



CDDF MULTI-STAKEHOLDER WORKSHOP

Current and Future Challenges of Innovative Oncology Drug Development



Innsbruck, Austria
26 - 28 February 2018

PROGRAMME



Day 2 Tuesday 27th February 2018

PLENARY SESSION 3: RARE CANCERS

- 09:00 **Rare Cancers Overview**
Jolanda De Vries (Radboud Institute for Molecular Life Sciences, NL)
- 09:20 **Case Study**
- 09:40 **European Initiatives**
- 10:00 **Statistical Aspects of Drug Development for Rare Cancers**
Lindsay Renfro (Mayo Clinic Rochester, USA)
- 10:20 **European Regulatory Perspective**
- 10:40 **US Regulatory Perspective**
- 11:00 **Industry Perspective**
- 11:20 **Academic Perspective**
- 11:40  **Roundtable discussion**
- 12:10  **Lunch**

PLENARY SESSION 4: PATIENTS' REPORTED OUTCOMES IN ONCOLOGY PATIENT-CENTERED DRUG DEVELOPMENT: OPPORTUNITIES & CHALLENGES

Co-chair: *Eva Skovlund*

Aim is to have a collaborative, insightful discussion. Each speaker can choose one or two topics and will be part of the panel.

- Trial design (i.e., blinding clinical trials, PROs in the testing hierarchy to inform symptomatic improvement, delayed symptomatic progression or functional impact)
- Selection of PRO dimensions (i.e., symptoms, physical function, health related QOL), instruments (i.e., EORTC, FHS, EQ5D), scales (i.e., tumor specific, general health)
- Opportunities and challenges with tailoring PRO data collection (e.g. Questionnaires) to meet oncology clinical development plans
- Challenges with PRO analysis, e.g. missing data, inferential analyses

13:10 **Spotlight presentations on selected topics:**

- Daniel O'Connor (MHRA, UK)
- Amylou Dueck (Mayo Clinic, USA)
- Sarah Bobiak (Merck, USA)
- Dan Danielson (Premara, USA)



15:00 **Roundtable / Panel Discussion**

15:30 Closing remarks

15:40  **Coffee break**

PLENARY SESSION 5: GETTING BIOMARKERS INTO THE MARKET

Co-Chair: Heinz Zwierzina

- 16:10 **Critical current assessment on companion diagnostics**
- 16:30 **Case Study**
- 16:50 **Regulatory Perspective**
- 17:10 **Industry Perspective**
- 17:30 **Payer's Perspective**
- 18:00  **Roundtable discussion**
- 18:30 End of day 2
- 19:30  **Networking event**
@Interalpen Hotel Restaurant

Day 3 Wednesday 28th February 2018

PLENARY SESSION 6: CELL THERAPY

- 09:00 **Clinical-case examples**
- 09:20 **Challenges with CAR T cells: a European regulatory perspective**
Martina Schussler-Lenz (Paul-Ehrlich-Institut, Germany)
- 09:40 **Clinical Considerations for Cancer Cell Therapy: US Regulatory Perspective**
Ke Liu (FDA, USA)
- 10:00 **Technical Development**
Mark Lowdell (Centre for Cell, Gene & Tissue Therapeutics, UK)
- 10:20 **Data from Lymphoma Pivotal Study and pALL study**
Oezlem Anak (Novartis, Switzerland)
- 10:40 **Early CAR-T development experience from an academic perspective**
- 11:00  **Roundtable discussion**
- 11:30 Concluding remarks
- 12:00 End of the meeting & lunch



Event Outline

The Alpine conference is a unique forum organised by the Cancer Drug Development Forum that convenes every 18 months and gathers the leaders in the world of innovative cancer therapy development.

The 10th edition will take place from 26 to 28 February 2018, in Innsbruck, Austria. This multi-stakeholder, interactive meeting will offer small group lectures with moderated discussions, plenary lectures including case studies and networking opportunities.

The programme will focus on the latest and future challenges with a special emphasis on biomarkers, cell therapy, rare cancers, patients' reported outcomes, clinical trial design and horizontal drug development.

Programme Committee

- Jaap Verweij (Erasmus MC, The Netherlands)
- Sonia Garcia Perez (AEMPS, Spain)
- Heinz Zwierzina (CDDF, Austria)
- Davy Chiodin (AstraZeneca, USA)
- Marnix Bosch (Northwest Biotherapeutics, USA)

Participants will

- discuss the current and future challenges of innovative oncology drug development
- address these highly relevant issues and their impact on the regulatory environment
- benefit from small group lectures, interactive and moderated discussions, and plenary lectures including case studies
- network with a multi-stakeholder audience of oncology experts.

Who should attend

Academics, regulators from European and international bodies, representatives from the pharmaceutical industry, policy makers, HTAs, the patients' advocacy community.



Networking dinners

Welcome Reception and dinner on 26th February 2018

Networking event on 27th February 2018

Conference venue

Interalpen Hotel Tyrol

Doktor-Hans-Liebherr-Alpenstraße 1

6410 Telfs-Buchen/Seefeld

Austria

