Neuroscience Cluster – Terms of Reference

23 January 2026

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

1. Goal and Objectives

Neurologic and psychiatric disorders are among the leading causes of disability and burden. Given the complex pathophysiology and the difficulties in objectively measuring patient-relevant outcomes, supporting the development of medicines for these conditions, as well as evaluating evidence, presents special challenges.

The joint EMA/FDA cluster collaboration on neuroscience aims to provide a confidential forum to fulfil the following objectives:

- Exchange information on the scientific evaluation of marketing applications concerning relevant neurologic and psychiatric medicinal products within the scope of EMA and FDA regulatory authority;
- Exchange information on relevant policy documents, regulatory guidance documents and legislation affecting neuroscience product development and evaluation;
- Exchange views on regulatory impacts, priorities and goals for neurosciences-related activities, especially in areas of emerging mutual interest;
- Identify and pursue specific activities of mutual benefit such as jointly sponsored scientific symposia or workshops to advance regulatory science and improve the evaluation of neuroscience therapeutics.
- Share regulatory experiences, lessons learned, and best practices in the assessment of novel endpoints, biomarkers, clinical trial designs, and emerging therapeutic modalities in neuroscience.

Cluster participants will regularly discuss and determine which topics will be addressed at the Cluster's meetings.

2. Participants

EMA's participation in this cluster includes EMA staff members from, but not limited to, the Office for Therapies for Neurological and Psychiatric Disorders, the International Affairs Division, relevant Scientific Committee or Working Party members and other EU experts as appropriate to the topics under discussion.

FDA's participants includes staff from the Office of Neuroscience within the Centre for Drug Evaluation and Research (CDER), EMA-FDA liaison officers and other FDA staff members as appropriate to the topics under discussion.
EMA and FDA agree that guests (e.g. observers from other regulatory authorities or organisations) may participate in cluster activities, subject to the prior agreement all parties. The scope of topics discussed in the presence of guests will be determined based on the existence of appropriate confidentiality arrangements.

3. Timing

The Neuroscience Cluster meetings are expected to be conducted remotely (approximately one-hour teleconferences) and will be chaired by the agencies in a rotational system.

Meetings will be held monthly unless otherwise agreed by both parties. A shared meeting calendar will be maintained and continuously updated by both agencies.

As needed, ad hoc meetings on specific topics may be scheduled with participation from additional EMA/FDA staff members or subject matter experts.

4. Working arrangements

EMA and FDA will alternate the responsibility to prepare the cluster meeting's agenda and agreed upon action points, including mutually agreed topics for discussion in alignment with the objectives of the cluster.

For each regular teleconference, topics will be selected by mutual agreement of EMA and FDA for discussion in line with the objectives described under Section 1. The topics will be selected on the grounds that they are relevant to both agencies and that exchange on these topics is anticipated to be beneficial to both agencies.

A draft agenda will be sent by the responsible agency approximately one or two weeks in advance of the meeting for review and mutual agreement and to ensure availability of relevant experts. Urgent topics may be added shortly before the meeting by mutual agreement.

EMA and FDA will co-develop the agendas and agreed upon action points to serve as the summary record of the teleconference.

5. Records and supporting documents

No specific document other than agendas and agreed upon action points will be routinely generated, although cluster member may decide to create documents that may be shared, as appropriate, with other clusters. The teleconferences may be supported by already existing EMA or FDA documents.

6. Confidentiality

- Confidentiality of the information shared within the cluster is covered under the bilateral information sharing Confidentiality Arrangements (CA) that exist between members and observers. 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.

7. Workplan and Reporting

A joint workplan outlining the cluster's priorities will be developed annually or bi-annually informed by meeting agendas and agreed upon action points. A yearly report highlighting the activities of the cluster will be prepared with a specified frequency.

These Terms of Reference will be reviewed annually and may be amended by mutual written agreement of both agencies.