Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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Supplementary Appendix

CLOPIDOGREL COMBINED WITH ASPIRIN VERSUS ASPIRIN ALONE IN ACUTE ISCHEMIC STROKE AND TRANSIENT ISCHEMIC ATTACK

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POINT Trial: Committees and Coordinating Centers

In addition to the authors, the following individuals contributed to the POINT Trial:

Executive Committee

S. Claiborne Johnston, MD, PhD, J. Donald Easton, MD, Anthony S. Kim, MD, MAS, Mary Farrant, MBA, Yuko Palesch, PhD, Jordan Elm, PhD, William Barsan, MD, Anne Lindblad, PhD, Robin Conwit, MD, Scott Janis, PhD.

Advisory Committee

S. Claiborne Johnston, MD, PhD, J. Donald Easton, MD, Anthony S. Kim, MD, MAS, Mary Farrant, MBA, Yuko Palesch, PhD, Jordan Elm, PhD, Holly Tillman, MS, Catherine Dillon, MS, William Barsan, MD, Renee Kasperek-Wynn, RN, BSN, Valerie Stevenson, BAS, RRT, CCRP, Lewis Morgenstern, MD, Anne Lindblad, PhD, Carolyn Burke, Lahna Jones, Kimberly Vogan, Robin Conwit, MD, Scott Janis, PhD.

Data and Safety Monitoring Board

Gregory J. del Zoppo, MD, Robert Cote, MD, Misha Eliasziw, PhD, Pierre Fayad, MD, FAHA, FAAN, Ann M. Lowe, MD, Ileana L. Piña, MD, MPH, Julie A. Swain, MD.

Clinical Event Adjudication Committee

Eric Adelman, MD, Brian Scott, MD, David Bach, MD, Claire S. Duvernoy, MD, Kevin A. Kerber, MD, Deborah A. Levine, MD, MPH, Matthew T. Lorincz, MD, PhD. Darin B. Zahuranec, MD.

National Institutes of Health

Scott Janis, PhD, Robin Conwit, MD.

NETT Clinical Coordinating Center

William Barsan, MD, Joy Black, BSN, RN, MS, Renee Kasperek-Wynn, RN, BSN, Robert Silbergleit, MD, Mickie Speers, BSN, Valerie Stevenson BAS, RRT, CCRP, Carol Van Huysen, BS, CCRP. Tess Bonham,BS, Andrace DeYampert, MSHS, CCRP, Shirley Frederikson, RN, MS, Samkeliso Mawocha, MS, CCRP, CCRA, Gina Neshewat, MPH, CCRP.

Data Coordination Unit/Department of Public Health Sciences (MUSC)

Jordan Elm, PhD, Catherine R. Dillon, MS, Faria Khattak, MPH, Yuko Palesch, PhD, Kavita Patel, BS, Keith Pauls, BS, Logan Sirline, MPH, Holly Tillman, MS, Wenle Zhao, PhD. Cassidy Conner, MS, Adam Henry, MPH, Aaron Perlmutter, MPH, MSW.

POINT Clinical Coordinating Center (UCSF)

Mary Farrant, BSN, MBA, Karla G. Zurita, AB, CCRP. Trese Biagini, BA, MA, MSN, ANCC, Marcos T. Contreras, PharmD, Caitlin Glennon, BA.

Clinical Research Collaboration (EMMES)

Anne Lindblad, PhD, Carolyn Burke, Kimberly Vogan, Lahna Jones, Sydney Avveduti, Elizabeth Hebert, Cathryn Luther-Lemmon, Rebecca Morgan, Kelley Rosborough; Carolyn Luce, Sharp Clinical Services; Shelley McKenna, Culzean Consulting; Maria Elena Lozano, Synteract, Inc.; Sandra Petrolo, Neuroscience Trials Australia.

CLINICAL RESEARCH COLLABORATION (CRC) INVESTIGATORS

AUSTRALIA ***Country Lead:*** Christopher LEVI

Site	Role	Team Member
Austin Hospital	Principal Investigator	Vincent THIJS
	Co-Investigator(s)	Amy BRODTMANN, Marion SIMPSON
	Study Coordinator(s)	Dennis YOUNG
Box Hill Hospital	Principal Investigator	Chris BLADIN
	Co-Investigator(s)	Jill CAMERON, Philip CHOI, Skye COOTE, Helen DEWEY, Amanda GILLIGAN, Sarah LEE, Claire MULLER, Poh SIEN LOH, Gabrielle TSE, Wenwen ZHANG
	Study Coordinator(s)	Zofia ROSS, Grace THOMAS
Footscray Hospital	Principal Investigator	Tissa WIJERATNE
	Co-Investigator(s)	Jennifer GOFF, Elizabeth MACKEY
	Study Coordinator(s)	Sherisse CELESTINO, Essie LOW
Gosford Hospital	Principal Investigator	Bill O'BRIEN
	Co-Investigator(s)	Patricia CARUANA, Denis CRIMMINS, James W. EVANS, Penelope GORDON, Yun HWANG, Tejas PATEL, Nathan PAVEY, Elizabeth REYNEKE, Alexis SELBY, Jonathan STURM, Scott WHYTE, Stephen WINTERS
	Study Coordinator(s)	Deborah ALCHIN, Susanne RHODES
John Hunter Hospital	Principal Investigators	Chris LEVI, Neil SPRATT
	Co-Investigator(s)	Timothy ANG, Jelle DEMEESTERE, Carlos ESPERON, Venkatesh KRISHNAMURTHY, Chris LEVI, Andre LOISELLE, Fredi MITEFF, Mark PARSONS, Ronak PATEL
	Study Coordinator(s)	Terri HAINES, Erin KERR, Gemma KITSOS
Monash Medical Centre	Principal Investigator	Thanh PHAN
	Co-Investigator(s)	Benjamin CLISSOLD, John LY, Henry MA
	Study Coordinator(s)	Kitty WONG, Dennis YOUNG
Royal Adelaide Hospital	Principal Investigator	Timothy KLEINIG
	Co-Investigator(s)	Edmund CHEONG, Craig KURUNAWAI
	Study Coordinator(s)	Jennifer CRANEFIELD
Royal Melbourne Hospital	Principal Investigator	Stephen DAVIS
	Co-Investigator(s)	Bruce CAMPBELL, Arvind CHANDRATHEVA, Thanuja DHARMADASA, Lauren GILES, Peter HAND, Nevin JOHN, Matthew LEE, Nyan LYNN, Andrew NEAL, Tom OXLEY, Darshan SHAH, Hans Tsuang-Han TU, Vinojini VIVEK, Teddy WU, Bernard YAN, Nawaf YASSI, Henry ZHAO
	Study Coordinator(s)	Amy MCDONALD, Gabriel SILVER

CANADA

Country Lead: Shelagh COUTTS

Enrolled 100 or more patients

Site	Role	Team Member
University of Alberta Hospital	Principal Investigator	Ashfaq SHUAIB
	Co-Investigator(s)	Aftab AHMAD, Ghazala BASIR, Bashir BREBESH, Asif Javed BUTT, Shubhabrata DAS, Atlantic D'SOUZA, Bikram GAJUREL, Esseddeeg GHROODA, Dulara HUSSAIN, Hayrapet KALASHYA, Harsha KAMBLE JAYAPRAKASH, Mahesh KATE, Sahrish Aieshah KAZI, Herbert Alejandro MANOSALVA, Raj PARTHASARATHY, Sibi THIRUNAVUKARASU, Andrew WASSEF
	Study Coordinator(s)	Brenda SCHWINDT

Enrolled 50-99 patients

Site	Role	Team Member
University of Calgary - Foothills Campus	Principal Investigator	Shelagh COUTTS
	Co-Investigator(s)	Abdulaziz AL SULTAN, Amjad ALSERAYA, Sarah BLAYNEY, Debabrata CHAKRABORTY, Shuo CHEN, Philip CHOI, Sadanand DEY, Veronique DUBUC, Prasanna ESWARADASS, James W. EVANS, Thalia FIELD, Brett GRAHAM, Janka HEGEDUS, Michael HILL, Oje IMOUKHUEDE, Evgenia KLOURFELD, Andrew LOCKEY, Aimen MOUSSADDY, Tapuwa MUSUKA, Nancy NEWCOMMON, Davar NIKNESHAN, Ramana REDDY, Dilip SINGH, Ravinder SINGH, Amith SITARAM, Ericka TELEG, Carol THAM, Anurag TRIVEDI, Stephen VAN GAAL, Amy YU, Charlotte ZERNA
	Study Coordinator(s)	Carol KENNEY, Supriya SAVE

Site	Role	Team Member
Charles LeMoyne Hospital	Principal Investigator	Jean-Martin BOULANGER
	Co-Investigator(s)	Leo BERGER
	Study Coordinator(s)	Lise BLAIS
Enfant-Jesus Hospital	Principal Investigator	Steve VERREAULT
	Co-Investigator(s)	Marie-Christine CAMDEN, Ariane MACKEY
	Study Coordinator(s)	Karine COLLARD, Annette HACHE
Grey Nuns Hospital	Principal Investigators	Brian BUCK, Muzaffar SIDDIQUI
	Co-Investigator(s)	Rajive JASSAL
	Study Coordinator(s)	Dana BERGQUIST, Lori PIQUETTE
London Health Sciences Center	Principal Investigator	Richard CHAN
	Co-Investigator(s)	Shahram ABOOTALEBI, Rasha ALSUBAIE, Reza AZARPAZHOOH, Sebastian FRIDMAN, Alexander KHAW, Jennifer MANDZIA,

Iryna PALAMARCHUK, Patricia RICCIO, Luciano SPOSATO

	Study Coordinator(s)	Belinda AMATO-MARZIALI, Beth BEAUCHAMP, Susan CRANN, Kim HESSER, Lindsay LAMBOURN
Montreal General Hospital	Principal Investigator	Theodore WEIN
	Co-Investigator(s)	Eric EHRENSPERGER, Lucy VIEIRA
	Study Coordinator(s)	Lisa WADUP
Notre-Dame Hospital	Principal Investigator	Celine ODIER
	Co-Investigator(s)	Nicole DANEAULT, Yan DESCHAINTRE, Andre DUROCHER, Laura GIOIA, Gregory JACQUIN, Sylvain LANTHIER, Alexandre POPPE, Christian STAPF
	Study Coordinator(s)	Marlene LAPIERRE
Vancouver General Hospital	Principal Investigator	Samuel YIP
	Co-Investigator(s)	Negar ASDAGHI, Oscar BENAVENTE, Thalia FIELD, Alejandra GOMEZ GONZALEZ, Asaf HONIG, Sharan MANN, Colleen MURPHY, Philip TEAL, Stephen VAN GAAL, Laura WILSON
	Study Coordinator(s)	Genoveva MACLEAN, Karina MURRAY

FINLAND ***Country Lead:*** Risto ROINE

Site	Role	Team Member
Helsinki University Central Hospital	Principal Investigator	Turgut TATLISUMAK
	Co-Investigator(s)	Sami CURTZE, Reetta KIVIOJA, Maija KOIVU, Tea LARJO, Ivan MARINKOVIC, Nicolas MARTINEZ-MAJANDER, Emilia OSTERLUND-TAURIALA, Anastasia SHULGA, Gerli SIBOLT, Anna TAPANAINEN, Marjaana TIAINEN, Liisa TOMPPO, Outi TUMPULA, Sannakaisa VAINIKKA, Kati VALKONEN, Jyri VIRTA, Emil YLIKALLIO
	Study Coordinator(s)	Saija EIROLA
Turku University Hospital	Principal Investigator	Risto ROINE
	Co-Investigator(s)	Julia AIVO, Anna BRUCK, Lauri HURRI, Manu JOKELA, Jaana KORPELA, Susanna ROINE, Jori RUUSKANEN, Pauli YLIKOTILA
	Study Coordinator(s)	Jaana ERIKSSON

FRANCE ***Country Lead:*** Pierre AMARENCO

Site	Role	Team Member
Adolphe de Rothschild Foundation	Principal Investigator	Michael OBADIA
	Co-Investigator(s)	Mathieu FISSELLIER, Laura GROSLIERE
	Study Coordinator(s)	Soukie JOUAVILLE, Elise PERRIOT, Alessandra PINCINI, Josephine TINE
Bichat-Claude Bernard Hospital	Principal Investigator	Elena MESEGUER
	Co-Investigator(s)	Pierre AMARENCO, Lucie CABREJO, Céline GUIDOUX, Cristina HOBEANU, Philippa LAVALLEE, Anna MARTIN BECHET, Ricardo RIGUAL
	Study Coordinator(s)	Estelle BEGON, Loubna DJEDIDI
Fleyriat Hospital	Principal Investigator	Frederic PHILIPPEAU

	Co-Investigator(s)	Angel-Christian OLARU, Taras SOSYAK
Foch Hospital	Principal Investigator	Bertrand LAPERGUE
	Co-Investigator(s)	Adrien WANG
	Study Coordinator(s)	Delphine LOPEZ
Pierre Wertheimer Hospital	Principal Investigator	Norbert NIGHOGHOSSIAN
	Co-Investigator(s)	Amandine BENOIT, Tae-Hee CHO, Laurent DEREX, Laura MECHTOUFF, Elodie ONG
	Study Coordinator(s)	Marielle BUISSON
Pitie-Salpetriere Hospital	Principal Investigator	Yves SAMSON
	Co-Investigator(s)	Flore BARONNET, Sophie CROZIER, Sandrine DELTOUR, Belen DIAZ FERNANDEZ, Raphael LE BOUC, Anne LEGER, Charlotte ROSSO, Marion YGER
	Study Coordinator(s)	Bachir AIDAOUI, Christine PIRES

GERMANY ***Country Lead:*** Hans-Christoph DIENER

Site	Role	Team Member
Central Bremen Hospital	Principal Investigator	Andreas KASTRUP
	Co-Investigator(s)	Uwe BECKER, Freimuth BRUNNER, Janina GUENTNER, Andreas SCHROTER
	Study Coordinator(s)	Halil MERDIVAN
Hannover Medical School	Principal Investigator	Karin WEISSENBORN
	Co-Investigator(s)	Maria GABRIEL, Gerrit GROSSE, Ramona SCHUPPNER, Hans WORTHMANN
	Study Coordinator(s)	Femke PLÜSCHKE, Karen SCHAEFFER, Frederike VON DER HAAR
University Hospital Essen	Principal Investigators	Hans-Christoph DIENER, Martin KOEHRMANN, Christian WEIMAR
	Co-Investigator(s)	Hsin-Chieh CHEN, Benedikt FRANK, Karim HAJJAR
	Study Coordinator(s)	Melanie DIETZOLD
University Hospital Frankfurt	Principal Investigator	Waltraud PFEILSCHIFTER
	Co-Investigator(s)	Ferdinand BOHMANN, Iris DIVE, Katharina FILIPSKI, Christian FOERCH, Roxane-Isabelle KESTNER, Matthias LORENZ, Jan Hendrik SCHAEFER, Alexander SEILER, Damla TAHTALI
	Study Coordinator(s)	Heike RAI
University Hospital of Ulm	Principal Investigator	Katharina ALTHAUS
	Co-Investigator(s)	Susanne MUELLER, Hermann NEUGEBAUER, Sebastian STOESSER, Sebastien STROH
	Study Coordinator(s)	Sabine RAUBOLD
University Medical Center Hamburg	Principal Investigator	Gotz THOMALLA
	Co-Investigator(s)	Christoph BECK, Bastian CHENG, Amir GOLSARI, Julia HOPPE, Anna C KRUTZELMANN, Julian SCHROEDER, Dieke VOGET
	Study Coordinator(s)	Dagmar OTTO

MEXICO ***Country Lead:*** Jorge VILLARREAL-CAREAGA

Site	Role	Team Member
Neurosciences Clinical Trials S.C.	Principal Investigator Co-Investigator(s) Study Coordinator(s)	Elmer Guillermo LOPEZ MEZA Karla Gabriela ALTAMIRANO BELTRAN, Claudia PEREZ CORONEL Wendy LOPEZ MEZA

NEW ZEALAND ***Country Lead:*** Peter Alan BARBER

Site	Role	Team Member
Auckland City Hospital	Principal Investigator Co-Investigator(s) Study Coordinator(s)	Peter Alan BARBER Neil ANDERSON, Mary BRENNAN, Nicole JENKINS, Justin KAO, Dominic TSE, Teddy WU Lily ZHAO

SPAIN ***Country Lead:*** Carlos MOLINA

Enrolled 50-99 patients

Site	Role	Team Member
Santa Creu and Sant Pau Hospital	Principal Investigator Co-Investigator(s) Study Coordinator(s)	Joan MARTÍ-FÀBREGAS Ignacio ARACIL- BOLAÑOS, Pol CAMPS-RENOM, Raquel DELGADO-MEDEROS, Sebastian FIGUEROA, Daniel GUISADO-ALONSO, Alejandro MARTÍNEZ-DOMEÑO, Luis PRATS-SÁNCHEZ, Manuel SIMÓN-TALERO, Javier SOTOCA Rebeca MARÍN

Site	Role	Team Member
Basurto Hospital	Principal Investigator Co-Investigator(s) Study Coordinator(s)	Maria del Mar FREIJO GUERRERO Borja AGUILERA, Laura AUZMENDI, Jose Maria FERNANDEZ, Maria del Carmen GIL ALZUETA, Sonia GONZALEZ, Juan Luis IDRO, Ana IKERNE, Ana Maria LORENZO GARCIA, Arancha SAINZ, Saul SILVARREY RODRIGUEZ Juan Manuel GARCIA SANCHEZ
Burgos University Hospital	Principal Investigator Co-Investigator(s)	Yolanda BRAVO ANGUIANO Monica BARTULOS IGLESIAS, Daniel PASCUAL CARRASCAL, Francisco Javier RODRIGUES PEGUERO, Jose Maria TREJO GABRIEL Y GALAN
Girona University Hospital	Principal Investigators Co-Investigator(s)	Maria del Mar CASTELLANOS RODRIGO, Joaquin SERENA Berta ALEMANY PERNA, Saima BASHIR, Irene BRAGADO, Cristina COLL, Ana COTS, Mar IRIDA LLORET VILLAS, Fabian MARQUEZ, Yolanda SILVA, Mikel TERCENO, Karol Enrique

		USCAMAITA, Cecile VAN EENDENBURG
	Study Coordinator(s)	Berta JORDAN, Martha KAZIMIERCZAK, Laura PARDO
Hospital del Mar	Principal Investigator	Jaume ROQUER
	Co-Investigator(s)	Elisa CUADRADO, Eva GIRALT, Jordi JIMENEZ CONDE, Angel OIS, Ana RODRIGUEZ, Rosa VIVANCO
	Study Coordinator(s)	Gemma ROMERAL
Hospital Donostia	Principal Investigator	Ana Maria DE ARCE BORDA
	Co-Investigator(s)	Noemi DIEZ GONZALEZ, Felix GONZALEZ LOPEZ, Maria Begona MARTINEZ PINEIRO, Maria Teresa MARTINEZ ZABALETA, Mikel TAINTA CUEZVA, Miren ZULAICA IJURCO
La Fe University Hospital	Principal Investigator	Aida LAGO
	Co-Investigator(s)	Gerardo FORTEA, Rogelio LOPEZ, Lluis MORALES-CABA, Jose Ignacio TEMBL
	Study Coordinator(s)	Patricia SAHUQUILLO
Miguel Servet Hospital	Principal Investigator	Javier MARTA-MORENO
	Co-Investigator(s)	Jorge ARTAL, Rocio CALDU, Ariadna FERNÁNDEZ, Maria SERAL-MORAL, Marta SERRANO
	Study Coordinator(s)	Herbert TEJADA MEZA
Vall d'Hebron Hospital	Principal Investigator	Carlos MOLINA
	Co-Investigator(s)	Sandra BONED, Jesus JUEGA, Marian MUCHADA, Noelia RODRIGUEZ
	Study Coordinator(s)	Estela SANJUAN

UNITED KINGDOM

Country Lead: James KENNEDY

Site	Role	Team Member
Addenbrooke's Hospital	Principal Investigator	Kayvan KHADJOOI
	Co-Investigator(s)	Denish CHANDRASENA
		Sarah CRISP, Nick EVANS, Barnaby FIDDES, Niamh HANNON, Derek HAYDEN, Helen HAYHOE, Siobhan KELLY, Eoin O'BRIEN, Elizabeth WARBURTON
	Study Coordinator(s)	Elaine AMIS, Charlotte FARRON, Jennifer MITCHELL
John Radcliffe Hospital	Principal Investigator	James KENNEDY
	Co-Investigator(s)	Gary FORD, Philip MATHIESON, Sara MAZZUCCO, George POPE, Ian RECKLESS, Ursula SCHULZ, Ku SHAH
	Study Coordinator(s)	Rachel TEAL
Luton & Dunstable University Hospital	Principal Investigator	Lakshmanan SEKARAN
	Co-Investigator(s)	Lankanatha ALWIS, Niaz MOHAMMAD, Johnson PHILIPPANATHAN, Duke PHIRI, Sakthivel SETHURAMAN
	Study Coordinator(s)	Margaret TATE
Northwick Park Hospital	Principal Investigator	David COHEN
	Co-Investigator(s)	Mudhar ABDUL-SAHEB, Lankanatha ALWIS, Raj BATHULA, Joe DEVINE, Silvie DOUBRAVSKA, Radim LICENIK, Mmua NGWAKO, Nabeela NISAR, Aravinth SIVAGNANARATNAM
	Study Coordinator(s)	Mushiya MPELEMBUE

Queen Elizabeth University Hospital	Principal Investigator	Keith MUIR
	Co-Investigator(s)	Barath CHERIPELLI, Jennifer ELLIOT, Xuya HUANG, Dheeraj KALLADKA, Fiona MORETON, Sankaranarayanan RAMACHANDRAN, Salwa EL TAWIL
	Study Coordinator(s)	Wilma SMITH
Royal Stoke University Hospital	Principal Investigator	Indira NATARAJAN
	Co-Investigator(s)	Jayan CHEMBALA, Christine ROFFE, Ranjan SANYAL, Anushka WARUSEVITANE, Janaka WEERATHUNGA
	Study Coordinator(s)	Racquel CARPIO
Royal United Hospital	Principal Investigator	Lukuman GBADAMOSHI
	Co-Investigator(s)	James CHOULERTON, Lindsey DOW, Helen NEWTON, Louise SHAW, Andrew STONE
	Study Coordinator(s)	Joanne AVIS, Suzanne LUCAS, Barbara MADIGAN
Southampton General Hospital	Principal Investigator	Nic WEIR
	Co-Investigator(s)	Pam CRAWFORD, Sue EVANS, James MARIGOLD, Emma WOOD
	Study Coordinator(s)	Imogen GARTRELL, Simon SMITH
University College Hospital	Principal Investigator	Richard PERRY
	Co-Investigator(s)	Gargi BANERGEE, Duncan WILSON
	Study Coordinator(s)	Azra BANARAS, Caroline WATCHURST

UNITED STATES

Enrolled 100 or more patients

Site	Role	Team Member
Guilford Neurological Associates	Principal Investigator	Pramod SETHI
	Co-Investigator(s)	Jindong XU, Yijun YAN
	Study Coordinator(s)	Rizwan SABIR
Benefis Hospitals Inc	Principal Investigator	Dennis DIETRICH
	Co-Investigator(s)	William HENNING
	Study Coordinator(s)	Laura ARMSTRONG, MegAnne CASEY, Veronica SCHAEFER

Enrolled 50-99 patients

Site	Role	Team Member
Buffalo General Medical Center	Principal Investigator	Marilou CHING
	Co-Investigator(s)	Christopher DELINE, Amit KANDEL, Robert SAWYER
	Study Coordinator(s)	Annemarie CRUMLISH, Dawn L. HOLLER
Houston	Principal Investigator	David CHIU

Methodist Hospital	Co-Investigator(s)	Donald BLEDSOE, Rajan GADHIA, Delmar IMPERIAL-AUBIN, Jason A. LEE, David MCCANE, Vivek MISRA, Eva MISTRY, Stacy MOYE, Haseeb RAHMAN, Abraham THOMAS, John VOLPI, Shannon WHITE
Northwestern Memorial Hospital	Principal Investigators	Mark ALBERTS, Richard BERNSTEIN
	Co-Investigator(s)	Fan CAPRIO, Philip CHANG, Chen LIN, Scott MENDELSON, Shyam PRABHAKARAN, Ilana RUFF TREIBER
	Study Coordinator(s)	Kathryn MUSKOVICH, Erin WYMORE
Cleveland Clinic	Principal Investigator	Irene KATZAN
	Co-Investigator(s)	Mahmoud AL-MASRY, Andrew BULETKO, Luzma CARDONA, Russell CEREJO, Esteban CHENG-CHING, Abeer FARRAG, Pravin GEORGE, Shazam HUSSAIN, Ahmed ITRAT, Seby JOHN, Zeshaun KHAWAJA, Mei LU, ShuMei MAN, Jason MATHEW, Johanna MORTON, Naresh MULLAGURI, Andrew RUSSMAN, Lakshmi SHANKAR, Lila SHEIKHI, Ather TAQUI, Tapan THACKER, Gabor TOTH, Ken UCHINO, Paul WASIELEWSKI, Dolora WISCO
	Study Coordinator(s)	Erin BYNUM, Vikram PUVENNA, Amy RICHMOND, Nancie TIGHE
UCSD Medical Center - Hillcrest Hospital	Principal Investigator	Dawn MEYER
	Co-Investigator(s)	Kunal AGRAWAL, Maysun ALI, Kevin ATTENHOFER, Nhu BRUCE, Jessica CHOE, Robert CLAYCOMB, Amy GUZIK, Lovella HAILEY, Thomas HEMMEN, Nabeel HERIAL, James HO, Branko HUISA, Kiet LOC, Abhishek LUNAGARIYA, Brett MEYER, Royya MODIR, Melissa MORTIN, Rajiv NARULA, William NEIL, David NGUYEN, Bruce OVBIAGELE, Mohsen PIRASTEHFAR, Hami RAMANI, Belma SADIKOVIC, Konrad SCHLICK, Pradeep SELVAN, Ajeet SODHI
	Study Coordinator(s)	Nancy KELLY, Brittney LEHMANN, Karen RAPP, Kathleen RICKES, Kristin WOODS

Site	Role	Team Member
Alexian Brothers Medical Center	Principal Investigator	Franklin MARDEN
	Co-Investigator(s)	Michele BEY, Phil GORELICK, Colleen HARRISON, Alkesh PATEL, Anna RAIMONDI, Ginger REILLY, Merrel REISS, Sanford SHERMAN, Theresa TERNA
	Study Coordinator(s)	Michele BEY, Elizabeth FOX (KIM)
Allegheny General Hospital	Principal Investigators	Hebah HEFZY, Ashis TAYAL
	Co-Investigator(s)	Beth BREMNER, Edward GETTINGS, Omar HAMMAD, Judy JAROUSE, Michael MARYNOWSKI, John O'NEILL, Ramnath RAMANATHAN, Laxmi SHAH, Arvind VENKAT, Crystal WONG, David WRIGHT
	Study Coordinator(s)	Vibha CHAUHAN, Gail LOVE, Melissa TIAN
Augusta Health	Principal Investigator	Robert MCMAHON
	Co-Investigator(s)	Roger GILDERSLEEVE
	Study Coordinator(s)	Rebecca CUTLIP

Augusta University Medical Center	Principal Investigator	Jeffrey SWITZER
	Co-Investigator(s)	Feroze AFZAL, Tia ARYAL, Askiel BRUNO, Hartmut GROSS, David HESS, Fenwick NICHOLS, Mihaela SALER, Shannon STEWART, Nabil WEES
	Study Coordinator(s)	Natalie BISHOP, Erin CHRISTENSEN, Brian CLOSE, Sneha JACOB, Julie JORDAN, Tawanna MASSENBERG, Kori WILLIAMS
Bon Secours St. Francis Medical Center	Principal Investigators	Chi-Kin NG, Amandeep SANGHA
	Co-Investigator(s)	Daniel ANGELI, Mudassar ASGHAR, Stacey EPPS
	Study Coordinator(s)	April CAMPBELL, Bonnie GRUBBS, Lavon HARRIS, Patricia LANE
Bon Secours St. Mary's Hospital	Principal Investigators	Chi-Kin NG, Amandeep SANGHA, Alan SCHULMAN
	Co-Investigator(s)	Matthew BOYCE, Robert COHEN, Rachel DONALDSON, Supakunya EDMONSON, Daniel HARDY, Kim HARRIS, Francis MCGEE, John O'BANNON, Mary RANSOM, Noma REHMAN, Thomas SMITH, Brian STUCKI, Robert WHITE, John WITTMAN
	Study Coordinator(s)	April CAMPBELL, Bonnie GRUBBS, Ileana KINNIE, Tamika WALTHOUR
Boston Medical Center	Principal Investigators	Carlos S. KASE, Jose Rafael ROMERO
	Co-Investigator(s)	Hugo APARICIO, Viken BABIKIAN, David GREER, Thanh NGUYEN
	Study Coordinator(s)	Saleh ABBAS, Helena LAU, Matthew OGRODNIK
Carolinas Medical Center	Principal Investigators	Phaniraj IYENGAR, Sanjay IYER
	Co-Investigator(s)	Andrew ASIMOS, Aristides CHACONAS, Joseph GIORDANO, Anita HOYT, Swatiben PATEL, Darla STEVENS, Mary TRAYNOR
	Study Coordinator(s)	Nicol BRANDON, Anja DAILEY, Megan KRAMER, Marlow PRICE, Blondene ROBINSON
Cedars-Sinai Medical Center	Principal Investigator	Shlee SONG
	Co-Investigator(s)	Oana DUMITRASCU, Duy LE, Patrick LYDEN, Fernando MAYORBASTO, Mani NEZHAD, Konrad SCHLICK, Mohammad SHAFIE, Yilin SHEK
	Study Coordinator(s)	Peter Chang KIM
Cleveland Regional	Principal Investigator	Gaurang PALIKH
	Study Coordinator(s)	Rayna EDWARDS, Amelia REYNOLDS
Dartmouth-Hitchcock Medical Center	Principal Investigator	Timothy LUKOVITS
	Co-Investigator(s)	Robin CLARK-ARBOGAST, Richard GODDEAU, Jason JOHNS, Vijay RENGA, Diana ROJAS-SOTO
	Study Coordinator(s)	Charlotte JEFFREYS, Margaret NOTESTINE
Desert Regional Medical Center	Principal Investigators	Luis ARANGUA, Ajeet SODHI, M. Asif TAQI
	Co-Investigator(s)	Robert CLAYCOMB, Glenn Mark FISCHBERG, XIAO-TANG KONG, Andrew NIK, Tami SALAHUDDIN, Nicholas TARLOV
	Study Coordinator(s)	Yasir KHAN
Eisenhower Medical Center	Principal Investigator	Bishoy LABIB
	Co-Investigator(s)	NAMIN-REZA SALARI
	Study Coordinator(s)	Moheib FAHEIM, Kamel KAMEL, Dianna LABIB
Ellis Hospital	Principal Investigator	Kejian TANG
	Co-Investigator(s)	Abdelhakim DINAR, Francisco GOMEZ
	Study Coordinator(s)	Margie PANETTA

Evanston Hospital	Principal Investigators	Rima DAFER, Archie ONG
	Co-Investigator(s)	Fulvio GIL, Deb LYNCH, Steven MEYERS, Richard MUNSON
	Study Coordinator(s)	Julie ANDERSON, Sherri LOEB, Mary-Lou MAHER, Stasia Diana ROUSE
Fletcher Allen Hospital of Vermont	Principal Investigator	Mark GORMAN
	Co-Investigator(s)	Christopher COMMICHAU
	Study Coordinator(s)	Cathy GREGORY, Sharon KENNEY
Forsyth Medical Center	Principal Investigator	Chere CHASE
	Co-Investigator(s)	Benjamin ANYANWU, Tamas BATHORY, Paul BURKE, Ashley CAMPBELL, Brittney CAMPBELL, Tarek DAKAKNI, Veronica HEATH, Howard KRAFT, Eric MELVIN, Olukayode ONASANYA, Charles STEWART
	Study Coordinator(s)	Debra NORWOOD
Great Falls Clinic Hospital	Principal Investigator	Dennis DIETRICH
	Study Coordinator(s)	Laura ARMSTRONG
Harborview Medical Center	Principal Investigator	David TIRSCHWELL
	Co-Investigator(s)	Kyra BECKER, Claire CREUTZFELDT, Rizwan KALANI, Marlan KAY, Sandeep KHOT, Will LONGSTRETH, Sara SCHEPP, Jon WEINSTEIN
	Study Coordinator(s)	Allison KUNZE, Glenn SCHUBERT, Patricia TANZI
Hartford Hospital	Principal Investigator	Louise MCCULLOUGH
	Co-Investigator(s)	Catherine HOSLEY, Lauren SANSING, Isaac SILVERMAN
	Study Coordinator(s)	Martha AHLQUIST
Henrico Doctors' Hospital - Forest Campus	Principal Investigator	Alan SCHULMAN
	Co-Investigator(s)	Matthew BOYCE, Daniel HARDY, George HARRIS, John O'BANNON, Stephen THURSTON, John WITTMAN
	Study Coordinator(s)	Melanie JOHNSON, Ileana KINNIE, Tamika WALTHOUR
Hollywood Presbyterian Medical Center	Principal Investigator	Tamika BURRUS
	Co-Investigator(s)	Philip ABDOUSH, Christian GALICIA
	Study Coordinator(s)	Laurie BERNDT, Nancy RAPPARD
Ingalls Memorial Hospital	Principal Investigator	Engin YILMAZ
	Co-Investigator(s)	Tonya FULLER
	Study Coordinator(s)	Deborah LAWRENCE
Jersey Shore University Medical Center	Principal Investigator	Stephen MARTINO
	Co-Investigator(s)	Alan DEUTSCH, John FITZPATRICK, Paul GILSON, Paul KOSTOULAKOS, Mary SEDAROUS, Edward SPELLMAN
	Study Coordinator(s)	Fiona COLLINS, AnneMarie DETORO, Jennifer ORTIZ
JFK Medical Center	Principal Investigators	Jawad KIRMANI, Spozhmy PANEZAI
	Co-Investigator(s)	Jaskiran BRAR, Daniel KORYA, Ashish KULHARI, Siddhart MEHTA, Mohammad MOUSSAVI, Aashish PATEL, Amrinder SINGH, Sara STRAUSS
	Study Coordinator(s)	Briana DECARVALHO
John Muir Medical Center - Concord Campus	Principal Investigator	Ray STEPHENS
	Co-Investigator(s)	Leslie GILLUM, Steven SCHADENDORF
	Study Coordinator(s)	Janice STEPHENS
John Muir Medical	Principal Investigator	Ray STEPHENS

Center - Walnut Creek Campus	Co-Investigator(s)	Robert ALGAR, Leslie GILLUM, Steven HOLTZ, Janet LIN, Steven SCHADENDORF, Brad VOLPI
	Study Coordinator(s)	Janice STEPHENS
Kaiser Permanente Los Angeles Medical Center	Principal Investigator	Zahra AJANI
	Co-Investigator(s)	Sierra FORD, Prasanth MANTHENA, Navdeep SANGHA, Theresa SEVILIS, Emanuela SOFRONI
	Study Coordinator(s)	Nancy FLORES, Raymond KIM, Catherine LUI, Vena SOBHAWONGSE, Grace TU, Kim TURNER, Cristina VALDOVINOS
Lehigh Valley Hospital	Principal Investigators	John CASTALDO, Frank-Chen ZHANG
	Co-Investigator(s)	Gary CLAUSER, Adam EDWARDS, Mohammed EL-HUNJUL, Yevgeniy ISAYEV, Megan LEARY, Yuebing LI, Dev MEHTA, Christopher MELINOSKY, Kenneth REICHENBACH, Hermann SCHUMACHER, Lorraine SPIKOL, Jay VARRATO, Hussam YACOUB
	Study Coordinator(s)	Carol FOX, Leighanne HARTMAN, Terry KLOIBER, Susan NABHAN
Los Robles Hospital Medical Center, Thousand Oaks	Principal Investigator	M. Asif TAQI
	Co-Investigator(s)	Sajid SURIYA
Loyola University Medical Center	Principal Investigator	Michael SCHNECK
	Co-Investigator(s)	Jose BILLER, Lisa MILLSAP, Sarkis MORALES-VIDAL
	Study Coordinator(s)	Tara BERNIER, Linda CHADWICK, Katelynn PRODOEHL
Maimonides Medical Center	Principal Investigator	Steven RUDOLPH
	Co-Investigator(s)	Susan LAW, Alina RABINOVICH
	Study Coordinator(s)	Holly MORHAIM
Manatee Memorial Hospital	Principal Investigator	W. Alvin MCELVEEN
	Co-Investigator(s)	Jane BESEN, Ralph GONZALEZ
	Study Coordinator(s)	Laurie EMMERT, Ericka MARINO, Vickie ROMAN
Mayo Clinic	Principal Investigator	Maria AGUILAR
	Co-Investigator(s)	Dan CAPAMPANGAN, Bart DEMAERSCHALK, David DODICK, Timothy INGALL, Terri KIERNAN, Joyce LEE-IANNOTTI, Bert VARGAS, Holly YANCY
	Study Coordinator(s)	Erica BOYD
Mercy Health Saint Mary's	Principal Investigator	Muhammad FAROOQ
	Co-Investigator(s)	Christopher GOSHGARIAN, Amy GROENHOUT, Bradley HAVEMAN-GOULD, Jiangyong MIN
	Study Coordinator(s)	Stacy L. SMITH
Mercy Hospital (Springfield, MO)	Principal Investigator	Robert S. DUFF
	Co-Investigator(s)	Emily CROUSE, Robert MEDLEY, Darwin RAMIREZ-ABREU
	Study Coordinator(s)	Linda THOMPSON
Mercy Hospital (St. Louis, MO)	Principal Investigators	Judd JENSEN, William LOGAN
	Co-Investigator(s)	Marnie DONOHOO, Barbara GREEN, David REMPE, Mary WILCOX
Mercy Hospital	and Medical	

Principal Investigator	Jeffrey KRAMER	Susan VAUGHAN
Co-Investig		

Center	Study Coordinator(s)	Amy-Leigh DAVIS, Elonia MARTIN
Mercy Hospital of Buffalo	Principal Investigator	Catalina IONITA
	Co-Investigator(s)	Lee GUTERMAN, Amy HEYDEN, Peterkin LEE-KWEN, Lorianne PEREIRA
	Study Coordinator(s)	Cheryl CONOVER, Shirley DUANE, Nicole ERNST, Kathy PARKES
MetroHealth Medical Center	Principal Investigator	Joseph HANNA
	Co-Investigator(s)	Michael BAHNTGE, Boris GARBER, Jon SCHROCK, Sandra WERNER, Marc WINKELMAN
	Study Coordinator(s)	Dana COOK
Miami Valley Hospital	Principal Investigator	Bradley JACOBS
	Co-Investigator(s)	Jeri BRAUNLIN, Esteban CHENG-CHING, Ahmed FATHY, Jacob KITCHENER, Bryan LUDWIG, Elizabeth MARRIOTT, Robb SNIDER, John TERRY
	Study Coordinator(s)	Angela SHOEN
Mission Hospital Memorial Campus	Principal Investigator	Reid TAYLOR
	Co-Investigator(s)	Cindy BENTON, Robin JONES, Jeanette LARSON, Seth LARSON, Rodney LEACOCK, Margaret PERKINS, Alex SCHNEIDER, Nora-Mae-Woolie WISHAM
	Study Coordinator(s)	Tracy NANNEY
Mount Sinai St. Luke's	Principal Investigator	Ji CHONG
	Co-Investigator(s)	Carolyn BROCKINGTON, Elissa FORY, John NASRALLAH, Christopher TEGTMEYER
	Study Coordinator(s)	Larissa BONILLA, Iris HARRIS
Mount Sinai West	Principal Investigator	Ji CHONG
	Co-Investigator(s)	Carolyn BROCKINGTON, Elissa FORY, David LIEBESKIND, John NASRALLAH, Shanna PATTERSON, Christopher TEGTMEYER
	Study Coordinator(s)	Larissa BONILLA, Iris HARRIS, Renata HARTUNG
Northern Westchester Hospital	Principal Investigator	Akira TODO
	Co-Investigator(s)	James DWYER, Miodrag VELIKOVIC
	Study Coordinator(s)	Jodi BELLANTONI
NorthShore Glenbrook Hospital	Principal Investigators	Rima DAFER, Archie ONG
	Co-Investigator(s)	Fulvio GIL, Deb LYNCH, Steven MEYERS, Richard MUNSON, Archie ONG, Mark RUBIN
	Study Coordinator(s)	Julie ANDERSON, Sherri LOEB, Mary-Lou MAHER, Stasia Diana ROUSE
NYP Weill Cornell Medical Center	Principal Investigator	Babak NAVI
	Co-Investigator(s)	Sunday CLARK, Michael CRIMMINS, Barry CZEISLER, Neha DANGAYACH, Jordan DUBOW, Matthew FINK, Brandon FOREMAN, Adam GANZMAN, Dara JAMIESON, Hooman KAMEL, Benjamin KUMMER, Richard LAPPIN, Dana LEIFER, Michael LERARIO, Atul MANGLA, Saad MIR, Sammy PISHANIDAR, Daniel SACCHETTI, Joseph SAFDIEH, Alan SEGAL, Jennifer SEVUSH, Rahul SHARMA, Natalie WEATHERED, Halina WHITE, Christopher ZAMMIT, Yi ZHANG
	Study Coordinator(s)	Ryna MATHIAS, Blagovest NIKOLOV, Entila XHORI
OSU Wexner	Principal Investigators	Reza BEHROUZ, Michel TORBEY

Medical Center	Co-Investigator(s)	Bryan GOUGH, Diana GREENE-CHANDOS, Noah GROSE, Deepak GULATI, Omar HUSSEIN, Shraddha MAINALI, Andrew SLIVKA, Karina WOODLING
	Study Coordinator(s)	Julie AGRIESTI, Laura BUCHWALDER, Sarah KOCH, Areej TARIQ
Palmetto Health Richland	Principal Investigator	Souvik SEN
	Co-Investigator(s)	Xiao Michelle ANDROULAKIS, Tom FABER, Bill GERARD, David HAMMETT, Priyantha HERATH, Te-Long HWANG, Sonal MEHTA, Davit MRELASHVILI, Paisith PIRIYAWAT, James SELPH, Swamy VENKATESH
	Study Coordinator(s)	Kyrra HALL, Evelyn KENNEDY, Shelley LAIRD
Park Nicollet Methodist Hospital	Principal Investigators	John DAVENPORT, Matthew OSTRANDER
	Co-Investigator(s)	Krista MELVIN
	Study Coordinator(s)	Dianna MARTIN
Parkland Hospital	Principal Investigator	Mark JOHNSON
	Co-Investigator(s)	Mark ALBERTS, Chirantan BANERJEE, Paul HANSEN, Yathish HARALUR SREEKANTAIAH, Rashedul HASAN, Jessica LEE, Alejandro MAGADAN, Tami SALAHUDDIN, Ty SHANG, Fazeel SIDDIQUI, Worthy WARNACK
	Study Coordinator(s)	Jan CAMERON-WATTS, Naomie GATHUA
Parkview Regional Medical Center	Principal Investigator	Fen-Lei CHANG
	Co-Investigator(s)	Ahmed AL HAMDA, Thomas BANAS, Madhav BHAT, Marlene BULTEMEYER, TJ CURFMAN, Ajay GUPTA, Atiya KHAN, Jessica KNIRK, Paul LATER, Nils MUELLER-KRONAST, James STEVENS
	Study Coordinator(s)	Sue BUDZON, Jeanne CAROL
Penn State Hershey Medical Center	Principal Investigator	Raymond REICHWEIN
	Co-Investigator(s)	Natalie AUCUTT-WALTER, Kerstin BETTERMANN, Mohammad EL-GHANEM, Prabhu EMMADY, David ERMAK, Michelle FISCHER, Kevin GARDNER, David GOOD, Muhammad IBRAHIMI, James LEAMING
	Study Coordinator(s)	Kimbra HITZ
Presence Saint Joseph Medical Center	Principal Investigator	Aamir BADRUDDIN
	Co-Investigator(s)	Kaiz ASIF, Sherman CHEN, Jennifer JOHANSEN, Dhru PANDYA
	Study Coordinator(s)	Lynn MCLENNAN, Laura PAGANESSI
Providence Portland Medical Center	Principal Investigators	Amit KANSARA
	Co-Investigator(s)	Cheri BELLING, Archit BHATT, Cesar David CACERES, Diane CLARK, Sandy DANCER, Amandeep DHILLON, Braidon FREEMAN, Lilith JUDD, Theodore LOWENKOPF, Bethany MCCLENATHAN, Paula PRINCE, John ROBISON, Andrew RONTAL, Tomoko SAMPSON, Biggya SAPKOTA, Tanya SCHEIBE-MIREK, Lisa YANASE, John ZURASKY
	Study Coordinator(s)	Emily JOHNSON, Darren LARSEN, Alexis YOUNG, Courtney ZERIZEF
Providence Sacred Heart Medical Center	Principal Investigator	Madeleine GERAGHTY
	Co-Investigator(s)	Kathryn AL-HAFIAN, Esther RAWNER
	Study Coordinator(s)	Beth AARON, Truman CANTRELL

Providence St.	Principal Investigators	Amit KANSARA

Vincent Medical Center	Co-Investigator(s)	Cheri BELLING, Archit BHATT, Cesar David CACERES, Diane CLARK, Sandy DANCER, Amandeep DHILLON, Braidon FREEMAN, Lilith JUDD, Theodore LOWENKOPF, Bethany MCCLENATHAN, Paula PRINCE, John ROBISON, Andrew RONTAL, Tomoko SAMPSON, Biggya SAPKOTA, Tanya SCHEIBE-MIREK, Lisa YANASE, John ZURASKY
	Study Coordinator(s)	Emily JOHNSON, Darren LARSEN, Alexis YOUNG, Courtney ZERIZEF
Rochester General Hospital	Principal Investigators	Scott BURGIN, Kelly MATMATI
	Co-Investigator(s)	Jeffrey BURDETTE, Candice JOB, Tammy MAHER, Celia MCINTOSH, Lawrence SAMKOFF, Kathleen SCHINDLER
	Study Coordinator(s)	Cheryl WEBER
Ronald Reagan UCLA Medical Center	Principal Investigator	Sidney STARKMAN
	Co-Investigator(s)	Linda ABCEDE, Peter ADAMCZYK, Allison ARCH, Mersedeh BAHRHOSSEINI, Mateo CALDERON-ARNULPHI, Arun CHHABRA, Chuan Frances FAN ,Lindsey FRISCHMANN, Nathan GAINES, Jason HINMAN, Josephine HUANG, Doojin KIM, Conrad LIANG, David LIEBESKIND, Konark MALHOTRA, Neil MALUSTE, Michael MCMANUS, Royya MODIR, Kwan NG, Alireza NOORIAN, May NOUR, Bruce OVBIAGELE, Lucas RAMIREZ, Neal RAO, Rado RAYCHEV, Melissa REIDER-DEMER, Jeffrey SAVER, Latisha SHARMA, Sunil SHETH, Parampreet SINGH, Sarah SONG, XianNan TANG, Aaron TANSY, Jason TARPLEY, Anita TIPIRNENI, Anil YALLAPRAGADA
	Study Coordinator(s)	Ileana GRUNBERG, Judy GUZY
Saint Barnabas Medical Center	Principal Investigators	Danielle HASKINS, Deviyani MEHTA
	Study Coordinator(s)	Kelly ROE
Saint Thomas West Hospital	Principal Investigator	Michael KAMINSKI
	Co-Investigator(s)	Robert FALLIS, James FLEMING, Frank LAFRANCHISE, Subir PRASAD, Timothy UPCHURCH
	Study Coordinator(s)	Diana COMAN, Marie PAYNE
San Antonio Community Hospital	Principal Investigator	Faisal QAZI
	Co-Investigator(s)	James ROSENTHAL
	Study Coordinator(s)	Satish SOOD
Sarasota Memorial Hospital	Principal Investigator	Mauricio CONCHA
	Co-Investigator(s)	Julio CANTERO, Kyle RUFFING, Leonie VAN PASSEL
	Study Coordinator(s)	Daniel HERNANDEZ, Jeanette WILSON
Scripps Mercy Hospital San Diego	Principal Investigator	Royya MODIR
	Co-Investigator(s)	Kunal AGRAWAL, Maysun ALI, Kevin ATTENHOFER, Robert CLAYCOMB, Thomas HEMMEN, Nabeel HERIAL, James HO, Branko HUISA, Abhishek LUNAGARIYA, Brett MEYER, Dawn MEYER, Rajiv NARULA, David NGUYEN, Lindsay OLSON-MACK, Mohsen PIRASTEHFAR, Hami RAMANI, Belma SADIKOVIC, Konrad SCHLICK, Pradeep SELVAN, Gilda TAFRESHI
	Study Coordinator(s)	Brittney LEHMANN, Karen RAPP, Kathleen RICKES, Kristin WOODS
Sentara Norfolk	Principal Investigator	Richard ZWEIFLER

General Hospital	Co-Investigator(s)	Pamela EVANS, Bruce LO, Renee-Scott WALKER
	Study Coordinator(s)	Samantha BRIGHT, Stacey CUMMINGS, Pam HOLLSTEN, Ana ROLDAN
Southern Illinois University Memorial Medical Center	Principal Investigator	Fazeel SIDDIQUI
	Co-Investigator(s)	Tamer ABDELHAK, Nicole ATWOOD, Rodger ELBLE, Sushant KALE, Sajjad MUEED, Valeriy SABODASH, Amita SINGH, Zeng WANG
	Study Coordinator(s)	Sally FRITZ, Dolly KELLEY
Sparrow Hospital	Principal Investigator	Syed HUSSAIN
	Co-Investigator(s)	Vibhav BANSAL, Vishal JANI, Mounzer KASSAB, Malathi RAO, Anmar RAZAK, Gautam SACHDEVA, Adan SAFDAR
	Study Coordinator(s)	Erin SHELL
St. Anthony Hospital	Principal Investigator	Mark MURRAY
	Co-Investigator(s)	Christy CASPER, Bill COPLIN, Alex GRAVES, Rick SMITH
	Study Coordinator(s)	Sheryl GIAMBARTOLOMEI
St. David's Medical Center	Principal Investigators	Kent ELLINGTON, Johanna MORTON, Angel PULIDO, James WALDRON
	Co-Investigator(s)	Hana AUBRECHTOVA, Ray BOGITCH, Elizabeth CARROLL, Albert HORN, David MORLEDGE
	Study Coordinator(s)	Sergio AVILA-MICHEL, Kaelyn KAPPELER, Karissa MORTON
St. John's Hospital	Principal Investigator	Fazeel SIDDIQUI
	Co-Investigator(s)	Rodger ELBLE, Sushant KALE, Sajjad MUEED, Valeriy SABODASH, Amita SINGH, Zeng WANG
	Study Coordinator(s)	Sally FRITZ, Dolly KELLEY
St. Jude Medical Center	Principal Investigator	Stephen WALDMAN
	Co-Investigator(s)	Kiran BATH, Anthony CIABARRA, Johnson MOON
	Study Coordinator(s)	Sheraz MOSSA
St. Louis University Hospital	Principal Investigator	Salvador CRUZ-FLORES
	Co-Investigator(s)	Aninda ACHARYA, Amer ALSHEKHLEE, Charles CALLISON, Tagann CHAISAM, Randall EDGELL, Eli FEEN, Sushant KALE, Jacob KITCHENER, Sonal MEHTA, Paisith PIRIYAWAT, Nirav VORA
	Study Coordinator(s)	Susan BROWN, Eve HOLZEMER
Strong Memorial Hospital	Principal Investigators	Adam KELLY, David REMPE
	Co-Investigator(s)	Curtis BENESCH, Scott BURGIN, Ania BUSZA, Justin CHANDLER, Gaurav DIGHE, Fulvio GIL, Todd HOLMQUIST, Michael MANCHAK, Anthony NOTO, Jennifer RICHARD, Jorge RISCO, Bogachan SAHIN, Eugene SCHARF, Roople UNIA
	Study Coordinator(s)	Heather FINLEY, Dawn MARTIN
Summa Akron City Hospital	Principal Investigator	Susana BOWLING
	Co-Investigator(s)	Mary-Colleen BHALLA, Joao GOMES, Kristy JACOBSON, Kirk STIFFLER, Scott WILBER
	Study Coordinator(s)	Kathy CUNNINGHAM, Linette MERCER, Robin ROTH, Rachelle SCHARSU, Patricia WOOD
SUNY Upstate	Principal Investigator	Julius-Gene LATORRE

Medical University	Co-Investigator(s)	Ahmad AHMAD, Sanam ANWER, Ilya BRAGIN, Elnour ELWALEED, Ziad EL-ZAMMAR, Anna Monica FERMIN, Shahnawaz KARIM, Michael MENDOZA, Mubashir PERVEZ, Wyssem RAMDANI, Rajbeer SANGHA, Elena SCHMIDT
	Study Coordinator(s)	Alisha HARTWELL, Muhammad IQBAL, Iulia MOVILEANU,
Sutter Medical Center	Principal Investigators	Wendy BROWN, Mohammad-Asim MAHMOOD
	Co-Investigator(s)	Peter ADAMCZYK, Richard ATKINSON
	Study Coordinator(s)	Barbara WELCHER
Sutter Memorial Hospital	Principal Investigator	Wendy BROWN
	Co-Investigator(s)	Richard ATKINSON
	Study Coordinator(s)	Barbara WELCHER
Sutter Roseville Medical Center	Principal Investigators	Wendy BROWN, Mohammad-Asim MAHMOOD
	Co-Investigator(s)	Richard ATKINSON
	Study Coordinator(s)	Teresa CARTER, Michele GUILLEN
Swedish Medical Center	Principal Investigator	Ira CHANG
	Co-Investigator(s)	Russell BARTT, Christian BURRELL, Christopher FANALE, Ananda FINE, Judd JENSEN, Emily LAMPE, Kathryn MCCARTHY (LEONARD), Amy NIEBERLEIN (LARSON), Robert PRATT, Stacy SHINE, Byron Rod SPENCER, Rebecca VANVLIET, Jeffrey WAGNER, Adrienne WALSH, Michelle WHALEY
	Study Coordinator(s)	Paula FISK, Tyler IRANI, Lenden NEEPER, Alicia NOVAK, Jeanne SWANSON
Texas Health Presbyterian Hospital Dallas	Principal Investigator	Samir SHAH
	Co-Investigator(s)	Nicholas ABSALOM, Karen SACKS
	Study Coordinator(s)	Shelley LONG, Michelle MORGAN
The Mount Sinai Hospital	Principal Investigator	Jesse WEINBERGER
	Co-Investigator(s)	Yu-Feng-Yvonne CHAN, Deborah HOROWITZ, Frank KIM, Aviva LUBIN, Kara SHEINART, Stanley TUHRIM, Qingliang WANG
	Study Coordinator(s)	Sandra AUGUSTINE
The Queen's Medical Center	Principal Investigators	Douglas FRANZ, Rony SALEM, Douglas VALENTA
	Co-Investigator(s)	Matthew KOENIG, Kazuma NAKAGAWA
	Study Coordinator(s)	Denise DITTRICH, Lyle OSHITA, Tina ROBERTSON, Tracy STERN
UCSD Health La Jolla	Principal Investigator	Dawn MEYER
	Co-Investigator(s)	Kunal AGRAWAL, Maysun ALI, Kevin ATTENHOFER, Nhu BRUCE, Jessica CHOE, Robert CLAYCOMB, Amy GUZIK, Lovella HAILEY, Thomas HEMMEN, Nabeel HERIAL, James HO, Branko HUISA, Kiet LOC, Abhishek LUNAGARIYA, Brett MEYER, Royya MODIR, Melissa MORTIN, Rajiv NARULA, William NEIL, David NGUYEN, Bruce OVBIAGELE, Mohsen PIRASTEHFAR, Hami RAMANI, Belma SADIKOVIC, Konrad SCHLICK, Pradeep SELVAN, Ajeet SODHI
	Study Coordinator(s)	Nancy KELLY, Brittney LEHMANN, Karen RAPP, Kathleen RICKES, Kristin WOODS
UF Health	Principal Investigator	Scott SILLIMAN

Jacksonville	Co-Investigator(s)	Nader ANTONIOS, Ryan CROOKS, Marianne DE LIMA, Mary-Ann FARES, Imran FAROOQUI, Constance KATSAFANAS, Zeshaun KHAWAJA, Somphanh KHOUSAKOUN, Shannon LABOY, Sherif MAKAR, Robert MANNEL, Fatima MILFRED, Omar MOORE, Raid OSSI, Wally Jamie PLANTE, Fatoumata SAKHO, Adil ZIA
	Study Coordinator(s)	Judy BULACAN, Rhonda CALHOUN, Jennifer ROBERTS, Mary STEGMAIER
UF Health Shands Hospital	Principal Investigator	Anna KHANNA
	Co-Investigator(s)	Ganesh ASAITHAMBI, Julie BERTHY, Haitham DABABNEH, Scott DELLORSO, Waldo GUERRERO, Paul MACDONALD, Katharine MASKAS, Walter MORGAN, Nandakumar NAGARAJA, Arash NAZIRIPOUR, Swetha RENATI, Christian ROSADO, Vishnumurthy SHUSHRUTHA HEDNA, Michael SMITH, Arnaldo VELEZ, Michael WATERS, Melissa WEAVER, Christina WILSON, Jindong XU, Teddy YOUN
	Study Coordinator(s)	Rosie KIZZA, Teresa LYLES, Stacy MCCOMBS, Stacy MERRITT, David PARFITT, Sonisha WARREN
UMASS Memorial Medical Center	Principal Investigator	Majaz MOONIS
	Co-Investigator(s)	Richard GODDEAU, Adalia JUN-O'CONNELL
	Study Coordinator(s)	Melissa ADAMS, Barbara GLIDDEN
University of Alabama Hospital	Principal Investigators	Andrei ALEXANDROV, Toby GROPEN, Gyanendra KUMAR
	Co-Investigator(s)	Karen ALBRIGHT, Asad CHAUDHARY, Michael LYERLY, Andrey SAMAL, Kara SANDS, Danny TKATCH
	Study Coordinator(s)	Brandie CLINE, Melissa GAZI, Lynn MERRITT, April SISSON
University of Colorado Hospital	Principal Investigator	Jennifer SIMPSON
	Co-Investigator(s)	David CASE, Christy CASPER, Dana COUTTS, Alexander GRAVES, William JONES, Pearce KORB, Michelle LEPPERT, Robert NEUMANN, Daniel PASTULA, Sharon POISSON, Angel PULIDO, Daniel VELA DUARTE, Matthew WEST
	Study Coordinator(s)	April BRYANT, Marissa HUDAK, Kaaren LINDSAY, Alexander STEIN, Ildiko TOROK
University of Illinois Hospital	Principal Investigators	Aslam KHAJA, Neelofer SHAFI, Fernando TESTAI
	Co-Investigator(s)	Phil GORELICK, Rebbeca GRYSIEWICZ, Laura PEDELTY, Fernando TESTAI
	Study Coordinator(s)	Maureen HILLMANN
University of Iowa Hospitals & Clinics	Principal Investigator	Harold ADAMS
	Co-Investigator(s)	Salman AL JERDI, Sami AL KASAB, Sudeepta DANDAPAT, Patricia DAVIS, Michael FROEHLER, Waldo GUERRERO, Emily JAKSICH, Enrique LEIRA, Kaustubh LIMAYE, Jeffrey MILLER, Nandakumar NAGARAJA, Santiago ORTEGA-GUITERREZ, Connie PIEPER, Edgar SAMANIEGO, Ali SHEHARYAR, Allison VOSS
	Study Coordinator(s)	Heena OLALDE, Jeri SIEREN
University of Louisville Hospital	Principal Investigators	Wei LIU, Anand VAISHNAV
	Co-Investigator(s)	Alex ABOU-CHEBL, Kerri REMMEL, Jignesh SHAH, Vincent TRUONG, Michael WILDER

	Study Coordinator(s)	Ann JERDE
University of North Carolina	Principal Investigator	Natalie AUCUTT-WALTER
	Co-Investigator(s)	Aaron ABATE, Anne BECKWITH, Octavio DE MARCHENA, David HUANG, Anahit MEHRABYAN, Leonardo MORANTES, Matthew OSTRANDER, Matthew SMITH, Michael WANG, Susan WILSON
	Study Coordinator(s)	Sierra MARINO, Roxanne POOLE
University of Washington Medical Center	Principal Investigator	David TIRSCHWELL
	Co-Investigator(s)	Claire CREUTZFELDT, Rizwan KALANI, Marlan KAY
	Study Coordinator(s)	Allison KUNZE, Wesley PLINKE, Glenn SCHUBERT, Patricia TANZI
University of Wisconsin University Hospital	Principal Investigators	Jim SVENSON, Natalie WHEELER
	Co-Investigator(s)	Eric ADELMAN, Azam AHMED, Tom AUFDERHEIDE, Edward-Luke BRADBURY, Marcus CHACON, Jamie ELLIOTT, Azita HAMEDANI, Matthew JENSEN, Krishna MYLAVARAPU, Justin SATTIN, Erick TARULA
	Study Coordinator(s)	Travis DORAN, Ashley HARRIS, Stephanie WILBRAND
UT Southwestern Zale Lipshy University Hospital	Principal Investigator	Mark JOHNSON
	Co-Investigator(s)	Mark ALBERTS, Mehari GEBREYOHANNAS, Jessica LEE, Alejandro MAGADAN, Ty SHANG
	Study Coordinator(s)	Jan CAMERON-WATTS, Naomie GATHUA
UVA Medical Center	Principal Investigator	Nina SOLENSKI
	Co-Investigator(s)	Leah ACOSTA, James ADDINGTON, Jimmy BERTHAUD, Halley BRIGLIA, Michael BROGAN, Michelle BROWN, Joseph CARRERA, Micaela CHATMAN, Christina CHEE, Nicole CHIOTA-MCCOLLUM, Allison CROWELL, Jason CROWELL, Bryan CUPKA, Alex DALRYMPLE, Maria DIAZ-ORDONEZ, Stephen DONAHUE, Byran ECKERLE, Matthew EHRLICH, Matthew ELLIOTT, Erin FOFF, Kaanchan GANGAL, Daryl GRESS, Christopher GROTH, Rahul GUHA, Amy GUZIK, Kelly GWATHMEY, Clark HALEY, Holly HENSLEY-JUDGE, Zsofia HOLE, Jasmin JO, Michelle JOHANSEN, Karen C. JOHNSTON, Sarah JONES, Kiran KANTH, Scott KOHLER, Noah KOLB, Greg KUHLMAN, David LAPIDES, Lauren MAHONEY, Shaneela MALIK, Sneha MANTRI, Matthew MCCONNELL, Mark MCDONALD, Prachi MEHNDIRATTA, Barnett NATHAN, Kathryn NEVEL, Whitney POLLOCK, Ryon POSTON, Surabhi RANJAN, Jeffrey RATLIFF, Chad SAUNDERS, Reza SEYEDSADJADI, Mohamed SHARABY, Sherita SMITH, Brian SORACE, Andrew SOUTHERLAND, Mohammad SUNBULLI, Joanna SUSKI, Lauren TALMAN, David TAPLINGER, Jennie TAYLOR, Liana THEROUX, Sarah TISEL, Lisa TORAN, Christopher VACHON, Hua WANG, Melanie WARD, Bradford WORRALL, Julie ZHOU
	Study Coordinator(s)	Theresa ALTHERR, Tracey BLOUNT, Amy FANSLER, Colleen HARMAN, Julia KRUPA, Claire McKinley
Vanderbilt	Principal Investigator	Howard KIRSHNER

University Hospital	Co-Investigator(s)	Mark BAKER, Brandi FRENCH, Ajay GUPTA, Rishi GUPTA, Lisa HERMANN, Shilpi MITTAL, Anne O'DUFFY, Derek RIEBAU, Eli ZIMMERMAN
	Study Coordinator(s)	Diane BROWN, Abbie HUDSON, Morgan PITTMAN, Dima SBENATY
Wake Forest Baptist Medical Center	Principal Investigator	Patrick REYNOLDS
	Co-Investigator(s)	Martinson ARNAN, Sanam BAGHSHOMALI, Edward-Luke BRADBURY, Cheryl BUSHNELL, Jeffrey CRAIG, Amy GUZIK, David LEFKOWITZ, Charles TEGELER
	Study Coordinator(s)	Barbara ANDERSON, LaGina BARKER, Sandra NORONA
Watauga Medical Center	Principal Investigator	Jeffrey CRITTENDEN
	Co-Investigator(s)	Burton KENNEDY
	Study Coordinator(s)	Shannon STOUT
Winthrop University Hospital	Principal Investigators	Sarah CHERIAN, Elzbieta WIRKOWSKI
	Co-Investigator(s)	Karin ANTAKY, Feliks KOYFMAN, Kathleen MICHEL, Jay YASEN
	Study Coordinator(s)	Kim BYRNES
WVU Healthcare Ruby Memorial Hospital	Principal Investigators	Amelia ADCOCK, John BRICK, Claudette BROOKS
	Co-Investigator(s)	Muhammad ALVI, Erica BLACKWELL, Todd CROCCO, Christopher CUMMINGS, Desiree GORDON, Laurie GUTMANN, Martha POWER, Adrienne SALOMON, Jay SHERMAN, Matthew S. SMITH, Tanya SMITH, Hannah YETZER

NEUROLOGICAL EMERGENCIES TREATMENT TRIALS (NETT) INVESTIGATORS

UNITED STATES

NETT Hub Principal Investigators: Opeolu ADEOYE, Tom AUFDERHEIDE, Jill BAREN, Michelle BIROS, Cliff CALLAWAY, Jan CLAASSEN, Kurt DENNINGHOFF, Nina GENTILE, Joshua GOLDSTEIN, Claude HEMPHILL, Roger HUMPHRIES, Elizabeth JONES, Steven LEVINE, Christopher LEWANDOWSKI, Joseph ORNATO, James QUINN, Sidney STARKMAN, Barney STERN, Michel TORBEY, Craig WARDEN, Robert WELCH, David WRIGHT

Enrolled 100 or more patients

Site	Role	Team Member
Hospital of the University of Pennsylvania	Principal Investigator	Brett CUCCHIARA
	Co-Investigator(s)	Jill BAREN, Lauren BESLOW, Christina BLUM, Christopher FAVILLA, Kimberly GANNON, Koto ISHIDA, Judy JIA, Scott KASNER, Glenn KONSKY, Donna KUROWSKI, Ava LIBERMAN, Caitlin LOOMIS, Jean LUCIANO, Michael MCGARVEY, Steven MESSE, Michael MULLEN, Claude NGUYEN, Swaroop PAWAR, Jonathan RASER-SCHRAMM, Christopher RENNER, David ROSE, Igor RYBINNIK, Lauren SANSING, Neelofer SHAFI, James SIEGLER, Laura STEIN, Sally SULTAN, Jose TORRES, Louis VENTURA, Christina WILSON, QingYang YUAN, Ali ZANDIEH, Cen ZHANG
	Study Coordinator(s)	Katherine BLACKBURN (Lamond), Mary Elizabeth DESANTO

Enrolled 50-99 patients

Site	Role	Team Member
Stanford University Medical Center	Principal Investigators	Gregory ALBERS, Nirali VORA
	Co-Investigator(s)	Pablo BRAVO, Marion BUCKWALTER, Charlene CHEN, Anna FINLEY-CAULFIELD, Paul GEORGE, Karen HIRSCH, Kyle HOBBS, Michael KE, Sun KIM, Prashanth KRISHNAMOHAN, Soo Young KWON, Maarten LANSBERG, Sarah LEE, Catherine LEGAULT, Adam MACLELLAN, Sharan MANN, Christina MIJALSKI, Gracia MUI, Jean-Marc OLIVOT, INDER PAUL SINGH, Reza PIRSAHELI, Divya PRABHU, Archana PURUSHOTHAM, James QUINN, Basit RAHIM, Adam RIZVI, Edgar SAMANIEGO, Neil SCHWARTZ, Christopher SOUTHWOOD, Ilanit SPOKOYNY, Waimei Amy TAI, Mohamed TELEB, Jenny TSAI, Christie TUNG, Chitra VENKATASUBRAMANIAN, Christine WIJMAN
	Study Coordinator(s)	Christine KELLER, Rosen MANN, Anita VISWESWARAN
Grady Memorial	Principal Investigator	Michael ROSS

Hospital	Co-Investigator(s)	Aaron ANDERSON, Anika BACKSTER, Samir BELAGAJE, Elizabeth ARROLL, Robin DHARIA, Adam EDWARDS, Tamara ESPINOZA, Michael FRANKEL, Minas GEBRU, Rishi GUPTA, Vijayakumar JAVALKAR, Omar KASS-HOUT, Tareq KASS-HOUT, Carlene KINGSTON, Andrey LIMA, Lisa MERCK, Fadi NAHAB, Raul NOGUEIRA, Mahmoud OBIDEEN, Anwar OSBORNE, Kumiko OWADA, Shelly OZARK, Vishal PATEL, Harrison PEARL, Haseeb RAHMAN, Jonathan RATCLIFF, Ali SAAD, Yasir SALEEM, Aaron STAYMAN, Melanie WINNINGHAM, David WRIGHT
	Study Coordinator(s)	Alex HALL, Nick STANLEY
NYP Columbia University Medical Center	Principal Investigator	Joshua WILLEY
	Co-Investigator(s)	Sachin AGARWAL, Fawaz AL MUFTI, Aws ALAWI, Ayham ALKHACHROUM, Neeraj BADJATIA, Andrew BAUERSCHMIDT, Huimahn CHOI, Jan CLAASSEN, Michael CRIMMINS, Barry CZEISLER, Elie DANCOUR, Neha DANGAYACH, Mandip DHAMOON, Charles ESENWA, Andres FERNANDEZ, Brandon FOREMAN, Shivani GHOSHAL, Randeep GILL, Emily GILMORE, Marco GONZALEZ CASTELLON, Jose GUTIERREZ, Khalid HANAFY, Gregory KAPINOS, Tomoko KITAGO, Shouri LAHIRI, Cappi LAY, Kiwon LEE, Tim LEKIC, Guillermo LINARES, Aaron LORD, Ali MAHTA, Rishi MALHOTRA, Adrian MARCHIDANN, Andrew MARTIN, Teresa MAY, Stephan MAYER, Kara R. MELMED, Alexander MERKLER, Eliza MILLER, Nicholas MORRIS, Sumiti NAYAR, Setareh S. OMRAN, Santiago ORTEGA-GUITERREZ, Gunjan PARIKH, Neal S. PARIKH, Nils PETERSEN, Jeremy RAGLAND, Alexandra REYNOLDS, Michael REZNIK, David ROH, Sara ROSTANSKI, Clio A. RUBINOS, Ayesha SHERZAI, Viktor SZEDER, Alan VELANDER, Matthew VIBBERT, Christopher ZAMMIT, Jiaying Jayne ZHANG
	Study Coordinator(s)	Cristina FALO, Angela VELAZQUEZ
Oregon Health & Science University Hospital	Principal Investigator	Helmi LUTSEP
	Co-Investigator(s)	Noah BEADELL, Hormozd BOZORGCHAMI, Wayne CLARK, Amandeep DHILLON, Julia DURRANT, Sierra FORD, Erek HELSETH, Kory HERRICK, David HOAK, Amit KANSARA, Seth KAREUS, Robert LOWE, Theodore LOWENKOPF, Logan MCDANELD, Madeline NGUYEN, Olajide OLOGUNTOYE, Andrew RONTAL, Michelle STACEY, Courtney TAKAHASHI, Craig WARDEN, Stewart WEBER, Corey WHITE, Lisa YANASE, John ZURASKY
	Study Coordinator(s)	Kelly FEEST, Jonathan FOLEY, Kali SEISLER
Detroit Receiving Hospital	Principal Investigators	Anthony LAGINA, Claire PEARSON
	Co-Investigator(s)	Benjamin ATKINSON, Pratik BHATTACHARYA, Seemant CHATURVEDI, William COPLIN, Angela GROVES, Amit KANSARA, Phillip LEVY, Ramesh MADHAVAN, Aniel MAJJHOO, Wazim MOHAMED, Meenakshi MUNSHI, Greg NORRIS, Brian O'NEIL, Kumar RAJAMANI, Sunitha ANTHAKUMAR, Robert SHERWIN, Kushak SUCHDEV, Ambooj TIWARI, Preet VARADE, Robert WELCH

	Study Coordinator(s)	Farhan AYAZ, Saikat BHUIYAN, Valerie MIKA
Temple University Hospital	Principal Investigator	Nina GENTILE
	Co-Investigator(s)	Derek ISENBERG, Mercedes JACOBSON, Paul KATZ, Yongwoo KIM, Tim LACHMAN, Guillermo LINARES, Imama NAQVI
	Study Coordinator(s)	Patricia MCNELIS, Hannah REIMER
Froedtert Memorial Lutheran	Principal Investigator	John LYNCH
	Co-Investigator(s)	Tom AUFDERHEIDE, Diana BOOK, Ann HELMS, Abigail LA NOU, Marc LAZZARO, Michel TORBEY, Osama ZAIDAT
	Study Coordinator(s)	Erin BRANDENBURG, Amanda EMMRICH, Caroline HERDEMAN, Jacob LABINSKI, Melissa MENA
Sinai-Grace Hospital	Principal Investigators	Anthony LAGINA, Claire PEARSON
	Co-Investigator(s)	Benjamin ATKINSON, Pratik BHATTACHARYA, Seemant CHATURVEDI, Angela GROVES, Amit KANSARA, Phillip LEVY, Ramesh MADHAVAN, Wazim MOHAMED, Meenakshi MUNSHI, Greg NORRIS, Brian O'NEIL, Kumar RAJAMANI, Robert SHERWIN, Kushak SUCHDEV, Ambooj TIWARI, Preet VARADE, Marc-Anthony VELILLA, Robert WELCH
	Study Coordinator(s)	Farhan AYAZ, Saikat BHUIYAN, Valerie MIKA
Hennepin County Medical Center	Principal Investigators	Michelle BIROS, Mustapha EZZEDDINE, Tapan THACKER
	Co-Investigator(s)	Mohammed ALKUWAITI, Shola ALUKO, David ANDERSON, Ganesh ASAITHAMBI, Kristen BARKLOW, Michelle BIROS, Laura FOSTER, Mikayel GRIGORYAN, Ameer HASSAN, Taka HIGASHIMORI, Haitham HUSSEIN, Katherine JACOBY, Chris JANSON, Jessica JARNOT, Daraspreet KAINTH, Amir KHAN, Asif KHAN, Jae KIM, Joni KOPITZKE, Saritha KUNDOOR, Shailesh MALE, Benjamin MILLER, Haejoe PARK, Rwoof RESHI, Gustavo RODRIGUEZ, Divyajot SANDHU, Biggya SAPKOTA, Kenneth SHEA, Nathan SIT, Jamie STARKS, Christopher STREIB, Robert TAYLOR, Wondwossen TEKLE, Huseyin TORE, Haralabos ZACHARATOS
	Study Coordinator(s)	Audrey HENDRICKSON, Kathleen MILLER, Mindy RUMBOLZ, Julie SCHERBER, Abbey STAUGAITIS
University of Kentucky Hospital	Principal Investigator	Roger HUMPHRIES
	Co-Investigator(s)	CRAIG CARTER, Sameer DESAI, Creed PETTIGREW
	Study Coordinator(s)	Joann SHORT
Henry Ford Hospital	Principal Investigators	Hebah HEFZY, Andrew RUSSMAN
	Co-Investigator(s)	Christopher LEWANDOWSKI, Daniel MILLER, Joseph MILLER, Taher VOHRA
	Study Coordinator(s)	Shannen BERRY, Anne Marie LUNDELL
Abington Memorial Hospital	Principal Investigator	Dan GZESH
	Co-Investigator(s)	Jill BAREN, James COOK, Brett CUCCHIARA, Franklin DIAMOND, Lee HARRIS, Karin KELLERMAN, John KHOURY, Brad KLEIN, Laurie KNEPPER, Osman KOZAK, Kandan KULANDAIVEL, Larami MACKENZIE, Jennifer MCGOWAN TRAINER ,Qaisar SHAH, David WEISMAN
WellSpan York	Principal Investigator	Erik KOCHERT

Hospital	Co-Investigator(s)	Jill BAREN, Brent BECKER, Ronald BENENSON, Kalpesh BHUVA, Mark COLLIN, Brett CUCCHIARA, William FIELDS, Mark GONZALES, Jeremy HUTCHINS, Eric KLOTZ, Justin KOCH, David LEE, John MINGLE, Nicholas PAPPAS, Marc POLLACK, Kim POPE, Teri REBERT, Robert REIF, Nels ROSE, Eric SANDERS, Lisa SMALE, Matthew STEPHENS, Robert STERLING, Robert STUNTZ, Colleen TRAN, Guy YOUNGBLOOD
	Study Coordinator(s)	Barbie STAHLMAN

Site	Role	Team Member
Abbott Northwestern Hospital	Principal Investigator	Mark YOUNG
	Co-Investigator(s)	Michelle BIROS, Mustapha EZZEDDINE, Pezhman ROOHANI, Holly SWANSON-CARROLL, Ronald TARREL
	Study Coordinator(s)	Jennifer FEASE, Sarah HOCHSPRUNG
Aria Health Frankford Campus	Principal Investigators	Nina GENTILE, Joshua SIMON, Gerald WYDRO
	Co-Investigator(s)	Pamela GOLDMAN, Mercedes JACOBSON
	Study Coordinator(s)	Hannah REIMER
Aurora St. Luke's Medical Center	Principal Investigators	Arvind AHUJA, Khaled ASI, Elizabeth MARRIOTT, Rehan SAJJAD
	Co-Investigator(s)	Tom AUFDERHEIDE, Akram SHHADEH
	Study Coordinator(s)	Carol HALLIDAY, Tonya HOLLRITH, Marilyn MILLER, Lynda YANNY
Baltimore Washington Medical Center	Principal Investigator	Sangjin OH
	Co-Investigator(s)	Carolyn CRONIN, Barney STERN
	Study Coordinator(s)	Virginia GANLEY, Jill HECKENDORF
Banner Good Samaritan Medical Center	Principal Investigator	Jeremy PAYNE
	Co-Investigator(s)	Douglas FRANZ, Paola LINYARD, Emily RAY, Aleksander TKACH
	Study Coordinator(s)	Tony DENISON
Banner University Medical Center - South Campus	Principal Investigator	Kendra DRAKE
	Co-Investigator(s)	Katherine BONSELL, Kurt DENNINGHOFF, Chelsea KIDWELL, David NGUYEN, Jennifer TAY
	Study Coordinator(s)	Isabelle CHEA, Kathryn SCHIERLING
Banner University Medical Center - Tucson Campus	Principal Investigators	Kendra DRAKE, Farshad SHIRAZI
	Co-Investigator(s)	Katherine BONSELL, Kurt DENNINGHOFF, Chelsea KIDWELL David NGUYEN, Jennifer TAY
	Study Coordinator(s)	Bruce BARNHART, Isabelle CHEA, Karen LUTRICK, Kathryn SCHIERLING
Barnes Jewish Hospital	Principal Investigators	Laura HEITSCH, Pete PANAGOS
	Co-Investigator(s)	Opeolu ADEOYE, Alla AL-HABIB, Hesham ALLAM, Vamshi BALASETTI, Christian BURRELL, David CARPENTER, David CURFMAN, Christopher DELINE, Colin DERDEYN, Javon EDGECOMBE, Andria FORD, Derek HOLDER, Naim KHOURY, Tobias KULIK, Gyan KUMAR, Jin-Moo LEE, Christopher LEON-GUERRERO, Art PANCIOLI
	Study Coordinator(s)	Jill NEWGENT

Ben Taub General Hospital	Principal Investigators	Dick KUO, Paulina SERGOT
	Co-Investigator(s)	Haitham HUSSEIN, Elizabeth JONES, Joseph KASS
	Study Coordinator(s)	Kelly KEENE
Beth Israel Deaconess Medical Center	Principal Investigator	Nathan SHAPIRO
	Co-Investigator(s)	Leslie BILELLO, Jeremy CAREY, Jonathan EDLOW, Lester LEUNG, Vasileios-Arsenios LIOUTAS, Mark MCALLISTER, Magdy SELIM, Edward ULLMAN
	Study Coordinator(s)	Sharon HAYES, James WAREING
Bethesda North Hospital	Principal Investigators	Rahul KARAMCHANDANI, Kyle WALSH
	Co-Investigator(s)	Opeolu ADEOYE, Jordan BONOMO, Joseph BRODERICK, Rhonda CADENA, Elisheva COLEMAN, Felipe DE LOS RIOS LA ROSA, Stacie DEMEL, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Rachel GARVIN, Anna GENSIC, Sabreena GILLOW, Aaron GROSSMAN, Jonah GROSSMAN, Laura HEITSCH, Adam JASNE, Daniel KANTER, Brian KATZ, Pooja KHATRI, Brett KISSELA, Dawn KLEINDORFER, William KNIGHT, Natalie KREITZER, Julian MACEDO, Jason MACKEY, Sharyl MARTINI, Erin MCDONOUGH, Eva MISTRY, Meena MUNSHI, Brian OLOIZIA, Art PANCIOLI, Katrina PEARISO, Jonathan RATCLIFF, Sameer SHARMA, Blake SMITH, Michael STAR, Brian STETTLER, Daniel WOO, Muhammad ZAGHLOULEH
	Study Coordinator(s)	Shannon DEEDS, Sara KEEGAN
Brigham and Women's Hospital	Principal Investigator	Daniel PALLIN
	Co-Investigator(s)	Imoigele AISIKU, Edilberto AMORIM, Philip ANDERSON, Khamid BAKHADIROV, Matthew BEVERS, Calvin BROWN, Xuemei CAI, David CHUNG, Ming-Cheih DING, Brian EDLOW, Guido FALCONE, Sarah FRASURE, Scott GOLDBERG, Eric GORALNICK, Peter HOU, Saef IZZY, Guruprasad JAMBAULIKAR, Ruchira JHA, Minjee KIM, Joshua KOSOWSKY, Ariane LEWIS, Sanjay MENON, Sarah NELSON, Ziad OBERMEYER, Kelli O'LAUGHLIN, Casey OLM-SHIPMAN, Kei OUCHI, Siddharth PARMAR, Nils PETERSEN, Chia-Ling PHUAH, Charles POZNER, Ali RAZMARA, Jeremiah SCHUUR, Raghu SEETHALA, Shreyansh SHAH, Sarah WAHLSTER, Scott WEINER, Sahar ZAFAR, Eli ZIMMERMAN
	Study Coordinator(s)	Rachel CATLIN, Rebecca GISH, Emily JAMIESON, Conor NAROVEC
California Pacific Medical Center Davies Campus	Principal Investigator	Nobl BARAZANGI
	Co-Investigator(s)	Ermias AYTENFISU, Ann BEDENK, Charlene CHEN, Shirley CHEN, Billy GAO, Victor JARAMILLO, Elena PODOLSKAYA, Jessica REDFORD, Jack ROSE, Oana SPATARU, David TONG, Christine WONG
	Study Coordinator(s)	Katie PONTING
California Pacific Medical Center Pacific Campus, San Francisco, CA	Principal Investigator	Nobl BARAZANGI
	Co-Investigator(s)	Ermias AYTENFISU, Ann BEDENK, Charlene CHEN, Shirley CHEN, Billy GAO, Victor JARAMILLO, Elena PODOLSKAYA, Jessica REDFORD, Jack ROSE, Oana SPATARU, David TONG, Christine WONG

	Study Coordinator(s)	Katie PONTING
Chandler Regional Medical Center	Principal Investigator	Brian TIFFANY
	Co-Investigator(s)	Hemant PANDEY, Euly SMITH
	Study Coordinator(s)	Annette RUIZ TAYLOR
Christ Hospital	Principal Investigators	Rahul KARAMCHANDANI, Kyle WALSH
	Co-Investigator(s)	Opeolu ADEOYE, Jordan BONOMO, Joseph BRODERICK, Elisheva COLEMAN, Felipe DE LOS RIOS LA ROSA, Stacie DEMEL, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Rachel GARVIN, Anna GENSIC, Sabreena GILLOW, Aaron GROSSMAN, Jonah GROSSMAN, Adam JASNE, Daniel KANTER, Brian KATZ, Pooja KHATRI, Brett KISSELA, Dawn KLEINDORFER, William KNIGHT, Natalie KREITZER, Julian MACEDO, Sharyl MARTINI, Erin MCDONOUGH, Meena MUNSHI, Brian OLOIZIA, Art PANCIOLI, Katrina PEARISO, Jonathan RATCLIFF, Sameer SHARMA, Blake SMITH, Michael STAR, Brian STETTLER, Daniel WOO, Muhammad ZAGHLOULEH
	Study Coordinator(s)	Shannon DEEDS, Sara KEEGAN
Christiana Hospital	Principal Investigator	Jason NOMURA
	Co-Investigator(s)	Mary CIECHANOWSKI, Christian COLETTI, Valerie DECHANT, Kimberly GANNON, Jonathan MCGHEE, Anthony MUNSON, Jason NACE, John POWELL, Jonathan RASER-SCHRAMM, Waimei Amy TAI, Eli ZESERSON
	Study Coordinator(s)	Amy CHERICO, Cynthia HOON
Columbia St. Mary's Hospital	Principal Investigator	Tom AUFDERHEIDE
	Co-Investigator(s)	Michael CONNOR, Marc LAZZARO, John LYNCH
	Study Coordinator(s)	Amanda EMMRICH, Melissa MENA
Cooper University Hospital	Principal Investigator	Thomas MIRSEN
	Co-Investigator(s)	Jill BAREN, Brigitte BAUMANN, Ankur BHARGAVA, Jia Zhen CHENG, Brett CUCCHIARA, Michael GALLAGHER, Xuan-Lan GRIFFITH, Christopher JONES, Bhavika KAKADIA, Tapan KAVI, Vladimir KLINOV, Mia KO, Dena LITTLE, Neil MASANGKAY, Eric NAGELE, Rajiv NARULA, James NOTO, Alok PATEL, Ruchir SHAH, Umang SHAH, George SHOKRI, Randip TANEJA, Ephrem TEKLEMARIAM, Ryna THEN, Michael WESTON, Furkan YILMAZ
	Study Coordinator(s)	Christine BESWICK, Lisa CAPANO-WEHRLE, Cory HACKMYER, Tamara LEE, Andrew MARCH, Patricia NIBLACK
Dell Seton Medical Center at UT	Principal Investigator	Truman MILLING
	Study Coordinator(s)	Laura LACHANCE
El Camino Hospital	Principal Investigator	Peter FUNG
	Study Coordinator(s)	Inderjit DHOKAL, Rebecca DUNN, Christine KELLER, Ryan SMITH
Emory University	Principal Investigator	Michael ROSS

Hospital	Co-Investigator(s)	Aaron ANDERSON, Anika BACKSTER, Samir BELAGAJE, Elizabeth CARROLL, Robin DHARIA, Adam EDWARDS, Tamara ESPINOZA, Michael FRANKEL, Minas GEBRU, Rishi GUPTA, Vijayakumar JAVALKAR, Omar KASS-HOUT, Tareq KASS-HOUT, Carlene KINGSTON, Andrey LIMA, Lisa MERCK, Fadi NAHAB, Raul NOGUEIRA, Mahmoud OBIDEEN, Anwar OSBORNE, Kumiko OWADA, Shelly OZARK, Vishal PATEL, Harrison PEARL, Haseeb RAHMAN, Jonathan RATCLIFF, Ali SAAD, Yasir SALEEM, Aaron STAYMAN, Melanie WINNINGHAM, David WRIGHT
	Study Coordinator(s)	Alex HALL, Nick STANLEY
Emory University Hospital Midtown	Principal Investigator	Michael ROSS
	Co-Investigator(s)	Aaron ANDERSON, Anika BACKSTER, Samir BELAGAJE, Robin DHARIA, Adam EDWARDS, Tamara ESPINOZA, Michael FRANKEL, Minas GEBRU, Rishi GUPTA, Vijayakumar JAVALKAR, Omar KASS-HOUT, Tareq KASS-HOUT, Andrey LIMA, Fadi NAHAB, Raul NOGUEIRA, Mahmoud OBIDEEN, Anwar OSBORNE, Kumiko OWADA, Vishal PATEL, Jonathan RATCLIFF, Ali SAAD, Aaron STAYMAN, Melanie WINNINGHAM, David WRIGHT
	Study Coordinator(s)	Alex HALL, Nick STANLEY
Essentia Health St. Mary's Medical Center	Principal Investigator	Dimitrios GIANNAKIDIS
	Co-Investigator(s)	Linda ANDERSON, Nick ITZIN, Diane ROACH, Ruth THOMSON, Gail WALLACE
	Study Coordinator(s)	Erica CHOPSKIE, Karen HARMON, Robert SHULTZ
Essentia Health-Fargo	Principal Investigator	M. Ziad DARKHABANI
	Co-Investigator(s)	Michelle BIROS, Jessica SIMS
	Study Coordinator(s)	Mandy BARTLETT, Marlee HURTT
Fairview Southdale Hospital	Principal Investigator	Mustapha EZZEDDINE
	Co-Investigator(s)	Michelle BIROS, David GRESBACK, Alexander ZUBKOV
	Study Coordinator(s)	Audrey HENDRICKSON, Kathleen MILLER, Mindy RUMBOLZ, Julie SCHERBER, Abbey STAUGAITIS
Frederick Memorial Hospital	Principal Investigator	Shahid RAFIQ
	Study Coordinator(s)	Tom SHUPP
George Washington University Hospital	Principal Investigator	Kathleen BURGER
	Co-Investigator(s)	Richard BENSON, Christopher LEON-GUERRERO, Andrew MELTZER, Zurab NADAREISHVILLI, Diane SAUTER
	Study Coordinator(s)	Radwa ALY, Angela KELLY
Good Samaritan	Principal Investigators	Rahul KARAMCHANDANI, Kyle WALSH

Hospital (Cincinnati, OH)	Co-Investigator(s)	Opeolu ADEOYE, Jordan BONOMO, Joseph BRODERICK, Rhonda CADENA, Elisheva COLEMAN, Felipe DE LOS RIOS LA ROSA, Stacie DEMEL, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Rachel GARVIN, Anna GENSIC, Sabreena GILLOW, Aaron GROSSMAN, Jonah GROSSMAN, Laura HEITSCH, Adam JASNE, Daniel KANTER, Brian KATZ, Pooja KHATRI, Brett KISSELA, Dawn KLEINDORFER, William KNIGHT, Natalie KREITZER, Julian MACEDO, Jason MACKEY, Sharyl MARTINI, Erin MCDONOUGH, Meena MUNSHI, Brian OLOIZIA, Art PANCIOLI, Katrina PEARISO, Jonathan RATCLIFF, Sameer SHARMA, Blake SMITH, Michael STAR, Brian STETTLER, Daniel WOO, Muhammad ZAGHLOULEH
	Study Coordinator(s)	Shannon DEEDS, Sara KEEGAN
Good Samaritan Hospital (San Jose, CA)	Principal Investigator	Harmeet SACHDEV
	Co-Investigator(s)	James QUINN
	Study Coordinator(s)	Christine KELLER
Hackensack University Medical Center	Principal Investigator	Chinwe OGEDEGBE
	Co-Investigator(s)	Subasini DASH, Nina GENTILE
	Study Coordinator(s)	Diana MCCARTHY, Arelis VILLOT-SANTIAGO
Hahnemann University Hospital	Principal Investigators	Ralph RIVIELLO, Mark SAKS
	Co-Investigator(s)	Theodore CORBIN, Nina GENTILE, Sharon GRISWOLD-THEODORSON, Todd MCGRATH, Daniel MULLIN, Edward RAMOSKA, Eric STANDER, David TABBY
	Study Coordinator(s)	Lisa BONACQUISTI, Anne JOHNSON, John MASSEY, Patricia MCNELIS, Romy NOCERA
Harper University Hospital	Principal Investigators	Anthony LAGINA, Claire PEARSON
	Co-Investigator(s)	Benjamin ATKINSON, Pratik BHATTACHARYA, Seemant CHATURVEDI, Angela GROVES, Amit KANSARA, Phillip LEVY, Ramesh MADHAVAN, Aniel MAJJHOO, Wazim MOHAMED, Meenakshi MUNSHI, Greg NORRIS, Brian O'NEIL, Kumar RAJAMANI, Sunitha SANTHAKUMAR, Robert SHERWIN, Kushak SUCHDEV, Ambooj TIWARI, Preet VARADE, Robert WELCH
	Study Coordinator(s)	Farhan AYAZ, Saikat BHUIYAN, Valerie MIKA
Henry Ford West Bloomfield Hospital	Principal Investigators	Hebah HEFZY, Andrew RUSSMAN
	Co-Investigator(s)	Christopher LEWANDOWSKI, Daniel MILLER, Joseph MILLER, Taher VOHRA
	Study Coordinator(s)	Shannen BERRY, Anne Marie LUNDELL
Huntington Memorial Hospital	Principal Investigator	Arbi OHANIAN
	Co-Investigator(s)	Candy CORRAL, Robert GOLDWEBER, Conrad LIANG, Artin MINAEIAN, Sharon YEGIAIAN
	Study Coordinator(s)	Marilyn PEREZ
Jeanes Hospital	Principal Investigator	Marcia HALPERN
	Co-Investigator(s)	Nina GENTILE
	Study Coordinator(s)	Maryellen NELSON
Johns Hopkins	Principal Investigator	Victor URRUTIA

Hospital	Co-Investigator(s)	Martinson ARNAN, Mona BAHOUTH, Mario CERDAN-TREVINO, Arjun CHANMUGAN, Yolanda CHIK, Jennifer DEARBORN, Romanus Roland FAIGLE, Ryan FELLING, Peter HILL, Shyian JEN, Richard LEIGH, Rafarl LINAS, Elisabeth MARSH, Bogachan SAHIN, Robert WITYK, Steven ZEILER
	Study Coordinator(s)	Susan RICE, Jennifer RONALD
Kings County Hospital Center	Principal Investigators	Pia CHATTERJEE, Susan LAW, Steven LEVINE, Richard SINERT
	Co-Investigator(s)	Anika BACKSTER, Clotilde BALUCANI, Ethan BRANDLER, Qing HAO, Ashika JAIN, Yongwoo KIM, Adrian MARCHIDANN, Jennifer MARTINDALE, Jay MELTON, Lorenzo PALADINO, Diana ROJAS-SOTO, Artem SUNIK, Benedict TAN, Helen VALSAMIS, Volodymyr VULKANOV, Shahriar ZEHTABCHI
	Study Coordinator(s)	Vanessa ARNEDO, Marijayne BUSHEY, Nadege GILLES, Saroj KUNNAKKAT, Catherine LUSHBOUGH, Schweta MALHOTRA, Shreya PANDYA, Bryce PETTY, Bruhati SHAH, Jonathan SINGER
Legacy Emanuel Medical Center	Principal Investigator	Helmi LUTSEP
	Co-Investigator(s)	Wayne CLARK, Alexandra DIMITROVA, Elizabeth NORTH
	Study Coordinator(s)	Kelly FEEST, Jonathan FOLEY
Lincoln Medical and Mental Health Center	Principal Investigator	Shekar MURTHY
	Co-Investigator(s)	Madan Mohan Reddy ARUGUNTA, Hussein ASSALLUM, Balavenkatesh KANNA, James ZISFEIN
	Study Coordinator(s)	Jessica MONTALVO
Long Beach Memorial Medical Center	Principal Investigator	Nima RAMEZAN-ARAB
	Co-Investigator(s)	Omid OMIDVAR, Nirav S. PATEL, Michael L. THOMPSON
	Study Coordinator(s)	Roxana FLORES, Dena HOPKINS, Françoise TOUSSAINT-JONES, Angie WEST
Marquette General Hospital	Principal Investigator	Karl MEISEL
	Study Coordinator(s)	Jodi NEASE
Massachusetts	Principal Investigators	Ferdinando BUONANNO, Scott SILVERMAN

General Hospital	Co-Investigator(s)	Edilberto AMORIM, Christopher ANDERSON, Khamid BAKHADIROV, Ribal BASSIL, Ayush BATRA, Matthew BEVERS, Gregoire BOULOUIS, Xuemei CAI, Andreas CHARIDIMOU, David CHUNG, Ming-Cheih DING, Brian EDLOW, Mark ETHERTON, Guido FALCONE, Ananda FINE, Rajan GADHIA, Anne-Katrin GIESE, Joshua GOLDSTEIN, Andrea HARRIOTT, Leigh HOCHBERG, Saef IZZY, Sameen JAFARI, Ruchira JHA, Abbas KHARAL, Ayaz KHAWAJA, Jennifer KIM, Minjee KIM, William Taylor KIMBERLY, Arne LAUER, David LERNER, Ariane LEWIS, David LIN, Sandro MARINI, Sanjay MENON, Christina MIJALSKI, Andrea MOROTTI, Sarah NELSON, MingMing NING, Casey OLM-SHIPMAN, Charlene ONG, Fadar OTITE, Marco PASI, Nils PETERSEN, Chia-Ling PHUAH, Pedro PINTO, Sergi RAMIREZ MARTINEZ, Shyam RAO, Ali RAZMARA, Jonathan ROSAND, Natalia ROST, Daniel RUBIN, Frieder SCHLUNK, Lee SCHWAMM, Shreyansh SHAH, Richa SHARMA, Starane SHEPHERD, Faheem SHERIFF, Matthew SIKET, Aneesh SINGHAL, Zachary THRELKELD, Anand ENKATRAMAN, Anand VISWANATHAN, Sarah WAHLSTER, Li XIONG, Sahar ZAFAR, Eli ZIMMERMAN
	Study Coordinator(s)	Lauren BARTON, Ryan CALLAHAN, Kathleen FEENEY, Melissa HOWELL, Eric LOESCH, Blair Alden PARRY, Eric RIKLIN, Chun Mei SU, Gregory TIRRELL
Mayo Clinic Saint Marys Campus	Principal Investigator	Fernanda BELLOLIO
	Co-Investigator(s)	Michelle BIROS, Jennifer FUGATE, Waqas GILANI, James KLAAS
	Study Coordinator(s)	Renee CABALKA
Medical University of South Carolina University Hospital	Principal Investigator	Christine HOLMSTEDT
	Co-Investigator(s)	Robert ADAMS, Opeolu ADEOYE, Charles ANDREWS, Chirantan BANERJEE, Julio CHALELA, Marc CHIMOWITZ, Wuwei FENG, Angela HAYS SHAPSHAK, Edward JAUCH, Shelly OZARK, Art PANCIOLI, Tanya TURAN, Ashley WABNITZ
	Study Coordinator(s)	Robert BURFEIND, Cheryl GRANT, Gina KELLER, Vicki STREETS
MedStar Washington Hospital Center	Principal Investigator	Munish GOYAL
	Co-Investigator(s)	Richard BENSON, Rahul BHAT, Amie HSIA, Lisa JACOBSON, Norine MCGRATH, Diane SAUTER
	Study Coordinator(s)	Theresa MORIARTY
Memorial	Principal Investigator	Elizabeth JONES

Hermann Texas Medical Center	Co-Investigator(s)	Arif AZAM, Carrie BAKUNAS, Andres BAYONA, Jonas BEYENE, Caroline BORGAN, Richard BRADLEY, Yashwant CHATHAMPALLY, Andrew COYNE, Daniel DE LOS SANTOS, Pratik DOSHI, Natalie ELLIOTT, Emily ENDACOTT, Lindley FOLKERSON, Christopher FREEMAN, Vanessa GARZA-MIRANDA, Keith GATES, Kasey GILDERSLEEVE, Joshua GUINDON, Kassie HAITZ, Stephen HECHT, Kevin HOFFMAN, Quyen HUYNH, Romeo JOSEPH, Brent KING, James LEONI, Jason LESNICK, Rohith MALYA, Justin MAZZILLO, Omar METWALLI, Amy NOLAND, Michael PANDYA, Andrew POTTER, Eric REICHMAN, David ROBINSON, Michael ROKYTA, Carlos ROLDAN, Jason SATTERFIELD, Paulina SERGOT, Justin SHEPARD, Soa-Yih SHER, Ian SMITH, Jeffrey STOWELL, Salvatore VALENTI, Richard WITKOV Monica
	Study Coordinator(s)	MENDOZA-MOORE, Misty OTTMAN
Mercy Franciscan Hospital - Mount Airy	Principal Investigator	Dawn KLEINDORFER
	Co-Investigator(s)	Opeolu ADEOYE, Jordan BONOMO, Joseph BRODERICK, Rhonda CADENA, Felipe DE LOS RIOS LA ROSA, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Rachel GARVIN, Anna GENSIC, Aaron GROSSMAN, Laura HEITSCH, Daniel KANTER, Pooja KHATRI, Brett KISSELA, William KNIGHT, Jason MACKEY, Sharyl MARTINI, Erin MCDONOUGH, Meena MUNSHI, Art PANCIOLI, Jonathan RATCLIFF, Blake SMITH, Brian STETTLER, Daniel WOO
	Study Coordinator(s)	Irene EWING
Mercy Franciscan Hospital - Western Hills	Principal Investigator	Dawn KLEINDORFER
	Co-Investigator(s)	Opeolu ADEOYE, Jordan BONOMO, Joseph BRODERICK, Rhonda CADENA, Felipe DE LOS RIOS LA ROSA, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Rachel GARVIN, Anna GENSIC, Aaron GROSSMAN, Laura HEITSCH, Daniel KANTER, Pooja KHATRI, Brett KISSELA, William KNIGHT, Jason MACKEY, Sharyl MARTINI, Erin MCDONOUGH, Meena MUNSHI, Art PANCIOLI, Jonathan RATCLIFF, Blake SMITH, Brian STETTLER, Daniel WOO
	Study Coordinator(s)	Irene EWING
Mercy General Hospital	Principal Investigators	Mohammad MAHMOOD, Lucian MAIDAN
	Co-Investigator(s)	Ryan ARMOUR, Asad CHAUDHARY, Edwin CRUZ, Michael-Karsten DENGEL, Ehsan HADI, Marc LENAERTS, Alex NEE, Reza PIRSAHELI, John SCHAFER, Alan SHATZEL, Peter SKAFF
	Study Coordinator(s)	Dawn DIORIO, Danielle HORNBUCKLE, Raveca PINTEA, Isabel REYES, Deidre WENTWORTH
Mercy Health	Principal Investigators	Rahul KARAMCHANDANI, Kyle WALSH

West Hospital	Co-Investigator(s)	Opeolu ADEOYE, Jordan BONOMO, Joseph BRODERICK, Elisheva COLEMAN, Stacie DEMEL, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Anna GENSIC, Sabreena GILLOW, Jonah GROSSMAN, Adam JASNE, Daniel KANTER, Brian KATZ, Pooja KHATRI, Brett KISSELA, Dawn KLEINDORFER, William KNIGHT, Natalie KREITZER, Julian MACEDO, Erin MCDONOUGH, Brian OLOIZIA, Art PANCIOLI, Katrina PEARISO, Sameer SHARMA, Blake SMITH, Michael STAR, Brian STETTLER, Daniel WOO, Muhammad ZAGHLOULEH
	Study Coordinator(s)	Shannon DEEDS, Sara KEEGAN
Mercy San Juan Medical Center	Principal Investigator	Lucian MAIDAN
	Co-Investigator(s)	Ryan ARMOUR, Asad CHAUDHARY, Edwin CRUZ, Michael-Karsten DENGEL, Ehsan HADI, Alex NEE, Reza PIRSAHELI, John SCHAFER, Alan SHATZEL, Peter SKAFF
	Study Coordinator(s)	Dawn DIORIO, Danielle HORNBUCKLE, Raveca PINTEA, Isabel REYES
Mills Peninsula Medical Center	Principal Investigator	Mike KOHN
	Co-Investigator(s)	Howard BELFER, Michael COHEN, Michael SIEGEL, Robert TELFER
	Study Coordinator(s)	Anke HEBIG
New York-Presbyterian Brooklyn Methodist	Principal Investigator	Robert BIRKHAHN
	Co-Investigator(s)	Alp ARKUN, Jeffrey BENJAMIN, Hilary FAIRBROTHER, Laura MELVILLE
	Study Coordinator(s)	Paris DATILLO
Norton Brownsboro Hospital	Principal Investigators	Ali CHOUCAIR, Nadeem TALPUR
	Co-Investigator(s)	Shervin DASHTI, Roger HUMPHRIES, Tom YAO
	Study Coordinator(s)	Robyn MCLEAN
Norton Hospital	Principal Investigators	Ali CHOUCAIR, Nadeem TALPUR
	Co-Investigator(s)	Shervin DASHTI, Roger HUMPHRIES, Tom YAO
	Study Coordinator(s)	Robyn MCLEAN
O'Connor Hospital	Principal Investigator	Raul GUISADO
	Co-Investigator(s)	Raj GUPTA, Jenelle JINDAL, Xihua SUN
	Study Coordinator(s)	Karen DE LA CUESTA, Christine KELLER
Penn Presbyterian Medical Center	Principal Investigator	Brett CUCCHIARA
	Co-Investigator(s)	Jill BAREN, Christina BLUM, Maria CHEN, Christopher FAVILLA, Kimberly GANNON, Judy JIA, Scott KASNER, Sami KHELLA, Donna KUROWSKI, Ava LIBERMAN, Caitlin LOOMIS, Jean LUCIANO, Michael MCGARVEY, Steven MESSE, Michael MULLEN, Claude NGUYEN, Laura STEIN, Jose TORRES, Ali ZANDIEH, Cen ZHANG
	Study Coordinator(s)	Mary Elizabeth DESANTO
Pennsylvania Hospital	Principal Investigators	Brett CUCCHIARA, Christopher REES
	Co-Investigator(s)	Jill BAREN, Christopher FAVILLA, Kimberly GANNON, Judy JIA, Scott KASNER, Donna KUROWSKI, Ava LIBERMAN, Jean LUCIANO, Michael MCGARVEY, Ellen MCPARTLAND-MONGIORI, Steven MESSE, Michael MULLEN, Claude NGUYEN, Paul NOVELLO, Laura STEIN, Ali ZANDIEH, Cen ZHANG

	Study Coordinator(s)	Mary Elizabeth DESANTO, Scott DROBNIS
Portland VA Medical Center	Principal Investigator	Helmi LUTSEP
	Co-Investigator(s)	Hormozd BOZORGCHAMI, Wayne CLARK, Sierra FORD, Kory HERRICK, David HOAK, Olajide OLOGUNTOYE, Courtney TAKAHASHI, Craig WARDEN, Stewart WEBER
	Study Coordinator(s)	Jonathan FOLEY
Regional Medical Center of San Jose	Principal Investigators	Raul GUISADO, Raj GUPTA
	Co-Investigator(s)	Jenelle JINDAL, James QUINN, Akshay SHAH
	Study Coordinator(s)	Christine KELLER
Regions Hospital	Principal Investigator	Aaron BURNETT
	Co-Investigator(s)	Michelle BIROS, Mustapha EZZEDDINE, Vivian FINK, Bret HAAKE, Kurt ISENBERGER, Josh SALZMAN, Michael ZWANK
	Study Coordinator(s)	Kari KRAGNESS, Emily MISCHEL-ABRAMOWSKI, Alyssa MORRIS, Sandi WEWERKA
Renown Regional Medical Center	Principal Investigator	Ivan LOPEZ
	Study Coordinator(s)	Peggie SMITH
Rhode Island Hospital	Principal Investigators	Brian SILVER, Shadi YAGHI
	Co-Investigator(s)	Jill BAREN, Brett CUCCHIARA, Shawna CUTTING, Lindsey FULLER, Muhib KHAN, Lisa MERCK, Lori OLIVER, Ali SAAD, Jo-Ann SARAFIN, Todd SEIGEL, Matthew SIKET
	Study Coordinator(s)	Karina BERTSCH, Lesley D'URSO (Wasilewski), Ashley SCHOMER
Ridgeview Medical Center	Principal Investigator	David LARSON
	Co-Investigator(s)	Kevin BROWN, Mustapha EZZEDDINE
	Study Coordinator(s)	Brenda ANDERSON, Jane ARCHER, Kathleen MILLER, Mindy RUMBOLZ
Robert Wood Johnson University Hospital	Principal Investigators	James MCKINNEY, Deviyani MEHTA
	Co-Investigator(s)	Catherine ALBRECHT, Jill BAREN, Brett CUCCHIARA, Subasini DASH, Robert EISENSTEIN, Raffi KAPITANYAN, Jonathan MCCOY, Mark MERLIN, Michelle MOCCIO, Ugo PAOLUCCI, Igor RYBINNIK, Chirag SHAH, Patricia SONSALLA, Win TOE
Rush University Medical Center	Principal Investigator	James CONNERS
	Co-Investigator(s)	Tom AUFDERHEIDE, Laurel CHERIAN (SMIT), Shawna CUTTING, Rima DAFER, Vivien LEE, Nicholas OSTERAAS, Sarah SONG, Alejandro VARGAS
	Study Coordinator(s)	Stephanie DAHL, Tiffany SINGSON
San Francisco	Principal Investigator	Claude HEMPHILL

General Hospital	Co-Investigator(s)	Ahmad AHMAD, Aimee AYSENNE, John BETJEMANN, Molly BURNETT, Tamika BURRUS, Elizabeth CAHILL, Sheila CHAN, Judy CHANG, Natalie CHENG, Roger CHENG, Rene COLORADO, Vanja DOUGLAS, Julia DURRANT, Nancy EDWARDS, Christine FOX, Alan GELB, Trevor GREGATH, Cathra HALABI, Karen HIRSCH, Andrew JOSEPHSON, Hooman KAMEL, Kevin KEENAN, Anthony KIM, Nerissa KO, Mohan KOTTAPALLY, Karl MEISEL, Asma MOHEET, Arturo MONTANO, Kazuma NAKAGAWA, Bharath NARAVETLA, Babak NAVI, Anh NGUYEN, Mai NGUYEN-HUYNH, Sharon POISSON, Prasanthi RAMANUJAM, Nirav SHAH, Michel SHAMY, Kevin SHAPIRO, Peyman SHIRANI, Vineeta SINGH, Neel SINGHAL, Wade SMITH, Karl SPORER, Abraham THOMAS, Shahed TOOSSI, Christine WONG, Alan YEE, Debbie YI MADHOK, QingYang YUAN
	Study Coordinator(s)	Michele MEEKER, Dominica RANDAZZO, Kelley ROSBOROUGH
Seton Medical Center	Principal Investigator	Truman MILLING
	Study Coordinator(s)	Laura LACHANCE
Spectrum Health Hospitals - Butterworth	Principal Investigator	John OOSTEMA (Adam)
	Co-Investigator(s)	Michael BROWN, Jeffrey JONES, Joshua REYNOLDS
	Study Coordinator(s)	Tiffany FLEEGER
St. Elizabeth Hospital	Principal Investigators	Rahul KARAMCHANDANI, Kyle WALSH
	Co-Investigator(s)	Opeolu ADEOYE, Jordan BONOMO, Joseph BRODERICK, Rhonda CADENA, Elisheva COLEMAN, Felipe DE LOS RIOS LA ROSA, Stacie DEMEL, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Rachel GARVIN, Anna GENSIC, Sabreena GILLOW, Aaron GROSSMAN, Jonah GROSSMAN, Laura HEITSCH, Adam JASNE, Daniel KANTER, Brian KATZ, Pooja KHATRI, Brett KISSELA, Dawn KLEINDORFER, William KNIGHT, Natalie KREITZER, Julian MACEDO, Jason MACKEY, Sharyl MARTINI, Erin MCDONOUGH, Meena MUNSHI, Brian OLOIZIA, Art PANCIOLI, Katrina PEARISO, Jonathan RATCLIFF, Sameer SHARMA, Blake SMITH, Michael STAR, Brian STETTLER, Daniel WOO, Muhammad ZAGHLOULEH
	Study Coordinator(s)	Shannon DEEDS, Sara KEEGAN
St. Elizabeth Hospital Fort Thomas	Principal Investigators	Rahul KARAMCHANDANI, Kyle WALSH
	Co-Investigator(s)	Opeolu ADEOYE, Jordan BONOMO, Joseph BRODERICK, Rhonda CADENA, Elisheva COLEMAN, Felipe DE LOS RIOS LA ROSA, Stacie DEMEL, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Rachel GARVIN, Anna GENSIC, Sabreena GILLOW, Aaron GROSSMAN, Jonah GROSSMAN, Laura HEITSCH, Adam JASNE, Daniel KANTER, Brian KATZ, Pooja KHATRI, Brett KISSELA, Dawn KLEINDORFER, William KNIGHT, Natalie KREITZER, Julian MACEDO, Jason MACKEY, Sharyl MARTINI, Erin MCDONOUGH, Meena MUNSHI, Brian OLOIZIA, Art PANCIOLI, Katrina PEARISO, Jonathan RATCLIFF, Sameer SHARMA, Blake SMITH, Michael STAR, Brian STETTLER, Daniel WOO, Muhammad ZAGHLOULEH
	Study Coordinator(s)	Shannon DEEDS, Sara KEEGAN

St. Elizabeth Medical Center South	Principal Investigators	Rahul KARAMCHANDANI, Kyle WALSH
	Co-Investigator(s)	Opeolu ADEOYE, Jordan BONOMO, Joseph BRODERICK, Rhonda CADENA, Elisheva COLEMAN, Felipe DE LOS RIOS LA ROSA, Stacie DEMEL, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Rachel GARVIN, Anna GENSIC, Sabreena GILLOW, Aaron GROSSMAN, Jonah GROSSMAN, Laura HEITSCH, Adam JASNE, Daniel KANTER, Brian KATZ, Pooja KHATRI, Brett KISSELA, Dawn KLEINDORFER, William KNIGHT, Natalie KREITZER, Julian MACEDO, Jason MACKEY, Sharyl MARTINI, Erin MCDONOUGH, Meena MUNSHI, Brian OLOIZIA, Art PANCIOLI, Katrina PEARISO, Jonathan RATCLIFF, Sameer SHARMA, Blake SMITH, Michael STAR, Brian STETTLER, Daniel WOO, Muhammad ZAGHLOULEH
	Study Coordinator(s)	Shannon DEEDS, Sara KEEGAN
St. John Hospital and Medical Center	Principal Investigators	Robert DUNNE, Claire PEARSON
	Co-Investigator(s)	Elizabeth BASCOM, Paul CULLIS, Patricia NOUHAN, Margarita PENA, Makenzie THIMM, Robert WELCH, Michelle WIENER
	Study Coordinator(s)	Lynne FROEHLICH
St. Joseph Regional Health Center	Principal Investigator	Michael SPOHN
	Co-Investigator(s)	Derek CARAWAY, Paul GOEN, Brandon LEWIS, Michael MCDONALD, Kimberly OAS, Marcus PURVIS, Carmen RAMIREZ
	Study Coordinator(s)	Debbie LEWIS, Donna WEBB
Stony Brook University Hospital	Principal Investigator	Ethan BRANDLER
	Co-Investigator(s)	Laura DONARUMMO, Michael GUIDO, Candice PERKINS, Galyna PUSHCHINSKA, Adam SINGER
	Study Coordinator(s)	Maria TAYLOR
SUNY Downstate Medical Center	Principal Investigators	Pia CHATTERJEE, Steven LEVINE, Adrian MARCHIDANN, Richard SINERT
	Co-Investigator(s)	Clotilde BALUCANI, Ethan BRANDLER, Qing HAO, Richard JACKSON, Yongwoo KIM, Susan LAW, Jennifer MARTINDALE, Jay MELTON, Lorenzo PALADINO, Diana ROJAS-SOTO, Artem SUNIK, Benedict TAN, Helen VALSAMIS, Volodymyr VULKANOV, Shahriar ZEHTABCHI
	Study Coordinator(s)	Vanessa ARNEDO, Nadege GILLES, Saroj KUNNAKKAT, Catherine LUSHBOUGH, Sarah WEINGAST (ZELONIS)
The Jewish	Principal Investigators	Rahul KARAMCHANDANI, Kyle WALSH

Hospital	Co-Investigator(s)	Opeolu ADEOYE, Jordan BONOMO, Joseph BRODERICK, Rhonda CADENA, Elisheva COLEMAN, Felipe DE LOS RIOS LA ROSA, Stacie DEMEL, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Rachel GARVIN, Anna GENSIC, Sabreena GILLOW, Aaron GROSSMAN, Jonah GROSSMAN, Laura HEITSCH, Adam JASNE, Daniel KANTER, Brian KATZ, Pooja KHATRI, Charles KIRCHER, Brett KISSELA, Dawn KLEINDORFER, William KNIGHT, Natalie KREITZER, Julian MACEDO, Jason MACKEY, Sharyl MARTINI, Erin MCDONOUGH, Eva MISTRY, Meena MUNSHI, Brian OLOIZIA, Art PANCIOLI, Katrina PEARISO, Jonathan RATCLIFF, Sameer SHARMA, Blake SMITH, Michael STAR, Brian STETTLER, Daniel WOO, Muhammad ZAGHLOULEH
	Study Coordinator(s)	Shannon DEEDS, Sara KEEGAN
Thomas Jefferson University Hospital	Principal Investigator	AnnaMarie CHANG
	Co-Investigator(s)	Norman AJIBOYE, Sanjay ANANDARAM, Rodney BELL, Lisa BOWMAN, Shruti CHANDRA, Nina GENTILE, Jack JALLO, William MCBRIDE, Michael MOUSSOUTTAS, Maria Carissa PINEDA, Pranoti PRADHAN, Ray REGAN, Fred RINCON, Diana TZENG, Jacqueline URTECHO, Matthew VIBBERT, Jennifer WHITE, Sridhara YADDANAPUDI
	Study Coordinator(s)	Amanda FURLONG-SALVATORE, Jennifer GLENDENING, Nicole RENZI, Kiriaki SERENIDIS, Meghan-Patricia WAKEFIELD, Melissa WITT
UC Davis Medical Center	Principal Investigator	Daniel NISHIJIMA
	Co-Investigator(s)	Glen JICKLING, Kwan NG
	Study Coordinator(s)	Michaela CANOVA
UCSF Medical Center	Principal Investigator	Wade SMITH
	Co-Investigator(s)	Ahmad AHMAD, Aimee AYSENNE, John BETJEMANN, Molly BURNETT, Tamika BURRUS, Elizabeth CAHILL, Sheila CHAN, Judy CHANG, Natalie CHENG, Roger CHENG, Rene COLORADO, Amar DHAND, Vanja DOUGLAS, Julia DURRANT, Nancy EDWARDS, Christine FOX, Alan GELB, Trevor GREGATH, Cathra HALABI, Claude HEMPHILL, Karen HIRSCH, Andrew JOSEPHSON, Hooman KAMEL, Kevin KEENAN, Anthony KIM, Nerissa KO, Mohan KOTTAPALLY, Kathryn KVAM, Karl MEISEL, Asma MOHEET, Arturo MONTANO, Kazuma NAKAGAWA, Bharath NARAVETLA, Babak NAVI, Anh NGUYEN, Mai NGUYEN-HUYNH, Sharon POISSON, Prasanthi RAMANUJAM, Maulik SHAH, Nirav SHAH, Michel SHAMY, Kevin SHAPIRO, Peyman SHIRANI, Vineeta SINGH, Neel SINGHAL, Karl SPORER, Abraham THOMAS, Shahed TOOSSI, Christine WONG, Alan YEE, Debbie YI MADHOK, QingYang YUAN
	Study Coordinator(s)	Michele MEEKER, Dominica RANDAZZO, Kelley ROSBOROUGH
United Hospital	Principal Investigator	Sandra HANSON
	Co-Investigator(s)	Ganesh ASAITHAMBI, Michelle BIROS, Jesse CORRY, Mustapha EZZEDDINE, Dimitrios GIANNAKIDIS, Jane MONITA, Sheetal PATEL, Karen PORTH

	Study Coordinator(s)	Bridget HO
University of Cincinnati Medical Center	Principal Investigators	Rahul KARAMCHANDANI, Kyle WALSH
	Co-Investigator(s)	Opeolu ADEOYE, Samir BELAGAJE, Jordan BONOMO, Joseph BRODERICK, Rhonda CADENA, Elisheva COLEMAN, Felipe DE LOS RIOS LA ROSA, Stacie DEMEL, Bryan ECKERLE, Simona FERIOLI, Matthew FLAHERTY, Sabreena GALLOW, Rachel GARVIN, Anna GENSIC, Sabreena GILLOW, Aaron GROSSMAN, Jonah GROSSMAN, Laura HEITSCH, Adam JASNE, Daniel KANTER, Brian KATZ, Pooja KHATRI, Charles KIRCHER, Brett KISSELA, Dawn KLEINDORFER, William KNIGHT, Shannon KOHAKE, Natalie KREITZER, Julian MACEDO, Jason MACKEY, Sharyl MARTINI, Erin MCDONOUGH, Eva MISTRY, Meena MUNSHI, Brian OLOIZIA, Arthur PANCIOLI, Katrina PEARISO, Jonathan RATCLIFF, Sameer SHARMA, Blake SMITH, Michael STAR, Brian STETTLER, Daniel WOO, Muhammad ZAGHLOULEH
	Study Coordinator(s)	Shannon Iris DEEDS, Irene Ewing, Sara KEEGAN
University of Kansas Hospital	Principal Investigator	Michael ABRAHAM
	Co-Investigator(s)	Rawan ALBADAREEN, Bradley BARTH, Michelle BIROS, Chad CANNON, Colleen LECHTENBERG, Manoj MITTAL, Michael RIPPEE, Lee ROSTERMAN, Craig SHIPLEY, Jayashree SUNDARARAJAN, Yunxia WANG
	Study Coordinator(s)	Alison BOYDSTON, Shannon GIFFORD
University of Maryland Medical Center	Principal Investigator	Carolyn CRONIN
	Co-Investigator(s)	Michael ABRAHAM, Ermias AYTENFISU, John COLE, Tarra DUTTA, Lisa HERMANN, Jon M. HIRSHON, Chandni KALARIA, Steven KITTNER, Jose MERINO, Melissa MOTTA, Michael PHIPPS, Anna ROSENBAUM, Jay SHAH, Kevin SHETH, Christopher STACK, Barney STERN, Marcella WOZNIAK
	Study Coordinator(s)	Cameron DELL, Virginia GANLEY, Mary J. SPARKS, Tiffany WATSON
University of Minnesota Medical Center Hospital	Principal Investigator	Mustapha EZZEDDINE
	Co-Investigator(s)	Mohammed ALKUWAITI, Shola ALUKO, David ANDERSON, Ganesh ASAITHAMBI, Kristen BARKLOW, Oladi BENTHO, Michelle BIROS, Laura FOSTER, Mikayel GRIGORYAN, Ameer HASSAN, Taka HIGASHIMORI, Haitham HUSSEIN, Vik JADHAV, Jessica JARNOT, Daraspreet KAINTH, Amir KHAN, Jae KIM, Saritha KUNDOOR, Shailesh MALE, Tapan MEHTA, Benjamin MILLER, Cathy O'BRIEN, Haejoe PARK, Rwoof RESHI, Gustavo RODRIGUEZ, Kalyan SAJJA, Divyajot SANDHU, Biggya SAPKOTA, Kenneth SHEA, Nathan SIT, Jamie STARKS, Christopher STREIB, Robert TAYLOR, Wondwossen TEKLE, Ruth THOMSON, Huseyin TORE, Haralabos ZACHARATOS
	Study Coordinator(s)	Audrey HENDRICKSON, Kathleen MILLER, Mindy RUMBOLZ, Julie SCHERBER, Abbey STAUGAITIS
University of New Mexico Hospital	Principal Investigators	Christopher CALDER, Branko HUISA, Vishnumurthy SHUSHRUTHA HEDNA
	Co-Investigator(s)	Kurt DENNINGHOFF, Marc MALKOFF, Matthew STARR
	Study Coordinator(s)	Jill PRESTOPNIK

University of Toledo Medical Center	Principal Investigator	Mouhammad JUMAA
	Co-Investigator(s)	Gretchen TIETJEN, Syed ZAIDI
	Study Coordinator(s)	Andrea KORSNACK
UPMC Northwest	Principal Investigators	Vivek REDDY, Matthew STARR
	Co-Investigator(s)	Amin AGHAEBRAHIM, Cliff CALLAWAY, David CAMPBELL, Cameron DEZFULIAN, Ankur DOSHI, Dan-Victor GIURGIUTIU, Deepak GULATI, Frank GUYETTE, Maxim HAMMER, Ashutosh JADHAV, Tudor JOVIN, James MCLAUGHLIN, Jon RITTENBERGER, Marcelo ROCHA, Christopher STREIB, Ruta TOTORAITIS
	Study Coordinator(s)	Sara DIFIORE, Mary KRUTH
UPMC Presbyterian Hospital	Principal Investigators	Vivek REDDY, Matthew STARR
	Co-Investigator(s)	Amin AGHAEBRAHIM, Cliff CALLAWAY, David CAMPBELL, Ankur DOSHI, Jonathan ELMER, Dan-Victor GIURGIUTIU, Deepak GULATI, Frank GUYETTE, Maxim HAMMER, Anat HOREV, Ashutosh JADHAV, Tudor JOVIN, Sunanda NANDURI, Srikant RANGARAJU, Jon RITTENBERGER, Marcelo ROCHA, Christopher STREIB, Ruta TOTORAITIS, Lawrence WECHSLER
	Study Coordinator(s)	Sara DIFIORE, Mary KRUTH
UPMC Shadyside Hospital	Principal Investigators	Vivek REDDY, Matthew STARR
	Co-Investigator(s)	Amin AGHAEBRAHIM, Cliff CALLAWAY, David CAMPBELL, Cameron DEZFULIAN, Ankur DOSHI, Jonathan ELMER, Dan-Victor GIURGIUTIU, Deepak GULATI, Frank GUYETTE, Maxim HAMMER, Ashutosh JADHAV, Tudor JOVIN, Srikant RANGARAJU, Jon RITTENBERGER, Marcelo ROCHA, Christopher STREIB, Ruta TOTORAITIS
	Study Coordinator(s)	Sara DIFIORE, Mary KRUTH
Valley Baptist Medical Center - Harlingen	Principal Investigator	Ameer HASSAN
	Co-Investigator(s)	Elizabeth JONES, Julio OLMEDA, Victoria PARADA, Wondwossen TEKLE
	Study Coordinator(s)	Cacy CATE, Lisa JONES-FULLINGIM, Pamela NAUERTH, Olive SANCHEZ
VCU Medical Center	Principal Investigator	Warren FELTON
	Co-Investigator(s)	Joseph ORNATO
	Study Coordinator(s)	Mary Beth DONNER, Jeneane HENRY
William Beaumont Hospital	Principal Investigator	Robert SWOR
	Co-Investigator(s)	Carol CLARK, Russell RAE, Vito ROCCO, Sunitha SANTHAKUMAR, Kelly SAWYER, Michelle TRACY-WIENER, Robert WELCH
	Study Coordinator(s)	Heather GRACE, Brian WALKER
William Beaumont Hospital-Troy	Principal Investigator	Aveh BASTANI
	Co-Investigator(s)	Matthew CHRISTENSEN, Aharon Gedaliah COOPER, Steven DIMSDALE, David DONALDSON, Michael OPSOMMER, Albert ROCCHINI, Robert SWOR, Brett TODD, Robert WELCH
	Study Coordinator(s)	Heonia HILLOCK, Pamela MARSACK
Yale-New Haven Hospital	Principal Investigator	Joseph SCHINDLER
	Study Coordinator(s)	Zachary KING, Cora ORMSETH, Lynda RYALL, Sonya ZHOU

SUMMARY OF DELIBERATIONS BY THE POINT DSMB
FOR STOPPING THE POINT TRIAL EARLY

Prepared by

Peter Gilbert
Misha Eliasziw
Gregory J. del Zoppo

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The Statistical Analysis Plan for the POINT trial specified the use of the O'Brien-Fleming alpha-spending function approach for the interim analyses, whereby the looks would occur after approximately 1/3 and 2/3 of the total anticipated number of primary endpoint events (530) had been observed and adjudicated. The investigators chose the alpha-spending function approach because it allows flexibility in the number and timing of interim analyses.

Early on, it became clear to the DSMB that the overall primary endpoint event rate in the trial was too low for the planned sample size of 4,150 participants to ever reach 530 primary events and the DSMB decided that due diligence dictated that a first interim analysis should be performed in March 2013 even though one-third of 530 events hadn't occurred. Because at the time of the first interim analysis 33% (n=1,352) of the participants had been enrolled, this ensured that the investigators and investigative team would remain blinded to the lower-than-expected overall event rate.

Following the rules set out in the Statistical Analysis Plan, the sample size following the first interim analysis was increased to 5,840 participants and the statistical power was reduced from 90% to 80%. This resulted in revising the total expected number of endpoint events to 388. As time went by, however, it became clear that even this number would not be reached given the overall event rate which, inexplicably, declined continually throughout the trial.

The observed Hazard Ratios in the trial (for adjudicated plus unadjudicated events) were 0.77, 0.70 and 0.75 for the primary efficacy outcome at the three interim analyses (database frozen on March 2013, April 2016, and November 2017, respectively), with observed p-values of 0.22, 0.012 and 0.015, and 91, 206, and 275 total events, respectively. Similar results held for analyses using adjudicated events only.

At the time of the second interim analysis, the p-value came close to crossing the stopping boundary (0.0079) based on the expected number of total enrollments. This information fraction was chosen because it was clear that calculating the information fraction based on an anticipated 388 total events was inappropriate.

The DSMB consisted of very experienced clinical trialists who were well-aware of the phenomenon that trials stopped early may overestimate the effectiveness of treatment. The DSMB wanted to make sure that the treatment effect observed at the second interim analysis

was “real” and not a “random high.” They asked the unblinded statistician to repeat the analysis for the primary endpoint using only the first 125 and the first 160 primary events. These analyses showed similar treatment effects and provided assurance that the observed HR was real. The DSMB also considered the results from the CHANCE trial during their deliberations, and the fact that the CHANCE trial showed a similar treatment effect was reassuring.

By this time in the trial, the DSMB felt confident that dual therapy was efficacious. Nevertheless, the DSMB decided to continue the trial until the interim analysis stopping boundary was officially crossed.

In addition, the DSMB had been monitoring the safety data in the trial on a monthly basis and had consistently observed an excess of hemorrhages (of all types and severities) in the dual therapy arm. The overall number of hemorrhages was small, however, and it was not until August 2017 when the 95% confidence interval around the RR (and HR) for major hemorrhage – the primary safety outcome – excluded 1. Because historically only very few clinical trials in this area showed a significant difference in major hemorrhages, and to be certain that the safety trend was sustained, it was agreed to follow the major hemorrhage events to the semi-annual meeting in December, 2017.

The DSMB anticipated that, given the trends observed over the course of the trial, a sufficient number of primary endpoint events and major hemorrhage events could accumulate by the time of its semi-annual meeting in December 2017 to breach the stopping boundaries, and therefore decided to request a third interim analysis. The analysis did indeed show that the stopping boundaries had been crossed. Thus, the DSMB recommended to the NINDS that the study stop enrollment because the trial had crossed the pre-specified safety threshold for major hemorrhage. At the same time, the primary efficacy endpoint was met and additional enrollment was not expected to markedly change the observed hazard ratio of 0.75, which was the target specified in the Statistical Analysis Plan.

Please let us know if you require further information or documentation.

Table S1. Summary of serious adverse events by MedDRA body system, excluding components of the primary efficacy outcome measure, by intention to treat.*

Body System	Number (%) of patients	
	Clopidogrel-Aspirin (N=2432)	Aspirin (N=2449)
Total	295 (12.1%)	272 (11.1%)
Nervous system disorders	113 (4.6%)	115 (4.7%)
Cardiac disorders	48 (2.0%)	33 (1.3%)
Vascular disorders	17 (0.7%)	24 (1.0%)
Infections and infestations	24 (1.0%)	16 (0.7%)
Gastrointestinal disorders	24 (1.0%)	14 (0.6%)
Surgical and medical procedures	15 (0.6%)	19 (0.8%)
Respiratory, thoracic and mediastinal disorders	14 (0.6%)	14 (0.6%)
Psychiatric disorders	14 (0.6%)	13 (0.5%)
General disorders and administration site conditions	19 (0.8%)	5 (0.2%)
Injury, poisoning and procedural complications	12 (0.5%)	7 (0.3%)
Renal and urinary disorders	10 (0.4%)	7 (0.3%)
Neoplasms benign, malignant,d unspecified (incl cysts and polyps)	6 (0.2%)	9 (0.4%)
Metabolism and nutrition disorders	10 (0.4%)	4 (0.2%)
Musculoskeletal and connective tissue disorders	6 (0.2%)	4 (0.2%)
Skin and subcutaneous tissue disorders	8 (0.3%)	2 (0.1%)
Congenital, familial and genetic disorders	2 (0.1%)	2 (0.1%)
Hepatobiliary disorders	4 (0.2%)	0 (0.0%)
Investigations	3 (0.1%)	0 (0.0%)
Eye disorders	1 (0.0%)	2 (0.1%)
Blood and lymphatic system disorders	1 (0.0%)	2 (0.1%)
Ear and labyrinth disorders	1 (0.0%)	2 (0.1%)
Immune system disorders	1 (0.0%)	1 (0.0%)
Reproductive system and breast disorders	1 (0.0%)	0 (0.0%)

*There were no differences by treatment group except for general disorders and administration site conditions (p=0.004).

Table S2. Summary of serious adverse events by MedDRA body system, excluding components of the primary efficacy outcome measure, in an as-treated analysis.*

Body System	Number (%) of patients	
	Clopidogrel-Aspirin (N=2398)	Aspirin (N=2421)
Total	254 (10.6%)	221 (9.1%)
Nervous system disorders	95 (4.0%)	98 (4.0%)
Cardiac disorders	37 (1.5%)	30 (1.2%)
Vascular disorders	14 (0.6%)	20 (0.8%)
Gastrointestinal disorders	20 (0.8%)	8 (0.3%)
Infections and infestations	17 (0.7%)	11 (0.5%)
Psychiatric disorders	12 (0.5%)	10 (0.4%)
General disorders and administration site conditions	16 (0.7%)	5 (0.2%)
Surgical and medical procedures	12 (0.5%)	9 (0.4%)
Respiratory, thoracic and mediastinal disorders	10 (0.4%)	9 (0.4%)
Injury, poisoning and procedural complications	9 (0.4%)	7 (0.3%)
Renal and urinary disorders	9 (0.4%)	6 (0.2%)
Metabolism and nutrition disorders	8 (0.3%)	2 (0.1%)
Musculoskeletal and connective tissue disorders	6 (0.3%)	3 (0.1%)
Skin and subcutaneous tissue disorders	8 (0.3%)	1 (0.0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.2%)	4 (0.2%)
Congenital, familial and genetic disorders	1 (0.0%)	2 (0.1%)
Eye disorders	1 (0.0%)	2 (0.1%)
Blood and lymphatic system disorders	1 (0.0%)	2 (0.1%)
Ear and labyrinth disorders	1 (0.0%)	2 (0.1%)
Investigations	2 (0.1%)	0 (0.0%)
Immune system disorders	1 (0.0%)	1 (0.0%)
Hepatobiliary disorders	2 (0.1%)	0 (0.0%)
Reproductive system and breast disorders	1 (0.0%)	0 (0.0%)

*There were no differences by treatment group except for gastrointestinal disorders (p=0.02) and general disorders and administration site conditions (p=0.02).

Table S3. Frequency of study drug discontinuation by reason.

		Treatment				Total	
		Clopidogrel-Aspirin		Aspirin			
		N	%	N	%	N	%
Total		721	100.0 %	674	100.0 %	1395	100.0 %
Decision Type	**Discontinuation Reason**						
Physician Decision	Candidate for prohibited med	151	20.9 %	157	23.2 %	308	22.0 %
	Experienced a possibly related adverse event (headache, GI, etc.)	179	24.8 %	117	17.3 %	296	21.2 %
	Primary physician discontinued	103	14.2 %	105	15.5 %	208	14.9 %
	Experienced an outcome event	44	6.1 %	50	7.4 %	94	6.7 %
	Pre-surgery or procedure and/or post-surgery or procedure	17	2.3 %	20	2.9 %	37	2.6 %
	Other ongoing intervening illness	9	1.2 %	15	2.2 %	24	1.7 %
Patient Decision	Declined continuation after reconsideration	119	16.5 %	105	15.5 %	224	16.0 %
	Declined continuation for unspecified reasons	21	2.9 %	27	4.0 %	48	3.4 %
	Subject error	11	1.5 %	4	0.5 %	15	1.0 %
	Study medication lost	5	0.6 %	8	1.1 %	13	0.9 %
	General (loss of interest)	2	0.2 %	8	1.1 %	10	0.7 %
Study Team Decision	Incorrect qualifying event diagnosis	38	5.2 %	44	6.5 %	82	5.8 %
	Site discontinued study medication	11	1.5 %	7	1.0 %	18	1.2 %
Other	Other	8	1.1 %	5	0.7 %	13	0.9 %
	Nursing home refused to administer	3	0.4 %	2	0.2 %	5	0.3 %

Table S4. Efficacy and Safety Stratified by Time Period

Time Period	Outcome	Clopidogrel-Aspirin (N=2432)		Aspirin (N=2449)		Hazard Ratio (95% CI)	P Value
		Patients with Event *no.*	Event Rate *%*	Patients with Event *no.*	Event Rate *%*		
0-7 days	Ischemic stroke, MI, or ischemic vascular death	70	2.9%	111	4.5%	0.74 (0.55 - 0.99)	0.04
	Major hemorrhage	7	0.3%	4	0.2%	1.82 (0.53 – 6.22)	0.34
8-90 days	Ischemic stroke, MI, or ischemic vascular death	51	2.1%	49	2.0%	1.03 (0.70-1.53)	0.88
	Major hemorrhage	16	0.7%	6	0.2%	2.69 (1.05 - 6.86)	0.04
0-30 days	Ischemic stroke, MI, or ischemic vascular death	96	3.9%	141	5.8%	0.73 (0.56 - 0.95)	0.02
	Major hemorrhage	12	0.5%	6	0.2%	2.05 (0.76 - 5.56)	0.16
31-90 days	Ischemic stroke, MI, or ischemic vascular death	25	1.0%	19	0.8%	1.30 (0.72 - 2.36)	0.39
	Major hemorrhage	11	0.5%	4	0.2%	2.77 (0.88 - 8.70)	0.08

Table S5. Additional Baseline Characteristics of the Participants*

Characteristic	Clopidogrel-Aspirin (N=2432)	Aspirin (N=2449)
Enrolling Country - no. (%)		
Australia	53 (2.2%)	51 (2.1%)
Canada	121 (5.0%)	119 (4.9%)
Finland	25 (1.0%)	25 (1.0%)
France	51 (2.1%)	47 (1.9%)
Germany	8 (0.3%)	10 (0.4%)
Mexico	5 (0.2%)	4 (0.2%)
New Zealand	3 (0.1%)	4 (0.2%)
Spain	119 (4.9%)	122 (5.0%)
United Kingdom	33 (1.4%)	38 (1.6%)
United States	2014 (82.8%)	2029 (82.9%)
Systolic blood pressure (mmHg) - median (interquartile range)	159.0 (143.0-180.0)	159.0 (142.0-179.0)
Diastolic blood pressure (mmHg) - median (interquartile range)	87.0 (77.0-98.0)	87.0 (76.0-98.0)
Medical History - no. (%)		
Congestive Heart Failure	64 (2.6%)	62 (2.5%)
Atrial fibrillation	31 (1.3%)	18 (0.7%)
Current tobacco smoker – no. (%)	496 (20.4%)	508 (20.8%)
Time from randomization to study drug administration (h) - median (interquartile range)	1.0 (0.0-1.0)	1.0 (0.0-1.0)

*The differences in baseline characteristics between the treatment groups were not significant.

Table S6. Pre-specified Secondary and Tertiary Analyses

Outcome	Clopidogrel-Aspirin (N=2432)		Aspirin (N=2449)		Hazard Ratio (95% CI)	P Value
	Patients with Event *no.*	Event Rate *%*	Patients with Event *no.*	Event Rate *%*		
Secondary Analyses (as-treated sample)	**(N=2398)**		**(N=2421)**			
Primary Outcome: ischemic stroke, MI, or ischemic vascular death analyzed with the as-treated sample	102	4.3%	141	5.8%	0.73 (0.56 -- 0.94)	0.01
Primary safety outcome: major hemorrhage analyzed with the as-treated sample	21	0.9%	6	0.2%	3.57 (1.44 -- 8.85)	<0.01
Tertiary Analyses (Intent-to-treat sample)	**(N=2432)**		**(N=2449)**			
Primary Outcome: ischemic stroke, MI, or ischemic vascular death analyzed with adjustment for enrolling site	-	-	-	-	0.75 (0.60 -- 0.95)	0.02
Primary Outcome: ischemic stroke, MI, or ischemic vascular death analyzed with adjustment for age, onset time, evidence of brain infarction, and enrolling site	-	-	-	-	0.74 (0.59--0.94)	0.01
Composite event of ischemic stroke, TIA, MI, or ischemic vascular death	197	8.1%	250	10.2%	0.79 (0.65 – 0.95)	0.01
Composite of ischemic stroke, MI, all-cause death, or major hemorrhage	149	6.1%	171	7.0%	0.87 (0.70 – 1.08)	0.21
TIA	89	3.7%	96	3.9%	0.94 (0.70 – 1.26)	0.68
Coronary Revascularization (with or without MI)	5	0.2%	5	0.2%	1.01 (0.29 – 3.48)	0.99
Vascular Death	9	0.4%	6	0.2%	1.51 (0.54 – 4.24)	0.43
Asymptomatic intracranial hemorrhage (ICH, SAH, SDH or IVH)	5	0.2%	2	0.1%	2.52 (0.49 – 13.00)	0.25
					Odds Ratio (95% CI)	
New handicap/disability defined as 90 day mRS (≥2) ł	324	13.3%	335	13.7%	0.97 (0.82--1.14)	0.71*
	Median	**IQR**	**Median**	**IQR**		**P Value**
90 day mRS[ł]	0	0-1	0	0-1		0.62**

*p-value is from Wald Chi-squared test of treatment group in a logistic regression of the mRS≥2

**p value is from a Wilcoxon-Rank sum test

ł Missing mRS scores at 90 days were imputed with the mRS score observed at the outcome event visit for 24 (0.5%) patients and with the predicted value from a regression model of 90 day mRS adjusted for baseline age, time from onset to randomization, and evidence of brain

infarct (CT/MRI) for 331 (6.7%) patients.