



CDDF
MULTI-STAKEHOLDER
WORKSHOP

29-30 NOVEMBER 2021

Gene-and Cell Therapies in Oncology

HYBRID WORKSHOP

WELCOME NOTE

On behalf of the Cancer Drug Development Forum, its partners, and my colleagues from the program committee, I would like to welcome you to the 2021 CDDF Multi-Stakeholder CDDF Workshop: Gene- and Cell Therapies in Oncology.

We have brought together experts from academia, regulators, industry and patient groups to explore a range of aspects in this important and still rather novel approach in cancer drug development. Over the 2 days of the workshop, we will explore the development of gene- and cell therapies, both from the scientific and clinical trial perspective, as well as a looking at approval pathways on both sides of the Atlantic. Furthermore, we will discuss how to improve patient access and explore future perspectives of this innovative therapeutic approach.

This will be the first official hybrid event organized by CDDF. The workshop has been set up to allow for exchange and interactions, regardless if you are joining us in person or online. Due to the recent developments, we realise that many attendees will be joining us virtually. Nevertheless, we are looking forward to an interactive meeting with plenty of opportunities for robust discussions, e.g., multi-stakeholder panels at the end of each session and online networking opportunities.

We are looking forward to the discussions with you, and to fulfill our mission to facilitate cancer drug development.

Catarina Edfjäll
CDDF Board member



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EVENT OUTLINE

Gene and cell therapy in oncology is a relatively new treatment approach that is in constant development. For this reason, the CDDF decided to organise this multi-stakeholder workshop that will outline how to generate the gene and cell “cancer killer” and will present some of the challenges involved in the clinical trials and in the marketing authorization of these therapies. Additionally, there will be a focus on how to improve patient access to the treatment and on the future perspectives of this innovative therapeutic approach.

PROGRAM COMMITTEE

- Catarina Edfjäll (CDDF Board, CH)
- Martina Schuessler-Lenz (Paul-Ehrlich-Institute, DE; Chair of EMA Committee for Advanced Therapies)
- Hans Scheurer (MPE, BE)
- Natacha Bolaños (Lymphoma Coalition, ES)
- Darko Miljkovic (GSK, CH)
- Simona Paratore (Novartis, IT)
- Alexander Yallouridis (Novartis, EL)

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

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PROGRAM

DAY 1 – MONDAY 29 NOVEMBER 2021

14:00 - 14:05	Welcome note Catarina Edfjäll (CDDF, SE)
SESSION 1: WHO IS THE GENE AND CELL CANCER-KILLER: DEEP DIVE ON THE GENE AND CELL SCIENTIFIC APPROACHES IN ONCOLOGY	
Session Chairs: Alexander Yallouridis (Novartis, EL); Alessandro Aiuti (San Raffaele Hospital, IT)	
14:05 - 14:20	TCR and CAR modified T cells as Cancer Immunotherapy - an overview Emma Morris (University College London, UK)
14:20 - 14:35	Cancer killer profile: T cell fitness, autologous or allo T cell, Tcell or NK? Jan Frič (Institute of Hematology and Blood Transfusion - UHKT, CZ)
14:35 - 14:50	Tumour and immunological environment influences in haematologic and solid tumours: engineering techniques or drug combination? Victor Moreno (Start Madrid, ES)
14:50 - 15:30	Panel Discussion Moderators: Alexander Yallouridis; Alessandro Aiuti. Panelists: Jan Frič, Emma Morris, Victor Moreno
15:30 - 16:00	Coffee Break

SESSION 2: HOW TO DEVELOP A GENE AND CELL CANCER KILLER: THE CLINICAL TRIALS.

Challenges in timely initiation and conduct of clinical trials in gene and cell therapies in hematology. From planning to trial authorisation to patient treatment and follow up

Session Chairs: Martina Schuessler-Lenz (EMA CAT Chair; Paul-Ehrlich-Institut, DE); Ulrich Jaeger (Medizinische Universität Wien, AT)

16:00 - 16:10	Session opening
16:10 - 16:25	From clinical trials to marketing authorisation of advanced therapies Martina Schuessler-Lenz (EMA CAT Chair; Paul-Ehrlich-Institut, DE)
16:25-16:40	Approval pathways for innovative gene & cell therapies Adnan Jaigirdar (FDA, USA)
16:40 - 16:55	Clinical trials with gene and cell therapies – challenges and opportunities. The industry perspective Laura Pearce (GSK, USA)
16:55 - 17:10	Challenges and learnings in conducting clinical trials with gene and cell therapies – the investigator perspective Michael Hudecek - (University of Würzburg, DE)
17:10 - 17:50	Panel Discussion Moderators: Martina Schuessler-Lenz & Ulrich Jaeger Panelists: Adnan Jaigirdar, Laura Pearce, Michael Hudecek, Hans Scheurer (MPE, NL), Carin Uyl-de Groot (Erasmus University Rotterdam, NL)
18:00 - 20:00	Onsite Dinner

DAY 2 – TUESDAY 30 NOVEMBER 2021**SESSION 3: HOW TO BRING A GENE AND CELL CANCER KILLER TO PATIENTS: HOW TO IMPROVE PATIENT ACCESS**

Session Chairs: Catarina Edfjäll (CDDF, SE); Hans Scheurer (MPE, NL)

13:30 - 13:40	Session opening
13:40 - 13:55	From marketing authorisation to patient access - the rollout from the industry perspective Bernd Eschgaeller (Novartis, CH)
13:55 - 14:10	Patient perspective Kate Morgan (MPE, UK)
14:10 - 14:25	HTA perspective and reimbursement models Carin Uyl-de Groot (Erasmus University Rotterdam, NL)
14:25 - 15:00	Panel Discussion Moderators: Catarina Edfjäll, Hans Scheurer. Panelists: Bernd Eschgaeller, Kate Morgan, Carin Uyl-de Groot, Michael Hudecek (University of Würzburg, DE)
15:00 - 15:30	Coffee break

SESSION 4: FUTURE PERSPECTIVE IN THE ECO-SYSTEM

Session Chairs: Darko Milijkoic (GSK, CH); Jaap Verweij (CDDF, NL)

15:30 - 15:40	Session opening
15:40 - 15:55	How can a collaborative CAR-T registry advance development? Nicolaus Kroeger (Medical Center Hamburg-Eppendorf, DE)
15:55 - 16:10	Innovative concepts for clinical trials: Synthetic Control Arms Emily Bratton (IQVIA, US)
16:10 - 16:25	Can Artificial Intelligence help to overcome current obstacles in CAR-T development? Thomas Clozel (Owkin, FR)
16:25 - 17:10	Panel Discussion and farewell Moderators: Darko Milijkoic, Jaap Verweij. Panelists: Nicolaus Kroeger, Emily Bratton, Thomas Clozel, Natacha Bolaños (Lymphoma Coalition, ES), Martina Schuessler-Lenz (PEI, DE; Chair of EMA CAT)