Advice to the European Medicines Agency from the clinical trial advisory group on Clinical trial data formats – Discussion document

Introductory Note

This is a proposal on how to structure the upcoming discussion among members of the advisory group on clinical trial data formats, which is set up to inform the upcoming EMA policy on access to clinical trial data. This document is not intended to pre-empt the content of the policy that the agency will ultimately adopt. All proposed questions are deliberately kept at a high level to enable open discussion.

Problem Statement

How can the Agency ensure through its policy that clinical trial data can be shared, in the interest of public health, in a clear and understandable format that enables appropriate analyses and a swift implementation without undue burden to stakeholders?

Discussion Proposal

1. Definitions

    1.1. This advice refers to all data recorded in a clinical trial (at a patient level or derived) that can be stored electronically and associated metadata (variable definition, terminology such as code lists or dictionaries) that are part of a submission for marketing authorisation to the Agency.

    1.2. In this discussion proposal, data formats refer to the organisation of information according to pre-set specifications that facilitate the storage, exchange and archive of clinical data. It includes both the type of electronic files and the content of the files, as well as associated metadata.

2. Are formats needed?

    2.1. What is the purpose of formatting data and providing associated metadata?

    2.2. As there are no universally agreed formats of reference, should there be a minimum set of rules defined?

3. What is to be included in data formats?

    3.1. Are all types of clinical trial data included (e.g., data from case report forms, computerised tomography scans, recording of interviews, etc.)?

4. Which formats?

    4.1. Should EMA allow for one or several formats? If the latter, should they be compatible?

4.2. Is Clinical Data Interchange Standards Consortium (CDISC) providing the reference model for data formats? What are the alternatives to CDISC?

4.3. In what situations would alternative formats be acceptable?

4.4. How can sustainability of formats be ensured? (see also 7.3)

4.5. Will old non-formatted data constitute a hurdle?

5. Who should adhere to the agreed formats?

5.1. Should formats be mandatory to all types of trial / stakeholder? (public or private, small or big entities, etc.)

5.2. How can small organisations be supported to use mandatory or recommended formats?

5.3. Are formats to be applicable to any data from within Europe as well as other regions?

5.4. Who is responsible for ensuring correct application of the formatting and any translation of the data for submission to the Agency?

6. By when should formats be implemented?

6.1. When should formats become mandatory?

6.2. Should different formats be required in a stepwise approach?

6.3. How often should format requirements be updated in the EMA policy?

7. International harmonisation across regulatory agencies

7.1. Should format requirements be harmonised between EMA, US FDA and Japan PMDA?

7.2. Should other countries be consulted?

7.3. Can harmonisation be achieved through the international standardisation process? This would include working with organisations such as the International Conference on Harmonisation (ICH), the Asia-Pacific Economic Cooperation (APEC), CDISC, Health Level Seven (HL7), the International Organization for Standardization (ISO) and the European Committee for Standardisation (CEN).