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Clinical trials training needs – survey to academia and SMEs

A deliverable of the ACT EU Priority Action on clinical trials training

An agency of the European Union

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Executive summary

The Accelerating Clinical Trials in the European Union (ACT EU) initiative aims for better, faster and smarter clinical trials in the EU, creating a favourable environment for clinical research. The initiative's Priority Action on clinical trials training, via stakeholder engagement, aims to create an educational 'ecosystem' to enable targeted training on clinical trials.

Researchers in the academic sector and Micro-, Small- and Medium-sized Enterprises (SMEs) may be more likely to face challenges or may face different challenges in conducting clinical trials compared to larger pharmaceutical industry stakeholders.

While some challenges could be addressed by undertaking relevant clinical trials training, both groups often have limited time, and resources which can limit their access to training. Additionally, there is no current assessment of what the training needs of these stakeholder groups are or how they should be prioritised. To address this issue, clinical trials training needs and challenges in training access of these two stakeholder groups were identified and analysed.

The identification of training needs was based on five milestones:

1. Development of a provisional list of training areas informed by the EU-funded project in Strengthening Training of Academia in Regulatory Sciences (STARS curriculum). The **clinical, non-clinical and quality** training areas identified by STARS were used as a basis to further refine the list of training areas and expand these to the needs of SMEs.
2. Identification and consultation of relevant European Medicines Regulatory Network (EMRN) members on the list of training needs.
3. Consultation of the academic sector and SMEs via a survey in January/February 2025.
4. Clinical trials training areas updated with feedback from the survey.
5. Final training needs, recommendations for implementation and next steps documented in a report.

A survey was conducted to measure their perceived importance and adequacy of a provisional list of training areas. Additionally, the survey collected training areas deemed as missing, identified the challenges in accessing training, and aimed to understand preferred training formats for researchers in academia and SMEs. The survey was comprised of the following sections: demographic profile, clinical training areas, non-clinical training areas, pharmaceutical quality training areas, and accessibility of training. The survey received 375 responses, which sufficiently represented both target groups (57% responses from the academic sector, 37% from SMEs, and 6% from 'other' organisations), as well as 22 out of 27 EU member states. The responses also reflected perspectives of individuals involved with different roles in clinical trials at these organisations and their experience regarding clinical trials training.

Considering the scope of training needs, researchers in both the academic sector and SMEs have similar needs for training across a variety of areas. Training related to clinical areas, such as **implementation of Clinical Trials Regulation (CTR), Clinical Trials Information System (CTIS), Good Clinical Practice (GCP)** or **safety and pharmacovigilance** were identified as most important for these stakeholders, having the biggest impact in their daily work. In contrast, as they work with non-clinical and pharmaceutical quality topics less frequently, those topics were considered of lower importance while still relevant.

The survey also highlighted that more effort should be made to **update and promote** training on the **application of scientific guidelines, development of the clinical study report** and the **application of General Data Protection Regulation (GDPR)**.

Using this input, the provisional list of clinical trial training areas (and associated learning outcomes) has been further refined and enriched. New training areas were identified across all three previously established categories (clinical, non-clinical, and pharmaceutical quality), as well as in a new multidisciplinary category.

In terms of access, both the academic sector and SMEs encounter the same **challenges** in accessing relevant trainings, the most frequent challenges being **finding relevant training**, **lack of training for continuous education, lack of time, and lack of resources**. More specifically, they named the volume and diverse source, as well as the high cost of training as barriers to access, and would like to access training provided in a central location. Additionally, **online training** (both interactive sessions and pre-made modules) was considered the **most attractive training format**, although in-person seminars should be considered for longer sessions that aim to cover several topics. Training organisers were also encouraged to include more interactive and practical elements into clinical trials training, such as critically analysing examples, case studies or simulations. Finally, the **need for more tailored training** was highlighted, as differences between organisation types and roles impact the learning experience and later application of practical knowledge.

ACT EU Priority Action on clinical trials training will proceed to mapping and signposting of the most important clinical trials training needs on ACT EU's website. The ACT EU Multistakeholder platform and EMRN will be consulted during this activity. Ongoing training initiatives will also be leveraged so better targeted and easily accessible clinical trials training can be made available to researchers in the academic sector and SMEs in support of ACT EU's vision for better, faster, more impactful clinical trials in the EU.

Introduction

The European Medicines Regulatory Network (EMRN) aims to support researchers in the academic sector and micro, small and medium-sized enterprises (SME) by sharing good regulatory practices that support the planning, set up and conduct of clinical trials. Such practices can take the form of recommendations, guidance or training.

The Accelerating Clinical Trials in the European Union (ACT EU) initiative supports smarter clinical trials through regulatory, technological, scientific and process innovation. ACT EU is a joint initiative by the European Commission, Heads of Medicines Agencies (HMA) and European Medicines Agency (EMA), aiming creating a favourable environment for clinical research.

One of the underpinning activities of ACT EU is to deliver a learning ecosystem for clinical trials, contributing to the transformation of the clinical research ecosystem. The training strategy published by this Priority Action identified clinical trial assessors, the academic sector and SMEs involved in the planning, initiation and/or conduct of clinical trials, as high priority stakeholder groups. Following the gap analysis for clinical trial assessors, the training needs of the remaining two stakeholder groups need to be evaluated.

The two target stakeholder groups are defined as follows:

Academia includes researchers, developers and health professionals from the academic sector; education and not-for-profit organisations conducting research; research infrastructures and consortia.[1]

Micro, small and medium-sized enterprise (SME) is a category of enterprises which employ fewer than 250 persons, and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million[2].

Problem statement

Clinical staff in the academic sector and SMEs are more likely to face challenges in conducting clinical trials compared to larger pharmaceutical industry players. Those challenges can be at multiple levels, such as upskilling staff, designing a research approach, writing a protocol, or obtaining regulatory support. While some of those challenges could be addressed by following relevant clinical trials training, both groups often have limited time, and resources. Therefore, these circumstances can create barriers in accessing said training.

Additionally, there is no current assessment of what the training needs of these stakeholder groups are or how they should be prioritised. Researchers in the academic sector and SMEs tend to have less frequent regulatory interactions than other stakeholders, such as the pharmaceutical industry, therefore their challenges might be less visible to the regulatory network. To address this issue, clinical trials training needs of these two stakeholder groups have been directly collected, categorised and analysed. This output will then inform the next steps in supporting the academic sector and SMEs in the clinical trials environment and serve as a baseline to measure if those efforts are effective.

[1] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/framework-collaboration-between-european-medicines-agency-and-academia_en.pdf
[2] SME Definition - user guide 2020

Background information

The published training strategy recognises the previous work performed by the EU funded STARS project[3], a collaboration within the EMRN, in creating a comprehensive curriculum for awareness of regulatory science in academia.

The STARS project "had the objective to complement, coordinate and harmonise regulatory efforts among Member States and at European level to support academic health research for the benefit of patients. The aim was to reach academic researchers very early in the planning of relevant grant applications. A further aim was to strengthen regulatory knowledge in general by reaching clinical scientists during professional training and qualification."

One of the main deliverables was the development of a core and a comprehensive curriculum, with a focus broader than clinical trials only, to serve as guidance for future training development targeting researchers in the academic sector. The project offered recommendations for the content and learning outcomes to be considered in implementing training activities to support academic research.

Meanwhile, no existing training curricula for SMEs were identified. Training opportunities for SMEs are organised by EMA's SME office, usually covering topics related to regulation, such as the impact of the CTR or CTIS use. Moreover, as SMEs have similar resource limitations to the academic sector, it could be assumed that they experience similar challenges in accessing relevant training. Consequently, the STARS curriculum[4] was used to gather information on training needs for researchers in the academic sector and SMEs.

Objective and expected benefits of the clinical trials training needs analysis

Performing the clinical trials training needs analysis will allow to better understand the current needs and challenges in training that impact the academic sector and SMEs alike. By having a clear overview of the current situation, mitigating actions can be implemented leading to better, faster, more impactful clinical trials overall, as laid out in the vision of ACT EU.

Goal of the report

The goal of this training needs analysis is to provide an overview of clinical trials training areas and their associated learning outcomes, as well as identify which training areas should be prioritised. Moreover, it aims to pinpoint the most common challenges regarding access to relevant training and preferred training formats for the target stakeholder groups.

The analysis also aims to check whether there are significant differences between academia and SME or individuals' roles in the clinical trials environment regarding training needs and training access.

The results of this analysis will inform the next steps to take in addressing these training needs, as well as further training development by other synergetic initiatives.

[3] Welcome to STARS! - Stars
[4] STARS Curricula - Stars

Approach to the identification of clinical trials training needs

The identification of training needs was based on five milestones.

First, a provisional list of training areas was developed based on the STARS curricula. The STARS curricula organise the training areas into four broader categories: quality, non-clinical, clinical and post-marketing surveillance. The **clinical, non-clinical and quality** training areas identified by STARS were used as a basis to further refine the list of training areas.

Second, relevant EMRN stakeholders were identified to consult and collect feedback from, as well as to disseminate training needs.

The third milestone included approaching the relevant EMRN stakeholders to consult them on the list of training needs and inform the clinical training areas list, later used to pose questions to the target groups. In particular, the training needs based on the findings of the STARS curricula were presented to the Clinical Trials Coordination Group (CTCG) and the Good Clinical Practice Inspectors' Working Group (GCP IWG) for feedback. Subsequently, consultation of the academic sector and SMEs took place via a survey in January/February 2025.

The fourth milestone included updating the clinical trials training areas list by incorporating feedback received via the survey.

Lastly, the fifth milestone aimed to incorporate the clinical trials training needs in a report, including recommendations for implementation and next steps. This report is the final deliverable and thus concludes the fifth milestone.

EMRN consultation

CTCG and GCP IWG members were consulted to further refine the list of clinical trials training areas (and associated learning outcomes) for the academic sector and SMEs based on the members' experience in reviewing Clinical Trial Applications (CTA) and supervising compliance from the two target groups.

CTCG members identified the following clinical areas as highest priority for training in our target group:

1. Clinical study protocol and clinical study report (structure and content);
2. Safety reporting & pharmacovigilance;
3. CTIS training;
4. CTR implementation.

Additionally, the clinical training areas list was amended with safety training with 'CTCG recommendations related to contraception and pregnancy' also included as a non-clinical training area.

Other new training areas identified which did not fit in the three pre-specified categories were statistical methodology, and the quality and presentation of the Clinical Trial Protocol, Investigator's Brochure, and Clinical Trial Application Dossier. CTCG members also shared some ongoing training initiatives focusing on academia and SMEs (*Annex 1* in supporting documentation).

Furthermore, the GCP IWG was consulted to identify which areas in GCP training for clinical trials teams in the academic sector and SMEs should focus on, as well as training activities that they are aware of which are included under *Annex 1 (found in supportive documentation)*. The members' input was categorised into three areas:

1. Documentation (Management of essential documents; quality and documentation requirements for source documents; documenting, arranging access and archiving of Trial Master File (TMF) and Site Master File (SMF));
2. Data management and computerised systems (Guideline on computerised systems and electronic data in clinical trials; management of computerised systems; assessment and demonstration that used computerised systems are fit for purpose; building of electronic case report form/electronic data capture and validation of systems; registering the institution/Principal Investigator as a sponsor in CTIS; monitoring quality of data and compliance with the protocol);
3. Responsibilities and oversight (Sponsor responsibilities and oversight; delegation of tasks and oversight by a principal investigator; service provider oversight; co-sponsorship and legal sponsorship responsibilities (incl. academic sponsorship models and oversight); safety management when assessment of expectedness of the serious adverse event is assigned to the site/investigator; investigational medicinal product management).

Academic sector and SME consultation

A survey was conducted to collect feedback from researchers in the academic sector and SMEs about the previously identified and potentially missing training areas, access to training, and preferred training formats.

The survey was created using EUSurvey. To reach a larger and more representative sample, it was broadly distributed, supported by the ACT EU Multistakeholder Platform Advisory Group (ACT EU MSP AG). The survey was promoted on the ACT EU website, CTIS Newsflash, CT Highlights newsletter, EMA LinkedIn, as well as via mailings to SME stakeholders, academic stakeholders, and industry associations. The survey was open from 13 January 2025 to 11 February 2025.

Survey results

Demographic profile of survey respondents

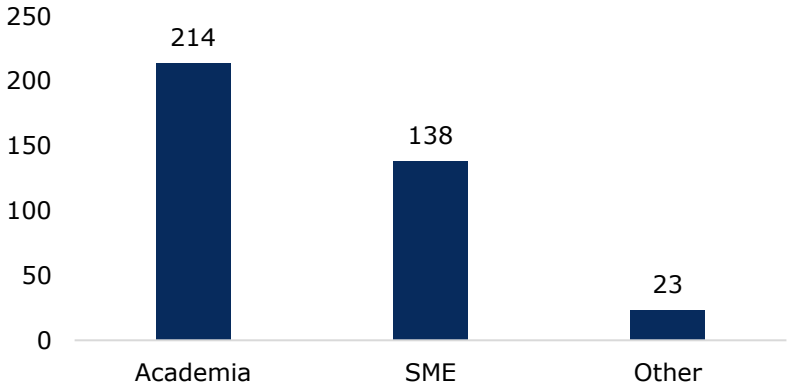
The survey received a total of 375 responses. Overall, the response sample sufficiently represented both target groups, and most EU member states (as well as several other countries). It also includes perspectives from a large range of people involved in clinical trials at these organisations. The following section illustrates the demographic characteristics of survey respondents.

Stakeholder group

An overview of responses received by stakeholder group is provided in *Figure 1.* 214 (57%) of the responses came from the academic sector, 138 (37%) from SMEs, and 21 (6%) from 'other' organisations. 'Other' organisations included stakeholders that do not meet the definitions of academia or SME (e.g., independent consultants, Contract Research Organisations, or

freelancers) but their feedback was considered in the analysis due to their close interaction with the survey's target groups.

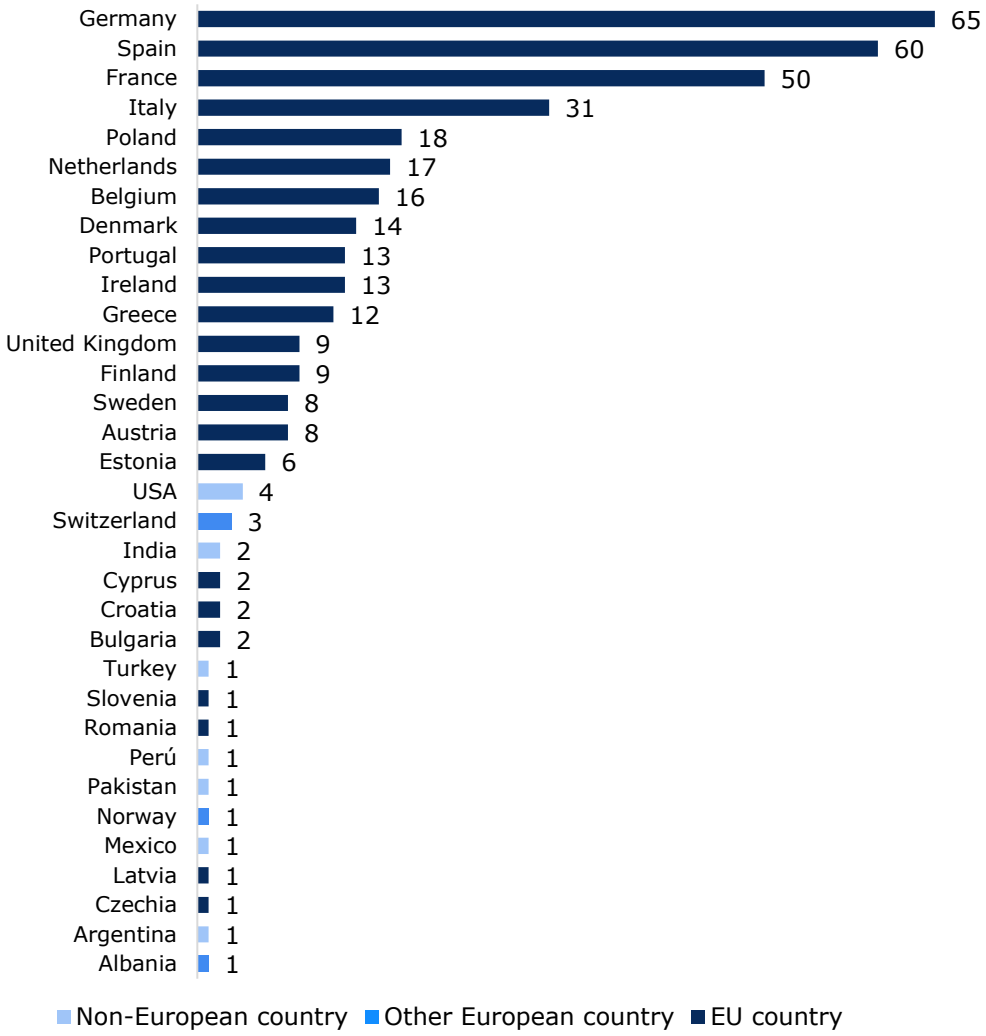
Figure 1. Number of respondents by stakeholder group



Country

Figure 2. provides an overview of responses received by country indicating that respondents were based in 22 EU countries (93% of responses), 4 other European countries (4% of responses) and 7 non-European countries (3% of responses). The majority of responses were from Western and Southern Europe, Germany and Spain accounting for 65 and 60 responses respectively. Meanwhile several Eastern European countries only account for less than 3 responses each or are not represented at all. It was decided to include the 25 responses that came from non-EU countries in the following analyses, as they appear to be active in the clinical trials environment in the EU as well.

Figure 2. Number of respondents by country



Roles

A list of ten role categories was available for the respondents to pick from, as well as the option to indicate any other role if needed. As respondents were able to fill in the survey on behalf of themselves or their teams, they were able to select more than one role.

This resulted into 578 total roles reported, out of which 116 were 'other role' entries. Due to the volume and heterogeneity in responses, they were re-organised into ten new categories, which included new additions, such as regulatory affairs, executive/senior management, auditor and quality professional (clustered together with clinical trials monitors). The remaining 16 'other roles' included freelancers, consultants, whole clinical trials organisations, and other more niche roles in the clinical trials environment.

As shown in *Table 1.* , the majority of respondents identified as clinical trial coordinators or managers (including project managers), as well as investigators (primary and sub-investigators), collectively making up nearly half of the total roles reported.

Table 1. Distribution of roles in the clinical trials environment (multiple roles per respondent possible)

Role (multiple answers possible*)	N (% of all roles)
Clinical trial coordinator/manager	169 (29%)
Investigator	119 (21%)
Clinical research associate	65 (11%)
Protocol writer	60 (10%)
Monitor/auditor/quality	50 (9%)
Statistician/methodologist/data scientist	37 (6%)
Regulatory affairs	27 (5%)
Funder and research reviewer	22 (4%)
Executive/senior management	13 (2%)
Other role	16 (3%)
Total	**578* (100%)**

Roles by stakeholder type

Due to different circumstances (i.e. organisational structure, mission) of the stakeholder groups, certain roles are unevenly spread across the two groups. For example, 84% of investigators in this sample came from the academic sector, compared to 15% from SMEs. Meanwhile, SMEs had substantially more regulatory affairs specialists (67%), funders and research reviewers (73%), as well as executives and senior management (69%) represented. It is also important to consider that over half of the total responses came from the academic sector.

A detailed overview of roles represented by stakeholder type can be found in *Table 2.*

Table 2. Distribution of roles by stakeholder group

	Academia	SME	Other
Clinical trial coordinator/manager	94 (56%)	65 (39%)	10 (6%)
Investigator	100 (84%)	18 (15%)	1 (1%)
Clinical research associate	42 (65%)	20 (31%)	3 (5%)
Protocol writer	32 (53%)	25 (42%)	3 (5%)
Monitor/auditor/quality	32 (64%)	16 (32%)	2 (4%)
Statistician/methodologist/data scientist	23 (62%)	12 (32%)	2 (5%)
Regulatory affairs	7 (26%)	18 (67%)	2 (7%)
Funder and research reviewer	6 (27%)	16 (73%)	-
Executive/senior management	2 (15%)	9 (69%)	2 (15%)
Other role	6 (38%)	6 (38%)	4 (25%)
Total	**214 (57%)**	**138 (37%)**	**23 (6%)**

Clinical training areas

In the survey, the importance and adequacy of identified clinical trials training areas was measured to get a better overview of the current state of training in these areas and identify which ones might require more attention. Also, a comparison of results across the stakeholder groups was performed to assess the prior assumption that the two groups have similar training

needs. Due to little variance in both importance and adequacy of clinical training areas across the different roles, a sub-group analysis by role is not reported.

The clinical training areas evaluated in the survey were:

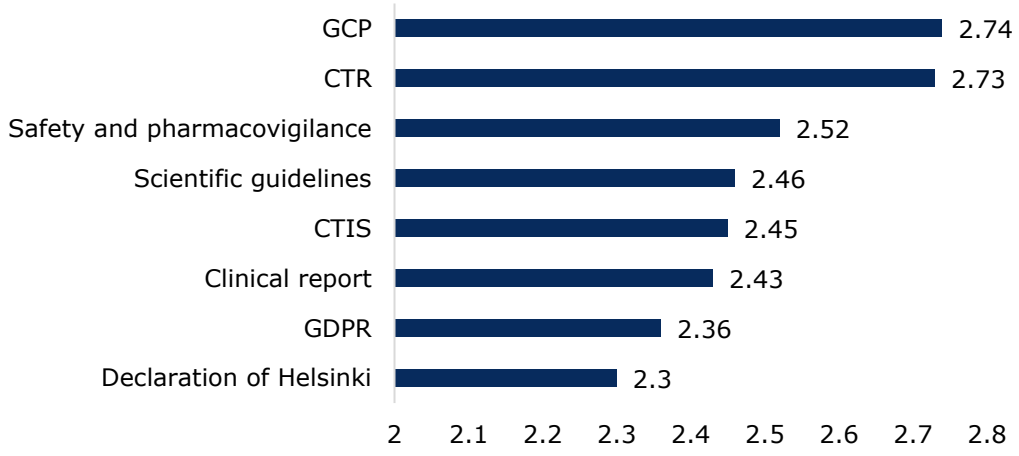
- Clinical Trials Regulation (CTR)
- Good Clinical Practice (GCP)
- Declaration of Helsinki
- Scientific guidelines
- Clinical Trials Information System (CTIS)
- General Data Protection Regulation (GDPR)
- Safety reporting and pharmacovigilance
- Clinical study report

The training areas and their associate learning outcomes are listed in *Table 9.*

Importance of clinical training areas

Respondents were able to evaluate the **importance** of each clinical training area on a 3-point Likert scale (1 – low importance, 2 – medium importance, 3 – high importance). Overall, as seen in *Figure 3.* , all clinical training areas were perceived to be above medium importance (average importance >2, total average importance = 2.5). GCP, CTR, and safety and pharmacovigilance were indicated to be of highest importance (2.74, 2.73, and 2.52 respectively). Meanwhile, declaration of Helsinki (2.3) and GDPR (2.36) were the clinical training areas with lowest importance.

Figure 3. Importance of clinical training areas



The average importance of clinical training areas follows a similar trend across the stakeholder groups as can be seen in *Table 3.* GCP and CTR remained the top two training areas of importance, with safety and pharmacovigilance, scientific guidelines, and GDPR being the third most important in academia, SMEs and other organisations respectively. It is also relevant to note that all eight identified clinical training needs were also evaluated to be above medium importance, regardless of stakeholder type or role (average importance of all training areas

>2). Therefore, being sufficiently knowledgeable about all aspects of clinical research is indicated as important for everyone involved in the clinical research environment, regardless of type of organisation or role.

Table 3. Average **importance** of top 3 clinical trials training areas by stakeholder type

Average importance of top 3 clinical training areas by stakeholder type						
Stakeholder	Most important training need		Second most important training need		Third most important training need	
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**

Adequacy of clinical training areas

The perception of training **adequacy** in clinical training areas received mixed responses as indicated in *Table 4.* Over half of all respondents (52%) were either not aware of training in the clinical areas, or aware of it but found it not adequate for their needs. Still, in most training areas, at least a third of respondents (>33%) found the available training adequate for their needs. GCP stood out as the area with the highest adequacy rate (244 responses) and the least respondents (48) unaware of training in the area. Meanwhile respondents had the least awareness of clinical study report (126 responses), scientific guideline (114 responses) and declaration of Helsinki (108 responses) training. GCP and CTR appeared to be of highest relevance to respondents regardless of their role, with only 12 and 13 respondents respectively, indicating that these areas were not relevant for their role.

Table 4. Adequacy of clinical training areas

Clinical training areas	**Not aware of training**	**Aware but training not adequate**	**Aware and training is adequate**	**Training not relevant for my role**
CTR	96 (26%)	99 (26%)	167 (45%)	13 (4%)
GCP	48 (13%)	71 (19%)	244 (65%)	12 (3%)
Declaration of Helsinki	108 (29%)	64 (17%)	186 (50%)	17 (5%)
Scientific guidelines	114 (30%)	100 (27%)	139 (37%)	22 (6%)
CTIS	69 (18%)	117 (31%)	153 (41%)	36 (10%)
GDPR	97 (26%)	106 (28%)	148 (40%)	24 (6%)
Safety reporting and pharmacovigilance	79 (21%)	93 (25%)	146 (39%)	57 (15%)
Clinical study report	126 (34%)	88 (24%)	123 (33%)	38 (10%)

Table 5. indicates that the top three non-adequate clinical training areas were similar for the three stakeholder groups, only in different order. Overall, scientific guidelines, clinical study

report, and GDPR were found to be the least adequate clinical training areas across all stakeholder groups.

Table 5. Top three non-adequate clinical training areas by stakeholder type

**: 'non-adequate' combines answer options 'not aware' and 'aware but not adequate for my needs', therefore multiple answers are possible.*

Top 3 non-adequate* clinical training areas by stakeholder type						
	Least adequate clinical training areas		Second least adequate clinical training areas		Third least adequate 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**

Identifying clinical training areas of high priority

Figure 4. and *Figure 5.* were generated to identify potentially high priority clinical training areas. These areas are situated in the top-right quadrants of the plots. They are the intersection of training areas that were indicated as above average importance but of low adequacy, or of low adequacy respectively.

In *Figure 4.* , this quadrant contains the training areas that simultaneously were reported as of above average importance and that at least 25% of all respondents having reported of no awareness in corresponding training. There are five high priority areas seen in this matrix: clinical report, scientific guidelines, declaration of Helsinki, GDPR and CTR.

Figure 4. Importance and training unawareness in clinical training areas

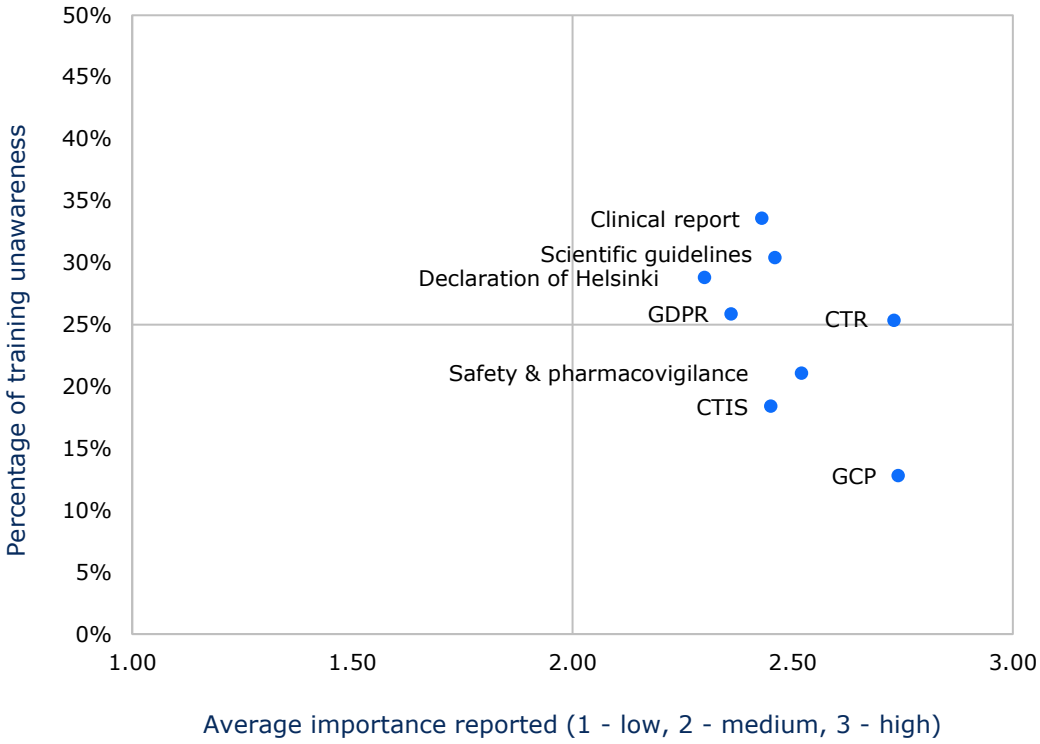
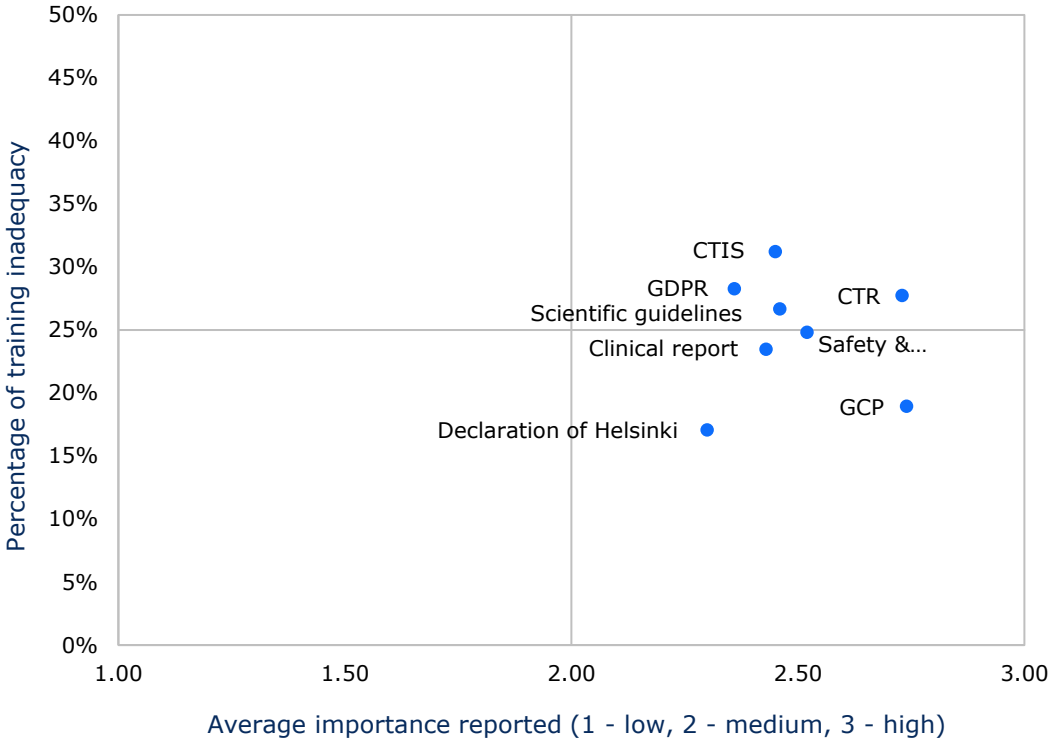


Figure 5. complements the previous matrix by identifying above average importance clinical training areas for which over 25% of respondents have found the existing training not adequate for their needs. Four such areas can be seen in the matrix: CTIS, GDPR, CTR, and scientific guidelines. The two matrices share **three clinical training areas that could be identified as high priority and might need more attention: scientific guidelines, GDPR and CTR**.

Figure 5. Importance and training inadequacy in clinical training areas



Other training areas

While clinical training topics are of most relevance to our target groups, non-clinical and pharmaceutical quality topics also inform the process of clinical trial preparation. Therefore, results for non-clinical and pharmaceutical quality training areas were merged in this report and referred to as 'other training areas'.

The 'other' training areas evaluated in the survey were:

Non-clinical training areas

- Proof of Principle (PoP) studies
- First in Human (FIH) studies
- Establishing clinical dose
- CTCG recommendations related to pregnancy and contraception
- Alternative approaches to animal models – replacement, reduction and refinement (3Rs principle)
- Good Laboratory Practice (GLP)

Pharmaceutical quality training areas

- Quality requirement for Investigational Medicinal Product Dossier (IMPD)
- Good Manufacturing Practice (GMP)

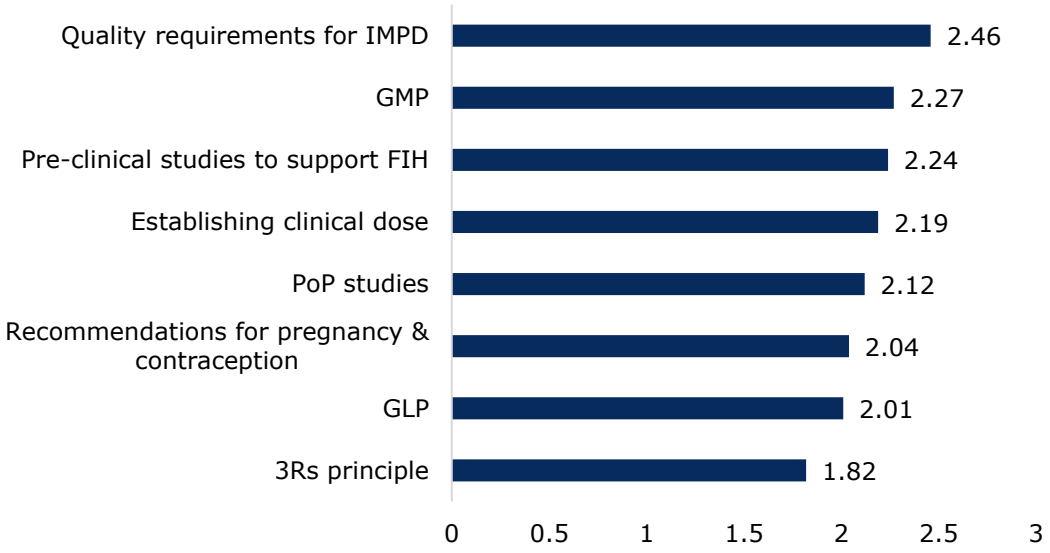
The training areas and their associate learning outcomes are listed in *Table 9.*

Importance of other training areas

Overall, the average importance of non-clinical and pharmaceutical quality training areas was 2.14. It is lower compared to clinical training areas, which could be explained by academia and SMEs being more likely to focus on clinical aspects of product development in their daily work compared to non-clinical or quality aspects.

Pharmaceutical quality requirements for IMPD (2.46), GMP (2.27) and preclinical studies to support FIH (2.27) were indicated to be of highest importance. Meanwhile, the alternative approaches to animal model (principle of 3Rs, 1.82), GLP (2.01) and CTCG recommendations related pregnancy and contraception (2.04) were evaluated to be the non-clinical training areas with lowest importance. Alternative approaches to animal model (principle of 3Rs) were also the only training area across all categories to be reported as below medium importance. A detailed overview of non-clinical and pharmaceutical quality training areas' importance reported can be seen in *Figure 6.*

Figure 6. Importance of other clinical trials training areas



Adequacy of other training areas

Following the overall lower importance of other training areas reported, significantly more respondents found them relevant for their role - at least 20% of respondents in each training area (*Table 6.*). Alternative approaches to animal models were relevant to the least respondents (117 found it not relevant). It was also indicated that at least a third of the respondents (>32%) lack awareness of training in each of the non-clinical and pharmaceutical quality training areas. Across all stakeholder groups, there was little difference between the perceived adequacy of the training areas, with CTCG recommendations related to pregnancy and contraception indicated to have the least adequate training.

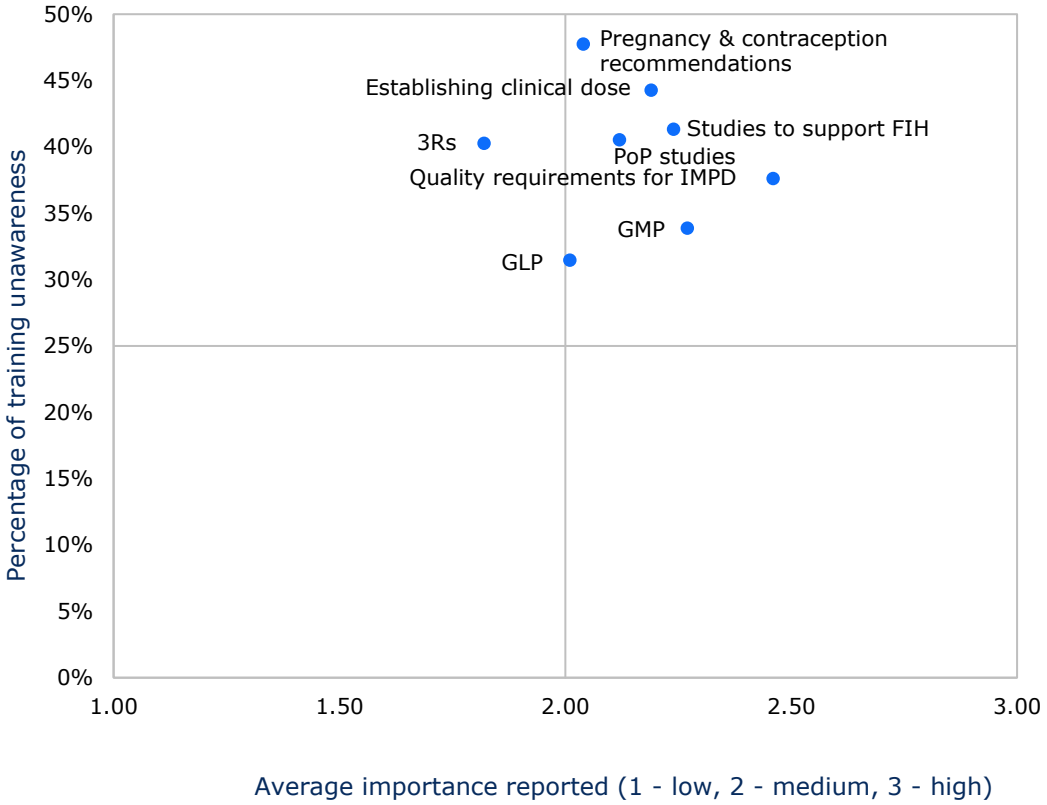
Table 6. Adequacy of non-clinical and pharmaceutical quality training areas

	Not aware of training	Aware but training not adequate	Aware and training is adequate	Training not relevant for my role
PoP studies	152 (41%)	65 (17%)	69 (18%)	89 (24%)
FIH studies	155 (41%)	73 (20%)	66 (18%)	81 (22%)
Establishing clinical dose	166 (44%)	63 (17%)	58 (16%)	88 (24%)
CTCG recommendations related to pregnancy and contraception	179 (48%)	55 (15%)	65 (17%)	76 (20%)
Alternative approaches to animal model - 3Rs	151 (40%)	56 (15%)	51 (14%)	117 (31%)
GLP	119 (32%)	71 (19%)	92 (25%)	93 (25%)
Quality requirement for IMPD	141 (38%)	73 (20%)	89 (24%)	72 (19%)
GMP	127 (34%)	78 (21%)	88 (24%)	82 (22%)

Identifying other training areas of high priority

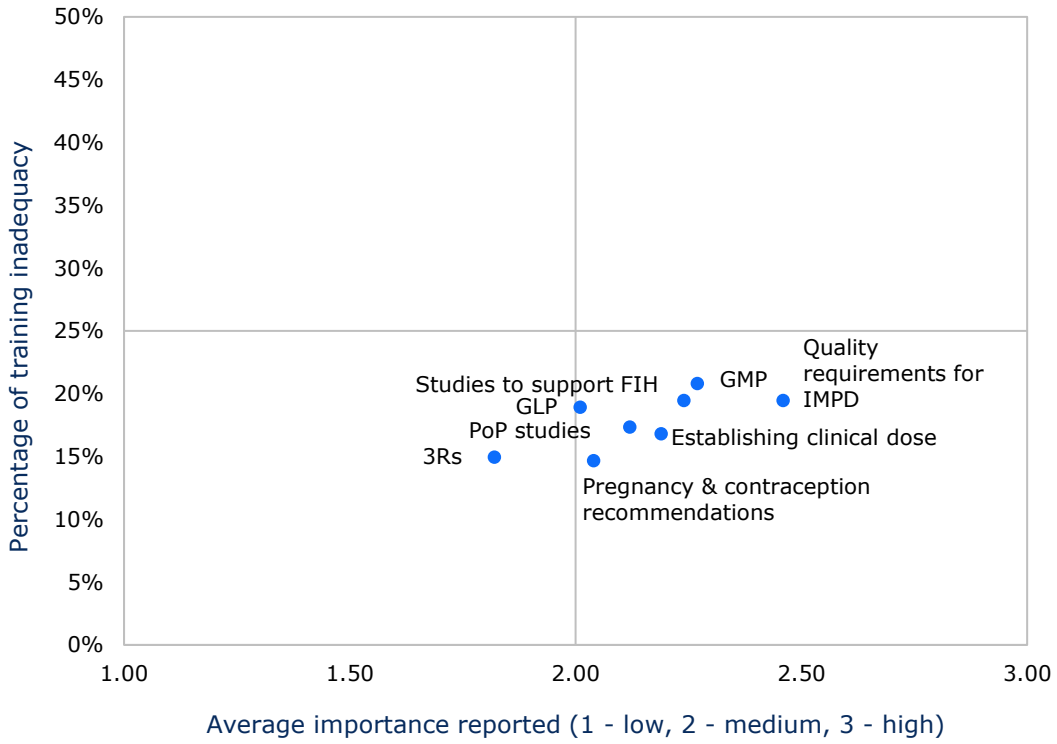
In *Figure 7.* , the top-right quadrant contains the training areas that simultaneously are reported as above average importance and that at least 25% of all respondents having reported of no awareness in corresponding training, therefore potentially of high importance in the context of non-clinical and pharmaceutical quality training. From the eight areas identified, seven of them are in this quadrant. The only training area that is excluded is the alternative approaches to animal model (principle of 3Rs) due to its reported lower than medium importance, while 31% of respondents were not aware of training in this area.

Figure 7. Importance and training unawareness in non-clinical and pharmaceutical quality training areas



Meanwhile, when looking at the interaction between average importance of other training areas for which over 25% of respondents have found the existing training not adequate for their needs, none of the other training areas fall into the top-right quadrant (*Figure 8.*). That is likely because of a high number of respondents being unaware of training in the areas or find it irrelevant for their role.

Figure 8. Importance and training inadequacy in non-clinical and pharmaceutical quality training areas



Subgroup analysis by role

Subgroup analyses were conducted to assess differences in perceived importance and adequacy of clinical and other training areas between roles. No considerable differences were identified thus no subgroup analyses results by role are included in this report. A possible explanation for no differences reported can be attributed to the fact that in many instances feedback was reported by organisations representing multiple roles. For more details, please refer to *Table 1.*

Additional training areas identified

Respondents were also asked to provide feedback on any missing or complementary clinical, non-clinical and pharmaceutical quality training areas in addition to those listed in the survey. As this question was based on a free text field, the feedback was first reviewed and categorised before it was used to complement the existing training areas.

98 respondents submitted proposals that were classified to fall under the Clinical domain, 19 for non-clinical and 21 for quality (multiple proposals per respondent were possible). Less than ten proposals were categorised as 'unclear' or 'not relevant'. Note that some existing training areas were also reported as 'missing', usually focusing on more specific topics within the areas. Proposals for missing clinical training areas were reviewed and narrowed down into 23 distinct training areas before they were considered for inclusion into the refined list of training areas.

New additions to the clinical training areas are **regulation on health technology assessment**, **repurposing**, and **operational aspects of clinical trials**.

New training areas included under non-clinical and quality categories are **non-clinical requirements for paediatric trials** and **quality requirements for combination products**.

Establishing clinical dose was merged with **pre-clinical studies to support first in human (FIH) study** under non-clinical training areas.

Additionally, based on feedback received, a new category of *multidisciplinary clinical trials training areas* emerged in addition to the three existing areas (clinical, non-clinical, quality). It includes training areas such as **general regulatory/medicinal product EU legislation training**, 'good practice' guidelines and regulations (**GxP)** training, training on **advanced therapy medicinal products (ATMPs), patient and public involvement** as well as more *specialised* ones, such as training on **clinical trials regulation (CTR)**, **medical device regulation (MDR) and in vitro diagnostics regulation (IVDR),** training on **methodology/statistics/study design** and training on **combination products**. Details on all refined training areas accompanied by relevant learning outcomes can be found in *Table 9.*

Accessibility of clinical trials training

As *Table 7.* indicates, the biggest challenge in accessing training is finding it, as 30% of all respondents indicated that they struggle with locating relevant training. The other commonly recognised challenges reported are finding training for continuous education (18%), lack of time (19%), and lack of resources (15%). It is also seen that there are no significant differences between the academic sector and SMEs in accessing relevant training, as they are affected by same challenges in a very similar frequency.

Table 7. Challenges in accessing relevant training

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

In free text entries of the survey, respondents further specified that the current volume and dispersion of training across the websites of many training providers and regulatory bodies make it difficult to locate relevant, high-quality training. Additionally, the high prices of training were also highlighted several times as an issue both in the academic sector and SMEs. Next to highlighting training access issues, respondents also shared that consolidating existing (free) clinical trials training in a central location and making it easily searchable would improve their situation.

Regarding training format, the respondents indicated that they prefer training to be conducted online, either via interactive webinars (40%) or online training modules (35%). Still, around a quarter of respondents (24%) find in-person seminars favourable as indicated in *Table 8.* Other

training formats that were suggested were summary documents and large manuals that could be used for reference beyond the initial training window.

Table 8. Adequacy of non-clinical and pharmaceutical quality training areas

	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%)

Additionally, respondents shared that the format of the training should depend based on their content and length: short trainings should be focused on one topic and held online, meanwhile trainings spanning multiple topics are more useful when conducted in-person. Several respondents also noted that training is often too the oretical and lacks a more interactive and practical teaching approach. The use of (positive and negative) examples, simulations of scenarios, or case studies, as well as critically analysing them and highlighting areas of non-compliance were highly requested to be included in future training. It was also highlighted that sharing training recordings, FAQs, document templates and other short informational material is very valuable for stakeholders with limited time to attend training, such as medical doctors.

Beyond training accessibility, many respondents found that clinical trials training needs to be more tailored to the user profile to meet their training needs. Currently a lot of training is perceived to be one-size-fits-all favouring larger companies, and therefore less suitable for the academic sector and SMEs. Therefore, respondents highlighted the need for more tailored training based on the organisation type and role, as well as more localised trainings.

Clinical trials training areas and associated learning outcomes

Table 9. Clinical trials training areas and associated learning outcomes (note: newly identified training areas are marked in yellow.)

Clinical	Non-clinical	Quality	Multidisciplinary
Clinical study protocol and report Understand structure, requirements and content of the clinical study protocol and report - ICH M11 and E3; identify relevant data to build a complete and informative report.	**Alternative approaches to animal model - 3Rs** Understand principles of replacement, reduction, and refinement in animal research.	**EU legal framework and national implementation of Good Manufacturing Practice (GMP), focusing on quality** Identify GMP requirements applying to the manufacturing of medicinal products in different phases of development; GMP for atypic biologicals and ATMPs.	**Advanced therapy medicinal products (ATMPs)** Understand pre-clinical and clinical requirements but also specific manufacturing requirements for imported material in support of ATMPs.
Declaration of Helsinki Understand ethical principles in conducting clinical trials.	**Basic principles of Good Laboratory Practice (GLP)** Understand how GLP principles can affect the reliability of study results.	**Quality requirements for investigational medicinal products (IMPs)** Understand requirements for vaccine and related products manufacturing; requirements for biosimilars	**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.
General Data Protection Regulation (GDPR) Understand the requirements for data protection.	**CTCG recommendations related to contraception and pregnancy** Understand and apply different risk categories for the early stages of pregnancy.		**Combination products** Understand requirements on substances and qualified suppliers for drug device combination products.
Good Clinical Practice (GCP)	**Non-clinical requirements for paediatric trials**		**GxP compliance**

Clinical	Non-clinical	Quality	Multidisciplinary
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.	Understand pre-clinical requirements and need to perform juvenile animal studies to support paediatric clinical trials.		Understand relationship between GLP, GCP, GMP and GVP, interfaces and the impact of non-compliance.
Operational aspects of Clinical trials Best practices and training for Legal issues (i.e. Informed Consent, contracts), Trial and Site organisation, implementation of a Quality management system.	**Pre-clinical studies to support first in human (FIH) study** Gain awareness of the regulatory requirements for FIH trials. Understand relevance of results obtained for clinical use, particularly for toxicity predictions for which no clinical data are expected; how animal studies inform human dose selection; the importance of the minimal anticipated biological effect level in addition to the no observed adverse effect level; the role of clinical pharmacology and dose escalation in early phase trials; regulatory and ethical considerations in dose selection. Learn about assessment of non-clinical data in submission for clinical trials; extent and type of preclinical		**Medical Device Regulation EU No 2017/745 (MDR) and In vitro Diagnostics Regulation EU No 2017/746 (IVDR)** Understand aims and scope of the regulation, including the Commission Implementing Decision (EU) 2019/1396.

Clinical	Non-clinical	Quality	Multidisciplinary
	studies required by regulatory authorities to initiate FIH trials.		
Repurposing Understand pathways, requirements and eligibility criteria for repurposing of authorised medicines, repurposing framework.			**Methodology/Statistics/Study design** Understand Data Management practices; Design of clinical trials, including optimisation of personalized medicine trials, early phase trials and platform trials; Statistical considerations such as improvement of statistical power; Strategies for validation of biomarkers; Implementation of PROMs; Role of Real-World Evidence.
Safety reporting and pharmacovigilance Understand how to describe pharmacovigilance management strategies, safety reporting, and preparation of safety related documents / better safeguard patients' safety, XEVMPD.			**New technologies** Learn how new technologies, such as AI, can be leveraged in support of science.
Use of the Clinical Trials Information System (CTIS)			**Patient and public involvement** Understand how to conduct meaningful and effective patient and

Clinical	Non-clinical	Quality	Multidisciplinary
Understand structure, content and process of Clinical Trial Application and the CTIS.			public involvement in clinical research.
			Essential records Understand scope and content of essential records, such as investigational medicinal product dossier and investigator's brochure.
			Scientific guidelines Understand aims and scope of relevant guidelines in the life cycle of medicines development, including design and conduct of clinical trials.
			Regulation on health technology assessment EU no 2021/2282 (HTAR) Understand the aims and scope of the regulation, including requirements for developers, Joint Scientific Consultation (JSC), Joint Clinical Assessments (JCA).

Conclusion and next steps

Based on the survey results outlined in section 3, and the feedback from the EMRN regulatory assessors described in section 2.1, researchers in both the academic sector and SMEs appear to have similar training needs across a range of clinical trials topics.

Training on the **implementation of the CTR, CTIS, GCP** as well as **safety and pharmacovigilance** were the clinical related areas identified as most important for these stakeholders, as they have the biggest impact in their daily work. In contrast, as they work with non-clinical and pharmaceutical quality topics less frequently, those topics are of lower importance but still relevant to have a good overview of. Consequently, these target groups have more awareness of training regarding clinical topics compared to the other two categories. The survey also highlighted that more effort should be made to **update and promote** training on the **application of scientific guidelines, development of the clinical study report** and the **application of General Data Protection Regulation (GDPR)**.

Using this input, the provisional list of clinical trial training areas (and associated learning outcomes) has been further refined and enriched. New training areas were identified across all three previously established categories (clinical, non-clinical, and pharmaceutical quality), as well as in a new multidisciplinary category. The complete table of clinical trials training areas can be found in *(Table 9.)*.

In terms of access, both the academic sector and SMEs encounter the same **challenges** in accessing relevant trainings, the most frequent challenges being **finding relevant training**, **lack of training for continuous education, lack of time, and lack of resources**. More specifically, they named the volume and diverse source, as well as the high cost of training as barriers to access, and would like to access training provided in a central location. Additionally, **online training** (both interactive sessions and pre-made modules) was considered the **most attractive training format**, although in-person seminars should be considered for longer sessions that aim to cover several topics. Training organisers were also encouraged to include more interactive and practical elements into clinical trials training, such as critically analysing examples, case studies or simulations. Finally, the **need for more tailored training** was highlighted, as differences between organisation types and roles impact the learning experience and later application of practical knowledge.

ACT EU Priority Action on clinical trials training will proceed to mapping and signposting of the most important clinical trials' related training needs on ACT EU's website. The ACT EU Multistakeholder platform and EMRN will be consulted during this activity. Ongoing training initiatives within and outside of the EMRN, such as 'Supporting the increased capacity and competence building of the EU medicines regulatory network (IncreaseNET)' and World Health Organisation's global action plan for clinical trial ecosystem strengthening will also be leveraged. Ultimate aim is to make better targeted and easily accessible clinical trials training available to researchers in the academic sector and SMEs in support of ACT EU's vision for better, faster, more impactful clinical trials in the EU.

List of acronyms

ACT EU	Accelerating Clinical Trials in the EU
ATMP	Advanced Therapy Medicinal Products
CTA	Clinical Trial Application
CTCG	Clinical Trial Coordination Group
CTIS	Clinical Trials Information System
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
FIH	First-in-human
GCP	Good Clinical Practice
GCP IWG	Good Clinical Practice Inspectors Working Group
GDPR	General Data Protection Regulation
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
MAA	Marketing Authorisation Application
SME	Micro-, Small- and Medium-sized Enterprises
SMF	Site Mater File
TMF	Trial Master File

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Clinical trials training needs – survey to academia and SMEs

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