Vaccines SIG News

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How to get in touch

If you wish to be on the email distribution list (or to unsubscribe), please contact David Radley (david.radley@pfizer.com).

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 first 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.**

Contents:

Special Issue News

Recent and Upcoming Events

Working Groups

Recent Publications of Potential Interest

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.

Special Issue News

Call for Submissions to Special issue of the Statistics in Biopharmaceutical Research dedicated to Vaccines and Biologics

The editorial board of the Statistics in Biopharmaceutical Research (SBR) journal plans to publish a special issue on Vaccines and Biologics. The special issue is motivated by the recognition that there are many unique statistical issues and challenges in vaccines and biologics development arising from the complex biological nature of these two classes of therapeutic products .

The special issue seeks to publish high quality manuscripts focused on innovative approaches and reviews related to the statistical design, modeling and analysis of clinical and nonclinical studies of vaccines and biologics. Innovative statistical designs in clinical trials, statistical approaches to biosimilarity, especially as relating to regulatory considerations and reviews of the literature are especially welcome, although a broad range of statistical topics is anticipated.

1. The window for submission will be November 1, 2018 – June 30, 2019. Submissions are made through the SBR portal.
2. At the time of the submission of the manuscript, authors are asked to check the VB2019 selection box at Step 1 on the submission page, so the manuscript will be designated for the 2019 Vaccines and Biologics special issue.
3. Manuscripts will go through the standard SBR refereeing process.
4. Goal is to have a set of papers ready for publication in late 2020.

We appreciate your consideration and contributions to make the special issue of the SBR a showcase for cutting edge statistical methods and applications on vaccines and biologics.

Editors: Stan Altan (Janssen R&D) and Frank Liu (Merck R&D).

Recent and Upcoming Events

The 2019 Annual Conference on Vaccinology Research (https://www.eventscribe.com/2019/NFIDACVR/) held a session on Study Design: Statistical Challenges in Vaccinology on 4 April 2019.

There will be an invited Vaccine Session at the VIth International Symposium on Biopharmaceutical Statistics, August 26-30, 2019, Kyoto, Japan. Please see https://www2.aeplan.co.jp/isbs2019/index.html for more information for the conference.
Session Title: Statistical Issues and Methods for Vaccine Development
Session Organizer: Frank Liu and Jie Chen, Merck & Co., Inc., North Wales, PA, USA.
Speakers: 1) Holly Janes, Fred Hutch, Seattle, WA, USA
2) Jing Jin, Sanofi, Beijing, China
3) Wenji Pu, GSK, Rockville, MD, USA
4) Bart Spiessens, J&J, Beerse, Belgium
Discussant: Scott Patterson, Sanofi Pasteur, Swiftwater, PA, USA.

Working Groups

The scientific interest group agreed to form a working group for the purpose of exploring implementation of the ICH E9 addendum on estimands to vaccine clinical trials.

Recent Publications of Potential Interest (in no particular order)

Pharmaceutical Statistics. (2018) **17:** 477-478. Missing data handling in non-inferiority and equivalence trials: A systematic review.

Pharmaceutical Statistics. (2018) **17:** 570-577. Sample size allocation in multiregional equivalence studies.

Biometrics. (2018) **74:** 1271-1281. Estimation of the optimal surrogate based on a randomized trial.

BMC Medical Research Methodology. (2019) **19:** 47. Assessing correlates of protection in vaccine trials: statistical solutions in the context of high vaccine efficacy.

Statistics in Medicine. (2017) **36**(4): 592-605. Designing therapeutic cancer vaccine trials with delayed treatment effect.

Human Vaccines and Immunotherapeutics. (2017) **13**(10): 2357-2363. Postdose 3 G1 serum neutralizing antibody as correlate of protection for pentavalent rotavirus vaccine.

Statistics in Medicine. (2019) **38**(7): 1135-1146. Optimizing and evaluating biomarker combinations as trial-level general surrogates.

Statistics in Medicine. (2019) **38**(7): 1170-1189. A Bayesian design for phase I cancer therapeutic vaccine trials.

Journal of the American Medical Association. (2019) **321**(4): 341-342. The Role of the Advisory Committee on Immunization Practices in Ensuring Optimal Use of Vaccines.