

## Supplementary Appendix

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

Supplement to: Baden LR, El Sahly HM, Essink B, et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. *N Engl J Med* 2021;384:403-16. DOI: [10.1056/NEJMoa2035389](https://doi.org/10.1056/NEJMoa2035389)

(PDF updated January 21, 2021.)

<b>Table of Contents</b>	<b>Pg.</b>
COVE Study Group.....	2
List of COVE Study Trial Investigators and Team.....	5
Supplemental Statistical Methods.....	15
Fig. S1. Study Disposition in Overall Randomized Set.....	18
Table S1. Primary and Secondary Objectives of the Trial.....	19
Table S2. Baseline Demographics and Characteristics by Randomization Strata.....	21
Table S3. Solicited Adverse Reactions Within 7 Days After First Injection by Grade.....	24
Table S4. Solicited Adverse Reactions Within 7 days After First Injection by Grade.....	26
Table S5. Number of Days Reporting Solicited Adverse Reactions After First Injection.....	28
Table S6. Solicited ARs by SARS-CoV-2 Baseline Status By Grade After Vaccination 1.....	29
Table S7. Solicited ARs by SARS-COV-2 Baseline Status By Grade After Vaccination 2.....	31
Table S8. Unsolicited AEs 28 Days After Any Injection, Overall Safety Set.....	33
Tables S9-11. Unsolicited AEs, Overall Safety Set.....	34
Table S12. Unsolicited Adverse Events of Hypersensitivity, Overall Safety Set.....	38
Table S13. Covid-19 Symptoms and Severity.....	39
Table S14. Characteristics of Participants with Severe Covid-19.....	40
Table S15. Serious and Severe Treatment-Related AEs Up to 28 Days After Any Injection...	41
Table S16. Efficacy of Key Secondary Endpoints.....	42
Table S17. Vaccine Efficacy by SARS-COV-2 Status.....	43
Table S18. Preliminary Analysis of Infection from Randomization.....	44

**COVE Study Group (pubmed listed, and ordered alphabetically by institution affiliation)**

Affiliation/Funding*	Study Group	Location
AB Clinical Trials	Atoya Adams, MD, MBA, Eric Miller	Las Vegas, NV
Accel Research Sites	Bruce G. Rankin DO, John Hill MD, Steven Shinn MD, Marshall Nash MD	DeLand, FL
Advanced Clinical Research	Sinikka L. Green MD, Colleen Jacobsen, Jayasree Krishnankutty, Sikhongi Phungwayo	Cedar Park, TX
Alliance for Multispecialty Research	Richard M. Glover, II MD, Drs. Stacy Slechta, Troy Holdeman, Robyn Hartvickson, Amber Grant	Newton, KS
Alliance for Multispecialty Research	Terry L. Poling MD, Terry D. Klein MD, Thomas C. Klein MD, Tracy R. Klein MD	Wichita, KS
Alliance for Multispecialty Research	William B. Smith MD, Richard L. Gibson MD, Jennifer Winbigler MD, Elizabeth Parker PA	Knoxville, TN
Baptist Health Center for Clinical Research	Priyantha N. Wijewardane, MD, Eric Bravo MD, Jeffrey Thessing MD, Michelle Maxwell APRN, Amanda Horn APRN	Little Rock, AR
Baylor College of Medicine, NIAID 1UM1AI148575-01S2	Hana El Sahly MD, Jennifer Whitaker MD, Catherine Mary Healy MD, Christine Akamine MD	Houston, TX
Benchmark Research	Laurence Chu, MD, R. Michelle Chouteau, MD	Austin, TX
Benchmark Research	Michael J. Cotugno MD, George H. Bauer, Jr. MD	Metairie, LA
Benchmark Research	Greg Hachigian MD, Masaru Oshita MD, Michael Cancilla NP, Deborah Murray NP, Kristen Kiersey NP	Sacramento, CA
Benchmark Research	William Seger MD, Mohammed Antwi, Allison Green, Anthony Kim	Fort Worth, TX
Brigham and Women's Hospital, NIAID UM1AI069412, NCATS UL1RR025758	Lindsey R Baden MD, Michael Desjardins MD, Jennifer A Johnson MD, Amy Sherman MD, Stephen R Walsh MD	Boston, MA
Carolina Institute for Clinical Research	Judith Borger DO, Ryan Starr DO, Scott Syndergaard DO, Nafisa Saleem MD	Fayetteville, NC
Centex Studies	Joel Soils MD, Martha Carmen Medina PA-C, Westly Keating PA-C, Edgar Garcia PA-C, Cynthia Bueno PA-C	McAllen, TX
Clinical Research Atlanta	Nathan Segall MD, Nathan Segall, Jon Finley, Mildred Stull	Stockbridge, GA
Clinical Trials of Texas	Douglas Scott Denham DO, Thomas Weiss MD, Ayoade Aworo DNP, Parke Hedges MD	San Antonio, TX
Coastal Carolina Research Center	Cynthia Becher Strout MD, Rica Santiago, Yvonne Davis, Patty Howenstine, Alison Bondell	Mount Pleasant, SC
Cornell Clinical Trials Unit - Weill Cornell Uptown & Weill Cornell Chelsea, NIAID UM1AI068619, NCAT UL1TR002384	Kristin Marks MS MD, Grant Ellsworth, MS, MD, Tina Wang, MD, Timothy Wilkin, MD, MPH, Mary Vogler, MD, Carrie Johnston, MD, MS	New York, NY
Covid19 Prevention Network (CoVPN, NIAID-NIH)	Michele P Andrasik, Jessica G Andriesen, Gail Broder, Lawrence Corey, Niles Eaton, Kathleen M Neuzil, Huub G Gelderblom, James G Kublin, Rachael McClennen, Nelson Michael, Merlin Robb, Carrie Sopher	Seattle, WA
DM Clinical Research	Vicki E. Miller MD, MPH, Fredric Santiago MD, Blanca Gomez FNP-C, Insiya Valika PA-C, Amy Starr FNP-C	Tomball, TX
Emory University – Ponce de Leon Clinical Research Site, NIAID 3UM1AI068614-14S1	Colleen Kelley MD MPH, Valeria D Cantos MD, Sheetal Kandiah MD MPH, Carlos del Rio MD	Atlanta, GA
Emory University – Hope Clinic, NIAID 1UM1AI148576-01	Nadine Rouphael MD, Paulina Rebolledo, Sriatha Edupuganti, Daniel Sans Graciaa	Decatur, GA
Emory University School of Medicine, NIAID 1UM1AI148576-01	Evan J Anderson MD, Andres Camacho-Gonzalez MD, Satoshi Kamidani MD, Christiana A Rostad MD, Meghan Teherani MD	Atlanta, GA
George Washington University, NIAID UM1AI068619	David Joseph Diemert MD, Elissa Malkin, Marc Siegel, Afsoon Roberts, Gary Simon	Washington, DC
Hackensack University Medical Center	Bindu Balani MD, Carolene Stephenson, Steven Sperber, Cristina Cicogna	Hackensack, NJ
Henry Ford Health System	Marcus J. Zervos MD, Paul Kilgore MD, MPH, Mayur Ramesh MD, Erica Herc MD, Kate Zenlea MPH	Detroit, MI
Hope Research Institute	Abram Burgher MD, Ann Marie Milliken	Phoenix, AZ
Hope Research Institute	Joseph D. Davis MD, Brendan Levy, Sandra Kelman	Chandler, AZ
Hope Research Institute	Matthew W. Doust MD, Denise Sample, Sandra Erickson	Phoenix, AZ
J. Lewis Research	Shane Glade Christensen MD, Christopher Matich, James Longe, John Witbeck	Salt Lake City, UT
J. Lewis Research	James Todd Peterson MD, Alexander Clark, Gerald Kelly, Issac Pena-Renteria	Salt Lake City, UT
Jacksonville Center for Clinical Research	Michael J. Koren MD, Darlene Bartilucci MD, Jeffery Jacqmeim MD, Alpa Patel MD, Carolyn Tran MD	Jacksonville, FL

Affiliation/Funding*	Study Group	Location
Javara	Christina Kennelly MD, Robert Brownlee, Jacob Coleman, Hala Webster	Charlotte, NC
Johnson County Clin-Trials	Carlos A. Fierro MD, Natalia Leistner, Amy Thompson, Celia Gonzalez	Lenexa, KS
Kaiser Permanente Washington Health Research Institute, NIAID 1UM1AI148373-01	Lisa A Jackson MD MPH, Janice Suyehira MD	Seattle, WA
Laguna Clinical Research Associates	Milton Haber MD, Maria M. Regalado MD, Veronica Procasky RN JD, Alisha Lutat	Laredo, TX
Lynn Health Science Institute	Carl P. Griffin MD, Raymond Cornelison, William Schnitz, Shanda Gower	Oklahoma City, OK
Lynn Institute of the Rockies	Ripley R. Hollister MD, Jeremy Brown DO, Melody Ronk PA-C	Colorado Springs, CO
M3 Wake Research	Wayne Lee Harper MD, Lisa Cohen DO, Lynn Eckert PA-C, Matthew Hong MD	Raleigh, NC
MediSync Clinical Research Hattiesburg Clinic	Rambod Rouhbakhsh MD, MBA, Elizabeth Danford MD, John Johnson MD, Richard Calderone MD	Petal, MS
Meridian Clinical Research	Shishir Kumar Khetan MD, Oyebisi Olanrewaju AC-CRNP, Nan Zhai NP-C, Kimberly Nieves AC-CRNP, Allison O'Brien AC-CRNP	Rockville, MD
Meridian Clinical Research	Paul Simon Bradley MD, Amanda L'ilienthal MSN NP-C, Jim Callis PA-C	Savannah, GA
Meridian Clinical Research	Adam Benson Brosz MD, Andrea Ciement PA, Whitney West APRN, Luke Friesen PA, Paul Cramer APRN	Grand Island, NE
Meridian Clinical Research	Frank Steven Eder MD, Ryan Little FNP, Victoria Engler FNP, John Tarbox FNP, Heather Rattenbury-Shaw DO	Binghamton, NY
Meridian Clinical Research	David Jon Ensz MD, Tavane Harrison, Allie Oplinger	Dakota Dunes, SD
Meridian Clinical Research	Brandon James Essink MD, Jay Meyer MD, Frederick Raiser, III MD, Kimberly Mueller APRN, Roni Gray PA	Omaha, NE
Meridian Clinical Research	Keith William Vrbicky MD, Charles Harper MD, Chelsie Nutsch MD, Wendell Lewis III MD, Cathy Laflan MD	Norfolk, NE
Meridian Clinical Research	Jordan L. Whatley MD, Nicole Harell MD, Amie Shannon MD, Crystal Rowell APRN, FNP-C, Christopher Dedon APRN, FNP-C	Baton Rouge, LA
NIH	Mamodikoe Makhene MD MPH	Bethesda, MD
New Horizons Clinical Research	Gregory Mark Gottschlich MD, Kate Harden PA-C, Melissa Gottschlich PA-C, Mary Smith MSN, FNP-C, Richard Powell MD	Cincinnati, OH
Optimal Research	Murray A. Kimmel DO, Simmy Pinto MD	Melbourne, FL
Optimal Research	Timothy P. Vachris MD, Mark Hutchens MD, Stephen Daniels DO, Margaret Wells MD	Austin, TX
Optimal Research	Mimi Van Der Leden MD, PhD, Peta Gay Jackson Booth MD	Rockville, MD
Palm Beach Research Center	Mira Baron MD, Pamela Kane DO, Shannen Severson PA-C, Mara Kryvicky PA-C, Julia Lord PA-C	West Palm Beach, FL
Paradigm Clinical Research Center	Jamshid Saleh MD, Matthew Miles, Rafael Lupercio	Redding, CA
Quality of Life Medical & Research Centers	John W. McGettigan Jr. MD, Walter Patton MD, Riemke Brakema MD, Karin Choquette MSN, ABNP-C, Jonlyn McGettigan MSN, RN	Tucson, AZ
Rancho Paseo Medical Group	Judith L. Kirstein MD, Marcia Bernard NP	Banning, CA
Rapid Medical Research	Mary Beth Manning MD, Joan Rothenberg MD, Toby Briskin MD, Denise Roadman PAC, Sharita Tedder-Edwards FNP	Cleveland, OH
Research Centers of America	Howard I. Schwartz MD, Surisday Mederos, Barbara Corral, Jennifer Schwartz, Nelia Sanchez-Crespo	Hollywood, FL
Rutgers New Jersey Medical School, NIAID UM1AI068619	Shobha Swaminathan MD, Amesika Nyaku MD MS, Tilly Varughese MD, Michelle DallaPiazza MD	Newark, NJ
Saint Louis University, NIAID 1UM1AI148685-01	Sharon E Frey MD, Irene Graham MD, Getahun Abate MD PhD MSc, Daniel Hofstetter MD PhD	St. Louis, MO
St. Vincent's Health System	Leland N. Allen III MD, Leslie Anne Edwards MSN, CRNP, William Simpson Davis Jr., MS PA-C, Jessica Maria Mena, PA	Birmingham, AL
Suncoast Research Group	Mark E. Kutner MD, Jorge Caso MD, CPI, Maria Hernandez Moran APRN, Marianela Carvajal APRN, Janet Mendez APRN	Miami, FL
Sundance Clinical Research	Larkin T. Wadsworth III MD, Horacio Marafioti, Lyly Dang, Jennifer Berry, Lauren Clement	St. Louis, MO
Synexus Clinical Research	Michael Ryan Adams MD, Leslie Iverson PA	Murray, UT
Synexus Clinical Research	Joseph Lee Newberg MD, Laura Pearlman MS, MD, MBA	Chicago, IL
Synexus Clinical Research	Paul Joseph Nugent DO, Leonard Singer	Cincinnati, OH
Synexus Clinical Research	Michele Diane Reynolds MD, Jennifer Bashour MD, Robert Schmidt MD	Dallas, TX
Synexus Clinical Research	Neil Parmanand Sheth MD, Kenneth Stell DO	Glendale, AZ

Affiliation/Funding*	Study Group	Location
Synexus Clinical Research	Ramy Joseph Toma MD, William Kirby MD, Pink Folmar MD, Samantha Williams NP	Birmingham, AL
Synexus Clinical Research	Judith White MD, Robert Meyer MD, Sejal Patel MD, Prity Patel APRN	Orlando, FL
Tekton Research	Paul Pickrell MD, Stefanie Mott FNP-C, Carol Ann Linebarger MD, Hussain Malbari MD, David Pampe MD	Austin, TX
Texas Center for Drug Development	Veronica G. Fragoso MD, Lisa Holloway MD, Cecilia McKeown-Bragas MD, Teresa Becker MD, Vicki Miller MD	Houston, TX
Trial Management Associates	Barton G. Williams MD, William H. Jones MD	Wilmington, NC
VA Greater Los Angeles Healthcare System	Michael Lewis MD, Elham Ghadishah, Joseph Yusin, Mai Pham	Los Angeles, CA
University of California Los Angeles, NIAID UM1AI068619	Jesse L Clark MD, Steven Shoptaw PhD, Michele Vertucci PA, NP, Will Hernandez NP	Los Angeles, CA
University of California San Diego, NIAID UM1AI068636	Stephen A. Spector MD, Amaran Moodley MD, Jill Blumenthal MD, Lisa Stangl NP, Karen Deutsch NP	La Jolla, CA
University of Chicago	Kathleen M. Mullane DO PharmD, David Pitrak MD, Cheryl Nuss FNP, Judy Pi PharmD	Chicago, IL
University of Cincinnati, NIAID UN1AI068619	Carl Fichtenbaum MD, Margaret Powers-Fletcher PhD, Michelle Saemann RN, Sharon Kohrs RN	Cincinnati, OH
University of Colorado Denver, Anschutz Medical Campus, NIAID UM1AI068636	Thomas B. Campbell MD, Andrew Lauria, Jose Castillo Mancilla, Hillary Dunlevy	Aurora, CO
University of Illinois at Chicago – Project WISH, NIAID UM1AI068619	Richard M Novak MD, Andrea Wendrow, Scott Borgetti, Ben Ladner	Chicago, IL
University of Maryland School of Medicine, NIAID 1UM1AI148689-01	Karen L Kotloff MD, Matthew Laurens, Milagritos Tapia, Lisa Chrisley, Cheryl Young	Baltimore, MD
University of Miami, NIAID 3UM1AI068614-14S1	Susanne Doblecki-Lewis MD, Maria Luisa Alcaide, Jose Gonzales-Zamora, Stephen Morris	Miami, FL
University of North Carolina at Chapel Hill, NIAID UM1AI068619	Cynthia Gay MD MPH, David Wohl MD, Joseph Eron, Jr. MD	Chapel Hill, NC
University of Pennsylvania, NIAID 3UM1AI068614-14S1	Ian Frank MD, Debora Dunbar, David Metzger, Florence Momplaisir	Philadelphia, PA
University of Pittsburgh Medical Center, NIAID 1UM1AI148452-01	Judith Martin MD, Alejandro Hoberman MD, Timothy Shope MD MPH, Gysella Muniz MD	Pittsburgh, PA
University of Texas Medical Branch, NIAID 1UM1AI148575-01	Richard Rupp MD, Amber Stanford PA-C, Megan Berman MD, Laura Porterfield MD	Galveston, TX
VA Greater Los Angeles Healthcare System	Michael Lewis MD, Elham Ghadishah, Joseph Yusin, Mai Pham	Los Angeles, CA
Vanderbilt University Medical Center, NIAID 1UM1AI148452-01	Clarence Buddy Creech II MD, Shannon Walker MD, Stephanie Rolsma MD PhD, Robert Samuels, Isaac Thomsen MD	Nashville, TN
Vanderbilt University Medical Center, NIAID 3UM1AI068614-14S1	Spyros Andrews Kalams MD, Greg Wilson MD	Nashville, TN
Velocity Clinical Research	Gregg H. Lucksinger MD, Kevin Parks MD, Ryan Israelsen MD, Jaleh Ostover FNP-C, Kary Kelly FNP-C	Medford, OR
Velocity Clinical Research, San Diego	Jeffrey Scott Overcash MD, Hanh Chu, Kia Lee, Karla Zepeda	La Mesa, CA
VitaLink Research	Luis I. De La Cruz MD, Steve Clemons, Elizabeth Everette, Suzanna Studdard	Greenville, SC
VitaLink Research	Gowdhami Mohan MD, Stefanie Tyson, Alyssa-Kay Peay, Danyel Johnson	Anderson, SC
VitaLink Research-Spartanburg	Gregory J. Feldman MD, May-Yin Suen, Jacqueline Muenzner, Joseph Boscia, Farhan Siddiqui	Spartanburg, SC
Wake Forest University Health Sciences	John Sanders MD, PhD, James Peacock MD, Julio Nasim MD	Winston Salem, NC
WR-Clinical Research Center of Nevada	Michael L. Levin MD, Julie Hussey MSN APRN FNP-C, Marcy Kulic MD	Las Vegas, NV
WR-ClinSearch	Mark Montgomery McKenzie MD, Teresa Deese, Erica Osmundsen, Christy Sweet	Chattanooga, TN
WR-Global Medical Research	Valentine Mbepson Ebuh MD MA MSc, Elwaleed Elnagar MD, Georgette Ebuh DNP APRN FNP-C, Genevieve Iwuala FNP	Dallas, TX
WR-Medical Center for Clinical Research	Laurie J. Han-Conrad MD, Todd Simmons MD, Denis Tarakjian MD	San Diego, CA

\*Funding of institutions by the National Institute of Allergy and Infectious Diseases (NIAID) and/or research support by the National Center for Advancing Translational Science (NCATS) as indicated. All other institutions were funded by Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority. The content of this publication is solely the responsibility of the authors and does not necessarily represent the official views of the funding sources.

## List of COVE Trial Investigators and Study Teams

Principal Investigator	Study Team	Institution	Location
Atoya Adams, MD, MBA	Miriah Campbell, Eric Miller, Daisy Langarica, Alia Bober, Diana Giraldo	AB Clinical Trials	Las Vegas, NV
Michael Ryan Adams, MD	Leslie Iverson, Andryelle Toledo, Melinda Bullington, Alicia Hanten, Carolyn Taylor, Shannon Wright, Chase Carnahan, Rachel Law, Natalie Smith, Julie Taylor, Jared-Robert Blake, Stefanie Vasconez, Courtney Jensen	Synexus Clinical Research	Murray, UT
Leland N. Allen III, MD	Leslie Anne Edwards, William Simpson Davis, Jr., Ronald Meza, Jordan Stauffer, John Farringer, Faith Holmes, Rhonda Buzbee, Cristina Velez, Huse Lisa, Lisa Huse, Camelia Speegle, Gregory Prestage, Mary Perez, Jessica Space, Matthew Todd, Jessica McDowell, Marha Bunnell-Pollak, Jackie Ziegler, Jasmine Ali, Dumitru Sirbu, Kellie Williams, Logan Sawyer, Richelle Chambliss, Samantha Blackmon, Stephanie Brennan, Tiffany Gibbs, Alexandria Anderson, Caitlin Roll, Candace Robinson, Zachary McCoy, Jessica Bartlett, Kimberly Cornelison, Chris Bovell, Vincent Baglini, Christy Greenhalgh, Jessica Maria Mena, David House, Matt Honold, Esteban Zurita	St. Vincent's Health System	Birmingham, AL
Evan J. Anderson, MD	Kathleen Stephens, Francine Dyer, Maya Stagg, Aaliyah Carron, Austin Lu, Julia Barton, Sy Tran, Leisa Bower, Esther Park, Jianguo Xu, Rebecca Gonzalez, Vy Ngo, Mike Shepard, Lezly Roxxette Zepeda, Karen Sytsma, Sandra Rojas-Honan, Felicia Glover, Susan Rogers, Theda Gibson, Christina A. Rostad, Andres Camacho-Gonzalez, Teresa Ball, Satoshi Kamidani, Mehgan Farah Teherani, Vikash Patel, Etza Peters, Peggy Kettle, Lisa Macoy, Cindy Lubbers, Amber Samuel, Laila Hussaini, Kathryn Zaks, Caroline Ciric, Meg Taylor, Oliver Smith, Amy Muchinsky, Sydney Biccum, Laura Clegg, Dean Kleinhenz, Angelle Ijeoma, Hannah Huston	Emory University School of Medicine	Atlanta, GA
Lindsey Baden, MD	Xhoi Mitre, Jon Gothing, Bruce Bausk, Jessica Cauley, Natalie Izaguirre, Lewis Novack, Michael Seaman, Katherine Yanosick, Henry Rutherford, Junghyun Kim, Dominique Betterbed, Kathleen Garvey, Lauren Clore, Alexander Mills, Deepesh Duwadi, Alessandra Setaro, Kyl Bowman, Kevin McManus, Sidali Beriane, Fadi Ghantous, Christy Lavine, Jasper Ophel, Joseph Sapiente, Jessica Dorning, Tessa Speidel, Lauren Gameau, Robert Dannemiller, Kirquenie Rolle, Mulika Chhorn, Bailey McCarthy, Hana Flaxman, Milenko Tanasijevic, Cameron Nutt, Javier Barria, Andre Avila-Paz, Buteau Malhaika, Tong Alexandra, Tenaizus Woods, Bethany Evans, Hannah Jin, LaKeisha Gandy, Stephanie St. Pierre, Carolyn Darcy, Michael Corrado, James Maguire, Adetoun Okenla, Tamara Roldon Sevilla, David Kubiak, Cassandre Titus, Movita Harrigan, Maria Alvarado, Rose Theodat, Amy Sherman, Laura Platt, Kirsten Goodman, Laura Nicholson, Wilfredo Matias, Emily Koleske, Ruth Rodriguez, Nicole Taikeff, Jun Bai Park Chang, Julia Klopfer, Phoebe Cunningham, Elizabeth Sampson, Karen Magsipoc, Maureen Macgowan, Lauren Donahue, Haley Schram, Noah Abasciano, Megan Powell, Janet Morgan, Yazad Alsowaida, Olivia Riccardi, Neha Limaye, Virginia Loudermilk, Austin Kim, Kevin Zinchuk, Caitlin Grant, Charles Kelly, David Mellace, Jamie Myers, Erika Gribb, Jose Licon, Monica Feeley, Stephen R Walsh, Jennifer A Johnson, Ann Woolley, Alexis Liakos, Jane Kleinjan, Jon Gothing, Nicolas Issa, Michael Desjardins, Raphael Dolin, Alka Patel, Opeyemi Talabi, Christin Price, Paulette Chandler, Elizabeth W Karlson, Allison P Moriarty	Brigham and Women's Hospital	Boston, MA
Bindu Balani, MD	Smith Kerowyn, Sergio Garcia, Charo Valdez, Shelly Chin, Caitlin DiBello, Silvia Lara, Chika Ekweghariri, Abena Roberts, Abimbola Coker, Marie-Therese Estantouli, Greg Eskinazi, Michael Tortoriello, Jay Elkareh, Meral Karakoc, Olga Spathis, Patrice Hassoun, Carolene Stephenson, Steven Sperber, Kaur Harveen, Cristina Cicogna, Ciaran Mannion	Hackensack University Medical Center	Hackensack, NJ
Mira Baron, MD	Pamela Kane, Maria Bermudez, Shannen Seversen, Mara Kryvicky, Julia Lord, Terri Barr, Daisy Acevedo, Elena Acosta, Delta Anderson, Alexandra Arango, Anne Bauer, Joshua Egbehor, Tim Flanary, Audrey Haber, Carol Henao, Patti Isaacson, Peter Jacob, Sakaiya Jackson, Karen Kodes, Ludovic La-Branche, Kimarie Lee-Russell, Carol Liso, Cristina Liso, Stephanie Morse, Michelle Navarrette, Christy Norcross, Nora Norcross, Annette Pitts, Mary Sergalis, David Scott, Tytiana Spearman, Danielle Theodore, Brian Thomas, Jennifer Torres	Palm Beach Research Center	West Palm Beach, FL
Judith Berger, DO	Jennifer Angell, Nicole Austin, Deanna Benz, Lucian Cappof, Nicole Davis, Lynn Eckert, Kathryn Hostetter, Stephanie Keating, Jeanette Mangual-Coughlin, Avia McClain-Stocker, Ifeanyi Momodu, Cheryl Norris, Brennan Opanasenko, Stacey Saldua, Nafisa Saleem, Amy Sheets, Ryan Starr, Scott Syndergaard, Jennifer Thomas, Michelle Wallace, Jeffery Pemberton, Mitchell Arildsen, Dan Tomita	Carolina Institute for Clinical Research	Fayetteville, NC
Paul Simon Bradley, MD	Taja Adams, Stephanie Ailey, Kira Bell, Shanice Bennett, Vincent Bernades, Jim Callis, Bounphone Chanthavong, Taryn Collett, Anne Crouch, Shannon Davis, Morgan Deal, Mimi Duncan, Brandon Essink, Laura Falcone, Debra Gabrielson, Brooke Halpern, Anyfa Hanna, Cassie Heisey, Dawn Kalloniatis, Andrew Kimball, Jeanette Lee, Amanda Lilienthal, Ginny McNew, Crystal Neely, Kay Lynn Olmsted, Nicole Osborn, Chevon Roberts, Pechoka Sanders, Cynthia Seedorf, Kathryn Stoddard, Jonathan Whelan, Stella Yoon	Meridian Clinical Research	Savannah, GA

Principal Investigator	Study Team	Institution	Location
Adam Benson Brosz, MD	Rhonda Richter, Debra Gabrielson, Kayla Flege, Ashley Bell, Karen Jo Johnson, Paul Cramer, Jessica Stanton, Andrea Clement, Whitney West, Laura Falcoone, Amanda Friesz, Kathy Osborne, Summer Tophoj, Kimber Breeden, Susan Newman, Douglas Herbek, Lindsey Mettenbrink, Luke Friesen, Alison Pierce	Meridian Clinical Research	Grand Island, NE
Abram Burgher, MD	Stephanie Catanzaro, Shauna Harrell, Magen Hess, Nate Alderson, Bettie D'Nise Corcoran, Norma Frederick, Adrian Alejo, Brian DeCraene, Karen Wakefield, Scarlett Hammett, Susan DeCraene, Ann Marie Milliken, Neil Pearson, Donald Terral Harper	Hope Research Institute	Phoenix, AZ
Thomas B. Campbell, MD	Andrew Lauria, Jenelynn Kimble, Steven Johnson, Matin Krsak, Andrew Monte, Patrisha Adkins, Michelle Barron, Suzanne Fiorillo, Amy Harrison, Anderson Victoria, Nga Le, Sara Berech, Jose Castillo-Mancilla, Kristine Erlandson, Laurel Ware, Josie Marshall, Stephen Bartlett, Hillary Dunlevy	University of Colorado Denver, Anschutz Medical Campus	Aurora, CO
Shane Glade Christensen, MD	Christopher Mickelson, Jessica Shaw, Emily Raming, Amy Nelson, Gabrielle Lewis, Jenessa Folsom, Mikaela Jones, Dylan Owen, Rachel Pugmire, Jennifer Bradley, Annjanette Kemp, Krista Marti, Allyson Christensen, Madison Ellis, Holly Anderson, Emily Bloomquist, Ross Brunetti, Thomas Conner, Jr., Gina Cox, Diana Grazulis, Wesley Lewis, James Longe, Christopher Matich, Bryan Nelson, Sarah Scott, John Witbeck, Stephen Wood	J. Lewis Research	Salt Lake City, UT
Laurence Chu, MD	Jennifer Bacchi, Maria Barrientes, Lamar Box, Christian Casas, R. Michelle Chouteau, Katherine Davis, Tandra Dora, Cindy Duran, Pamela Fidler, Ruth Fitch, Brooke Harris, Isaiah Knight, Jennifer Leyva, Michelle Listz, Jennifer Montes, Javier Perez, Jessica Ruff, Dean Skiles, Sean Turnbow, Francesca Vigil, Breana Wade, Kelly Weber	Benchmark Research	Austin, TX
Jesse L. Clark, MD	Sandy MacNicol, Somaieh Talebi, Timothy Hall, Steven Shoptaw, Emery Chang, Michael Li, David Goodman, Paul Adamson, Oladunni Adeyiga, Inez Bentancourt, Susan Reed, Christopher Blades, Jasmin Tavares, Demetria Villanueva, Simone Riley, Jonathan Veloz, Schuyler Thomas, Will Hernandez, Jennifer Baughman, Mitchell Stern, Michele Vertucci	University of California, Los Angeles	Los Angeles, CA
Michael J. Cotugno, MD	Kyra Lawson, Kim Harper, Edwin Adamson, George H. Bauer Jr., Julie Bilich, Brenda Lawson, Brandon Illickal, Lois Eaglin, Heather Salisbury, Jeff Segner	Benchmark Research	Metairie, LA
Clarence Buddy Creech II, MD	Shanda Phillips, Naomi Kown, Katherine Sokolow, Wendy Winn, Katherine Wright, Shannon Walker, Stephanie Rolsma, Anna Gallion, April Hanlotxomphou, Deborah Myers, Robert Adkisson, Natalia Jimenez, Cindy Trimmer, Roberta Winfrey, Matthew Donio, John Oleis, Donna Torr, Shelly McGehee, Robert Samuels, Sandra Yoder, Eric Brady, Isaac Thomsen, Madeleine Guy, Emma Alexander, Lana Howard, Krisha Alexander, Shane Moore, Tacora Wright, Tara Evans, Ursula Powell, Jenna Caserta, Valerie Mitchell, Meryk Moore, Melissa Lehman, Diane Anders, Constance Dotye, Crystal Rice, Lamar Bowman, Sherri Hails, Monique Bennett, Nicki Soper, Leigh Howard	Vanderbilt University Medical Center	Nashville, TN
Joseph D. Davis, MD	Sandra Kelman, Sandra Braden, Sabrina Bolland, Mia Munoz, Jose Barocio, Brendan Levy, Dhwan Shah, Neil Pearson, Stephanie Catanzaro, Nathan Alderson, Susan DeCraene, Maureen Godfrey, Skyla Clark	Hope Research Institute	Chandler, AZ
Luis I. De La Cruz, MD	Amy Ford, Taylor Wilson, Cindy Smith, Austin Lambert, Erin Zeiler, Kaelyn Rowland, Marlee Smith, Suzanna Studdard, Zandra Hamilton, Meredith Benfield, Sara Poff, David Godwin, Elizabeth Everette, Steven Clemons, Kayla Peay, Stephanie Gilreath	VitaLink Research	Greenville, SC
Douglas Scott Denham, DO	Thomas Weiss, Parke Hedges, Ayoade Aworo, Kay Scroggins, Leisel Koerber, Antonio Gutierrez, Nathan Cortez, Andrea Gomez, Darlington Akahara, Michelle Smith, Kristy Trevino, Beatriz Herrera, Shaiane Dickerson, Kerry de Jesus, Matthew Korte, Cynthia Ramos, Reanna Martinez, Erica Leal, Shakera Flores, Paul Esparza, Brian Hemming, Melinda Axton, D'Andre White, Terri Perez, Carolina Coronado, Rebecca Many, Clayton Stone, Kimberly Evans, Anshumaan Maharaj, Stephen Brick, Steffanie Barrera, Staci Poettgen, Dawn Killian, Gerardo Pena, Karol Perez, Victoria Hernandez, Kevin Martinez, Amy Griffith, Nolan Payton, Quincey Hogue, Jamie Padilla, Emily Merdez, Lily Hays, Maristelle Co, Nicholas Trinidad, Ismael Rodriguez, Amy Lewis, Cindi Nellis, Lele Simmons, Marissa Johnson	Clinical Trials of Texas	San Antonio, TX
David Joseph Diemert, MD	Linda Witkin, Aimee Desrosiers, DeEnna Wedding, Bertran Walton, LaKeisha Queen, Ryan Mouton, Caroline Thoreson, Many Magnus, Jennifer Wald, Erika Faust, Nicholas Heredia, Robbie Kattappuram, Hira Qadir, Chelsea Ware, Hannah Yellin, Kegan Dasher, Daniel Mullen, Jeanne Jordan, Taylor Ladson, Madison Lintner, Kaitlyn Macnair, Bitana Saintilma, Kelly Thomas, Samantha Walker, Neha Rampally, Madhu Balachandran, Elissa Malkin, David Parenti, Hana Akseirod, Marc Siegel, Gary Simon, Afsoon Roberts, Aileen Chang	George Washington University	Washington, DC

Principal Investigator	Study Team	Institution	Location
Susanne Doblecki-Lewis, MD	Maria Luisa Alcaide, Jose Gonzalez-Zamora, Stephen Morris, Yimy Puerto, Annie Salvarrey, Claudia Baigas, Claudia Santos, Katherine King, Brahian Steven Erazo, Mayra Fernandez, Leopoldo Cordova-Garcia, Elisa Corzo-Sanchez, Edgar Fernandez, Loreta Padron, Stefani Ann Butts, Kenia Moreno, Juan Casuso, Maria de Pilar Valanzasca, Thomas Tanner, Marilyn Fernandez, Mary Aloise, Inza Patton, Vivian Pastrana, Sedy Puerto, Irma Barreto Ojeda, Junlin Long, Barbara Huang, Gilianne Narcisse, Vanessa Perez	University of Miami	Miami, FL
Matthew W. Doust, MD	Denise Sample, Sandra Erickson, Nate Alderson, Adrian Alejo, Stephanie Catanzaro, Susan DeCraene, Cassie Enricco, Sandra Erickson, Alex Gueraque, Shauna Harrell, Shana Harshell, Stephanie Junker, Stephanie Laufenberg, Madison Mikulak, Makayla Morra, Nicole Olson, Neil Pearson, Jasmin Redden, Monique Romo, Denise Sample, Dhwan Shah, Sahara Vega, Emma Kar	Hope Research Institute	Phoenix, AZ
Valentine Mbepson Ebu, MD	Elwaleed Elnagar, Georgette Ebu, Genevieve Iwuala, Catina Adams, Marissa Cervenka, Ezgar Del Real, Shraddha Dubal, Elwaleed Elnagar, Jenifer Fiate, Kathy Harrell, Genevieve Iwuala, Vicki Martinez, Robert Miranda, Brennan Opanasenko, Destiny Robinson, Liz Ruiz, Amy Sheets, Shoniece Wallace	WR-Global Medical Research	Dallas, TX
Frank Steven Eder, MD	Ryan Little, Victoria Engler, John Tarbox, Heather Rattenbury-Shaw, Deborah Hubish, Jessie Taylor, Debra Gabrielson, Jessica Fellows, Jennifer Molstead, Kathe Olmstead, Ashley Conover, Tammy Kohn, Chelsea Briar, Corrine Young, Colleen McVannan, Kelli Quick, Shaylyne Hubanks, Kimber Breeden, Ann Marie Sampson, Traci Hull, Tarin Gordon, Susan Owen, Kate Macarak, Tonya Rackett, Jacob Blattstein, Partidge Jane Aton, Nicole Croft, Carolyn Grausgruber, Rebecca Miller, Ryan Little, Victoria Engler, John Tarbox, Heather Rattenbury-Shaw, Nathan Kimball, Courtney Heisey, Ginny McNew, Abigail Wine, Cindi VanKuren, Jared Frick, Tammy Dennis, Andrew Kimball	Meridian Clinical Research	Binghamton, NY
Hana M. El Sahly, MD	Jennifer A. Whitaker, C. Mary Healy, Christine Akamine, Wendy A Keitel, Robert L Atmar, Annette Nagel, Sandra Francisco, Thea Marie Cordero, Janet Brown, Jennifer Christensen, Caroline Doughty-Skierski, Connie Rangel, Carrie Kibler, Coni Cheesman, Lisreina Toro, Chaneil Henry, Chianti Wade Bowers, Pedro Piedra, Kathy Bosworth, Kayla Burrell, Jesus Banay, Tykel Eddy, Trent Davis, Shetel Anassi, Yvette Rugeley, Olga Rybina-Willis	Baylor College of Medicine	Houston, TX
David Jon Ensz, MD	Pamela Allen, Taylor Bergh, Kimber Breeden, Avery Dunn, Brandon Essink, Debra Gabrielson, Rylea Gulick, Tavane Harrison, Courtney Heisey, Andrew Kimball, Shelby Kiaschen, Jessica Knight, Makayla Langston, Meagan Miller, Allie Oplinger, Heather Persinger, Alison Pierce, Kathryn Stoddard, Kayla Sturgeon, Jamie Thompson, Melissa Wiseman	Meridian Clinical Research	Dakota Dunes, SD
Brandon James Essink, MD	Jay Meyer, Frederick Raiser, Kimberly Mueller, Roni Gray, Riley Brockman, Tabitha Campbell, Carrie Essink, Laura Falcone, Roni Gray, Linda Layton, Jay Meyer, Kimberly Mueller, Tiffany Nemecek, Frederick "Fritz" Raiser, III, Jessica Satorie, Chelsea Steinmetz, Nicole Osborn, Cassie Heisey, Maria Nguyen	Meridian Clinical Research	Omaha, NE
Gregory J. Feldman, MD	May-Yin Suen, Brittany Cooksey, Madison Fowler, Sarah Chynoweth, Gary Clemons, Laura Jolly, Charlie Jordan, Heather Allison, Steve Clemons, Amber Brittany Belcher, Allison Kelly, Marsha Gossett, Wendy Taylor, Amy Witt, Kendal Nelson, Jeffrey Witt, Jacqueline Muenzner, Elizabeth Everette, Supinder Channa, Allison Ayers, Joseph Boscia, Farhan Siddiqui	VitaLink Research-Spartanburg	Spartanburg, SC
Carl J. Fichtenbaum, MD	Maggie Powers-Fletcher, Michelle Saemann, Sharon Kohrs, Kimberly Mullins, Lindsay Davis, Moises Huaman, Angela Snyder, Kristin Weghorn, Brenda Miller, Elizabeth Costea, Lisa Schira, Romana Saeed, Helen Shelton, Kathleen Ballman, Laura Browning-Cho, Sherry Donaworth, Chris Goddard, Jeanine Goodin, Elizabeth Niederegger, Lisa Hachey, Tamara Maus, Pam Fletcher, Makayla Bishop, Victoria Straughn, Shaina Horner, Carrie Christofield, Dana Burns, Jason Mayes, Kelly Windholtz, Lisa Proffitt, Faizan Qureshi, Michelle O'Neil, Arustamyan Lisa, Sarah Trentman, Eva Whitehead, Jennifer Baer, Linda Hinds, Jaasiel Chapman, D'Vaughn House, Gary Frazier, Judy Houston, Lisa Altenau, Mary Burns, Dorice Smith, Justin Ragle, Eric Mueller, Cynthia Nypaver, Jaime Robertson, Anissa Moussa, Geronimo Feria Garzon, Sierra Bennett, Marlena Petrie	University of Cincinnati	Cincinnati, OH
Carlos A. Fierro, MD	Mazen Zari, Celia Gonzalez, Natalia Leistner, Mary Easley, Mary Provost, Krista Estrada, Ann Geier, Amy Thompson, Heather Barker, Karol Moore, Kelly Moen, Monica Atwood, Amber Wolf, Brandi Dickerson, Manyohn Rinehart, Dina Hammime, Angela Eichler, Casey Johnson, Nathan Arthur	Johnson County Clin-Trials	Lenexa, KS
Veronica G. Fragoso, MD	Lisa Holloway, Cecilia McKeown-Bragas, Teresa Becker, Vicki Miller, Leena Mir, Elton Oliveira, Moez Talpur, Enya Rentas-Sherman, Gabriela Maria Becerra, Dewayne Hicks, Robert Krbashyan, Shakira Barr, Ashraf Jafri, Herman Ortiz, Zohair Harianawala, Chandra Tobin, Norma Gonzalez, Sajj Perinjellil, Khorshid Amirhosravi, Tracy Kowalski, Birman Goswami, Waheeda Sureshbabu, Amy Anderson, Berenice Ferrero, Simeen Khan, Chen-Ho Yang, Nazanin Zarinkamar, Scott Ward, Crystal Reese, Miyosha Lewis, Olga Konshina, Lorian Yates, Joel Cano, Quiana Wilson, Kara	Texas Center for Drug Development, Inc.	Houston, TX



Principal Investigator	Study Team	Institution	Location
	Sikes, Diana Chehab, Joanna Quezan, Maryam Rabbani, Sadaf Batla, Abbyssinia Diego Carrington, Matthew Joseph, Laura Grissanty, Dean Jang, Dustin McFadden, Misbah Baloch, Elisa Morales, Abdeali Datal, Frances Saubon, William Fernandez, Jenny Toress, Blessing Felix, Zain Rizvi		
Ian Frank, MD	Annet Davis, Eileen Donaghy, Nicole Sundo, Juan Ramirez, Laura Schankel, Dana Brown, Katharine Bar, Dana Brown, Christopher Chianese, Gillain Constantino, Dovie Watson, Kathleen Degnan, Helen Koening, William Short, Petra Alexander, Eileen Mergliano, Jie Ho, Michele Wisniewski, Debora Dunbar, Liani Santini-Lopez, Rosemarie Kappes, Angela Cabassa, Tammy Chen, Berry SotoVega, Deborah Kim, Devon Cliett, Kate Kearns, Jillian Baron, Vivian Leung, Florence Mompalaisir, Sarah Wood, Tameka Matthews, David Metzger, Richard Tustin	University of Pennsylvania	Philadelphia, PA
Sharon E. Frey, MD	Irene Graham, Getahun Abate, Daniel Hoft, Heather Douds, Cassandra Zehenny, Joan Siegner, Helay Hassas, Kim Cooper, Shirley Dettlebach, Sabrina DiPiazza, Carol Duane, Linda Eggemeyer-Sharpe, Lauren Foreman, Jerry Hutter, Ryan Kerr, Kate Liefer, Tracy Montauk, Karia Mosby, Janice Tennant, Nicole Purcell, Kiana Wilder, Kathleen Chirco, Sharon Irby-Moore, Kathleen Koehler, Melissa Loyet, Thomas Pacatte, Susan Stewart, Azra Blazevic, Tamara Blevins, Chase Colbert, Christopher Eickhoff, Lainej Mejia Jauregui, Keith Meyer, Krystal Meza, Amanda Nethington, Huan Ning, Brittany Williams, Mei Xia, Yinyi Yu, Stanley Doublin, Mary Pat Eastman, Eric Eggemeyer, Mikayla Frye, Michelle Harris, Aleshia McCoy, Donna Duncan, Gwendolyn Tatum, Nicole Purcell, Kiana Wilder, Tammy Grant, Claudia Castillo Paredes, Rong Hou, Jin Wang, Qian Wang, Sarah George	Saint Louis University	St. Louis, MO
Cynthia Gay, MD	David Wohl, Joseph Eron, Jr., Andrew Thorne, Michelle Floris-Moore, Christopher Hurt, David Wohl, Chidinma Okafor, Janette Goins, Ulrike Adam, Ekundayo Nylander-Thompson, Anna Furlong, XinHong Ao, Kathy Guerrero, Melinda Hart, Kathleen Loeven, Rachael Mossey, Esther Speight, Rachel White, Chloe Twomey, Kristen Gray, Miriam Chicurel-Bayard, Susanne Henderson, Patti Vasquez, April Welch, Camille O'Reilly, Maureen Furlong, Noshima Darden-Tabb, Elizabeth DuBose, Marie Oriol, Dynesha Perry, Maria Stetson, Maria Bullis, Shelby Turner, Ebony Harrington, Michael Herce, Suzanne Blevins, Alexander Bradley, Susan Pedersen, Becky Straub, Sandra Barnhart, Felicia Barriga Munante, Nazneen Howerton, Tevnan Keller, Mandy Tipton, Abigail Riddick, Kristi Kirkland, Maggie Harman, Tania Hossain, Centhia Washington, Erin Hoffman, Carolina Pastrana Medina, William Johnson, Samantha Eamhardt, Amy James Loftis, Catherine Kronk, Yaa Ofori-Marfoh, Julie A Nelson, Nicole Maponga, Lina Rosengren-Hovee, William Zhao, Jennifer Thompson, Sarah Law, Holly Milner, Jonathan Oakes, Rachel Cook, Erin Cardot, Oesa Vinesett, Victoria Rucinski, Joy Wannamaker, Tanailly Giralt Smith, Eliza DuBose, Chidinma Okafor	University of North Carolina at Chapel Hill	Chapel Hill, NC
Richard M. Glover, II, MD	Stacy Siechta, Troy Holdeman, Robyn Hartvickson, Amber Grant, Jennifer Bennett, Lindsey Brewer, Janelle Brown, Kelsey Burden, Melissa Burton, Brianna Burton, Jordan Danby, Sheri Duncan, Amber Grant, Robyn Hartvickson, Lisa Hemmelgarn, Sherry Henning, Jeri King, Riley King, Colton King, April Kitterman, Shannen Lassiter, Cayla Lawless, Janna Martinez, Ragene Moore, Marissa Mueller, Aaron Nguyen, Justin Phillips, Jordan Reheis, Rebecca Ring, Katherine Saengerhausen, Shannon Thomas, Dylan Thomas, Cindy Thome, Denae Villines, Amber Wenzel, Eileen Wilbert, Avi Woods, Caressa Presley, Brianna Newport, Olivia Allen, Miranda Santiago, Cheryl Sauerwein, Jill Longstaff, Sadie Allen, Candace Heckart	Alliance for Multispecialty Research	Newton, KS
Gregory Mark Gottschlich, MD	Melissa Gottschlich, Steven Anderson, Gregory Mark Gottschlich II, Mary Woeste, Kate Harden, Cindy Young, Michael Pordy, Audrius Rukenas, Lacy Baird, Kim Krogman, Lori Stanton, Melissa Fuson, Mason Urban, Christine Watson, Richard Powell, Mary Smith, Jacob Sekinger, Diamond Russell, Nicole Lim, Mylene Asmar-Rios, Yusef Museitif, Craig Mitchell, Tarik Whitham, Zachary Rutledge, Troy Porter, Andrea Newlands, Jami Ramsey, Mary Frances Curry, Nishay Holloman, Crystal Barket, Michelle Spear, Shelley Mahan, Taeleighe Greene, Zachary Eardley, Gen Moussa, Mary Ann Gottschlich	New Horizons Clinical Research	Cincinnati, OH
Sinikka L. Green, MD	Julie Hamilton, Alex Fuller, Jeanette Dickhaus, Colleen Jacobson, Triny Cooper, Michelle Jackson, Taylor Evans, Tabitha Judd, Kathryn Alexander, Megan Rosallo, Sikhongi Phungwayo, Robin Dotson, Dana Finley, Michael Vasquez, Cyndi Foster, Gregg Lucksinger, Sarah Smiley, Jayasree Krishnankutty, Ray Coon, Grishma Dhimmer, Melanie Wilkerson, Tatum Shawver, Mercedes Coffman, Devin Teal, Laura Crenshaw	Advanced Clinical Research	Cedar Park, TX
Carl P. Griffin, MD	William Schnitz, Andrea Romero, Kim Hamilton, Raymond Cornelison, Angela Genovese, Shelly Brunson, April Green, Lacey Dietz, Kim Calloway, Chris Hyatt, Destiny Heinzig-Cartwright, Chalimar Rojo, Sharee Wright, Kathi Shaw, Michael Pojezny, Avery Keller, Krystal Hightower, Dalia Tovar, Shanda Gower	Lynn Health Science Institute	Oklahoma City, OK
Milton Haber, MD	Maria Candelario, Martha Bunnell-Pollak, Lauren Wade, Jackie Ziegler, Deena Ramirez, Perla Avalos, Maria Drada, Jasmine Ali, Jessica McDowell, Kehinde Busari, Patricia Church, Ronald Meza, Marco Vela, Esteban Zurita, Chris Connolly, Ruben	Laguna Clinical Research Associates	Laredo, TX

Principal Investigator	Study Team	Institution	Location
	Del Bosque, Alisha Lutat, Chelsea Fleming, Brett Potthoff, Anita Suri, Cynthia Priester, Brenda Hernandez, Veronica Procasky, Eva Cerreta, Matt Honold, Melinda Rodriguez, Maria Regalado, Jordan Stauffer		
Greg Hachigian, MD	Michael Cancilla, Ricardo Castellanos, Angela Cuellar, Yaman Darmarathne, Shaila Faulker, Yana Gordeyeva, Michelle Hisey, Ashley Jungsten, Kristin Kiersey, Pawandeep Nagra, Nav Nagra-Kooner, Jazmin Nauta, Masaru Oshita, Kenneth Quick, Julie Raygoza, Amanny Sadek, Melisa Tinder, Jhoana Torres, Deborah Murray, Kristen Kiersey	Benchmark Research	Sacramento, CA
Laurie J. Han-Conrad, MD	Brandon Baldwin, Lucian Cappoli, Tenisha Garcia, Ella Grach, Brenda Grande, Nicolle Mendez, Natalie Moy, Matthew Musikanth, Karen Mylerberg, Brennan Opanasenko, Mark Pulera, Patti Sanchez-Emery, Mireles Sarah, Todd Simmons, Denis Tarakjian	WR-Medical Center for Clinical Research	San Diego, CA
Wayne Lee Harper, MD	Toni Bland, Lori Bridges, Lucian Cappoli, Lisa Cohen, Leah Corts, Annie Craft, James Earnhardt, Lynn Eckert, Aubrey Farray, Laura Hoer, Matthew Hong, Chris Hoyle, Jenee Jiggetts, Brian Joseph, Bradley Killebrew, Kendra Lisec, Lucie Mangala, David Musante, Adnan Nasir, Amanda Olsen, Brennan Opanasenko, Marci Parks, Marion Peoples, Katherine Schuch, Judith Shand, Sabine Ucik, Douglas Wadeson, Barbara Wheeler	M3 Wake Research	Raleigh, NC
Ripley R. Hollister, MD	Jeremy Brown, Brandy Ball, Jeremy Brown, Valerie Dyster, Dalia Jeronimo, Shelby Pickle, Michael Pojezny, Melody Ronk, Kathi Shaw, Bobbi Shofner, Jami Wagner, Meghan York, Jill York	Lynn Institute of the Rockies	Colorado Springs, CO
Lisa A. Jackson, MD, MPH	Marilyn Nguyen, Maya Dunstan, Barbara Carste, Sarah Friend, Diana McFeters, Lynn Gross, Mohamed Ajenah, Jana Ffitch, Audra Mccoy, David Skatula, Susan Lasicka, Kimberly Brinker, Karen Sherwin, Melissa Scheer, Paula Lins, Roger Calvert, Roxanne Erolin, Stella Lee, Vi Tran, Stephanie Pimienta, Bruce Douglas, Lee Barr, Colin Fields, Erika Kiniry, Joe Choe, Janice Suyeaira, Joyce Benoit, Michael Witte, Rebecca Lau	Kaiser Permanente Washington Health Research Institute	Seattle, WA
Spyros Andrews Kalams, MD	Greg Wilson, Kyle Rybczyk, Katie Crumbo, Carly Griffin, Latoya Hannah, Amy Kerrigan, Valerie Mitchell, Jenna Caserta, Mary Downey, Nicole Swindle, Shonda Sumner, Amber Massey, Trudy Sullivan, Rita Smith, Cindy Nochowicz, Eric Olson, Christian Warren, Josh Simmons, Dana King, Gwendolyn Rees, Matt Donio, Jesse Case, Keith Richardson, Jarissa Greenard	Vanderbilt University Medical Center	Nashville, TN
Colleen Kelley, MD, MPH	Valeria D. Cantos, Sheetal Kandiah, Carlos del Rio, Christina Bacher, Hannah Huston, Juliet Brown, Divya Bhamidipati, Nithin Gopalsamy, Brittany Lynn Speigel, Elizabeth (Betsy) Hall, Brandon Spratt, Kiran Dhillon, Caitlin Moran, Michael Chung, Felecia Wright, Marcia Peters, Rondell Jagers, Vanessa Soliman, Ron Gaston, Christopher Foster, Sarah Wiatrek, Bezuayehu Mandefro, Pamela Weizel, Pamela Lankford-Turner, Anandi Sheth, John Gharbin, Catherine Abrams, Philip Powers, Paulina Rebollo, Christin Root, Tiraje Lester, Sha Yi, Damien Swearing, Fred Ede, Isaac Perez, Kelly Likos, Meen Dhir, Aastha KC, Gabriela Georgial, Tucker Colvin, Nabeel Yar Khan, Valarie Hunter, D'Jamel Young, Felecia Atkinson	Emory University Emory University – Ponce de Leon Clinical Research Site	Atlanta, GA
Christina Kennelly, MD	Jacob Coleman, Brittany Bundeuff, Melissa C. Hennessey, Kenneth Owen, Caroline Wilds Wilds, Jennifer Womack, Susan Martello, Chiedza Hooker, Robert Brownlee, Melissa James, Deborah Wesley-Farrington, Lori Whiteheart, Hala Webster, David Framm, Courtney Fretz, Gwyn Gibson, Susan Donahue, Kelly Woodell, Linda McCarty, Jim Vesely, Scott Chatterton, Andrew Ottesen, Enrico Belgrave, Krishna Shah, James Chester Alexander, Brittain Callahan	Javara	Charlotte, NC
Shishir Kumar Khetan, MD	Taja Adams, Tanya Alexander, Tanya Alexaner, Sydney Barmoy, Jake Bart, Kira Bell, Ira Berger, Jemario Blackwell, Priscilla Buahin, Bounphone Chanthavong, Juliana DeVito, Azure Erskine, Brandon Essink, Laura Falcone, Debra Gabrielson, Beau Garland, Barb Geiger, Tiana Oliver, Courtney Heisey, Sucharita Katikala, Andrew Kimball, Heather Lang, Jeanette Lee, Asefa Mekonnen, Devan Myers, Kimberly Nieves, Allison O'Brien, Oyebisi Olanrewaju, Nicole Osborn, Adunola Oshiyoye, Rahul Patel, Alan Pollack, April Poole, Collin Smith, Kathryn Stoddard, Chao Wang, Sean Whelan, Jonathan Whelan, Graciela Zapata, Nan Zhai	Meridian Clinical Research	Rockville, MD
Murray A. Kimmel, DO	Alexa Diec, Ann Riley, Bette Denmat, Bram Swarr, Christina Raidl, Dania Billman, Denise Dixon, Donald Dawson, Elaine Crudo, James Crowley, Katrina Carlson, Kaylie Worzick, Laura Worth, Lisbeth Gordon, Marlon Oliver, Robert Holt, Simmy Pinto, Taylor Atkinson, Traci Mitchell, Lana Ghomrawi, Norma Rokoff	Optimal Research	Melbourne, FL
Judith L. Kirstein, MD	Jared Bradshaw, Krista Forster, Jeanette Dickhaus, Marcia Bernard, Erica Sanchez, Nikki Abels, Cynthia Kunakom, Vanessa Vandergoot, Jessica Fisher, Carol Remigio, Jourdan Manfred, Frederick Lloyd, Tiffany Williams, Clarisse Baudelaire, Lovette Cherelle, Nolan Mackey, Alan Valenzuela, Theodore Wyman, Alyssa Taber, Karen Myers, Craig Koch	Rancho Paseo Medical Group	Banning, CA
Michael J. Koren, MD	Shannon Trull, Amanda Elwood, Mary Strickland, Ivy Gulliermo, Chistopher Ganzhorn, Sonia Gerardo, Taylor Johnson, Victoria Kaposchansky, Cassie Lawler, Laura Little, Amanda Pratt, Sheldon Warren, Andrea West, Emery Noies, Nathaniel	Jacksonville Center for Clinical Research	Jacksonville, FL

Principal Investigator	Study Team	Institution	Location
	Grant, Jillian Agnew, Lori Alexander, Brenda Anderson, Deirdre Arrington, Sara Benner, Lisa Carl, Allison Crain, Nafisa Ishaku, Robert Nix, Sharon Smith, Amber Devries, Sandy Salceiro, Opara Chukwudi, Mikaela Karney-Trull, Ramil Castillo, David Graham, Gail Lowe, Alexander Hill, Carolyn Tran, Jeffrey Jacqmeim, Darlene Bartilucci, Alpa Patel, Janet Garvey, Mitchell Rothstein, Kenneth Aung-Din, Margaret Gannaway, Arman Mughal, Sandra Fuit, Jolenne Wolfer, Erin Schelhorn, Jacob Wolfer, Madison Martinez, Melissa Parks, Patricia Neal		
Karen L. Kottloff, MD	Matthew Laurens, Milagritos Tapia, Lisa Chrisley, Cheryl Young, Barbara Albert, Robin Barnes, Shernel Barrett, Andrea Berry, Melissa Billington, Shannon Bittner, Colleen Boyce, Faith Pa'Ahana Brown, James Campbell, Regina Carpenter, Jamonie Carter, Ginny Cummings, Brenda Dorsey, Jorge Flores, DeAnna Friedman-Klabanoff, Shirley George, Nancy Greenberg, Hassan Haji, Elizabeth Hammershaimb, Susan Holian, Leslie Howe, Myounghee Lee, Alyson Kwon, Kirsten Lyke, Alma Valle Maldonado, Jennifer Marron, Kaitlin Mason, Monica McArthur, Rosa McBryde, Sherry McCammon, Sandra Molina, Kathleen Neuzil, Daniele Nitkowski, Justin Ortiz, Rekha Rapaka, Mardi Reymann, Toni Robinson, Wanda Somrajit, Mark Travassos	University of Maryland, School of Medicine	Baltimore, MD
Mark E. Kutner, MD	Amanda Colina, Iselt Caro, Frances Beltran, Jessie Downs, Jonathan Fernandez, Mariete Renden, Miryaya Mujica-Alabaci, Susel Figueredo, Yanelis Dominguez, Jaime Blandon, Bryan Ruiz, Leidy Montoya, Edgardo Rodriguez, Jessie Downs, Jason Rothschild, Janett Aclé, Yaime Martinez, Soraya Ricardo, Maria Hernandez Moran, Eloisa Guerra, Heidie Perez, Claudia Rodriguez, Victoria Moreno, Vanessa Hechavarría, Saray Carvajal, Daniel Lopez, Carlos Ivricu, Neiner Enriquez, Paola Garcia, Chris Hoyle, Mariana Carvajal, Janet Mendez, Edisleidy Mesa, Marco Ramirez, Dalila Del Valle, Jennifer Ortega, Yeni Hernandez, Jhobana Vargas, Carmen Amador, Juan Delgado, Maury Santos, Meredith Arguelles, Leyanis Coello, Vanessa Ansorena, Jorge Caso, Stacy Machado, Raydel Valdes, Giann Lightbourn, Dayami Dovales, Alain Chang	Suncoast Research Group	Miami, FL
Mimi Van Der Leden, MD, PhD	Chrishea Harvey, Tricia Oyeyemi, Aicha Moutanni, Stephanie Melton, Peta-Gay Jackson Booth, Jennifer Yoon, Gloria Kim, Atanas Filev, Francis Uwandu, Meyling Lopez, Janice Spreitzer, Courtney Gennes, Xiangfei Cheng, Matthew Van Sickle, Nick Bart, Brianne Okunji, Frank Maloba	Optimal Research	Rockville, MD
Michael L. Levin, MD	Brennan Opanasenko, Yajaira Ramos, Shonda Lester, Rebecca Boucher, Shawn Harrell, Shon Boucher, Patti Sanchez, Nina Scharbach, Alex Sanchez, Shyane Raniello, Wendy Guerra, Krystal Tyner, Kimberly Temple, Ruby Ortiz, Daniel Terreault, Amy Kill, Jade Odynski, Adolfo DeLeon, Debbie Carter, Eduardo Rodriguez, Julia Gass, Sara Esparza, Sierra Dansbee, Tammy Harrison, Marcy Kulic, Lucian Cappoli, Mora Klm, Matthew Fenner, Heather Jimenez, Shradha Dubal, Julie Hussey	WR-Clinical Research Center of Nevada	Las Vegas, NV
Michael Lewis, MD	Nancy Mohler, Mai Pham, Ron Waldorf, Elham Ghadishah, Samantha Feril, Stella Lee, Dzuyen Nguyen, Ruoxiang Wang, Justine Velandria, Benjamin Dreskin, Joseph Yusin, Lauren Vigil, Sara Wong, Suchi Tiwari, Joseph Pisegna, Sunita Dergalust, Wayman Lee, Krissa Caroff	VA Greater Los Angeles Healthcare System	Los Angeles, CA
Gregg H. Lucksinger, MD	Jaleh Ostovar, Craig Koch, Danuel Hamlin, Kelly Chase, Jeanette Dickhaus, Edward Kerwin, Frederick Forde, Allison Alvord, Dawn Stewart, Dan Hamlin, Kevin Parks, Ryan Israelsen, Kary Kelly, Tiffany Smith, Melissa Myers, Ryan Rackley, Audrey Kuehl, Savannah Peterson, Hannah Hall, Jay Weisbart, Alison Dodenhoff, Emily Kelly	Velocity Clinical Research	Medford, OR
Mary Beth Manning, MD	Carol Salango, Alec Ireland, Lisa Hoagland, Jeanette Dickhaus, Toby Briskin, Joan Rothenberg, Michael Gaston, Sharita Tedder-Edwards, Denise Roadman, Megan Sokolowski, Tina Shickluna, Katherine Bielanski, Samantha Hood, Talia Chandler, Brianna Aman, Melinda DeLong, Naqib Ahmad, Karly Tarase, Jade Svoboda, Lisle Merriman, Melisa Sebera, Emma Landskroner, Amy Maroun, Brooke Glivar, Jennifer Gaston, Sarah Dzigiel, Cassandra Uminski, Karol Sabol, Devan Patel, Nick Zarbo, Briana Jackson, Brian Sharpe, Nicole, Baitt, Kaitlyn Duffy, Gabrielle Jacobs, Ann Czuprun, Tracee Cash, Diamond Ivey, Kaitlyn Rubell	Rapid Medical Research	Cleveland, OH
Kristen Marks, MD	Grant Ellsworth, Tina Wang, Timothy Wilkin, Mary Vogler, Carrie Johnston, Marshall Giesby, Roy Gulick, Ole Vielmeyer, Rebecca Fry, Todd Stroberg, Caitlin Rhoades, Noah Goss, Shaun Barcavage, Valery Hughes, Jonathan Berardi, Caroline Greene, Sarah Galloway, Caique Mello, Ashley Machado, Mia Crowley, Monique Williams, Katherine Fee, Elizabeth DeJesus, Andrew Yu, Minkyung Lee, Susan Herder, Mary Ann Zweibel, Patrice Weller, Antonio Rivera-Lopez, Edward Kenny, Hetal May, Natella Fridman, Parul Shah, Ruby Lee, Venus Fernandez, Victoria Lesina, Celine Arar, Byron Bullough, Kinge-Ann Marcelin, Brian Mangano, Jessenia Fuentes, Jiamin Li, Genessi Rodriguez, Catherine Jerry, Nadi Islam, Liqun Cai, Wayne Burns, Akinbayo Caulcrick, Andrika Thomas, Barbara Batog, Guoan He, Sara Yoder, Tamara Crowder, Gianna Resso, Sophia Alvarez, Tahera Begum, Elizabeth Connolly, Roxanne Rosario, Paul Kim, Steven Wang, Vasilika Koci	Cornell Clinical Trials Units - Weill Cornell Chelsea and Uptown	New York, NY

Principal Investigator	Study Team	Institution	Location
Judith Martin, MD	Alejandro Hoberman, Timothy Shope, Gysella Muniz, Sonika Bhatnagar, Kumaravel Rajakumar, Anne-Marie Rick, Peri Unligil, Jennifer Nagg, Melissa Andrasko, Mary Ann Sieber, Jennifer Opal, Leticia Roman, Spenser Kinsey, Michelle Burke, Matthew Lee, Dominic Kramer, Linette Milkovich, Emily Dougherty, Emily Carney, Shannon Mance, Nader Shaikh, Diana Kearney, Jamie Fries, Lisa Vavro, Shayla Goller	UPMC University Center	Pittsburgh, PA
John W. McGettigan, Jr., MD	Walter Patton, Jennifer Schnider, Riemeka Brakema, Heeten Desai, Mikell Brett Karsten, Patricia Jalomo, Cindy Finch Benoy, Karin Choquette, Jorlyn McGettigan, Yvonne De Los Reyes, Melissa Cozzens, Amanda Hemosillo, Cindy Montgomery, Susan Tarwid, Annette Elzy, Tianna Young, Saysamone Banks, Cristina Fernandez, Damaris Atondo, Zoe Sesma, Norma Barrientos, Maggie Tono, Kisha Adams, JoAnn Wilkins, Arianna Bermudez, Carol Sayer, Julie McDowell, Angelina Navarro, Mercedes Sullivan, Crystal Mata, Sheldon Gingrich, Aaliyah Sestiaga, Gia Longo	Quality of Life Medical & Research Centers	Tucson, AZ
Mark Montgomery McKenzie, MD	Tiffany Jewell, Zackery Harmon, Michael Elizabeth, Christy Sweet, Teresa Deese, Catherine Schon, Misti Earwood, Lou Cappoli, Brennan Opanasenko, Lisa Guider, Michelle Forgey, Justin Jarrett, Rachel Scott, Elizabeth Michael, Erica Osmundsen, Andrew Wood, Shelly Brooks, Gisela Heintz, Lillian Nukuna	WR-ClinSearch	Chattanooga, TN
Vicki E. Miller, MD	Sajjad Naqvi, Soofia Masood, Fredric Santiago, Sonia Guerrero, Subhash Koneru, Nirja Shah, Andrea Torres, Ramani Gali, Talha Baig, Heather Leary, Afifah Ayub, Nayab Goher, Patti Tate, Reagan Reed, Muhammad Irfan, Amy Starr, Alefiyah Motiwala, Julia Kenny, Victoria Aguilar, Jessica Arguijo, Insiya Valika, Victoria Aguilar, Jagruti Patel, Anna Pena, Faryal Mahmood, Bianca Gomez, Nancy Torres, Kristyn Latif, Tarori Mark, Laura Djampou, Lindsey Kueng, Marianne Tadros, Mohammad Millwala, Monica Murray, Murtaza Marvi, Shivani Shah, Vanessa Gonzalez, Zohair Harianawala, Zainab Rizvi, Ambily Dileep, Jaquelyn Gonzales, Ragen Powell, Carolina Deandres, Syed Fahad Ali Kazmi, Sandra Natalia Perez, Shannon Amacker, Shiela Varghese	DM Clinical Research	Tomball, TX
Gowdhami Mohan, MD	Rodolfo Barrera, Emma Partin, Kelly White, Ashley Rochester, Charles Thompson, Stefanie Tyson, Ashten Sheriff, Alyssa-Kay Peay, Kayla Corn, Barbara A. Richardson, Kristin Miller, Steven Clemons, Cameron King, Emma Partin, Gary Clemons, Brianna Starr, Danyel Johnson, Taylor Davis, Niki Tyson	Vitalink Research	Anderson, SC
Kathleen M. Mullane, DO, PharmD	David L. Pitrak, Cheryl Nuss, Karen Cornelius, Rande Estes, Amy Luckett, Michelle Moore, Judi Pi, Stephen Schrantz, Jill Stetkevych	University of Chicago	Chicago, IL
Joseph Lee Newberg, MD	Mary Reyes, Nicole Leahy, Victoria Andriulis, Herbert Whinna, Patricia James, Lana Ghomrawi, Carole Kempfer, Miriam Arroyo, Maria Castro, Anna Maddox, Reuben Martinez, Jacquelyn McCormick-Burks, Laura Pearlman, Rosalinda Vazquez, Shaheera Suleiman, Neha Atai, Rosalind Vazquez	Synexus Clinical Research	Chicago, IL
Richard M. Novak, MD	Regina Harden, Maria Schwarber, Michael Pacini, Rebeca Gansari, Margie Villarreal, Stephanie Martin, Michelle Lee, Richard Morrissy, Taylor Ellis, Samuel Rene, Tara Cobbs, Claudia Preciado, Scott Borgetti, Maximo Brito, Olamide Jarrett, Mahesh Patel, Tracy Cable, Charity Ball, Maryann Holtcamp, Rodrigo Burgos, Sarah Michienzi, Emily Drwiega, Mikayla Johnson, Fischer Herald, Benjamin Ladner, Minseung Chu, Carolyn Dickens, Alfredo Mena Lora, Stockton Mayer, Andrea Wendrow, Habiba Sultana, Nanu Nunwar, David Chan, Marla Schwarber, Khandaker Anwar, Mahmood Ghassemi, Md Ruhul Amin, Doris Carroll, Rosa Valencia, Michelle Agnoli, Elena Linas, Samuel Rene, Liam Morrissy, Adrian Raygoza, Addis Mekonnen, Lisa Lindemann, Daniel Meslar, Karen Pacini, Corey Ringhisen, Amy Kennedy-Krage, Claudia Miller, Lorna Sanchez McCann, Gizelle Alvarez, Nia Moragne-Oneal, Nusirat Williams, Ian Feather, Nikki Griffith, Wardrick Nealon, Renyce Powell, Nila Safaeian, Monica Gingell, Diana Bahena, Gerald Beck, Brad Farrington, Rod Reyes, Monica Wilson, Juline Wondrasek, Kimberly Shapiro, Shannon Whitted, Victoria Roehl, Braulio Carrasco, Michael Chen, Olivia Murray, Yasiel Lacalle, Tessa Eckley, Anna Schlukebier, Kevin Cao, Elise DeBruyn	University of Illinois at Chicago - Project WISH	Chicago, IL
Paul Joseph Nugent, DO	Leonard Singer, Jennifer Jones, April Smith, Georgettea Geuss, Lana Ghomrawi, Christine Bennett, Norma Blevins, Linda Brotherton, Michele Byrd, Krista Doss, Victoria Holden, Christine Hull, Jean Montgomery, Nancy Cipolone, Savannah Torline, Brandon Brown, Meagan Thomas, Katie Ziska, Dana Sias, Hannah Wagner	Synexus Clinical Research	Cincinnati, OH
Jeffrey Scott Overcash, MD	Hanh Chu, Kia Lee, Karla Zepeda, John Rodriguez, Adam Prince, Yashveer Dubbula, Elizabeth Tomatsu Michael Voskianian, Crystle Rajania, Stephanie Ramirez, Claudia Camacho, Lauren Arnett, Kecia Darbeau, Ashley Smith, Kimberly Quillin, Cesar Ramirez, Daniel Robitaille, Erica Sanchez, Allie Davis, Michael Waters, Pat Kappen, Valerie Horne, Thao Vuong, Andrew Dennis, Nikki Abels, Dominique Panis, Richard McQuaid, Whitley Harbison, Erika Trujillo, Andrea Garcia, Jose Jacob Esparza, Carlos Vera, Raquel Taitingfong, Cathy Meza, He Pu, Jackie Lynn Smith, Shandel Odum, Zahira Nieves, Ashliegh Lindsay, Ariana Nasatka, Jose Cazarez, Nora Martinez, Angela Hunt, Antonio Delgado, Linda Vega, Angela Anorve, Erica Martinelli, Melania Riordan, Sylvia Lindholm, Gina Ciezkowski, Grecia Perez, Jacob Pineda,	Velocity Clinical Research, San Diego	La Mesa, CA

Principal Investigator	Study Team	Institution	Location
	Nathan Tyler, Ranya Salem, Amara Yilmaz, Jessica Gonzales, Zabrana Ruiz, Laura Castillo, Yajaira Contreras, Angelica Guzman, Makenna Orel, Jeffery Alvarez, Gordon Bovee, Roxana Ramirez, Joan Esquivel		
James Todd Peterson, MD	Christopher Mickelson, Madeline Maldonado, Alison Charlton, Ashley Bragg, Sean Hansen, Emily Wilcox, Colby Bostock, Megan Henry, Pam Iwasaki, Bradley Young, Katelyn Walker, Joy Nguyen, Lindsey Bevan, Megan Grimmett, Madeline Grote, Heather Littell, Natalie Bee, Alexander Clark, Shana Eborn, Susan Edwards, Dan Henry, Heather Jackson, Gerald Kelty, Issac Pena-Renteria, Jacqueline Rohrer, Jack Taylor, Brooke Barrick, Ty Henry, Anna Dansie, Kenadie Hamblin	J. Lewis Research	Salt Lake City, UT
Paul Pickrell, MD	Susan Bonner, Blaire Graham, Staci Taggart, Hussain Malbari, Tiffany Lemuz, Ethan Shotton, Andrew Bell, Megan Malek, David Pampe, Carol Ann Linebarger, Michelle Peterson, Brandi Chalman, John Luna, Elizabeth Santellanes, Christina Martinez, Lisa Johnson, Lisa Savage, Melissa Winn, Wendi McKenzie, Eileen Euperio, Stefanie Mott, Paul Menefee, Katie Caballero, Darrell O'Brien, Morgan Schulle, Kate Jurek, Olivia Hapanowicz	Tekton Research, Inc.	Austin, TX
Terry L. Poling, MD	Meenakshi (Kavya) Natesan, Patricia Contreras, Denise Hole, Avi Woods, Jill Hiebert, Melissa Burton, Olivia Eagleson, Laura Holz, Terri Ford, Cindy Thome, Terry D Klein, Gregory Greer, Diandra Henriques, Tracy R Klein, Thomas C Klein, Christa Shue, Gina Young, Brenna Sprout	Alliance for Multispecialty Research	Wichita, KS
Bruce G. Rankin, DO	Jennifer Dittman, Lora Parahovnik, Crystal Paccione, Melissa Hodges, Katina Marchione, Matt Maxwell, Any Dominy, Diana Toney, Andrea Marrafino, Laura Isbell, Leandro Fernandez, Claxton Copeland, Michelle Tutt, Adam VanDeusen, Kevin Feldman, Clark Mason, Tifany Huertas, Over Seijas, Jennifer Cline, Christian Beierschmitt, Ryan Hobbick, Jessica Gilliam, Jeanette de Leon, Iman Mencia, Daniel Layish, Vienna Bauer, Shatonia Fields, Albert Garcia, Carrie Rycort, Tasha Brocato, Marshall Nash, Samantha Watts, Amy Houck-Dominy, Angela Hammerle, Teresa Logsdon, Erika Wierzbicki, Taylor Martin, Ranie Hutchins, Fadhel Aiyunis, Gail Lavine, Jeffery Hood, Robert Duran, Michelle Jones, Ginny McClanahan, Heather Jackson, Leandra Fernandez, Douglas Winter, Antonio Rivera, Amber Vasquez, Thais Truffa, Daniel Campbell, Grace Newcomb, Elizabeth Orlando, Steven Shinn, John Hill, Christina Isbell, Dhaneshwar Oomrow, Alicia Cevera	Accel Research Sites	DeLand, FL
Michele Diane Reynolds, MD	Jennifer Bashour, Robert Schmidt, Cynthia Mayeux, Uvoka Huffman, Lisa Nicholson, Jacklyn Newton, Lynn Yauch, Cathy Monroe, Kathleen Carty, Angelica Banks, Taylor Werner, Pamela Echols, Pauline Jackson, Chana Hines, Lorine Cook, Cristina Puig, Patrick Brooks, Jennifer Ruiz, Deanna Bowman, Ladina Garcia	Synexus Clinical Research	Dallas, TX
Rambod Rouhbakhsh, MD, MBA	John Johnston, Richard Calderone, Tasha Stevenson, Tameka Fortune, Brandi Pace, Adreanna Pou, Jerrica Sullivan, Yolanda Lewis, April Rouse, Tiffany Jefferson, Elizabeth Danford, Jeff Repper, Mason Boutwell, Alexycia Washington, Krista Hirth, Meagan Grabel	MediSync Clinical Research Hattiesburg Clinic	Petal, MS
Nadine Roupheal, MD	Renata Dennis, Tigisty Girmay, Michelle Wiles, Sharon Curate-Ingram, Lauren Hewitt, Alexis Ahonen, Mari Hart, Sarah Bechnak, Erin Carter, Lauren Nolan, Daniel Sans Graciaa, Geoffrey Kamau, Easton Beshears, Sy Tran, Mary Atha, Mary Bower, Ghina Alaaedine, Brandy Johnson, Jacob Usher, Eileen Osinski, Erin Scherer, C. Tae Stallworth, Stephanie Ramer, Rose Pope, Esther Park, Francine Dyer, Laura Clegg, Rebecca Gonzalez, Stacey Wheeler, Susan Rogers, Vy Ngo, Vanessa Soliman, Kristen Unterberger, Bernadine Panganiban, Christopher Huerta, Juton Winston, Ali Alvarez, Jianguo Xu, Colleen Kelley, Paulina Rebolledo, Nicholas Scanlon, Jessica Traenkner, Matthew Collins, Hollie Macenczak, Cassie Grimsely-Ackerley, Tiffany Lee, Amy Anderson, Michele Paine McCullough, Hannah Huston, Daniella Carter, Lisa Harewood, Srilatha Edupuganti, Varun Phadke, Mindee Adamson, Jeanne Allen, Debbie Bartenfeld, Lily Berz, Amy Cromwell, Sergio Cruz, Fred Ede, Monica Godfrey, Evan Gutter, Angelle Ijeoma, Sara Jo Johnson, Vinit Karmali, Dean Kleinhenz, Jennifer Kleinhenz, Alexandra Koumanelis, Maranda Leary, Tiraje Lester, Juliet Alise Morales, Shashi Nagar, Julia Paine, Dilshad Rafi Ahmed, Brittany Robinson, Amanda Rosner, Renee Silver, Trevor William Simon, Talib Sirajud-Deen, Damien Swearing, Maliya Tolbert, Pamela Turner, Chia Uzuegbunam, Claire Wan, Dongli Wang, Erika Wimberly, Jean Winter, Joy Winters, Yong Xu, Sha Yi	Emory University - Hope Clinic	Decatur, GA
Richard Rupp, MD	Amber Stanford, Megan Berman, Laura Porterfield, Gerianne Casey, Hala Ghoson, Doreen Jones, Michael Willig, Cori Burkett, Robert Cox, Amy McMahan, Diane Barrett, Kristin Pollock	University of Texas Medical Branch	Galveston, TX
Jamshid Saleh, MD	Matthew Miles, Rafael Lupercio, Vicky Martin, Marla Clark, Matthew Pohmeyer, Ruba Zanaid, Veronica Blevins, Tara Ulberg, Carlyee Chambers, Marisol Corrales, Emily Crews, Mohamed Yassin, Sarah Sandberg, Frank Chen, Mandy Swanson	Paradigm Clinical Research Center	Redding, CA
John W. Sanders, MD, MPH	Stacy Harpe-Hall, Jesse Hopkins, Ann Schweppe, Jaymous Fayssoux, Kathryn Bender, James Peacock, Katharine Pearsall, Brandy Snyder, Deidre Knox, Megan Thorpe, Melissa Ellingson, Brittany Bundeiff, Lisa Ashworth, Meredith Hiatt, Ritu Rathee, Stacy Woodliff, Brian Strittmatter, Amanda Wright, Daisy DeWeese-Gatt,	Wake Forest University Health Sciences	Winston Salem, NC

Principal Investigator	Study Team	Institution	Location
	Caryn Morse, John Williamson, Samantha Wheeler, Lori Whiteheart, Susan Donahue, James Lovette, Kaitlyn Van Leuvan, Kelly Ledbetter, Scott Chatterton, Julio Nasim, Amie Sidberry, Ashley Davis, Carter Noecker, Chie Hooker, Johanna Breenan, Sam Cable, Anna Bowman, Stephanie Boothe, Shea Overcash		
Howard I. Schwartz, MD	Carlos Valladares, Jocelyn Morrera, Yulexis Amestoy, Tori Wallenburg, Thelma Beltran, Terry Piedra, Monica Garces, Alexandra Galvis, Wanda Delgado, Catherine Casas, Lesly Miguel Sosa, Vivian Rosales, Jose Fernando Henriquez, Mikael Yaniz, Beatriz Rivera, Peter Ventre, Gabriella Huyke, Maria Companioni, Jessie De Vega, Brianna Gamez, Stephanie Diaz, James Jean-Mary, Americo Padilla, Nikita Notise, Yorlina Luquetta, Monifa Wilson-Morris, Kenia Gutierrez, Roilan Garcia, Karla Pentzke, Leyda Valentin, Lazara Novas, Marlein Camacho, Jazmin Henfield, Laymis Alvarez, Myriam Rosado, Maxine Bryant, Maria Pinero, Laura Raucchi, Francisco Ramirez, Angelic Gamez, Mailin Perez, Yasmin Baddour, Hary Leon Joseph, Yaquelin De la Cruz, Dunia Torres, Rosaidaliz Carreira, Chanella Garcia, Surisaday Mederos, Jose Muniz, Karenda Plotka, Sara Gomez, Maria Soto, Cathy Cruz, Nella Sanchez-Crespo, Jennifer Schwartz, Barbara Corral, Matthew Muniz, Dayana Dellejo, Ana Castro, Reem Hassan	Research Centers of America	Hollywood, FL
Nathan Segall, MD	Michelle Sowell, Nancy Levine, Erynn McKinley, Hannah Smith, Karen Hickson, Elizabeth West, Patrizia Greene, Jon Finley, Mildred Stull, Susan Jones, Jennifer LeBrun, Pamela Talbott, Kwamda Whatley, Jeffrey Jones, Michelle Binns, Donna Toepfer, Cynthia Steele, Grace Newville, Gillian Waite, Cynthia Pinckney, Karen Yangapatty, Kiara Tyner, Kimberly Cobb, Kourtney Richardson	Clinical Research Atlanta	Stockbridge, GA
William Seger, MD	Kimberly Pullen, Jean Seignon, Anthony Kim, Mohammed Antwi, Allison Green, Lizzy Seger, Elizabeth Boydston, Abdur Rafay Qadri, Deborah Devlin, Tasha Todd, Oluwatosin Akingbala, Alma Guel, Tisha Davis, Melody Duffrene, Samantha Loudermilk, Virginia Loudermilk, Crystal Starr, John Villegas, Ben Seger, Katherine Hollie	Benchmark Research	Fort Worth, TX
Neil Parmanand Sheth, MD	Kenneth Stell, David Beckett, Enitt Gonzalez, Donna McGunigal, Amanda Burns, Nancy Wood, Shelley Miceli, Christina Avila, Rebecca Baker, Laura Vigiotti, Sarah Kading, Samer Salama	Synexus Clinical Research	Glendale, AZ
William B. Smith, MD	Richard L Gibson, Jennifer Winbigler, Elizabeth Parker, Madison Watts, Suzann Cloninger, Talya Thomas	Alliance for Multispecialty Research	Knoxville, TN
Joel Solis, MD	Martha Carmen Medina, Xavier Morales, Hank Heller, Blake Torrence, Joanna Gurrola-Mahoney, Cynthia Bueno, Heather Holloway, Irving Salinas, Joel Perez, Paola Garcia, Erica Canales, Blanca Urbina, Brancisilio Gutierrez, Carolina Cantu, Chelsea Vargas, Cindy Vasquez, Cody McIntire, Gabriela Gutierrez, Hugo Sosa, Irvin Munoz, Jessica Estrada, Jonna Lopez, Kaegan Knox, Mirella Melendez, Natalia Valle, Natalie Echavarria, Nicole Litton, Amber Victor, Nancy Torrence, Madhu Shreya, Mathew Maran, Asfak Alam, Westly Keating, Tara Green, Devora Torrence, Gerardo Sedas, Shruti Konda, Prem Jangam, Mario Echavarria, Alejandro Silva, Anne McNulty, Daniel Contreras, Daniel Gomez, Edgar Garcia, Elizabeth Weber, Luis Lopez, Samuel Ramirez, Kayla Lopez, Pedro Penaio, Angel Salinas, Jaime Solis, Shannon Moyer, Aryana Ibarra, Guadalupe Gurrola, Jenna Anastasiades, Uchechi Ehiemua, Sara Solorzano	Centex Studies, Inc.	McAllen, TX
Stephen A. Spector, MD	Amaran Moodley, Jill Blumenthal, Baharin Abdullah, Christina Addington, Juan Carlos Alcantar, Deyna Arellano, Bernadette Cale, Brendan Costello, Tammelita Cotton-Pineda, Fanny Delebecque, Karen Deutsch, Aram Dimayuga, Son Do, Yasmeen Eshaki, Aileen Everhart, Cindy Ewing, Veronica Figueroa, Medardo Gaytan, Crystal Groom, Carolyn Hernandez, Heather Huitema, Benjamin Hull, Sylvia Isaac, Jaclyn Jaskowiak, Cindy Knott, Leander Lazaro, Thuan Le, Megan Loughran, Michelle Madey, Rosalva Martha-Patten, Colleen McLellan, Jeff Ledford-Mills, Asami Mimura, Patty Moraes, Jennifer Morales, Jessica Nasca, Phirum Nguyen, Marielys Padilla-Martinez, Dennis Perpetua, Mike Pizza, Shannon Ransom, Emily Rizo, Carlos Rojas, Thaine Ross, Marie Sagrado, Eugene Sato, Lisa Stangi, Ji Sun, Nancy Tang, Mina Trivedi, Rodney Trout, Donna Voss, Lindsey Woronicz	University of California, San Diego	La Jolla, CA
Cynthia Becher Strout, MD	Rica Santiago, Yvonne Davis, Patty Howenstine, Alison Bondell, Jaime Robertson, Anissa Moussa, Geronimo Fera Garzon, Sierra Bennett, Marlana Petrie	Coastal Carolina Research Center	Mount Pleasant, SC
Shobha Swaminathan, MD	Amesika Nyaku, Tilly Varughese, Rondalya Deshields, Michelle L DallaPiazza, Elise Lewis, Jennifer Punsal, Mario Portilla, Malithi Desilva, Christina Daliani, Susana Rivera, Aidan Ziobro, Andressa Rebellatto, Brian Murloy, Christina Ninan, Ernest Pianim, Eunice Wang, Merit Henen, Muhammad Usman, Rebecca Kim, Shiao Wang, Gener Eric Cruz, Bethany Birago, Joyell Arscott, Dina Meawad, Christie Lyn Costanza, Francesca Escaleira, Zoraida Cruz-Barahona, Jared Khan, Valeria Cadoret, Jamir Tuten, Travis Love, Eric Asencio, Sukhwinder Singh	Rutgers New Jersey Medical School	Newark, NJ

Principal Investigator	Study Team	Institution	Location
Ramy Joseph Toma, MD	Olivia Graves, Josiah Robinson, Patricia Hammonds, Lana Ghomrawi, Kara Quinnelly, Shaun O'Connor, Michael Lambe, Rachell Stewart, William Kirby, Pink Folmar, Rachel Culbreth, Heidi Leblanc, Julie McDaniel, Rian Montgomery, Andrea Woodle, Samantha Williams, Hunter Russell, Shereen Lowe, Maureen Mayer, Hollis Ryan, Elaine Reese	Synexus Clinical Research	Birmingham, AL
Timothy P. Vachris, MD	Mark Hutchens, Stephen Daniels, Margaret Wells, Sandra Clancy, Rebecca Martinez, Jessica Buot, Merissa Daugherty, Julie Hamilton, Kimberly Hernandez, Ashli Alejandro, Amy Collins, Monique Gawlik, Patricia Johnson, Maria Moreno, Ashley Washington, Tina Rountree, Daniel Dore, Ravi Davuluri, Ashlee Brunaugh, Jorge Martinez, James Hermon, Vianai Carreno, Mia Rountree, Colleen Coelho	Optimal Research	Austin, TX
Keith William Vrbicky, MD	Charles Harper, Chelsie Nutsch, Wendell Lewis III, Cathy Laffan, Linden DeBoer, Kayla Andal, Misty Appeldorn, Jenniger Grebe, Russell Herstein, Catherine King, Samantha Wieseler, Alisha Kiepe, Christy Lee, Kelsey Kelley, Kelli James, Ashley Frisch, Courtney Green, Taysha Hingst, Jeni Hoppe, Kimber Breeden, Debra Gabrielson, Ginny McNew	Meridian Clinical Research	Norfolk, NE
Larkin T. Wadsworth III, MD	Ashley Dale, Christy Schultz, Rebecca Munsch, Anya Penly, Liz Garner, Stephanie Tesson, George Cherniawski, Angie Kean, Dan Reed, Courtney Kubiak, Maureen Dempsey, Heather Cherniawski, Breanna Galibert, Kristin Branson, Laura Hartupée, Karen Knapp, Horacio Marafioti, Lyly Dang, Jennifer Berry, Lauren Clement, Megan Dandurand	Sundance Clinical Research	St. Louis, MO
Jordan L. Whatley, MD	Patricia Whatley, Christopher Dedon, Anika Payne, Amie Shannon, Kristen Losavio, Nicole Harrell, Mary Margaret Dobson, Lindsey Hall, Chaney Bennett, Crystal Rowell, Mimi Dimmick, Amy Thomassie, Kimber Breeden, Cody LaFleur, Makaylea Truitt, Taryn Collett, Emily Best, Alexandra Caillouet	Meridian Clinical Research	Baton Rouge, LA
Judith White, MD	Amy Edridge, Chelsea Montalvo, Eugenia Clark, Lisa Russell, Zahra Somji, Lesli Leimer, Robert Meyer, Christine Murphy, Prity Patel, Sejal Patel, Ruben Moliere, Samantha Merveillard, Yarnick Mirjah, Bryn Walls, Joey Cruz, Aaron Cooper, Jessica Bienaime, Ashley Gilcrist, Alisa Petit, Tyler Knightly, Kimberly Stokes, Christina Rosario, Talhia Matos, Ilona Boggs, Nicholas Weber, Felix Busot, Linda Colon, Heather Gillenwater, Cristina Kaplun, Melissa Caputi, Shayna Siplin, Daminee Shah, Samuel Martin, Alexis Waldorf, Vihar Upadhyay, Adolfo Henriquez, Saskia Singh, Maria Roberts, John Caporelli, Shirley Salvador, Quevina Scarver, Vanessa Garcia, Taylor Moore, Jayasen Singh, Curshinda Galvin-Burch, Mary Kesner, Jasmin Gil, Shay Gray, Steven Monsegur, Michele Steinmetz, Michael Lambe, Heather Powell, Sandra Torres, Shaban Katbeh, Taylor Wilson	Synexus Clinical Research	Orlando, FL
Priyantha N. Wijewardane, MD	Natalie Johnson, Martha Evans, Sondra Wright, Richard Pellegrino, Lastida Burns, Natasha Williams, Haylee Rowe, Kayla Graham, Amanda Horn, Eric Bravo, Jeffrey Thessing, A. Michele Maxwell, Amy Cooper, Lauren Evans, Tonya Cato, Haylee Tucker, Lesa Gann, Hannah Jones, Amanda May, Tiffany Walker, A. LeiAn Diaz, Laura Khalil, Lydia Purcell, Timothy Campbell, Charlotte Garcia-Velez, Andrea Scarborough, Beatrice A. Miller, Keith Bracy, Aujanja Thompson, Cassandra Johnson, Krishana Day, Freddie Hicks, Jamie Pettus	Baptist Health Center for Clinical Research	Little Rock, AR
Barton G. Williams, MD	Flo Abbott, Nicole Burton, Alice Cipollini, Madison Croucher, Philip Dattilo, Erin Harrelson, Kelsey Heston, James Ingram, William H Jones, Karla Lane, Brandy Lowman, Evan Lucas, Megan Marles, Morgan Mathis, Angie Northcott, Clyda Pasquantonio, Alyssa Valente, Ciara Winders, Stephanie Graham	Trial Management Associates	Wilmington, NC
Marcus J. Zervos, MD	Paul Kigore, Mayur Ramesh, Jelena Verkler, Pardeep Pabla, Andrew Clark, Katrina Williams, Dee Dee Wang, Beverley Duthie, Samia Arshad, Alandra White, Anna Kern, Ashley Mattern, Bilqis Mosed, Dana Parke, Doreen Dankerlui, Dragana Spasevska, Hanah Woods, Helina Misikir, Howard Klausner, Janay Scott, Jessica Heinonen, John Zervos, Joseph Miller, Kate Zenlea, Kristin Eis, Marissa Vasquez, Maurice Slaughter, Meaghan Flynn, Michael Garcia, Michelle Sankah, Nina Paeilli, Philip Benson, Robert Devore, Stevanya Baho, Tony Eljallad, Tyler Prentiss, Yaman Ahmed, Sharon Mathys, Linda Kaljee, Jeffrey Van Laere, Claudia Hanni, Hassan Zafar, Mona Desai, Gina Maki, Mary Perri, Dora Vager, Shannon Thomas, Autumn Robinson, Isis Hamilton, Sonia Eliya, Jehan Jazrawi, Biljana Popovic, Sharon Zahul, Joshua Ruzzin, John Laguio, Ali Mathena, Bobby Cook Jr., Marlene Hesler, Rochelle Fleming, Terria Minniefield, John Simons, Sherese Henderson, Ashley Hopkins, Rebecca McFarlane, Raeshell Carson, Jonathan Williams, Katherine Reyes, Erica Herc, Indira Brar, Mayur Ramesh, John McKinnon, Lacquis Duncan, Tim Asmar, Margaret Beyer, Kaleem Chaudhry, Madison Lee, Jo-Ann Rammal, Karthik Sridasyam, Siddesh Veer, Angelique Buluran, Kimberlyn Lott, Jeremiah Rooker, Alayna Wilder, Kathieen Wilson, Allison Weinmann, Hassan Mourtada	Henry Ford Health System	Detroit, MI

## Supplemental Statistical Methods

### *Statistical aspects of the vaccine efficacy analysis*

Vaccine efficacy (VE) is defined as the percent reduction in the hazard, i.e. one minus the hazard ratio (HR, mRNA 1273 vs. placebo).

For the primary efficacy and secondary efficacy endpoints, a stratified Cox proportional hazard (PH) model with Efron's method of tie handling and with vaccine groups (mRNA-1273 or Placebo) as covariate is used to assess the vaccine efficacy (i.e.  $1 - \text{HR}$ ) between mRNA-1273 vs. placebo. The model is adjusted for the same stratification factors used for randomization. The estimator of VE and its 95% CI is provided from the stratified Cox proportional model.

For the primary efficacy endpoint, Covid-19 cases based on adjudication committee assessments starting 14 days after the second injection in the Per-Protocol (PP) set, the one-sided p-value for testing the null hypothesis ( $\text{VE} \leq 30\%$ ) derived from the stratified Cox model is provided. At IA1, based on a total of 95 cases, the one-sided p-value was  $<0.0001$ , and was compared to a one-sided alpha of 0.0047 based on 62.9% information of the target total number (95/151) using the Lan-DeMets O'Brien-Fleming approximation. Therefore, the pre-specified statistical criterion for study success was demonstrated at IA1.

For the primary and secondary efficacy endpoints, incidence rate, defined as the number of participants with an event divided by the number of participants at risk and adjusted by person-years (total time at risk) is calculated. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years. \*VE is defined as  $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$ . The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

### *Stratified Cox regression model to derive estimates of vaccine efficacy as 1-HR.*

The assumption of the cox proportional hazard model is that the hazard rate ratio is a constant, i.e. the vaccine efficacy is independent of the rate at which cases occur in the Placebo group in any short time interval. At the first interim analysis with a median follow-up time of 49 days after the second dose, based on 95 cases, the vaccine efficacy estimate from the stratified Cox model was 94.5%. At the primary analysis with a median follow-up time of approximately 9 weeks after the second dose, based on 196 cases, the vaccine efficacy estimate from the stratified Cox model was 94.1%. These results indicate the vaccine efficacy is independent of the rate on Placebo. Analyses based on the exact method conditional on the total number of cases have also been performed and the results are consistent with that from the stratified Cox model.

In addition, the pattern of cumulative incidence curves (based on  $1 - \text{Kaplan-Meier estimate}$ ) for two treatment groups on Covid-19 counted starting 14 days after second dose in the PP set (primary analysis, Figure 3A) and Covid-19 counted starting from randomization in modified intent-to-treat (mITT) set (sensitivity analysis, Figure 3B) show that the proportional hazard assumption holds: two curves of the treatment groups start together with 0 events, separate around day 42 (14 days after second dose) in Figure 3A and Day 14 in Figure 3B, and then diverge over time without crossing.



The plot of log-log transformation of estimated survival probability was examined, based on November 25, 2020 data, of primary endpoint in the PP set. The curves for the two groups were approximately parallel, which supports that the proportional hazard assumption holds

***Rationale for Assessment of Vaccine Efficacy in the Per-Protocol Population.***

It is not uncommon to use the PP Set as the primary analysis population for efficacy for vaccine studies, as it usually includes participants who have received the intended vaccine regimen. In the PP set, participants are included in the vaccine group to which they were randomized. In our study, the PP Set excluded randomized participants who had positive or missing baseline SARS-CoV-2 status at baseline, who received the incorrect study vaccine, discontinued study before receiving dose 2, or received dose 2 outside of [day 22, 42] window, and other major protocol deviations that impacted critical data. The reasons for exclusions are summarized in Figures 1 and S1. Additionally, sensitivity analyses in the mITT set were performed to assess the consistency of vaccine efficacy.

***Additional details supporting Figures 3A and 3B.***

In Figures 3 and 4, the time axis started from randomization in days. Figure 3A presents the primary analysis of Covid-19 based on adjudication committee assessments starting 14 days after the second vaccination in the Per-Protocol Set. In this analysis, participants with an onset date of Covid-19 starting 14 days after second dose are events with date of onset; participants with an onset date for Covid-19 <14 days after the second dose (early case) were censored at the date of Covid-19. Participants who did not have Covid-19 were censored at the data cutoff date for efficacy. Participants who discontinued the study early or died due to cause unrelated to Covid-19 without documented Covid-19 are censored at the date of early discontinuation or death. Therefore, the cumulative incidence curves started to separate around 42 days after randomization as the date of Covid-19 in this analysis starts 14 days after second vaccination (with a target day of Day 29). The censoring started around day 29 as the earliest discontinuation in the Per-Protocol Set. Participants who discontinued before dose 2, received dose 2 outside of day [23, 42] window have been excluded from the Per-Protocol Set.

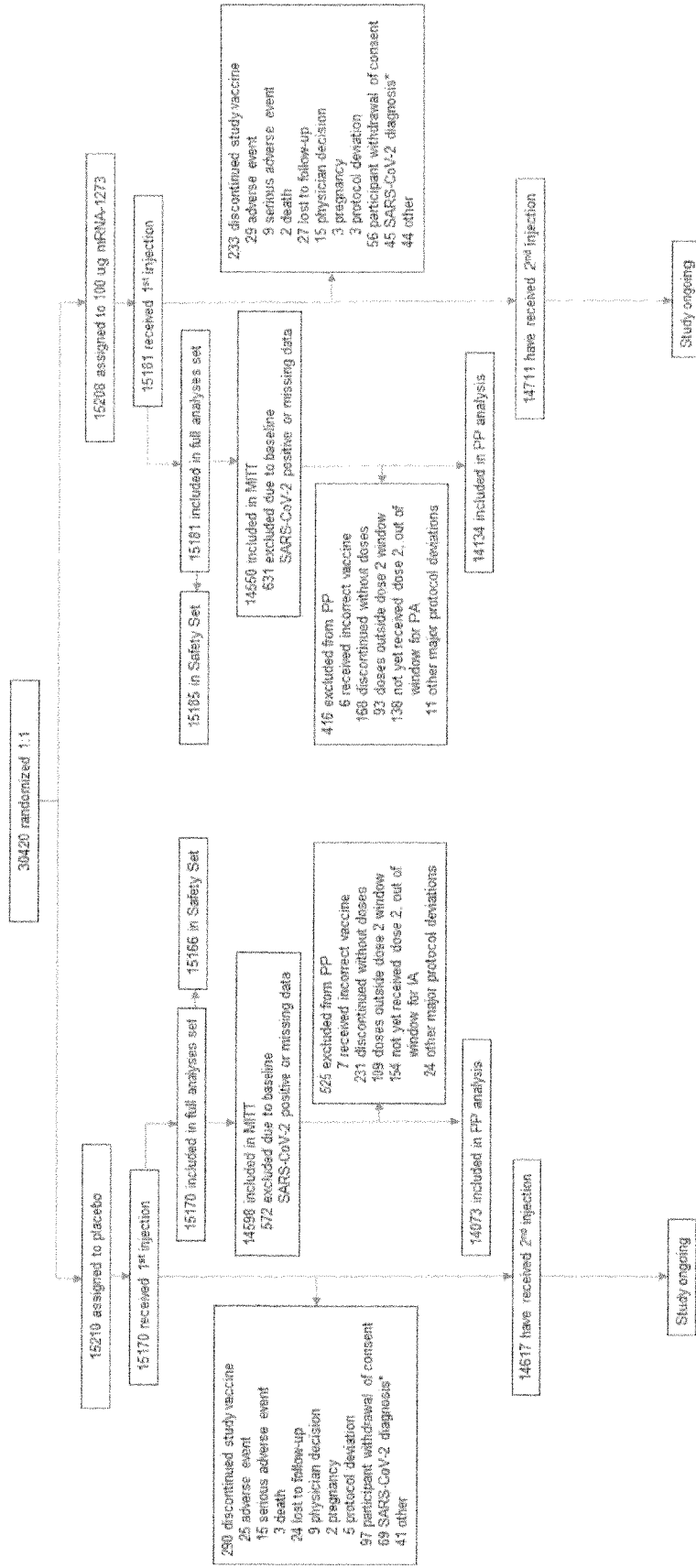
Figure 3B presents a sensitivity analysis of Covid-19 from randomization in the mITT Set. In this analysis, participants who had Covid-19 were events with date of onset. The other censoring rules are the same as above. The mITT Set only excludes randomized participants who did not receive any dose, or had positive or missing baseline SARS-CoV-2 status. Therefore, censoring starts early after randomization (early discontinuations), and the two curves started to separate early.

*Baseline demographics and characteristics using the per-protocol set are provided as supportive data for Table 1 based on the randomized participants.*

<b>Baseline Demographics and Characteristics Based in the Per-Protocol Set</b>			
<b>Characteristics n (%)</b>	<b>Placebo (N=14073)</b>	<b>mRNA-1273 (N=14134)</b>	<b>Total (N=28207)</b>
Sex			
Male	7462 (53.0)	7366 (52.1)	14828 (52.6)
Female	6611 (47.0)	6768 (47.9)	13379 (47.4)
Age at Screening (yr)			
Mean (range)	51.6 (18- 95)	51.6 (18- 95)	51.6 (18- 95)
Age (yr) and health risk for severe Covid-19*			
≥18 and <65 and Not at Risk	8200 (58.3)	8189 (57.9)	16389 (58.1)
≥18 and <65 and at Risk	2324 (16.5)	2367 (16.7)	4691 (16.6)
≥65	3549 (25.2)	3578 (25.3)	7127 (25.3)
Ethnicity			
Hispanic or Latino	2780 (19.8)	2789 (19.7)	5569 (19.7)
Not Hispanic or Latino	11165 (79.3)	11212 (79.3)	22377 (79.3)
Not reported and unknown	128 (0.9)	133 (1.0)	261 (0.9)
Race†			
White	11174 (79.4)	11253 (79.6)	22427 (79.5)
Black or African American	1349 (9.6)	1385 (9.8)	2734 (9.7)
Asian	689 (4.9)	620 (4.4)	1309 (4.6)
American Indian or Alaska Native	111 (0.8)	108 (0.8)	219 (0.8)
Native Hawaiian or Other Pacific Islander	31 (0.2)	35 (0.2)	66 (0.2)
Multiracial	307 (2.2)	295 (2.1)	602 (2.1)
Other	295 (2.1)	299 (2.1)	594 (2.1)
Not reported and unknown	117 (0.9)	139 (1.0)	256 (0.9)
Baseline SARS-CoV-2 Status†			
Negative	14073 (100)	14134 (100)	28207 (100)
Positive	0	0	0
Missing	0	0	0
Baseline RT-PCR			
Negative	14073 (100)	14134 (100)	28207 (100)
Positive	0	0	0
Missing	0	0	0
Baseline bAb Anti-SARS-CoV-2			
Negative	14073 (100)	14134 (100)	28207 (100)
Positive	0	0	0
Missing	0	0	0
Risk Factor for Severe Covid-19 at Screening‡			
Chronic lung disease	688(4.9)	673 (4.8)	1361 (4.8)
Significant cardiac disease	694 (4.9)	711 (5.0)	1405 (5.0)
Severe obesity	936 (6.7)	956 (6.8)	1892 (6.7)
Diabetes	1345 (9.6)	1364 (9.7)	2709 (9.6)
Liver disease	90 (0.6)	95(0.7)	185(0.7)
HIV	77 (0.5)	82 (0.6)	159 (0.6)
Body Mass Index, (kg/m <sup>2</sup> )			
Mean (SD)	29.27 (6.650)	29.28 (6.827)	29.28 (6.739)

bAb = binding antibody concentration; IRT = interactive response technology; RT-PCR = reverse transcription polymerase chain reaction. Internet-based randomization was used to randomize participants to treatment groups based on the information the Investigator entered regarding the age and potential comorbid conditions. \*Based on stratification factor from IRT, participants who were <65 years old were categorized as at risk for severe Covid-19 illness if they had at least 1 of the risk factors specified in the study protocol at screening. †Baseline SARS-CoV-2 status was positive if there was immunologic or virologic evidence of prior Covid-19, defined as positive RT-PCR test, or bAb against SARS-CoV-2 nucleocapsid above limit of detection; or lower limit of quantification at Day 1. Negative was defined as negative RT-PCR test and negative bAb against SARS-CoV-2 assay result at Day 1. ‡Participants could be under one or more categories and were counted once at each category.

**Fig. S1. Study Disposition in Overall Randomized Set**



**Table S1. Primary and Secondary Objectives of the Trial**

<b>Objectives and Endpoints</b>	
<b>Primary Objective</b>	<b>Primary Endpoints</b>
<p><b>Efficacy Objective (Primary):</b> To demonstrate the efficacy of mRNA-1273 to prevent Covid-19.</p>	<p><b>Efficacy Endpoints (Primary):</b> Vaccine efficacy of mRNA-1273 to prevent the first occurrence of Covid-19 starting 14 days after the second dose of investigational product (IP), where Covid-19 is defined as symptomatic disease based on the following criteria:</p> <ul style="list-style-type: none"> <li>• The participant must have experienced at least TWO of the following systemic symptoms: Fever (<math>\geq 38^{\circ}\text{C}</math>), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), OR</li> <li>• The participant must have experienced at least ONE of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia; AND</li> <li>• The participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR.</li> </ul>
<p><b>Safety Objective (Primary):</b> To evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart.</p>	<p><b>Safety Endpoint (Primary):</b></p> <ul style="list-style-type: none"> <li>• Solicited local and systemic ARs through 7 days after each dose of IP.</li> <li>• Unsolicited AEs through 28 days after each dose of IP.</li> <li>• Medically attended adverse events (MAAEs) or AEs leading to withdrawal through the entire study period.</li> <li>• SAEs throughout the entire study period.</li> </ul>
<b>Efficacy Objectives (Secondary)</b>	<b>Efficacy Endpoints (Secondary)</b>
<p>To evaluate the efficacy of mRNA-1273 to prevent severe Covid-19.</p>	<ul style="list-style-type: none"> <li>• Vaccine efficacy of mRNA-1273 to prevent severe Covid-19, defined as first occurrence of Covid-19 starting 14 days after the second dose of IP, (as per the primary endpoint) AND any of the following: <ul style="list-style-type: none"> <li>○ Clinical signs indicative of severe systemic illness, Respiratory Rate <math>\geq 30</math> per minute, Heart Rate <math>\geq 125</math> beats per minute, <math>\text{SpO}_2 \leq 93\%</math> on room air at sea level or <math>\text{PaO}_2/\text{FIO}_2 &lt; 300</math> mm Hg, OR</li> <li>○ Respiratory failure or Acute Respiratory Distress Syndrome (ARDS), (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <math>&lt; 90</math> mmHg, diastolic BP <math>&lt; 60</math> mmHg or requiring vasopressors), OR</li> <li>○ Significant acute renal, hepatic or neurologic dysfunction, OR</li> <li>○ Admission to an intensive care unit or death.</li> </ul> </li> </ul>
<p>To evaluate the efficacy of mRNA-1273 to prevent serologically confirmed SARS-CoV-2 infection or Covid-19 regardless of symptomatology or severity.</p>	<p>Vaccine efficacy of mRNA-1273 to prevent the first occurrence of either Covid-19 or SARS-CoV-2 infection starting 14 days after the second IP dose. This endpoint is a combination of Covid-19, defined as for the primary endpoint, and asymptomatic SARS-CoV-2 infection, determined by seroconversion assessed by bAb levels against SARS-CoV-2 as measured by a ligand-binding assay specific to the SARS-CoV-2 nucleocapsid protein and with a negative nasopharyngeal (NP) swab sample for SARS-CoV-2 at Day 1.</p>
<p>To evaluate VE against a secondary definition of Covid-19.</p>	<p>Vaccine efficacy of mRNA-1273 to prevent the secondary case definition of Covid-19 starting 14 days after the second IP dose. The secondary case definition of Covid-19 is defined as the following systemic symptoms: fever (temperature <math>\geq 38^{\circ}\text{C}</math>), or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches or body aches, headache, new loss of taste or smell, sore throat, nasal congestion or rhinorrhea, nausea or vomiting, or diarrhea AND a positive NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) for SARS-CoV-2 by RT-PCR.</p>
<p>To evaluate VE to prevent death caused by Covid-19.</p>	<p>Vaccine efficacy of mRNA-1273 to prevent death due to a cause directly attributed to a complication of Covid-19, starting 14 days after the second IP dose.</p>
<p>To evaluate the efficacy of mRNA-1273 to prevent Covid-19 after the first dose of IP.</p>	<p>Vaccine efficacy of mRNA-1273 to prevent the first occurrence of Covid-19 starting 14 days after the first dose of IP.</p>

<p>To evaluate the efficacy of mRNA-1273 to prevent Covid-19 in all study participants, regardless of evidence of prior SARS-CoV-2 infection.</p>	<p>Vaccine efficacy of mRNA-1273 to prevent the first occurrence of Covid-19 starting 14 days after the second dose of IP regardless of evidence of prior SARS-CoV-2 infection determined by serologic titer against SARS-CoV-2 nucleocapsid (FAS analysis population).</p>
<p>To evaluate the efficacy of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection.</p>	<p>Vaccine efficacy to prevent the first occurrence of SARS-CoV-2 infection in the absence of symptoms defining Covid-19 starting 14 days after the second IP dose. SARS-CoV-2 infection determined by seroconversion assessed by bAb levels against SARS-CoV-2 as measured by a ligand-binding assay specific to the SARS-CoV-2 nucleocapsid protein and with a negative NP swab sample for SARS-CoV-2 at Day 1.</p>

**Table S2. Baseline Demographics and Characteristics by Randomized Strata Groups, Full Analysis Set**

Characteristic n (%)	≥18-65 yr and not at risk			≥18-65 yr and at risk			≥65 yr			Overall		
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total
	N=8886	N=8888	N=17774	N=2535	N=2530	N=5065	N=3749	N=3763	N=7512	N=15170	N=15181	N=30351
Age at screening, yr mean (range)	43.8 (18-72)	44.0 (18-64)	43.9 (18-72)	49.2 (18-79)	48.9 (18-76)	49.0 (18-79)	70.7 (40-95)	70.4 (64-95)	70.6 (40-95)	51.3 (18-95)	51.4 (18-95)	51.4 (18-95)
Sex												
Male	4632 (52.1)	4544 (51.1)	9176 (51.6)	1329 (52.4)	1305 (51.6)	2634 (52.0)	2101 (56.0)	2074 (55.1)	4175 (55.6)	8062 (53.1)	7923 (52.2)	15986 (52.7)
Female	4254 (47.9)	4344 (48.9)	8598 (48.4)	1206 (47.6)	1225 (48.4)	2431 (48.0)	1648 (44.0)	1889 (44.9)	3337 (44.4)	7108 (46.9)	7258 (47.8)	14366 (47.3)
Race												
White	6789 (76.4)	6756 (76.0)	13545 (76.2)	1870 (73.8)	1900 (75.1)	3770 (74.4)	3336 (89.0)	3373 (89.6)	6709 (89.3)	11895 (79.1)	12029 (79.2)	24024 (79.2)
Black or African American	899 (10.1)	968 (10.9)	1867 (10.5)	413 (16.3)	374 (14.8)	787 (15.5)	215 (5.7)	221 (5.9)	436 (5.8)	1527 (10.1)	1563 (10.3)	3090 (10.2)
Asian	570 (6.4)	501 (5.6)	1071 (6.0)	84 (3.3)	85 (3.4)	169 (3.3)	77 (2.1)	65 (1.7)	142 (1.9)	731 (4.8)	661 (4.3)	1382 (4.6)
American Indian or Alaska Native	72 (0.8)	65 (0.7)	137 (0.8)	23 (0.9)	26 (1.0)	49 (1.0)	28 (0.7)	21 (0.6)	47 (0.6)	121 (0.8)	112 (0.7)	233 (0.8)
Native Hawaiian or Pacific Islander	20 (0.2)	25 (0.3)	45 (0.3)	9 (0.4)	7 (0.3)	16 (0.3)	3 (<0.1)	3 (<0.1)	6 (<0.1)	32 (0.2)	35 (0.2)	67 (0.2)
Multiracial	232 (2.6)	231 (2.6)	463 (2.6)	51 (2.0)	50 (2.0)	101 (2.0)	38 (1.0)	34 (0.9)	72 (1.0)	321 (2.1)	315 (2.1)	636 (2.1)
Other	229 (2.6)	233 (2.6)	462 (2.6)	54 (2.1)	61 (2.4)	115 (2.3)	33 (0.9)	27 (0.7)	60 (0.8)	316 (2.1)	321 (2.1)	637 (2.1)
Not reported	42 (0.5)	67 (0.8)	109 (0.6)	1 (0.7)	16 (0.6)	34 (0.7)	13 (0.3)	13 (0.3)	26 (0.3)	73 (0.5)	96 (0.6)	169 (0.6)
Unknown	33 (0.4)	42 (0.5)	75 (0.4)	13 (0.5)	11 (0.4)	24 (0.5)	8 (0.2)	6 (0.2)	14 (0.2)	54 (0.4)	59 (0.4)	113 (0.4)
Race and Ethnicity Group*												
White	4975 (56.0)	5005 (56.3)	9980 (56.1)	1426 (56.3)	1456 (57.5)	2882 (56.9)	3060 (81.6)	3068 (81.5)	6128 (81.6)	9461 (62.4)	9529 (62.8)	18990 (62.6)
Communities of color	3903 (43.9)	3869 (43.5)	7772 (43.7)	1104 (43.6)	1068 (42.2)	2172 (42.9)	676 (18.0)	689 (18.3)	1365 (18.2)	5663 (37.5)	5626 (37.1)	11309 (37.3)
Missing	8 (<0.1)	14 (0.2)	22 (0.1)	5 (0.2)	6 (0.2)	11 (0.2)	13 (0.3)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)
Ethnicity												
Hispanic or Latino	2228 (25.1)	2209 (24.9)	4437 (25.0)	552 (21.8)	568 (22.1)	1110 (21.9)	334 (8.9)	354 (9.4)	688 (9.2)	3114 (20.5)	3121 (20.6)	6235 (20.5)
Not Hispanic or Latino	6585 (74.1)	6599 (74.2)	13184 (74.2)	1980 (77.3)	1953 (77.2)	3933 (77.3)	3372 (89.9)	3366 (89.4)	6738 (89.7)	11917 (78.6)	11918 (78.5)	23635 (78.5)
Not Reported	43 (0.5)	58 (0.7)	101 (0.6)	15 (0.6)	14 (0.6)	29 (0.6)	27 (0.7)	32 (0.9)	59 (0.8)	85 (0.6)	104 (0.7)	189 (0.6)
Unknown	30 (0.3)	22 (0.2)	52 (0.3)	8 (0.3)	5 (0.2)	13 (0.3)	16 (0.4)	11 (0.3)	27 (0.4)	54 (0.4)	38 (0.3)	92 (0.3)
BMI kg/m2, mean (SD)	28.0 (5.2)	28.0 (5.3)	28.0 (5.2)	35.0 (9.2)	35.2 (9.6)	35.1 (9.4)	28.7 (5.9)	28.7 (5.9)	28.7 (5.9)	29.3 (6.7)	29.3 (6.9)	29.3 (6.8)
At risk for severe Covid-19 at screening												
Yes	141 (1.6)	127 (1.4)	268 (1.5)	2163 (85.3)	2171 (85.8)	4334 (85.6)	1114 (29.7)	1101 (29.3)	2215 (29.5)	3418 (22.5)	3399 (22.4)	6817 (22.5)
No	8745 (98.4)	8761 (98.6)	17506 (98.5)	372 (14.7)	359 (14.2)	731 (14.4)	2635 (70.3)	2662 (70.7)	5297 (70.5)	11752 (77.5)	11782 (77.6)	23534 (77.5)



Transportation and Delivery	313 (3.5)	335 (3.8)	648 (3.6)	9 (3.9)	97 (3.8)	195 (3.6)	62 (1.7)	50 (1.3)	112 (1.5)	473 (3.1)	482 (3.2)	955 (3.1)
Border Protection and Military Personnel	51 (0.6)	53 (0.6)	104 (0.6)	11 (0.4)	13 (0.5)	24 (0.5)	6 (0.2)	3 (<0.1)	9 (0.1)	6 (0.4)	69 (0.5)	137 (0.5)
Personal Care and In-Home Services	330 (3.7)	299 (3.4)	629 (3.5)	78 (3.1)	103 (4.1)	181 (3.6)	61 (1.6)	67 (1.8)	128 (1.7)	469 (3.1)	469 (3.1)	938 (3.1)
Hospitality and Tourism Workers	149 (1.7)	163 (1.8)	312 (1.8)	40 (1.6)	38 (1.5)	78 (1.5)	43 (1.1)	36 (1.0)	79 (1.1)	292 (1.5)	237 (1.6)	469 (1.5)
Pastoral, Social or Public Health Workers	264 (3.0)	296 (3.3)	560 (3.2)	101 (4.0)	90 (3.6)	19 (3.8)	138 (3.7)	147 (3.9)	265 (3.8)	503 (3.3)	533 (3.5)	1036 (3.4)
Educators and Students	1113 (12.5)	1083 (12.2)	2196 (12.4)	270 (10.7)	276 (10.9)	546 (10.8)	169 (4.5)	184 (4.9)	353 (4.7)	1552 (10.2)	1543 (10.2)	3095 (10.2)
Other	2591 (29.2)	2582 (29.1)	5173 (29.1)	789 (31.1)	810 (32.0)	1599 (31.6)	1423 (38.0)	1426 (37.9)	2849 (37.9)	4803 (31.7)	4818 (31.7)	9621 (31.7)
Location and Living Circumstances Risk	7444 (83.8)	7481 (84.2)	14925 (84.0)	2080 (82.1)	2046 (80.9)	4126 (81.5)	3089 (82.4)	3119 (82.9)	6208 (82.6)	12613 (83.1)	12648 (83.3)	25259 (83.2)
Nursing Home or Assisted Living Facility	6 (<0.1)	11 (0.1)	17 (<0.1)	3 (0.1)	11 (0.4)	14 (0.3)	20 (0.5)	11 (0.3)	31 (0.4)	29 (0.2)	33 (0.2)	62 (0.2)
Multi-Family Dwelling	266 (3.0)	304 (3.4)	570 (3.2)	80 (3.2)	92 (3.6)	172 (3.4)	63 (1.7)	66 (1.8)	129 (1.7)	409 (2.7)	462 (3.0)	871 (2.8)
High Density Housing	873 (9.8)	839 (9.4)	1712 (9.6)	195 (7.7)	195 (7.7)	350 (7.7)	239 (6.4)	251 (6.7)	490 (6.5)	1307 (8.6)	1285 (8.5)	2592 (8.5)
Low Density, Multi-Family Setting	952 (10.7)	934 (10.5)	1886 (10.6)	275 (10.8)	301 (11.9)	576 (11.4)	255 (6.8)	244 (6.5)	499 (6.6)	1482 (9.8)	1479 (9.7)	2981 (9.8)
Single Family Home	4739 (53.3)	4771 (53.7)	9510 (53.5)	1366 (53.9)	1288 (50.9)	2654 (52.4)	2245 (59.9)	2270 (60.3)	4515 (60.1)	8350 (55.0)	8329 (54.9)	16679 (55.0)
Other	1306 (14.7)	1329 (15.0)	2635 (14.8)	331 (13.1)	315 (12.5)	646 (12.8)	528 (14.1)	545 (14.5)	1073 (14.3)	2165 (14.3)	2189 (14.4)	4354 (14.3)

Percentages are based on the number of participants in full analysis set (FAS), presented for overall and 3 age stratification groups. Baseline SARS-CoV-2 status was positive if there was immunologic or virologic evidence of prior Covid-19, defined as positive RT-PCR test or positive bAb result at day 1; negative was defined as negative RT-PCR test and negative bAb result at day 1. \*White was defined as white and non-Hispanic, and communities of color includes all the others whose race or ethnicity is not unknown, unreported or missing. †Baseline SARS-CoV-2 Status was considered positive if there was immunologic or virologic evidence of prior Covid-19, defined as positive RT-PCR test or bAb result at day 1; negative was defined as negative RT-PCR test and bAb results at day 1. Age and health risk for severe Covid-19 are derived from age and risk factors collected on case report form. Note that some participants were incorrectly stratified on the basis of Covid-19 risk.



**Table S3. Solicited Adverse Reactions Within 7 Days After First Vaccination by Grade, Solicited Safety Set**

Adverse reaction Vaccination 1 n (%)	Overall Safety Set						≥18-<65 years		≥65 years	
	Placebo (N=15155)	mRNA-1273 (N=15168)	Total (N=30323)	Placebo (N=11407)	mRNA-1273 (N=11406)	Total (N=22813)	Placebo (N=3748)	mRNA-1273 (N=3762)	Total (N=7510)	
Any solicited AR	7284 (48)	13319 (87.8)	20603 (67.9)	5738 (50.3)	10261 (90.0)	15999 (70.1)	1546 (41.2)	3058 (81.3)	4604 (61.3)	
Grade 1	5147 (34.0)	9342 (61.6)	14489 (47.8)	4003 (35.1)	6959 (61.0)	10962 (48.1)	1144 (30.5)	2383 (63.3)	3527 (47.0)	
Grade 2	1770 (11.7)	3124 (20.6)	4894 (16.1)	1459 (12.8)	2593 (22.7)	4052 (17.8)	311 (8.3)	531 (14.1)	842 (11.2)	
Grade 3	361(2.4)	848 (5.6)	1209 (4.0)	272 (2.4)	704 (6.2)	976 (4.3)	89 (2.4)	144 (3.8)	233 (3.1)	
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)	4 (<0.1)	5 (<0.1)	9 (<0.1)	2 (<0.1)	0	2 (<0.1)	
Any Local AR	2997 (19.8)	12765 (84.2)	15762 (52.0)	2430 (21.3)	9960 (87.4)	12390 (54.3)	567 (15.1)	2805 (74.6)	3372 (44.9)	
Grade 1	2837 (18.7)	10731 (70.8)	13568 (44.8)	2333 (20.5)	8154 (71.5)	10487 (46.0)	504 (13.5)	2577 (68.5)	3081 (41.0)	
Grade 2	82 (0.5)	1505 (9.9)	1587 (5.2)	58 (0.5)	1354 (11.9)	1412 (6.2)	24 (0.6)	151 (4.0)	175 (2.3)	
Grade 3	78 (0.5)	529 (3.5)	607 (2.0)	39 (0.3)	452 (4.0)	491 (2.2)	39 (1.0)	77 (2.0)	116 (1.5)	
Grade 4	0	0	0	0	0	0	0	0	0	
Local AR										
Pain	2658 (17.5)	12690 (83.7)	15348 (50.6)	2177 (19.1)	9908 (86.9)	12085 (53.0)	481 (12.8)	2782 (74.0)	3263 (43.5)	
Grade 1	2549 (16.8)	10990 (72.5)	13539 (44.7)	2114 (18.5)	8362 (73.3)	10476 (45.9)	435 (11.6)	2628 (69.9)	3063 (40.8)	
Grade 2	54 (0.4)	1284 (8.5)	1338 (4.4)	40 (0.4)	1180 (10.3)	1220 (5.3)	14 (0.4)	104 (2.8)	118 (1.6)	
Grade 3	55 (0.4)	416 (2.7)	471 (1.6)	23 (0.2)	366 (3.2)	389 (1.7)	32 (0.9)	50 (1.3)	82 (1.1)	
Erythema	67 (0.4)	430 (2.8)	497 (1.6)	47 (0.4)	344 (3.0)	391 (1.7)	20 (0.5)	86 (2.3)	106 (1.4)	
Grade 1	47 (0.3)	287 (1.8)	314 (1.0)	32 (0.3)	212 (1.9)	244 (1.1)	15 (0.4)	55 (1.5)	70 (0.9)	
Grade 2	7 (<0.1)	121 (0.8)	128 (0.4)	4 (<0.1)	98 (0.9)	102 (0.4)	3 (<0.1)	23 (0.6)	26 (0.3)	
Grade 3	13 (<0.1)	42 (0.3)	55 (0.2)	11 (<0.1)	34 (0.3)	45 (0.2)	2 (<0.1)	8 (0.2)	10 (0.1)	
Swelling	52 (0.3)	932 (6.1)	984 (3.2)	34 (0.3)	767 (6.7)	801 (3.5)	18 (0.5)	165 (4.4)	183 (2.4)	
Grade 1	39 (0.3)	605 (4.0)	644 (2.1)	28 (0.2)	500 (4.4)	528 (2.3)	11 (0.3)	105 (2.8)	116 (1.5)	
Grade 2	7 (<0.1)	245 (1.6)	252 (0.8)	3 (<0.1)	205 (1.8)	208 (0.9)	4 (0.1)	40 (1.1)	44 (0.6)	
Grade 3	6 (<0.1)	82 (0.5)	88 (0.3)	3 (<0.1)	62 (0.5)	65 (0.3)	3 (<0.1)	20 (0.5)	23 (0.3)	
Axillary swelling/tenderness*	722 (4.8)	1553 (10.2)	2275 (7.5)	567 (5.0)	1322 (11.6)	1889 (8.3)	155 (4.1)	231 (6.1)	386 (5.1)	
Grade 1	688 (4.4)	1395 (9.2)	2063 (6.8)	534 (4.7)	1181 (10.4)	1715 (7.5)	134 (3.6)	214 (5.7)	348 (4.6)	
Grade 2	27 (0.2)	109 (0.7)	136 (0.4)	20 (0.2)	104 (0.9)	124 (0.5)	7 (0.2)	5 (0.1)	12 (0.2)	
Grade 3	27 (0.2)	49 (0.3)	76 (0.3)	13 (0.1)	37 (0.3)	50 (0.2)	14 (0.4)	12 (0.3)	26 (0.3)	
Any Systemic AR	6399 (42.2)	8320 (54.9)	14719 (48.5)	5065 (44.4)	6503 (57.0)	11568 (50.7)	1334 (35.6)	1817 (48.3)	3151 (42.0)	
Grade 1	4346 (28.7)	5372 (35.4)	9718 (32.0)	3375 (29.6)	4092 (35.9)	7467 (32.7)	971 (25.9)	1280 (34.0)	2251 (30.0)	
Grade 2	1739 (11.5)	2496 (16.5)	4235 (14.0)	1438 (12.6)	2043 (17.9)	3481 (15.3)	301 (8.0)	453 (12.0)	754 (10.0)	
Grade 3	308 (2.0)	447 (2.9)	755 (2.5)	248 (2.2)	363 (3.2)	611 (2.7)	60 (1.6)	84 (2.2)	144 (1.9)	
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)	4 (<0.1)	5 (<0.1)	9 (<0.1)	2 (<0.1)	0	2 (<0.1)	
Systemic AR										
Fever	44 (0.3)	115 (0.8)	159 (0.5)	37 (0.3)	105 (0.9)	142 (0.6)	7 (0.2)	10 (0.3)	17 (0.2)	
Grade 1	29 (0.2)	74 (0.5)	103 (0.3)	26 (0.2)	67 (0.6)	93 (0.4)	3 (<0.1)	7 (0.2)	10 (0.1)	
Grade 2	7 (<0.1)	26 (0.2)	33 (0.1)	6 (<0.1)	24 (0.2)	30 (0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	
Grade 3	2 (<0.1)	11 (<0.1)	13 (<0.1)	1 (<0.1)	10 (<0.1)	11 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	

Grade 4	6 (<0.1)	4 (<0.1)	10 (<0.1)	4 (<0.1)	4 (<0.1)	4 (<0.1)	8 (<0.1)	2 (<0.1)	0	2 (<0.1)
Headache	4027 (26.6)	4951 (32.7)	8978 (29.6)	3304 (29.0)	4030 (35.3)	7334 (32.2)	723 (19.3)	921 (24.5)	1644 (21.9)	
Grade 1	3306 (21.8)	3953 (26.1)	7259 (23.9)	2676 (23.5)	3174 (27.8)	5850 (25.7)	630 (16.8)	779 (20.7)	1409 (18.8)	
Grade 2	525 (3.5)	727 (4.8)	1252 (4.1)	466 (4.1)	637 (5.6)	1103 (4.8)	59 (1.6)	90 (2.4)	149 (2.0)	
Grade 3	196 (1.3)	271 (1.8)	467 (1.5)	162 (1.4)	219 (1.9)	381 (1.7)	34 (0.9)	52 (1.4)	86 (1.1)	
Fatigue	4133 (27.3)	5635 (37.2)	9768 (32.2)	3282 (28.8)	4394 (38.4)	7666 (33.6)	851 (22.7)	1251 (33.3)	2102 (28.0)	
Grade 1	2709 (17.9)	3599 (23.7)	6308 (20.8)	2104 (18.4)	2744 (24.1)	4848 (21.3)	605 (16.2)	855 (22.7)	1460 (19.5)	
Grade 2	1319 (8.7)	1885 (12.4)	3204 (10.6)	1095 (9.6)	1519 (13.3)	2614 (11.5)	224 (6.0)	366 (9.7)	590 (7.9)	
Grade 3	105 (0.7)	150 (1.0)	255 (0.8)	83 (0.7)	120 (1.1)	203 (0.9)	22 (0.6)	30 (0.8)	52 (0.7)	
Grade 4	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	0	0	
Myalgia	2071 (13.7)	3441 (22.7)	5512 (18.2)	1628 (14.3)	2699 (23.7)	4327 (19.0)	443 (11.8)	742 (19.7)	1185 (15.8)	
Grade 1	1567 (10.3)	2445 (16.1)	4012 (13.2)	1205 (10.6)	1876 (16.5)	3081 (13.5)	362 (9.7)	569 (15.1)	931 (12.4)	
Grade 2	457 (3.0)	906 (6.0)	1363 (4.5)	385 (3.4)	750 (6.6)	1135 (5.0)	72 (1.9)	156 (4.1)	228 (3.0)	
Grade 3	47 (0.3)	90 (0.6)	137 (0.5)	38 (0.3)	73 (0.6)	111 (0.5)	9 (0.2)	17 (0.5)	26 (0.3)	
Arthralgia	1783 (11.8)	2511 (16.6)	4294 (14.2)	1327 (11.6)	1893 (16.6)	3220 (14.1)	456 (12.2)	618 (16.4)	1074 (14.3)	
Grade 1	1341 (8.9)	1846 (12.2)	3187 (10.5)	970 (8.5)	1371 (12.0)	2341 (10.3)	371 (9.9)	475 (12.6)	848 (11.3)	
Grade 2	405 (2.7)	604 (4.0)	1009 (3.3)	328 (2.9)	474 (4.2)	802 (3.5)	77 (2.1)	130 (3.5)	207 (2.8)	
Grade 3	37 (0.2)	60 (0.4)	97 (0.3)	29 (0.3)	47 (0.4)	76 (0.3)	8 (0.2)	13 (0.3)	21 (0.3)	
Grade 4	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	0	0	
Nausea/vomiting	1074 (7.1)	1262 (8.3)	2336 (7.7)	908 (8.0)	1068 (9.4)	1976 (8.7)	166 (4.4)	194 (5.2)	360 (4.8)	
Grade 1	890 (5.9)	1048 (6.9)	1938 (6.4)	752 (6.6)	889 (7.8)	1641 (7.2)	138 (3.7)	159 (4.2)	297 (4.0)	
Grade 2	172 (1.1)	204 (1.3)	376 (1.2)	148 (1.3)	173 (1.5)	321 (1.4)	24 (0.6)	31 (0.8)	55 (0.7)	
Grade 3	12 (<0.1)	10 (<0.1)	22 (<0.1)	8 (<0.1)	6 (<0.1)	14 (<0.1)	4 (0.1)	4 (0.1)	8 (0.1)	
Chills	878 (5.8)	1253 (8.3)	2131 (7.0)	730 (6.4)	1051 (9.2)	1781 (7.8)	148 (4.0)	202 (5.4)	350 (4.7)	
Grade 1	706 (4.7)	940 (6.2)	1646 (5.4)	584 (5.1)	781 (6.8)	1365 (6.0)	122 (3.3)	159 (4.2)	281 (3.7)	
Grade 2	158 (1.0)	289 (1.9)	447 (1.5)	138 (1.2)	253 (2.2)	391 (1.7)	20 (0.5)	36 (1.0)	56 (0.7)	
Grade 3	14 (<0.1)	24 (0.2)	38 (0.1)	8 (<0.1)	17 (0.1)	25 (0.1)	6 (0.2)	7 (0.2)	13 (0.2)	

n=Number of exposed participants who submitted any data for the event; percentages are based on the number of exposed participants who submitted any data for the event in the solicited safety set. Any = Grade 1 or higher. Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = >100 mm. Toxicity grade for fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = >40 C. \*Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

**Table S4. Solicited Adverse Reactions Within 7 Days After Second Vaccination by Grade, Solicited Safety Set**

Adverse reaction Vaccination 2 n (%)	Overall Safety Set			≥18-65 years			≥65 years		
	Placebo (N=14566)	mRNA (N=14677)	Total (N=29243)	Placebo (N=10918)	mRNA-1273 (N=10985)	Total (N=21903)	Placebo (N=3648)	mRNA-1273 (N=3692)	Total
Any solicited AR	6232 (42.8)	13534 (92.2)	19766 (67.6)	4902 (44.9)	10231 (93.1)	15133 (69.1)	1330 (36.5)	3303 (89.5)	4633 (63.1)
Grade 1	4354 (29.9)	4855 (33.1)	9209 (31.5)	3997 (31.1)	3294 (30.0)	6691 (30.5)	957 (26.2)	1561 (42.3)	2518 (34.3)
Grade 2	1534 (10.5)	5781 (39.4)	7315 (25.0)	1248 (11.4)	4576 (41.7)	5824 (26.6)	286 (7.8)	1205 (32.6)	1491 (20.3)
Grade 3	341 (2.3)	2884 (19.6)	3225 (11.0)	255 (2.3)	2349 (21.4)	2604 (11.9)	86 (2.4)	535 (14.5)	621 (8.5)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)	2 (<0.1)	12 (0.1)	14 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)
Any Local AR	2735 (18.8)	13006 (88.6)	15741 (53.8)	2244 (20.6)	9915 (90.3)	12159 (55.5)	491 (13.5)	3091 (83.8)	3582 (48.8)
Grade 1	2581 (17.7)	8778 (59.8)	11359 (38.9)	2135 (19.6)	6410 (58.4)	8545 (39.0)	446 (12.2)	2368 (64.2)	2814 (38.4)
Grade 2	82 (0.6)	3208 (21.9)	3290 (11.3)	67 (0.6)	2703 (24.6)	2770 (12.6)	15 (0.4)	505 (13.7)	520 (7.1)
Grade 3	72 (0.5)	1020 (7.0)	1092 (3.7)	42 (0.4)	802 (7.3)	844 (3.9)	30 (0.8)	218 (5.9)	248 (3.4)
Grade 4	0	0	0	0	0	0	0	0	0
Local AR									
Pain	2477 (17.0)	12943 (88.2)	15420 (52.7)	2040 (18.7)	9873 (89.9)	11913 (54.4)	437 (12.0)	3070 (83.2)	3507 (47.8)
Grade 1	2378 (16.3)	9498 (64.7)	11876 (40.6)	1972 (18.1)	6923 (63.0)	8895 (40.6)	406 (11.1)	2575 (69.8)	2981 (40.6)
Grade 2	59 (0.4)	2841 (19.4)	2900 (9.9)	46 (0.4)	2444 (22.3)	2490 (11.4)	13 (0.4)	397 (10.8)	410 (5.6)
Grade 3	40 (0.3)	604 (4.1)	644 (2.2)	22 (0.2)	506 (4.6)	528 (2.4)	18 (0.5)	98 (2.7)	116 (1.6)
Erythema	56 (0.4)	1257 (8.6)	1313 (4.5)	43 (0.4)	982 (8.9)	1025 (4.7)	13 (0.4)	275 (7.5)	288 (3.9)
Grade 1	38 (0.3)	442 (3.0)	480 (1.6)	28 (0.3)	352 (3.2)	380 (1.7)	10 (0.3)	90 (2.4)	100 (1.4)
Grade 2	3 (<0.1)	528 (3.6)	531 (1.8)	3 (<0.1)	420 (3.8)	423 (1.9)	0	108 (2.9)	108 (1.5)
Grade 3	15 (0.1)	287 (2.0)	302 (1.0)	12 (0.1)	210 (1.9)	222 (1.0)	3 (<0.1)	77 (2.1)	80 (1.1)
Swelling	49 (0.3)	1789 (12.2)	1838 (6.3)	36 (0.3)	1389 (12.6)	1425 (6.5)	13 (0.4)	400 (10.8)	413 (5.6)
Grade 1	29 (0.2)	890 (6.1)	919 (3.1)	24 (0.2)	700 (6.4)	724 (3.3)	5 (0.1)	190 (5.2)	195 (2.7)
Grade 2	9 (<0.1)	645 (4.4)	654 (2.2)	8 (<0.1)	507 (4.6)	515 (2.4)	1 (<0.1)	138 (3.7)	139 (1.9)
Grade 3	11 (<0.1)	254 (1.7)	265 (0.9)	4 (<0.1)	182 (1.7)	186 (0.8)	7 (0.2)	72 (2.0)	79 (1.1)
Axillary swelling/tenderness	567 (3.9)	2090 (14.2)	2657 (9.1)	470 (4.3)	1775 (16.2)	2245 (10.3)	97 (2.7)	315 (8.5)	412 (5.6)
Grade 1	521 (3.6)	1737 (11.8)	2258 (7.7)	433 (4.0)	1469 (13.4)	1902 (8.7)	88 (2.4)	268 (7.3)	356 (4.9)
Grade 2	27 (0.2)	286 (1.9)	313 (1.1)	26 (0.2)	260 (2.4)	286 (1.3)	1 (<0.1)	26 (0.7)	27 (0.4)
Grade 3	19 (0.1)	67 (0.5)	86 (0.3)	11 (0.1)	46 (0.4)	57 (0.3)	8 (0.2)	21 (0.6)	29 (0.4)
Any Systemic AR	5323 (36.5)	11652 (79.4)	16975 (58.1)	4192 (38.4)	8999 (81.9)	13191 (60.2)	1131 (31.0)	2653 (71.9)	3784 (51.6)
Grade 1	3526 (24.2)	3723 (25.4)	7249 (24.8)	2734 (25.0)	2618 (23.8)	5352 (24.4)	792 (21.7)	1105 (29.9)	1897 (25.8)
Grade 2	1512 (10.4)	5590 (38.1)	7102 (24.3)	1233 (11.3)	4441 (40.4)	5674 (25.9)	279 (7.6)	1149 (31.1)	1428 (19.5)
Grade 3	282 (1.9)	2325 (15.8)	2607 (8.9)	223 (2.0)	1928 (17.6)	2151 (9.8)	59 (1.6)	397 (10.8)	456 (6.2)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)	2 (<0.1)	12 (0.1)	14 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)
Systemic AR									
Fever	43 (0.3)	2278 (15.5)	2321 (7.9)	39 (0.4)	1908 (17.4)	1947 (8.9)	4 (0.1)	370 (10.0)	374 (5.1)
Grade 1	33 (0.2)	1364 (9.3)	1397 (4.8)	31 (0.3)	1111 (10.1)	1142 (5.2)	2 (<0.1)	253 (6.9)	255 (3.5)
Grade 2	5 (<0.1)	699 (4.8)	704 (2.4)	4 (<0.1)	601 (5.5)	605 (2.8)	1 (<0.1)	98 (2.7)	99 (1.3)
Grade 3	2 (<0.1)	202 (1.4)	204 (0.7)	2 (<0.1)	184 (1.7)	186 (0.8)	0	18 (0.5)	18 (0.2)
Grade 4	3 (<0.1)	13 (<0.1)	16 (<0.1)	2 (<0.1)	12 (0.1)	14 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Headache	3410 (23.4)	8602 (58.6)	12012 (41.1)	2760 (25.3)	6898 (62.8)	9658 (44.1)	650 (17.8)	1704 (46.2)	2354 (32.1)

Grade 1	2739 (18.8)	4804 (32.7)	7543 (25.8)	2180 (20.0)	3658 (33.3)	5838 (26.7)	559 (15.3)	1146 (31.1)	1705 (23.2)
Grade 2	509 (3.5)	3139 (21.4)	3648 (12.5)	451 (4.1)	2687 (24.5)	3138 (14.3)	58 (1.6)	452 (12.3)	510 (7.0)
Grade 3	162 (1.1)	659 (4.5)	821 (2.8)	129 (1.2)	553 (5.0)	682 (3.1)	33 (0.9)	106 (2.9)	139 (1.9)
Fatigue	3403 (23.4)	9582 (65.3)	12985 (44.4)	2687 (24.6)	7430 (67.6)	10117 (46.2)	716 (19.6)	2152 (58.3)	2868 (39.1)
Grade 1	2182 (15.0)	3432 (23.4)	5614 (19.2)	1700 (15.6)	2525 (23.0)	4225 (19.3)	482 (13.2)	907 (24.6)	1389 (18.9)
Grade 2	1115 (7.7)	4722 (32.2)	5837 (20.0)	901 (8.3)	3731 (34.0)	4832 (21.2)	214 (5.9)	991 (26.9)	1205 (16.4)
Grade 3	106 (0.7)	1428 (9.7)	1534 (5.2)	86 (0.8)	1174 (10.7)	1260 (5.8)	20 (0.5)	254 (6.9)	274 (3.7)
Myalgia	1809 (12.4)	8508 (58.0)	10317 (35.3)	1411 (12.9)	6769 (61.6)	8180 (37.4)	398 (10.9)	1739 (47.1)	2137 (29.1)
Grade 1	1300 (8.9)	3239 (22.1)	4539 (15.5)	994 (9.1)	2411 (22.0)	3405 (15.6)	306 (8.4)	828 (22.4)	1134 (15.5)
Grade 2	457 (3.1)	3951 (26.9)	4408 (15.1)	375 (3.4)	3245 (29.5)	3620 (16.5)	82 (2.2)	706 (19.1)	788 (10.7)
Grade 3	52 (0.4)	1318 (9.0)	1370 (4.7)	42 (0.4)	1113 (10.1)	1155 (5.3)	10 (0.3)	205 (5.6)	215 (2.9)
Arthralgia	1569 (10.8)	6284 (42.8)	7853 (26.9)	1172 (10.7)	4993 (45.5)	6165 (28.2)	397 (10.9)	1291 (35.0)	1688 (23.0)
Grade 1	1142 (7.8)	2802 (19.1)	3944 (13.5)	837 (7.7)	2105 (19.2)	2942 (13.4)	305 (8.4)	697 (18.9)	1002 (13.7)
Grade 2	383 (2.6)	2742 (18.5)	3095 (10.6)	298 (2.7)	2241 (20.4)	2539 (11.6)	85 (2.3)	471 (12.8)	556 (7.6)
Grade 3	44 (0.3)	770 (5.2)	814 (2.8)	37 (0.3)	647 (5.9)	684 (3.1)	7 (0.2)	123 (3.3)	130 (1.8)
Nausea/vomiting	934 (6.4)	2785 (19.0)	3719 (12.7)	801 (7.3)	2348 (21.4)	3149 (14.4)	133 (3.6)	437 (11.8)	570 (7.8)
Grade 1	756 (5.2)	2090 (14.2)	2846 (9.7)	646 (5.9)	1752 (16.0)	2398 (11.0)	110 (3.0)	338 (9.2)	448 (6.1)
Grade 2	167 (1.1)	674 (4.6)	841 (2.9)	147 (1.3)	586 (5.3)	733 (3.3)	20 (0.5)	88 (2.4)	108 (1.5)
Grade 3	11 (<0.1)	20 (0.1)	31 (0.1)	8 (<0.1)	10 (<0.1)	18 (<0.1)	3 (<0.1)	10 (0.3)	13 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)	0	0	0	0	1 (<0.1)	1 (<0.1)
Chills	809 (5.6)	6482 (44.2)	7291 (24.9)	658 (6.0)	5341 (48.6)	5999 (27.4)	151 (4.1)	1141 (30.9)	1292 (17.6)
Grade 1	626 (4.3)	2899 (19.8)	3525 (12.1)	502 (4.6)	2307 (21.0)	2809 (12.8)	124 (3.4)	592 (16.0)	716 (9.8)
Grade 2	166 (1.1)	3392 (23.1)	3558 (12.2)	141 (1.3)	2870 (26.1)	3011 (13.8)	25 (0.7)	522 (14.2)	547 (7.5)
Grade 3	17 (0.1)	191 (1.3)	208 (0.7)	15 (0.1)	164 (1.5)	179 (0.8)	2 (<0.1)	27 (0.7)	29 (0.4)

n=Number of exposed participants who submitted any data for the event; percentages are based on the number of exposed participants who submitted any data for the event. Any = Grade 1 or higher. Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C. Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

**Table S5. Number of Days Reporting Solicited Adverse Reactions After First and Second Vaccinations, Solicited Safety Set**

Adverse reaction duration days	Vaccination 1			Vaccination 2		
	Placebo (N=15155)	mRNA-1273 (N=15168)	Total (N=30323)	Placebo (N=14566)	mRNA-1273 (N=14677)	Total (N=29243)
Any solicited (n)	7284	13319	20603	6232	13534	19766
Mean days (SD)	3.2 (4.2)	3.4 (3.3)	3.3 (3.6)	3.4 (5.7)	4.0 (4.8)	3.8 (5.1)
Any local (n)	2997	12765	15762	2735	13006	15741
Mean days (SD)	1.9 (2.6)	2.6 (2.0)	2.5 (2.0)	2.1 (4.1)	3.2 (2.9)	3.0 (3.2)
Pain (n)	2658	12690	15348	2477	12943	15420
Mean, days (SD)	1.7 (2.1)	2.4 (1.4)	2.3 (1.5)	1.8 (3.3)	3.0 (2.2)	2.8 (2.4)
Erythema (n)	67	430	497	56	1257	1313
Mean, days (SD)	3.2 (5.6)	2.5 (4.1)	2.6 (4.4)	3.8 (10.6)	2.7 (3.9)	2.7 (4.4)
Swelling (n)	52	932	984	49	1789	1838
Mean, days (SD)	5.1 (7.8)	2.1 (2.2)	2.2 (2.8)	2.7 (4.9)	2.6 (4.1)	2.6 (4.2)
Axillary swelling/tenderness* (n)	722	1553	2275	567	2090	2657
Mean, days (SD)	2.1 (2.8)	2.3 (2.9)	2.2 (2.9)	2.6 (5.3)	2.4 (3.2)	2.4 (3.7)
Any Systemic AR	6399	8320	14719	5323	11652	16975
Mean, days (SD)	3.1 (4.2)	2.9 (3.7)	3.0 (3.9)	3.4 (5.6)	3.1 (4.6)	3.2 (4.9)
Fever (n)	44	115	159	43	2278	2321
Mean, days (SD)	1.4 (0.6)	1.3 (0.7)	1.3 (0.7)	1.2 (0.5)	1.2 (1.7)	1.2 (1.7)
Headache (n)	4027	4951	8978	3410	8602	12012
Mean, days (SD)	2.1 (2.4)	2.1 (2.2)	2.1 (2.3)	2.3 (3.3)	2.3 (2.9)	2.3 (3.0)
Fatigue (n)	4133	5635	9768	3403	9582	12985
Mean, days (SD)	2.8 (3.7)	2.7 (3.6)	2.7 (3.6)	3.0 (5.1)	2.6 (3.7)	2.7 (4.1)
Myalgia (n)	2071	3441	5512	1809	8508	10317
Mean, days (SD)	2.7 (3.7)	2.3 (3.2)	2.4 (3.4)	3.2 (6.1)	2.1 (3.1)	2.3 (3.8)
Arthralgia (n)	1783	2511	4294	1569	6284	7853
Mean, days (SD)	3.2 (5.0)	2.6 (4.1)	2.9 (4.5)	3.7 (7.0)	2.3 (3.5)	2.5 (4.5)
Nausea/vomiting (n)	1074	1262	2336	934	2785	3719
Mean, days (SD)	1.8 (2.2)	1.7 (1.5)	1.7 (1.9)	1.9 (3.8)	1.7 (2.4)	1.8 (2.8)
Chills (n)	878	1253	2131	809	6482	7291
Mean, days (SD)	1.7 (1.7)	1.5 (1.7)	1.6 (1.7)	1.9 (3.2)	1.5 (1.6)	1.5 (1.8)

n = Number of exposed participants who reported the event on any day within 7 days of the first injection. Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continued beyond 7 days, the consecutive days a solicited adverse reaction was reported after 7 days are included. \*Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Table S6. Solicited Adverse reactions by SARS-CoV-2 Baseline Status by Grade After Vaccination 1, Solicited Safety Set

Vaccination 1 ARs n (%)	Baseline SARS-CoV-2 negative			Baseline SARS-CoV-2 positive			Missing data		
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total
	(N=14583)	(N=14538)	(N=29121)	(N=337)	(N=342)	(N=679)	(N=235)	(N=288)	(N=523)
Any solicited AR	7023 (48.2)	12800 (88.0)	19823 (68.1)	137 (40.7)	261 (76.3)	398 (58.6)	124 (52.8)	258 (89.6)	382 (73.0)
Grade 1	4978 (34.1)	9029 (62.1)	14007 (48.1)	82 (24.3)	136 (39.8)	218 (32.1)	87 (37.0)	177 (61.5)	264 (50.5)
Grade 2	1696 (11.6)	2972 (20.4)	4668 (16.0)	41 (12.2)	96 (28.1)	137 (20.2)	33 (14.0)	56 (19.4)	89 (17.0)
Grade 3	344 (2.4)	795 (5.5)	1139 (3.9)	13 (3.9)	28 (8.2)	41 (6.0)	4 (1.7)	25 (8.7)	29 (5.5)
Grade 4	5 (<0.1)	4 (<0.1)	9 (<0.1)	1 (0.3)	1 (0.3)	2 (0.3)	0	0	0
Any Local AR	2891 (19.8)	12276 (84.5)	15167 (52.1)	60 (17.8)	246 (71.9)	306 (45.1)	46 (19.6)	243 (84.4)	289 (55.3)
Grade 1	2738 (18.8)	10352 (71.2)	13090 (45.0)	56 (16.6)	178 (52.0)	234 (34.5)	43 (18.3)	201 (69.8)	244 (46.7)
Grade 2	80 (0.5)	1423 (9.8)	1503 (5.2)	1 (0.3)	55 (16.1)	56 (8.2)	1 (0.4)	27 (9.4)	28 (5.4)
Grade 3	73 (0.5)	501 (3.4)	574 (2.0)	3 (0.9)	13 (3.8)	16 (2.4)	2 (0.9)	15 (5.2)	17 (3.3)
Grade 4	0	0	0	0	0	0	0	0	0
Local AR									
Pain	2563 (17.6)	12207 (84.0)	14770 (50.7)	56 (16.6)	244 (71.3)	300 (44.2)	39 (16.6)	239 (83.0)	278 (53.2)
Grade 1	2459 (16.9)	10601 (72.9)	13060 (44.9)	54 (16.0)	183 (53.5)	237 (34.9)	36 (15.3)	206 (71.5)	242 (46.3)
Grade 2	52 (0.4)	1211 (8.3)	1263 (4.3)	1 (0.3)	51 (14.9)	52 (7.7)	1 (0.4)	22 (7.6)	23 (4.4)
Grade 3	52 (0.4)	395 (2.7)	447 (1.5)	1 (0.3)	10 (2.9)	11 (1.6)	2 (0.9)	11 (3.8)	13 (2.5)
Erythema	63 (0.4)	409 (2.8)	472 (1.6)	3 (0.9)	9 (2.6)	12 (1.8)	1 (0.4)	12 (4.2)	13 (2.5)
Grade 1	45 (0.3)	254 (1.7)	299 (1.0)	1 (0.3)	5 (1.5)	6 (0.9)	1 (0.4)	8 (2.8)	9 (1.7)
Grade 2	7 (<0.1)	115 (0.8)	122 (0.4)	0	2 (0.6)	2 (0.3)	0	4 (1.4)	4 (0.8)
Grade 3	11 (<0.1)	40 (0.3)	51 (0.2)	2 (0.6)	2 (0.6)	4 (0.6)	0	0	0
Swelling	49 (0.3)	895 (6.2)	944 (3.2)	2 (0.6)	19 (5.6)	21 (3.1)	1 (0.4)	18 (6.3)	19 (3.6)
Grade 1	36 (0.2)	582 (4.0)	618 (2.1)	2 (0.6)	10 (2.9)	12 (1.8)	1 (0.4)	13 (4.5)	14 (2.7)
Grade 2	7 (<0.1)	235 (1.6)	242 (0.8)	0	8 (2.3)	8 (1.2)	0	2 (0.7)	2 (0.4)
Grade 3	6 (<0.1)	78 (0.5)	84 (0.3)	0	1 (0.3)	1 (0.1)	0	3 (1.0)	3 (0.6)
Axillary swelling/tenderness*	689 (4.7)	1465 (10.1)	2154 (7.4)	18 (5.3)	53 (15.5)	71 (10.5)	15 (6.4)	35 (12.2)	50 (9.6)
Grade 1	637 (4.4)	1327 (9.1)	1964 (6.7)	17 (5.0)	38 (11.1)	55 (8.1)	14 (6.0)	30 (10.4)	44 (8.4)
Grade 2	27 (0.2)	94 (0.6)	121 (0.4)	0	11 (3.2)	11 (1.6)	0	4 (1.4)	4 (0.8)
Grade 3	25 (0.2)	44 (0.3)	69 (0.2)	1 (0.3)	4 (1.2)	5 (0.7)	1 (0.4)	1 (0.3)	2 (0.4)
Any Systemic AR	6167 (42.3)	7954 (54.7)	14121 (48.5)	121 (35.9)	210 (61.4)	331 (48.7)	111 (47.2)	156 (54.2)	267 (51.1)
Grade 1	4203 (28.8)	5171 (35.6)	9374 (32.2)	69 (20.5)	107 (31.3)	176 (25.9)	74 (31.5)	94 (32.6)	168 (32.1)
Grade 2	1665 (11.4)	2367 (16.3)	4032 (13.8)	40 (11.9)	80 (23.4)	120 (17.7)	34 (14.5)	49 (17.0)	83 (15.9)
Grade 3	294 (2.0)	412 (2.8)	706 (2.4)	11 (3.3)	22 (6.4)	33 (4.9)	3 (1.3)	13 (4.5)	16 (3.1)
Grade 4	5 (<0.1)	4 (<0.1)	9 (<0.1)	1 (0.3)	1 (0.3)	2 (0.3)	0	0	0
Systemic AR									
Fever	38 (0.3)	79 (0.5)	117 (0.4)	6 (1.8)	32 (9.4)	38 (5.6)	0	4 (1.4)	4 (0.8)
Grade 1	26 (0.2)	51 (0.4)	77 (0.3)	3 (0.9)	20 (5.8)	23 (3.4)	0	3 (1.0)	3 (0.6)
Grade 2	5 (<0.1)	16 (0.1)	21 (<0.1)	2 (0.6)	9 (2.6)	11 (1.6)	0	1 (0.3)	1 (0.2)
Grade 3	2 (<0.1)	9 (<0.1)	11 (<0.1)	0	2 (0.6)	2 (0.3)	0	0	0
Grade 4	5 (<0.1)	3 (<0.1)	8 (<0.1)	1 (0.3)	1 (0.3)	2 (0.3)	0	0	0
Headache	3865 (26.5)	4723 (32.5)	8588 (29.5)	82 (24.3)	131 (38.3)	213 (31.4)	80 (34.0)	97 (33.7)	177 (33.8)
Grade 1	3182 (21.8)	3795 (26.1)	6977 (24.0)	59 (17.5)	88 (25.7)	147 (21.6)	65 (27.7)	70 (24.3)	135 (25.8)
Grade 2	496 (3.4)	679 (4.7)	1175 (4.0)	16 (4.7)	31 (9.1)	47 (6.9)	13 (5.5)	17 (5.9)	30 (5.7)
Grade 3	187 (1.3)	249 (1.7)	436 (1.5)	7 (2.1)	12 (3.5)	19 (2.8)	2 (0.9)	10 (3.5)	12 (2.3)

Fatigue	3988 (27.4)	5400 (37.2)	9388 (32.2)	72 (21.4)	134 (39.2)	206 (30.3)	73 (31.1)	101 (35.1)	174 (33.3)
Grade 1	2618 (18.0)	3468 (23.9)	6086 (20.9)	40 (11.9)	69 (20.2)	109 (16.1)	51 (21.7)	62 (21.5)	113 (21.6)
Grade 2	1271 (8.7)	1793 (12.3)	3064 (10.5)	28 (8.3)	56 (16.4)	84 (12.4)	20 (8.5)	36 (12.5)	56 (10.7)
Grade 3	99 (0.7)	138 (0.9)	237 (0.8)	4 (1.2)	9 (2.6)	13 (1.9)	2 (0.9)	3 (1.0)	5 (1.0)
Grade 4	0	1 (<0.1)	1 (<0.1)	0	0	0	0	0	0
Myalgia	1987 (13.6)	3244 (22.3)	5231 (18.0)	47 (13.9)	124 (36.3)	171 (25.2)	37 (15.7)	73 (25.3)	110 (21.0)
Grade 1	1510 (10.4)	2318 (15.9)	3828 (13.1)	27 (8.0)	70 (20.5)	97 (14.3)	30 (12.8)	57 (19.8)	87 (16.6)
Grade 2	433 (3.0)	845 (5.8)	1278 (4.4)	18 (5.3)	48 (14.0)	66 (9.7)	6 (2.6)	13 (4.5)	19 (3.6)
Grade 3	44 (0.3)	81 (0.6)	125 (0.4)	2 (0.6)	6 (1.8)	8 (1.2)	1 (0.4)	3 (1.0)	4 (0.8)
Athralgia	1707 (11.7)	2381 (16.4)	4088 (14.0)	40 (11.9)	85 (24.9)	125 (18.4)	36 (15.3)	45 (15.6)	81 (15.5)
Grade 1	1294 (8.9)	1761 (12.1)	3055 (10.5)	21 (6.2)	53 (15.5)	74 (10.9)	26 (11.1)	32 (11.1)	58 (11.1)
Grade 2	379 (2.6)	565 (3.9)	944 (3.2)	17 (5.0)	27 (7.9)	44 (6.5)	9 (3.8)	12 (4.2)	21 (4.0)
Grade 3	34 (0.2)	54 (0.4)	88 (0.3)	2 (0.6)	5 (1.5)	7 (1.0)	1 (0.4)	1 (0.3)	2 (0.4)
Grade 4	0	1 (<0.1)	1 (<0.1)	0	0	0	0	0	0
Nausea/vomiting	1033 (7.1)	1193 (8.2)	2226 (7.6)	26 (7.7)	42 (12.3)	68 (10.0)	15 (6.4)	27 (9.4)	42 (8.0)
Grade 1	860 (5.9)	998 (6.9)	1858 (6.4)	18 (5.3)	30 (8.8)	48 (7.1)	12 (5.1)	20 (6.9)	32 (6.1)
Grade 2	161 (1.1)	186 (1.3)	347 (1.2)	8 (2.4)	12 (3.5)	20 (2.9)	3 (1.3)	6 (2.1)	9 (1.7)
Grade 3	12 (<0.1)	9 (<0.1)	21 (<0.1)	0	0	0	0	1 (0.3)	1 (0.2)
Chills	836 (5.7)	1144 (7.9)	1980 (6.8)	27 (8.0)	80 (23.4)	107 (15.8)	15 (6.4)	29 (10.1)	44 (8.4)
Grade 1	675 (4.6)	878 (6.0)	1553 (5.3)	17 (5.0)	43 (12.6)	60 (8.8)	14 (6.0)	19 (6.6)	33 (6.3)
Grade 2	148 (1.0)	246 (1.7)	394 (1.4)	9 (2.7)	34 (9.9)	43 (6.3)	1 (0.4)	9 (3.1)	10 (1.9)
Grade 3	13 (<0.1)	20 (0.1)	33 (0.1)	1 (0.3)	3 (0.9)	4 (0.6)	0	1 (0.3)	1 (0.2)

CI = Confidence intervals. N1 = Number of exposed participants who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed participants who submitted any data for the event. 95% CI is calculated using the Clopper-Pearson method. Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C. \*Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

**Table S7. Solicited Adverse reactions by SARS-CoV-2 Baseline Status by Grade After Vaccination 2, Solicited Safety Set**

Vaccination 2 ARs n (%)	Baseline SARS-CoV-2 negative			Baseline SARS-CoV-2 positive			Missing data	
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273
	(N=14119)	(N=14183)	(N=28302)	(N=232)	(N=230)	(N=462)	(N=215)	(N=264)
Any solicited AR	6056 (42.9)	13101 (92.4)	19157 (67.7)	81 (34.9)	188 (80.9)	267 (57.8)	95 (44.2)	247 (93.6)
Grade 1	4235 (30.0)	4676 (33.0)	8911 (31.5)	51 (22.0)	91 (39.6)	142 (30.7)	68 (31.6)	88 (33.3)
Grade 2	1485 (10.5)	5609 (39.5)	7094 (25.1)	27 (11.6)	66 (28.7)	93 (20.1)	22 (10.2)	106 (40.2)
Grade 3	333 (2.4)	2802 (19.8)	3135 (11.1)	3 (1.3)	29 (12.6)	32 (6.9)	5 (2.3)	53 (20.1)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)	0	0	0	0	0
Any Local AR	2650 (18.8)	12594 (88.8)	15244 (53.9)	42 (18.2)	172 (74.8)	214 (46.4)	43 (20.0)	240 (90.9)
Grade 1	2505 (17.7)	8489 (59.9)	10994 (38.9)	35 (15.2)	125 (54.3)	160 (34.7)	41 (19.1)	164 (62.1)
Grade 2	77 (0.5)	3122 (22.0)	3199 (11.3)	5 (2.2)	35 (15.2)	40 (8.7)	0	51 (19.3)
Grade 3	68 (0.5)	983 (6.9)	1051 (3.7)	2 (0.9)	12 (5.2)	14 (3.0)	2 (0.9)	25 (9.5)
Grade 4	0	0	0	0	0	0	0	0
Local AR								
Pain	2403 (17.0)	12536 (88.4)	14939 (52.8)	36 (15.6)	169 (73.5)	205 (44.5)	38 (17.7)	238 (90.2)
Grade 1	2310 (16.4)	9194 (64.8)	11504 (40.7)	32 (13.9)	125 (54.3)	157 (34.1)	36 (16.7)	179 (67.8)
Grade 2	56 (0.4)	2758 (19.5)	2814 (9.9)	3 (1.3)	36 (15.7)	39 (8.5)	0	47 (17.8)
Grade 3	37 (0.3)	584 (4.1)	621 (2.2)	1 (0.4)	8 (3.5)	9 (2.0)	2 (0.9)	12 (4.5)
Erythema	52 (0.4)	1227 (8.7)	1279 (4.5)	1 (0.4)	8 (3.5)	9 (2.0)	3 (1.4)	22 (8.3)
Grade 1	35 (0.2)	434 (3.1)	469 (1.7)	0	2 (0.9)	2 (0.4)	3 (1.4)	6 (2.3)
Grade 2	3 (<0.1)	521 (3.7)	524 (1.9)	0	3 (1.3)	3 (0.7)	0	4 (1.5)
Grade 3	14 (<0.1)	272 (1.9)	286 (1.0)	1 (0.4)	3 (1.3)	4 (0.9)	0	12 (4.5)
Swelling	47 (0.3)	1746 (12.3)	1793 (6.3)	1 (0.4)	11 (4.8)	12 (2.6)	1 (0.5)	32 (12.1)
Grade 1	28 (0.2)	874 (6.2)	902 (3.2)	0	4 (1.7)	4 (0.9)	1 (0.5)	12 (4.5)
Grade 2	8 (<0.1)	629 (4.4)	637 (2.3)	1 (0.4)	5 (2.2)	6 (1.3)	0	11 (4.2)
Grade 3	11 (<0.1)	243 (1.7)	254 (0.9)	0	2 (0.9)	2 (0.4)	0	9 (3.4)
Axillary swelling/tenderness*	546 (3.9)	2018 (14.2)	2564 (9.1)	11 (4.8)	30 (13.0)	41 (8.9)	10 (4.7)	42 (15.9)
Grade 1	503 (3.6)	1682 (11.9)	2185 (7.7)	8 (3.5)	20 (8.7)	28 (6.1)	10 (4.7)	35 (13.3)
Grade 2	24 (0.2)	271 (1.9)	295 (1.0)	3 (1.3)	8 (3.5)	11 (2.4)	0	7 (2.7)
Grade 3	19 (0.1)	65 (0.5)	84 (0.3)	0	2 (0.9)	2 (0.4)	0	0
Any Systemic AR	5168 (36.6)	11290 (79.6)	16458 (58.2)	71 (30.6)	150 (65.2)	221 (47.8)	84 (39.1)	212 (80.3)
Grade 1	3427 (24.3)	3593 (25.3)	7020 (24.8)	42 (18.1)	61 (26.5)	103 (22.3)	57 (26.5)	69 (26.1)
Grade 2	1462 (10.4)	5414 (38.2)	6876 (24.3)	28 (12.1)	68 (29.6)	96 (20.8)	22 (10.2)	108 (40.9)
Grade 3	276 (2.0)	2269 (16.0)	2545 (9.0)	1 (0.4)	21 (9.1)	22 (4.8)	5 (2.3)	35 (13.3)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)	0	0	0	0	0
Systemic AR								
Fever	42 (0.3)	2223 (15.7)	2265 (8.0)	1 (0.4)	31 (13.5)	32 (6.9)	0	24 (9.1)
Grade 1	32 (0.2)	1326 (9.4)	1358 (4.8)	1 (0.4)	20 (8.7)	21 (4.6)	0	18 (6.8)
Grade 2	5 (<0.1)	685 (4.8)	690 (2.4)	0	9 (3.9)	9 (2.0)	0	5 (1.9)
Grade 3	2 (<0.1)	199 (1.4)	201 (0.7)	0	2 (0.9)	2 (0.4)	0	1 (0.4)
Grade 4	3 (<0.1)	13 (<0.1)	16 (<0.1)	0	0	0	0	0
Headache	3311 (23.5)	8348 (58.9)	11659 (41.2)	43 (18.6)	97 (42.2)	140 (30.4)	56 (26.0)	157 (59.5)
Grade 1	2655 (18.8)	4648 (32.8)	7303 (25.8)	36 (15.6)	60 (26.1)	96 (20.8)	48 (22.3)	96 (36.4)
Grade 2	497 (3.5)	3058 (21.6)	3555 (12.6)	7 (3.0)	31 (13.5)	38 (8.2)	5 (2.3)	50 (18.9)
Grade 3	159 (1.1)	642 (4.5)	801 (2.8)	0	6 (2.6)	6 (1.3)	3 (1.4)	11 (4.2)



Fatigue	3294 (23.3)	9310 (65.7)	12604 (44.5)	53 (22.9)	104 (45.2)	157 (34.1)	56 (26.0)	168 (63.6)	224 (46.8)
Grade 1	2115 (15.0)	3332 (23.5)	5447 (19.3)	30 (13.0)	42 (18.3)	72 (15.6)	37 (17.2)	58 (22.0)	95 (19.8)
Grade 2	1077 (7.6)	4583 (32.3)	5660 (20.0)	22 (9.5)	50 (21.7)	72 (15.6)	16 (7.4)	89 (33.7)	105 (21.9)
Grade 3	102 (0.7)	1395 (9.8)	1497 (5.3)	1 (0.4)	12 (5.2)	13 (2.8)	3 (1.4)	21 (8.0)	24 (5.0)
Grade 4	0	0	0	0	0	0	0	0	0
Myalgia	1738 (12.3)	8229 (58.0)	9967 (35.2)	32 (13.9)	115 (50.0)	147 (31.9)	39 (18.1)	164 (62.1)	203 (42.4)
Grade 1	1252 (8.9)	3117 (22.0)	4369 (15.4)	20 (8.7)	59 (25.7)	79 (17.1)	28 (13.0)	63 (23.9)	91 (19.0)
Grade 2	436 (3.1)	3828 (27.0)	4264 (15.1)	12 (5.2)	45 (19.6)	57 (12.4)	9 (4.2)	78 (29.5)	87 (18.2)
Grade 3	50 (0.4)	1284 (9.1)	1334 (4.7)	0	11 (4.8)	11 (2.4)	2 (0.9)	23 (8.7)	25 (5.2)
Arthralgia	1516 (10.7)	6083 (42.9)	7599 (26.9)	24 (10.4)	76 (33.0)	100 (21.7)	29 (13.5)	125 (47.3)	154 (32.2)
Grade 1	1102 (7.8)	2717 (19.2)	3819 (13.5)	17 (7.4)	37 (16.1)	54 (11.7)	23 (10.7)	48 (18.2)	71 (14.8)
Grade 2	371 (2.6)	2613 (18.4)	2984 (10.5)	7 (3.0)	35 (15.2)	42 (9.1)	5 (2.3)	64 (24.2)	69 (14.4)
Grade 3	43 (0.3)	753 (5.3)	796 (2.8)	0	4 (1.7)	4 (0.9)	1 (0.5)	13 (4.9)	14 (2.9)
Grade 4	0	0	0	0	0	0	0	0	0
Nausea/vomiting	912 (6.5)	2700 (19.0)	3612 (12.8)	13 (5.6)	34 (14.8)	47 (10.2)	9 (4.2)	51 (19.3)	60 (12.5)
Grade 1	740 (5.2)	2022 (14.3)	2762 (9.8)	10 (4.3)	26 (11.3)	36 (7.8)	6 (2.8)	42 (15.9)	48 (10.0)
Grade 2	161 (1.1)	658 (4.6)	819 (2.9)	3 (1.3)	7 (3.0)	10 (2.2)	3 (1.4)	9 (3.4)	12 (2.5)
Grade 3	11 (<0.1)	19 (0.1)	(0.1)	0	1 (0.4)	1 (0.2)	0	0	0
Grade 4	0	1 (<0.1)	1 (<0.1)	0	0	0	0	0	0
Chills	778 (5.5)	6292 (44.4)	7070 (25.0)	17 (7.4)	78 (33.9)	95 (20.6)	14 (6.5)	112 (42.4)	126 (26.3)
Grade 1	604 (4.3)	2807 (19.8)	3411 (12.1)	14 (6.1)	39 (17.0)	53 (11.5)	8 (3.7)	53 (20.1)	61 (12.7)
Grade 2	157 (1.1)	3296 (23.2)	3453 (12.2)	3 (1.3)	39 (17.0)	42 (9.1)	6 (2.8)	57 (21.6)	63 (13.2)
Grade 3	17 (0.1)	189 (1.3)	206 (0.7)	0	0	0	0	2 (0.8)	2 (0.4)

CI = Confidence intervals. N1 = Number of exposed participants who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed participants who submitted any data for the event. 95% CI is calculated using the Clopper-Pearson method. Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = >40 C. \*Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

**Table S8. Unsolicited Adverse Events 28 Days after Any Injection, Overall Safety Set**

Unsolicited Adverse Event n (%)	Overall Safety Set				≥18-<65 years		≥65 years		
	Placebo N=15166	mRNA-1273 N=15185	Total N=30351	Placebo (N=11416)	mRNA-1273 (N=11415)	Total (N=22831)	Placebo N=3750	mRNA-1273 N=3770	Total N=7520
Regardless of relationship to study vaccination									
All	3277 (21.6)	3632 (23.9)	6909 (22.8)	2463 (21.6)	2674 (23.4)	5137 (22.5)	814 (21.7)	958 (25.4)	1772 (23.6)
Serious	89 (0.6)	93 (0.6)	182 (0.6)	46 (0.4)	54 (0.5)	100 (0.4)	43 (1.1)	39 (1.0)	82 (1.1)
Fatal	3 (<0.1)	2 (<0.1)	5 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)
Medically-attended Leading to discontinuation from study	1465 (9.7)	1372 (9.0)	2837 (9.3)	1051 (9.2)	991 (8.7)	2042 (8.9)	414 (11.0)	381 (10.1)	795 (10.6)
vaccine*	80 (0.5)	50 (0.3)	130 (0.4)	62 (0.5)	37 (0.3)	99 (0.4)	18 (0.5)	13 (0.3)	31 (0.4)
Leading to discontinuation from study†	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	202 (1.3)	234 (1.5)	436 (1.4)	132 (1.2)	156 (1.4)	288 (1.3)	70 (1.9)	78 (2.1)	148 (2.0)
Related to study vaccination									
All	686 (4.5)	1242 (8.2)	1928 (6.4)	526 (4.6)	938 (8.2)	1464 (6.4)	160 (4.3)	304 (8.1)	464 (6.2)
Serious	4 (<0.1)	6 (<0.1)	10 (<0.1)	3 (<0.1)	4 (<0.1)	7 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)
Fatal	0	0	0	0	0	0	0	0	0
Medically-attended Leading to discontinuation from study	83 (0.5)	140 (0.9)	223 (0.7)	68 (0.6)	110 (1.0)	178 (0.8)	15 (0.4)	30 (0.8)	45 (0.6)
vaccine*	15 (<0.1)	18 (0.1)	33 (0.1)	10 (<0.1)	14 (0.1)	24 (0.1)	5 (0.1)	4 (0.1)	9 (0.1)
Leading to discontinuation from study†	0	0	0	0	0	0	0	0	0
Severe	28 (0.2)	71 (0.5)	99 (0.3)	19 (0.2)	49 (0.4)	68 (0.3)	9 (0.2)	22 (0.6)	31 (0.4)

An adverse event is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on overall safety set. \*AEs leading to study discontinuation 28 days after first dose. †AEs leading to discontinuation from study after either dose.

**Tables S9-11. Unsolicited Adverse Events, Overall Safety Set**

**Table S9. Summary of Unsolicited AE Reported by  $\geq 1\%$  of Participants in Any Treatment Group up to 28 Days After Any Injection**

<b>System Organ Class Preferred Term n (%)</b>	<b>Placebo (N=15166)</b>	<b>mRNA-1273 (N=15185)</b>
Number of participants reporting unsolicited AEs	3277 (21.6)	3632 (23.9)
Number of unsolicited AEs	6085	6798
Nervous system disorders	622 (4.1)	684 (4.5)
Headache	458 (3.0)	466 (3.1)
Respiratory, thoracic and mediastinal disorders	583 (3.8)	536 (3.5)
Cough	156 (1.0)	164 (1.1)
Oropharyngeal pain	203 (1.3)	147 (1.0)
Gastrointestinal disorders	440 (2.9)	478 (3.1)
Diarrhea	162 (1.1)	189 (1.2)
Musculoskeletal and connective tissue disorders	617 (4.1)	671 (4.4)
Arthralgia	167 (1.1)	207 (1.4)
Myalgia	181 (1.2)	200 (1.3)
General disorders and administration site conditions	622 (4.1)	1006 (6.6)
Fatigue	336 (2.2)	372 (2.4)
Injection site pain	54 (0.4)	151 (1.0)
<small>AE = adverse event. An AE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of participants in the safety set. All AEs were coded using MedDRA Version 23.0.</small>		

**Table S10. Unsolicited Severe AEs Reported by  $\geq 5$  Participants in Any Treatment Group up to 28 Days After Any Injection, Overall Safety Set**

<b>System Organ Class Preferred Term n (%)</b>	<b>Placebo (N=15166)</b>	<b>mRNA-1273 (N=15185)</b>
Number of participants reporting unsolicited severe AEs	202 (1.3)	234 (1.5)
Nervous system disorders		
Headache	21 (0.1)	30 (0.2)
Cardiac disorders	12 (<0.1)	20 (0.1)
Bradycardia	13 (<0.1)	13 (<0.1)
Atrial Fibrillation	5 (<0.1)	4 (<0.1)
3 (<0.1)	3 (<0.1)	4 (<0.1)
Vascular disorders	43 (0.3)	30 (0.2)
Hypertension	32 (0.2)	23 (0.2)
Musculoskeletal and connective tissue disorders	24 (0.2)	23 (0.2)
Myalgia	2 (<0.1)	10 (<0.1)
Arthralgia	2 (<0.1)	8 (<0.1)
Back pain	7 (<0.1)	1 (<0.1)
General disorders and administration site conditions	13 (<0.1)	49 (0.3)
Fatigue	6 (<0.1)	12 (<0.1)
Injection site erythema	0	11 (<0.1)
Injection site pain	1 (<0.1)	3 (<0.1)
Investigations	13 (<0.1)	23 (0.2)
Blood pressure increased	6 (<0.1)	11 (<0.1)
Blood pressure systolic increased	7 (<0.1)	7 (<0.1)

An AE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages were based on the number of safety set participants. All AEs were coded using MedDRA Version 23.0.

**Table S11. Serious AEs Reported by Preferred Term in Any Treatment Group, Overall Safety Set**

<b>System Organ Class Preferred Term n (%)</b>	<b>Placebo (N=15166)</b>	<b>mRNA-1273 N=15185</b>
Number of participants reporting serious AEs	153 (1.0)	147 (1.0)
Number of serious AEs	211	207
Atrial fibrillation	5 (<0.1)	5 (<0.1)
Myocardial infarction	3 (<0.1)	5 (<0.1)
Pneumonia	7 (<0.1)	5 (<0.1)
Pulmonary embolism	5 (<0.1)	4 (<0.1)
Abdominal pain upper	0	3 (<0.1)
Cardiac failure congestive	3 (<0.1)	3 (<0.1)
Cerebrovascular accident	1 (<0.1)	3 (<0.1)
Cholecystitis	0	3 (<0.1)
Dehydration	3 (<0.1)	3 (<0.1)
Dyspnoea	0	3 (<0.1)
Nausea	1 (<0.1)	3 (<0.1)
Nephrolithiasis	0	3 (<0.1)
Prostate cancer	3 (<0.1)	3 (<0.1)
Acute respiratory failure	2 (<0.1)	2 (<0.1)
Acute coronary syndrome	0	2 (<0.1)
Acute myocardial infarction	4 (<0.1)	2 (<0.1)
Appendicitis	3 (<0.1)	2 (<0.1)
Arthritis	1 (<0.1)	2 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)
Chest pain	1 (<0.1)	2 (<0.1)
Colitis	1 (<0.1)	2 (<0.1)
Coronary artery disease	2 (<0.1)	2 (<0.1)
Deep vein thrombosis	0	2 (<0.1)
Diarrhoea	1 (<0.1)	2 (<0.1)
Embolic stroke	0	2 (<0.1)
Fall	3 (<0.1)	2 (<0.1)
Hiatus hernia	1 (<0.1)	2 (<0.1)
Hypertension	1 (<0.1)	2 (<0.1)
Respiratory Failure	1 (<0.1)	2 (<0.1)
Road traffic accident	1 (<0.1)	2 (<0.1)
Seizure	0	2 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)
Subdural hematoma	0	2 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)
Syncope	4 (<0.1)	2 (<0.1)
Acute kidney injury	3 (<0.1)	1 (<0.1)
Covid-19	15 (<0.1)	1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)
Thyroidectomy	0	1 (<0.1)
Abdominal pain	2 (<0.1)	0
Anaemia	2 (<0.1)	0
Ankle fracture	3 (<0.1)	0
Chronic obstructive pulmonary disease	4 (<0.1)	0
Confusional state	2 (<0.1)	0
Depression	3 (<0.1)	0
Diverticulitis	2 (<0.1)	0
Hypertensive emergency	2 (<0.1)	0
Intervertebral disc protrusion	1 (<0.1)	0
Intraductal proliferative breast lesion	2 (<0.1)	0
Major depression	2 (<0.1)	0
Urinary tract infection	4 (<0.1)	0

AE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of participants in the safety set. All AEs were coded using MedDRA Version 23.0.

**Table S12. Unsolicited Adverse Events of Hypersensitivity, Overall Safety Set**

Preferred term n (%)	Placebo	mRNA-1273
	(N=15166)	(N=15185)
Participants reporting hypersensitivity	166 (1.1)	233 (1.5)
Allergic sinusitis	1 (<0.1)	2 (<0.1)
Anaphylactic reaction	1 (<0.1)	1 (<0.1)
Angioedema	3 (<0.1)	1 (<0.1)
Bronchospasm	0	1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)
Dermatitis	8 (<0.1)	8 (<0.1)
Dermatitis allergic	3 (<0.1)	2 (<0.1)
Dermatitis atopic	7 (<0.1)	4 (<0.1)
Dermatitis bullous	2 (<0.1)	0
Dermatitis contact	29 (0.2)	21 (0.1)
Drug hypersensitivity	4 (<0.1)	4 (<0.1)
Eczema	4 (<0.1)	3 (<0.1)
Exfoliative rash	0	1 (<0.1)
Eye swelling	2 (<0.1)	2 (<0.1)
Hand dermatitis	0	2 (<0.1)
Hypersensitivity	4 (<0.1)	5 (<0.1)
Idiopathic urticaria	1 (<0.1)	0
Injection related reaction	1 (<0.1)	1 (<0.1)
Injection site rash	1 (<0.1)	37 (0.2)
Injection site urticaria	0	15 (<0.1)
Laryngeal oedema	1 (<0.1)	0
Lip swelling	2 (<0.1)	2 (<0.1)
Palatal oedema	1 (<0.1)	0
Periorbital oedema	1 (<0.1)	0
Periorbital swelling	2 (<0.1)	0
Rash	34 (0.2)	45 (0.3)
Rash erythematous	2 (<0.1)	6 (<0.1)
Rash follicular	1 (<0.1)	0
Rash macular	4 (<0.1)	6 (<0.1)
Rash maculo-papular	2 (<0.1)	11 (<0.1)
Rash pruritic	4 (<0.1)	6 (<0.1)
Rash vesicular	0	3 (<0.1)
Rhinitis allergic	13 (<0.1)	10 (<0.1)
Serum sickness	1 (<0.1)	0
Swelling face	2 (<0.1)	4 (<0.1)
Swelling of eyelid	1 (<0.1)	2 (<0.1)
Swollen tongue	0	2 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)
Urticaria	23 (0.2)	27 (0.2)
Urticaria papular	5 (<0.1)	3 (<0.1)
Vaccination site rash	0	1 (<0.1)

Percentages are based on the number of participants in the safety set. Preferred term by MedDRA version 23.0. Hypersensitivity was identified through selected SMQ.

**Table S13. Covid-19 Symptoms and Severity, Per-protocol Set**

Covid-19 Symptom n (%)	All Covid-19 cases		Severe Covid-19 cases	
	Placebo (N=185)	mRNA-1273 (N=11)*	Placebo (N=30)	mRNA-1273 (N=0)
Number of participants with any symptom	185 (100)	11 (100)	30 (100)	0
Respiratory symptom				
Clinical evidence of pneumonia	4 (2.2)	0	4 (13.3)	0
Cough	155 (83.8)	6 (54.5)	28 (93.3)	0
Difficulty breathing	55 (29.7)	1 (9.1)	16 (53.3)	0
Radiographical evidence of pneumonia	3 (1.6)	0	3 (10.0)	0
Shortness of breath	78 (42.2)	2 (18.2)	23 (76.7)	0
Systemic symptom				
Body aches	111 (60.0)	7 (63.6)	26 (86.7)	0
Chills	95 (51.4)	4 (36.4)	19 (63.3)	0
Diarrhea	70 (37.8)	2 (18.2)	14 (46.7)	0
Fatigue	156 (84.3)	9 (81.8)	27 (90.0)	0
Fever†	54 (29.2)	2 (18.2)	13 (43.3)	0
Headache	145 (78.4)	10 (90.9)	25 (83.3)	0
Muscle aches (myalgia)	114 (61.6)	5 (45.5)	24 (80.0)	0
Nasal congestion	138 (74.6)	8 (72.7)	21 (70.0)	0
Nausea	65 (35.1)	3 (27.3)	13 (43.3)	0
New loss of smell	115 (62.2)	3 (27.3)	16 (53.3)	0
New loss of taste	106 (57.3)	3 (27.3)	15 (50.0)	0
Runny nose (rhinorrhea)	121 (65.4)	6 (54.5)	18 (60.0)	0
Sore throat	85 (45.9)	7 (63.6)	15 (50.0)	0
Vomiting	18 (9.7)	1 (9.1)	7 (23.3)	0
Number of participants with any severe symptom	32 (17.3)	0	30 (100)	0
Acute renal dysfunction	2 (1.1)	0	2 (6.7)	0
Acute Respiratory Distress Syndrome	1 (0.5)	0	1 (3.3)	0
ECMO	0	0	0	0
High-flow oxygen	1 (0.5)	0	1 (3.3)	0
Mechanical ventilation	0	0	0	0
Non-Invasive ventilation	1 (0.5)	0	1 (3.3)	0
Admission to an intensive care unit due to SARS-CoV-2	1 (0.5)	0	1 (3.3)	0
Heart Rate ≥125 beats per minute	0	0	0	0
Hepatic dysfunction	0	0	0	0
Neurologic dysfunction	1 (0.5)	0	1 (3.3)	0
Oxygen saturation ≤93‡	28 (15.1)	0	27 (90.0)	0
Oxygen saturation SpO2 ≤93% on room air at sea level	29 (15.7)	0	28 (93.3)	0
PaO2/FIO2 ratio <300 mmHg	0	0	0	0
Respiratory failure	1 (0.5)	0	1 (3.3)	0
Respiratory rate ≥30 per minute	0	0	0	0
Systolic blood pressure <90 mmHg, diastolic blood Pressure <60 mmHg	5 (2.7)	0	4 (13.3)	0
Vasopressors required	0	0	0	0

Note symptoms are shown for participants with all cases of 196 Covid-19 and those 30 that were considered severe cases. All symptoms reported are included, regardless of relationship with the positive RT-PCR test used to define the case of Covid-19 in PP set. Participants can be counted in more than one category. \*There were 7 Covid-19 cases reported before 14 days post-dose 2. †Derived based on temperature collected on case report form (CRF) symptoms. ‡Derived based on oxygen saturation collected on CRF symptom log page.



**Table S14. Characteristics of Participants with Severe Covid-19 Cases, Per-protocol Set**

Characteristics n (%)	Covid-19 cases Placebo N=30
Sex	
Female	17 (57)
Male	13 (43)
Age, years	
Mean (range)	54.4 (23-80)
≥65 years	10 (33)
Race/Ethnicity	
White, not Hispanic or Latino	24 (80)
White, Hispanic or Latino	2 (7)
Black/African American, Not Hispanic or Latino	1 (3)
Not reported/other, Hispanic or Latino	2 (7)
Multiple, Not Hispanic or Latino	1 (3)
Hospitalized	9 (30)
ICU	2 (7)
Co-morbid conditions (chronic lung, severe obesity, cardiac, diabetes, hypertension and/or asthma)	20 (67)
Clinical signs indicative of severe system illness	
Oxygen saturation ≤93%*	28 (93)
Respiratory failure or Acute Respiratory Distress Syndrome	6 (20)
Significant acute renal or neurologic dysfunction	2 (7)
*Derived based on oxygen saturation collected on CRF symptom log page. Covid-19 cases in the PP set. Data from December 3 <sup>rd</sup> , 2020.	

**Table S15. Serious and Severe Treatment-related AEs Up to 28 days after Any Injection, Overall Safety Set**

System organ class, preferred term n (%)	Placebo N=15166	mRNA-1273 N=15185	Total (N=30351)
<b>Serious AEs</b>			
Incidence of unsolicited AEs	4 (<0.1)	6 (<0.1)	10 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Paraesthesia	1 (<0.1)	0	1 (<0.1)
Dyspnoea	0	1 (<0.1)	1 (<0.1)
Pulmonary embolism	1 (<0.1)	0	1 (<0.1)
Nausea	0	1 (<0.1)	1 (<0.1)
Vomiting	0	1 (<0.1)	1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)	3 (<0.1)
Edema peripheral	0	1 (<0.1)	1 (<0.1)
Feeling hot	1 (<0.1)	0	1 (<0.1)
Immunization anxiety-related reaction	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
<b>Severe AEs</b>			
Incidence of unsolicited severe AEs	28 (0.2)	71 (0.5)	99 (0.3)
Lymphadenopathy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Headache	8 (<0.1)	9 (<0.1)	17 (<0.1)
Dizziness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
Syncope	0	1 (<0.1)	1 (<0.1)
Migraine	1 (<0.1)	0	1 (<0.1)
Vertigo	0	0	1 (<0.1)
Hypertension	9 (<0.1)	4 (<0.1)	13 (<0.1)
Nausea	0	1 (<0.1)	1 (<0.1)
Dermatitis	0	1 (<0.1)	1 (<0.1)
Rash	0	1 (<0.1)	1 (<0.1)
Rash macular	0	1 (<0.1)	1 (<0.1)
Myalgia	0	6 (<0.1)	6 (<0.1)
Arthralgia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Muscle spasms	0	2 (<0.1)	2 (<0.1)
Neck pain	0	1 (<0.1)	1 (<0.1)
Pain in extremity	0	1 (<0.1)	1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)	1 (<0.1)
Back pain	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Injection site erythema	0	11 (<0.1)	11 (<0.1)
Fatigue	2 (<0.1)	9 (<0.1)	11 (<0.1)
Injection site swelling	0	4 (<0.1)	4 (<0.1)
Injection site macule	0	3 (<0.1)	3 (<0.1)
Chills	0	2 (<0.1)	2 (<0.1)
Injection site lymphadenopathy	0	2 (<0.1)	2 (<0.1)
Injection site pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Adverse drug reaction	0	1 (<0.1)	1 (<0.1)
Chest discomfort	0	1 (<0.1)	1 (<0.1)
Injection site induration	0	1 (<0.1)	1 (<0.1)
Injection site rash	0	1 (<0.1)	1 (<0.1)
Malaise	0	1 (<0.1)	1 (<0.1)
Pyrexia	0	1 (<0.1)	1 (<0.1)
Swelling face	0	1 (<0.1)	1 (<0.1)
Asthenia	1 (<0.1)	0	1 (<0.1)
Blood pressure increased	2 (<0.1)	5 (<0.1)	7 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)	1 (<0.1)

Adverse event (AE) was defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of participants in the safety set. All AEs were coded using MedDRA Version 23.0.

**Table S16. Efficacy of Key Secondary Endpoints, Per-protocol Set**

Secondary endpoint	Placebo (N=14073)	mRNA-1273 (N=14134)
Severe Covid-19 starting 14 days after second injection, adjudicated		
n, events, PP	30	0
VE based on Hazard Ratio (95% CI)*		1.00 (NE-1.00)
Covid-19 after the first dose†		
n, events, PP	225	11
VE based on Hazard Ratio (95% CI)		0.952 (0.912-0.974)
Secondary definition of Covid-19 starting 14 days after second injection‡		
n, events, PP	221	11
VE based on Hazard Ratio (95% CI)		0.951 (0.911-0.973)
Covid-19 after the second injection regardless of prior SARS-CoV-2 infection, adjudicated		
n/N events§ FAS	187/15170	12/15181
VE based on Hazard Ratio (95% CI)		0.936 (0.886-0.965)
PP=per-protocol set; FAS=full analysis set. *Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs placebo), and 95% CI estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor. †Inclusive of second doses. ‡Secondary case definition of Covid-19 was defined as including systemic symptoms: fever (temperature ≥ 38°C) or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches or body aches, headache, new loss of taste or smell, sore throat, nasal congestion or rhinorrhea, nausea or vomiting or diarrhea AND a positive NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) for SARS-CoV-2 by RT-PCR. §n and N are based on the number of participants in the FAS.		

**Table S17. Vaccine Efficacy by SARS-COV-2 Status, Modified Intent-to-Treat**

<b>Baseline SARS-CoV-2 Status n (%)</b>	<b>Placebo</b>	<b>mRNA-1273</b>
<b>Negative</b>	<b>N=14598</b>	<b>N=14550</b>
Number with Covid-19	185 (1.3)	12 (<0.1)
Number censored	14413 (98.7)	14538 (>99.9)
VE Based on HR (95% CI)		0.936 (0.885-0.964)
Person-Years	3382.9	3390.1
Incidence rate per 1,000 Person-Years (95% CI)	54.7 (47.1- 63.2)	3.6 (1.8-6.2)
VE based on incidence rate (95% CI)		0.935 (0.884-0.967)
<b>Positive</b>	<b>N=337</b>	<b>N=343</b>
Number with Covid-19	1 (0.3)	0
Number Censored	336 (99.7)	343 (100)
VE Based on HR (95% CI)		1.000 (NE-1.000)
Person-Years	71.9	71.4
Incidence rate per 1,000 Person-Years (95% CI)*	13.9 (0.4-77.5)	0.0 (NE-51.7)
VE based on incidence rate (95% CI)		1.000 (-38.3-NE)

HR=hazard ratio. VE=vaccine efficacy. VE was defined as 1 - hazard ratio (mRNA-1273 vs. placebo); 95% CI were estimated using a stratified Cox proportional hazard model with Efron's method of tie handling with the treatment group as a covariate, adjusting for stratification factor if applicable in mITT set. Person-years was defined as the total years from randomization date to the date of Covid-19, last date of study participation, or efficacy data cutoff date, whichever was earlier. \*Incidence rate was defined as the number of participants with an event divided by the number of participants at risk, adjusted by person-years (total time at risk) in each treatment group; the 95% CI was calculated using the exact method (Poisson distribution) adjusted by person-years and VE was defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). Baseline SARS-CoV-2 Status was considered positive based on immunologic or virologic evidence of prior Covid-19, defined as positive RT-PCR test or bAb result at day 1; negative was defined as negative RT-PCR test and bAb results at day 1. Covid-19 cases were diagnosed by symptoms and RT-PCR.

**Table S18. Preliminary Analysis of Infection from Randomization, Modified Intent-to-Treat**

	<b>Placebo N=14598</b>	<b>mRNA-1273 N=14550</b>	<b>Vaccine efficacy (95% CI)</b>
Symptomatic Covid-19	293	20	
Covid -19	269	19	
Secondary definition of Covid -19	24	1	
Positive RT-PCR at scheduled pre-dose 2*	39	15	
Total infection (symptomatic or RT-PCR+ at pre-dose 2)	332	35	89.6% (85.2%-92.6%) <sup>†</sup>
Person-years‡	3365.6	3386.6	
Incidence rate (95% CI) <sup>§</sup>	98.6 (88.3-109.8)	10.3 (7.2-14.4)	89.5% (85.1%-92.8%)

Preliminary analysis of infection from randomization performed based on the modified intent-to-treat set (data cut-off November 25, 2020). Infection was defined as symptomatic Covid-19, either Covid-19 (positive RT-PCR with two eligible systemic or one eligible respiratory symptom), or secondary/CDC definition of Covid-19 requiring one symptom, or, asymptomatic infection, as measured by positive RT-PCR at the scheduled pre-Dose 2 visit.). \*Positive RT-PCR at the scheduled pre-Dose 2 visit and no Covid-19 symptoms. <sup>†</sup>From stratified Cox proportional model adjusting for the stratification factor. <sup>‡</sup>Person-years defined as the total years from randomization date to the date of Covid-19, last date of study participation, or efficacy data cutoff date, whichever was earlier. <sup>§</sup>Incidence rate was defined as the number of participants with an event divided by the number at risk adjusted by person-years (total time at risk) in each treatment group and 95% CI calculated using the exact method (Poisson distribution) conditional on total number of events adjusted by person-years.