



CDDF MULTI-STAKEHOLDER WORKSHOP

Innovation in Oncology Clinical Trial Design

Frankfurt, Germany
12–13 June 2017

PROGRAMME



PROGRAMME

Day 1 Monday 12 June 2017

12:30 Welcome Reception

13:00 Introduction

SESSION 1: OPPORTUNITIES AND CHALLENGES WITH CLINICAL TRIAL DESIGN FOR EARLY AND ACCELERATED DEVELOPMENT PLANS

Chairs: Jaap Verweij and Stefan Schwoch

13:10 **Introduction to opportunities and challenges with Clinical Trial Design**
Jaap Verweij (Erasmus MC)

13:20 **Current challenges and opportunities with CTs in oncology - a regulatory agency point of view**
Blanca Garcia Ochoa (EMA SAWP, AEMPS)

13:40 **Current challenges and opportunities with CTs in oncology – an industry point of view**
Stefan Schwoch (Lilly)

13:50 **Innovations and combinations for novel anticancer strategies**
Axel Hanauske (Lilly)

14:40 **Example of a multistage early clinical trial design**
Friedrich Graf Finckenstein (F. Hoffmann La Roche Ltd)

14:55 **Present on Basket of Baskets or other clinical trials to show relevance of innovative trial design today**
Irene Braña Spain (Vall d'Hebron Institute of Oncology, VHIO)

15:20 **Innovative Oncology Study Designs – industry experience and case studies**
Volker Wacheck (Lilly)

15:45  **Panel discussion: Overcoming challenges during CTA review and approval**
All speakers and Trine Stissing (Danish Medicines Agency)

16:30  Coffee break

SESSION 2 : INNOVATIVE CLINICAL TRIAL DESIGNS TO ACCELERATE DEVELOPMENT AND APPROVAL

Chairs: John Smyth and Irmela Radtke

17:00 **Early decision making**
Heiko Goette (Merckgroup)

17:20 **Possibilities and risks associated with directly moving from Phase I to Phase III: An opportunity for adaptive designs?**
Dominik Heinzmann (F. Hoffmann-La Roche Ltd)

- 17:40 **Current statistical considerations and regulatory perspectives on the planning of basket/ umbrella trials and on the integration of historical controls**
Olivier Collignon (Luxembourg Institute of Health, seconded national expert to the EMA)
- 18:10 **Heterogenous populations: subgroup analyses for survival benefit (and enrichment potential)**
Paolo Bruzzi (National Cancer Research Institute Genoa)
- 18:30  **Panel discussion:** All speakers
- 19:30  Networking Dinner in Restaurant "RISE"

Day 2 Tuesday 13th June 2017

SESSION 3 : INNOVATIVE CLINICAL TRIAL DESIGNS TO ACCELERATE DEVELOPMENT AND APPROVAL

Chairs: Jaap Verweij and Jan Gross

- 08:30 **Data requirements from early trials in the context of an MAA**
Jorge Camarero (AEMPS)
- 08:50 **A snapshot on the regulatory environment of accelerated developments**
Jan Gross (Merckgroup)
- 09:15 **Case study of umbrella study in context of accelerated development**
Todd Riehl (Genentech Inc.)
- 09:40  **Panel discussion:** All speakers
- 10:15  Coffee break

SESSION 4 : A NEW FRAMEWORK FOR PLANNING, CONDUCTING AND INTERPRETING CLINICAL TRIAL RESULTS: ESTIMANDS

Chairs: Dominik Heinzmann and Steven Teerenstra

- 10:45 **How the ICH E9 addendum around estimands may impact our clinical trials**
Frank Bretz (Novartis)
- 11:10 **Expectations and advice from regulators how to use the new framework of estimands in clinical trials**
Steven Teerenstra (MEB and University Medical Center Nijmegen)
- 11:35 **Treatment effect measures for time-to-event endpoints - Estimands and beyond**
Kaspar Rufibach (F. Hoffmann La Roche Ltd)
- 12:00  **Panel discussion:** All speakers and Dominik Heinzmann (F. Hoffmann La Roche Ltd)
- 12:20  Lunch

SESSION 5 : OPPORTUNITIES AND CHALLENGES WHEN IMPLEMENTING PHC CONCEPTS INTO CLINICAL TRIAL DESIGNS

Chair: *Rosa Giuliani and Claudia Dollins*

- 13:30 **Regulation of diagnostics in clinical trials**
Stephen Lee (Devices Division, MHRA)
- 13:50 **A clinical/regulatory perspective on experience so far with biomarkers in EU approvals – Outlook and Challenges**
Rosa Giuliani (SAG-O EMA, San Camillo Forlanini Hospital Rome)
- 14:20 **Treatment decision making based on molecular phenotyping**
H. Zwierzina (Medical University Innsbruck)
- 14:40 **Impact of clinical trial design on potential IVD regulatory claims**
Claudia Dollins (Merckgroup)
- 15:00  **Panel discussion:** All speakers

SESSION 6 : WRAP UP

- 16:00 **Summary and Wrap up**
- 16:30 End of the meeting



Event Outline

The CDDF multi-stakeholder workshop on Innovation in Oncology Clinical Trial Design aims at discussing clinical trial study designs for oncology with current and recent challenges together with a multi-stakeholder audience of experts from academia, regulatory authorities, pharmaceutical industry and patient advocate groups.

The aim of the workshop is to better understand the position and concerns of the other stakeholders to ensure better study designs can be developed for more efficient drug development.

While the pharmaceutical industry is going more 'innovative' and regulators more 'cautious' (first-in-human trials experience), these highly relevant issues will be addressed: basket trials, multi cohort trials, addition of new arms and new combinations, etc.

Programme Committee

- Jan Gross (Merckgroup)
- Kinga Komar Malinowska (Bayer)
- Irmela Radtke (F. Hoffmann La Roche Ltd)
- Stefan Schwoch (Lilly)
- Jaap Verweij (Erasmus MC)



Workshop venue

Hilton Frankfurt Airport
THE SQUAIRE Am Flughafen
60549 Frankfurt am Main

Tel: +49-69-26012000

Website: <http://reise.hiltonhotels.de/hotels/hilton-frankfurt-airport/>

Conference Secretariat

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