ACT EU - Academia & SME clinical trials training needs

Survey preliminary results and next steps

ACT EU MSP Advisory Group meeting 12 March 2025

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Priority Action on Clinical trial training

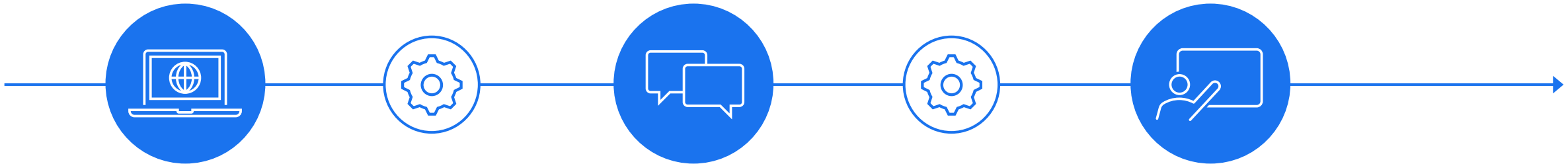
Vision

- ACT EU aims to provide a training curriculum informed by regulatory experience, with modules on **drug development** and **regulatory science.**
- This curriculum is expected to engage with universities and small and medium-sized enterprises and serve as an **educational 'ecosystem'.**

Objectives

- Increase scientific and regulatory knowledge, maintain and improve the quality of clinical trials in the EU / EEA, their assessment and supervision.
- Training sponsors/investigators on new methodologies and guidance to collect reliable and robust data, fit for regulatory decisions/licensing submissions.
- Bring together together knowledge from EU stakeholders, to further align in the assessment of clinical trials in the region.

How will we achieve our goals?



Training strategy

How the overall aim can be achieved

- Completed in December 2022

Training needs analysis

Overview of recommended areas of training

- EU Regulators analysis completed in March 2024
- Academia & SME analysis in progress

Training curriculum

Governance and process for maintenance

- Planned for 2025/2026

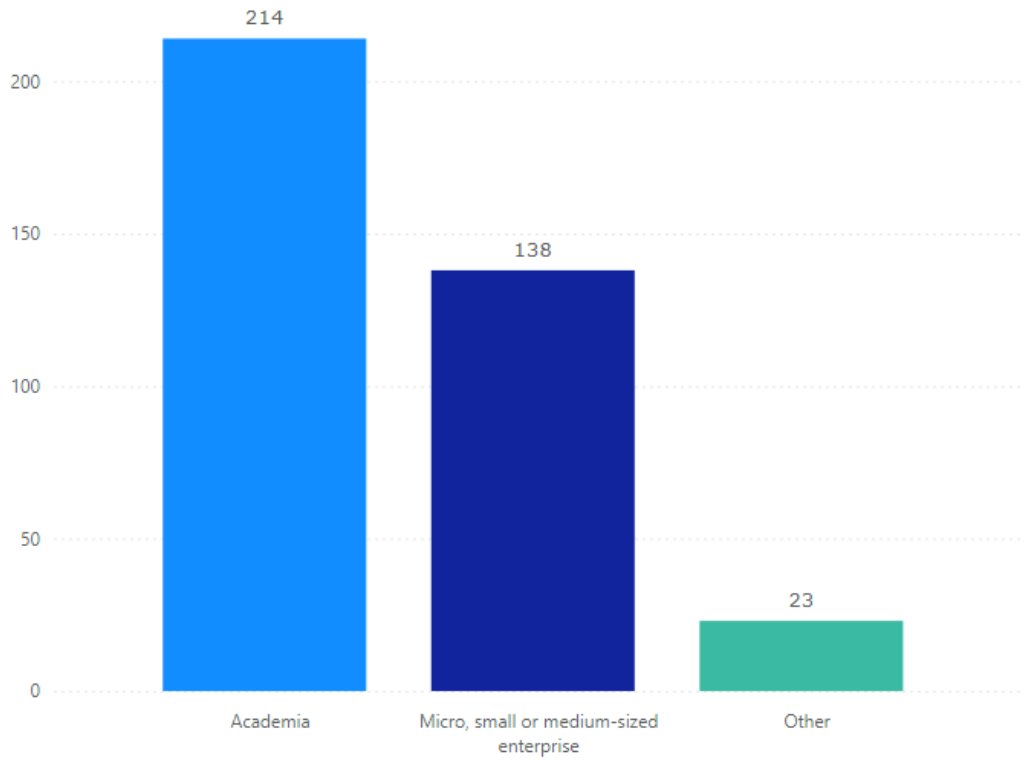
Academia & SMEs consultation

Survey targeting academic stakeholders and SMEs involved in the development of medicines for human use launched to gain insight in their clinical trial training needs

- Responses were collected between 14 January and 11 February 2025
- **375 responses** received on:
  - Importance and adequacy of training on clinical, non-clinical and quality areas
  - Accessibility of training (challenges, preferred format)

Survey demographics (1/2)

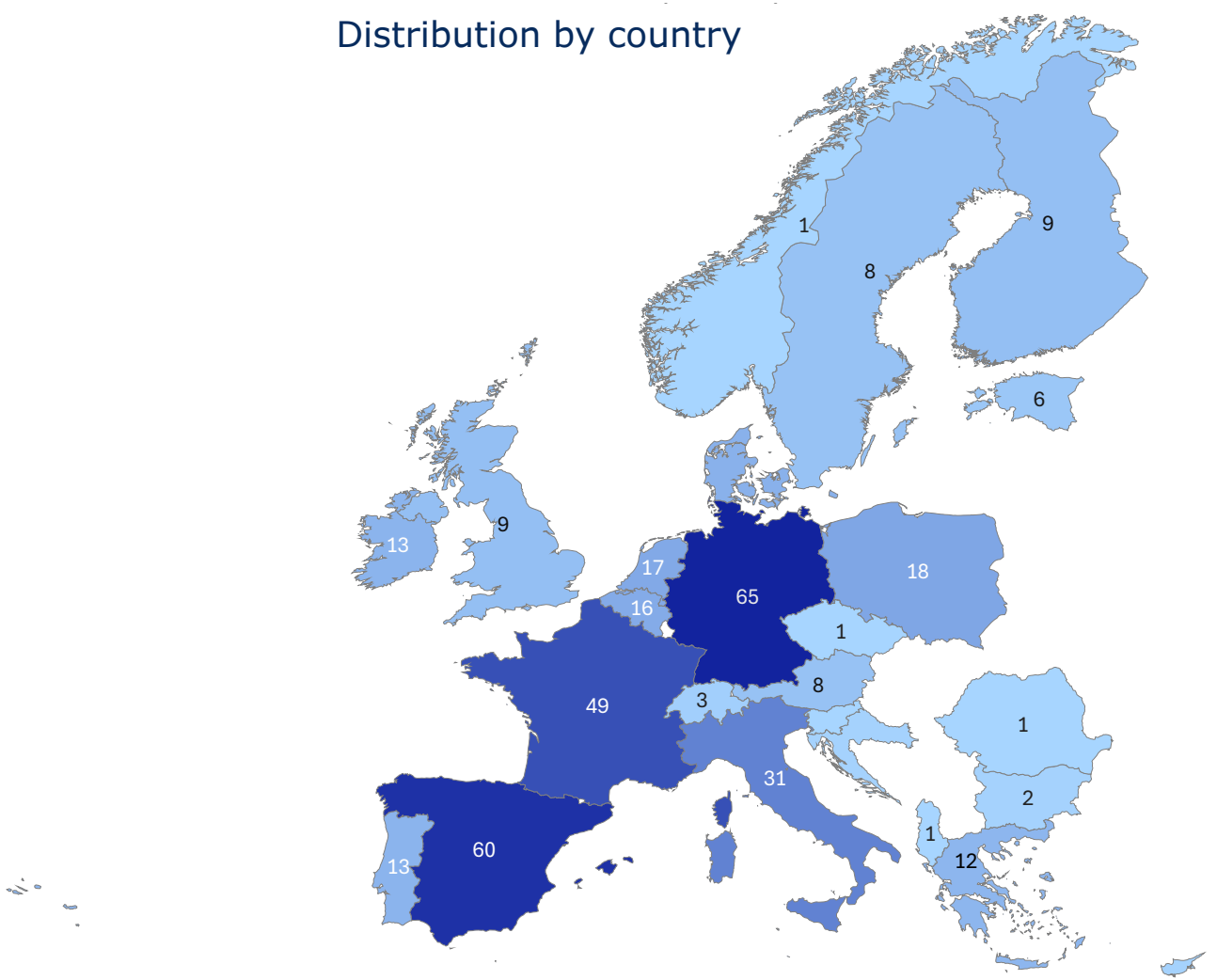
Distribution by stakeholder type



Role (multiple answers possible*)	N	(%)
Clinical trial coordinator/manager	169	45%
Investigator	119	32%
Clinical research associate	65	17%
Protocol writer	60	16%
Monitor/auditor/quality	50	13%
Statistician/methodologist/data scientist	37	10%
Regulatory affairs	27	7%
Funder and research reviewer	22	6%
Executive/senior management	13	3%
Other role	16	4%
Total	**578***	**100%**

Survey demographics (2/2)

Distribution by country



Pre-specified clinical trial training areas

- Clinical Trials Regulation, EU No 536/2014 (CTR)
- Good Clinical Practice (GCP)
- Declaration of Helsinki
- Scientific guidelines
- Use of the Clinical Trials Information System (CTIS)
- General Data Protection Regulation (GDPR)
- Safety reporting and pharmacovigilance
- Clinical study report

Clinical trial training areas (1/2)

Pre-specified training areas marked as ***most important*** by stakeholder type *(Importance rating: 1 - low, 2 - medium, 3 – high)*

	Average importance of top 3 clinical training areas					
Academia	CTR	2.74	GCP	2.71	Safety & pharmacovigilance	2.53
SME	GCP	2.79	CTR	2.69	Scientific guidelines	2.57
Other organisations	CTR	2.96	GCP	2.65	GDPR	2.61
Total (average score)	**GCP**	**2.74**	**CTR**	**2.73**	**Safety & pharmacovigilance**	**2.52**

Pre-specified training areas determined as ***not adequate**** by stakeholder type

	Top 3 non-adequate clinical training areas (multiple answers possible**)					
Academia	Clinical study report	125	Scientific guidelines	125	GDPR	114
SME	Scientific guidelines	77	GDPR	77	CTR	76
Other organisations	Clinical study report	14	CTIS	13	CTR	13
Total**	**Scientific guidelines**	**214**	**Clinical study report**	**214**	**GDPR**	**203**

**not adequate: training not adequate to my needs & not aware of training in this area*

Clinical trial training areas (2/2)

Selected additional clinical training areas reported by respondents:

- Medical Device Regulation (MDR)/ In-vitro diagnostic Regulation(IVDR)
    - Combined trials (CTR, IVDR) and clinical investigation of a medical device combined with a clinical trial
- Advanced treatment medicinal products (ATMPs)
- Biomarkers
- Regulation on Health Technology Assessment (HTAR)
- Clinical trial protocol
- Repurposing
- Trial and site organisation
- Combination products
- Stakeholder involvement
- Legal
- XEVMPD system
- Methodology/Statistics/Study design -> overlap with scientific guidelines

Accessibility of training

Training access challenges by stakeholder type (multiple answers possible*)

	Finding relevant training	Training for continuous education	Lack of time	Lack of resources	Format not suitable	Not available in my preferred language	Other challenges	No challenges
Academia	153 (28%)	88 (16%)	113 (21%)	82 (15%)	44 (8%)	42 (8%)	11 (2%)	11 (2%)
SME	109 (33%)	72 (22%)	57 (17%)	50 (15%)	18 (5%)	17 (5%)	6 (2%)	3 (1%)
Other organisations	18 (31%)	12 (20%)	10 (17%)	9 (15%)	3 (5%)	3 (5%)	2 (3%)	2 (3%)
Total*	**280 (30%)**	**172 (18%)**	**180 (19%)**	141 (15%)	65 (7%)	62 (7%)	19 (2%)	16 (2%)

Preferred training formats by stakeholder type (multiple answers possible*)

	Online webinar/interactive session	Online training modules	In-person seminar	Other format
Academia	167 (39%)	140 (33%)	113 (27%)	4 (1%)
SME	106 (42%)	95 (37%)	52 (20%)	1 (0.4%)
Other organisations	20 (41%)	17 (35%)	11 (22%)	1 (2%)
Total*	**293 (40%)**	**252 (35%)**	176 (24%)	6 (1%)

Other comments relevant to clinical trial training areas

*"Most training modules I know are **too theoretical**"*

*"Emphasise **practical application** in the trainings and focus on areas of non-compliance"*

*"Provide **training tailored to specific roles and type of studies**"*

*"The available **CTIS training is spread** out into too many documents and videos, it is **difficult to get the whole picture**"*

*"**Searching CTR/CTIS training material** on the EMA website is **challenging**. Need for improving the search engine efficiency"*

*"The **volume of training material is too large** and **not manageable by organisations with limited resources**. Need for simplification and streamlining of the training material"*

*"**Trainings** should be **free of charge for academia**"*

What's coming up…

Analysis to continue

- Subgroup analysis of clinical trial training areas by organisation and role
- Non-clinical training areas
- Pharmaceutical quality training areas

Towards a '*training ecosystem*'

Focus of this priority action has evolved

Enable learning via:

- Facilitating access to training (e.g. training signposting)
- Incorporating *regulatory angle* into training aiming at academia & SMEs
- Bi-directional exchanges with stakeholders

Your input and priorities are sought to inform the development of a '*training ecosystem*'

Appendix

Pre-specified training areas identified and included in survey

Clinical	Non-clinical	Pharmaceutical quality
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)	**Proof of principle studies** (Understand advantage and limitation of in vitro and in vivo assays / animal species selection / possibility to minimise animal testing)	**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)
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)	**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)	**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)
Declaration of Helsinki (Understand ethical principles in conducting clinical trials)	**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)	
Scientific guidelines (Understand aims and scope of relevant guidelines in the clinical phase of medicines development, including design and conduct of clinical trials)	**CTCG recommendations related to contraception and pregnancy** (Understand and apply different risk categories for the early stages of pregnancy)	
Use of the Clinical Trials Information System (CTIS) (Understand structure, content and process of Clinical Trial Application and the CTIS)	**Alternative approaches to animal model - 3Rs** (Understand principles of replacement, reduction, and refinement in animal research)	
General Data Protection Regulation (GDPR) (Understand the requirements for data protection)	**Basic principles of Good Laboratory Practice (GLP)** (Understand how GLP principles can affect the reliability of study results)	
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 - ICH E3 / identify relevant data to build a complete and informative report)		

Thank you