Outline of the learning curricula and competency frameworks

MS 5.2: Summary Document

WP5 – Delivery of Training Materials

Author(s):

Naomi Beard – HPRA (IE)

Date: 03.01.2025

Dissemination level: Public

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

Contents

Introduction

The aim of the IncreaseNET Joint Action (JA) is to increase the necessary regulatory expertise and competences in the European Medicines Regulatory Network (EMRN) and to develop additional capacities to face challenges represented by upcoming scientific developments.

As part of this work, a learning needs assessment was done that identified high priority learning needs in the European Medicines Regulatory Network (EMRN). This identified a number of subject areas requiring training development: ATMPs, Biological Active Substances, Clinical Trials, Combination Products, Modelling & Simulation, Pharmacokinetics, and Statistics.

Work Package 5 (WP5) plans to develop training in the above areas via a novel approach that utilises a core learning design team to lead the process. The first phase of this training development process (Phase 1) and its results are summarized in this report. To access the full report please click here.

Methodology

Considering the above identified high priority learning needs, time and resource constraints for training development, IncreaseNET WP5 decided to develop short, focussed curricula addressing each individual learning need. The developed curricula focus on real-world skills and knowledge, and how the learner will apply these in their assessment work.

IncreaseNET WP5 developed a novel approach to the training development process, with one of the key elements being incorporation of a learning design team (LDT). The LDT is made of up two learning design professionals who run the process and support and co-ordinate topic experts (TEs) throughout.

Bespoke template training analysis and design documents were developed and utilised throughout Phase 1:

- Document 1: Learning Analysis Document: A tool to aid TEs in determining the module title, target audience, a high-level module description, key topics for inclusion, and overarching training aims.
- Document 2: Learning Outcomes and Objectives Document: A tool to aid topic TEs in developing an aligned set of practical outcomes and objectives for the module. This promotes an agreed, unified approach to the training module that will facilitate rapid training development in Phase 2.

Topic experts (TEs) were sourced from the EMRN to comprehensively scope each piece of training. Small subgroups per topic area were developed to work as a collaborative unit to draft the scoping documents for each learning need.

To ensure that the scoping documents for each piece of training were comprehensive and technically accurate, peer review was undertaken by additional topic experts (generally from a working party/group/committee).

Results

24 different modular (learning need) frameworks have been developed. This is a culmination of the scoping work done by TE groups throughout Phase 1 and contains the learning outcomes and learning objectives that can be considered focussed curricula. These frameworks demonstrate an aligned and agreed approach to the content and practical aims of each module.

Table 1: List of modular frameworks per area of learning need

Learning Need	Module(s)
ATMP	Requirements for Investigational ATMPs
Biological Active Substances	Characterisation and Control Strategy of Recombinant Proteins
	Comparability and Statistical Approaches to Demonstrate Drug Comparability
	Assessing Analytical Procedures for Release and Characterisation
	In vitro and in vivo analytical methods
Clinical Trials	CTCG Best Practices throughout the CT Lifecycle: Specific Best Practices
	How to Write a Draft and a Final Assessment Report for a Clinical Trial Application
	General Introduction to Different CT Types and Designs
	Specific Clinical Trial Types and Linked Case Studies
	EMA and ICH Guidelines: How to Apply Them
Modelling and Simulation	Introduction to Model-Informed Drug Development
	Introduction to Model-Informed Dose Finding/Selection
	Regulatory Assessment of Model-Informed Dose Finding and Selection
Pharmacokinetics	Pharmacokinetics for Assessors (Module 1): Assessment of Abridged Applications
	Pharmacokinetics for Assessors (Module 2): Assessment of New Active Substances
Statistics	Intro to Biostatistics 1 – Descriptive statistics and the principles of hypothesis testing
	Intro to Biostatistics 2 – Basic and/or common statistical tests
	Intro to Biostatistics 3 – Most common regression approaches in biostatistics
	Phase I trials: Moving from traditional approaches to dynamic modelling approaches including Bayesian approaches

	Design of experiments for confirmatory trials
	Adaptive trial design 1 – Intro and group sequential design
	Adaptive trial design 2 – interim analysis to drop arms, change sample size or population
	Platform trials, how to detect threats to outcome robustness?
	Comparability and Statistical Approaches to Demonstrate Drug Comparability

Conclusion

The developed modular frameworks will be a practical and useful tool for both Phase 2 training development and creating standardised practical curricula that can potentially inform EMRN competence development in the future.

Phase 1 of the IncreaseNET training development process adopted a novel approach that has not been trialled in the EMRN to date. It attempted to formalise the training scoping process, transfer responsibility for co-ordination and facilitation of decision-making to a core LDT and embed consistent support and guidance for TEs throughout.

Feedback from TEs has been overwhelmingly positive, with the majority stating that the support and guidance from the LDT gave them confidence to partake in this novel process. In addition, TEs state they now understand the importance and complexities involved in scoping a piece of learning prior to moving into its development.

The LDT is looking forward to starting Phase 2 of the training development process in 2025 and the resources and learnings that will come from this.