

# Safety, Efficacy and Tolerability of Ianalumab Versus Placebo, Combination With SoC Therapy, in Participants With Active Lupus Nephritis

Last Update: Jan 27, 2025

A Randomized, Double-blind, Parallel Group, Placebo-controlled, Multicenter Phase 3 Trial to Evaluate Efficacy, Safety and Tolerability of Ianalumab on Top of Standard-of-care Therapy in Participants With Active Lupus Nephritis (SIRIUS-LN).

ClinicalTrials.gov Identifier:

[NCT05126277](#)

Novartis Reference Number:CVAY736K12301

[See if you Pre-qualify](#)

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

## Study Description

This trial will evaluate efficacy, safety, and tolerability of subcutaneous (s.c.) ianalumab given every 4 weeks (q4w) or every 12 weeks (q12w) compared to placebo, in combination with SoC, in adult participants with active LN. This trial will evaluate the efficacy, safety, and tolerability of subcutaneous (s.c.) ianalumab given every 4 weeks (q4w) or ianalumab given every 12 weeks (q12w) compared to placebo, in combination with SoC, in adult participants with active LN (ISN/RPS class III, IV active glomerulonephritis with or without co-existing class V features, or pure class V membranous). using the 2003 International Society for Nephrology (ISN)/Renal Pathology Society (RPS) criteria).

Condition

Lupus Nephritis

Phase

Phase3

Overall Status

Recruiting

Number of Participants

420

Start Date

Jul 14, 2022

Completion Date

Jul 15, 2030

Gender

All

Age(s)

18 Years - 100 Years (Adult, Older Adult)

# Interventions

Drug

## **ianalumab s.c. q12w**

ianalumab s.c. q12w in addition to SoC

Drug

## **ianalumab s.c. q4w**

ianalumab s.c. q4w in addition to SoC

Drug

## **placebo s.c.**

placebo s.c. q4w in addition to SoC

# Eligibility Criteria

Inclusion Criteria:

Participants eligible for inclusion in this study must meet all of the following criteria:

- \* Adult male and female participants aged 18 years or older at the time of screening
- \* Weigh at least 35 kg at screening
- \* Have a confirmed clinical diagnosis of SLE according to European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) Systemic Lupus Erythematosus (SLE) classification criteria
- \* Have a positive anti-nuclear antibody (ANA) test result; ANA titer  $\geq 1:80$  at screening visit based on central or local laboratory result
- \* Active LN at screening, as defined by meeting the 3 following criteria:
  - \* Renal biopsy within 6 months prior to screening period indicating ISN/RPS class III or IV active glomerulonephritis with or without co-existing class V features, or pure class V membranous LN. If no biopsy was performed within 6 months prior to screening period, a biopsy will need to be performed during the screening period after having met all other inclusion/exclusion criteria.
  - \* UPCR  $\geq 1.0$  g/g on 24h urine collection at Screening
  - \* eGFR  $\geq 25$ mL/min/1.73 m<sup>2</sup>. Participants with eGFR  $< 30$  mL/min/1.73 m<sup>2</sup> require renal biopsy during the screening period showing sclerosis in  $\leq 50\%$  of glomeruli
- \* Newly diagnosed participants as well as pre-treated LN participants (including refractory cases) can be included, as long as they are currently on, or willing to initiate SoC induction therapy for LN using MPA
- \* Induction therapy, as defined by treatment including both high dose corticosteroids and MPA, should be initiated prior to or on day of randomization
- \* Anti-malarial treatment at stable dosing prior to randomization is strongly recommended, in the absence of contraindications
- \* Participants on azathioprine treatment at Screening must be switched to MPA prior to randomization
- \* Receipt of at least one dose of pulse methylprednisolone i.v. (250 - 1000 mg per day up to 3000 mg cumulative dose) or equivalent for treatment of current episode of active LN within 60 days prior randomization. Participant who cannot take the pulse corticosteroid therapy should directly start on 0.8-1.0

mg/day (max 80mg/day) oral predniso(lo)ne.

\* Able to communicate well with the Investigator to understand and comply with the requirements of the study

#### Exclusion Criteria:

Participants meeting any of the following criteria are not eligible for inclusion in this study:

- \* Severe renal impairment as defined by i.) presence of oliguria (defined as a documented urine volume <400 mL/24 hrs) or ii.) End-Stage Renal Disease (ESRD) requiring dialysis or transplantation
- \* Sclerosis in > 50% of glomeruli on renal biopsy
- \* Use of other investigational drugs within 5 half-lives of enrollment, or within 30 days or until the expected pharmacodynamic effect has returned to baseline. Use of certain Traditional Chinese Medicines
- \* Prior use of ianalumab (ever); or prior use other B cell depleting therapy within 36 weeks prior to randomization or if therapy was administered < 36 weeks prior to randomization, B cell count less than the lower limit of normal or patient's own baseline value prior to having received an earlier B cell-depleting therapy
- \* Prior treatment with any of the following within 12 weeks prior to randomization
- \* Belimumab, telitacicept, abatacept, TNF- $\alpha$  mAb, immunoglobulins (i.v./s.c.) plasmapheresis
- \* Any other immuno-suppressants (i.v. or oral cyclophosphamide, calcineurin inhibitors, JAK inhibitors or other kinase inhibitors)
- \* Thalidomide treatment and/or methotrexate
- \* Combination of DMARDs
- \* Imidazole derivative (e.g., azathioprine, mizoribine) must be discontinued prior to starting treatment with MPA
- \* Receipt of more than 3000 mg i.v. pulse methylprednisolone (cumulative dose) within 12 weeks prior to randomization
- \* History of major organ transplant or hematopoietic stem cell/bone marrow transplant or are due to receive transplantation
- \* Any one of the following laboratory values at screening:
  - \* Hemoglobin levels < 8.0 g/dL (< 5 mmol/L), or < 7.0 g/dL (< 4.3 mmol/L) if related to participant's SLE such as in active hemolytic anaemia
  - \* Platelet count < 25 x 1000/ $\mu$ L
  - \* Absolute neutrophil count (ANC) < 0.8 x 1000/ $\mu$ L
  - \* Active viral, bacterial or other infections requiring intravenous or intramuscular treatment for clinically significant infection or history of recurrent clinically significant infection which in the opinion of the investigator will place the participant at risk for participation.
  - \* History of known intolerance/hypersensitivity to MPA, oral corticosteroids, or any component of the study drug(s) or its excipients
  - \* Receipt of live/attenuated vaccine within a 4-week period prior to randomization
  - \* History of primary or secondary immunodeficiency, including a positive HIV test result
  - \* History of malignancy of any organ system (other than localized basal cell carcinoma or squamous cell carcinoma of the skin or or in-situ cervical cancer), treated or untreated, within the past 5 years, regardless of whether there is evidence of local recurrence or metastases
  - \* Any surgical, medical (e.g., uncontrolled hypertension, heart failure or diabetes), psychiatric or additional physical condition that the Investigator feels may jeopardize the participants in case of participation in this study
  - \* Chronic infection with hepatitis B (HBV) or hepatitis C (HCV). Positive serology for hepatitis B surface antigen (HBsAg) excludes the participant
  - \* Evidence of active tuberculosis (TB) infection (after anti-TB treatment, participants with history of TB may become eligible according to national local guidelines)

- \* Pregnant or nursing (lactating) women
- \* Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception during dosing and for 6 months after stopping of investigational medication
- \* Sexually active male participants, who do not agree to use barrier protection during intercourse with women of child-bearing potential while taking study treatment

Other protocol -defined Inclusion/Exclusion may apply.

## **Argentina**

### **Novartis Investigative Site**

Recruiting

Ciudad Autonoma de Buenos Aire,1426,Argentina

### **Novartis Investigative Site**

Recruiting

Tucuman,4000,Argentina

### **Novartis Investigative Site**

Recruiting

Caba,Buenos Aires,C1056abj,Argentina

### **Novartis Investigative Site**

Recruiting

Ciudad Autonoma de Bs As,Buenos Aires,C1015abo,Argentina

### **Novartis Investigative Site**

Recruiting

Ciudad Autonoma de Bs As,Buenos Aires,C1119acn,Argentina

### **Novartis Investigative Site**

Recruiting

La Plata,Buenos Aires,B1900awt,Argentina

## **Brazil**

### **Novartis Investigative Site**

Recruiting

Juiz de Fora,MG,36010 570,Brazil

**Novartis Investigative Site**

Recruiting

Pernambuco,Recife,50740-900,Brazil

**Novartis Investigative Site**

Recruiting

Porto Alegre,RS,90020-090,Brazil

**Novartis Investigative Site**

Recruiting

Salvador,BA,40150 150,Brazil

**Novartis Investigative Site**

Recruiting

Porto Alegre,RS,90035-003,Brazil

**Novartis Investigative Site**

Recruiting

Vitoria,ES,29055 450,Brazil

**Novartis Investigative Site**

Recruiting

Santo Andre,SP,09090-790,Brazil

**Novartis Investigative Site**

Recruiting

Sao Luis,Maranhao,65020-600,Brazil

**Novartis Investigative Site**

Recruiting

Salvador,40301-155,Brazil

**Novartis Investigative Site**

Recruiting

Belo Horizonte,MG,30150-221,Brazil

**Canada**

**Novartis Investigative Site**

Recruiting

London,Ontario,N6a 5w9,Canada

**Novartis Investigative Site**

Recruiting

Montreal,Quebec,H1t 2m4,Canada

**Novartis Investigative Site**

Recruiting

Sherbrooke,Quebec,J1g 2e8,Canada

**Novartis Investigative Site**

Recruiting

Winnipeg,Manitoba,R3a 1r9,Canada

**Novartis Investigative Site**

Recruiting

Toronto,Ontario,M5t 2s8,Canada

**Novartis Investigative Site**

Recruiting

Calgary,Alberta,T2n 4z6,Canada

**Novartis Investigative Site**

Recruiting

Vancouver,British Columbia,V5z 1l7,Canada

**Chile**

**Novartis Investigative Site**

Recruiting

Santiago,RM,7500922,Chile

**Novartis Investigative Site**

Recruiting

Temuco,4790084,Chile

**China**

**Novartis Investigative Site**

Recruiting

Guangzhou,510280,China

**Novartis Investigative Site**

Recruiting

Guang Zhou,Guangdong,510120,China

**Novartis Investigative Site**

Recruiting

Binzhou,Shandong,256603,China

**Novartis Investigative Site**

Recruiting

Haikou,Hainan,570311,China

**Novartis Investigative Site**

Recruiting

Shanghai,200040,China

**Novartis Investigative Site**

Recruiting

Guangzhou,Guangdong,510000,China

**Novartis Investigative Site**

Recruiting

Linyi,Shandong,276000,China

**Novartis Investigative Site**

Recruiting

Changsha,Hunan,410008,China

**Novartis Investigative Site**

Recruiting

Shanghai,200080,China

**Novartis Investigative Site**

Recruiting

Guang Zhou,510080,China

**Novartis Investigative Site**

Recruiting

Xian,Shanxi,710004,China

**Novartis Investigative Site**

Recruiting

Nanjing,Jiangsu,210029,China

**Novartis Investigative Site**

Recruiting

Shanghai,200127,China

**Novartis Investigative Site**

Recruiting

Shantou,Guangdong,515041,China

**Novartis Investigative Site**

Recruiting

Chengdu,Sichuan,610041,China

**Novartis Investigative Site**

Recruiting

Wuhan,430022,China

**Novartis Investigative Site**

Recruiting

Shenzhen,Guangdong,518020,China

**Novartis Investigative Site**

Recruiting

Chongqing,400038,China

**Novartis Investigative Site**

Recruiting

Nanchang,Jiangxi,330006,China

**Novartis Investigative Site**

Recruiting

Zhejiang,315016,China

**Novartis Investigative Site**

Recruiting

Shenzhen,Guangdong,518037,China

**Novartis Investigative Site**

Recruiting

Hefei,Anhui,230022,China

**Novartis Investigative Site**

Recruiting

Shenyang,Liaoning,110003,China

**Novartis Investigative Site**

Recruiting

Liuzhou,Guangxi,545005,China

**Colombia**

**Novartis Investigative Site**

Recruiting

Bogota,Cundinamarca,110111,Colombia

**Novartis Investigative Site**

Recruiting

Barranquilla,080020,Colombia

**Novartis Investigative Site**

Recruiting

Medellin,Antioquia,050001,Colombia

**Czechia**

**Novartis Investigative Site**

Recruiting

Praha 2,128 50,Czechia

**Novartis Investigative Site**

Recruiting

Olomouc,779 00,Czechia

**Estonia**

**Novartis Investigative Site**

Recruiting

Tallinn,10117,Estonia

**Novartis Investigative Site**

Recruiting

Tallinn,10138,Estonia

**France**

**Novartis Investigative Site**

Recruiting

Besancon Cedex,25030,France

**Novartis Investigative Site**

Recruiting

Bordeaux Cedex,33076,France

**Novartis Investigative Site**

Recruiting

Grenoble,38043,France

**Novartis Investigative Site**

Recruiting

Lyon,69003,France

**Novartis Investigative Site**

Recruiting

Marseille,13385,France

**Novartis Investigative Site**

Recruiting

Poitiers,86021,France

**Novartis Investigative Site**

Recruiting

Angers Cedex 9,49933,France

**Germany**

**Novartis Investigative Site**

Recruiting

Bochum,44791,Germany

**Novartis Investigative Site**

Recruiting

Muenster,48149,Germany

**Novartis Investigative Site**

Recruiting

Aachen,52074,Germany

**Guatemala**

**Novartis Investigative Site**

Recruiting

Guatemala City,01011,Guatemala

**Novartis Investigative Site**

Recruiting

Guatemala,01010,Guatemala

**Novartis Investigative Site**

Recruiting

Quetzaltenango,9001,Guatemala

**Hong Kong**

**Novartis Investigative Site**

Recruiting

Tuen Mun,999077,Hong Kong

**Novartis Investigative Site**

Recruiting

Kwun Tong,Kowloon,Hong Kong

**Hungary**

**Novartis Investigative Site**

Recruiting

Budapest,H-1032,Hungary

**Novartis Investigative Site**

Recruiting

Budapest,H-1097,Hungary

**Novartis Investigative Site**

Recruiting

Debrecen,4032,Hungary

**Novartis Investigative Site**

Recruiting

Kaposvar,7400,Hungary

## **India**

### **Novartis Investigative Site**

Recruiting

Secunderabad,Telangana,500003,India

### **Novartis Investigative Site**

Recruiting

Lucknow,Uttar Pradesh,226014,India

### **Novartis Investigative Site**

Recruiting

Chandigarh,160 012,India

### **Novartis Investigative Site**

Recruiting

Bangalore,Karnataka,560 079,India

## **Italy**

### **Novartis Investigative Site**

Recruiting

Pavia,PV,27100,Italy

### **Novartis Investigative Site**

Recruiting

Roma,RM,00168,Italy

### **Novartis Investigative Site**

Recruiting

Torino,TO,10154,Italy

### **Novartis Investigative Site**

Recruiting

Cagliari,CA,09134,Italy

### **Novartis Investigative Site**

Recruiting

Udine,UD,33100,Italy

**Novartis Investigative Site**

Recruiting

Foggia,FG,71122,Italy

**Novartis Investigative Site**

Recruiting

Napoli,80131,Italy

**Novartis Investigative Site**

Recruiting

Firenze,FI,50134,Italy

**Novartis Investigative Site**

Recruiting

Milano,MI,20132,Italy

**Korea, Republic of**

**Novartis Investigative Site**

Recruiting

Suwon si,Gyeonggi Do,16499,Korea, Republic of

**Novartis Investigative Site**

Recruiting

Gwangju,61469,Korea, Republic of

**Novartis Investigative Site**

Recruiting

Daejeon,Korea,35015,Korea, Republic of

**Novartis Investigative Site**

Recruiting

Seoul,03722,Korea, Republic of

**Novartis Investigative Site**

Recruiting

Busan,602 715,Korea, Republic of

**Novartis Investigative Site**

Recruiting

Seoul,04763,Korea, Republic of

**Novartis Investigative Site**

Recruiting

Daegu,705 718,Korea, Republic of

**Novartis Investigative Site**

Recruiting

Seoul,05030,Korea, Republic of

**Novartis Investigative Site**

Recruiting

Seoul,05505,Korea, Republic of

**Novartis Investigative Site**

Recruiting

Seoul,06591,Korea, Republic of

**Novartis Investigative Site**

Recruiting

Bundang Gu,Gyeonggi Do,13620,Korea, Republic of

**Lithuania****Novartis Investigative Site**

Recruiting

Kaunas,LTU,Lt 50161,Lithuania

**Novartis Investigative Site**

Recruiting

Vilnius,Lt-08661,Lithuania

## **Malaysia**

### **Novartis Investigative Site**

Recruiting

Sibu,Sarawak,96000,Malaysia

### **Novartis Investigative Site**

Recruiting

Kuala Terengganu,Terengganu,20400,Malaysia

### **Novartis Investigative Site**

Recruiting

Kuala Lumpur,Wilayah Persekutuan,50586,Malaysia

## **Mexico**

### **Novartis Investigative Site**

Recruiting

Oaxaca,68020,Mexico

### **Novartis Investigative Site**

Recruiting

Queretaro,76070,Mexico

### **Novartis Investigative Site**

Recruiting

Leon,Guanajuato,37160,Mexico

### **Novartis Investigative Site**

Recruiting

Monterrey,Nuevo Leon,64440,Mexico

## **Romania**

### **Novartis Investigative Site**

Recruiting

Oradea,Jud Bihor,410619,Romania

**Novartis Investigative Site**

Recruiting

Bucharest,022328,Romania

**Novartis Investigative Site**

Recruiting

Cluj Napoca,400006,Romania

**Novartis Investigative Site**

Recruiting

Timisoara,300736,Romania

**Singapore**

**Novartis Investigative Site**

Recruiting

Singapore,169608,Singapore

**Novartis Investigative Site**

Recruiting

Singapore,S308433,Singapore

**Spain**

**Novartis Investigative Site**

Recruiting

Vigo,Pontevedra,36200,Spain

**Novartis Investigative Site**

Recruiting

La Laguna,Santa Cruz De Tenerife,38320,Spain

**Novartis Investigative Site**

Recruiting

Barcelona,Catalunya,08003,Spain

**Novartis Investigative Site**

Recruiting

Madrid,28040,Spain

**Novartis Investigative Site**

Recruiting

Barcelona,Catalunya,08035,Spain

**Novartis Investigative Site**

Recruiting

Madrid,28041,Spain

**Novartis Investigative Site**

Recruiting

Valencia,Comunidad Valenciana,46017,Spain

**Novartis Investigative Site**

Recruiting

Madrid,280796,Spain

**Novartis Investigative Site**

Recruiting

Santiago De Compostela, Galicia,15706,Spain

**Novartis Investigative Site**

Recruiting

Pamplona,Navarra,31008,Spain

**Taiwan**

**Novartis Investigative Site**

Recruiting

Taichung,40447,Taiwan

**Novartis Investigative Site**

Recruiting

Taichung,407219,Taiwan

**Novartis Investigative Site**

Recruiting

Taipei,11217,Taiwan

**Novartis Investigative Site**

Recruiting

Kaohsiung,83301,Taiwan

**Thailand**

**Novartis Investigative Site**

Recruiting

Bangkok,10700,Thailand

**Novartis Investigative Site**

Recruiting

Chiang Mai,50200,Thailand

**Novartis Investigative Site**

Recruiting

Songkhla,Hat Yai,90110,Thailand

**Novartis Investigative Site**

Recruiting

Bangkok,10330,Thailand

**Novartis Investigative Site**

Recruiting

Bangkok,10400,Thailand

**United Kingdom**

**Novartis Investigative Site**

Recruiting

Bradford,West Yorkshire,Bd9 6rj,United Kingdom

## **Novartis Investigative Site**

Recruiting

London,Se1 9rt,United Kingdom

### **United States**

#### **UMC New Orleans**

Recruiting

New Orleans,Louisiana,70112,United States

**Stephen Lindsey**

**Jasmine McGary**

Email: [jasmine.mcgary@lcmchealth.org](mailto:jasmine.mcgary@lcmchealth.org)

#### **Emory University School of Medicine**

Recruiting

Atlanta,Georgia,30303,United States

**Kennedy Vela**

Phone: [404-616-4440](tel:404-616-4440)

Email: [Kennedy.vela@emory.edu](mailto:Kennedy.vela@emory.edu)

**S Sam Lim**

#### **Univ of Pennsylvania Medical Center**

Recruiting

Philadelphia,Pennsylvania,19104,United States

**Marleny Montero**

Email: [Marleny.Montero@Pennmedicine.upenn.edu](mailto:Marleny.Montero@Pennmedicine.upenn.edu)

**Gaia Coppock**

#### **UC Davis School of Medicine**

Recruiting

Sacramento,California,95817,United States

**Nasim Wiegley**

Annie Trinh

Email: [anntrinh@ucdavis.edu](mailto:anntrinh@ucdavis.edu)

### **NY Nephrology**

Recruiting

Clifton Park, New York, 12065, United States

Howard Phelan

Phone: [518-579-0017](tel:518-579-0017)

Email: [howard.phelan@nyneph.com](mailto:howard.phelan@nyneph.com)

Frank Cortazar

### **Circuit Clinical**

Recruiting

Orchard Park, New York, 14127, United States

Isha Gupta

### **University Of Alabama**

Recruiting

Birmingham, Alabama, 35294, United States

Jose Mosquera Rubio

Jane Vines

Email: [jsnowden@uabmc.edu](mailto:jsnowden@uabmc.edu)

### **Wayne State University**

Recruiting

Detroit, Michigan, 48201, United States

Yanni Zhuang

Phone: [313-745-7371](tel:313-745-7371)

Email: [yzhuang@med.wayne.edu](mailto:yzhuang@med.wayne.edu)

Yahya Osman

### **Sahni Rheumatology and Therapy**

Recruiting

21/29

West Long Branch,New Jersey,07764,United States

Kiren Sahni

Sachit Sudharshan

Phone: [732-272-1456](#)

Email: [manager@sahnirheumatology.com](mailto:manager@sahnirheumatology.com)

### **Northern Assoc of Northern VA**

Recruiting

Fairfax,Virginia,22033,United States

Phone: [703-953-0155](#)

Gregory Wang

### **Univ of Nevada School of Med**

Recruiting

Las Vegas,Nevada,89102,United States

Katherin Mendez

Email: [katherin.mendez@unlv.edu](mailto:katherin.mendez@unlv.edu)

Walter Winn Chatham

### **Univof Texas Southwestern Med Cntr**

Recruiting

Dallas,Texas,75235,United States

David Karp

### **Kaiser Permanente**

Recruiting

San Diego,California,92111,United States

Hui Xue

Jaqueleine Gomez Solis

Phone: [858-401-7205](#)

Email: [Jaqueline.X.GomezSolis@kp.org](mailto:Jaqueline.X.GomezSolis@kp.org)

## **Liberty Research Center**

Recruiting

Dallas,Texas,75230,United States

Irfan Agha

Laurie Jones

Phone: [972-274-5555](#)

Email: [laurie.jones@usoncology.com](mailto:laurie.jones@usoncology.com)

## **VA NM Healthcare System**

Recruiting

Albuquerque,New Mexico,87108,United States

Anthony Sedillo

Phone: [505-265-1711](#)

Email: [anthony.sedillo@va.gov](mailto:anthony.sedillo@va.gov)

Kavitha Ganta

## **Brookview Hills Research Assoc**

Recruiting

Winston-Salem,North Carolina,27103,United States

Janice Rogers

Phone: [336-768-2425](#)

Email: [jrogers@brookviewhills.com](mailto:jrogers@brookviewhills.com)

Nicholas McLean

## **University of California LA**

Recruiting

Los Angeles,California,90095,United States

Lori Sahakian

Phone: [310-825-9447](#)

Email: [L.Sahakian@mednet.ucla.edu](mailto:L.Sahakian@mednet.ucla.edu)

Maureen McMahon

**Fides Clinical Research**

Recruiting

Atlanta, Georgia, 30342, United States

Dillon Ha

Phone: [404-252-0256](#)

Email: [dha@fidesclinicalresearch.com](mailto:dha@fidesclinicalresearch.com)

Elizabeth Nguyen

**University of Texas Medical Branch**

Recruiting

Galveston, Texas, 77555-0144, United States

Elizabeth Hennessy

Phone: [409-772-1062](#)

Email: [eahennes@utmb.edu](mailto:eahennes@utmb.edu)

Tina Kochar

**Hospital for Special Surgery**

Recruiting

New York, New York, 10021, United States

Haley Slosberg

Phone: [212-606-1728](#)

Email: [slosbergh@hss.edu](mailto:slosbergh@hss.edu)

Kyriakos Kirou

**Mayo Clinic Jacksonville**

Recruiting

Jacksonville, Florida, 32224, United States

Carolyne Stevens

Phone: [904-953-2451](#)

Email: [Thomas.Carolyne@mayo.edu](mailto:Thomas.Carolyne@mayo.edu)

Nabeel Aslam

**Uni of Texas Health Science Center**

Recruiting

San Antonio,Texas,78284,United States

Phone: [210-617-5111](#)

**Agustin Escalante**

**University Of Cincinnati**

Recruiting

Cincinnati,Ohio,45267,United States

**Leksi Travitz**

Phone: [513-559-3362](#)

Email: [Leksi.travitz@uc.edu](mailto:Leksi.travitz@uc.edu)

**Manish Anand**

**University of California Irvine**

Recruiting

Orange,California,92868,United States

**Kelly Acero**

Email: [kacero@hs.uci.edu](mailto:kacero@hs.uci.edu)

**Sheetal Desai**

**James J Peters VA Medical Center**

Recruiting

Bronx,New York,10468,United States

**Kelly Steed**

**Serena Yeung**

Phone: [+17185849000#6667](#)

Email: [serena.yeung@va.gov](mailto:serena.yeung@va.gov)

**Parris and Associates Rheumatology**

Recruiting

Lawrenceville,Georgia,30044,United States

Phone: +17709621616#8334

Glenn Parris

**Uni Wisconsin School Med Pub Health**

Recruiting

Madison,Wisconsin,53792,United States

Tripti Singh

**University of Kansas Hospital**

Recruiting

Kansas City,Kansas,66160,United States

Kelly Liang

Phone: 913-588-0053

**University Of Miami**

Recruiting

Miami,Florida,33136,United States

Maria Fernanda Carpintero

Michael Mijares

Phone: 305-243-2568

Email: mmijares74@med.miami.edu

**Northwell Health**

Recruiting

New York,New York,10028,United States

Justina D Costa

Phone: 516-708-2550

Email: jdcosta@northwell.edu

Richard Furie

**University of California San Diego**

Recruiting

San Diego,California,92037,United States

26/29

**Kenneth Carekin Kalunian**

**Linda Mendoza**

Phone: [+1 858 534 2555](#)

Email: [lnmendoza@health.ucsd.edu](mailto:lnmendoza@health.ucsd.edu)

### **Baylor Scott and White Research**

Recruiting

Temple, Texas, 76502, United States

**Michell Trevino**

Phone: [254-935-5838](#)

Email: [michelle.trevino1@bswhealth.org](mailto:michelle.trevino1@bswhealth.org)

**Mohanram Narayanan**

### **Vietnam**

#### **Novartis Investigative Site**

Recruiting

Hanoi, 100000, Vietnam

#### **Novartis Investigative Site**

Recruiting

Ho Chi Minh, 700000, Vietnam

## **Worldwide Contacts**

If the location of your choosing does not feature any contact detail, please reach out using the information below.

#### **Novartis Pharmaceuticals**

Phone: [+41613241111](#)

Email:

#### **Novartis Pharmaceuticals**

Phone: [1-888-669-6682](#)

Email: [novartis.email@novartis.com](mailto:novartis.email@novartis.com)

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1. <https://clinicaltrials.gov/ct2/show/NCT05126277>
2. #trial-eligibility
3. mailto:jasmine.mcgary@lcmchealth.org
4. tel:404-616-4440
5. mailto:Kennedy.vela@emory.edu
6. mailto:Marleny.Montero@Pennmedicine.upenn.edu
7. mailto:anntrinh@ucdavis.edu
8. tel:518-579-0017
9. mailto:howard.phelan@nyneph.com
10. mailto:jsnowden@uabmc.edu
11. tel:313-745-7371
12. mailto:yzhuang@med.wayne.edu
13. tel:732-272-1456
14. mailto:manager@sahnirheumatology.com
15. tel:703-953-0155
16. mailto:katherin.mendez@unlv.edu
17. tel:858-401-7205
18. mailto:Jaqueline.X.GomezSolis@kp.org
19. tel:972-274-5555
20. mailto:laurie.jones@usoncology.com
21. tel:505-265-1711
22. mailto:anthony.sedillo@va.gov
23. tel:336-768-2425
24. mailto:jrogers@brookviewhills.com
25. tel:310-825-9447
26. mailto:L.Sahakian@mednet.ucla.edu
27. tel:404-252-0256
28. mailto:dha@fidesclinicalresearch.com
29. tel:409-772-1062
30. mailto:eahennes@utmb.edu
31. tel:212-606-1728
32. mailto:slosbergh@hss.edu
33. tel:904-953-2451
34. mailto:Thomas.Carolyne@mayo.edu
35. tel:210-617-5111
36. tel:513-559-3362
37. mailto:Leksi.travitz@uc.edu
38. mailto:kacero@hs.uci.edu
39. tel:+17185849000#6667
40. mailto:serena.yeung@va.gov
41. tel:+17709621616#8334
42. tel:913-588-0053
43. tel:305-243-2568
44. mailto:mmijares74@med.miami.edu
45. tel:516-708-2550
46. mailto:jdcosta@northwell.edu
47. tel:+1 858 534 2555
48. mailto:lnmendoza@health.ucsd.edu
49. tel:254-935-5838
50. mailto:michelle.trevino1@bswhealth.org
51. tel:+41613241111
52. mailto:
53. tel:1-888-669-6682
54. mailto:novartis.email@novartis.com

