AHPPI

Association for Human Pharmacology in the Pharmaceutical Industry

Update on the implementation of the new **EU Clinical Trial Regulation's transparency rules for early phase trials**

Presented at:

Association for Human Pharmacology in the Pharmaceutical Industry

Annual Meeting

Academy of Medical Sciences

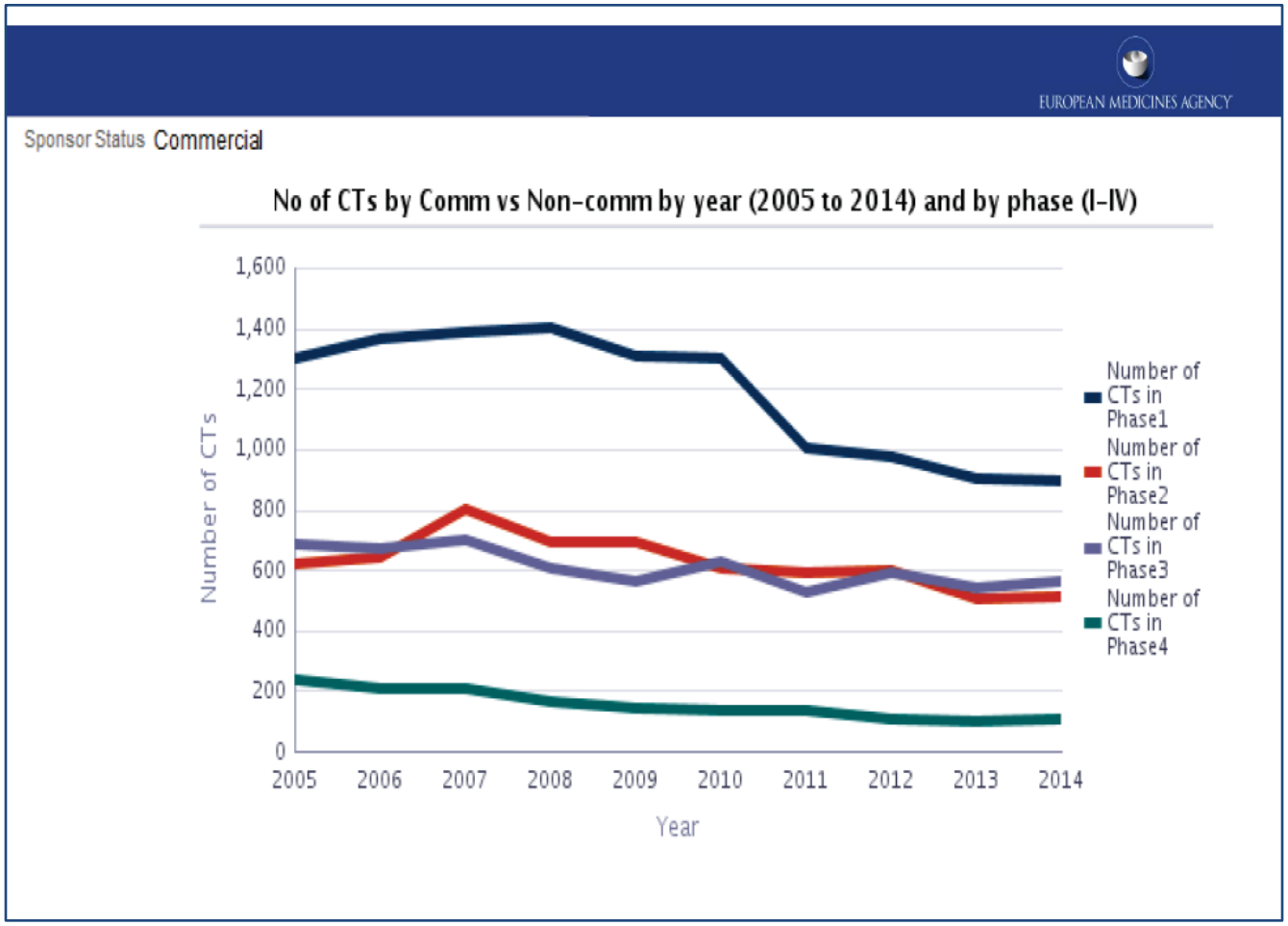
London 29 October 2015

U Lorch MD FRCA FFPM

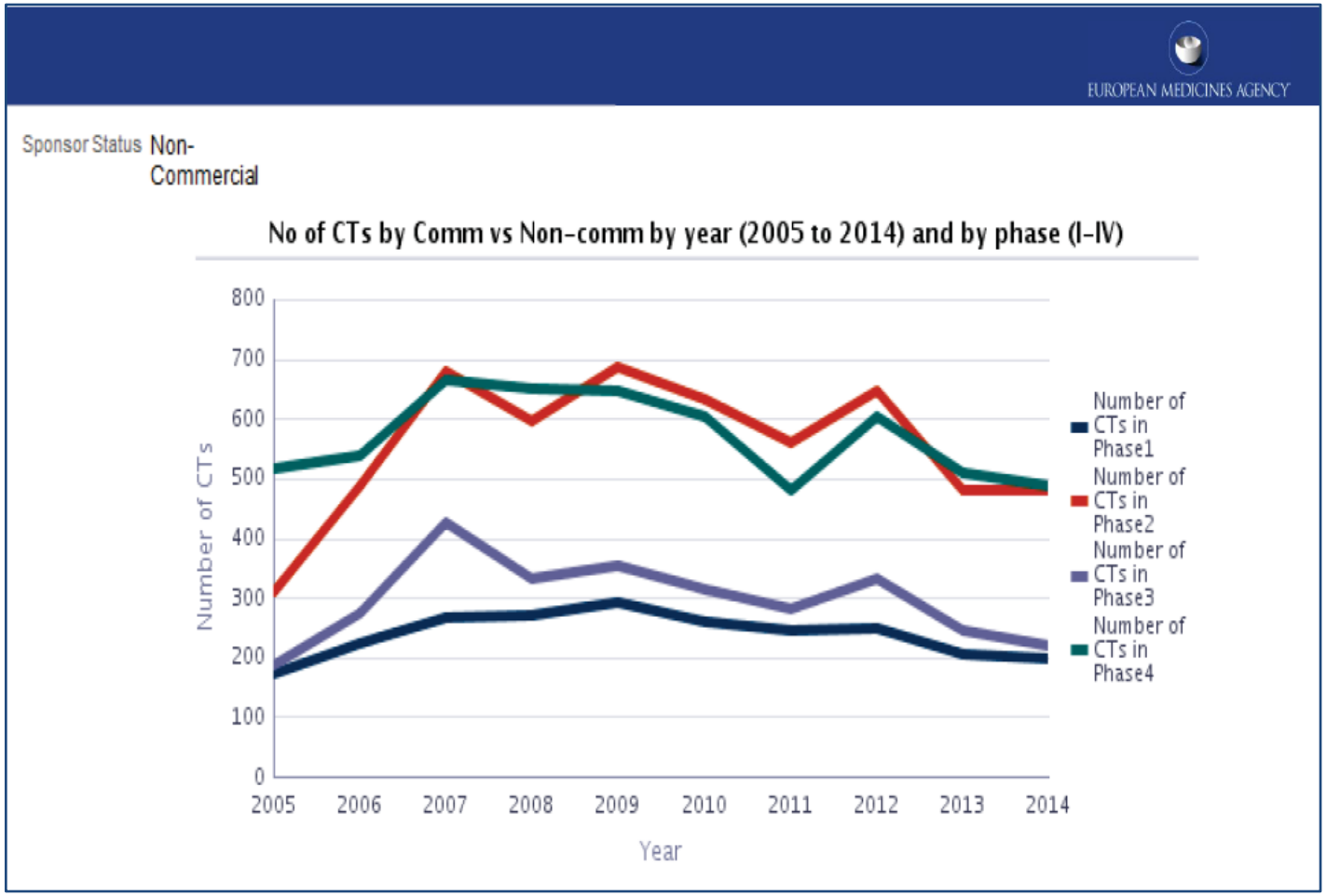
Overview

- Phase I trials in the EU
- EU Clinical Trials Regulation (EU CTR): Aims
- EU CTR: New transparency requirements for Phase 1 studies; benefits &risks
- EU CTR: Transparency versus Commercially Confidential Information
- Early Phase Stakeholder Activities
- The Outcome
- What are the next steps?

Phase 1 trials in EU – data from EudraCT



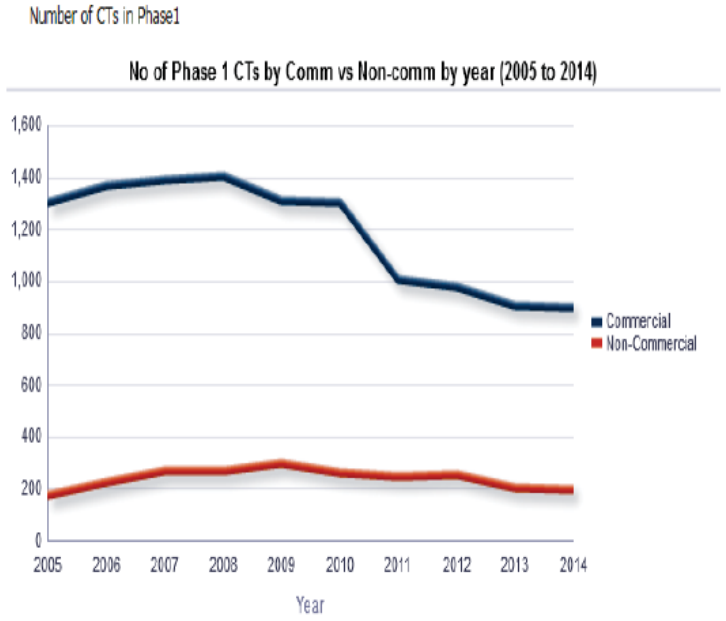
Phase 1 trials in EU – data from EudraCT



Phase 1 trials in EU – data from EudraCT

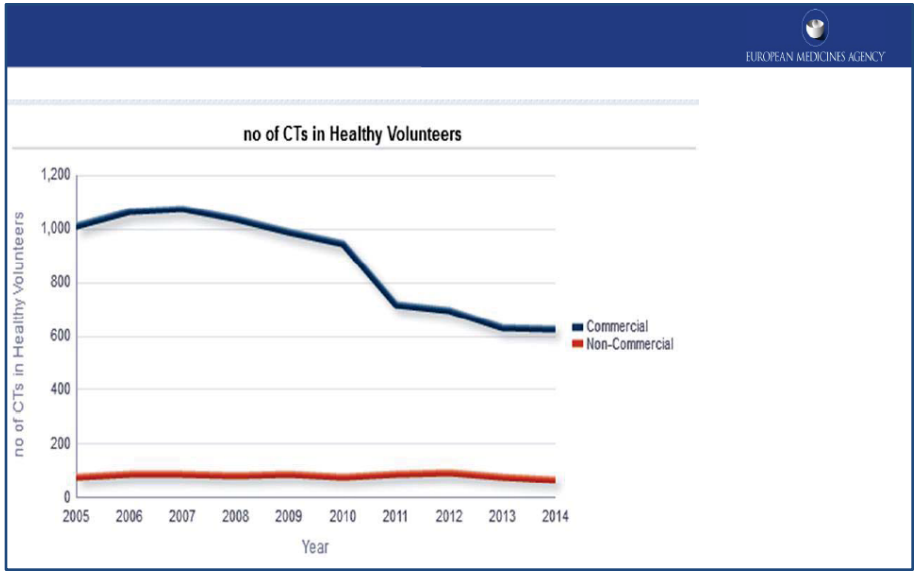
EUROPEAN MEDICINES AGENCY

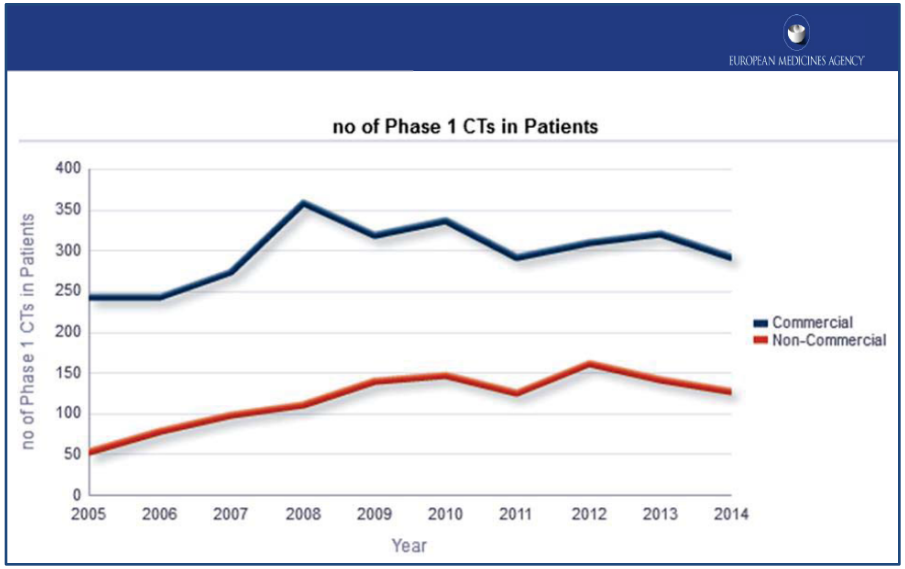
No of phase 1 CTs by Comm vs Non-comm by year (2005 to 2014)

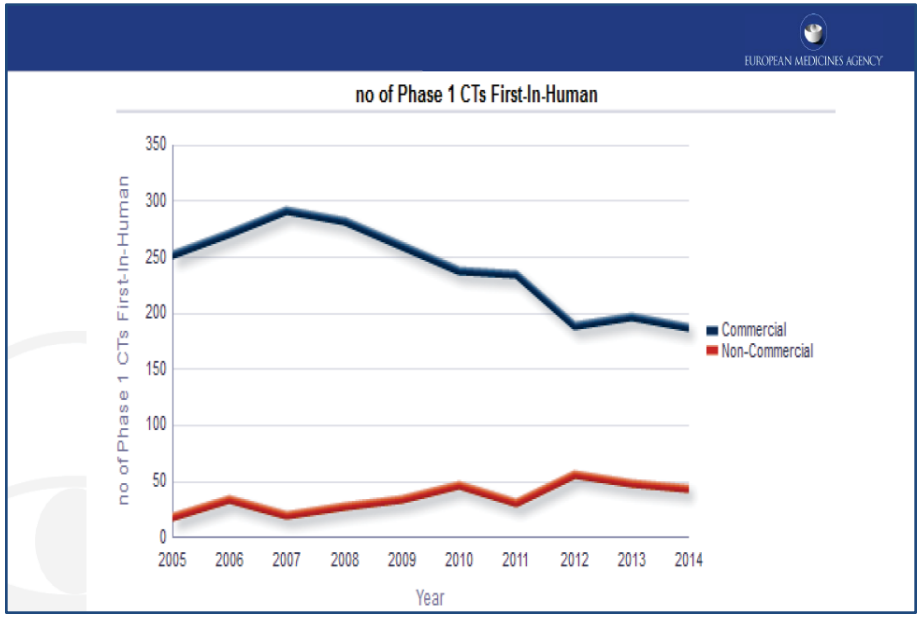


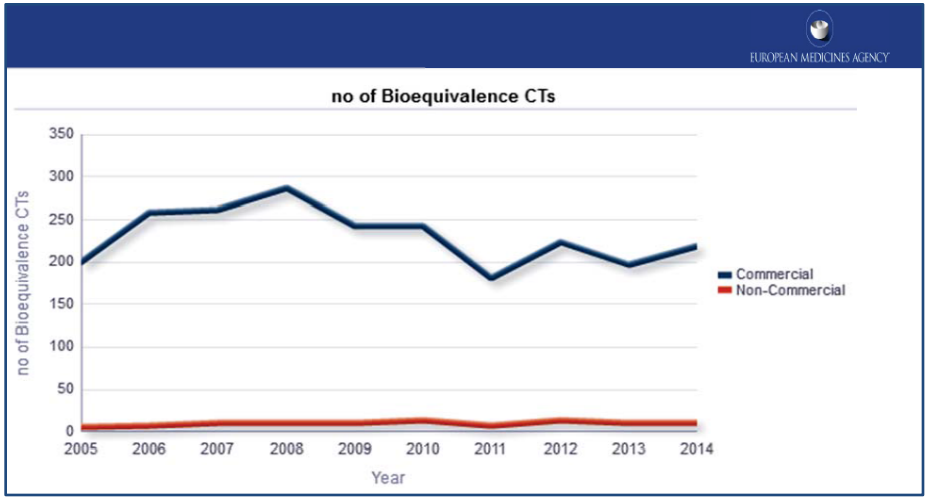
Year	Sponsor Status	Number of CTs in Phase1
2005	Commercial	1,300
	Non-Commercial	175
2006	Commercial	1,369
	Non-Commercial	223
2007	Commercial	1,392
	Non-Commercial	268
2008	Commercial	1,405
	Non-Commercial	271
2009	Commercial	1,310
	Non-Commercial	295
2010	Commercial	1,306
	Non-Commercial	262
2011	Commercial	1,004
	Non-Commercial	247
2012	Commercial	979
	Non-Commercial	251
2013	Commercial	905
	Non-Commercial	206
2014	Commercial	901
	Non-Commercial	199
Grand Total		**14,268**

Phase 1 trials in EU – data from EudraCT









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"

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 **[To be published at the time of decision on trial]**
- 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 publication 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

Publication could affect patent protection

Phase 1 trials are usually short which would lead to early publication of summary results

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

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

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 […];

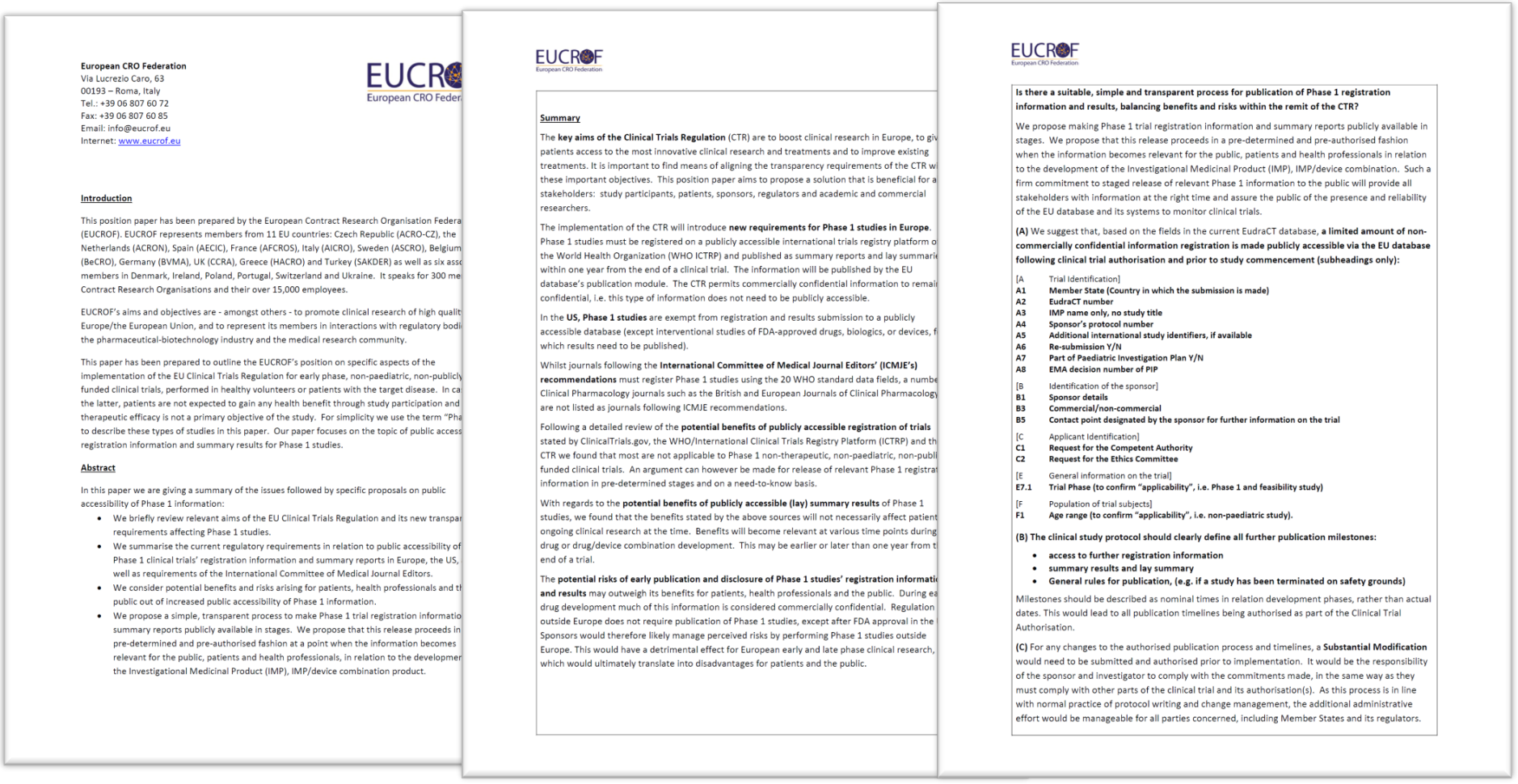
Will be used for submission and maintenance of clinical trial applications and authorisations within the EU […];

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"

Advocating a balanced approach Position Paper 31 Oct 2014



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Introduction

This position paper has been prepared by the European Contract Research Organisation Federa (EUCROF). EUCROF represents members from 11 EU countries: Czech Republic (ACRO-CZ), the Netherlands (ACRON), Spain (AECIC), France (AFCROS), Italy (AICRO), Sweden (ASCRO), Belgium (BeCRO), Germany (BVMA), UK (CCRA), Greece (HACRO) and Turkey (SAKDER) as well as six asso members in Denmark, Ireland, Poland, Portugal, Switzerland and Ukraine. It speaks for 300 me Contract Research Organisations and their over 15,000 employees.

EUCROF's aims and objectives are - amongst others - to promote clinical research of high qualit Europe/the European Union, and to represent its members in interactions with regulatory bodi the pharmaceutical-biotechnology industry and the medical research community.

This paper has been prepared to outline the EUCROF's position on specific aspects of the implementation of the EU Clinical Trials Regulation for early phase, non-paediatric, non-publicly funded clinical trials, performed in healthy volunteers or patients with the target disease. In ca the latter, patients are not expected to gain any health benefit through study participation and therapeutic efficacy is not a primary objective of the study. For simplicity we use the term "Pha to describe these types of studies in this paper. Our paper focuses on the topic of public access registration information and summary results for Phase 1 studies.

Abstract

In this paper we are giving a summary of the issues followed by specific proposals on public accessibility of Phase 1 information:

- We briefly review relevant aims of the EU Clinical Trials Regulation and its new transpar requirements affecting Phase 1 studies.
- We summarise the current regulatory requirements in relation to public accessibility of Phase 1 clinical trials' registration information and summary reports in Europe, the US, well as requirements of the International Committee of Medical Journal Editors.
- We consider potential benefits and risks arising for patients, health professionals and th public out of increased public accessibility of Phase 1 information.
- We propose a simple, transparent process to make Phase 1 trial registration informatio summary reports publicly available in stages. We propose that this release proceeds in pre-determined and pre-authorised fashion at a point when the information becomes relevant for the public, patients and health professionals, in relation to the developmer the Investigational Medicinal Product (IMP), IMP/device combination product.

Summary

The **key aims of the Clinical Trials Regulation** (CTR) are to boost clinical research in Europe, to giv patients access to the most innovative clinical research and treatments and to improve existing treatments. It is important to find means of aligning the transparency requirements of the CTR wi these important objectives. This position paper aims to propose a solution that is beneficial for a stakeholders: study participants, patients, sponsors, regulators and academic and commercial researchers.

The implementation of the CTR will introduce **new requirements for Phase 1 studies in Europe**. Phase 1 studies must be registered on a publicly accessible international trials registry platform o the World Health Organization (WHO ICTRP) and published as summary reports and lay summari within one year from the end of a clinical trial. The information will be published by the EU database's publication module. The CTR permits commercially confidential information to remai confidential, i.e. this type of information does not need to be publicly accessible.

In the **US, Phase 1 studies** are exempt from registration and results submission to a publicly accessible database (except interventional studies of FDA-approved drugs, biologics, or devices, f which results need to be published).

Whilst journals following the **International Committee of Medical Journal Editors' (ICMJE's) recommendations** must register Phase 1 studies using the 20 WHO standard data fields, a numbe Clinical Pharmacology journals such as the British and European Journals of Clinical Pharmacology are not listed as journals following ICMJE recommendations.

Following a detailed review of the **potential benefits of publicly accessible registration of trials** stated by ClinicalTrials.gov, the WHO/International Clinical Trials Registry Platform (ICTRP) and th CTR we found that most are not applicable to Phase 1 non-therapeutic, non-paediatric, non-publi funded clinical trials. An argument can however be made for release of relevant Phase 1 registrat information in pre-determined stages and on a need-to-know basis.

With regards to the **potential benefits of publicly accessible (lay) summary results** of Phase 1 studies, we found that the benefits stated by the above sources will not necessarily affect patient ongoing clinical research at the time. Benefits will become relevant at various time points during drug or drug/device combination development. This may be earlier or later than one year from t end of a trial.

The **potential risks of early publication and disclosure of Phase 1 studies' registration informati and results** may outweigh its benefits for patients, health professionals and the public. During ea drug development much of this information is considered commercially confidential. Regulation outside Europe does not require publication of Phase 1 studies, except after FDA approval in the Sponsors would therefore likely manage perceived risks by performing Phase 1 studies outside Europe. This would have a detrimental effect for European early and late phase clinical research, which would ultimately translate into disadvantages for patients and the public.

Is there a suitable, simple and transparent process for publication of Phase 1 registration information and results, balancing benefits and risks within the remit of the CTR?

We propose making Phase 1 trial registration information and summary reports publicly available in stages. We propose that this release proceeds in a pre-determined and pre-authorised fashion when the information becomes relevant for the public, patients and health professionals in relation to the development of the Investigational Medicinal Product (IMP), IMP/device combination. Such a firm commitment to staged release of relevant Phase 1 information to the public will provide all stakeholders with information at the right time and assure the public of the presence and reliability of the EU database and its systems to monitor clinical trials.

(A) We suggest that, based on the fields in the current EudraCT database, **a limited amount of non-commercially confidential information registration is made publicly accessible via the EU database following clinical trial authorisation and prior to study commencement (subheadings only):**

[A Trial Identification]
A1 Member State (Country in which the submission is made)
A2 EudraCT number
A3 IMP name only, no study title
A4 Sponsor's protocol number
A5 Additional international study identifiers, if available
A6 Re-submission Y/N
A7 Part of Paediatric Investigation Plan Y/N
A8 EMA decision number of PIP

[B Identification of the sponsor]
B1 Sponsor details
B3 Commercial/non-commercial
B5 Contact point designated by the sponsor for further information on the trial

[C Applicant Identification]
C1 Request for the Competent Authority
C2 Request for the Ethics Committee

[E General information on the trial]
E7.1 Trial Phase (to confirm "applicability", i.e. Phase 1 and feasibility study)

[F Population of trial subjects]
F1 Age range (to confirm "applicability", i.e. non-paediatric study).

(B) The clinical study protocol should clearly define all further publication milestones:

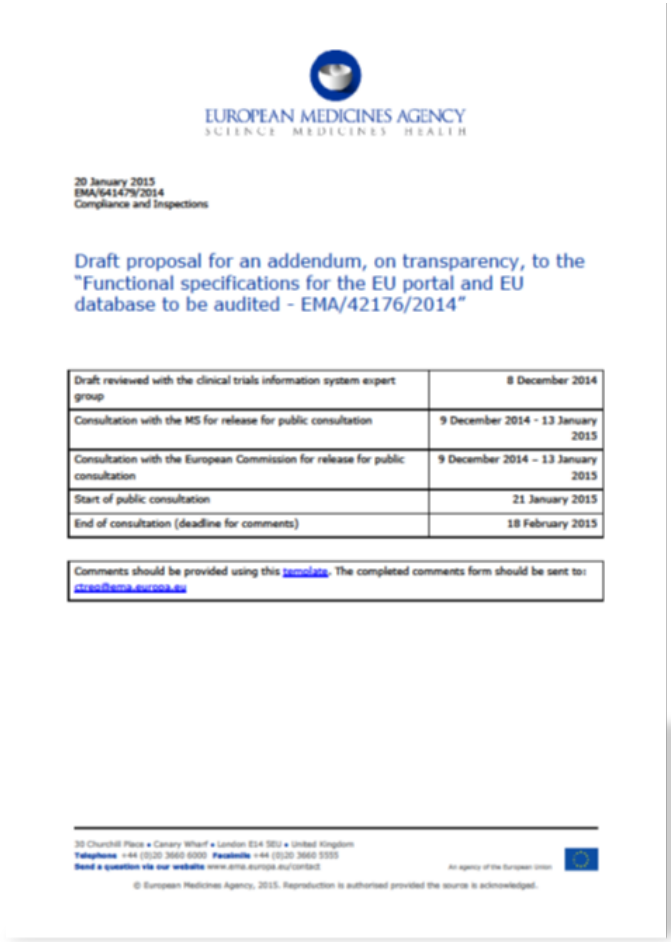
- **access to further registration information**
- **summary results and lay summary**
- **General rules for publication, (e.g. if a study has been terminated on safety grounds)**

Milestones should be described as nominal times in relation development phases, rather than actual dates. This would lead to all publication timelines being authorised as part of the Clinical Trial Authorisation.

(C) For any changes to the authorised publication process and timelines, a **Substantial Modification** would need to be submitted and authorised prior to implementation. It would be the responsibility of the sponsor and investigator to comply with the commitments made, in the same way as they must comply with other parts of the clinical trial and its authorisation(s). As this process is in line with normal practice of protocol writing and change management, the additional administrative effort would be manageable for all parties concerned, including Member States and its regulators.

http://www.eucrof.eu/images/EUCROF_Position_Paper_Public_Access_to_Early_Phase_EU_database_information_31_OCT_2014.pdf

EMA consultation on transparency Jan/Feb 2015 EU Clinical Trial Portal and Database



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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: ctep@ema.europa.eu

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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.

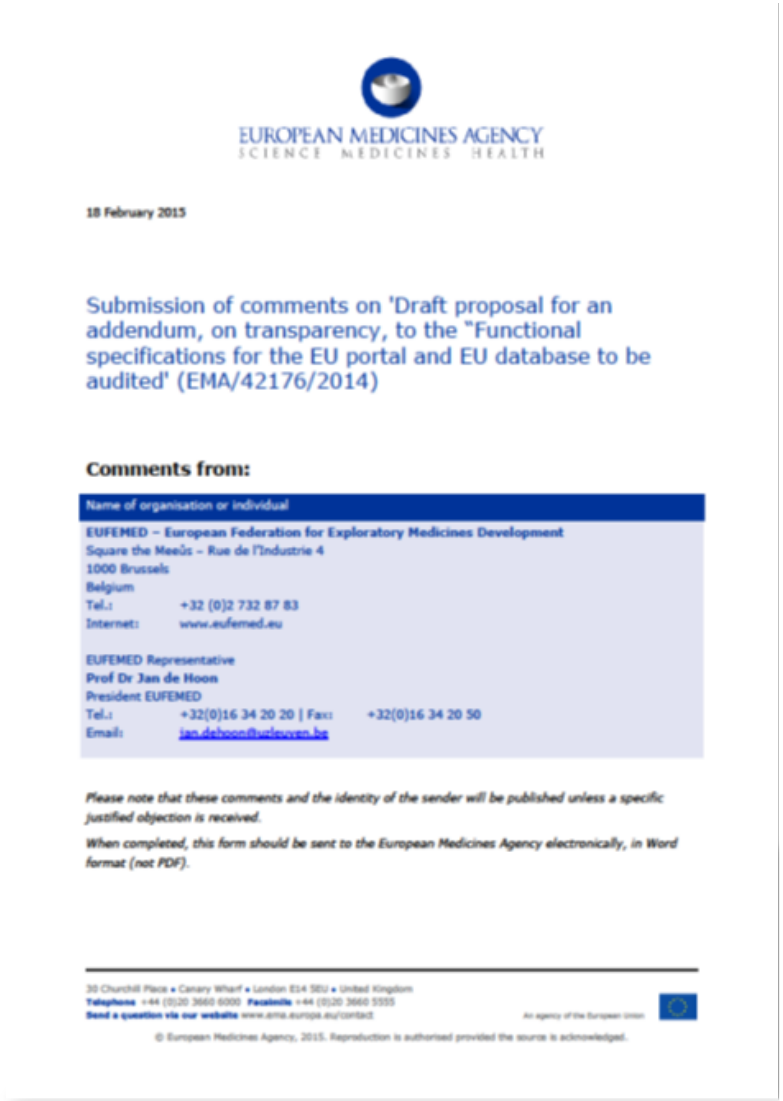
A **balanced approach** is needed to **protect public health and also foster the innovation capacity of European medical research**, thus supporting the EU as a location for innovative, cutting edge research that results in development of novel products and research into new and better uses of existing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

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/01/WC500180618.pdf

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



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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).

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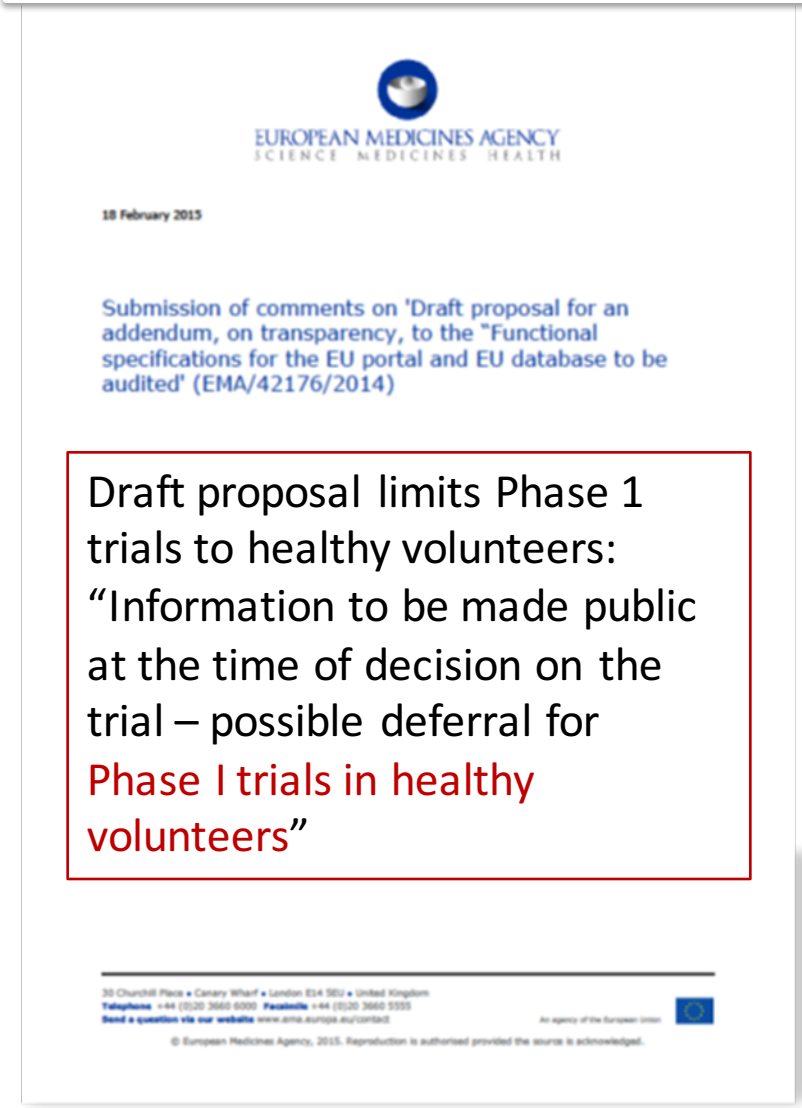
- 80: "Phase 1 trials are commercially particularly sensitive […]"
- 345: "In the case of Phase I clinical trials in healthy volunteers there is particular sensitivity about the commercial confidentiality of information on the trial.
- 617: "Thus, the extent of information made public could progressively 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"



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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)

Draft proposal limits Phase 1 trials to healthy volunteers: "Information to be made public at the time of decision on the trial – possible deferral for Phase I trials in healthy volunteers"

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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

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".

Phase 1 stakeholder submissions Jun/Sep 2015 Publication of Phase 1 summary results

Re: EU Clinical Trials Regulation – Publication of the (lay) summary of results for "Category 1" trials (trials without therapeutic and/or prophylactic intent)

We write on behalf of the European Federation for Exploratory Medicines Development (EUFEMED) and the European CRO Federation (EUCROF).

This letter follows a recent stakeholder meeting on the transparency addendum for the EU portal and EU database, [...]

The requirement to publish summary results of Category 1 trials should, due to their commercially confidential nature and the impact their publication may have on patent rights, be waived - or the publication should be delayed to no less than 24 months after the end of a trial.

EUFEMED EUCROF letter to EC 19 JUN 2015 Page 1 of 5

Supported by:

AHPPI
Association for Human Pharmacology in the Pharmaceutical Industry

Re: EU Clinical Trials Regulation – Publication of the (lay) summary of results for Phase 1/"Category 1" trials (trials without therapeutic and/or prophylactic intent)

We write on behalf of the European CRO Federation (EUCROF). This is a further follow-up on our letters to the EMA and EC of June and July 2015.

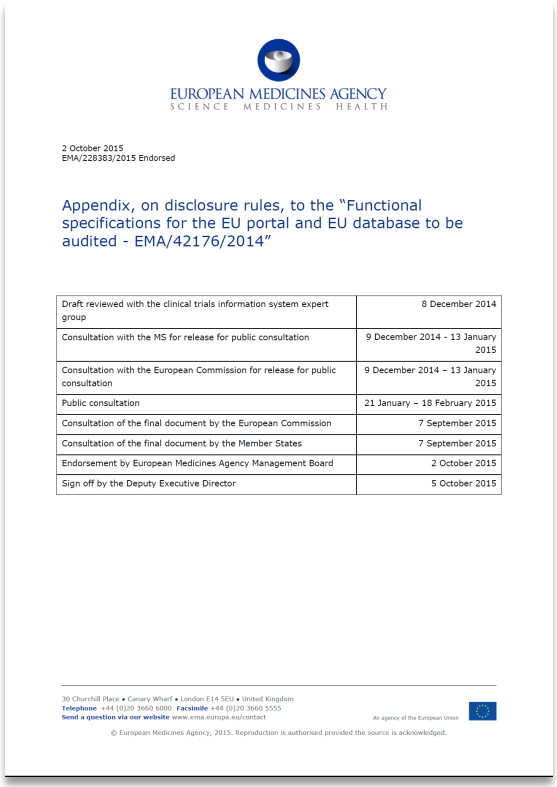
In our previous letters we advocated that the requirement to publish summary results of Phase 1 trials should, due to their commercially confidential nature and the impact their publication may have on patent rights, be waived - or the publication should be delayed.

In support of our previous submissions we attach an expert opinion by [...]. This opinion outlines the potential risks to patent protection arising by early publication of summary reports of results, in particular those of Phase 1 clinical trials.

The opinion confirms that a one-year window between concluding a Phase 1 trial and public access to a summary of its results will in most cases not be sufficient to protect inventions arising from the results of the trial by patents, which are based on sufficient evidence to support their validity.

EUCROF letter to EMA EC MS 04 SEP 2015 Final Page 1 of 2

The outcome:
Final appendix on Disclosure Rules, Oct 2015
Definition of Phase 1 (Category 1) trials



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SCIENCE MEDICINES HEALTH

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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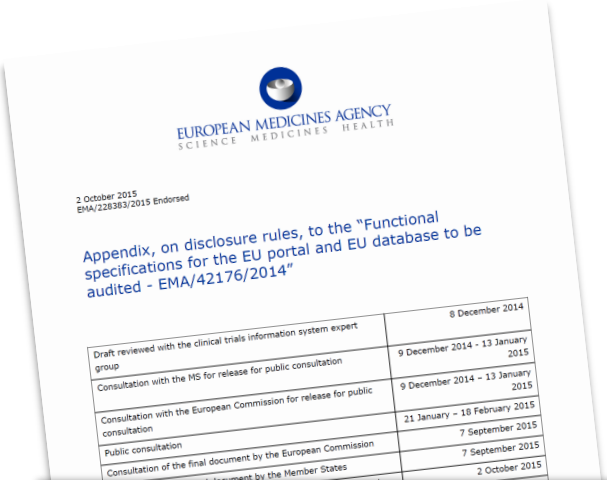
In order to recognise the legitimate economic interests of sponsors and take account of the marketing authorisation status of the IMPs under study in a clinical trial, but still have a predictable and automatic system for publication of information from the database, the rules and criteria are established below by grouping clinical trials (based on the use and status of their IMPs) into three categories:

Category 1 clinical trials (pharmaceutical development clinical trials):

Category 1 clinical trials are:

- Phase I clinical trials in healthy volunteers or patients, that are carried out to test whether a treatment is safe for people to take, rather than to try to treat, prevent or diagnose a condition, and to study pharmacokinetics and pharmacodynamics (where possible). These trials are usually very small, (typically around 30 people), and usually involve healthy volunteers or sometimes patients.
- So called Phase 0 trials - trials in healthy volunteers or patients, without therapeutic or prophylactic intent, and often used at low doses (thought this may include pharmacologically active doses) to explore pharmacokinetics or pharmacodynamics.
- Bioequivalence and bioavailability trials of innovative products, new generic products and bio-similar products. This includes such trials on new formulations of products with a marketing authorisation (originator, generic or biosimilar).
- Similarity trials for biosimilar products including those conducted in patients where efficacy endpoints are used to determine biosimilarity, where pharmacokinetic and or pharmacodynamic studies are not possible.
- Equivalence trials for combination products or topical products where a pharmacodynamic or efficacy endpoint is used to determine equivalence, and where pharmacokinetic and or pharmacodynamic studies are not possible.

The outcome: Publication of Registration Information



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2 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"

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
	2 October 2015

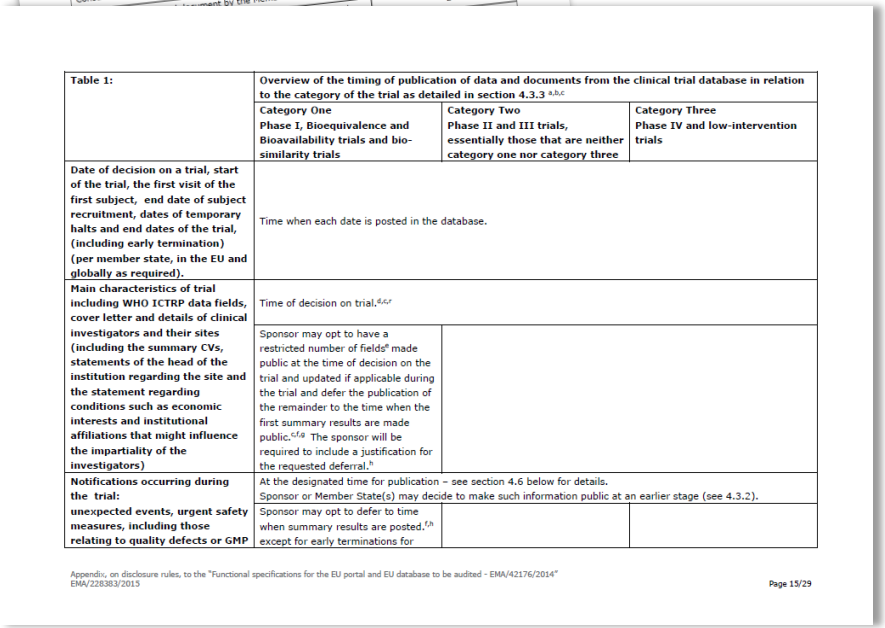

Table 1:	Overview of the timing of publication of data and documents from the clinical trial database in relation to the category of the trial as detailed in section 4.3.3 [a,b,c]		
	Category One Phase I, Bioequivalence and Bioavailability trials and bio-similarity trials	**Category Two** Phase II and III trials, essentially those that are neither category one nor category three	**Category Three** Phase IV and low-intervention trials
Date of decision on a trial, start of the trial, the first visit of the first subject, end date of subject recruitment, dates of temporary halts and end dates of the trial, (including early termination) (per member state, in the EU and globally as required).	Time when each date is posted in the database.		
Main characteristics of trial including WHO ICTRP data fields, cover letter and details of clinical investigators and their sites (including the summary CVs, statements of the head of the institution regarding the site and the statement regarding conditions such as economic interests and institutional affiliations that might influence the impartiality of the investigators)	Time of decision on trial.[d,e,r]		
	Sponsor may opt to have a restricted number of fields[g] made public at the time of decision on the trial and updated if applicable during the trial and defer the publication of the remainder to the time when the first summary results are made public.[f,g] The sponsor will be required to include a justification for the requested deferral.[h]		
Notifications occurring during the trial: unexpected events, urgent safety measures, including those relating to quality defects or GMP	At the designated time for publication – see section 4.6 below for details. Sponsor or Member State(s) may decide to make such information public at an earlier stage (see 4.3.2).		
	Sponsor may opt to defer to time when summary results are posted,[f,h] except for early terminations for		

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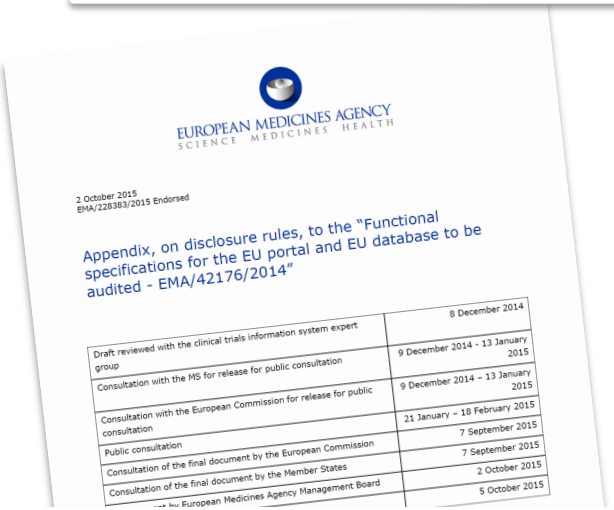
The publication of the characteristics (registration) of Category 1 (non-paediatric) clinical trials may be done in stages;

upon authorisation a very limited amount of non-commercially confidential information can be published, the remaining information's publication can be deferred until the summary reports of results are published.

"The fields to be made public, even in the case of a deferral, are:

- EU Clinical Trial Number
- Sponsor name and address
- Investigator name and site address
- nature of clinical trial (e.g. bioequivalence in 24 healthy volunteers)
- decision on the trial
- date of decision on the trial
- date of start of the trial
- dates of start and end of recruitment
- date of end of the trial in the Member State(s) in the EU and globally (including early termination of the trial)
- summary CVs
- statements of the head of the institution regarding the site
- statement regarding conditions such as economic interests and institutional affiliations that might influence the impartiality of the investigators"

The outcome: Publication of Summary Results



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Consultation of the final document by European Medicines Agency Management Board	2 October 2015
	5 October 2015

subject to conditions, or not acceptable)			
Decision on the trial, or a substantial modification. (authorised, authorised subject to conditions or refused),			
Product specific documents – IMPD Q and all related assessment reports, requests for additional information, and conditions relating to these.	IMPD-Q section will not be made public. If a SmPC is referred to, instead of a IMPD Q section being submitted that reference will be made public.		
Clinical trial results summary for an intermediate data analysis - that should be made public in accordance with article 37(8).	12 months after the intermediate data analysis date where its publication is required in accordance with article 37(8).[n]		
	Sponsor may opt to defer the publication of the summary of results of an intermediate data analysis (if foreseen) in all or in part up to a maximum of 18[q] months after the due date (usually 12 months after the end of the trial unless article 37(4) applies) of the final summary of results and layperson summary (in total, a potential maximum of 30 months after the end of the trial) or until the time of MA if the time is earlier. [f,g,h,o]		
Clinical trial results summary and lay person summary	12months after the end of the trial in the EU, unless this is later for scientifically justified reasons in accordance with article 37(4).[p]		
	Sponsor may opt to defer the publication of the summary of results and layperson summary in all or in part up to a maximum of 18q		

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- The publication of summary reports of results can be deferred from a default of 12 months after the end of a Category 1 trial to up to 30 months after the end of a trial. At this time then also the remaining registration information -see above- will be published.
- The publication of urgent safety measures and unexpected events occurring during Category 1 clinical trials can be deferred until publication of summary results, as long as these matters are dealt with by using adaptive study design or via substantial amendments, as is normal practice for exploratory trials.
- The publication of IMPD sections S and E, IB, protocol and subject information may be deferred to
  - up to seven years after the end of a Category 1 trial and
  - up to five years after the end of a therapeutic exploratory and confirmatory clinical trial, to protect commercial confidentiality.
  - IMPD section Q will not be published.
- Deferrals require appropriate justifications.
- The EMA stated that the processes involved will be straight forward.

What are the next steps?

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

The plan is to have the system available for an independent audit by the end of the third quarter of 2016

If the portal and database get a green light from the audit, the Regulation will come into application by the end of 2017

From that point onwards the portal and database will be operational for sponsors and Member States to use for all new clinical trial applications in the EU, and the information from the database will be publicly available

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/10/news_detail_002409.jsp&mid=WC0b01ac058004d5c1

AHPPI

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Association for Human Pharmacology in the Pharmaceutical Industry

Thank You!