TransCelerate BIOPHARMA INC.

ICH E6 R2: Guideline for Clinical Practice

Integrated Addendum

Source Documentation Module

Source Documentation Module

Certified Copy [1.6.3]

A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describes the context, content, and structure as the original. Moreover, the certified copy should be signed by study personnel qualified to perform the task to certify that is complete however they key part that is missing is the validated process of certifying the document as close to the original record as possible.

Section 4.9.0

"The investigator should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should be attributable, legible, contemporaneous, original, accurate, and complete. Changes to source data should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail)."

Note the adoption of the ALCOA (attributable, legible, contemporaneous, original, and accurate) acronym for creating adequate documentation which now becomes ALCOA-C as Complete is added to the source data requirements. Source records must be complete – including medical history records when applicable.

Certificate of Completion

This is to certify that :

Has completed reviewing the Topic:

ICH E6 R2: Guideline for Clinical Practice Integrated Addendum; Source Documentation Module, on: (insert date below)

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