Final Announcement with Agenda:

"Pre-approval and Post-approval Challenges in the Clinical Development and Reimbursement of CAR-T Cell Therapies"

Wednesday, October 4, 2023 & Thursday, Oct. 5, 2023 (15:00-17:00 CEST both days)

Meeting Agenda

Day 1 – Pre-Approval Challenges:

15:00-15:10 ***Welcome and Introduction***
Roland MARION-GALLOIS (Director Statistics, Cell Therapies, Medical Affairs, BMS, Switzerland)

15:10-15:35 ***CAR-T regulatory and clinical development considerations: perspectives for today and the future***
Manisha PATEL (Global Program Regulatory Director, Novartis, USA)

15:35 -16:00 ***CAR T-cell Therapies: Challenges, Lessons Learned, and Implications for Future Studies***
Revathi ANANTHAKRISHNAN (Dir. Biostatistics, Cell Therapies CD, BMS, USA)

16:00 -16:25 ***Statistical considerations for CAR-T cell development – Updates from an European regulator's perspective***
Benjamin HOFNER (Head of Data Science and Methods, PEI, Germany / Statistical Assessor, EMA, Netherlands)

16:25 -16:55 ***Panel discussion on pre-approval statistical challenges moderated by***
Aiesha ZIA (Associate Director, Cell Therapy Biostatistics, Novartis, Switzerland)
including the 3 speakers above, and in addition
Elina ASIKANIUS (Statistical Assessor FIMEA/PEI & EMA, Finland/Germany)
Khadija RANTEL (Statistical Assessor, MHRA, UK)
Boguang ZHEN (Statistical Assessor, FDA, USA)

16:55-17:00 **Close-out and end of the meeting**
Aiesha ZIA (Novartis)

BBS
Basel Biometric Society

Venue

Free BBS Webinar

Please click on link below

Register for BBS webinar on CAR-T cell therapies 2023

For information regarding the scientific content, please feel free to contact any one of the webinar organizers:

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"Pre-approval and Post-approval Challenges in the Clinical Development and Reimbursement of CAR-T Cell Therapies"

Meeting Agenda
Thursday, Oct. 5, 2023
Day 2 – Post-Approval Challenges:

15:00-15:10 ***Introduction and Summary from the previous day's session***
Alessandro PREVITALI (Associate Director, Cell Therapy Biostatistics, BMS, Switzerland)

15:10 -15:35 ***Lessons learnt from long-term outcomes of CAR T therapies, HTA and RWE evidence implications***
Sachin VADGAMA (Health Economist, Kite, a Gilead company, HEOR Centre of Excellence, UK) and **Francis NISSEN** (Director Medical Affairs – RWE, Kite, a Gilead company, Switzerland)

15:35 -16:00 ***RWE generation for CAR-Ts – Payers' evolving approaches***
Karen FACEY (Sr Advisor & Sr Research Fellow, RWE4Decisions & Univ. of Edinburgh, UK)

16:00 -16:25 ***RWE data: EBMT Registry, Data collection and Use of Data (in PASS)***
Anja van BIEZEN (EBMT, Netherlands)

16:25 -16:55 ***Panel discussion on post-approval challenges moderated by***
Fred SORENSON (Assistant Director, Global Market Access & Support, Cencora/ Xcenda, Switzerland*) including the 4 speakers above, and in addition*
Patrice VERPILLAT (Head of Real World Evidence, EMA, Netherlands)
Roland MARION-GALLOIS (Dir. Statistics, Cell Therapies, Medical Affairs, BMS, Switzerland)
Payer representative (to be confirmed

16:55-17:00 **Close-out and end of the meeting**
Fred SORENSON (Cencora/Xcenda)

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Short Summary of the BBS Webinar

"Pre-approval and Post-approval Challenges in the Clinical Development and Reimbursement of CAR-T Cell Therapies"

Developing CAR-T cell therapies, and cell and gene therapies in general, have unique challenges not observed with traditional drugs.

In light of the progress in cell therapy development, innovative development strategies need to be explored to accelerate development of the next generation of cell therapy products. On top of the crucial manufactory and logistical challenges, clinical development of CAR-Ts is facing unique statistical questions leading to authorization which need to be resolved for delivering the full treatment effect. Additionally, health care systems and payers face challenges associated with pricing and reimbursement that has resulted in the need for long-term registry studies designed to optimize treatment as well as provide a basis for outcomes-based agreements.

The Basel Biometric Section (BBS) is pleased to host a 2-day scientific meeting on this relevant and far-reaching topic by bringing together experts from the pharmaceutical industry, academia and the European/US regulatory bodies and health technology assessment (HTA) agencies and payers to present the current state of the art and discuss the statistical and other challenges and opportunities of CAR-T cell therapies.

The 1st day of the webinar (Oct. 4) will concentrate on the pre-approval challenges and the 2nd day (Oct. 5) on the post-authorization challenges. The final announcement, expected to come out in mid-September, will include the full agenda along with the titles of the talks, which on both days will be concluded with a panel discussion.

As additional background, please feel free to view the recording and presentations from the webinar the BBS held in 2021 on the same subject provided in the link below:

https://baselbiometrics.github.io/home/docs/events_past.html#bbs-webinar-statistical-challenges-in-the-clinical-development-of-car-t-cell-therapies