



CDDF
MULTI-STAKEHOLDER
WORKSHOP

27-28 SEPTEMBER 2021

*Digital Tools and Artificial Intelligence
in Oncology Drug Development*

ONLINE WORKSHOP



WELCOME NOTE

On behalf of the whole organising committee welcome to this CDDF workshop on Digital Tools and Artificial Intelligence in Oncology Drug Development.

We have brought together experts from academia, regulators, industry and most importantly our patient groups to explore a range of aspects in this emerging area in cancer drug development.

Over the 2 days of the workshop we will explore the development and integration of digital tools within clinic trials, in clinical decision support and innovative patient care, hearing opinions from patients, clinicians, industry and the regulators of how best these tools add to our quest for better cancer drug development.

Despite the virtual format we are looking forward to an interactive meeting, with plenty of opportunities for robust discussion of the issues and networking for further research

Ruth Plummer
CDDF Deputy Chairperson .



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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 2-day meeting consists of 5 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.

PROGRAMME COMMITTEE

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

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.

EVENT PLATFORM

The workshop will be held online via the unique event platform (as the CDDF Multi-Stakeholder Workshop on Endpoint In Cancer Drug Development). Only approved participants will receive the information including the link to the platform and log-in details closer to the date.

CONTACT

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PROGRAMME

DAY 1 – MONDAY 27 SEPTEMBER 2021

14:00 - 14:05	Welcome note Ruth Plummer (CDDF, UK)
SESSION 1: APPLYING AI IN CLINICAL DRUG DEVELOPMENT – KEY CHALLENGES	
Session Chair: Ruth Plummer (CDDF, UK)	
14:05 - 14:35	Keynote lecture Dónal Landers (Digital Experimental Cancer Medicine Team, CRUK Manchester Institute, UK)
14:35 - 14:50	Questions and Answers
14:50 - 15:00	Coffee Break
SESSION 2: DIGITAL TOOLS IN CLINICAL TRIALS	
Session Chairs: Ruth Plummer (CDDF, UK) ; Donna Graham (The Christie / Digital Experimental Cancer Medicine Team, UK)	
15:00 - 15:05	Session opening
15:05 - 15:20	Digital tools in trials for monitoring Larsson Omberg (Sage Bionetworks, USA)
15:20 - 15:35	Endpoints using digital tools Donna Graham (The Christie / Digital ECMT UK)
15:35 - 15:50	Digital tools for recruitment Chris Plummer (Newcastle Hospitals NHS Foundation Trust, UK)
15:50 - 16:05	Regulatory aspects Ib Alstrup (Danish Medicines Agency, DK)
16:05 - 16:25	Panel Discussion

16:25 - 16:40	Coffee Break
SESSION 3: CLINICAL DECISION SUPPORT TOOLS AND CLINICAL PRACTICE	
Session Chairs: Nafsika Kronidou (Roche, CH) ; Torsten Haferlach (Munich Leukemia Laboratory, DE)	
16:40 - 16:45	Session opening
16:45 - 17:00	Regulatory considerations on EU trustworthy AI Gabriele Mazzini (European Commission, IT)
17:00 - 17:15	Digital diagnosis Joachim H. Schmid (Roche Tissue Diagnostic, USA)
17:15 - 17:30	How AI can support best diagnostic approaches in hematology Torsten Haferlach (Munich Leukemia Laboratory, DE)
17:30 - 17:50	Panel Discussion

DAY 2 – TUESDAY 28 SEPTEMBER 2021

14:00 - 14:05	Welcome note Denis Costello (CML Advocates Network, ES)
SESSION 4: DIGITAL TOOLS SUPPORTING INNOVATIVE PATIENT CARE	
Session Chairs: Denis Costello (CML Advocates Network, ES) & Jan Geissler (Patvocates, DE)	
14:05 - 14:20	Patient perspective Hans Scheurer (WECAN, MPE, NL)
14:20 - 14:35	Clinician perspective Sanna Iivanainen (Oulu University Hospital, FI)
14:35 - 14:50	Regulatory aspects Bleddyn Rees (European Connected Health Alliance, IE)
14:50 - 15:35	Panel Discussion
15:35 - 15:55	Coffee Break
SESSION 5: INTEGRATION OF PATIENTS IN DIGITAL TOOL TRIAL DESIGN AND DEVELOPMENT	
Session Chairs: Nathalie Bere (EMA, NL); Dónal Landers (Digital Experimental Cancer Medicine Team, CRUK Manchester Institute, UK)	
15:55 - 16:00	Session Opening
16:00 - 16:15	Patient engagement in designing the clinical studies Leanna Goodwin (Digital Experimental Cancer Medicine Team, CRUK Manchester Institute, UK)
16:15 - 16:30	Design and delivery of the In-home study Leanne Philips (Manchester Foundation Trust / Digital ECMT, UK)
16:30 - 16:40	Data security and regulation Petra Wilson (Health Connect Partners, BE)
16:40 - 17:15	Panel Discussion and closing remarks