20 December 2022
EMA/42033/2023

Accelerating Clinical Trials in the European Union (ACT EU)

Priority Action 10: Training strategy

Sent for comments to ACT EU co-leads	30 September 2022
Sent for comments to ACT EU matrix	18 November 2022
Adopted by ACT EU Steering Group	20 December 2022

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List of Acronyms

Acronym	Explanation
ACT EU	Accelerating Clinical Trials in the EU
CRO	Contract Research Organisation
CSR	Clinical Study Report
CT	Clinical Trial
CTIS	Clinical Trials Information System
CTTI	Clinical Trials Transformation Initiative
DCT	Decentralised Clinical Trial
EC	European Commission
EMA	European Medicines Agency
EU NTC	EU Network Training Centre
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HTA	Health Technology Assessment
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IMI	Innovative Medicines Initiative
ITF	Innovation Task Force
IVDR	In Vitro Diagnostic Medical Devices Regulation
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
NCA	National competent Authority
PA	Priority Action

Acronym	Explanation
SME	Micro, Small and Medium-sized Enterprises
TMF	Trial Master file
WHO	World Health Organization

Scope

This paper sets out the overview of the Priority Action 10 of the EU clinical trials transformation initiative: Accelerating Clinical Trials in the EU (ACT EU). The implementation of ACT EU will contribute to delivering the Network strategy to 2025 and the Commission Pharmaceutical Strategy.

The overall aim of Priority Action 10 is to deliver a **clinical trials curriculum, with a particular focus on building capacity in all aspects of drug development and regulatory science**. The target audience are Clinical Trial sponsors/investigators & Marketing Authorisation Applicants/Holders, Authorities (e.g. regulatory authorities, Ethics committees) and members of the public. Specifically, Priority Action 10 will "Deliver a **clinical trials training curriculum** including modules on drug development and **regulatory science** with links to universities and SMEs (serving as an **educational 'ecosystem**').

The regulatory system needs rapid **access to appropriate expertise** to ensure adequate, fit-for-purpose and effective regulation so the latest scientific and technological knowledge can be built into medicines development where it benefits public health. This requires close collaboration on an international level with academics, research centres and infrastructures to ensure that such expertise is present or can be built in the ongoing dialogue between regulators and developers. In the absence of the required expertise there will be a need to identify **training needs and to source / develop training to meet these needs**.

The curriculum aims to increase scientific and regulatory knowledge and maintain, as well as further improve, the quality of clinical trials in the EU / EEA, their assessment and supervision during the trial life cycle. It will train sponsors/investigators on new methodologies and guidance in order to collect reliable and robust data which are fit for regulatory decisions/licensing submissions. This work will bring together knowledge from across various stakeholders within the EU, therefore contributing to further alignment in the assessment of clinical trials in the European Union.

This Strategy Paper will clarify relevant terms and set out a strategy how the overall aim of Priority Action 10 can be achieved. The paper includes high-level objectives, organisational aspects to be fulfilled within the timelines provided by the ACT EU multi-annual Workplan 2022-2026[1].

[1] https://www.ema.europa.eu/en/documents/other/act-eu-multi-annual-workplan-2022-2026_en.pdf

Objectives

The objectives for this Training Strategy set out a strategy to fulfil the overall ACT EU[2] objectives 1, 2 and 6 related to training. In particular, the following items are of relevance to Priority Action 10 with the most relevant aspects highlighted in bold:

ACT EU objectives	
1.	Optimise the EU environment for clinical research in Europe, whilst maintaining high-level participant protection, data robustness and transparency, by: a) Strengthening leadership and coordination on clinical trial authorisation and execution. b) **Optimising ethical oversight and further integrate ethics committees into the clinical trial and medicines regulatory lifecycle**. **c) Supporting the conduct of large-scale multinational clinical trials with broader geographical scope.** d) Reducing administrative burden and **increasing efficiency.**
2.	**Strengthening clinical trials that deliver decisional evidence for unmet medical needs, rare diseases, and on vaccines and therapeutics for public health crises and pandemics, ensuring support for HTA bodies as well as for academic and SME sponsors.**
6.	**Build capacity in all aspects of drug development and regulatory science through, amongst others, research collaboration and training with academia**.

In addition, objective 4 of the ACT EU strategy paper can indirectly be supported through this Priority Action 10, which **contributes to developing competencies in designing and executing trials** that subscribe to patient-oriented medicines development.

> 4. Engage all stakeholders to proactively deliver inclusive patient-oriented medicines development and delivery across populations.

As a direct consequence of the aforementioned objectives, the implicit objectives of a **better understanding of training needs** *(of those involved in the design, execution and authorisation of clinical trials)* and **better knowledge-sharing** have been identified during the initial analysis phase.

Looking more closely at what is encompassed in this Priority action (and definitions behind):

To develop a '**clinical trials training curriculum**' an inventory of training needs must be created in a first instance. For certain training needs a dedicated curriculum will be developed, whereas for others

[2] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/accelerating-clinical-trials-eu-act-eu-delivering-eu-clinical-trials-transformation-initiative_en.pdf

already existing training modules will be compiled. An example of a dedicated curriculum is the Big Data Curriculum where modules will be developed via multiple framework contracts, and one of them is in the field of clinical trials.[3]

The work will also comprise the compilation and curation of already existing modules that may not have been developed within the EU regulatory network. Those modules need to be in line with the training needs and be subject to a quality management system which is yet to be established.

- '**Regulatory science**' refers to the range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine.[4]
- '**Educational ecosystem**' is understood as a working model or sustained system for the development and maintenance of trainings that will be made available to stakeholders and its content serves specific target audiences. It includes bi-directional interactions with (key) stakeholders and refers to a continuous development cycle.

Definition of Target Audience, preliminary review of target audience priorities and content of interest

In considering the target audience, a number of stakeholders that were identified based on existing work carried out under ACT EU.

Taking account of the wide range of stakeholders involved in the design, execution and authorisation of clinical trials, and the potential interest / need of all these stakeholders in training (i.e. potential target audience for training provided through the curriculum), a review exercise was carried out to consider the needs / interest areas of all stakeholders and to propose a prioritisation for addressing training needs through the curriculum / inventory. A list of these stakeholders and their training needs / areas of interest can be found in the appendix. It should be noted that this list and its prioritisation are restricted to the training needs.

The Target audience for the curriculum is defined as those stakeholders for which trainings will be developed or compiled.

Initial activities in the development of the training curriculum will include **clear identification of those target audiences** with (timelines for) compilation of relevant existing and planned training to meet their training needs and putting forward process and governance for development of any new training required.

Recognising that curriculum topics may be of broad relevance and interest for all stakeholders and specific for one or two of them, and also recognising the need to manage expectations, it is proposed, as a general principle, to start with a narrow focus and then to broaden the activities over the course of the project. Specifically, this means that the inventory of training needs **starts with the EU regulatory network (NCA, Ethics Committees, EMA) needs and then extends to needs of**

[3] Details regarding the modules to be developed can be found here: https://etendering.ted.europa.eu/cft/cft-display.html?cftId=10491
[4] RSS 2025: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

sponsors and investigators. If possible, within the timeframe of the project, other stakeholders will also be included. It is also acknowledged that the knowledge varies across and within different stakeholders, so that trainings need to be adapted and updated to meet the individual knowledge level.

This approach is in line with ongoing activities to develop a Big Data Curriculum, including modules on Data Science, Pharmacoepidemiology, Biostatistics and Clinical Trial Methodologies, primarily intended for the EU Regulatory Network, including EMA staff and National Competent Authorities, with selected modules to be opened to academics.

Review of existing training material/curricula

Much work has been carried out over the last few years on the development of training in the clinical trials area. In addition, there are several ongoing initiatives to develop new and relevant training in this important area, including on the implementation of the Regulation on clinical trials (EU) No. 536/2014 and its implementing acts. Activities to be carried out under the Clinical Trials Curriculum will include the compilation and curation of these existing training materials, as well as the identification of areas where no suitable training is available. The following, non-exhaustive list gives examples of trainings:

- Several training events were organised in in the context of the EU Network Training Centre (EU NTC) Training Curriculum on Clinical Trials, with the involvement of the previous Clinical Trials Facilitation Group. A number of these were recorded and are available to the Network on the EU NTC Learning Management System platform.
- In the context of the Clinical Trials Regulation EU No 536/2014 (implemented in January 2022) and the requirement for submission of clinical trial applications through a single-entry portal, an online modular training programme was developed to help **clinical trial sponsors, National Competent Authorities, Ethics Committees, European Commission and EMA staff** prepare for using the Clinical Trials Information System (CTIS). The training programme consists of several modules, (including modules specific for sponsor users and NCA users) covering the full lifecycle of clinical trial submission, authorisation and supervision. Link to the Training catalogue on the use of the CTIS can be found here: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme
- A Big Data Curriculum is under development, including modules on Data Science, Pharmacoepidemiology, Biostatistics and Clinical Trial Methodologies, intended for the EU Regulatory Network, including EMA staff and National Competent Authorities, with selected modules to be opened to patients, healthcare professionals and academics
- As part of the EU4Health Joint Action Safety Assessment Cooperation and Facilitated Conduct of Clinical Trials (Safe-CT), under Priority Action 9, a training curriculum for pharmacovigilance (safety) assessors in clinical trials will be developed.
- The Strengthening Training of Academia in Regulatory Science (CSA STARS) Initiative ended in 2022 and published a core and a comprehensive curriculum along with recommendations.

- The EUPATI platform and EATRIS programme provide a variety of courses on medicines' research & development and patient engagement.
- IMI Pharma Train was a programme that evolved into the PharmaTrain Federation
- EURORDIS also provide training for rare disease patients on clinical trials and medicines development.

Approach to delivery of curricula

Priority Action 10 foresees the delivery of a **Clinical Trials curriculum** (to contribute to the achievement of the objective to build capacity in (all aspects of) drug development and regulatory science **through** (amongst other means) **training with and for academia.**

As indicated in the high level workplan for PA10: An overarching strategy and needs and gap analysis will serve as the basis for the development of the curriculum. Subsequently a comprehensive compilation of modules covering relevant areas to clinical trials enablement will be rolled out.

Activities within Priority Action 10 foresee: Framework contracts for Big Data training curriculum; launch of modules in Data Science, Pharmacoepidemiology, Biostatistics & Clinical Trials; training gap analysis; Dialogue on training needs with academia and SMEs – and compilation of modules for different target audiences.

Regular interactions with other Priority Actions will be needed for input, alignment, and exchange; for instance, in PA08 guidance on methodologies will be developed, PA04 works on aspects of GCP modernisation, and PA09 on pharmacovigilance/safety.

The Clinical Trials Training Curriculum (framework) will:

- clearly specify the intended **target audiences** for the Curriculum (Authorities (NCAs, Ethics Committees, EMA), Clinical Trials sponsors and Marketing Authorisation (MA) applicants / holders, with focus on Academic sponsors and SMEs)
- Provide a comprehensive overview of **recommended areas of training**, (in drug development and regulatory science relevant to clinical trials area) based on a **Training needs analysis** (looking what is required for each of the identified target audiences). Such training needs analysis will take account the outcome of other initiatives / surveys of relevant target audiences (e.g. STARs Initiative). It is assumed that certain training modules will be relevant to all target audiences, whilst others will be specific to an individual target audience.
- Interact with the main target audiences outside of the Regulatory Network (Academic Sponsors, SMEs).
- Set out the high-level **goals for such training**, and what it is intended to achieve.
- Based on the overview of recommended areas of training, develop a comprehensive compilation of (existing) modules covering relevant areas to clinical trials. This will include the CT modules developed under the Big Data Curriculum. This may include "external" training

modules developed by academia / training organisations. We will also build upon previous initiatives.

- For identified needs for training, where there is currently no existing training, description of process, responsibilities, timelines for developing such training, validation and quality control of materials developed. (Consideration of how academia might be involved in developing such training).
- A similar approach will be needed to review existing materials to ensure that up-to date and trainings of high quality are recommended.
- Provide an overview of governance behind curriculum and process for maintenance (regular assessment of training needs, curriculum and trainings).

As a general it is proposed to follow the Curriculum Framework developed under the EU Network Training Centre.

Benefits and Risks

There are several benefits and risks associated with this project, and the following section will be an attempt to list them as far as they are foreseeable. Benefits include

- a unified approach towards training,
- multi-disciplinary collaboration,
- better translation of research into product development by strengthening the collaboration and interactions across the regulatory network and beyond, to ensure key stakeholders are equipped with the right competencies to face the rapidly evolving clinical trials landscape in regards to innovation, digitalisation and big data, and
- avoidance of duplication of work.

Potential risks include the following:

- Lack of resources and capacity,
- dependency on external parties which may affect the quality and timely delivery of training modules,
- stakeholders may prefer different approaches or ways of interaction,
- the training needs may differ across member states,
- there may be restrictions of issues with dissemination depending on the chosen platform.

In order to mitigate risks, the approach will be to have regular interactions with the ACT EU programme team to highlight, discuss and resolve potential issues. Agreement needs to be sought on quality criteria for external providers and how the maintenance of modules is ensured. In terms of dissemination, the aim is to focus not only on a single platform, but rather have at least one platform as a backup solution in case of shortfalls.

Appendix

Table 1: Listing of stakeholders with assigned priorities and content that is relevant for their training

	Stakeholder	**Priority** (Low, Medium, High)	**Content** Which elements are relevant for them? What should they be trained in?
Clinical Trial sponsors/ investigators & Marketing Authorisation Applicants/Holders	Academia acting as CT sponsors	High Priority	Upskilling their resources Awareness on guidelines (including ICH), risk management plans, clinical trial design, possibility to request scientific advice, interaction with EU Regulators (including ITF), preparation of CTA, use of CTIS, obligations under CTR during CT conduct, GCP principles, obligations on maintaining the TMF, submission of trial results. Understanding of GDPR principles. Understanding marketing authorisation process CSR obligations for MAA/MAH, as applicable.
	SMEs	High priority	Upskilling their resources As above with academic sponsors, also good understanding GCP principles considered important for software development, obligations on maintaining the TMF, understanding of GDPR principles. CSR obligations for MAA/MAH, as applicable.
	Investigators and their team [including future, past]	High priority	Competencies are needed for running the trial at the site, GCP trainings, facilitate the conduct of the trial, [safety] reporting obligation, obligations on maintaining the

			TMF, additional training needs to be provided by the investigators
	Large pharma & CROs [e.g. companies as sponsors, MAAs/MAHs, European Associations representing pharma/CROs]	Low Priority	Training on sponsors' obligations are considered low priority at this stage.
Authorities	National Competent Authorities (NCA)	High priority	Training on new trends and work on clinical trial relevant topics e.g.: DCT, CCT, safety, interplay with IVDR (in particular companion diagnostics) and medical devices, training on new regulations, assessment and supervision of clinical trials, understanding of GDPR principles, scientific aspects how NCAs collaborate between them for individual trials, methodology of clinical trials
	Ethics committees	High priority	upskilling their resources: Clinical Trials Regulation, GDPR, clinical trial design, monitoring of participants, reporting obligations
	EMA	High priority	
	European Commission	Low Priority	They should be offered all trainings; legal and scientific staff, they should have access, a dedicated training may not possible
	International Organisations such as WHO, FDA, CTTI	Low priority	Keep them informed
	Payers/HTA	Low priority	Keep them informed
	Funding bodies e.g. IMI	Low priority	Keep them informed
	Investors: Private equity	Stakeholder group not targeted	

Members of the public	Healthcare professionals [not involved in Clinical Trials]	Medium priority	How to find/interpret clinical trials
	Trial participants [includes patients and healthy volunteers; prospective, existing, and past participants]	Medium priority	Raise awareness about their rights, where they benefit from trials, learning about CT terminology and get understanding on basic principles of trial design. Explain how they can have access to trial results after completion of the trial.
	Patients [in general]	Medium priority	There is a lot of material already existing. Raise awareness about their rights
	Transparency and clinical trials campaigners	Low priority	To be further discussed
	Media	Low priority, stakeholder group may not be directly targeted	To be further discussed