CDDF: a multistakeholder collaboration to speed up access of European patients to immuno-oncology therapies

Heinz Zwierzina, M.D.
Innsbruck Medical University
Cancer Drug Development Forum (CDDF)

Who we are

- The *Cancer Drug Development Forum* (CDDF – www.cddf.org) is a not-for-profit organization registered in Austria and funded by "unrestricted educational grants" from the industry
- CDDF was founded in 2001 as the Biotherapy Development Association (BDA) in collaboration with a group of pre-clinical and clinical researchers. In 2014, the organisation changed its name to CDDF.

The organisation

CDDF Board

Heinz Zwierzina, Austria
Chairman

Leif Håkansson, Sweden
Vice-chairman

Volkmar Nüssler, Germany
Treasurer

Max Scheulen, Germany
Secretary

Eva Skovlund, Norway

John Smyth, United Kingdom

Gilles Vassal, France

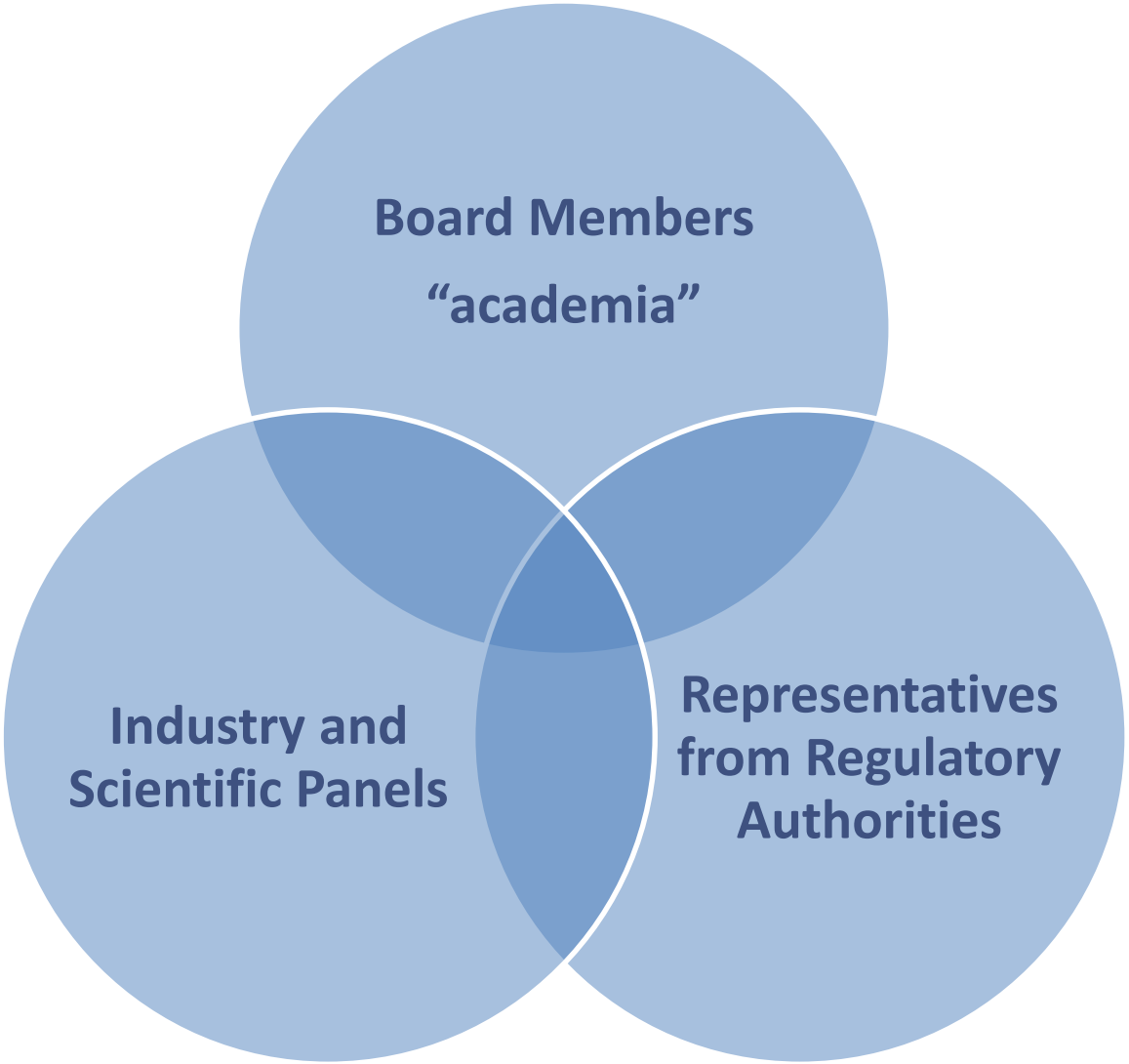
CDDF Office

Located at the European Cancer Organisation-ECCO premises in Brussels, Belgium

Marjorie Recorbet – CDDF Manager

Anissa Brennet – CDDF Administrator

The organization when it started



CDDF
Cancer Drug Development Forum

Mission

To provide a **unique platform** to facilitate interactions between **all stakeholders** (academia, regulatory authorities, industry, patient advocacy groups, health technology assessors and policymakers) to improve the efficiency of cancer drug development.

“Collaboration is key”

Interaction with Representatives from Regulatory Authorities

CDDF interacts with representatives from the regulatory authorities (EMA, FDA and PMDA Japan) to obtain their views on drug development.

Our initial approach

- **Organize tripartite** (Academia , Industry and Regulatory Authorities) **meetings** and workshops focused on specific oncology themes to translate science into clinical practice.
- **Advise** on drug development strategies and latest trends in drug development in oncology.
- **Advise** on the set-up of translational research accompanying early clinical studies (**“bench to bedside and back to bench”**).

Meeting activities

- All CDDF meeting programmes are created by a **multi-disciplinary team of international expert** in their field
- They address **subjects that are of great importance** to ALL CDDF stakeholders
- The CDDF is able to convene meetings where some of the **most influential and senior regulators** are present
- The CDDF reaches out to **HTA bodies, patient advocacy groups** and policy makers
- Meeting proceedings are **published in scientific journals**

Structure of CDDF Meetings

- **Alpine Conferences** (8th conference March 2015)
  Address upcoming issues in drug development among all stakeholders
- **Workshops** (CDx, **immunotherapy**, HTA, etc.)
  address specific topics that have come up at the Alpine conference
- **Working groups** (biomarkers, technology platform)

  are designed to create a forum for all stakeholders in a specific area of cancer research

Development of CDDF fora - examples

- **8th Alpine Conference :**

  Current and future challenges of innovative oncology drug development

  Buchen/Innsbruck, Austria – 2 - 4 March, 2015

- **CDDF – SIOPE 3rd Pediatric Oncology Conference :**

  Prioritisation in paediatric oncology drug development

  Vienna, Austria – 5 & 6 February 2015

- **2nd Immunotherapy of Cancer Conference (ITOC-2)**

  Munich, Germany – 25 to 27 March 2015

- **4th HTA Workshop – development to an HTA forum?**

ITOC meeting

- Formerly known as Biological Therapy of Cancer (BTOC 1-11 since 1992)
- ITOC meetings focus on translational research in immuno-oncology
- ITOC-2 was held in Munich, March 2015 (itoc-conference.eu)
- Creation of the ITOC forum initiated

ITOC forum

- ITOC-3 (March 2016)
- Technology platform for definition / validation of biomarkers in the peripheral blood
- Meetings with regulatory authorities (EMA etc.)
- **Close interaction with ECPC in the field of immunotherapy (if acceptable to ECPC)**
- HTA initiative
- Fund raising (IMI? Other EU grant systems?)

Activities

ECCO/CDDF Joint Session (Vienna 2015): European Regulation and Health Technology Assessments in Immunotherapy

Chair: J. Smyth

EMA (F. Pignatti), HTA (B. Flamion)
ECPC presentation: Prof. F. de Lorenzo

Clinical drug development follows new rules

- Endpoints for “conventional” chemotherapy (cytotoxic)

  Phase I: Define “maximum tolerated dose (MTD)”, and move to Phase II: Prove efficacy by RECIST criteria

  Empirical approach,

  as long as it works mode of action of less importance

- Endpoints for molecular targeted therapy (usually cytostatic)

  Frequently the MTD “cannot” be determined

  Response according to RECIST criteria less meaningful

It is critical to understand the science behind and develop biomarkers (prospectively)

Biomarkers - the future

- Given the shortcomings of single biomarkers and the complexity of cancer biology, multiple / composite biomarkers will be increasingly relied on to assess safety and efficacy of the new generation of anticancer drugs
- Serum / blood markers may help to overcome the logistic challenges of taking repeated biopsies
- Without the development of biomarkers that define subgroups of patients that may/may not respond our health care system will be in serious troubles

Who owns the material?

Goals for 2015/2016

- Establish collaboration with patient advocat groups (ECPC)
- Establishment of an HTA forum
- Scientific grant application: Definition and validation of biomarkers (IMI, other European grant system)

“Collaboration is key”

Cancer Drug Development Forum - CDDF Office
c/o ECCO - The European Cancer Organisation
Avenue E. Mounier 83
B-1200 Brussels
Belgium
marjorie.recorbet@ecco-org.eu