

Final Announcement: "Statistical challenges in the clinical development of CAR-T cell therapies"

March 22, 2021

Virtual seminar

15:00 – 18:00 CET

Developing CAR-T Cell therapies has unique challenges not observed with traditional drugs. On top of the manufactory and logistical challenges, clinical development is facing unique statistical questions which need to be resolved for delivering the treatment effect.

The Basel Biometric Section (BBS) is pleased to host a scientific meeting on this relevant and far-reaching topic. The purpose is to bring together experts from the pharmaceutical industry, academia and the European and US regulatory bodies to present the current state of the art and discuss the statistical and other challenges and opportunities of CAR-T cell therapies.

Organizing committee:

Simon Newsome (Novartis), Fred Sorenson (Xcenda), Roland Marion-Gallois (BMS)

Final Agenda *

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| 15:00-15:10 | Welcome and Introduction - Roland MARION-GALLOIS, BMS, Switzerland |
| 15:10-15:25 | Introduction to Cell Therapies: A Clinical Perspective Caroline ARBER BATH, CHUV, Switzerland |
| 15:25-15:40 | Perspective from EMA Elina ASIKANIUS, FIMEA, Finland |
| 15:40-15:55 | Perspective from FDA Zhenzhen XU, FDA, USA |
| 15:55-16:10 | Phase 2 / Phase 3, Treatment effect or therapeutic strategy effect? Khadija RANTELL, MHRA, UK |
| 16:10-16:25 | Phase 2 / Phase 3, Estimands in the context of cell therapy development Alessandro PREVITALI, BMS, Switzerland |
| 16:25-16:40 | Challenges for new CAR-T therapies Nigel YATEMAN, Novartis, Switzerland |
| 16:40-16:50 | 10-minute break |
| 16:50-17:05 | Introduction on Post-Approval challenges, reimbursement and HTA assessments Oriana CIANI, Università Bocconi, Italy |
| 17:05-17:20 | HTA-Perspective on the assessment of CAR-T-Cell Therapies Andrea SMITH, G-BA, Germany |
| 17:20-17:35 | CAR-T cell therapy registries Marcelo PASQUINI and Zhenuan HU, CIBMTR, USA |
| 17:35-17:55 | Panel discussion moderated by Oriana CIANI including all speakers and Daniel LI, BMS, USA Frank PETAVY, EMA, NL |
| 17:55 | Close-out summary |
| 18:00 | End of the meeting |

* titles of presentation may be modified by the speakers.



Venue

Virtual seminar.

The event is for free.

Registration

Please register via the following link

[Click here to Register](#)

Questions for Q&A

Please send questions for the panel discussion to

Simon Newsome
Simon.newsome@novartis.com

or

Fred Sorenson
fred.sorenson@xcenda.com

or use the chat room during the meeting.