

# Statistical Challenges in the Clinical Development of CAR-T Cell Therapies

**Monday, March 22, 2021**  
**15:00 to 18:00 (CET)**

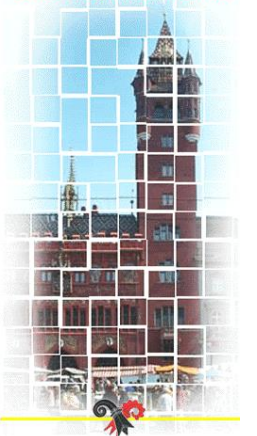


# Webinar introduction

On behalf of the Organizing Committee:

- Roland MARION-GALLOIS (BMS, Boudry, Switzerland)
  - Simon NEWSOME (Novartis, Basel, Switzerland)
  - Fred SORENSON (Xcenda, Basel, Switzerland)
  - Bibiana BLATNA (Novartis, Basel, Switzerland)
- 
- Meeting rules
  - BBS
  - Agenda

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# Meeting rules

- On time
- Switch-off micros and cameras / preserve network bandwidth
  - Only the speaker is on
- Questions to be asked via the chat room
- Q&A pushed to the panel discussion

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# Basel Biometrics Society

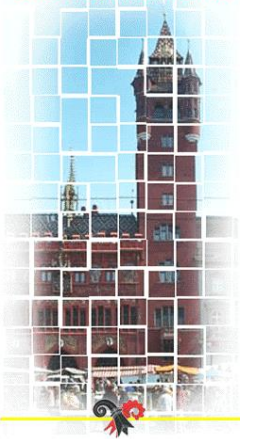
A section of the Swiss Austrian biometric society (ROeS), a member of the International Biometrics Society (IBS)

BBS is an independent, non-profit organization which provides a forum for discussions of how to apply statistical methods in biological and medical science

BBS is a Swiss scientific society, member of the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI)

BBS council is chaired by Hans Ulrich BURGER (Roche, Basel)

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# Agenda

15:10: Introduction to CAR-T Cell Therapies: a clinical perspective

*Pr. Caroline ARBER BARTH, CHUV, Lausanne*

15:25: A perspective from EMA

*Elina ASIKANIUS, FIMEA*

15:40: A perspective from FDA

*Zhenzhen XU, FDA*

15:55: Challenges and opportunities: perspective from MHRA

*Khadija RANTELL, MHRA*

16:10: Estimands in the context of cell therapy development

*Alessandro PREVITALI, Bristol Myers Squibb, Boudry*

16:25: Challenges for new CAR-T therapies

*Nigel YATEMAN, Novartis*

16:50: Introduction on Post-Approval challenges, reimbursement and HTA

*Oriana CIANI, Università Bocconi, Milano*

17:05: HTA-Perspective on the assessment of CAR-T-Cell Therapies

*Andrea SMITH, G-BA*

17:20: Registries

*Marcelo PASQUINI + Zhenuan (Kenny) HU, CIBMTR*

17:35: Panel discussion moderated by Oriana CIANI

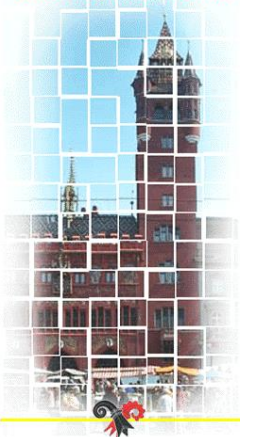
*ALL speakers +*

*Daniel LI (Bristol Myers Squibb) + Frank PETAVY (EMA)*

17:55: Close out summary

16:40-16:50 10-min break

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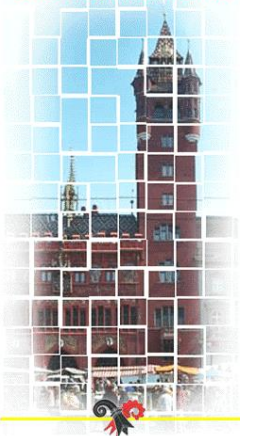
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# Introduction to CAR-T Cell Therapies: a clinical perspective

Pr Caroline ARBER BARTH

CHUV, Lausanne

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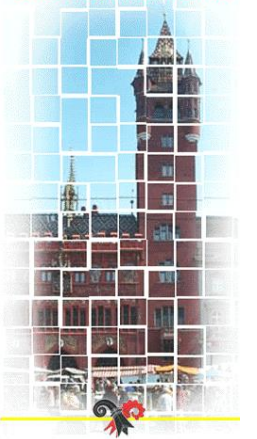
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# A perspective from EMA

Elina ASIKANIUS

FIMEA

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# A perspective from FDA

Zhenzhen XU

FDA



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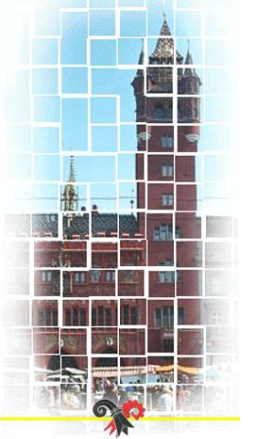
# Challenges and opportunities: Perspective from MHRA

Khadija RANTELL

MHRA

[Link to slides](#)

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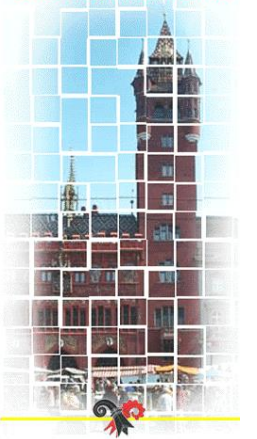
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# Estimands in the context of cell therapy development

Alessandro PREVITALI

Bristol Myers Squibb, Boudry

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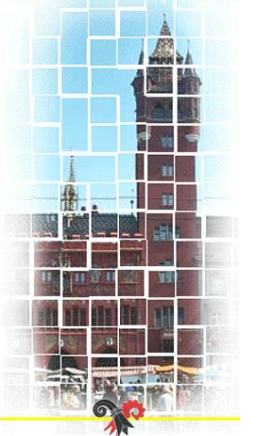
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# Challenges for new CAR-T therapies

Nigel YATEMAN

Novartis, Basel

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# Statistical Challenges in the Clinical Development of CAR-T Cell Therapies

**Break time**



**Restart at 16:50 CET**



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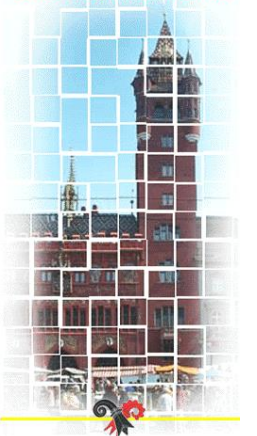
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# Introduction to Post-Approval challenges, reimbursement and HTA

Oriana CIANI

Università Bocconi, Milano

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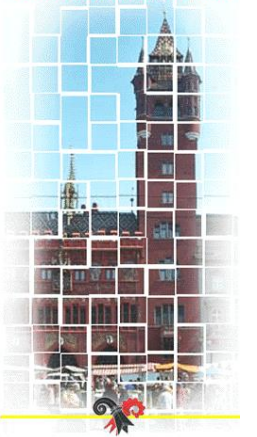
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HTA perspective

Andrea SMITH

Gba

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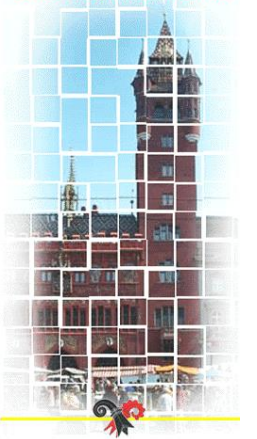
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# Registries

Marcelo PASQUINI + Zhenuan (Kenny) HU

CIBMTR

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## Panel discussions

Moderated by

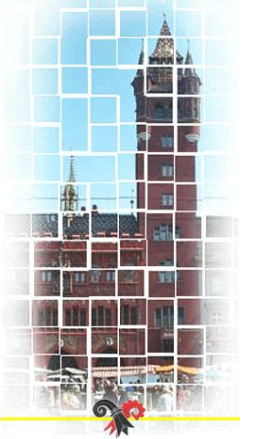
Oriana CIANI, Università Bocconi, Milano

All presenters +

Daniel LI, Bristol Myers Squibb

Frank PETAVY, EMA

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