Annexes of Clinical Trials Training Needs: Survey to Academia and SMEs

Annex 1: Resources suggested in survey responses

The list of training sources below was compiled from EMRN consultations and survey responses to the prompt "Please share any sources of useful trainings or modules on the clinical trials environment that you are aware of".

Please note that neither the content nor the quality of the trainings could be checked; hence, the list should not be used to construct an endorsement of any of the trainings or its providers.

Identified useful training sources

- Agência de Investigação Clínica e Inovação Biomédica (AICIB) [only in Portuguese]
- CITI program
- Cochrane
- CONSCIOUS II
- EMA events and training targeted at SMEs
- EMA training for the Clinical Trials Information System (CTIS)
- ERA4Health Partnership (overview of free training developed by different institutions)
- EUPATI Learning Lab
- European Centre for Clinical Research Training (ECCRT)
- European Clinical Research Infrastructure Network (ECRIN)
- European CRO Federation (EUCROF)
- FDA/CDER Small Business & Industry Assistance (SBIA) Program*
- Forum Institut
- GCP Service
- Global Leading Conferences (GLC) Europe
- Health Research Board Trial Research Methodology Network (HRB-TRM)
- KKS-Netzwerk [only in German] *
- LuSciMED Akademie [only in German]
- Mass General Brigham
- Pharmaca
- Reagan Udall Foundation for the Food and Drug Administration webinars
- Sunnikan [only in French]

* Training shared by assesors during the EMRN consultation.

- The British Standards Institution (BSI)
- The Global Health Training Centre
- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) *
- Uppsala Monitoring Centre

Annex 2: Survey questions

1. Please indicate your organisation type.

- Micro, small or medium-sized enterprise
- Academia
- Other

  1.1. If selected other, please specify.

2. Please indicate your role/function in the clinical research environment. If you are answering this survey on behalf of a team, please select all that apply.

- Principal investigator
- Clinical research associate
- Investigator (sub-investigator/delegated personnel)
- Clinical trial monitor
- Clinical trial coordinator/manager
- Statistician/methodologist/data scientist
- Other

  2.1. If selected other, please specify.

3. Please indicate which country you are based in.

- AT –Austria
- BE - Belgium
- BG – Bulgaria
- HR - Croatia
- CY - Cyprus
- CZ - Czechia
- DK – Denmark
- EE - Estonia
- FI - Finland
- FR - France
- DE - Germany
- EL - Greece
- HU - Hungary
- IE - Ireland
- IT - Italy
- LV - Latvia

- LT - Lithuania
- LU - Luxembourg
- MT - Malta
- NL - Netherlands
- PL - Poland
- PT – Portugal
- RO - Romania
- SK - Slovak Republic
- SI - Slovenia
- ES - Spain
- SE - Sweden
- Other - Other

3.1. If selected other, please specify.

4. On a scale of 1-3, please indicate the importance of the following clinical training areas (and associated learning outcomes). The scale is interpreted as follows: 1 (low importance), 2 (medium importance), 3 (high importance).

- Clinical Trials Regulation EU No 536/2014 (CTR)

  (Understand aims and scope of CTR, its implementing acts, and relevant Q&A on CTR, from sources such as European Commission and CTCG)

- Good Clinical Practice (GCP)

  (Understand aims and scope of the GCP requirements, on safety and rights of clinical trial participants and the reliability and robustness of the data generated in the clinical trial. This also includes documentation, data management & computerised systems and responsibilities)

- Declaration of Helsinki

  (Understand ethical principles in conducting clinical trials)

- Scientific guidelines

  (Understand aims and scope of relevant guidelines in the clinical phase of medicines development, including design and conduct of clinical trials)

- Use of the Clinical Trials Information System (CTIS)

  (Understand structure, content and process of Clinical Trial Application and the CTIS)

- General Data Protection Regulation (GDPR)

  (Understand the requirements for data protection)

- Safety reporting and pharmacovigilance

  (Understand how to describe pharmacovigilance management strategies, safety reporting, and preparation of safety related documents / better safeguard patients' safety)

- Clinical study report

  (Understand structure and content of the clinical study report / identify relevant data to build a complete and informative report)

5. Please evaluate the adequacy of training needs in the following areas (and associated learning outcomes). Consider in how far the training leads not only to understand the matter but also is sufficient to enable applying the learning and improve functioning in the applicable roles. Please take into account all training that you are aware of that would cover the training area, regardless of the source (in-house, professional societies, national agencies/European Medicines Agency, external training providers, etc.)

   [Answer options: "No training is known to be available"; "Training exists but is not sufficient"; "Training exists and is sufficient"; "Training is not relevant for my role".]

- Clinical Trials Regulation EU No 536/2014 (CTR)

  (Understand aims and scope of CTR, its implementing acts, and relevant Q&A on CTR, from sources such as European Commission and CTCG)

- Good Clinical Practice (GCP)

  (Understand aims and scope of the GCP requirements, on safety and rights of clinical trial participants and the reliability and robustness of the data generated in the clinical trial. This also includes documentation, data management & computerised systems and responsibilities)

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- Safety reporting and pharmacovigilance

  (Understand how to describe pharmacovigilance management strategies, safety reporting, and preparation of safety related documents / better safeguard patients' safety)

- Clinical study report

  (Understand structure and content of the clinical study report / identify relevant data to build a complete and informative report)

6. Are there any clinical training areas missing from the list provided?

7. Do you have any comments about the training on clinical topics?

8. On a scale of 1-3, please indicate the importance of the following non-clinical training areas (and associated learning outcomes). The scale is interpreted as follows: 1 (low importance), 2 (medium importance), 3 (high importance).

- Proof of principle studies

  (Understand advantage and limitation of in vitro and in vivo assays / animal species selection / possibility to minimise animal testing)

- Pre-clinical studies to support first in human (FIH) study

  (Understand relevance of results obtained for clinical use, particularly for toxicity predictions for which no clinical data are expected)

- Establishing the clinical dose

  (Identify principles for capturing the most relevant toxicity finding to establish the no observed adverse effect level (NOAEL) and exposure margins)

- CTCG recommendations related to contraception and pregnancy

  (Understand and apply different risk categories for the early stages of pregnancy)

- Alternative approaches to animal model – 3Rs

  (Understand principles of replacement, reduction and refinement in animal research)

- Basic principles of Good Laboratory Practice (GLP)

  (Understand how GLP principles can affect the reliability of study results)

9. Please evaluate the adequacy of training in the following non-clinical training areas (and associated learning outcomes). Please take into account all training that you are aware of, regardless of the source (in-house, European Commission/European Medicines Agency, external training providers, etc.).

- Proof of principle studies

  (Understand advantage and limitation of in vitro and in vivo assays / animal species selection / possibility to minimise animal testing)

- Pre-clinical studies to support first in human (FIH) study

  (Understand relevance of results obtained for clinical use, particularly for toxicity predictions for which no clinical data are expected)

- Establishing the clinical dose

  (Identify principles for capturing the most relevant toxicity finding to establish the no observed adverse effect level (NOAEL) and exposure margins)

- CTCG recommendations related to contraception and pregnancy

  (Understand and apply different risk categories for the early stages of pregnancy)

- Alternative approaches to animal model – 3Rs

  (Understand principles of replacement, reduction and refinement in animal research)

- Basic principles of Good Laboratory Practice (GLP)

  (Understand how GLP principles can affect the reliability of study results)

10. Are there any non-clinical training areas missing from the list provided?
11. Do you have any comments about the training on non-clinical topics?

12. On a scale of 1-3, please indicate the importance of the following pharmaceutical quality training areas (and associated learning outcomes). The scale is interpreted as follows: 1 (low importance), 2 (medium importance), 3 (high importance).

- Quality requirements for investigational medicinal products

  (Identify minimum quality requirements to build an IMPD for a medicinal product to be investigated in a clinical trial)

- EU legal framework and national implementation of Good Manufacturing Practice (GMP)

  (Identify GMP requirements applying to the manufacturing of medicinal products in different phases of development)

13. Please evaluate the adequacy of training in the following quality training areas (and associated learning outcomes). Please take into account all training that you are aware of, regardless of the source (in-house, European Commission, European Medicines Agency, external training providers, etc.).

    [Answer options: "No training is known to be available"; "Training exists but is not sufficient"; "Training exists and is sufficient"; "Training is not relevant for my role".]

- Quality requirements for investigational medicinal products

  (Identify minimum quality requirements to build an IMPD for a medicinal product to be investigated in a clinical trial)

- EU legal framework and national implementation of Good Manufacturing Practice (GMP)

  (Identify GMP requirements applying to the manufacturing of medicinal products in different phases of development)

14. Are there any quality training areas missing from the list provided?

15. Do you have any comments about the training on quality topics?

16. What challenges do you encounter in accessing relevant training for clinical trials? Please check all answers that apply.

- Lack of resources.
- Lack of time.
- Training not available in my preferred language.
- The format of the training.
- Difficulties finding the relevant training.
- Difficulty finding training for continuous education.
- I do not encounter any challenges in accessing training.
- Other

  16.1. Please specify what other challenges you encounter in accessing relevant training.

17. What is your preferred format of training being delivered? Please check all that apply.

- In-person seminar

- Online webinar/interactive session
- Online training modules
- Other

    17.1. Please specify what other training formats you find preferrable.

18. Please share any sources of useful trainings or modules on the clinical trials environment that you are aware of.
19. Please share any other comments regarding training in the clinical trials environment