

# 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 third newsletter of the Vaccines Statistics 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.**

***Editor's Note: Fabian will chair the 2020 Vax-SIG. Best Wishes, Scott Patterson***

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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 an invited Vaccine Session at the VIth International Symposium on Biopharmaceutical Statistics, August 26-30, 2019, Kyoto, Japan entitled *Statistical Issues and Methods for Vaccine Development*

At the FDA-Biopharmaceutical Section Regulatory-Industry Statistics Workshop in September 2019, a session was held on *Statistical Considerations in the Evaluation of Vaccine Efficacy and Effectiveness*.

Contributed vaccines sessions are being prepared for the American Statistical Association Joint Statistics Meeting (Philadelphia, August 1-6, 2020) and for the FDA-Biopharmaceutical Section Regulatory-Industry Statistics Workshop (Washington DC, September 23-25, 2020.)

A stand-alone vaccines statistics conference is being planned for the second week of October, 2020 in Belgium.

Look out for more news on these and other upcoming events in the new year.

## Working Groups

The academic-industry-regulatory working group has formed for the purpose of exploring implementation of the ICH E9 addendum on estimands to vaccine clinical trials and is developing its plan for working together.

## Recent Publications of Potential Interest (in no particular order)

Issue 4 of *Statistics in Biopharmaceutical Research* in 2019 is a special issue devoted to Adaptive Designs.

Vaccine <https://doi.org/10.1016/j.vaccine.2019.09.034>

ADVANCE System Testing: Benefit-risk analysis of a marketed vaccine using multi-criteria decision analysis and individual-level state transition modelling.

BMC Med Res Methodol. 2019 Mar 6;19(1):47.

Assessing correlates of protection in vaccine trials: statistical solutions in the context of high vaccine efficacy.

Biom J. 2019 Jan;61(1):162-165.

A note on tests for relevant differences with extremely large sample sizes.

Stat Methods Med Res. 2019 Mar;28(3):953-961.

Futility for subgroup analyses in the adaptive signature design.