



CDDF
MULTI-STAKEHOLDER
WORKSHOP

25-26 APRIL 2022

Measurable Residual Disease (MRD) and Circulating Tumour Nucleotides (ct DNA) in cancer drug development

HYBRID WORKSHOP



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WELCOME NOTE

On behalf of the Cancer Drug Development Forum and its partners, the program committee would like to welcome you to the CDDF Multi-stakeholder Workshop on "Measurable Residual Disease (MRD) and Circulating Tumour Nucleotides (ctDNA) in Cancer Drug Development".

The program builds on three previous Multi-Stakeholder Workshops:

- Minimal Residual Disease: Endpoints in Clinical Trials, London, UK, May 13-14, 2014
- Minimal Residual Disease (MM), London, UK, October 18-19, 2017
- Minimal Residual Disease (AML/CLL), London, UK, November 8-9, 2018

The workshop aims to provide updates on new technologies (like ctDNA and next-generation flow cytometry and sequencing) and analyse these from key perspectives (patients, regulatory, academic, payers and industry). Discussions among expert panels and, most important, with the participants will address open questions, next steps and collaborative opportunities.

We are excited about the excellent speakers who have accepted our invitation and incredibly thankful for the support of the regulatory agencies, esp. EMA and FDA, in building the program. Many clinical researchers, pharmaceutical industry representatives, patient advocacy representatives, and regulators, will join us in undoubtedly lively discussions.

Like everyone else we are watching the SARS-CoV2 pandemic closely. The workshop is currently planned as a 'hybrid' meeting, i.e. with on-site and virtual participation. According to the further development of the pandemic this may be modified. We have intensively invested in video technology and the adaptation of formats to ensure a high-quality experience also for virtual participants.

We are looking forward to the discussions with you, which are at the core of our mission to facilitate oncology drug development.

PROGRAMME COMMITTEE

- Axel Glasmacher (CDDF)
- John Smyth (CDDF)
- Hans Scheurer (MPE)
- Reshma Patel (Johnson & Johnson)
- Natalie Dimier (Roche)
- Veerendra Munugalavadla (AstraZeneca)

EVENT OUTLINE

This workshop is aimed at all relevant stakeholders in cancer drug development, patients, academic researchers, regulatory agencies and pharmaceutical companies. It will address the latest developments in the use of measurable residual disease (MRD) and circulating tumor DNA as endpoints in cancer drug development.

The success of modern drug and immunotherapy has made unprecedented reductions of tumor load possible which has in many diseases translated into relevant survival benefits. The assessment of tumor burden beyond conventional definition of complete remission can predict outcomes and may therefore accelerate the development of new treatments in oncology. Also, these outcomes may be used to modify therapeutic approaches.

The workshop focuses on the analysis of these rapidly evolving endpoints from all relevant perspectives and looks to define a problem-solving, multi-stakeholder approach to next steps and further development.

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.

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The workshop will be held in Amsterdam. However, participation online via the unique event platform will also be possible. Only approved participants will receive further information about the event location or the link to the virtual platform and log-in details

CONTACT

Cancer Drug Development Forum (CDDF)

Email: giorgia@cddf.org, info@cddf.org

Website: www.cddf.org

Address: c/o BLSI Clos Chapelle-aux-Champs 30, 1200 Brussels, Belgium



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PROGRAMME

DAY 1 – MONDAY 25 APRIL 2022

13:00 - 13:10	Welcome note Axel Glasmacher (CDDF, DE), John Smyth (CDDF, UK)
SESSION 1: STATE OF THE ART AND NEW TECHNOLOGY	
Session Chairs: Axel Glasmacher (CDDF, DE), John Smyth (CDDF, UK)	
13:10 - 13:40	MRD concepts, methods and application + Q&A Bruno Paiva (Universidad de Navarra, ES)
13:40 - 14:10	Established and Novel ctDNA Methodology + Q&A Dominic Rothwell (CRUK Manchester Institute Cancer Biomarker Centre, UK)
14:10 - 14:40	ctDNA and MRD, an academic point of view + Q&A Marie Morfouace (EORTC, BE)
14:40 - 15:00	Current Status and Clinical Application of Circulating Tumour DNA (ctDNA) and its Future Role in Clinical Practice + Q&A Jürgen Gschwend (Technical University Munich, DE)
15:00 - 15:30	Coffee Break

SESSION 2: COLLABORATION - PATHWAY TO INNOVATION

Session Chairs: Veerendra Munugalavadla (AstraZeneca, US); Pierre Demolis (ANSM, FR)

15:30 - 15:35	Session opening
15:35 - 16:05	MPAACT Consortium to Establish Measurable Residual Disease as a Surrogate Endpoint in Acute Myeloid Leukemia Drug Development + Q&A Natalie Dimier (Roche, CH); Reshma Patel (Johnson & Johnson, UK)
16:05 - 16:35	The Foundation for the National Institutes of Health (FNIH) initiative on AML MRD + Q&A Christopher Hourigan (National Institutes of Health, USA)
16:35 - 17:05	Exploring the use of ctDNA for Monitoring Treatment Response: The Friends of Cancer Research ctMoniTR Project + Q&A Jeff Allen (Friends of Cancer Research, USA)

SESSION 3: REGULATORY PERSPECTIVES

Session Chairs: Natalie Dimier (Roche, CH); Jaap Verweij (CDDF, NL)

17:05 - 17:10	Session opening
17:10 - 17:25	Summary of Regulatory Uses of MRD and ctDNA Nicole Gormley (FDA, USA)
17:25 - 18:20	Panel Discussion Moderators: Natalie Dimier (Roche); Jaap Verweij (CDDF, NL) Panelists: <ul style="list-style-type: none"> • Nicole Gormley (FDA, USA) • Shirley Hopper (MHRA, UK) • Donna Roscoe (FDA, USA) • Carla Herberts (Medicines Evaluation Board, NL)
19:00 - 22:00	Onsite Dinner

DAY 2 – TUESDAY 26 APRIL 2022**SESSION 4: IMPORTANT VIEWPOINTS**

Session Chairs: Hans Scheurer (MPE, NL); Reshma Patel (Johnson and Johnson, UK)

10:30 - 10:40	Session opening
10:40 - 11:10	European In Vitro Diagnostic Regulations - Industry perspective + Q&A Claudia Popp (Roche, CH)
11:10 - 11:40	The value of MRD and ctDNA in cancer drug development, from the patient group perspective + Q&A Hans Scheurer (MPE, NL)
11:40 - 12:10	HTA perspective + Q&A Carole Longson (NICE, UK)
12:10 - 12:40	MRD in Solid Cancers: perspective of industry + Q&A Darren Hodgson (AstraZeneca, UK)

SESSION 5: HOW SHOULD WE MOVE FORWARD?

Session Chairs: Axel Glasmacher (CDDF, DE); John Smyth (CDDF, UK)

12:40 - 13:20	Panel Discussion Moderators: Axel Glasmacher (CDDF); John Smyth (CDDF) Panelists: All speakers
13:20 - 13:30	Next steps and farewell
13:30 - 14:00	Sandwich lunch (take away)