QUICK GUIDANCE

Out-of-Window Visits

What to do when a subject attends a visit outside the protocol-specified window

WHAT IS IT?

> **Out-of-Window Visit:**
>
> A study visit that occurs outside the protocol-specified visit window (e.g., a visit scheduled at Day 30 ± 3 days that occurs on Day 34 or later). The allowable window is defined in the protocol schedule of events.

WHEN DOES THIS APPLY?

- A subject completes a visit outside the protocol-defined acceptable window
- A visit occurs early or late due to subject availability, scheduling conflicts, or unforeseen circumstances
- A site-initiated change results in a visit occurring outside the window
- A subject misses a visit and attends at an alternate time

PROCESS AT A GLANCE

1. Identify the Out-of-Window Visit

- Review the protocol Schedule of Events to confirm the required visit window for the affected visit
- Compare the actual visit date against the target date and allowable window
- Confirm the visit is outside the window before proceeding

2. Assess the Impact on Subject Safety and Data

- Determine whether the timing deviation affects subject safety (e.g., delayed lab draws, missed safety assessments)
- Assess whether any protocol-required procedures were missed or affected by the timing
- Consult the PI immediately if there is any safety concern

3. Notify the Principal Investigator

- Inform the PI of the out-of-window visit as soon as it is identified
- Document the PI's awareness and any instructions given in the subject's source record
- The PI will determine whether the deviation is clinically significant and whether additional follow-up is needed

4. Document in Source Records

- Record the actual visit date and the reason for the timing deviation in the subject's source documents
- Note the protocol-specified window and the actual date clearly
- Include any impact assessments, PI comments, and corrective actions taken

5. Complete a Protocol Deviation Report

- Initiate a Reportable New Information report – (RNI) form Reportable New Information
- Include: subject ID, visit name, target date, actual date, reason, impact assessment
- Have the PI review and sign the deviation report

6. Report to the IRB and Sponsor

- Determine if the deviation requires prompt reporting to the IRB
- Submit the deviation to the sponsor per protocol or sponsor reporting requirements
- Retain copies of all submissions in the regulatory binder

7. Enter in the EDC System

- Enter the visit data in the EDC system using the actual visit date
- Respond to any queries generated by the EDC related to the out-of-window date promptly
- Do not alter or backdate entries — document the reason for the deviation transparently

8. Implement CAPA (if applicable)

- Identify the root cause (e.g., scheduling error, subject non-compliance, site workflow issue)
- Implement corrective actions to address the immediate issue
- Implement preventive actions to reduce recurrence and document all CAPA actions in the deviation report

KEEP IN MIND

x Avoid: Do not alter, backdate, or falsify any records. Do not attempt to hide or minimize a deviation. Inaccurate documentation is a serious GCP violation.

✓ **Best practice:** Document everything transparently and contemporaneously. When in doubt, consult your PI or sponsor monitor.

REFERENCES

- ICH E6(R2) Good Clinical Practice Guidelines
- Reportable New Information https://research.arizona.edu/sites/default/files/2025-08/Reportable-New-Information-v2025-07.pdf
- Applicable Study Protocol and Schedule of Events