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SCIENCE MEDICINES HEALTH

Clinical trial transparency

Paediatric Medicines Workshop, 20 March 2018

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Objectives of transparency

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- Have all clinical trials been publicly registered?
- Is there a trial in which I could participate?
- What was the outcome of the trial I did participate in?
- What trials were the basis of the marketing authorisation, what were their results?
- What is known about the medicine I am taking/prescribing?
- Can we review the data used to support the marketing authorisation?
- Has the trial we are designing already been conducted? Were there problems with similar trials?
- Strike the right balance to inform the public, protect public health and foster the innovation capacity of European medical research.

Proactive publication of clinical study reports

EU Clinical Trials Register

Clinical Trial Regulation and EU Portal and Database – public information clinical trials authorized in EU

Summary of differences

	ATD	CDP	CTR
Basis	Reg(EC) 1049/2001 Policy 0043	Policy 0070	Reg(EC) 536/2014
What	Any documents held by the EMA	Clinical reports supporting MAA	Data on Clinical Trials conducted in EU
When	Upon request	Pro-actively	Pro-actively
Where	Provided directly to requester	On a website	In an EU database

Clinical Data Publication –1 year data

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Type of procedure published	
Initial marketing authorisation	36
Extension of indication	18
Line extension	0
Total number of procedures published	54

Documents published	
Anonymisation Report	54
Module 2.5	63
Module 2.7.1-2.7.4	160
Module 5.3 (CSR)	3,002
Total number of documents	3,279
Total number of pages	1,308,244

Proactive publication of clinical study reports

EU Clinical Trials Register

Clinical Trial Regulation and EU Portal and Database – public information clinical trials authorized in EU

EU Clinical Trials Register

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- Launched in March 2011
- Contains protocol and results related data for interventional CT started after May 2004
  - Phase II-III-IV trials conducted in adults in the EEA
  - Phase I-II-III-IV paediatric trials in the EEA
  - Only phase I trials conducted in adults & part of a PIP are made public (small %)
  - NCA decision positive and IEC opinion positive recorded in EudraCT for adult trials – for paediatric trials IEC opinion positive or negative
  - Paediatric CT outside of the EEA if they are part of an agreed Paediatric Investigation Plan (PIP) (including a small % of adult phase I trials if they are part of a PIP)

EU Clinical Trials Register

Home & Search | Joining a trial | Contacts | About

Clinical trials

The European Union Clinical Trials Register allows you to search for protocol and results information on:

- interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA);
- clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development.

Learn more about the EU Clinical Trials Register including the source of the information and the legal basis.

The EU Clinical Trials Register currently displays **32061** clinical trials with a EudraCT protocol, of which **5170** are clinical trials conducted with subjects les
years old.
The register also displays information on **18700** older paediatric trials (in scope of Article 45 of the Paediatric Regulation (EC) No 1901/2006).

X Search

Examples: Cancer AND drug name. Pneumonia AND sponsor name.
How to search [pdf]

Advanced Search: Search tools

Additional Paediatric trials also have results posted.

9,761 trials registered as being conducted in EU now have results posted.

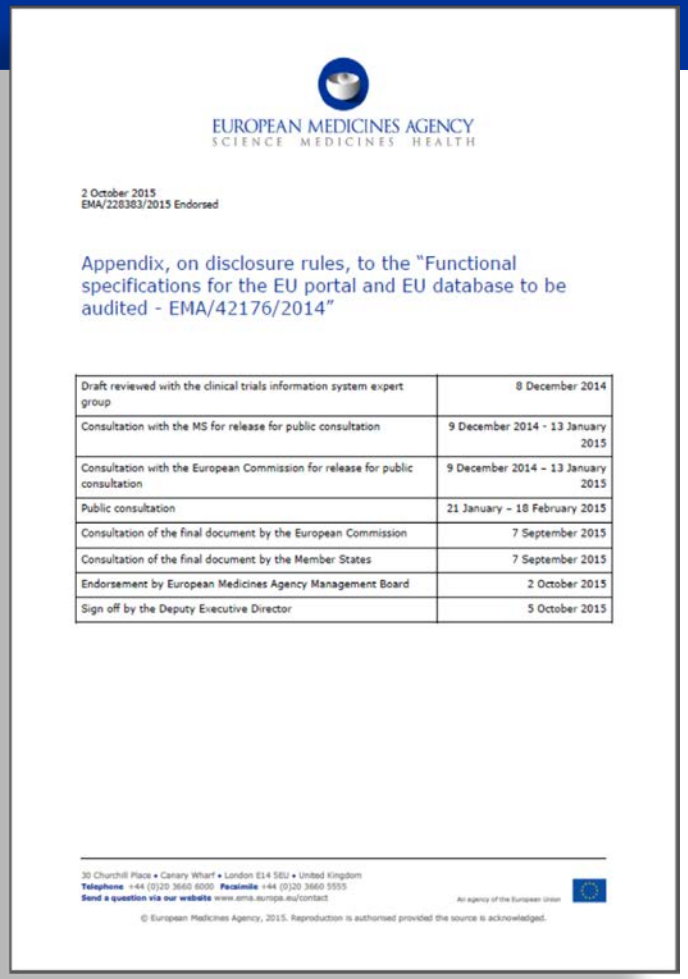
Trials with a EudraCT protocol (9,761) | Paediatric studies in scope of Art45 of the Paediatric Regulation (3,885)

9,761 result(s) found. Displaying page 1 of 489.

Proactive publication of clinical study reports

EU Clinical Trials Register

Clinical Trial Regulation and EU Portal and Database



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2 October 2015
EMA/228383/2015 Endorsed

Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"

Draft reviewed with the clinical trials information system expert group	8 December 2014
Consultation with the MS for release for public consultation	9 December 2014 - 13 January 2015
Consultation with the European Commission for release for public consultation	9 December 2014 – 13 January 2015
Public consultation	21 January – 18 February 2015
Consultation of the final document by the European Commission	7 September 2015
Consultation of the final document by the Member States	7 September 2015
Endorsement by European Medicines Agency Management Board	2 October 2015
Sign off by the Deputy Executive Director	5 October 2015

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- Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"

- Endorsed on 2 October 2015 by EMA Management Board and published on 6 October 2015

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/10/WC500195084.pdf

Summary of Rules

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- The default is to make documents and data public at the first opportunity.
- All data and documents in the system will be made public except for manufacturing/quality information, details of financial agreements between sponsors and investigators, and specified personal data.
- Public registration of trials at their start including all information needed for patients who may wish to participate in trials with therapeutic, diagnostic or preventive objectives.
- Publication of all results (summary, layperson summary and in case of MA application the clinical study report).
- Possibility of justified deferral for summary results only in case of category I trials up to a maximum of 30 months post end of trial (i.e. maximum 18 months deferral).
- Option to defer publication of the IMPD, IB, protocol and subject information sheet, up to maximum of: 7 years post end of trial for category I and 5 years for category II or the time of MA using that trial, whichever is earlier.

Summary - Clinical Trial Transparency – and EMA

- Clinical Trials authorised in EU/EEA:
  - Growing body of clinical trial information and results summaries in EU Clinical Trial Register for trials authorised since 2004.
- Contains protocol and results related data for interventional CT started after May 2004
  - Phase II-III-IV trials conducted in adults in the EEA
  - Phase I-II-III-IV paediatric trials in the EEA
  - Only phase I trials conducted in adults & part of a PIP are made public (small %)
- New clinical trial Regulation - Extensive information on clinical trials from authorisation to the trial summary results of all trials authorised in EU/EEA under the new Regulation.

Thank you for your attention

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Public data and information about medicines, their development and authorisation

- **Generate trust** – information is available;
- **Build confidence** – I understand what is happening;
- **Empower** – knowledge enables decision-making

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Further information

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