Terms of Reference for the Non-Clinical Oncology EMA/FDA Cluster

The European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) agree on the following:

1. Objectives and goals

The EMA/FDA cluster for non-clinical oncology should fulfil the following objectives:

- Focus primarily on non-clinical aspects of products under marketing review.
- Discuss non-clinical aspects for products at the investigational stage.
- For drugs and biologicals, generally discuss products covered by ICH S9 and the Q&A.
- Discuss interpretation of ICH S9 with related Q&A and other relevant EMA or FDA guidance documents.
- Discuss general approaches e.g. need for proof of concept, general toxicology, DART or carcinogenicity studies for product classes in oncology.
- Streamlining nonclinical development in oncology.
- Discuss non-clinical approaches for products intended for treatment of benign (non-malignant) tumours.
- Promote the principles of the 3Rs when discussing topics.

The primary goal of this cluster is to share best practices in the medicine's regulatory lifecycle within the respective agencies and to support each other's aim to further improve the non-clinical review of applications. Where possible, seeking alignment on regulatory science aspects related to non-clinical development of oncology products. The main mechanism to achieve this goal will be regularly scheduled teleconferences for exchange of information and experience.

It may be appropriate to agree on additional discussions on specific topics through ad hoc teleconferences and where relevant to include participation of additional EMA/FDA staff members or experts.

The work of the cluster is conducted within the confidentiality arrangements in place between the participating parties.

2. Participants

The FDA participants will consist of non-clinical Reviewers, Team Leads, and Supervisors from the Division of Hematology Oncology Toxicology (DHOT) in Office of Oncologic Diseases (OOD), within the Center for Drug Evaluation and Research (CDER). Staff from other Divisions in CDER may be invited based on the topics. On occasion, appropriate staff from the Center for Biologics Evaluations and Research (CBER) may be invited to the meeting, for instance when a proposed topic on streamlining may affect products in CBER.

From the EMA side, participants will include Non-clinical working party (NcWP) members, EMA staff members (from Translational Sciences office, who will also be supporting the cluster secretariat), and depending on the topic and issue to be discussed, additional non-clinical assessors and EMA staff may take part in the evaluation of the products.

The lead discussant should generally be the product reviewer from the organization that nominated the topic for discussion.

The teleconferences will be co-chaired by the EMA and the FDA.

3. Timing

It is anticipated that teleconferences will occur 3 times per year, subject to need and predefined in advance, each lasting approximately 1.5 hours.

Ad-hoc teleconferences, on product-related assessments, of a more pressing nature can be held at any time.

4. Working arrangements

The EMA and the FDA will alternate in having responsibility to prepare the agenda, including mutually agreed topics for discussion in line with the objectives described under section 1. The topics should be selected on the grounds that they are of mutual interest and are anticipated to be beneficial for both agencies.

A proposed draft agenda will be sent by either the EMA or the FDA about two weeks in advance of a teleconference for verifying topic proposals for mutual agreement. Urgent topics may be added shortly before the teleconference by mutual agreement.
Once the agenda has been agreed upon, the need for additional ad hoc teleconferences may be identified for in-depth discussion of specific issues, and a specific agenda for such ad hoc teleconference will be set.

5. Confidentiality

- Confidentiality of the information shared within the cluster is covered under the bilateral information sharing Confidentiality Arrangements (CA) that exist between members. Cluster members and observers are responsible for the implementation and maintenance of these arrangements.
- Cluster members, as well as observers and guests, shall not disclose publicly or do anything that would lead to the disclosure of information shared or discussed during meetings without prior authorization of the members that provide such information.
- The chair will inform meeting attendees if there are participants from outside of member or permanent observer organizations.

6. Reaching agreement

The cluster will come to final decisions using the process of consensus, defined as general verbal agreement, to the greatest extent possible.

Discussions and recommendations from this cluster are consultative in nature and non-binding.

7. Workplan and reporting

A joint annual/bi-annual workplan outlining the cluster's priorities and a cluster report are encouraged. Agenda and actions points will be routinely generated. No specific document other than agendas and action points will be generated, but the teleconferences may be supported by already existing EMA or FDA documents. Recording for the purpose of assisting with drafting minutes is acceptable. After minutes are generated the recordings and transcripts will be deleted.

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