Training Disclaimer

This training and training materials are for educational and informational purposes only.

This training material should be read in conjunction with the applicable latest research policy and regulations from the learner's research organisation and/or institution, Singapore Regulatory Authority and Ministry of Health.

Kindly note that all information and opinions presented in this training and training materials were written to the best knowledge available at the time of writing.

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Module Outline

1. Purpose of site monitoring visit
2. Activities during site monitoring visit
3. Preparation for site monitoring visit

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Purpose of Monitoring
ICH-GCP E6(R2): 5.18.1

To verify that:

- The rights and well-being of human subjects are protected.
- The reported trial data are accurate, complete, and verifiable from source documents.
- The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

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Types of Monitoring Visits

- Site Initiation Visit
- Interim / Routine Monitoring Visit
  (interval depends on monitoring plan)
- Close-out Visit

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Monitor's Responsibilities
ICH-GCP E6(R2): 5.18.4

During SMV, Monitors will:

- Verify Investigator has adequate qualifications and resources.
- Check on investigational product.
- Verify that approved protocol was followed.
- Verify signed ICFs.
- Verify all essential documents filed at site.
- Verify all site study personnel are performing the specified trial functions as delegated.
- Verify eligibility of subjects.
- Report the subject recruitment rate.
- Verify accuracy and completeness of source documents.
- Verify that the investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.

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Monitor's Responsibilities
ICH-GCP E6(R2): 5.18.4

During SMV, Monitors will:

- Check the accuracy and completeness of the CRF entries, source documents against each other.
- Inform the investigator of any CRF entry error, omission, or illegibility.
- Determine whether all adverse events (AEs) are appropriately reported within the time periods.
- Determine whether the investigator is maintaining the essential documents.
- Communicate deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations.

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SMV Confirmation Letter from CRA
Before SMV

- Visit date and time
- Who needs to be present (PI + SC)
- Agenda
- Study trial document required
- Subject numbers for source document verification (CRC to prepare medical records)

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Preparation Tasks by CRC
Before SMV

- Logistic
  - SMV room (conducive/quiet & private, Wifi)
  - Book in advance
  - Documents to provide
  - Medical Case Notes (Hardcopy / Electronic)
    - ✓Request timely, if not available inform CRA.
  - If electronic, apply access for CRA
  - Essential documents (ISF)
- Case report form (Paper / Electronic)
  - Up-to-date entry

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Preparation Tasks by CRC
Before SMV

- Meeting with Pharmacist
  - Confirm Pharmacist's availability & Share SMV details
  - Pharmacy folder
  - Investigational Product (Accuracy of Drug Count)
- Meeting with PI
  - Confirm PI's availability
- Meeting any other study personnel (e.g. Co-I)

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Key Takeaways

- Ensure all the preparation work are done before the monitoring visit.
- If unsure what to prepare for the monitoring visit, always check with the CRA.

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Thank you for Completing the
Monitoring Visit Preparation
Online Learning!

References

- ICH GCP E6(R2)

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- Ethics and Study Visits
- Informed Consent
- Site File and Monitoring
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