

Vaccines SIG News

May 11, 2020

Volume 2020-1

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.

Fabian Tibaldi,
*GSK Vaccines, Belgium.
(Chair 2020)*

An Vandebosch,
*Johnson & Johnson,
Belgium*

Ad Theeuwes
*Seqirus – A CSL Company
The Netherlands*

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 2020. 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:

- COVID-19 and the Conferences, Meetings, and Workshops
- Vaccine Workshop in 2020 ASA
- Upcoming vaccines sessions at statistical and other conferences
- Recent publications in the field of statistics of vaccines research
- Website, Unsubscribe etc., Contact us

Vaccines Statistics Newsletter from the SIG of PSI

Newsletter
11 May 2020

Dear colleagues,

Here's the latest news on the statistics of vaccines research from the SIG team of the PSI.

In this issue:

- [COVID-19 and the Conferences, Meetings, and Workshops](#)
- [Vaccine Workshop in 2020 ASA](#)
- [Upcoming vaccines sessions at statistical and other conferences](#)
- [Recent publications in the field of statistics of vaccines research](#)
- [Website, Unsubscribe etc., Contact us](#)

A Message About COVID-19 and the Conferences, Meetings, and Workshops

The different organizing groups of future events are closely monitoring the spread of COVID-19 and its implications for conferences, meetings, and workshops. As the situation evolves daily, they are looking into solutions and options and they will provide information as they have it. Questions about potential delays or cancelations should be checked directly in their internet's sites.

Vaccine Workshop in 2020 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop

The ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop will be held from September 23 to 25 in Bethesda North Marriott Hotel & Conference Center 5701 Marinelli Road, Rockville, MD 20852.

There is a vaccine related Session, the information is included below:

Statistical Innovations and Practices in Vaccine Development

Vaccines have been playing a critical role in public health through prevention of infectious diseases. An effective vaccine could prevent serious diseases, reduce disease burden on families and communities, or even eradicate diseases (e.g. smallpox). Vaccine research and development have been and will be important in this everchanging world. In developing new vaccines and managing life cycles of existing vaccines, new challenges keep emerging, and innovations are following.

As an integral part of the vaccine development, statisticians also come up with innovations in study designs and analysis methodologies. Speakers from academia, industry and government will share their experiences with some of the following innovations in solving challenges in vaccine development: biomarker assessment (correlates of risk and correlates of protection)

especially for first-in-class vaccines; bridging of vaccine efficacy to new settings; multiplicity challenges in multivalent vaccines (multiple serotypes of a pathogen) or due to co-administration with routine vaccines that results in testing of many hypotheses to show non-inferiority of the routine vaccines with vs. without investigational vaccine; evaluation of effects for new serotypes added on top of an existing vaccine; real world data/evidence implementation (e.g. hybrid trial design); application of estimands in vaccine trials to address intercurrent events; and safety assessment/monitoring.

Chair: Josh Chen (Sanofi)

Organizers: Frank Liu (Merck), Lihan Yan (FDA CBER) and Wenquan Wang (Sanofi)

Potential speakers for the session include, to be confirmed

Dr. Peter Gilbert, Fred Hutch

Dr. Lihan Yan, CBER, FDA

Dr. Judy Pan, Sanofi Pasteur

Dr. Jianing Li, Merck & Co., Inc.

Upcoming Vaccines Sessions at Statistical and Other Conferences

Aug. 6, 2020

JSM 2020: Joint Statistical Meeting Philadelphia. (Virtual Conference) Session 614 on Thursday, August 6th.

Recent advances in vaccine dose and regimen finding

<https://www2.amstat.org/meetings/jsm/2020/onlineprogram/index.cfm>

Organizer(s): Robert D Small, Dr.

Chair(s): Ayca Ozol-Godfrey, Sunovion Pharmaceuticals

Some adaptive methods for vaccine dose-finding.

James Bolognese, Cytel Inc.

Considerations in vaccine dose-finding studies

Aiyong Chen, sanofi Pasteur; Scott Patterson, Sanofi Pasteur ; Fabrice

Bailleux, Sanofi Pasteur; Tiffany Machabert, Sanofi Pasteur

Model Informed Development in Vaccines Immunizes Against Choosing Poor Vaccine Candidates and/or Non-informative Dose-levels

Radha Raikar, Merck & Co., Inc.; Jeff Sachs, Merck; Jos Lommerse,

Certara; Nele Mueller-Plock, Certara; S.Y. Amy Cheung, Certara; Brian

Maas, Merck; Luzelena Caro, Merck; Antonios Aliprantis, Merck; Kalpit

Vora, Merck; Amy Espeseth, Merck; Andrew Lee, Merck

Sept. 17-18, 2020

FDA Public Workshop for Real World Evidence

will be held September 17-18, 2020 (Virtual Conference)

A useful **calendar of statistical conferences** is managed by the International Statistical Institute at <https://www.isi-web.org>

If you are organizing or know of a vaccines or infectious disease session or presentation at an upcoming statistics conference, or a statistics session at a vaccines or infectious disease conference, please email details to us so it may be included in future issues of the newsletter and on our SIG's website.

Recent Publications in the Field of Statistics of Vaccines Research (in no particular order)

Statistics in Medicine. (2020) 39(3):220-238. Ecological inference for infectious disease data, with application to vaccination strategies.

Statistics in Medicine. (2019) 38:5603–5622. Confidence, prediction, and tolerance in linear mixed models

Pharmaceutical Statistics. (2020);1–12. Designing cancer immunotherapy trials with delayed treatment effect using maximin efficiency robust statistics

Statistics in Biopharmaceutical Research (2020) Bayesian Approaches on Borrowing Historical Data for Vaccine Efficacy Trials

Statistics in Biopharmaceutical Research (2020) Imbalanced Randomization in Vaccine Clinical Safety Trials

Statistics in Biopharmaceutical Research (2020): Confidence and Prediction in Linear Mixed Models: Don't Concatenate the Random Effects. Application in an Assay Qualification Study

Book : Statistics in Clinical and Observational Vaccine Studies (2020) Springer Series in Pharmaceutical Statistics

If you are an author of or know of a recent publication relevant to the statistics of vaccines research, please email us to fabian.tibaldi@gsk.com so it may be included in the newsletter and on the website.

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. All team members provided their backgrounds and contributed ideas after a team meeting late last year. The next step is to summarize the ideas and to finalize the scope for the working group in May 2020. For more information about this group contact Wenquan.Wang@sanofi.com

Website

The SIG's website at <https://psiweb.org/sigs-special-interest-groups/vaccines> contains information on upcoming events in the field of statistics of vaccines research as well as archives of material from the newsletter.

Remove/Add your Name and Spam Blockers.

To add a name to the mailing list, update your address or remove your name email please send an email to David.Radley@pfizer.com.

Some newsletters have bounced apparently due to over-enthusiastic spam blockers.

- check with your colleagues that they have also received this newsletter
- set your spam blocker to allow messages from iscb-vaccines.info

Contact Us

If you would like to contact us regarding the activities of these SIG, email any of the committee members or visit our 'contact us' page at <https://psiweb.org/sigs-special-interest-groups/vaccines>

With best regards,

Vaccines Special Interest Groups (SIGs) of the Statisticians in the Pharmaceutical Industry (PSI)

Disclaimer

The opinions, selections and summaries in this newsletter reflect the personal opinions of the members of the sub-committee and do not represent the policies or recommendations of their employing agencies, corporations or institutions.