31 October 2025
REFERENCE NUMBER

# Terms of reference for EMA-FDA Oncology early-dialogue Cluster

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

## 1. Goal and Objectives

*The primary goal of the EMA-FDA Oncology early-dialogue cluster is to promote early discussion, knowledge and regulatory information sharing between the EMA and FDA for oncology products during the Scientific Advice and Pre-Authorisation phase at EMA* and the *Investigational New Drug (IND) phase at FDA or beyond, if requested. Important aspects pertaining to development, evaluation and post-marketing that affect products that they regulate in common concerning oncology indications may be discussed. These discussions help understanding of the rationale behind respective regulatory approaches.*

*Specific examples of the work include:*

- Engaging in product or class specific discussion such as, but not limited to, interpretation and requirement of data, clinical trial/study design, extrapolation of data, labelling, and risk management.
- Sharing best practices that address new approaches, scientific and regulatory barriers to promote global clinical trial development for oncology related products.
- Encouraging early alignment, and consistent feedback with sponsors during product development.
- Offering a confidential forum to exchange draft documents, policies in development and more detailed information supporting the scientific basis for scientific advice and decision making.

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

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## 2. Membership

***Attendees of Monthly Meeting:*** *Participants should attend and participate in teleconferences, provide strategic advice informed by expertise and experience, collaborate with other members through information-sharing.*
*EMA: Scientific Committees and Working Party members (mainly CHMP, SAWP and ONCO-WP) and relevant EU national experts/assessors; EMA staff members, including but not limited to Human Division-Therapeutic offices [mainly Oncology and Radiopharmaceuticals (H-TA-ONC), Advanced therapies and haemato-oncology (H-TA-ATH)], Scientific Evidence generation (mainly H-EG-SCA), Data Analytics and Methodologies, International Affairs.*
*FDA: OCE International Team, OCE Leadership, Office of Oncologic Diseases leadership, FDA Liaison to EMA, and review staff associated with topics coming before the committee for a given month.*

## 3. Timing

*One-hour virtual teleconferences will be scheduled monthly at the end of the calendar year or beginning of each calendar year to encompass one calendar year of meetings. Meetings are to be scheduled on Wednesday of the same week that EMA has Scientific Advice Working Group scheduled (exceptions maybe requested for Holidays, etc.).*

## 4. Working arrangements

*Cluster leads will agree which topics be discussed at this cluster and which should be deferred to other platforms/clusters, e.g. Oncology International Cluster (FDA/EMA/HC/PMDA/TGA/SMC), etc. to avoid duplication.*

*The agenda will be set based on a list of topics. EMA will initiate and draft the list of monthly topics to the EMA FDA International Oncology SharePoint once available for the coming month. FDA will then research the topics and provide information on the draft excel list, including any other FDA IND ongoing topics of interest. Any information regarding the application at FDA will be shared with EMA so that they may ask sponsor for minutes, discussions, etc and vice versa.*

*EMA will notify the FDA on the list of final topics selected for the bilateral on the Monday before the Wednesday meeting by COB, with a maximum of 4 topics per meeting. An agenda with confirmed topics will be provided as soon as possible before the meeting commences. Urgent topics may be added shortly before the meeting by mutual agreement and availability of team members to discuss.*

*Confirmation of availability will follow to confirm topic discussion on the planned Wednesday. If any additional follow up is needed for a topic once discussed, it can be brought up via email to EMA or FDA and the coordinators will facilitate answering.*

*FDA will oversee sending the calendar invitations to facilitate organization.*

*Concise minutes / action points including conclusions of the discussion will be generated during the discussion and circulated after the meeting.*

## 5. Confidentiality

*Confidentiality of the information shared is covered under the bilateral information sharing agreements that exist between members. Members are responsible for the implementation and maintenance of these agreements. All 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.*

## 6. Reaching Agreement

*Not applicable. This meeting is to discuss opinions and scientific exchange; it is not meant to reach an agreement between EMA and FDA nor meant to harmonise scientific advice to the sponsors.*

*Discussion outcomes may be to exchange follow-up information in writing, share written minutes, or to work on joint communications.*

## *7. Workplan and Reporting*

*An annual report highlighting the activities of the cluster will be drawn up with a specific frequency (yearly)*

*EMA and FDA will review this Terms of Reference every two years, or as otherwise required.*

*No specific document other than agendas, and high-level summary captured during the meeting on the agenda that is presented during the meeting will routinely be generated. Agreed upon action points and responsible parties will be documented in the agenda during the meeting.*

*Adoption Date: 31 October 2025, review annually.*