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
Association Internationale de la Mutualité (AIM) Health Action International (HAI) Europe International Society of Drug Bulletins (ISDB) Medicines in Europe Forum (MiEF)

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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1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
FOREWORD	***Access to clinical data (efficacy and safety data) protects public health from preventable harm*** Public access to full clinical data, including raw data, is particularly important to protect public health as it allows for independent analysis, enhancing knowledge about the real effects of medicines and allowing comparative effectiveness reviews (1). Yet, the EMA draft proposal for an addendum, on transparency, to "the functional specifications for the EU portal" will prevent the reanalysis of data by independent stakeholders: no access to individual participants' data (raw data) even if they are anonymised, extensive delays in the publication of the information up to 10 years, etc. (read below) This goes against the requirements and objectives of the Regulation (EU) No 536/2014, especially that of increasing the reliability and robustness of clinical data.	
	Clinical data belongs to the public, not to pharmaceutical companies The clinical data held by the new EU Clinical Trial Portal will be related to clinical trials conducted under the auspices of the Declaration of Helsinki. The Declaration of Helsinki explicitly refers to the ethical obligation to disclose the results from research and insists on the completeness and accuracy of the reports (articles 30 and 33) (2). In fact, patients accept to put themselves at risk, taking part in clinical trials, notably in the hope that their participation will benefit society through the advancement of science. The WHO Informed Consent Form Template for Clinical Studies clearly divides benefits into: "*benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.*" (3) Yet science is hampered when data from these studies are never made public, which is often the case especially when their results do not favour the sponsor's product- "publication bias").	Emphasize in the document that clinical data is scientific data of an overriding public interest and therefore a public good (and adapt CCI definition – read below).

	Since publication bias and the selective reporting of positive study results are widespread practices in biomedical research, failure to make all the data available greatly diminishes the social value of research (4). Granting public access to detailed clinical data, including raw data, is crucial to minimise dangerous practices of reporting bias, which overrate the benefits of a drug while underestimating its harm (5). Moreover, industry-funded research often benefits from publicly funded research bodies (access to investigators and research teams at publicly research sites; public funding for basic research through EU grants and Member State funding, etc.). It is therefore more than reasonable to expect that all data from biomedical research is made publicly available.	
	The EMA restrictively misinterprets Regulation (EU) No 536/2014 As soon as the Clinical Trials Regulation was adopted, the European Federation of Pharmaceutical Industries and Associations **(EFPIA) called in particular for "*the Commission and EMA [to] interpret the Clinical Trial Regulation in a manner that respects (…) incentives for companies* to make long-term investments in biomedical research"** [i.e to protect what they consider commercially confidential information] (6). Judging by the draft consultation paper, their demands have been widely accommodated. The EMA's interpretation of Regulation (EU) No 536/2014 does little to meet the needs of patients and the public across the European Union but goes a long way to soothe the requests of "clinical trial sponsors" such as the pharmaceutical industry, by **introducing non-disclosure as the norm** and by providing all the wiggle room sponsors need to circumvent their legal obligations to disclose clinical trial data (read below).	
	Patient health is the priority The document mentions that the provision of information needs to be weighed against the "*legitimate interest of sponsors*" (Line 123). But it should underline, as priority, the public interests in defending and upholding patients' health, since that is the ultimate goal of the Regulation.	Maintain the ultimate goal of the Regulation rather than misinterpreting it and emphasize throughout the document that the disclosure of clinical trial data is an overriding public interest vis-a-vis commercial interests.

	The EMA must in fact fully comply with the Regulation on access to documents and the TFEU, which identifies the *"protection of health and life of humans"* as an overriding public interest. (7) Moreover, under Regulation No 1049/2001 on access to documents, **confidentiality is an exception**: *"In principle, all documents of the institutions should be accessible to the public. However, certain public and private interests should be protected by way of exceptions"* (Regulation 1049/2001, recital 11).	
Question 1: Please comment on whether these proposals meet the requirements and objectives of the Regulation (EU) No536/2014	***The EMA draft proposal does not reflect Regulation (EU) No 536/2014: non-disclosure becomes the norm, rather than the exception, public trust in regulatory-decision making decreases*** It is stated that the consultation document sets out proposals and options on the exceptions established as to the transparency provisions on the European Clinical Trials Regulation. In our view, the consultation paper does not reflect the spirit of the Regulation, which aims to increase transparency and allow public access to important and much needed information on clinical trials. On the contrary, it is of great concern to realise that **EMA's proposal considers non-disclosure the norm, rather than the exception**. In fact, when it comes to the practical application of the exceptions, this draft introduces plenty of leeway for abuse by clinical trial sponsors, by legitimising the non- publication of clinical data on the grounds of commercial confidentiality, and allowing deferrals in publication of key data for long periods (i.e. up to ten years after trial registration!). The EMA's proposal is unacceptable and at odds with the principles enshrined in the Clinical Trials Regulation and the transparency advances it promised to bring. Contrary to the approach taken by the EMA, if comprehensive transparency was applied, that would truly facilitate the implementation of the disclosure policy (and its automation). The EMA's has the responsibility to protect and strengthen public health. However, by upholding non-disclosure as the rule, and granting commercial interests higher ground, the EMA is compromising public health and diminishing public trust in regulatory-decision making.	

Access to individual patient data (lines 92, 219, 372)	The document states that "*the database will not contain any individual patient listings from clinical trials*". Apparently, EMA's views have dramatically changed since November 2012, when it announced that it would "*proactively publish clinical-trial data and enable access to full data sets by interested parties*" – the aim being to allow for reanalysis of trials' results. (8) In fact, it is important to distinguish patient personal data from de-identified participants' data. Participants accept to put themselves at risk, taking part in clinical trials, hoping that their participation will benefit society through the advancement of science. Furthermore, according to EU regulations, data submitted to regulatory authorities for marketing authorisation is submitted in non-identifiable form. Currently applied anonymisation methods safeguard patient confidentiality. Only in very specific cases (e.g., rare diseases) additional measures might be required to prevent re-identification. There is no public health rationale in preventing access to de-identified data by researchers and the European Medicines Agency should strive to do so in the future implementation of its access to clinical trials policies. Bearing in mind that there is an overlap between the EMA's policy on access and publication of clinical data and this draft addendum, it would be injudicious not to align both initiatives towards the highest transparency standards possible (9).	Emphasize that **the development of guidelines by the European Commission for the formatting and sharing of raw data in the EU database has to become a priority.**
Scope (line 173)	The draft addendum mentions that clinical trials conducted under current legislation (Directive 2001/20/EC) will not be subject to the transparency rules of the new Regulation EU Regulation 536/2014, unless they are still ongoing three years after the Regulation comes into force. Since the ultimate goal of the EMA should be to increase transparency and public access to scientific data, the EMA and the CMDh (Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human) must progressively publish all the clinical data they hold on medicines that are already on the market [10].	The EMA should consider broadening the scope of its disclosure policy to include all clinical data held by the Agency and the CMDh on medicines which are already on the market i.e. to provide **retrospective access to clinical-trial data part of the common technical documents provided to the EMA and the CMDh over the 10 last years (period 2004-2014).**
4.2 What will be made public for every clinical trial **(Line 324)**	***At the time of the decision of the trial*** Contrary to what is stated in the consultation document "*the protocol can (…) contain extensive detail of commercially confidential nature*", the European Ombudsman (decision 2560/2007/BEH) has concluded that neither study protocols	Add to the list of documents to be made available at the time of decision of the trial: - the full protocol; - information on the statistical plan.

(Line 513)	nor clinical study reports can be classified as trade secrets and/or commercial confidences. Therefore, we would like to stress that at the time of decision on the trial the full protocol must be published, not simply a summary as proposed in the consultation paper. Moreover, when the pharmaceutical industry advocated a similar approach during the adoption of the clinical trials Regulation, the European Parliament and the Council reiterated that: *"(…) 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 (…)" (recital 67).* The publication of summaries does not address nor solve the problem of reporting bias. In addition, information on the statistical plan should be disclosed at the same time that a decision on the trial has been made. If the aim of the EU Portal is to inform, among others, healthcare professionals and participants, there is no rationale whatsoever not to include the full protocol at the time of the decision of the trial, or to defer its publication until "*the time that the summary of trial results is loaded into the database and made public (i.e. 12 months after the trial*", as proposed in the consultation paper (section 4.4.3 – line 648).	**The publication of the clinical trial protocol and related subject information sheet must take place at the time of the decision of the trial and must not be deferred**. Any changes to the clinical trial protocol should also be made public. **The publication of the Investigational Medicinal Products Dossier (IMPD) safety and efficacy sections must not be deferred** and should ideally be published at the time of trial decision.
(Line 345-350)	***After the end of the trial*** There is no public health rationale in allowing a deferral in the publication of the safety and efficacy sections of the Investigational Medicinal Products Dossier (IMPD), or the study protocol, as proposed in the consultation paper (section 4.4.3).	

4.4.1 What should be considered to be commercially confidential information?	***A vague definition of "commercial confidentiality information": clinical trial data are not "trade secrets"*** The EMA proposes to define "commercially confidential information" as: "*any information contained in the data or documents submitted to the database that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the sponsor*". This definition, which was not the democratically discussed nor accepted during the adoption of the clinical trials Regulation, is more encompassing than that put forward by the European Commission in its proposed directive on trade secrets (11). Moreover, despite the claim that "*the implementation of the transparency rules of the Clinical Trial Regulation is without prejudice to the application of Regulation (EC) No 1049/2001 and citizens' right to request documents under that Regulation*" (lines 256-257), this definition could influence the way the EMA answers to information requests. The implementation of such a definition would allow clinical trial sponsors to circumvent the publication of scientific data – of public interest - on the grounds that their economic interests might *potentially* be undermined. For instance, safety-related clinical data would likely be considered CCI by a clinical trial sponsor and thus withheld. Moreover, the EMA outlines the following as "legitimate economic interest" for the sponsors: - "*because the clinical trial forms part of the development of a medicinal product for commercialisation of that product (i.e. seeking a marketing authorisation or variation)*" (lines 469-470); - "*because the clinical trial is conducted to (…) research on medicines and as such may be part of a process for which research funds have been obtained or may contribute to the obtaining of future research funds*" (lines 471-472). This is unacceptable. The statement that "*specific situations may occur where the **overriding public interest would prevail in ad hoc situations** over and above the general transparency rules established for the database and documents and data not usually made public may be published or made public at an earlier time point than would be usual*" is not sufficiently reassuring. In fact, no information is provided about the "*decision making process [that] will need to be established in order to invoke use of the overriding public interest in such ad hoc cases*" (line 489), and thus the statement above suggests rather clearly that opacity will be the rule and transparency the exception…	***Redefine CCI to become an exception, by adopting transparency as a general rule as follows:*** "***Scientific data that is in the public interest, such as clinical or regulatory data, should not be considered commercially confidential***". **"(…)** ***CCI can be considered as meaning ~~any~~ information contained in documents submitted to the database that is not in the public domain or publicly available and where disclosure ~~may~~ is duly justified and documented to undermine to an unreasonable degree of prejudice the legitimate economic interest of the clinical trial sponsor, provided there is no overriding public interest that justifies immediate disclosure. The period of time for which commercial confidentiality is required is duly specified.*** ***Accepted CCI can be blacked out but the document shall be released so that the remaining sections of the documents which do not contain CCI can be publicly accessible."*** ***Delete the examples presented from line 467 to line 479.***

Whole documents to be withheld: EMA's one size hides all approach

According to the EMA, to structure "the complex documents" included in the EU database into "*confidential and non-confidential parts would impose a significant burden on sponsors who would have to prepare them for input into the portal in a very different way for the EU compared to elsewhere*".

The EMA then goes along to propose the non-disclosure of whole documents, not just sections. It goes as far as claiming that study specific documents – such as the protocol, the subject information sheet, related list of questions to sponsors, response and assessment reports - (line 502) could be considered CCI, as well as product specific documents – such as the investigator brochure, the investigational medicinal product dossier, the related list of questions and the response and assessment reports (line 535).

In addition, EMA's **"one size *hides* all approach"** is based on a complicated classification of clinical trial documents into different categories, depending on the "*stage of development*" (phase I trials are considered more "commercially sensitive" than phase IV trials or "low intervention" studies).

The rationale behind EMA's approach seems to be that of reducing a subjectively perceived burden on authorities and sponsors rather than improving transparency.

A redefinition and narrowing of the notion of *commercially confidential information* (line 457) is essential to prevent the EMA from relying solely on the self-classification by the sponsor of the information that may undermine the sponsor's economic interest or competitive position (read right column on page 7).

Companies must be required to provide detailed information that shows that the release of information that they claim to be commercially confidential would truly harm their interests and at the same time to prove that non-disclosure would not be detrimental to public health.
In light of the objectives pursued in Regulation No 1049/2001 (article 4(2)), CCI can be overturned whenever there is an "*overriding public interest in disclosure*". This needs to be clearly stated in the definition of CCI.

In addition, **any exception to disclosure rules should only involve the removal of specific elements of information within a document and never be applied to an entire section or certain types of documents**. As clearly stated in article 4.6 in Regulation No 1049/2001: "*If only parts of the requested document are covered by any of the exceptions, the remaining parts of the document shall be released*."

Question 2: Identity of Member State experts (mainly scientific assessors, regulatory officials, ethics committee members, inspectors)	The consultation paper proposes to exclude the names of member state experts from the database. If the aim is to increase Transparency in clinical trials information, there is no rationale for not sharing their names, since they hold a public position.	Change text to: The names of the Member State experts are to be included in the database.
Question 5: Contact details of clinical investigator	We consider pertinent to include a contact email for the clinical investigator.	Add contact email for the clinical investigator
4.4.2 How should the status of marketing authorisation of the medicinal product be applied in the context of article 81(4)(b) of the Regulation? **Question 6.**	Article 81(4)b of the Clinical trials Regulation states "*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 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*". "*Taking into account the status of the marketing authorisation for the medicinal product*" means to us "*once a marketing authorisation has been issued, by at least one Member State, for the active substance contained in that medicinal product*" (proposal 1.1. of the consultation document). This is in fact the notion borne in mind by the EU Parliament and the Council when defining a "*low intervention trial*" and **there is no reason to interpret it differently**. Proposal 1.1. is the most inclusive proposal since it regards the active substance, not the specific medicinal product, nor the particular indication. Access to information about other clinical trials concerning the same active substance (even if in different medicinal products) might be relevant to the public, sponsors, healthcare professionals and patients. In addition, proposals 1.2. and 1.3. could be used to delay the entry into the market of generics and of biosimilars.	Choose option 1.1.
Question 7:	We do not agree to *indefinitely* withhold important scientific information as it would	

Please comment and give a brief rationale for your support or disagreement with this proposal regarding the IMPD-Q section.	hamper science. Research is largely based on knowledge transfer. The IMPD-Q section constitutes regulatory data that needs to be made publicly available particularly when relevant from a patient and public health perspective (impurities, stability). Regulatory data protection safeguards the interests of innovator companies by preventing generic and biosimilar companies from using this data for 10 years. In specific circumstances, such as a new manufacturing process or new analytical methods for example, it could be accepted that the information would only be made available after a defined period of time, but that should be decided on a case-by-case basis. It is not acceptable to withhold other IMPD sections (efficacy and safety) or trial-specific documents.	
Question 8: **Please comment and give a brief rationale for your support or disagreement with this proposal regarding clinical trials on products with a marketing authorisation.**	If clinical trial sponsors in Phase IV and low-intervention trials are given the possibility to defer the publication of documents until 12 months after the end of the trial, they will most likely do so. Yet, there is no public health rationale in accepting such a deferral, since information about these types of trials is of value to healthcare professionals (the product has already been approved). It often concerns research being done outside the indication for which the drug has been approved (off-label use). We would therefore urge the EMA not to introduce any deferral, as timely access to this information is key to protect patients from avoidable harm.	Do not include any deferrals for *Phase IV and low-intervention trials.* In addition, Phase IV trials and low-intervention trials in the same category, as their aims and their potential harms are very different.
Question 9: **Please comment on proposals one, two, three or four regarding clinical trials on products with a marketing authorisation indicating which proposal best meets the requirements and objectives of the Regulation. Please provide a brief rationale for your choice of proposal and explain briefly disagreement**	***Refuse deferral rules that would postpone the release of information up to ten years*** We disagree with the creation of ***trial*** categories, which were not mentioned in the Clinical trials Regulation, to justify and allow "deferrals" that would grant sponsors the possibility to withhold information up to 10 years. According to the EMA, "*the period of 10 years have been chosen to give a reasonable period after the trial has been completed, before publication, 10 years corresponding, by analogy, though not actually linked to, the data protection period provided for in the EU*" (lines 718-720). The EMA seems thereby to confuse two concepts. Regulatory data protection means that generic and biosimilar producers cannot use data of the "innovator" industry during 10 years for request for a marketing authorisation even if it is publicly available. It does however not prevent for data transparency, which is needed to	***Choose option 1 for all trials***, both pre and post- marketing authorisation and regardless of the intent of the trial (having or not a therapeutic or prophylactic intent). This entails: - Amending section on 'phase I trials' to remove any deferrals; - Amending section on '*Phase IV and low-intervention trials' to remove any deferrals.* *Reject options 2, 3 and 4 which are not in line with the Clinical trials Regulation.*

with the other proposals.	avoid publication bias, allow for the reanalysis of clinical trial results and cost-effectiveness assessments. **Only the proposal 1 is acceptable** and in line with the Clinical trials regulation, provided the following changes are made: "*the study specific and product specific documents are made public at the time of the decision of the trial, and the exception set out in Article 81(4)b would only apply to the IMDP-Q section,* ***~~which would not be made public at any stage~~, unless there is an overriding public interest in disclosure***". We urge the EMA not to introduce any deferral rules in Phase IV and low-intervention trials that would allow sponsors to avoid the timely publication of information. Similarly, no deferral rules can be accepted in phase I trials (see comment below, page 14). The other proposals (proposal two, three and four) allow deferral rules that would arbitrarily postpone the release of information up to ten years. That is unacceptable.	
Question 10: Please comment on the proposed time points in paragraphs 6.5.1 and 6.5.2 [triggers for timing of publication] and indicate whether they meet the requirements and objectives of the Regulation. Please provide a brief rationale for your support or disagreement.	Option 6.5.1 mentions "*The granting, refusal or the withdrawal of the marketing authorisation application has triggered the loading into the EU database and therefore publication by the marketing authorisation applicant of the clinical study report for the same trial.*" This option is not adequate, as many clinical trials would fall outside its scope, since as pointed out in the draft proposal "*there are many clinical trials carried out on non-authorised medicines, in the early phases of development prior to marketing authorisation, which are never later used in a marketing authorisation*." The second option foresees deferrals of 9 to 10 years, which is, in our view unacceptable. (see answer above to Question 9).	Do not establish triggers for timing of publication, just apply overall rule.
Question 11: Please comment and give a brief rationale for your support or disagreement with this proposal regarding Phase I trials.	The proposal on Phase I trials foresees the possibility for sponsors to "*opt to have only a very minimal public information at the time of decision on the trial*". If sponsors are given such an opportunity, they will certainly seize it and delay the publication of information. Yet at Phase I, there might be very little information available about a new drug or active substance. This is therefore inadequate. Also, in it is unclear whether these exceptions will also apply to those Phase I trials conducted on actual patients (for instance to test drugs against cancer).	Do not grant sponsors of Phase I the possibility to "*opt to have only a very minimal public information at the time of decision on the trial.*"
Question 12: Please	The proposal mentions "*The arrangements for payment of investigators and sites as*	Any arrangements to fund investigators per

comment on whether this proposal meets the requirements and objectives of the Regulation.	*set out in Annex I (P) (69-71) of the Regulation, should not be published as they relate in all cases to the commercial financial arrangements between the parties and the exception set out under Article 81(4)(b) should apply in all 749 cases, because this information can be considered to be commercially confidential."* Any arrangements to fund investigators per patient recruited could be considered a perverse incentive and should therefore not be considered confidential.	patient recruited could be considered a perverse incentive and should therefore not be considered confidential.
Question 13.Protecting confidential communication between Member States in relation to the preparation of the assessment report	The proposal includes: "*The confidentiality of communication between Member States in relation to the preparation of the assessment report is required to enable the preparation and drafting of assessment reports to be conducted in confidence to ensure that the assessment and hence where applicable the decision making process is not subject to interference.* *The Regulation does not require the draft assessment reports to be submitted through the portal to the database and therefore they will not be made public.* "	If the product is already in the market then there should not be a problem to publish all the information related with a trial. Openness and publication should be the rule. This should also include the publication of any report by a member state that does not agree with the assessment (minority vote).
4.7. Reporting of unexpected events in accordance with Article 53 and 844 urgent safety measures in accordance with Article 54 Question 17.	We do not agree that the reports of unexpected events made public are to be "*redacted, by the sponsor, (…).*" (line 851)	Modify text as follows: "The report made public in accordance with Articles 53 and 54 ***~~should~~ can*** be redacted, by the ***~~sponsor~~ regulatory authorities***, in line with the principles set out in accordance with exceptions under Article 81(4)(a) [protection of personal data] ***~~and (b)~~***. The report should nonetheless identify the relevant clinical trials by their EU number and or protocol number (for third country trials). Redacted and unredacted versions should be submitted to the database but only the redacted version made public. No ***identifiable ~~personal~~*** data of trial subjects should be included."
4.8. Clinical study reports submitted by the marketing-authorisation applicant/holder **Question 18.**	Listings of de-identified individual patient data should be made available to allow independent reanalysis of data.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		Please take into consideration all the modifications proposed above within the "General comments".	
Line 617		Comment: "In applying the concepts of protecting commercially confidential information, in particular taking account of the marketing authorisation status of a product, and of overriding public interest, a graduated approach could be taken to the release of information on clinical trials. 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. " Proposed change (if any):This general consideration needs clarification, only if the EMA would refuse option 1. What does the EMA consider a graduated approach? Patients and healthcare professionals are interested in consulting information on ongoing clinical trials regardless of the trial Phase.	
Line 781		Comment: Deferral of the publication of inspection reports is not in line with the spirit of the Regulation 536/2014. In fact, recent evidence from the US highlights the importance of having public access to inspection reports in a timely manner. (12) Proposed change (if any): Delete deferral of reports and include requirements from prompt publication of inspection reports.	
Line 866		Comment: Clarify what is meant by EU expert group, who is in that group and how members are selected. Proposed change (if any): clarification of who will sit in that group, how will member recruitment take place, what will be	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		the timeline for development of raw data sharing guidelines.	
Line 895		Comment: The publication of clinical trial documents and/or information will be an automatic process, with "No manual intervention". It is mentioned that a "manual override" will be made available to enable publication in exceptional circumstances" but transparency will be an exception rather than the overall rule. Proposed change (if any): Transparency must be the rule, not the exception, therefore manual intervention will take place when a company invokes that the information is commercially confidential. Companies must be required to provide detailed information that shows that the release of information that they claim to be commercially confidential would truly harm their interests and that non-disclosure would not be detrimental to public health.	

1- Tucker M *"How should clinical trial data be shared?"* BMJ 2013; 347 doi: http://dx.doi.org/10.1136/bmj.f4465
2- Helsinki Declaration available at: www.wma.net/e/policy/b3.htm.
3 - WHO Informed Consent Template Form. Available at: http://www.who.int/rpc/research_ethics/InformedConsent-clinicalstudies.doc
4- McGauran N, Wieseler B, Kreis J et al ''Reporting bias in medical research- a narrative review'' Trials 11:37 (2010)
5- Gøtzsche PC. ''Why we need easy access to all data from all clinical trials and how to accomplish it.'' *Trials*, 12:249 (2011) doi: 10.1186/1745-6215-12-249
6- "EFPIA calls for collaboration in the implementation of clinical trials regulation following vote in the European Parliament" press release, 3 April 2014: 2 pages.
7- Health Action International (HAI) Europe ''Protecting citizens' health: Transparency of clinical trial data on medicines in the EU'. (Policy paper, October 2013).
8- European Medicines Agency "Proactive publication of clinical-trial data – discussing the way forward" 9 August 2012. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/08/news_detail_001588.jsp&mid=WC0b01ac058004d5c1
9- EMA "European Medicines Agency policy on publication of clinical data for medicinal products for human use" POLICY/0070 (EMA/240810/2013); 2 October 2014: 22 pages.
10- "All trials Campaign: All Trials Registered | All Results Reported" http://www.alltrials.net/
11- Trade secrets are defined in Article 2(1) of the proposed directive as: "*information which meets all of the following requirements:*
a) is secret (…);
b) has commercial value because it is secret;
c) has been subject (…) to reasonable steps (…) to keep it secret".
12- Seife C *"Research Misconduct Identified by the US Food and Drug Administration"JAMA Intern Med*. Published online February 09, 2015. doi:10.1001/jamainternmed.2014.7774