PP18

Approach To EMA Policy 0070

From Data Science Perspective

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With ever changing regulatory requirements, we data scientists must become increasingly agile, not only in our thinking towards how data should be collected, prepared, and reported, but also with "future-proofing" our patients' privacy from attacks stemming from future technological advancements. Our approaches need to be even more pragmatic and risk based when our business models may be widely spread between in-house products/compounds and in-licensed products/compounds during various phases of the lifecycle of drug development.

The aim is to find a healthy balance between greater data utility and minimized risk to our patients' privacy (as illustrated below by the green area).

The European Medicines Agency (EMA) policy on the publication of clinical data for medicinal products for human use was developed by the EMA, in accordance with Article 80 of Regulation (EC) No 726/2004.

Policy 0070 is composed of two phases. Phase 1 entered into force on 1st January 2015. Phase 1 pertains to publication of clinical reports only. For further information on the full scope and any further information related to this please consult http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/04/WC500225880.pdf

The chart to the right is a graphical depiction of several approaches when applying EMA Policy 0070 Part 1. Note that the focus is only on Part 1 of the policy, as well as personally protected data (PPD), and not on commercially confidential information (CCI).

Clinical trial data is represented by the description of the house in the top right. As anonymization is applied, the description becomes more vague, and the data utility of the information decreases.

After an anonymization strategy is applied, a data utilization assessment is required. The description in the green area retains enough information to be clinically useful, while also presenting a low risk of re-identification.

When anonymization is applied it's an iterative process until an acceptable risk of re-identification (EMA notes a 9% risk could be considered, however this greatly depends on e.g. indication, population size, company, etc.) and data utilization is reached.

The current trend in the industry is to be reactive to these topics, however to ensure compliance and minimize the risk to our patients' privacy, there needs to be a mind shift to proactive thinking and planning and not treating this as an afterthought.