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MINI SUMMIT XIV: R&D COMPLIANCE -- CASE STUDY ON CLINICAL TRIAL DATA DISCLOSURES

4:30 p.m. – 5:45pm

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Current framework in the EU

- There are currently three bases on which clinical data can be disclosed in the EU:
  1. New European Medicines Agency (EMA) Disclosure Policy;
  2. EMA Access to Documents Policy;
  3. Voluntary commitments by industry associations and pharmaceutical companies such as the EFPIA/PhRMA Joint Principles. [covered by Ima]

EMA Policy on Access to Documents

EMA Policy on Access to Documents – Reactive publication

- Legal basis: Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.
- In response to a request from a third party, the EMA may provide access to such third parties to certain documents held by the EMA.
- The documents include:
  - Internally generated documents and those provided by third parties;
  - clinical trial data submitted as part of an application for marketing authorisation.

Commercially confidential information

- As a general rule, the EMA will not disclose trade secrets or "*commercially confidential information*" ("CCI").
- The EMA and the Heads of Medicines Agencies (HMA) have defined CCI as:

  > *"any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information."*

- The EMA will communicate the request to the company that submitted the data to the EMA who can submit arguments in support of a claim that the data in question constitutes CCI that should not be disclosed.

Examples of what the EMA considers as CCI

- Detailed quality and manufacturing information.
- Pharmaceutical development information.
- Detailed information on the synthesis or manufacture of the active substance.
- Detailed descriptions of the manufacturing and control processes for the finished product.
- Information concerning the validation of the manufacturing process.
- Contractual agreements between companies.

Personal data [to be covered by Daniela]

- Documents will be redacted before disclosure to ensure that personal data is not disclosed.
- The legal framework governing such redaction is Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

Procedure

- Requests for access to documents must be processed by the EMA within 15 working days from registration of the request.
- The time limit of 15 days may be extended in exceptional circumstances such as requests for access to a large number of documents.
- If the applicant is refused access, they are granted a right to submit a confirmatory application requesting the EMA to reconsider its refusal.
- Confirmatory applications are also subject to a 15 day processing time limit.

New EMA Disclosure Policy

The new EMA Disclosure Policy - Proactive publication

- The Disclosure Policy was adopted on 2 October 2014.
- The Disclosure Policy provides specific access by third parties to clinical reports and individual patient data submitted as part of:
  - applications for marketing authorisation (MA); or
  - a post-authorisation procedure for a centrally authorised medicinal product.

Effective Date

- The Disclosure Policy will apply to clinical reports submitted to the EMA after:

Effective Date	Clinical Reports Submitted as Part of:
1 January 2015	Application for centralised marketing authorisation of a medicinal product submitted after the Effective Date
1 July 2015	Application for extension of a therapeutic indication and line extension applications submitted after the Effective Date
To be determined	All other post-authorisation procedures

How will the data be disclosed?

- The data will be published on the EMA's website.
- Access by third parties to the clinical data will be conditional on acceptance by visitors of Terms of Use (ToU).
- There are two separate ToU depending on the intended purpose of which data accessed will be used:
  - ToU concerning access for general information purposes; and
  - ToU concerning access for academic and non-commercial research purposes.
- Users must complete a registration process and agree to the related ToU.

Conditions attached to the ToU

- The conditions to the ToU ensure that users cannot:
  - make any attempt to re-identify the trial subjects or other individuals from the information;
  - use the clinical data to support an application to obtain a marketing authorisation and any extensions or variations thereof for a product anywhere in the world;
  - make any unfair commercial use of the clinical data.
- A watermark is applied to the published information to emphasise the prohibition of its use for commercial purposes.
- Unfair commercial use does not include use of clinical data by pharmaceutical companies as part of their preparation for a dossier to be submitted to HTA bodies.

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