



TransCelerate
BIOPHARMA INC.

ICH E6 R2: Guideline for Clinical Practice

Integrated Addendum

Introduction

Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)

In November 2016, ICH released the first major update in 20 years to E6 Good Clinical Practice Guidelines. The addendum focuses on the implementation of technology to improve patient safety and the reliability of study data. The updated guideline is often referred to as ICH E6 R2. The information provided in this topic was developed to supplement the TransCelerate Informational Program for Site Staff Less Experienced in Conducting Clinical Research by providing the updates required by the new GCP guidelines.

Certificate of Completion

This is to certify that :

Has completed reviewing the Topic:

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

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