EMA – Transparency Policy

- **EU Clinical Trials Register**
- **Policy on publication of data**

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EU - Clinical Trial Data - Access -

Policy on publication of data

- **Freedom of Information Regulation (EC) 1049/2001**

→ POLICY/0070 dated 2 October 2014 EMA/240810/2013

Clinical Trials Register

- **EudraCT in 2011 „goes live“ without results**
- **CTAs only**

→ „In force“ July 2014

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Management Board delays formal adoption of EMA CT-Data Policy

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 July 2014
EMA/415308/2014
Press Office

Press release

Management Board delays formal adoption of EMA publication of clinical trial data policy to October 2014

Further discussion required on wording and practical arrangements

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Policy on publication of CT Data

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 October 2014
EMA/240810/2013

European Medicines Agency policy on publication of clinical data for medicinal products for human use

POLICY/0070
Status: Adopted
Effective date: 1 January 2015
Review date: No later than June 2016
Supersedes: Not applicable

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Policy on publication of CT Data

1. Introduction and purpose

The aim of the European Medicines Agency ('the Agency') is to protect and foster public health. Transparency is a key consideration for the Agency in delivering its service to patients and society.

…

This policy are not intended in any manner to limit the application or the rights given by Regulation (EC) No. 1049/2001. Any natural or legal person may continue to submit a request for access to documents to the Agency independently of the proactive publication mechanisms established by this policy.

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Transparency FOI Request

Applications:

80 % Pharmaceutical companies

10 % Law firms

10 % HCP! only

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Transparency – Impact on competition

The policy has the potential to make medicine development more efficient by establishing a level playing field that allows all medicine developers to learn from past successes and failures.

➔ **Support for unfair competition in clinical trial research?!**

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Transparency – Impact on Commercially confidential information – CCI

<u>Commercially confidential information (CCI)</u>:

CCI shall mean any information contained in the clinical reports submitted to the Agency by the applicant/MAH that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH.

➔ Are protected – especially chemistry and pharmacy

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Transparency – Impact on Protection of individual patient data – IPD

Individual patient data (IPD):

IPD shall mean the individual data separately recorded for each participant in a clinical study.

Personal data:

Personal data shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to their physical, physiological, mental, economic, cultural or social identity (Article 2(a) of Regulation (EC) No 45/2001).

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Transparency – Impact on Protection of individual patient data – IPD

Risk of re-identification especially for orphans is extremely high!
Infringement of Privacy Directive/Regulation

Informed consent?!

➔ Definitely no!

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Transparency – Impact on Protection of individual patient data – IPD

- → **Publication of individual patient data is illegal, because the risk of re-identification via Internet is high. Cochrane publishes all the data assessed in the Internet!**
- → **No informed consent in the past!**
- → **In the future? Acceptance?**

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Transparency – Impact on Protection of individual patient data – IPD

EMA Policy: 4.2.4

- **stepwise implementation**
- **first phase: clinical reports only**
- **second phase: Agency will review various aspects in relation to IPD …. in compliance with privacy and data protection laws!**

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Transparency – Impact on misuse for commercial purposes

- **Annex 1 → Term of use for general information purposes - ToU**
- **Common to the two sets of ToU are the following elements:**
  - **No attempt shall be made to re-identify the trial subjects or other individuals from the information.**
  - **The clinical reports may not be used to support a MAA/ extensions or variations to a MA nor to make any unfair commercial use of the clinical reports.**
  - **A watermark is applied to the published information to emphasise the prohibition of its use for commercial purposes.**
  - **The Agency accepts no responsibility for the user's compliance with the ToU.**

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Transparency – Impact on misuse for commercial purposes

- **Regulatory data protection can be bypassed by use of FOI data.**
- **Maybe avoidable in EU, however what's about misuse in non-EU-States, especially BRICS**

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Coming into effect

- **January 1st 2015 on MAAs submitted from that date onwards**
- **1st of July 2015 for extensions of indications and line extensions to existing centrally authorized products submitted from that date onwards**
- **For all others the effected date will be determined in 2015**

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EU Clinical Trials Register goes live

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 March 2011
EMA/199558/2011
Press Office

Press release

EU Clinical Trials Register goes live Without results - CTA

Public online register gives access to information on clinical trials

→ **for CTAs only!**

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Clinical Trials Register
Result-related-Information

Commission Guideline – on posting and publication of result – related information on clinical trials ….

(2012/C 302/03)

Scope, content of result-related information, modalities, timing for ended trials, implementation

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Clinical Trial Register
Implementation

6.10.2012 EN Official Journal of the European Union C 302/7

Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006

(2012/C 302/03)

……..

6. IMPLEMENTATION

This guidance document applies as soon as the programming of the relevant databases has been finalised.

Finalisation of the programming will be publicly announced by the Agency.

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Clinical Trial Register

up to May 2014	**EudraCT – CTAs only and 45, 46 Reg. (EC) 1901 paediatric trials**
June 2014	**Announcement of EMA**
	→ Programming finalized!!
	→ Guidance applies → obligatory?

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Posting of clinical trial summary results

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency - Science, medicines, health

Posting of clinical trial summary results in European Clinical Trials Database (EudraCT) to become mandatory for sponsors as of 21 July 2014

19/06/2014

Posting of clinical trial summary results in European Clinical Trials Database (EudraCT) to become mandatory for sponsors as of 21 July 2014

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EU Clinical Trials Register Guide 2012/C 302/03

No. 4.3 – Timing

After the end of the trial

- **Six months for paediatric CTs and one year for the others**

  → in the future

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EU Clinical Trials Register Guide 2012/C 302/03

No. 4.6

Timing for CTs which have ended in the past:

- **CTs ended less than one year prior to July 2014**
  → One year after the finalisation of the programming Section 6

  → in the future

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EU Clinical Trials Register Guide 2012/C 302/03

No. 4.6

Timing for CTs which have ended in the past:

- **CT with ended one more year prior to finalisation**
  - **→ 24 months after the finalisation program referred in Section 6**

  - **→ Retroactive! for all CT under Dir. 2001/20 Mai 2004!!!**

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EU Clinical Trials Register

Commission Guideline 2012/C 302/03

Scope:

→ Clinical trials as defined in Dir. 2001/20/EC with at least one of the following characteristics:

- **At least one investigator site of the CT in the EU or EEC**
- **CT is part of a PIP**
- **CT falls within Article 45 and 46 Reg. (EC) No 1901/2006**

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EU Clinical Trials Register Guide 2012/C 302/03

No. 4 – Modalities – who posts?

The information is posted:

- **by the addressee of a PIP**
- **by the marketing authorisation holder, where CT falls in Article 45 or 46 Reg. (EC) No 1901/2006**
- **By the sponsor in all other cases**

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EU Clinical Trials Register Guide 2012/C 302/03

No. 2 – Scope

→ **Does not apply for non interventional trials - NIS**

→ **PASS Studies posted to the data base ENCEP as a valid EU PASS Register**

→ **national register according to § 67 Abs. 6 AMG is closed to finalisation for non PASSes**

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EU Clinical Trials Register Guide 2012/C 302/03

No. 3 para. 2 + 3 – Content

Content of posted result-related information

Reference to "full data set"

Ref. → 2009/C28/01 (very general)

→ Technical guidance on the format of the data fields … (more detailed)

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EU Clinical Trials Register Guide 2012/C 302/03

No. 4 para. 4

Content:

The content of the data fields is kept identical with the U.S.-database „clinicaltrials.gov",

with limited exceptions to take account of particularities like the EU paediatric investigation plan, as wall as evolving changes of international databases or international harmonisation efforts.

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Clinical Trials Register

→ Guidance (2012/C 302/03) applies

→ Legal character: Guidance

→ Legal obligation?
- Art. 57 para. 2 Regulation (EC) 726/2004 provides the right to establish a data bank
- Not the obligation of sponsors to report to the data base

No. 4.7 Guide 2012/C 302/03 – Non-Compliance
→ Member States will verify …
Will they?

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Non-Compliance – Factual Inaccuracy

→ CTs for which result-related information has been not posted 9 months after the end of the trial (Sec. 4.3) “will be flagged”. This information will be publicly available.

→ If inspections on compliance with GCP reveal that serious doubts about accuracy of the result-related data, the Agency will be informed immediately.

→ Consequences?

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EU Clinical Trials Register

Legal base **Art. 57 (2) Reg. (EC) 726/2004**
➔ no obligation to report

In the future: Art. 81 Reg. (EC) 536/2014
(not applicable yet!)

New legal base to establish an other new data base beside EUDRACT? Or a new legal base for EUDRACT?
However no obligation for MAH to post!

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EU Clinical Trials Register

- → **§ 42b AMG remains in force containing clear obligation for MAHs and Sponsors to notify to BfArM and PEI**
- → **EU Law Guideline only**
- → **will EUDRA-CT-Register work?**

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EU Clinical Trials Register

Conflict of obligations due to § 42 b AMG

→ **Guide is not a law**
→ **can not replace or overrule § 42 b AMG**

→ **§ 42 b AMG will stay in force until it is obsolete due to a proper function in EUDRA-CT-Register!**

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EU Clinical Trials Register

Conflict of EU and national obligations

Posting to clinical trial register

– Interactions with national obligations according to § 13 Abs. 9 GCP-VO and § 42b AMG

→ **Posting in addition or "catch in all" by posting to EMA**

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EU Clinical Trials Register Guide 2012/C 302/03

No. 4.0 – end-of-trial-declaration

Modalities:

Moreover, this posting is considered as a submission of the clinical trial summary report as part of the end-of-trial-declaration to national competent authorities as set out in Section 4.3 of the detailed guidance CT-1.
(vgl. § 13 para. 9 GCP-VO)

Where the result-related information is published (see section 5), it is considered as submission to the Ethics Committees as set out in Section 4.2.1 of the detailed guidance CT-1.
(vgl. § 13 para. 9 GCP-VO)

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EU Clinical Trials Register

→ **Maybe the authorities will accept this instead of a report according to § 13, para. 9 GCP-VO.**

→ **But what's about the Ethic Committees – Are they willing investigate the EU Clinical Trials Register??**

→ **Let's wait for the reaction of the "Arbeitskreis der Ethikkommissionen"**

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Thank you very much for your attention!

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