

**16.1.4.1 LIST OF INVESTIGATORS AND NUMBER OF SITES AND PARTICIPANTS BY COUNTRY**

Total Number of Sites (Per Study): 29  
 Total Number of Subjects Screened (Per Study): 2268  
 Total Number of Subjects Randomized/Entered (Per Study): 2268

**UNITED STATES**

Number of Sites (Per Country): 29  
 Number of Subjects Screened (Per Country): 6713  
 Number of Subjects Randomized/Entered (Per Country): 6500  
 Coordinating Investigator:  
 Stephen Thomas

<u>Study Site Number</u>	<u>Principal Investigator</u>	<u>Sub-Investigator</u>	<u>Study Conducted at Address(es)</u>	<u>Subjects Screened per Site</u>	<u>Subjects Randomized/Entered per Site</u>
1005	Matthew Davis	Chelsea Bork Michelle Burgett Therese Dayton Kathleen Ebeling Victoria Fink Jennifer Foley Deborah Hodges Sarah Ingalsbe-Geno (b) (6) Patricia Larrabee Joseph Mann Julie Mooney Katherine Pagenkemper Tammi Shlotzhauer Susan Willer	Rochester Clinical Research, Inc. 500 Helendale Rd, L20 Rochester, NY 14609 UNITED STATES  Rochester Clinical Research, Inc. 500 Helendale Rd, Ste 265 Rochester, NEW YORK 14609 UNITED STATES	34	34

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<u>Study Site Number</u>	<u>Principal Investigator</u>	<u>Sub-Investigator</u>	<u>Study Conducted at Address(es)</u>	<u>Subjects Screened per Site</u>	<u>Subjects Randomized/ Entered per Site</u>
		Jaclyn Zona			
		Zerina Zornic			
		Jenna Baer(Previous SubI)			
		Julie Callahan(Previous SubI)			
		Cristina Cramer-Mills(Previous SubI)			
		Kara Cristales(Previous SubI)			
		Geesue Hah(Previous SubI)			
		(b) (6) (b) (6) Previous SubI			
		Diana Kailburn(Previous SubI)			
		Mackay Kanaley(Previous SubI)			
		Abigail Miller(Previous SubI)			
		Jennifer Rowlinson(Previous SubI)			
		Sally Thomas(Previous SubI)			
		Julie Wentworth(Previous			

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		SubI)			
1006	James Peterson	Natalie Bee Alexander Clark Shana Eborn Susan Edwards Dan Henry Heather Jackson Gerald Kelty Jacqueline Rohrer Issac Pena-Renteria(Previous SubI) Jack Taylor(Previous SubI)	J. Lewis Research, Inc. / Foothill Family Clinic 2295 Foothill Dr Salt Lake City, UT 84109 UNITED STATES	89	89
1007	Robert Frenck	Rebecca Brady Kristen Buschle Michelle Dickey Grant Paulsen Felicia Scaggs-Huang Paul Spearman Eleanor Widdice David Bernstein(Previous SubI)	Cincinnati Children's Hospital Medical Center Cincinnati Center for Clinical Research (CCCR) 619 Oak St Cincinnati, OH 45206 UNITED STATES  Cincinnati Children's Hospital Medical Center Gamble Program for Clinical Studies 3333 Burnet Ave, MLC 6014 Cincinnati, OH 45229-3039 UNITED STATES	173	173
1008	Timothy Jennings	(b) (6) Tonya Clausen Siddharth Kaul Anthony Margherita Brittany Nguyen Ann Patek	Clinical Research Professionals 17998 Chesterfield Airport Rd, Ste 100 Chesterfield, MO 63005 UNITED STATES	179	179

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1009	Shane Christensen	Fredric Prater Dawn Ringling Richard Summa Terry Weis Alaina Yarber Stacey Miner(Previous SubI) Holly Anderson Emily Bloomquist Ross Brunetti Thomas Conner Gina Cox Diana Grazulis Wesley Lewis James Longe Christopher Matich Bryan Nelson John Witbeck Stephen Wood Emily Raming(Previous SubI) Sarah Scott(Previous SubI)	J. Lewis Research, Inc. / Foothill Family Clinic South 6360 S 3000 E, Ste 100 Salt Lake City, UT 84121 UNITED STATES	158	158
1013	Michael Dever	Chanel Adams Patricia Brown Joan Cutillo Letitia Griffin Linda Harper Rebecca Klipper Robert Molpus Priya Moorhouse	Clinical Neuroscience Solutions, Inc. dba CNS Healthcare 618 E. S St, Ste 100 Orlando, FL 32801 UNITED STATES	53	53

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1016	Daniel Finn	Penny O'Neal Felipe Suplicy Geraldine Marino(Previous SubI) Deborah Renner(Previous SubI) Trey (William) Schesser(Previous SubI) Ashley Bennett Melanie Bishop Lindsay Blackmon Stanley Block (b) (6) Christal Denton Lisa Dones Rebecca Findlay Kayla Hamilton James Hedrick Kali Lewis Brittany Lisby Wendy Mattingly Michelle Newton Martha Osbourn Robert Smith Monica Strenecky (b) (6) Ronald Tyler Shannon Woods Whitney Downs(Previous	Kentucky Pediatric/ Adult Research 201 S 5th St Bardstown, KENTUCKY 40004 UNITED STATES	65	65

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		SubI Erica Koch(Previous SubI) Abby O'Bryan-Wimsett(Previous SubI) Lea Rust(Previous SubI) Andrea Yates(Previous SubI) Tabitha Yates(Previous SubI)			
1039	Gretchen Crook	Jennifer Beanblossom (b) (6) Kristen Hansen Peterman Sarah Higgs Camille Horony Ana Paez Bandana Risal Linda Nguyen(Previous SubI) Amy Siegel(Previous SubI)	ARC Clinical Research at Wilson Parke 11714 Wilson Parke Ave., Ste 150 Austin, TX 78726 UNITED STATES	88	88
1044	Aaron Hartman	Raymond Decker Rachel Martin(Previous SubI)	Virginia Research Center LLC 13911 St. Francis Blvd., Ste 101 Midlothian, VA 23114 UNITED STATES	133	133

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1057	Fadi Chalhoub	Susan Angel Sujeeta Dhakhwa Brett Gellers Nandita Jones John Mark Joyce Niketa Kamble	Clinical Neuroscience Solutions, Inc. 5200 Belfort Rd, Ste 420 Jacksonville, FL 32256 UNITED STATES	78	78
1066	David Butuk	Janelle Barney Janaie Bounsana Erin Brennan Melissa Conrad Scott Frisby Paige McKenzie Kaylee Ruckrigl Meredith Mangum(Previous SubI)	Solaris Clinical Research 1525 E Leigh Field Dr, # 100 Meridian, ID 83646 UNITED STATES	36	36
1077	Suchet Patel	Caitlyn Burford Kimberly Desantis Michael Federico Demetrios Gasparis Lazarus Gehring James Holler Eric Lorraine Katherine Macarak Rekha Patel John Perry Duncan Sze-Tu	Meridian Clinical Research 415 Hooper Rd Endwell, NEW YORK 13760 UNITED STATES  Meridian Clinical Research LLC 409 Hooper Rd Endwell, NEW YORK 13760 UNITED STATES	26	26
1084	Douglas Denham	Ayoade Avworo Maristelle Co Parke Hedges Matthew Korte	Clinical Trials of Texas, Inc. (Storage Only) 5430 Fredericksburg Rd., Ste 601 San Antonio, TEXAS 78229	54	54

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		Mary Perez-Jenkins Cynthia Ramos Thomas Weiss Darlington Akahara(Previous SubI) Muhammad Ata(Previous SubI) Stephen Brick(Previous SubI) Cathleen Chen(Previous SubI) Graham Ellis(Previous SubI) Kimberly Evans(Previous SubI) Zachariah Francois(Previous SubI) Anshumaan Maharaj(Previous SubI) Clayton Stone(Previous SubI)	UNITED STATES  Clinical Trials of Texas, Inc. 5430 Fredericksburg Rd, Ste 200 San Antonio, TEXAS 78229 UNITED STATES		
1091	Samir Arora	(b) (6) Brennan Brothers Grazia Cannon Jordan Carpenter Jess DeMaria Roger Faubel Allison Forsythe	Aventiv Research Inc (Facility and Drug Shipment Address) 99 N. Brice Rd, Ste 260 Columbus, OHIO 43213 UNITED STATES  Aventiv Research Inc. 99 N. Brice Rd, Ste 210 Columbus, OHIO 43213	70	70

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<u>Study Site Number</u>	<u>Principal Investigator</u>	<u>Sub-Investigator</u>	<u>Study Conducted at Address(es)</u>	<u>Subjects Screened per Site</u>	<u>Subjects Randomized/ Entered per Site</u>
		Sridhar Guduri Layne Mikanik Lindsay Newton (b) (6) Roy St. John Sarah Wilcox Rafe Bari(Previous Subl) Brittany Biro(Previous Subl) (b) (6) (b) (6) Previous Subl) Danijela Cvijetinovic(Previous Subl) Sophia Gaines(Previous Subl) Jessica Harpel(Previous Subl) Chelsea Hughes(Previous Subl) Grace Purkey(Previous Subl) Jessica Spear(Previous Subl)	UNITED STATES		
1123	Brandon Essink	(b) (6) Laura Falcone Roni Gray Frederick Raiser	Meridian Clinical Research, LLC 3319 N 107th St. Omaha, NEBRASKA 68134	89	89

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		Akossiwa Yovogan Jacob Bumsted(Previous SubI) Cassie Heisey(Previous SubI) Linda Layton(Previous SubI) Jay Meyer(Previous SubI) Kimberly Mueller(Previous SubI) Tiffany Nemecek(Previous SubI)	UNITED STATES		
1124	David Fried	Jacqueline DiFazio Patricia Feole Helena Godley Kristina Haughey Lynne Haughey Courtney Langlois Amanda ONeill Johnna Pezzullo Lisa Rameaka Ariana Stanton Amanda Cole(Previous SubI) Molly Savitzky(Previous	Velocity Clinical Research, Providence 400 Bald Hill Rd Warwick, RI 02886 UNITED STATES	39	39

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		SubI)			
1125	Charles Harper	Sally Eppenbach Alisha Kiepke Cathy Laflan Wendell Lewis Brett Loseke Chelsie Nutsch Keith Vrbicky Kari Uhlir(Previous SubI)	Meridian Clinical Research, LLC 1410 N 13th St, Ste 5 Norfolk, NE 68701 UNITED STATES	12	12
1126	Nicola Klein	Rebecca Alexander Janelle Baires Latisha Burun Christine Cash David Cooper JOLYNNE ENCARNACION Douglas Ernst Lauren Fontenot La Vonne Freed Sarah Kang Roma Kullar Ludy Lemus Eva Lowe Lorrie Lowe Nicole Makram Shannon Mullen Courtney Oxandale Kenneth Purdy Sally Upadhyaya Dana Weisshaar Amy Wiesner	Kaiser Permanente Sacramento 1650 Response Rd Sacramento, CA 95815 UNITED STATES  Kaiser Permanente Santa Clara 710 Lawrence Expy Santa Clara, CALIFORNIA 95051 UNITED STATES	75	75

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		Jessica Barraza(Previous SubI) Gail Cook(Previous SubI) Jeremy Giese(Previous SubI) Julia Glanternik(Previous SubI) Lisa Kennedy(Previous SubI) Rebekah Kotyk(Previous SubI)			
1131	William Randall	(b) (6) Ann Moell Crystal Osman Caitlyn Smith Gilbert Templeton Heather Goins(Previous SubI) Zachariah Komon(Previous SubI) Kimberly Lyons(Previous SubI) (b) (6) (Previous SubI)	PriMED Clinical Research 948 Patterson Rd Dayton, OHIO 45419 UNITED STATES	25	25
1139	Emmanuel Walter	Michael Smith (b) (6) Christopher	Accessioning Unit and Repository 2 Genome Court Durham, NORTH CAROLINA 27710	107	107

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		Clark(Previous SubI) Jennifer Dougherty(Previous SubI) Geeta Swamy(Previous SubI)	UNITED STATES  Clinical Research Pickett Road 3024 Pickett Rd, Durham County Durham, NORTH CAROLINA 27705 UNITED STATES  Duke University Medicine Circle- Duke Early Phase Clinical Research Unit 40 Duke Medicine Circle Durham, NC 27710 UNITED STATES  Duke Vaccine and Trials Unit 2608 Erwin Rd, Ste 210 Durham, NORTH CAROLINA 27705 UNITED STATES		
1140	Stephen Thomas	Kathryn Anderson Elizabeth Asiago-Reddy DONALD BLAIR RACHAEL CAVELLI Joseph Domachowske Sriharsha Gowtham Elizabeth Harausz Kristopher Paolino Timothy Endy(Previous SubI)	SUNY Upstate Medical University Institute for Human Performance 505 Irving Ave, Clinical Research Unit Syracuse, NEW YORK 13210 UNITED STATES  SUNY Upstate Medical University Global Health Research Unit 4900 Broad Rd, Onondaga County, POB N Ste 4U Syracuse, NEW YORK 13215 UNITED STATES	75	75
1142	Richard Rupp	Megan Berman Cori Burkett Laura Porterfield Elizabeth	University of Texas Medical Branch SIVS Clinical Trials Program, Primary Care Pavilion, 400 Harborside Dr., Ste 126 Galveston, TEXAS 77555	63	63

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1147	Julia Garcia-Diaz	Ginn(Previous SubI) Julie Castex Hailey Anderson(Previous SubI) Melinda Benvenuti(Previous SubI) Freda Dunhurst(Previous SubI) Lisa Fredenburg(Previous SubI) Jenna Griffin(Previous SubI) Samuel King(Previous SubI) James McMullen(Previous SubI)	UNITED STATES Ochsner Clinic Foundation 1514 Jefferson Hwy New Orleans, LA 70121 UNITED STATES	78	78
1150	Shelly Senders	Sarah Ball Elizabeth Bucchieri Laura Caserta Christopher Fackelmann Caitlin Fillioe Kelly Kelmes Katie Passarell Jill Sangree Allison	Senders Pediatrics 2054 S Green Rd South Euclid, OH 44121 UNITED STATES	144	144

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		Effron(Previous SubI) Jennifer McKinnon(Previous SubI) Keili Mistovich(Previous SubI) Eliza Pereira(Previous SubI)			
1152	Donald Brandon	William Davis Daniel Lawler (b) (6)	California Research Foundation 4180 Ruffin Rd, Ste 255 San Diego, CALIFORNIA 92123-1881 UNITED STATES	138	138
1156	Hector Rodriguez	Armando Acevedo Armando Garcia Yeniska Hall Nieves Lizz Hernandez Diaz Iris Izquierdo Alina Monteagudo Canto (b) (6) Israel Zagales Elaine Martinez(Previous SubI)	Acevedo Clinical Research Associates 2400 Nw 54th St Miami, FL 33142 UNITED STATES	88	88
1223	Onyema Ogbuagu	Laurie Andrews Jessica Tuan Thilinie Bandaranayake(Previ	Yale Center for Clinical Investigations (CSRU) 2 Church St S, Ste 114 New Haven, CT 06519 UNITED STATES	19	19

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		ous SubI) Melissa Campbell(Previous SubI) Frances Santiago(Previous SubI)	Yale University School of Medicine 135 College St, Ste 392 New Haven, CT 06510 UNITED STATES  Yale-New Haven Hospital 55 Park St, LL-15 New Haven, CT 06511 UNITED STATES		
1235	John Vanchiere	Pat Bass Paul Cooper Keith Scott(Previous SubI)	LSU Health Sciences Center at Shreveport Clinical Trials Office 1801 Fairfield Ave, Ste 203 Shreveport, LA 71101 UNITED STATES  LSUHSC-Shreveport 1501 Kings Hwy Shreveport, LA 71103 UNITED STATES	20	20
1270	Nicola Klein	Rebecca Alexander Janelle Baires Latisha Burun Christine Cash (b) (6) David Cooper JOLYNNE ENCARNACION Douglas Ernst Lauren Fontenot La Vonne Freed Sarah Kang Roma Kullar	Kaiser Permanente Sacramento 1650 Response Rd Sacramento, CA 95815 UNITED STATES  Kaiser Permanente Santa Clara 710 Lawrence Expy Santa Clara, CALIFORNIA 95051 UNITED STATES	59	59

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Ludy Lemus  
 Eva Lowe  
 Lorrie Lowe  
 Nicole Makram  
 Shannon Mullen  
 Courtney Oxandale  
 Kenneth Purdy  
 Sally Upadhyaya  
 Dana Weisshaar  
 Amy Wiesner  
 Jessica  
 Barraza(Previous SubI)  
 Gail Cook(Previous SubI)  
 Jeremy  
 Giese(Previous SubI)  
 Lisa  
 Kennedy(Previous SubI)

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16.1.4.2 List of CROs and Vendors

**List of Contract Research Organizations and Vendors**

CRO or Vendor Name and Address(es)	Service Conducted
Almac Clinical Services LLC 25 Fretz Road Souderton PA 18964 United States	Clinical Research Pharmacist Pfizer Investigational Product Coordinator Support
C3i Solutions 410 Horsham Road Horsham, PA 19044 United States	Medical Escalation and IRT Unblinding Support
CRF Health Management Limited, an affiliate of Bracket Global LLC Ground Floor Waterfront Building Manbre Road Hammersmith London W6 9RH United Kingdom	Subject Data Assessment Tool (eDiary) and Data Collection
DrugDev Inc. (an IQVIA company) 228 N. Market Street Frederick, MD 21701 United States	eConsent Services
Eliassen Group 55 Walkers Brook Drive, 6 <sup>th</sup> Floor Reading, MA 01867 United States	Statistical Programming
Execupharm 610 Freedom Business Center Drive, Suite 200 King of Prussia, PA 19406 United States	Study Management

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16.1.4.2 List of CROs and Vendors

CRO or Vendor Name and Address(es)	Service Conducted
ICON Clinical Research Limited South County Business Park Leopardstown, Dublin 18 Ireland	Study Management Investigator Site Monitoring
MMS Holdings Inc. 6880 Commerce Boulevard Canton, MI 48187 United States	Medical Writing (Clinical Study Report Narratives)
PRA Health Sciences 4130 Park Lake Avenue Suite 400, Raleigh, NC 27612 United States	Study Management
Premier Research Group Limited 234 Copeland Street Suite 400 Quincy, MA 02169 United States	Clinical Trial Coding, Dictionary Mapping and Maintenance
Syneos Health 1030 Sync Street Morrisville, North Carolina, 27560 USA	Statistical Analysis
Tata America International 7th Floor, Trent House G-Block, Bandra Kurla Complex Mumbai 400051 India	Statistical Programming
Verily Life Sciences LLC 269 East Grand Avenue South San Francisco, CA 94080 United States	Recruitment Services
WCG-THREEWIRE Inc. 7500 Flying Cloud Drive Suite 300 Eden Prairie, MN 55344 United States	Clinical Research Coordinator Support for Investigator Sites

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