CDDF Diversity Initiative – Call for Participation

Brussels, September 6, 2024

The Cancer Drug Development Forum (CDDF) is initiating an initiative on diversity in oncology clinical trials and invites pharmaceutical companies to participate and nominate a representative to the CDDF working group.

The CDDF (www.cddf.org) is a neutral, non–competitive platform for multi-stakeholder discussions and collaboration in the development of cancer drugs.

The question of representativeness of the population included in clinical trials is an important topic in the public debate, including in several sessions at CDDF workshops and annual meetings over recent years. As clinical trials have become increasingly multiregional and since the same trials are used for applications to regulators on a worldwide basis, it is important for patients, healthcare professionals, developers and regulators to have clear approaches to including diverse populations in clinical trials.

In general, the proportion of patients from European investigator sites included in clinical trials submitted for marketing authorisation is about 20-30% overall, whilst very variable on a product-by-product basis. Wherever clinical trials are conducted many factors influence which patient groups are finally included. It is important that we understand which factors are important when selecting patient populations for testing of cancer treatments so that we can all understand how those medicines safety and efficacy will work in the diverse populations who are finally treated.

Whilst FDA has published several draft guidance on diversity action plans, these are specific to the US context and not generally applicable for the European context.

It is therefore very timely that CDDF is launching this project to develop a consensus paper on diversity in clinical trial populations.

After discussion with multiple stakeholders, including many from companies developing oncology products, a CDDF co-ordination group was formed. This group has put forward a proposal for an initiative to form a working group of regulators, payers, patients, academic researchers, and pharmaceutical companies to consider parameters of inclusion / diversity to support planning and evaluation of clinical research and the applicability of clinical trial outcomes to Europe's diverse population. The CDDF board approved the initiative on July 30, 2024.

The main objectives for the initiative are

- To review and summarize the existing research, guidance and data on variables that capture diversity and representativeness relevant for oncology clinical trials.
- To describe a set of variables relating to diversity and representativeness that can serve to plan and evaluate oncology clinical trials for their applicability to Europe's population.
- To include the perspectives of key stakeholders: patients, healthcare professionals, academia, pharmaceutical industry, HTA views and medicines regulators.
- To consider the impact of such datasets on clinical trial planning/advice, conduct and evaluation of outcomes including for regulatory assessment / benefit-risk determination as well as HTA assessment.

The key deliverables of the initiative are

- To publish a consensus paper describing the selected variables, rationale for their selection, methodological approaches and respective best practices for clinical trials and studies with the related stakeholder perspectives.
- To outline open questions for further research.
- To publish a systematic review, if possible with a meta-analysis, of published data and guidance.

The initiative will work in two phases: The first phase includes formulation of scope, objectives and work-plan for the second phase. Phase 2 will involve preparation the analysis of literature, potential variables, research on their use and preparation of publications, the detail of which work will be undertaken by the working group's academic partner. The group will also need to define the budget for funding this work.

This budget would cover the academic research work involved as well as the CDDF project management and meeting costs. This budget is not included in the annual budget of the CDDF and will need to be funded by the companies participating in phase 2 of the initiative. The size of the budget and the individual contributions will depend on the number and size of participating companies as well as on the cost of work undertaken by our academic partners. The CDDF coordinates the budget and will be reimbursed for project management and meeting-related expenses. We expect that the total amount per (large) company will be around or less than €25.000 in a two-year period.

The first meeting of the working group is planned for October 2024, and it anticipates completing its activities by the end of 2025. There will be one face to face meeting of the working group mid 2025, in Brussels, to finalise the consensus paper. Other activities will be conducted online via email or videoconference.

The project is open for all interested pharmaceutical companies independent of their membership in the CDDF. Please let the CDDF office know if you are interested to participate. We look forward to hearing from you and to receiving a nomination of a representative to participate in the working group.

If you do want to participate or seek further information, please contact the CDDF office at info@cddf.org .

We are at your disposal for questions and more information at any time. Hyunmin Park is the co-ordinator in the CDDF office, and the undersigned, Axel Glasmacher and Fergus Sweeney, are the representatives of the CDDF board.

With many thanks and kind regards,

Axel Glasmacher
CDDF Board

Fergus Sweeney
CDDF Board