

# GUIDANCE FOR USE OF PRINCIPAL INVESTIGATOR OVERSIGHT INFORMATIONAL PROGRAM

# GUIDANCE FOR USE OF PRINCIPAL INVESTIGATOR OVERSIGHT INFORMATIONAL PROGRAM

## Program Description

Informational program outlining the basic components related to Principal Investigator oversight of clinical trials.

This program uses scenarios of clinical trial conduct to convey key concepts. Examples and tools referenced in the program are for guidance only. This program will be available for use by any investigator via the TransCelerate website. It will also be available on the Shared Investigator Platform. Sites may access the program through either:

- » the TransCelerate website, or
- » a link to the program within a member company's Learning Management System (LMS),

If you have any questions regarding implementation of the program, you may contact Sheri Jacobsen ([sheri.jacobsen@abbvie.com](mailto:sheri.jacobsen@abbvie.com)).

## Background

- » Program covers responsibilities of an investigator relative to his/her oversight of a clinical trial common across industry
- » Inspections and audits cite inadequate supervision of clinical trials across sponsors and sites
- » Site surveys reveal general lack of understanding by investigators of what oversight means

[www.transceleratebiopharmainc.com](http://www.transceleratebiopharmainc.com)

## Use

This informational program is intended for investigators that may have less experience in conducting clinical trials, or for investigators for which lack of appropriate oversight has been identified as a potential concern. It may also be useful for investigators in preparation for a known inspection or audit.

Your internal Clinical and Quality Assurance departments and other departments as appropriate will need to consider whether and how your member company may use the program and who the intended audience for this program might be.

The program is not intended to be an all-inclusive list of oversight activities nor is it intended to be used with all investigators.

Remember, this is an informational program and is not intended to be used as the only means to ensure appropriate investigator oversight, but rather as a tool that can be used in conjunction with other measures, for example, monitoring.

[www.transceleratebiopharmainc.com](http://www.transceleratebiopharmainc.com)