Biostatistics Cluster – Terms of Reference

17 June 2026

The European Medicines Agency (EMA), the United States (US) Food and Drug Administration (FDA) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan agree on the following:

1. Introduction

This document has been developed and agreed upon in the framework of the confidentiality commitments between the following regulatory agencies: the European Medicines Agency (EMA) of the European Union (EU), the United States (US) Food and Drug Administration (FDA), and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan. These regulatory agencies have created a confidential forum for discussion of biostatistics issues in medical product development. This is known as the Biostatistics Cluster.

Regulatory statisticians play a critical role in promoting and ensuring the development of safe and effective new medical products. Statisticians provide expertise throughout product development, such as by reviewing clinical trial design and analysis plans, analyzing data, interpreting results, and contributing to policy and guidance.

2. Goal and Objectives

The primary goal of the joint EMA-FDA-PMDA cluster collaboration in the area of biostatistics is to provide a forum for statisticians from different regulatory agencies to exchange knowledge and experiences and discuss important emerging biostatistics issues in medical product development. This cluster helps support regulatory coordination and transparency.

The specific objectives of the Biostatistics cluster are:

1. To facilitate the regular exchange of knowledge and experiences related to important emerging biostatistics issues in medical product development.

2. To discuss challenging biostatistics topics and foster global harmonization in areas important for the development of safe and effective medical products.

3. To understand the scientific rationale when differences in opinions exist between regulatory agencies on important biostatistics issues.

4. To contribute to the harmonisation of regulatory standards by exchanging perspectives on methodological and operational aspects of clinical study data access and analysis but also discussing best practices.

3. Participants

- EMA's participation in this cluster includes EMA staff members from, but not limited to, the Methodology workstream, International Affairs, members of the Methodology European Specialised Expert Community, which brings together experts from EMA and national competent authorities (NCAs) of the European Medicines Regulatory Network (EMRN), and other EU experts as relevant.

- FDA's participation in this cluster includes members from the Office of Biostatistics in the Center for Drug Evaluation and Research, the Division of Biostatistics in the Center for Biologics Evaluation and Research, and other staff as appropriate.

- PMDA's participation in this cluster includes members from the Office of New Drug I to V, the Office of Vaccines and Blood Products, the Office of Cellular and Tissue-based Products, and other staff as appropriate.

EMA, FDA and PMDA agree that observers from other regulatory authorities may participate in cluster activities subject to previous agreement of the lead agencies and appropriate confidentiality arrangements being in place.

4. Working Arrangements

The Biostatistics Cluster meetings are expected to be conducted remotely, last for 90 minutes and be held twice per year, typically in the spring and fall. Additional ad hoc meetings may be scheduled as desired.

The chair of the meeting will rotate between the EMA, FDA, and PMDA at each meeting. Potential agenda topics will be discussed on a regular basis by participating agencies, with specific meeting topics agreed upon based on importance and shared interests. Proposals should be circulated via email at least three weeks in advance to verify topics for mutual agreement. Urgent topics may be added shortly before the teleconference by mutual agreement.

The agency chairing the meeting is responsible for identifying an agreeable meeting date, scheduling the meeting, sharing the topic, agenda, and materials with participants in advance of the meeting, and leading the meeting discussion. Minutes or action points are prepared after every meeting.

Background materials (e.g., agenda, slide presentations, discussion topics/questions) should be shared with meeting participants in advance of the meeting, ideally at least one week prior to the meeting to allow time for participants to review materials and prepare for discussion.

5. 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.

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.

7. Workplan and Reporting

A joint annual or biannual workplan stating the priorities of the cluster will be generated. A report highlighting the activities of the cluster will be prepared with a specified frequency.