

Vaccines SIG News

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How to get in touch

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Steering Committee

- Fabrice Bailleux, Sanofi Pasteur, France.

- Holly Janes, Fred Hutchinson Cancer Research Center, USA.

- Tsai-Lien Lin, FDA, USA.

- Frank Liu, Merck Sharp & Dohme corp., USA

- Larry Moulton, Johns Hopkins University, USA.

- David Radley, Pfizer, USA.

- Scott Patterson, Sanofi Pasteur, USA. (Chair 2019, News Ed. 2019)

- Fabian Tibaldi, GlaxoSmithKline Vaccines, Belgium. (Chair 2020)

- An Vandebosch, Johnson & Johnson, Belgium

From the Vaccines Scientific Interest Group of the Statisticians in the Pharmaceutical Industry (PSI)

(<https://psiweb.org/sigs-special-interest-groups/vaccines>)

Welcome to the second newsletter of the Vaccines Scientific Interest group in 2019. This group exists through the PSI to:

- To create a professional platform for statisticians in the Pharmaceutical industry, Regulatory agencies, and Public Health organizations working on the research and development of vaccines to understand how best to apply methodologies.
- To keep up-to-date, discuss, apply and encourage relevant statistical and methodological developments.
- To encourage professional development.
- To organise (web) seminars and sessions in worldwide conferences on topics related to methodological developments in vaccines research.

The steering committee plans to provide email newsletters three times a year for the information of interested colleagues. **If you have relevant information to be shared with our scientific community please contact any of our steering committee representatives.**

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Disclaimer: The opinions, selections, and summaries of this newsletter reflect the personal opinions of the members of the Vaccines SIG steering committee and do not represent the policies or recommendations of their employing agencies, corporations, or institutions.

Recent and Upcoming Events

There was a session entitled *Causal Inference in Vaccine Trials and Outbreak Investigations: Epidemiologic Study Design and Statistical Analysis* at the ASA Joint Stats Meetings (<https://ww2.amstat.org/meetings/jsm/2019/>). Organizer and chair: Eben Kenah (The Ohio State University). Speakers were Natalie E Dean (University of Florida), Justin O'Hagan (Centers for Disease Control and Prevention), M Elizabeth Halloran (University of Washington and Fred Hutchinson Cancer Research Center), and Forrest W Crawford (Yale School of Public Health) with discussant Michael Hudgens (University of North Carolina at Chapel Hill).

There will be an invited Vaccine Session at the VIth International Symposium on Biopharmaceutical Statistics, August 26-30, 2019, Kyoto, Japan (<https://www2.aeplan.co.jp/isbs2019/index.html>) entitled *Statistical Issues and Methods for Vaccine Development*. Session Organizer: Frank Liu and Jie Chen, Merck. Speakers are Holly Janes (Fred Hutch), Jing Jin (Sanofi), Wenji Pu (GSK), and Bart Spiessens (J&J) with discussant Wenquan Wang (Sanofi Pasteur).

At the FDA-Industry Workshop in September (<https://ww2.amstat.org/meetings/biop/2019/>), a session will be held on *Statistical Considerations in the Evaluation of Vaccine Efficacy and Effectiveness*, Organizer(s): Aiyong Chen (Sanofi Pasteur); Lei Huang (FDA); Kevin Yi (Pfizer). Chair(s): Josh Chen (Sanofi Pasteur). Speakers are Judy Pan (Sanofi Pasteur), John McLaughlin (Pfizer), and Jennifer Kirk (CBER, FDA.)

Update on Special Issue of SBR

The submission deadline for the special issue for Vaccines and Biologics with Statistics in Biopharmaceutical Research (SBR) has been extended to September 30th, 2019. Please select VB2019 if you want to submit a paper online to the special issue. Editors of the Special Issue: Stan Altan (Janssen R&D) and Frank Liu (Merck R&D).

Working Groups

A working group has formed for the purpose of exploring implementation of the ICH E9 addendum on estimands to vaccine clinical trials. There will be joint leadership from regulatory, academia, and industry. Current participants are: Sang Ahnn (Co-lead, CBER, FDA), Holly Janes (Co-lead, Fred Hutch), Larry Moulton (Co-Lead, John Hopkins), Wenquan Wang (Co-chair, Sanofi Pasteur), An Vandebosch (Co-chair, J&J), Jianing Li (Merck), and Brigitte Cheuvart (GSK). If you are interested in contributing, please contact Wenquan Wang at wenquan.wang@sanofi.com for more information.

Recent Publications of Potential Interest (in no particular order)

Pharmaceutical Statistics. (2019); **18**:126–139. Subgroup analysis and interpretation for phase 3 confirmatory trials: White paper of the EFSPI/PSI working group on subgroup analysis.

Statistical Methods in Medical Research. (2019); **28**: 1141–1156. Methods for assessing and controlling placebo effects.

Statistics in Medicine. (2019); **38**: 2524–2543. Randomised trials with provision for early stopping for benefit (or harm): The impact on the estimated treatment effect.

Statistics in Medicine. (2019); **38**: 2561–2572. Level of evidence for promising subgroup findings: The case of trends and multiple subgroups.

Statistics in Medicine. (2019); **38**: 3073–3090. Targeted learning with daily EHR data.

Sci Immunol. (2017); **2**: PMC5800877. Multicohort analysis reveals baseline transcriptional predictors of influenza vaccination responses.

Annals of Applied Statistics. (2019); **3**: 1147-1165. Nonparametric inference for immune response thresholds of risk in vaccine studies.

Statistics in Biosciences. (2019). Likelihood-Based Methods for Assessing Principal Surrogate Endpoints in Vaccine Trials. DOI: 10.1007/s12561-019-09239-1.

Biometrics. (2019). Integer-Valued Functional Data Analysis for Measles Forecasting. DOI: 10.1111/biom.13110.

Therapeutic Innovation & Regulatory Science. (2019). Aligning estimators with estimands in clinical trials: putting the ICH E9(R1) guidelines into practice. DOI: 10.1177/2168479019836979.