EMA/240810/2013

Submission of comments on 'Policy 0070 on publication and access to clinical-trial data'

Comments from:

Name and affiliation
EFPIA

Please note that these comments and the identity of the sender (not contact details) will be published unless a specific justified objection is received.

When completed, this form should be sent in Word format (not PDF) to: ctdatapolicy@ema.europa.eu

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Introduction

EFPIA continues its active involvement in the important issue of responsible clinical trial data transparency and welcomes the opportunity afforded to comment on the EMA draft Policy 0070 on *Publication and access to clinical-trial data* (EMA/240810/2013, referenced as 'draft Policy' in these comments). EFPIA recognises the potential scientific and public health benefits of providing greater access to information from clinical trials.

Biopharmaceutical companies are indeed committed to advancing public health goals through responsible sharing of their clinical trial data in a manner which is consistent with the following imperatives:

- Safeguarding the privacy of patients;
- Preserving scientific rigor and the trust in the regulatory systems; and
- Maintaining incentives for investments in biomedical research.

Under the draft Policy, the EMA will begin to proactively publish on its website the clinical trial data submitted by applicants in marketing authorisation (MA) applications, which it designates as 'open access', and will also reactively provide 'controlled access' to those clinical trial data which may contain patient-identifiable information (patient level data), under described conditions.

EFPIA has considerable concerns with several of the concepts outlined within the draft Policy, the implementation of which, in its current form, we believe would not benefit public health and would conflict with the imperatives referred to above. The published draft Policy does not adequately acknowledge or address key recommendations from stakeholders in the five advisory groups established by EMA earlier this year. Above all, we are concerned that the draft Policy presented could actually (1) weaken safeguards intended to ensure the privacy of patients and other individuals identified in MA dossiers, (2) undermine the trust in the regulatory approval system governing biopharmaceutical products and introduce risks of misinterpretation and misuse of clinical data into the process; and (3) weaken incentives for companies to invest in biomedical research by disclosing companies' commercially confidential information (CCI), without due consideration of the competing interests that may or may not justify disclosure, in each particular case. A consultation process with the MA holder (MAH) needs to be established to allow for removal of commercially confidential information (CCI). Consequences of the EMA draft Policy, as currently written, may inadvertently, but negatively impact public health.

Specifically, in recognition of these stated imperatives, EFPIA is concerned that the "controlled access" proposals would not provide adequate: (1) protection of patient privacy, through appropriate de-identification of patient data and access via a controlled environment that does not allow downloading of the data or (2) review of research proposals to ensure good science.

It appears from this draft policy that the EMA intends to request information from companies that is not currently required as part of an MA application (e.g. individual patient data sets, SAS logs, SAS programs) without justification based on public health need. In this respect the draft Policy goes beyond the purpose of the legislator to provide access to documents of the institutions (Art. 2 para 1 of Reg. 1049/2001). EFPIA believes that the provision of access to such additional data falls under industry's own responsibility and commitments, which are summarised below.

Biopharmaceutical companies already publish their clinical research, collaborate with academic researchers, and share clinical trial information on public web sites at the time of patient recruitment, after marketing authorisation, and when investigational research programs have been discontinued. Building on those continuing efforts, EFPIA and PhRMA have recently adopted Principles for Responsible Clinical Trial Data Sharing. These set out industry's commitments to: (i) enhance data sharing with researchers; (ii) enhance public access to clinical study information; (iii) share results with patients who participate in clinical trials; (iv) certify procedures for sharing clinical trial information; and (v) reaffirm commitments to publish clinical trial results.

We request that the EMA take into account the Principles for Responsible Clinical Trial Data Sharing adopted by EFPIA and PhRMA and assess the added value of its draft Policy against these broad ranging commitments. These Joint Principles represent the consensus views of a large part of the world-wide biopharmaceutical industry, which commits to data sharing of study level and patient level data, and protocol information with researchers, to enhance public access to clinical study information. Following approval of a new medicine or new indication for an approved medicine in the US and EU, biopharmaceutical companies will make publicly available, at a minimum, the synopses of clinical study reports (CSRs) for clinical trials in patients submitted to the Food and Drug Administration (FDA), European Medicines Agency (EMA), or national competent authorities of EU Member States', and to share results with patients who participate in clinical trials. The EFPIA/PhRMA principles include responsible controls on disclosure in order to ensure that clinical trial information released is used to conduct quality research, respecting patient privacy, and is not used inappropriately for competitive commercial purposes. Release of clinical trial information under these principles will therefore be assured of serving the public health interest, while at the same time protecting personal data and CCI.

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Fundamental Comments

1. Protection of Patient Privacy and Personal Protected Data (PPD)

The draft Policy states that "protection of patient privacy is a paramount concern when sharing raw CT data", with which EFPIA strongly agrees. However, EFPIA is concerned that the measures set out in the draft Policy may not be sufficient to provide the necessary level of protection for patient privacy. Data should not be provided if there is a reasonable likelihood of re-identification. As stated above, the controlled provision of patient level data properly falls within the remit of the clinical trial sponsor, and the industry is committed to sharing such data in a way that effectively safeguards patient privacy, as set out in the Joint Principles.

EFPIA is open to discussing with the EMA and other stakeholders the most efficient technological means of directing researchers to the relevant clinical trial sponsor/company to request the data they need.

Recent studies have tested long-held assumptions that de-identifying data protects patient privacy and have shown that the risk of re-identification is particularly acute when de-identified data are made widely available. Re-identification technology is advancing rapidly, allowing re-identification of data once thought to be anonymised. Therefore, if EMA is to ensure the privacy of clinical trial participants, before implementing its proposal, the Agency should ensure that these technologies provide the necessary de-identification measures to adequately protect patients. As the Agency recognizes, it would need to consider not only the clinical data themselves, but also all other public information that could be combined with study data to deduce subject identities, including discharge data, data in public study databases, claims data, U.S. and EMA clinical trials databases, and even social media. To appropriately execute this task, EMA would need the detailed input of information security and bioinformatics experts. In any event, a controlled access model should not allow for the data to be downloaded, in order to reduce the risk of re-identification described here.

EFPIA is also concerned that protection of the personal data of investigators, sponsor, and study personnel named in MA submissions is excluded in the draft policy, which states that "these personal data are considered exempt from PPD considerations". There seems to be no legal basis for this assertion – the EMA must respect and protect the privacy of *all* individuals, whether they are investigators, study personnel or patients. EU Data Protection Regulation (EC) No. 45/2001 (Data Protection Regulation),[1] which imposes on the EMA requirements similar to those in the Data Protection Directive 95/46/EC (DPD),[2] defines "personal data" broadly to encompass any information relating to an "identified or identifiable natural person," which obviously includes any individuals involved in clinical trials, such as investigators as well as patients. EFPIA does not agree that this general exclusion of study personnel from personal data protection is correct or lawful.

In relation to the 'open access' data category, the draft Policy requires that MA applicants provide the EMA with an additional set of documents "that are appropriately de-identified to ensure protection of personal data". Notwithstanding the efforts that would be required of MA applicants to de-identify documents, EFPIA notes that, in this case, it is the EMA that will be making the actual disclosures from its website and the Agency will therefore be responsible for the publication of any information released. Specifically, as the publisher, under Regulation (EC) No. 45/2001, EMA remains legally responsible for ensuring that any information published under open access is appropriately de-identified and for addressing any breaches of privacy or consequences from inappropriate re-identification based on information made available through its open access policy. Likewise, the EMA will have the same legal responsibility to ensure that information published under open access is appropriately de-identified in compliance with (where applicable) non-EU privacy laws - which may vary from those in the EU - given the fact that CSRs frequently include data from patients from countries outside the EU.

[1] Regulation (EC) No. 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:008:0001:0022:EN:PDF

[2] Directive 95/46/EC of the European Parliament and of the Council of October 24, 1995 on the protection of individuals with regards to the processing of personal data and on the free movement of such data. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1995L0046:20031120:EN:PDF

Since the Agency is subject to the Data Protection Regulation (EC) No. 45/2001 concerning the processing of personal data by Community institutions, the proposed draft Policy must be submitted to the European Data Protection Supervisor for review and feedback. We also strongly recommend that the Agency submit the proposed policy to the Article 29 Working Party established under the Data Protection Directive as the policy requires the cooperation of organizations and individuals subject to Directive 95/46/EC. As part of this consultation, the Article 29 Working Party should be asked to opine on appropriate methods for anonymising clinical trial data. Without the agreement of EU data protection authorities (via the Article 29 Working Party) on when data can be deemed "anonymised", MA applicants will be forced to comply with the most conservative national privacy laws, which could mean the marking of all data containing indirect identifiers as potentially personal data.

In addition to considerations of personal data privacy under the data protection legislation, there remains the imperative of respect for the terms of the informed consent given by the patients participating in clinical trials, both in the EU and 3rd countries, with regard to the subsequent or secondary use of their data (whether "anonymised" or not), as a matter of ethics and a central tenet of good clinical practice. In the draft Policy, the EMA appears to infer a broader scope to individual patient informed consent than may in fact be the case, especially historically in past clinical trials, when the current issues now being debated were not envisaged. The draft Policy ambiguously refers to the "spirit of informed consent", whereas in reality trial sponsors (and by definition, any other party handling the data, including the EMA) must respect the informed consent in its particular terms and according to the laws of the country where it was given. The release of clinical trial data – whether by the sponsor or EMA - can only ethically and lawfully take place within the scope of the specific informed consent given by the patient to the trial sponsor and is not distorted so as to deprive the concept of 'informed' of its meaning, and the party releasing the data must bear this responsibility.

2. Providing Access to Data for Legitimate Research

As demonstrated by the joint PhRMA/EFPIA principles, biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data to help facilitate bona fide scientific and medical research. We believe that it is in the interests of transparency and medical research that the secondary research is subject to the same standards of transparency as the original clinical trial and a proportionate review that determines whether the release of "CT data with PPD concerns" is justified in any given case.

Firstly, in relation to the scheme set out in the draft Policy for controlled (reactive) access, there are inadequate controls to ensure that the research/secondary analyses for which the patient level data are used is robust and scientifically credible. Under the draft Policy, the requester is not required to provide or publish their statistical analysis plan at all, and any information that they do provide will not be published until up to one year after accessing the data, hence there is no prior review of the statistical analysis plan, nor of the qualifications of the requester to conduct the research to ensure its legitimacy and scientific rigour. Essentially, any researchers requesting controlled access to patient level data should be held to the same standard as the clinical trial sponsor in terms of transparency, namely to (i) publicly register their research before initiation and (ii) post the results of their research within 1 year of completion.

Secondly, the proposed mechanism does not include any review of the purpose for which data will be used or the relevance of the proposed research to medical science or patient care. The notion that access to individual level health and clinical data should be restricted to legitimate research and subject to proportionate review (even when steps have been taken to protect individual privacy) is well established and enjoys broad support in the context of access to electronic health records and biological data in biobank-type repositories. EFPIA believes that a case-by-case assessment is necessary to determine whether access to "CT data with PPD concerns" is justified in any given case and without this review it is unclear how the proposed mechanism will meet the stated requirement that "analyses are in the interest of public health, in line with the spirit of informed consent".

A recent article authored by European regulators, including the Head of the EMA, indicates that the regulators share EFPIA's concerns. In 'Open Clinical Trial Data for All? A View from the Regulators'[1], senior officials from the EMA and French, Dutch and UK national competent authorities, suggest that data sharing could occur only after receipt of a full analysis plan in order to guard against independent analyses "vulnerable to distortion." According to the regulators:

> *Unrestricted availability of full datasets may in some cases facilitate the publication of papers containing misleading results, which in turn lead to urgent calls for regulatory action. In a worst case, this would give rise to unfounded health scares with negative public health consequences such as patients refusing vaccinations or discontinuing drug treatment.*

EFPIA agrees with the regulators' observations in this article that "independent analysis per se is no guarantee of high quality" and "independent analyses warrant a similar level of scrutiny as sponsor-conducted analyses do." It is a well-established principle of the scientific process that requests for access to clinical data should be subject to prior review, to help ensure appropriate use and analyses of the data. Such controls represent a step towards *responsible* transparency, better assured of serving the public health interest. Unfortunately, the draft EMA policy lacks the controls necessary to address the risks of unfettered access to clinical trial data identified in the 2012 article. EFPIA thus strongly encourages the EMA to adopt the EFPIA/PhRMA Joint Principles referred to above, which contain provisions intended to address these issues, including the requirement that third parties seeking access to clinical trial data in MA dossiers submit a plan for analysis of the data with a scientific review board that will participate in the review of these data requests.

3. Maintaining Incentives for Investments in Biomedical Research - Protection of Commercially Confidential Information (CCI) – Open Access to Clinical Trials Data

The EMA draft Policy designates most elements of the clinical trial data submitted to it by MA applicants as 'open access' suitable for proactive publication on its website. The EMA policy states that commercially confidential information (CCI) will not be divulged, but that "in general, however, CT data cannot be considered CCI; the interests of public health outweigh considerations of CCI".

[1] Eichler H-G, Abadie E, Breckenridge A, Leufkens H, Rasi G (2012) PLoS Med 9(4):e1001202. Doi: 10.137/journal.pmed. 1001202.

The EMA's assertion that clinical trial data and information in MA dossiers cannot be considered CCI is inconsistent with the definition of CCI adopted by the EMA in the draft Policy itself. More fundamentally, this assertion is inconsistent with core protections afforded to MA applicants/holders under EU law. EMA should develop and implement a robust procedure for the consultation of the MAH and review of the data proposed for disclosure, and for the MAH to appeal against the EMA's decision to disclose, in advance of any disclosure of information (i.e., "open" or "controlled" access).

In Section 3, Definitions, at lines 109-111 of the draft Policy, the EMA defines CCI as "any information that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the owner of the information." EFPIA agrees with the general formulation of this definition, but fails to understand how, in light of the definition, EMA can then declare elsewhere in the policy that "CT data cannot be considered CCI" (Line 50). The EMA's own CCI definition requires on its face an inquiry into whether the information is in the public domain or publicly available; whether the owner of the information protects such information from disclosure; and whether, if released, disclosure could harm the competitive interests of the sponsor.

Some information in certain MA dossiers, depending on the sponsor, product at issue, therapeutic area, and value of the information to competitors may, indeed, meet the EMA's definition of CCI. Clinical trials data within the MA dossier may include commercially sensitive information, the protection of which helps incentivise companies to continue innovating and investing in medical and scientific research. This appears to be evidenced by the fact that the majority of requests for disclosure are from pharmaceutical companies as opposed to healthcare professionals or members of the public.[3] Broad dissemination of clinical trial data may negatively impact upon industry's commercial opportunities in markets outside the EU which have no or different standards of regulatory data protection, and may prejudice intellectual property rights. The EMA elsewhere in its draft Policy recognizes this very point by stating that access to "controlled release" documents will be conditioned upon a commitment by the requestor to refrain from using the released information to gain an MA in a non-EU jurisdiction (Line 193).

The fact that certain clinical trials data and other information in MA dossiers may, in principle, constitute CCI does not end the inquiry. EFPIA agrees with the EMA that, in particular cases, public health interests in disclosure of CCI may outweigh considerations supporting non-disclosure of protected information. If information in a MA dossier meets the definition of CCI adopted by the EMA in this draft Policy, and if the EMA seeks to release such information over the owner's objections, then a separate inquiry needs to be made prior to public disclosure to determine whether an overriding public health interest justifies release of the information. This stepwise analysis is, in fact, required by EU law pursuant to Article (4)(2) of Regulation 1049/2001 Regarding Public Access to Documents, which expressly states that EU institutions, including the EMA, will refuse public access to documents that would undermine the protection of the commercial interests of a natural or legal person unless there is an overriding public interest in disclosure. This view is also consistent with Article 39(3) of the TRIPS Agreement, which obliges the EMA to protect against release of data submitted for MA purposes, "[e]xcept where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

[3] Doshi P, Jefferson T. *The first 2 years of the European Medicines Agency's policy on access to documents*: secret no longer. *Arch Intern Med*. Published online December 19, 2012. doi:10.1001/jamainternmed.2013.3838.

Further, EFPIA believes that the required analysis cannot be avoided by collapsing the inquiry into one, all-encompassing finding that "CT data cannot be considered CCI; the interests of public health outweigh considerations of CCI," as stated in the draft Policy. The fundamental principles of EU law require that an analysis weighing the relative CCI and public health interests at stake be made on a case-by-case basis, should the EMA seek to release information over the objections of a sponsor. The European court has confirmed that the protection of confidential information is a right to privacy under the European Convention on Human Rights (Convention) and the Charter of Fundamental Rights of the EU (Charter).[4] In addition, sponsors have vested property rights in CCI information present in MA dossiers. Economically valuable confidential clinical trial information submitted to the EMA in MA dossiers is a form of possession pursuant to the Convention and the Charter,[5] to be protected according to European courts.[6] EFPIA agrees that the interference with such property rights by an EU institution may, in appropriate circumstances, be justified by reference to other rights and interests, such as the public interest, but the consequences to the owner of confidential information flowing from disclosure cannot be taken lightly - any disclosure of commercially confidential information will destroy the value in the property right. EMA is required, therefore, to conduct a careful case-by-case balancing exercise, including consultation with the owner of the confidential information, before it reaches a decision as to whether disclosure of the confidential information would be proportionate in light of the public interest.

There is an element of timing and circumstance to this balance of interests that can only be accounted for through a robust process giving the MA holder the opportunity to assert and resolve a CCI claim. The EMA's draft Policy, for example, applies to clinical trial data in withdrawn or denied MA applications; EFPIA is very concerned that the release of certain data from these dossiers could prejudice the integrity of the regulatory process for any future re-submission, as well as potential MA submissions in markets outside the EU, and could therefore undermine the future commercial viability of such products. Therefore, EFPIA believes that the policy should not apply to withdrawn or denied MA applications. EFPIA believes that these situations illustrate with particularity how meaningful consultation with applicants is indispensable in order to determine whether information is CCI and whether, even if CCI, disclosure of information is justified by an overriding public health interest, in any particular case.

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[4] Article 7 of the Charter and Article 8 of the Convention, as confirmed in Case C-450/06 *Varec v Belgian State* [2008] ECR I-581

[5] Article 1 of the Protocol to the European Convention on Human Rights, as amended by Protocols Nos. 11 and 14, Council of Europe Treaty Series, No. 5 provides:

> "*Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law*."

This right to the protection of possessions is repeated in Article 17 of the Charter of Fundamental Rights of the European Union, 2010/C 83/02, 2010 O.J. (C 83) 389 as follows:

> "*Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest.*"

[6] Case C-450/06 *Varec v Belgian State* [2008] ECR I-581 and *Interseroh Scrap and Metals Trading GmbH v Sonderabfall-Management-Gesellschaft Rheinland-Pfalz mbH (SAM)* (Case-1/11, para. 43); *R (on the application of Veolia ES Nottinghamshire Ltd) v Nottinghamshire County Council (Dowen and another, interested parties)* [2010] EWCA Civ 1214, at paras. 120 and 121; *Van Marle and others v The Netherlands (Application No. 8543/79, Judgement of 26 June 1986) paras. 41-42;* [6] *Smith Kline & French Laboratories Ltd v The Netherlands* (1990) 66 DR 70 in a case relating to patents. The ECHR has also considered that licenses are a form of possession *Tre Traktörer AB v Sweden (App No 10873/84);* [6] *R (on the application of Malik) v Waltham Forest NHS Primary Care Trust* [2007] EWCA Civ 265, para. 29.

The EMA's stated broad assertion that it may disclose MA data because MA data cannot be considered CCI is inconsistent with the recent decision on the release by the EMA of clinical data issued in the on-going litigation before the General Court of the EU.[7] As stated by the President of the General Court, who ordered the EMA not to release clinical trial information in a MA dossier that the applicants in those cases considered CCI, it is not "entirely unfounded" to conclude that the hundreds of pages in a clinical study report, containing as they do the intellectual analysis and know-how of sponsors, contain CCI.[8] Moreover, the Court decided that " the question whether an overriding public interest might nevertheless justify disclosure of CCI will call for "delicate assessment," in the "weighing up of the applicants' commercial interest in not having the reports disclosed and the general interest intended to guarantee the broadest public access to documents held by the European Union. "[9] Clearly, the President of the Court rejected the blanket position, articulated in the draft Policy that the public interest, in all cases, prevails over the interests supporting non-disclosure of CCI. EFPIA believes, and the Court has acknowledged[10], that there are important legal questions to be resolved in this respect, and that the two elements of CCI and the public health interest both need to be considered.

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Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
15:	There is a growing demand for full transparency from certain external stakeholders in the debate. EFPIA supports responsible transparency, which recognizes that full and unfettered transparency of all information submitted as part of MA dossiers could also have unintended detrimental consequences.	
28- 32:	Here the intent is described as improving the efficiency of the drug development process by enabling competitors to benefit from access to each other's proprietary information. This is not a proper purpose under EU law for disclosing CCI and should not be the primary intent of the EMA's transparency initiatives. In particular, the reference to establishing a level playing field is unfortunate and open to misinterpretation.	This premise should be further considered.

[7] Cases T-29/13, T-44/13, T-44/13 R; T-73/13 and T-73/13 R.
[8] Paragraphs 59-61 & 68 of the Decision.
[9] Paragraph 69 of the Decision.
[10] Interim measures rulings in T-44/13 R and T-73/13 R, 25 April 2013.

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	EFPIA does not share the current EMA vision that enabling untracked, uncoordinated and unsupervised secondary analysis of CT data on which MAs are based will provide substantial benefits for the public health. Ultimately, data access and enhanced, responsible transparency can only positively contribute to society if robust conditions for secondary analysis are established and enforced.	
32-35:	Greater transparency of the regulatory decision making process is laudable and may increase confidence of patients and prescribers, if implemented responsibly. However, the contention that replicating the clinical trial analyses will improve confidence and rigour without compromising the regulatory process may be too simplistic. It could equally undermine the regulatory evaluation process and may not offer any positive benefit over a high quality review by the health authorities. In our view, and based on EU legislative framework, the regulator's core function is to ensure the validity and robustness of the clinical trial process. Indeed, the regulatory framework is designed to enable this rigorous scientific oversight for all Industry-sponsored trials to ensure scientific validity in the design and conduct of clinical trials including pre-specification of the trial protocol, associated statistical analytic plan, careful documentation of any changes in the protocol, and oversight by institutional review boards (IRBs) and data and safety monitoring committees. Also, implementation of this draft Policy would require variable use of resources within the Agency (in order to validate or invalidate interpretations) inevitably diverting energy from core responsibilities – i.e., evaluating the safety and efficacy of medicines. EFPIA considers that a more robust mechanism of data sharing should be put in place,	

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	and is committed to implement a system to receive and review research proposals and provide applicable data to help facilitate such scientific and medical research.	
44-47:	In the draft Policy, the EMA infers a far broader scope to individual patient informed consent than is given in reality. The release of patient level data can only take place within the scope of the specific informed consent given by the patient to the trial sponsor. How will the Agency ensure that the integrity of patient consent and the use of data do not overstep the boundaries of an individual patient's informed consent (e.g., informed consent specifically does not permit release, informed consent is silent on the subject of release)? Unless explicitly stated in the informed consent, it cannot be assumed that patients have consented to their information being released in order to "benefit the advancement of science and public health". Without the prospective understanding of the effectiveness of the measures that will be put in place to ensure their anonymity, it is difficult to envisage how a subject can give truly informed consent to the ongoing use of their personal data. It is unclear from the draft Policy how international studies would be managed, if informed consent forms varied across countries in relation to release of patient level data.	
50-51:	The EMA statement "CT data cannot be considered CCI; the interests of public health outweigh considerations of CCI" – EFPIA strongly contests the EMA's assertion in this regard. This precise issue is currently the subject of litigation before the General Court of the EU. Furthermore, on 25 April 2013 the President of the General Court granted interim measures in favour of AbbVie[11] and InterMune[12] preventing the Agency from disclosing to third parties certain clinical data from these companies' MAA dossiers before the companies' respective legal	In the light of the decision of the General Court, the draft Policy should either be revised substantially in relation to the protection of CCI, or implementation should await the final outcome of the litigation. Otherwise, companies will be denied effective redress should their CCI or PPD be at risk of inappropriate disclosure.

[11] Case T44-13
[12] Case T73-13

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	challenges to the Agency's proposed actions had been fully examined by the Court. The President considered that both companies had demonstrated a prima facie case that the Agency's decisions to disclose such documents were in breach of Article 4(2) of the Transparency Regulation; the fundamental right to the protection of information covered by business secrets and information of a confidential nature under Article 7 of the EU Charter of Fundamental Rights; and the obligation by EU institutions under Article 339 of the Treaty on the Functioning of the European Union not to disclose information that is covered by the obligation of professional secrecy. The EMA's broad and unexplained contention that CT data cannot generally be considered CCI and its intention to implement this in its new proactive disclosure draft Policy in the near term, directly contradicts this ruling of the General Court. Also, this statement is inconsistent with the CCI definition adopted by the EMA and set out in line numbers 109-111 of this draft Policy. Some information in certain MA dossiers, depending on the sponsor, product at issue, competitive landscape, therapeutic area, and value of the information to competitors may, indeed, be CCI. Considerations of an overriding public health interest are relevant for the distinct purpose of determining whether in certain circumstances, public health interests in disclosure of CCI outweigh considerations supporting non-disclosure of protected information. If information in a MA dossier meets the definition of CCI adopted by the EMA in this draft Policy at lines 109-111, and if the EMA seeks to release such information over the owner's objections, then a separate inquiry needs to be made prior to public disclosure to determine whether an overriding public health interest justifies release of the information. Please note EFPIA's Fundamental Comments, Section 3, for a detailed discussion of the topic of CCI within	One approach would be to replace the statement "CT data cannot be considered CCI; the interests of public health outweigh considerations of CCI" with the following: CT data and other information present in MA dossiers submitted by sponsors may qualify as CCI, as defined below in this Policy. If the EMA seeks to release CT data, the EMA will engage in a process with each affected sponsor to determine whether such data constitute CCI. If the data constitute CCI, a separate inquiry will be made prior to public disclosure to determine whether an overriding public health interest justifies release of the information. Also, a robust process for consultation with the MAH prior to release of information should be implemented.

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	the draft Policy.	
55-56:	It is stated that the draft Policy "is designed to guard against unintended consequences, e.g. breaches of intellectual property rights…." but the nature and effectiveness of these safeguards are unclear. The draft policy contains no procedure for the consultation of the MAH and review of the data, or for the MAH to appeal against the EMA's decision to disclose, in advance.	In order for EMA to provide safeguards against unintended consequences by controlled access as set out in line 176, "dissuasive, effective and proportionate sanctions" for the requester should be envisaged in the case of violation of the requester's obligations. The MAH, as the party which will suffer from breach of controlled access terms, should be able to enforce the controlled access and seek imposition of the sanctions. Also and as previously described, a robust process for consultation with the MAH prior to release of information should be implemented.
57-61:	"It <u>should</u> be possible to "guarantee that all secondary data analyses (….) will be conducted and reported to the highest possible scientific standard". If this is not possible with a "truly open approach", then that approach should not be taken, especially given that the stated goal (according to line 75, protecting and fostering public health) can be achieved by a more controlled and responsible approach. The EMA asserts application of the best safeguards to achieve the highest possible scientific standard, to protect public health and regulatory decisions. However, EFPIA strongly believes that the safeguards are insufficient, e.g. • Why are there no legal obligations resulting from the document on CT data-analysis standards (see line nr. 207/209)? • Why is it not mandatory to upload a statistical analysis plan (see	

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	210)? Is it actually possible to review/challenge the secondary analysis without a SAP? • Why is the granting of access to "C" documents not influenced by the requester's decision to upload a SAP or not? (see 214/215) Does the upload of a SAP have an impact on EMA's goal to enable independent replication of CT data analysis? (see 33) • Why are there no requirements with regard to the requester's professional competence or inclusion of a qualified statistician to conduct analyses, etc.? (see 216-218) What are the measures to ensure the best-possible protection of public health against claims resulting from inappropriate analyses EMA is referring to in line 60? When would such measures be put in place? Unless these measures are appropriate, comprehensive, effective, and enforceable then there will continue to be substantive public health concerns around inappropriate analyses and false hopes or concerns from patients based on improper research. These measures will need to be detailed and validated with particularity before legitimate determinations can be made as to whether the public disclosure of otherwise protected information is in the public health interest.	
65-66:	EMA's draft Policy states: "Once a decision has been reached, this consideration [= protection against external pressures in whatever direction] no longer applies." This statement does not take into account the case that EMA's final decisions are subsequently disputed.	
67-72:	We fully support the need for two way transparency and equal level of scientific standard for all clinical studies, but it is unclear what is meant by the statement "allowed a reasonable period of time during which their analyses and deliberations are protected against external	

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	interventions". A key part of the recommendations from the Good Analysis Practice advisory group was the need for the availability and review of the analysis plan, in advance of data access to ensure a high quality analysis and the ability to determine if the analysis can be replicated by others. It appears that the draft Policy affords protection for confidentiality to third party researchers (planned analyses would not be disclosed until up to a year after accessing the data) inconsistently to the standards for MA applicants (who must disclose information on their CT's prior to commencement). All documents relating to a third party researcher's request would appear to be disclosable under Regulation 1049/2001. Regulation 1049/2001 requires an Institution to notify the third party owner of information held by the Institution prior to disclosure of the information. Based on Regulation 1049/2001, there should be a notification to the third party owner of the information that disclosure is contemplated and allow the third party the right either to contest its disclosure or review any proposed redacted version of the document.	
91-98	The Annex II reference to ICH E3 format should clearly indicate that the structure is not meant to dictate E3 use as a template since this would be in direct contradiction to ICH E3 Q&A (R1) of July 2012. As the CSRs for other types of studies will differ in format, it is unclear which general principles are expected to apply.	
113-115:	The statement "It is emphasized that categorisation of information as CCI in the policy does not limit access to documents or information under other agency policies" is inappropriate, and misleading because it suggests that standards used to designate certain information as CCI, and the consequences with respect to disclosure flowing from such	Remove this statement.

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	designation, vary across regulatory processes administered by the EMA. The definition of CCI set forth and adopted by the EMA at lines 109-111 reflects general EU legal principles, natural and fundamental rights, and applies across all EMA purposes and policies. Access to such information is subject to the analysis set forth at Article (4)(2) of Regulation 1049/2001 Regarding Public Access to Documents, as discussed in more detail in the Fundamental Comments section of this EFPIA submission. This is true regardless of the EMA access to documents policy or transparency initiative at issue in any particular situation involving disclosure of CT data or MA dossier CCI information over the objections of a sponsor.	
116-117:	The "elements submitted as a study report" may not follow the format of the ICH E3 document.	
121:	It is not clear what is meant by "test outputs". We would traditionally consider test output as being output that is created by a program prior to the program being peer-reviewed, validated and put in 'production' (i.e., its final read-only location). We see no purpose in storing test outputs or providing them to anyone. Perhaps "test output" has a different meaning in the draft Policy.	Remove reference to or define what is meant by test output, as it is not clear how it relates to raw data.
122-123:	In this draft Policy, EMA appears to express its intentions to request, for the particular purpose of transparency, more information from companies than requested in the past as part of an application (e.g. SAS logs, SAS programs). In that respect, the draft Policy goes beyond the purpose of the legislation to provide access to documents of the institutions (Art. 2 para 1 of Reg. 1049/2001). Further, it is not clear how SAS code and SAS logs are covered as supporting documents. These are tools for analysis. An appropriate SAP including a description of the statistical model will qualify for repeating all analyses. Pharmaceutical companies put a lot of effort (time and money—often developed by third parties) into developing and validating	The Statistical Analysis Plan should suffice for requesters to understand what was planned and done.

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	macro (i.e., computer code) libraries. We believe these would be considered intellectual property.	
129-132:	"CT data/documents containing CCI: a small number of CT data/documents can contain CCI. […] However, this information will only be deemed CCI in duly justified cases" Clarification is needed for the process by which companies can justify that information is CCI, and disputes resolved. This process must involve a case-by-case analysis of the relevant factors defining CCI, and a precise and careful weighing of any public interest at stake sufficient to justify release of otherwise protected information. Likewise, as stated by the President of the General Court in paragraph 69 of the interim measures case cited earlier in these EFPIA comments, judicial review of disclosure disputes that cannot be resolved between regulator and regulated must ultimately be made available -- "the weighing up of the various interests present will call for delicate assessments which must be a matter for the Court adjudicating on the substance of the case."	The following approach should be added and applicable to all data/documents: Any information contemplated for release by the Agency will be provided to the MA applicant of the information, prior to release, in order to ensure that no information contemplated for disclosure constitutes CCI. A reasonable time will be afforded the sponsor to confirm that information to be released by the EMA is already in the public domain, or is otherwise not information the sponsor considers confidential, or not the sort of information that, if released, could harm the competitive interests of the owner of the information. Justification in support of CCI claims should be provided by the sponsor to the EMA. Such justification will be respected by the Agency, but may be rebutted by, for example, information indicating that information to be released has in fact already been made available, or is the sort of information that the owner of such information does not normally protect from disclosure, or is information that would not cause competitive injury if released. Likewise, because even CCI may be released if justified by reference to an overriding public interest, the EMA will have the

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		opportunity to justify release of CCI by articulating such a public health interest, as warranted and appropriate under the circumstances of any particular case. Ultimately, disputes over release of purportedly CCI information that cannot be resolved by consultation between Agency and applicant will be subject to judicial resolution prior to disclosure, through well-established, fair and orderly processes regarding judicial review of regulatory Agency decision-making.
139-143:	The draft Policy would treat certain documents as "without protection of personal data (PPD) concerns" (i.e., "open access"). This is to include documents where "any personal data in the document have been adequately de-identified". Further, the proposal indicates that all documents meeting the open-access criteria that are submitted to the Agency on or after 1 March 2014 will be subject to the new policy. Nevertheless, the proposal also indicates that the Agency's timeframe for publishing guidance concerning "appropriate standards, rules and procedures for de-identification" will occur much later - possibly not before 31 October 2014. This presents marketing authorisation applicants with a paradox: Until clear guidelines are issued for what constitutes "adequately de-identified" data, applicants will be unable to determine when this criterion has been met; yet, the proposal would require applicants to make these determinations starting in March 2014, prior to the promulgation of the guidelines. We presume that the Agency intends for the term "de-identified" to be synonymous with "anonymised". The Data Protection Directive 95/46/EC specifies that it will not apply to "data rendered anonymous in	At a minimum, the Agency should discuss this topic with industry and other major regions to

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	such a way that the data subject is no longer identifiable" (Recital 26). To determine whether data has been properly anonymised, "account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the said person". Unfortunately, there is no commonly accepted definition across the EU of what it means for data to be anonymised. There are two competing views - one, that "anonymised" means the risk of re-identification is very low; the other, that "anonymised" means there is no risk of re-identification. Providing certainty about re-identification of a patient is not possible today. This is likely to become increasingly the case in the future as technologies and publicly available data increase. It is therefore recommended that the term de-identified is used to indicate that a level of risk exists but is actively managed. Finally, the policy should acknowledge that there are situations where even aggregated data can still be considered PPD (e.g., rare diseases with very small populations).	determine a definition for "de-identified" that is approved by the relevant data protection authorities and indicate which of these views it is adopting.
144-149:	The open-access category is proposed to also include "personal data of CT personnel" for which "there are public-health reasons why personal data can be made public, overriding considerations of [protection of personal data]". This appears to reflect a broader disclosure policy than that put forth in the March 2012 HMA/EMA Guidance Document on the Identification of Commercially Confidential Information and Personal Data within the Structure of the Marketing Authorisation (MA) Application. The March 2012 Guidance distinguishes whether personal data can be released based upon the individuals legally defined role or responsibility and indicates that the names of experts and designated personnel with legally defined roles or responsibilities can be released because "it is in the public interest to release this data". (§ 2(A).) However, with respect to names and personal details of other staff members, the Guidance indicates that such information should be considered protected personal data. We believe that no information in	

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	relation to the names, or technical or professional qualifications of any company employees or experts (whether or not directly involved with animal research) should be publicly disclosed; all such information should be classed as PPD.	
151-152:	The draft Policy states that it will be applicable "at the time of publication of the European Public Assessment Report (EPAR) for positive decisions..." It is important that any CT data disclosure takes place only after the product has been authorised in major regions including the US, Japan and the EU, if applicable. Otherwise the information could be released in one region while the assessment for authorisation would still be ongoing in another region, which could undermine the integrity of global regulatory processes.	EMA's policy should only apply following regulatory approval in major regions including EU, US, and Japan – participants of The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).
152-154 and 219-231:	If an application is withdrawn there may still be an ongoing development program requiring more data to be generated or the exploration of, for example, a different indication. Proactive dissemination of the data submitted for this type of compound could prejudice the integrity of the regulatory process for any future re-submission, and undermine the future commercial viability of the product.	The policy should not apply to withdrawn or denied MA applications. Of note, the EFPIA/PhRMA principles reaffirm that, "At a minimum, results from all phase 3 clinical trials and any clinical trial results of significant medical importance should be submitted for publication. This commitment also pertains to investigational medicines whose development programs have been discontinued."
165-175:	The Agency's proposal does not provide a clear definition of what will constitute "de-identified" data. It is unclear what "limited" means in the statement of limited number of identifiers. The proposed standards are minimal and more exacting standards should be developed to ensure patient confidentiality is maintained. At lines 169-170, the Agency suggests that data will be considered de-identified where "the risk of compromising subjects' identity in case of wide publication of those data is considered to be absent or sufficiently low". This suggests the Agency supports a risk-based threshold for de-identification. However, at lines 174-175, the Agency appears to support	A standard for de-identifying data would need to be developed that all can follow; however, complete de-identification would be difficult to achieve.

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	an absolute "zero-risk" standard: "The methods of de-identification should be such that adherence will preclude subject [r]e-identification, even when applying linkages with other data carriers (e.g. social media)." We contend that it will be very difficult to implement the recommendation to de-identify data in such a way that "adherence will **preclude** [emphasis added] subject de-identification" (presumably "re-identification"). Even the cited references (Hrynaszkiewicz and Norton, 2010) suggest some options that are difficult to implement such as "Consent for publication of appropriately anonymised raw data should ideally be sought from participants in clinical research" and that in some cases there should be a review by an ethics committee. Requirements and guidance would be necessary, which have the agreement of data protection authorities, to provide assurance to patients that their privacy is appropriately being protected. Finally, the proposal should make clear who is responsible for determining whether the proposed uses of the data (as proposed by the requester) are within the boundaries of the patients' informed consent or whether an oversight mechanism is envisaged. Ultimately, the EMA would be responsible as the body disclosing the data. Prior to disclosure, there should be an assessment to ensure that the proposed research use aligns with the research use of the original study (and therefore with the informed consent). When considering the possibility to provide access to clinical data involving personal data, it is necessary to address both data privacy obligations and the potential benefits that could result from the analyses.	
176-178	There should be a requirement for third party requesters to submit their analysis plan. In addition, the resources required to enable access to the data should be sufficiently balanced against the public health benefit	Request should submit their analysis plan.

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	expected from the analysis. Therefore, a robust review of the planned analysis for its scientific merit should be mandatory before enabling any data access.	Also, please add the clarification below: "'Controlled access' shall mean that access to 'C' data will only be granted after the requester has fulfilled **all of** the following requirements…"
181-183:	The EMA conditions access to 'C' documents on execution of a "legally binding data sharing agreement," but it is not explained who the parties to such an agreement will be, the legal basis for the EMA entering into such an agreement, how the EMA will ensure the enforcement of such agreements, or the penalties or remedies available to a company or an individual harmed by use of data released inconsistent with such agreements. Implementation of a controlled access regime cannot be implemented until these critical questions are answered. If parties qualifying for controlled access must comply with certain contractual conditions, then the EMA must with particularity describe the enforcement mechanisms and penalties to be enforced in cases of breach or noncompliance. The MAH should likewise be a party to the agreement, so as to provide it with the possibility of enforcement of compliance with the agreement.	
183	The reference to the "spirit of informed consent" implies a very permissive approach to the respect of the informed consent in disclosing patient level data. Please note above EFPIA's comments on Lines 165-175.	
191-192:	It is not clear how or by whom a particular disclosure is to be "deemed" outside the scope of patients' informed consent.	Further explanation is required.
193	The restriction on using CT data to gain a marketing authorisation in a non-EU jurisdiction should be extended to the EU as well.	Explicitly state that the restriction applies to the EU and non-EU.
222-231:	Any postponement of disclosure of details about the secondary analysis seems to go to the expense of the MAH if his interests are impacted before the end of the 1-year period. The period may limit the MAH's possibilities to review the secondary analysis and impede MAH's chances to promptly and effectively challenge it.	

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205:	The draft Policy states: "destroy CT data accessed"; however, it is not stated how the Agency would ensure that the CT data is destroyed appropriately and in a way that no third party can re-use it. It would be reasonable to oblige the requester of the CT data to provide evidence about the necessary deletion of the CT data. We would also recommend adding expectations around appropriate storage of PPD data between downloading and destroying (e.g. Access, security – Physical/logical etc…). The data should stay in a "closed secure environment" that would help ensure appropriate protection of personal data.	A secure environment, without the possibility to download, copy or otherwise remove the data, should be implemented.
206-215	"Before access to 'C' data is granted, the requester will be: ...however, the requester may decline to upload any documents at that time; the granting of access to 'C' documents is not influenced by the requester's choice to upload or not." It is inconsistent to state that an analysis plan is of utmost importance, but then not require that such a plan be submitted prior to the granting of access to the data. The level of disclosure required of the requester regarding analyses and results should be the same as required of the MAH.	
219-221:	The draft Policy states that it will be applicable "at the time of publication of the European Public Assessment Report (EPAR) for positive decisions...."	EMA's policy should only apply following regulatory approval in major regions including EU, US, and Japan.
222:	In the context of this policy we consider it is appropriate for the EMA to immediately disclose the identity of the requestor.	The Agency will ~~not~~ immediately disclose any information about the requester, ~~but will publish~~ **including** the identity (name, affiliation**, funding**

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		source, and contact details provided)**.**~~,~~ **T**~~t~~he list of the aims of accessing the data provided…
235 – 244:	In this section, the requirements are expressed in the passive ("shall be provided", "shall be published", "shall be made available",) but there is no clarity as to who is responsible for these requirements.	Clarification is requested using active rather than passive language.
242-247:	This request appears to go beyond what is normally submitted for the purpose of EMA's assessment for a marketing authorisation. Industry commits to provide - upon request - patient level data under a self-responsibility scheme. The information requested here could be provided under this scheme (Also, see comments to line 253-255 and scope of definition of raw data line 121-123).	
249:	EMA draft Policy states that it will come into effect on 1 January 2014. EFPIA believes that there are numerous issues to resolve prior to full implementation.	Suggest an implementation date well beyond 1 January 2014 reflecting the need for additional clarification, regulation and sufficient time for implementation.
253-255:	"MAH shall provide the Agency with an additional set of 'O' documents that are appropriately de-identified to ensure protection of personal data…." We would query the legal basis for this requirement. It is unclear how the Agency can legally implement this unilateral request if the MAH explicitly indicates that the documents might contain PPD and that EMA cannot disclose it without prior de-identification of the relevant data. In addition, it should be noted that the obligation for providing access to documents is with EMA, which means that EMA is responsible for ensuring that all data are appropriately anonymised.	
266-267:	We fully agree that the impact of the EMA's final Policy should be	

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	thoroughly evaluated and the impact assessed in line with impact assessment rules for EU Institutions before being adopted. Specifically the impact on resources needs to be determined. In order to facilitate this assessment, EMA should provide a formal consultation process so stakeholders could provide input into the EMA's methodologies for assessing the impact (i.e., impact not only on the Agency, but also on MAH's, clinical trial participation, overall investment in medicine R&D in Europe, etc.).	
279:	It would be helpful to explain further what is meant by "key codes".	
292:	EMA explains that the personal data of trial personnel will be "considered exempt from PPD considerations". The legal basis for this assertion is unclear and it seems to be inconsistent with current or recent EMA practice in making reactive disclosures of CT data. Therefore, we do not believe that the names of investigators, site staff and company personnel should be included in disclosed CSRs without the individuals' consent. We do not agree with the statement in the draft Policy that there is an overriding public interest in the disclosure of these names. It is particularly difficult to understand how the inclusion of these names (or not) in a CSR has any impact on public health. Furthermore, the inclusion of company names poses significant risks for individuals. EFPIA member company employees have been targeted in the past by animal rights extremists even though they have not been directly involved in animal research. The EMA's position on information on company staff is also inconsistent with their position on disclosure of information on EMA staff. In response to requests for access to documents held by EMA, names of EMA staff involved in pre- and post-authorisation activities will be redacted, on the grounds that disclosure would undermine the protection of privacy and the integrity of the individual, in particular in accordance with EU legislation regarding the protection of personal data.	

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Annex 1:	2.7.2: The clinical pharmacology studies may include PET studies (or similar) which provide receptor occupancy and kinetics of the compound target interaction which the company may feel is CCI. 5.3.7: Access to patient line listings should not be within the scope of the Policy, because of the practical difficulties and significant resources associated with redaction/anonymisation, and the questionable additional value of the listings over and above the datasets.	
Annex 2:	For Annex 2, EFPIA do not believe that patient listings in the CSR and CSR Appendices should be made available nor be included within the scope of the policy under either "open" or "controlled access". The documents would be difficult and extensively resource intensive to de-identify or redact, and the information would in any case be provided in the datasets under the industry commitments. At the very least, Annex 2 patient listings should be "controlled access". 16.1.4: We do not agree that information for all research staff should be available.	Should be controlled access.
General	It needs to be ensured that copyright considerations are covered appropriately. For example, Patient Reported Outcomes questionnaires may be copyrighted and therefore those Case Report Form pages should not be made publicly available.	