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Training & Delegation of Trial Duties

Training Requirements and Expectations, and
Delegation of Duties for Investigator Site Staff

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Presentation Topics

1. Training Requirements and Expectations
2. Delegation of Duties
3. CVs
4. Subject Education
5. Common Deficiencies
6. Summary

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References

- Note for Guidance on Good Clinical Practice: Consolidated Guideline (ICH Topic E6, Step 5, CPMP/ICH/135/95);
- European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 to 2009 (SI No.190 of 2004, as amended);
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001
- EudraLex - Volume 10, Clinical Trials Guidelines

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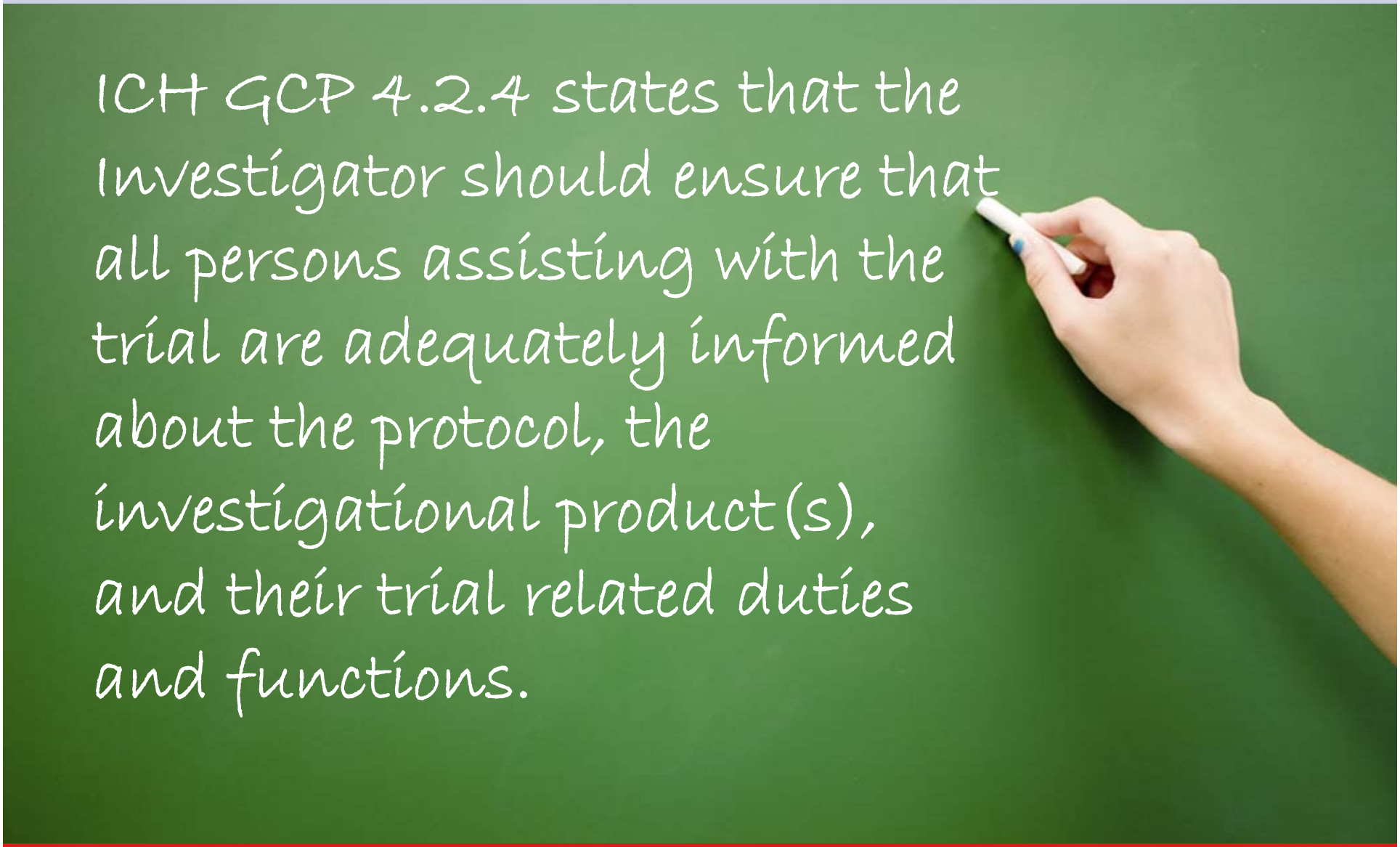
GCP Training Requirements

ICH GCP Principle 2.8 states that each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)

GCP Training Requirements



Provision of Training

- By the Sponsor
  - Investigator Meeting
  - Initiation Meeting
  - Ongoing (as necessary)

- By the Investigator
  - Staff/Departmental Meetings
  - One to One
  - Any training not provided by Sponsor

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Training Needs – Points to Consider

- Legislation
- GCP requirements
- Study Protocol/Study Manuals

With particular focus on non-routine/non-standard elements

- CRF completion
- Safety reporting
- Product information/IMP management
- Good documentation practices

List not exhaustive

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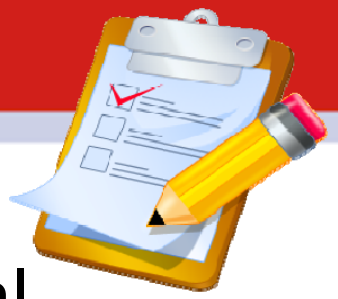
Importance of Adequate Training



- Emphasis on content of training material

  → Ensure effective training

- Training relative to role of individual
- Training prior to carrying out activities
- Evaluation of training
- Documentation of training
- Refresher training

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Effectiveness of Training

Regulations & Guidelines

Trial specific requirements/Protocol

How to meet and adhere to the requirements

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Training Needs – Points to Consider (example)

ICH GCP 4.9.1 states that the investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports

Source Data	• Investigator • Research Nurse
CRF Completion	• Research Nurse • Data Manager
Query Resolution	• Investigator • Research Nurse • Data Manager

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Training Updates

- Amendments
- New Staff
- Refresher

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Training Records

List not exhaustive

- Should contain:
  - Copy of Agenda
  - Presentation slides
  - Attendance Record
  - Certificates of Attendance
  - “Read & Understood” records
- Contents should include:
  - Date of training
  - Trainer name
  - Trainee name
- Per Person/Per Investigator Team

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Delegation of Duties

ICH GCP 4.1.5 states that the Investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties

- Careful consideration of delegation
- Delegation only to trained & qualified individuals
- PI authorisation of delegation
- Delegation prior to carrying out trial duties
- Include:
  - Start & stop dates
  - Signature of delegate & date of signature
  - List of duties

List not exhaustive

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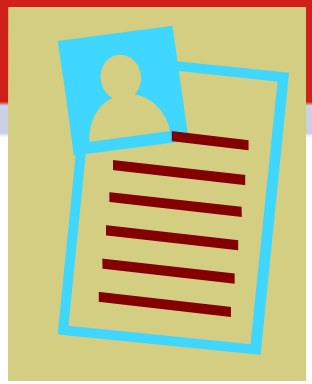
CVs



- Up to date at time of delegation of duty
- Any changes added throughout trial
- Signed and dated
- On file for all delegated staff

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Subject Education

- Compliance with visit schedule
- Compliance with IMP administration
- Returning used/unused IMP
- Maintenance of diaries (if applicable)
- Questionnaire completion (if applicable)
- Remembering AE and Concomitant Medications

Re-training as needed for persistent non-compliance

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Escalation

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Common Deficiencies

- Delegation prior to training
- Inadequate training
- No training
- Missing/None/Inadequate training records
- No training in amendments
- No training for new staff

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Summary

- *Effective training*
- *Adequate training records*
- *Appropriate Delegation*
- *Subject Compliance*

→ *Ensure overall compliance*

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Thank You

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