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Version 1.0

ACT EU Training curriculum for clinical trial assessors

Summary of gap analysis

Introduction

The Priority Action on training of the Accelerating Clinical Trials in the EU (ACT EU) initiative aims to deliver a clinical trials training curriculum for the different stakeholders as indicated in the strategy paper.

As part of this work, an inventory of training needs was initiated with the stakeholder group of regulators (National Competent Authorities, Ethics Committees) involved in the assessment of clinical trials applications submitted under the Clinical Trial Regulation (EU) No 536/2014 (CTR).

The needs will then be matched with available trainings and potential gaps identified. It is planned to carry out similar exercises for additional stakeholders, especially those which were assigned high priority as per the strategy paper.

Approach

As an initial step in the delivery of a training curriculum for clinical trial assessors, the template for the draft assessment report part I for clinical trials applications submitted under CTR was used as the basis for the development of an inventory of training needs.

A call for volunteers to define the needs for regulators, based on the template, was launched via the Clinical Trials Coordination Group (CTCG). Subgroups were established with experts on the following domains: Quality, Non-clinical and Clinical/Regulatory to address training needs.

To complement the identified needs with available trainings:

i. A search was performed in the Learning Management System (LMS), a platform that makes trainings available via the EU Network Training Centre (EU NTC), for potential training material.

ii. EU NTC training champions at National Competent Authorities were contacted and asked for available internal trainings at their agency.

Findings

A total of 48 specific training needs were identified by the CTCG experts and categorised into:

1. General overarching training;
2. Quality;
3. Non-clinical; and
4. Clinical/Regulatory.

The search in the EU NTC LMS revealed 82 potential trainings in the area of clinical trials. However, the majority of these trainings are focused on marketing authorisation and not on clinical trial assessments.

Responses from the training champions on the availability of training in the identified areas of need, showed that internal trainings were primarily on-the-job trainings, combined with internal mentoring. Available internal training materials were also usually only available in the national language. For these reasons, the availability of existing training materials at National Competent Authorities, which could form part of a clinical trial curriculum for regulators, is limited. National training champions further highlighted in their responses that mentoring by senior experts is important, and that trainings through case studies are required.

The full report contains a summary based on four tables where the identified needs and the available trainings are mapped against each other.

Recommendations and next steps

There were a number of training needs identified which are currently not fulfilled or which seem to be only partly addressed. Three recommendations are proposed to close the gaps:

First, there is the possibility that some training needs may be addressed in the future by the Big Data curriculum which is a self-standing project in the Big Data workplan.

Second, the new initiative EU4Health Joint Action IncreaseNet on Supporting the increased capacity and competence building of the EU medicines regulatory network has two work packages on training (WP5 and WP7) which seem relevant. ACT EU, together with CTCG, will explore the possibilities to interact with the JA IncreaseNet in order to join efforts in addressing assessors' training needs in clinical trial topics and to avoid any duplication and overlap of initiatives in the European Regulatory Medicines Network (ERMN).

Third, as a future step, it is proposed to select a number of priority topics where there is common interest from clinical trial assessors and academic researchers or other parties, to cooperate in the development of training as a follow up to the EU funded Coordination and Support Action on Strengthening Training of Academia in Regulatory Science (CSA STARS) and the ACT EU Priority Action that delivers support to non-commercial sponsors in multinational clinical trials.

There is also the possibility that specific training needs are addressed by a National Competent Authority. Sharing any such training via the EU NTC is encouraged.

This work can be seen as a first step to elaborating a clinical trials curriculum. ACT EU also brings in stakeholders to inform them of trainings needs and offerings. It may also be a good opportunity to link this activity with the Multi-stakeholder Platform. In the context of identifying new needs which arise in this area and to fill the gap, the clinical trial training curriculum will be updated regularly.