

## Supplementary Appendix

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

Supplement to: Vesikari T, Matson DO, Dennehy P, et al. Safety and efficacy of a pentavalent human-bovine (WC3) reassortant rotavirus vaccine. *N Engl J Med* 2006;354:23-33.

## SUPPLEMENTARY APPENDIX

### Part I. Study Sites and Boards.

#### A. Clinical Study Sites (listed in alphabetical order by country and by principal investigator).

##### Belgium

P. Aerssens, Kinderartsenpraktijk, Hasselt, Belgium; N. Balduck, Zaventem, Belgium; H. Buydens, Ninove, Belgium; L. Callewaert, Sint-Niklaas, Belgium; M. Claeys, Sint Vincentius Hospital, Antwerp, Belgium; A. De Cocker, Asse, Belgium; B. Delmotte, Heilig Hart Ziekenhuis, Roeselare, Belgium; E. DeLoof, Heilig Hart Ziekenhuis, Leuven, Belgium; E. Devos, Heilig Hart Ziekenhuis, Consultation Pediatrics, Roeselare, Belgium; D. Dhondt, Gent, Belgium; J. Franckx, Mollem – Asse, Belgium; D. Haentjens, O.L.V. Middelaars, Deume, Belgium; J-L Hennecker, Clinique Notre Dame de Grâce, Gosselies, Belgium; R-A Lemahieu, Tervuren, Belgium; K. Logghe, Heilig Hart Ziekenhuis, Consultation Pediatrics, Roeselare, Belgium; J.M.Ariel de Selys Longchamps, Cabinet de Pédiatrie, Bruxelles, Belgium; M. Michel, Clinique Saint-Pierre, Ottignies, Belgium; S. Peeters, ASZ – Afdeling Pédiatrie, Aalst, Belgium; F. Roelens, Heilig Hart Ziekenhuis, Consultation Pediatrics, Roeselare, Belgium; E. Rummens, A.S.Z. – Afdeling Pédiatrie, Aalst, Belgium; C. Saintes, Cabinet de Pédiatrie, Bruxelles, Belgium; B. Schoenmakers, Katholieke Universiteit Leuven, Leuven, Belgium; E. Sokal, Cliniques Universitaires Saint-Luc, Brussels, Belgium; S. Traen, Maldegem, Belgium; J. Vanclaire, Cabinet de Pédiatrie, Kraainem, Belgium; E. Vandenbussche, Kinderarts, Heist-Op-Den-Berg, Belgium; C. Vandermeulen, Katholieke Universiteit Leuven, Leuven, Belgium; B. Vanheule, Heilig Hart Ziekenhuis, Roeselare, Belgium; M. Verboven, Brussels, Belgium; T. Vercruysse, Gent, Belgium; C. Verelst, Hasselt, Belgium; A. Vertruyen, Schoten, Belgium; A. Wilikens, Pediater – Kinderarts, Meise, Belgium; Marie Van der Wielen, University of Antwerp, Antwerp, Belgium

##### Costa Rica

J.U. Bogantes, Clinica de Especialidades, Medicas Santa Teresita, San José, Costa Rica; L.M.A. Cruz, Clínica Santa Catalina, San José, Costa Rica; J.E.M-M Diaz, Clinica San Agustin, San Jose, Costa Rica; M.C. Hernandez, Centro Médico la Guaria, San José, Costa Rica; J.V. Saenz-Castro – Centro de Especialidades Medicas, Heredia, Costa Rica; J.P.A. Sancho, San Jose, Costa Rica; R.A.G. Varela, Clinica San Agustin, San Jose, Costa Rica; E.E. Vargas, Hospital Cristiano Jerusalem, San Jose, Costa Rica; J.C. Vargas, Clinica San Agustin, San José, Costa Rica

##### Finland

Timo Vesikari, Principal Investigator; Aino Karvonen, Physician Coordinator, University of Tampere, Vaccine Research Center with the following clinical trial sites: T.S.M Korhonen, Tampere Clinic, Tampere, Finland; N. Lindblad, M.H. Grönroos, J.P. Maunu, Turku Clinic, Turku, Finland; ; P.E. Riikonen, Pori Clinic, Pori, Finland; T. Karppa, J. Majuri, Lahti Clinic, Lahti, Finland; H. Siljander, C.J. Anttila-Bondestam, M.E. Koskikallio, M.T. Lumia, Helsinki West Clinic, Helsinki East Clinic and Helsinki South Clinic, Helsinki, Finland; H. Siljander, M. Espo, S. Sairanen, E.A. Pere, Vantaa East Clinic and Vantaa West Clinic, Vantaa, Finland; H. Siljander, M. Aaltonen, Espoo Clinic, Espoo, Finland; S.M. Parry, Jyväskylä Clinic, Jyväskylä, Finland, A. Kotaniemi-Syrjänen, Kuopio Clinic, Kuopio, Finland; H.A-M Laurent, Lappeenranta Clinic, Lappeenranta, Finland; S. Ylitalo, Oulu Clinic, Oulu, Finland; O. Nyblom, Vaasa Clinic, Vaasa, Finland; J. H. Khan, H. M. Khary, P. Laitinen, Järvenpää Clinic, Järvenpää, Finland; L-K. Kujala, Nurmijärvi Clinic, Klaukkala, Finland; V. Vähäsarja, Seinäjoki Clinic, Seinäjoki, Finland; K.J. A. Lönnberg, Porvoo Clinic, Porvoo, Finland; M. Espo, Kotka Clinic, Kotka, Finland; M. Cederberg, Rauma Clinic, Rauma, Finland; C. Häggqvist, Kokkola Clinic, Kokkola, Finland; A. Benyamin, Kouvola Clinic, Kouvola, Finland

##### Germany

H. Althen, Beckum, Germany; R. Bahr, Eckernförde, Germany; C. Bakowski, Herrsching, Germany; C.W. Baukhage, Munich, Germany; B. Becker (principal investigator), T. Beck, Bochum, Germany; T. Becker, Alsfeld, Germany; U. Behre, Kehl, Germany; V. Bekelaer, Zwiesel, Germany; J. Berger, Linz, Germany; B. Bittmann, Tutzing, Germany; M. Bölich, Jena, Germany; J. Bonanati, Aalen, Germany; G. Börzsonyi, Freising, Germany; H. Boss, Minden, Germany; S-H Braun, Viernsen, Germany; H. Brück,

Korschenbroich, Germany; F. Bundscherer, Geretstried, Germany; M. Burk, Crailsheim, Germany; A. Busse, Tegernsee, Germany; H-J Büttner, Gau-Odernheim, Germany; S. Caspers-Hazay, Hamburg, Germany; R. Clementsen, Neumünster, Germany; E. Danners, Steinfurt, Germany; J. Dawoud, Ingolstadt, Germany; R. Dierschke, Oppenheim, Germany; E. Dietmair, Bobingen, Germany; D. Distel, Neustadt/Aisch, Germany; D. Drexler, Wolfenbüttel, Germany; F-P Drobnitzky, Gütersloh, Germany; D. Faul, Stuttgart, Germany; T. Fendel, Munich, Germany; C. Fiedler, Eisenberg, Germany; R. Freund, Berlin, Germany; T. Fröhlich, Bammental, Germany; R. Gall, Bernau, Germany; U. Goering, Pegnitz, Germany; D. Grunert, Nördlingen, Germany; P. Habermehl, Universitätskinderklinik, Mainz, Germany; T. Hangen, Landshut, Germany; K. Helm, Detmold, Germany; E. Herm, Bad Oeynhausen, Germany; I. Hiller, Furth, Germany; M.R. Holtorf, Brunsbüttel, Germany; J. Hornivius, Mönchengladbach, Germany; H. Hornstein, Oberhausen, Germany; W. Hultzsch, Munich, Germany; H. Husgen, Willich, Germany; U. Jakob, Mainz, Germany; U. Janssen, Hochberg, Germany; P-J Kaas, Wesseling, Germany; J. Kandzora, Neumünster, Germany; R. Kemmerich, Weinstadt, Germany; S. Kiran, Heilbronn, Germany; B. Klaassen, Oppenheim, Germany; G. Knapp, Schwieberdigen, Germany; N. Kniess, Ingolstadt, Germany; R. Köllges, Mönchengladbach, Germany; K-H Krause, Goch, Germany; W.H. Kustermann, Veitshöchheim, Germany; D. Lasius, Berlin, Germany; O.F. Laub, Rosenheim, Germany; N. Lüttringhaus, Oberhausen, Germany; U. Macholdt, Neuhaus am Rennweg, Germany; S. Mahdi, Lubeck, Germany; A. Maurer, Frankenthal, Germany; N. Meister, Bayreuth, Germany; H-J Merkel, Ludwigshafen, Germany; W. Mollmann, Wuerzburg, Germany; K. Müller, Bamberg, Germany; S. Noll, Porta Westfalica, Germany; H. Pabel, Herford, Germany; H. Pankow-Culot, Heiligenhaus, Germany; C. Pauli (principal investigator), H. Preidel, Olching, Germany; A. Paulus-Koschik, Erkrath, Germany; U. Pflutschinger, Stuttgart, Germany; A. Pizzulli, Koeln, Germany; W. Pösentrup, Beckum, Germany; V. Reschke, Kaugbeuren, Germany; H-H Rohé, Hille, Germany; F. Ruland, Ahrweiler, Germany; H. Sauter, Echterdingen, Germany; G. Schacker, Bielefeld, Germany; M. Schaefer, Mainz, Germany; H. Scheele, Niedernhausen, Germany; F. Scheffer, Bochum, Germany; H. Schirmer, Marktredwitz, Germany; R. Schleupner, Würzbur, Germany; S. Schloesser, Kirchlegern, Germany; A. Schmetzer, Aalen, Germany; E. Schmitz-Hauss, Willich, Germany; H. Schöpfer, Espelkamp, Germany; D. Schweingel, Bayreuth, Germany; H-C Sengespeik, Munich, Germany; C. Sievers, Worms, Germany; S. Simmet, Schweigen-Rechtenbach, Germany; U. Sträubler, Berlin, Germany; K-J Taube, Berlin, Germany; P. Tcherepnine, Roding, Germany; I. Tichmann-Schumann, München, Germany; A. Timnik, Neusäss, Germany; K. Vogel, Bodenheim, Germany; G. Voigt, Melle, Germany; M. Vomstein, Schwäbisch Hall, Germany; P.F. von Feldegg, Münster, Germany; K.T. Weber, Berlin, Germany; J. Weidinger (principal investigator), W. Wolf, Nabburg, Germany; K-W Weigel, Karlstadt, Germany; O. Weise (principal investigator), E. Clapier, Landsberg am Lech, Germany; M. Wendeborn, Munich, Germany; T. Wenzel, Ulm, Germany; C. Wittermann, Weilheim, Germany; C. Wolff, Hagen, Germany; H. Wolschner, Minden, Germany; M. Zinke, Hamburg, Germany; W. Zöllner, Wittmund, Germany

#### Guatemala

L.A.R. Palomo, Edificio Multimédica, Roosevelt Hospital, Guatemala City, Guatemala; J.R.U. Pivaral, Centro Clínica, Dr. Raphael E. Monteil H., Guatemala City, Guatemala

#### Italy

G. Bona, Instituto di Clinica Pediatrica, NOVARA, Italy; M. Vitali, Unitá Operativa di Pediatria, Ospedale di Borgomanero, Borgomanero – NOVARA, Italy

#### Jamaica

C.D.C. Christie, University of West Indies - Mona Campus, Jamaica, West Indies

#### Mexico

M.G. Brito, Hospital Para el Niño Poblano, Puebla, Mexico; D.B.G. De Regil, Medica Sur Cif-Biotec, Toriello Guerra, Tlalpan, Mexico; R.S.R. Suarez, Hospital Infantil de Mexico Federico Gomez, Delagación Cuauhtémoc, Mexico

#### Puerto Rico

E.A. Barranco-Santana (principal investigator), I. Rivera, CAIMED (Centro Ambulatorio de Investigaciones Medicas), Ponce School of Medicine, Ponce, Puerto Rico; Z.M. Rodriguez, University of Puerto Rico, San Juan, Puerto Rico

### Sweden

M. Blennow, Barn-och ungdomskliniken, Stockholm, Sweden; C-E Flodmark, Barn-och ungdomsenheten, Universitetssjukhuset MAS, Malmö, Sweden; L. Gothefors, Umeå University Hospital, UMEA, Sweden; L. Nilsson, Barn-och ungdomskliniken, Universitetssjukhuset, Linköping, Sweden

### Taiwan

M-H Chang, National Taiwan University Hospital, Taipei, Taiwan; H-C Lee, Mackay Memorial Hospital, Taipei, Taiwan; T-Y Lin, Chang Gung Children's Hospital, Taoyuan, Taiwan

### United States

W. Abuhammour, Hurley Medical Center, Flint, MI; R. Aguilar, Saltzer Medical Group, Nampa, ID; S.J. Alter, The Children's Medical Center, Wright State University School of Medicine, Dayton, OH; A. Amer, Children's Hospital of Michigan, Detroit, MI; M.M. Aouthmany, St. Vincent Mercy Medical Center, Toledo, OH; J.E. Aton (principal investigator), T. Kalkiewicz, Essex-Morris Pediatric Group, Livingston, NJ; P.H. Azimi, Children's Hospital & Research Centers in Oakland, Oakland, CA; R.T. Bain, Suncoast Clinical Research, New Port Richey, FL; R.E. Begue, Children's Hospital, New Orleans, LA; H.H. Bernstein, Children's Hospital Primary Care Center, Boston, MA; H.R. Bertrand, Lowcountry Medical Associates, Charleston, SC; J.P. Bien, Arnett Clinic, West Lafayette, IN; M.J. Bishop, Bishop, Bryant and Dickerson Pediatrics, Memorial Hermann Health Center, Sugar Land, TX; S.B. Black, Kaiser Permanente Vaccine Study Center, Oakland, CA; E.L. Blackman, Plaza Pediatrics, New Brunswick, NJ; S.L. Block, Kentucky Pediatric/Adult Research, Bardstown, KY; D.A. Blumberg, University of California Davis, Sacramento, CA; J.L. Blumer, University Hospitals of Cleveland, Cleveland, OH; J.A. Bocchini, Louisiana State University Health Sciences Center-Shreveport, Shreveport, LA; D.K. Brannan, Traveler's Health Clinic, Oklahoma City, OK; T.R. Breneman, North Raleigh Pediatric Group, Raleigh, NC; K.H. Brownogehl, Drexel Hill Pediatric Associates, Drexel Hill, PA; J.A. Calgano, Calgano Pediatrics, Gresham, OR; L.C. Cantor, Salinas, CA; D.W. Cardona, Family Care Providers Medical Group, Fresno, CA; C. Chang, Treehouse Children's Clinic, Crescent City, CA; A. Chatterjee (principal investigator), S.A. Chartrand, Creighton University, Omaha, NE; S. Chuipek, Swarthmore Pediatrics, Swarthmore, PA; R.E. Coifman, Allergy and Asthma of South Jersey, Millville, NJ; B.L. Congeni, Children's Hospital Medical Center of Akron, Akron, OH; R.M. Conti, Clinical Research Center of Nevada, Las Vegas, NV; K.E. Coopersmith, Bear Care Pediatrics, Ogden, UT; M.N. Cox, Families First Pediatrics, South Jordan, UT; D.E. Danhauer (principal investigator), J. Houston, Pedia Research, LLC, Owensboro, KY; J.B. Davis, Oxford Pediatrics & Adolescents, Inc., Oxford, OH; P.H. Dennehy, Rhode Island Hospital, Providence, RI; L.S. Deutsch, Red Lion Pediatrics, Philadelphia, PA; J.J. Diaz, Houston, TX; A.M. Douglass-Bright (principal investigator), S.E. Courtney, Cooper Health System, Cooper Hospital, Camden, NJ; R. Dracker, North Area Pediatrics, North Syracuse, NY; K.K. Feinstein, Children's Primary Care Medical Center, El Cajon, CA; S.C. Fiedorek, Clinical Study Centers, LLC, Little Rock, AR; R.J. Field, North County Pediatrics, Paso Robles, CA; A.L. Frank, University of Illinois Medical Center, UIC Pediatrics, Chicago, IL; E.R. Franklin, Capitol Pediatrics and Adolescent Center, Raleigh, NC; L.D. Frenkel, University of Illinois College of Medicine at Rockford, Rockford, IL; L.E. Garrison (principal investigator), D. Malkovich, Promed Physicians-Pediatrics, Portage, MI; J. Geary-Brinton, Utah Valley Pediatrics, Orem, UT; B.S. Gendleman, Edgewood Center Pediatrics, P.C., Commerce, MI; R.S. Gerstle, Baystate Medical Center Children's Hospital, Springfield, MA; R.J. Gluckman, Cobb Pediatrics, Austell, GA; M.C. Goessler, Bellevue Pediatric Associates, Pittsburgh, PA; E. Goldblatt, Clinical Research Consultants, Inc., Hoover, AL; G.R. Greene, Arrowhead Regional Medical Center, Department of Pediatrics, Colton, CA; S.E. Grogg, Oklahoma State University, Center for Health Sciences, OSU Physicians, Houston Parke Clinic, Tulsa, OK; F.C. Hampel, Central Texas Health Research, New Braunfels, TX; P.H. Hastings, Palmetto Pediatrics, Charleston, SC; R.L. Hines, Southwestern Medical Clinic, Stevensville, MI; B.J. Hoggarth, Altru Health System Clinic, Grand Forks, ND; S.R. Horner, Allergy, Asthma & Immunology Services, LLC, Jefferson City, MO; M.L. Hudak, University of Florida, Health Science Center – Jacksonville, Jacksonville, FL; D.C. Hurley, Cottonwood Pediatrics, Murray, UT; M.P. Husseman, Wee Care Pediatrics, Layton, UT; K. Iqbal, Pediatrics Associates of Youngstown, Youngstown, OH; A.D. Johnson, Arkansas Pediatric Research Group, Little Rock, AR; D.S. Johnson, Alpine Pediatrics, Pleasant Grove, UT; W.H. Johnston, Clinical Research Consultants, Inc., Hoover, AL; R.C. Jones, Pediatric Care, Provo, UT; J.O. Kaltman, Lake Forest Pediatric Associates, Lake Forest, IL;

S.J. Kamdar, Texas Research Partners, Katy, Texas; Y.A. Kaweblum, Boca Raton, FL; J.J. Kelly, Maricopa Medical Center, Phoenix, AZ; C.K. Klauber, Discovery Alliance, Inc., Charleston, SC; W. Koo, Hutzel Hospital, Detroit, MI; A. Kovacs (principal investigator), N. Khoury, LAC University of Southern California Medical Center, Los Angeles, CA; J. Kratzer, Kratzer/Graves Pediatrics, Fresno, CA; I. Kunos, Georgetown University Hospital, Washington, DC; T.H. Lam, Alpine Medical Group, Salt Lake City, UT; T.G. Latiolais, ARK-LA-TEX Children's Clinic, Bossier City, LA; M.H. Lauret, Utah Valley Pediatrics, Provo, UT; K.H. Lee, Lakewood Regional Medical Center, Lakewood, CA; P.S. Lei, Cooperview Medical Center, South Jordan, UT; M.L. Levin, Henderson Pediatrics, Henderson, NV; F. Lombana, Houston Medical and Dental Center, Houston, TX; S.R. Luber, Rockwood Clinic, Spokane, WA; M.L. Macknin, Cleveland Clinic Foundation, Cleveland, OH; R.L. Makabali, Clinica Los Remedios, Los Angeles, CA; E.A. Malacaman, Canton Pediatrics, Inc., North Canton, OH; R.E. Mallard, Heritage Medical Associates, Nashville, TN; C.D. Marchant, Boston University Medical Center – University Hospital, Boston, MA; E.P. Marcus, Pediatric Health Care at Newton-Wellesley, Newton, MA; G.S. Marshall, University of Louisville, Louisville, KY; D.O. Matson, Center for Pediatric Research, Norfolk, VA; S.O. Medford, Amarillo Children's Clinic, Amarillo, TX; I.R. Melamed, 1st Allergy & Clinical Research Center, Centennial, CO; L.D. Meloy, Virginia Commonwealth University Medical Center, Richmond, VA; M.R. Mintz, Diagnostic Pediatric Associates, Houston, TX; A. Mireles, Progressive Pediatrics, PA, Longwood, FL; S. Misra, University of Illinois College of Medicine, Peoria, IL; P.F. Mubarak, University of Missouri, Columbia Hospitals and Clinics, Columbia, MO; J.R. Murph, University of Iowa Hospitals and Clinics, Iowa City, IA; L.K. Nassri, Sparks Regional Medical Center, Fort Smith, AR; M.D. Nathan (principal investigator), W.G. Bithoney, Paterson, NJ; A.A. Naz, Madera Family Medical Group, Madera, CA; D. Newton, East Carolina University, Greenville, NC; C. Norlin, University of Utah Health Sciences Center, Salt Lake City, UT; R. O'Hern, Pediatrics in Brevard, Rockledge, FL; S.A. Olmos, Pediatric Associates, Houston, TX; J.A. Patel, University of Texas Medical Branch at Galveston, Galveston, TX; T.S. Payton, Northwest Arkansas Pediatric Clinic, Fayetteville, AR; B. Pollara, University of South Florida College of Medicine, Tampa, FL; J.R. Pringle, Kernodle Clinic, Burlington, NC; M.U. Purswani, Bronx-Lebanon Hospital Center, Bronx, NY; P.Y. Qaundah, Pediatric Care Medical Group, Huntington Beach, CA; K.P. Ramsey, Pediatrics and Adolescent Medicine, South Jordan, UT; P.H. Ratner, Sylvana Research Associates, San Antonio, TX; K.S. Reisinger, Primary Physicians Research, Inc., Pittsburgh, PA; D.R. Reynolds, Lexington Pediatric Practice, PA, Lexington, SC; T.D. Rice (principal investigator), E.L. Anderson, St. Louis University Health Sciences Center, Saint Louis, MO; D.G. Roberts (principal investigator), M.S. Richard, Metro Health Medical Center, Cleveland, OH; R. Rosenberg, Northlake Pediatric Associates, P.C., Stone Mountain, GA; H.M. Rosenthal, Ashford Pediatric Associates, Houston, TX; M.B. Samson, Associated Pharmaceutical Research Center, Inc., Buena Park, CA; V.H. San Joaquin, Oklahoma State University, Center for Health Sciences, Oklahoma City, OK; V. Sanchez-Bal, Center for Clinical Trials, LLC, Paramount, CA; M. Santosham (principal investigator), K.L. O'Brien, R. Reid, J.P. Watt, Johns Hopkins University, Bloomberg School of Public Health, Center for American Indian Health, Baltimore, MD; T.J. Schechtman, Pediatric Research Center of South Florida, Jupiter, FL; T.J. Selva, University of Missouri-Columbia Hospital and Clinics/Department of Child Health, Columbia, MO; M.V. Severson, Brainerd Medical Center, P.A., Brainerd, MN; M. Shaffer-Wells, Discovery Alliance, Inc., Mobile, AL; R.A. Sheikh, Fresno, CA; J.S. Shepard, Ohio Pediatrics, Inc., Huber Heights, OH; L.D. Sher, Peninsula Research Associates, Rolling Hills Estates, CA; P.A. Shurin, Montefiore Medical Center, Bronx, NY; W.D. Sinclair, Montana Medical Research, LLC, Missoula, MT; E.J. Slosberg, Promed Pediatrics, Richland, MI; J.J. Spitzer, ProMed Physicians – Pediatrics, Kalamazoo, MI; R.D. Stacks, Roslindale Pediatric Assoc., Boston, MA; J.E. Stahlman, The Allergy & Asthma Clinical Research Center, Lawrenceville, GA; L.M. Stern, Valencia Pediatric Associates, Plaza Posada Medical Center, Newhall, CA; J.J. Storlazzi, ADHD Behavioral & Learning Disability Center, Wilmington, DE; M. Taghadosi, Houston, TX; K.G. Thusu, Lexington Biomedical Research Institute, Inc., AHA Family Health Clinic, Dinuba, CA; J.D. Twiggs, Dixie Pediatrics, Saint George, UT; B.R. Uy, Roy Medical Group, Canoga Park, CA; T.I. Villalobos, Affinity Health Group, Tifton, GA; H.L. Villar, Valley View Family Medical Clinic, Panorama City, CA; J.V. Volk, Hendersonville Pediatrics, Hendersonville, NC; E.B. Walter, Duke Children's Primary Care, Durham, NC; H.J. Wander, Sutter North Medical Group, Yuba City, CA; W.K. Warren, Center for Clinical Trials of San Gabriel, West Covina, CA; R.C. Welliver, Children's Hospital of Buffalo, Buffalo, NY; L.N. Werk, Outpatient Pediatric Center, Orlando, FL; M.L. Wexler, Texas Research Partners, Katy, TX; J.F. Whalley, Mountain View Pediatrics, Morganton, NC; R. Wieting, Missouri City, TX; J.R.

Wynn, Utah Valley Pediatrics, Orem, UT; A.O. Yap, Yap Medical Clinic, Los Angeles, CA; R.J. Yetman, University of Texas-Houston Medical Center, Houston, TX; C.W. Yut, The Woodlands, TX; N.R. Zosa, Clinical Health Research Institute for the Sciences, Pico Rivera, CA.

#### **B. Data and Safety Monitoring Board**

The members of the Data and Safety Monitoring Board were as follows: K. Holmes (Chairman), Professor of Medicine, Director, Center for AIDS and STDs, University of Washington, Seattle, WA; E. Ledbetter, National Network on Immunization Information, Technical Reviewer, Adjunct Professor of Pediatrics, University of Texas Medical Branch, San Antonio, TX; M. Levin (Consultant), Professor of Pediatrics and Medicine, University of Colorado, Denver, Colorado; G. Peter, Professor of Pediatrics, Brown University, Providence, RI; D.P. Torres, Professor of Pediatrics, Universidad de Costa Rica, San José, Costa Rica; M. Uhari, Professor of Pediatrics, University of Oulu, Oulu, Finland; J. Wittes, Biostatistician, Statistics Collaborative, Inc., Washington, DC; D. Yost, Medical Director of Indian Health Services, Clinical Director's Office, Whiteriver Indian Health Service Hospital, Whiteriver, AZ.

#### **C. Safety Endpoint Adjudication Committee**

The members of the Safety Endpoint Adjudication Committee were as follows: J. Steinberg (Chairman), Children's Medical Center, Dallas, TX; G. Bates, Children's Hospital, Columbus, OH; D. Doody, Harvard Medical School, Boston, MA.

**Part II. Clinical Scoring System<sup>(22,34)</sup> for Acute Rotavirus Gastroenteritis.**

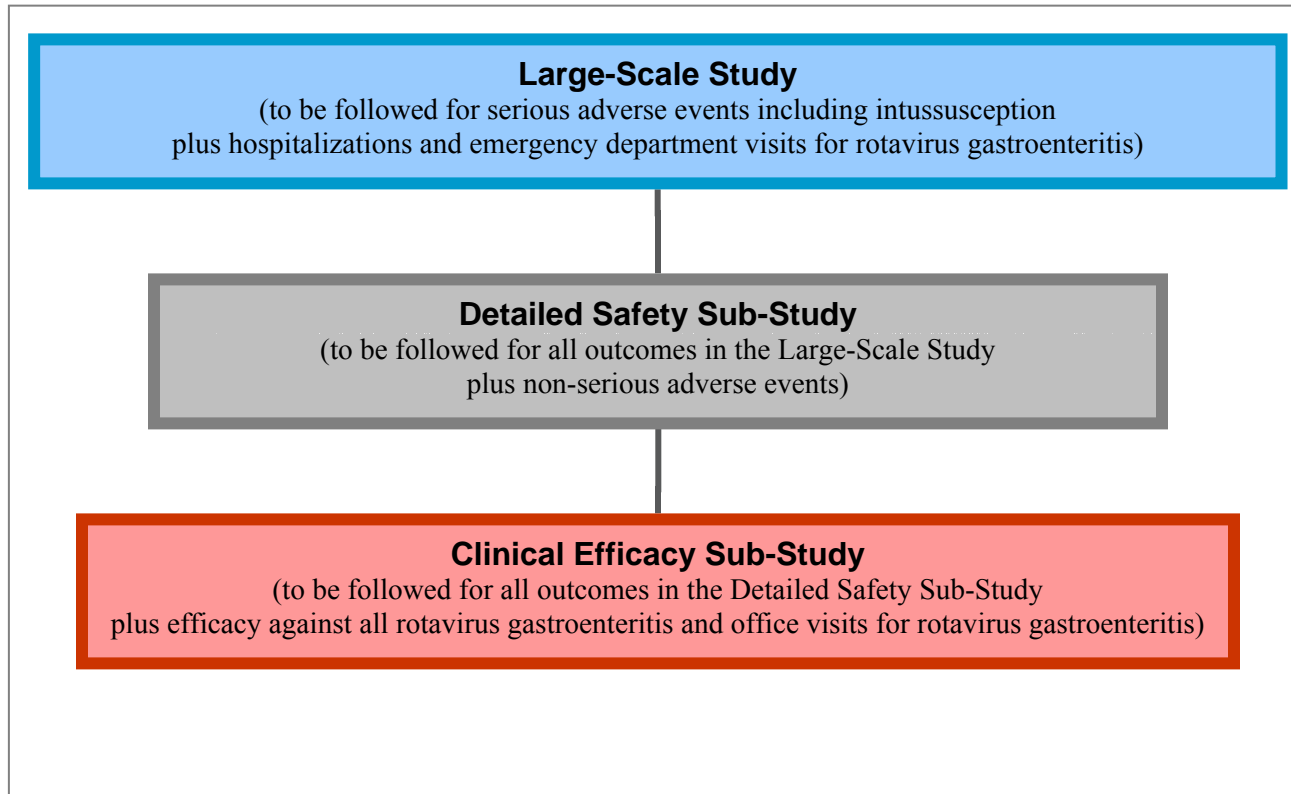
<b>Point value</b> <sup>*</sup>	<b>1</b>	<b>2</b>	<b>3</b>
<b>Diarrhea</b> Number of stools/day <sup>†</sup> Duration in days <sup>‡</sup>	2 to 4 1 to 4	5 to 7 5 to 7	≥8 ≥8
<b>Vomiting</b> Number of emeses/day <sup>§</sup> Duration in days <sup>‡</sup>	1 to 3 2	4 to 6 3 to 5	≥7 ≥6
<b>Rectal Temperature</b> Degrees in Celsius <sup>  </sup> Duration in days <sup>‡</sup>	38.1 to 38.2 1 to 2	38.3 to 38.7 3 to 4	≥38.8 ≥5
<b>Behavioral Symptoms/Signs</b> Description <sup>¶</sup> Duration in days <sup>‡</sup>	Irritable/Less Playful 1 to 2	Lethargic/Listless 3 to 4	Seizure ≥5
<p><sup>*</sup> Final score represented the sum of the individual components. Scores &gt;8 were considered moderate-and-severe and scores &gt;16 were considered severe disease.</p> <p><sup>†</sup> Maximum number of watery or looser-than-normal stools/day on any given day over the course of the episode.</p> <p><sup>‡</sup> Number of days in which the subject had relevant symptom(s) or sign(s). Total days did not need to be consecutive.</p> <p><sup>§</sup> Maximum number of emeses on any given day over the course of the episode.</p> <p><sup>  </sup> Highest rectal temperature recorded during the episode (only counted when the equivalent of a rectal temperature exceeded 38°C). Reported temperatures were converted to rectal equivalents by adding 1°F to otic and oral temperatures and 2°F to axillary temperatures.</p> <p><sup>¶</sup> When a subject had ≥2 behavioral symptoms/signs, only the highest score was counted.</p>			

### **Part III. Figure Legend**

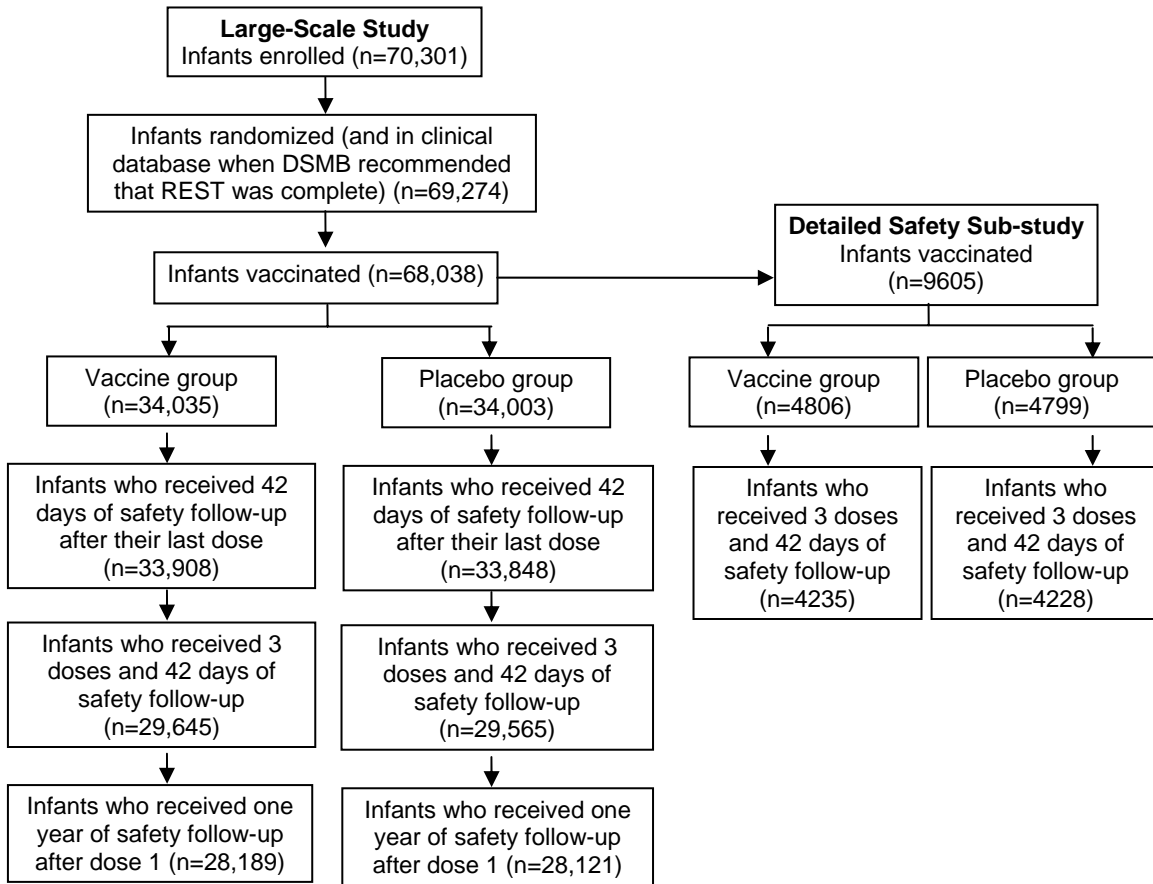
**Figure 1. REST organization and subject accounting.**

- Panel A. Relationship of the prospectively identified sub-studies to the large-scale study.
- Panel B. Subject accounting in the large-scale study and detailed safety sub-study.
- Panel C. Subject accounting in the large-scale study followed for efficacy against hospitalizations and emergency department visits due to rotavirus gastroenteritis.
- Panel D. Subject accounting in the clinical efficacy sub-study.

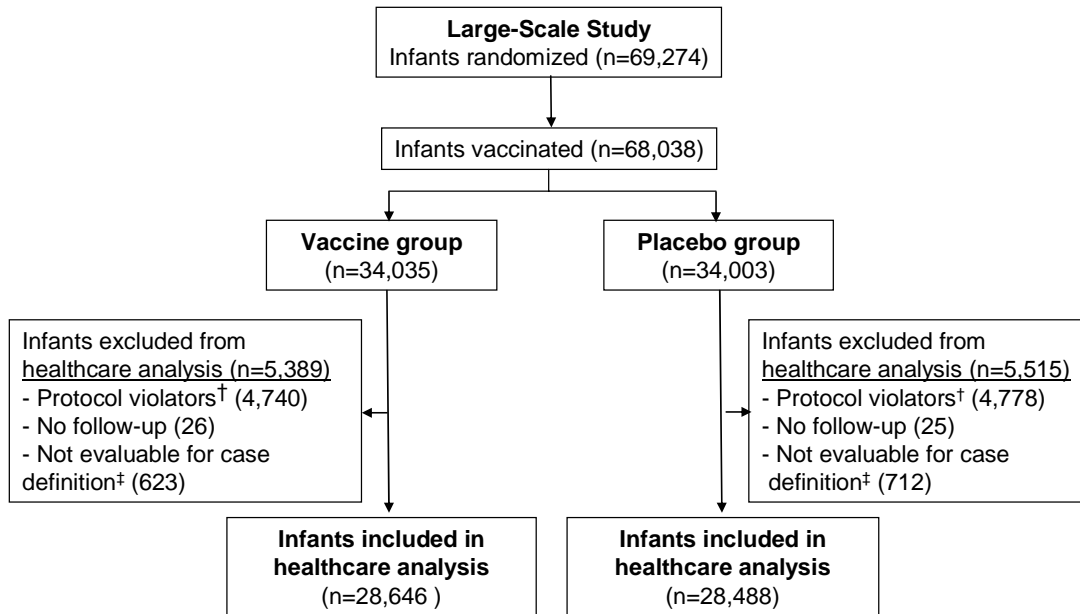
Figure 1A.



**Figure 1B.**



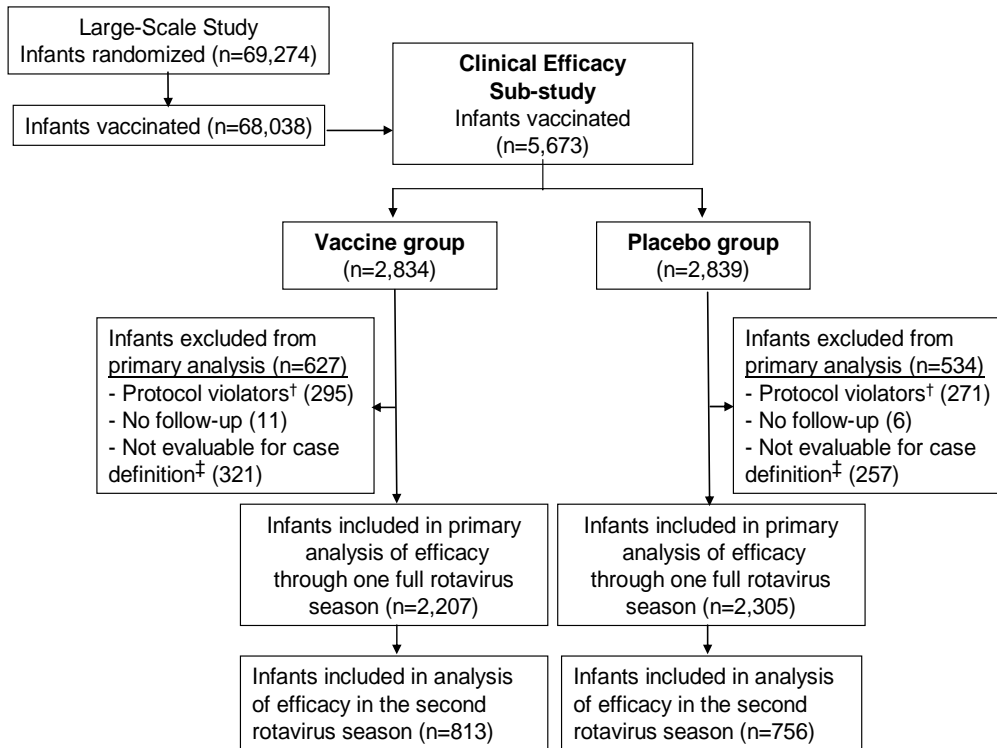
**Figure 1C.**



†The large majority (>80%) of protocol violators did not receive all 3 doses.

‡Includes infants with incomplete clinical or laboratory data, wild-type rotavirus EIA-positive stool before the third dose, or stool samples collected >14 days after symptom onset.

**Figure 1D.**



†The large majority (>90%) of protocol violators did not receive all 3 doses.

‡Includes infants with incomplete clinical or laboratory data, wild-type rotavirus EIA-positive stool before the third dose, or stool samples collected >14 days after symptom onset.