

## Scientific Committee

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Bruno FALISSARD      Université Paris Sud

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Luc BIJNENS      Johnson and Johnson  
Frank BRETZ      Novartis  
Peter BÜHLMANN      ETH Zurich  
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Jelle GOEMAN      LUMC  
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## Organizing Committee

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Philippe SAINT-PIERRE      Université Toulouse III  
Michel VAILLANT      LIH  
Françoise VEYRIAC      Lincoln & Aixial  
Laurence WATIER      INSERM

All information will be available on the Web site:

[www.smb2017.fr](http://www.smb2017.fr)

This meeting will focus on the latest progress in selected statistical topics of high relevance to clinical drug development.

The Scientific Committee, chaired by Pr Bruno FALISSARD, has identified four areas of research that may change the face of clinical drug development in the near future:

- . **Regulatory statistics and beyond**
- . **Statistical inference in biostatistics of the XXI<sup>st</sup> century**
- . **Successful marriage between bioinformatics and biostatistics**
- . **Recurrent event analyses**

Contributed papers will be welcome for an oral presentation if they are relevant to any of these areas, or as a poster presentation if they describe unrelated but innovative research on clinical drug development.

All invited and selected papers may be submitted for publication in a special issue of Statistics in Medicine.



INTERNATIONAL MEETING  
Statistical Methods in Biopharmacy

*"THE FUTURE OF BIOSTATISTICS  
IN AN EMERGING WORLD  
OF DATA SCIENCES"*



2017  
September  
14 - 15

NEW CAP  
Event Center  
1-13 quai de Grenelle  
PARIS





**DAY 1: Thursday 14 September, 2017**

### Regulatory statistics and beyond

Biological treatments with clear-cut mechanism of action, small targeted populations challenge the way regulatory authorities evaluate drugs. Post approval, including market access and pricing implies studies, data and analyses that differs substantially from the routine of large phase 3 randomized controlled trials.

**Bruno FALISSARD,**

Université Paris Sud

*Post-approval appraisal: What are the main methodological issues?*

**Stephen J. RUBERG,** Eli Lilly and Company

*Disruptive approaches for clinical trials pre- and post-approval*

### Statistical inference in biostatistics of the XXI<sup>st</sup> century

Statistical inference is the corner stone of biostatistics. The quiet situation that characterized the end of the XX<sup>th</sup> century, with the prominence of the very orthodox Neyman-Pearson background, is now over. Even if this important change has been due, in part, to the rise of omics data and of the Bayesian perspective, new research put some interesting light on this crucial question.

**Hans van HOUWELINGEN,** LUMC

(Leiden University Medical Center)

*The future of biostatistics: Robust prediction!*

**Antoine CHAMBAZ,** Université Paris Ouest

*The future of biostatistics: Targeted learning in action*

## “THE FUTURE OF BIOSTATISTICS IN AN EMERGING WORLD OF DATA SCIENCES”

**DAY 2: Friday 15 September, 2017**

### Successful marriage between bioinformatics and biostatistics

Biostatistics was not traditionally involved in data sets counting more than millions of variables, so that omics data opened the door to "newcomers" among which bioinformatics professionals. There is a need to think a global framework in which a marriage between bioinformatics and biostatistics can be considered. Practical examples will surely help to think such framework.

**Jean-Philippe VERT,**

Institut Curie, Mines ParisTech & ENS Paris

*Identifying predictive biomarkers in high-dimensional genomic data from randomized clinical trials*

**Jelle GOEMAN,** LUMC (Leiden University Medical Center)

*New directions in multiple testing of biomarkers: Flexible approaches with rigorous control*

### Recurrent event analyses

Cancer, HIV, cardiac or psychiatric diseases are now most often chronic situations. Outcomes collected in trials have thus changed and, most often, they can no more be considered as simply as "success or failure". This raises the question of "recurrent event analysis", a technical but well formulated problem for which many solutions do exist now.

**Richard COOK,** University of Waterloo

**Yujie ZHONG,** University of Cambridge

*Marginal and partially conditional analysis of recurrent events in clinical trials*

**Mouna AKACHA,** Novartis

*Are we making good use of our data: Moving beyond time-to-event data*

### Venue

Métro: Bir Hakeim (line 6)  
RER C: Champ-de-Mars / Tour Eiffel

### Organization

The conference will be organized with four plenary sessions and two sessions dedicated to poster presentations (exclusively size landscape). Each plenary session will alternate invited and contributed papers. Three contributed papers related to each area of interest will be selected for oral presentation. Two poster sessions will present a limited number of selected contributed papers.

The working language will be English (papers, posters and oral presentations).

### Key Dates

Opening of abstract submission ..... November, 2016  
Deadline for abstract submission.....28 February, 2017  
Notification of abstract acceptance..... 31 May, 2017  
Submission of final presentation.....31 August, 2017  
Submission of papers for publication..... November, 2017

Opening of registration ..... November, 2016  
Deadline for early registration..... 1 June, 2017

### Registration Fees

	Reduced*	Standard
	<u>Before 1 June, 2017</u>	
Academic	350€	420€
Non Academic	650€	720€
	<u>After 1 June, 2017</u>	
Academic	450€	520€
Non Academic	850€	920€
Student	80 € **	150 € **

\* Reduced prices for

- SFdS Members

- Selected speakers and posters (early registration fees)

\*\* Student with document in proof.