Global Regulatory Writing and Consulting | Clinical Operations

Tools to Aid in Inspection Readiness

A Two Part Guide

AN INTRODUCTION

Inspection Readiness - Through the Entire Study

Readiness comprises many essential activities, but their completion and appropriate documentation is easier with the right tools. We will discuss here two such tools: An actions, decisions, and issues (ADI) log and a storyboarding template. This guide provides a basic framework for setting up an ADI log and for implementing storyboarding, as applicable.

Part One:
Capturing Applicable Actions, Decisions, and Issues

An ADI log, typically in a tabular form created within a spreadsheet or applicable system, is one method for capturing relevant details over the course of a study and is intended to be a living document. An ADI log is typically filed within a study's Trial Master File (TMF).

There are many benefits to an ADI log when used to its maximum potential:

1. Aids in the coordination and oversight of cross-functional operations through review during team meetings and used as a basis for assigning functional areas, as applicable.

2. Acts as a reminder to applicable staff/functional areas for any long-term and/or follow-up items that may not be applicable until certain points in time.

3. Provides a history of actions, decisions, and issues that have been made over the course of a study that may prove to be useful in various situations. For example this is useful during a change in operational staff, in which historical information might become important for understanding why particular decisions were made.

To ensure completeness, an ADI log may be set up to include the following information (though additional information may be appropriate):

1) General information
   - ADI number – used to keep track of all ADIs over time
   - ADI identifier – used to capture multiple ADIs belonging to one central issue
   - Date ADI identified
   - Reporter – the person who identified the need for the specific ADI
   - Category – used to allow for categorization of ADIs (eg, Site Management, Project Management, Investigational Product[s], etc.)

2) Issue description
3) Decision & group(s)/SME(s) involved
4) Action, action owner, & expected/actual completion date
5) Additional information
   - Status of ADI (eg, closed, open)
   - Additional information
   - Outcome
   - Post-completion guidance

Part Two:
Utilizing Storyboarding

Storyboarding is a method of communication that can be used to capture and clarify pivotal points in time or scenarios. The purpose is to convey a clear and consistent message throughout time and among cross-functional team members. A storyboard is typically 1 to 2 pages long.

Key Elements

1. Storyboards do not duplicate or contradict any documentation filed in the TMF or any controlled documents (eg, standard operating procedures [SOPs]) for the Company.
2. They are a tool that ensures an event is captured accurately for historical documentation, as team members may change over time.
3. This document should not include negative statements that may lead to a negative interpretation of the event. Storyboards should be factual and unbiased.
4. Storyboards are not provided to an inspector and are for internal use only.
5. Storyboards can be used as a tool for an SME to prepare for an inspection.

Storyboard Uses

- Title that is clear and concise, leaving no room for confusion.
- High-level description of the event including when/if an issue was identified
- Brief background information.
- List of key actions taken or proposed and if ongoing/completed.
- Brief statement regarding any regulatory risk or impact to subject safety, subject rights, or data integrity.
- Proposed, structured, strategic response that could be utilized to explain the event in case of an inspection.
- Reference to additional documents and/or resources where additional information can be found regarding the event.

Storyboard Event Summary Example

General Information:
Include high-level introductory information that is important for identifying what study(ies) and applicable protocols are included in the storyboard.

Background:
Provide a clear statement on the topic/issue/deviation. Include references on processes/plans/SOPs followed at the time of the event, including document title, version, effective date, and owner of that document, if applicable.

Event Description:
Include timeline and root cause summary and analysis, as applicable. Who? What? Where? When? Why?

Impact Assessment:
Include and annotate impact on other departments, other studies on a global level, if applicable. Include assessment on impact, if any, to subject safety, subject rights, data integrity, or potential regulatory impact.

Proposed Strategic Response:
Include how you would structure this information into a concise explanation during an inspection.

Actions Taken:
Include actions taken to prevent recurrence and any current/new SOPs that address the issue. Also note if actions are ongoing/completed.

Supporting Documents:
List all documents that help explain the story (ie, how the issue was addressed). This includes past/current SOPs pertinent to the issue or study-management tools (ie, report or tracker).

WANT MORE INFORMATION?

The pace of clinical development and demands on the clinical research professional are greater than ever. If you would like more information, or would like a to have a discussion about your particular situation don't be a stranger.

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