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| Summary of comments for:EMA DRAFT Guidance document on protection of PD and CCI in documents uploaded in CTIS |
| Author:Merete Jørgensen, Wendy Wimmer, Julie Holtzople, Brendan Barnes and Silvia Garcia on behalf of EFPIADate:10/Mar/2022Version:final  |

We want to thank EMA for the opportunity to provide feedback to this **Guidance on protection of PPD and CCI for the documents and information uploaded to CTIS.**

Detailed and specific comments are provided in the Excel sheet provided together with this document. As the topic about protection of PPD and CCI is crucial for industry’s ability to operate the comments provided from the expert’s topic matter are large and detailed.

**General observations and considerations for the draft guidance:**

**Alignment with EMA Policy 0070** (External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use-EMA/90915/2016 Version 1.3 published 22 September 2017), as some CSR documents are subject to disclosure through both systems. When the same document is applicable to publication via two different systems and processes it seems natural to operate according to same set of principles.

We suggest:

* This guidance is concentrating on the redaction principles to be applied and what is considered to be sufficient for most CTIS documents in general. Use of Anonymization methodologies likely only applies to CSRs used in a marketing application, and this topic is detailed in section 3.2 of the EMA Policy 0070 guidance.
* Content in scope for CSRs to be aligned, Current scope of which appendices to include is specified for EMA policy 0070, but is less stringently defined for CTIS. To align it might be needed to update the Appendix of the Disclosure rules slightly to ensure consistency.
* Timing of the submission of the CSRs (CTR - 30 days after MA; EMA Policy 0070 - 60 days after MA)

**Consistency by Design of documents**

Further to ensure consistency by design, between the many documents, by using reference to these other document rather than providing an extract from these document, where the information if taken out of context might oversimplify and lead users not to look for the exact requirements.

Examples:

* Disclosure Rules to be provided via reference to the Appendix to the Functional Specification EMA/228383/2015
* Data protection principles and information related to the joint controllership arrangement should point to the JCA
* In general refer to the EMA policy principles, to avoid variance between these two guidance’s, as this could confuse sponsors and public users alike.
* Anonymization information to refer to the EMA Policy 0070 Guidance (section 3.2)- Version 1.3 from 2017 - External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use-EMA/90915/2016 )
* For information on what is not considered CCI reference could be given to EMA policy 0070 (section 4.5) with the small difference that this guidance is specific to documents used in a marketing application and does not take into consideration the timing of the information being released during product development, specifically at the time of a CTA submission.
* The new drafted 3 step process for CCI adds a new, higher bar of agreeing what is innovative (Step 2). This is not per the previously published definitions of CCI and it is preferable this guideline is not seeking to change that standard and/or legal definition.

We proposal to remove the draft step 2.

* Use of consistent terminology with other published guidance
* Avoid providing information that is readily available and/or repeated from other publications

**Deferral process and mechanism**

Many stakeholder comments/questions have been provided to the deferral process and mechanism to be applied (e.g., rules, acceptance criteria, rejections, standards, alignment between sponsor request, Part 1 and Part 2 documents, and the MSs documents). These comments have not been included here as we would like to ask for this being considered for addition to the EC Q&A document.

The risk of the requested deferral timeline not being accepted has also called for concern. It is suggested that for clarification it could be noted that the only change of the requested deferral timeline would be if the category chosen has turned out to be wrong.

**Other areas of concern (see specific comments provided in the Excel document**

* The JCA accepts availability of Subject ids when needed, but for ASRs only Case ids are allowed. The principles of when Subject ids are allowed in documents for CTIS seem inconsistent.
* Questions are raised on how MSs are going to ensure consistent protection of CCI with the protection applied by sponsors.
* Questions also raised if MSs will be in a position to reject PPD or CCI within the for public documents or not.
* EFPIA would like to restate its reservations about the applicability of joint controllership and hopes that the existing JCA can be reviewed when experience has been gained of its operation in practice.

We look forward to working with EMA to finalize this important document and remain at EMA disposition in case clarification of some of the raised concerns should be wanted.