EMA Regulation on Data Transparency

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The European Journey on Data Transparency

EU Reg. 726/ 2004
On procedures for the authorization and supervision of medicinal products for human and veterinary use

EU Reg. 1091/2006
on medicinal products for paediatric use

Commission Guideline to the implementation of EU reg. n. 726/2004 and n.1901/2006 on 2012

EU Reg. 1049/2001
on public access to European Parliament, Council and Commission documents

Policy/ 0043

Effective date: 1/12/2010
European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use

Results of the reactive disclosure

Table. Requests for Documents Handled Under the European Medicines Agency's Policy Announced on November 30, 2010 (as of November 19, 2012)

					Analysis of Successful Requests		
					Median (IQR)		
Requestor's Affiliation	Total[a]	Pending[b]	No Access[b]	Access Granted[b]	Time to Access, d	Length Released, Pages per Request	Total Pages
Industry	149 (33)	6 (4)	46 (31)	97 (65)	25 (18-60)	78 (13-919)	491 989
Media	84 (18)	5 (6)	20 (24)	59 (70)	26 (13-40)	64 (17-358)	380 563
Legal	71 (16)	6 (8)	15 (21)	50 (70)	37 (21-112)	49 (14-1244)	274 163
Academia	38 (8)	6 (16)	7 (18)	25 (66)	30 (19-68)	210 (41-2796)	286 045
General public	31 (7)	1 (3)	8 (26)	22 (71)	31 (16-62)	183 (32-1873)	134 782
Institution	28 (6)	1 (4)	13 (46)	14 (50)	21 (15-35)	48 (6-167)	17 620
Consultant	27 (6)	5 (19)	4 (15)	18 (67)	27 (14-62)	75 (25-299)	45 982
Health care professional	16 (4)	1 (6)	6 (38)	9 (56)	20 (19-24)	89 (25-1534)	18 795
Patients' organization	9 (2)	0	3 (33)	6 (67)	51 (4-183)	404 (404-1018)	5942
Financial sector	4 (1)	0	2 (50)	2 (50)	33 (1-64)	202 (2-402)	404
Total	**457**	**31** (7)	**124** (27)	**302** (66)	26 (16-60)	81 (17-825)	**1 656 285**

Abbreviation: IQR, interquartile range.
[a] Data are given as number of requests (proportion of total, overall).
[b] Data are given as number of requests (proportion of total, per category).

The First 2 Years of the European Medicines Agency's Policy on Access to Documents: Secret No Longer

JAMA Intern Med. 2013;173(5):380-382. doi:10.1001/jamainternmed.2013.3838

The global call for full clinical trial transparency

The **AllTrials campaign** was launched in **January 2013** and calls for all past and present clinical trials to be registered and their results reported. It is an initiative of Ben Goldacre, *BMJ*, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, *PLOS* and Sense About Science and is being led in the US by Sense About Science USA, Dartmouth's Geisel School of Medicine and the Dartmouth Institute for Health Policy & Clinical Practice. Since then, the AllTrials petition has been signed by 88235 people and 667 organizations.

The global call for full clinical trial transparency

The BMJ was one of the first medical journals to require sharing of individual patient data for trials of drugs or devices. That policy took effect in **January 2013** and specified that such trials would be considered for publication only if the authors agreed to make the relevant anonymized patient level data available on reasonable request.

Towards a Proactive Publication of Clinical Trial Data

-November 2012-

"We are committed to **proactive publication of clinical trial data**, once a marketing authorization decision has been taken.

We will deliver this project in **dialogue with our stakeholders**.

We acknowledge that there are practical and other considerations that need to be addressed and resolved.

Today's **WORKSHOP** is the first step in the process to deliver this vision.

We are not here to decide if we publish clinical trial data, but how, focusing on the future."

Guido Rasi, Executive Director of EMA

Towards a Proactive Publication of Clinical Trial Data

-November 2012-

WHY?

- Build trust and confidence in the system
- Ethical responsibility to the patients enrolled in clinical trials
- Public health benefit: independent (re)analysis of data broadens knowledge base
- Scientific progress: sharing of complex data can open new horizons

Towards a Proactive Publication of Clinical Trial Data

-November 2012-

THE DEBATE

*Data must be more easily accessible and in a **format** we can work with.*
We should go further and make the data available to everybody.

Academia

Peter Gøtzsche,
Director of the Nordic Cochrane Centre

Attendees need to take into consideration three issues: ***transparency - reproducibility - practicality***

*Any move towards better transparency must be a **global initiative**.*

Media

Virgina Barbour,
Medicine Editorial Director, Chief Editor
PLoS Medicine

Towards a Proactive Publication of Clinical Trial Data

-November 2012-

*Data access would be reviewed on a case-by-case basis. The **protection of intellectual property rights** should be fully considered.*

Industry

Susan Forda
Chair of EPFIA's Scientific Regulatory and Manufacturing Policy Committee

*There is a great concern with industry around the **interpretation of the data**.*

Neil Weir
Member of EFPIA's Research Directors Group

*There are risks around **data privacy** depending on the disease area.*

Patients' Advocate

Francois Houyez Health
Policy officer at EURORDIS

Towards a Proactive Publication of Clinical Trial Data

-November 2012-

THE WAY FORWARD

Five advisory groups have been established on:

- protecting patient confidentiality
- clinical-trial-data formats
- rules of engagement
- good analysis practice
- legal aspects

The advisory groups should propose policies that the Agency can adopt or politely refuse

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2013
EMA/382397/2013
Press Office

Press release

European Medicines Agency releases for public consultation its draft policy on the publication and access to clinical-trial data

The European Medicines Agency has released a draft policy on the publication and access to clinical-trial data for a three-month public consultation. Stakeholders have until 30 September 2013 to send their comments on the draft policy to the Agency.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 November 2013
EMA/690893/2013
Press Office

Press release

European Medicines Agency updates on development of its policy on publication and access to clinical-trial data

In-depth analysis of more than 1000 stakeholders' comments received on draft policy currently underway

The European Medicines Agency is currently reviewing and analysing more than 1,000 comments received during the public consultation on its draft policy on publication and access to clinical-trial data, which ran from June to end of September 2013.

EC Regulation 536/2014
(April 2014)

In order to ensure a sufficient level of transparency in the clinical trials, the EU database should contain all relevant information as regards the clinical trial submitted through the EU portal. The **EU database should be publicly accessible** and data should be presented in an easily searchable format, with related data and documents linked together by the EU trial number and with hyperlinks, for example **linking together the summary, the layperson's summary, the protocol and the clinical study report of one clinical trial**, as well as linking to data from other clinical trials which used the same investigational medicinal product. All clinical trials should be registered in the EU database prior to being started. As a rule, the start and end dates of the recruitment of subjects should also be published in the EU database.

- On 19 June 2014, EMA announced that “For any interventional clinical trials that ended on or after 21 July 2014, sponsors will have to post results within six (pediatric studies) or twelve months following the end of the trial, depending on the type of trial concerned.”

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

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

Policy 0070

Scope of the policy

It relates to clinical data, composed of clinical reports and individual patient data (IPD), of trial submitted under the centralised marketing authorisation procedure after 1st January 2015.

Clinical reports

- clinical overviews (generally submitted in module 2.5)
- clinical summaries (generally submitted in module 2.7)
- clinical study reports (generally submitted in module 5)
- protocol and its amendments (appendices n. 16.1.1)
- sample case report form (appendices n.16.1.2)
- documentation of statistical methods (appendices n. 16.1.9)

Individual patient data (IPD)

The individual data separately recorded for each participant in a clinical study.

Policy 0070

Objectives of the policy

- A high degree of transparency will take regulatory decision-making **one step closer to EU citizens**, and promote better-informed use of medicines.
- 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.**
- It will enable the wider scientific community to make use of detailed clinical data to develop **new knowledge** in the interest of public health.
- Access to clinical data will allow third parties to **verify the original analysis** and conclusions, to conduct further analyses, and to examine the regulatory authority's positions and challenge them where appropriate.

Policy 0070

Protection of personal data

It must be fully compliant with applicable regulations in the EU, in particular Regulation (EC) No 45/2001 and Directive 95/46/EC. There are ways and means to **anonymize data** and **protect patients from retroactive identification**.

Protection of commercially confident information

Clinical data cannot be considered CCI. However, in limited circumstances the clinical reports could contain CCI and could be subject to **redaction** prior to publication.

Policy 0070

Stepwise implementation of the policy

1. Publication of clinical reports only

2. Publication of IPD, after finding the most appropriate way to make IPD available in compliance with privacy and data protection laws

Summary of Policy 0070

- EMA Policy/0070 is effective from January 1st, 2015
- It applies to all trials included in a centralized MAA
- It applies to all new MAA and article 58 applications (medicines that are intended exclusively for markets outside the EU) submitted after January 1st, 2015
- Data will be public 30 days after the final MAA decision (irrespective from the MAA outcome)
- Initially, only clinical reports will be published –there will be new documents, such as redacted clinical reports-
- Once the system is established, individual patient data will also be accessible

The European Journey on Data Transparency

Policy/ 0070
Effective date: 1/1/2015
European Medicine Agency policy on publication of clinical data for medicinal products for human use

EU Regulation 536/2014
on clinical trials on medicinal products for human use

Guidance on Policy/ 0070 2016
on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use

THANK YOU FOR YOUR ATTENTION!