

Lp(a) Lowering Study of Pelacarsen (TQJ230) in US Black/African American and Hispanic Participants With Elevated Lp(a) and Established ASCVD

Last Update: Mar 19, 2025

A Randomized Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of Pelacarsen (TQJ230) in US Black/African American & Hispanic Patient Populations With Elevated Lp(a) and Established Atherosclerotic Cardiovascular Disease

ClinicalTrials.gov Identifier:

[NCT06267560](#)

Novartis Reference Number:CTQJ230A12303

[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

Study CTQJ230A12303 is a randomized, double-blind placebo-controlled, Phase IIIb study to evaluate the efficacy, safety and tolerability of pelacarsen (TQJ230) 80 mg s.c. QM compared with placebo s.c. QM in US Black/African American and Hispanic participants with established ASCVD and elevated levels of Lp(a) who are treated for cardiovascular (CV) risk factors according to local practice/guidelines for the reduction of cardiovascular risk. CTQJ230A12303 is a randomized, double-blind, placebo-controlled, multi-center, Phase IIIb study to evaluate the efficacy (measured by reduction of the Lp(a) levels) and safety of pelacarsen (TQJ230) 80mg s.c. QM compared to placebo in US Black/African American and US Hispanic participants, with established atherosclerotic cardiovascular disease (ASCVD) as evidenced by history of coronary heart disease, cerebrovascular disease or symptomatic peripheral artery disease (PAD) and elevated levels of Lp(a).

Condition

Elevated Lp(a) and Established Atherosclerotic Cardiovascular Disease

Phase

Phase3

Overall Status

Recruiting

Number of Participants

400

Start Date

Apr 24, 2024

Completion Date

Mar 11, 2027

Gender

All

Age(s)

18 Years - 80 Years (Adult, Older Adult)

Interventions

Drug

Placebo

matching placebo

Drug

TQJ230

TQJ230 80mg QM s.c.

Eligibility Criteria

Inclusion Criteria:

- * Male and female US Black/African American and US Hispanic participants 18 to $\leq$ 80 years of age
- * Lp(a) $\geq$ 125 nmol/L at the screening visit, measured at the Central laboratory
- * On Standard of Care (SoC) therapy for risk factors other than Lp(a), including LDL-C (LDL-C lowering therapy dose stable for at least 30 days), elevated blood pressure and diabetes, at the randomization visit according to local practice/guidelines.
- * Established ASCVD disease defined as documented:
 - * Coronary heart disease (CHD) and/or
 - * Cerebrovascular disease (CVD) and/or
 - * Peripheral arterial disease (PAD):

Exclusion Criteria:

- * Uncontrolled hypertension
- * Heart failure New York Heart Association (NYHA) class IV
- * History of malignancy of any organ system
- * History of hemorrhagic stroke or other major bleeding
- * Platelet count $< 140,000$ per mm³
- * Active liver disease or hepatic dysfunction
- * Significant kidney disease
- * Pregnant or nursing women

Puerto Rico

Advanced Clinical Research LLC

Recruiting

Bayamon,00959,Puerto Rico

Email: vperez@prohealthams.com

Angel Comulada

Latin Clinical Trial Center Inc

Recruiting

San Juan,00909,Puerto Rico

Juana Olivo

Phone: [+1 787 249 4763](tel:+17872494763)

Email: Crc3@latinclinicaltrialcenter.com

Alex Gonzalez Bossolo

Dr Yolanda Figueroa Private Pr

Recruiting

Humacao,00791,Puerto Rico

Yolanda Figueroa

VA Caribbean Healthcare System

Recruiting

San Juan,00921,Puerto Rico

Jonathan Rolon-Negron

Phone: [+17876417582#10393](tel:+17876417582#10393)

Email: Jonathan.rolon-negron@va.gov

Luis Rodriguez-Ospina

CAIMED Center

Recruiting

Ponce,00716,Puerto Rico

Elizabeth A. Barranco

Sara Cancel

Phone: [+1 787 840 2580](tel:+17878402580)

Email: scancel@psm.edu

Advanced Medical Research Center

Recruiting

San Juan,00926,Puerto Rico

Michelle Nunez

Phone: +1 787 628 4463

Email: michellenurse@advanceresearchpr.com

Orvil F Martinez Rivera

Research and Cardiovascular Corp

Recruiting

Ponce,00717-1322,Puerto Rico

Jose B Vazquez-Tanus

Jovannia Galarza Perez

Phone: +1 787 259 0526

Email: jgalarzaperez.research@gmail.com

United States

Mid Hudson Medical Research PLLC

Recruiting

New Windsor,New York,12553,United States

Phone: 845-235-4196

TBC Research LLC

Recruiting

Tamarac,Florida,33321,United States

Barry Streit

Ricardo Zambrano

Email: rzambrano@tbcresearch.com

Cardiovascular Associates Research

Recruiting

Covington,Louisiana,70433,United States

Dale Presser

Darlene Wilson

Phone: [985-893-9090](tel:985-893-9090)

Email: darlene.wilson5378@gmail.com

Ascension Saint Agnes Heart Care

Recruiting

Baltimore, Maryland, 21229, United States

Molly Koch

Phone: [410-615-6641](tel:410-615-6641)

Email: mkoch@scritrials.com

Martin Albornoz

American Institute of Research

Recruiting

Los Angeles, California, 90017, United States

Abel Woldeabezegi

Phone: [213-481-7142](tel:213-481-7142)

Email: awoldeabezegi@airesearch.us

Anil Mohin

Discovery Clinical Trials

Recruiting

Pflugerville, Texas, 78660-3015, United States

Brian K MacGillivray

Tracy Fuentes

Phone: [210-764-4842](tel:210-764-4842)

Email: operations@discoverytrials.com

Synexus Clinical Research US Inc

Recruiting

Chicago, Illinois, 60602, United States

Joseph Newberg

Phone: 312-494-2250

Virginia Heart

Recruiting

Falls Church, Virginia, 22042, United States

Tariq Haddad

Cynthia E Alvarez

Phone: 703-766-5920

Email: Calvarez@VirginiaHeart.com

Flint Clinical Research

Recruiting

Flint, Michigan, 48503, United States

Asmaa El Assad

Phone: 810-835-4533

Email: aelassad@aamrc.net

Khalid Ahmed

National Research Institute

Recruiting

Hialeah, Florida, 33013, United States

Luis Rivera

Phone: 208-346-8900

Email: Lrivera@thesisterresearch.com

Raul Alonso

Idania Cruz

Email: icruz@nationalri.org

Luis Cabrera Haber

Valley Clinical Trials Inc

Recruiting

Covina, California, 91723, United States

Mannie Lyons

Email: mannie@valleyclinicaltrials.com

Fahed Bitar

Javara Research

Recruiting

Alexandria, Virginia, 22311, United States

Aslam Khan

Monique Langston

Benjamin Marcum

Ronald M Pucillo

Chelsi Holliday

Email: chelsi.holliday@javararesearch.com

Aimee Kaczorowski

Email: aimee.kaczorowski@javararesearch.com

Sangeeta Wagner

Gabriela Obeidat

Email: gobeidat@javararesearch.com

Amara Akujieze

Email: amarachukwu.akujieze@javararesearch.com

Scott Kahney

Habib Chotani

Amine Segueni

Stacy Jones

Email: smjones@javararesearch.com

Jason Elenberger

Email: jason.elenberger@javararesearch.com

Amy Reyna

Email: areyna@javararesearch.com

Kathryn McSpadden

Email: Kathryn.mcspadden@javararesearch.com

Care Access Research

Recruiting

Easton, Pennsylvania, 18045, United States

Melissa Sexton

Email: m.sexton@careaccess.com

Rebecca Larimore

Email: r.larimore@careaccess.com

Eromonsele Idahosa

Jimmy Alele

Biopharma Informatic LLC

Recruiting

Houston, Texas, 77084, United States

Imran Afridi

Saleha Balach

Phone: [281-944-3610](tel:281-944-3610)

Email: saleha@biopharmainfo.net

Shah Mohammed

Email: SMohammed@Biopharmainfo.net

Syed Humayun Naqvi

Christian Assad-Kottner

Clarisa Garza

Email: Cgarza@biopharmainfo.net

Overlook Medical Center

Recruiting

Summit, New Jersey, 07901, United States

Kathleen Haft

Phone: [908-522-6279](tel:908-522-6279)

Email: Kathleen.Haft@atlanticealth.org

Robert Fishberg

Baptist Health Medical Group

Recruiting

Miami, Florida, 33173, United States

Margie Mckercher

Phone: [786-595-8078](tel:786-595-8078)

Email: Margie.Mckercher@baptisthealth.net

Adedapo Iluyomade

Eminat LLC

Recruiting

Miramar, Florida, 33027, United States

Leonardo Salazar

Phone: [208-346-8900](tel:208-346-8900)

Email: lsalazar@eminat.net

Yaneth Trujillo

Heart Care Associates P C

Recruiting

Hopewell, Virginia, 23860, United States

Megh Jariwala

Phone: [804-526-3500](tel:804-526-3500)

Email: megh_jariwala99@gwu.edu

Kamlesh Dave

Southern Clin Research Clinic

Recruiting

Zachary,Louisiana,70791,United States

Ernest Thompson

Tammy Dours

Email: Tammy@southernclinicalresearch.com

National Heart Institute

Recruiting

Beverly Hills,California,90211,United States

Maria Flores

Phone: [301-289-5221](tel:301-289-5221)

Email: mflores@nationalheartinstitute.org

Norman Lepor

Hometown Urgent Care and Research

Recruiting

Columbus,Ohio,43214,United States

Amanada Applegate

Phone: [937-912-4364](tel:937-912-4364)

Email: aapplegate@myhometownuc.com

Steve Choi

Cardiology Partners Clinical Research Institute

Recruiting

Wellington,Florida,33449,United States

Duccio Baldari

Christina Lacquey

Phone: [561-537-4778](tel:561-537-4778)

Email: christina.lacquey@cardiologypartnerspl.com

Apex Cardiology Research Associates of Jackson

Recruiting

Jackson,Tennessee,38301,United States

Mohsin Alhaddad

Lani Holman

Phone: 731-423-8200

Email: lholman@researchjackson.com

Capitol Cardiology Associates

Recruiting

Lanham, Maryland, 20706, United States

Iluyomade Adeusi

Phone: 301-312-0575

Email: iluyomade@capitolcardiology.com

Vineet Venugopal

Acclaim Clinical Research

Recruiting

San Diego, California, 92120, United States

John Beckes

Julia Armstrong

Phone: 858-901-8235

Email: karmstrong@allianceclinicalnetwork.com

Sugar Lakes Family Practice

Recruiting

Sugar Land, Texas, 77479, United States

John Vanderzyl

Whitney Nwole

Phone: 303-957-7478

Email: Whitney.Nwole@Elligodirect.com

Cambridge Medical Trials

Recruiting

Alexandria, Louisiana, 71301, United States

Crystal Dubois

Phone: [318-704-5853](tel:318-704-5853)

Email: crystal.dubois2@christushealth.org

Naseem A Jaffrani

Optimal Research LLC

Recruiting

Huntsville,Alabama,35802,United States

Jared-Robert Blake

Email: jared-robert.blake@globalaes.com

Randle T Middleton

Las Vegas Endocrinology

Recruiting

Henderson,Nevada,89074,United States

Quang Nguyen

Sheila Texidor Rodriguez

Phone: [702-605-5750](tel:702-605-5750)

Email: Sheila@lasvegasendocrinology.com

Columbus Clinical Services LLC

Recruiting

Miami,Florida,33125,United States

Sara Llerena

Lianet Trujillo

Phone: [305-559-5957](tel:305-559-5957)

Email: l.trujillo@columbusclinical.net

Proactive Clinical Research

Recruiting

Fort Lauderdale,Florida,33308,United States

Juan Garcia

Email: jgarcia@proactivecr.com

Maria Coimbra

Phone: 956-731-1260

David Mishkin

Plano Primary Care Clinic

Recruiting

Allen, Texas, 75002-3688, United States

Muhammad Moin Farooqi

Jennifer Velasquez

Phone: +1 214 317 8322

Email: jennifervelasquez177@yahoo.com

Wake Forest Health Network LLC

Recruiting

Asheboro, North Carolina, 27203, United States

Robert Dough

Stacy Jones

Email: smjones@javararesearch.com

Johns Hopkins Univ School of Med

Recruiting

Baltimore, Maryland, 21287, United States

Nadim Nasrallah

Phone: 410-955-1160

Email: nnasral1@jh.edu

Thorsten Leucker

Chicago Clinical Research Inst

Recruiting

Chicago, Illinois, 60607, United States

Dennis Levinson

Stephanie Sandoval

Phone: [312-791-3241](tel:312-791-3241)

Email: stephanie@ccrii.us

Dominion Medical Associates

Recruiting

Richmond, Virginia, 23219, United States

Claretha Nelson

Phone: [804-836-6540](tel:804-836-6540)

Email: clarethanelson@dominionmedicalinc.com

Richard A Jackson

Excel Medical Clinical Trials LLC

Recruiting

Boca Raton, Florida, 33434, United States

Ashanti McKenzie

Phone: [561-756-8206](tel:561-756-8206)

Email: amckenzie@flourishresearch.com

David Funt

Clinical Trials of Florida

Recruiting

Miami, Florida, 33186, United States

Lina Gallego

Phone: [305-255-7452](tel:305-255-7452)

Email: lgallego@flourishresearch.com

Mark Rosenthal

Virginia Commonwealth University

Recruiting

Richmond, Virginia, 23298-0111, United States

Anurag Mehta

Joshua West

Email: Joshua.west@vcuhealth.org

Morehouse School Of Medicine

Recruiting

Atlanta,Georgia,30310,United States

Phone: [404-756-8819](tel:404-756-8819)

Priscilla Igho-Pemu

Pharma Tex Research

Recruiting

Amarillo,Texas,79106,United States

David Brabham

Emily Peterson

Phone: [806-355-2581](tel:806-355-2581)

Email: epetersonptx@gmail.com

North Hills Medical Research Inc

Recruiting

Bedford,Texas,76021,United States

John D Gabriel

Steven Vasquez

Phone: [817-595-3399](tel:817-595-3399)

Email: regulatoryspecialist1@nhmr-inc.com

Finlay Medical Research

Recruiting

Miami,Florida,33126,United States

Lilia Rodriguez-Ables

Melissa Aloma Bello

Phone: [305-459-3578](tel:305-459-3578)

Email: maloma@finlaymr.com

Angel City Research Inc

Recruiting

Los Angeles, California, 90026, United States

Felix Sigal

Joanna Cuevas

Email: joanna@angelcityresearch.com

Clinical Trials of Texas

Recruiting

San Antonio, Texas, 78229, United States

Aimee Blanco

Phone: [210-949-0122](tel:210-949-0122)

Email: aiblanco@flourishresearch.com

Douglas Denham

New Tampa Health

Recruiting

Tampa, Florida, 33603, United States

Esther Echevarria-Crespo

Loraine Gonzalez

Email: l.gonzalez@newtampahealthresearch.com

Anderson Medical Research

Recruiting

Fort Washington, Maryland, 20744, United States

Phone: [301-542-6741](tel:301-542-6741)

Felton Anderson

TCV Clinical Studies

Recruiting

Linwood, Pennsylvania, 19061, United States

Edward Stankiewicz

Jocelynn Vega

Email: jvega@tcvclinicalstudies.com

Aa Mrc Llc

Recruiting

Flint,Michigan,48504,United States

Ahmed Arif

Rania Takriti

Email: rtakriti@aamrc.net

Sinai Ct for Throm Res and Drug Dev

Recruiting

Baltimore,Maryland,21209,United States

Paul Gurbel

Taylor Stude

Phone: [410-367-2590](tel:410-367-2590)

Email: tstude@lifebridgehealth.org

NICRs Research Center

Recruiting

Garden Grove,California,92844,United States

Mallu Reddy

Vincent Ribaya

Email: vribaya@nicresearch.com

University At Buffalo

Recruiting

Buffalo,New York,14203,United States

Courtney Bishop

Phone: [716-888-4859](tel:716-888-4859)

Email: cbishop@buffalo.edu

Thomas Cimato

DBC Research USA

Recruiting

Pembroke Pines,Florida,33029,United States

Alvaro Murcia

Carolyn Zambrano

Phone: 954-537-2100

Email: czambrano@dbcresearch.com

NexGen Research

Recruiting

Lima,Ohio,45801,United States

Manijah Amerson

Phone: 260-300-6394

Email: manijah.amerson@nexgenresearch.com

Nonso Ezema

MD Medical Research

Recruiting

Oxon Hill,Maryland,20745,United States

John Hakim

Siddhi Bambakar

Phone: 301-839-2008

Email: siddhi.bambarkar@mdmedicalresearch.com

Ventura Heart Institute

Recruiting

Thousand Oaks,California,91360,United States

Irving Kent Loh

Rocio Ma

Email: rocio.ma@careaccess.com

Omega Clinical Research

Recruiting

Metairie, Louisiana, 70006, United States

Rosina Ducote

Phone: 504-914-8726

Email: rosinaducote@gmail.com

Tuan-Huy Tran

Synexus

Recruiting

Glendale, Arizona, 85306, United States

Elysa Shaw

Tahmina Stanikzai

Email: Tahmina.stanikzai@globalaes.com

Angiocardiatic Care of Texas PA

Recruiting

Houston, Texas, 77025, United States

Phone: 877-339-0254

Amin Karim

Clinical Research of South Nevada

Recruiting

Las Vegas, Nevada, 89121, United States

Roger Estevez

Shelly Heredia

Phone: 702-570-6107

Email: shelly@crosnlv.com

Zenith Clinical Research

Recruiting

Hollywood, Florida, 33021, United States

Carmen Rosa

Phone: [305-546-1311](tel:305-546-1311)

Email: crosa@zenithclinicalresearch.com

Moises Issa

Metropolitan Cardiovascular Consultants Llc

Recruiting

Beltsville, Maryland, 20705, United States

Ayim Akyea-Djamson

Sruthi Ramesh

Phone: [301-595-0356](tel:301-595-0356)

Email: sramesh@metresearch.org

Monroe Biomedical Research

Recruiting

Monroe, North Carolina, 28112, United States

Anna Drake

Phone: [704-283-7359](tel:704-283-7359)

Email: anna.tramble@monroereseach.com

Awawu Igbinadolor

C and A Clinical Trials

Recruiting

Cape Coral, Florida, 33990, United States

Arturo Alvarez

Email: arturo@caclinicaltrial.com

Juan Antonio Carmona Herrera

Flourish Research

Recruiting

Grandwood Park, Illinois, 60031, United States

Alfonso Gonzales-Rodriguez

Angelica Perez

Email: aperez@flourishresearch.com

Daniel Stokes

Email: dstokes@flourishresearch.com

Sara Collins

Synexus Clinical Research Advantage

Recruiting

Birmingham,Alabama,35211,United States

Adrienne Baltscheit

Phone: [205-870-8803](tel:205-870-8803)

Email: adrienne.baltscheit@globalaes.com

William Kirby

University of Washington

Recruiting

Seattle,Washington,98195,United States

Francis Kim

Lily Zavala

Email: lilyz123@uw.edu

CTMD Research

Recruiting

Palm Springs,Florida,33406,United States

Luis Castillo

Sylvia Cubillos

Phone: [561-770-3537](tel:561-770-3537)

Email: Scubillos@ctmdresearch.com

Atlanta Heart Specialists LLC

Recruiting

Tucker,Georgia,30084,United States

Alexandria Hurt

Phone: [678-679-6800](tel:678-679-6800)

Email: alexhurt@ahsmed.com

David Suh

SW Family Medicine Associates

Recruiting

Dallas,Texas,75235,United States

Chrisette Dharma

Kehinde Ogunremi

Phone: [214-393-2940](tel:214-393-2940)

Email: kehinde@swmedicalgroup.com

David Turbay MD PLLC

Recruiting

El Paso,Texas,79905,United States

David Turbay

Paola Rojas

Phone: [915-259-0510](tel:915-259-0510)

Email: research@davidturbaymd.com

International Research Associates, LLC

Recruiting

Miami,Florida,33156,United States

Cristian Breton

Juan J Calderon

Email: jcalderon@intrallc.com

Velocity Clinical Trials

Recruiting

Los Angeles,California,90057,United States

Leslic Diaz

Phone: [+1 323 588 1968](tel:+13235881968)

Email: ldiaz@velocityclinical.com

Stanley Hsin-Wei Hsia

Javara Research

Recruiting

San Marcos,Texas,78666,United States

Alan Lee

Heather Helms

Phone: 432-558-9256

Email: hhelms@javararesearch.com

James A Haley Veterans Hospital

Recruiting

Tampa,Florida,33612,United States

David Whitaker

Stephanie Gonzalez

Phone: +1 813 972 2000#2089

Email: Stephanie.Gonzalez2@va.gov

AB Clinical Trials

Recruiting

Las Vegas,Nevada,89119,United States

Anas Alubaidi

Phone: 702-804-5900

Email: aalubaidiabct@gmail.com

Atoya Adams

Elite Clinical Research LLC

Recruiting

Jackson,Mississippi,39211,United States

Honey East

The Stern Cardiovascular Foundation

Recruiting

Germantown,Tennessee,38138,United States

Frank Augustus McGrew

Meshun Briscoe

Phone: +1 901 271 4063

Email: meshun.briscoe@sterncardio.com

Grady Health System

Recruiting

Atlanta,Georgia,30303,United States

Chadrick M Anderson

Phone: 404-616-7349

Email: canderson@gmh.edu

Jalal Ghali

Long Beach Clinical Trials

Recruiting

Long Beach,California,90806,United States

Mayra Rodriguez

Phone: 608-855-9124

Email: myra@lbclinicaltrials.com

Suzanne Fussell

Epic Clinical Research

Recruiting

Lewisville,Texas,75057,United States

Jessica Powell

Phone: 469-599-4909

Email: jpowell@allianceclinicalnetwork.com

Manjoo Sharma

Jamaica Hospital Medical Center

Recruiting

Jamaica, New York, 11418, United States

Aishah Aponte

Phone: [718-206-7318](tel:718-206-7318)

Email: aaponte1@jhmc.org

David Coven

Henry Ford Hospital

Recruiting

Detroit, Michigan, 48202, United States

Kayla A Baker

Phone: [313-916-3502](tel:313-916-3502)

Email: KBaker9@hfhs.org

Sachin Parikh

Inpatient Research Clinical LLC

Recruiting

Miami Lakes, Florida, 33014, United States

Alexis Gutierrez

Ana Laura Lopez

Phone: [786-502-4303](tel:786-502-4303)

Email: alopez@inpatientresearch.com

CV Ins of the South

Recruiting

Opelousas, Louisiana, 70570, United States

Ariel Quebedeaux

Phone: [337-942-3006](tel:337-942-3006)

Email: Ariel.Quebedeaux@cardio.com

siby george ayalloore

Cardiology and Medicine Clinic PA

Recruiting

Little Rock,Arkansas,72204,United States

Phone: [501-664-0941](tel:501-664-0941)

Joe L Hargrove

Robert Wood Johnson Medical School

Recruiting

New Brunswick,New Jersey,08901,United States

Heena Gandhi

Email: hg358@rwjms.rutgers.edu

Tudor D Vagaonescu

Johns Hopkins University

Recruiting

Columbia,Maryland,21044,United States

Daniel Kim

Tanya Burley

Phone: [443-276-9033](tel:443-276-9033)

Email: tburley1@jhmi.edu

Velocity Clin Research Springdale

Recruiting

Cincinnati,Ohio,45246,United States

Brandon Frost

Phone: [513-671-8080](tel:513-671-8080)

Email: bfrost@velocityclinical.com

Douglas K Logan

Stern Cardiovascular Foundation Inc

Recruiting

Southaven,Mississippi,38671,United States

Dharmesh Patel

Rishi Bhula

Phone: [901-271-2229](tel:901-271-2229)

Email: rishi.bhula@sterncardio.com

Parkway Medical Center

Recruiting

Birmingham,Alabama,35215,United States

James Sullivan

Trina Gray

Phone: [205-815-5000](tel:205-815-5000)

Email: graytrina1989@gmail.com

Fam Medical Specialists Of Fl Plc

Recruiting

Plant City,Florida,33563,United States

Michael Gimness

Ctr For Clin Rsrch And Innovation

Recruiting

Spring,Texas,77389,United States

Jorge Guerrero

Worldwide Contacts

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

Novartis Pharmaceuticals

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

Email: novartis.email@novartis.com

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5. <mailto:Crc3@latinclinicaltrialcenter.com>
6. <tel:+17876417582#10393>

7. <mailto:Jonathan.rolon-negron@va.gov>
8. tel:+1 787 840 2580
9. <mailto:scancel@psm.edu>
10. tel:+1 787 628 4463
11. <mailto:michellenurse@advanceresearchpr.com>
12. tel:+1 787 259 0526
13. <mailto:jgalarzaperez.research@gmail.com>
14. tel:845-235-4196
15. <mailto:rzambrano@tbcresearch.com>
16. tel:985-893-9090
17. <mailto:darlene.wilson5378@gmail.com>
18. tel:410-615-6641
19. <mailto:mkoch@scritrials.com>
20. tel:213-481-7142
21. <mailto:awoldeabezegi@airesearch.us>
22. tel:210-764-4842
23. <mailto:operations@discoverytrials.com>
24. tel:312-494-2250
25. tel:703-766-5920
26. <mailto:Calvarez@VirginiaHeart.com>
27. tel:810-835-4533
28. <mailto:aelassad@aamrc.net>
29. tel:208-346-8900
30. <mailto:Lrivera@thesisterresearch.com>
31. <mailto:icruz@nationalri.org>
32. <mailto:mannie@valleyclinicaltrials.com>
33. <mailto:chelsi.holliday@javararesearch.com>
34. <mailto:aimee.kaczorowski@javararesearch.com>
35. <mailto:gobeidat@javararesearch.com>
36. <mailto:amarachukwu.akujieze@javararesearch.com>
37. <mailto:smjones@javararesearch.com>
38. <mailto:jason.elenberger@javararesearch.com>
39. <mailto:areyna@javararesearch.com>
40. <mailto:Kathryn.mcspadden@javararesearch.com>
41. <mailto:m.sexton@careaccess.com>
42. <mailto:r.larimore@careaccess.com>
43. tel:281-944-3610
44. <mailto:saleha@biopharmainfo.net>
45. <mailto:SMohammed@Biopharmainfo.net>
46. <mailto:Cgarza@biopharmainfo.net>
47. tel:908-522-6279
48. <mailto:Kathleen.Haft@atlanticehealth.org>
49. tel:786-595-8078
50. <mailto:Margie.Mckercher@baptisthealth.net>
51. tel:208-346-8900
52. <mailto:lsalazar@eminat.net>
53. tel:804-526-3500
54. mailto:megh_jariwala99@gwu.edu
55. <mailto:Tammy@southernclinicalresearch.com>
56. tel:301-289-5221
57. <mailto:mflores@nationalheartinstitute.org>
58. tel:937-912-4364
59. <mailto:aaplegate@myhometownuc.com>
60. tel:561-537-4778

61. <mailto:christina.lacquey@cardiologypartnerspl.com>
62. tel:731-423-8200
63. <mailto:lholman@researchjackson.com>
64. tel:301-312-0575
65. <mailto:iluyomade@capitolcardiology.com>
66. tel:858-901-8235
67. <mailto:karmstrong@allianceclinicalnetwork.com>
68. tel:303-957-7478
69. <mailto:Whitney.Nwole@Elligodirect.com>
70. tel:318-704-5853
71. <mailto:crystal.dubois2@christushealth.org>
72. <mailto:jared-robert.blake@globalaes.com>
73. tel:702-605-5750
74. <mailto:Sheila@lasvegasendocrinology.com>
75. tel:305-559-5957
76. <mailto:l.trujillo@columbusclinical.net>
77. <mailto:jgarcia@proactivecr.com>
78. tel:956-731-1260
79. tel:+1 214 317 8322
80. <mailto:jennifervelasquez177@yahoo.com>
81. <mailto:smjones@javararesearch.com>
82. tel:410-955-1160
83. <mailto:nasral1@jh.edu>
84. tel:312-791-3241
85. <mailto:stephanie@ccrii.us>
86. tel:804-836-6540
87. <mailto:clarethanelson@dominionmedicalinc.com>
88. tel:561-756-8206
89. <mailto:amckenzie@flourishresearch.com>
90. tel:305-255-7452
91. <mailto:lgallego@flourishresearch.com>
92. <mailto:Joshua.west@vcuhealth.org>
93. tel:404-756-8819
94. tel:806-355-2581
95. <mailto:epetersonptx@gmail.com>
96. tel:817-595-3399
97. <mailto:regulatoryspecialist1@nhmr-inc.com>
98. tel:305-459-3578
99. <mailto:maloma@finlaymr.com>
100. <mailto:joanna@angelcityresearch.com>
101. tel:210-949-0122
102. <mailto:aiblanco@flourishresearch.com>
103. <mailto:l.gonzalez@newtampahealthresearch.com>
104. tel:301-542-6741
105. <mailto:jvega@tcvclinicalstudies.com>
106. <mailto:rtakriti@aamrc.net>
107. tel:410-367-2590
108. <mailto:tstude@lifebridgehealth.org>
109. <mailto:vribaya@nicresearch.com>
110. tel:716-888-4859
111. <mailto:cabishop@buffalo.edu>
112. tel:954-537-2100
113. <mailto:czambrano@dbcresearch.com>
114. tel:260-300-6394

115. <mailto:manijah.amerson@nexgenresearch.com>
116. tel:301-839-2008
117. <mailto:siddhi.bambarkar@mdmedicalresearch.com>
118. <mailto:rocio.ma@careaccess.com>
119. tel:504-914-8726
120. <mailto:rosinaducote@gmail.com>
121. <mailto:Tahmina.stanikzai@globalaes.com>
122. tel:877-339-0254
123. tel:702-570-6107
124. <mailto:shelly@crosnlv.com>
125. tel:305-546-1311
126. <mailto:crosa@zenithclinicalresearch.com>
127. tel:301-595-0356
128. <mailto:sramesh@metresearch.org>
129. tel:704-283-7359
130. <mailto:anna.tramble@monroeresearch.com>
131. <mailto:arturo@caclinicaltrial.com>
132. <mailto:aperez@flourishresearch.com>
133. <mailto:dstokes@flourishresearch.com>
134. tel:205-870-8803
135. <mailto:adrienne.baltscheit@globalaes.com>
136. <mailto:lilyz123@uw.edu>
137. tel:561-770-3537
138. <mailto:Scubillos@ctmdresearch.com>
139. tel:678-679-6800
140. <mailto:alexhurt@ahsmed.com>
141. tel:214-393-2940
142. <mailto:kehinde@swmedicalgroup.com>
143. tel:915-259-0510
144. <mailto:research@davidturbaymd.com>
145. <mailto:jcalderon@intrallc.com>
146. tel:+1 323 588 1968
147. <mailto:ldiaz@velocityclinical.com>
148. tel:432-558-9256
149. <mailto:hhelms@javararesearch.com>
150. tel:+1 813 972 2000#2089
151. <mailto:Stephanie.Gonzalez2@va.gov>
152. tel:702-804-5900
153. <mailto:aalubaidiabct@gmail.com>
154. tel:+1 901 271 4063
155. <mailto:meshun.briscoe@sterncardio.com>
156. tel:404-616-7349
157. <mailto:canderson@gmh.edu>
158. tel:608-855-9124
159. <mailto:myra@lbclinicaltrials.com>
160. tel:469-599-4909
161. <mailto:jpowell@allianceclinicalnetwork.com>
162. tel:718-206-7318
163. <mailto:aaponte1@jhmc.org>
164. tel:313-916-3502
165. <mailto:KBaker9@hfhs.org>
166. tel:786-502-4303
167. <mailto:alopez@inpatientresearch.com>
168. tel:337-942-3006

- 169. <mailto:Ariel.Quebedeaux@cardio.com>
- 170. tel:501-664-0941
- 171. <mailto:hg358@rwjms.rutgers.edu>
- 172. tel:443-276-9033
- 173. <mailto:tburley1@jhmi.edu>
- 174. tel:513-671-8080
- 175. <mailto:bfrost@velocityclinical.com>
- 176. tel:901-271-2229
- 177. <mailto:rishi.bhula@sterncardio.com>
- 178. tel:205-815-5000
- 179. <mailto:graytrina1989@gmail.com>
- 180. tel:1-888-669-6682
- 181. <mailto:novartis.email@novartis.com>