VIRTUAL CONFERENCE
7 - 9 FEBRUARY 2022

CDDF ANNUAL CONFERENCE 2022

VIRTUAL CONFERENCE

PROGRAMME

WWW.CDDF.ORG

WELCOME NOTE

On behalf of the Cancer Drug Development Forum, its partners, and my colleagues from the organizing committee, Claudia Hey, Michael Zaiac, Roger Wilson, and Kim Lyerly I would like to welcome you to the 2022 CDDF Annual Conference. We are still in the midst of the lasting COVID-19 pandemic, for which reason this will this annual meeting aim only for online participation. Given the fact that we are all now used to virtual meetings, we are convinced that this Annual Conference will be as exciting as all the previous ones.

The program has been built to facilitate participation from many parts of the globe, although the focus is on Europe and North America. We will have discussions on topics such as integration of regulatory assessment and the assessment of reimbursement, enhancing the future of clinical trials, lessons learned from acceleration in pediatric oncology programs, collaboration in the post-COVID regulatory environment. We will also briefly revisit the outcomes of 4 CDDF workshops that took place in 2021. The lecturers will lead us towards a discussion that should help precising the content of the workshops involved.

We are excited with the great speakers who have accepted our invitation, and incredibly thankful for the support of 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.

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

Jaap Verweij
Managing Director CDDF
Chair of the CDDF Annual Conference Program Committee

CDDF Cancer Drug Development Forum
FACILITATE DEBATE ACTIVATE INNOVATE
Annual Conference 2022

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EVENT OUTLINE

The Cancer Drug Development Forum (CDDF) Annual conference is a unique forum that convenes every year and gathers the leaders in the world of innovative cancer therapy development, including medical researchers, pharmaceutical industry representatives, regulatory authority representatives, and patient advocacy groups. The 12th edition takes place from 7 to 9 February 2022.

This multi-stakeholder, interactive meeting offers plenary lectures with moderated discussions, including case studies as well as networking opportunities. The programme focuses on the latest and future challenges of innovative oncology drug development with a special emphasis on Integration of regulatory assessment and the assessment of reimbursement of novel agents, enhancing the future of (de-central) clinical trials, lessons learned from acceleration in pediatric oncology drug development programs, and global regulatory collaboration in oncology drug development assessment.

PROGRAMME COMMITTEE

- Jaap Verweij (CDDF Board, NL)
- Claudia Hey (Merck Healthcare KGaA, DE)
- Michael Zaiac (Novartis, CH)
- Roger Wilson (WECAN/ SPAEN, UK)
- Kim H. Lyerly (AAADV, US)
- Committee advisor: Ralf Herold (EMA, NL)

TARGET AUDIENCE

The target is a multidisciplinary audience of representatives from academia, EU and US regulatory bodies (EMA, FDA, and national agencies), the pharmaceutical industry, HTAs, and patient advocates.

Meeting platform

Brella, https://www.brella.io/

Meeting Secretariat

Cancer Drug Development Forum (CDDF) - info@cddf.org - www.cddf.org

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

PROGRAMME (CET TIME ZONE)

Day 1 – Monday 7 February 2022

12:50 - 13:00	Welcome note Jaap Verweij (CDDF, NL)
SESSION 1: INTEGRATION OF REGULATORY ASSESSMENT AND THE ASSESSMENT OF REIMBURSEMENT	
Session chairs: Roger Wilson (WECAN, UK) & Mark Lawler (Queen's University Belfast, UK)	
13:00 - 13:25	Adaptive pathway development: a clinical approach in fabry disease Prof. Carla Hollak (Amsterdam University Medical Center, NL)
13:25 - 13:50	ILAP - co-operation and accelerated approval Dan O'Connor (MHRA, UK)
13:50 - 14:15	Industry experience with ILAP Daniel Martin (Merck Healthcare KGaA, DE)
14:15 - 14:35	Moving the statistical analysis of randomized trials from a single endpoint to a patient-centric benefit-risk assessment Marc Buyse (IDDI, BE)
14:35 - 15:15	Panel discussion Panelists: session chairs, speakers, Anne Willemsen (EUnetHTA, NL)
15:15 - 15:45	Coffee break & individual networking
SESSION 2: REFLECTION ON CDDF WORKSHOPS 2021	
Session chair: Ruth Plummer (CDDF, UK)	
15:45 - 16:00	Endpoints in cancer drug development Chitkala Kalidas (Bayer, US)
16:00 - 16:15	*Discussion*
16:15 - 16:30	Digital tools and artificial intelligence Nafsika Kronidou Horst (Roche, CH)
16:30 - 16:45	*Discussion*
16:45 - 17:00	CDDF-AAADV satellite session on global pediatric neuro-oncology network Kim Lyerly (AAADV, US)
17:00 - 17:15	*Discussion*
17:15 - 17:30	Gene and cell therapies Catarina Edfjäll (CDDF, UK)
17:30 - 17:45	*Discussion*

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Day 2 – Tuesday 8 February 2022

SESSION 3: ENHANCING THE FUTURE OF CLINICAL TRIALS	
Session Chairs: Jaap Verweij (CDDF, NL) & Jan Geissler (Patvocates, DE)	
13:00 - 13:05	Introduction Session chairs
13:05 - 13:25	CTFG's perspective on ehancing the future of clinical trials Elke Stahl (BfArM, DE)
13:25 - 13:45	Delivering on innovative trials: an industry's perspective Mireille Muller (Novartis, CH)
13:45 - 14:15	Patient centric, decentralised clinical trials – a national project Gunilla Andrew-Nielsen (Swedish MPA, SE)
14:15 - 14:45	Coffee break & individual networking
14:45 - 15:45	Q&A and panel discussion Panelists: Session chairs & speakers
15:45 - 15:55	Break & individual networking
SESSION 4: LESSONS LEARNED FROM ACCELERATION IN PEDIATRIC ONCOLOGY PROGRAMS	
Session Chairs: Dominik Karres (EMA, DE) & Claudia Hey (Merck Healthcare KGaA, DE)	
15:55 - 16:00	Introduction Session chairs
16:00 - 16:25	C4C IMI project Heidrun Hildebrand (Bayer, DE)
16:25 - 16:50	Academic & industry perspective Peter Adamson (Sanofi, US)
16:50 - 17:05	European perspective on collaborations to accelerate global paediatric oncology drug developments Dominik Karres (EMA, DE)
17:05 - 17:20	Research Foundation perspective: How nonprofits can be the changemakers Annette Bakker, PhD (President of Children's Tumor Foundation US and chair of CTF Europe, US)
17:20 - 17:35	Lessons learned from AAADV meeting + FDA experience with pediatric accelerated programs Gregory Reaman (FDA, US)
17:35 - 18:00	Coffee break & individual networking
18:00 - 19:00	Q&A and panel discussion Panelists: Session chairs & speakers

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Day 3 – Wednesday 9 February 2022

SESSION 5: COLLABORATION IN THE POST-COVID REGULATORY ENVIRONMENT	
Session Chairs: Kim H. Lyerly (AAADV, US) & John Smyth (CDDF, UK)	
14:00 - 14:05	Introduction Session chairs
14:05 - 14:35	Boosting international regulatory collaboration Agnes Saint-Raymond (Former EMA Head of International Affairs Division, NL)
14:35 - 15:05	Project Orbis, experience and expansion Angelo DeClaro (FDA, US)
15:05 - 15:20	Swissmedic: Current Status & Future Considerations on International Regulatory Collaborations Ulrich Peter Rohr (Swissmedic, CH)
15:20 - 15:50	Coffee break & individual networking
15:50 - 16:50	Panel discussion Panelists: Session chairs & speakers
16:50 - 17:00	Farewell Jaap Verweij (CDDF, NL)