MARTHA C. NASON, PH.D.

Biostatistics Research Branch, National Institutes of Allergy and Infectious Diseases, NIH
5601 Fisher's Lane, Room 4C31, Rockville, MD 20852
240-669-5251
mnason@nih.gov

PROFESSIONAL EXPERIENCE:

Mathematical Statistician, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD (Sept 7 2003 – Present)

- Participate in designing phase 3 clinical trials for assessing the safety and efficacy of Covid-19 vaccines, including as a member of the protocol team for AstraZeneca and Novavax vaccine trials; share information and discuss best-practices with other members of US Government's Operation Warp Speed/ Countermeasures Acceleration Group.
- Provide statistical and mathematical leadership and expert consultation to scientists on design and analysis of pre-clinical and clinical research projects
- Advise NIAID leadership and other senior officials on interpretation of ongoing studies or results, especially those with complex statistical issues; initiating new statistical methods or major revisions to current statistical methodology.
- Act as liaison between pharmaceutical companies, NIH, and independent experts as Executive Secretary of Data Safety Monitoring Boards for HIV Vaccines and Covid-19 preventive Antibodies.
- Support the NIH Covid-19 Treatment Guidelines Panel on evaluation of published research and crafting of recommendations
- Lead and/or co-teaching multiple workshops on Biostatistics, Clinical Trial Design, Protocol Development and Manuscript development to collaborating researchers in international settings in order to further develop capacity. Locations include Indonesia, Mali, Uganda, South Africa, and Rwanda.
- Provide expert advice on the use of statistics in developing software for integration of statistical models into statistical analysis plans (SAPs) of ongoing and future clinical trials.
- Develop and evaluate new statistical methodologies for a wide range of research projects to ensure that conclusions and statistical results are scientifically sound, relevant, valid and reliable. Provide oversight or prepare original manuscripts describing novel mathematical statistical techniques developed.
- Review manuscripts for statistical importance, content and accuracy for multiple prominent journals.
- Present original research and collaborating with other statisticians and researchers at workshops, forums, summits, or conferences to help identify and meet cross-institutional research needs. Communicate statistical methodology research to interested groups from external organizations.
- Provide statistical expertise within NIAID and to other Government and non-Governmental Agencies, including the NIAID Internal Review Board (IRB), Division of AIDS scientific review committees (PSRC and CSRC), Vaccine Research Center scientific review committee and hiring committee, multiple FDA Advisory committees and World Health Organization World Health Organization Blueprint working group on Vaccine Trial Designs during Public Health Emergencies.

- Review, design and implementation of clinical study protocols, including sample size calculations, selecting, planning and implementing final and interim data analysis and designing enrollment and randomization to avoid biased sampling.
- Use principles of mathematical statistics in selecting, developing and applying methods of analysis, including simulations for sample size and power calculations and study design, multivariate regression and robust estimation.
- Provide statistical consultation and advice to and collaborate with NIH scientists in order to select and implement appropriate methods for data analysis

Adjunct Faculty, Johns Hopkins University, Advanced Academic Programs, Rockville, MD (2008 – Present).

- Teach 1-2 sections per semester of an introductory Biostatistics class to graduate students enrolled in a Master's Degree program for Bioinformatics or Biotechnology.

Research Statistician, Talaria Inc., Seattle, WA (1998–2003) (Part-time).

- Assisted in applying for and implementing multiple SBIR grants, including a large grant on software for Bayesian analysis of randomized clinical trials

EDUCATION:

Diploma Advanced Course in Vaccinology (ADVAC) Annecy, France (2022)

Ph.D. Department of Biostatistics, University of Washington, Seattle, WA (2003)
Dissertation: Variable Importance in Tree-Based models (Advised by Dr. Scott Emerson & Dr. Michael LeBlanc)

M.S. Department of Biostatistics, University of Washington, Seattle, WA (1999)

B.S. Department of Psychology, University of Washington, Seattle, WA (1996)
Brown University, Providence, RI (1990 – 1992)

RESEARCH INTERESTS:

Statistical issues in Infectious Diseases, Epidemics, Vaccines, Therapeutics and Diagnostics; Statistical Methodology for Vaccine Trials; Data and Safety Monitoring Boards; Statistics for Flow Cytometry and related large-scale cellular assays; Bioinformatics; International Biostatistical Capacity Building; Global Health; Design and Analysis of Clinical Trials; Statistical Programming; Statistical Consulting; Exploratory Data Analysis; Graphics & Visualization of complex models; Statistics Education; Classification and Regression Trees.

PROFESSIONAL SERVICE:

Executive Secretary:

- NIAID Preventive Antibodies for COVID-19 Data Safety Monitoring Board (July 2020-Present)
- NIAID Vaccine Data Safety Monitoring Board (2011-Present)

Member:

- Chair, three Data Safety Monitoring Committees for Oxford Vaccine Group
  - MERS vaccine trial (2023-present)
  - CCHF vaccine trial (2023-present)
  - Nipah vaccine trial (2023-present)
- Arthritis Advisory Committee, FDA (2019- present)
- Endocrinologic and Metabolic Drugs Advisory Committee, FDA (Consultant) (2014-present)
- Operation Warp Speed / CoVPN Statistics Group (2020-2022)
- World Health Organization Blueprint working group on Vaccine Trial Designs during Public Health Emergencies (2016 - 2022)
- Data Safety Monitoring Board for Immunotherapeutics for HIV Disease, American Gene Therapeutics (2017 – 2019)
- NIAID Institutional Review Board (IRB) (2014-2019)
- Prevention Review Committee & Consensus Review Committee, Division of AIDS, NIAID (2003-2014)
- Data Monitoring Committee for Trial of Ciproflaxin for Plague in Uganda, CDC (2011-2018)
- Data Monitoring Committee, Division of Allergy, Immunology and Transplantation, NIAID, NIH (2011-2015)
- Safety Monitoring Committee, AERAS Global TB Vaccine Foundation (2004)

Reviewer, *NEJM; Nature; Nature Medicine; Trials; Journal of Immunological Methods; BMC Bioinformatics; Cytometry; Statistics in Medicine; Vaccine; PLOS ONE* (2007 - Present)

AWARDS AND HONORS:

NIH Director's Award (2023, 2021, 2013)
NIH Merit Award (2020 (x2), 2019 (x2), 2010)
Secretary's Award for Distinguished Service, Department of Health and Human Services (2016)
Graduate Research Fellowship, National Science Foundation (1997 – 2000)

INVITED PRESENTATIONS:

NIAID Zika Virus Therapeutics Workshop. "Clinical trial considerations for Prophylactics" and "Clinical trial considerations for Therapeutics" (2017)

Moderna Pharmaceuticals on Correlates of Immunity and the Animal Rule (2017)

Society for Clinical Trials. “Statistics, logistics, and optics: design of Ebola vaccine trials in West Africa.” (2015)

Joint Statistical Meetings. “The Statistical Landscape of Infectious Disease” (2014)

Joint Statistical Meetings. “Design and analysis of crossover trials for absorbing binary endpoints” (2011)

ENAR Annual Meeting. “Characterizing Immune Responses via Flow Cytometry.” (2009)

WNAR Annual Meeting. “Defining Immune Responses using Intracellular Cytokine Staining: Pitfalls and Possibilities” (2008)

ENAR Annual Meeting. “Investigating Associations between Functional Patterns of Immune Response to HIV and Disease Progression” (2006)

PUBLICATIONS:

1. Gagne, M., et al., *Mucosal Adenoviral-vectored Vaccine Boosting Durably Prevents XBB. 1.16 Infection in Nonhuman Primates (preprint).* 2023.

2. Gagne, M., et al., *RBD-based high affinity ACE2 antagonist limits SARS-CoV-2 replication in upper and lower airways.* bioRxiv, 2023: p. 2023.06. 09.544432.

3. Doritchamou, J., et al., *Aotus nancymaae model predicts human immune response to the placental malaria vaccine candidate VAR2CSA.* Lab Animal, 2023. **52**(12): p. 315-323.

4. Swindells, S., et al., *Letter to the Editor.* Clin Infect Dis, 2023.

5. Houser KV, et al., *Safety and immunogenicity of an HIV-1 prefusion-stabilized envelope trimer (Trimer 4571) vaccine in healthy adults: A first-in-human open-label, randomized, dose-escalation, phase 1 clinical trial.* eClinicalMedicine, 2022: p. 101477.

6. Doritchamou, J., et al., *Aotus nancymaae model predicts human immune response to the placental malaria vaccine candidate VAR2CSA.* bioRxiv, 2022.

7. Casazza JP, C.E., Narpala S, Yamshchikov GV, Coates EE, Hendel CS, Novik L, Holman LA, Widge AT, Apte P, Gordon I, Gaudinski MR, Conan-Cibotti M, Lin BC, Nason MC, Trofymenko O, Telscher S, Plummer SH, Wycuff D, Adams WC, Pandey JP, McDermott A, Roederer M, Sukienik AN, O'Dell S, Gall JG, Flach B, Terry TL, Choe M, Shi W, Chen X, Kaltovich F, Saunders KO, Stein JA, Doria-Rose NA, Schwartz RM, Balazs AB, Baltimore D, Nabel GJ, Koup RA, Graham BS, Ledgerwood JE, Mascola JR;, *Safety and tolerability of AAV8 delivery of a broadly neutralizing antibody in adults living with HIV: a phase 1, dose-escalation trial.* Nature Medicine, 2022. **28**(5): p. 1022-1030.

8. Doritchamou, J., et al., *Aotus nancymaae model predicts human immune response to the placental malaria vaccine candidate VAR2CSA.* bioRxiv, 2022: p. 2022.06.24.497389.

9. Longini, I.M., et al., *A platform trial design for preventive vaccines against Marburg virus and other emerging infectious disease threats.* Clinical Trials, 2022. **19**(6): p. 647-654.

10. Keller, M.B., et al., *Preintubation Sequential Organ Failure Assessment Score for Predicting COVID-19 Mortality: External Validation Using Electronic Health Record From 86 US Healthcare Systems to Appraise Current Ventilator Triage Algorithms.* Critical care medicine, 2022.

11. Gagne M, M.J., Foulds KE, Andrew SF, Flynn BJ, Werner AP, Wagner DA, Teng IT, Lin BC, Moore C, Jean-Baptiste N, Carroll R, Foster SL, Patel M, Ellis M, Edara VV, Maldonado NV, Minai M, McCormick L, Honeycutt CC, Nagata BM, Bock KW, Dulan CNM, Cordon J, Flebbe DR, Todd JM, McCarthy E, Pessaint L, Van Ry A, Narvaez B, Valentin D, Cook A, Dodson A, Steingrebe K, Nurmukhambetova ST, Godbole S, Henry AR, Laboune F, Roberts-Torres J, Lorang CG, Amin S, Trost J, Naisan M, Basappa M, Willis J, Wang L, Shi W, Doria-Rose NA, Zhang Y, Yang ES, Leung K, O'Dell S, Schmidt SD, Olia AS, Liu C, Harris DR, Chuang GY, Stewart-Jones G, Renzi I, Lai YT, Malinowski A, Wu K, Mascola JR, Carfi A, Kwong PD, Edwards DK, Lewis MG, Andersen H, Corbett KS, Nason MC, McDermott AB, Suthar MS, Moore IN, Roederer M, Sullivan NJ, Douek DC, Seder RA. , *mRNA-1273 or mRNA-Omicron boost in vaccinated macaques elicits similar B cell expansion, neutralizing responses, and protection from Omicron.* Cell, 2022. **185**(9): p. 1556-1571. e18.

12. Gagne, M., et al., *mRNA-1273 or mRNA-Omicron boost in vaccinated macaques elicits similar B cell expansion, neutralizing responses, and protection from Omicron.* Cell, 2022. **185**(9): p. 1556-1571.e18.

13. Gagne, M., et al., *Protection from SARS-CoV-2 Delta one year after mRNA-1273 vaccination in rhesus macaques coincides with anamnestic antibody response in the lung.* Cell, 2022. **185**(1): p. 113-130 e15.

14. Gagne, M., et al., *Protection from SARS-CoV-2 Delta one year after mRNA-1273 vaccination in rhesus macaques coincides with anamnestic antibody response in the lung.* Cell, 2022. **185**(1): p. 113-130.e15.

15. Corbett, K.S., et al., *Immune Correlates of Protection by mRNA-1273 Immunization against SARS-CoV-2 Infection in Nonhuman Primates.* bioRxiv, 2021.

16. Follmann, D., et al., *A Deferred-Vaccination Design to Assess Durability of COVID-19 Vaccine Effect After the Placebo Group Is Vaccinated.* Ann Intern Med, 2021. **174**(8): p. 1118-1125.

17. Kuriakose, S., et al., *Developing Treatment Guidelines During a Pandemic Health Crisis: Lessons Learned From COVID-19.* Ann Intern Med, 2021. **174**(8): p. 1151-1158.

18. Fleming, T.R., et al., *COVID-19 vaccine trials: The potential for "hybrid" analyses.* Clin Trials, 2021. **18**(4): p. 391-397.

19. Garber, D.A., et al., *Broadly neutralizing antibody-mediated protection of macaques against repeated intravenous exposures to simian-human immunodeficiency virus.* AIDS, 2021. **35**(10): p. 1567-1574.

20. Corbett, K.S., et al., *Protection against SARS-CoV-2 Beta Variant in mRNA-1273 Boosted Nonhuman Primates.* bioRxiv, 2021.

21. Mehrotra, D.V., et al., *Clinical Endpoints for Evaluating Efficacy in COVID-19 Vaccine Trials.* Ann Intern Med, 2021. **174**(2): p. 221-228.

22. Evaluation, W.H.O.A.H.E.G.o.t.N.S.f.C.-V., et al., *Placebo-Controlled Trials of Covid-19 Vaccines - Why We Still Need Them.* N Engl J Med, 2021. **384**(2): p. e2.

23. Mwakingwe-Omari, A., et al., *Two chemoattenuated PfSPZ malaria vaccines induce sterile hepatic immunity.* Nature, 2021. **595**(7866): p. 289-294.

24. Fleming, T.R., et al., *COVID-19 vaccine trials: The use of active controls and non-inferiority studies.* Clin Trials, 2021. **18**(3): p. 335-342.

25. Breglio, K.F., et al., *Clinical and Immunologic Predictors of Mycobacterium avium Complex Immune Reconstitution Inflammatory Syndrome in a Contemporary Cohort of Patients With Human Immunodeficiency Virus.* J Infect Dis, 2021. **223**(12): p. 2124-2135.

26. Higgs, E.S., et al., *PREVAIL IV: A Randomized, Double-Blind, Two-Phase, Phase 2 Trial of Remdesivir versus Placebo for Reduction of Ebola Virus RNA in the Semen of Male Survivors.* Clin Infect Dis, 2021.

27. Parta, M., et al., *Hematopoietic Cell Transplantation and Outcomes Related to Human Papillomavirus Disease in GATA2 Deficiency.* Transplant Cell Ther, 2021. **27**(5): p. 435 e1-435 e11.

28. Corbett, K.S., et al., *Evaluation of mRNA-1273 against SARS-CoV-2 B.1.351 Infection in Nonhuman Primates.* bioRxiv, 2021.

29. Higgs, E.S., et al., *PREVAIL IV: A Randomized, Double-Blind, 2-Phase, Phase 2 Trial of Remdesivir vs Placebo for Reduction of Ebola Virus RNA in the Semen of Male Survivors.* Clin Infect Dis, 2021. **73**(10): p. 1849-1856.

30. Ruckwardt, T.J., et al., *Safety, tolerability, and immunogenicity of the respiratory syncytial virus prefusion F subunit vaccine DS-Cav1: a phase 1, randomised, open-label, dose-escalation clinical trial.* Lancet Respir Med, 2021. **9**(10): p. 1111-1120.

31. Corbett, K.S., et al., *mRNA-1273 protects against SARS-CoV-2 beta infection in nonhuman primates.* Nat Immunol, 2021. **22**(10): p. 1306-1315.

32. Corbett, K.S., et al., *Protection against SARS-CoV-2 beta variant in mRNA-1273 vaccine-boosted nonhuman primates.* Science, 2021: p. eabl8912.

33. Gagne, M., et al., *Protection from SARS-CoV-2 Delta one year after mRNA-1273 vaccination in nonhuman primates is coincident with an anamnestic antibody response in the lower airway.* bioRxiv, 2021.

34. Ciocanea-Teodorescu, I., et al., *Adjustment for Disease Severity in the Test-Negative Study Design.* Am J Epidemiol, 2021. **190**(9): p. 1882-1889.

35. Ortega-Villa, A.M., M.C. Nason, and D. Follmann, *The mechanistic analysis of founder virus data in challenge models.* Stat Med, 2021. **40**(20): p. 4492-4504.

36. Narayanam, M.K., et al., *Positron Emission Tomography Tracer Design of Targeted Synthetic Peptides via (18)F-Sydnone Alkyne Cycloaddition.* Bioconjug Chem, 2021. **32**(9): p. 2073-2082.

37. Corbett, K.S., et al., *Immune correlates of protection by mRNA-1273 vaccine against SARS-CoV-2 in nonhuman primates.* Science, 2021. **373**(6561): p. eabj0299.

38. Pegu, A., et al., *Durability of mRNA-1273 vaccine-induced antibodies against SARS-CoV-2 variants.* Science, 2021. **373**(6561): p. 1372-1377.

39. Falsey, A.R., et al., *Phase 3 Safety and Efficacy of AZD1222 (ChAdOx1 nCoV-19) Covid-19 Vaccine.* N Engl J Med, 2021.

40. Dean, N.E., et al., *Creating a Framework for Conducting Randomized Clinical Trials during Disease Outbreaks.* N Engl J Med, 2020. **382**(14): p. 1366-1369.

41. Ssempijja, V., et al., *Adaptive Viral Load Monitoring Frequency to Facilitate Differentiated Care: A Modeling Study From Rakai, Uganda.* Clin Infect Dis, 2020. **71**(4): p. 1017-1021.

42. Follmann, D., et al., *Assessing Durability of Vaccine Effect Following Blinded Crossover in COVID-19 Vaccine Efficacy Trials.* medRxiv, 2020.

43. Redd, A.D., et al., *Longitudinal Antibody Responses in People Who Inject Drugs Infected With Similar Human Immunodeficiency Virus Strains.* J Infect Dis, 2020. **221**(5): p. 756-765.

44. Gouel-Cheron, A., et al., *Cardiovascular Biomarker Profile on Antiretroviral Therapy Is Not Influenced by History of an IRIS Event in People With HIV and Suppressed Viremia.* Open Forum Infect Dis, 2020. **7**(1): p. ofaa017.

45. Sereti, I., et al., *Prospective International Study of Incidence and Predictors of Immune Reconstitution Inflammatory Syndrome and Death in People Living With Human Immunodeficiency Virus and Severe Lymphopenia.* Clin Infect Dis, 2020. **71**(3): p. 652-660.

46. Maciejewski, S., et al., *Distinct neutralizing antibody correlates of protection among related Zika virus vaccines identify a role for antibody quality.* Sci Transl Med, 2020. **12**(547).

47. Corbett, K.S., et al., *SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness.* bioRxiv, 2020.

48. Rosenke, K., et al., *Hydroxychloroquine Proves Ineffective in Hamsters and Macaques Infected with SARS-CoV-2.* bioRxiv, 2020.

49. Garber, D.A., et al., *Durable protection against repeated penile exposures to simian-human immunodeficiency virus by broadly neutralizing antibodies.* Nat Commun, 2020. **11**(1): p. 3195.

50. Finch, C.L., et al., *Characteristic and quantifiable COVID-19-like abnormalities in CT- and PET/CT-imaged lungs of SARS-CoV-2-infected crab-eating macaques (Macaca fascicularis).* bioRxiv, 2020.

51. Corbett, K.S., et al., *SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness.* Nature, 2020. **586**(7830): p. 567-571.

52. Corbett, K.S., et al., *Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates.* N Engl J Med, 2020. **383**(16): p. 1544-1555.

53. Hunsberger, S., et al., *Patterns of signs, symptoms, and laboratory values associated with Zika, dengue, and undefined acute illnesses in a dengue endemic region: Secondary analysis of a prospective cohort study in southern Mexico.* Int J Infect Dis, 2020. **98**: p. 241-249.

54. Brody, I.B., et al., *Susceptibility to SIV Infection After Adenoviral Vaccination in a Low Dose Rhesus Macaque Challenge Model.* Pathog Immun, 2019. **4**(1): p. 1-20.

55. Dorjbal, B., et al., *Hypomorphic caspase activation and recruitment domain 11 (CARD11) mutations associated with diverse immunologic phenotypes with or without atopic disease.* J Allergy Clin Immunol, 2019. **143**(4): p. 1482-1495.

56. Crank, M.C., et al., *A proof of concept for structure-based vaccine design targeting RSV in humans.* Science, 2019. **365**(6452): p. 505-509.

57. Janes, H., et al., *Taking stock of the present and looking ahead: envisioning challenges in the design of future HIV prevention efficacy trials.* Lancet HIV, 2019. **6**(7): p. e475-e482.

58. Dean, N.E., et al., *Design of vaccine efficacy trials during public health emergencies.* Sci Transl Med, 2019. **11**(499).

59. Kong, R., et al., *Antibody Lineages with Vaccine-Induced Antigen-Binding Hotspots Develop Broad HIV Neutralization.* Cell, 2019. **178**(3): p. 567-584 e19.

60. Gaudinski, M.R., et al., *Safety, tolerability, pharmacokinetics, and immunogenicity of the therapeutic monoclonal antibody mAb114 targeting Ebola virus glycoprotein (VRC 608): an open-label phase 1 study.* Lancet, 2019. **393**(10174): p. 889-898.

61. Nganou-Makamdop, K., et al., *Type I IFN signaling blockade by a PASylated antagonist during chronic SIV infection suppresses specific inflammatory pathways but does not alter T cell activation or virus replication.* PLoS Pathog, 2018. **14**(8): p. e1007246.

62. Duan, H., et al., *Glycan Masking Focuses Immune Responses to the HIV-1 CD4-Binding Site and Enhances Elicitation of VRC01-Class Precursor Antibodies.* Immunity, 2018. **49**(2): p. 301-311 e5.

63. Le, K., et al., *A Survey on Including Risks in the New "Key Information" Section of an Informed Consent Form.* Clin Res (Alex), 2018. **32**(10): p. 18-29.

64. Gabriel, E.E., et al., *Response to letter by Antonio Martin Andres on "A boundary-optimized rejection region test for the two-sample binomial problem".* Stat Med, 2018. **37**(14): p. 2303-2306.

65. Gabriel, E.E., et al., *A boundary-optimized rejection region test for the two-sample binomial problem.* Stat Med, 2018. **37**(7): p. 1047-1058.

66. Higgs, E.S., et al., *Accelerating Vaccine Development During the 2013-2016 West African Ebola Virus Disease Outbreak.* Curr Top Microbiol Immunol, 2017. **411**: p. 229-261.

67. Nason, M., *Ebola Vaccine Trials.* , in *Marburg- and Ebolaviruses: From Ecosystems to Molecules.*, E. Mühlberger, Hensley, Lisa L., Towner, Jonathan S. , Editor. 2017, Springer.

68. Pettitt, J., et al., *Assessment and Optimization of the GeneXpert Diagnostic Platform for Detection of Ebola Virus RNA in Seminal Fluid.* J Infect Dis, 2017. **215**(4): p. 547-553.

69. Lyke, K.E., et al., *Attenuated PfSPZ Vaccine induces strain-transcending T cells and durable protection against heterologous controlled human malaria infection.* Proc Natl Acad Sci U S A, 2017. **114**(10): p. 2711-2716.

70. Coates, E.E., et al., *Lymph Node Activation by PET/CT Following Vaccination With Licensed Vaccines for Human Papillomaviruses.* Clin Nucl Med, 2017. **42**(5): p. 329-334.

71. Kennedy, S.B., et al., *Phase 2 Placebo-Controlled Trial of Two Vaccines to Prevent Ebola in Liberia.* N Engl J Med, 2017. **377**(15): p. 1438-1447.

72. Prodger, J.L., et al., *Reduced Frequency of Cells Latently Infected With Replication-Competent Human Immunodeficiency Virus-1 in Virally Suppressed Individuals Living in Rakai, Uganda.* Clin Infect Dis, 2017. **65**(8): p. 1308-1315.

73. Crank, M.C., et al., *Safety and Immunogenicity of a rAd35-EnvA Prototype HIV-1 Vaccine in Combination with rAd5-EnvA in Healthy Adults (VRC 012).* PLoS One, 2016. **11**(11): p. e0166393.

74. Kennedy, S.B., et al., *Implementation of an Ebola virus disease vaccine clinical trial during the Ebola epidemic in Liberia: Design, procedures, and challenges.* Clin Trials, 2016. **13**(1): p. 49-56.

75. Nason, M., *Statistics and logistics: Design of Ebola vaccine trials in West Africa.* Clin Trials, 2016. **13**(1): p. 87-91.

76. Bolton, D.L., et al., *Human Immunodeficiency Virus Type 1 Monoclonal Antibodies Suppress Acute Simian-Human Immunodeficiency Virus Viremia and Limit Seeding of Cell-Associated Viral Reservoirs.* J Virol, 2016. **90**(3): p. 1321-32.

77. Ishizuka, A.S., et al., *Protection against malaria at 1 year and immune correlates following PfSPZ vaccination.* Nat Med, 2016. **22**(6): p. 614-23.

78. Ishizuka, A.S., et al., *Corrigendum: Protection against malaria at 1 year and immune correlates following PfSPZ vaccination.* Nat Med, 2016. **22**(6): p. 692.

79. Nason, M.C., et al., *Immunological Signaling During Herpes Simplex Virus-2 and Cytomegalovirus Vaginal Shedding After Initiation of Antiretroviral Treatment.* Open Forum Infect Dis, 2016. **3**(2): p. ofw073.

80. Gautam, R., et al., *A single injection of anti-HIV-1 antibodies protects against repeated SHIV challenges.* Nature, 2016. **533**(7601): p. 105-109.

81. Dowd, K.A., et al., *Rapid development of a DNA vaccine for Zika virus.* Science, 2016. **354**(6309): p. 237-240.

82. Huang, Y., et al., *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): p. e0136626.

83. Lynch, R.M., et al., *HIV-1 fitness cost associated with escape from the VRC01 class of CD4 binding site neutralizing antibodies.* J Virol, 2015. **89**(8): p. 4201-13.

84. Francica, J.R., et al., *Analysis of immunoglobulin transcripts and hypermutation following SHIV(AD8) infection and protein-plus-adjuvant immunization.* Nat Commun, 2015. **6**: p. 6565.

85. Huang, Y., et al., *Use of placebos in Phase 1 preventive HIV vaccine clinical trials.* Vaccine, 2015. **33**(6): p. 749-52.

86. Siddiqui, S., et al., *Tuberculosis specific responses following therapy for TB: Impact of HIV co-infection.* Clin Immunol, 2015. **159**(1): p. 1-12.

87. Ngwuta, J.O., et al., *Prefusion F-specific antibodies determine the magnitude of RSV neutralizing activity in human sera.* Sci Transl Med, 2015. **7**(309): p. 309ra162.

88. Laeyendecker, O., et al., *Antibody Maturation in Women Who Acquire HIV Infection While Using Antiretroviral Preexposure Prophylaxis.* J Infect Dis, 2015. **212**(5): p. 754-9.

89. Herrin, D.M., et al., *Comparison of adaptive and innate immune responses induced by licensed vaccines for Human Papillomavirus.* Hum Vaccin Immunother, 2014. **10**(12): p. 3446-54.

90. Sarwar, U.N., et al., *Homologous boosting with adenoviral serotype 5 HIV vaccine (rAd5) vector can boost antibody responses despite preexisting vector-specific immunity in a randomized phase I clinical trial.* PLoS One, 2014. **9**(9): p. e106240.

91. Enama, M.E., et al., *Phase I randomized clinical trial of VRC DNA and rAd5 HIV-1 vaccine delivery by intramuscular (i.m.), subcutaneous (s.c.) and intradermal (i.d.) administration (VRC 011).* PLoS One, 2014. **9**(3): p. e91366.

92. Roederer, M., et al., *Immunological and virological mechanisms of vaccine-mediated protection against SIV and HIV.* Nature, 2014. **505**(7484): p. 502-8.

93. Pegu, A., et al., *Neutralizing antibodies to HIV-1 envelope protect more effectively in vivo than those to the CD4 receptor.* Sci Transl Med, 2014. **6**(243): p. 243ra88.

94. Sandler, N.G., et al., *Type I interferon responses in rhesus macaques prevent SIV infection and slow disease progression.* Nature, 2014. **511**(7511): p. 601-5.

95. Wentzensen, N., et al., *No evidence for synergy between human papillomavirus genotypes for the risk of high-grade squamous intraepithelial lesions in a large population-based study.* J Infect Dis, 2014. **209**(6): p. 855-64.

96. Rudicell, R.S., et al., *Enhanced potency of a broadly neutralizing HIV-1 antibody in vitro improves protection against lentiviral infection in vivo.* J Virol, 2014. **88**(21): p. 12669-82.

97. Ko, S.Y., et al., *Enhanced neonatal Fc receptor function improves protection against primate SHIV infection.* Nature, 2014. **514**(7524): p. 642-5.

98. Shingai, M., et al., *Passive transfer of modest titers of potent and broadly neutralizing anti-HIV monoclonal antibodies block SHIV infection in macaques.* J Exp Med, 2014. **211**(10): p. 2061-74.

99. Graham, B.S., et al., *DNA vaccine delivered by a needle-free injection device improves potency of priming for antibody and CD8+ T-cell responses after rAd5 boost in a randomized clinical trial.* PLoS One, 2013. **8**(4): p. e59340.

100. Casazza, J.P., et al., *Therapeutic vaccination expands and improves the function of the HIV-specific memory T-cell repertoire.* J Infect Dis, 2013. **207**(12): p. 1829-40.

101. Mahnke, Y.D., et al., *Early immunologic and virologic predictors of clinical HIV-1 disease progression.* AIDS, 2013. **27**(5): p. 697-706.

102. Georgiev, I.S., et al., *Delineating antibody recognition in polyclonal sera from patterns of HIV-1 isolate neutralization.* Science, 2013. **340**(6133): p. 751-6.

103. Seder, R.A., et al., *Protection against malaria by intravenous immunization with a nonreplicating sporozoite vaccine.* Science, 2013. **341**(6152): p. 1359-65.

104. Cheng, C., et al., *Decreased pre-existing Ad5 capsid and Ad35 neutralizing antibodies increase HIV-1 infection risk in the Step trial independent of vaccination.* PLoS One, 2012. **7**(4): p. e33969.

105. Doria-Rose, N.A., et al., *HIV-1 neutralization coverage is improved by combining monoclonal antibodies that target independent epitopes.* J Virol, 2012. **86**(6): p. 3393-7.

106. Yamamoto, T., et al., *Virus inhibition activity of effector memory CD8(+) T cells determines simian immunodeficiency virus load in vaccinated monkeys after vaccine breakthrough infection.* J Virol, 2012. **86**(10): p. 5877-84.

107. Roederer, M., J.L. Nozzi, and M.C. Nason, *SPICE: exploration and analysis of post-cytometric complex multivariate datasets.* Cytometry A, 2011. **79**(2): p. 167-74.

108. Nason, M.W., Jr., et al., *Disrupted activity in the hippocampal-accumbens circuit of type III neuregulin 1 mutant mice.* Neuropsychopharmacology, 2011. **36**(2): p. 488-96.

109. Sandler, N.G., et al., *Plasma levels of soluble CD14 independently predict mortality in HIV infection.* J Infect Dis, 2011. **203**(6): p. 780-90.

110. Yamamoto, T., et al., *Surface expression patterns of negative regulatory molecules identify determinants of virus-specific CD8+ T-cell exhaustion in HIV infection.* Blood, 2011. **117**(18): p. 4805-15.

111. Ledgerwood, J.E., et al., *A West Nile virus DNA vaccine utilizing a modified promoter induces neutralizing antibody in younger and older healthy adults in a phase I clinical trial.* J Infect Dis, 2011. **203**(10): p. 1396-404.

112. Follmann, D. and M. Nason, *An augmented probit model for missing predictable covariates in quantal bioassay with small sample size.* Biometrics, 2011. **67**(3): p. 1127-34.

113. Wu, X., et al., *Rational design of envelope identifies broadly neutralizing human monoclonal antibodies to HIV-1.* Science, 2010. **329**(5993): p. 856-61.

114. Doria-Rose, N.A., et al., *Breadth of human immunodeficiency virus-specific neutralizing activity in sera: clustering analysis and association with clinical variables.* J Virol, 2010. **84**(3): p. 1631-6.

115. Koup, R.A., et al., *Priming immunization with DNA augments immunogenicity of recombinant adenoviral vectors for both HIV-1 specific antibody and T-cell responses.* PLoS One, 2010. **5**(2): p. e9015.

116. Willey, R., et al., *Neutralizing antibody titers conferring protection to macaques from a simian/human immunodeficiency virus challenge using the TZM-bl assay.* AIDS Res Hum Retroviruses, 2010. **26**(1): p. 89-98.

117. Cheng, C., et al., *Differential specificity and immunogenicity of adenovirus type 5 neutralizing antibodies elicited by natural infection or immunization.* J Virol, 2010. **84**(1): p. 630-8.

118. Rao, S.S., et al., *Comparative efficacy of hemagglutinin, nucleoprotein, and matrix 2 protein gene-based vaccination against H5N1 influenza in mouse and ferret.* PLoS One, 2010. **5**(3): p. e9812.

119. Hersperger, A.R., et al., *Perforin expression directly ex vivo by HIV-specific CD8 T-cells is a correlate of HIV elite control.* PLoS Pathog, 2010. **6**(5): p. e1000917.

120. Chen, M., et al., *A flow cytometry-based assay to assess RSV-specific neutralizing antibody is reproducible, efficient and accurate.* J Immunol Methods, 2010. **362**(1-2): p. 180-4.

121. Nason, M. and D. Follmann, *Design and analysis of crossover trials for absorbing binary endpoints.* Biometrics, 2010. **66**(3): p. 958-65.

122. Ruckwardt, T.J., et al., *Regulatory T cells promote early influx of CD8+ T cells in the lungs of respiratory syncytial virus-infected mice and diminish immunodominance disparities.* J Virol, 2009. **83**(7): p. 3019-28.

123. Price, D.A., et al., *Public clonotype usage identifies protective Gag-specific CD8+ T cell responses in SIV infection.* J Exp Med, 2009. **206**(4): p. 923-36.

124. Doria-Rose, N.A., et al., *Frequency and phenotype of human immunodeficiency virus envelope-specific B cells from patients with broadly cross-neutralizing antibodies.* J Virol, 2009. **83**(1): p. 188-99.

125. Proschan, M.A. and M. Nason, *Conditioning in 2 x 2 tables.* Biometrics, 2009. **65**(1): p. 316-22.

126. Rao, S., et al., *Multivalent HA DNA vaccination protects against highly pathogenic H5N1 avian influenza infection in chickens and mice.* PLoS One, 2008. **3**(6): p. e2432.

127. Sheets, R.L., et al., *Biodistribution and toxicological safety of adenovirus type 5 and type 35 vectored vaccines against human immunodeficiency virus-1 (HIV-1), Ebola, or Marburg are similar despite differing adenovirus serotype vector, manufacturer's construct, or gene inserts.* J Immunotoxicol, 2008. **5**(3): p. 315-35.

128. Martin, J.E., et al., *A SARS DNA vaccine induces neutralizing antibody and cellular immune responses in healthy adults in a Phase I clinical trial.* Vaccine, 2008. **26**(50): p. 6338-43.

129. Wu, X., et al., *Soluble CD4 broadens neutralization of V3-directed monoclonal antibodies and guinea pig vaccine sera against HIV-1 subtype B and C reference viruses.* Virology, 2008. **380**(2): p. 285-95.

130. Nason, M.A., J. Farrar, and D. Bartlett, *Strobilurin fungicides induce changes in photosynthetic gas exchange that do not improve water use efficiency of plants grown under conditions of water stress.* Pest Manag Sci, 2007. **63**(12): p. 1191-200.

131. Geldmacher, C., et al., *A high viral burden predicts the loss of CD8 T-cell responses specific for subdominant gag epitopes during chronic human immunodeficiency virus infection.* J Virol, 2007. **81**(24): p. 13809-15.

132. Martin, J.E., et al., *A West Nile virus DNA vaccine induces neutralizing antibody in healthy adults during a phase 1 clinical trial.* J Infect Dis, 2007. **196**(12): p. 1732-40.

133. Seggewiss, R., et al., *Keratinocyte growth factor augments immune reconstitution after autologous hematopoietic progenitor cell transplantation in rhesus macaques.* Blood, 2007. **110**(1): p. 441-9.

134. Catanzaro, A.T., et al., *Phase I clinical evaluation of a six-plasmid multiclade HIV-1 DNA candidate vaccine.* Vaccine, 2007. **25**(20): p. 4085-92.

135. Elloumi, F. and M. Nason, *SEARCHPATTOOL: a new method for mining the most specific frequent patterns for binding sites with application to prokaryotic DNA sequences.* BMC Bioinformatics, 2007. **8**: p. 354.

136. Nason, M., *Patterns of immune response to a vaccine or virus as measured by intracellular cytokine staining in flow cytometry: hypothesis generation and comparison of groups.* J Biopharm Stat, 2006. **16**(4): p. 483-98.

137. Read, S.W., et al., *Decreased CD127 expression on T Cells in HIV-1-infected adults receiving antiretroviral therapy with or without intermittent IL-2 therapy.* J Acquir Immune Defic Syndr, 2006. **42**(5): p. 537-44.

138. Sheets, R.L., et al., *Biodistribution of DNA plasmid vaccines against HIV-1, Ebola, Severe Acute Respiratory Syndrome, or West Nile virus is similar, without integration, despite differing plasmid backbones or gene inserts.* Toxicol Sci, 2006. **91**(2): p. 610-9.

139. Betts, M.R., et al., *HIV nonprogressors preferentially maintain highly functional HIV-specific CD8+ T cells.* Blood, 2006. **107**(12): p. 4781-9.

140. Higgins, J., et al., *Effects of lymphocyte isolation and timing of processing on detection of CD127 expression on T cells in human immunodeficiency virus-infected patients.* Clin Diagn Lab Immunol, 2005. **12**(1): p. 228-30.

141. Nason, M., S. Emerson, and M. LeBlanc, *CARTScans: A Tool for Visualizing Complex Models.* Journal of Computational and Graphical Statistics, 2004.

142. Madigan, D.a.N., M., *Sampling Techniques & Statistics Perspectives on Data and Knowledge*, in *Handbook of Knowledge Discovery and Data Mining*. 2003, Oxford University Press.

143. Madigan, D., Raghavan, N., DuMouchel, W., Nason, M., Posse, C., and Ridgeway, G. , *Likelihood-based data squashing: A modeling approach to instance construction.* Journal of Data Mining and Knowledge Discovery, 2001.

144. Schaffner, A.M., D.; Hunt, E.; Graf, E.; Minstrell, J.; and Nason, M., *Benchmark Lessons and the World Wide Web: Tools for Teaching Statistics*, in *Proceedings of ICLS 96*, D.E.a.E. Domeshek, Editor. 1996, Association for the Advancement of Computing in Education.