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What's New in GCP?
EMA Suggests Three Categories for Release of Clinical Trial Data

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The European Medicines Agency (EMA) released a draft guidance June 24 on allowing external parties access to clinical trial data and documents held by the agency.

The agency noted that the policy will apply only to data submitted to the EMA after the policy comes into effect. "All other CT data currently held by the agency (e.g., those on products already on the market) or pre-existing CT data of marketed products that will be submitted to the agency, e.g., in the context of a referral procedure ('legacy data'), continue to be made available to external requesters on a 'reactive' basis, as outlined in the agency's current policy on access to documents," the EMA said.

Under the new policy, which will be open for comments until Sept. 30, the EMA would have three categories of clinical trial information that would have different levels of access.

EMA expects that the vast majority of the information it has will be classified as open access, which means the data or documents do not contain patient personal data or commercially confidential information. Open access data will be downloadable from the EMA's website, at the time of publication of the European public assessment report (EPAR) for positive decisions, negative decisions or withdrawals, or 30 days following withdrawal, in cases where no withdrawal EPAR is published.

Protecting Industry Secrets, Patient Privacy

Clinical trial data or documents that may contain commercially confidential information (CCI) will not be made available under the policy; however, such documents could still be requested under Regulation (EC) No. 1049/2001, but different procedures and guarantees apply. "The agency cannot disclose commercially confidential information unless there is an overriding public interest in disclosure," EMA's announcement of the draft policy said.

The EMA noted that a very small number of clinical trial data or documents contain CCI and include details of the investigational medicinal product itself, some in vitro studies or bioanalytical data characterizing the product.

The third category is controlled access and covers data or documents containing patient personal information. These include individual patient data sets, individual patient line-listings, individual case report forms, and documentation explaining the structure and content of data sets. "Protection of personal data is a fundamental right of European Union (EU) citizens, enshrined in EU legislation," the EMA noted.

The controlled access category will have two complementary levels of protection "to provide the best possible assurance against retroactive patient identification." In the first level, the data will need to be adequately de-identified, according to a recommended minimum standard before it is released. "The methods of de-identification should be such that adherence will preclude subject re-identification, even when applying linkages with other data carriers (e.g., social media)," the agency said.

The second level is controlled access to the data, granted only after a requester has identified itself and the EMA has verified the requestor's identity, whether as a natural or

legal person established in the EU, and has agreed by way of a legally binding data-sharing agreement to:

- access controlled data for the sole purpose of addressing a question or conducting analyses that are in the interest of public health and in line with the spirit of informed consent. This may include, for example, meta-analyses, re-analysis or exploratory analyses for additional hypothesis generation. An exhaustive and detailed list of the aims of accessing the data must be submitted at the time of the request (though not necessarily a statistical analysis plan);
- refrain from any attempt to retroactively identify patients. This includes linkage of the data accessed with other databases or programs that could result in the identification of patients;
- refrain from using data accessed for any purposes that are deemed outside the boundaries of patients' informed consent, and refrain from using data accessed to gain a marketing authorization in a non-EU jurisdiction;
- not share, in any way or format, data accessed from the agency with anyone else. Where research groups wish to collectively access a data set, the names of all members of the group shall be communicated to the EMA, and all members have to individually commit themselves to the conditions for access;
- obtain ethics committee approval, as appropriate;
- be aware of standards for good analysis practice. A document describing the agency's views on good analysis practice will be made available to the requester.
- agree to the EMA publishing its identity, aim(s) of accessing the data, and (statistical) analysis plan status;
- make all results of their analyses public within a reasonable period of time — normally one year after accessing the data; and destroy the data accessed, once the analysis is completed.

Before access to controlled data is granted, the requester will be:

- made aware of a document on trial data analysis standards. In the document, the agency will communicate its expectations relating to good analysis and transparency. Requesters are advised to read the document, but there are no legal obligations resulting from the document; and
- given the opportunity to upload their (statistical) analysis plan (and/or other relevant documents) to EMA. The agency considers preparation and uploading of a detailed protocol/statistical analysis to be important to ensure the credibility of subsequent results. The availability of an analysis plan will influence the agency's interpretation of any subsequent reported results; however, the requester may decline to upload any documents at that time. The granting of access to the documents is not influenced by the requester's decision to upload or not.

The EMA will not, at the time of allowing access to controlled data, judge the requester's professional competence to conduct analyses or the requester's (statistical) analysis plan (if uploaded).

Controlled data and documents will be made available at the time of EPAR publication for positive or negative decisions or withdrawals or 30 days following withdrawal in cases where no withdrawal EPAR is published.

The EMA will not immediately disclose any information about the requester but will publish the identity (name, affiliation and contact details provided), the list of the aims of accessing the data provided, and any uploaded documents (statistical analysis plan and/or others), or the requester's decision to decline to upload documents (as applicable):

- one year after the date of accessing the data or;
- upon publication, in whatever format or medium, of results, conclusions or other communications that resulted from the requester accessing the data, or;
- in case of an urgent public-health need, or;
- upon court order, whichever comes first.

To Find Out More

The draft policy is available at www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf.

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