EMA
EUROPEAN MEDICINES AGENCY

EMA/HMA European Platform for Regulatory Science Research

Showcasing EMA's Clinical Data Publication and use by researchers

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29 September 2025

A regulatory framework

Reg(EC) 2018/1725
Personal Data Regulation

Art 13 Reg(EC) 726/2004
European Public Assessment Report

Art 80 Reg(EC) 726/2004
Appropriate level of transparency

Reg(EC) 1049/2001
Access to document Regulation
+ Policy 0043

Policy 0070
Clinical data publication

Eudravigilance access policy

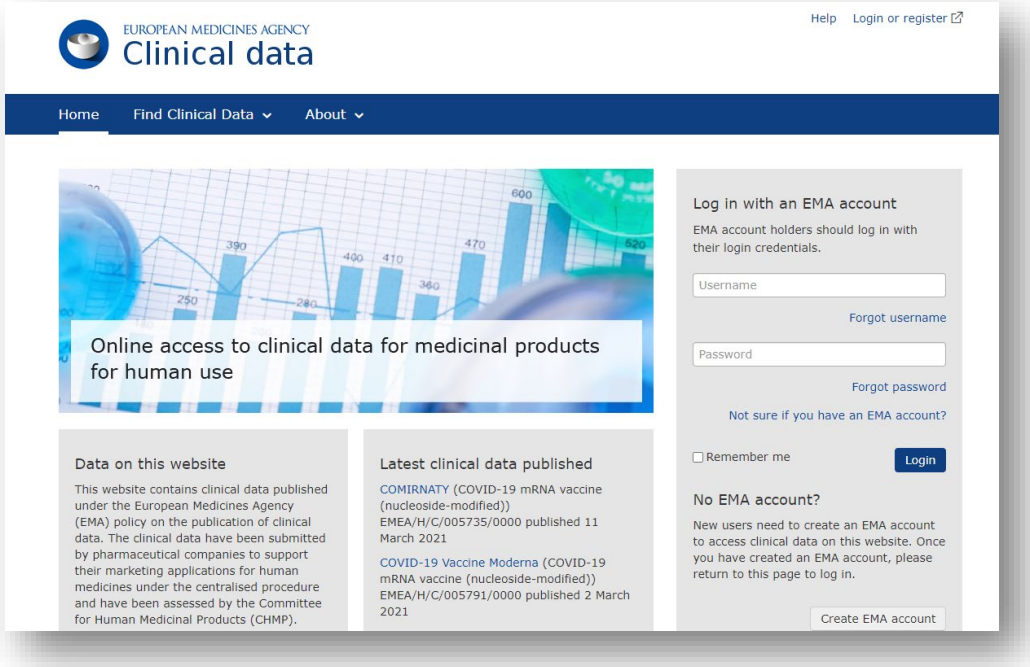
Reg(EC) 536/2014
Clinical trial Regulation

Reg(EC) 2017/745
Medical Device Regulation

Sharing Clinical data at EMA

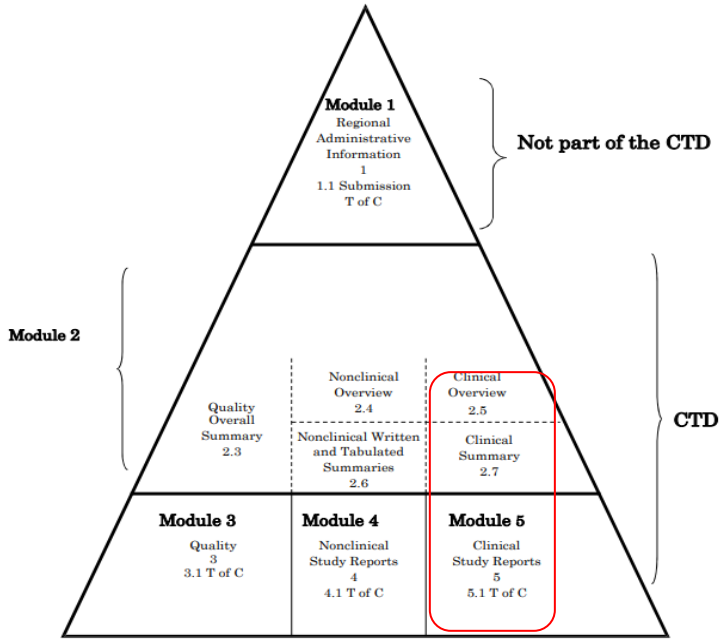
	European Public Assessment Report (EPAR)	Access to Documents (ATD)	Clinical data Publication (CDP)	Clinical Trial Regulation (CTR) or CTIS (Clinical Trial Info System)
Basis	Reg(EC) 726/2004	Reg(EC) 1049/2001 Policy 0043	Policy 0070	Reg(EC) 536/2014
What	Scientific grounds whether or not an application has been approved	Any documents held by EMA	Clinical reports supporting MAA for human medicines via central authorisation	Data on Clinical Trials conducted in EU
When	At the end of the assessment process	Upon request	Pro-actively	Pro-actively
Where	https://www.ema.europa.eu	Provided directly to requester	https://clinicaldata.ema.europa.eu	https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en

EMA’s Clinical Publication website



clinicaldata.ema.europa.eu/web/cdp

Structure of a Marketing Authorisation Application (Dossier)



ICH guideline M4 (R4) on common technical document (CTD) for the registration of pharmaceuticals for human use - organisation of CTD

Dealing with personal data of study participants

Take into account the **context**, not only the data, e.g.

- Type of medicinal product: Orphan/non-orphan drug?
- Prevalence and therapeutic indication: Rare disease?
- Number of subjects enrolled / patients exposed during the reporting period / the size of the data set
- The type of population: paediatric? adults? geriatric? vulnerable?
- Number of countries where the study is conducted / where the product is marketed
- Number of sites for clinical studies
- Duration of the clinical study / reporting period

⇒ Will help to establish the level of risk of reidentification of individuals

Navigating through the CDP website, Demo from Karen Quigley, Head of CDP Service at EMA

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Thank you

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