

1. BIOGRAPHICAL INFORMATION

Name: Peter B. Gilbert

Address: Fred Hutchinson Cancer Center
1100 Fairview Avenue North, M2-C200 • PO Box 19024
Seattle, Washington 98109 U.S.A.

Phone and Fax: 206.667.7299 (phone) • 206.667.4378 (fax)

Email: pgilbert@fredhutch.org peterg@uw.edu

2. EDUCATION

1988-1992 University of Washington Honors Program, B.S., Mathematics

1992-1994 University of Washington, M.S., Biostatistics

1994-1996 University of Washington, Ph.D., Biostatistics

3. LICENSURE

N/A

4. PROFESSIONAL POSITIONS

1997 Postdoctoral Research Fellow: Department of Biostatistics, Harvard School of Public Health

1998-2001 Assistant Professor, Department of Biostatistics, Harvard School of Public Health

2001-2002 Assistant Member, Fred Hutchinson Cancer Research Center

2002-2004 Research Assistant Professor, Department of Biostatistics, University of Washington School of Public Health

2002-2007 Associate Member, Fred Hutchinson Cancer Research Center

2004-2008 Research Associate Professor, Department of Biostatistics, University of Washington School of Public Health

2004-2011 Co-Principal Investigator, Statistical Data Management Center of the HIV Vaccine Trials Network, Fred Hutchinson Cancer Research Center

2007-present Member/Professor, Fred Hutchinson Cancer Center

2008-present Research Professor, Department of Biostatistics, University of Washington School of Public Health

2011-present Principal Investigator, Statistical Data Management Center of the HIV Vaccine Trials Network, Fred Hutchinson Cancer Center

2013-2019 Chair, Program in Biostatistics, Bioinformatics, and Epidemiology, Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Center

2020-2025 Principal Investigator, Statistical Data Management Center of the Coronavirus Prevention Network (CoVPN) (Vaccine Clinical Trials Component)

5. HONORS, AWARDS, SCHOLARSHIPS

1992 B.S, Magna Cum Laude

1994 Honorary Donovan J. Thompson Award for outstanding performance as a student in biostatistics, University of Washington School of Public Health and Community Medicine Outstanding Student Scholarship, University of Washington

1995 Senior Biostatistics Student Award, University of Washington

1996 Ross L. Prentice Professorship at the Department of Biostatistics,

2005-

2006	University of Washington
2010	MERIT Award (R37) from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, for the grant, "Statistical Methods in HIV Vaccine Efficacy Trials"
2014	Fellow, American Statistical Association
2018	Highly Cited Researcher list: Web of Science citation record in the top 1% of citations for the "Cross-Field" category (Clarivate Analytics)
2019	Highly Cited Researcher list: Web of Science citation record in the top 1% of citations for the "Cross-Field" category (Clarivate Analytics)
2019	2019 ASA SPAIG Award for the Fred Hutch/Sanofi Pasteur academic/industry partnership. Citation: "For addressing critical public health concerns on safety and efficacy of a dengue vaccine through development and application of novel statistical methods."
2020	MERIT Award (R37) from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, for the grant, "Statistical Methods for Efficacy Trials of Vaccines and Monoclonal Antibodies Against Genetically-Diverse Pathogens"
2021	2021 Statistics in Biosciences Best Paper Award "Generating survival times using Cox proportional hazards models with cyclic and piecewise time-varying covariates" by Yunda Huang, Yuanyuan Zhang, Zong Zhang, Peter B Gilbert
2021	Keynote Speaker 2021 Georgia Statistics Day, Emory University
2021	Gilbert, Montefiori, McDermott et al. (2022, <i>Science</i>) featured in the NIH Director's Blog on December 7, 2021
2023	Fred Hutch Conclave Award for Prevention Innovation: for his work managing the Statistical Data Management Center for the HIV Vaccine Trials Network and for being in the top 1% of citations in his field
2024	2024 Statistics in Biosciences Best Paper Award "Analysis of the Cox Model with Longitudinal Covariates with Measurement Errors and Partly Interval Censored Failure Times, with Application to an AIDS Clinical Trial" by Qingning Zhou, Yanqing Sun, Peter B Gilbert
2024	Impact in VIDD Award for International Partnership Excellence (CoVPN 3008 Study Team)
2025	Marvin Zelen Leadership Award in Statistical Science (from Department of Biostatistics, Harvard School of Public Health)

6. PROFESSIONAL ACTIVITIES

Membership in Professional Organizations:

- 1997-present American Statistical Association
- 1997-present International Biometric Society
- 2014-present American Society of Tropical Medicine & Hygiene

Editorial Responsibilities:

- 2006-2007 Associate Editor, *Annals of Applied Statistics*
- 2018-2021 Associate Editor, *Biometrics*
- 1996-present Referee for many statistical/biostatistical and biomedical journals

International Responsibilities and Service:

- 2011-2014 Chair, Data and Safety Monitoring Board for the FACTS 001 Phase 3 randomized trial of a microbicide gel (Truvada) to prevent HIV infection in South Africa
- 2020 Member, World Health Organization (WHO) Solidarity Vaccines Trial Expert Group
- 2022 Organizing Committee, Workshop on Realising the Potential of Correlates of Protection for Vaccine Development and Licensure, Wellcome Trust, London (September)
- 2022 Co-organizer, Workshop on Statistical Challenges in the Identification, Validation, & Use of Surrogate Markers, Banff International Research Station, Oaxaca, Mexico (3 co-organizers) (August)

National Responsibilities and Service:

- 2004-2008 Member, NIH AIDS Clinical Studies and Epidemiology Study Section: AIDS and Related Research Integrated Review Group (ACE)
- 2004-2011 Member, Safety Monitoring Committee for a Phase II Extended Safety Study of Tenofovir, Centers of Disease Control and Prevention
- 2005-2010 Member, Safety and Efficacy Monitoring Committee for an AIEDRP/ACTG Phase II trial of Cyclosporine A, Trizivir, and Kaletra in subjects with primary HIV infection
- 2008-2010 Alternate Member of the Institute of Medicine's Study on Intermittent Preventive Therapy for Malaria in Infants (IPTi)
- 2008-2010 Member, Data and Safety Monitoring Board for an Adenovirus Serotype Vector Influenza Vaccine Phase 1 Trial
- 2008-2012 Member of the Vaccines and Related Biological Products Advisory Committee to the Food and Drug Administration
- 2011 Member, U.S. Military HIV Research Program Product Development Advisory Group
- 2014-2015 Member, National Cancer Institute HPV Vaccine Working Group for the Costa Rica HPV-16/18 Vaccine Trial and Long-term Follow-up
- 2013-present Ad-hoc Member of Particular Meetings of the Vaccines and Related Biological Products Advisory Committee to the Food and Drug Administration
- 2015 Member, External Advisory Board, University of Vermont Rotavirus Vaccine Correlates of Protection
- 2017-present Member, Curevo Vaccine Scientific Advisory Board
- 2017 Expert, Dengue NS1 Expert Meeting, Sanofi-Pasteur, New York
- 2017 Expert, Dengue NS1 Expert Meeting, Sanofi-Pasteur, Baltimore
- 2018 Co-Organizer, Invited Session at the Joint Statistical Meetings on "Advances and Applications of Joint Modeling for Longitudinal and Time-to-Event Data"
- 2018 Member, Disease Modification Statistical Advisory Board, Biogen, Cambridge
- 2019 Member, Pertussis Vaccine Advisory Board, Sanofi, Lyon, France
- 2020-present Member, Bill & Melinda Gates Foundation Correlates Advisory Board
- 2021 Co-Chair, Group B Streptococcus Correlate of Protection Methodology Workshop, Bill and Melinda Gates Foundation (February) (remote)
- 2021 Member, NIH/NIAID grant review panel for COVID-19 Clinical Trials applications (U01).
- 2021 Member, Sanofi Pertussis Vaccine Virtual Advisory Board, Sanofi Pasteur

2022	Member, Sanofi RSVeC Vaccine Virtual Advisory Board, Sanofi Pasteur
2022	Member, NIH grant review panel for Research on Pathobiological Mechanisms Underpinning the Clinical Phenotypes, Symptomatic Manifestations, and Multi-tissue/organ Pathology of Post-Acute Sequelae of SARS-CoV-2 Infection
2022	Member, Expert Taskforce for development of The Coronavirus R&D Roadmap. Center for Infectious Disease Research and Policy, University of Minnesota
2022	Member, Sanofi RSV/hMPV/PIV3 Combo Vaccine Virtual Advisory Board, Sanofi Pasteur
2022	Member, NIH/NIA grant review committee for the RFA-AG-23-008 "Pharmacokinetic and Pharmacodynamic (PK/PD) Studies of mTOR Inhibitors on Aging-Related Indications (U01 Clinical Trial Required)"
2022-present	Member, Vaccine Company Scientific Advisory Board
2023-present	Member, Minervax GBS Vaccine Scientific Advisory Board
2023	Member, NIH/NIAID grant review committee ZA11 MSA-D (M1) 1 NIAID New Innovators Awards
2023	Member, Moderna Zika Vaccine Scientific Advisory Board
2023	Member, NIH Special Emphasis Panel for All of Us Awards
2023-present	Member, Moderna US COVID-19 Advisory Board
2024-present	Member, AstraZeneca Vaccine Advisory Board
2025	Member, NIH/NIAID grant review committee DP2 NIAID New Innovators Awards
2025	Chair, Invited session, "Recent advances on analysis of missing or mis-measured data" 2025 WNAR/IMS Annual Meeting, Whistler, Canada

7. BIBLIOGRAPHY (Asterisks mark papers by doctoral students for whom chaired doctoral dissertation committee)

A. Refereed Research Articles

1. DeGruttola V, Hughes M, **Gilbert PB**, Phillips A. Trial design in the era of highly effective antiviral drug combinations for HIV infection. *AIDS*. 1998;12 Suppl A:S149-56. PMID: 9632997.
2. **Gilbert PB**, DeGruttola V, Hammer S. Efficient trial designs for studying combination antiretroviral treatments in patients with various resistance profiles. *Journal of Infectious Diseases*. 1998;178(2):340-8. PMID: 9697713.
3. **Gilbert PB**, Self SG, Ashby MA. Statistical methods for assessing differential vaccine protection against human immunodeficiency virus types. *Biometrics*. 1998;54(3):799-814. PMID: 9750238.
4. Scharfstein DO, Tsiatis AA, **Gilbert PB**. Semiparametric efficient estimation in the generalized odds-rate class of regression models for right-censored time-to-event data. *Lifetime Data Analysis*. 1998;4(4):355-91. PMID: 9880995.
5. Christie PD, Edelberg JM, Picard MH, Foulkes AS, Mamuya W, Weiler-Guettler H, Rubin RH, **Gilbert PB**, Rosenberg RD. A murine model of myocardial microvascular thrombosis. *Journal of Clinical Investigation*. 1999;104(5):533-39. PMCID: PMC408542.
6. **Gilbert PB**, Lele SR, Vardi Y. Maximum likelihood estimation in semiparametric selection bias models with application to AIDS vaccine trials. *Biometrika*. 1999;86(1):27-43.
7. Renjifo B, **Gilbert PB**, Chaplin B, Vannberg F, Mwakagile D, Msamanga G, Hunter D, Fawzi W, Essex M. Emerging recombinant human immunodeficiency viruses: Uneven representation of the envelope V3 region. *AIDS*. 1999;13(13):1613-21. PMID: 10509561.
8. **Gilbert PB**. Comparison of competing risks failure time methods and time-independent methods for assessing strain variations in vaccine protection. *Statistics in Medicine*. 2000;19(22):3065-86. PMID: 11113943.

9. **Gilbert PB.** Some statistical issues in the design of HIV-1 vaccine and treatment trials. *Statistical Methods in Medical Research.* 2000;9(3):207-29. PMID: 11084705.
10. **Gilbert PB.** Large sample theory of maximum likelihood estimates in semiparametric biased sampling models. *Annals of Statistics.* 2000;28(1):151-94.
11. **Gilbert PB.** Developing an AIDS vaccine by sieving. *Chance.* 2000; 13:16-21.
12. **Gilbert PB,** Hanna GJ, De Gruttola V, Martinez-Picado J, Kuritzkes DR, Johnson VA, Richman DD, D'Aquila RT. Comparative analysis of HIV type 1 genotypic resistance across antiretroviral trial treatment regimens. *AIDS Research and Human Retroviruses.* 2000;16(14):1325-36. PMID: 11018852.
13. **Gilbert PB,** Ribaud HJ, Greenberg L, Yu G, Bosch RJ, Tierney C, Kuritzkes DR. Considerations in choosing a primary endpoint that measures durability of virological suppression in an antiretroviral trial. *AIDS.* 2000;14(13):1961-72. PMID: 10997401.
14. Segal S, Su M, **Gilbert PB.** The effect of a rapid change in availability of epidural analgesia on the cesarean delivery rate: a meta-analysis. *American Journal of Obstetrics and Gynecology.* 2000;183(4):974-78. PMID: 11035349.
15. **Gilbert PB.** Interpretability and robustness of sieve analysis models for assessing HIV strain variations in vaccine efficacy. *Statistics in Medicine.* 2001;20(2):263-79. PMID: 11169601.
16. **Gilbert PB,** DeGruttola V, Hammer SM, Kuritzkes DR. Virologic and regimen termination surrogate end points in AIDS clinical trials. *JAMA: The Journal of the American Medical Association.* 2001;285(6):777-84. PMID: 11176916.
17. **Gilbert PB,** Novitsky VA, Montano MA, Essex M. An efficient test for comparing sequence diversity between two populations. *Journal of Computational Biology.* 2001;8(2):123-39. PMID: 11454301.
18. **Gilbert PB,** Self SG, Rao M, Naficy A, Clemens J. Sieve analysis: Methods for assessing from vaccine trial data how vaccine efficacy varies with genotypic and phenotypic pathogen variation. *Journal of Clinical Epidemiology.* 2001;54(1):68-85. PMID: 11165470.
19. Havlir DV, Bassett R, Levitan D, **Gilbert PB,** Tebas P, Collier AC, Hirsch MS, Ignacio C, Condra J, Gunthard HF, Richman DD, Wong JK. Prevalence and predictive value of intermittent viremia with combination HIV therapy. *JAMA: The Journal of the American Medical Association.* 2001;286(2):171-79. PMID: 11448280.
20. Havlir DV, **Gilbert PB,** Bennett K, Collier AC, Hirsch MS, Tebas P, Adams EM, Wheat LJ, Goodwin D, Schnittman S, Holohan MK, Richman DD. Effects of treatment intensification with hydroxyurea in HIV-infected patients with virologic suppression. *AIDS.* 2001;15(11):1379-88. PMID: 11504959.
21. McKeague IW, **Gilbert PB,** Kanki PJ. Omnibus tests for comparison of competing risks with adjustment for covariate effects. *Biometrics.* 2001;57(3):818-28. PMID: 11550933.
22. Novitsky V, Rybak N, McLane MF, **Gilbert PB,** Chigwedere P, Klein I, Gaolekwe S, Chang SY, Peter T, Thior I, Ndung'u T, Vannberg F, Foley BT, Marlink R, Lee TH, Essex M. Identification of human immunodeficiency virus type 1 subtype C Gag-, Tat-, Rev-, and Nef-specific elispot-based cytotoxic T-lymphocyte responses for AIDS vaccine design. *Journal of Virology.* 2001;75(19):9210-28. PMID: 114489. PMID: 11533184.
23. Rivera-Morales LG, Novitsky VA, Trujillo JR, Lavallo-Montalvo C, Cano-Dominguez C, Ramos-Jimenez J, Jimenez-Rios E, Flores-Flores L, Lopez-Guillen P, **Gilbert PB,** Vannberg F, Tamez-Guerra R, Rodriguez-Padilla C, Essex M. The molecular epidemiology of HIV type 1 of men in Mexico. *AIDS Research and Human Retroviruses.* 2001;17(1):87-92. PMID: 11177387.
24. **Gilbert PB,** Wei LJ, Kosorok MR, Clemens JD. Simultaneous inferences on the contrast of two hazard functions with censored observations. *Biometrics.* 2002;58(4):773-80. PMID: 12495131.
25. Mani I, **Gilbert PB,** Sankale JL, Eisen G, Mboup S, Kanki PJ. Inpatient diversity and its correlation with viral setpoint in human immunodeficiency virus type 1 CRF02_AG-IbNG infection. *Journal of Virology.* 2002;76(21):10745-55. PMID: PMC136616.
26. Novitsky V, Cao H, Rybak N, **Gilbert PB,** McLane MF, Gaolekwe S, Peter T, Thior I, Ndung'u T, Marlink R, Lee TH, Essex M. Magnitude and frequency of cytotoxic T-lymphocyte responses: identification of immunodominant regions of human immunodeficiency virus type 1 subtype C. *Journal of Virology.* 2002;76(20):10155-68. PMID: PMC136554.

27. Novitsky V, Smith UR, **Gilbert PB**, McLane MF, Chigwedere P, Williamson C, Ndung'u T, Klein I, Chang SY, Peter T, Thior I, Foley BT, Gaolekwe S, Rybak N, Gaseitsiwe S, Vannberg F, Marlink R, Lee TH, Essex M. Human immunodeficiency virus type 1 subtype C molecular phylogeny: consensus sequence for an AIDS vaccine design? *Journal of Virology*. 2002;76(11):5435-51. PMID: PMC137027.
28. Wu L, **Gilbert PB**. Flexible weighted log-rank tests optimal for detecting early and/or late survival differences. *Biometrics*. 2002;58(4):997-1004. PMID: 12495155.
29. ***Gilbert PB**, Bosch RJ, Hudgens MG. Sensitivity analysis for the assessment of causal vaccine effects on viral load in HIV vaccine trials. *Biometrics*. 2003;59(3):531-41. PMID: 14601754.
30. **Gilbert PB**, Chiu YL, Allen M, Lawrence DN, Chapdu C, Israel H, Holman D, Keefer MC, Wolff M, Frey SE. Long-term safety analysis of preventive HIV-1 vaccines evaluated in AIDS vaccine evaluation group NIAID-sponsored Phase I and II clinical trials. *Vaccine*. 2003;21(21-22):2933-47. PMID: 12798637.
31. **Gilbert PB**, DeGruttola VG, Hudgens MG, Self SG, Hammer SM, Corey L. What constitutes efficacy for a human immunodeficiency virus vaccine that ameliorates viremia: Issues involving surrogate end points in phase 3 trials. *Journal of Infectious Diseases*. 2003;188(2):179-93. PMID: 12854072.
32. **Gilbert PB**, McKeague IW, Eisen G, Mullins C, Gueye NA, Mboup S, Kanki PJ. Comparison of HIV-1 and HIV-2 infectivity from a prospective cohort study in Senegal. *Statistics in Medicine*. 2003;22(4):573-93. PMID: 12590415.
33. Montano M, Russell M, **Gilbert PB**, Thior I, Lockman S, Shapiro R, Chang SY, Lee Tun-Hou, Essex M. Comparative prediction of perinatal human immunodeficiency virus type 1 transmission, using multiple virus load markers. *Journal of Infectious Diseases*. 2003;188(3):406-13. PMID: 12870122.
34. Novitsky V, **Gilbert PB**, Peter T, McLane MF, Gaolekwe S, Rybak N, Thior I, Ndung'u T, Marlink R, Lee TH, Essex M. Association between virus-specific T-cell responses and plasma viral load in human immunodeficiency virus type 1 subtype C infection. *Journal of Virology*. 2003;77(2):882-90. PMID: PMC140844.
35. Renjifo B, Chung M, **Gilbert PB**, Mwakagile D, Msamanga G, Fawzi W, Essex M. In-utero transmission of quasispecies among human immunodeficiency virus type 1 genotypes. *Virology*. 2003;307(2):278-82. PMID: 12667797.
36. Weiser S, Wolfe W, Bangsberg D, Thior I, **Gilbert PB**, Makhema J, Kebaabetswe P, Dickenson D, Mompoti K, Essex M, Marlink R. Barriers to antiretroviral adherence for patients living with HIV infection and AIDS in Botswana. *Journal of Acquired Immune Deficiency Syndromes*. 2003;34(3):281-88. PMID: 14600572.
37. Evans TG, Frey S, Israel H, Chiu J, El-Habib R, **Gilbert PB**, Gaitan A, Montefiori DC. Long-term memory B-cell responses in recipients of candidate human immunodeficiency virus type 1 vaccines. *Vaccine*. 2004;22(20):2626-30. PMID: 15193388.
38. **Gilbert PB**. Goodness-of-fit tests for semiparametric biased sampling models. *Journal of Statistical Planning and Inference*. 2004;118(1-2):51-81.
39. **Gilbert PB**, McKeague IW, Sun Y. Tests for comparing mark-specific hazards and cumulative incidence functions. *Lifetime Data Analysis*. 2004;10(1):5-28. PMID: 15130048.
40. Huang CC, Barreda P, Mendoza V, Guzman L, **Gilbert PB**. A comparative analysis of abandoned street children and formerly abandoned street children in La Paz, Bolivia. *Archives of Disease in Childhood*. 2004;89(9):821-26. PMID: PMC1763218.
41. Hudgens MG, **Gilbert PB**, Self SG. Endpoints in vaccine trials. *Statistical Methods in Medical Research*. 2004;13(2):89-114. PMID: 15068256.
42. Lee D, Graham BS, Chiu YL, **Gilbert PB**, McElrath MJ, Belshe RB, Buchbinder SP, Sheppard HW, Koblin BA, Mayer KH, Keefer MC, Mulligan MJ, Celum CL. Breakthrough infections during phase 1 and 2 prime-boost HIV-1 vaccine trials with canarypox vectors (ALVAC) and booster dose of recombinant gp120 or gp160. *Journal of Infectious Diseases*. 2004;190(5):903-7. PMID: 15295694.
43. Renjifo B, **Gilbert PB**, Chaplin B, Msamanga G, Mwakagile D, Fawzi W, Essex M. Preferential in-utero transmission of HIV-1 subtype C as compared to HIV-1 subtype A or D. *AIDS*. 2004;18(12):1629-36. PMID: 15280773.

44. Flynn MN, Forthal DN, Harro CD, Judson FN, Mayer KH, Para MF, **Gilbert PB**, Hudgens MG, Metch BJ, Self SG, Berman PW, Francis DP, Gurwith M, Heyward WL, Jobes DV, Peterson ML, Popovic V, Sinangil FM, Adamczyk A, Baker RL, Brand D, Brown SJ, Buchbinder S, Buggy BP, Cade J, Caldwell MC, Celum C, Creticos C, Coutinho RA, Lindenburg K, Daly P, DeJesus E, Di-Carlo R, Fenstersheib M, Gripshover B, Gorse GJ, Belshe R, Grossman H, Henry K, Hewitt RG, Hogg R, Jacobson JM, Jemsek J, Judson F, Kahn JO, Keefer MC, Kessler H, Koblin B, Kostman J, Lally M, Logue K, Marmor M, Mayer K, McKinsey D, Miskin BM, Morales JO, Mulligan MJ, Myers RA, Novak R, Para M, Piliero P, Pobleto R, Rhame F, Riddler S, Richter RW, Sampson JH, Sands M, Santiago S, Shikuma C, Somero MS, Thomas E, Thompson M, Tying SK, Vincelette J, Vrooman PS, Yangco BG, rgp120 HIV Vaccine Study Group. Placebo-controlled phase 3 trial of a recombinant glycoprotein 120 vaccine to prevent HIV-1 infection. *Journal of Infectious Diseases*. 2005;191(5):654-65. PMID: 15688278.
45. **Gilbert PB**. A modified false discovery rate multiple-comparisons procedure for discrete data, applied to human immunodeficiency virus genetics. *Journal of the Royal Statistical Society, Series C-Applied Statistics*. 2005;54:143-58.
46. **Gilbert PB**, Ackers ML, Berman PW, Francis DP, Popovic V, Hu DJ, Heyward WL, Sinangil F, Shepherd BE*, Gurwith M. HIV-1 virologic and immunologic progression and initiation of antiretroviral therapy among HIV-1-infected subjects in a trial of the efficacy of recombinant glycoprotein 120 vaccine. *Journal of Infectious Diseases*. 2005;192(6):974-83. PMID: 16107949.
47. **Gilbert PB**, Novitsky V, Essex M. Covariability of selected amino acid positions for HIV type 1 subtypes C and B. *AIDS Research and Human Retroviruses*. 2005;21(12):1016-30. PMID: 16379605.
48. **Gilbert PB**, Peterson ML, Follmann D, Hudgens MG, Francis DP, Gurwith M, Heyward WL, Jobes DV, Popovic V, Self SG, Sinangil F, Burke D, Berman PW. Correlation between immunologic responses to a recombinant glycoprotein 120 vaccine and incidence of HIV-1 infection in a phase 3 HIV-1 preventive vaccine trial. *Journal of Infectious Diseases*. 2005;191(5):666-77. PMID: 15688279.
49. **Gilbert PB**, Rossini AJ, Shankarappa R. Two-sample tests for comparing intra-individual genetic sequence diversity between populations. *Biometrics*. 2005;61(1):106-17. PMID: 15797083.
50. **Gilbert PB**, Sun Y. Failure time analysis of HIV vaccine effects on viral load and antiretroviral therapy initiation. *Biostatistics*. 2005;6(3):374-94. PMID: 15831584.
51. Li M, Gao F, Mascola JR, Stamatatos L, Polonis VR, Koutsoukos M, Voss G, Goepfert P, **Gilbert PB**, Greene KM, Bilska M, Kothe DL, Salazar-Gonzalez JF, Wei X, Decker JM, Hahn BH, Montefiori DC. Human immunodeficiency virus type 1 env clones from acute and early subtype B infections for standardized assessments of vaccine-elicited neutralizing antibodies. *Journal of Virology*. 2005;79(16):10108-25. PMCID: PMC1182643.
52. Mascola JR, D'Souza P, **Gilbert PB**, Hahn BH, Haigwood NL, Morris L, Petropoulos CJ, Polonis VR, Sarzotti M, Montefiori DC. Recommendations for the design and use of standard virus panels to assess neutralizing antibody responses elicited by candidate human immunodeficiency virus type 1 vaccines. *Journal of Virology*. 2005;79(16):10103-7. PMCID: PMC1182642.
53. Meier AS, **Gilbert PB**. Accuracy and precision of estimating intervention efficacy when the timing of observed events differ by treatment arm. *Contemporary Clinical Trials*. 2005;26(5):598-610. PMID: 16112914.
54. Cai T, **Gilbert PB**, Self SG. Joint inferences on vaccine efficacy against infection and disease with application to the first HIV vaccine efficacy trial. *Journal of Biopharmaceutical Statistics*. 2006;16(4):517-38. PMID: 16892911.
55. Li F, Malhotra U, **Gilbert PB**, Hawkins NR, Duerr AC, McElrath MJ, Corey L, Self SG. Peptide selection for human immunodeficiency virus type 1 CTL-based vaccine evaluation. *Vaccine*. 2006;24(47-48):6893-904. PMID: 16890329.
56. Mehrotra DV, Li X, **Gilbert PB**. A comparison of eight methods for the dual-endpoint evaluation of efficacy in a proof-of-concept HIV vaccine trial. *Biometrics*. 2006;62(3):893-900. PMID: 16984333.
57. Moodie Z, Rossini AJ, Hudgens MG, **Gilbert PB**, Self SG, Russell ND. Statistical evaluation of HIV vaccines in early clinical trials. *Contemporary Clinical Trials*. 2006;27(2):147-60. PMID: 16426900.

58. Ndung'u T, Sepako E, McLane MF, Chand F, Bedi K, Gaseitsiwe S, Doualla-Bell F, Peter T, Thior I, Moyo SM, **Gilbert PB**, Novitsky VA, Essex M. HIV-1 subtype C in vitro growth and coreceptor utilization. *Virology*. 2006;347(2):247-60. PMID: 16406460.
59. Novitsky VA, **Gilbert PB**, Shea K, McLane MF, Rybak N, Klein I, Thior I, Ndung'u T, Lee TH, Essex ME. Interactive association of proviral load and IFN-gamma-secreting T cell responses in HIV-1C infection. *Virology*. 2006;349(1):142-55. PMID: 16519915.
60. Pitisuttithum P, **Gilbert PB**, Gurwith M, Heyward W, Martin M, van Griensven F, Hu D, Tappero JW, Choopanya K. Randomized, double-blind, placebo-controlled efficacy trial of a bivalent recombinant glycoprotein 120 HIV-1 vaccine among injection drug users in Bangkok, Thailand. *Journal of Infectious Diseases*. 2006;194(12):1661-71. PMID: 17109337.
61. Shapiro RL, Thior I, **Gilbert PB**, Lockman S, Wester C, Smeaton LM, Stevens L, Heymann SJ, Ndung'u T, Gaseitsiwe S, Novitsky V, Makhema J, Lagakos S, Essex M. Maternal single-dose nevirapine versus placebo as part of an antiretroviral strategy to prevent mother-to-child HIV transmission in Botswana. *AIDS*. 2006;20(9):1281-88. PMID: 16816557.
62. Shepherd BE*, **Gilbert PB**, Jemai Y, Rotnitzky A. Sensitivity analyses comparing outcomes only existing in a subset selected post-randomization, conditional on covariates, with application to HIV vaccine trials. *Biometrics*. 2006;62(2):332-42. PMID: 16918897.
63. Thior I, Lockman S, Smeaton LM, Shapiro RL, Wester C, Heymann SJ, **Gilbert PB**, Stevens L, Peter T, Kim S, van Widenfelt E, Moffat C, Ndase P, Arimi P, Kebaabetswe P, Mazonde P, Makhema J, McIntosh K, Novitsky V, Lee TH, Marlink R, Lagakos S, Essex M. Breastfeeding plus infant zidovudine prophylaxis for 6 months vs formula feeding plus infant zidovudine for 1 month to reduce mother-to-child HIV transmission in Botswana: a randomized trial: the Mashi Study. *JAMA: The Journal of the American Medical Association*. 2006;296(7):794-805. PMID: 16905785.
64. Wick WD, **Gilbert PB**, Self SG. On modeling HIV and T cells in vivo: assessing causal estimators in vaccine trials. *PLoS Computational Biology*. 2006;2(6):e64. PMCID: 16789816.
65. Follmann D, Duerr A, Tabet S, **Gilbert PB**, Moodie Z, Fast P, Cardinali M, Self SG. Endpoints and regulatory issues in HIV vaccine clinical trials: lessons from a workshop. *Journal of Acquired Immune Deficiency Syndromes*. 2007;44(1):49-60. PMCID: PMC2682948.
66. Forthal DN, **Gilbert PB**, Landucci G, Phan T. Recombinant gp120 vaccine-induced antibodies inhibit clinical strains of HIV-1 in the presence of Fc receptor-bearing effector cells and correlate inversely with HIV infection rate. *Journal of Immunology*. 2007;178(10):6596-603. PMID: 17475891.
67. Hudgens MG, Maathuis MH, **Gilbert PB**. Nonparametric estimation of the joint distribution of a survival time subject to interval censoring and a continuous mark variable. *Biometrics*. 2007;63(2):372-80. PMID: 17688489.
68. Jemai Y, Rotnitzky A, Shepherd BE*, **Gilbert PB**. Semiparametric estimation of treatment effects given base-line covariates on an outcome measured after a post-randomization event occurs. *Journal of the Royal Statistical Society, Series B-Statistical Methodology*. 2007;69:879-901. PMCID: PMC2837843.
69. Li F, **Gilbert PB**, Self SG. Identification of cross-neutralization determinants by GAP analysis: a mutational behavior approach. *Current HIV Research*. 2007;5(1):87-96. PMID: 17266560.
70. Li F, Horton H, **Gilbert PB**, McElrath MJ, Corey L, Self SG. HIV-1 CTL-based vaccine immunogen selection: antigen diversity and cellular response features. *Current HIV Research*. 2007;5(1):97-107. PMID: 17266561.
71. Nickle DC, Heath L, Jensen MA, **Gilbert PB**, Mullins JI, Kosakovsky Pond SL. HIV-specific probabilistic models of protein evolution. *PLoS One*. 2007;2(6):e503. PMCID: PMC1876811.
72. Qin L**, **Gilbert PB****, Corey L, McElrath MJ, Self SG. A framework for assessing immunological correlates of protection in vaccine trials. *Journal of Infectious Diseases*. 2007;196(9):1304-12. PMID: 17922394. **Contributed equally.
73. Shepherd BE*, **Gilbert PB**, Lumley T. Sensitivity analyses comparing time-to-event outcomes existing only in a subset selected postrandomization. *Journal of the American Statistical Association*. 2007;102(478):573-82. PMCID: PMC2613336.
74. Shepherd BE*, **Gilbert PB**, Mehrotra DV. Eliciting a counterfactual sensitivity parameter. *American Statistician*. 2007;61(1):56-63.

75. Buchbinder SP, Mehrotra DV, Duerr A, Fitzgerald DW, Mogg R, Li D, **Gilbert PB**, Lama JR, Marmor M, Del Rio C, McElrath MJ, Casimiro DR, Gottesdiener KM, Chodakewitz JA, Corey L, Robertson MN. Efficacy assessment of a cell-mediated immunity HIV-1 vaccine (the Step Study): a double-blind, randomised, placebo-controlled, test-of-concept trial. *Lancet*. 2008;372(9653):1881-93. PMID: PMC2721012.
76. **Gilbert PB**, Hudgens MG. Evaluating candidate principal surrogate endpoints. *Biometrics*. 2008;64(4):1146-54. PMID: PMC2726718.
77. **Gilbert PB**, McKeague IW, Sun Y. The 2-sample problem for failure rates depending on a continuous mark: an application to vaccine efficacy. *Biostatistics*. 2008;9(2):263-76. PMID: 17704528.
78. **Gilbert PB**, Qin L, Self SG. Evaluating a surrogate endpoint at three levels, with application to vaccine development. *Statistics in Medicine*. 2008;27(23):4758-78. PMID: PMC2646675.
79. **Gilbert PB**, Qin L, Self SG. Comment on "Evaluating a surrogate endpoint at three levels, with application to vaccine development". *Statistics in Medicine*. 2008;27(29):6268-70. PMID: PMC4510047.
80. **Gilbert PB**, Wu C, Jobes DV. Genome scanning tests for comparing amino acid sequences between groups. *Biometrics*. 2008;64(1):198-207. PMID: 17608781.
81. Li Z, **Gilbert PB**, Nan B. Weighted likelihood method for grouped survival data in case-cohort studies with application to HIV vaccine trials. *Biometrics*. 2008;64(4):1247-55. PMID: 19032178.
82. Qin L, **Gilbert PB**, Follmann D, Li D. Assessing surrogate endpoints in vaccine trials with case-cohort sampling and the Cox model. *Annals of Applied Statistics*. 2008;2(1):386-407. PMID: PMC2601643.
83. Sun Y, Hyun S, **Gilbert PB**. Testing and estimation of time-varying cause-specific hazard ratios with covariate adjustment. *Biometrics*. 2008;64(4):1070-9. PMID: 18355384.
84. Yang Y, **Gilbert PB**, Longini IM, Halloran ME. A Bayesian framework for estimating vaccine efficacy per infectious contact. *Annals of Applied Statistics*. 2008;2(4):1409-31. PMID: PMC2630256.
85. **Gilbert PB**, Sato A, Sun X, Mehrotra DV. Efficient and robust method for comparing the immunogenicity of candidate vaccines in randomized clinical trials. *Vaccine*. 2009;27(3):396-401. PMID: PMC2653280.
86. Gray ES, Taylor N, Wycuff D, Moore PL, Tomaras GD, Wibmer CK, Puren A, deCamp A*, **Gilbert PB**, Wood B, Montefiori DC, Binley JM, Shaw GM, Haynes BF, Mascola JR, Morris L. Antibody specificities associated with neutralization breadth in plasma from human immunodeficiency virus type 1 subtype C-infected blood donors. *Journal of Virology*. 2009;83(17):8925-37. PMID: PMC2738176.
87. Huang Y, **Gilbert PB**, Montefiori DC, Self SG. Simultaneous evaluation of the magnitude and breadth of a left and right censored multivariate response, with application to HIV vaccine development. *Statistics in Biopharmaceutical Research*. 2009;1(1):81-91. PMID: PMC2805400.
88. Hudgens MG, **Gilbert PB**. Assessing vaccine effects in repeated low-dose challenge experiments. *Biometrics*. 2009;65(4):1223-32. PMID: PMC2794923.
89. Hudgens MG, **Gilbert PB**, Mascola JR, Wu CD, Barouch DH, Self SG. Power to detect the effects of HIV vaccination in repeated low-dose challenge experiments. *Journal of Infectious Diseases*. 2009;200(4):609-13. PMID: PMC2754821.
90. Jones NG, deCamp A*, **Gilbert PB**, Peterson ML, Gurwith M, Cao H. AIDSVAX immunization induces HIV-specific CD8+ T-cell responses in high-risk, HIV-negative volunteers who subsequently acquire HIV infection. *Vaccine*. 2009;27(7):1136-40. PMID: PMC2676722.
91. Kittikraisak W, van Griensven F, Martin M, McNicholl J, **Gilbert PB**, Chuachoowong R, Vanichseni S, Sutthent R, Tappero JW, Mastro TD, Hu DJ, Gurwith M, Kitayaporn D, Sangkum U, Choopanya K. Blood and seminal plasma HIV-1 RNA levels among HIV-1-infected injecting drug users participating in the AIDSVAX B/E efficacy trial in Bangkok, Thailand. *Journal of Acquired Immune Deficiency Syndromes*. 2009;51(5):601-8. PMID: PMC2764047.

92. Sun Y, **Gilbert PB**, McKeague IW. Proportional hazards models with continuous marks. *Annals of Statistics*. 2009;37(1):394-426. PMID: PMC2762218.
93. Wick WD, **Gilbert PB**, Yang OO. Predicting the impact of blocking human immunodeficiency virus type 1 Nef in vivo. *Journal of Virology*. 2009;83(5):2349-56. PMID: PMC2643708.
94. **Gilbert PB**. Some design issues in phase 2b vs phase 3 prevention trials for testing efficacy of products or concepts. *Statistics in Medicine*. 2010;29(10):1061-71. PMID: PMC2929839.
95. **Gilbert PB**, Jin Y. Semiparametric estimation of the average causal effect of treatment on an outcome measured after a postrandomization event, with missing outcome data. *Biostatistics*. 2010;11(1):34-47. PMID: PMC2800161.
96. **Gilbert PB**, Wang M, Wrin T, Petropoulos C, Gurwith M, Sinangil F, D'Souza P, Rodriguez-Chavez IR, deCamp A*, Giganti M, Berman PW, Self SG, Montefiori DC. Magnitude and breadth of a nonprotective neutralizing antibody response in an efficacy trial of a candidate HIV-1 gp120 vaccine. *Journal of Infectious Diseases*. 2010;202(4):595-605. PMID: PMC2946208.
97. Novitsky V, Wang R, Bussmann H, Lockman S, Baum M, Shapiro R, Thior I, Wester C, Wester CW, Ogwu A, Asmelash A, Musonda R, Campa A, Moyo S, van Widenfelt E, Mine M, Moffat C, Mmalane M, Makhema J, Marlink R, **Gilbert PB**, Seage GR, 3rd, DeGruttola V, Essex M. HIV-1 subtype C-infected individuals maintaining high viral load as potential targets for the "test-and-treat" approach to reduce HIV transmission. *PLoS One*. 2010;5(4):e10148. PMID: PMC2853582.
98. Seaman MS, Janes H, Hawkins N, Grandpre LE, Devoy C, Giri A, Coffey RT, Harris L, Wood B, Daniels MG, Bhattacharya T, Lapedes A, Polonis VR, McCutchan FE, **Gilbert PB**, Self SG, Korber BT, Montefiori DC, Mascola JR. Tiered categorization of a diverse panel of HIV-1 Env pseudoviruses for assessment of neutralizing antibodies. *Journal of Virology*. 2010;84(3):1439-52. PMID: PMC2812321.
99. Wolfson J*, **Gilbert PB**. Statistical identifiability and the surrogate endpoint problem, with application to vaccine trials. *Biometrics*. 2010;66(4):1153-61. PMID: PMC3597127.
100. Zhang M, **Gilbert PB**. Increasing the efficiency of prevention trials by incorporating baseline covariates. *Statistical Communications in Infectious Diseases*. 2010;2(1). PMID: PMC2997740.
101. **Gilbert PB**, Grove D, Gabriel EE*, Huang Y, Gray G, Hammer SM, Buchbinder SP, Kublin J, Corey L, Self SG. A sequential Phase 2b trial design for evaluating vaccine efficacy and immune correlates for multiple HIV vaccine regimens. *Statistical Communications in Infectious Diseases*. 2011;3(1): 1. PMID: PMC3502884.
102. Billings EA, Karasavvas N, de Souza MS, Currier J, Pitisuttithum P, Kaewkunwal J, Nitayaphan S, **Gilbert PB**, Tomaras GD, Zolla-Pazner SB, Haynes BF, Michael NL, Rerks-Ngarm S, Kim JH, Rao M. Surface plasmon resonance analysis of anti-gp120 V2-specific IgG antibodies generated in the RV144 Thai Trial. *AIDS Research and Human Retroviruses*. 2011;27(10):A21-A22.
103. Corey L, Nabel GJ, Dieffenbach C, **Gilbert PB**, Haynes BF, Johnston M, Kublin J, Lane HC, Pantaleo G, Picker LJ, Fauci AS. HIV-1 vaccines and adaptive trial designs. *Science Translational Medicine*. 2011;3(79):79ps13. PMID: PMC3616511.
104. Fitzgerald DW, Janes H, Robertson M, Coombs R, Frank I, **Gilbert PB**, Loufty M, Mehrotra D, Duerr A, Step Study Protocol Team. An Ad5-vectored HIV-1 vaccine elicits cell-mediated immunity but does not affect disease progression in HIV-1-infected male subjects: results from a randomized placebo-controlled trial (the Step study). *Journal of Infectious Diseases*. 2011;203(6):765-72. PMID: PMC3119328.
105. **Gilbert PB**, Berger JO, Stablein D, Becker S, Essex M, Hammer SM, Kim JH, Degruttola VG. Statistical interpretation of the RV144 HIV vaccine efficacy trial in Thailand: A case study for statistical issues in efficacy trials. *Journal of Infectious Diseases*. 2011;203(7):969-75. PMID: PMC3068028.
106. **Gilbert PB**, Hudgens MG, Wolfson J*. Commentary on "Principal stratification - a goal or a tool?" by Judea Pearl. *International Journal of Biostatistics*. 2011;7(1):Article 36. PMID: PMC3204668.
107. Gnanakaran S, Bhattacharya T, Daniels M, Keele BF, Hraber PT, Lapedes AS, Shen T, Gaschen B, Krishnamoorthy M, Li H, Decker JM, Salazar-Gonzalez JF, Wang S, Jiang C, Gao F, Swanstrom R, Anderson JA, Ping LH, Cohen MS, Markowitz M, Goepfert PA, Saag MS, Eron JJ, Hicks CB, Blattner WA, Tomaras GD, Asmal M, Letvin NL, **Gilbert PB**, deCamp A*, Magaret CA, Schief WR, Ban YE, Zhang M, Soderberg KA, Sodroski JG, Haynes BF, Shaw GM, Hahn BH, Korber B. Recurrent signature

- patterns in HIV-1 B clade envelope glycoproteins associated with either early or chronic infections. *PLoS Pathogens*. 2011;7(9):e1002209. PMCID: PMC3182927.
108. Huang Y, **Gilbert PB**. Comparing biomarkers as principal surrogate endpoints. *Biometrics*. 2011;67(4):1442-51. PMCID: PMC3163011.
109. Letvin NL, Rao SS, Montefiori DC, Seaman MS, Sun Y, Lim SY, Yeh WW, Asmal M, Gelman RS, Shen L, Whitney JB, Seoighe C, Lacerda M, Keating S, Norris PJ, Hudgens MG, **Gilbert PB**, Buzby AP, Mach LV, Zhang J, Balachandran H, Shaw GM, Schmidt SD, Todd JP, Dodson A, Mascola JR, Nabel GJ. Immune and genetic correlates of vaccine protection against mucosal infection by SIV in monkeys. *Science Translational Medicine*. 2011;3(81):81ra36. PMCID: PMC3718279.
110. Rolland M, Tovanabutra S, deCamp A*, Frahm N, **Gilbert PB**, Sanders-Buell E, Heath L, Magaret CA, Bose M, Bradfield A, O'Sullivan A, Crossler J, Jones T, Nau M, Wong K, Zhao H, Raugi DN, Sorensen S, Stoddard JN, Maust BS, Deng W, Hural J, Dubey S, Michael NL, Shiver J, Corey L, Li F, Self SG, Kim J, Buchbinder S, Casimiro DR, Robertson MN, Duerr A, McElrath MJ, McCutchan FE, Mullins JI. Genetic impact of vaccination on breakthrough HIV-1 sequences from the STEP trial. *Nature Medicine*. 2011;17(3):366-71. PMCID: PMC3053571.
111. Shepherd BE*, **Gilbert PB**, Dupont CT. Sensitivity analyses comparing time-to-event outcomes only existing in a subset selected postrandomization and relaxing monotonicity. *Biometrics*. 2011;67(3):1100-10. PMCID: PMC3116075.
112. Bonsignori M, Pollara J, Moody MA, Alpert MD, Chen X, Hwang KK, **Gilbert PB**, Huang Y, Gurley TC, Kozink DM, Marshall DJ, Whitesides JF, Tsao CY, Kaewkungwal J, Nitayaphan S, Pitisuttithum P, Rerks-Ngarm S, Kim JH, Michael NL, Tomaras GD, Montefiori DC, Lewis GK, DeVico A, Evans DT, Ferrari G, Liao HX, Haynes BF. Antibody-dependent cellular cytotoxicity-mediating antibodies from an HIV-1 vaccine efficacy trial target multiple epitopes and preferentially use the VH1 gene family. *Journal of Virology*. 2012;86(21):11521-32. PMCID: PMC3486290.
113. Dai JY, **Gilbert PB**, Masse BR. Partially hidden Markov model for time-varying principal stratification in HIV prevention trials. *Journal of the American Statistical Association*. 2012;107(497):52-65. PMCID: PMC3649016.
114. Duerr A, Huang Y, Buchbinder S, Coombs RW, Sanchez J, del Rio C, Casapia M, Santiago S, **Gilbert PB**, Corey L, Robertson MN, Step HST. Extended follow-up confirms early vaccine-enhanced risk of HIV acquisition and demonstrates waning effect over time among participants in a randomized trial of recombinant adenovirus HIV vaccine (Step Study). *Journal of Infectious Diseases*. 2012;206(2):258-66. PMCID: PMC3490694.
115. Fuchs JD, Morgan C, Bart P, Kochar N, Frahm N, Swann E, **Gilbert PB**, DeRosa S, Graham B, Nabel G, Liao H, Haynes B, Tomaras G. DNA and recombinant adenovirus serotype 35 and 5 preventive HIV-1 vaccines with Env A inserts elicit cross-clade binding and V1V2 antibodies. *Retrovirology*. 2012;9(Suppl 2): P136. PMCID: PMC3442017.
116. *Haynes BF, **Gilbert PB**, McElrath MJ, Zolla-Pazner S, Tomaras GD, Alam SM, Evans DT, Montefiori DC, Karnasuta C, Sutthent R, Liao HX, DeVico AL, Lewis GK, Williams C, Pinter A, Fong Y, Janes H, deCamp A*, Huang Y, Rao M, Billings E, Karasavvas N, Robb ML, Ngauy V, de Souza MS, Paris R, Ferrari G, Bailer RT, Soderberg KA, Andrews C, Berman PW, Frahm N, De Rosa SC, Alpert MD, Yates NL, Shen X, Koup RA, Pitisuttithum P, Kaewkungwal J, Nitayaphan S, Rerks-Ngarm S, Michael NL, Kim JH. Immune-correlates analysis of an HIV-1 vaccine efficacy trial. *New England Journal of Medicine*. 2012;366(14):1275-86. PMCID: PMC3371689.
117. Huang Y, **Gilbert PB**, Janes H. Assessing treatment-selection markers using a potential outcomes framework. *Biometrics*. 2012;68(3):687-96. PMCID: PMC3417090.
118. Janes H, Frahm N, deCamp A*, Rolland M, Gabriel EE*, Wolfson J*, Hertz T, Kallas E, Goepfert P, Friedrich DP, Corey L, Mullins JI, McElrath MJ, **Gilbert PB**. MRKAd5 HIV-1 Gag/Pol/Nef vaccine-induced T-cell responses inadequately predict distance of breakthrough HIV-1 sequences to the vaccine or viral load. *PLoS One*. 2012;7(8):e43396. PMCID: PMC3428369.
119. Karasavvas N, Billings E, Rao M, Williams C, Zolla-Pazner S, Bailer RT, Koup RA, Madnote S, Arworn D, Shen X, Tomaras GD, Currier JR, Jiang M, Magaret C, Andrews C, Gottardo R, **Gilbert PB**, Cardozo TJ, Rerks-Ngarm S, Nitayaphan S, Pitisuttithum P, Kaewkungwal J, Paris R, Greene K, Gao H,

- Gurunathan S, Tartaglia J, Sinangil F, Korber BT, Montefiori DC, Mascola JR, Robb ML, Haynes BF, Ngaay V, Michael NL, Kim JH, de Souza MS, for the MOPH TAVEG Collaboration. The Thai phase III HIV type 1 vaccine trial (RV144) regimen induces antibodies that target conserved regions within the V2 loop of gp120. *AIDS Research and Human Retroviruses*. 2012;28(11):1444-57. PMID: PMC3484815.
120. Kublin JG, Morgan CA, Day TA, **Gilbert PB**, Self SG, McElrath MJ, Corey L. HIV Vaccine Trials Network: activities and achievements of the first decade and beyond. *Clinical Investigation*. 2012;2(3):245-54. PMID: PMC3521567.
121. Montefiori DC, Karnasuta C, Huang Y, Ahmed H, **Gilbert PB**, de Souza MS, McLinden R, Tovanabutra S, Laurence-Chenine A, Sanders-Buell E, Moody MA, Bonsignori M, Ochsenbauer C, Kappes J, Tang H, Greene K, Gao H, LaBranche CC, Andrews C, Polonis VR, Rerks-Ngarm S, Pitisuttithum P, Nitayaphan S, Kaewkungwal J, Self SG, Berman PW, Francis D, Sinangil F, Lee C, Tartaglia J, Robb ML, Haynes BF, Michael NL, Kim JH. Magnitude and breadth of the neutralizing antibody response in the RV144 and Vax003 HIV-1 vaccine efficacy trials. *Journal of Infectious Diseases*. 2012;206(3):431-41. PMID: PMC3392187.
122. Plotkin SA, **Gilbert PB**. Nomenclature for immune correlates of protection after vaccination. *Clinical Infectious Diseases*. 2012;54(11):1615-7. PMID: PMC3348952.
123. Qureshi H, Ma ZM, Huang Y, Hodge G, Thomas MA, DiPasquale J, DeSilva V, Fritts L, Bett AJ, Casimiro DR, Shiver JW, Robert-Guroff M, Robertson MN, McChesney MB, **Gilbert PB**, Miller CJ. Low-dose penile SIVmac251 exposure of rhesus macaques infected with adenovirus type 5 (Ad5) and then immunized with a replication-defective Ad5-based SIV gag/pol/nef vaccine recapitulates the results of the phase IIb step trial of a similar HIV-1 vaccine. *Journal of Virology*. 2012;86(4):2239-50. PMID: PMC3302390.
124. Robb ML, Rerks-Ngarm S, Nitayaphan S, Pitisuttithum P, Kaewkungwal J, Kunasol P, Khamboonruang C, Thongcharoen P, Morgan P, Benenson M, Paris RM, Chiu J, Adams E, Francis D, Gurunathan S, Tartaglia J, **Gilbert PB**, Stablein D, Michael NL, Kim JH. Risk behaviour and time as covariates for efficacy of the HIV vaccine regimen ALVAC-HIV (vCP1521) and AIDSVAX B/E: a post-hoc analysis of the Thai phase 3 efficacy trial RV 144. *Lancet Infectious Diseases*. 2012;12(7):531-7. PMID: PMC3530398.
125. Rolland M**, Edlefsen PT**, Larsen BB, Tovanabutra S, Sanders-Buell E, Hertz T, deCamp AC*, Carrico C, Menis S, Magaret CA, Ahmed H, Juraska MJ*, Chen L, Konopa P, Nariya S, Stoddard JN, Wong K, Zhao H, Deng W, Maust BS, Bose M, Howell S, Bates A, Lazzaro M, O'Sullivan A, Lei E, Bradfield A, Ibitamuno G, Assawadarachai V, O'Connell RJ, deSouza MS, Nitayaphan S, Rerks-Ngarm S, Robb ML, McLellan JS, Georgiev I, Kwong PD, Carlson JM, Michael NL, Schief WR, **Gilbert PB****, Mullins JI**, Kim JH**. Increased HIV-1 vaccine efficacy against viruses with genetic signatures in Env V2. *Nature*. 2012;490(7420):417-20. PMID: PMC3551291. **Contributed equally.
126. Rolland M, **Gilbert PB**. Evaluating immune correlates in HIV type 1 vaccine efficacy trials: what RV144 may provide. *AIDS Research and Human Retroviruses*. 2012;28(4):400-4. PMID: PMC3316118.
127. Sindhi R, Ashokkumar C, Higgs BW, **Gilbert PB**, Sun Q, Ranganathan S, Jaffe R, Snyder S, Ningappa M, Soltys KA, Bond GJ, Mazariegos GV, Abu-Elmagd K, Zeevi A. Allospecific CD154 + T-cytotoxic memory cells as potential surrogate for rejection risk in pediatric intestine transplantation. *Pediatric Transplantation*. 2012;16(1):83-91. PMID: 22122074.
128. Sun Y, **Gilbert PB**. Estimation of stratified mark-specific proportional hazards models with missing marks. *Scandinavian Journal of Statistics, Theory and Applications*. 2012;39(1):34-52. PMID: PMC3601495.
129. Sun Y, Wang HJ, **Gilbert PB**. Quantile regression for competing risks data with missing cause of failure. *Statistica Sinica*. 2012;22(2):703-28. PMID: PMC3742132.
130. Todd CA, Greene KM, Yu X, Ozaki DA, Gao H, Huang Y, Wang M, Li G, Brown R, Wood B, D'Souza MP, **Gilbert PB**, Montefiori DC, Sarzotti-Kelsoe M. Development and implementation of an international proficiency testing program for a neutralizing antibody assay for HIV-1 in TZM-bl cells. *Journal of Immunological Methods*. 2012;375(1-2):57-67. PMID: PMC3332116.

131. Wecker M, **Gilbert PB**, Russell N, Hural J, Allen M, Pensiero M, Chulay J, Chiu YL, Abdool Karim SS, Burke DS, and the HIV Vaccine Trials Network. Phase I safety and immunogenicity evaluations of an alphavirus replicon HIV-1 subtype C gag vaccine in healthy HIV-1-uninfected adults. *Clinical and Vaccine Immunology*. 2012;19(10):1651-60. PMID: PMC3485893.
132. Yu XS, **Gilbert PB**, Hioe CE, Zolla-Pazner S, Self SG. Statistical approaches to analyzing HIV-1 neutralizing antibody assay data. *Statistics in Biopharmaceutical Research*. 2012;4(1):1-13. PMID: PMC3959164.
133. Dai JY, **Gilbert PB**, Hughes JP, Brown ER. Estimating the efficacy of preexposure prophylaxis for HIV prevention among participants with a threshold level of drug concentration. *American Journal of Epidemiology*. 2013;177(3):256-63. PMID: PMC3577049.
134. Duerr A, Huang Y, Buchbinder S, Coombs RW, Sanchez J, del Rio C, Casapia M, Santiago S, Huang Y, **Gilbert PB**, Corey L, Robertson MN. Reply to Richie and Villasante. *Journal of Infectious Diseases*. 2013;207(4):690-2. PMID: PMC4200031.
135. Edlefsen PT, **Gilbert PB**, Roland M. Sieve analysis in HIV-1 vaccine efficacy trials. *Current Opinion in HIV and AIDS*. 2013;8(5):432-6. PMID: PMC3863593.
136. Fong Y, Sebestyen K, Yu X, **Gilbert PB**, Self SG. nCal: an R package for non-linear calibration. *Bioinformatics*. 2013;29(20):2653-4. PMID: PMC3789552.
137. **Gilbert PB**, Shepherd BE*, Hudgens MG. Sensitivity analysis of per-protocol time-to-event treatment efficacy in randomized clinical trials. *Journal of the American Statistical Association*. 2013;108(503):789-800. PMID: PMC3811958.
138. Gottardo R, Bailer RT, Korber BT, Gnanakaran S, Phillips J, Shen X, Tomaras GD, Turk E, Imholte G, Eckler L, Wenschuh H, Zerweck J, Greene K, Gao H, Berman PW, Francis D, Sinangil F, Lee C, Nitayaphan S, Rerks-Ngarm S, Kaewkungwal J, Pitisuttithum P, Tartaglia J, Robb ML, Michael NL, Kim JH, Zolla-Pazner S, Haynes BF, Mascola JR, Self S, **Gilbert PB**, Montefiori DC. Plasma IgG to linear epitopes in the V2 and V3 regions of HIV-1 gp120 correlate with a reduced risk of infection in the RV144 vaccine efficacy trial. *PLoS One*. 2013;8(9):e75665. PMID: PMC3784573.
139. *Hammer SM, Sobieszczyk ME, Janes H, Karuna ST, Mulligan MJ, Grove D, Koblin BA, Buchbinder SP, Keefer MC, Tomaras GD, Frahm N, Hural J, Anude C, Graham BS, Enama ME, Adams E, DeJesus E, Novak RM, Frank I, Bentley C, Ramirez S, Fu R*, Koup RA, Mascola J, Nabel GJ, Montefiori DC, Kublin J, McElrath MJ, Corey L, **Gilbert PB**, on behalf of the HIV Vaccine Trials Network 505 Study Team. Efficacy trial of a DNA/rAd5 HIV-1 preventive vaccine. *New England Journal of Medicine*. 2013;369(22):2083-2092. PMID: PMC4030634.
140. Hertz T, Ahmed H, Friedrich DP, Casimiro DR, Self SG, Corey L, McElrath MJ, Buchbinder S, Horton H, Frahm N, Robertson MN, Graham BS, **Gilbert PB**. HIV-1 Vaccine-induced T-Cell response cluster in epitope hotspots that differ from those induced in natural infection with HIV-1. *PLoS Pathogens*. 2013;9(6):e1003404. PMID: PMC3688560.
141. Huang Y, **Gilbert PB**, Wolfson J*. Design and estimation for evaluating principal surrogate markers in vaccine trials. *Biometrics*. 2013;69(2):301-9. PMID: PMC3713795.
142. Janes H, Friedrich DP, Krambrink A, Smith RJ, Kallas EG, Horton H, Casimiro DR, Carrington M, Geraghty DE, **Gilbert PB**, McElrath MJ, Frahm N. Vaccine-induced gag-specific T cells are associated with reduced viremia after HIV-1 infection. *Journal of Infectious Diseases*. 2013;208(8):1231-9. PMID: PMC3778967.
143. Janes H, **Gilbert PB**, Buchbinder S, Kublin J, Sobieszczyk ME, Hammer SM. In pursuit of an HIV vaccine: designing efficacy trials in the context of partially effective nonvaccine prevention modalities. *AIDS Research and Human Retroviruses*. 2013;29(11):1513-23. PMID: PMC3809388.
144. Juraska MJ*, **Gilbert PB**. Mark-specific hazard ratio model with multivariate continuous marks: an application to vaccine efficacy. *Biometrics*. 2013;69(2):328-37. PMID: PMC3940058.
145. Liu P, Yates NL, Shen X, Bonsignori M, Moody MA, Liao HX, Fong Y, Alam SM, Overman RG, Denny T, Ferrari G, Ochsenbauer C, Kappes JC, Polonis VR, Pitisuttithum P, Kaewkungwal J, Nitayaphan S, Rerks-Ngarm S, Montefiori DC, **Gilbert PB**, Michael NL, Kim JH, Haynes BF, Tomaras GD. Infectious virion capture by HIV-1 gp120-specific IgG from RV144 vaccinees. *Journal of Virology*. 2013;87(14):7828-36. PMID: PMC3700223.

146. Rerks-Ngarm S, Paris RM, Chunsutthiwat S, Prem Sri N, Namwat C, Bowonwatanuwong C, Li SS, Kaewkungkal J, Trichavaroj R, Churikanont N, de Souza MS, Andrews C, Francis D, Adams E, Flores J, Gurunathan S, Tartaglia J, O'Connell RJ, Eamsila C, Nitayaphan S, Ngaui V, Thongcharoen P, Kunasol P, Michael NL, Robb ML, **Gilbert PB**, Kim JH. Extended evaluation of the virologic, immunologic, and clinical course of volunteers who acquired HIV-1 infection in a phase III vaccine trial of ALVAC-HIV and AIDSVAX B/E. *Journal of Infectious Diseases*. 2013;207(8):1195-205. PMID: 22837492.
147. Rolland M, Manochewa S, Swain JV, Lanxon-Cookson EC, Kim M, Westfall DH, Larsen BB, **Gilbert PB**, Mullins JI. HIV-1 conserved-element vaccines: relationship between sequence conservation and replicative capacity. *Journal of Virology*. 2013;87(10):5461-7. PMID: PMC3648173.
148. Sun Y, Li M, **Gilbert PB**. Mark-specific proportional hazards model with multivariate continuous marks and its application to HIV vaccine efficacy trials. *Biostatistics*. 2013;14(1):60-74. PMID: PMC3520499.
149. Tomaras GD, Ferrari G, Shen X, Alam SM, Liao HX, Pollara J, Bonsignori M, Moody MA, Fong Y, Chen X, Poling B, Nicholson CO, Zhang R, Lu X, Parks R, Kaewkungwal J, Nitayaphan S, Pitisuttithum P, Rerks-Ngarm S, **Gilbert PB**, Kim JH, Michael NL, Montefiori DC, Haynes BF. Vaccine-induced plasma IgA specific for the C1 region of the HIV-1 envelope blocks binding and effector function of IgG. *Proceedings of the National Academy of Sciences of the United States of America*. 2013;110(22):9019-24. PMID: PMC3670311.
150. Zolla-Pazner S, deCamp A*, Cardozo T, Karasavvas N, Gottardo R, Williams C, Morris DE, Tomaras G, Rao M, Billings E, Berman P, Shen X, Andrews C, O'Connell RJ, Ngaui V, Nitayaphan S, de Souza M, Korber B, Koup R, Bailer RT, Mascola JR, Pinter A, Montefiori D, Haynes BF, Robb ML, Rerks-Ngarm S, Michael NL, **Gilbert PB**, Kim JH. Analysis of V2 antibody responses induced in vaccinees in the ALVAC/AIDSVAX HIV-1 vaccine efficacy trial. *PLoS One*. 2013;8(1):e53629. PMID: PMD3547933.
151. Bart P, Huang Y, Karuna ST, Chappuis S, Gaillard J, Kocher N, Shen X, Allen MA, Ding S, Hural J, Liao HX, Haynes BF, Graham BS, **Gilbert PB**, McElrath MJ, Montefiori DC, Tomaras GD, Pantaleo G, Frahm N. HIV-specific humoral responses benefit from stronger prime in phase 1b clinical trial. *Journal of Clinical Investigation*. 2014;124(11):4843-56. PMID: PMC4347219.
152. Dai JY, Li SS, **Gilbert PB**. Case-only method for cause-specific hazards models with application to assessing differential vaccine efficacy by viral and host genetics. *Biostatistics*. 2014;15(1):196-203. PMID: PMC3862206.
153. Frey S, Peiperl L, McElrath MJ, Goepfert P, Keefer M, Baden L, Lally M, Blattner B, Harro C, Hammer S, Gorse G, Mayer K, Hural J, Tomaras G, Levy Y, **Gilbert PB**, deCamp A*, Russell N, Elizaga M, Allen M, Corey L. Phase I/II randomized trial of safety and immunogenicity of LIPO-5 alone, ALVAC-HIV (vCP1452) alone, and ALVAC-HIV (vCP1452) prime/LIPO-5 boost in healthy, HIV-1 uninfected adult participants. *Clinical and Vaccine Immunology*. 2014;21(11):1589-99. PMID: PMC4248765.
154. Gabriel EE*, **Gilbert PB**. Evaluating principal surrogate endpoints with time-to-event data accounting for time-varying treatment efficacy. *Biostatistics*. 2014;15(2):251-65. PMID: PMC3944974.
155. Gartland A, Li S, McNevin J, Tomaras GD, Gottardo R, Janes H, Fong Y, Morris D, Geraghty D, Kijak GH, Edlefsen PT, Frahm N, Larsen BB, Tovanabutra S, Sanders-Buell E, deCamp A*, Margaret CA, Ahmed H, Goodridge JP, Chen L, Konopa P, Nariya S, Stoddard JN, Wong K, Zhao H, Deng W, Maust BS, Bose M, Howell S, Bates A, Lazzaro M, O'Sullivan A, Lei E, Bradfield A, Ibitamuno G, Assawadarachai V, O'Connell RJ, deSouza MS, Nitayaphan S, Rerks-Ngarm S, Robb ML, Sidney J, Sette A, Zolla-Pazner S, Montefiori D, McElrath MJ, Mullins JI, Kim JH, **Gilbert PB**, Hertz T. Analysis of HLA A*02 association with vaccine efficacy in the RV144 HIV-1 vaccine trial. *Journal of Virology*. 2014;88(15):8242-55. PMID: PMC4135964.
156. **Gilbert PB****, Gabriel EE***, Miao X, Li X, Su SC, Parrino J, Chan IS. Fold rise in antibody titers by measured by glycoprotein-based enzyme-linked immunosorbent assay is an excellent correlate of protection for a herpes zoster vaccine, demonstrated via the vaccine efficacy curve. *Journal of Infectious Diseases*. 2014;210(10):1573-81. PMID: PMC4215071. **Contributed equally.
156. **Gilbert PB**, Yu X, Rotnitzky A. Optimal auxiliary-covariate-based two-phase sampling design for semiparametric efficient estimation of a mean or mean difference, with application to clinical trials. *Statistics in Medicine*. 2014;33(6):901-17. PMID: PMC4021041.

157. Gray GE, Moodie Z, Metch B, **Gilbert PB**, Bekker LG, Churchyard G, Nchabeleng M, Mlisana K, Laher F, Roux S, Mngadi K, Innes C, Mathebula M, Allen M, McElrath MJ, Robertson M, Kublin J, Corey L, on behalf of the HVTN 503/Phambili study team. Recombinant adenovirus type 5 HIV gag/pol/nef vaccine in South Africa: unblinded, long-term follow-up of the phase 2b HVTN 503/Phambili study. *The Lancet Infectious Diseases*. 2014;14(5):388-96. PMID: PMC4174314.
158. Huang Y, Duerr A, Frahm N, Zhang L, Moodie Z, De Rosa S, McElrath MJ, **Gilbert PB**. Immune-correlates analysis of an HIV-1 vaccine efficacy trial reveals an association of nonspecific interferon-gamma secretion with increased HIV-1 infection risk: A cohort-based modeling study. *PLoS One*. 2014;9(11):e108631. PMID: PMC4219669.
159. Li SS**, **Gilbert PB****, Tomaras GD, Kijak G, Ferrari G, Thomas R, Pyo CW, Zolla-Pazner S, Montefiori D, Liao HX, Nabel G, Pinter A, Evans DT, Gottardo R, Dai JY, Janes H, Morris D, Fong Y, Edlefsen PT, Li F, Frahm N, Alpert MD, Prentice H, Rerks-Ngarm S, Pitisuttithum P, Kaewkungwal J, Nitayaphan S, Robb ML, O'Connell RJ, Haynes BF, Michael NL, Kim JH, McElrath MJ, Geraghty DE. FCGR2C polymorphisms associate with HIV-1 vaccine protection in RV144 trial. *Journal of Clinical Investigation*. 2014;124(9):3879-90. PMID: PMC4151214. **Contributed equally.
160. Richardson A, Hudgens MG, **Gilbert PB**, Fine JP. Nonparametric bounds and sensitivity analysis of treatment effects. *Statistical Science*. 2014;29(4):596-618. PMID: PMC4317325.
161. Scott J*, deCamp A*, Juraska MJ*, Fay MP, **Gilbert PB**. Finite-sample corrected generalized estimating equation of population average treatment effects in stepped wedge cluster randomized trials. *Statistical Methods in Medical Research*. 2014;0962280214552092. PMID: PMC4411204.
162. Talley AK, Healy SA, Finney OC, Murphy SC, Kublin J, Salas CJ, Lundebjerg S, **Gilbert PB**, Van Voorhis WC, Whisler J, Wang R, Ockenhouse CF, Heppner DG, Kappe SH, Duffy PE. Safety and comparability of controlled human *Plasmodium falciparum* infection by mosquito bite in malaria-naïve subjects at a new facility for sporozoite challenge. *PLoS One*. 2014;9(11):e109654. PMID: PMC4236046.
163. Yates NL, Liao HX, Fong Y, deCamp A*, Vandergrift NA, Williams WT, Alam SM, Ferrari G, Yang ZY, Seaton KE, Berman PW, Alpert MD, Evans DT, O'Connell RJ, Francis D, Sinangil F, Lee C, Nitayaphan S, Rerks-Ngarm S, Kaewkungwal J, Pitisuttithum P, Tartaglia J, Pinter A, Zolla-Pazner S, **Gilbert PB**, Nabel GJ, Michael NL, Kim JH, Montefiori DC, Haynes BF, Tomaras GD. Vaccine-induced Env V1-V2 IgG3 correlates with lower HIV-1 infection risk and declines soon after vaccination. *Science Translational Medicine*. 2014;6(228):228ra39. PMID: PMC4116665.
164. Zolla-Pazner S, deCamp A*, **Gilbert PB**, Williams C, Yates NL, Williams WT, Howington R, Fong Y, Morris DE, Soderberg KA, Irene C, Reichman C, Pinter A, Parks R, Pitisuttithum P, Kaewkungwal J, Rerks-Ngarm S, Nitayaphan S, Andrews C, O'Connell RJ, Yang ZY, Nabel GJ, Kim JH, Michael NL, Montefiori DC, Liao HX, Haynes BF, Tomaras GD. Vaccine-induced IgG antibodies to V1V2 regions of multiple HIV-1 subtypes correlate with decreased risk of HIV-1 infection. *PLoS One*. 2014;9(2):e87572. PMID: PMC3913641.
165. Zolla-Pazner S, Edlefsen PT, Rolland M, Kong XP, deCamp A*, Gottardo R, Williams C, Tovanabutra S, Sharpe-Cohen S, Mullins JI, deSouza MS, Karasavvas N, Nitayaphan S, Rerks-Ngarm S, Pitisuttithum P, Kaewkungwal J, O'Connell RJ, Robb ML, Michael NL, Kim JH, **Gilbert PB**. Vaccine-induced human antibodies specific for the third variable region of HIV-1 gp120 impose immune pressure on infecting viruses. *EBioMedicine*. 2014;1(1):37-45. PMID: PMC4293639.
166. Corey L, **Gilbert PB**, Tomaras G, Haynes BF, Pantaleo G, Fauci AS. Immune correlates of vaccine protection against HIV-1 acquisition. *Science Translational Medicine*. 2015;21;7(310):310rv7. PMID: PMC4751141.
167. Edlefsen PT, Rolland M, Hertz T, Tovanabutra S, Gartland AJ, deCamp A*, Magaret CA, Ahmed H, Gottardo R, Juraska MJ*, McCoy C, Larsen BB, Sanders-Buell E, Carrico C, Menis S, Bose M, Team RVS, Arroyo MA, O'Connell RJ, Nitayaphan S, Pitisuttithum P, Kaewkungwal J, Rerks-Ngarm S, Robb ML, Kirys T, Georgiev IS, Kwong PD, Scheffler K, Pond SL, Carlson JM, Michael NL, Schief WR, Mullins JI, Kim JH, **Gilbert PB**. Comprehensive sieve analysis of breakthrough HIV-1 sequences in the RV144 vaccine efficacy trial. *PLoS Computational Biology*. 2015;11(2):e1003973. PMID: PMC4315437.

168. Fong Y, **Gilbert PB**. Calibration weighted estimation of semiparametric transformation models for two-phase sampling. *Statistics in Medicine*. 2015;34(10):1695-707. PMID: PMC4390487.
169. Fuchs JD, Bart PA, Frahm N, Morgan C, **Gilbert PB**, Kochar N, DeRosa S, Tomaras G, Wagner T, Baden L, Koblin B, Roupheal N, Kalams S, Keefer M, Goepfert P, Sobieszczyk M, Mayer K, Swann E, Liao H-X, Haynes B, Graham B, McElrath MJ for the NIAID HIV Vaccine Trials Network. Safety and immunogenicity of a recombinant adenovirus serotype 35-vectored HIV-1 vaccine in adenovirus serotype 5 seronegative and seropositive individuals. *Journal of AIDS and Clinical Research*. 2015;6(5). PMID: PMC4648371.
170. Gabriel EE*, Sachs MC, **Gilbert PB**. Comparing and combining biomarkers as principal surrogates for time-to-event clinical endpoints. *Statistics in Medicine*. 2015;34(3):381-95. PMID: PMC4801510.
171. **Gilbert PB**, Gabriel EE*, Huang Y, Chan ISF. Surrogate endpoint evaluation: Principal surrogate criteria and the Prentice definition. *Journal of Causal Inference*. 2015;3(2):157-175. PMID: PMC4692254.
172. **Gilbert PB**, Sun Y. Inferences on relative failure rates in stratified mark-specific proportional hazards models with missing marks, with application to human immunodeficiency virus vaccine efficacy trials. *Journal of the Royal Statistical Society: Series C (Applied Statistics)*. 2015;64(1):49-73. PMID: PMC4310507.
173. Huang Y, Follmann D, Nason M, Zhang L, Huang Y, Mehrotra D, Moodie Z, Metch B, Janes HE, Keefer M, Churchyard G, Robb M, Fast PE, Duerr A, McElrath MJ, Corey L, Mascola JR, Graham BS, Sobieszczyk M, Kublin J, Robertson M, Hammer SM, Gray GE, Buchbinder S, **Gilbert PB**. Effect of rAd5-vector HIV-1 preventive vaccines on HIV-1 acquisition: a participant-level meta-analysis of randomized trials. *PLoS One*. 2015; 10(9):e0136626. PMID: PMC4558095.
174. Huang Y, Karuna ST, Janes H, Frahm N, Nason M, Edlefsen PT, Kublin JG, Corey L, McElrath MJ, **Gilbert PB**. Use of placebos in Phase 1 preventive HIV vaccine clinical trials. *Vaccine*. 2015;33(6):749-52. PMID: PMC4554766.
175. Janes H, Herbeck JT, Tovanabutra S, Thomas R, Frahm N, Duerr A, Hural J, Corey L, Self SG, Buchbinder S, McElrath MJ, O'Connell RJ, Paris RM, Rerks-Ngarm S, Nitayaphan S, Pitisuttithum P, Kaewkungwal J, Robb ML, Michael NL, Mullins JI, Kim JH, **Gilbert PB**, Rolland M. HIV-1 infections with multiple founders are associated with higher viral loads than infections with single founders. *Nature Medicine*. 2015;21(10):1139-41. PMID: PMC4598284.
176. Lin L, Finak G, Ushey K, Seshadri C, Hawn TR, Frahm N, Scriba TJ, Mahomed H, Hanekom W, Bart P-A, Pantaleo G, Tomaras GD, Rerks-Ngarm S, Kaewkungwal J, Nitayaphan S, Pitisuttithum P, Michael NL, Kim JH, Robb ML, O'Connell RJ, Karasavvas N, **Gilbert PB**, DeRosa S, McElrath MJ, Gottardo R. COMPASS identifies T-cell subsets correlated with clinical outcomes. *Nature Biotechnology*. 2015;33(6):610-16. PMID: PMC4569006.
177. Moodie Z, Metch B, Bekker LG, Churchyard G, Nchabeleng M, Mlisana K, Laher F, Roux S, Mngadi K, Innes C, Mathebula M, Allen M, Bentley C, **Gilbert PB**, Robertson M, Kublin J, Corey L, Gray G. Continued follow-up of Phambili Phase 2b randomized HIV-1 vaccine trial participants supports increased HIV-1 acquisition among vaccinated men. *PLoS One*. 2015;10(9):e0137666. PMID: PMC4569275.
178. Neafsey DE, Juraska MJ*, Bedford T, Benkeser D*, Valim C, Griggs A, Lievens M, Abdulla S, Adjei S, Agbenyega T, Agnandji ST, Aide P, Anderson S, Anson D, Aponte JJ, Asante KP, Ejon P, Birkett AJ, Bruls M, Connolly KM, D'Alessandro U, Dobaño C, Gesase S, Greenwood B, Grimsby J, Tinto H, Hamel MJ, Hoffman I, Kamthunzi S, Kremsner PG, Leach A, Lell B, Lennon NJ, Lusingu J, Marsh K, Martinson F, Molel JT, Moss EL, Njuguna P, Ockenhouse CF, Ragama Oqutu B, Otieno W, Otieno L, Otieno K, Owusu-Agyei S, Park DJ, Pellé K, Robbins D, Russ C, Ryan EM, Sacarial J, Sogoloff B, SorghoH, Tanner M, Theander T, Valea I, Volkman SK, Yu Q, Lapierre D, Birren BW, **Gilbert PB****, Wirth DF**. Genetic diversity and protective efficacy of the RTS,S/AS01 malaria vaccine. *New England Journal of Medicine*. 2015;373(21):2025-2037. PMID: PMC4762279. **Contributed equally.
179. Permar SR, Fong Y, Vandergrift N, Fouda GG, **Gilbert PB**, Parks R, Jaeger FH, Pollara J, Martelli A, Liebl BE, Lloyd K, Yates NL, Overman RG, Shen X, Whitaker K, Chen H, Pritchett J, Solomon E, Friberg E, Marshall DJ, Whitesides JF, Gurley TC, Von Holle T, Martinez DR, Cai F, Kumar A, Xia

- SM, Lu X, Louzao R, Wilkes S, Datta S, Sarzotti-Kelsoe M, Liao HX, Ferrari G, Alam SM, Montefiori DC, Denny TN, Moody MA, Tomaras GD, Gao F, Haynes BF. Maternal HIV-1 envelope-specific antibody responses and reduced risk of perinatal transmission. *The Journal of Clinical Investigation*. 2015;125(7):2702-6. PMID: PMC4613557.
180. Prentice HA, Tomaras GD, Geraghty DE, Apps R, Fong Y, Ehrenberg PK, Rolland M, Kijak GH, Krebs SJ, Nelson W, DeCamp A*, Shen X, Yates NL, Zolla-Pazner S, Nitayaphan S, Rerks-Ngarm S, Kaewkungwal J, Pitisuttithum P, Ferrari G, McElrath MJ, Montefiori DC, Bailer RT, Koup RA, O'Connell RJ, Robb ML, Michael NL, **Gilbert PB**, Kim JH, Thomas R. HLA class II genes modulate vaccine-induced antibody responses to affect HIV-1 acquisition. *Science Translational Medicine*. 2015;7(296):296ra112. PMID: PMC4911012.
181. Vasan S, Rerks-Ngarm S, **Gilbert PB**, Haynes B, Nitayapan S, Pitisuttithum P, Kaewkungwal J, Excler JL, Robb M, Michael N, Kim J, O'Connell R. Letter to the Editor on: The RV144 vaccine regimen was not associated with enhancement of infection. *Human Vaccines & Immunotherapeutics*. 2015;11(4):1036-7. PMID: PMC4514177.
182. Williams WB, Liao HX, Moody MA, Kepler TB, Alam SM, Gao F, Wiehe K, Trama AM, Jones K, Zhang R, Song H, Marshall DJ, Whitesides JF, Sawatzki K, Hua A, Liu P, Tay MZ, Seaton KE, Shen X, Foulger A, Lloyd KE, Parks R, Pollara J, Ferrari G, Yu JS, Vandergrift N, Montefiori DC, Sobieszczyk ME, Hammer S, Karuna S, **Gilbert PB**, Grove D, Grunenberg N, McElrath MJ, Mascola JR, Koup RA, Corey L, Nabel GJ, Morgan C, Churchyard G, Maenza J, Keefer M, Graham BS, Baden LR, Tomaras GD, Haynes BF. Diversion of HIV-1 vaccine-induced immunity by gp41-microbiota cross-reactive antibodies. *Science*. 2015;349(6249):aab1253. PMID: PMC4562404.
183. Boeckh M, **Gilbert PB**. Search continues for a CMV vaccine for transplant recipients. *The Lancet Haematology*. 2016;3(2):e58-9. PMID: 26853642.
184. Churchyard G, Mlisana K, Karuna S, Williamson AL, Williamson C, Morris L, Tomaras G, De Rosa SC, **Gilbert PB**, Gu N, Mkhize N, Hermanus T, Allen M, Pensiero M, Barnett S, Gray G, Bekker LG, Montefiori DC, Kublin J, Corey L and the NIAID-funded HIV Vaccine Trials Network. Sequential immunization with gp140 boosts immune responses primed by Modified Vaccinia Ankara or DNA in HIV-uninfected South African participants. *PLoS One*. 2016;11(9):e0161753. PMID: PMC5008759.
185. Fiore-Gartland A, Manso BA, Friedrich DP, Gabriel EE*, Finak G, Moodie Z, Hertz T, De Rosa SC, Frahm N, **Gilbert PB**, McElrath MJ. Pooled-peptide epitope mapping strategies are efficient and highly sensitive: an evaluation of methods for identifying human T cell epitope specificities in large-scale HIV vaccine efficacy trials. *PLoS One*. 2016;11(2):e0147812. PMID: PMC4749288.
186. Fong Y, Di C, Huang Y, **Gilbert PB**. Model-robust inference for continuous change point models. *Biometrics*. 2017;73(2):452-62. Epub 2016/11/20. doi: 10.1111/biom.12623. PubMed PMID: 27858965; PMID: PMC5435560.
187. **Gilbert PB**, Huang Y. Predicting overall vaccine efficacy in a new setting by re-calibrating baseline covariate and intermediate response endpoint effect modifiers of type-specific vaccine efficacy. *Epidemiologic Methods*. 2016 Dec;5(1). Epub 2016 Jan 23. PMID: 28154793; PMID: PMC5279575.
188. **Gilbert PB**, Huang Y, Janes HE. Modeling HIV vaccine trials of the future. *Current Opinion in HIV&AIDS*. 2016; 11(6):620-627. PMID: PMC5077275.
189. **Gilbert PB**, Janes HE, Huang Y. Power/sample size calculations for assessing correlates of risk in clinical efficacy trials. *Statistics in Medicine*. 2016;35(21):45-59. PMID: PMC4965346.
190. Hanscom B, Janes H, Guarino P, Huang Y, Brown E, Chen YQ, Hammer S, **Gilbert PB**, Donnell D. Preventing HIV-1 infection in women using oral Pre-Exposure Prophylaxis: A Meta-analysis of current evidence. *Journal of Acquired Immune Deficiency Syndromes*. 2016;83(5):606-608. PMID: PMC5175411.
191. Hertz T, Logan MG, Rolland M, Magaret CA, Rademeyer C, Fiore-Gartland A, Edlefsen PT, DeCamp A*, Ahmed H, Ngandu N, Larsen BB, Frahm N, Marais J, Thebus R, Geraghty D, Hural J, Corey L, Kublin J, Gray G, McElrath MJ, Mullin JI, **Gilbert PB**, Williamson C. A study of vaccine-induced immune pressure on breakthrough infections in the Phambili Phase 2b HIV-1 vaccine efficacy trial. *Vaccine*. 2016;34(47):5792-5801. PMID: 27756485.

192. Huang Y, DiazGranados C, Janes H, Huang Y, deCamp A*, Metch B, Grant S, Sanchez B, Phogat S, Koutsoukos M, Kanesa-Thanan N, Bourguignon P, Collard A, Buchbinder S, Tomaras GD, McElrath MJ, Kublin J, Corey L, **Gilbert PB**. Selection of HIV vaccine candidates for concurrent testing in an efficacy trial. *Current Opinion in Virology*. 2016;17:57-65. PMID: PMC4902743.
193. Huang Y, **Gilbert PB**, Fu R*, Janes HE. Statistical methods for down-selection of treatment regimens based on multiple endpoints, with application to HIV vaccine trials. *Biostatistics*. 2016. PMID: 27649715. *Published ahead of print*.
194. Juraska MJ*, **Gilbert PB**. Mark-specific hazard ratio model with missing multivariate marks. *Lifetime Data Analysis*. 2016;22(4):606-25. PMID: PMC4848257.
195. Peng X, Li SS, **Gilbert PB**, Geraghty DE, Katze MG. *FCGR2C* polymorphisms associated with HIV-1 vaccine protection are linked to altered expression of Fc- γ receptors in human B cells. *PLoS One*. 2016;11(3):e0152425. PMID: PMC4807760.
196. Sun Y, Li M, **Gilbert PB**. Goodness-of-fit test of the stratified mark-specific proportional hazards model with continuous mark. *Computational Statistics and Data Analysis*. 2016;93:348-358. PMID: PMC4598956.
197. Qi L, Sun Y, **Gilbert PB**. Generalized semiparametric varying-coefficient model for longitudinal data with applications to adaptive treatment randomizations. *Biometrics*. 2017;73(2):441-451. PMID: PMC5459686.
198. Sun Y, Qian X, Shou Q, **Gilbert PB**. Analysis of two-phase sampling data with semiparametric additive hazards models. *Lifetime Data Analysis*. 2017;23:377-399 PMID: 26995733.
199. Yang G, Sun Y, Qi L, **Gilbert PB**. Estimation of stratified mark-specific proportional hazards models under two-phase sampling with application to HIV vaccine efficacy trials. *Statistics in Biosciences*. 2017; 9(1):259-283.
200. Fu R*, **Gilbert PB**. Joint modeling of longitudinal and survival data with the Cox model and two-phase sampling. *Lifetime Data Analysis*. 2017;23(1):136-159. PMID: PMC5035179.
201. Huang Y, Zhang L, Janes H, Frahm N, Isaac A, Kim J, Montefiori D, McElrath MJ, Tomaras GD, **Gilbert PB**. Predictors of durable immune responses six months after the last vaccinations in preventative HIV vaccine trials. *Vaccine*. 2017;35(8):1184-93. PMID: 28131393.
202. Huang Y, Zhang L, Ledgerwood J, Gruneberg N, Bailer R, Isaacs A, Seaton K, Mayer KH, Capparelli E, Corey L, **Gilbert PB**. Population pharmacokinetics analysis of VRC01, a broadly neutralizing HIV-1 monoclonal antibody, in healthy adults. *mAbs*. 2017 Apr3;1-9. PMID: 28368743
203. **Gilbert PB**, Excler JL, Tomaras GD, Carpp LN, Haynes BF, Liao HX, Montefiori DC, Rerks-Ngarm S, Pitisuttithum P, Nitayaphan S, Kaewkungwal J, Tovanabutra S, Francis DP, Lee C, Sinangil F, Berman PW, Prensri N, Kunasol P, O'Connell RJ, Michael NL, Robb ML. Antibody to HSV gD peptide induced by vaccination does not protect against HSV-2 infection in HSV-2 seronegative women. *PLoS One*. 2017 May 11;12(5). PMID: PMC5426618
204. Perez LG, Martinez DR, deCamp A*, Pinter A, Berman PW, Francis D, Sinangil F, Lee C, Greene K, Gao H, Nitayaphan S, Rerks-Ngarm S, Kaewkungwal J, Pitisuttithum P, Tartaglia J, O'Connell RJ, Robb ML, Michael NL, Kim JH, **Gilbert PB**, Montefiori DC. V1V2-Specific Complement Activating Serum IgG as a Correlate of Reduced HIV-1 Infection Risk in RV144. *PLoS One*. 2017 Jul 5;12(7). PMID: 28678869.
205. Fiore-Gartland A, Kullman N, deCamp A*, Clenaghan G, Yang W, Margaret CA, Edlefsen PT, **Gilbert PB**. SieveSifter: a web-based tool for visualizing the sieve analyses of HIV-1 vaccine efficacy trials. *Bioinformatics*. 2017 Apr 4;bt168. PMID: 28379332; PMID: PMC5860116.
206. Janes HE, Cohen KW, Frahm N, DeRosa SC, Sanchez B, Hural J, Margaret CA, Karuna S, Bentley C, Gottardo R, Finak G, Grove D, Shen M, Graham BS, Koup RA, Mulligan MJ, Koblin B, Buchbinder SP, Keefer MC, Adams E, Anude C, Corey L, Sobieszczyk M, Hammer SM, **Gilbert PB**, McElrath MJ. Higher T cell responses induced by DNA/rAd5 HIV-1 preventive vaccine are associated with lower HIV-1 infection risk in an efficacy trial. *Journal of Infectious Diseases*. 2017 May 1;215(9):1376–1385. doi: 10.1093/infdis/jix086. PMID: 28199679; PMID: PMC5853653.
207. **Gilbert PB**, Juraska MJ*, deCamp A*, Karuna S, Edupuganti S, Mgodini N, Donnell D, Bentley C, Sista N, Andrew P, Isaacs A, Huang Y, Zhang L, Capparelli E, Kochar N, Wang J, Eshleman S, Mayer K,

- Magaret C, Hural J, Kublin J, Gray G, Montefiori D, Gomez M, Burns D, McElrath MJ, Ledgerwood J, Graham B, Mascola J, Cohen M, Corey L. Basis and statistical design of the passive HIV-1 Antibody Mediated Prevention (AMP) test-of-concept efficacy trials. *Statistical Communications in Infectious Diseases*. 2017;9(1). doi: 10.1515/scid-2016-0001. PMID: 29218117; PMCID: PMC5714515.
208. deCamp A*, Rolland M, Edlefsen P, Sanders-Buell E, Hall B, Magaret CA, Fiore-Gartland AJ, Juraska MJ*, Carpp LN, Karuna ST, Bose M, LePore S, Miller S, O'Sullivan A, Poltavee K, Bai H, Dommaraju K, Zhao H, Wong K, Chen L, Ahmed H, Gottardo R, Koup RA, Bailer R, Mascola JR, Graham BS, Roederer M, O'Connell RJ, Michael NL, Robb ML, Adams E, D'Souza P, Kublin J, Corey L, Geraghty DE, Frahm N, Tomaras GD, McElrath MJ, Frenkel L, Strychak S, Tovanabutra S, Sobieszczyk M, Hammer SM, Kim JH, Mullins JI, **Gilbert PB**. Sieve analysis of breakthrough HIV-1 sequences in HVTN 505 identifies vaccine pressure targeting the CD4 binding site of Env-gp120. *PLoS One* 2017 Nov 17;12(11):e0185959. doi: 10.1371/journal.pone.0185959. PMID: 29149197; PMCID: PMC5693417.
209. Fong Y, Huang Y, **Gilbert PB**, Permar S. chngpt: Threshold regression model estimation and inference. *BMC Bioinformatics* 2017; 18:454. doi: 10.1186/s12859-017-1863-x. PMID: 29037149; PMCID: PMC5644082.
210. Buchbinder S, Grunenberg N, Sanchez B, Seaton K, Ferrari G, Moody A, Frahm N, Montefiori D, Hay C, Goepfert P, Baden L, Robinson H, Yu X, **Gilbert PB**, McElrath MJ, Huang Y, Tomaras G. Immunogenicity of a novel clade B HIV-1 vaccine combination: Results of Phase 1 randomized placebo controlled trial of an HIV-1 GM-CSF-expressing DNA prime with a Modified Vaccinia Ankara vaccine boost in healthy HIV-1 uninfected adults. *PLoS One*. 2017 Jul 20;12(7):e0179597. doi: 10.1371/journal.pone.0179597. PMID: 28727817; PMCID: PMC5519050.
211. Aiyegbo MS, Shmelkov E, Dominguez L, Goger M, Battacharya S, **Gilbert PB**, Berman PW, Cardozo T. Peptide Targeted by Human Antibodies Associated with HIV Vaccine-Associated Protection Assumes a Dynamic α -Helical Structure. *PloS one*. 2017 Jan 20;12(1):e0170530. doi: 10.1371/journal.pone.0170530. PMID: 28107435; PMCID: PMC5249078.
212. Benkeser D*, Carone M, van der Laan MJ, **Gilbert PB**. Doubly robust nonparametric inference on the average treatment effect. *Biometrika*, Volume 104, Issue 4, 1 December 2017, Pages 863–880, doi: 10.1093/biomet/asx053. Epub 2017 Oct 16. PMID: 29430041; PMCID: PMC5793673.
213. Li S, Kochar N, Elizaga M, Hay C, Wilson G, Cohen K, De Rosa S, Xu R, Ota-Selik A, Morris D, Finak G, Allen M, Tieu H, Frank I, Sobieszczyk, Hannaman D, Gottardo R, **Gilbert PB**, Tomaras GD, Corey L, Clarke DK, Egan MA, Eldridge JH, McElrath MJ, Frahm N, NIAID HIV Vaccine Trials Network. DNA priming increases frequency of T-cell responses to a VSV HIV vaccine with specific enhancement of CD8⁺ T-cell responses by IL-12 pDNA. *Clinical and Vaccine Immunology* 2017 Nov 6;24(11). pii: e00263-17. doi: 10.1128/CVI.00263-17. PMID: 28931520; PMCID: PMC5674193.
214. Yu T, Wu L, **Gilbert PB**. A joint model for mixed and truncated longitudinal data and survival data, with application to HIV vaccine studies. *Biostatistics*. 2017 Jul 1;19(3):374-390. doi: 10.1093/biostatistics/kxx047. PMID: 29028943; PMCID: PMC6193623.
215. Moodie Z, Juraska MJ*, Huang Y, Zhuang Y*, Fong Y, Carpp LN, Self SG, Chambonneau L, Small R, Jackson N, Noriega F, **Gilbert PB**. Neutralizing antibody correlates analysis of tetravalent dengue vaccine efficacy trials in Asia and Latin America. *Journal of Infectious Diseases*. 2018 Feb 14;217(5):742-753. doi: 10.1093/infdis/jix609. PMID: 29194547; PMCID: PMC5854020.
216. Fong Y**, Shen X**, Ashley VC, Deal A, Seaton KE, Yu C, Grant SP, Ferrari G, deCamp A*, Bailer RT, Koup RA, Montefiori D, Haynes BF, Sarzotti-Kelsoe M, Graham BS, Carpp LN, Hammer SM, Sobieszczyk M, Karuna S, Swann E, DeJesus E, Mulligan M, Frank I, Buchbinder S, Novak RM, McElrath MJ, Kalams S, Keefer M, Frahm NA, Janes HE, **Gilbert PB****, Tomaras GD**. Modification of the Association Between T-Cell Immune Responses and Human Immunodeficiency Virus Type 1 Infection Risk by Vaccine-Induced Antibody Responses in the HVTN 505 Trial. *J Infect Dis*. 2018 Mar 28;217(8):1280-1288. doi: 10.1093/infdis/jiy008. PMID: 29325070; PMCID: PMC6018910.
**Contributed equally.
217. De Montigny S***, Adamson B, Masse B, Garrison LP, Kublin JG, **Gilbert PB**, Dimitriv D. Projected effectiveness and added value of HIV vaccination campaigns in South Africa: A modeling study.

Scientific Reports 2018; 8(1). doi: 10.1038/s41598-018-24268-4. PMID: 29666455; PMCID: PMC5904131.

***Winner, HVTN 2019 Bonnie Mathieson Young Investigator Award

218. Lee U, Sun Y, Scheike T, **Gilbert PB**. Analysis of generalized semiparametric regression models for cumulative incidence functions with missing covariates. *Computational Statistics & Data Analysis*. 2018;122, 59-79. doi: 10.1016/j.csda.2018.01.003. Epub 2018 Feb 2. PMID: 29892140; PMCID: PMC5993453.
219. Benkeser D*, Carone M, **Gilbert PB**. Improved estimation of the cumulative incidence of rare outcomes. *Statistics in Medicine*. 2018 Jan 30; 37(2): 280–293. doi: 10.1002/sim.7337. Epub 2017 Jul 2. PMID: 28670687; PMCID: PMC5735003.
220. Janes H, Corey L, Ramjee G, Carpp LN, Lombard C, Cohen MS, Gilbert PB, Gray GE. Weighing the Evidence of Efficacy of Oral PrEP for HIV Prevention in Women in Southern Africa. *AIDS Res Hum Retroviruses*. 2018 Aug;34(8):645-656. doi: 10.1089/AID.2018.0031. Epub 2018 Jun 19. PMID: 29732896; PMCID: PMC6080090.
221. Bekker LG, Moodie Z, Grunenberg N, Laher F, Tomaras GD, Cohen KW, Allen M, Malahleha M, Mngadi K, Daniels B, Innes C, Bentley C, Frahm N, Morris DE, Morris L, Mkhize NN, Montefior DCi, Sarzotti-Kelsoe M, Grant S, Yu C, Mehra VL, Pensiero MN, Phogat S, DiazGranados CA, Barnett SW, Kanesa-athan N, Koutsoukos M, Michael NL, Robb ML, Kublin JG, **Gilbert PB**, Corey L, Gray GE, McElrath MJ. Subtype C ALVAC-HIV and bivalent subtype C gp120/MF59 HIV-1 vaccine in low-risk, HIV-uninfected, South African adults: a phase 1/2 trial. *The Lancet HIV* 2018 5(7): e366-e378. doi: 10.1016/S2352-3018(18)30071-7. Epub 2018 Jun 18. PMID: 29898870; PMCID: PMC6028742.
222. Sridhar S, Luedtke A, Langevin E, Zhu M, Bonaparte M, Machabert T, Savarino S, Zambrano B, Moureau A, Khromava A, Moodie Z, Westling T, Mascarenas C, Frago C, Cortes M, Chansinghakul D, Noriega F, Bouckennooghe A, Chen J, Ng S-P, **Gilbert PB**, Gurunathan S, DiazGranados CA. Effect of Dengue Serostatus on Dengue Vaccine Safety and Efficacy. *New England Journal of Medicine*. 2018 Jul 26;379(4):327-340. doi: 10.1056/NEJMoa1800820. Epub 2018 Jun 13. PMID: 29897841.
223. Huang Y, Karuna S, Carpp LN, Reeves D, Pegu A, Seaton K, Mayer K, Schiffer J, Mascola J, **Gilbert PB**. Modeling Cumulative Overall Prevention Efficacy for the VRC01 Phase 2b Efficacy Trials. *Human Vaccines and Immunotherapeutics*. 2018 Apr 23:1-12. doi: 10.1080/21645515.2018.1462640. PMID: 29683765; PMCID: PMC6183277.
224. Price BL*, **Gilbert PB**, van der Laan MJ. Estimation of the optimal surrogate based on a randomized trial. *Biometrics*. 2018 74(4), 1271-1281. doi: 10.1111/biom.12879. Epub 2018 Apr 27. PMID: 29701875; PMCID: PMC6393111.
225. **Gilbert PB**, Luedtke AR. Statistical Learning Methods to Determine Immune Correlates of Herpes Zoster in Vaccine Efficacy Trials. *Journal of Infectious Diseases*. 2018;218(S2):S99–101. doi: 10.1093/infdis/jiy421. PMID: 30247601; PMCID: PMC6151089.
226. Sun Y, Qi L, Yang GR, **Gilbert PB**. Hypothesis tests for stratified mark-specific proportional hazards models with missing covariates, with application to HIV vaccine efficacy trials. *Biometrical Journal*. 2018 May;60(3):516-536. doi: 10.1002/bimj.201700002. Epub 2018 Feb 28. PMID: 29488249; PMCID: PMC6447062.
227. Juraska MJ*, Magaret CA, Shao J, Carpp LN, Fiore-Gartland AJ, Benkeser D*, Girerd-Chambaz Y, Langevin E, Frago C, Guy B, Edlefsen PT, **Gilbert PB**. Viral genetic diversity and protective efficacy of a tetravalent dengue vaccine in a Phase 3 trial in Asia. *Proceedings of the National Academy of Sciences of the United States of America*. 2018;115(36):E8378-E8387. doi: 10.1073/pnas.1714250115. Epub 2018 Aug 20. PMID: 30127007; PMCID: PMC6130398.
228. Yu T, Wu L, **Gilbert PB**. New approaches for censored longitudinal data in joint modelling of longitudinal and survival data, with application to HIV vaccine studies. *Lifetime Data Analysis*. 2018 Jun 8. doi: 10.1007/s10985-018-9434-7. PMID: 29948579; PMCID: PMC6286694.
229. Juraska MJ*, Huang Y, **Gilbert PB**. Inference on treatment effect modification by biomarker response in a three-phase sampling design. *Biostatistics*. 2018; doi:10.1093/biostatistics/kxy074. PMID: 30590450; PMCID: PMC7308066.

230. Qiu Z, Wan A, Zhou Y, **Gilbert PB**. Smoothed rank regression for the accelerated failure time competing risks model with missing cause of failure. *Statistica Sinica*. 2019 29;23-46. doi: 10.5705/ss.202016.0231. PMID: 30740005; PMCID: PMC6364751.
231. Pasin C, Halloran ME, **Gilbert PB**, Langevin E, Ochiai R, Pitisuttithum P, Capeding R, Carrasquilla G, Frago C; Cortés M, Chambonneau L, Moodie Z. Periods of high dengue transmission defined by rainfall do not impact efficacy of dengue vaccine in regions of endemic disease. *PLoS One*. 2018 Dec 13;13(12):e0207878. doi: 10.1371/journal.pone.0207878. eCollection 2018. PMID: 30543657; PMCID: PMC6292612.
232. Westling T, Juraska MJ*, Seaton K, Tomaras GD, **Gilbert PB**, Janes HE. Methods for comparing durability of immune responses between vaccine regimens in early-phase trials. *Statistical Methods in Medical Research*. 2019 Jan 9;962280218820881. doi: 10.1177/0962280218820881. PMID: 30623732; PMCID: PMC6682462.
233. Magaret CA**, Benkeser D*,**, Williamson BD**, Borate BR, Carpp LN, Georgiev IS, Setliff I, Dingens AS, Simon N, Carone M, Simpkins C, Montefiori DC, Alter G, Yu W-H, Juraska MJ*, Edlefsen PT, Karuna S, Mgodini NM, Edupuganti S, **Gilbert PB**. Prediction of VRC01 neutralization sensitivity by HIV-1 gp160 sequence features. *PLoS Computational Biology*. 2019 Apr 1;15(4):e1006952. doi: 10.1371/journal.pcbi.1006952. PMID: 30933973; PMCID: PMC6459550. **Contributed equally
234. Donovan K, Hudgens M, **Gilbert PB**. Nonparametric inference for immune response thresholds of risk in vaccine studies. *Annals of Applied Statistics*. 2019 13(2):1147–1165. doi: 10.1214/18-AOAS1237. Epub 2019 Jun 17. PMID: 31285781; PMCID: PMC6613658.
235. Janes HE, Donnell D, **Gilbert PB**, Brown ER, Nason M. Taking stock of the present and looking to the future: Envisioning challenges in the design of future HIV prevention efficacy trials. *Lancet HIV*. 2019 Jul;6(7):e475-e482. doi: 10.1016/S2352-3018(19)30133-X. Epub 2019 May 8. PMID: 31078451; PMCID: PMC6612578.
236. Zhuang Y*, Huang Y, **Gilbert PB**. Simultaneous inference of treatment effect modification by intermediate response endpoint principal strata with application to vaccine trials. *International Journal of Biostatistics*. 2019 Jul 2;16(1):/ijb.2020.16.issue-1/ijb-2018-0058/ijb-2018-0058.xml. doi: 10.1515/ijb-2018-0058. PMID: 31265429; PMCID: PMC6939148.
237. Benkeser D*, **Gilbert PB**, Carone M. Estimating and testing vaccine sieve effects using machine learning. *Journal of the American Statistical Association*. 2019 Jul 3;114(527):1038-1049. doi: 10.1080/01621459.2018.1529594. Epub 2019 Apr 3. PMID: 31649413; PMCID: PMC6812562.
238. Fourati S, Ribeiro SP, Tavares FB, Lopes P, Talla A, Lefebvre F, Cameron M, Kaewkungwal J, Pitisuttithum P, Nitayaphan S, Rerks-Ngarm S, Kim JH, Thomas R, **Gilbert PB**, Tomaras GD, Koup RA, Michael NL, McElrath JM, Gottardo R, Sékaly R-P. Integrated systems approach defines the antiviral mechanism conferring protection by the RV144 HIV vaccine. *Nature Communications*. 2019 Feb 20;10(1):863. doi: 10.1038/s41467-019-08854-2. PMID: 30787294; PMCID: PMC6382801.
239. Sun Y, Fei H, Qi L, **Gilbert PB**. Analysis of generalized semiparametric mixed varying-coefficient effects models for longitudinal data. *Canadian Journal of Statistics*. 2019 Sep;47(3):352-73. doi: 10.1002/cjs.11498. Epub 2019 May 1. PMID: 31827312; PMCID: PMC6905629.
240. Li SS, Gilbert PB, Carpp LN, Pyo C-W, Janes H, Fong Y, Shen X, Neidich SD, Goodman D, deCamp A*, Cohen KW, Ferrari G, Hammer SM, Sobieszczyk ME, Mulligan MJ, Buchbinder SP, Keefer MC, DeJesus E, Novak RM, Frank I, McElrath MJ, Tomaras GD, Geraghty DE, Peng X. Fc gamma receptor polymorphisms modulated the vaccine effect on HIV-1 risk in the HVTN 505 HIV vaccine trial. *Journal of Virology*. 2019. 93:e02041-18. doi: 10.1128/JVI.02041-18. PMID: 31434737; PMCID: PMC6803257.
241. **Gilbert PB**, Fong Y, Carpp LN, Monto AS, Martin ET, Petrie JG. HAI and NAI titer correlates of inactivated and live attenuated influenza vaccine efficacy. *BMC Infectious Diseases*. 2019 May 22;19(1):453. doi: 10.1186/s12879-019-4049-5. PMID: 31117986; PMCID: PMC6530189.
242. Pegu A, Borate B, Huang Y, Pauthner MG, Hessel AJ, Julg B, Doria-Rose NA, Schmidt SD, Carpp LN, Cully MD, Chen X, Shaw GM, Barouch DH, Haigwood NL, Corey L, Burton DR, Roederer M, **Gilbert PB**, Mascola JR, Huang Y. A Meta-analysis of passive immunization studies shows that serum-neutralizing antibody titer associates with protection against SHIV challenge. *Cell Host & Microbe*. 2019 Sep 11;26(3):336-46. doi: 10.1016/j.chom.2019.08.014. PMID: 31513771; PMCID: PMC6755677.

243. Pantaleo G, Janes H, Karuna S, Grant S, Quedraogo L, Allen M, Tomaras GD, Frahm N, Montefiori DC, Ferrari G, Ding S, Lee C, Robb ML, Esteban M, Wagner R, Bart P-A, Rettby N, McElrath MJ, **Gilbert PB**, Kublin JG, Corey L. Co-administration of HIV Env protein with DNA and/or NYVAC vaccines results in earlier and potent generation of anti-Env antibody responses. *The Lancet HIV* 2019 Nov;6(11):e737-e749. [https://doi.org/10.1016/S2352-3018\(19\)30262-0](https://doi.org/10.1016/S2352-3018(19)30262-0) PMID: 31601541
244. Zolla-Pazner S, **Gilbert PB**. Revisiting the correlate of reduced HIV infection risk in the RV144 vaccine trial. *Journal of Virology*. 2019 Sep 1;93(17):10-128. doi: 10.1128/JVI.00629-19. PMID: 31189712; PMCID: PMC6694814.
245. Pantaleo G, Janes H, Karuna S, Grant S, Ouedraogo GL, Allen M, Tomaras GD, Frahm N, Montefiori DC, Ferrari G, Ding S, Lee C, Robb ML, Esteban M, Wagner R, Bart P-A, Rettby N, McElrath JM, **Gilbert PB**, Kublin J, Corey L, NIAID HIV Vaccine Trials Network. 2019. Safety and immunogenicity of a multivalent HIV vaccine comprising envelope protein with either DNA or NYVAC vectors (HVTN 096): a phase 1b, double-blind, placebo-controlled trial. *The Lancet HIV*. 2019. 6(11), pp.e737-e749. doi: 10.1016/S2352-3018(20)30002-3. PMID: 31601541; PMCID: PMC7156919.
246. **Gilbert PB**, Huang Y, Juraska MJ*, Moodie Z, Fong Y, Luedtke AR, Zhuang Y*, Shao J, Carpp LN, Jackson N, Chambonneau L, Bouckennooghe A, Zambrano B, Frago C, Pallardy S, Noriega F. Bridging efficacy of a tetravalent dengue vaccine from children/adolescents to adults in high endemic countries based on neutralizing antibody response. *American Journal of Tropical Medicine & Hygiene*. 2019 Jul;101(1):164. doi: 10.4269/ajtmh.18-0534. PMID: 31115304; PMCID: PMC6609170.
247. **Gilbert PB**, Zhang L, Rudnicki E, Huang Y. Assessing pharmacokinetic marker correlates of outcome, with application to antibody prevention efficacy trials. *Statistics in Medicine*. 2019;38(23):4503-4518. doi: 10.1002/sim.8310. Epub 2019 Jul 17. PMID: 31313349; PMCID: PMC6736712.
248. Rossenkhon R, Rolland M, Labuschagne JPL, Ferreira R-C, Magaret CA, Carpp LN, Matsen IV FA, Huang Y, Rudnicki EE, Zhang Y, Ndabambi N, Logan M, Holzman T, Abrahams M-R, Anthony C, Tovanabutra S, Warth C, Botha G, Matten D, Nitayaphan S, Kibuuka H, Sawe FK, Chopera D, Eller LA, Travers S, Robb ML, Williamson C, **Gilbert PB**, Edlefsen PT. Combining viral genetics and statistical modeling to improve HIV-1 time-of-infection estimation towards enhanced vaccine efficacy assessment. *Viruses*. 2019;11(7):607. doi: 10.3390/v11070607. PMID: 31277299; PMCID: PMC6669737.
249. Neidich SD, Fong Y, Li S, Geraghty D, Williamson BD, Young WC, Goodman D, Seaton KE, Shen X, Sawant S, Zhang L, deCamp A*, Blette BS, Shao M, Yates NL, Feely F, Pyo C-W, Ferrari G, Frank I, Karuna ST, Swann E, Mascola JM, Graham BS, Hammer SM, Sobieszczyk M, Corey L, Janes HE, McElrath MJ, Gottardo R, **Gilbert PB**, Tomaras GD. Antibody Fc effector functions and IgG3 associate with decreased HIV-1 risk. *Journal of Clinical Investigation*. 2019;10-1172. doi: 10.1172/JCI126391. PMID: 31589165; PMCID: PMC6819135.
250. **Gilbert PB**. Ongoing vaccine and monoclonal antibody HIV prevention efficacy trials and considerations for sequel efficacy trial design. *Statistical Communications in Infectious Diseases*. 2019 Jun 20;11(1). doi: 10.1515/scid-2019-0003. Epub 2019 Jul 27. PMID: 33312415; PMCID: PMC7731930.
251. Kallas EG, Grunenberg NA, Yu C, Manso B, Pantaleo G, Casapia M, Baden LR, Valencia J, Sobieszczyk M, Tieu HV, Allen M, Hural J, Graham BS, Kublin J, **Gilbert PB**, Corey L, Goepfert PA, McElrath MJ, Johnson RP, Huang Y, Frahm N. Antigenic competition in CD4+ T cell responses in a randomized, multicenter, double-blind clinical HIV vaccine trial. *Science Translational Medicine*. 11, eaaw1673. 2019. Nov 20;11(519):eaaw1673. doi: 10.1126/scitranslmed.aaw1673. PMID: 31748227; PMCID: PMC7003991.
252. Ditse Z, Mkhize N, Yin M, Keefer M, Montefiori DC, Tomaras GD, Churchyard G, Mayer KH, Karuna S, Morgan C, Bekker L-G, Mlisana K, Gray G, Moodie Z, **Gilbert PB**, Moore PL, Williamson C, Morris L and the HIV Vaccine Trials Network. Effect of HIV envelope vaccination on the subsequent antibody response to HIV infection. *mSphere*. 2020;5:1 e00738-19. doi: 10.1128/mSphere.00738-19. PMID: 31996422; PMCID: PMC6992371.
253. Shen X, Laher F, Moodie Z, McMillan AS, Spreng RL, **Gilbert PB**, Huang Y, Yates NL, Grunenberg N, McElrath MJ, Allen M, Pensiero M, Mehra VL, Van Der Meeren O, Barnett SW, Phogat S, Gray GE, Bekker L-G, Corey L, Tomaras GD and the HVTN 097 and HVTN 100 Teams. HIV-1 Vaccine

- Sequences Impact V1V2 Antibody Responses: A Comparison of Two Poxvirus Prime gp120 Boost Vaccine Regimens. *Scientific Reports*. 2020. Feb 7;10(1):2093. doi: 10.1038/s41598-020-57491-z. PMID: 32034163; PMCID: PMC7005751.
254. Laher F, Moodie Z, Cohen KW, Grunenberg N, Bekker LG, Allen M, Frahm N, Yates NL, Morris L, Malahleha M, Mngadi K, Daniels B, Innes C, Saunders K, Grant S, Yu C, **Gilbert PB**, Phogat S, DiazGranados CA, Koutsoukos M, Van Der Meeren O, Bentley C, Mkhize NN, Pensiero MN, Mehra VL, Kublin JG, Corey L, Montefiori DC, Gray GE, McElrath MJ, Tomaras GD. Safety and immune responses after a 12-month booster in healthy HIV-uninfected adults in HVTN 100 in South Africa: A randomized double-blind placebo-controlled trial of ALVAC-HIV (vCP2438) and bivalent subtype C gp120/MF59 vaccines. *PLoS Medicine*. 2020 Feb 24;17(2):e1003038. doi: 10.1371/journal.pmed.1003038. PMID: 32092060; PMCID: PMC7039414.
255. Gray GE, Huang Y, Grunenberg N, Laher F, Roux S, Anderson-Nissen E, De Rosa SC, Flach B, Jensen RL, Swann EM, Innes C, Lazarus E, Morris L, Mkhize NN, Ferrari G, Montefiori DC, Hural J, Isaacs A, Phogat S, DiazGranados CA, Lee C, Sinangil F, Michael NL, Robb ML, Kublin JG, **Gilbert PB**, McElrath MJ, Tomaras GD, Corey L. Immune correlates of the Thai RV144 HIV vaccine regimen in South Africa. *Science Translational Medicine*. 2019 Sep 18;11(510):eaax1880. PMID: 31534016; PMCID: PMC7199879.
256. Fisher L, Zinter M, Stanfield-Oakley S, Carpp LN, Edwards RW, Denny T, Moodie Z, Laher F, Bekker LG, McElrath MJ, **Gilbert PB**. Vaccine-Induced Antibodies Mediate Higher Antibody-Dependent Cellular Cytotoxicity After Interleukin-15 Pretreatment of Natural Killer Effector Cells. *Frontiers in Immunology*. 2019 Nov 27;10:2741. PMID: 31827470; PMCID: PMC6890556.
257. Zhao LP, Fiore-Gartland A, Carpp LN, Cohen KW, Rouphael N, Fleurs L, Dintwe O, Zhao M, Moodie Z, Fong Y, Garrett N, Huang Y, Innes C, Janes HE, Lazarus E, Michael NL, Nitayaphan S, Pitisuttithum P, Rerks-Ngarm S, Robb ML, De Rosa SC, Corey L, Gray GE, Seaton KE, Yates NL, McElrath MJ, Frahm N, Tomaras GD, **Gilbert PB**. Landscapes of binding antibody and T-cell responses to pox-protein HIV vaccines in Thais and South Africans. *PloS One*. 2020 Jan 30;15(1):e0226803. doi: 10.1371/journal.pone.0226803. PMID: 31999736; PMCID: PMC6992005.
258. Huang Y, Zhang Y, Bailer R, Grunenberg N, Carpp LN, Seaton K, Mayer KH, Ledgerwood J, Corey L, Mascola J, Montefiori D, **Gilbert PB**. Brief Report: Prediction of Serum HIV-1 Neutralization Titers After Passive Administration of VRC01. *JAIDS Journal of Acquired Immune Deficiency Syndromes*. 2020 Apr 1;83(4):434-9. doi: 10.1097/QAI.0000000000002272. PMID: 31855881; PMCID: PMC7594341.
259. Reeves DB, Huang Y, Duke E, Mayer B, Cardozo-Ojeda F, Boshier F, Swan D, Rolland M, Robb M, Mascola J, Cohen M, Corey L, **Gilbert PB**, Schiffer JT. Mathematical modeling to reveal breakthrough mechanisms in the HIV antibody mediated prevention (AMP) trials. *PLOS Computational Biology*. 2020 Feb 21;16(2):e1007626. doi: 10.1371/journal.pcbi.1007626. PMID: 32084132; PMCID: PMC7055956.
260. Bellach A, Kosorok MR, **Gilbert PB**, Fine JP. General regression model for the subdistribution of a competing risk under left-truncation and right-censoring. *Biometrika*. 2020 Dec;107(4):949-64. doi: 10.1093/biomet/asaa034. PMID: 33462536; PMCID: PMC7799183.
261. Westling T, **Gilbert PB**, Carone M. Causal isotonic regression. *Journal of the Royal Statistical Society: Series B (Statistical Methodology)*. 2020 Jul;82(3):719-47. doi: 10.1111/rssb.12372. Epub 2020 May 13. PMID: 33986625; PMCID: PMC8112616.
262. Benkeser D*, Juraska MJ*, **Gilbert PB**. Assessing trends in vaccine efficacy by pathogen genetic distance. *Journal de la Société Française de Statistique*. 2020 Vol. 161 No. 1, 164-75. PMID: 33244440; PMCID: PMC7685316.
263. Zhao H, Wu Q, **Gilbert PB**, Chen Y-Q, Sun J. A regularized estimation approach for case-cohort periodic follow-up studies with an application to HIV vaccine trials. *Biometrical Journal*. 2020. Sep;62(5):1176-91. doi: 10.1002/bimj.201900180. Epub 2020 Feb 20. PMID: 32080888; PMCID: PMC7768636.
264. Krause P, Fleming TR, Longini I, Henao-Restrepo AM, Peto R, Dean NE, Halloran ME, Huang Y, Fleming TR, **Gilbert PB**, DeGruttola V. COVID-19 vaccine trials should seek worthwhile efficacy. *The*

- Lancet. 2020 Sep 12;396(10253):741-3. doi: 10.1016/S0140-6736(20)31821-3. Epub 2020 Aug 27. PMID: 32861315; PMCID: PMC7832749.
265. Halloran ME, Longini IM, **Gilbert PB**. Designing a Study of Correlates of Risk for Ebola Vaccination. *American Journal of Epidemiology*. 2020 Aug 1;189(8):747-54. doi: 10.1093/aje/kwaa001. PMID: 31971229; PMCID: PMC7407270.
266. Huang Y, Zhang L, **Gilbert PB**. Generating survival times using Cox proportional hazards models with cyclic and piecewise time-varying covariates, with application to multiple-dose HIV monoclonal antibody trials. *Statistics in Biosciences*. 2020 Dec;12:324-39. PubMed PMID: 32421033; PMCID: PMC7223425.
267. Dayan GH, Langevin E, **Gilbert PB**, Wu Y, Moodie Z, Forrat R, Price B*, Frago C, Bouckenooghie A, Cortes M, Noriega F, DiazGranados CA. Long-term efficacy of a dengue vaccine against symptomatic, virologically-confirmed dengue disease by baseline serostatus. *Vaccine*. 2020; 38(19):3531-3536. PMID: 32204943.
268. Heng F, Sun Y, Hyun S, **Gilbert PB**. Analysis of the time-varying Cox model for cause-specific hazard functions with missing causes. *Lifetime Data Analysis*. 2020 Apr 9:1-30. PMID: 32274677; PMCID: PMC7487047.
269. Sun Y, Qi L, Heng F, **Gilbert PB**. A hybrid approach for the stratified mark-specific proportional hazards models with missing covariates and missing marks, with applications to dengue vaccine efficacy trials. *Journal of the Royal Statistical Society Series C: Applied Statistics*. 2020 Aug;69(4):791-814. doi: 10.1111/rssc.12417. Epub 2020 May 22. PMID: 33191955; PMCID: PMC7664296.
270. Moodie Z, Walsh SR, Laher F, Maganga L, Herce ME, Naidoo S, Hosseinipour MC, Innes C, Bekker LG, Grunenberg N, Mann P, Yu C, deCamp AC*, Miner MD, Yates NL, Heptinstall J, Mkhize NN, Dintwe O, Frahm N, Cohen KW, Allen M, Hutter J, Wagner R, Pantaleo G, McElrath MJ, Tomaras GD, Morris L, Montefiori DC, Andersen-Nissen E, Gray GE, **Gilbert PB**, Kublin JG, NIAID HVTN 100 and HVTN 111 Trial Teams. Antibody and cellular responses to HIV vaccine regimens with DNA plasmid as compared with ALVAC priming: An analysis of two randomized controlled trials. *PLoS Medicine*. 2020. May 22;17(5):e1003117. PubMed PMID: 32442195; PMCID: PMC7244095.
271. **Gilbert PB**, Blette BS, Shepherd BE*, Hudgens MG. Post-randomization Biomarker Effect Modification Analysis in an HIV Vaccine Clinical Trial. *Journal of Causal Inference*. 2020;8(1):54-69. doi: 10.1515/jci-2019-0022. Epub 2020 Jul 25. PMID: 33777613; PMCID: PMC7996712.
272. Zhuang Y*, Huang Y, **Gilbert PB**. Evaluation of treatment effect modification by biomarkers measured pre- and post-randomization in the presence of non-monotone missingness. *Biostatistics*. 2022 Apr 1;23(2):541-57. PubMed PMID: 32978622.
273. Haynes BF, Corey L, Fernandes P, **Gilbert PB**, Hotez PJ, Rao S, Santos MR, Schuitemaker H, Watson M, Arvin A. Prospects for a safe COVID-19 vaccine. *Science Translational Medicine*. 2020 Nov 4;12(568):eabe0948. PubMed PMID: 33077678.
274. Edupuganti S, S CDR, Elizaga M, Lu Y, Han X, Huang Y, Swann E, Polakowski L, S AK, Keefer M, Maenza J, M CW, Yan J, Morrow MP, Khan AS, Boyer JD, Humeau L, White S, Sardesai NY, Bagarazzi ML, **Gilbert PB**, Kublin JG, Corey L, Weiner DB, On Behalf Of The HVTN Study Team, The NIAID-Funded HIV Vaccine Trials Network. Intramuscular and Intradermal Electroporation of HIV-1 PENNVAX-GP((R)) DNA Vaccine and IL-12 Is Safe, Tolerable, Acceptable in Healthy Adults. *Vaccines*. 2020 Dec 7;8(4):741. PubMed PMID: 33297341; PMCID: PMC7762306.
275. Mdluli T, Jian N, Slike B, Paquin-Proulx D, Donofrio G, Alrubayyi A, Gift S, Grande R, Bryson M, Lee A, Dussupt V, Mendez-Riveria L, Sanders-Buell E, Chenine AL, Tran U, Li Y, Brown E, Edlefsen PT, O'Connell R, **Gilbert PB**, Nitayaphan S, Pitisuttithum P, Rerks-Ngarm S, Robb ML, Gramzinski R, Alter G, Tovanabutra S, Georgiev IS, Ackerman ME, Polonis VR, Vasan S, Michael NL, Kim JH, Eller MA, Krebs SJ, Rolland M. RV144 HIV-1 vaccination impacts post-infection antibody responses. *Plos Pathogens*. 2020 Dec 8;16(12):e1009101. PubMed PMID: 33290394.
276. Carpp LN, Fong Y, Bonaparte M, Moodie M, Juraska MJ*, Huang Y, Price BL*, Zhuang Y*, Shao J, Zheng L, Chambonneau L, Small R, Sridhar S, DiazGranados C, **Gilbert PB**. Microneutralization Assay Titer Correlates Analysis in Two Phase 3 Trials of the CYD-TDV Tetravalent Dengue Vaccine in Asia

- and Latin America. PLoS One. 2020 Jun 15;15(6):e0234236. doi: 10.1371/journal.pone.0234236. PMID: 32542024; PMCID: PMC7295445.
277. Duke ER, Williamson BD, Borate B, Golob JL, Wychera C, Stevens-Ayers T, Huang M-L, Cossrow N, Wan H, Mast CT, Marks MA, Flowers ME, Jerome KR, Corey L, **Gilbert PB**, Schiffer JT, and Boeckh MJ. Cytomegalovirus viral load kinetics as surrogate endpoints after allogeneic transplantation. The Journal of Clinical Investigation. 2021 Jan 4;131(1). PMCID: PMC7773411.
278. Mdluli T, Jian N, Slike B, Paquin-Proulx D, Donofrio G, Alrubayyi A, Gift S, Grande R, Bryson M, Lee A, Dussupt V, Mendez-Riveria L, Sanders-Buell E, Chenine AL, Tran U, Li Y, Brown E, Edlefsen PT, O'Connell R, **Gilbert PB**, Nitayaphan S, Pitisuttithum P, Rerks-Ngarm S, Robb ML, Gramzinski R, Alter G, Tovanabutra S, Georgiev IS, Ackerman ME, Polonis VR, Vasan S, Michael NL, Kim JH, Eller MA, Krebs SJ, Rolland M. Correction: RV144 HIV-1 vaccination impacts post-infection antibody responses. PLoS Pathogens. 2021 Mar 2;17(3):e1009386. PMCID: PMC7924741.
279. Williamson BD, **Gilbert PB**, Simon N, Carone M. Nonparametric variable importance assessment using machine learning techniques. Biometrics. 2021 Mar;77(1):9-22. doi: 10.1111/biom.13392. Epub 2020 Dec 8. PMID: 33043428; PMCID: PMC7946807.
280. Andersen-Nissen E, Fiore-Gartland A, Ballweber Fleming L, Carpp LN, Naidoo AF, Harper MS, Voillet V, Grunenberg N, Laher F, Innes C, Bekker LG, Kublin JG, Huang Y, Ferrari G, Tomaras GD, Gray G, **Gilbert PB**, McElrath MJ. Innate immune signatures to a partially-efficacious HIV vaccine predict correlates of HIV-1 infection risk. PLoS Pathogens. 2021 Mar 15;17(3):e1009363. PMCID: PMC7959397.
281. Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Rouphael N, Creech CB, McGettigan J, Khetan S, Segall N, Solis J, Brosz A, Fierro C, Schwartz H, Neuzil K, Corey L, **Gilbert PB**, Janes H, Follmann D, Marovich M, Mascola J, Polakowski L, Ledgerwood J, Graham BS, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T, on behalf of the COVE Study Group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. New England Journal of Medicine. 2021 Feb 4;384(5):403-16. PMCID: PMC7787219
282. Corey L**, **Gilbert PB****, Juraska MJ*, Montefiori DC, Morris L, Karuna ST, Edupuganti S, Mgodini NM, deCamp AC*, Rudnicki E, Huang Y, Gonzales P, Cabello R, Orrell C, Lama JR, Laher F, Lazarus EM, Sanchez J, Frank I, Hinojosa J, Sobieszczyk ME, Marshall KE, Mukwekwerere PG, Makhema J, Baden LR, Mullins JI, Williamson C, Hural J, McElrath MJ, Bentley C, Takuva S, Gomez Lorenzo MM, Burns DN, Espy N, Randhawa AK, Kochar N, Piwowar-Manning E, Donnell DJ, Sista N, Andrew P, Kublin JG, Gray G, Ledgerwood JE, Mascola JR, Cohen MS, HVTN 704/HPTN 085 and HVTN 703/HPTN 081 Study Teams. Two Randomized Trials of Neutralizing Antibodies to Prevent HIV-1 Acquisition. The New England Journal of Medicine. 2021 Mar 18;384(11):1003-14. PMCID: PMC8189692. **Contributed equally
283. Earle KA, Ambrosino DM, Fiore-Gartland A, Goldblatt D, **Gilbert PB**, Siber GR, Dull P, Plotkin SA. Evidence for antibody as a protective correlate for COVID-19 vaccines. 2021 Jul 22;39(32):4423-8. PMCID: PMC8142841.
284. Edupuganti S, Mgodini N, Karuna ST, Andrew P, Rudnicki E, Kochar N, deCamp A*, De La Grecca R, Anderson M, Karg C, Tindale I, Greene E, Broder GB, Lucas J, Hural J, Gallardo-Cartagena JA, Gonzales P, Frank I, Sobieszczyk M, Gomez Lorenzo MM, Burns D, Anderson PL, Miner MD, Ledgerwood J, Mascola JR, **Gilbert PB**, Cohen MS, Corey L, HVTN 704/HPTN 085 Study Group. Feasibility and Successful Enrollment in a Proof-of-Concept HIV Prevention Trial of VRC01, a Broadly Neutralizing HIV-1 Monoclonal Antibody. JAIDS Journal of Acquired Immune Deficiency Syndromes. 2021 May 1;87(1):671-9. PMCID: PMC8397466.
285. El Sahly HM, Baden LR, Essink B, Doblecki-Lewis S, Martin JM, Anderson EJ, Campbell T, Clark J, Jackson LA, Fichtenbaum CJ, Zervos M, Rankin B, Eder F, Feldman G, Kennelly C, Han-Conrad L, Levin M, Neuzil KM, Corey L, **Gilbert PB**, Janes HE, Follmann D, Marovich M, Polakowski L, Mascola JR, Ledgerwood JE, Graham BS, August A, Clouting H, Deng W, Han S, Leav B, Manzo D, Pajon R, Schödel F, Tomassini JE, Zhou H, Miller J on behalf of the COVE Study Group. Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase. New England Journal of Medicine. 2021. Nov 4;385(19):1774-85. PMCID: PMC8482810.

286. Follmann D, Fintzi J, Fay MP, Janes HE, Baden LR, El Sahly HM, Fleming TR, Mehrotra DV, Carpp LN, Juraska MJ*, Benkeser D*, Donnell D, Fong Y, Han S, Hirsch I, Huang Y, Huang Y, Hyrien O, Luedtke A, Carone M, Nason M, Vandebosch A, Zhou H, Cho I, Gabriel EE*, Kublin JG, Cohen MS, Corey L, **Gilbert PB**, Neuzil KM. A Deferred-Vaccination Design to Assess Durability of COVID-19 Vaccine Effect After the Placebo Group Is Vaccinated. *Annals of Internal Medicine*. 2021 Aug;174(8):1118-25. PMID: PMC8099035.
287. Gray GE, Bekker LG, Laher F, Malahleha M, Allen M, Moodie Z, Grunenberg N, Huang Y, Grove D, Prigmore B, Kee JJ, Benkeser D*, Hural J, Innes C, Lazarus E, Meintjes G, Naicker N, Kalonji D, Nchabeleng M, Sebe M, Singh N, Kotze P, Kassim S, Dubula T, Naicker V, Brumskine W, Ncayiya CN, Ward AM, Garrett N, Kistnasami G, Gaffoor Z, Selepe P, Makhoba PB, Mathebula MP, Mda P, Adonis T, Mapetla KS, Modibedi B, Philip T, Kobane G, Bentley C, Ramirez S, Takuva S, Jones M, Sikhosana M, Atujuna M, Andrasik M, Hejazi NS, Puren A, Wiesner L, Phogat S, DiazGranados C, Koutsoukos M, Van Der Meeren O, Barnett SW, Kanasa-Thanan N, Kublin JG, McElrath MJ, **Gilbert PB**, Janes H, Corey L, HVTN 702 Study Team. Vaccine Efficacy of ALVAC-HIV and Bivalent Subtype C gp120-MF59 in Adults. *The New England Journal of Medicine*. 2021 Mar 25;384(12):1089-100. PMID: PMC7888373.
288. Hejazi NS, Van der Laan ME, Janes HE, **Gilbert PB**, Benkeser DC*. Efficient nonparametric inference on the effects of stochastic interventions under two-phase sampling, with applications to vaccine efficacy trials. *Biometrics*. 2021 77(4):1241-1253. PMID: PMC8016405.
289. Huang Y, Borisov O, Kee JJ, Carpp LN, Wrin T, Cai S, Sarzotti-Kelsoe M, McDanal C, Eaton A, Pajon R, Hural J, Posavad CM, Gill K, Karuna S, Corey L, McElrath MJ, **Gilbert PB**, Petropoulos CJ, Montefiori DC. Calibration of two validated SARS-CoV-2 pseudovirus neutralization assays for COVID-19 vaccine evaluation. *Scientific Reports*. 2021 Dec 14;11(1):23921. PMID: PMC8671391.
290. Huang Y, Moodie Z, Juraska MJ*, Fong Y, Carpp LN, Chambonneau L, Coronel DL, Dayan GH, DiazGranados CA, **Gilbert PB**. Immunobridging efficacy of a tetravalent dengue vaccine against dengue and against hospitalized dengue from children/adolescents to adults in highly endemic countries. *Transactions of The Royal Society of Tropical Medicine and Hygiene*. 2021. Jul;115(7):750-63. doi: 10.1093/trstmh/traa154. PMID: 33369671; PMID: PMC8245293.
291. Huang Y, Naidoo L, Zhang L, Carpp LN, Rudnicki E, Randhawa A, Gonzales P, McDermott A, Ledgerwood J, Lorenzo MMG, Burns D, DeCamp A*, Juraska MJ*, Mascola J, Edupuganti S, Mgodini N, Cohen M, Corey L, Andrew P, Karuna S, **Gilbert PB**, Mngadi K, Lazarus E. Pharmacokinetics and predicted neutralisation coverage of VRC01 in HIV-uninfected participants of the Antibody Mediated Prevention (AMP) trials. *EBioMedicine*. 2021 Feb 1;64. PMID: PMC7841500.
292. Mehrotra DV, Janes HE, Fleming TR, Annunziato PW, Neuzil KM, Carpp LN, Benkeser DC*, Brown ER, Carone M, Cho I, Donnell D, Fay MP, Fong Y, Han S, Hirsch I, Huang Y, Huang Y, Hyrien O, Juraska MJ*, Luedtke A, Nason M, Vandebosch A, Zhou H, Cohen MS, Corey L, Hartzel J, Follmann D, **Gilbert PB**. Clinical Endpoints for Evaluating Efficacy in COVID-19 Vaccine Trials. *Annals of Internal Medicine*. 2021 Feb;174(2):221-8. PMID: PMC7596738.
293. Koup R, Donis RO, **Gilbert PB**, Li AW, Shah NA, Houchens CR. A government-led effort to identify correlates of protection for COVID-19 vaccines. *Nature Medicine*. 2021. 27(9), pp.1493-1494. PMID: 34518674.
294. Lewitus E, Sanders-Buell E, Bose M, O'Sullivan AM, Poltavee K, Li Y, Bai H, Mdluli T, Donofrio G, Slike B, Zhao H, Wong K, Chen L, Miller S, Lee J, Ahani B, Lepore S, Muhammad S, Grande R, Tran U, Dussupt V, Mendez-Rivera L, Nitayaphan S, Kaewkungwal J, Pitisuttithum P, Rerks-Ngarm S, O'Connell RJ, Janes H, **Gilbert PB**, Gramzinski R, Vasani S, Robb ML, Michael NL, Krebs SJ, Herbeck JT, Edlefsen PT, Mullins JI, Kim JH, Tovanabutra S, Rolland M. RV144 vaccine imprinting constrained HIV-1 evolution following breakthrough infection. *Virus Evolution*. 2021 Dec;7(2):veab057. PMID: PMC8438874.
295. Lin DY, Zeng D, **Gilbert PB**. Evaluating the long-term efficacy of coronavirus disease 2019 (COVID-19) vaccines. *Clinical Infectious Diseases*. 2021 Nov 15;73(10):1927-39. PMID: PMC7989522.
296. Lin DY, Zeng D, Mehrotra DV, Corey L, **Gilbert PB**. Evaluating the efficacy of coronavirus disease 2019 vaccines. *Clinical Infectious Diseases*. 2021 Oct 15;73(8):1540-4. PMID: PMC7799296.

297. Reeves DB, Rolland M, Dearlove BL, Li Y, Robb ML, Schiffer JT, **Gilbert PB**, Cardozo-Ojeda EF, Mayer BT. Timing HIV infection with a simple and accurate population viral dynamics model. *Journal of the Royal Society Interface*. 2021 Jun 30;18(179):20210314. PMCID: PMC8241492.
298. Rolland M, **Gilbert PB**. Sieve analysis to understand how SARS-CoV-2 diversity can impact vaccine protection. *PLoS Pathogens*. 2021 Mar 25;17(3):e1009406. PMCID: PMC7993616.
299. Seaton KE, Deal A, Han X, Li SS, Clayton A, Heptinstall J, Duerr A, Allen MA, Shen X, Sawant S, Yates NL, Spearman P, Churchyard G, Goepfert PA, Maenza J, Gray G, Pantaleo G, Polakowski L, Robinson HL, Grant S, Randhawa AK, Huang Y, Morgan C, Grunenberg N, Karuna S, **Gilbert PB**, McElrath MJ, Huang Y, Tomaras GD, NIAID HIV Vaccine Trials Network (HVTN) 076, 088, 086, 096, 097, 205 Study Teams. Meta-analysis of HIV-1 vaccine elicited mucosal antibodies in humans. *npj Vaccines*. 2021 Apr 15;6(1):56. PMCID: PMC8050318.
300. Shangguan S, Ehrenberg PK, Geretz A, Yum L, Kundu G, May K, Fourati S, Nganou-Makamdop K, Williams LD, Sawant S, Lewitus E, Pitisuttithum P, Nitayaphan S, Chariyalertsak S, Rerks-Ngarm S, Rolland M, Douek DC, **Gilbert PB**, Tomaras GD, Michael NL, Vasan S, Thomas R. Monocyte-derived transcriptome signature indicates antibody-dependent cellular phagocytosis as a potential mechanism of vaccine-induced protection against HIV-1. *Elife*. 2021 Sep 17;10:e69577. PMCID: PMC8514236.
301. Swan DA, Goyal A, Bracis C, Moore M, Krantz E, Brown ER, Cardozo-Ojeda F, Reeves DB, Gao F, **Gilbert PB**, Corey L, Cohen MS, Janes HE, Dimitrov D, Schiffer JT. Mathematical modeling of vaccines that prevent SARS-CoV-2 transmission. 2021 Sep 24;13(10):1921. PMCID: PMC8539635.
302. Williamson BD, **Gilbert PB**, Simon N, Carone M. Rejoinder to “Nonparametric variable importance assessment using machine learning techniques.” *Biometrics*. 2021 Mar;77(1):28-30. PMCID: PMC8029259.
303. Williamson BD, Magaret CA, **Gilbert PB**, Nizam S, Simmons C, Benkeser D. Super LeArner Prediction of NAb Panels (SLAPNAP): a containerized tool for predicting combination monoclonal broadly neutralizing antibody sensitivity. *Bioinformatics*. 2021 Nov 15;37(22):4187-92. PMID: 34021743.
304. Zhao LP, Lybrand TP, **Gilbert PB**, Hawn TR, Schiffer JT, Stamatatos L, Payne TH, Carpp LN, Geraghty DE, Jerome KR. Tracking SARS-CoV-2 Spike Protein Mutations in the United States (January 2020—March 2021) Using a Statistical Learning Strategy. *Viruses*. 2021 Dec 21;14(1):9. PMCID: PMC8777887.
305. Zhou Q, Sun Y, **Gilbert PB**. Semiparametric regression analysis of partly interval-censored failure time data with application to an AIDS clinical trial. *Statistics in Medicine*. 2021 Sep 10;40(20):4376-94. PMID: 34080723.
306. Williamson BD, **Gilbert PB**, Simon NR, Carone M. A general framework for inference on algorithm-agnostic variable importance. *Journal of the American Statistical Association*. 2021. Dec 22:1-14. PMID: 37982008; PMCID: PMC10652709.
307. Zhang L, **Gilbert PB**, Capparelli E, Huang YD. Simulation-Based Pharmacokinetics Sampling Design for Evaluating Correlates of Prevention Efficacy of Passive HIV Monoclonal Antibody Prophylaxis. *Statistics in Biopharmaceutical Research*. 2022. Oct 2;14(4):611-25. doi: 10.1080/19466315.2021.1919196. Epub 2021 Jun 28. PMID: 36684526; PMCID: PMC9856202.
308. **Gilbert PB***, Montefiori DC*, McDermott A*, Fong Y, Benkeser D*, Deng W, Zhou H, Houchens CR, Martins K, Jayashankar L, Castellino F, Flach B, Lin BC, O’Connell S, McDanal C, Eaton A, Sarzotti-Kelsoe M, Lu Y, Yu C, Borate B, van der Laan LWP, Hejazi N, Huynh C, Miller J, El Sahly HM, Baden LR, Baron M, De La Cruz L, Gay C, Kalams S, Kelley CF, Kutner M, Andrasik MP, Kublin JG, Corey L, Neuzil KM, Carpp LN, Pajon R, Follmann D, Donis RO*, Koup RA*, on behalf of the Immune Assays; Moderna, Inc.; Coronavirus Vaccine Prevention Network (CoVPN)/Coronavirus Efficacy (COVE); and United States Government (USG)/CoVPN Biostatistics Teams. Immune Correlates Analysis of the mRNA-1273 COVID-19 Vaccine Efficacy Trial. *Science*. 2022 Jan 7;375(6576):43-50. 2022;375(6576):43-50. PMID: 34812653.
309. Huang Y, Williamson BD, Moodie Z, Carpp LN, Chambonneau L, DiazGranados CA, **Gilbert PB**. Analysis of Neutralizing Antibodies as a Correlate of Instantaneous Risk of Hospitalized Dengue in Placebo Recipients of Dengue Vaccine Efficacy Trials. *Journal of Infectious Diseases*. 2022. Jan 15;225(2):332-40. PMCID: PMC8915240.

310. Huang Y, Zhang L, Eaton A, Mkhize NN, Carpp LN, Rudnicki E, DeCamp A*, Juraska MJ*, Randhawa A, McDermott A, Ledgerwood J, Andrew P, Karuna S, Edupuganti S, Mgodi N, Cohen M, Corey L, Mascola J, **Gilbert PB**, Morris L, Montefiori DC. Prediction of serum HIV-1 neutralization titers of VRC01 in HIV-uninfected Antibody Mediated Prevention (AMP) trial participants. *Human Vaccines & Immunotherapeutics*. 2022 Jan 31;18(1):1908030. PMID: PMC8928800.
311. Lin DY, Gu Y, Zeng D, Janes HE, **Gilbert PB**. Evaluating Vaccine Efficacy Against Severe Acute Respiratory Syndrome Coronavirus 2 Infection. *Clinical Infectious Diseases*. 2022. 74(3):544-52. PMID: PMC8406869.
312. Mayer BT, deCamp AC*, Huang Y, Schiffer JT, Gottardo R, **Gilbert PB**, Reeves DB. Optimizing clinical dosing of combination broadly neutralizing antibodies for HIV prevention. *PLoS Computational Biology*. 2022. 18(4):e1010003. PMID: 35385469.
313. Thomas R, Chansinghakul D, Limkittikul K, **Gilbert PB**, Hattasingh W, Moodie Z, Shangguan S, Frago C, Dulyachai W, Li SS, Jarman RG, Geretz A, Bouckennooghe A, Sabchareon A, Juraska MJ*, Ehrenberg P, Michael NL, Bailleux F, Bryant C, Gurunathan S. Associations of human leukocyte antigen with neutralizing antibody titers in a tetravalent dengue vaccine phase 2 efficacy trial in Thailand. *Human Immunology*. 2022 Jan 1;83(1):53-60. PMID: 34635391.
314. Zhao LP, Roychoudhury P, **Gilbert PB**, Schiffer J, Lybrand TP, Payne TH, Randhawa A, Thiebaud S, Mills M, Greninger A, Pyo CW, Wang R, Li R, Thomas A, Norris B, Nelson WC, Jerome KR, Geraghty DE. Mutations in viral nucleocapsid protein and endoRNase are discovered to associate with COVID-19 hospitalization risk. *Scientific Reports*. 2022;12(1):1206. PMID: PMC8786941.
315. Zhao LP, Roychoudhury P, **Gilbert PB**, Schiffer J, Lybrand TP, Payne TH, Randhawa A, Thiebaud S, Mills M, Greninger A, Pyo CW, Wang R, Li R, Thomas A, Norris B, Nelson WC, Jerome KR, Geraghty DE. Author Correction: Mutations in viral nucleocapsid protein and endoRNase are discovered to associate with COVID19 hospitalization risk. *Scientific Reports*. 2022;12(1):3274. PMID: PMC8864003.
316. Dull P, Plotkin SA, **Gilbert PB**, Cassels F. Correlates of protection for SARS-CoV-2 vaccines. *Expert Roundtable. VaccineInsights*. 2022. 1(1), 85-93. DOI: 10.18609/cgti.2021/013. Published 4 June 2022.
317. Huang Y, Zhuang Y*, **Gilbert PB**. Sensitivity analysis for evaluating principal surrogate endpoints relaxing the equal early clinical risk assumption. *Annals of Applied Statistics*. 2022. Sep;16(3):1774-94. doi: 10.1214/21-aos1566. Epub 2022 Jul 19. PMID: 37008748; PMID: PMC10065750.
318. Zhao LP, Geraghty D, **Gilbert PB**, Jerome K. Mutations in viral nucleocapsid protein and endoRNase are discovered to associate with COVID-19 hospitalization risk. *Scientific Reports*. 2022 Jan 24;12(1):1206. doi: 10.1038/s41598-022-07002-z. PMID: 35075180; PMID: PMC8786941.
319. Li SS, Hickey A, Shangguan S, Ehrenberg PK, Geretz A, Butler L, Kundu G, Apps R, Creegan M, Clifford RJ, Pinyakorn S, Eller LA, Luechai P, **Gilbert PB**, Holtz TH, Chitwarakorn A, Sacdalan C, Kroon E, Phanuphak N, de Souza M, Ananworanich J, O'Connell RJ, Robb ML, Michael NL, Vasan S, Thomas R. HLA-B*46 associates with rapid HIV disease progression in Asian cohorts and more prominent differences in NK cell phenotypes. *Cell Host & Microbe*. 2022 30;8. 1173-1185.e8 doi: 10.1016/j.chom.2022.06.005. Epub 2022 Jul 15. PMID: 35841889; PMID: PMC9380401.
320. Zhao LP, Lybrand TP, **Gilbert PB**, Madeleine M, Payne TH, Cohen S, Geraghty DE, Jerome KR, Corey L. Application of statistical learning to identify omicron mutations in SARS-CoV-2 viral genome sequence data from populations in Africa and the United States. *JAMA Network Open*. 2022. Sep 1;5(9):e2230293. doi: 10.1001/jamanetworkopen.2022.39195. PMID: 36069983; PMID: PMC9453543.
321. **Gilbert PB**, Isbrucker R, Andrews N, Goldblatt D, Heath PT, Izu A, Madhi SA, Moulton L, Schrag SJ, Shang N, Siber G, Sobanjo-ter Meulen A. Methodology for a correlate of protection for group B Streptococcus: Report from the Bill & Melinda Gates Foundation workshop held on 10 and 11 February 2021. *Vaccine*. 2022 Jul 30;40(32):4283-91. doi: 10.1016/j.vaccine.2022.05.016. Epub 2022 Jun 29. PMID: 35779963; PMID: PMC11299424.
322. Qi L, Sun Y, Juraska MJ*, Moodie Z, Carpp LN, **Gilbert PB**. Neutralizing antibody correlates of sequence specific dengue disease in a tetravalent dengue vaccine efficacy trial in Asia. *Vaccine*. 2022

- Sep 29;40(41):5912-23. doi: 10.1016/j.vaccine.2022.08.055. Epub 2022 Sep 5. PMID: 36068106; PMCID: PMC9881745.
323. **Gilbert PB****, Huang Y**, deCamp AC*, Karuna S, Zhang Y, Magaret CA, Giorgi EE, Korber B, Edlefsen PT, Rossenkhon R, Juraska MJ*, Rudnicki E, Kochar N, Huang Y, Carpp LN, Barouch DN, Mkhize NN, Hermanus T, Kgagudi P, Bekker V, Kaldine H, Mapengo R, Eaton A, Domin E, West C, Feng W, Tang H, Seaton KE, Heptinstall J, Brackett C, Chiong K, Tomaras GD, Andrew P, Mayer BT, Reeves DB, Sobieszczyk ME, Garrett N, Sanchez J, Gay C, Makhema J, Williamson C, Mullins JI, Hural J, Cohen MS, Corey L, Montefiori DC**, Morris L**. Neutralization Titer Biomarker for Antibody Mediated Prevention of HIV-1 Acquisition. *Nature Medicine*. 2022 Sep;28(9):1924-32. doi: 10.1038/s41591-022-01953-6. Epub 2022 Aug 22. PMID: 35995954; PMCID: PMC9499869. **Contributed equally
324. Moodie Z, Dintwe O, Sawant S, Grove D, Huang Y, Janes H, Heptinstall J, Laher Omar F, Cohen K, DeRosa SC, Zhang L, Yates NL, Sarzotti-Kelsoe M, Seaton KE, Bekker LG, Malahlena M, Innes C, Kassim S, Naicker N, Govender V, Sebe M, Singh N, Kotze P, Lazarus E, Nchabeleng M, Ward AM, Brumskine W, Dubula T, Randhawa AK, Grunenberg N, Hural J, Kee JJ, Benkeser D*, Jin Y, Carpp LN, Allen M, D'Souza P, Tartaglia J, DiazGranados CA, Koutsoukos M, **Gilbert PB**, Kublin JG, Corey LC, Andersen-Nissen E, Gray GE, Tomaras GD, McElrath MJ. Analysis of the HVTN 702 Phase 2b-3 HIV-1 vaccine trial in South Africa assessing RV144 antibody and T-cell correlates of HIV-1 acquisition risk. *The Journal of Infectious Diseases*. 2022. Jul 15;226(2):246-57. doi: 10.1093/infdis/jiac260. PMID: 35758878; PMCID: PMC9890908.
325. Fong Y, McDermott B, Benkeser D*, Roels S, Stieh DJ, Vandebosch A, Le Gars M, Van Roey GA, Houchens CR, Martins K, Jayashankar L, Castellino F, Amoa-Awua O, Basappa M, Flach B, Lin BC, Moore C, Naisan M, Naqvi M, Narpala S, O'Connell S, Mueller A, Serebryannyy L, Castro M, Wang J, Petropoulos CJ, Luedtke A, Hyrien O, Lu Y, Yu C, Borate B, van der Laan LWP, Hejazi NS, Kenny A, Carone M, Wolfe DN, Sadoff J, Gray GE, Grinsztejn B, Goepfert PA, Little SJ, de Sousa LP, Maboja R, Randhawa AK, Andrasik MP, Hendriks J, Truysers C, Struyf F, Schuitemaker H, Douguilh M, Kublin JG, Corey L, Neuzil KM, Carpp LN, Follmann D, **Gilbert PB****, Koup RA**, and Donis RO** on behalf of the Immune Assays Team, the Janssen Team, the Coronavirus Vaccine Prevention Network (CoVPN)/ENSEMBLE Team, and the United States Government (USG)/CoVPN Biostatistics Team. Immune Correlates Analysis of a Single Ad26.COVS.2 Dose in the ENSEMBLE COVID-19 Vaccine Efficacy Clinical Trial. *Nature Microbiology*. 2022: 1-15. doi: 10.1038/s41564-022-01262-1. PMID: 35441174; PMCID: PMC9016647. **Contributed equally
326. Zhao LP, Lybrand T, **Gilbert PB**, Payne TH, Pyo CW, Geraghty D, Jerome K. Rapidly identifying new coronavirus mutations of potential concern in the omicron variant using an unsupervised learning strategy. *Scientific Reports*. 2022 Nov 9;12(1):19089. doi: 10.1038/s41598-022-23342-2. PMID: 36352021; PMCID: PMC9645309.
327. Cohen D, Ashkenazi S, Schneerson R, Farzam N, Bialik A, Meron-Sudai S, Asato V, Goren S, Ziv Baran T, Muhsen K, **Gilbert PB**, MacLennan C. Threshold protective levels of serum IgG to Shigella lipopolysaccharide: re-analysis of Shigella vaccine trials data. *Clinical Microbiology and Infection*. 2023 Mar 1;29(3):366-71. doi: 10.1016/j.cmi.2022.10.011. Epub 2022 Oct 13. PMID: 36243351; PMCID: PMC9993342.
328. Nemes E, Fiore-Gartland A, Boggiano C, Coccia M, D'Souza P, **Gilbert PB**, Ginsberg A, Hyrien O, Laddy D, Makar K, McElrath MJ, Ramachandra L, Schmidt AC, Shotorbani S, Sunshine J, Tomaras G, Yu W-H, Scriba TJ, Frahm N, the BCG Correlates PIs Study Team & the M72 Correlates PIs Study Team. The quest for vaccine-induced immune correlates of protection against tuberculosis. *VaccineInsights*. 2022 Jul;1(3):165. doi: 10.18609/vac/2022.027. Epub 2022 Jul 29. PMID: 37091190; PMCID: PMC10117634.
329. Sun Y, Shou Q, **Gilbert PB**, Heng F, Qian X. Semiparametric additive time-varying coefficients model for longitudinal data with censored time origin. *Biometrics*. 2023 Jun;79(2):695-710. PMID: 34877661.
330. **Gilbert PB**, Donis RO, Koup RA, Fong Y, Plotkin SA, Follmann D. A Covid-19 Milestone Attained—A Correlate of Protection for Vaccines. *New England Journal of Medicine*. 2022 Dec 15;387(24):2203-6. doi: 10.1056/NEJMp2211314. Epub 2022 Dec 10. PMID: 36507702.

331. Wan ATK, Zhao W, **Gilbert PB**, Zhou Y. A varying-coefficient partially linear transformation model for length-biased data with an application to HIV vaccine studies. *International Journal of Biostatistics*. 2023 Jun 5;19(1):131-62. doi: 10.1515/ijb-2021-0057. PMID: 35801995; PMCID: PMC9832178.
332. Donnell D, Kansiime S, Glidden DV, Luedtke A, **Gilbert PB**, Gao F, Janes H. Study design approaches for future active-controlled HIV prevention trials. *Statistical Communications in Infectious Diseases*. 2023 Jan 27;15(1):20230002. doi: 10.1515/scid-2023-0002. PMID: 38250627; PMCID: PMC10798828.
333. Van der Laan L, Zhang W, **Gilbert PB**. Nonparametric estimation of the causal effect of a stochastic threshold-based intervention. *Biometrics*. 2023;79(2):1014-1028. doi: 10.1111/biom.13690. Epub 2022 May 26. PMID: 35526218; PMCID: PMC10024462.
334. **Gilbert PB**, Fong Y, Kenny A, Carone M. A controlled effects approach to assessing immune correlates of protection. *Biostatistics*. 2023 Oct 1;24(4):850-865. doi: 10.1093/biostatistics/kxac024. PMID: 37850938; PMCID: PMC10583729.
335. Dayan GH, Roupheal N, Walsh SR, Chen A, Grunenberg N, Allen M, Antony J, Asante KP, Bhate AS, Beresnev T, Bonaparte MI. (**Gilbert PB** member of the VAT00008 Study Team.) Efficacy of a monovalent (D614) SARS-CoV-2 recombinant protein vaccine with AS03 adjuvant in adults: a phase 3, multi-country study. *eClinicalMedicine*. 2023 Oct 1;64. doi: 10.1016/j.eclinm.2023.102168. PMID: 37936652; PMCID: PMC10626161.
336. Dayan GH, Roupheal N, Walsh SR, Chen A, Grunenberg N, Allen M, Antony J, Asante KP, Bhate AS, Beresnev T, Bonaparte MI. (**Gilbert PB** member of the VAT00008 Study Team.) Efficacy of a bivalent (D614+ B. 1.351) SARS-CoV-2 recombinant protein vaccine with AS03 adjuvant in adults: a phase 3, parallel, randomised, modified double-blind, placebo-controlled trial. *The Lancet Respiratory Medicine*. 2023 Nov 1;11(11):975-90. doi: 10.1016/S2213-2600(23)00263-1. Epub 2023 Sep 13. PMID: 37716365; PMCID: PMC10872639.
337. Sun Y, Heng F, Lee U, **Gilbert PB**. Estimation of conditional cumulative incidence functions under generalized semiparametric regression models with missing covariates, with application to analysis of biomarker correlates in vaccine trials. *Canadian Journal of Statistics*. 2023;51(1): 235-257. doi: 10.1002/cjs.11693. Epub 2022 Feb 24. PMID: 36937899; PMCID: PMC10022693.
338. Khoury DS, Schlub TE, Cromer D, Steain M, Fong Y, **Gilbert PB**, Subbarao K, Triccas JA, Kent SJ, Davenport MP. Correlates of protection, thresholds of protection, and immunobridging among persons in SARS-CoV-2 infection. *Emerging Infectious Diseases*. 2023;29(2). doi: 10.3201/eid2902.221422. PMID: 36692375; PMCID: PMC9881762.
339. Mena Lora AJ, Long J, Huang Y, Baden LR, El Sahly HM, Follmann D, Goepfert Paul, Gray G, Grinsztejn B, Kotloff K, Roupheal N, Sobieszczyk M, Walsh S, Andriesen J, Shah KA, Zhang Y, **Gilbert PB**, Janes H, Gay CL, Falsey AR, Tripp RL, Gorman RL, Tong T, Marovich M, Neuzil K, Corey L, Kublin JG. Responding to a pandemic: Rapid development of an integrated network infrastructure to conduct phase 3 COVID-19 vaccine efficacy trials. *JAMA Network*. 2023 3 Jan 3;6(1):e2251974. doi: 10.1001/jamanetworkopen.2023.17317. PMID: 36689221; PMCID: PMC10546713.
340. Fong Y, Huang Y, Borate B, van der Laan LWP, Zhang W, Carpp LC, Cho I, Glenn G, Fries L, Gottardo R, **Gilbert PB**. Antibody Correlates of Protection from Severe RSV Disease in a Vaccine Efficacy Trial. *Open Forum Infectious Diseases*. 2023 Jan (Vol. 10, No. 1, p. ofac693). US: Oxford University Press. PMID: 36655191; PMCID: PMC9835761.
341. Cohen KW, Fiore-Gartland A, Walsh SR, Yusim K, Frahm N, Elizaga ML, Maenza J, Scott H, Mayer KH, Goepfert PA, Edupuganti S, Pantaleo G, Hutter J, Morris DE, De Rosa SC, Robb ML, Michael1 NL, Fischer W, Giorgi EE, Malhi H, Pensiero MN, Ferrari G, Tomaras GD, Montefiori DC, **Gilbert PB**, McElrath MJ, Haynes BF, Korber BT, Baden LR, and the NIAID HVTN 106 Study Group. Trivalent Mosaic or Consensus HIV Immunogens Prime Broad Cellular and Humoral Immune Responses in Healthy Adults (HVTN 106). *Journal of Clinical Investigation*. 2023 Feb 15;133(4). doi: 10.1172/JCI163338. PMID: 36787249; PMCID: PMC9927951.
342. Moore KA, Leighton T, Ostrowsky JT, Anderson CJ, Danila RN, Ulrich AK, Lackritz EM, Mehr AJ, Baric RS, Baylor NW, Gellin BG, Gordon JL, Krammer F, Perlman S, Rees HV, Saville M, Weller CL, Osterholm MT, and The Coronavirus Vaccines R&D Roadmap Taskforce (**Gilbert PB** member of

- Taskforce). A Research and Development (R&D) Roadmap for Broadly Protective Coronavirus Vaccines: A Pandemic Preparedness Strategy. *Vaccine*. 2023 41;24:2101-2112. doi: 10.1016/j.vaccine.2023.02.032. Epub 2023 Feb 21. PMID: 36870874; PMCID: PMC9941884.
343. Benkeser D*, Fong Y, Janes HE, Kelly EJ, Hirsch I, Sproule S, Stanley AM, Maaske J, Villafana T, Houchens CR, Martins K, Jayashankar L, Castellino F, Ayala V, Petropoulos CJ, Leith A, Haugaard D, Webb B, Lu Y, Yu C, Borate B, van der Laan LWP, Hejazi NS, Carpp LN, Randhawa A, Andrasik MP, Kublin JG, Isaacs MB, Makhene M, Tong T, Robb ML, Corey L, Neuzil KM, Follmann D, Hoffman C, Falsey AR, Sobieszczyk M, Koup RA**, Donis RO**, **Gilbert PB****, on behalf of the AstraZeneca AZD1222 Clinical Study Group, the Immune Assays Team, and the United States Government (USG)/CoVPN Biostatistics Team. Immune Correlates Analysis of a Phase 3 Trial of the AZD1222 (ChAdOx1 nCoV-19) vaccine. *npj Vaccines*. 2023 8(1); 36. doi: 10.1038/s41541-023-00630-0. PMID: 36899062; PMCID: PMC10005913. **Contributed equally
 344. Yu T, Qiu J, **Gilbert PB**, Wu L. Robust joint modelling of left-censored longitudinal data and survival data, with application to HIV vaccine studies. *Annals of Applied Statistics*. 2023; 17(2): 1017-1037. PMID: 37396148; PMCID: PMC10312337.
 345. Fong Y, Huang Y, Benkeser D*, Carpp LN, Áñez G, Woo W, McGarry A, Dunkle LM, Cho I, Houchens C, Martins K, Jayashankar L, Castellino F, Petropoulos CJ, Leith A, Haugaard D, Webb B, Lu Y, Yu C, Borate B, van der Laan LWP, Hejazi NS, Randhawa AK, Andrasik MP, Kublin JG, Hutter J, Keshtkar-Jahromi M, Beresnev TH, Corey L, Neuzil KM, Follmann D, Ake JA, Gay CL, Kotloff KL, Koup RA, Donis RO, **Gilbert PB**, the Immune Assays Team, the Coronavirus Vaccine Prevention Network (CoVPN)/2019nCoV-301 Principal Investigators and Study Team, the United States Government (USG)/CoVPN Biostatistics Team. Immune Correlates Analysis of the PREVENT-19 COVID-19 Vaccine Efficacy Clinical Trial. *Nature Communications*. 2023; Jan 19;14(1):331. doi: 10.1038/s41467-022-35768-3. PMID: 36949083; PMCID: PMC10031713.
 346. Benkeser D***, Montefiori DC**, McDermott AB**, Fong Y, Janes HE, Deng W, Zhou H, Houchens CR, Martins K, Jayashankar L, Castellino F, Flach B, Lin BC, O'Connell S, McDanal C, Eaton A, Sarzotti-Kelsoe M, Lu Y, Yu C, Borate B, van der Laan LWP, Hejazi NS, Kenny A, Carone C, Garver J, Altonen E, Rudge T, Huynh C, Miller J, El Sahly HM, Baden LR, Frey S, Malkin E, Spector SA, Andrasik MP, Kublin JG, Corey L, Neuzil KM, Carpp LN, Pajon R, Follmann D, Donis RO, Koup RA, **Gilbert PB**, on behalf of the Immune Assays; Moderna, Inc.; Coronavirus Vaccine Prevention Network (CoVPN)/Coronavirus Efficacy (COVE); and United States Government (USG)/CoVPN Biostatistics Teams. Comparing antibody assays as correlates of protection against COVID-19 in the COVE mRNA-1273 vaccine efficacy trial. *Science Translational Medicine*. 2023 Apr 19;15(692):eade9078. doi: 10.1126/scitranslmed.ade9078. Epub 2023 Apr 19. PMID: 37075127; PMCID: PMC10243212. **Contributed equally
 347. Westling T, Luedtke A, **Gilbert PB**, Carone M. Inference for treatment-specific survival curves using machine learning. *Journal of the American Statistical Association*. 2023 May 30:1-3. doi: 10.1080/01621459.2023.2205060. Epub 2023 Jun 5. PMID: 39184837; PMCID: PMC11339859.
 348. Seaton KE**, Huang Y**, Karuna S, Heptinstall J, Brackett C, Chiong K, Zhang Y, Yates NL, Sampson M, Rudnicki E, Juraska MJ*, deCamp AC*, Edlefsen PT, Mullins JI, Williamson C, Rossenkhan R, Giorgi EE, Kenny A, Angier H, Randhawa A, Rojas M, Sarzotti-Kelsoe M, Zhang L, Sawant S, McDermott AB, Mascola JR, Hural J, McElrath MJ, Andrew P, Hidalgo JA, Clark J, Laher F, Orrell C, Frank I, Gonzales P, Edupuganti S, Mgodi N, Corey L, Morris L, Montefiori D, Cohen MS, **Gilbert PB****, Tomaras GD**. Pharmacokinetic serum concentrations of VRC01 correlate with prevention of HIV-1 acquisition. *EBioMedicine*. 2023; 93:104590. doi: 10.1016/j.ebiom.2023.104590. Epub 2023 Jun 8. PMID: 37300931; PMCID: PMC10363420. **Contributed equally
 349. Theodore DA, Branche AR, Zhang L, Graciaa S, Choudhary M, Hatlen TJ, Osman R, Babu TM, Robinson ST, **Gilbert PB**, Follmann D, Janes H, Kublin JG, Baden LR, Goepfert P, Gray GE, Grinsztejn B, Kotloff KL, Gay CL, Leav B, Miller J, Hirsch I, Sadoff J, Dunkle LM, Neuzil KM, Corey L, Falsey AR, El Sahly HM, Sobieszczyk ME, Huang Y, for the COVID-19 Prevention Network (CoVPN). Clinical and Demographic Factors Associated With COVID-19, Severe COVID-19, and SARS-CoV-2 Infection in Adults: A Secondary Cross-Protocol Analysis of 4 Randomized Clinical Trials. *JAMA*

- Network Open. 2023. 6(7), pp.e2323349-e2323349. doi: 10.1001/jamanetworkopen.2023.23349. PMID: 37440227; PMCID: PMC10346130.
350. Follmann D, O'Brien MP, Fintzi J, Fay MP, Montefiori D, Mateja A, Herman GA, Hooper A, Turner KC, Chan K-C, Forleo-Neto E, Isa F, Baden LR, El Sahly HM, Janes HE, Doria-Rose N, Miller J, Zhou H, Deng W, Benkeser D*, Fong Y, **Gilbert PB**, Marovich MD, Cohen MS. Examining Protective effects of SARS-CoV-2 neutralizing antibodies after vaccination or monoclonal antibody administration. *Nature Communications*. 2023 Jun 17;14(1):3605. doi: 10.1038/s41467-023-39292-w. PMID: 37330602; PMCID: PMC10276829.
351. Mkhize NN, Yssel A, Kaldine H, van Dorsten RT, Woodward Davis AS, Beaume N, Matten D, Lambson B, Modise T, Kgagudi P, York T, Westfall DH, Giorgi EE, Anthony C, Mapengo RE, Bekker V, Domin E, Eaton A, Deng W, DeCamp A*, Huang Y, **Gilbert PB**, Gwashu-Nyangiwe A, Thebus R, Ndabambi N, Mielke D, Mgodi N, Karuna S, Edupuganti S, Seaman M, Corey L, Cohen MS, Hural J, McElrath J, Mullins JI, Montefiori D, Moore PL, Williamson C, Morris L, the HVTN703/HPTN081 and HVTN704/HPTN085 protocol teams, community and participants. Neutralization Profiles of HIV-1 Viruses from the VRC01 AMP trials in Africa and the Americas. *PLoS Pathogens*. 2023 Jun 29;19(6):e1011469. doi: 10.1371/journal.ppat.1011469. PMID: 37384759; PMCID: PMC10337935.
352. Zhou Q, **Gilbert PB**, Sun Y. Analysis of the Cox Model with Longitudinal Covariates with Measurement Errors and Partly Interval Censored Failure Times, with Application to an AIDS Clinical Trial. *Statistics in Biosciences*. 2023 May 20:1-25. doi: 10.1007/s12561-023-09372-y. Epub 2023 May 20. PMID: 37313548; PMCID: PMC10198790.
353. Rick A-M, Laurens MB, Huang Y, Yu C, Martin TCS, Rodriguez CA, Rostad CA, Maboia RM, Baden LR, El Sahly HM, Grinsztejn B, Gray GE, Gay CL, **Gilbert PB**, Janes HE, Kublin JG, Huang Y, Leav B, Hirsch I, Struyf F, Dunkle LM, Neuzil KM, Corey L, Goepfert PA, Walsh SR, Follmann D, Kotloff KL. Risk of COVID-19 after Natural Infection or Vaccination. *eBioMedicine*. 2023; 96:104799. doi: 10.1016/j.ebiom.2023.104799. Epub 2023 Sep 20. PMID: 37738833; PMCID: PMC10518569.
354. Ciani O, Manyara AM, Davies P, Stewart D, Weir CJ, Young AE, Blazeby J, Butcher NJ, Bujkiewicz S, Chan AW, Dawoud D, Offringa M, Ouwers M, Hróbjartsson A, Amstutz A, Bertolaccini L, Bruno VD, Devane D, Faria CDCM, **Gilbert PB**, Harris R, Lassere M, Marinelli L, Markham S, Powers JH, Rezaei Y, Richert L, Schwendicke F, Tereshchenko LG, Thoma A, Turan A, Worrall A, Christensen R, Collins GS, Ross JS, Taylor RS. A Framework for the Definition and Interpretation of the Use of Surrogate Endpoints in Interventional Trials. *eClinicalMedicine*. 2023;65:102283. doi: 10.1016/j.eclinm.2023.102283. PMID: 37877001; PMCID: PMC10590868.
355. Antkowiak L, Boynton-Jarrett R, Chiang SS, Castellon D, **Gilbert PB**, Juraska MJ*, Sox CM, Huang CC. Violence exposure among women in the sex industry and their children in El Alto, Bolivia: a comparative cross-sectional study. *Violence and Victims*. 2023 Oct 23;38(5):736-53. doi: 10.1891/VV-2021-0002. Epub 2023 Oct 12. PMID: 37827582.
356. Hejazi NS, Shen X, Carpp LN, Benkeser D*, Follmann D, Janes HE, Baden LR, El Sahly HM, Deng W, Zhou H, Leav B, Montefiori DC, **Gilbert PB**. Stochastic Interventional Correlates of Protection Analysis of the COVE Trial, with Application to Predict mRNA-1273 Vaccine Efficacy Against SARS-CoV-2 Variants. *International Journal of Infectious Diseases*. 2023. 137:28-39. doi: 10.1016/j.ijid.2023.09.012. Epub 2023 Oct 25. PMID: 37820782; PMCID: PMC10841741.
357. Huang Y, Hejazi NS, Blette B, Carpp LN, Benkeser D*, Montefiori DC, McDermott AB, Fong Y, Janes HE, Deng W, Zhou H, Houchens CR, Martins K, Jayashankar L, Flach B, Lin BC, O'Connell S, McDanal C, Eaton A, Sarzotti-Kelsoe M, Lu Y, Yu C, Kenny A, Carone M, Huynh C, Miller J, El Sahly HM, Baden LR, Jackson LA, Campbell TB, Clark J, Andrasik MP, Kublin JG, Corey L, Neuzil KM, Pajon R, Follmann D, Donis RO, Koup RA, **Gilbert PB**, on behalf of the Immune Assays, Moderna, Inc., Coronavirus Vaccine Prevention Network (CoVPN)/Coronavirus Efficacy (COVE) and United States Government (USG)/CoVPN Biostatistics Teams. Stochastic interventional vaccine efficacy and principal surrogate analyses of antibody markers as correlates of protection against symptomatic COVID-19 in the COVE mRNA-1273 Trial. *Viruses*. 2023 Sep 29;15(10):2029. doi: 10.3390/v15102029. PMID: 37896806; PMCID: PMC10612023.

358. Reeves DB**, Mayer BT**, deCamp AC*, Huang Y, Zhang B, Carpp LN, Magaret CA, **Gilbert PB**, Montefiori D, Bar K, Morris L, Mkhize NN, Williamson C, Mullins JI, Seaton KE, Tomaras GD, Andrew P, Mgodi N, Ledgerwood J, Cohen MS, Corey L, Naidoo L, Orrell C, Goepfert PA, Casapia M, Sobieszczyk ME, Karuna ST**, Edupuganti S**. High monoclonal neutralization titers reduced breakthrough HIV-1 viral loads in the Antibody Mediated Prevention trials. *Nature Communications*. 2023 Dec 14;14(1):8299. doi: 10.1038/s41467-023-43384-y. PMID: 38519455; PMCID: PMC10959920. **Contributed equally
359. Turley CB, Tables L, Fuller T, Sanders LJ, Scott H, Moodley A, Woodward AS, Leav B, Miller J, Hirsch I, Dunkle LM, Li S, van der Laan L, **Gilbert PB**, Follmann D, Janes H, Kublin JG, Baden L, Goepfert P, Kotloff K, Gay C, Falsey AR, El Sahly HM, Sobieszczyk ME, Huang Y, Neuzil K, Grinsztejn B, Chagas E, Gray G, Roupheal N, Luedtke A, on behalf of the COVID Prevention Network (CoVPN). Modifiers of COVID-19 vaccine efficacy: Results from four COVID-19 prevention network efficacy trials. *Vaccine*. 2023 Jul 25;41(33):4899-4906. doi: 10.1016/j.vaccine.2023.06.066. Epub 2023 Jun 23. PMID: 37385888; PMCID: PMC10288314.
360. Williamson BD, Magaret CA, Karuna S, Carpp LN, Gelderblom HC, Huang Y, Benkeser D*, **Gilbert PB**. Application of the SLAPNAP statistical learning tool to broadly neutralizing antibody HIV prevention research. *iScience*. 2023 Sep 15;26(9). doi: 10.1016/j.isci.2023.107595. PMID: 37654470; PMCID: PMC10466901.
361. Ning X, Pan Y, Sun Y, **Gilbert PB**. A semiparametric Cox–Aalen transformation model with censored data. *Biometrics*. 2023 Dec;79(4):3111-25. doi: 10.1111/biom.13895. Epub 2023 Jul 4. PMID: 37403227; PMCID: PMC10764654.
362. Huang Y, Zhang L, Karuna S, Andrew P, Juraska MJ*, Weiner JA, Angier H, Morgan E, Azzam Y, Swann E, Edupuganti S, Mgodi NM, Ackerman ME, Donnell D, Gama L, Anderson PL, Koup RA, Hural J, Cohen MS, Core L, McElrath JM, **Gilbert PB**, Lemos MP. Adults on pre-exposure prophylaxis (tenofovir-emtricitabine) have faster clearance of anti-HIV monoclonal antibody VRC01. *Nature Communications*. 2023 Nov 28;14(1):7813. doi: 10.1038/s41467-023-43399-5. PMID: 38016958; PMCID: PMC10684488.
363. Juraska MJ*, Bai H, deCamp AC*, Magaret CA, Li L, Gillespie K, Carpp LN, Giorgi EE, Ludwig J, Molitor C, Hudson A, Williamson BD, Espy N, Simpkins B, Rudnicki E, Shao D, Rossenkhan R, Edlefsen PT, Westfall DH, Deng W, Chen L, Zhao H, Bhattacharya T, Pankow A, Murrell B, Yssel A, Matten D, York T, Beaume N, Gwashu-Nyangiwe A, Ndabambi N, Thebus R, Karuna ST, Morris L, Montefiori DC, Hural JA, Cohen MS, Corey L, Rolland M, **Gilbert PB**, Williamson C, Mullins JI. Prevention efficacy of the broadly neutralizing antibody VRC01 depends on HIV-1 envelope sequence features. *Proceedings of the National Academy of Sciences of the United States of America*. 2024 Jan 23;121(4):e2308942121. doi: 10.1073/pnas.2308942121. Epub 2024 Jan 19. PMID: 38241441; PMCID: PMC10823214.
364. Wolock CJ, **Gilbert PB**, Simon N, Carone M. A framework for leveraging machine learning tools to estimate personalized survival curves. *Journal of Computational and Graphical Statistics*. 2024;33(3):1098-1108. doi: 10.1080/10618600.2024.2304070. Epub 2024 Feb 13. PMID: 39175935; PMCID: PMC11338658.
365. **Gilbert PB**, Fong Y, Hejazi NS, Kenny A, Huang Y, Carone M, Benkeser D*, Follmann D. Four Statistical Frameworks for Assessing an Immune Correlate of Protection (Surrogate Endpoint) from a Randomized, Controlled, Vaccine Efficacy Trial. *Vaccine*. 2024 Mar 8. doi: 10.1016/j.vaccine.2024.02.071. Epub 2024 Mar 8. PMID: 38458870; PMCID: PMC10999339.
366. Magaret CA, Li L, deCamp AC*, Rolland M, Juraska MJ*, Williamson BD, Ludwig J, Molitor C, Benkeser D*, Luedtke A, Simpkins B, Carpp LN, Bai H, Dearlove BL, Greninger AL, Roychoudhury P, Sadoff J, Gray GE, Roels S, Vandebosch A, Stieh DJ, Le Gars M, Vingerhoets J, Grinsztejn B, Goepfert PA, Truysers C, Van Dromme I, Swann E, Marovich MA, Follmann D, Neuzil KM, Corey L, Hyrien O, **Gilbert PB**. Quantifying how single dose Ad26.CoV2.S vaccine efficacy depends on Spike sequence features. *Nature Communications*. 2024 Mar 11;15(1):2175. doi: 10.1038/s41467-024-46536-w. PMID: 38467646; PMCID: PMC10928100.
367. Sherman A, Tuan J, Cantos VD, Adeyiga O, Mahoney S, Ortega-Villa AM, Tillman A, Whitaker J, Woodward Davis AS, Leav B, Hirsch I, Sadoff J, Dunkle LM, **Gilbert PB**, Janes HE, Kublin JG,

- Goepfert PA, Kotloff K, Rouphael N, Falsey AR, El Sahly HM, Sobieszczyk ME, Huang Y, Neuzil KM, Corey L, Grinsztejn B, Gray G, Nason M, Baden LR, Gay CL. COVID-19 vaccine efficacy in participants with weakened immune systems from four randomized-controlled trials. *Clinical Infectious Diseases*. 2024 Apr 10; doi: 10.1093/cid/ciae192. PMID: 38598658; PMCID: PMC11327800.
368. King D, Groves H, Weller C, Jones I, Plotkin SA, Kampmann B, Gruber MF, **Gilbert PB**, Goldblatt D, Maïga D, Precioso A, Wittke F, Pasetti MF, Wassie L, Cramer JP, Kaslow DC. Realising the potential of Correlates of Protection for vaccine development and licensure. *npj Vaccines*. 2024 Apr 29;9(1):82. doi: 10.1038/s41541-024-00872-6. PMID: 38684704; PMCID: PMC11058756.
369. Manyara AM, Davies P, Stewart D, Weir CJ, Young AE, Blazeby J, Butcher NJ, Bujkiewicz S, Chan AW, Dawoud D, Offringa M, Ouwens M, Hróbjartsson A, Amstutz A, Bertolaccini L, Bruno VD, Devane D, Faria CDCM, **Gilbert PB**, Harris R, Lassere M, Marinelli L, Markham S, Powers JH, Rezaei Y, Richert L, Schwendicke F, Tereshchenko LG, Thoma A, Turan A, Worrall A, Christensen R, Collins GS, Ross JS, Taylor RS, Ciani O. Reporting of surrogate endpoints in randomised controlled trial reports (CONSORT-Surrogate): extension checklist with explanation and elaboration. *British Medical Journal*. 2024; 386:e078524. doi: 10.1136/bmj-2023-078524. PMID: 38981645; PMCID: PMC11231881.
370. Manyara AM, Davies P, Stewart D, Weir CJ, Young AE, Blazeby J, Butcher NJ, Bujkiewicz S, Chan AW, Dawoud D, Offringa M, Ouwens M, Hróbjartsson A, Amstutz A, Bertolaccini L, Bruno VD, Devane D, Faria CDCM, **Gilbert PB**, Harris R, Lassere M, Marinelli L, Markham S, Powers JH, Rezaei Y, Richert L, Schwendicke F, Tereshchenko LG, Thoma A, Turan A, Worrall A, Christensen R, Collins GS, Ross JS, Taylor RS, Ciani O. Reporting of surrogate endpoints in randomised controlled trial protocols (SPIRIT-Surrogate): extension checklist with explanation and elaboration. *British Medical Journal*. 2024;386:e078525. doi: 10.1136/bmj-2023-078525. PMID: 38981624; PMCID: PMC11231880.
371. Mayer BT, Zhang L, deCamp AC*, Yu C, Sato A, Angier H, Seaton KE, Ledgerwood J, Mayer K, Caskey M, Nussenzweig M, Stephenson K, Julg B, Barouch D, Sobieszczyk ME, Edupuganti S, Kelley C, McElrath MJ, Gelderblom H, **Gilbert PB**, Cohen M, Corey L, Pensiero M, McDermott A, Gama L, Koup R, Hyrien O, Tomaras GD, Huang Y. Impact of LS mutation on pharmacokinetics of HIV broadly neutralizing monoclonal antibodies: a cross-protocol analysis of 16 clinical trials in people living without HIV. *Pharmaceutics*. 2024 Apr 27;16(5):594.
372. Fisher LH, Kee JJ, Liu A, Espinosa CM, Randhawa AK, Ludwig J, Magaret CA, Robinson ST, **Gilbert PB**, Hyrien O, Kublin JG, Rouphael N, Falsey AR, Sobieszczyk ME, El Sahly HM, Grinsztejn B, Gray GE, Kotloff KL, Gay CL, Leav B, Hirsch I, Struyf F, Dunkle LM, Neuzil KM, Corey C, Huang Y, Goepfert PA, Walsh SR, Baden LR, Janes HE and the COVID-19 Prevention Network (CoVPN). SARS-CoV-2 Viral Load in the Nasopharynx at Time of First Infection Among Unvaccinated Individuals: A Secondary Cross-Protocol Analysis of 4 Randomized Trials. *JAMA Network Open*. 2024 May 1;7(5):e2412835. doi: 10.1001/jamanetworkopen.2024.12835. PMID: 38780941; PMCID: PMC11117088.
373. Mosmann TR, Rebhahn JA, De Rosa SC, Keefer MC, McElrath MJ, Rouphael NG, Pantaleo G, **Gilbert PB**, Corey L, Kobie JJ, Thakar J. SWIFT clustering analysis of intracellular cytokine staining flow cytometry data of the HVTN 105 vaccine trial reveals high frequencies of HIV-specific CD4+ T cell responses and associations with humoral responses. *Frontiers in Immunology*. 2024 Jun 6;15:1347926. doi: 10.3389/fimmu.2024.1347926. PMID: 38903517; PMCID: PMC11187089.
374. Gray GE, Mngadi K, Lavreys L, Nijs S, **Gilbert PB**, Hural J, Hyrien O, Juraska MJ*, Luedtke A, Mann P, McElrath MJ, Odhiambo JA, Stieh DJ, Takalani AN, Willems W, Tapley A, Tomaras GD, Van Hoof J, Schuitemaker J, Swann E, Barouch DH, Kublin JG, Corey L, Pau MG, Buchbinder S, Tomaka F. Mosaic HIV-1 vaccine regimen in southern African women (Imbokodo/HVTN 705/HPX2008): a randomised, double-blind, placebo-controlled, phase 2b trial. *The Lancet Infectious Diseases*. doi: 10.1016/S1473-3099(24)00358-X. Epub 2024 Jul 19. PMID: 39038477; PMCID: PMC11512672.
375. Garrett NJ, Dintwe O, Monaco CL, Jones M, Seaton KE, Church EC, Grunenberg N, Hutter J, deCamp A*, Huang Y, Lu H, Mann P, Robinson ST, Heptinstall J, Jensen RL, Pantaleo G, Ding S, Koutsoukos M, Hosseinipour MC, Van Der Meeren O, **Gilbert PB**, Ferrari G, Andersen-Nissen E, McElrath MJ, Tomaras GD, Gray GE, Corey L, Kublin JG. Safety and Immunogenicity of a DNA Vaccine With Subtype C gp120 Protein Adjuvanted With MF59 or AS01B: A Phase 1/2a HIV-1 Vaccine Trial. *JAIDS*

- Journal of Acquired Immune Deficiency Syndromes. 2024 Aug 1;96(4):350-60. doi: 10.1097/QAI.0000000000003438. Epub 2024 Jun 21. PMID: 38916429; PMCID: PMC11195930.
376. Williamson BD, Wu L, Huang Y, Hudson A, **Gilbert PB**. Predicting neutralization susceptibility to combination HIV-1 monoclonal broadly neutralizing antibody regimens. PLoS One. 2024 19(9): e0310042. doi: 10.1371/journal.pone.0310042. PMID: 39240995; PMCID: PMC11379218.
377. Follmann D, Wang X, Baden LR, El Sahly HM, Essink B, **Gilbert PB**, Janes HE, Kelley CF, Berman Huang H, Alam S, Andersen-Nissen E, Carpp LN, Dintwe OB, Flach BS, Grunenberg N, Laher F, De Rosa SC, Ferrari G, Innes C, Bekker L-G, Kublin JG, McElrath MJ, Tomaras GD, Gray GE, **Gilbert PB**. Non-HIV vaccine-induced immune responses as potential baseline immunogenicity predictors of ALVAC-HIV and AIDSVAX B/E-induced immune responses. Viruses. 2024 Aug 27;16(9):1365.
378. Zhang B, Fong Y, Fintzi J, Chu E, Janes HE, Carpp LN, Kenny A, Carone M, Benkeser D*, van der Laan LWP, Deng W, Zhou H, Wang X, Lu Y, Yu C, Borate B, Houchens CR, Martins K, Jayashankar L, Huynh C, Fichtenbaum CJ, Kalams S, Gay CL, Andrasik MP, Kublin JG, Corey L, Neuzil KM, Priddy F, Das R, Girard B, El Sahly HM, Baden LR, Donis RO, Koup RA, **Gilbert PB**, Follmann D, on behalf of the Immune Assays Team, the Moderna Inc. Team, the Coronavirus Vaccine Prevention Network (CoVPN)/Coronavirus Efficacy (COVE) Team, and the United States Government (USG)/CoVPN Biostatistics Team. Omicron COVID-19 immune correlates analysis of a third dose of mRNA-1273 in the COVE trial. Nature Communications. 2024 Sep 11;15(1):7954. doi: 10.1038/s41467-024-52348-9. PMID: 39261482; PMCID: PMC11390939.
379. Juraska MJ*, Early AM, Li L, Schaffner SF, Lievens M, Khorgade AR, Simpkins B, Hejazi N, Benkeser DC*, Wang Q, Mercer LD, Adjei S, Agbenyega T, Anderson S, Ansong D, Bii DK, Buabeng PBY, English S, Fitzgerald N, Grimsby J, Kariuki SK, Otieno K, Roman FP, Samuels AM, Westercamp N, Ockenhouse CF, Ofori-Anyinam O, Lee CK, MacInnis BL, Wirth DF, **Gilbert PB**, Neafsey DE. Genotypic analysis of RTS, S/AS01E malaria vaccine efficacy against parasite infection as a function of dosage regimen and baseline malaria infection status in children aged 5–17 months in Ghana and Kenya: a longitudinal phase 2b randomised controlled trial. The Lancet Infectious Diseases. 2024 Sep 1;24(9):1025-36. doi: 10.1016/S1473-3099(24)00179-8. Epub 2024 May 6. PMID: 38723650; PMCID: PMC11339203.
380. MA, Frank I, Chu E, Deng W, Priddy F, Dixit A, Tomassini JE, Das R, Miller J, Zhou H. Who to Boost When: The Effect of Age and Dosing Interval on Delta and Omicron COVID-19 Incidence in the Open Label Phase of the COVE Trial. Open Forum Infect Dis. 2024 Nov 25;11(12):ofae689. doi: 10.1093/ofid/ofae689. PMID: 39679349; PMCID: PMC11639572.
381. Carpp LN, Hyrien O, Fong Y, Benkeser D*, Roels S, Stieh DJ, Van Dromme I, Van Roey GA, Kenny A, Carone M, McDermott AB, Houchens CR, Martins K, Jayashankar L, Castellino F, Amoa-Awua O, Basappa M, Flach B, Lin BC, Moore C, Naisan M, Naqvi M, Narpala S, O'Connell S, Mueller A, Serebryanny L, Castro M, Wang J, Petropoulos CJ, Luedtke A, Lu Y, Yu C, Juraska MJ*, Hejazi NS, Wolfe DN, Sadoff J, Gray GE, Grinsztejn B, Goepfert PA, Bekker L-G, Gaur AH, Veloso VG, Randhawa AK, Andrasik MP, Hendriks J, Truyers C, Vandebosch A, Struyf F, Schuitemaker H, Douoguih M, Kublin JG, Corey L, Neuzil KM, Follmann D, Koup RA, Donis RO, **Gilbert PB** on behalf of the Immune Assays Team, the Coronavirus Vaccine Prevention Network (CoVPN)/ENSEMBLE Team, and the United States Government (USG)/CoVPN Biostatistics Team. Neutralizing Antibody Correlate of Vaccine Protection Against Severe-Critical COVID-19. Nature Communications. 2024 Nov 12;15(1):9785.
382. Kenny A**, van Duijn J**, Dintwe O**, Heptinstall J**, Burnham R, Sawant S, Zhang L, Mielke D, Khuzwayo S, Laher Omar F, Stanfield-Oakley S, Keyes T, Dunn B, Goodman D, Fong Y, Benkeser D*, Zou R, Hural J, Hyrien O, Juraska MJ*, Luedtke A, van der Laan L, Giorgi EE, Margaret CA, Carpp LN, Pattacini L, van de Kerkhof T, Korber B, Willems W, Fisher LH, Schuitemaker H, Swann E, Kublin JG, Pau MJ, Buchbinder S, Tomaka F, Nijs S, Lavreys L, Gelderblom HC, Corey L, Mngadi K, Gray GE, Borducchi E, Hendriks J, Seaton KE, Zolla-Pazner S, Barouch DH, Ferrari G, De Rosa SC, McElrath MJ, Andersen-Nissen E, Stieh DJ, Tomaras GD**, **Gilbert PB****. Imbokodo Study and Correlates Group. Immune Correlates Results for the Imbokodo (HVTN 705/HPX2008) Efficacy Trial of a Mosaic

- HIV-1 Vaccine Regimen Evaluated in Southern African Women. *EBioMedicine*. 2024 Oct 1;108.
 **Contributed equally
383. Lin L, Spreng RL, Seaton KE, Dennison M, Dahora LC, Schuster DJ, Sawant S, **Gilbert PB**, Fong Y, Kisalu N, Pollard AJ, Tomaras GD, Li J. GeM-LR: Discovering predictive biomarkers for small datasets in vaccine studies. *PLoS Computational Biology*. 2024 Nov 14;20(11):e1012581.
 384. Cohen P, Lambson BE, Mkhize NN, Moodley C, Yssel AEJ, Moyo-Gwete T, York T, Gwashu-Nyangiwe A, Ndabambi N, Thebus R, Juraska MJ*, DeCamp A*, Williamson B, Magaret CA, **Gilbert PB**, Westfall D, Deng W, Mullins JJ, Morris L, Williamson C**, Moore PL**. Resistance mutations that distinguish HIV-1 envelopes with discordant VRC01 phenotypes from multi-lineage infections in the HVTN 703/HPTN 081 Trial: Implications for cross resistance. *Journal of Virology*. 2025 Jan 16:e01730-24.**Contributed equally
 385. Wolock CJ, **Gilbert PB**, Simon N, Carone M. Assessing variable importance in survival analysis using machine learning. *Biometrika*. 2025;112(2):asae061.
 386. Fong Y, Dang L, Zhang B, Fintzi J, Chen S, Wang J, Roupheal NG, Branche AR, Diemert DJ, Falsey AR, Losada C, Baden LR, Frey SE, Whitaker JA, Little SJ, Kamidani S, Walter EB, Novak RM, Rupp R, Jackson LA, Yu C, Magaret CA, Molitor C, Borate B, Babu TM, Kottkamp AC, Luetkemeyer AF, Immergluck LC, Presti RM, Bäcker M, Winokur PL, Mahgoub SM, Goepfert PA, Fusco DN, Atmar RL, Posavad CM, Mu J, Makowski M, Makhene MK, Crandon S, Roberts PC, Follmann D, **Gilbert PB** and the Coronavirus Variant Immunologic Landscape Trial (COVAIL) Study Team. Neutralizing Antibody Immune Correlates for a Recombinant Protein Vaccine in the COVAIL Trial. *Clinical Infectious Diseases*. 2025 Jan 15;80(1):223-7.
 387. Ning X, Sun Y, Pan Y, **Gilbert PB**. Regression analysis of semiparametric Cox-Aalen transformation models with partly interval-censored data. *Electronic Journal of Statistics*. 2025 Vol. 19, No. 1, 240-290.
 388. Garrett N**, Tapley A**, Hudson A, Dadabhai S, Zhang B, Mgodi NM, Andriesen J, Takalani A, Fisher LH, Kee JJ, Magaret CA, Villaran M, Hural J, Andersen-Nissen E, Ferarri G, Le Roux B, Wilkinson E, Lessells R, de Oliveira T, Odhiambo J, Shah P, Polakowski L, Yacovone, M, Samandari T, Chirenje Z, Elyanu PJ, Makhema J, Kamuti E, Nuwagaba-Biribonwoha H, Badal-Faesens S, Brumskine W, Coetzer S, Dawson R, Delany-Moretlwe S, Henri Diacon A, Fry S, Gill KM, Ebrahim Hoosain ZA, Hosseinipour MC, Inambao M, Innes C, Innes S, Kalonji D, Kasaro M, Kassim P, Kayange N, Kilembe W, Laher F, Malahleha M, Maluleke VL, Mboya G, McHarry K, Mitha E, Mngadi K, Mda P, Moloantsoa T, Kityo Mutuluza C, Naicker N, Naicker V, Nana A, Nanvubya A, Nchabeleng M, Otieno W, Potgieter EL, Potloane D, Punt Z, Said J, Singh Y, Siddique Tayob M, Vahed Y, Ogema Wabwire D, McElrath JM, Kublin JG, Bekker L-J, **Gilbert PB**, Corey L, Gray GE, Huang Y**, Kotze P**, for the Ubuntu Study Team. Hybrid versus vaccine immunity of mRNA-1273 among people living with HIV in East and Southern Africa: the multicentre, open-label COVPN 3008 (Ubuntu) clinical trial. *eClinicalMedicine*. 2025;80: 103054. **Contributed equally
 389. Zhang B, Fong Y, Dang L, Fintzi J, Chen S, Wang J, Roupheal NG, Branche AR, Diemert DJ, Falsey AR, Graciaa DS, Baden LR, Frey SE, Whitaker JA, Little SJ, Kamidani S, Walter EB, Novak RM, Rupp R, Jackson LA, Yu C, Magaret CA, Molitor C, Borate B, Busch S, Benkeser D*, Netzl A, Smith DJ, Babu RM, Kottkamp AC, Luetkemeyer AF, Immergluck LC, Presti RM, Bäcker M, Winokur PL, Mahgoub SM, Goepfert PA, Fusco DN, Atmar RL, Posavad CM, Mu J, Makowski M, Makhene MK, Nayak SU, Roberts PC, **Gilbert PB**, Follmann D and the Coronavirus Variant Immunologic Landscape Trial (COVAIL) Study Team. Neutralizing antibody immune correlates in COVAIL trial recipients of an mRNA second COVID-19 vaccine boost. *Nature Communications*. 2025 Jan 17;16(1):759.
 390. Heng F, Sun Y, Li L, **Gilbert PB**. Estimation and Hypothesis Testing of Strain-Specific Vaccine Efficacy With Missing Strain Types With Application to a COVID-19 Vaccine Trial. *Statistics in Medicine*. 2025 44: e10345. <https://doi.org/10.1002/sim.10345>
 391. Li S, **Gilbert PB**, Duan R, Luedtke A. Data fusion using weakly aligned sources. *Journal of the American Statistical Association*. 2025. 1–28. <https://doi.org/10.1080/01621459.2025.2476780>
 392. Fisher L, Lazarus E, Yu C, Moodie Z, Stieh DJ, Yates N, Zhang L, Sawant S, De Rosa SC, Cohen KC, Morris D, Grant S, Randhawa A, Miner MD, Hendriks J, Wegmann F, Gill KM, Laher F, Bekker L-G, Gray GE, Corey L, McElrath MJ, Martin T, **Gilbert PB**, Tomaras GD, Walsh SR, Baden LR. ALVAC-

- Prime and Monomeric gp120 Protein Boost Induces Distinct HIV-1 Specific Humoral and Cellular Responses Compared with Adenovirus-Prime and Trimeric gp140 Protein Boost. *PLoS Global Public Health*. 2025 April 11. <https://doi.org/10.1371/journal.pgph.0004250>
393. **Gilbert PB**, Peng J*, Han L, Lange T, Lu Y, Nie L, Shih M-C, Waddy SP, Wiley K, Yann M, Zafari Z, Ghosh D, Follmann D, Juraska MJ*, Díaz I. A Surrogate Endpoint Based Provisional Approval Causal Roadmap, Illustrated by Vaccine Development. *Biostatistics* 2025;26(1):kxaf018.
 394. Andrews LIB*, Halloran ME, Neuzil KM, van der Laan L, Huang Y, Andriesen J, Patel M, Fisher LH, Janes H, Roupheal N, Walsh SR, Theodore DA, Tieu H-V, Sobieszczyk M, El Sahly HE, Baden LR, Falsey AR, Campbell TB, Kelley CF, Healy CM, Immergluck L, Luft B, Hirsch I, de Bruyn G, Truyers C, Priddy F, Sumner KM, Flannery BM, Follmann D, **Gilbert PB**, COVID-19 Prevention Network (CoVPN) Team. Evaluating the Test-Negative Design for COVID-19 Vaccine Effectiveness Using Randomized Trial Data: A Secondary Cross-Protocol Analysis of 5 Randomized Clinical Trials. *JAMA Network Open*, 8(5), pp.e2512763-e2512763.
 395. Richardson BD, Blette BS, Gilbert PB, **Hudgens MG**. Addressing confounding and continuous exposure measurement error using corrected score functions. *Biometrics*. 2025 Jun;81(2):ujaf045.
 396. Moodie Z, Li SS, Giorgi EE, Williams LD, Dintwe O, Carpp LN, Chen S, Seaton KE, Sawant SS, Zhang L, Heptinstall J, Liu S, Grunenber N, Tomaka F, Rerks-Ngarm S, Pitisuttithum P, Nitayaphan S, Ake JA, Vasan S, Pantaleo G, Frank I, Baden LR, Goepfert PA, Keefer M, Chirenje M, Hosseinipour MC, Mngadi K, Laher F, Garrett N, Bekker L-G, De Rosa S, Andersen-Nissen E, Kublin JG, Lu S, **Gilbert PB**, Gray GE, Corey L, McElrath MJ, Tomaras GD. A polyvalent DNA prime with matched polyvalent protein/GLA-SE boost regimen elicited the most robust and broad IgG and IgG3 V1V2 binding antibody and CD4+ T cell responses among 13 HIV vaccine trials. *Emerging microbes & Infections*. 2025. 14(1), p.2485317.
 397. Huang Y, Zhang L, Gelderblom H, Seaton K, Yates N, Paez C, Karuna S, Andrew P, Gamble T, Robinson S, Ledgerwood J, Hyrien O, Walsh S, Gay C, Gwira J, Spiegel H, Sobieszczyk M, Mannheimer S, Edupuganti S, Hurt C, Stephenson K, Yu C, Kelley C, Mahomed S, Siegel M, Yacovone M, Pensiero M, Donnell D, Cohen M, Corey L, **Gilbert PB**, Koup R, Tomaras G on behalf of VRC 605, HVTN 127/HPTN 087, HVTN 130/HPTN 089, HVTN 136/HPTN 091, and HVTN 140/HPTN 101 study teams. Fixed Dosing Versus Weight-Based Dosing of HIV-1 Prophylactic Monoclonal Antibodies in Adults: A Pharmacokinetics Modeling Study. *eBioMedicine*. 2025. Volume 117, 105804.

In Press:

1. Luedtke A, Fong Y, van der Laan L, Heng F, Lu Y, Yu C, Carpp LN, Roels S, Le Gars M, Van Roey GA, Stieh DJ, Van Dromme I, Kenny A, Carone M, Hyrien O, Houchens CR, Martins K, Jayashankar L, Castellino F, DeGrace MM, Amoa-Awua O, Basappa M, Flach B, Lin BC, Moore C, Naisan M, Naqvi M, Narpala S, O'Connell S, Mueller A, Serebryanny L, Castro M, Wang J, Randhawa AK, Andrasik MP, Hendriks J, Truyers C, Struyf F, Schuitemaker H, Douoguih M, Kublin JG, Corey L, Neuzil KM, Wolfe DN, Bekker L-G, Garrett N, Cardoso SW, DelaFontaine P, Magaret CA, Vingerhoets J, Casapia M, Losso MH, Little SJ, Gaur A, Swann E, Petropoulos CJ, McDermott AB, Sadoff J, Gray GE, Grinsztejn B, Goepfert PA, Follmann D, Roychoudhury P, Greninger AL, Koup RA, Donis RO, **Gilbert PB** on behalf of the Immune Assays Team, the Coronavirus Vaccine Prevention Network (CoVPN)/ENSEMBLE Team, and the United States Government (USG)/CoVPN Biostatistics Team. Immune correlates analysis of antibody responses against SARS-CoV-2 variants in the ENSEMBLE vaccine efficacy trial (*eScience*).
2. Rossenkhon R, Giorgi E, Shao D, Ludwig J, Labuschagne P, Magaret C, Ndung'u T, Muema D, Gounder K, Dong K, Walker BD, Rolland M, Robb M, Eller LA, Sawe F, Nitayaphan S, Grebe E, Busch M, Delaney K, Facente S, Carpp L, deCamp A, Huang Y, Korber B, Juraska M, Rudnicki E, Kosmider E, Reeves D, Mayer B, Hural J, Deng W, Westfall D, Yssel A, Matten D, Bhattacharya T, Corey L, **Gilbert PB**, Williamson C, Mullins J, Edlefsen P. Bayesian estimation of HIV acquisition dates for prevention trials (*mBio*).
3. Chu HY, Janes H, Carone M, **Gilbert PB**, Plotkin S. Improving the evidence base for COVID-19 vaccines (*Nature Medicine*).

4. Buchbinder SP, Guzman SS, Sanchez J, Willems W, Stieh DJ, van Duijn J, van Rosmalen MGM, Hendriks J, Nijs S, Lavreys L, Paez CA, Grinzstejn B, Hutter J, Mann P, Sierra Madero JG, Cahn P, Castagna A, Truysers C, Roels S, **Gilbert PB**, Carone M, Luedtke A, Corey L, Pau MG, Tomaka F. Efficacy and Safety of a Mosaic HIV-1 Vaccine Regimen: A Global, Randomised, Double-blind, Placebo-controlled, Phase 3 Trial (HVTN 706/HPX3002/Mosaico) (*Lancet HIV*).
5. Ashby E, Janes H, Follmann D, **Gilbert PB**, Zhou H, Wang X, Girard B, Priddy F, Kublin JG, Corey L, Neuzil KM, Baden LR, El Sahly HM, Zhang B, on behalf of COVE study group. Validating and Leveraging Non-SARS-CoV-2 Respiratory Infection as a Negative Control Outcome in a Phase 3 COVID-19 Vaccine Trial with Extended Observational Follow-Up (*American Journal of Epidemiology*).
6. **Mkhize N*, Zhang B*, Beckett C*, et al., Tomaras G, Gilbert PB**. Neutralizing and Binding Antibodies are a Correlate of Risk of COVID-19 in the CoVPN 3008 Study in People with HIV (*Nature Communications*). *Contributed equally
7. Carone M, Wolock CJ, Olivas-Martinez A, Rotnitzky A, **Gilbert PB**. Immune Correlates and Vaccine Immunobridging: Statistical Innovations, Challenges and Opportunities (*Journal of Infectious Diseases*).

Under Peer-review:

1. Erdmann N, Williams W, Walsh SR, Grunenber N, Edlefsen E, Goepfert PA, Cain DW, Parks R, Maenza J, Mayer K, Van Tieu H, Sobieszczyk ME, Swann E, Lu H, De Rosa SC, Sagawa Z, Moody MA, Fox CB, Ferrari G, Edwards RJ, Acharya P, Alam SM, Parks R, Barr M, Tomaras GD, Montefiori DC, **Gilbert PB**, McElrath MJ, Corey L, Haynes BF, Baden LR and the NIAID HVTN 133 Study Group. Title. A HIV-1 Gp41 Peptide-Liposome Vaccine Elicits Neutralizing Epitope-Targeted Antibody Responses in Healthy Individuals (Submitted for peer-review).
2. Janes HE, Fong Y, Huang Y, Benkeser D, Kelly EJ, Hirsch I, Stanley AM, Villafana T, Houchens CR, Martins K, Jayashankar L, Castellino F, Ayala VI, Petropoulos CJ, Leith A, Haugaard D, Webb B, Lu Y, Yu C, Borate B, van der Laan LWP, Hejazi NS, Randhawa AK, Andrasik MP, Kublin JG, Isaacs MB, Makhene M, Tong T, Robb ML, Corey L, Neuzil KM, Follmann D, Hoffman C, Falsey AR, Sobieszczyk M, Koup RA, Donis RO, **Gilbert PB** on behalf of the AstraZeneca AZD1222 Clinical Study Group, the Immune Assays Team, & the United States Government (USG)/CoVPN Biostatistics Team. Immune Correlates of Severe and Delta COVID-19 in a Phase 3 Trial of the AZD1222 (ChAdOx1 nCoV-19) Vaccine (Submitted for peer-review).
3. Fong Y, Huang Y, Huang Y, Woo W, McGarry A, Áñez G, Dunkle LM, Cho I, Houchens CR, Martins K, Jayashankar L, Castellino F, Petropoulos CJ, Leith A, Haugaard D, Webb B, Lu Y, Yu C, Carpp LN, Randhawa AK, Andrasik MP, Kublin JG, Hutter J, Keshtkar-Jahromi M, Beresnev TH, Rodriguez CA, Tapia M, Turley CB, Zorrilla CD, Cohen SH, Kline SE, Barranco E, Corey L, Neuzil KM, Follmann D, Ake JA, Gay CL, Kotloff KL, Koup RA*, Donis RO*, **Gilbert PB*** on behalf of the Immune Assays Team, the Coronavirus Vaccine Prevention Network (CoVPN)/2019nCoV-301 Principal Investigators and Study Team, and the United States Government (USG)/CoVPN Biostatistics Team. Analysis of Antibody Markers as Immune Correlates of Risk of Severe COVID-19 and of Delta COVID-19 in the PREVENT-19 Vaccine Efficacy Trial (Submitted for peer-review). *Contributed equally
4. Giesemann L, DeLaitch AT, Gruell H, Kreer C, Ercanoglu MS, Gristick HB, Schommers P, Ahmadov E, Radford C, Mazzolini A, Rohde M, Zhang L, West Jr. AP, Reichwein L, Knüfer J, Stumpf R, Mkhize NN, Kroidl A, Geldmacher C, Adhikari A, Nanfack AJ, Ambada GE, Duerr R, Maganga L, William W, Ntinginya NE, Wolf T, Hoelscher M, Lehmann C, Moore P, Mora T, Walczak AM, **Gilbert PB**, Doria-Rose NA, Huang Y, Bloom JD, Seaman M, Bjorkman PJ, Klein F. Profiling a large HIV-1 elite neutralizer cohort reveals remarkable CD4bs bNAb for HIV-1 prevention and therapy (Submitted for peer-review).
5. Edge R, Ahani B, Aksyuk A, Clegg L, Matthews S, Esser MT, Hirsch I, Perez J, Pura J, Stepanov O, Streicher K, White T, Cohen TS, Follmann D, **Gilbert PB**, Seegobin S. A SARS-CoV-2 variant-adjusted threshold of protection model for monoclonal antibody pre-exposure prophylaxis against COVID-19 (Submitted for peer-review).
6. Hudson A, Borgetti S, Rick AM, Laurens MB, Robinson S, Gay C, Baden L, Goepfert P, Roupheal N, El Sahly H, Gray G, Grinsztejn B, Sobieszczyk M, Falsey A, Huang Y, Janes H, Follmann D, Koup R, Donis R, Jayashankar L, Ayala V, Jones T, DeGrace M, Priddy F, Hendriks J, Shoemaker K, Dunkle L, De Bruyn

- G, Devlin L, Neuzil K, Kublin J, Corey L, Walsh S, Kotloff K, **Gilbert PB**. Impact of prior SARS-CoV-2 acquisition on binding and neutralizing antibody responses following COVID-19 vaccination: A cross-protocol analysis of individual-level data from six phase 3 clinical trials. (Submitted for peer-review).
7. Jin Y, **Gilbert PB**, Hudson A. A class of nonparametric methods for evaluating the effect of continuous treatments on survival outcomes (Submitted for peer-review).
 8. Wang, CY, Tapsoba JD, Moodie Z, **Gilbert PB**. Combined Assessment of Efficacy in Dengue Vaccine Trials with Two-Phase Follow-up Data (Submitted for peer review).
 9. Gao C, **Gilbert PB**, Han L. On the Role of Surrogates in Conformal Inference of Individual Causal Effects (Submitted for peer review).
 10. Juraska MJ*, Li L, Magaret CA, Giorgi EE, Molitor C, Ludwig J, Carpp LN, Peng J*, deCamp AC*, Kee JJ, Edlefsen PT, Rossenkhani R, Westfall DH, Deng W, Chen L, Zhao H, Yssel A, Matten D, York T, Gwashu-Nyangiwe A, Ndabambi N, Thebus R, Swann EM, Hural JA, van Duijn J, Buchbinder S, Tomaka F, Corey L, Mngadi K, Gray GE, **Gilbert PB**, Williamson C, Mullins JI. Quantifying how a Mosaic HIV-1 Vaccine Regimen's Efficacy Depends on Envelope Sequence Features in the HVTN 705/HPX2008 Trial (Submitted for peer review).
 11. Kenny A, van der Laan L, **Gilbert PB**, Carone M. Inference on controlled effects for assessing immune correlates of protection based on a Cox model (Submitted for peer review).
 12. Follmann D, Dang L, Chu E, Fintzi J, Janes HE, **Gilbert PB**, Andrews LIB*, Serebryanny L, Carroll R, Lin B, Koup R, Toma J, Deng W, Priddy F, Dixit A, Zhou H, Baden LA, El Sahly H. A test negative design for immune correlates approximates a traditional exposure proximal design but requires far fewer blood samples (Submitted for peer review).
 13. van der Laan L, **Gilbert PB**. Semiparametric logistic regression for inference on relative vaccine efficacy in case-only studies with informative missingness (Submitted for peer review).
 14. Xu J, Sun Y, Heng F, **Gilbert PB**. Estimation and Inference of Semiparametric Temporal Intensity Models for Recurrent Events with Application to a Malaria Vaccine Trial (Submitted for peer review).
 15. Meissner HC, **Gilbert PB**, Eisnor D, Wolfe DN. Thoughts regarding the contribution of cellular immunity to a correlate of protection for viral infections (Submitted for peer review).

B. Other Refereed Scholarly Articles

N/A

C. Books and Book Chapters

1. **Gilbert PB**, Bosch R. Applications of semiparametric biased sampling models to AIDS vaccine and treatment trials. Probability Theory and Mathematical Statistics, Proceedings of the 7th Vilnius Conference on Probability Theory and Mathematical Statistics, published by VSP, Utrecht, the Netherlands and TEV, Vilnius, Lithuania, 1999.
2. **Gilbert PB**, Esparza J. HIV-1 vaccine testing, trial design, and ethics. In: *AIDS in Africa, Second Edition*, Editors M. Essex, S. M'Boup, P. Kanki, R. Marlink, S. Tlou, 2002. Kluwer Academic, New York.
3. Cai T, **Gilbert PB**, Self SG. Cox model inferences on relative risks linked in two stages. Cambridge, Massachusetts; Harvard University, 2004.
4. **Gilbert PB**, Sun Y. Simultaneous inferences of HIV vaccine effects on viral load, CD4 cell counts, and antiretroviral therapy initiation in Phase 3 trials. In: *Deterministic and Stochastic Models of HIV with Intervention*, Editors W.-Y. Tan and H. Wu, 2005. World Scientific Publishing Co, Singapore, Hackensack, New Jersey London.
5. **Gilbert PB**, Grove D. A sequential two-stage trial design for evaluating efficacy and immune correlates for multiple vaccine regimens. HVTN News (a publication of the HIV Vaccine Trials Network), Seattle, Washington USA 2011; 3(1) 2-4.

6. **Gilbert PB**, deCamp A*, Edlefsen P, Magaret C, Hertz T. Sieve analysis of HIV sequences in vaccine efficacy trials. HVTN News (a publication of the HIV Vaccine Trials Network), Seattle, Washington USA, 2011; 3(1) 5-7.
7. **Gilbert PB**, Sun Y. Testing mark-specific vaccine efficacy with missing marks. Proceedings of the 59th ISI World Statistics Congress, Hong Kong, China, 2013.
8. Adamson B, Hertz T, Duerr A, Morgan C, Keefer M, Churchyard G, Graham B, **Gilbert PB**, Kublin J, NIAID HIV Vaccine Trials Network. Baseline predictors of immunogenicity in HVTN 204. Proceedings of the 2013 AIDS Vaccine Conference, Barcelona, Spain, October 2013. AIDS Research and Human Retroviruses. 2013; 29(11): A64-A65.
9. Hammer S, Sobieszczyk M, Janes H, **Gilbert PB**, Karuna S, Grove D, Ramirez S, Bentley C, Anude C, Mulligan M, Koblin B, Buchbinder S, Keefer M, Hural J, McElrath MJ, Frahm N, Tomaras G, Graham B, Enama M, Broder G, Maynard J, Wakefield S, Holt R, DeJesus E, Frank I, Novak R, Martinez A, Kublin J, Corey L, HIV Vaccine Trials Network. HVTN 505: Efficacy of a multi-gene DNA Prime/Recombinant adeno 5 (rAd5) vector boost vaccine in men & transgender women (TGW) who have sex with men. Proceedings of the 2013 AIDS Vaccine Conference, Barcelona, Spain, October 2013. AIDS Research and Human Retroviruses. 2013; 29(11): A172-A172.
10. Huang Y, Duerr A, Moodie Z, Frahm N, DeRosa S, McElrath J, **Gilbert PB**. Immune-correlates analysis of the Step HIV vaccine efficacy trial-A post-hoc analysis of HIV-specific and non-specific cellular immune responses. Proceedings of the 2013 AIDS Vaccine Conference, Barcelona, Spain, October 2013. AIDS Research and Human Retroviruses. 2013; 29(11): A119-A119.
11. Li SS, **Gilbert PB**, Tomaras GD, Kijak G, Ferrari G, Thomas R, Zolla-Pazner S, Evans DT, Li Y, Gottardo R, Dai JY, Janes H, Morris D, Fong Y, Edlefsen PT, Li F, Magaret CA, Frahm N, Alpert MD, Rerks-Ngarm S, Pitisuttithum P, Kaewkungwal J, Nitayaphan S, Robb ML, O'Connell RJ, Michael NL, Kim JH, McElrath MJ, Geraghty DE. Association of Fc gamma RIIC polymorphism with vaccine efficacy and correlates of HIV-1 infection risk in RV144. Proceedings of the 2013 AIDS Vaccine Conference, Barcelona, Spain, October 2013. AIDS Research and Human Retroviruses. 2013; 29(11): A178-A179.
12. Prentice H, Geraghty DE, Tomaras GD, Fong Y, Nelson W, Kijak GH, Zolla-Pazner S, Nitayaphan S, Rerks-Ngarm S, Kaewkungwal J, Pitisuttithum P, **Gilbert PB**, Haynes BF, Kim JH, Michael N, Thomas R. HLA class II genes interact with the immune correlates from the RV144 vaccine efficacy trial and impact HIV-1 acquisition. Proceedings of the 2013 AIDS Vaccine Conference, Barcelona, Spain, October 2013. AIDS Research and Human Retroviruses. 2013; 29(11): A178-A178.
13. Rolland M, Edlefsen PT, Gottardo R, Montefiori DC, Zolla-Pazner S, Moody A, Liao LH, Liu P, Tomaras GD, Haynes BF, Bailer RT, Koup RA, Mascola JR, Shen X, Korber BT, Tovanabutra S, Rerks-Ngarm S, Nitayaphan S, Pitisuttithum P, Kaewkungwal J, Robb ML, Michael NL, Mullins JI, **Gilbert PB**, Kim JH. Genetic and immunological evidence for a role of env-V3 antibodies in the RV144 trial. Proceedings of the 2013 AIDS Vaccine Conference, Barcelona, Spain, October 2013. AIDS Research and Human Retroviruses. 2013; 29(11): A168-A168.
14. Seaton K, Yates N, Williams W, Liao L, deCamp A*, Fong Y, Montefiori D, Spearman P, Elizaga M, Barnett S, Koutsoukos M, Bourguignon P, McElrath MJ, Corey L, Michael N, Pitisuttithum P, Rerks-Ngarm S, Kim J, Voss G, **Gilbert PB**, Haynes B, Tomaras G. Human induced antibody durability and env IgG3 responses. Proceedings of the 2013 AIDS Vaccine Conference, Barcelona, Spain, October 2013. AIDS Research and Human Retroviruses. 2013; 29(11): A187-A187.
15. Williams WB, Jones K, Liu P, Trama AM, Seaton K, Moody MA, Vandergrift N, Wiehe K, Liao H, Montefiori DC, Ochsenbauer C, Kappes J, Hammer SM, Mascola J, Koup R, Corey L, Nabel G, **Gilbert PB**, Morgan CA, Churchyard G, Maenza J, Baden LR, Keefer M, Graham BS, Tomaras GD, Haynes BF. Antibody repertoire induced by the multiclade (env A, B, C) HIV-1 DNA prime, rAd5 boost VRC vaccine. Proceedings of the 2013 AIDS Vaccine Conference, Barcelona, Spain, October 2013. AIDS Research and Human Retroviruses. 2013; 29(11): A9-A9.
16. Miao X, Li X, **Gilbert PB**, Chan ISF. A multiple imputation approach for surrogate marker evaluation in the principal stratification causal inference framework. In: Risk Assessment and Evaluation of Predictions Volume 210, Editors Mei-Ling Ting Lee, Mitchell Gail, Glen Satten, Tianxi Cai, Ruth Pfeiffer, Axel Gandy, 2013. Springer, New York.

17. **Gilbert PB**, Gottardo R. Methodological considerations in vaccine trials. In: Human Vaccines: Emerging Technologies in Design & Development, Editors Kayvon Modjarrad, Wayne C. Koff, 2016. Elsevier Science and Technologies.
18. Plotkin SA, **Gilbert PB**. Correlates of Protection. In: Vaccines, Seventh Edition, Editors Stanley Plotkin, Walter Orenstein, Paul Offit. Pages 35-40. Elsevier Inc., New York, 2018.
19. Benkeser D*, Carone M, **Gilbert PB**. Targeted estimation of cumulative vaccine sieve effects. In: Targeted Learning in Data Science: Causal Inference for Complex Longitudinal Studies, Editors Mark J. van der Laan and Sherri Rose. 2018. Springer, New York.
20. Plotkin SA, **Gilbert PB**. Correlates of Protection. In: Vaccines, Eighth Edition, Editors Walter Orenstein, Paul Offit, Kathryn Edwards, Stanley Plotkin. Pages 35-40. Elsevier Inc., New York, 2022.

D. Other Non-Refereed Published Scholarly Publications

1. Workshop and report participant. Considerations regarding efficacy endpoints in HIV vaccine trials: Executive summary and recommendations of an expert panel consultation jointly organized by WHO, UNAIDS and ANRS in support of the Global HIV Vaccine Enterprise. *Vaccine*. 2009;27(14):1989-96.
2. **Gilbert PB**. Review of "Design of Observational Studies" by PR Rosenbaum. *Biometrics*. 2010 Sep;66(3):994-5.
3. Luedtke AR, **Gilbert PB**. Partial Bridging of Vaccine Efficacy to New Populations. *arXiv preprint arXiv:1701.06739*. 2017.
4. Fong Y, Huang Y, Benkeser D*, Carpp LN, Áñez G, Woo W, McGarry A, Dunkle LM, Cho I, Houchens C, Martins K, Jayashankar L, Castellino F, Petropoulos CJ, Leith A, Haugaard D, Webb B, Lu Y, Yu C, Borate B, van der Laan LWP, Hejazi NS, Randhawa AK, Andrasik MP, Kublin JG, Hutter J, Keshtkar-Jahromi M, Beresnev TH, Corey L, Neuzil KM, Follmann D, Ake JA, Gay CL, Kotloff KL, Koup RA, Donis RO, **Gilbert PB**, the Immune Assays Team, the Coronavirus Vaccine Prevention Network (CoVPN)/2019nCoV-301 Principal Investigators and Study Team, the United States Government (USG)/CoVPN Biostatistics Team. Immune Correlates Analysis of the PREVENT-19 COVID-19 Vaccine Efficacy Clinical Trial. *medRxiv preprint* doi: <https://doi.org/10.1101/2022.06.22.22276362>. 2022.
5. Khoury DS, Schlub TE, Cromer D, Steain M, Fong Y, **Gilbert PB**, Subbarao K, Triccas JA, Kent SJ, Davenport MP. Correlates of protection, thresholds of protection, and immunobridging in SARS-CoV-2 infection. *medRxiv*. 2022 Jan 1.
6. Elder A, Carone M, **Gilbert PB**, Luedtke A. A general adaptive framework for multivariate point null testing. *arXiv:2203.01897*. 2022 Mar 3.
7. **Gilbert PB**, Rolland M, DeCamp A*, Juraska MJ*, Li L, Ludwig J, et al. (2023): ENSEMBLE Phase 3 Trial Sieve Analysis Statistical Analysis Plan. figshare. Online resource. <https://doi.org/10.6084/m9.figshare.21920652.v1>
8. Van der Laan L, **Gilbert PB**. Semiparametric inference for relative heterogeneous vaccine efficacy between strains in observational case-only studies. *arXiv*. 2023. 2303.11462.
9. Dayan GH, Roupahel N, Walsh SR, Chen A, Grunenber N, Allen M, Antony J, Asante KP, Bhate AS, Beresnev T, Bonaparte MI. Efficacy of a bivalent (D614+ B. 1.351) SARS-CoV-2 recombinant protein vaccine with AS03 adjuvant in adults: a phase 3, parallel, randomised, modified double-blind, placebo-controlled trial. *The Lancet Respiratory Medicine*. 2023 Sep 13. **Gilbert PB** member of the VAT00008 Study Team.
10. Zhang B, Fong Y, Fintzi J, Chu E, Janes HE, Carpp LN, Kenny A, Carone M, Benkeser D*, van der Laan LWP, Deng W, Zhou H, Wang X, Lu Y, Yu C, Borate B, Houchens CR, Martins K, Jayashankar L, Huynh C, Fichtenbaum CJ, Kalams S, Gay CL, Andrasik MP, Kublin JG, Corey L, Neuzil KM, Priddy F, Das R, Girard B, El Sahly HM, Baden LR, Donis RO, Koup RA, **Gilbert PB**, Follmann D, on behalf of the Immune Assays Team, the Moderna Inc. Team, the Coronavirus Vaccine Prevention Network (CoVPN)/Coronavirus Efficacy (COVE) Team, and the United States Government (USG)/CoVPN Biostatistics Team. Omicron Covid-19 Immune Correlates Analysis of Third Dose of mRNA-1273 in the COVE Trial. *medrxiv* Oct 2023 <https://www.medrxiv.org/content/10.1101/2023.10.15.23295628v1>
11. Juraska MJ*, Early AM, Li L, Schaffner SF, Lievens M, Khorgade AR, Simpkins B, Hejazi N, Benkeser

- DC*, Wang Q, Mercer LD, Adjei S, Agbenyega T, Anderson S, Ansong D, Bii DK, Buabeng PBY, English S, Fitzgerald N, Grimsby J, Kariuki SK, Otieno K, Roman FP, Samuels AM, Westercamp N, Ockenhouse CF, Ofori-Anyinam O, Lee CK, MacInnis BL, Wirth DF, **Gilbert PB**, Neafsey DE. Baseline malaria infection status and RTS,S/AS01E malaria vaccine efficacy. *medRxiv* Nov 2023 <https://www.medrxiv.org/content/early/2023/11/23/2023.11.22.23298907>
12. Wolock CJ, **Gilbert PB**, Simon N, Carone M. Nonparametric variable importance for time-to-event outcomes with application to prediction of HIV infection. arXiv preprint arXiv:2311.12726. 2023 Nov 21.
 13. **Gilbert PB**, Peng J*, Han L, Lange T, Lu Y, Nie L, Shih M-C, Waddy SP, Wiley K, Yann M, Zafari Z, Ghosh D, Follmann D, Juraska MJ*, Díaz I. A Surrogate Endpoint Based Provisional Approval Causal Roadmap. July 8 2024 *arXiv*:2407.06350
 14. R code implementing various statistical methods: <http://faculty.washington.edu/peterg/programs.html>?
 15. Juraska MJ*, **Gilbert PB**, Wu S, Huang Y. CoRpower: Power Calculations for Assessing Correlates of Risk in Clinical Efficacy Trials (Implementation of Gilbert, Janes, Huang, 2016, *Stat Med*). R package available at CRAN.
 16. Yi L, Levis AW, Zhu K, Yang S, **Gilbert PB**, Han L. Targeted Data Fusion for Causal Survival Analysis Under Distribution Shift. January 30 2025 *arXiv*:2501.18798v1.

8. PATENTS AND OTHER INTELLECTUAL PROPERTY

N/A

9. RESEARCH FUNDING

A. Current

2006-2027	NIH/NIAID 3UM1 AI068635 SDMC: HIV Vaccine Trials Network \$142,770,580 (current cycle funding: 2020-2027)) Role: Principal Investigator
2019-2026	NIH/NIAID (subaward from Scripps Research) Consortium for HIV/AIDS Vaccine Development: Data Management SRSU. \$1,479,405 (total subaward costs) Role: Consortium Co-Lead Principal Investigator
2020-2024	NIH/NIAID 5R37 AI054165 Statistical Methods for Efficacy Trials of Vaccines and Monoclonal Antibodies Against Genetically-Diverse Pathogens Role: Principal Investigator
2020-2025	NIH/NIAID 5R01 AI52115 (subaward from University of Cape Town) Antigenic and virological traits of breakthrough HIV-1 subtype C infections in the VRC01 antibody-mediated protection trial Role: Co-Principal Investigator
2021-2024	Sanofi Pasteur, Inc. (SAVAT0008) DSMB: A parallel-group, Phase III, multi-stage, modified double-blind, multi-armed study to assess the efficacy, safety, and immunogenicity of two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for prevention against COVID-19 in adults 18 years of age and older \$1,072,702 Role: Principal Investigator
2023-2024	CoVPN: Cross Protocol Analysis NIH/NIAID 3UM1 AI068635–17S2 \$1,846,794 Role: Principal Investigator
2023-2024	Stage 2 (Durability, Variants, Boosters) Correlates of Protection Statistical Analysis for the First Four USG COVID-19 Response Team Phase 3 COVID-19 Vaccine Efficacy

- Trials
\$992,108
Role: Principal Investigator 2022-2025 BARDA (subcontract from Q Squared Solutions LLC)
- 2023-2024 NIH/NIAID 3UM1 AI068635-18S1
CoVPN 3008 - Multi-Center, Randomized, Efficacy Study of COVID-19 mRNA Vaccine in Regions with SARS-COV-2 Variants of Concern
\$12,647,369
Role: Principal Investigator
- 2023-2024 Ragon Funds
HIV Vaccine Trials Network (HVTN) Protocol 705
\$195,000
- 2023-2024 NIH/NIAID (subcontract from Leidos) 23X077F1
COVID-19 Variant Immunologic Landscape (COVAIL) Trial – Correlates or Protection
\$155,099
Role: Principal Investigator
- 2023-2024 Novavax
Novavax Protocol 2019nCOV-302
\$46,680
Role: Principal Investigator
- 2023-2024 Novavax
Novavax Protocol 2019nCOV-301
\$74,418
Role: Principal Investigator
- 2023-2026 BARDA (subcontract from Gritstone bio, Inc)
GO-015
\$26,837,178 (\$8,470,736 for SDMC)
Role: Key Personnel, Principal Investigator for SDMC
- A. Pending**
- 2024-2029 CEPI (subaward from Imperial College of London)
Biostatistics Support for the Data Science Work Package 5 – Mucosal Immunity in Human Coronavirus Challenge (MusICC)
\$404,196
Role: Subaward Consortium Principal Investigator
- B. Past**
- 2003-2006 NIH-NIAID 1 RO1 AI054165-01
Statistical Methods in HIV Vaccine Efficacy Trials
\$375,000 direct costs over three years
Role: Principal Investigator
- 2004-2005 NIH-SBIR Fast Track Grant
Determining Correlates of Protection Against HIV Infection
\$58,000 direct costs over one year
Role: Principal Investigator (subcontract)
- 2004-2005 NIH-NIAID 1 U01AI46703-01
HIV Vaccine Trials Network Leadership Group, Statistical Methods
Role: co-Principal Investigator
- 2004-2014 NIH SRA171204
Statistical Issues in AIDS Research
Role: Principal Investigator (subaward from University of Washington)
- 2005-2010 NIH/NIAID 1 U01 AI067854

- Statistical Data Management Center for the Center for HIV/AIDS Vaccine Immunology (CHAVI)
\$1,059,612 over five years
Role: Investigator, 10% effort (PI: Haynes) (Sub-award from Duke University)
- 2005-2011 NIH-NIAID 2 U01AI46703-06
HIV Vaccine Trials Network Leadership Group, Statistical Methods
Role: co-Principal Investigator
- 2006-2010 NIH-NIAID 2 RO1 AI054165-04
Statistical Methods in HIV Vaccine Efficacy Trials
\$700,000 direct costs over four years
Role: Principal Investigator
- 2011-2020 NIH/NIAID MERIT R37 AI054165
Statistical Methods in HIV Vaccine Efficacy Trials
\$268,268 (current years' direct)
Role: Principal Investigator
- 2006-2011 Bill & Melinda Gates Foundation
Vaccine Immunology Statistical Center (VISC)
\$1,936,568 over five years,
Role: Director of Biostatistical Unit, 10% effort (PI: Self)
- 2006-2011 NIH-NIAID
Seattle Biomedical Research Institute Malaria Antigen Discovery Program, Statistics and Data Center
Role: Principal Investigator (Subcontract)
- 2013-2018 USAMRAA JACKSONFND 792087 - NCE
Statistical and Data Management Support for Analysis Related to Vaccine Trial (RV144) and Associated Trials
\$382,484 (current years' direct)
Role: Principal Investigator (subcontract from Henry M. Jackson Foundation)
- 2016-2019 Sanofi Pasteur, Inc.
Bridging methods application in dengue vaccine adults data and support to the Type C/PreBLA meeting
\$331,658 (total)
Role: Principal Investigator
- 2016-2021 NIH/NIAID R01AI122991
Statistical methods for HIV-1 immune correlates studies
\$179,583 (current years' direct)
Role: Co-Investigator (PI: Fong)
- 2016-2022 Bill & Melinda Gates Foundation
Vaccine Statistical Support (VSS)
\$5,220,242
Role: Co-Investigator
- 2018-2023 PATH
MAL-095 Ancillary Amplicon Sequencing Study: Molecular Detection and Genotyping of Plasmodium Falciparum Parasites in Young African Children After Immunization with RTS, S/AS01E Malaria Vaccine
\$56,454
Role: Principal Investigator (subcontract from Harvard University)
- 2020-2022 NIH/NIAID 3UM1AI068635-14S2 / 3UM1AI068635-15S1 / 3UM1A9068635-17S4
CoVPN 3001 A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine SDMC
\$1,824,271

- 2020-2022 Role: Principal Investigator
 NIH/NIAID 3UM1AI068635-14S2 / 3UM1AI068635-15S1 / 3UM1AI068635-17S6,
 CoVPN 3002 A Phase III Randomized, Double-blind, Placebo-controlled Multicenter
 Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222
 for the Prevention of COVID-19 SDMC
 \$1,441,220
- 2020-2023 Role: Principal Investigator
 NIH/NIAID 3UM1AI068635-14S3 / 3UM1AI068635-15S1 / 3UM1AI068635-16S3
 CoVPN Cross-Protocol Analyses
 \$1,808,622
- 2020-2022 Role: Principal Investigator
 NIH/NIAID 3UM1AI068635-14S2 / 3UM1AI068635-15S4 / 3UM1AI068635-16S1 /
 3UM1AI068635-17S2
 CoVPN 5001 A prospective study of acute immune responses to SARS-CoV-2
 infection SDMC
 \$13,572,835
- 2020-2022 Role: Principal Investigator
 NIH/NIAID 3UM1AI068635-14S1 / 3UM1AI068635-15S3 / 3UM1AI068635-16S2 /
 3UM1AI068635-17S5,
 HVTN SDMC: 405 HPTN 1901 Characterizing SARS-COV-2-Specific Immunity in
 Convalescent Individuals – CoVPN Supplement
 \$4,742,987
- 2021-2022 Role: Principal Investigator
 NIH/NIAID 3UM1AI068635-15S1 / 3UM1AI068635-17S7
 CoVPN 3003 A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled
 Study to Evaluate the Efficacy, Safety, and Immunogenicity of Ad26.COV.2S SARS-
 CoV-2 Vaccine SDMC
 \$1,097,418
- 2021-2022 Role: Principal Investigator
 NIH/NIAID 3UM1AI068635-15S1 / 3UM1AI068635-17S8
 CoVPN 3004 – A Phase 3, Randomized, Observer-Blinded, Placebo-Controlled Study
 to Evaluate the Efficacy, Safety and Immunogenicity of a SARS-CoV-2 Recombinant
 Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M™ Adjuvant in
 Adult Subjects ≥ 18 years
 \$808,308
- 2021-2022 Role: Principal Investigator
 NIH/NIAID 3UM1AI068635-15S1 / 3UM1AI068625-17S9
 CoVPN 3005: Efficacy, Immunogenicity, and Safety of SARS-CoV-2 Recombinant
 Protein Vaccine with Adjuvant in Adults 18 Years of Age and Older
 \$1,080,052
- 2021-2023 Role: Principal Investigator
 NIH/NIAID 3UM1AI068635-15S1 / 3UM1AI068625-17S1 / 3UM1AI068635-18S1
 CoVPN 3008 - Multi-Center, Randomized, Efficacy Study of COVID-19 mRNA
 Vaccine in Regions with SARS-COV-2 Variants of Concern
 \$15,049,086
- Role: Principal Investigator

10. PUBLIC HEALTH PRACTICE ACTIVITIES

N/A

11. CONFERENCES AND SYMPOSIUMA

Invited Lectures:

- 1995 "Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine." *DIMACS International Conference on HIV-1 Sequence Variation and Statistical Methods*, Rutgers University, New Brunswick, New Jersey.
- 1996 "Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine." *Biostatistics Departmental Seminar*, University of California at Los Angeles, Los Angeles, California.
- 1996 "Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine." *Division of Statistics Seminar*, University of California at Davis, Davis, California.
- 1996 "Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine." *Biostatistics Departmental Seminar*, University of Wisconsin, Madison, Wisconsin.
- 1996 "Maximum likelihood estimation in semiparametric selection bias models with application to AIDS vaccine trials." *Biostatistics Departmental Seminar*, University of Rochester, Rochester, New York.
- 1996 "Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine." *Biostatistics Departmental Seminar*, Harvard University, Cambridge, Massachusetts.
- 1996 "Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 vaccine." *Statistics Departmental Seminar*, Stanford University, Palo Alto, California.
- 1996 "Sieve analysis: Statistical methods for assessing differential protection of an HIV-1 Vaccine." *Biostatistics Departmental Seminar*, University of Washington, Seattle, Washington.
- 1996 "Statistical issues in assessing secondary endpoints in HIV-1 vaccine trials." *HIV-1 Vaccines for Developing Countries: Design of Efficacy Trials*, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Dedham, Massachusetts.
- 1997 "Maximum likelihood estimation in semiparametric selection bias models with application to AIDS vaccine trials." *Statistics Departmental Seminar*, Rutgers University, New Brunswick, New Jersey.
- 1997 "Sieve analysis: Statistical methods for assessing differential vaccine protection against HIV-1 types." *ENAR*, Session Statistical Methods in HIV-1 Genomic Research and HIV-1 Vaccines, organized by Francoise Seillier-Moiseiwitsch, Memphis, Tennessee.
- 1997 "Maximum likelihood estimation in semiparametric selection bias models with application to AIDS vaccine trials." *Biostatistics Departmental Seminar*, Johns Hopkins University, Baltimore, Maryland.
- 1997 "Sieve analysis: statistical methods for assessing type-specific vaccine protection from vaccine trial data." *Epidemiology and Statistics Division*, National Institute of Child Health and Human Development, Rockville, Maryland.
- 1998 "Preventive HIV-1 vaccine efficacy trial design." *International Conference, HIV-1 Vaccines in Thailand: Current Progress 1998*. Co-sponsored by the Harvard AIDS Institute, UNAIDS, AIDS Division of the Department of Communicable Disease Control of the Thailand Ministry of Public Health; Asean Institute for Health Development; and Center for Vaccine Development of Mahidol University, Bangkok, Thailand.
- 1998 "Design and analysis issues for assessing viral and immune correlates of vaccine protection." *HIV-1 Vaccines for developing countries: Immune Correlates of Protection*, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Dedham, Massachusetts.

- 1998 “Applications of semiparametric biased sampling models to AIDS vaccine and treatment trials.” *22nd European Meeting of Statisticians; 7th Vilnius Conference on Probability Theory and Mathematical Statistics*, session on Semiparametric Models, organized by Susan Murphy, Vilnius, Lithuania.
- 1998 “Empirical processes and semiparametric biased sampling models.” *Empirical Processes in Non- and Semiparametric Statistics*, Humboldt University, Berlin, Germany.”
- 1998 “Empirical processes and semiparametric biased sampling models.” *Statistics Departmental Seminar*, Yale University, New Haven, Connecticut.
- 1998 “Two randomized trial designs for studying HIV-1 vaccines in infants.” *HIV-1 Vaccines for Developing Countries: Vaccinating Against the Leading Infectious Killers in Children*, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Dakar, Senegal.
- 1999 “Sieve analysis.” *VaxGen Incorporated*, Brisbane, California.
- 1999 “Strain selection for HIV-1 vaccine design.” *HIV-1 Vaccines for Developing Countries: Prioritizing Vaccine Candidates for Human Trials*, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Dedham, Massachusetts.
- 2000 “Scientific issues in preventive HIV-1 vaccine efficacy trials.” *Second National Conference on HIV-1 and AIDS in Botswana*, Gaborone, Botswana.
- 2000 “Comparison of HIV-1 and HIV-2 infectivity from a prospective cohort study in Senegal.” Fred Hutchinson Cancer Research Center, Seattle, Washington.
- 2000 “Comparison of HIV-1 and HIV-2 infectivity from a prospective cohort study in Senegal.” *International Biometric Society Meeting*, San Francisco, California.
- 2000 Comparison of HIV-1 and HIV-2 infectivity from a prospective cohort study in Senegal. *Statistics Departmental Seminar*, University of British Columbia, Vancouver, Canada.
- 2000 “Scientific issues in preventive HIV-1 vaccine efficacy trials.” *HIV-1 Vaccines for Developing Countries: Vaccines for Southern Africa*. Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Arusha, Tanzania.
- 2001 “Issues in primary endpoint selection in AIDS clinical trials.” *U.S. FDA Meeting on Endpoints for AIDS Clinical Trials*, Division of AIDS, Rockville, Maryland.
- 2001 “Sieve analysis.” *Harvard AIDS Institute Seminar*, Harvard School of Public Health, Boston, Massachusetts.
- 2001 “Data management in HIV-1 vaccine trials.” *HIV-1 Vaccines for Developing Countries: Establishing networks for HIV-1 trials in Southern Africa*, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Gaborone, Botswana.
- 2001 “Monitoring of HIV-1 vaccine efficacy trials. *HIV-1 Vaccines for Developing Countries: Establishing networks for HIV-1 trials in Southern Africa*, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Gaborone, Botswana.
- 2002 “Assessing HIV vaccine effects on viral load in preventive vaccine efficacy trials.” *Biostatistics Departmental Seminar*, University of Washington School of Public Health, Seattle, Washington.
- 2003 “Data management for clinical trials.” *HIV-1 Vaccines for Developing Countries: Prospects for an HIV-1 Vaccine for West Africa*, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Abuja, Nigeria.
- 2003 “Methods for comparing mark-specific hazards and cumulative incidence functions between two groups, with application to HIV vaccine trials.” *International Conference on Reliability and Survival Analysis*, University of South Carolina, Columbia, South Carolina.
- 2003 “Methods for comparing mark-specific hazards and cumulative incidence functions between two groups, with application to HIV vaccine trials.” *Biostatistics Departmental Seminar*, University of Washington School of Public Health, Seattle, Washington.
- 2003 Gilbert PB, Popovic V, Gurwith M, Francis D. “Immunologic responses to rgp-120 vaccine and correlation with the risk of HIV infection - results from the world’s first HIV

- vaccine efficacy trial.” In: *Program and abstracts of AIDS Vaccine 2003*, New York, New York.
- 2004 Gilbert PB, Shepherd BE*. “Sensitivity analyses comparing outcomes measured only in a subset selected post-randomization, with application to HIV vaccine trials.” *Genentech*, San Francisco, California.
- 2004 Gilbert PB, Shepherd BE*. “Sensitivity analyses comparing outcomes measured only in a subset selected post-randomization, with application to HIV vaccine trials.” *Department of Biostatistics*, University of California San Francisco, San Francisco, California.
- 2004 “Analysis of post-infection vaccine effects in VaxGen’s two Phase 3 trials.” *Workshop on End Points and Regulatory Issues in HIV Vaccines and Clinical Trials*, Rockville, Maryland.
- 2004 “Surrogate and clinical endpoints for HIV vaccine efficacy trials.” *HIV-1 Vaccines for Developing Countries: Initiation of Vaccine Trials in Africa*, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Gaborone, Botswana.
- 2004 “Moving up the ladder in HIV vaccine trials.” *HIV-1 Vaccines for Developing Countries: Initiation of Vaccine Trials in Africa*, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Gaborone, Botswana.
- 2004 “Inferring dependency of HIV vaccine efficacy on HIV distance.” *Schering-Plough Symposium*, Department of Biostatistics, Harvard School of Public Health, Boston, Massachusetts.
- 2004 “Endpoints and analytics for Phase IIb/III HIV vaccine trials.” *Meeting of the External Advisory Panel on the Scientific Agenda of the HVTN*, Bethesda, Maryland.
- 2005 Gilbert PB, Shepherd BE*, Jemai Y, Rotnitzky A. “Sensitivity analysis comparing outcomes measured only in a subset selected post-randomization.” *Joint Statistical Meetings*, Minneapolis, Minnesota.
- 2005 Gilbert PB, Hudgens M. “Comparison of group testing algorithms for identifying acute HIV-1 infections.” *Acute HIV-1 Infection*, Harvard AIDS Institute Symposium Series on Vaccine Solutions for Developing Countries, Nairobi, Kenya.
- 2005 Gilbert PB, Forthal D. “Role of FcγRIIa and FcγRIIIa genotype in risk of HIV infection and VEs.” *HIV Vaccine Trials Network Group Meeting*, Seattle, Washington.
- 2006 Gilbert PB, Hudgens M. “Evaluating causal effect predictiveness of candidate surrogate endpoints.” *Prentice Professorship Lecture*, Fred Hutchinson Cancer Research Center, Seattle, Washington.
- 2006 Gilbert PB, Hudgens M. “Evaluating causal effect predictiveness of candidate surrogate endpoints.” Department of Biostatistics, University of Washington, Seattle, Washington.
- 2006 Gilbert PB, Qin L, Self SG. “A framework for evaluating immunological correlates of protection in vaccine trials.” *NIH/NIAID Workshop on Statistical Methods in HIV/AIDS and its Practical Application*, Bethesda, Maryland.
- 2006 Gilbert PB, Qin L, Self SG. “Evaluating immunological correlates of protection.” *HIV Vaccine Trials Network Group Meeting*, Seattle, Washington.
- 2007 Gilbert PB, Hudgens M. “Evaluating causal effect predictiveness of surrogate endpoints, with application to HIV vaccine trials.” *UCLA Biostatistics Departmental Seminar*, Los Angeles, California.
- 2007 “Sieve analysis in HIV vaccine trials.” *First Vaccine Infectious Disease Institute Symposium*, Seattle, Washington.
- 2007 “Sieve analysis for PAVE-100: Toward a statistical analysis plan.” *PAVE 100 Viral and Host Genetics Workshop*, Vaccine Research Center, NIH, Bethesda, Maryland.
- 2007 Gilbert PB, McKeague I, Sun Y. “Evaluating dependency of HIV vaccine efficacy on viral genetics via mark-specific hazard function modeling.” Fred Hutchinson Cancer Research Center, Seattle, Washington.
- 2007 Gilbert PB. Molecular signatures of acutely infecting viruses.” *Second International Conference on HIV Transmission*, Washington, DC.

- 2007 “Overview of correlates and surrogates.” *World Health Organization workshop on HIV Vaccine Trial Endpoints*, Agence Nationale de Recherches sur le Sida (ANRS), Paris.
- 2007 Gilbert PB, Self SG, Mehrotra D, Duerr A. “Longer-term follow-up of STEP study volunteers.” *HIV Vaccine Trials Network Group Meeting*, Seattle, Washington.
- 2007 “Evaluating immunological correlates of protection.” *Center for AIDS Research Seminar*, University of Washington, Seattle, Washington.
- 2008 “Test of concept vaccine trials.” Merck Vaccines, Blue Bell, Pennsylvania.
- 2008 “Test of concept vaccine trials.” *University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials*, Philadelphia, Pennsylvania.
- 2008 “Test of concept vaccine trials.” *Division of AIDS*, NIAID, NIH, Bethesda, Maryland.
- 2008 “Assessing how vaccine efficacy depends on HIV genetics by competing risks failure time methods.” *Joint Statistical Meetings*, Denver, Colorado.
- 2009 “Mark-specific proportional hazards model with missing marks.” *WNAR International Biometric Society Meeting*, Portland, Oregon.
- 2009 Gilbert PB, Sun Y. “Sieve analysis of STEP sequences.” *AIDS Vaccine Research Subcommittee*, Bethesda, Maryland.
- 2009 “Leveraging baseline characteristics to improve HIV prevention trials.” In: *Keystone Symposium on HIV Prevention*, Keystone, Colorado.
- 2009 “Sieve analysis of STEP sequences.” *HIV Vaccine Trials Network Full Group Meeting*, Washington, DC.
- 2009 “Endpoints and monitoring for HVTN 505.” *HIV Vaccine Trials Network Full Group Meeting*, Washington, DC.
- 2010 “Thailand HIV vaccine efficacy trial: secondary/exploratory analyses for interpreting the efficacy result and for guiding future vaccine research.” *Memorial Symposium for Stephen Lagakos*, Harvard Medical School, Boston, Massachusetts.
- 2011 “What is an immune correlate?” *Military HIV Research Program – Thai Ministry of Public Health Immune Correlates Briefing*, Bangkok, Thailand.
- 2011 “Statistical considerations in the RV144 pilot and case control studies.” *Military HIV Research Program – Thai Ministry of Public Health Immune Correlates Briefing*, Bangkok, Thailand.
- 2011 “What is an immune correlate and how can it be used to guide vaccine development?” *Sixth Annual Meeting of the Collaboration for AIDS Vaccine Discovery*, Seattle, Washington.
- 2012 “Immune correlates and sieve analysis of RV144, plus follow-up research.” *AIDS Vaccine Research Subcommittee* Bethesda, Maryland.
- 2012 “Sequential phase 2b and 3 efficacy trial designs for evaluating vaccine efficacy and immune correlates for multiple HIV vaccine regimens.” *AIDS Vaccine Research Subcommittee*, Bethesda, Maryland.
- 2012 “Surrogate endpoints in the current era of HIV clinical trials.” *Clinical Trials Workshop, Nineteenth Conference on Retroviruses and Opportunistic Infections*, Seattle, Washington.
- 2012 “Statistical science perspective on the way forward.” *HIV Vaccine Trials Network Full Group Meeting*, Washington, DC.
- 2012 “A two-stage sequential phase 2b trial design for evaluating vaccine efficacy and immune correlates for multiple HIV vaccine regimens.” *ASA Biopharmaceutical Section FDA-Industry Statistics Workshop*, Washington, DC.
- 2012 “Analytics and the SDMC.” *HIV Vaccine Trials Network Full Group Meeting*, Seattle, Washington, DC.
- 2012 “Evaluating vaccine efficacy and immune correlates of protection.” *Harvard School of Public Health-China 7th Annual HIV/AIDS Workshop, HIV/AIDS Treatment Strategies in Resource Poor Settings*, Hainan Island, China.
- 2012 “Assessing immune correlates of protection via the vaccine efficacy curve.” *Webinar for the Vaccines Sub-Committee of the International Society for Clinical Biostatistics*.

- 2012 “Global acquisition sieve analysis in HIV vaccine efficacy trials.” *Vaccine and Infectious Disease Division (VIDD) Faculty Seminar*, Fred Hutchinson Cancer Research Center, Seattle, Washington.
- 2013 “Analysis of immune correlates of protection in the RV144 HIV vaccine efficacy trial.” *HIV Grand Rounds CME Series and CFAR Seminar*, University of Pennsylvania, Philadelphia, Pennsylvania.
- 2013 “Assessment of treatment efficacy in per-protocol and biomarker-response subgroups in randomized placebo-controlled trials.” *Atlantic Causal Inference Conference*, Cambridge, Massachusetts.
- 2013 Gilbert PB, Gabriel EE*, Huang Y, Chan I. “Assessment of immune correlates of protection via the vaccine efficacy curve: Application to the ZEST trial.” *Joint Statistical Meetings*, Montreal, Quebec, Canada.
- 2013 Gilbert PB, Huang Y, Zhang L, Huang Y. “Meta-analysis of Ad5 vector HIV vaccine trials.” *NIAID Mini-Summit on Adenovirus Platforms for HIV Vaccines*, Washington, DC.
- 2013 Gilbert PB, Grove D, Yu X, Kublin J, Gray G, Hammer SM, Corey L. “HVTN statistical approach to assessing vaccine efficacy and immune correlates of protection.” *NIAID HIV/AIDS Clinical Trials Network Strategic Working Group and AIDS Research Advisory Committee*, Bethesda, Maryland.
- 2013 “Meta-analysis of Ad5 vector HIV vaccine trials.” *AIDS Vaccine 2013*, Barcelona, Spain.
- 2013 Gilbert PB, Fong Y, Li S, Huang Y. “Analysis of IgA breadth/blocking in RV144 and design priorities for assessing immune correlates.” *BMGF CAVD Annual Meeting*, Seattle, Washington.
- 2014 Gilbert PB, Huang Y, Janes HE, deCamp A*, Metch B. “HVTN immune correlates down-selection statistical framework.” *NIAID HIV/AIDS Clinical Trials Network Strategic Working Group and AIDS Research Advisory Committee*, Bethesda, Maryland.
- 2014 “Overview of HVTN 505 marker studies.” *HIV Vaccine Trials Network Full Group Meeting*, Washington, DC.
- 2014 “Immunobridging formula for predicting vaccine efficacy, accounting for baseline covariates, post-baseline biomarker surrogate endpoints, and geno/serotypes of circulating pathogens.” *Joint Statistical Meetings*, Boston, Massachusetts.
- 2014 Gilbert PB, Juraska MJ*, Huang Y, deCamp A*. “Statistical issues in assessing treatment efficacy and correlates of protection in monoclonal antibody efficacy trials.” *Passive Immunization Trials to Inform Vaccine Design*, Global HIV Vaccine Enterprise, New York, New York.
- 2014 Gilbert PB, Juraska MJ*, Huang Y, deCamp A*. “Statistical issues in assessing mAb treatment efficacy and correlates of protection in efficacy trials.” *HIV Vaccine Trials Network Full Group Meeting*, Seattle, Washington.
- 2014 Gilbert PB, Huang Y. “What could be learned from new studies of correlates of enhanced susceptibility to HIV-1 infection in Step and Phambili?” *BMGF CAVD Annual Meeting*, Seattle, Washington.
- 2015 Gilbert PB, Huang Y. “Predicting overall vaccine efficacy in a new setting by re-calibrating effect modifiers of type-specific vaccine efficacy.” *Causal Inference Working Group. Department of Biostatistics, University of North Carolina at Chapel Hill*. Chapel Hill, North Carolina.
- 2015 “The state of the HIV vaccine field from the perspective of the HIV Vaccine Trials Network (HVTN).” *UNC Institute for Global Health & Infectious Diseases, Friday Morning Conference. Department of Medicine, University of North Carolina at Chapel Hill*. Chapel Hill, North Carolina.
- 2015 Gilbert PB, Juraska MJ*, Benkeser D*, Bedford T. “Primary Sieve Analysis Results for the RTS,S Vaccine Efficacy Trial.” *Bill and Melinda Gates Foundation Malaria Vaccine Initiative Meeting*. Seattle, Washington.

- 2015 "FACTS001 DSMB Case Study: Inefficacy Monitoring." *Clinical Trials Affinity Group (CTAG), Fred Hutchinson Cancer Research Center*. Seattle, Washington.
- 2015 "Summary of Immune Correlates of Protection in RV144." *HIV Vaccine Trials Network Full Group Meeting*. Cape Town, South Africa.
- 2015 "Relationship of different surrogate evaluation frameworks to the definition of a valid surrogate/replacement endpoint." *Joint Statistical Meeting*. Seattle, Washington.
- 2016 "Immune Correlates: The HIV Vaccine Experience." *Summit on Dengue Immune Correlates of Protection*. Les Pensieres, Annecy, France.
- 2016 "Parasite Genetic Diversity Affects RTS,S/AS01 Malaria Vaccine Efficacy in a Phase 3 Trial." *Harvard Malaria Forum*. Boston, Massachusetts.
- 2016 Gilbert PB, Juraska MJ*. Parasite Genetic Diversity Affects RTS,S/AS01 Malaria Vaccine Efficacy. *4th Annual Institute for Disease Modeling Symposium*, Bellevue, Washington.
- 2016 Gilbert PB, Yang G, Qi L, Sun Y. "Estimation of Mark-Specific Proportional Hazards Models for Competing Risks Outcomes under Two-Phase Covariate Sampling with Application to HIV Vaccine Efficacy Trials." *International Biometric Conference*. Victoria, Canada.
- 2016 Gilbert PB, Huang Y. "Predicting Overall Vaccine Efficacy in a New Setting by Re-Calibrating Baseline Covariate and Immune Response Endpoint Effect Modifiers of Genotype/Phenotype-Specific Vaccine Efficacy." Workshop on *Simulating Intervention Trials in Infectious Diseases*, Fred Hutch, Seattle, Washington.
- 2016 Gilbert PB, Edlefsen P. "Report from the Next-Generation Sequencing in Efficacy Trials Workshop. [Cape Town, October 10-12, 2016]." *HIV Vaccine Trials Network Full Group Meeting*. Seattle, Washington.
- 2016 "Approaches to assessing correlates of vaccine efficacy." *Eleventh Annual CAVD Meeting, Bill and Melinda Gates Foundation*. Seattle, Washington.
- 2016 Gilbert PB, Benkeser D*, Carone M. "Data-adaptive estimation of genotype-specific vaccine efficacy in HIV and Malaria Phase III trials." *10th ICSA International Conference*. Shanghai, China.
- 2017 Gilbert PB, Luedtke AR. "Statistical Learning of Correlates of Herpes Zoster Vaccine Efficacy from Efficacy Trials." Workshop on *Advances and Controversies in our Understanding of Herpes Zoster*. *The Royal Society of Medicine*. London, United Kingdom.
- 2017 Gilbert PB, Price BL*, Van der Laan MJ. "Estimation of the optimal surrogate based on a randomized trial." Harvard T.H. Chan School of Public Health Department of Biostatistics. Boston, Massachusetts.
- 2017 "Neutralizing antibody and viral genetic correlates of vaccine efficacy in two phase 3 trials of the CYD-TDV dengue vaccine." Harvard T.H. Chan School of Public Health Department of Immunology and Infectious Diseases. Boston, Massachusetts.
- 2017 "Neutralizing antibody correlates of risk and vaccine efficacy in two dengue Phase 3 trials." UNC-Sanofi-VaxDesign Meeting. Greensboro, North Carolina.
- 2017 "Estimation of the Optimal Surrogate Based on a Randomized Trial." Division of Biostatistics, University of California at Berkeley. Berkeley, California.
- 2017 "Phase IIb Test of Concept Studies for HIV." *International Society for Vaccines Congress*. Paris, France.
- 2017 "Correlates Analysis of CYD Phase 3 Trials based on Microneutralizing Antibody Titers (MNv2)." *Dengue Research Consortium*. Baltimore, Maryland.
- 2017 Gilbert PB, Moodie Z, Juraska MJ*, Huang Y, Zhuang Y*, Fong Y, Carpp LN, Self SG, Chambonneau L, Small R, Jackson N, Noriega F. "Correlates of Risk and Protection for CYD-TDV, the First Licensed Dengue Vaccine in Endemic Countries." *American Society of Tropical Medicine and Hygiene (ASTMH)*. Baltimore, Maryland.
- 2017 Gilbert PB, Price BL*, van der Laan MJ. "Estimation of the Optimal Surrogate Based on a Randomized Trial." CMStatistics 2017. London, United Kingdom.

- 2017 Gilbert PB, Price BL*, van der Laan MJ. "The Search for a Surrogate: Estimation of the Optimal Surrogate Based on a Randomized Trial." Janssen Biostatistics, Beerse, Belgium.
- 2017 "Statistical methods for establishing correlates of protection." *Initiative for Vaccine Research, World Health Organization Consultation on GBS candidate vaccines: The role of correlates of protection in the pathway to licensure and policy decision*. London, United Kingdom.
- 2018 "Statistical methods for assessing correlates of vaccine protection." Departmental Seminar, Statistics, SanofiPasteur. Lyon, France.
- 2018 "SDMC Perspective: Priorities and Challenges for 2018/2019." *HIV Vaccine Trials Network Full Group Meeting*, Washington, DC.
- 2018 "HVTN 704/HPTN 085 and HVTN 703/HPTN 081. AMP Trials: Planning for Correlates and Sieve Analyses." *HIV Vaccine Trials Network Full Group Meeting*, Washington, DC.
- 2018 "Statistical Framework for Assessing Correlates of Vaccine Protection, with Application to Dengue Vaccine Efficacy Trials." Max Planck Institute of Infection and Biology, Berlin, Germany.
- 2018 "Statistical Framework for Assessing Correlates of Vaccine Protection." *5-Year Review Talk*, Fred Hutch, Seattle, Washington.
- 2018 Gilbert PB, Zhang L, Thommes E, Huang Y. "Assessing Pharmacokinetic Marker Correlates of HIV-1 Infection in the Antibody Mediated Prevention (AMP) Efficacy Trials." *Joint Statistical Meeting*, Vancouver BC, Canada.
- 2018 Gilbert PB, Price BL*, van der Laan MJ. "The Search for an Optimal Immunological Surrogate Endpoint in Randomized Vaccine Efficacy Trials." *Sanofi Pasteur Statistical Seminar*, Swiftwater, PA.
- 2018 "Ongoing Vaccine and Monoclonal Antibody Efficacy Trials in the HVTN and Considerations for Sequel Designs." *HIV Prevention Efficacy Trial Designs of the Future*, Fred Hutch, Seattle, Washington.
- 2018 "Defining Sieving and Time of Acquisition in AMP: New Dimensions in Real Time Molecular Assays." *HIV Vaccine Trials Network Investigators Meeting*, Seattle, Washington.
- 2018 "Dengue Vaccine Efficacy: Are there Immunological and Virus Markers of Differential Protection?" *UW Biostatistics Colloquium: Connecting Investigators and Senior Students*. University of Washington, Seattle, Washington.
- 2019 "Levels of neutralizing antibodies that provide protection in NHPs." Year 7 Scripps CHAVI-ID All-Investigators Retreat, La Jolla, California.
- 2019 "Assessing Pharmacokinetic Marker Correlates of HIV-1 Infection in the Antibody Mediated Prevention (AMP) Efficacy Trials." *Statistical Challenges and Opportunities in HIV/AIDS Research in the Era of Getting-to-Zero HIV Infections*. Philadelphia, Pennsylvania.
- 2019 "Superlearning/Targeted Learning: A Statistical Framework for Robustly and Efficiently Addressing Scientific Questions in HIV Vaccine Research." *HIV Vaccine Trials Network Full Group Meeting*, Washington, DC.
- 2019 "Discerning a VRC01 neutralization correlate of prevention efficacy in the Antibody Mediated Prevention (AMP) efficacy trials." *Fourteenth Annual Meeting of the Collaboration for AIDS Vaccine Discovery*, Bill and Melinda Gates Foundation, Seattle, Washington.
- 2019 "Assessing pharmacokinetic marker correlates of HIV-1 infection in the Antibody Mediated Prevention (AMP) efficacy trials." *Clinical Trials Affinity Group (CTAG)*, Fred Hutchinson Cancer Research Center. Seattle, Washington.
- 2020 "Summary of Approaches for Assessing a VRC01 Neutralization Surrogate Endpoint in the AMP Trials." *HIV Vaccine Trials Network Full Group Meeting*. Cape Town, South Africa.

- 2020 “Phenotypic and Amino Acid Sequence Sieve Analysis in the AMP Trials.” *HIV Vaccine Trials Network Full Group Meeting*. Cape Town, South Africa.
- 2020 “Designing Studies for Regulatory Parsimony: Lessons from HIV and SARS-CoV-2.” Next Generation of Assays, Tools, Technologies to Evaluate Immune Responses to Vaccines for Infectious Diseases. NIAID-sponsored remote workshop.
- 2020 Assessing Sequence Distance-Specific Correlates of Risk in Vaccine Efficacy Trials. ASA/Biopharmaceutical Regulatory-Industry Statistics Workshop (remote).
- 2020 “Planning for Assessment of Immune Correlates of Risk and Protection in COVID-19 Vaccine Efficacy Trials.” Vanderbilt Department Biostatistics Seminar (remote).
- 2020 “Assessing Immune Correlates of Risk and Protection in COVID-19 Vaccine Efficacy Trials.” World Health Organization ad hoc consultation Next steps for COVID-19 vaccine clinical evaluation (remote).
- 2020 “Assessing Immunological Biomarker Surrogate Endpoints in COVID-19 Vaccine Efficacy Trials.” Department of Biostatistics, Harvard School of Public Health (remote).
- 2020 “Statistical Approaches for Assessment of Immune Correlates of Protection.” COVAX SWAT Workshop on COVID-19 Correlates of Protection (remote).
- 2020 “AMP Study: Pursuit of a serum neutralization surrogate endpoint.” *BMGF CAVD Annual Meeting* (remote).
- 2020 “Early Immune Correlates of Risk Analysis to Guide Us.” *BMGF CAVD Annual Meeting* (remote).
- 2021 “Design of the AMP Study.” *HIV Research for Prevention (HIVR4P)*, Cape Town, South Africa (remote).
- 2021 “Assessing Immunological Biomarker Surrogate Endpoints in COVID-19 Vaccine Efficacy Trials.” Seminar, Division of Biostatistics, University of Pennsylvania (remote).
- 2021 “Experience with Designating CoPs and Statistical Approaches for the GBS Sero-Epi Studies.” Group B Streptococcus Correlate of Protection Methodology Workshop, Bill and Melinda Gates Foundation (remote).
- 2021 “Evaluating Vaccine Efficacy of a Candidate HIV-1 Vaccine vs. Counterfactual Placebo: Immune Marker Mediator Approach.” ID-PRISM Seminar, Fred Hutchinson Cancer Research Center, Seattle, WA (remote).
- 2021 “Assessing Immune Correlates of Protection in COVID-19 Vaccine Efficacy Trials.” *ENAR*, Session Scientific and Regulatory Aspects of Developing COVID-19 Vaccine During Pandemic (remote).
- 2021 “Defining the ID80 for the future in the AMP studies.” *HIV Vaccine Trials Network Full Group Meeting* (remote).
- 2021 “Correlates Analysis of Phase 3 Trials, Illustrated with a Mock Data Set Previewing Moderna COVE Trial Results.” COVID-19 Vaccines: World Health Organization Meeting on Correlates of Protection (remote).
- 2021 “Monoclonal Antibody Program: Insights from the AMP Trials.” NIAID HIV/AIDS Clinical Trials Networks Strategic Working Group, June, 2021 (remote).
- 2021 “Monoclonal Antibody Program: Follow-up Phase 3 Efficacy Trial.” NIAID HIV/AIDS Clinical Trials Networks Strategic Working Group, June, 2021 (remote).
- 2021 “Pursuit of COVID Vaccine Approval Based on an Immune Marker Surrogate Endpoint.” American Statistical Association Statistics in Epidemiology Section Webinar Series, June, 2021 (remote).
- 2021 “Planning for Correlates for Phase 3 Studies: Lessons from COVID.” Joint with Larry Corey. Keystone Meeting on Innovative Vaccine Approaches, June, 2021 (remote).
- 2021 “Immune Correlates Analysis of the mRNA-1273 Vaccine Efficacy Trial.” Vaccine Infectious Diseases (VIDD) Seminar, Fred Hutchinson Cancer Research Center, August, 2021 (remote).
- 2021 “Immune Correlates Analysis of the mRNA-1273 Vaccine Efficacy Trial.” World Health Organization Global Consultation on Correlates of Protection, September, 2021 (remote).

- 2021 "Initiatives to Analyze and Synthesize Available Data." World Health Organization Global Consultation on Correlates of Protection, September, 2021 (remote).
- 2021 "Sieve Analysis in COVID-19 Vaccine Efficacy Trials, by Cox Modeling." *ICSA International Conference*, September, 2021 (remote).
- 2021 "Immune Correlates Analysis of the mRNA-1273 Vaccine Efficacy Trial." ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop (COVID-19 Vaccine Development Session), September, 2021 (remote).
- 2021 "COVID-19 Vaccine Efficacy Trials and "Immune Correlates of Protection" in the Moderna COVE Trial. Keynote Speaker 2021 Georgia Statistics Day, October, 2021, Emory University, Atlanta, GA.
- 2021 "Forthcoming Correlates of Protection Analyses for COVID-19 Vaccines." HIV Vaccine Trials Network Full Group Meeting, October, 2021 (remote).
- 2021 "Immune Correlates Analysis of the mRNA-1273 Vaccine Efficacy Trial." Global COVID Lab Meeting Webinar, Human Vaccines Project, October, 2021 (remote).
- 2021 "Immune Correlates Analyses of COVID-19 Vaccine Efficacy." Vaccine Immunology Statistical Center Scientific Advisory Board, October, 2021 (remote).
- 2021 "Statistical Evaluation of Immune Correlates of Protection in the Moderna COVE COVID-19 Vaccine Efficacy Trial." 2021 Program in Quantitative Genomics (PQG) Conference, Harvard School of Public Health, October, 2021 (remote).
- 2022 "AMP Trial Insights on bnAb Titers Needed to Protect Humans." Scripps 3rd Annual CHAVD All-Investigators Retreat, February, 2022 (remote)
- 2022 "Analysis of Correlates of Vaccine Efficacy." Conference on Retroviruses and Opportunistic Infections (CROI) Clinical Trial Design and Analysis Workshop, February, 2022 (remote)
- 2022 "Immune correlates of protection (CoP) in the Moderna COVE study and CoP for variants," Webinar, COVID-19 Evidence Accelerator, Reagan-Udall Foundation for the FDA, May, 2022
- 2022 "Update on Learnings about Immune Correlates of Protection from COVID-19 Vaccine Efficacy Trials: Pursuit Through Multiple Causal Inference Approaches", Keynote Panel Session: Statisticians Rise to the Occasion to Meet Pandemic: Perspectives on COVID-19 Vaccine Development. 35th New England Statistics Symposium (NESS), May, 2022 (remote)
- 2022 "Correlates of protection from the first 4 phase 3 vaccine trials + planning for durability/variants/booster correlates", CoVPN All Site/Investigator Meeting, June, 2022 (remote)
- 2022 "Interventional and Principal Stratification Causal Effects for Evaluation and Use of Surrogate Endpoints, with Application to Vaccine Trials", Statistical Challenges in the Identification, Validation, & Use of Surrogate Markers Banff International Research Station, August, 2022 (remote)
- 2022 "Immune Correlates Analyses of 4 COVID-19 Vaccine Efficacy Trials", GVIRF WEBINAR Correlates of protection: Learnings from COVID and applications for other global health, October, 2022 (remote)
- 2022 "Immune Correlates Results for the Uhambo and Imbokodo HIV Vaccine Efficacy Trials", HIV Vaccine Trials Network Full Group Meeting, Seattle, WA, October, 2022
- 2022 "Assessment of Immune Marker Surrogate Endpoints in COVID-19 Vaccine Efficacy Trials: Pursuit Through Multiple Causal Inference Approaches", University of North Carolina at Chapel Hill Biostatistics Department Seminar, November, 2022 (remote)
- 2022 "Pursuit of Immune Marker Surrogate Endpoints Through Multiple Causal Inference Approaches Applied to COVID-19 Vaccine Efficacy Trials." University of Washington Biostatistics Department Seminar, December, 2022.
- 2022 "Lessons on Correlates of Protection from COVID-19 Vaccines and HIV-1 Monoclonal Antibodies." European Medicines Agency (EMA)/FDA workshop "Efficacy of

- monoclonal antibodies in the context of rapidly evolving SARS-CoV-2 variants”, December, 2022 (remote).”
- 2023 “Assessing Sequence Distance-Specific Correlates of Risk in Vaccine Efficacy Trials.” Janssen Statistics Departmental Seminar, Beerse, Belgium, February, 2023.
- 2023 “Knowledge gaps and future research for antibody CoP.” Workshop “Enabling the Evaluation of COVID-19 Vaccines with Correlates of Protection.” European Plotkin Institute for Vaccinology, Vaccinopolis, University of Antwerp, Belgium, February, 2023.
- 2023 “Correlates of Protection for COVID-19 Vaccines: Latest Findings and Research Directions.” Clinical and Translational Serology Task Force Round Table on Correlates of Protection, Frederick National Laboratory for Cancer Research, February, 2023 (remote)
- 2023 “Novel Study Designs to Support Correlates of Protection Studies.” International Society for Influenza and Other Respiratory Virus Diseases (ISIRV) Workshop on Correlates of Protection for Next Generation Influenza Vaccines: Lessons Learned from the COVID Pandemic, Bill and Melinda Gates Foundation, Seattle, WA, March, 2023.
- 2023 Speaker/panelist at the White House Workshop on Bridging Scientific Gaps on Correlates of Immune Protection for Next Generation Coronavirus Vaccines and Treatments. March, 2023 (remote)
- 2023 “Connections between vaccine and monoclonal antibody correlates of protection for COVID-19 and HIV-1.” Vaccine Company Advisory Board. April, 2023 (remote)
- 2023 “Correlates of Risk vs. Correlates of Protection: Overview on Terminology and Applications for Therapeutic Vaccines.” Bill & Melinda Gates Foundation Correlates Advisory Board: Therapeutic HPV Vaccines. June, 2023 (remote)
- 2023 “Assessing Pathogen-Sequence Dependent Immune Correlates in Vaccine Efficacy Trials.” Seminar, Harvard Biostatistics Seminar Series. Boston MA, October 2023
- 2023 “Causal Estimands for Evaluating Surrogate Endpoints in RCTs and Observational Studies.” FIORD 2023 Forum on the Integration of Observational and Randomized Data: Advancing the Integration of Real-World Evidence for Regulatory Decision-Making. Washington DC, November 2023
- 2023 “Assessing Pathogen-Sequence Dependent Immune Correlates in Vaccine Efficacy Trials.” Seminar, University of California San Diego Biostatistics Seminar Series, December 2023 (remote)
- 2023 “Correlates of Protection for COVID-19 Vaccines from the USG Program: Summary of Findings and Current Research.” H-CORE Immune Assays Assay Sub Team All Hands Meeting, December 2023 (remote)
- 2024 “Learning about Immune CoPs from Randomized Vaccine Efficacy Trials with Application to LASV.” Coalition for Epidemic Preparedness Innovations (CEPI) Workshop Searching for Immune Correlates in Lassa Vaccine Development, Data Science Session, February 2024 (remote)
- 2024 “Developing immune marker surrogate endpoints in vaccine efficacy clinical trials: Illustration with COVID-19.” United Kingdom Medical Research Council, Hubs for Trials Methodology Research Seminar Series, March 2024 (remote)
- 2024 (with Bo Zhang and Lauren Dang) “Neutralizing Antibody Correlates of Protection in the COVID-19 Variant Immunologic Landscape Trial (COVAIL Trial).” H-CORE Immune Assays Assay Sub Team All Hands Meeting, March 2024 (remote)
- 2024 “PT80 Biomarker for HIV-1 Monoclonal Antibody Prevention Research.” IAVI PNP Task Force, April 2024 (remote)
- 2024 [joint with Lindsay Carpp] “Immune Correlates of Protection in the ENSEMBLE COVID-19 Vaccine Efficacy Trial Accounting for Spike Sequence Variation.” H-CORE Immune Assays Assay Sub Team All Hands Meeting, April 2024 (remote)
- 2024 “ENSEMBLE Variant Antibody COVID-19 Correlate of Protection Over 7 Months Post One Dose”, CoVPN All Site/Investigator Meeting, September, 2024 (remote)
- 2024 “Immune Correlates Analysis of the Sanofi Phase 3 COVID-19 Vaccine Efficacy Trial.”

- 2024 H-CORE Immune Assays Assay Sub Team All Hands Meeting, September 2024 (remote)
“Immune Correlates Analysis of the Sanofi Phase 3 COVID-19 Vaccine Efficacy Trial.”
Sanofi QSF Forum, September, 2024 (remote)
- 2024 “Assessing How Immune Correlates of Risk and Protection Depend on Viral Genetics in
Vaccine Efficacy Trials: Application to Ad26.COVS.2.S ENSEMBLE.” 32nd International
Biometric Conference, Atlanta, December, 2024.
- 2024 [joint with Erica Andersen-Nissen] “Antibody and T-cell Immune Correlates of COVID-
19 in the CoVPN 3008 Ubuntu Study of mRNA-1273 Vaccine and Hybrid Immunity.” H-
CORE Immune Assays Assay Sub Team All Hands Meeting, December, 2024 (remote)
- 2025 “Statistical science for the first efficacy trials of HIV-1 monoclonal antibody prevention.”
Marvin Zelen Leadership Award in Statistical Science, Department of Biostatistics,
Harvard University, Boston, May, 2025.
- 2025 “V2 antibody correlates of protection for HIV-1 vaccines.” International Society for
Vaccines Mini-Symposium, June, 2025 (remote)

Conferences and Symposium Talks:

- February 1999 Mayers D, **Gilbert PB**, Merigan T for the ACTG244/RV79 Study Team. T215Y/F
mutation associated with zidovudine resistance leads to poor response to ZDV+ddI or
ZDV+ddI+NVP: ACTG244/RV79. In: *Program and abstracts of the Sixth Conference
on Retroviruses and Opportunistic Infections*, Abstract 129 Chicago, Illinois
- February 2000 Havlir D, **Gilbert PB**, Bennett K, Collier A, Hirsch M, Tebas P, Adams E, Holohan
MK, Richman D and the ACTG 5025 Study Team. Randomized trial of continued
Indinavir (IDV)/ZDV/3TC versus switch to IDV/ddI/d4T or
IDV/ddI/d4T+hydroxyurea in patients with viral suppression. In: *Program and
abstracts of the Seventh Conference on Retroviruses and Opportunistic Infections*, San
Francisco, California.
- June 2000 Havlir D, Levitan D, Bassett R, **Gilbert PB**, Richman D, Wong J. Prevalence and
predictive value of intermittent viremia in patients with viral suppression. In: *Program
and abstracts of the Fourth International Workshop on HIV-1 Drug Resistance and
Treatment Strategies*, Stiges, Spain.
- July 2002 Novitsky V, Rybak N, **Gilbert PB**, Gaolekwe S, Peter T, McLane MF, Thior I, Lee
TH, Ndung'u T, Marlink R, Essex M. Magnitude and frequency of CTL responses to
HIV-1 subtype C. In: *Program and abstracts of the Fourteenth International AIDS
Conference*, Barcelona, Spain.
- July 2002 Renjifo B, **Gilbert PB**, Chaplin B, Msamanga G, Mwakagile, Fawzi W, Essex M, and
the Tanzania Vitamin and HIV Study Group. Preferential in-utero transmission of
HIV-1 subtype C compared to subtype A or D. In: *Program and abstracts of the
Fourteenth International AIDS Conference*, Barcelona, Spain.
- February 2003 **Gilbert PB**, De Gruttola V, Hudgens M, Self SG, Hammer S, Corey L. What
constitutes effectiveness for an HIV vaccine that ameliorates viremia: Issues involving
surrogate endpoints in efficacy trials. In: *Abstracts of the 10th Conference on
Retroviruses and Opportunistic Infections*, Abstract 84, Boston, Massachusetts.
- September 2003 Popovic V, Gurwith M, Francis D, Heyward W, Berman P, **Gilbert PB**. Evaluation of
vaccine efficacy in populations with high risk behavior and high HIV incidence -
results from the world's first phase III trial of HIV vaccine. In: *Program and abstracts
of AIDS Vaccine 2003*, New York, New York ().
- September 2003 Popovic V, Gurwith M, Francis D, Harro C, Mayer KH, Heyward W, Berman P,
Gilbert PB. Differential efficacy in prevention of HIV infection by rgp120 HIV-1
vaccine by gender and race – is it real? In: *Program and abstracts of AIDS Vaccine
2003*, New York, New York.

- September 2003 Djomand G, **Gilbert PB**, Chiu Y-L, Malone S, Sullivan P, Russell N, Hammer S, Celum C, Wasserheit J. Incidence of HIV-1 breakthrough infection among participants enrolled in HIV vaccine trials from 1988 to 2002. In: *Program and abstracts of AIDS Vaccine 2003*, New York, New York.
- July 2003 Djomand G, **Gilbert PB**, Chiu Y-L, Malone S, Sullivan P, Russell N, Hammer S, Celum C. Incidence of HIV-1 breakthrough infection among participants enrolled in HIV vaccine trials from 1988 to 2002. In: *Program and abstracts of the Second International AIDS Society Conference on HIV Pathogenesis and Treatment*, Paris, France.
- February 2004 Follmann D, **Gilbert PB**, Self SG, Hudgens M, Gurwith M, Popovic V, Ackers M, Hu D, Flores J. An independent analysis of the effect of race in VAX004. In: *Program and abstracts of the Eleventh Conference on Retroviruses and Opportunistic Infections*, Abstract 106, San Francisco, California).
- February 2005 Shapiro R, Thior I, **Gilbert PB**, Lockman S, Wester C, Smeaton L, Stevens L, Ndung'u T, Novitsky V, van Widenfelt E, Mazonde P, Lee TH, Marlink R, Lagakos S, Essex M, and the Mashi Study Group. Maternal single-dose Nevirapine may not be needed to reduce mother-to-child transmission in the setting of maternal and infant Zidovudine and infant single-dose Nevirapine: Results of a randomized clinical trial in Botswana. In: *Program and abstracts of the Twelfth Conference on Retroviruses and Opportunistic Infections*, Abstract 74LB, Boston, Massachusetts.
- February 2005 Thior I, Lockman S, Smeaton L, Shapiro R, Wester C, Heymann J, **Gilbert PB**, Stevens L, Peter T, Kim S, Makhema J, McIntosh K, Marlink R, Lagakos S, Essex M, and the Mashi Study Team. Breast-feeding with 6 months of infant Zidovudine prophylaxis vs. formula-feeding for reducing post-natal HIV transmission and infant mortality: A randomized trial in Southern Africa. In: *Program and abstracts of the Twelfth Conference on Retroviruses and Opportunistic Infections*, Boston, Massachusetts.
- September 2005 Frey SE, Peiperl L, Baden L, McElrath J, Wright P, Goepfert P, Keefer M, Blattner W, Harro C, Hammer S, Baglyos L, Guillet J-G, **Gilbert PB**, Deers M, Elizaga M, Corey L, and the HIV Vaccine Trials Network. Safety of ANRS LIPO-5 alone, Sanofi-Pasteur ALVAC-HIV (vCP1452) alone, and ALVAC HIV prime/LIPO-5 boost in healthy, HIV-1 uninfected adult participants. In: *Program and abstracts of AIDS Vaccine 2005*, Montreal, Quebec, Canada.
- September 2006 Frey SE, Peiperl L, Baden L, McElrath MJ, Wright P, Goepfert P, Keefer M, Blattner W, Harro C, Hammer S, Hural J, Tomaras G, Baglyos L, Guillet J-G, **Gilbert PB**, Deers M, Elizaga M, Russell N, Corey L, and the HIV Vaccine Trials Network. Immunogenicity of ANRS LIPO-5 alone, Sanofi-Pasteur ALVAC-HIV (vCP1452) alone, and ALVAC HIV prime/LIPO-5 boost in healthy, HIV-1 uninfected adult participants. In: *Program and Abstracts of AIDS Vaccine 2006*, Amsterdam, the Netherlands.
- September 2006 Burke D, Karim SSA, Russel N, Wecker M, Allen M, Ferarri G, **Gilbert PB**, Chulay J. (2006). Safety and immunogenicity of an alphavirus replicon HIV Gag vaccine (AVX101) in healthy HIV-uninfected adults. In: *Program and Abstracts of AIDS Vaccine 2006*, Amsterdam, the Netherlands.
- February 2006 Forthal D, Landucci G, Phan T, Higa-Tanner R, **Gilbert PB**. Fcγ receptor IIa and IIIa polymorphisms are associated with risk of HIV infection. In: *Program and abstracts of the Thirteenth Conference on Retroviruses and Opportunistic Infections*, Denver, Colorado.
- September 2007 Mehrotra D, **Gilbert PB**, Li X, Heyse J, Buchbinder S, Self SG, Robertson M. (2007). A prototype test-of-concept efficacy trial design for cell mediated immunity-based vaccines. In: *Program and Abstracts of AIDS Vaccine 2007*, Seattle, Washington.

- September 2007 Jones N, **Gilbert PB**, deCamp A*, Peterson M, Gurwith M, Cao H. AIDSVAX immunization induces HIV-specific CD8+T cell responses in high-risk HIV negative volunteers who subsequently acquire HIV infection. In: *Program and Abstracts of AIDS Vaccine 2007*, Seattle, Washington.
- September 2011 Rerks-Ngarm S, Paris RM, Chunsutthiwat S, Prensri N, Namwat C, Bowornwatanuwong J, Li S, Kaewkungkal J, Trichavaroj R, de Souza M, Francis D, Adams E, Gurunathan S, Tartaglia J, O'Connell R, Eamsila C, Nitayaphan S, Ngauy V, Thongcharoen P, Kunasol P, Michael N, Robb M, **Gilbert PB**, Kim J. Extended evaluation of volunteers who become HIV-1 infected during participation in a phase III vaccine trial of ALVAC-HIV and AIDSVAX® B/E. In: *AIDS Vaccine 2011*, Patumwan, Bangkok, Thailand.
- September 2011 Billings EA, Karasavvas N, de Souza MS, Currier J, Pitisuttithum P, Kaewkunwal J, Nitayaphan S, **Gilbert PB**, Tomaras GD, Zolla-Pazner SB, Haynes BF, Michael NL, Rerks-Ngarm S, Kim JH, Rao M. Surface plasmon resonance analysis of anti-gp120 V2-specific IgG antibodies generated in the RV144 Thai trial. In: *AIDS Vaccine 2011*, Patumwan, Bangkok, Thailand.
- September 2011 Iyer S, Bouzek H, Kim HM, Larsen B, Casey E, Rolland M, Edlefsen P, Hertz T, Magaret C, Frahm N, Westfall D, Wong K, Zhao H, Sanders-Buell E, Tovanabutra S, Stoddard JN, Nariya S, Konopa P, Maust BS, Deng W, A. Bates A, Bradfield A, Bose M, O'Sullivan A, Hural J, Casimiro DR, Robertson MN, Michael N, McElrath MJ, Corey L, Buchbinder S, **Gilbert PB**, Kim J, Mullins JI. A deeper look at the virus populations infecting Step trial volunteers. In: *AIDS Vaccine 2011*, Patumwan, Bangkok, Thailand.
- September 2011 Edlefsen P, Hertz T, Magaret C, deCamp A*, **Gilbert PB**. Sieve analysis of RV144. In: *AIDS Vaccine 2011*, Patumwan, Bangkok, Thailand.
- March 2012 Liao H-X, Bonsignori M, Alam SM, Tomaras GD, Moody MA, Tsao C-Y, Hwang K-K, Rolland M, Mullins J, Edlefsen P, **Gilbert PB**, Lu X-Z, Parks R, Montefiori D, Ferrari G, Rao M, Karasavvas N, McLellan J, Yang Z-Y, Dai K, Pancera M, Rerks-Ngarm S, Nitayaphan S, Kaewkungwal J, Tovanabutra S, Pitisuttithum P, Tartaglia J, Sinangil F, Kim J, Michael NL, Nabel G, Mascola J, Kwong P, Pinter A, Zolla-Pazner S., Haynes BF. HIV-1 envelope antibodies induced by ALVAC-AIDSVAX B/E vaccine target a site of vaccine immune pressure within the C β strand of gp120 V1V2. In: *Keystone Symposium HIV Vaccines 2012*, Keystone, Colorado.
- April 2012 Rolland M, Edlefsen P, Tovanabutra S, Larsen B, Sanders-Buell E, Mullins JI, Michael NL, Kim JH, **Gilbert PB**. Sieve analysis of HIV-1 breakthrough infections in the RV144 trial. In: *19th International Conference on HIV Dynamics and Evolution*, Ashville, North Carolina.
- September 2012 Frahm N, Tomaras G, Montefiori D, **Gilbert PB**, Corey L, McElrath MJ. Comparative immunogenicity of HIV vaccine candidates in the HVTN. In: *AIDS Vaccine 2012*, Boston, Massachusetts.
- September 2012 Williams WB, Jones K, Krambrink A, Grove D, Liu P, Yates NL, Moody MA, Ferrari G, Pollara J, Moodie Z, Morgan CA, Liao H, Montefiori DC, Ochsenbauer C, Kappes J, Hammer S, Mascola J, Koup R, Corey L, Nabel G, **Gilbert PB**, Churchyard G, Keefer M, Graham BS, Haynes BF, Tomaras GD. Multiple antibody specificities, including gp41, V1V2, and V3 elicited in the phase II multiclade (A,B,C) HIV-1 DNA prime, multiclade (A,B,C) rAd5 boost vaccine trial. In: *AIDS Vaccine 2012*, Boston, Massachusetts.

- October 2013 Williams WB, Jones K, Liu P, Trama AM, Moody MA, Seaton K, Vandergrift N, Wiehe K, Liao H, Montefiori DC, Ochsenbauer C, Kappes J, Hammer S, Mascola J, Koup R, Corey L, Nabel G, **Gilbert PB**, Morgan C, Churchyard G, Keefer M, Graham BS, Tomaras GD, Haynes BF. The Antibody Repertoire Induced by the Multiclade (A, B, C) HIV-1 DNA Prime, Multiclade (A, B, C) rAd5 boost VRC vaccine. In: *AIDS Vaccine 2013*, Barcelona, Spain.
- March 2014 Zolla-Pazner S, Williams C, Rolland M, Edlefsen P, **Gilbert PB**, XP Kong XP, Mullins J, Tovanabutra S, Rerks-Ngarm S, Nitayaphan S, Pitisuttithum P, Kaewkungwal J, Robb M, Michael N, Kim J. IgG V3-specific antibody (Ab) reactivity in plasma from RV144: Implications for vaccine efficacy. In: *Keystone Symposia: HIV Vaccines: Adaptive Immunity and Beyond (X3)*, Banff, Alberta, Canada.
- October 2014 Edlefsen PT, Rolland M, Hertz T, Tovanabutra S, Gartland AJ, deCamp A*, Magaret CA, Ahmed H, Gottardo R, Juraska MJ*, McCoy C, Larsen BB, Sanders-Buell E, Carrico C, Menis S, Bose M, RV144 Sequencing Team, Arroyo MA, O'Connell RJ, deSouza MS, Nitayaphan S, Pitisuttithum P, Kaewkungwal J, Rerks-Ngarm S, Robb ML, McLellan JS, Georgiev IS, Kirys T, Kwong PD, Carlson JM, Michael NL, Schief WR, Mullins JI, Kim JH, **Gilbert PB**. Comprehensive sieve analysis of breakthrough HIV-1 sequences in the RV144 vaccine efficacy trial. In: *HIV Research for Prevention 2014*, Cape Town, South Africa.
- October 2014 Liao H-X, Trama AM, Williams WB, Moody MA, Vandergrift N, Tomaras GD, Marshall DJ, Gurley T, Whitesides J, Eudailey J, Foulger A, Parks R, Stolarchuk, Lloyd KE, Soderberg K, Mascola JR, Koup R, Corey L, Nabel GB, **Gilbert PB**, Morgan C, Maenza J, Keefer M, Hammer S, Churchyard G, Montefiori DC, Graham BS, Baden LR, Kepler TB, Haynes BF. Role of intestinal microbiota in shaping the B cell repertoire in HIV infection and Env vaccination. In: *HIV Transmission Workshop 2014*, Cape Town, South Africa.
- October 2014 Prentice H, Geraghty DE, Tomaras GD, Fong Y, Nelson W, Kijak GH, Zolla-Pazner S, Nitayaphan S, Rerks-Ngarm S, Kaewkungwal J, Pitisuttithum P, Haynes BF, Michael NL, **Gilbert PB**, Kim JH, Thomas R. Immune correlates identified in the RV144 vaccine efficacy trial impact HIV-1 acquisition only in the presence of certain HLA class II genes. In: *HIV Research for Prevention 2014*, Cape Town, South Africa.
- October 2014 Sachdev D, Ahmed H, Huang Y, Buchbinder S, Morgan C, Frahm N, **Gilbert PB**, Rerks-Ngarm S, Kaewsungwal J, Nitayaphan S, Pitisuttithum P, Michael NL, Kim JH, Robb ML, O'Connell RJ. Sex differences in immune variables in the RV144 trial. In: *HIV Research for Prevention 2014*, Cape Town, South Africa.
- November 2014 Seaton KE, Deal A, Yu X, Huang Y, Ashley V, Ferrari G, Lewis G, Liu P, Zirui-Tay M, Shen X, Duffy R, Montefiori DC, Hay C, Grunenberg N, Goepfert P, Sato A, Elizaga M, **Gilbert PB**, Moss B, Frahm N, Buchbinder SP, McElrath MJ, Robinson H, Tomaras GD. Durable Env-specific IgG antibody responses elicited in a Clade B DNA/MVA prime boost vaccine regimen (HVTN 205 and HVTN 094) with a 4-month rest period. *Duke Center for HIV/AIDS Vaccine Immunology and Immunogen Discovery Annual Meeting*, Durham, North Carolina.
- February 2015 Janes H, Tovanabutra S, Herbeck JT, Rerks-Ngarm S, Robb ML, Michael NL, **Gilbert PB**, Kim JH, Rolland M and the Step/HVTN502 and RV144 study teams. HIV-1 infections with multiple founders are associated with higher viral loads. *Conference on Retroviruses and Opportunistic Infections (CROI)*, Seattle, Washington.
- February 2015 Rolland M**, DeCamp A***, Hall BM, Tovanabutra S, McElrath J, Hammer SM, Sobieszczyk ME, **Gilbert PB**, Kim JH, Mullins JI and the HVTN505 sieve analysis team. HVTN505 breakthrough sequences showed HIV vaccine-associated differences in Env-gp120. *Conference on Retroviruses and Opportunistic Infections (CROI)*, Seattle, Washington. **Contributed equally.

- February 2015 Williams WB, Liao HX, Moody MA, Kepler TB, Wiehe K, Jones KL, Marshall DJ, Whitesides JF, Pollara J, Liu P, Trama AM, Seaton K, Shen X, Foulger A, Stolarchuk C, Lloyd KE, Parks R, Vandergrift N, **Gilbert PB**, Grove D, Ferrari G, Montefiori DC, Sobieszczyk ME, Hammer S, Mascola JR, Koup R, McElrath MJ, Corey L, Nabel GB, Grunenberg N, Morgan C, Churchyard G, Maenza J, Keefer M, Graham BS, Baden LR, Tomaras GD, Haynes BF. HIV Vaccine Induced Non-Neutralizing Antibodies Originating From Pre-Vaccination Env Cross-Reactive B Cells. *Keystone HIV-1 Vaccines Conference*, Banff, Alberta, Canada.
- July 2016 Bekker LG, Laher F, Moodie Z, Tomaras G, Grunenberg N, Allen M, Daniels B, Innes C, Mngadi K, Malahleha M, **Gilbert PB**, Michael N, Phogat S, Diaz Granados C, Kanasa-Thanan N, Corey L, Gray G, McElrath MJ, The HVTN 100 Study Team. Meeting the “Go” Criteria: Immunogenicity from HVTN100, a phase 1/2 randomized, double blind, placebo-controlled trial of clade C ALVAC-® (vCP2438) and Bivalent Subtype C gp120/MF59® in HIV-uninfected South African adults. Late-Breaker, Oral Presentation, AIDS 2016, Durban, South Africa.
- April 2016 Dimitrov D, **Gilbert PB**. Projected effectiveness of mass HIV vaccination with multi-dose regimens to be tested in South Africa. *4th Annual Institute for Disease Modeling Symposium*, Bellevue, WA.
- October 2016 Buchbinder S, Grunenberg N, Sanchez B, Seaton K, Ferrari G, Moody MA, Frahm N, Montefiori D, Goepfert P, Baden L, Hay C, Yu X, **Gilbert PB**, McElrath MJ, Huang Y, Robinson H, Tomaras GD, HVTN 094 Study Group. DNA/MVA HIV vaccine producing virus-like particles (VLPs) is well-tolerated and induces durable functional antibodies (Abs) in HVTN 094. *HIV Research for Prevention (HIVR4P)*, Chicago, Illinois.
- October 2016 Tomaras GD, Ferrari G, Moodie Z, Montefiori D, Yates NL, Ashley VA, Deal A, Seaton KE, Lin Y, Goodman D, Tay M, Shen X, Frahm N, Grunenberg N, Sarzotti-Kelsoe M, Pinter A, Saunders KO, Peacock J, Korber B, Haynes BF, Michael N, Rerks-Ngarm S, Pitisuttithum P, Nitayapan S, Kaewkungwal J, Phogat S, Granados CD, Kanasa-Thanan N, Gray G, Laher F, Bekker LG, Corey L, **Gilbert PB**, McElrath J. Comparative Humoral Immunogenicity of HVTN 100 and RV144 in HIV-uninfected South Africans. To be presented at the Duke Center for HIV/AIDS Vaccine Immunology and Immunogen Discovery (CHAVID-ID) meeting, Durham, North Carolina.
- December 2017 Sun Y, Qi L, **Gilbert PB**. A hybrid method for the stratified mark-specific proportional hazards models with missing data with applications. *10th International Conference of the ERCIM WG on Computational and Methodological Statistics*, London, United Kingdom.
- March 2018 Adamson B, Montigny S, Mâsse B, Garrison L, Kublin J, **Gilbert PB**, Dimitrov D. Policy Analysis of HIV Vaccine Delivery Design in South Africa. *Conference on Retroviruses and Opportunistic Infections (CROI)*, Boston, Massachusetts.
- October 2018 Moodie Z, Innes C, Hosseinipour M, Naidoo S, Bekker L.-G., Laher F, Grunenberg N, Mann P, Yu C, McElrath MJ, Tomaras G, Yates N, Morris L, Mkhize N, Montefiori DC, Allen M, Kublin J, Gray G, **Gilbert PB**, Corey L, and the HVTN 100 and HVTN 111 trial teams. DNA-prime Induces Higher Magnitude Humoral Responses than ALVAC-prime in HIV Vaccine Regimens with the Same Protein Boost. *HIV Research for Prevention (HIVR4P)*, Madrid, Spain.
- October 2018 Huang Y, Pegu A, Huang Y, Pauthner M, Larry Corey, **Gilbert PB**, Burton D, Mascola JA. Meta-analysis to evaluate the relationship between serum antibody neutralizing titer and protection against SHIV challenge in nonhuman primates. *HIV Research for Prevention (HIVR4P)*, Madrid, Spain.
- May 2020 Labuschagne P, Rossenkhani R, Rudnicki E, Espy N, Juraska MJ*, Zhang Y, Li K, DeCamp A*, Huang Y, Hural J, **Gilbert PB**, Edlefsen P. Accuracy of HIV-1 infection

- time estimates using diagnostic test histories in prevention studies with frequent follow-up. *27th International Dynamics and Evolution of HIV and Other Human Viruses*. Lake Arrowhead, California.
- May 2020 Williamson BD, Benkeser DC*, Magaret CA, Carpp LN, Borate B, **Gilbert PB**. Guiding HIV-1 antibody regimen down-selection and prevention efficacy trial design using machine learning. *27th International Dynamics and Evolution of HIV and Other Human Viruses*. Lake Arrowhead, California.
- January 2021 Williamson C, ..., **Gilbert PB**, Mullins JI. Analysis of genetic diversity and VRC01 pressure on HIV-1 breakthrough viruses from the AMP trial (HVTN 703/HPTN 081 and HVTN 704/085). *4th IAS HIV Research for Prevention Conference (HIV R4P Virtual)*
- February 2022 Mbadu AZ, Cohen P, Lambson B, Magaret CA, **Gilbert PB**, Williamson C, Morris L, Moore PL, Mufhandu HT. Identification of viral mutations that confer cross resistance to VRC01 antibody in HIV-1 subtype C viruses. *AIDS 2022*.
- March 2022 Huang Y, Karuna S, Zhang L, deCamp A*, Montefiori D, Morris L, Rudnicki E, Juraska MJ*, Mkhize NN, Seaton K, Tomaras G, Andrew P, Kublin J, Barouch D, Cohen M, Mascola J, **Gilbert PB**, Corey L. Predicting HIV Prevention Efficacy of a Broadly Neutralizing Antibody (bnAb) Combination in Follow-up to the Antibody Mediated Prevention (AMP) Trials. *Keystone Symposia Next Generation Vaccines and Therapies*.
- July 2022 Kenny A, Luedtke A, Hyrien O, Fong Y, Burnham R, Heptinstall J, Sawant S, Stanfield-Oakley S, Laher Omar F, Khuzwayo S, Dintwe O, Borducchi E, Pattacini L, Willems W, Lavreys L, van Duijn J, Stieh DJ, Tomaka F, Pau MG, Gray GE, Buchbinder S, Mngadi K, McElrath MJ, Corey L, Barouch DH, De Rosa SC, Ferrari G, Andersen-Nissen E, Tomaras G, **Gilbert PB**. Immune Correlates Analysis of the Imbokodo HIV-1 Vaccine Efficacy Trial. *24th International AIDS Conference (Virtual, Montreal, Canada)*
- September 2022 **Gilbert PB**. Immune Correlates Results for the Uhambo and Imbokodo HIV Vaccine Efficacy Trials. *2022 International Society of Vaccines (ISV) Annual Congress (Virtual, Quebec City, Canada)*
- October 2023 Follmann D, Wang X, **Gilbert PB**, Baden LR, El Sahly H, Essink B, Janes HE, Marovich M, Deng W, Priddy F, Dixit A, Tomassini JE, Das R, Miller J, Zhou H. *Who to Boost When: An Analysis of Dosing Interval and Age on COVID-19 Outcomes in the COVE Trial During the Delta and Omicron Waves (IDweek, Boston, MA)*
- October 2024 Moodley C, Margaret C, Mkhize N, Yssel A, Westfall D, Deng W, Mullins J, Cohen P, Hural J, McElrath MJ, Cohen M, Corey L, **Gilbert PB**, Montefiori D, Moore P, Williamson C. Discordant VRC01 sensitivity phenotype in participants with HIV-1 multi-lineage infections from the AMP trials. *HIVR4P 2024 (Lima, Peru)*.
- May 2024 Andrews LIB*, Halloran ME, Neuzil KM, van der Laan L, Huang Y, Andriesen J, Patel M, Fisher LH, Janes HE, Sumner K, Flannery B, Follmann D, **Gilbert PB**. COVID-19 Vaccine Effectiveness: An Evaluation of the Test Negative Design using Randomized Placebo-Controlled Clinical Trials (*Society for Epidemiological Research Annual Meeting*) May 2024, Austin, Texas.
- June 2024 Andrews LIB*, van der Laan L, **Gilbert PB**. Semiparametric Methods for Evaluating COVID-19 Vaccine Regimens in Test-Negative Designs with Missing Data (*WNAR/Institute of Mathematical Statistics Meeting*) June 2024, Fort Collins, Colorado.
- August 2024 Andrews LIB*, van der Laan L, **Gilbert PB**. Semiparametric Methods for Evaluating COVID-19 Vaccine Regimens in Test-Negative Designs with Missing Data (*Joint Statistical Meetings*) August 2024, Portland, Oregon)
- September 2024 Jayashankar L, Ayala V, Ravji A, Jones T, Castellino F, DeGrace MM, Wolfe DN, Zhou J, Armstrong KL, **Gilbert PB**, Koup RA, Donis RA. The Quest for Correlates of

Protection for COVID-19 Vaccines: Past, Present and Future (*Options XII for the Control of Influenza*) September 2024, Brisbane, Australia.

Meeting Posters:

- 1998 **Gilbert PB.** Methods for comparing genotypic resistance across antiretroviral trial treatment regimens from sequence data in virologic failures only. In: *AIDS Clinical Trials Group Meeting*, Washington, D.C.
- 1998 **Gilbert PB.** Assessing genotypic resistance in antiretroviral trials using sequence data only from virologic failures. In: *Fifth Annual HIV-1 Dynamics and Evolution Meeting*, Santa Fe, New Mexico.
- 2001 Novitsky V, Rybak N, McLane MF, **Gilbert PB**, Chigwedere P, Klein I, Gaolekwe S, Chang SY, Peter T, Thior I, N'dungu T, Vannberg F, Foley BT, Marlink R, Lee TH, Essex M. Predominant HIV-1C-specific CTL responses. In: *Program and abstracts of AIDS Vaccine 2001*, Philadelphia, Pennsylvania.
- 2001 Rossini AJ, Self SG, Hudgens M, **Gilbert PB.** Rational approach for HVTN Phase I/II HIV-1 vaccine trials. In: *Program and abstracts of AIDS Vaccine 2001*, Philadelphia, Pennsylvania.
- 2002 Chung M, Renjifo B, **Gilbert PB**, Msamanga G, Mwakagile, Fawzi W, Essex M. In-utero transmission of quasi-species among HIV-1 subtypes. In: *Program and abstracts of the Fourteenth International AIDS Conference*, Barcelona, Spain.
- 2002 **Gilbert PB**, Self SG, DeGruttola V, Hudgens M, Hammer S. Interpreting observed vaccine effects on post infection surrogate endpoints in preventive HIV vaccine efficacy trials. In: *Program and abstracts of the Fourteenth International AIDS Conference*, Barcelona, Spain.
- 2003 Novitsky V, **Gilbert PB**, Peter T, Lee TH, Essex M. Viral load, viral diversity, and T-cell immune responses in HIV-1C infection: Implications for vaccine design. In: *Abstracts of the 10th Conference on Retroviruses and Opportunistic Infections*, Abstract 458, Boston, Massachusetts.
- 2004 Novitsky V, **Gilbert PB**, Ndung'u T, Peter T, Thior I, Lee TH, Essex M. Virus-host interactions in HIV-1C infection. In: *Program and abstracts of The Fourteenth International AIDS Conference*, Bangkok, Thailand.
- 2004 Malone S, Djomand G, Critchlow C, **Gilbert PB**, Chiu Y-L. Risk of HIV infection among HIV vaccine and placebo control recipients enrolled in NIAID-funded network HIV vaccine trials in the United States, 1988-2002. In: *Program and abstracts of The Fourteenth International AIDS Conference*, Bangkok, Thailand.
- 2004 **Gilbert PB**, Cai T, Self SG, Gurwith M. Joint assessment of HIV vaccine effects on preventing infection and delaying disease in the Phase III trial of AIDSVAX B/B. In: *Program and abstracts of the Eleventh Conference on Retroviruses and Opportunistic Infections*, Abstract 283, San Francisco, California.
- 2004 Shepherd BE*, **Gilbert PB**, Gurwith M, Francis D. Assessment of HIV vaccine effects on viral load in the Phase III trial of AIDSVAX B/B. In: *Program and abstracts of the Eleventh Conference on Retroviruses and Opportunistic Infections*, Abstract 284, San Francisco, California.
- 2008 Hudgens M, **Gilbert PB**, Wu Chih-da, Barouch D, Mascola J, Self SG. Power to detect vaccine effects in repeated low-dose challenge experiments. In: *Program and Abstracts of AIDS Vaccine 2008*, Poster #P03-02, Cape Town, South Africa.
- 2011 Kunwar P, He D, Hawkins NR, Liu Y, Collier A, Hertz T, **Gilbert PB**, Horton H. Analysis of epitope-specific HIV T cell responses during early HIV-1 infection and their association with viral control. In: *Abstracts presented at AIDS Vaccine 2011*, Poster #P01.01, Patumwan, Bangkok, Thailand.
- 2011 Janes H, **Gilbert PB**, Frahm N, Rolland M, deCamp A*, Gabriel EE*, Wolfson J*, Mullins J, McElrath MJ. Integrated analysis of immunogenicity, viral sequence, and viral load data

- in the step study. In: *Abstracts presented at AIDS Vaccine 2011*, Poster #P01.08, Patumwan, Bangkok, Thailand.
- 2012 Kijak G, Li S, Paris R, Ngaury V, Michael N, Rerks-Ngarm S, **Gilbert PB**, Kim J. Modulation of vaccine effect by FcGamma receptor 3a genetic polymorphism in RV144. *Conference on Retroviruses and Opportunistic Infections (CROI)*, Seattle, Washington.
- 2012 *Conference on Retroviruses and Opportunistic Infections (CROI)*, Seattle, Washington ().
- 2012 Defawe O, DeRosa S, Frahm N, Carter D, Fong Y, Moodie Z, Michael N, Kim J, Rerks-Ngarm S, **Gilbert PB**, McElrath MJ. Vaccine-induced cytokine production is associated with lower risk of HIV infection among RV144 vaccine recipients. *Keystone Symposium on HIV Vaccines 2012*, Keystone, Colorado.
- 2012 Rolland M, Maust B, Bonsignori M, deSouza M, Edlefsen P, **Gilbert PB**, Haynes B, HwangK, KimJ, Larsen B, Liao H, Michael N, Mullins J, Nitayaphan S, Rerks-Ngarm S, Robb M, Sanders-Buell E, Tovanabutra S, Hertz T, deCamp A*, Magaret C, Ahmed H, Juraska MJ*, Chen L, Konopa P, Nariya S, Stoddard J, Wong K, Zhao H, Deng W, Bose M, Howell S, Lazzaro M, O'Sullivan A, Lei E, Bradfield A, Ibitanumo G, Pham D, Carlson J, Assawadarachai V, Heckerman D, Bates A. Sieve signature in the V2 target of RV144-induced antibodies. *Keystone Symposium on HIV Vaccines 2012*, Keystone, Colorado.
- 2012 Huang Y, Self S, Gilbert PB, Yao L, Shao Y. U.S.-China collaborations on the design of China's first Phase IIb HIV vaccine efficacy trial. *33rd Annual Meeting of the Society for Clinical Trials*, Miami, Florida ().
- 2013 Seaton KE*, Yates NL*, Williams WT, Liao L, deCamp A*, Fong Y, Montefiori D, Spearman P, Elizaga M, Barnett S, Koutsoukos M, GSK PROHIV-002 Protocol Team, HVTN 088 Protocol Team, RV144 Protocol Team, VAX003 Protocol Team, McElrath MJ, Corey L, Michael N, Kim J, Voss G, **Gilbert PB**, Haynes BF, Tomaras GD. Human HIV-1 vaccine induced antibody durability and Env IgG3 responses. *AIDS Vaccine Conference*, Barcelona, Spain.
- 2013 Li S, **Gilbert PB**, Tomaras GD, Kijak G, Ferrari G, Thomas R, Zolla-Pazner S, Evans DT, Li Y, Gottardo R, Dai JY, Janes H, Morris D, Fong Y, Edlefsen PT, Li F, Magaret CA, Frahm N, Alpert MD, Rerks-Ngarm S, Pitisuttithum P, Kaewkungwal J, Nitayaphan S, Robb ML, O'Connell RJ, Michael NL, Kim JH, McElrath MJ, Geraghty DE. association of FcγRIIC polymorphism with vaccine efficacy and correlates of HIV-1 infection risk in RV144. *AIDS Vaccine Conference*, Barcelona, Spain.
- 2013 Huang Y, Duerr A, Zhang L, Moodie Z, Frahm N, DeRosa SC, McElrath MJ, **Gilbert PB**. Immune correlates analysis of the Step HIV vaccine efficacy trial. *AIDS Vaccine Conference*, Barcelona, Spain.
- 2013 Gartland A, Li D, McNevin J, Tomaras GD, Gottardo R, Janes H, Fong Y, Morris D, Geraghty D, Kijak GH, Edlefsen PT, Frahm N, Larsen BB, Tovanabutra S, Sanders-Buell E, deCamp A*, Magaret CA, Ahmed H, Goodridge JP, Chen L, Konopa P, Nariya S, Stoddard JN, Wong K, Zhao H, Deng W, Maust BS, Bose M, Howell S, Bates A, Lazzaro M, O'Sullivan A, Lei E, Bradfield A, Ibitamuno G, Assawadarachai V, O'Connell RJ, deSouza MS, Nitayaphan S, Rerks-Ngarm S, Robb ML, Sidney J, Sette A, Zolla-Pazner S, Montefiori D, McElrath MJ, Mullins JI, Kim JH, **Gilbert PB**, Hertz T. Analysis of HLA A*02 association with vaccine efficacy in the RV144 Thai trial. *Advancing Vaccines in the Genomics Era (T1)*, Rio de Janeiro, Barra da Tijuca, Brazil.
- 2013 Gartland A, deCamp A*, Hertz T, **Gilbert PB**. Detection of T-cell mediated sieve effects in vaccine efficacy trials. *Advancing Vaccines in the Genomics Era (T1)*, Rio de Janeiro, Barra da Tijuca, Brazil.
- 2014 Zolla-Pazner S, Williams C, Rolland M, Edlefsen PT, **Gilbert PB**, Kong X, Mullins JI, Tovanabutra S, Rerks-Ngarm S, Nitayaphan S, Pitisuttithum P, Kaewkungwal J, Robb M, Michael N, Kim J. IgV V3-specific antibody reactivity in plasma from RV144: implications for vaccine efficacy. *HIV Vaccines: Adaptive Immunity and Beyond*, *Keystone Symposia on Molecular and Cellular Biology*, Banff, Alberta, Canada.

- 2016 deCamp A*, Rolland M, Edlefsen P, Sanders-Buell E, Hall B, Magaret C, Fiore-Gartland A, Juraska MJ*, Graham B, Roederer M, Michael N, Robb M, McElrath MJ, Tovanabutra S, Sobieszczyk M, Hammer S, Kim J, Mullins J, **Gilbert PB** and the HVTN505 sieve analysis team. Sieve Pressure toward the CD4 Binding Site of Env in HVTN 505 Breakthrough Infections. *HIV Research for Prevention (HIVR4P)*, Chicago, Illinois.
- 2016 de Montigny S, Mâsse BR, **Gilbert PB**, Dimitrov DT. Projected effectiveness of Mass HIV vaccination in South Africa. *Keystone Symposia on Molecular and Cellular Biology*, Olympic Valley, California ().
- 2016 de Montigny S, Mâsse BR, Wood D, **Gilbert PB**, Dimitrov D. Assessing the Impact of the Vaccine Efficacy Profile and Regimen Adherence on Projected Effectiveness of the HVTN 702 Vaccine Regimen in South Africa. *HIV Research for Prevention (HIVR4P)*, Chicago, Illinois.
- 2016 Edlefsen P, Magaret C, Warth C, Labuschagne P, Eller L, Rolland M, Chopera D, Tovanabutra S, Matsen IV F, Poon A, Sekiziyivu A, Nitayaphan S, Rono K, Botha G, Matten D, Logan M, Anthony C, Rossenkhan R, Abrahams M, Holzman T, Robb M, **Gilbert PB**, Michael N, Williamson C, Ndabambi N, Teavers S. Systematic evaluation of HIV infection time and founder inferences using SGA and Illumina sequences. *Keystone Symposia on Molecular and Cellular Biology*, Olympic Valley, California.
- 2016 Janes H, Cohen K, Sobieszczyk M, Frahm N, Karuna S, Sanchez B, Magaret C, Adams E, Hammer S, **Gilbert PB**, McElrath MJ. Vaccine-induced CD8+ T Cell immunity strongly predicts lower HIV infection risk in HVTN 505. *HIV Research for Prevention (HIVR4P)*, Chicago, Illinois.
- 2016 Selinger C, Bershteyn A, Wood D, **Gilbert PB**, Dimitrov D. Population-level Impact of an ALVAC/AIDSVAX Vaccine Augmented with Additional Booster through Targeted Campaigns in South Africa. *HIV Research for Prevention (HIVR4P)*, Chicago, Illinois.
- 2016 Huang Y, Zhang L, Gruenberg N, Bailer R, Isaacs A, Ledgerwood J, Season K, Mayer K, Corey L, **Gilbert PB**. Population Pharmacokinetics (popPK) Analysis of VRC01, a Broadly Neutralizing HIV-1 Monoclonal Antibody, in Healthy Adults. *Conference on Retroviruses and Opportunistic Infections (CROI)*, Seattle, Washington.
- 2017 Montigny de Simon, Masse B, Wood D, Bershteyn A, Kublin J, **Gilbert PB**, Dimitrov D. Modulating effects of epidemic conditions on projected HIV vaccination efficiency in South Africa. *Canadian Conference on HIV/AIDS Research Conference (CAHR)*, Montreal, Quebec.
- 2018 Adamson BJ, de Montigny S, Mâsse BR, Garrison L, Kublin JG, **Gilbert PB**, Dimitrov D, University of Washington, Seattle, WA, University of Montreal, Montreal, QC, Fred Hutchinson Cancer Research Center, Seattle, WA. Designing Hiv Vaccine Delivery Strategies In South Africa: A Policy Analysis. *2018 Conference on Retroviruses and Opportunistic Infections (CROI)*, Boston, Massachusetts.
- 2018 de Montigny S, Mâsse BR, Kublin JG, **Gilbert PB**, Dimitrov D. Modulating Effects of Revaccination Rates and Immune Refractoriness on the Projected Impact of Future HIV Vaccination in South Africa. *HIVR4P*, Madrid, Spain.
- 2019 Dintwe O, Andersen-Nissen E, Hosseinipour M, Innes C, Naidoo S, Mann P, DeCamp A*, Metch B, De Rosa S, Hutter J, Rohith S, Omarjee S, Wilcox S, Marshall K, Morris D, Ramjee G, Sebe M, Maganga L, Herce M, Koutsoukos M, Van Der Meeren O, Ding S, Pantaleo G, **Gilbert PB**, Corey L, Kublin J, McElrath MJ, and HVTN 111 trial team. Biojector administration on an HIV DNA vaccine enhances CD4+ T-cell response rates in DNA prime, DNA/Protein boost HIV vaccine regimen, but shows no effect on DNA protein co-administration regime. *Keystone Symposia on B Cell-T Cell Interactions*, Keystone, Colorado.
- 2022 Michal Juraska*, Early AM, Li L, Khorgade A, Schaffner SF, Lievens M, Simpkins B, Hejazi N, Benkeser DC*, Magaret CA, Mercer LD, Adjei S, Agbenyega T, Ansong D, Bii D, Bollaerts A, Buabeng PBY, Kariuki S, Otieno K, Roman F, Samuels AM, Westercamp

- N, Ockenhouse C, Ofori-Anyinam O, Lee CK, MacInnis BL, **Gilbert PB**, Wirth DF, Neafsey DE. Efficacy against Molecular Infection of Fractional-Dose RTS,S/AS01_E Malaria Vaccine Regimens under Natural Exposure in a Phase 2b Trial with Monthly Blood Sampling. American Society of Tropical Medicine and Hygiene Annual Meeting, Seattle, WA (October 2022).
- 2023 Dayan GH, Roupael N, Walsh SR, Celle M, **Gilbert PB**, Grunenber N, Antony J, Grillet M-H, Schuerman L, Michael N, Savarino S, Sridhar S for the VAT00008 study team. Efficacy of monovalent [D614] and bivalent [D614 + B.1.351] SARS-CoV-2 recombinant protein vaccines with AS03 adjuvant (CoV2 preS dTM-AS0) in adults. 33rd European Congress of Clinical Microbiology & Infectious Diseases, Copenhagen, Denmark (April 2023)
- 2024 Moodley C, Magaret C, Mkhize N, Yssel A, Westfall D, Deng W, Mullis J, Cohen P, Hural J, McElrath MJ, Cohen M, Corey L, **Gilbert PB**, Montefiori D, Moore P, Williamson C. Discordant VRC01 sensitivity phenotype in participants with HIV-1 multi-lineage infections from the AMP trials. *HIV R4P* Lima, Peru (October, 2024).

12. UNIVERSITY SERVICE

Fred Hutchinson Cancer Center:

- 2005-2006 Deputy Director of Statistical Sciences, Statistical Center for HIV/AIDS Research and Prevention, Fred Hutchinson Cancer Research Center
- 2006 Chair, Public Health Science Division Biostatistics Faculty Search Committee
- 2010 Chair, Vaccine and Infectious Disease Institute Biostatistics Faculty Search Committee
- 2011- Member, Executive Management Team of the HIV Vaccine Trials Network
- 2011-2015 Member, SCHARP Steering Committee
- 2012-2019 Member, Executive Committee of Vaccine and Infectious Disease Division
- 2012-2019 Member, Steering Committee for the Interdisciplinary Training Grant, Fred Hutchinson Cancer Research Center
- 2013-2019 Program Head/Director, Biostatistics, Bioinformatics, and Epidemiology Program, Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Research Center
- 2016 Chair, 2 Vaccine and Infectious Disease Division Biostatistics Faculty Search Committees
- 2018-2019 Member, Vaccine and Infectious Disease Division and Public Health Sciences Division Biostatistics Faculty Search Committee
- 2019-2021 Leadership Group, Center for Infectious Diseases Prevention Research via Innovative Statistical Methods (ID-PRISM), Biostatistics, Bioinformatics, and Epidemiology Program, Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Center, and Departments of Biostatistics and Statistics, University of Washington
- 2021-2022 Chair, Vaccine and Infectious Disease Division Biostatistics Faculty Search Committee
- 2020-2023 Chair, Leslie Goo's Faculty Mentoring Committee, Vaccine Infectious Disease Division, Fred Hutchinson Cancer Center
- 2022-present Chair, Aaron Hudson's Faculty Mentoring Committee, Vaccine Infectious Disease Division, Fred Hutchinson Cancer Center
- 2022-present Chair, Bo Zhang's Faculty Mentoring Committee, Vaccine Infectious Disease Division, Fred Hutchinson Cancer Center
- 2023 Member, Promotion Committee for a VIDD Associate Professor
- 2023-present Co-Organizer, 7th Seattle Symposium in Biostatistics November 2025
- 2023-present Member, Search Committee for PHS Biostatistics Program Head
- 2024 Biostatistics Shared Resource Working Group, Fred Hutchinson Cancer Center

2024 Chair, Organizing Committee, The Halloran Symposium, Fred Hutchinson Cancer Center (July)

Harvard University:

1998-1999 Center for Biostatistics in AIDS Research Statistical Computing Committee, Harvard School of Public Health, Member
1998-1999 Student Advising Committee, Department of Biostatistics, Harvard School of Public Health, Member
1998-1999 Committee for a Master of Science in Applied Biostatistics, Department of Biostatistics, Harvard School of Public Health, Member
1999-2000 Admissions and Recruiting Committee, Department of Biostatistics, Harvard School of Public Health, Member
1999-2000 Curriculum Committee, Department of Biostatistics, Harvard School of Public Health, Member
1999-2000 Postdoctoral Committee, Department of Biostatistics, Harvard School of Public Health, Member
1999-2001 Committee for the Summer Program in Biostatistics for Underrepresented Minority Groups, Department of Biostatistics Harvard School of Public Health, Member
1999-2001 Diversity Committee, Department of Biostatistics, Harvard School of Public Health, Member
1999-2001 Center for Biostatistics in AIDS Research Design Review Committee, Harvard School of Public Health, Member
2000-2001 Committee on the Future of Public Health, Department of Biostatistics, Harvard School of Public Health, Member
2000-2001 Degree Program Committee, Department of Biostatistics, Harvard School of Public Health, Member
2000-2001 Teaching Effectiveness Committee, Department of Biostatistics, Harvard School of Public Health, Member
2000-2001 Webpage Committee, Department of Biostatistics, Harvard School of Public Health, Member

University of Washington:

2002-2004 Core Curriculum Committee, Department of Biostatistics, University of Washington School of Public Health, Member
2002-2006 Faculty Development Committee, Department of Biostatistics, University of Washington School of Public Health, Member
2004-2005 PhD Theory Exam Committee, Department of Biostatistics, University of Washington School of Public Health, Member
2006-2007 PhD Applied Exam Committee, Department of Biostatistics, University of Washington School of Public Health, Member
2013 Faculty Development Committee, Department of Biostatistics, University of Washington School of Public Health, Member
2013, 2014 Applied Exam Committee, Department of Biostatistics, University of Washington School of Public Health, Co-chair
2019 Promotion Committee for an Assistant Professor of Biostatistics, Department of Biostatistics, University of Washington School of Public Health, Chair
2020 Applied Exam Committee, Department of Biostatistics, University of Washington School of Public Health, Member
2023 Promotion Committee for an Associate Professor of Biostatistics, Department of Biostatistics, University of Washington School of Public Health

2023-2024 Affiliates/Adjuncts/Clinical Appointments Committee, Department of Biostatistics, University of Washington School of Public Health, Member

13. PROFESSIONALLY-RELATED COMMUNITY SERVICE

1997-present Speaker at public and private elementary, middle school, and high schools on HIV/AIDS and other vaccine infectious disease research

14. TEACHING HISTORY

A. Formal Courses, Including Distance Learning

1998-1999 Director of the Biostatistics Department's student consultation laboratory for two semesters, Biostatistics Consultation (Bio 312ab and Bio 312cd), Department of Biostatistics, Harvard School of Public Health

2000 Instructor, Statistical Methods in Biology (DBB 207cd), Division of Biological Sciences, Harvard School of Public Health, 5 credits

2001 Instructor, Regression and ANOVA in Experimental Research (Bio 211), Harvard School of Public Health, 5 credits

2002 Seminar in Biostatistics (Biostat 580), Department of Biostatistics, University of Washington, 1 credit

2003 Instructor, Medical Biometry III (Biostat 513), Department of Biostatistics, University of Washington, 4 credits

2006 Instructor, Evaluating Vaccine Efficacy (Biostat 578A), Department of Biostatistics, University of Washington, 4 credits

B. Other Teaching

Guest Lectures:

2004-2009 Guest lecturer, Biostat 511, EPI 590B, University of Washington School of Public Health

2012 Guest lecturer, Global Health H563/Epidemiology 549, University of Washington

2020 Guest lecturer on "COVID-19 vaccine efficacy trials", Global Health H563/Epidemiology 549, University of Washington

2023 Guest Lecturer on "Sieve analysis in COVID-19 vaccine efficacy trials", Biostat 511, University of Washington

Curriculum and Training Program Development:

1999 Course developer and lecturer (4 lectures), School of Modern Statistical Methods in Medical Research, International Centre for Theoretical Physics, Trieste, Italy

1999 Course co-developer and lecturer; Statistics, Data Management, and Monitoring of Clinical Trials (one-week short course, Part I), Institute of Population Scientific Research, Mahidol University, Bangkok, Thailand

2000 Course co-developer and lecturer; Statistics, Data Management, and Monitoring of Clinical Trials (one-week short course, Part II), Department of Biostatistics, Mahidol University, Bangkok, Thailand

2009-2014 Course co-developer and lecturer, Module on 'Immune Correlates of Vaccine-Induced Protection' at the University of Washington Summer Institute in Statistics and Modeling for Infectious Diseases

2011 Course co-developer and instructor (for Thailand workshop), Statistical Issues for HIV Vaccine Efficacy Trials. Global HIV

	Vaccine Enterprise Young Investigator Training Workshop (OCTAVE), Rio de Janeiro, Brazil and Bangkok, Thailand
2012	Course developer and instructor, Workshop on Concepts and Assessment of Immune Correlates of Vaccine Protection. Center for Biologics Evaluation and Research (CBER), FDA
2015	Course co-developer and instructor, Workshop on Statistical Issues in HIV Vaccine Trial Design and Evaluation, Cape Town, South Africa
2016	Course co-developer and instructor, Workshop on Next Generation Sequencing in Clinical Vaccine Trials with Application to Vaccine and Monoclonal Antibody Efficacy Trials, Cape Town, South Africa
2016-2017	Course co-developer and lecturer with Dean Follmann, Module on ‘Evaluating Vaccine Efficacy’ at the University of Washington Summer Institute in Statistics and Modeling for Infectious Diseases
2018	Course co-developer and instructor, Short-course (2 days) on Statistical Methods and R Code Tutorials for the Analysis of Immune Correlates in Vaccine Efficacy Trials, Sanofi Pasteur, Swiftwater, PA https://faculty.washington.edu/peterg/SanofiPasteurCorrelatesRTraining.2018.html
2023-2024	Member, Research training program for the NIH D43 Training Grant “African Tuberculosis Bioinformatics Training Program (D43)” held by Stellenbosch University in South Africa.
2024	Biomedical Research Integrity Program, Facilitator of a Case Study from the NIH Office of Research Misconduct, Fred Hutchinson Cancer Center (September)

C. Independent Study

2006-2009	Julian Wolfson, Research Assistant Supervision, Independent Study, Department of Biostatistics, University of Washington
2006-2013	Allan deCamp, Research Assistant Supervision, Independent Study, Department of Biostatistics Department of Biostatistics, University of Washington
2007	Charlotte Gard, Research Assistant Supervision, Department of Biostatistics, University of Washington
2007-2009	Yuying Jin, Research Assistant Supervision, Department of Biostatistics, University of Washington
2009-2012	Michal Juraska, Research Assistant Supervision, Independent Study, Department of Biostatistics, University of Washington
2009-2012	Erin Gabriel, Research Assistant Supervision, Independent Study, Department of Biostatistics, University of Washington
2012-2014	Rong Fu; Independent Study, Research Assistant Supervision, Department of Biostatistics, University of Washington
2015	David Benkeser, PhD Dissertation, Research Assistant Supervision, Department of Biostatistics, University of Washington
2013-2017	Yingying Zhuang, Research Assistant Supervision, Independent Study, Department of Biostatistics, University of Washington
2016-2020	Brenda Price, Research Assistant Supervision, Independent Study, Department of Biostatistics, University of Washington
2016-2018	Ted Westling, Research Assistant Supervision, Department of Statistics, University of Washington
2017-2019	Yunqi Bu, Research Assistant Supervision, Department of Statistics, University of Washington

- 2019-2021 Qijun (Kendrick) Li, Research Assistant Supervision, Department of Biostatistics, University of Washington
- 2020-2021 Wenbo Zhang, Research Project Supervision, Department of Biostatistics, MS Capstone Program, University of Washington
- 2020-present Leah Andrews, Research Assistant Supervision, Independent Study, Department of Biostatistics, University of Washington
- 2022-2023 Gavin Pierce, Department of Biostatistics MS Capstone Program, University of Washington
- 2023 Qi Wang, Independent Study, Department of Statistics MS Program, University of Washington
- 2022-present James Peng, Independent Reading, Department of Biostatistics, University of Washington
- 2024-present Charlotte Talham, Research Assistant Supervision, Department of Biostatistics, University of Washington

15. ADVISING AND FORMAL MENTORING

A. PhD Dissertations, Chair

- 2002-2005 Bryan Shepherd, Doctoral Committee Chair, Department of Biostatistics, University of Washington
- 2006-2008 Joanna Scott, Doctoral Committee Chair, Department of Biostatistics, University of Washington
- 2006-2008 Julian Wolfson, Doctoral Committee Chair, Department of Biostatistics, University of Washington
- 2006-2009 Allan deCamp, Doctoral Committee Chair, Department of Biostatistics, Department of Biostatistics, University of Washington
- 2008-2010 Michal Juraska, Doctoral Committee Chair, Department of Biostatistics, University of Washington
- 2009-2012 Erin Gabriel, Doctoral Committee Chair, Department of Biostatistics, University of Washington
- 2012-2014 Rong Fu, Doctoral Committee Chair; Department of Biostatistics, University of Washington
- 2013-2015 David Benkeser, Doctoral Committee co-Chair (with Marco Carone), Department of Biostatistics, University of Washington
- 2013-2015 Yingying Zhuang, Doctoral Committee co-Chair (with Ying Huang), Department of Biostatistics, University of Washington
- 2017-2019 Brenda Price, Doctoral Committee Chair, Department of Biostatistics, University of Washington
- 2020-present Leah Andrews, Doctoral Committee Chair, Department of Biostatistics, University of Washington
- 2023-present James Peng, Doctoral Committee Chair, Department of Biostatistics, University of Washington
- 2025 Helena Manguerra, START Program, University of Washington

B. Master Theses, Chair

- 2005-2006 Bo Zhang, Masters' Thesis Committee Chair, Department of Biostatistics, University of Washington
- 2015-2016 Clara Oromendia, Masters' Thesis Committee co-Chair (with Marco Carone), Department of Biostatistics, University of Washington
- 2023-2024

Yichen Wang, Masters' Thesis Committee co-Chair (with Marco Carone), Department of Biostatistics MS Program, University of Washington

C. Mentored Scientists and Postdocs

- 2005-2007 Zhu Wang, Public Health Sciences Division, Fred Hutchinson Cancer Research Center
- 2011-2014 Andrew Fiore-Gartland, Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Research Center
- 2013-2014 Michal Juraska, Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Research Center
- 2023-present Yutong Jin, Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Center (secondary postdoctoral fellowship supervisor; primary supervisor Aaron Hudson)

D. MS and PhD Committees (Non-Chair Role)

PhD Committees:

- 1998-1999 Andrea Foulkes, Doctoral Committee Member, Department of Biostatistics, Harvard School of Public Health
- 1999-2001 Raji Balasubramanian, Doctoral Committee Member, Department of Biostatistics, Harvard School of Public Health
- 2001 Sung-Kiang Chuang, Doctoral Committee Member, Harvard School of Dental Medicine, Harvard School of Public Health
- 2002 Jinbo Chen, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2002 Yingye Zheng, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2003 Petra Buzkova, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2004-2006 Marloes Maathuis, Doctoral Committee Member, Department of Statistics, University of Washington
- 2006-2007 Ying Huang, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2006-2008 Leslie Taylor, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2008-2009 Cecilia Cotton, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2009-2010 Blythe Adamson, Doctoral Committee Member, Department of Epidemiology, University of Washington
- 2008-2009 Jessie Wu, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2008-2010 Ken Wu, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2009-2013 Tanya Granston, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2010-2012 Takumi Saegusa, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2012-2014 Megan Smith, Doctoral Committee Member, Department of Biostatistics, University of Washington
- 2013-2014 Jie Hu, Doctoral Committee Member, Department of Biostatistics, University of Washington

2013-2015	Leila Zelnick, Doctoral Committee Member, Department of Biostatistics, University of Washington
2014-2016	Linbo Wang, Doctoral Committee Member, Department of Biostatistics, University of Washington
2015-2017	Tracey Marsh, Doctoral Committee Member, Department of Biostatistics, University of Washington
2016-2018	Ted Westling, Doctoral Committee Member, Department of Statistics, University of Washington
2017-2019	Brian Williamson, Doctoral Committee Member, Department of Biostatistics, University of Washington
2018-2019	Yuxiang Xie, Doctoral Committee Member, Department of Biostatistics, University of Washington
2019-2021	Gui Liu, Doctoral Committee Member, Graduate School Representative, Department of Epidemiology, University of Washington
2021-2023	Avi Kenny, Doctoral Committee Member, Department of Biostatistics, University of Washington
2022-2023	Sijia Li, Doctoral Committee Member, Department of Biostatistics, University of Washington
2024-2025	Antonio Olivas-Martinez, Doctoral Committee Member, Department of Biostatistics, University of Washington
2025	Anand Hemmady, Doctoral Committee Member, Department of Biostatistics, University of Washington

M.S. Committees:

1998-1999	Rose Dahliwahl, Masters' Thesis Committee Member, Department of Pharmacy, Northeastern University
2008-2010	Richard Newman, Masters' Thesis Committee Member, Department of Health Services, University of Washington
2017	Jason Shao, Masters' Thesis Committee Member, Department of Biostatistics, University of Washington

E. Other Mentoring

Undergraduate Student Supervision:

2014, 2016	Alexander Chao, Student Internship Supervision, Fred Hutchinson Cancer Research Center
2017	Audra Fain, Student Internship Supervision, Fred Hutchinson Cancer Research Center
2017, 2018	Stephanie Wu, Student Internship Supervision, Fred Hutchinson Cancer Research Center
2017, 2018	Christopher Simpkins, Student Internship Supervision, Fred Hutchinson Cancer Research Center
2019	Leoncie Bizimana, Summer Undergraduate Research Program (SURP) Student Internship Supervision, Fred Hutchinson Cancer Research Center
2020-2021	Brian Simpkins, Student Internship Supervision, Fred Hutchinson Cancer Research Center
2021	Maria Alejandr Cuevas, Student Internship Supervision, Fred Hutchinson Cancer Research Center
2021-2022	Lars van der Laan, Research Assistant Supervision, Department of Statistics, University of Washington

2024-2025 Marthin Mandig, Student Internship Supervision, Fred Hutchinson
Cancer Research Center

F. Academic Advising

N/A