

Holly Janes, Ph.D.
Fred Hutchinson Cancer Center
Vaccine and Infectious Disease Division
1100 Fairview Avenue North, M2-C200 • P.O. Box 19024
Seattle, Washington 98109 USA
206.667.6353 (office) • E-mail: hjanes@fredhutch.org

EDUCATION

1998 B.A. with honors; Skidmore College, Saratoga Springs, NY
2000 M.S., Mathematics; University of Massachusetts, Amherst, MA
2005 Ph.D., Biostatistics; University of Washington, Seattle, WA.

POSTGRADUATE TRAINING

2005-2007 Post-Doctoral Fellow, Department of Biostatistics, Johns Hopkins Bloomberg
School of Public Health, Baltimore, MD

FACULTY POSITIONS

2007-2011 Assistant Member, Vaccine and Infectious Disease Division and Division of Public
Health Sciences, Fred Hutchinson Cancer Research Center, Seattle, WA
2008-2012 Affiliate Assistant Professor, Department of Biostatistics, University of
Washington, Seattle, WA
2011-2018 Associate Member, Vaccine and Infectious Disease Division and Division of Public
Health Sciences, Fred Hutchinson Cancer Research Center, Seattle, WA
2012-present Affiliate Associate Professor, Department of Biostatistics, University of
Washington, Seattle, WA
2018-present Professor, Vaccine and Infectious Disease Division and Division of Public Health
Sciences, Fred Hutchinson Cancer Research Center, Seattle, WA
2020-present Affiliate Professor, Department of Biostatistics, University of Washington, Seattle,
WA
2021-present Associate Program Head, Biostatistics, Biomathematics, and Epidemiology
Program, Vaccine and Infectious Disease Division, Fred Hutchinson Cancer
Research Center, Seattle, WA

HOSPITAL POSITIONS

N/A

HONORS, AWARDS, SCHOLARSHIPS

2000 Cardiovascular Biostatistics Training Grant, National Institutes of Health

| | |
|------|--|
| 2004 | Student Paper Award, Section on Statistics and the Environment, American Statistical Association |
| 2004 | Student Poster Award, Department of Biostatistics, University of Washington |
| 2005 | Senior Student Award, Department of Biostatistics, University of Washington |
| 2005 | Student Conference Award, International Society for Clinical Biostatistics |
| 2005 | Gilbert S. Omenn Graduate Student Award for Academic Excellence, School of Public Health, University of Washington |
| 2006 | Young Investigator Award, Section on Statistical Epidemiology, American Statistical Association |
| 2008 | Travel Award, AIDS Vaccine Conference, Global HIV Vaccine Enterprise |
| 2021 | Prentice Professorship, University of Washington, Department of Biostatistics |

BOARD CERTIFICATION

N/A

LICENSURE

N/A

PROFESSIONAL ORGANIZATIONS

| | |
|--------------|---|
| 2000-present | American Statistical Association (AMSTAT) |
| 2012-present | International Biometrics Society (IBS) |

TEACHING RESPONSIBILITIES

| | |
|-----------|--|
| 1998 | University of Massachusetts, Department of Mathematics, Amherst, MA; Math 121 (Linear Methods), Teaching Assistant |
| 1998-2000 | University of Massachusetts, Department of Mathematics, Amherst, MA; Math 100 (Basic Math Skills), Instructor |
| 1998-2000 | University of Massachusetts, Department of Mathematics, Amherst, MA; Math 101 (Pre-Calculus Algebra), Instructor |
| 1998-2000 | University of Massachusetts, Department of Mathematics, Amherst, MA; Math 101 (Calculus II for the Life and Social Sciences), Instructor |
| 2000-2002 | Department of Biostatistics, University of Washington, Seattle, WA; Biost 502, (Introduction to Statistics in Health Sciences), Teaching Assistant |
| 2000-2002 | Department of Biostatistics, University of Washington, Seattle, WA; Biost 503 (Application of Statistics to Health Sciences), Teaching Assistant |
| 2000-2002 | Department of Biostatistics, University of Washington, Seattle, WA; Biost 511,512,513 (Medical Biometry I, II, III), Teaching Assistant |

- 2000-2002 Department of Biostatistics, University of Washington, Seattle, WA; Biost 517 (Applied Biostat I), Teaching Assistant
- 2000-2002 Department of Biostatistics, University of Washington, Seattle, WA; Biost 537 (Survival Data Analysis in Epidemiology), Teaching Assistant
- 2000-2002 Department of Biostatistics, University of Washington, Seattle, WA; Biost 540 (Correlated Data Regression), Teaching Assistant
- 2006 Center for Devices and Radiological Health, Food and Drug Administration, Washington, D.C.; Statistical Methods for Evaluating Tests and Biomarkers in Medicine, Short Course Instructor
- 2006-2007 Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD; Biost 622,623 (Statistical Methods in Public Health II, III), Teaching Assistant
- 2007 Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD; Biost 550.711 (Methods in Clinical Research), Co-instructor
- 2007 Summer Institute in Statistical Genetics, Department of Biostatistics, University of Washington, Seattle, WA ; Evaluating Biomarker Performance , Short Course Co-instructor
- 2007 Joint Statistical Meetings, Salt Lake City, UT; Statistical Evaluation of Medical Tests and Biomarkers for Classification, Short Course Co-instructor
- 2008 Joint Statistical Meetings, Statistical Evaluation of Medical Tests and Biomarkers for Classification, Denver Co; Short Course Co-instructor
- 2013 Albert Einstein College of Medicine, New York, NY; Development and Evaluation of Risk Prediction Models, Short Course Instructor
- 2014, 2015 Summer Institute in Statistics for Clinical Research, University of Washington, Seattle, WA; Development and Evaluation of Risk Prediction Models, Short Course Co-Instructor
- 2016, 2017 Summer Institute in Statistics for Clinical Research, University of Washington, Seattle, WA; Discovering and Evaluating Biomarkers for Guiding Treatment: Methodology for Precision Medicine, Short Course Co-instructor
- 2013-2019 University of Washington, Seattle, WA; Biostatistics Essentials for STD/HIV Research. Principles of STD/HIV Research.
- 2018-2019 Summer Institute in Statistics for Clinical Research, University of Washington, Seattle, WA; Leveraging Individual Subject Characteristics to Guide Treatment Decisions: Methodology for Precision Medicine, Short Course Co-instructor
- 2021 Department of Biostatistics, University of Washington, Seattle, WA: Biost 578 (Special Issues in Clinical Trials)

MENTORING***Mentees***

2011-2014 Chaeryon Kang, Post-Doctoral Fellow, Fred Hutchinson Cancer Research Center

2015-2016 Jason Liang, Post-Doctoral Fellow, Fred Hutchinson Cancer Research Center

Graduate Committees and Advising

2007-2009 Yuying Jin, PhD Student, Department of Biostatistics, University of Washington;
Research Assistant Advisor

2009 Jessie Wen Gu, PhD Student, Department of Biostatistics, University of
Washington; Member of Dissertation Committee

2009-2011 Kelly Stratton, Masters Student, Department of Biostatistics, University of
Washington; Academic Advisor

2009-2012 Erin Gabriel, PhD Student, Department of Biostatistics, University of Washington;
Research Assistant Advisor and Member of Dissertation Reading Committee

2010-2013 David Prince, PhD Student, Department of Biostatistics, University of
Washington; Academic Advisor

2011 Traci Bartz, Masters Student, Department of Biostatistics, University of
Washington; Masters Thesis Advisor

2011 Sean Devlin, PhD Student, Department of Biostatistics, University of Washington;
Member of Dissertation Committee

2011-2012 Clara Dominguez Islas, PhD Student, Department of Biostatistics, University of
Washington; Research Assistant Advisor

2015-2017 Allison Meisner, PhD Student, Department of Biostatistics, University of
Washington; Member of Dissertation Reading Committee

2016-2017 Tracey Marsh, PhD Student, Department of Biostatistics, University of
Washington; Member of Dissertation Reading Committee

2016-2018 Ted Westling, PhD Student, Department of Biostatistics, University of
Washington, Research Assistant Advisor

2017-2019 Jeremy Roth, PhD Student, Department of Biostatistics, University of
Washington; Member of Dissertation Committee

2018-2019 Anu Mishra, PhD Student, Department of Biostatistics, University of Washington;
Member of Dissertation Committee

2019 Xiaowen Tian, PhD Student, Department of Biostatistics, University of
Washington, Research Assistant Advisor

2019-2021 John Hocter, MS Student, Department of Biostatistics, University of Washington,
Thesis and Research Assistant Advisor

2020- 2022 Allen Roberts, PhD Student, Department of Epidemiology, University of Washington,
Member of Dissertation Committee (Graduate School Representative)

2020- 2022 Diana Hergot, PhD Student, Department of Epidemiology, University of Washington,
Member of Dissertation Committee (Graduate School Representative)

- 2021-present Yutong Jin, PhD Student, Department of Biostatistics, Emory University, Member of Dissertation Committee
- 2021-present Ethan Ashby, PhD Student, Department of Biostatistics, University of Washington; Research Assistant Advisor
- 2022-present Fredericka Albertina Sesay, Department of Epidemiology, University of Washington, Member of Dissertation Committee (Graduate School Representative)
- 2022-present Antonio Olivas-Martinez, Department of Biostatistics, University of Washington, Chair of Dissertation Committee

EDITORIAL RESPONSIBILITIES

Associate Editor

Biometrics (2020-present)

Statistical Communications in Infectious Diseases (2019-2021)

Journal of the National Cancer Institute (2015-2018)

Diagnostic and Prognostic Research (2016-2019)

SPECIAL NATIONAL RESPONSIBILITIES

N/A

SPECIAL LOCAL RESPONSIBILITIES

N/A

RESEARCH FUNDING

Active Funding

2 R01 CA152089 (PI: Janes H)

07/01/2010 – 11/30/2023

2.4 Calendar

NIH/NCI

Statistical Methods for Evaluating Markers for Treatment Selection

Interventions for disease treatment and prevention can potentially be made more cost-effective by using markers to identify in advance the individuals most likely to benefit from the treatment, and thus avoid treating those unlikely to benefit. This project develops methods to help realize this potential, by developing standards for evaluating candidate markers. These standards will help distinguish the good markers from the bad, optimize how the markers are used to select treatment, and ensure that research studies are designed so that the markers can be properly evaluated.

Role: Principal Investigator

U19 A1089688 (PI: Rathod P)

07/01/2017- 6/30/2024

0.60 Calendar

NIH/NIAID

Malaria Evolution in South Asia International Center of Excellence for Malaria Research (MESA-ICEMR)

The objective of this study is to understand the genetic plasticity (or adaptability) of malaria parasites in the region and its relationship to drug resistance, virulence, transmission and human immunity.

Role: Co-Investigator

R01 AI43418-01A1 (PI: Stephens)

12/5/2019-11/30/2026

0.60 Calendar

NIH/NIAID (subaward from Emory University)

Leadership Group for an Infectious Diseases Clinical Research: SDSU

The objectives of the SDSU are to implement and oversee data collection and management for successful implementation of proposed IDCRC clinical trials and other clinical studies, monitor safety data in a timely fashion, deliver statistical leadership in monitoring and reporting on clinical trials and provide scientific leadership in statistics and data science to further our understanding of clinical trial and cohort results.

Role: Co-Investigator

2 UM1 AI068635-15 (PI: Gilbert PB)

12/1/2020 – 11/30/2027

3.6 calendar

NIH/NIAID

SDMC: HIV Vaccine Trials Network

The HVTN SDMC provides data management and statistical/bioinformatical design and analysis for HVTN clinical trials. We aim to utilize our experience in the design, conduct and analysis of global HIV vaccine and prevention studies in a network-wide effort to develop a safe and effective HIV vaccine. In addition, SDMC statisticians and computational biologists will develop novel quantitative methodologies to increase the efficiency, rigor, and scientific incisiveness of the proposed program of HIV vaccine trials. We also conduct these activities for HIV monoclonal antibody immunoprophylaxis and TB vaccine clinical trials.

Role: Co-Principal Investigator**Past Funding**

2 UM1 AI068635 (PI: Gilbert P)

01/01/2014 – 11/30/2020

3.0 Calendar

NIH/NIAID

SDMC HIV Vaccine Trials Network

The Statistical and Data Management Center (SDMC) (1) provides statistical leadership for the design, conduct, analysis and publication of Network clinical trials/studies; (2) provides central data management capability that includes randomization, data set and case report form design,

central storage, security, processing and retrieval of study results; (3) provides data management and protocol training throughout the Network; (4) provides data-focused clinical trials implementation and operation; and (5) contributes to cross-Network efforts in developing common data elements.

Role: Faculty Statistician

R56 AI143418 (PI: Janes H)

08/15/2019 – 07/31/2020
3.0 calendar

NIH/NIAID

Statistical Methods for Evaluating and Guiding Implementation of New HIV Prevention Strategies

This project will develop and assess specific research study designs to evaluate new interventions in the presence of existing interventions, as well as provide statistical analysis methods for guiding the implementation of those that prove effective.

Role: Principal Investigator

OPP11075954 (PI: McElrath MJ)

11/17/2014 – 10/31/2019
0.60 Calendar

BMGF

Durability of HIV-specific Protective Ab Responses in Human Immunology-based Experimental Medicine Trials

This research project will employ experimental phase I human studies with in-depth immunologic analyses to determine if one or more novel HIV-1 Env glycoprotein/adjuvant vaccine formulations can induce greater antibody potency and durability than seen with alum-formulated envelope proteins more commonly used in clinical studies. The overall experimental design will determine if one or more Env/adjuvant formulation(s) can heighten the peak and extend the duration of antibody (Ab) responses at Year 01 and thereafter, and if HIV-1 Env induces inherently different and less potent/durable antibodies than other viral subunit protein vaccines (e.g., HBVsAg). The selection of adjuvants and immunogens will be based upon the ability to trigger diverse innate pathways (adjuvants), feasibility of obtaining and formulating stable, clinical grade material in a timely way, and agreement among developers to provide and compare products in head-to-head studies with subunit protein immunogens.

Role: Co-Investigator

R01 GM054438 (PI: Pepe MS)

09/01/2011 – 08/31/2016

NIH/NIGMS

Statistical Methods for Medical Tests and Biomarkers

This grant continues to develop statistical methods for the evaluation of studies that seek to investigate the performance of biomarkers for classification and prediction. Aim 1 concerns the improvement in performance gained by adding a marker to a set of baseline predictors. Aim 2 concerns a coherent approach to evaluating risk prediction models and their classification performance in a unified framework.

Role: Co-investigator

R01 CA138165 (PI: Casper C) 9/16/2010 – 6/31/2015
NIH/NCI

Impact of HIV and HHV-8 Co-Infection on Antiretroviral Therapy Efficacy in Africa

This project seeks to understand how HIV and human herpesvirus 8 co-infection may impact the natural history of both HIV and HHV-8 associated disease.

Role: Co-investigator

UM1 AI068635 (PI: Gilbert P) 6/29/2006-5/31/2013
NIH/NIAID

Leadership for HIV/AIDS Clinical Trials Networks: HIV Vaccine Trials Network

This project will provide statistical leadership for the design, conduct, analysis and publication of Network clinical trials/studies.

Role: Faculty Statistician

W81XWH-07-2-0067 (PI: Gilbert P) 1/01/2010 – 12/31/2012
USAMRAA (subcontract from Henry M. Jackson Foundation)

Statistical and Data Management Support for Analysis Related to Vaccine Trial (RV144) and Associated Trials

This project will provide statistical and data management support to the USMHRP for analyses related to the Phase III HIV vaccine trial (RV144) of the ALVAC-HIV-1 (vCP1521) and AIDSVAX B/E products, conducted by the USMHRP in Thailand.

Role: Faculty Statistician

38744 7/1/2006-4/30/2012
Bill & Melinda Gates Foundation

Vaccine Immunology Statistical Center (VISC)

The VISC will provide 1) statistical and study design support for pre-clinical vaccine performance trials, 2) centralized data management services for the standardized evaluation of vaccine candidates, 3) development of new statistical methods for cross-species correlates-of-protection analysis.

Role: Faculty Statistician

RC2 CA148433-01 (PI: Kessler L) 10/1/2009 – 9/30/2011
NIH

Advancing Innovative Comparative Effectiveness Research in Cancer Diagnostics (ADVICE)

This project will establish a multi-disciplinary and cross-institutional network of health delivery systems and researchers in Western Washington State (ADVICE) compiling regional population-based data from a variety of health care delivery systems, including fee-for-service private plans, public agencies, and a large managed care system.

Role: Co-investigator

RO1 CA129934 (PI: Pepe M)
NIH/NCI

8/1/2007 - 5/31/2011

Considerations of Covariates in Biomarker Studies

This project will develop an understanding of the various roles of covariates in biomarker evaluations and to develop simple techniques and software for including them in data analysis.

Role: Co-investigator

RO1 GM054438 (PI: Pepe M)
NIH/NIGMS

5/10/2007 – 4/30/2011

Statistical Methods for Medical Tests and Biomarkers

This grant will continue to develop statistical methods for the evaluation of studies that seek to investigate predictive markers.

Role: Co-investigator

BIBLIOGRAPHY

Publications in Refereed Journals

1. Pepe MS, **Janes H**, Longton G, Leisenring W, Newcomb P. Limitations of the odds ratio in gauging the performance of a diagnostic, prognostic, or screening marker. *Am J Epidemiol.* 2004;159(9):882-90.
2. **Janes H**, Pepe M, Kooperberg C, Newcomb P. Identifying target populations for screening or not screening using logic regression. *Stat Med.* 2005;24(9):1321-38.
3. **Janes H**, Sheppard L, Lumley T. Case-crossover analyses of air pollution exposure data: Referent selection strategies and their implications for bias. *Epidemiology.* 2005;16(6):717-26.
4. **Janes H**, Sheppard L, Lumley T. Overlap bias in the case-crossover design, with application to air pollution exposures. *Stat Med.* 2005;24(2):285-300.
5. **Janes H**, Pepe M. The optimal ratio of cases to controls for estimating the classification accuracy of a biomarker. *Biostatistics.* 2006;7(3):456-68.
6. **Janes H**, Dominici F, Zeger SL. Trends in air pollution and mortality: An approach to the assessment of unmeasured confounding. *Epidemiol.* 2007;18(4):416-23.
7. Pepe MS, **Janes H**. Insights into latent class analysis of diagnostic test performance. *Biostatistics.* 2007;8(2):474-84.
8. Eftim SE, Samet JM, **Janes H**, McDermott A, Dominici F. Fine particulate matter and mortality: A comparison of the six cities and American Cancer Society cohorts with a medicare cohort. *Epidemiol.* 2008;19(2):209-16.
9. **Janes H**, Pepe MS. Matching in studies of classification accuracy: Implications for analysis, efficiency, and assessment of incremental value. *Biometrics.* 2008;64(1):1-9.
10. **Janes H**, Pepe MS. Adjusting for covariates in studies of diagnostic, screening, or prognostic markers: An old concept in a new setting. *Am J Epidemiol.* 2008;168(1):89-97.
11. **Janes H**, Sheppard L, Shepherd K. Statistical analysis of air pollution panel studies: An illustration. *Ann Epidemiol.* 2008;18(10):792-802.

12. McElrath MJ, De Rosa SC, Moodie Z, Dubey S, Kierstead L, **Janes H**, Defawe OD, Carter DK, Hural J, Akondy R, Buchbinder SP, Robertson MN, Mehrotra DV, Self SG, Corey L, Shiver JW, Casimiro DR. HIV-1 vaccine-induced immunity in the test-of-concept Step study: A case-cohort analysis. *Lancet*. 2008;372(9653):1894-905. PMID: 2774110.
13. Pepe MS, Feng Z, **Janes H**, Bossuyt PM, Potter JD. Pivotal evaluation of the accuracy of a biomarker used for classification or prediction: Standards for study design. *J Natl Cancer Inst*. 2008;100(20):1432-8. PMID: 2567415.
14. Pepe MS, **Janes H**. Gauging the performance of SNPs, biomarkers, and clinical factors for predicting risk of breast cancer. *J Natl Cancer Inst*. 2008;100(14):978-9. PMID: 3132154.
15. **Janes H**, Pepe MS, Gu W. Assessing the value of risk predictions by using risk stratification tables. *Ann Intern Med*. 2008;149(10):751-60. PMID: 3091826.
16. **Janes H**, Longton G, Pepe M. Accommodating covariates in ROC analysis. *Stata J*. 2009;9(1):17-39. PMID: 2758790.
17. **Janes H**, Pepe MS. Adjusting for covariate effects on classification accuracy using the covariate-adjusted receiver operating characteristic curve. *Biometrika*. 2009;96(2):371-82. PMID: 3371718.
18. Pepe M, Longton G, **Janes H**. Estimation and comparison of receiver operating characteristic curves. *Stata J*. 2009;9(1):1. PMID: 2774909.
19. **Janes H**, Dominici F, Zeger S. On quantifying the magnitude of confounding. *Biostatistics*. 2010;11(3):572-82. PMID: 2883302.
20. 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. *J Virol*. 2010;84(3):1439-52. PMID: 2812321.
21. Barnabas RV, Wasserheit JN, Huang Y, **Janes H**, Morrow R, Fuchs J, Mark KE, Casapia M, Mehrotra DV, Buchbinder SP, Corey L. Impact of herpes simplex virus type 2 on HIV-1 acquisition and progression in an HIV vaccine trial (the Step study). *J Acquir Immune Defic Syndr*. 2011;57(3):238-44. PMID: 3446850.
22. Fitzgerald DW, **Janes H**, Robertson M, Coombs R, Frank I, Gilbert P, Loufty M, Mehrotra D, Duerr A. 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). *J Infect Dis*. 2011;203(6):765-72. PMID: 3119328.
23. **Janes H**, Pepe MS, Bossuyt PM, Barlow WE. Measuring the performance of markers for guiding treatment decisions. *Ann Intern Med*. 2011;154(4):253-9. PMID: 3085402.
24. Janssens AC, Ioannidis JP, Bedrosian S, Boffetta P, Dolan SM, Dowling N, Fortier I, Freedman AN, Grimshaw JM, Gulcher J, Gwinn M, Hlatky MA, **Janes H**, Kraft P, Melillo S, O'Donnell CJ, Pencina MJ, Ransohoff D, Schully SD, Seminara D, Winn DM, Wright CF, van Duijn CM, Little J, Khoury MJ. Strengthening the reporting of genetic risk prediction studies (GRIPS): Explanation and elaboration. *Eur J Hum Genet*. 2011;19(5):18 p preceding 494. PMID: 3083630.
25. Pepe MS, **Janes H**. Commentary: Reporting standards are needed for evaluations of risk reclassification. *Int J Epidemiol*. 2011;40(4):1106-8. PMID: 3156371.
26. Abu-Raddad LJ, Barnabas RV, **Janes H**, Weiss HA, Kublin JG, Longini IM, Jr., Wasserheit JN, the HIVVLWG. Have the explosive HIV epidemics in sub-Saharan Africa been driven by higher community viral load? *AIDS*. 2012. PMID: 3725236.

27. 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. *N Engl J Med*. 2012;366(14):1275-86. PMID: 3371689.
28. Huang Y, Gilbert PB, **Janes H**. Assessing treatment-selection markers using a potential outcomes framework. *Biometrics*. 2012;68(3):687-96. PMID: 3417090.
29. **Janes H**, Frahm N, DeCamp A, Rolland M, Gabriel E, Wolfson J, Hertz T, Kallas E, Goepfert P, Friedrich DP, Corey L, Mullins JI, McElrath MJ, Gilbert P. 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. PMID: 3428369.
30. **Janes H**, Friedrich DP, Krambrink AM, Smith RJ, Kallas E, Horton H, Casimiro DR, Carrington M, Geraghty D, Gilbert PB, McElrath J, Frahm N. Vaccine-induced Gag-specific T cells are associated with reduced viremia after HIV infection. *J Infect Dis*. 2013;208(8):1231-9. PMID: 23878319.
31. Moodie Z, **Janes H**, Huang Y. New clinical trial designs for HIV vaccine evaluation. *Curr Opin HIV AIDS*. 2013;8(5):437-42. PMID: 23872613.
32. **Janes H**, Pepe MS, Huang Y. A framework for evaluating markers used to select patient treatment. *Med Decis Making*. 2014;34(2):159-67. PMID: 23811760.
33. 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 JR, Nabel GJ, Montefiori DC, Kublin J, McElrath MJ, Corey L, Gilbert PB, HVTN 505 Study Team. Efficacy trial of a DNA/rAd5 HIV-1 preventive vaccine. *N Engl J Med*. 2013;369(22):2083-92. PMID: 4030634.
34. **Janes H**, Gilbert P, Buchbinder S, Kublin J, Sobieszczyk ME, Hammer SM. In pursuit of an HIV vaccine: Designing efficacy trials in the context of partially effective non-vaccine prevention modalities. *AIDS Res Hum Retroviruses*. 2013;29(11):1513-23. PMID: 3809388.
35. Kerr KF, Wang Z, **Janes H**, McClelland RL, Psaty BM, Pepe MS. Net reclassification indices for evaluating risk prediction instruments: A critical review. *Epidemiol*. 2014;25(1):114-21. PMID: 24240655.
36. **Janes H**, Brown MD, Pepe MS, Huang Y. An approach to evaluating and comparing biomarkers for patient treatment selection. *Int J Biostat*. 2014;10(1):99-121. PMID: PMC4341986.
37. Pepe MS, **Janes H**, Li CI. Net risk reclassification p values: valid or misleading? *J Natl Cancer Inst*. 2014;106(4):dju041. PMID: 3982889.
38. Huang Y, Laber E, **Janes H**. Characterizing expected benefits of biomarkers in treatment selection. *Biostatistics*. 2014;16(2):383-99. PMID: 4786637.
39. Kang C*, **Janes H**, Huang Y. Combining biomarkers to optimize patient treatment recommendations. *Biometrics- article with discussion*. 2014;70(3):695-707. PMID: 4248022.

40. Li SS, Gilbert PB, Tomaras GD, Kijak G, Ferrari G, Thomas R, Pyo C-W, Zolla-Pazner S, Montefiori D, Liao H-X, 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, Connell RJ, Haynes BF, Michael NL, Kim JH, McElrath MJ, Geraghty DE. FCGR2C polymorphisms associate with HIV-1 vaccine protection in RV144 trial. *J Clin Invest*. 2014;124(9):3879-90. PMID: 4151214.
41. Gartland AJ, Li S, McNevin J, Tomaras GD, Gottardo R, **Janes H**, Fong Y, Morris D, Geraghty DE, Kijak GH, Edlefsen PT, Frahm N, Larsen BB, Tovanabutra S, Sanders-Buell E, deCamp AC, 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 HIV-1 Vaccine Trial. *J Virol*. 2014;88(15):8242-55. PMID: 4135964.
42. **Janes H**, Pepe MS, McShane LM, Sargent DJ, Heagerty PJ. The fundamental difficulty with evaluating the accuracy of biomarkers for guiding treatment. *J Nat Cancer Inst*. 2015;107(8): pii: djv157. PMID: 4609557.
43. 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(5):74952. PMID: 4554766.
44. **Janes H**, Brown MD, Pepe MS. Designing a study to evaluate the benefit of a biomarker for selecting patient treatment. *Stat Med*. 2015;34(27):3503-15. PMID: 4626364.
45. Huang Y, Follmann D, Nason M, Zhang L, Huang Y, Mehrotra DV, Moodie Z, Metch B, **Janes H**, Keefer MC, Churchyard G, Robb ML, Fast PE, Duerr A, McElrath MJ, Corey L, Mascola JR, Graham BS, Sobieszczyk ME, Kublin JG, Robertson M, Hammer SM, Gray G, Buchbinder SP, 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: 4558095.
46. Urban N, Hawley S, **Janes H**, Karlan BY, Berg CD, Drescher CW, Manson JE, Palomares MR, Daly MB, Wactawski-Wende J, O'Sullivan MJ, Thorpe J, Robinson RD, Lane D, Li CI, Anderson GL. Identifying post-menopausal women at elevated risk for epithelial ovarian cancer. *Gyn Oncol*. 2015;139(2):253-60. PMID: 4664187.
47. **Janes H**, Tovanabutra S, Herbeck JT, Frahm N, Duerr A, Hural J, Corey L, Self SG, Buchbinder S, McElrath JM, O'Connell RJ, Paris R, Rerks-Ngarm S, Nitayaphan S, Pitisuttithum P, Kaewkungwal J, Robb ML, Michael NM, Mullins JI, Kim JH, Gilbert PB, Rolland M. HIV-1 infections with multiple founders are associated with higher viral loads. *Nat Med*. 2015;21(10):1139-41. PMID: 4598284.
48. Huang Y, Diaz Granados C, **Janes H**, Huang Y, deCamp A, Metch B, Grant SP, Sanchez B, Phogat S, Tomaras GD, McElrath J, Kublin J, Corey L, Gilbert PB. Selection of HIV vaccine candidates for concurrent testing in an efficacy trial. *Curr Opin Virol*. 2016;17:57-65. PMID: 4902743.
49. Gilbert PB, **Janes H**, Huang Y. Power/sample size calculations for assessing correlates of risk in clinical efficacy trials. *Stat Med*. 2016;35(21):3745-59. PMID: 4965346.
50. Kerr K, Brown MD, Zhu K, **Janes H**. Assessing the clinical impact of risk prediction models with decision curves: Guidance for correct interpretation and appropriate use. *J Clin Onc*. 2016;34(21):2534-40. PMID: 4962736.

51. Pepe MS, **Janes H**, Li CL, Bossuyt PM, Feng Z, Hilden J. Early phase studies of biomarkers: What target sensitivity and specificity values might confer clinical utility? *Clin Chem*. 2016;62(5):737-42. PMID: 5003106.
52. Gilbert PB[±], Huang Y[±], **Janes H**[±]. Modeling vaccine trials of the future. *Curr Opin HIV AIDS*. 2016;11(5):620-27. PMID: 5077275.
53. Hanscom B, **Janes H**, Guarino PD, Huang Y, Brown ER, Chen YQ, Hammer SM, Gilbert PB, Donnell DJ. Brief Report: Preventing HIV-1 infection in women using oral pre-exposure prophylaxis: A meta-analysis of current evidence. *J Acquir Immune Defic Syndr*. 2016;73(5):606-8. PMID: 5175411.
54. Huang Y, Gilbert PB, Fu R, **Janes H**. Statistical methods for down-selection of treatment regimens based on multiple endpoints, with application to HIV vaccine trials. *Biostatistics*. 2017;18(2):230-43. Epub 2016/09/22. doi: 10.1093/biostatistics/kxw043. PubMed PMID: 27649715; PMID: PMC6092735.
55. Huang Y, Zhang L, **Janes H**, Frahm N, Isaacs A, Kim JH, Montefiori DM, McElrath J, Tomaras GD, Gilbert PB. Predictors of durable immune responses six months after the last vaccination in preventive HIV vaccine trials. *Vaccine*. 2017;35(8):1184-93. Epub 2017/01/31. doi: 10.1016/j.vaccine.2016.09.053. PubMed PMID: 28131393; PMID: PMC5319823.
56. **Janes H**, Cohen K, Frahm N, DeRosa S, Sanchez B, Hural J, Magaret C, Karuna C, Bentley R, Gottardo G, Finak G, Grove D, Shen M, Graham B, Koup R, Mulligan M, Koblin B, Buchbinder S, Keefer M, Adams E, Anude C, Corey L, Sobieszczyk M, Hammer S, Gilbert PB, McElrath MJ. Higher T cell responses induced by DNA/rAd5 HIV-1 preventative vaccine are associated with lower HIV-1 infection risk in an efficacy trial. *J Infect Dis*. 2017;215(9):1376-85. Epub 2017/02/16. doi: 10.1093/infdis/jix086. PubMed PMID: 28199679; PMID: PMC5853653. Reply to A.J. Vickers
57. Dai J, Liang J, LeBlanc M, Prentice R, **Janes H**. Case-only approach to identifying markers predicting treatment effects on the relative risk scale. *Biometrics*. 2018;74(2):753-63. Epub 2017/09/30. doi: 10.1111/biom.12789. PubMed PMID: 28960244; PMID: PMC5874156.
58. Murphy SC, Duke ER, Shipman KJ, Jensen RL, Fong Y, Ferguson S, **Janes H**, Gillespie K, Seilie AM, Hanron AE, Rinn L, Fishbaugher M, VonGoedert T, Fritzen E, Kappe SH, Chang M, Sousa JC, Marcsisin SR, Chalon S, Duparc S, Kerr N, Mohrle JJ, Andenmatten N, Rueckle T, Kublin JG. A Randomized Trial Evaluating the Prophylactic Activity of DSM265 Against Preerythrocytic *Plasmodium falciparum* Infection During Controlled Human Malarial Infection by Mosquito Bites and Direct Venous Inoculation. *J Infect Dis*. 2018;217(5):693-702. Epub 2017/12/08. doi: 10.1093/infdis/jix613. PubMed PMID: 29216395; PMID: PMC5853383.
59. **Janes H**, Brown MD, Crager MR, Miller DP, Barlow WE. Adjusting for covariates in evaluating markers for selecting treatment, with application to guiding chemotherapy for treating estrogen-receptor-positive, node-positive breast cancer. *Contemp Clin Trials*. 2017 Aug 14. pii: S1551-7144(16)30502-X. PMID: 5696084.
60. Kang C*, **Janes H**, Tajik P, Groen H, Mol MJB, Koopmans CM, Broekhuijsen K, Zwertbroek E, van Pampus MG, Franssen MTM. Evaluation of biomarkers for treatment selection using individual participant data meta-analysis. *Statistics in Medicine*. 2018;37(9):1439-53. Epub 2018/02/15. doi: 10.1002/sim.7608. PubMed PMID: 29444553; PMID: PMC5889758.

61. Fong Y, Shen X, Ashley VC, Seaton KE, Yu C, Grant SP, Ferrari G, deCamp AC, 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 H**, 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;217(8):1280-8. Epub 2018/01/13. doi: 10.1093/infdis/jiy008. PubMed PMID: 29325070; PMCID: PMC6018910.
62. **Janes H**, Corey L, Ramjee G, Carpp L, Lombard L, Cohen M, Gilbert P, Gray G. Weighing the evidence of efficacy of oral PrEP for HIV prevention in women in southern Africa. *AIDS Res Human Retroviruses*. 2018;34(8):645-56. Epub 2018/05/08. doi: 10.1089/AID.2018.0031. PubMed PMID: 29732896; PMCID: PMC6080090
63. Kerr K, Brown MD, Marsh T, **Janes H**. Assessing the clinical impact of risk prediction models for opting out of treatment. *Med Decis Making* 2019; 39(2):86-90. PMCID: 6374190.
64. Westling T*, Juraska M, Seaton K, Tomaras G, Gilbert P, **Janes H**. Methods for comparing durability of immune responses between vaccine regimens in early-phase trials. *Stat Meth Med Res* 2020;29(1):78-93. Epub 2019/01/10. doi: 10.1177/0962280218820881. PubMed PMID: 30623732; PMCID: PMC6682462.
65. **Janes H**, Donnell D, Gilbert P, Brown E, 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;6(7): e475-e482. PMCID: 6612578.
66. **Janes H**, Donnell D, Nason M. Designing the next generation of HIV prevention efficacy trials: synopsis of a 2018 symposium. *Stat Comm Infect Dis* 2019; 11(1): scid-2019-0004. PMCID: pending.
67. Li S, Gilbert P, Carpp L, Pyo C-W, **Janes H**, Fong Y, Shen X, Neidich S, Goodman D, decamp A, Cohen K, Ferrari G, Hammer S, Sobieszczyk M, Mulligan M, Buchbinder S, Keefer M, DeJesus E, Novak R, Frank I, McElrath J, Tomaras G, Geraghty D, and Peng X. Fc gamma receptor polymorphisms modulated the vaccine effect on HIV-1 risk in the HVTN 505 HIV vaccine trial. *J Virol* 2019;93(21). Epub 2019/08/23. doi: 10.1128/JVI.02041-18. PubMed PMID: 31434737; PMCID: PMC6803257.
68. Neidich SD, Fong Y, Li S, Geraghty D, Goodman D, Seaton KE, Shen X, Sawant S, Zhang L Shao M, Yates NL, Feely F, Ferrari G, Graham B, Hammer SM, Sobieszczyk M, Corey L, **Janes H**, McElrath J, Gilbert PB, Tomaras GD. Antibody Fc-Functions and IgG3 Associates with Decreased HIV-1 Risk. *J Clin Invest* 2019; 129(11): 4838-49. PMCID: 6819135.
69. Pantaleo G, **Janes H**, Karuna S, Grant S, Ouedraogo L, Allen M, Tomaras GD, Fram N, Montefiori DC, Ferrari G, Ding S, Lee C, Robb ML, Esteban M, Wagner R, Alexandre-Bart P, Rettby N, McElrath JM, Gilbert PB, Kublin J, Corey L and the NIAID HIV Vaccine Trials Network. HIV Co-administration of HIV Env protein with DNA and/or NYVAC vaccines in humans results in earlier and potent generation of anti-Env antibody responses. *Lancet HIV* 2019; 6(11):e737-e749. PMCID: pending.
70. **Janes H**, Brown MD, Glidden DV, Mayer KH, Buchbinder SP, McMahan V, Schechter M, Guanira J, Casapia M. Evaluating the impact of policies that recommend PrEP to subpopulations of men and transgender women who have sex with men based on demographic and behavioural risk factors. *PLOS ONE* 2019; 14(9):e0222183. PMCID: 6752862.

71. Zhao LP, Fiore-Gartland A, Carpp LN, Cohen KW, Roupheal N, Fleurs L, Dintwe O, Zhao M, Moodie Z, Fong Y, Garrett N, Huang Y, Innes C, **Janes H**, 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;15(1):e0226803. Epub 2020/01/31. doi: 10.1371/journal.pone.0226803. PubMed PMID: 31999736; PMCID: PMC6992005.
72. Kerr KF, Brown MD, Marsh TL, **Janes H**. Assessing the clinical impact of risk models for opting out of treatment. *Medical Decision Making*. 2019;39(2):86-90. Epub 2019/01/17. doi: 10.1177/0272989X18819479. PubMed PMID: 30649998; PMCID: PMC6374190.
73. Kerr KF, Marsh TL, **Janes H**. The importance of uncertainty and opt-in v. opt-out: Best practices for decision curve analysis. *Medical Decision Making*. 2019;39(5):491-2. Epub 2019/05/21. doi: 10.1177/0272989X19849436. PubMed PMID: 31104561; PMCID: PMC6786944.
74. Marsh T, **Janes H**, Pepe M. Statistical inference for net benefit measures in biomarker validation studies. *Biometrics* 2019. Epub 2019/11/17. doi: 10.1111/biom.13190. PubMed PMID: 31732971; PMCID: PMC7228830.
75. Palli R, Season K, Piepenbrink M, Huang Y, **Janes H**, Kobie J, Keefer M, Tomaras G, Thakar J. Impact of vaccine type on HIV-1 vaccine elicited antibody durability and B cell gene signature. *Scientific Reports*. 2020;10(1):13031. Epub 2020/08/05. doi: 10.1038/s41598-020-69007-w. PubMed PMID: 32747654; PMCID: PMC7398916.
76. Hejazi N, van der Laan MJ, **Janes H**, Gilbert PB, Benkeser DC. Efficient nonparametric inference on the effects of stochastic interventions under two-phase sampling, with applications to vaccine efficacy trials. *Biometrics*. doi: 10.1111/biom.13375. PMID: 32949147 PMCID: PMC8016405
77. Krause P, Fleming TR, Longini I, Henao-Restrepo AM, Peto R for the World Health Organization Solidarity Vaccines Trial Expert Group [incl. **Janes H**] COVID-19 vaccine trials should seek worthwhile efficacy. *Lancet* 2020;396: 741-743. PMID: 32861315 PMCID: PMC7832749.
78. Mehrotra D, **Janes H**, Fleming T, Annunziato P, Neuzil K, Carpp L, Benkeser D, Brown E, Cho I, Donnell D, Fay M, Fong Y, Han S, Hirsch I, Huang Y, Huang Y, Hyrien O, Juraska M, Luedtke A, Nason M, Vandebosch A, Zhou H, Cohen M, Corey L, Hartzel J, Follmann D, Gilbert P. Clinical endpoints for evaluating efficacy in COVID-19 vaccine trials. *Ann Int Med*. doi: 10.7326/M20-6169. PMID: 33090877; PMCID: PMC7596738.
79. Martin A, Patel E, Kirby C, Astemborski J, Kirk G, Mehta S, Marshall K, **Janes H**, Clayton A, Corey L, Hammer S, Arthos J, Cicala C, Redd A, Quinn T. The association of $\alpha 4\beta 7$ expression with HIV acquisition and progression in people who inject drugs and men who have sex with men: Case control studies. *EBioMedicine* 2020;62:103102. DOI: 10.1016/j.ebiom.2020.103102. PMID: 33166790 PMCID: PMC7658649.
80. **Janes H**, Zhu Y, Brown ER. Designing HIV vaccine efficacy trials in the context of highly effective non-vaccine prevention modalities. *Statistics in Biosciences* 2020;12:468-494.
81. Follmann D, Fintzi J, Fay MP, **Janes H**, Baden L, El Sahly H, Fleming T, Mehrotra D, Lindsay Carpp LN, Juraska M, Benkeser D, Donnell D, Fong Y, Han S, Hirsch I, Huang YI, Huang Y, Hyrien O, Luedtke A, Carone M, Nason M, Vandebosch A, Zhou H, Cho I, Gabriel E, Kublin J, Cohen M, Corey L, Gilbert PB, Neuzil KM. A deferred-vaccination design to assess durability of COVID-19 vaccine effect after the placebo group is vaccinated. *Ann Int Med*. 2021;174:1118-1125. PMID: 33844575 PMCID: PMC8099035.

82. Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Roupael N, Creech CB, McGettigan J, Khetan S, Segal 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 B, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T, for the COVE study group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *NEJM* 2020 Dec 30. DOI: 10.1056/NEJMoa2035389. PMID: 33378609 PMCID: PMC7787219.
83. Gray GE, Bekker L-G, Laher F, Malahlenha 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, Garrett N, Kistnasami G, Gaffoor Z, Sleepe P, Makhoba PB, Mathebula MP, Mda P, Adonis T, Mapetla KS, Modibedi B, Philip T, Kobane G, Bentley C, Ramirez S, Takuvda S, Jones M, Sikhosana M, Atujuna M, Andrasik M, Hejazi NS, Puren A, Wiesner L, Phogat S, Diaz Granados C, Koutsoukos M, Van Der Meeren O, Barnett SW, Kanesa-athan N, Pensiero MN, Johnston MI, Kublin JG, Russell N, McElrath J, Gilbert PB, **Janes H**, Corey L. Vaccine efficacy of ALVAC-HIV (vCP2438) and bivalent subtype C gp120/MF59 in HIV-uninfected adults – HVTN 702 (Uhambo). *NEJM* 2021; 25:1089-1100. PMID: 33761206 PMCID: PMC7888373
84. Matrajt L, Eaton J, Leung T, Dimitrov D, Schiffer JT, Swan DA, **Janes H**. Optimizing vaccine allocation for COVID-19 vaccines: critical role of single-dose vaccination. *Nature Comm* 2021;12: 3449. PMID: 34103510 PMCID: PMC8187351.
85. Matrajt L, **Janes H**, Schiffer JT, Dimitrov D. Quantifying the impact of lifting community non-pharmaceutical interventions for COVID-19 during vaccination rollout in the United States. *Open Forum Infect Dis* 2021;8:ofab341. PMID: 34307733 PMCID: PMC8294674.
86. Lin D-Y, Gu Y, Zeng D, **Janes H**, Gilbert PB. Evaluating vaccine efficacy against SARS-CoV-2 infection. *Clin Inf Dis* 2021; 2021 Jul 14;ciab630. PMID: 34260716 DOI: 10.1093/cid/ciab630
87. Swan DA, Bracis C, **Janes H**, Moore M, Matrajt L, Reeves DM, Burns E, Donnell D, Cohen MS, Schiffer JT, Dimitrov D. COVID-19 vaccines that reduce symptoms but do not block infection need higher coverage and faster rollout to achieve population impact. *Sci Rep* 2021;11:15531. PMID: 34330945 PMCID: PMC8324774.
88. **Janes H**, Gao F, Luedtke A. Discussion on “Estimating vaccine efficacy over time after a randomized study is unblinded” by Anastasios A. Tsiatis and Marie Davidian. *Biometrics* 2021;1-3. PMID: 34492117 PMCID: PMC8653041.
89. Falsey AR, Sobieszczyk MR, Hirsch I, Sproule S, Robb ML, Corey L, Neuzil KM, Hahn W, Hunt J, Mulligan MJ, McEvoy C, DeJesus E, Hassman M, Little SJ, Pahud B, Durbin A, Pickrell Pe, Daar ES, Bush L, Solis J, Carr QO, Oyedele T, Buchbinder S, Cowden J, Vargas SL, Benavides AG, Call R, Keefer MC, Kirkpatrick BD, Pullman J, Tong T, Brewinski Isaacs M, Benkeser D, **Janes H**, Nason MC, Green JA, Kelly EJ, Maaske J, Mueller N, Shoemaker K, Therese T, Marshall RP, Pangalos MN, Villafana T, Gonzalez-Lopez A, on behalf of the AstraZeneca AZD1222 Clinical Study Group. Phase 3 safety and efficacy of AZD1222 (ChAdOx1 nCoV-19) COVID-19 vaccine. *NEJM* 2021;385:2348-2360. PMID: 34587382 PMCID: PMC8522798.
90. El Sahly HM, Baden LR, Essink B, Doblecki-Lewis S, Martin J, Andersen EJ, Campbell T, Clark J, Jackson L, Fichtenbaum C, Zervos M, Rankin B, Eder F, Feldman G, Kennely C, HanConrad L, Levin M, Neuzil K, Corey L, Gilbert P, **Janes H**, 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. Phase 3 trial of mRNA-1273 SARS-CoV-2 vaccine: Completion of blinded phase. *NEJM* 2021;385:1774-85. PMID: 34551225 PMCID: PMC8482810.

91. Swan D, Goyal A, Bracis C, Moore M, Krantz E, Brown E, Cardozo-Ojeda F, Reeves DB, Gao F, Gilbert PB, Corey L, Cohen M, **Janes H**, Dimitrov D, Schiffer J. Mathematical modeling of vaccines that prevent SARS-CoV-2 transmission. *Viruses* 2021;13:1921. PMID: 34696352 PMCID: PMC8539635.
92. Bender Ignacio RA, Long J, Saha A, Nguyen F, Joudeh L, Valinetz E, Mendelsohn SC, Scriba TJ, Hatherill M, **Janes H**, Churchyard G, Buchbinder S, Duerr A, Shah JA, Hawn TR. Mycobacterium tuberculosis infection, immune activation, and risk of HIV acquisition. *J Inf Dis* 2022;17(5):e0267729. PMID: 35503767 PMCID: PMC9064099.
93. Marcelin JR, Pettifor A, **Janes H**, Brown ER, Kublin JR, Stephenson KE. COVID-19 vaccines and SARS-CoV-2 transmission in the era of new variants: A review and perspective. *Open Forum Infect Dis* 2022;9:ofac124. PMID: 35493113 PMCID: PMC8992234.
94. Follmann D[¶], **Janes H**[¶], Buhule O, Zhou H, Girard B, Marks K, Kotloff K, Dejardin M, Corey L, Neuzil KM, Miller JM, El Sahly HM*, Baden LR*. Anti-nucleocapsid antibodies following SARS-CoV-2 infection in the 1 blinded phase of the mRNA-2 1273 Covid-19 vaccine efficacy clinical trial. *Ann Int Med* 2022; Jul 5;M22-1300. PMID: 35785530 PMCID: PMC9258784
95. Moodie Z, Dintwe O, Sawant S, Grove D, Huang Y, **Janes H**, Heptinstall J, Laher F, Cohen K, DeRosa SC, Zhang L, Yates NL, Sarzotti-Kelsoe M, Seaton K, Laher F, Bekker L-G, Malahleha M, Innes C, Kassim S Naicker N, Govender V, Sebe M, Singh N, Kotze P, Lazarus E, Nchabeleng M, Meintjies G, Brumskine W, Dubula T, Randhawa AK, Grunenberg N, Hural J, KJJ, Benkeser D, Jin Y, Carpp LN, Allen M, D'Souza P, Tartaglia J, DiazGranados CA, Koutsoukos M, Gilbert PB, Kublin JG, Corey L, 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. *J Inf Dis* 2022; Jun 27;jiac260. PMID: 35758878 PMCID: PMC9890908
96. Sobieszczyk ME, Maaske J, Falsey AR, Sproule S, Robb ML, Frenck RW, Tieu H-V, Mayer KH, Corey L, Neuzil KM, Tong T, Brewinski Isaacs M, **Janes H**, Bansal H, Edwards LM, Green JA, Kelly EJ, Shoemaker K, Takas T, White T, Buyan P, Villafana T, Hirsch I and the AstraZeneca AZD1222 Clinical Study Group. Durability of protection and immunogenicity of AZD1222 (ChAdOx1 nCoV-19) COVID-19 vaccine over 6 months. *J Clin Invest* 2022; 132(18):e160565. PMID: 36106642 PMCID: PMC9479753
97. Matrajt L, Brown ER, Cohen MS, Dimitrov D, **Janes H**. Could widespread use of antiviral treatment curb the COVID-19 pandemic? A modeling study. *BMC Inf Dis* 2022; 22: 683. PMID: 35945513 PMCID: PMC9361252
98. Bannick M*, Gao F, Brown ER, **Janes H**. Retrospective, observational studies for estimating vaccine effects on the secondary attack rate of SARS-CoV-2. *Am J Epidemiol.* 2023 Jun 2;192(6):1016-1028. doi: 10.1093/aje/kwad046.PMID: 36883907
99. Malahleha M, Laher F, Dilraj A, Smith P, Gray GE, Grove D, Odhiambo J, Andrasik M, Grunenberg N, Moodie Z, Huang Y, Borate B, Gillespie K, Allen M, Atujuna M, Singh Ni, Kalonji D, Meintjies G, Kotze P, **Janes H**. Risk factors associated with HIV transmission in males participating in HIV vaccine efficacy trials in South Africa. *AIDS Behav.* 2023 Sep;27(9):3027-3037. doi: 10.1007/s10461-023-04025-z. Epub 2023 Mar 16.PMID: 36929319
100. Lora M, Long A, Long J, Huang Y, Baden L, El Sahly H, Follmann D, Goepfert P, Gray G, Grinsztejn B, Kotloff K, Roupael N, Sobieszczyk M, Walsh S, Andriesen J, Shah K, Zhang Y, Gilbert P, **Janes H**, Gay C, Falsey A, Tripp R, Gorman RL, Tong T, Marovich M, Neuzil K, Corey L, Kublin J. Responding to a pandemic: Rapidly developing an integrated phase 3 Covid-19 vaccine portfolio to accelerate the clinical evaluation and regulatory approval process. *JAMA Netw Open.* 2023 Jan 3;6(1):e2251974. doi: 10.1001/jamanetworkopen.2022.51974.PMID: 36689221

101. Benkeser D, Fong Y, **Janes H**, Kelly EJ, Hirsch I, Sproule S, Houchens CR, Martins K, Jayashanar 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 AK, Andrasik MP, Kublin JG, Brewinski Issacs M, Makhene M, Tong T, Robb ML, Core L, Neuzil KM, Follmann D, Hoffman C, Falsey AR, Sobieszczyk M, Koup RA, Donis RO, Gilbert PB. Immune correlates analysis of a phase 3 trial of the AZD1222 (ChAdOx1 nCoV-19) vaccine. *NPJ Vaccines*. 2023 Mar 11;8(1):36. doi: 10.1038/s41541-023-00630-0.PMID: 36899062
102. Follmann, D, **Janes H**, Chu E, Jayashankar L, Petropoulos C, Serebryanny L, Carooll R, Jean-Baptiste N, Narpala S, Lin, BC, McDermott A, Novak RM, Graciaa DS, Rolsma S, Margaret CA, Doria-Rose N, Corey L, Neuzil KM, Pajon R, Miller JM, Donis RO, Koup RA, Baden LR, El Sahly HM. Kinetics of the antibody response to COVID-19 in vaccinated and unvaccinated individuals in the blinded phase of the mRNA-1273 COVID-19 vaccine efficacy trial. *Open Forum Infect Dis*. 2023 Feb 13;10(3):ofad069. doi: 10.1093/ofid/ofad069. eCollection 2023 Mar.PMID: 36895286
103. Follmann D, O'Brien MP, Fintzi J, Fay MP, Montefiori D, Mateja A, Herman GA, Hooper AT, Turner KC, Chan K-C, Forleo-Neto E, Isa F, Baden LR, El Sahly HM, **Janes H**, Doria-Rose N, Miller J, Zhou H, Dang W, Benkeser D, Fong Y, Gilbert PB, Marovich M, Cohen MS. Examining Protective effects of SARS-CoV-2 Neutralizing antibodies after vaccination or monoclonal antibody administration. *Nat Commun*. 2023 Jun 17;14(1):3605. doi: 10.1038/s41467-023-39292-w.
104. Theodore DA, Branche AR, Zhang L, Graciaa DS, Choudhardy 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. 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 Netw Open*. 2023 Jul 3;6(7):e2323349. doi: 10.1001/jamanetworkopen.2023.23349.PMID: 37440227
105. Turley CB, Tables L, Fuller T, Sanders LJ, Scott H, Moodley A, Woodward Davis AS, Leav B, Miller J, Hirsch I, Dundle 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 KM, Corey L, Grinsztjn B, Gray G, Roupheal N, Luedtke A. Modifiers of COVID-19 vaccine efficacy: Results from the COVID-19 Prevention Network efficacy trials. *Vaccine* 2023; 41:4899-4906.
106. Zhu Y, Gao F, Glidden D, Donnell D, **Janes H**. Estimating counterfactual placebo HIV incidence in HIV prevention trials without placebo arms based on markers of HIV exposure. *Clin Trials* (under review).
107. Prudden H, Tatoud R, **Janes H**, Wallace S, Miller V, Bekker L-G, Donnell D. Perspectives on design approaches for HIV prevention efficacy trials. 2023 Jun 30. doi: 10.1089/AID.2022.0150 PMID: 37392020
108. Hejazi NS, Xhen X, Carpp LN, Benkeser D, Follmann D, **Janes H**, Baden LR, El Sahly HM, 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 (under review).

109. Benkeser D, Montefiori DC, McDermott AB, Fong Y, **Janes H**, 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 M, 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, o. Donnis R, Koup RA, Gilbert PB. Comparing and combining antibody assays as correlates of protection against symptomatic COVID-19 in the COVE mRNA-1273 vaccine efficacy clinical trial. *Sci Transl Med.* 2023 Apr 19;15(692):eade9078. doi: 10.1126/scitranslmed.ade9078. Epub 2023 Apr 19. PMID: 37075127
110. Stephenson KE, Marcelin JR, Pettifor AE, **Janes H**, Brown E, Neradilek M, Yen C, Andriesen J, Grunenberg N, Espy N, Trahey M, Fischer R, DeSouza CA, Shisler JL, Connick E, Houtp ER, Chu HY, McCulloh RJ, Becker-Dreps S, Vielot NA, Kalbaugh CA, Cherabuddi K, Kreuger KM, Rosenberg M, Greenberg RN, Joaquin A, Immergluck LC, Corey L, Kublin JG. Efficacy of mRNA-1273 to prevent SARS-CoV-2 acquisition in young adults from March-December 2021 *N Engl J Med.* 2021 Feb 4;384(5):403-416. doi: 10.1056/NEJMoa2035389. Epub 2020 Dec 30.
111. Rick AR, 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 BP, **Janes H**, Kublin JG, Huang Y, Leav B, Hirsch I, Struyf LM, Neuzil KM, Corey L, Goepfert PA, Walsh SR, Follmann D, Kotloff KL. Risk of COVID-19 after natural infection or vaccination (under review).
112. Tian X*, **Janes H**, Kublin JG. Statistical design and analysis of controlled human malaria infection trials (under review).
113. Donnell D, Kansime S, Glidden DV, Luedtke A, Gilbert PB, Gao F, **Janes H**. Study design approaches for future active-controlled HIV prevention trials (under review).
114. **Janes H** and Buchbinder S. Control groups for HIV prevention efficacy trials: What does the future hold? (under review).
115. Moore M, Zhu Y, Hirsch I, White T, Reiner RC, Barber RM, Pigott D, Collins JK, Santoni S, Sobieszczyk M, **Janes H**. Estimating vaccine efficacy during open-label follow-up of COVID-19 vaccine trials based on population-level surveillance data (under review).

‡ These authors contributed equally to this work.

* Lead author is student/trainee mentored by H Janes.

Books and Book Chapters

1. **Janes H**, Magaret A. "Statistical evaluation of diagnostic tests." In: *Laboratory Diagnosis of Viral Infections, Fourth Edition*, Ed: Jerome KR. Informa Healthcare, New York (2010), 9-18.
2. Pepe MS, **Janes H**. Methods for evaluating prediction performance of biomarkers and tests. In: *Risk Assessment and Evaluation of Predictions*. Eds: Cai T, Gail M, Gandy A, Lee MLT, Pfeiffer R, Satten G. Springer, New York (2013), 107-142.

Other Publications

1. **Janes H**, Sheppard L, Lumley T. Do subject characteristics modify the effects of particulate air pollution on daily mortality among the elderly? Letter to the Editor. *J Occup Environ Med.* 2005;47(6):543.
2. Lumley T, **Janes H**, Sheppard L. Cox models for ecologic time-series data? Letter to the Editor. *Environ Health Perspect.* 2006;114(12):A690-1. PMID: 1764157.

3. **Janes H**, Dominici F, Zeger S. Letter to the editor. Response to Dr.s. Pope and Burnett: Partitioning evidence of association between air pollution and mortality. *Epidemiol.* 2007;18(4):427-8.
4. Pepe MS, **Janes H**, Gu JW. Letter to the editor regarding article, "Use and misuse of the receiver operating characteristic curve in risk prediction". *Circulation.* 2007;116(6):e132.
5. **Janes H**, Pepe MS, Gu W. Assessing the value of risk predictions by using risk stratification tables. *Ann Intern Med.* 2008;149(10):751-60. PMID: 3091826.
6. **Janes H**, Pepe MS, Gu W. Are Risk Stratification Tables the Best Way to Evaluate Model Performance? Response. *Ann Intern Med.* 2009;150(6):428.
7. **Janes H**, Pepe M. Letter to the editor re: "Clinical usefulness of the Framingham cardiovascular risk profile beyond its statistical performance: The Tehran lipid and glucose study". *Am J Epidemiol.* 2013;177(8):864-5. PMID: 23524037.
8. **Janes H**. Letter to the editor. *Biostatistics.* 2013;14(4):807-8. PMID: 3841383.
9. Kang C*, **Janes H**, Huang Y. Rejoinder: Combining biomarkers to optimize patient treatment recommendations. *Biometrics.* 2014: May 30; [Epub ahead of print]. PMID: 4247994.
10. Kerr KF, Brown M, **Janes H**. Reply to A.J. Vickers et al. *J Clin Oncol.* 2017;35(4):473-5. Epub 2017/01/28. doi: 10.1200/JCO.2016.70.4288. PubMed PMID: 28129522.
11. **Janes H**. Book Review: Analysis of Biomarker Data: A Practical Guide. *Biometrics.* 2017 Dec 27.
12. Kerr K, **Janes H**. First things first: Risk model performance metrics should reflect the clinical application. *Stat Med.* 2017;36(28):4503-8. Epub 2017/11/21. doi: 10.1002/sim.7341. PubMed PMID: 29156498; PMID: PMC5726302.
13. Kerr K, **Janes H**, LeBlanc M. Comparisons of cancer staging systems should be based on overall performance in the population. *Clin Trials.* 2017;14(6):659-60. PMID: 5714691.
14. Kerr KF, Marsh T, **Janes H**. The Importance of Uncertainty and Opt In vs. Opt Out: Best Practices for Decision Curve Analysis. *Med Decis Making* 2017/08/19. doi: 10.1177/1740774517722141. PubMed PMID: WOS:000417030600014; PMID: PMC5714691.

Abstracts

1. **Janes H**, Mehrotra D, Duerr A, Gilbert P, Buchbinder S, Robertson M, Fitzgerald D, HIV Vaccine Trials Network (HVTN). Vaccine Effects on HIV-1 Progression in the STEP Study. *AIDS Vaccine*, Cape Town, South Africa (2008).
2. Frahm N, DeRosa S, Defawe O, Carter D, **Janes H**, Moodie Z, Noonan L, Duerr A, Fitzgerald D, Kublin J, Buchbinder S, Robertson M, Casimiro D, McElrath MJ, HIV Vaccine Trials Network (HVTN). HIV infected cases have lower pre-infection Ad5-specific T-cell response rates than non-cases after Ad5/HIV vaccination in the Step trial. *AIDS Vaccine*, Cape Town, South Africa (2008).
3. Barnabas R, Huang Y, **Janes H**, Morrow R, Fuchs J, Mark K, Casapia M, Mehrotra D, Buchbinder S, Corey L, Wasserheit J and the NIAID HIV Vaccine Trials Network. HSV-2 is associated with HIV acquisition among both placebo and vaccine recipients in the STEP trial of the Merck Adenovirus 5 (MRKAd5) HIV-1 vaccine. *International AIDS Society Conference*, Cape Town, South Africa (2009).

4. Frahm N, **Janes H**, Friedrich D, Slichter C, Smith R, Site PI author, Geraghty D, Self S, McElrath J and the NIAID HIV Vaccine Trials Network (HVTN). Beneficial effects of protective HLA class I allele expression on HIV viral load are not mediated through increased vaccine-induced immunity. AIDS Vaccine, Atlanta, GA (2010).
5. **Janes H**, Gilbert PB, Frahm N, Rolland M, DeCamp A, Gabriel E, Wolfson J, Mullins J, McElrath J. Integrated analysis of immunogenicity, viral sequence, and viral load data in the step study. AIDS Vaccine, Bangkok, Thailand (2011).
6. 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, Margaret 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, Barcelona, Spain (2013).
7. Hammer S, Sobieszczyk M, **Janes H**, Gilbert P, Karuna S, Grove D, Ramirez S, Bentley C, Anude C, Mulligan M, Koblin B, Buchbinder S, Keefer M, Hural J, McElrath J, Frahm N, Tomaras G, Enama M, Broder G, Maynard J, Wakefield S, Holt R, DeJesus E, Frank I, Novak R, Martinez A, Kublin J, Corey L, and the 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. AIDS Vaccine, Barcelona, Spain (2013).
8. **Janes H**, Tovanabutra S, Herbeck J, Rerks-Ngarm S, Robb M, Michael N, Gilbert P, Kim J, Rolland M. HIV-1 infections with multiple founders are associated with higher viral loads. Conference on Retroviruses and Opportunistic Infections (CROI), Seattle, WA (2015).
9. **Janes H**, Cohen K, Sobieszczyk M, Frahm N, Karuna S, Sanchez B, Margaret C, Adams E, Hammer S, Gilbert P, McElrath J. Vaccine-Induced CD8+ T Cell Immunity Strongly Predicts Lower HIV Infection Risk in HVTN 505. R4P, Chicago, IL (2016)
10. **Janes H**, Innes C, Kalonji D, Grove D, Laher F, Kee JJ, Bekker LG, Allen M, Andrasik M, Atujuna M, Malahleha M, Grunenberg N, Nishanta S, Naicker N, Kotze P, Kassim S, Dubula T, Huang Y, Moodie Z, Gray G. High HIV Incidence among Women in the HVTN 72 Vaccine Trial. Poster at R4P virtual conference (2020)
11. Malahleha M, **Janes H**, Laher F, Bekker LG, Prigmore B, Grove D, Kee JJ, Allen M, Andrasik M, Atujuna M, Singh N, Kalonji D, Mientjes G, Kotze P, Grunenberg N, Huang Y, Moozie Z, Odhiambo J, Smith P, Gray G. Risk factors for HIV transmission in heterosexual men, men who have sex with men, and transgender women participating in the HVTN 702 “Uhambo” and HVTN 503/503-S “Phambili” HIV vaccine trials. Oral presentation at R4P virtual conference (2020)
12. Follmann D, Wang X, Gilbert P, Baden LR, El Sahly HM, Essink B, **Janes H**, 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, Massachusetts (2023).
13. Zhang B, Fong Y, Fintzi J, Chu E, **Janes H**, Carpp LN, Kenny A, Carone M, Benkeser D, Deng W, Wang X, Zhou H, Lu Y, Yu C, Houchens CR, Martins K, Jayashankar L, Huynh C, 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. Omicron Covid-19 Immune Correlates Analysis of Three-Dose mRNA-1273 Vaccine Recipients in the COVE Trial. IDWeek, Boston, Massachusetts (2023).

PROFESSIONAL SERVICE***National/International***

- 2014 Ad-hoc grant reviewer for Bill and Melinda Gates Foundation
- 2015, 2017 Ad-hoc grant reviewer for Medical Research Council (United Kingdom)
- 2015-2017 Member of Research Oversight Committee for stroke proteomics project (Genome BC)
- 2018 Co-organizer, one-day symposium, "HIV Prevention Efficacy Trial Designs of the Future"
- 2015-2019 DSMB member for Phase II trial of Targeted Anticoagulation Therapy in Long-Term HIV Disease (University of Minnesota)
- 2017-2020 SMC member for Phase I influenza vaccine study (Baylor College of Medicine)
- 2020 Member, World Health Organization R&D Blueprint Clinical Trials Expert Group.
- 2020-2021 Co-organizer, virtual workshop series, "Design Approaches for Current and Future HIV Prevention Efficacy Trials"
- 2022 Grant reviewer, NIH study section
- 2014-present Co-chair, HIV Vaccine Trials Network (HVTN) Efficacy Trials Working Group
- 2016-present Member of Vaccines and Related Biological Products Advisory Committee, US Food and Drug Administration
- 2018-present DSMB member for three HPV vaccine trials (Phase III, Phase IIIb, Phase IV), NIH/NCI
- 2022-present DSMB member for Phase II monkeypox vaccine study (DMID)
- 2023-present DSMB member for Phase I oral cholera vaccine study (DMID)

Local

- 2007-2008 Organizer, SCHARP seminar series
- 2010 Member, VIDC faculty search committee
- 2010-2011 Member, UW Biostatistics affiliates and adjunct committee
- 2011-2020 Organizer, Fred Hutch/UW Biomarker Reading Group (bi-weekly meetings)
- 2012 Member, PHS faculty promotion committee
- 2012 Invited talk, Fred Hutch Development Office, Innovators Network Happy Hour
- 2012 Member, SWOG faculty search committee
- 2012-2013 Member, VIDC Staff scientist promotion committee
- 2013 Chair, VIDC faculty search committee
- 2013 Member, VIDC faculty promotion committee

| | |
|--------------|--|
| 2013 | Invited talk, HIV Vaccine Trials Network (HVTN), HIV Vaccine Awareness Day Community Event |
| 2016 | Member, VID D faculty search committee |
| 2017 | Chair, PHS faculty promotion committee |
| 2018 | Member, VID D faculty search committee |
| 2018-2021 | Member, Executive Committee for Data Science Integrated Research Center, Fred Hutch |
| 2020 | Chair, VID D faculty promotion committee |
| 2020 | Member, VID D faculty search committee |
| 2021 | Chair, PHS faculty promotion committee |
| 2021 | Member, PHS faculty search committee |
| 2013-present | Co-organizer, Clinical Trials Affinity Group, VID D and PHS (monthly meetings) |
| 2018-present | Member, VID D Appointments and Promotions Committee |
| 2021-present | Member, VID D Executive Committee |

INVITED PRESENTATIONS *(only includes presentations given by H. Janes)*

1. Overlap bias in the case-crossover design, with application to air pollution exposures. Department of Biostatistics, University of Washington, Seattle, WA (2004).
2. Overlap bias in the case-crossover design, with application to air pollution exposures. Environmental Biostatistics and Epidemiology Working Group, Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD (2005).
3. Adjusting for covariate effects on classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Student conference award presentation at the 26th annual conference of the International Society for Clinical Biostatistics, Szeged, Hungary (2005).
4. Adjusting for covariate effects on classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD (2005).
5. Adjusting for covariate effects on classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Division of Epidemiology, Statistics and Prevention Research, National Institute of Child Health and Human Development, Rockville, MD (2006).
6. Matching in studies of classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Division of Cancer Treatment and Diagnosis, Biometric Research Branch, National Cancer Institute, Rockville, MD (2006).

7. Matching in studies of classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Division of Cancer Treatment and Diagnosis, Biometric Research Branch, National Cancer Institute, Rockville, MD (2006).
8. Matching in studies of classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Annual meeting of the Western North American Region of the International Biometric Society, Irvine, CA (2007).
9. On quantifying the magnitude of confounding. Annual meeting of the American Public Health Association, Washington, DC (2007).
10. Covariate adjustment in studies of classification accuracy: An old concept in a new setting. Oregon Health and Science University, Portland, OR (2007).
11. Calculating disease risk: Evaluating risk prediction models using risk stratification tables. Annual meeting of the Eastern North American Region of the International Biometric Society, San Antonio, TX (2009).
12. Calculating disease risk: Evaluating risk prediction models using risk stratification tables. International Chinese Statistical Association Applied Statistics Symposium, San Francisco, CA (2009).
13. Assessing the clinical value of risk prediction tools. HuGENet Workshop: Strengthening the reporting of genetic risk prediction studies, Centers for Disease Control and Prevention, Atlanta, GA (2009).
14. Statistical methods for evaluating markers for treatment selection. Annual meeting of the Western North American Region of the International Biometric Society, Seattle, WA (2010).
15. Statistical methods for evaluating markers for treatment selection. Joint Statistical Meetings, Vancouver, Canada (2010).
16. Designing studies to evaluate biomarkers for selecting patient treatment. Conference on risk assessment and evaluation of predictions, Silver Spring, MD (2011).
17. A statistical perspective on the RV144 immune correlates analysis. HIV Vaccine Trials Network Full Group Meeting, Seattle, WA, Plenary Presentation (2011).
18. Designing studies to evaluate biomarkers for selecting patient treatment. Annual meeting of the Eastern North American Region of the International Biometric Society, Washington, DC (2012).
19. Incorporating covariates in assessing the performance of markers for treatment selection. Annual meeting of the Eastern North American Region of the International Biometric Society, Orlando, FL (2013).
20. Designing HIV vaccine efficacy trials in the PrEP era. Workshop on clinical trial design for long-acting PrEP agents at the Aaron Diamond AIDS Research Center, New York City, NY (2013).
21. Designing a phase III HIV vaccine efficacy trial. Annual meeting of the International Society for Clinical Biostatistics, Munich, Germany (2013).
22. HVTN 505: Immunogenetics, HIV infection and viral load. HIV Vaccine Trials Network Full Group Meeting, Washington, DC, Plenary Presentation (2014).
23. Methods for evaluating biomarkers for guiding therapy. Fifth Seattle Symposium in Biostatistics, Seattle, WA (2015).

24. The challenge in making inference about a biomarker's predictive capacity. International Chinese Statistical Association Annual Meeting, Fort Collins, CO (2015).
25. The challenge in making inference about a biomarker's predictive capacity. Joint Statistical Meetings, Seattle, WA (2015).
26. Evaluating biomarkers for guiding therapy. Biostatistics Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, MD (2016).
27. Evaluating biomarkers for guiding therapy. Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY (2016).
28. Evaluating biomarkers for guiding therapy. Department of Biostatistics, University of Michigan, Ann Arbor, MI (2016).
29. A framework for evaluating precision prevention. Annual meeting of the Eastern North American Region of the International Biometric Society. Washington, DC (2017).
30. Weighing the evidence of efficacy of oral PrEP for HIV prevention in women in Southern Africa. HIV Vaccine Trials Network Full Group Meeting, Seattle, WA, Plenary Presentation (2017).
31. Evaluating the ability of a biomarker to improve the diagnosis of malaria infection in malaria "challenge" trials. Joint Statistical Meetings, Vancouver, Canada (2018).
32. Potential study designs for HIV vaccine efficacy trials in the era of an expanding portfolio of non-vaccine HIV prevention strategies. International Society for Biopharmaceutical Statistics, Kyoto, Japan (2019).
33. Design of future efficacy trials to evaluate new HIV prevention modalities. UNAIDS/WHO Meeting: Ethical considerations for HIV prevention research in the era of highly effective HIV prevention, Montreaux, Switzerland (2019).
34. Study designs for future HIV prevention efficacy trials in the era of highly effective prevention. CFAR Science Seminar, Emory University, Atlanta, GA (2020).
35. Designing efficacy trials of passive and active immunization strategies to prevent breastmilk transmission of HIV. HIV Vaccine Trials Network Regional Meeting, Cape Town, South Africa, Plenary Presentation (2020).
36. COVID-19 vaccine efficacy trial design: Key statistical considerations and best practices. COVAX Workshop: COVID-19 Efficacy Trial Design Considerations and Early Learnings from Ongoing Studies (2020)
37. COVID-19 vaccine efficacy trial design: Key statistical considerations and best practices. ICAP at Columbia University: Special Webinar- COVID-19 Vaccines: Where We Stand (2020)
38. Phase 2b trial design to assess COVID-19 vaccine efficacy against infection, viral load, and secondary transmission. COVAX Workshop: Pre-/Post Licensure Assessments of COVID-19 Vaccine Efficacy Against Infection and Transmission (2020)
39. Study designs for evaluating COVID-19 vaccine efficacy against infectiousness. McGill University, Department of Biostatistics Seminar Series (2021).
40. Study designs for evaluating COVID-19 vaccine efficacy against infectiousness. Vanderbilt University, Department of Biostatistics Seminar Series (2021).
41. Understanding the effects of COVID-19 vaccines on reducing secondary transmission. Joint Statistical Meetings (2021).

42. Challenges in designing and interpreting COVID-19 vaccine trials. Conference on Retroviruses and Opportunistic Infections (CROI): Clinical Trial Design Workshop (2021).
43. Evaluating COVID-19 vaccine effects on infectiousness: Current status and next steps. Oregon Sciences University, Department of Biostatistics Seminar Series (2021).
44. Clinical trial designs for evaluating COVID-19 vaccine effects on transmission. COVID-19 Vaccine Development & Implementation Workshop, Virtual (2021).
45. COVID-19 vaccine efficacy trial designs: A review and summary of open questions. IDWeek (2021).
46. Lessons learned from COVID-19 vaccine trials that inform HIV prevention science. NIAID/NIH webinar (2021).
47. COVID-19 vaccine efficacy trial design and analysis. Statistics in the Pharmaceutical Industry webinar (2021).
48. Lessons in clinical trial design from the COVID-19 vaccine field. Joint Mathematical Meetings (2022).
49. Augmenting randomized, controlled trials with observational data: Lessons from trials past and present. Prentice Lecture, University of Washington and Fred Hutchinson Cancer Research Center (2022).
50. Augmenting randomized, controlled trials with observational data: Lessons from trials past and present. NIH/NIAID (2022).
51. Strawman designs for infant post-natal prophylaxis for HIV: Statistical considerations. Stakeholder consultation to inform the clinical development plan for bnAbs in infant post-natal prophylaxis for HIV. Cape Town, South Africa (2023).
52. Four statistical designs for evaluating efficacy of a combination bnAb regimen. HIV Vaccine Trials Network Regional Meeting, Johannesburg, South Africa, Plenary Presentation (2023).
53. Potential statistical designs for evaluating efficacy of a combination bnAb regimen. HIV Vaccine Trials Network Full Group Meeting, Washington, DC, Plenary Presentation (2023).