CDDF Multi-stakeholder Workshop

Digital Tools and Artificial Intelligence in Cancer Drug Development

27 - 28 September 2021

Online Workshop

Meeting Secretariat

Cancer Drug Development Forum (info@cddf.org)

EVENT OUTLINE

This workshop is needed to evaluate the current state of play in terms of opportunity and regulatory perspectives as increasing numbers of digital tools are being incorporated into clinical trials. This is bringing challenges in terms of validation of endpoints, interpretation of data and also data security – a CDDF workshop bringing together industry, academic and regulatory partners presents a unique opportunity to explore these issues.

At this multi-stakeholder workshop, meeting delegates will have the opportunity to discuss the use of digital tools and AI in cancer drug development, covering digital tools, digital diagnosis and AI within clinical trials. The 1.5-day meeting consists of 4 plenary sessions and adequate discussion and networking time. Each session will also include various perspectives of academics, HTAs, regulatory agencies, patient advocates and industry and discuss challenges of digital tools.

LEARNING OBJECTIVES

From this interactive workshop, participants will achieve the following outcomes:

- To understand the current landscape of use to digital tools in cancer drug development
- To explore regulatory aspects, challenges and plans for formal registration of digital tools from trial data
- To learn about the various digital options to support trials and improve data collection and outcomes

PROGRAMME COMMITTEE

- Ruth Plummer (CDDF, UK)
- Nafsika Kronidou Horst (Roche, CH)
- Ralf Herold (EMA, NL)
- Denis Costello (CML Advocates Network, ES)
- Dónal Landers (Digital Experimental Cancer Medicine Team, CRUK Manchester Institute, UK)

TARGET AUDIENCE

The target is a multidisciplinary audience of academia representatives, EU and US regulatory bodies (EMA, FDA, National Agencies), pharmaceutical Industry, HTAs and patient advocates.

MEETING DATE

27 - 28 September 2021

DRAFT PROGRAMME

DAY 1

Session 1: What is a Digital Tool and What It is Not

14:00-14:05 **Welcome note and polls**

14:05-14:35 **Keynote lecture**
Dónal Landers (Digital Experimental Cancer Medicine Team, CRUK Manchester Institute, UK)

14:35-14:50 **Q&A**

Session 2: Digital Tools in Clinical Trials

14:50-14:55 **Session opening and polls**

14:55-15:10 **Digital tools in trials for monitoring**
Larsson Omberg (Sage Bionetworks, USA)

15:10-15:25 **Endpoints using digital tools**
Donna Graham (The Christie / Digital Experimental Cancer Medicine Team, UK)

15:25-15:35 **Coffee Break (10')**

15:35-15:50 **Algorithms for recruitment**
Chris Plummer (Newcastle Hospitals NHS Foundation Trust, UK)

15:50-16:05 **Regulatory aspects**
TBC

16:05-16:25 **Panel discussion (20')**

16:25-16:40 **Coffee break (15')**

Session 3: Clinical Decision Support Tools and Clinical Practice

16:40-16:45 **Session opening and polls**

16:45-17:00 **Imaging and staging**
Prof. Dr. Torsten Haferlach (MLL Laboratory in Munich, DE)

17:00-17:15 **Digital diagnosis**
Dr. Joachim H. Schmid (Roche Tissue Diagnostics, USA)

17:15-17:30 **EMA/FDA thoughts on data quality/use for registration**
TBC

17:30-17:50 **Panel discussion (20')**

DAY 2

Session 4: Digital Tools transforming patient care

14:00-14:05 **Welcome note and polls**

14:05-14:20 **Topic 1**
Hans Scheurer (MPE/WECAN, NL) (TBC)

14:20-14:35 **Topic 2**
TBC

14:35-14:50 **Regulatory aspects**
Bleddyn Rees (European Connected Health Alliance, UK)

14:50-15:10 **Breakout room discussion**

15:10-15:40 **Panel discussion (30')**

15:40-16:00 **Coffee Break (20')**

Session 5: Integration of patients in digital tool trial design and development

16:00-16:05 **Session opening and polling**

16:05-16:20 **Novartis – Project Data 42**
TBC

16:20-16:35 **Design and Delivery of the InHome study**
Leanne Philips (Manchester Foundation Trust/ Digital Experimental Cancer Medicine Team, UK)

16:35-16:50 **Data security and regulation**
Petra Wilson (FTI Consulting)

16:50-17:10 **Panel discussion (20')**

17:10-17:15 **Closing remarks**