TransCelerate BIOPHARMA INC.

ICH E6 R2: Guideline for Clinical Practice

Integrated Addendum

Essential Documents for Clinical Study Module

Essential Documents for a Clinical Study

Section 8

"The sponsor and investigator/institution should maintain a record of the location(s) of their respective essential documents including source documents. The storage system used during the trial and for archiving (irrespective of the type of media used) should provide for document identification, version history, search, and retrieval. Essential documents for the trial should be supplemented or may be reduced where justified (in advance of trial initiation) based on the importance and relevance of the specific documents to the trial. The sponsor should ensure that the investigator has control of and continuous access to the CRF data reported to the sponsor. The sponsor should not have exclusive control of those data. When a copy is used to replace an original document (e.g., source documents, CRF), the copy should fulfill the requirements for certified copies. The investigator/institution should have control of all essential documents and records generated by the investigator/institution before, during, and after the trial."

The investigator/institution should maintain control at all times of essential and source documents. A record detailing the location of documents should be created at the start of the study and updated throughout the trial when applicable. This listing is particularly applicable to documents stored outside of the Investigator Site File (regulatory binder)– for example, the study contract. . The investigator should ensure a copy of the eCRF data is received at the end of the study on media with "read only" access.

Certificate of Completion

This is to certify that :

Has completed reviewing the Topic:

ICH E6 R2: Guideline for Clinical Practice Integrated Addendum; Essential Documents for Clinical Study Module, on: (insert date below)

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