2nd Announcement with Invited Speakers and Panelists:

"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)

Free BBS Webinar

Confirmed speakers and panelists to date include:

Day 1 - Pre-Approval Challenges:

Elina ASIKANIUS, Biostatistician (FIMEA & EMA Methods Working Party, Finland)

Revathi ANANTHAKRISHNAN, Director Cell Therapy Biostatistics (BMS, USA)

Benjamin HOFNER (Paul Ehrlich Institute / European Medicines Agency, Germany and Netherlands)

Manisha PATEL, Global Program Regulatory Director (Novartis, USA)

Khadija RANTEL, Statistical Assessor (MHRA, UK)

Boguang ZHEN (FDA, USA)

Other potential speakers and/or panelists still TBC

Day 2 - Post-Approval Challenges:

Karen FACEY, Senior Advisor and Senior Research Fellow (RWE4Decisions & Univ. of Edinburgh, UK)

Konstantinos LYKOPOULOS, Executive Director – Value and Access (Kite, a Gilead Company, UK)

Roland MARION-GALLOIS, Director Biostatistics (BMS, Switzerland)

Francis NISSEN, Director Medical Affairs – Real World Evidence (Kite, a Gilead Company, Switzerland)

Patrice VERPILLAT, Head of Real World Evidence (European Medicines Agency, NL)

Other potential speakers and/or panelists still TBC

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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The full agenda along with the titles of the presentations will be sent out as a final announcement in mid-September.

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 needs 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