO_2 emissions. The new inhaler produces over 25 times less CO_2 than pMDIs a day and has one of the lowest footprints amongst DPIs.[300]

Zero emission vehicles

In 2019, Novartis generated nearly 900,000 tons of GHG emissions globally, including 124,000 tons of CO_2 emissions generated by its 26,000 company vehicles (corresponding to 14 per cent of total emissions). In order to address this, the Executive Committee of Novartis endorsed a new Green Fleet Strategy and the commitment that its global fleet will be carbon neutral by 2025. With this strategy Novartis has committed to a phased switch from reliance on internal combustion engines to alternative powertrain vehicles.[301] This aligns with the EV100 industry ambition.

Novartis equally acknowledges the differences between countries in terms of the maturity and readiness for this transition. Therefore, a roadmap was agreed which indicates individual country timelines for the carbon neutral transition. Based on continuous assessments and local ambitions, these timelines may be shortened.[302]

Pharmaceuticals in the environment

Novartis has also created an operating procedure for Pharmaceuticals in the Environment which was effective since the end of 2019. The procedure considers the whole product life cycle of the medicine (including early research, market access, production, patient use and disposal) with the aim of reducing the risk of pharmaceuticals in the environment through clear guidelines for every steps of the process. For example, this includes the use of green solvents during manufacturing or managing manufacturing wastewater.[303]

[298] Novartis (October 2020) "Repackaging medicine" [online] [last accessed 23/10/2020].
[299] Novartis (September 2020) "Dissolving a toxic tradition" [online] [last accessed 07/10/2020].
[300] Novartis "Data on File. Ref 007".
[301] Novartis (October 2020) Global Green Fleet Strategy.
[302] Novartis (October 2020) Global Green Fleet Strategy.
[303] Novartis (September 2020) "Making medicines in an environmentally sustainable fashion" [online] [last accessed 23/10/2020].

Moreover, Novartis is part of the Innovative Medicines Initiative focused on the Prioritisation and Risk Evaluation of Medicines in the EnviRonment (PREMIER). The initiative – a public-private partnership between pharmaceutical companies, research institutes and the European Medicines Agency – seeks to develop an innovative framework around the environmental risks associated with APIs which then, for example, can be used to further investigate the greener design of drugs both in terms of feasibility and practicality.[304]

Novartis is also part of an initiative including over 20 leading pharmaceutical companies to address antimicrobial resistance. In particular, Novartis is contributing to the Antimicrobial Resistance (AMR) Action Fund which seeks to support the development of novel antibiotics through sustainable investment to tackle antimicrobial resistance.[305]

Novartis Biome

Novartis Biome is a digital innovation lab that aims to collaborate with health tech companies and people to develop solutions through the use of data and digital technologies.[306] In turn, this can lead to green innovations in the NHS and broader global healthcare environment. Further information about Novartis biome is included in Chapter 6.

Box 15: Impacts of the COVID-19 pandemic

Novartis has participated in combatting and mitigating the impacts of the ongoing COVID-19 pandemic across a number of dimensions. For example, at least 15 Novartis medicines are currently being examined in 35 investigator-initiated trials globally to treat COVID-related conditions, including a Phase III clinical trial with patients with COVID-19 pneumonia.[307]

In terms of corporate culture, as part of its COVID-19 response Novartis adopted and further advanced smart ways of working. For example, through "Choice with Responsibility" Novartis gives associates greater flexibility regarding how, when and where to work within UK national borders. In addition, selected associates may receive a one-off lump sum payment of up to £350 (net of taxes and National Insurance) to assist with the costs of transitioning to working from home, such as the purchase of equipment or furniture. These flexible working arrangements, and in particular an increase in working from home, are likely to lead to a significant decrease in travel, and associated CO_2 emissions.

For clinical trials, Novartis has also taken a flexible and responsible approach to mitigating the risks to participant safety and trial efficacy, for example through the introduction of remote follow-ups, which further reduces the environmental impact of travel. Further details on Novartis approach to remote follow-ups and clinical trials during the COVID-19 pandemic are included in Chapter 5 "Incubating Innovation".

7.4 Summary

Novartis measures and reports its environmental impacts, targets and achievements in a transparent manner, and as reflected by its ambitious targets is committed to reducing its carbon footprint, consistent with the greenhouse gas emission targets set by the UK government and the NHS. This includes steps to calculate and reduce its use of water, energy and materials through a combination of planning, energy management and increased reliance on renewables. Further, Novartis has also been active in seeking ways to reduce the impact

[304] AstraZeneca (September 2020) "Mitigating the risk of pharmaceuticals in the environment" [online] [last accessed 23/10/2020].
[305] Novartis (August 2020) "Novartis joins forces with leading global health experts to tackle antimicrobial resistance" [online] [last accessed 23/10/2020].
[306] Novartis (n.d.) "The Novartis Biome" [online] [last accessed 23/10/2020].
[307] Novartis (September 2020) "Novartis announces ambitious ESG targets to increase access to medicines and achieve full carbon neutrality" [online] [last accessed: 09/10/2020].

of toxic chemicals through green chemistry and decrease the CO2 emissions associated with inhalers through the use of low carbon alternatives. In addition to reducing the footprint from its own operations, Novartis is equally engaged in supporting its suppliers to include environmental sustainability goals in their own policies and processes. At the same time it is also the stated ambition of Novartis to ensure that the benefits generated through positive externalities via the combatting of communicable diseases, and accountability through ESG targets and reporting are shared across businesses, the life sciences sector and the wider society.

8 Generating a Skilled UK Workforce

8.1 Overview

Novartis supports and develops the human capital of its UK workforce and that of its suppliers and collaborators. It does this both through its direct employment and collaboration activities, and indirectly through its impact along the supply chain. It contributes to the development of skills through its apprenticeships, on-the-job training and through its investment in universities, as well as more widely through its collaborative training activities with the NHS and other organisations. Novartis' company-wide efforts to mitigate the impacts of the COVID-19 pandemic have extended to the management and support of its workforce.

8.2 Economic Theory

8.2.1 Employment creation

Employment can be created through direct, indirect and induced effects. The direct employment effect relates to the immediate effect of job creation within an organisation through its employees, while the indirect employment effect relates to the intermediate impacts of business activity leading to the creation of jobs along the supply chain. The induced effect refers to the effect on jobs in other industries caused by the expenditure of personal incomes (both employment income and investment income) by individuals employed within the organisation and along the supply chain and by those that invest in them.

Given the size of the pharmaceutical industry, which PwC estimated supported a total 312,000 jobs in the UK in 2015,[308] the direct effect on employment for organisations in the industry is expected to be significant. Furthermore, the pharmaceutical industry on average consists of highly productive individuals which feeds through to higher salaries.[309] This in turn implies a large induced effect on employment. Through higher-than-average wages, employees within the pharmaceutical industry will have a higher-than-average disposable income and therefore will contribute to a larger-than-average number of jobs in other industries through higher spending. PwC estimates that in 2016, for every one job created in the pharmaceutical industry within the UK, a further three jobs are created in the supply chain and through employees spending their wages, i.e. indirect and induced employment.[310] A similar exercise shows that for every person Novartis directly employs, a further 19 'indirect' and 'induced' jobs are generated throughout the economy. We discuss this further in the chapter.

8.2.2 High-quality jobs

A report by Eurostat found that wage levels in the pharmaceutical industry within Europe are higher than those in the non-financial business economy.[311] It also found that average wages within the pharmaceutical

[308] This is the figure quoted for firms engaged in the "Development and manufacture of pharmaceutical products". PwC (2017) "The economic contribution of the UK life sciences industry" [online] [last accessed 21/09/2020].
[309] PwC (2017) "The economic contribution of the UK life sciences industry" [online] [last accessed 21/09/2020].
[310] PwC (2019) "The economic and societal footprint of the pharmaceutical industry in Europe" [online] [last accessed 21/09/2020].
[311] Eurostat (2005) "The pharmaceutical industry in the European Union" [online] [last accessed 21/09/2020].

industry were over 50 per cent higher than in the manufacturing sector for 25 European countries including the UK.

8.2.3 Returns to training and education

Apprenticeships can create human capital value through increasing productivity. They are considered especially valuable by the UK Government. In its 2020 vision for apprenticeships in England, it emphasised the role played by apprenticeships in strengthening UK labour productivity and opening new career paths to young people.[312] In particular, evidence shows that these benefits translate into significant monetary returns for individuals over a working life through higher wages. A report by the UK government in 2011 found that people who complete level 2 apprenticeships in England gain between £48,000 and £74,000 over their lifetimes, in present value terms, above what they would be expected to earn otherwise, and between £77,000 and £117,000 for those who complete level 3 apprenticeships.[313] Individuals with a level 4 or above apprenticeship qualification could earn £150,000 more on average over their lifetime.[314]

On-the-job training and investment into academia also increases the skillset and productivity of individuals. Investment into universities has the potential to deliver exceptionally strong economic and social benefits. It is estimated that the accumulation of graduate skills generated roughly 20 per cent of GDP growth in the UK from 1982 to 2005.[315] Investment can also fund research and development within universities as well as promote innovation. There is evidence to show that investment in R&D typically has a social rate of return of between 20 and 50 per cent.[316]

The value created through apprenticeships in the pharmaceutical industry is likely to be high due to the intensity and quality of the training and with the high gross value added per head in the industry. According to the ABPI some 83 per cent of R&D apprenticeships are relatively high-level (level 5 or level 6). For example, apprenticeships include highly specialised areas such as the use of robotics in cell culture. Generally speaking, the training is highly technical and allows individuals to progress into demanding jobs.[317]

Collaboration between academic institutions and the pharmaceutical industry (which we have discussed in our Creating a Collaborative Ecosystem chapter) is a well-honed model of conducting research and development. With ever-increasing pressure on public resources and higher costs-per-unit of medicine development, pooling the resources of the pharmaceutical industry with the expertise of research institutions can be expected to yield more promising results than always going it alone. Two key aspects of this are:

- increased human capital through a combination of knowledge transfer and learning-by-doing; and
- increased productivity through synergies and better use of resources (including knowledge resources).

A well-known example of these effects on human capital is that researchers can gain invaluable access to research resources and additional guidance in medicine development and clinical testing.[318]

We can illustrate the economic value of collaboration with universities with the following research. In 2017, Oxford Economics estimated that for every £1m spent on UK universities, £1.9m is generated as direct

[312] HM Government (2017) "English apprenticeships: Our 2020 vision" [online] [last accessed 21/09/2020].
[313] BIS (2011) "Returns to intermediate and low level vocational qualifications" [online] [last accessed 21/09/2020].
[314] AAT and CEBR (2013) "University education – Is this the best route into employment?" [online] [last accessed 21/09/2020].
[315] Holland, D, Liadze, I, Rienzo, C, and Wilkinson, D (2013) "The relationship between graduates and economic growth across countries" *BIS* [online] [last accessed 21/09/2020].
[316] Allas, T (2014) "Insights from international benchmarking of the UK science and innovation system" *BIS* [online] [last accessed 21/09/2020].
[317] ABPI (2017) "Apprenticeships by level vs. business area" [online] [last accessed 21/09/2020].
[318] Academy of Medical Sciences (2010) "Academia, industry and the NHS: collaboration and innovation" [online] [last accessed 21/09/2020].

output and GDP increases by £0.9m. The supply chains of universities are largely comprised of UK firms which has the effect of increasing the output impact higher than that of many comparator sectors. They also tend to make expenditures in labour-intensive activities, such as administrative, catering and employment services.[319] Oxford Economics' estimates can therefore be used as a mechanism to evaluate the total economic impact of expenditure on universities.

8.2.4 Benefit of a diverse and supportive working environment

Human capital can also be developed through a diverse and supportive workplace. A study exploring the relationship between workforce diversity and productivity found that diversity can stimulate innovation and productivity.[320] Referring to diversity as the inclusion of different ages, ethnicities, genders, religion and other personal characteristics, the increased innovation is understood to stem from differing perspectives and knowledge, which can lead to greater creativity as well as different interpretations for dealing with complex issues. The study concludes that workplace diversity is best exploited when supported by a supportive internal structure: providing mentoring programmes, encouraging open communication between employees and managers, and encouraging the participations of all.

Research-focused and high-tech industries generally benefit greatly from diversity as having a broad base of talents generates more creativity and ideas.[321] Diversity within pharmaceutical companies therefore can have a significant impact on productivity.

8.2.5 Smart working

As we have seen in the 'Incubating Innovation' chapter, new technologies offer novel approaches to help solve today's healthcare problems. The pace of technological progress has also led to the introduction of methods of making workplaces more dynamic and efficient. One of these methods is 'smart working'.

Smart working is a model of working that takes an evidence-based approach to flexible working, seizing on the opportunities created by the development of technologies. The defining concept is that people can work more productively in locations that suit them and the task to hand, beyond the confines of the traditional office space. The UK Civil Service officially adopted smart working as a recognised method of working in its 'The Way We Work' programme in 2016. It considered smart working as a means of saving 'money on property that empowers the individual and improves productivity'.[322]

Smart working has become even more prominent due to the COVID-19 pandemic. Although approximately only five per cent of the workforce used to work mainly from home prior to the pandemic,[323] ONS estimated that in April 2020 approximately 46.6 per cent of the labour force did some work from home.[324] Moreover, early indications suggest that employees would like to keep the current flexibility of remote working even after the restrictions imposed due to the COVID-19 pandemic have ended.[325] It will therefore be important for employers to recognise and support these continuing changes in working culture.

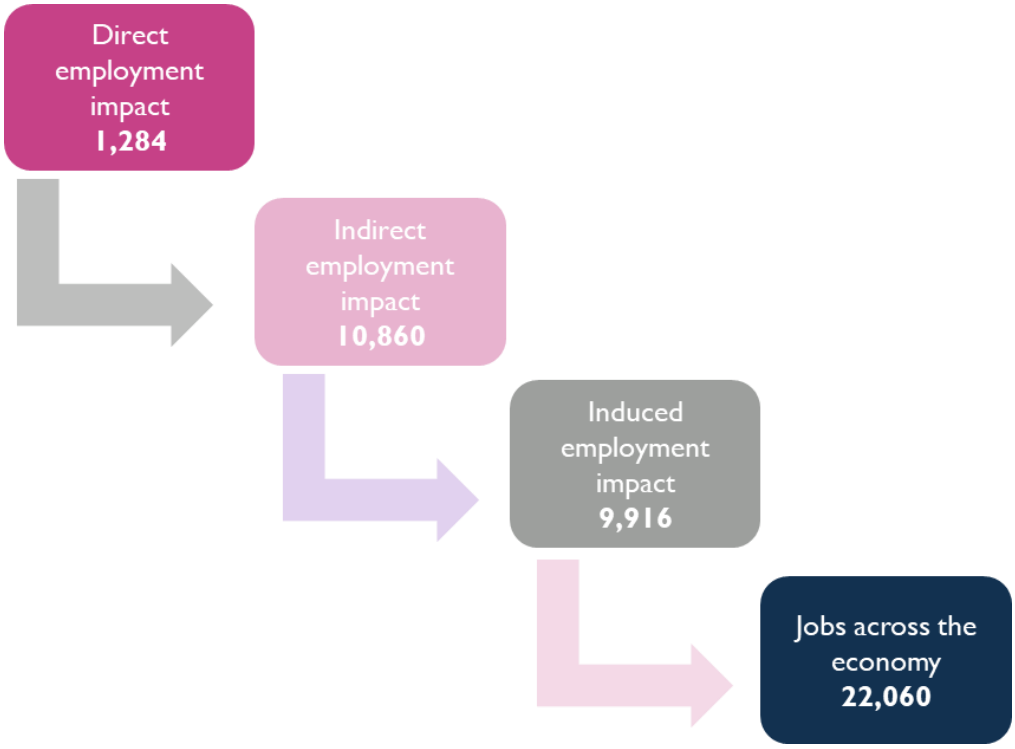
[319] Oxford Economics (2017) "The economic impact of universities in 2014-15" [online] [last accessed 21/09/2020].
[320] Saxena, A (2014) "Workforce diversity: A key to improve productivity" *Procedia Economics and Finance,* Vol 11, p76-85.
[321] Saxena, A (2014) "Workforce diversity: A key to improve productivity" *Procedia Economics and Finance,* Vol 11, p76-85.
[322] Barnes, R, and Mann, B (2016) "Smart working: The quiet revolution" [online] [last accessed 21/09/2020].
[323] CIPD (2020) "Coronavirus (COVID-19): Flexible working during the pandemic and beyond" [online] [last accessed 21/09/2020].
[324] ONS (2020) "Coronavirus and homeworking in the UK: April 2020" [online] [last accessed 08/10/2020].
[325] Sharman, J. (2020) "Coronavirus: 'Millions' in Britain want permanent flexible working after lockdown, survey suggests" [online] [last accessed 21/09/2020].

8.3 Examples of how Novartis adds value in the UK

8.3.1 Employment creation

Novartis had a significant impact on employment in the UK in 2019, creating 22,060 jobs across the economy. The company had 1,284 full time equivalent workers, reflecting its direct employment impact. The indirect employment impact is estimated at 10,860 jobs, stemming from the jobs created due to Novartis buying goods and services from vendors in the UK along the entire supply chain. The induced employment impact contributed to 9,916 jobs, which comes from the jobs resulting from consumption of goods and services by employees of Novartis and its supply chain.[326]

Figure 43: Novartis total employment impact in the UK, 2019



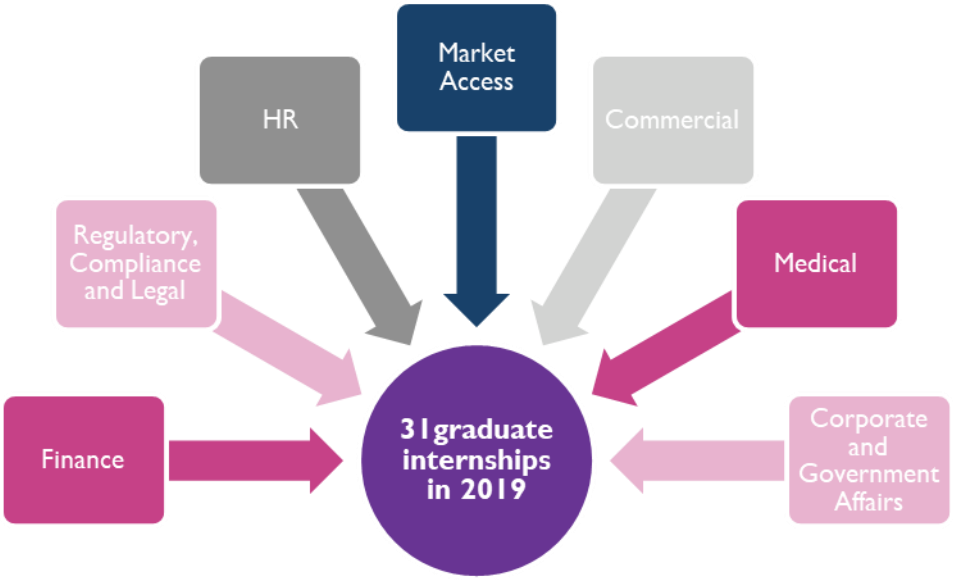
Source: Novartis (2019) "FES Impact Valuation Results UK".

8.3.2 Returns to training and education

Novartis UK offers a range of undergraduate and graduate internships, placements and apprenticeships. Novartis internships usually last for 12-18 months, although due to the COVID-19 pandemic, some of the internships have been extended, giving greater security to young people during these turbulent times. Novartis also offers graduate 'sandwich' placements between students' second and third years, largely within the Oncology and Pharmaceuticals units and Sandoz, and all of which are paid placements. In 2019, a total of 31 students benefitted from these programmes by joining Novartis departments (see Figure 44). Moreover, Novartis has had great success in taking interns into permanent roles within the company following their internships. Two of every three interns accept a permanent role after their internship, whilst in the Sandoz arm more than four-fifths take a permanent role. Even if Novartis interns decide not to continue with the company, more than three-quarters have gone on to have a career in healthcare and pharmaceuticals.

[326] Novartis (2019) "FES Impact Valuation Results UK".

Figure 44: Novartis graduates and internship departments for 2019



Novartis apprenticeships cover a range of levels, e.g. mechanical engineering, chemical science and applied bioscience technology positions. A total of 32 apprenticeships have been undertaken between 2015 and 2019. Based on estimates from the literature that individuals with a level 4 or above apprenticeship qualification could earn £150,000 more on average over their lifetime,[327] we estimate that Novartis apprenticeships could contribute approximately £4.8m in additional earnings.

Novartis also supports employees through training increasing their skills and capabilities. The impact can be measured looking at the accumulated training hours during tenure at Novartis and assessing the incremental contribution to future salaries. In 2019, this was estimated to be £1.57m.[328] Moreover, Novartis launched the "Learn 100" Campaign to encourage associates to invest 100 hours (5 per cent) of their working time in learning and it also provided support in applying what they learnt. In addition to that, over 260 hours of personal one to one coaching was provided by the UK learning team through the height of the COVID pandemic, demonstrating Novartis commitment to continually engaging and developing its associates.[329]

As part of its commitment to collaborative working, Novartis has been an active player in bringing expert minds together, fusing creative start-ups with the necessary resources and contributing its own experience and expertise to the development of innovative healthcare solutions. In recent periods, Novartis has brought experts from far afield to share their research with the NHS and UK academia.

[327] AAT and CEBR (2013) "University education – Is this the best route into employment?" [online] [last accessed 21/09/2020].
[328] Novartis (2019) "FES Impact Valuation Results UK".
[329] Novartis "Data on File. Ref 008".

Box 16: Leadership Workshop by Professor Edmondson hosted by Novartis

In the summer of 2019, Novartis hosted Professor Amy C Edmondson, the Novartis Professor of Leadership and Management at Harvard Business School, to London. Professor Edmondson teaches and writes on leadership, teaming and organisational learning, and her articles appear in top academic journals. She is best known for her pioneering work on psychological safety – the idea that organisations function best when individual team members are unafraid of talking about their experiences and, importantly, their mistakes.

Professor Edmondson headlined two days of learning and collaboration that Novartis held over four workshops in association with The King's Fund, NHS England, NHS Improvement and the Academic Health Science Network. The workshops aimed to enhance Novartis culture, motivating individuals to take advantage of collaborative synergies and encouraging openness amongst colleagues, to allow successful engagement. For example, the concept of '**Extreme Teaming**' to create a more agile way of working was discussed as an alternative to more traditional approaches to team working. Within the NHS, where teams can disband almost as quickly as they are formed, applying a 'teaming' mind-set can create better synergy and higher quality care.

Another important topic covered by these seminars was **Psychological Safety** in the workplace. A psychologically safe work environment, where employees feel safe to speak up and share ideas, concerns and questions, is one of the Novartis commitments to its employees. In the midst of the COVID-19 pandemic, where companies have to face new challenges, psychological safety in the workplace has become an even greater priority. To this end Novartis has also created its own internal programme where 'champions' from across the business share their insights and engage with the employees to help them face their challenges. This is consistent with the Novartis aim to develop a 'speak up culture', which is also all the more important in order to promote diversity and inclusion.

Source: Novartis (2019) "Transforming company culture to reimagine medicine: Novartis professor addresses NHS leaders at the Kings Fund"; Novartis (2020) "New ways of working. Empowering our people to adapt".

Novartis development includes youth leadership. Novartis is a firm supporter of the One Young World initiative, a global forum which brings together the world's most impactful young leaders to share ideas and create a better world. Novartis support can be demonstrated by both its CEO speaking at the 2019 conference as well as from its "The Novartis Reimagining Healthcare Scholarship" which gives the opportunity to candidates to attend the seminar with travel and accommodation costs covered, a forum to share their ideas within Novartis and a mentorship program from Novartis employees.[330]

As we discussed in our chapter "Creating a Collaborative Ecosystem", Novartis routinely collaborates with academic institutions. Between 2014 and 2019, Novartis published 869 studies jointly with UK academics at 288 institutions.[331] As well as the spillover benefits and other benefits of collaboration we discuss in that chapter, there are more specific benefits in terms of human capital improvement. There is evidence that collaborative R&D boosts productivity within the firm: an analysis found that business impacts can be double the size for projects with two or more academic partners compared to projects without academic partners.[332] In addition firms which invest heavily in R&D have, on average, 13 per cent higher productivity levels than firms which do no invest in R&D.[333]

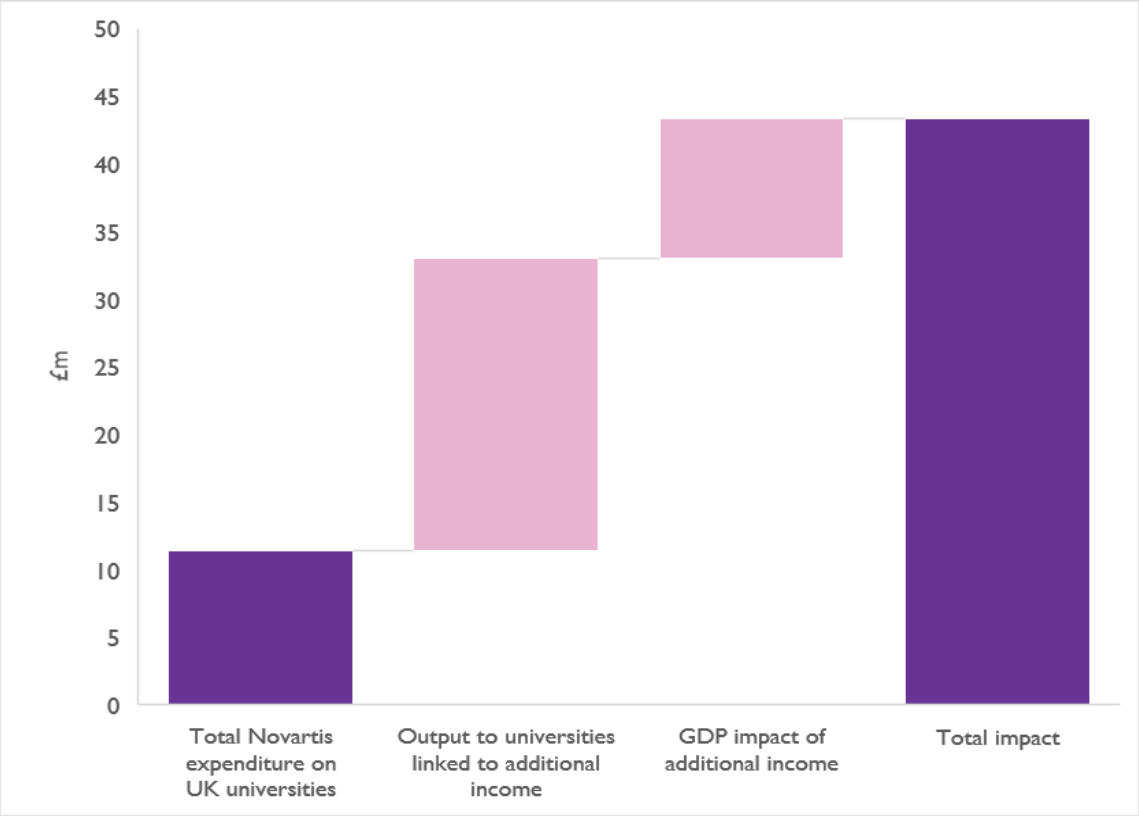
Besides external collaborations, Novartis is also committed in promoting in-house learning and development of its employees. It has partnered with Coursera to offer its associates the opportunity to learn and earn

[330] One Young World (2020) "The Novartis Reimagining Healthcare Scholarship" [online] [last accessed 09/10/2020].
[331] Deloitte Innovation Dashboard source data Pub-Med publications 2014-2019.
[332] PACEC (2011) "Evaluation of the collaborative research and development programmes".
[333] Dowling, A (2015) "The Dowling review of business-university research collaborations" [online] [last accessed 09/10/2020].

certificates from 190 universities around the world. Moreover, its employees can also access more than 14,500 video-based programs from leading experts through LinkedIn Learning. Novartis Learning Institute is another source of employee development through which Novartis associates can follow courses on personal effectiveness, digital capability as well as language, talent acceleration and leadership programs.[334]

In 2019, Novartis spent approximately £11.4m on UK universities (excluding university hospitals, research institutes and presses). Given the total expenditure, we can estimate Novartis' pharma-academic collaboration within the framework set out above. With a multiplier of 1.9 for direct output and 0.9 for GDP, this sums to a total impact of approximately £43.4m, as illustrated in Figure 45 below.[335]

Figure 45: Estimated impact of Novartis expenditure on UK universities, 2019



Source: Novartis (2019) "Novartis Third Party Spend data". Oxford Economics expenditure multipliers used (see 8.2.3).

Moreover, Novartis also offers the NIBR Global Scholars Programme (NGSP) which is a competitive program of grant support for researchers from invited institutions whose work focuses on breakthrough science not typically covered by existing grant programmes. Academic researchers who qualify for the programme benefit from collaborating with other researchers to challenge the status quo. More than 30 institutions around the world, including Oxford University and Imperial College London from the UK, are part of NGSP.[336]

8.3.3 Benefit of a diverse and supportive working environment

Novartis takes specific steps to encourage diversity amongst its workforce, not only in terms of recruitment and retention but also in terms of diversity of aspirations and personal values amongst its staff whilst they

[334] Novartis (2020) "Learning and Development" [online] [last accessed 09/10/2020].
[335] Novartis (2019) "Novartis Third Party Spend data" and Europe Economics analysis.
[336] Novartis (2020) "NIBR Global Scholars Program" [online] [last accessed 09/10/2020].

work for Novartis.[337] This is also supported by the fact the number one reason that inspired people to join Novartis is the opportunities for personal growth.[338] The firm has a specific organisation-wide Diversity Programme, promoting collaboration between a range of individuals with different skillsets and perspectives, potentially increasing productivity and innovation. An employee survey illustrated that over 75 per cent of employees at Novartis view their work as meaningful and consider they have good opportunities to learn and grow in the company.[339] This compares favourably to a UK survey, where only two fifths of employees surveyed consider their employer to create meaningful work.[340] Given that the vast majority of employees in the survey stated that productivity is linked to employee engagement, this suggests further evidence that Novartis is contributing to the increased productivity of the life sciences sector and the UK as a whole.

Box 17: Leadership in the midst of the COVID-19 pandemic

The COVID-19 pandemic has changed the ways we work. Novartis, as a leading company, has taken measures early to assist its employees to better cope with the changes brought about by the pandemic. As employees' health and safety is one of the core priorities of Novartis, it has provided remote working solutions for 95 per cent of its associates and has made the virtual environment as the new default option for its meetings. It has also provided flexible working time and home-office equipment to those who need it. Moreover, in order to assist its employees during these times, Novartis has provided 12 days for emergency leave for parents and caretakers and has committed to "no COVID terminations". It has made available online learning, such as Coursera courses and Khan academy courses not only for its associates but for family members and their children as well.

As we have previously discussed, Novartis has taken measures to help its employees cope with the psychological effects of the pandemic by promoting Psychological Safety within the organisation. Moreover, Novartis has an 'unboss' culture, which aims at transforming companies into purposeful social institutions. The aim is to leave behind the traditional role of the 'authoritative' boss and switch to a team-player manager.

Source: Novartis (2020) "New ways of working. Empowering our people to adapt"

Pay equity, irrespective of gender, race or sexual orientation, is of fundamental importance to Novartis. Novartis has pledged for equal pay audits and has already performed some in multiple countries. It aims to perform pay equity assessments in all markets by 2023.[341] In 2020, 42 per cent of management roles in the UK were filled by women,[342] which is far higher than the 29.6 per cent average of chief executives and senior officials across the UK. [343]

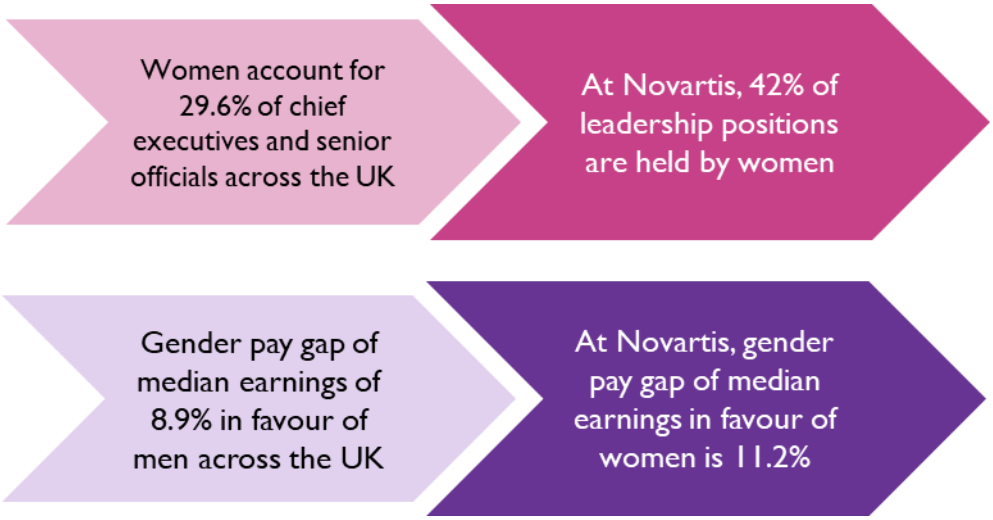
Data from 2019, reflecting all employees working at Novartis UK, demonstrates pay equity. Overall, women at Novartis earned on average between 3.5 per cent and 11.2 per cent more than men, across mean and median pay gaps respectively.[344] This is in strong contrast to the average gender pay gap across the UK, which was 8.9 per cent in favour of men in 2019.[345] This may well have a material impact on the UK economy –

[337] Novartis UK (2019) "Employee handbook".
[338] 44,000 out of 67,000 global applications over 8 weeks in Q3 of 2019 mentioned that as their main reason for applying at Novartis as mentioned in Novartis "Data on File. Ref 008".
[339] Novartis (2020) "Our Voice survey results".
[340] Eltringham, M. (2019) "UK productivity slump linked to employee experience and lack of meaning, claims Deloitte report" [online] [last accessed 16/10/2020].
[341] Novartis (2020) "ESG Investor Event" [online] [last accessed 08/10/2020].
[342] Novartis (2020) "Our People and Culture" [online] [last accessed 22/09/2020].
[343] Hampton-Alexander (2019) "Hampton-Alexander Review: FTSE Women Leaders" [online] [last accessed 08/10/2020].
[344] Novartis UK (2020) "Gender Pay Dashboard 2019" [online] [last accessed 22/09/2020].
[345] Gender pay gap for median gross hourly earnings (excluding overtime), UK, April 1997 to 2019. Office of National Statistics (2019) "Gender pay gap in the UK: 2019" [online] [last accessed 22/09/2020].

research by PwC in 2020 finds that closing the gender pay gap in the UK could realise an increase in female wages of $121.4bn.[346]

Novartis also has a wide-ranging age distribution, employing individuals from the age of 20 through to 75.[347]

Figure 46: Novartis gender statistics compared to the rest of the UK, 2019



8.3.4 Smart working

In keeping with its commitment to a supportive working environment, Novartis has adopted the 'Flexibility First' approach embodied by the smart working model.[348] It offers associates a range of training courses designed to help them develop their skills and manage workloads, including courses on the principles of smart working. A specific leaflet is distributed that informs Novartis staff of sources of more information on the concepts, including a direction to its internal bulletin board Yammer, on which all smart working and related learning activities are advertised.

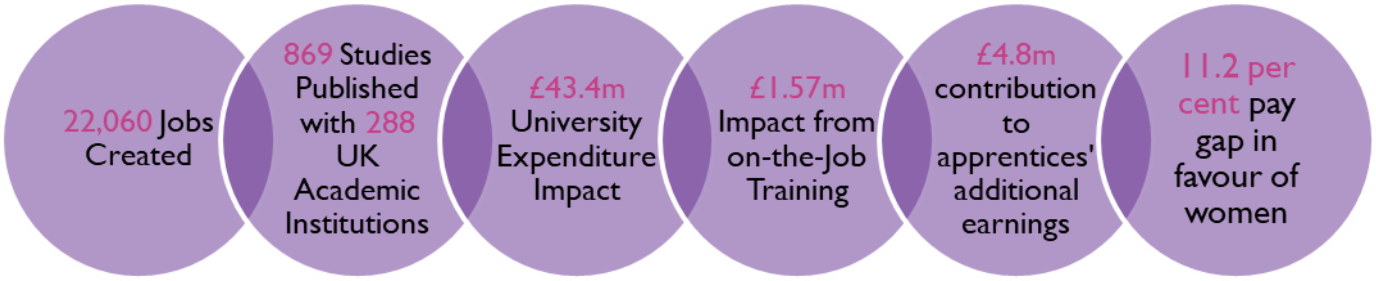
Moreover, because of the current COVID-19 pandemic, Novartis UK has also introduced "Choice with Responsibility", aimed at further evolving the smart working approaches already adopted by Novartis.[349] This new approach allows office-based associates to choose where, when and how they want to work. Novartis is also supporting its staff during these challenging times through its helplines and apps which are available to its employees.[350]

8.4 Summary

As a high-skill sector, pharmaceuticals and life sciences firms make a comparatively larger contribution to gross domestic product than other sectors. The wide variety of labour requirement in the sector offers a multitude of opportunities for human capital attainment, through apprenticeships and graduate internships to on-the-job training. Novartis offers a great number of opportunities for employees to expand their knowledge beyond, hosting speaker events and through collaboration with universities. The key impacts of Novartis on the UK labour force are summarised below.

[346] PwC (2020) "Women in Work Index 2020" [online] [last accessed 22/09/2020].
[347] Novartis UK (2018/9) "Gender Spread 2018-2019".
[348] Novartis (n.d.) "Smart Working leaflet".
[349] Novartis "Data on File. Ref 009"
[350] Novartis "Data on File. Ref 010"

Figure 47: Summary of Novartis contribution to a skilled UK workforce



Appendix

Estimating the social impact of Novartis Medicines

Our analysis estimating the social impact of Novartis medicines uses an approach developed by a German economic consultancy WifOR to demonstrate the social impact of Novartis medicines in economic terms.

Background to WifOR and its methodology

WifOR Institute is an independent economic research institute based in Germany. The team comprises of over 50 economists, analysts and consultants who work on projects providing objective analytics and research for a range of organisations, including government associations and NGOs.

WifOR has previously been commissioned by the European Federation of Pharmaceutical Industries and Associations to deliver a report on the "Economic Footprint of selected pharmaceutical companies in Europe". EFPIA represents 40 leading pharmaceutical companies in Europe, including UCB, Sanofi and Teva Pharmaceutical Europe.[351] In 2013, the International Federation of Pharmaceutical Manufacturers and Associations, who represent research-based biopharmaceutical companies globally, also appointed WifOR to deliver a research project "Measuring the Economic Footprint of the Pharmaceutical Industry".[352]

Novartis commissioned WifOR to deliver a study to quantify and value the social impact of the Novartis UK product portfolio in monetary terms. An overview of the methodology is presented in Chapter 1. WifOR has used this methodology in a number of published studies for Novartis Global, such as to estimate the impact of Novartis medicines in Africa.[353] The company has also published a paper using this methodology to estimate the impact of A Novartis medicines in the *Expert Review of Pharmacoeconomics & Outcomes Research*.[354]

The methodology represents a novel framework for estimating the economic contributions of medicines. As set out in Chapter 1, this method has its limitations, but is a valuable contribution to attempts to quantify the impacts of medicines on GDP. A similar methodology is used in PwC's recent report on the economic footprint of the pharmaceutical industry for EFPIA.[355]

WifOR has updated its methodology since its last direct application to Novartis UK medicines in 2019 (for the year 2018). The key changes include updated GVA per employee figures from the World Bank, and the application of "unpaid work activities" to all patients over 20 year of age as opposed to only those of working age (20 – 60 years), as in Figure 49 below.

[351] WifOR, Efpia (2016) "The Economic Footprint of Selected Pharmaceutical Companies in Europe" [online] [last accessed 06/11/2020].
[352] WifOR (2013) "Measuring the Economic Footprint of the Pharmaceutical Industry" [online] [last accessed 06/11/2020].
[353] WifOR, EFPIA (2018) "The social impact of Novartis medicines: Two case studies from South Africa and Kenya" [online] [last accessed 18/10/2020].
[354] Himmler, S et al. (2019) "A case study applying a novel approach to estimate the social impact of a medical innovation - the use of secukinumab for psoriatic arthritis in Germany" *Expert Review of Pharmacoeconomics & Outcomes Research*, (July).
[355] PWC, EFPIA (2019) "Economic and societal footprint of the pharmaceutical industry in Europe. A report for EFPIA" [online] [last accessed 25/09/2020].

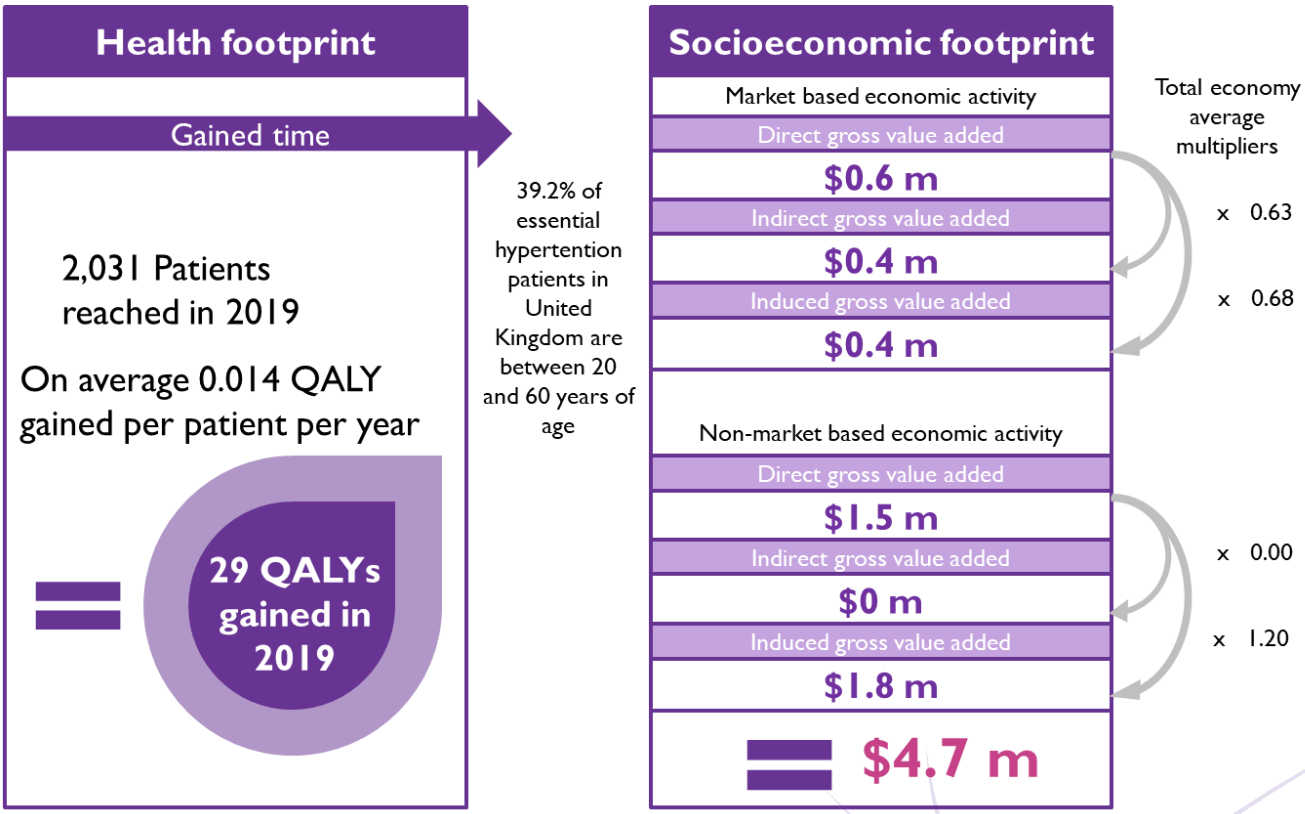
WifOR method for estimating the social impact of medicines

The method estimates the health gains generated by Novartis' medicines expressed in Quality Adjusted Life Years (QALYs). These health gains create a healthier and more active patient population, which consequently feeds through to gains in paid and unpaid work activities and eventually contributes to the national Gross Domestic Product (GDP).

The specific steps of the methodology can be seen in the diagrams below showcasing the calculations for a Novartis medicine used to treat hypertention. This uses the key national inputs from the WifOR study for Novartis, and WifOR-sourced QALY values. For all case studies in this report we gathered values for QALYs gained from UK-specific references, namely NICE appraisals and guidance documents, or internal Novartis calculations.

The calculations are in US dollars, as used in the WifOR study, however we have converted the total impact on GDP into GBP using the average exchange rate for 2019.[356] This gives a total impact of the Novartis' medicine of approximately £3.7m.

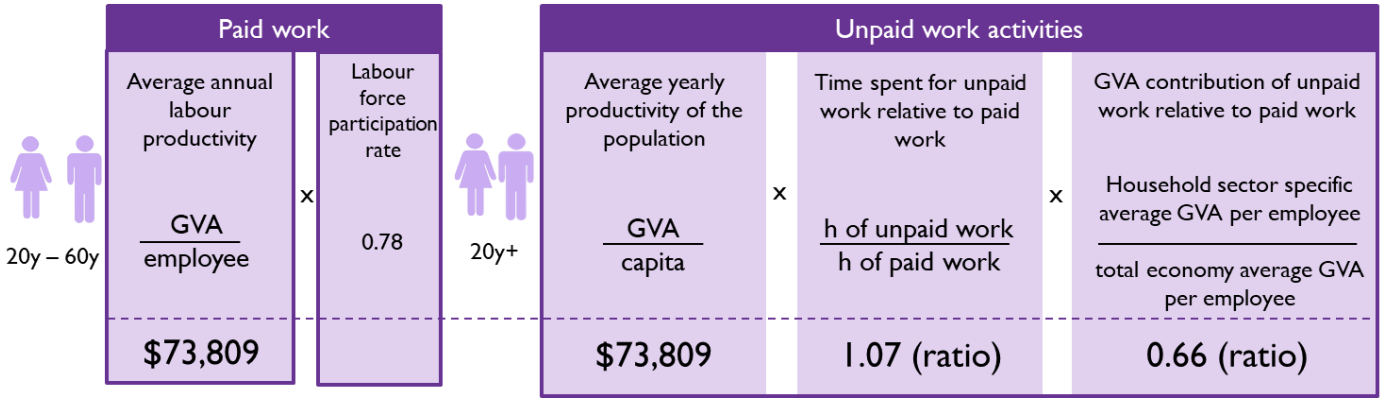
Figure 48: Case study demonstrating WifOR methodology, using a Novartis medicine for hypertension, 2019



Source: WifOR (2020) "The Social Impact of Novartis Innovative Medicines and Sandoz Products in United Kingdom in 2019".

[356] 1 USD = 0.783652 GBP from OFX (2020) "Yearly average exchange rate" [online] [last accessed 01/09/2020].

Figure 49: Key inputs for WifOR's methodology



Input Parameter	National Value	Source
QALY / YLS	Medicine / sub-indication specific	
Proportion of patients below 60	Medicine / sub-indication specific	Global Burden of Disease Collaborative Network, "Global Burden of Disease study 2016 (GBD 2017) Results"
Ratio between unpaid and paid work activities	1.07	The World Bank. World Development Indicators (2018) & United Nations (UN), Statistics Division. Time Use Data Portal. Collection of National Time Use Surveys (2017)
GVA per employee (current US $) total economy	73,809	The World Bank. World Development Indicators (2018)
GVA per employee (current US $) household sector	48,394	The World Bank. World Development Indicators (2018) & Timmer MP, Dietzenbacher E, Los B, Stehrer R, de Vries GJ. An Illustrate User Guide to the World Input-Output Database: the Case of Global Automotive Production: User Guide to World Input-Output Database. Rev Int Econ, (2015)
GVA ratio unpaid-paid	0.66	The World Bank. World Development Indicators (2018) & Timmer MP, Dietzenbacher E, Los B, Stehrer R, de Vries GJ. An Illustrate User Guide to the World Input-Output Database: the Case of Global Automotive Production: User Guide to World Input-Output Database. Rev Int Econ, (2015)
Estimated annual welfare equivalent of unpaid work (current US $)	51,548	The World Bank. World Development Indicators (2018) & Timmer MP, Dietzenbacher E, Los B, Stehrer R, de Vries GJ. An Illustrate User Guide to the World Input-Output Database: the Case of Global Automotive Production: User Guide to World Input-Output Database. Rev Int Econ, (2015) & & United Nations (UN), Statistics Division. Time Use Data Portal. Collection of National Time Use Surveys (2017)
Total economy average GVA multiplier (indirect / induced)	0.63 / 0.68	Timmer MP, Dietzenbacher E, Los B, Steher R, de Vries GJ. An Illustrate User Guide to the World Input-Output Database: the Case of Global Automotive Production: User Guide to World Input-Output Database. Rev Int Econ, (2015)
Total economy average GVA multiplier (indirect / induced)	0 / 1.2	Timmer MP, Dietzenbacher E, Los B, Steher R, de Vries GJ. An Illustrate User Guide to the World Input-Output Database: the Case of Global Automotive Production: User Guide to World Input-Output Database. Rev Int Econ, (2015)
Labour force participation rate	0.78	The World Bank. World Development Indicators (2018)

Source: WifOR (2020) "The Social Impact of Novartis Innovative Medicines and Sandoz Products in United Kingdom in 2019".

Patient numbers

WifOR's methodology uses patient numbers generated by Novartis according to its global framework for estimating patient numbers from volume data.[357] We use these same patient numbers for the three pharmaceutical case studies in this report (heart failure, AMD and multiple sclerosis) and one Sandoz case study on high blood pressure. However, for the three oncology case studies in Chapter 2 and the transplant rejection case study in Chapter 3, we use patient numbers sourced by Novartis as these medicines were not included in the WifOR original basket of products in its study for Novartis.

[357] Novartis (n.d.) "Patient equivalent methodology".