"European Competitiveness in Early Clinical Drug Development: Threats and Opportunities"

New transparency rules for early phase clinical trials

European Federation for Exploratory Medicines Development – EUFEMED

CLUB PHASE 1

AGAH

bapu

AHPPI

Association for Human Pharmacology in the Pharmaceutical Industry

Brussels, 21 May 2015
U Lorch MD FRCA FFPM - Richmond Pharmacology

Overview

- Transparency for early phase clinical trials: areas concerned
- Publication in peer reviewed journals
- Regulatory requirements in relation to public accessibility of Phase 1 clinical trials' registration information/summary reports (US/Europe); benefits &risks
- Phase 1 market situation in the EU; Aims of the new EU CTR
- CTR: Transparency versus Commercially Confidential Information
- EMA consultation on implementation of transparency rules of the CTR
- What has been achieved so far?
- What are the next steps?
- Potential points for discussion

Transparency for early phase clinical trials

Publication of clinical trial results
in peer reviewed journals

Publicly accessible clinical trial registration
(20-item standardized WHO International Clinical Trials Registry Platform registration set)

Publicly accessible (lay) summary results

What are the requirements of the International Committee of Medical Journal Editors (ICMJE) in relation to publicly accessible clinical trial registration?

- Registration of all interventional studies, including Phase 1 studies as a condition of the publication of research results generated by a clinical trial
- Completion of at least the 20-item standardized WHO trial data registration set,
- The following journals are not listed as journals following the International Committee of Medical Journal Editors' recommendations:
  - British Journal of Clinical Pharmacology
  - European Journal of Clinical Pharmacology
  - American Journal of Clinical Pharmacology
  - PLOS One (Open access)

http://www.icmje.org/recommendations/

http://www.icmje.org/journals-following-the-icmje-recommendations/#A

WHO Statement on Public Disclosure of Clinical Trial Results

"Clinical trial results are to be reported according to the timeframes outlined below. **Reporting is to occur in BOTH of the following two modalities.**

1. The **main findings of clinical trials** are to be submitted for **publication in a peer reviewed journal within 12 months of study completion** and are to be **published through an open access mechanism** unless there is a specific reason why open access cannot be used, or **otherwise made available publicly at most within 24 months of study completion**.

2. In addition, the key outcomes are to be made publicly available within 12 months of study completion by posting to the results section of the primary clinical trial registry. Where a registry is used without a results database available, the results should be posted on a free-to-access, publicly available, searchable institutional website of the Regulatory Sponsor, Funder or Principal Investigator.

It is noted that several journals allow **open access publication of clinical trial findings**. **Some journals have an explicit policy of supporting publication of negative trials. These 12 month and 24 month timeframes represent the longest possible acceptable timeframe for reporting and shorter timeframes are strongly encouraged. It should be possible in most instances for reporting to occur in shorter timeframes."**

* http://www.who.int/ictrp/results/en/

**http://www.who.int/ictrp/results/reporting/en/

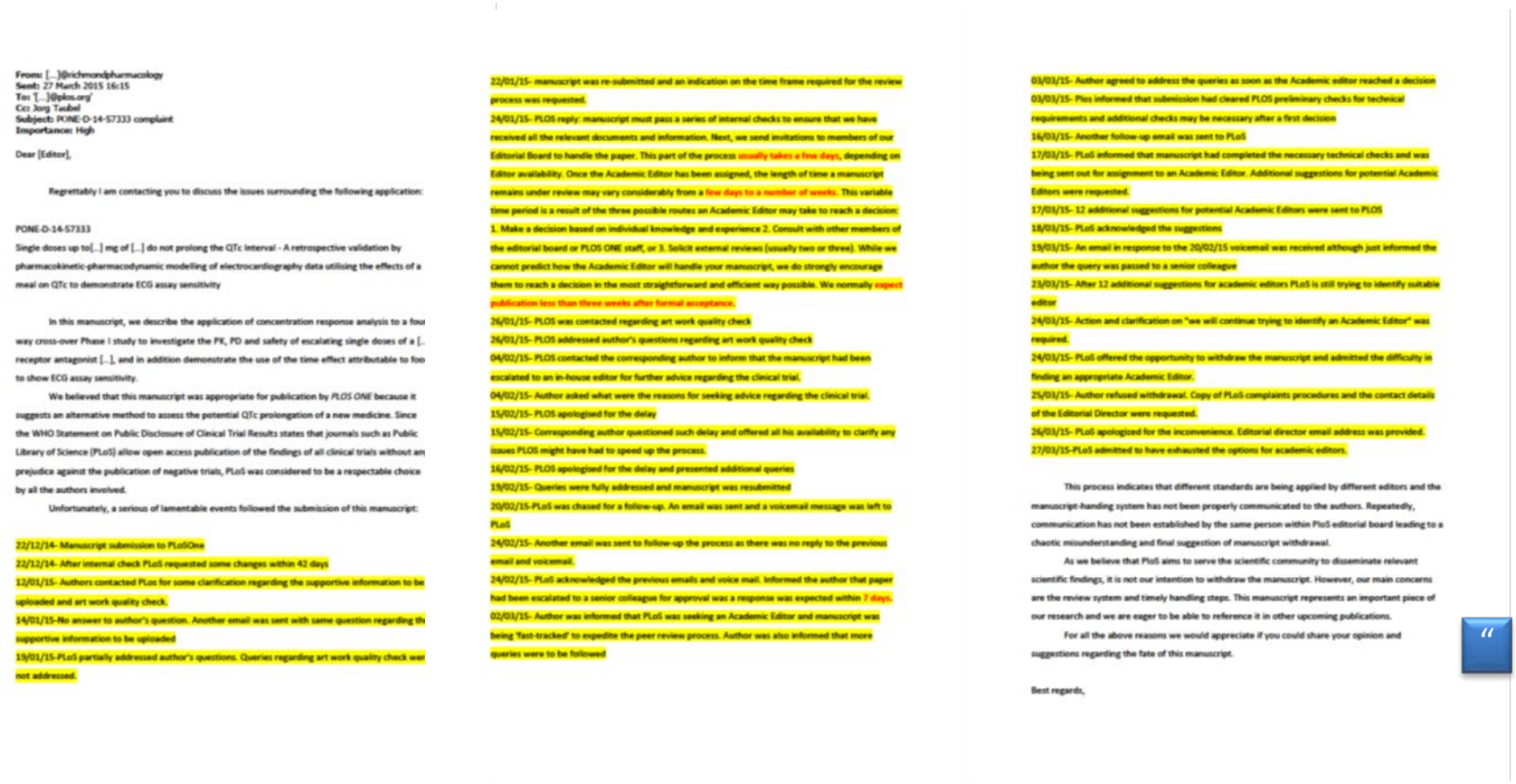
The reality

"In this manuscript, we describe the application of concentration response analysis to a four-way cross-over Phase I study to investigate the PK, PD and safety of escalating single doses of a […] antagonist […], and in addition demonstrate the use of the time effect attributable to food to show ECG assay sensitivity.

We believed that this manuscript was appropriate for publication by *PLOS ONE* because it suggests an alternative method to assess the potential QTc prolongation of a new medicine. Since the WHO Statement on Public Disclosure of Clinical Trial Results states that journals such as Public Library of Science (PLoS) allow open access publication of the findings of all clinical trials without any prejudice against the publication of negative trials, PLoS was considered to be a respectable choice by all the authors involved.

Unfortunately, a series of lamentable events followed the submission of this manuscript:

The reality



From: [...]@richmond@pharmacology
Sent: 27 March 2015 16:15
To: '[...]@plos.org'
Cc: Jorg Taubel
Subject: PONE-D-14-57333 complaint
Importance: High

Dear [Editor],

Regrettably I am contacting you to discuss the issues surrounding the following application:

PONE-D-14-57333

Single doses up to[...] mg of [...] do not prolong the QTc interval - A retrospective validation by pharmacokinetic-pharmacodynamic modelling of electrocardiography data utilising the effects of a meal on QTc to demonstrate ECG assay sensitivity

In this manuscript, we describe the application of concentration response analysis to a four way cross-over Phase I study to investigate the PK, PD and safety of escalating single doses of a [.. receptor antagonist [...], and in addition demonstrate the use of the time effect attributable to food to show ECG assay sensitivity.

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Unfortunately, a serious of lamentable events followed the submission of this manuscript:

22/12/14- Manuscript submission to PLoSOne
22/12/14- After internal check PLoS requested some changes within 42 days
12/01/15- Authors contacted PLos for some clarification regarding the supportive information to be uploaded and art work quality check.
14/01/15-No answer to author's question. Another email was sent with same question regarding the supportive information to be uploaded
19/01/15-PLoS partially addressed author's questions. Queries regarding art work quality check were not addressed.
22/01/15- manuscript was re-submitted and an indication on the time frame required for the review process was requested.
24/01/15- PLOS reply: manuscript must pass a series of internal checks to ensure that we have received all the relevant documents and information. Next, we send invitations to members of our Editorial Board to handle the paper. This part of the process usually takes a few days, depending on Editor availability. Once the Academic Editor has been assigned, the length of time a manuscript remains under review may vary considerably from a few days to a number of weeks. This variable time period is a result of the three possible routes an Academic Editor may take to reach a decision: 1. Make a decision based on individual knowledge and experience 2. Consult with other members of the editorial board or PLOS ONE staff, or 3. Solicit external reviews (usually two or three). While we cannot predict how the Academic Editor will handle your manuscript, we do strongly encourage them to reach a decision in the most straightforward and efficient way possible. We normally expect publication less than three weeks after formal acceptance.
26/01/15- PLOS was contacted regarding art work quality check
26/01/15- PLOS addressed author's questions regarding art work quality check
04/02/15- PLOS contacted the corresponding author to inform that the manuscript had been escalated to an in-house editor for further advice regarding the clinical trial.
04/02/15- Author asked what were the reasons for seeking advice regarding the clinical trial.
15/02/15- PLOS apologised for the delay
15/02/15- Corresponding author questioned such delay and offered all his availability to clarify any issues PLOS might have had to speed up the process.
16/02/15- PLOS apologised for the delay and presented additional queries
19/02/15- Queries were fully addressed and manuscript was resubmitted
20/02/15-PLoS was chased for a follow-up. An email was sent and a voicemail message was left to PLoS
24/02/15- Another email was sent to follow-up the process as there was no reply to the previous email and voicemail.
24/02/15- PLoS acknowledged the previous emails and voice mail. Informed the author that paper had been escalated to a senior colleague for approval was a response was expected within 7 days.
02/03/15- Author was informed that PLoS was seeking an Academic Editor and manuscript was being 'fast-tracked' to expedite the peer review process. Author was also informed that more queries were to be followed
03/03/15- Author agreed to address the queries as soon as the Academic editor reached a decision
03/03/15- Plos informed that submission had cleared PLOS preliminary checks for technical requirements and additional checks may be necessary after a first decision
16/03/15- Another follow-up email was sent to PLoS
17/03/15- PLoS informed that manuscript had completed the necessary technical checks and was being sent out for assignment to an Academic Editor. Additional suggestions for potential Academic Editors were requested.
17/03/15- 12 additional suggestions for potential Academic Editors were sent to PLOS
18/03/15- PLoS acknowledged the suggestions
19/03/15- An email in response to the 20/02/15 voicemail was received although just informed the author the query was passed to a senior colleague
23/03/15- After 12 additional suggestions for academic editors PLoS is still trying to identify suitable editor
24/03/15- Action and clarification on "we will continue trying to identify an Academic Editor" was required.
24/03/15- PLoS offered the opportunity to withdraw the manuscript and admitted the difficulty in finding an appropriate Academic Editor.
25/03/15- Author refused withdrawal. Copy of PLoS complaints procedures and the contact details of the Editorial Director were requested.
26/03/15- PLoS apologized for the inconvenience. Editorial director email address was provided.
27/03/15-PLoS admitted to have exhausted the options for academic editors.

This process indicates that different standards are being applied by different editors and the manuscript-handing system has not been properly communicated to the authors. Repeatedly, communication has not been established by the same person within PloS editorial board leading to a chaotic misunderstanding and final suggestion of manuscript withdrawal.

As we believe that PloS aims to serve the scientific community to disseminate relevant scientific findings, it is not our intention to withdraw the manuscript. However, our main concerns are the review system and timely handling steps. This manuscript represents an important piece of our research and we are eager to be able to reference it in other upcoming publications.

For all the above reasons we would appreciate if you could share your opinion and suggestions regarding the fate of this manuscript.

Best regards,

22 December 2014 to 27 March 2015: 34 communications between authors and PLOS: The manuscript is still not published…

Regulatory Requirements USA: What are the FDA's requirements in relation to registration and submission of results?

Name	Type	Intervention Type	Registration Policy Scope	Results Submission Policy Scope
Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) (PDF)	U.S. Federal law enacted in 2007	Drugs, biologics, and devices	Controlled clinical investigations of a Food and Drug Administration (FDA)-regulated drug, biologic, or device, **other than Phase 1 (drugs/biologics)** or **small feasibility studies**	**Same scope as registration,** but **interventional studies of FDA-approved drugs, biologics, or devices**

http://clinicaltrials.gov/ct2/manage-recs/background

European Clinical Trial Regulation: New transparency requirements for Phase 1 studies

The information that will be made public for all clinical trials registered in the system will include:

- **The Clinical Trial Application Form, being in effect a structured synopsis of the clinical trial protocol:** the main characteristics of the trial comprising design, scientific and, where applicable, therapeutic intent, title, identification of the investigational medicinal products (IMPs), treatment arms, treatment population and number of subjects, inclusion and exclusion criteria and main objectives and endpoints
- conclusion of the assessment and decision on the trial;
- information updated during the trial to indicate the start and end dates of recruitment;
- substantial modifications to the trial;
- **the end date of the trial and 12 months later the summary of results and a summary in lay language;**
- clinical study reports for medicines for which a marketing authorisation has been granted, the procedure completed or the marketing authorisation application withdrawn

Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014" EMA/641479/2014

Potential benefits of early publication of Phase 1 trial registration and (lay) summary results for patients, health professionals and the public

Benefits stated on ClinicalTrials.gov and WHO/International Clinical Trials Registry Platform

Most potential benefits of registration are **not applicable** to
Phase 1
non-therapeutic
non-paediatric
non-publicly funded clinical trials

Benefits of publication of **(lay) summary results occur at different times** during a drug or drug/device development process. For Phase 1 trials this will often be **later than one year from the end of a trial**

The underreporting of unfavourable data can lead to **duplication** of work and **safety issues**. Due to the nature of Phase 1 studies, this is **unlikely to affect ongoing clinical research at the time**, as all parties involved are fully informed about study design and safety information and any changes thereof.

Sources:
ClinicalTrials.gov: https://clinicaltrials.gov/ct2/manage-recs/background;
WHO/International Clinical Trials Registry Platform (ICTRP): http://www.who.int/ictrp/trial_reg/en/

Potential risks of early publication of Phase 1 registration and (lay) summary results for patients, health professionals and the public

Information that may be considered commercially confidential:

- Pharmaceutical details
- Novel molecular target(s)
- Non-clinical data
- Formulation/formulation switches and new delivery route(s)
- Projected timelines & key milestones e.g. First-in-Human, Proof of Concept and NDA/MAA
- Disease indication(s) being pursued
- Biomarkers employed
- Clinical trial designs
- Development strategy
- Lifecycle management strategy

No requirement to publish Phase 1 registration and summary results in the US

Phase 1 trials are usually short leading to early publication of summary results

In locations outside Europe the risks in relation to early disclosure of commercially confidentially information will be less.

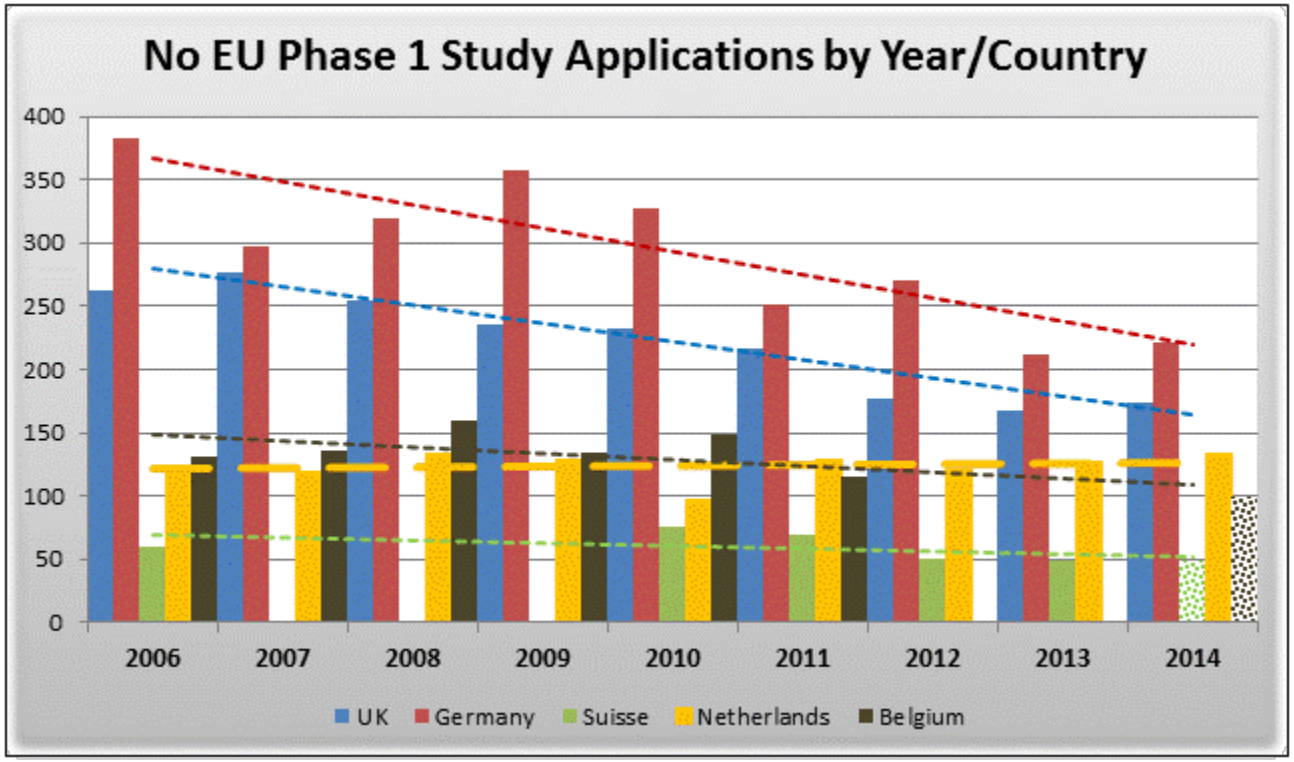
Sponsors may choose to conduct early phase and follow-on later phase studies outside Europe

EU: Phase 1 market situation

CTA data from regulatory agencies show a decline in Phase I trials (~20%).

Most notable for the UK and Germany.

The Netherlands have shown a consistent number of trials over the entire period of this survey.



	Market Share	
	2006	*2014*
UK	27%	26%
Germany	40%	33%
Suisse*	6%	7%
Netherlands	13%	20%
Belgium*	14%	15%

** Estimates*

Note: The data has been extracted form the regulatory agencies' official publications: Belgian and Swiss data were incomplete: therefore the 2013/14 (Belgium) and 2006/2014 (Switzerland) numbers were extrapolated (shaded bars) to allow for an assessment of trends.

Key aims of the new European Clinical Trials Regulation (EU) No 536/2014

"to foster innovation through simplification of the clinical trial application process, and to increase transparency and availability of information on clinical trials and their results"*

"to give patients access to the most innovative clinical research and treatments, and to improve existing treatments

clinical research" […] investment […] makes a significant contribution to the growth policy of the Europe 2020 agenda […]. Very significant costs "could be saved in regulatory costs and boost research and development in the EU, thus contributing to economic growth

to reverse some unfavourable effects of the 'Clinical Trials Directive' of 2001 which has contributed "to a decrease of 25% of clinical trials conducted in the period between 2007 and 2011"**

* Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"

**European Commission Press Release 17 July 2012: "Fostering EU's attractiveness in clinical research: Commission proposes to revamp rules on trials with medicines"

CTR: Transparency versus Commercially Confidential Information

– Article 67 […] "Publicly available information contained in the EU database should contribute to protecting public health and fostering the innovation capacity of European medical research, while recognising the legitimate economic interests of sponsors."

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

CTR: Transparency versus Commercially Confidential Information

- Article 81(4). "The EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the following grounds:
  - protecting personal data in accordance with Regulation (EC) No 45/2001;
  - **protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product, unless there is an overriding public interest in disclosure;**
  - Protecting confidential communication between Member States in relation to the preparation of the assessment report;
  - Ensuring effective supervision of the conduct of a clinical trial by Member States"

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

EU Clinical Trial Portal and Database

"Key instrument to ensure transparency […];

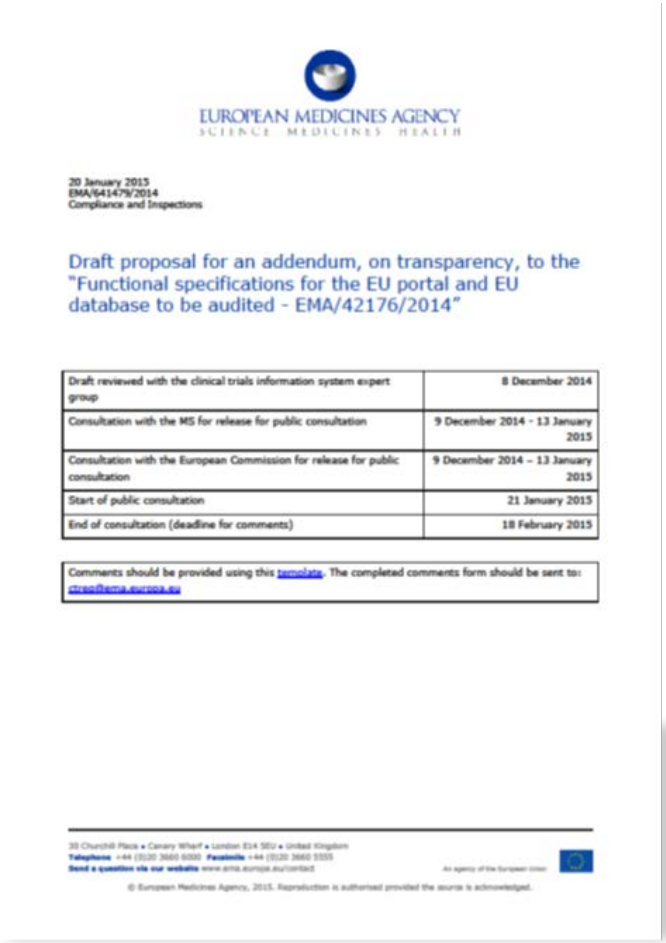
Will be used for submission and maintenance of clinical trial applications and authorisations within the EU […];

Source of public information on CTA assessed, clinical trials conducted in the EU, from the time of decision to authorise a trial, up to finalisation of those trials and inclusion of their results in the database" […]

The European Medicines Agency (EMA) is responsible for its development and maintenance

Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"

EMA consultation on transparency EU Clinical Trial Portal and Database



EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

20 January 2015
EMA/641479/2014
Compliance and Inspections

Draft proposal for an addendum, on transparency, 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
Start of public consultation	21 January 2015
End of consultation (deadline for comments)	18 February 2015

Comments should be provided using this template. The completed comments form should be sent to: ctregdfema.europa.eu

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Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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The aim of this **consultation** is to seek **stakeholders' views** on the **application of these exceptions**, so that they strike the right **balance** between respecting patients' and doctors' needs and the publics' entitlement to extensive and timely information about clinical trials and developers' and researchers' need to protect their investments.

A **balanced approach** is needed to **protect public health and also foster the innovation capacity of European medical research**, thus supporting the EU as a location for innovative, cutting edge research that results in development of novel products and research into new and better uses of existing products.

The **consultation did not include** any proposal that the requirement to publish the **summary of results and a summary in lay language 12 months after the end of a trial** could be **deferred** due to commercial confidentiality.

CTR Article 2 (26) Definition of "end of trial": **Last Subject Last Visit** or "**at a later point as defined in the protocol**".

EMA consultation on transparency: EUFEMED submission in support of EMA statements

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 February 2015

Submission of comments on 'Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited' (EMA/42176/2014)

Comments from:

Name of organisation or individual
EUFEMED – European Federation for Exploratory Medicines Development Square the Meeûs – Rue de l'Industrie 4 1000 Brussels Belgium Tel.: +32 (0)2 732 87 83 Internet: www.eufemed.eu EUFEMED Representative **Prof Dr Jan de Hoon** President EUFEMED Tel.: +32(0)16 34 20 20 | Fax: +32(0)16 34 20 50 Email: jan.dehoon@uzleuven.be

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

- 80: "Phase 1 trials are commercially particularly sensitive […]"
- 345: "In the case of Phase I clinical trials in healthy volunteers there is particular sensitivity about the commercial confidentiality of information on the trial.
- 617: "Thus, the extent of information made public could progressively increase during the development period to the marketing authorisation of a medicine from first in human Phase I trials to post-authorisation Phase IV and low-intervention trials."

EMA consultation on transparency: EUFEMED submission Definition of “Phase 1”

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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We advocate defining a “Phase 1” trial for the purpose of applying transparency rules as follows:

- Phase 1 trials are clinical trials using IMP, device & IMP/device combinations, performed in healthy volunteers and/or patients without therapeutic (or prophylactic) intent

EMA consultation on transparency: EUFEMED submission Definition of MA status

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SCIENCE MEDICINES HEALTH

18 February 2015

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"Question 6: How should the status of marketing authorisation of the medicinal product be applied in the context of Article 81(4)(b) of the Regulation:"

"[…] protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product […]

Proposal 1.3: Commercially confidential information should be considered taking into account, in particular, the status of the marketing authorisation using the following concept:

"Once a marketing authorisation has been issued, by at least one Member State, for a medicinal product using that active substance and for the indication and formulation/route of administration under study."

EUFEMED support of EMA proposal on Public access to Phase 1 clinical trials registration information

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 February 2015

Submission of comments on 'Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited' (EMA/42176/2014)

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"Question 11: "Please comment and give a brief rationale for your **support** or disagreement with [the] proposal that the sponsor will have the possibility to opt to have only very minimal public information at the time of decision on the trial", i.e.

"a subset of the fields of the WHO ICTRP:

- in particular the EU number of the trial,
- the sponsor
- the investigator site, the phase of the trial (i.e. Phase I)
- the number of trial subjects and the
- population under study […]
- The decision on the trial would also be made public, but identifying the trial only by this minimum set of information"

and for the "remainder to be made public at the point when the summary of trial results is published".

EMA consultation on transparency: Public access to study and product specific documents

Table 1. Description of proposals 1 - 4 and optional deferral for Phase IV trials

	Clinical trials on medicinal products without marketing authorisation				Clinical trials on medicinal products with marketing authorisation
	Proposal One	Proposal Two	Proposal Three	Proposal Four	Phase IV and low-intervention trials
Study specific documents – protocol and subject information sheet	Time of decision on trial	Time of MA or 9 years after first summary results posted	Phase I and II time of MA or 9 years after first summary results posted Phase III – time when first summary results are posted	Non therapeutic trials – time of MA or 9 years after first summary results posted Therapeutic trials – time when first summary results are posted	Time of decision on trial, but sponsor may opt to defer to time when first summary results are posted
Product specific documents – IMPD S and E sections and investigator brochure	Time of decision on trial	Time of MA or 9 years after first summary results posted	Time of MA or 9 years after first summary results posted	Time of MA or 9 years after first summary results posted	Time of decision on trial, but sponsor may opt to defer to time when first summary results are posted on trial

"Question 6: Please comment on proposals one, two, three or four regarding clinical trials without a marketing authorisation indicating which proposal best meets the requirements and objectives of the Regulation. […]

A proposal for
Public access to study and product specific documents

Document	Publication via EU Portal
All documents	**Voluntary** publication by the sponsor should be permitted
Study specific documents - **Protocol synopsis-** "as set out in the **clinical trial application form –** being in effect a structured synopsis of the clinical trial protocol"	**Phase I** trials (without therapeutic/prophylactic intent) - Time of **first summary results** being posted
	Phase II and III trials (with therapeutic/prophylactic intent) – At the time of **decision on the trial**
Study specific documents - **Subject information sheet**	**Phase I** and II trials - **Time of MA or 9 years after first summary results posted**
	Phase III trials - Time of first summary results being posted
	Note: For Phase II and III **trials** (with therapeutic / prophylactic intent) – Patients and other interested **parties can approach sponsor and/or investigator to obtain a subject information sheet at the time of decision on a trial**. Contact details and study synopsis are available via EU portal at that time.
Study specific documents - **Protocol**	**Phase I** and II trials - **Time of MA or 9 years after first summary results posted**
	Phase III - Time of first summary results being posted
Product specific documents – **IMPD S** and **E** sections and investigator brochure	**Time of MA or 9 years after first summary results posted**

What has been achieved so far?

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 March 2015
EMA/129363/2015 Final
Compliance and Inspections

Revision of section 6 of the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014" setting out features to support making information public

Draft reviewed with the EU clinical trial information system expert group as section 5 of proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"	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
Start of public consultation	21 January 2015
End of consultation (deadline for comments)	18 February 2015
Consultation of the final document by the European Commission	5 March 2015
Consultation of the final document by the Member States	2 March 2015
Endorsement by European Medicines Agency Management Board	19 March 2015
Sign off by the Deputy Executive Director	10 April 2015

EMA's Management Board adopted **high level technical functionality to support publication of clinical trial information** (March 2015):

The document **leaves options open** to allow implementation in accordance with outcomes of recent consultation (closed 18 Feb 2015):

- IMPD Q,S,E separate with different rules
- Protocol synopsis and protocol separate with different rules
- Application form will contain questions & answers to set data/trigger points for publication:
  - Therapeutic/prophylactic intent
  - Marketing authorisation already granted in the EU for
    - Active substance under study
    - Indication(s) under study for that active substance
    - Formulation(s) under study for that active substance
    - Route(s) of administration under study for that active substance
  - Phase of trial
  - Deferral request for publication of registration data until publication of summary results (Phase 1 trial only)

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/04/WC500185677.pdf

What are the next steps?

Publication of information/data via publication module of EU database will be mostly automated

Rules for publication (what, when, criteria, triggers) need to be agreed, taking into account EMA consultation outcomes

Appendix to the 'Revision of section 6 of the "Functional specifications for the EU portal and EU database to be audited – EMA/42176/2014" setting out features to support making information public'

Stakeholder (patients, industry, academia, healthcare providers) involvement in the EMA's process of finalising this appendix. Communications and meetings have commenced

Final document will be submitted to EMA Management Board and published following their endorsement and sign-off by the Agency Deputy Executive Director (expected by October 2015)

Potential Points for Discussion

- How can we influence the finalisation of the functional specifications of the EU portal and database and their transparency rules?
- How can we deal with commercially confidential information in the context of the publication of (lay) summary reports 12 months after the end of a trial?
- Ambitions to publish in peer reviewed journals: How can we achieve this with a reasonable effort and within reasonable time frames?

Thank you

To my colleagues and contributors from the

- European Federation for Exploratory Medicines Development - EUFEMED
- European CRO Federation - EUCROF