

The EMA Transparency Department's journey

The perspective of a regulator

Anne-Sophie Henry-Eude, Head of Transparency, EMA
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Disclaimer

The views expressed in this presentation are mine and should not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

Timelines of our story...

Sept 2013

Centralisation of access to documents (ATD) and requests for information (RFI) EMA. The **ATD Service** is born!

Oct 2014

Adoption of **Policy 0070** on pro-active publication of Clinical Data (**CDP**)

Oct 2016

First package published on the EMA CDP portal

2020

CDP as **exceptional transparency measures** for Covid-19 medicines

2023

CDP is **relaunched**
The **Transparency Department** is in place together with its 2 Services

A regulatory framework

Reg(EC) 2018/1725 Personal Data Regulation

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

Policy 0070
Clinical data publication

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

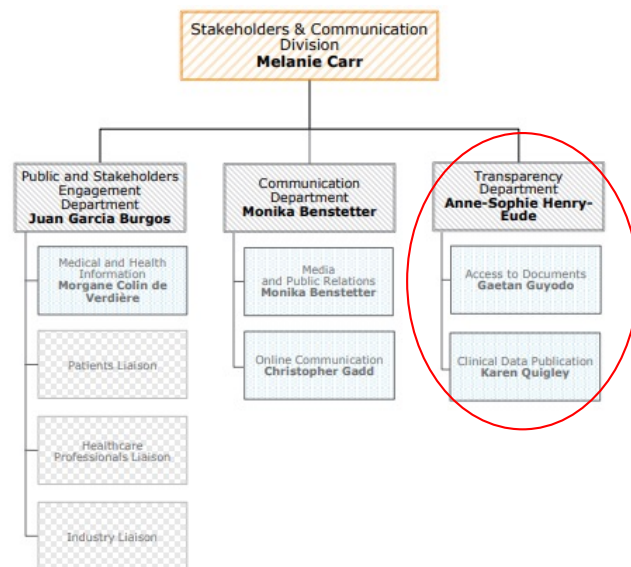
Eudravigilance access policy

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

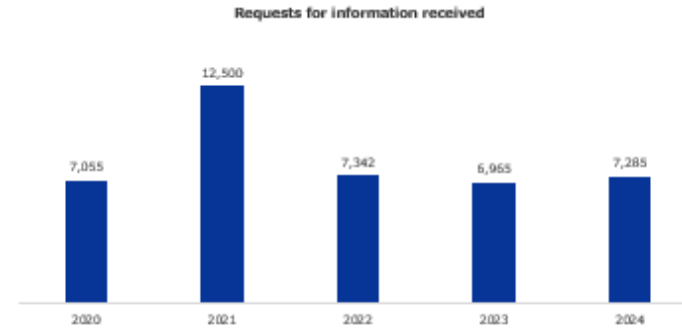
Reg(EC) 536/2014
Clinical trial Regulation

Reg(EC) 2017/745
Medical Device Regulation

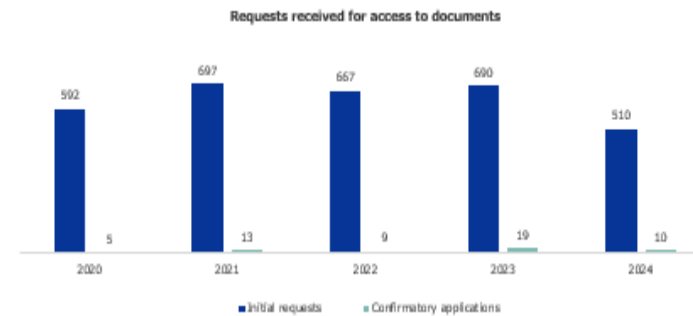
Who we are



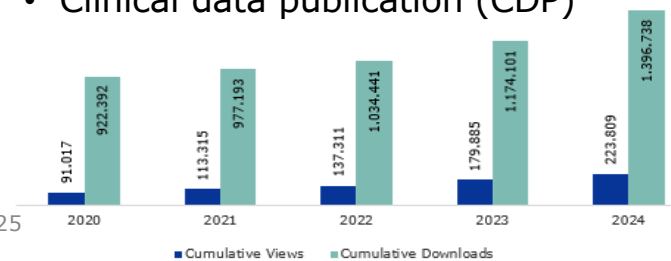
- Requests for information (RFI)



- Requests to access documents (ATD)



- Clinical data publication (CDP)



An advisory role within EMA

- **Bringing expertise** on CCI* and anonymisation of PD** in
 - EPARs and Assessment Reports linked to [Art.46](#) of Reg(EC) 1901/2006
 - Guidance on CCI & PD management in documents uploaded in [CTIS](#)
 - Transparency aspects of the [Raw Data](#) project
 - Publication of experts Opinions for [medical devices](#)
- Analysing **interest of stakeholders**
 - Publication of [RMP](#) (Risk Management plans),
 - Publication of [PSURs](#) (Periodic Safety Update Reports) & [PRAC Assessment Reports](#) for Covid-19 vaccines
 - [Extraordinary transparency measures](#) linked to Covid-19 related medicines
- **Data Protection coordination for the Division**
 - With 3 staff members [DPO](#) (Data Protection Officer) [certified](#)
 - Review of risk of re-identification of individuals in case of [suspicion of data breach](#)
 - Active involvement in ROPA, DPN, TIA, DPIA***

* Commercially Confidential Information
** Personal Data
*** Records Of Processing Activities, Data Provision Notice, Transfer Impact Assessment, Data Protection Impact Assessment

Strengths of the transparency team

- Diverse backgrounds and areas of expertise
- Strong believer in transparency
- Supported by leadership team
- Willingness to learn, grow and get out of the comfort zone
- Analytical and persuasive
- Resilient, still able to make informed decision
- Collaborative mindset within and outside the team

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	In an EU database

When dealing with Clinical data

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

More recently...

2024

Revision of the HMA/EMA guidance document on the identification of personal data and commercially confidential information within the structure of the marketing authorisation application (MAA) dossier*

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Annex 1 for medicinal products for **human** use

2025

Revision of the Clinical Data Publication external guidance**

2025

Preparation of an Annex 2 for medicinal products for **veterinary** use

*
https://www.ema.europa.eu/en/documents/other/heads-medicines-agencies-european-medicines-agency-guidance-document-identification-commercially-confidential-information-personal-data-within-structure-marketing-authorisation-application_en.pdf
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https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use-version-15_en.pdf

What is next in transparency

Reform of the EU Pharmaceutical Legislation*, a very transparent piece of legislation

- Outcome of Environmental Risk Assessment (ERA)
- List of Conditional Marketing Authorisations (CMA)
- Periodic Safety Update Reports (PSUR)
- Risk Management Plans (RMP)
- Transfers of Marketing Authorisations
- Notifications on compassionate use authorisations
- ...etc...

European Health Data Space (EHDS)**, for better healthcare across EU

- To improve individuals' access to and control of their personal health data
- To promote health-data exchange for continuity of healthcare
- To make data available for research and public interest purposes
- To create a single market for electronic health records (EHR) with common rules and infrastructures
- Orchestrated by Health Data Access Bodies (HDAB) on the basis of permits for data use

*https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/reform-eu-pharmaceutical-legislation_en
** https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202500327

*In a time when public trust in health systems is both fragile and essential, **transparency in health data** is no longer a regulatory checkbox, it **is a strategic imperative***

*To ensure public trust, we need **sustainable and responsible transparency***





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Thank you

anne-sophie.henry-eude@ema.europa.eu

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