



CDDF WORKSHOP

USE OF REAL WORLD DATA TO OPTIMISE ONCOLOGY DRUG DEVELOPMENT AND ACCESS

London, United Kingdom, 6–7 July 2016

PROGRAMME



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Day 1 Wednesday 6th July 2016

- 13:00 **Introduction**
Eva Skovlund (Norwegian University of Science and Technology & CDDF Board Member, NO)
- 13:10 **State of the situation in EU for Oncology RWD**
Adrian Cassidy (Roche, CH)



SESSION 1: SOURCES OF REAL WORLD DATA IN ONCOLOGY

Session chairs: Eva Skovlund (NTNU, NO) & Adrian Cassidy (Roche, CH)

- 13:25 **Insight from IMI Get Real Project - From the Industry perspective**
Chris Chinn (Sanofi, UK)
- 13:45 **Insight from IMI Get Real Project - From the HTA perspective**
Pall Jonsson (NICE, UK)
- 14:05 **The Flatiron experience**
Amy Abernethy (Flatiron Health, USA)
- 14:25 **Utilizing Cancer Registry Data**
Giske Ursin (Norwegian Cancer Registry and University of Oslo, NO)
- 14:45  **Panel Discussion**

SESSION 2: USE OF RWD TO SUPPORT EFFICACY AND/OR SAFETY ASSESSMENTS IN LABEL EXPANSIONS

Session chairs: Bert Leufkens (Utrecht University and MeB, NL) & Stefan Schwoch (Lilly, UK)

- 15:15 **RWD to complement clinical trial data in the evaluation of a targeted therapy in a rare cancer** - Bill Capra (Genentech, USA)
- 15:35 **The regulators perspective on the role of RWD**
Paolo Foggi (AIFA, IT)
- 15:55  **Panel Discussion**
- 16:25  Coffee break

SESSION 3: REAL WORLD ONCOLOGY CLINICAL OUTCOMES

Session chairs: John Smyth (University of Edinburgh, UK) & Denis Lacombe (EORTC, BE)



- 16:45 **Experience in using RWD in metastatic colorectal cancer**
Halfdan Sørbye (Haukeland University Hospital, NO)
- 17:05 **Unicancer & ESME Project activities and the asset for health authorities and marketing authorisation holders**
Coralie Courtinard (Unicancer, FR)

- 17:25 **The industry perspective on clinical outcomes using RWD**
Michael Taylor (Genentech, USA)
- 17:45  **Panel Discussion**
- 18:15 Closure of day 1
- 19:30  Networking dinner (DoubleTree by Hilton – Docklands)

Day 2 Thursday 7th July 2016


SESSION 4 : ADVANCES IN METHODOLOGY FOR OBSERVATIONAL RESEARCH

Session chairs: David Wright (MHRA) & Eva Skovlund (NTNU, NO)

- 09:00 **Causal inference**
Jon Michael Gran (University of Oslo, NO)
- 09:20 **Methods to control for unmeasured confounding in pharmacoepidemiology**
Olaf Klungel (Utrecht University, NL)
- 09:40 **Pragmatic trials**
Tjeerd-Pieter van Staa (University of Manchester, UK)
- 10:00  **Panel Discussion**
- 10:30  Coffee break

SESSION 5 : CAN RWD ACCELERATE PATIENT ACCESS TO MEDICINES?

Session chairs: Marit Hystad (Norwegian Medicines Agency & CAT/EMA, NO) & Ansgar Hebborn (Roche, CH)

- 10:50 **The regulatory perspective**
Francesca Cerreta (EMA, UK)
- 11:10 **AIFA's post-marketing registries and accelerated patient access. Opportunities and challenges in the context of MAPPs**
Entela Xoxi (AIFA, IT)
- 11:30 **RWD in the context of MAPPs**
Chris Chinn (Sanofi, UK)
- 11:50  **Panel Discussion**

WRAP UP SESSION

- 12:20 *Eva Skovlund (NTNU, NO) - Linda McNamara (Roche, UK) - Felipe Fernandez (Novartis, IT)*
- 12:50 Closure of meeting and lunch

Event outline and objective

There is a need from regulators and HTA bodies for medicines to have a continuum of evidence generated from clinical trials which is then further complemented by data collected in routine clinical practice, so called Real World Data (RWD). The drive for this is to look beyond safety and efficacy parameters to gain marketing authorisation. The focus will be on generation of evidence on efficacy and safety in the real world setting to also inform reimbursement decisions better. For cancer medicines this is a burning issue. Development of initiatives such as Adaptive Pathways provides a mechanism for investigating these concepts further for medicines with smaller populations or unclear safety/benefit profiles. However, the utility of RWD ought to be focused on both accelerating drug development of cancer medicines and providing the confidence of true benefits in the real world setting.

The aim of the workshop organized by the Cancer Drug Development Forum (CDDF) is to have a multi-stakeholder discussion representing regulators, clinicians, HTA / payers, and policy makers on the challenges of developing RWD proposals in Oncology and share current experience on the best sources of RWD of high quality in Oncology Drug Development to enhance knowledge on benefit/risk as well as development and access to optimal treatment regimens.

Programme chairs

- Francesca Cerreta (European Medicines Agency, UK)
- Felipe Fernandez (Novartis)
- Linda McNamara (Roche)
- Eva Skovlund (Norwegian University of Science and Technology - CDDF Board Member)

Audience

Oncologists/scientists, government officials (EMA, policymakers, HTA), pharmaceutical industry representatives

Workshop venue

DoubleTree by Hilton - London Docklands Riverside 265 Rotherhithe Street, SE16 5HW London, UK

Meeting secretariat

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