


Study Interim Data Analyses and Reports		
 VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-575.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure defines the general considerations and processes in relation to interim data analyses and reporting. This SOP applies to investigator-initiated clinical research studies at VCU/VCU Health institutions, facilities, or affiliated sites.

2. REQUIREMENTS

The main purpose of performing interim analyses (IA) in a clinical study is to review the data collected up to that point and to determine if the study should proceed as is, be modified or be stopped prematurely.

For some clinical studies, the responsibility for monitoring comparisons of efficacy and/or safety outcomes is assigned to an external independent group, often called an independent data monitoring committee (IDMC) or data safety monitoring board (DSMB).

3. DEFINITIONS

Interim Analysis- Interim data analysis is the analysis of data that is being collected for a clinical study before all the study data collection is complete. Interim analysis should be defined in the study protocol and only be done to monitor trends in a clinical trial to see if protocol changes are required or if early study termination is warranted.

4. PROCESS

- A. In investigator-initiated trials where the investigator is also the sponsor, the PI should ensure a qualified individual with no conflict of interest, such as a medical statistician, plans and performs statistical analyses, including interim analyses.
- B. All interim analyses should be carefully planned in advance and described in the protocol, data management plan (DMP), or data validation plan (DVP). Modifications to IRB-approved interim analysis plans must receive prior IRB approval. Any interim analyses that are not prospectively defined may bias the results of a trial and possibly weaken confidence in the conclusions drawn.
- C. The protocol DMP, or DVP should describe the plan for interim analyses. The trial termination guidelines based on interim analyses should be clearly described.

- D. If an IDMC is established for the study, the interim analysis plan and stopping rules should be provided for their review and approval in advance.
- E. Do not deviate from the planned interim analysis procedures, as it may cause invalidation of the trial results.
- F. If it becomes necessary to make changes to the trial in general, or to the interim analyses, any consequent changes to the statistical procedures should be specified in an amendment to the protocol.
- G. If an unplanned interim analysis is conducted, a clinical study report should explain why it was necessary and the degree to which blindness had to be broken (if the study is blinded), and provide an assessment of the potential magnitude of bias introduced and any impact on the interpretation of the final trial results, if applicable.
- H. The execution of interim analyses should be a completely confidential process since unblinded data and results are potentially involved. The procedures related to the control of dissemination of interim trial results should be established beforehand.
- I. All investigators and study personnel should remain blinded to the results of the interim analysis. The IDMC will only inform investigators about the decision to continue or discontinue the trial, or implement modifications to trial procedures, based on the outcome of the interim analysis. The PI will provide a summary report, including the IDMC's decision and conclusions from the interim analysis, to the IRB.

5. REFERENCES

- A. US Food and Drug Administration
 - [E9 Statistical Principles for Clinical Trials](#)
 - [E9 \(R1\) Statistical Principles for Clinical Trials Addendum: Estimands and Sensitivity Analysis in Clinical Trials](#)
- B. Good Clinical Practice
 - [ICH Harmonised Guideline Guideline For Good Clinical Practice E6\(R3\)](#)
 - Section 2 – Investigator
 - Section 2.4 – Communication with IRB/IEC
 - Section 2.5 – Compliance with Protocol
 - Section 3 – Sponsor
 - Section 3.1 – Trial Design

Review/Revision History CR-CO-575		
Version No.	Effective Date	Description
CR-CO-575.3	08/04/2025	<ul style="list-style-type: none"> ● Clarified purpose and conditions under which interim analyses may warrant study modification or termination ● Refined definition of interim analysis for clarity and alignment with protocol planning requirements ● Added requirement for IRB approval of modifications to planned interim analyses ● Strengthened language around confidentiality and blinding during interim analysis procedures ● Included references to updated FDA E9 (R1) guidance on estimands and sensitivity analysis ● Aligned with ICH E6(R3) ● Aligned with HRPP Toolkit ● Updated references ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-575.2	06-01-2021	<ul style="list-style-type: none"> ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-575.1	06-01-2018	<ul style="list-style-type: none"> ● Original