

# Disclosure of Clinical Trial Data in EU

What are the implications of the new rules?

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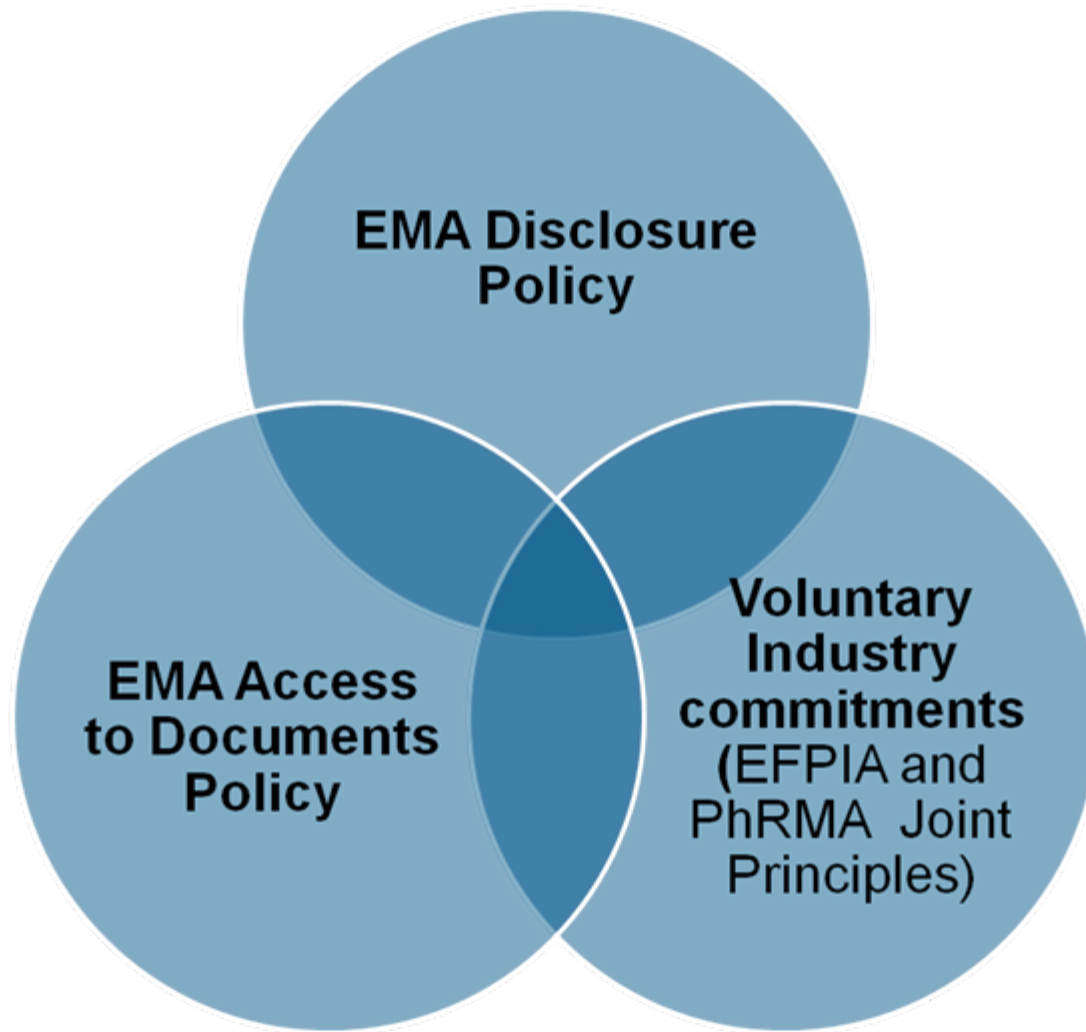
# Current framework in the EU

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- 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.

# Current framework in the EU

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# EMA Policies

# EMA Policy on Access to Documents – Reactive publication

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- 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

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- 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.

# The new EMA Disclosure Policy - Proactive publication

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- 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

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- 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 in 2015	All other post-authorisation procedures



# How will the data be disclosed?

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- 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

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- 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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# **Voluntary Industry Commitments**

# EFPIA and PhRMA Joint Principles

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- Adopted by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).
- The Joint Principles came into force on 1 January 2014.
- The Joint Principles concern the sharing of clinical trial data by pharmaceutical companies to patients and healthcare researchers.
- The Joint Principles are voluntary commitments that apply to all EFPIA Member Companies and EFPIA Member Associations.

# The Principles

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- The disclosure requirements are established on the basis of the following principles:
  - Enhancing data sharing with researchers;
  - Enhancing public access to clinical study information;
  - Sharing results with patients who participate in clinical trials.
- A number of member companies of EFPIA have begun to include clinical data on their company websites.

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# Clinical Trials Regulation

# Clinical Trials Regulation

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- The Clinical Trials Regulation aims to increase the transparency of data generated from authorised clinical trials conducted within the EU.
- The Regulation requires the public disclosure of clinical study reports on a publically accessible database.
- The Regulation will replace the current Clinical Trials Directive.
- The new Clinical Trials Regulation is expected to enter into force no earlier than 28 May 2016.

# EU Database

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- The EMA will establish and maintain a publicly accessible and searchable EU database of all data and information submitted as part of an application for authorisation of a clinical trial (“EU Database”).
- All approved clinical trials will be registered in the EU Database with a unique EU trial number (separate database to EudraCT).



# Disclosure of clinical study reports

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- Sponsors are required to upload the following information into the EU Database:
  - Detailed summaries of the results of authorised clinical trials.
  - A summary of the clinical trial results must be drafted by the sponsor in plain language and submitted within one year of the completion of the clinical trial.
  - Following an application for marketing authorisation of a medicinal product, final clinical study reports that were submitted in support of the application must be submitted within thirty days of the authorization, rejection, or withdrawal of an application for marketing authorisation of a medicinal product.
- Summaries of the results of the clinical trial and the final clinical study reports must be submitted irrespective of the outcome of the clinical trial.

# Confidentiality

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- Confidentiality may be claimed in the following circumstances:
  - protection of patients' personal data, including personal health data;
  - commercially confidential information;
  - protecting confidential communication between EU Member States in relation to the preparation of the assessment report; and
  - ensuring effective supervision of the conduct of a clinical trial by an EU Member State.
- Clinical study reports will not be considered commercially confidential information once the review of an application for marketing authorisation has been finalised.

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