

## IncreaseNET: A One-Year Progress Overview

Since its launch on January 1, 2024, IncreaseNET has been dedicated to strengthening collaboration, knowledge-sharing, and training within the European Medicines Regulatory Network (EMRN). Over the past year, the project has made significant strides in developing innovative training programs, analysing learning resources, and mapping the capacities and processes of National Competent Authorities (NCAs). By leveraging existing resources and fostering new concepts, IncreaseNET continues to build a sustainable framework for regulatory training and professional development.

### Highlights:

- Actively running and evolving **On-the-job learning and coaching pilot program**.
- **NCA Capacity Survey** to map and determine NCAs' capacities and skills conducted.
- Realization of a **report on analysis of gaps in learning possibilities in EMRN**.
- Development of **Learning Methodologies** and **Learning Curricula** for the education of regulatory assessors.
- Development in **assessment of NCAs' innovation support**.

### Project Kick-off and Laying the Groundwork

The IncreaseNET kick-off meeting was held in Ljubljana on January 31, 2024, during which key tasks and activities were presented to project partners representatives and representatives of the European Commission, the European Medicines Agency (EMA) and the European Health and Digital Executive Agency (HaDEA).

To ensure successful implementation and management of the project, several tools were developed:

- **Administrative and Financial Manual:** Guides partners to operate in line with Grant Agreement rules.
- **Communication and Dissemination Toolkit:** Provides visual materials for project promotion.
- **Dissemination Plan:** Outlines guidelines for effective dissemination and communication of project activities.
- **Evaluation Plan:** Sets continuous monitoring and evaluation of the project's progress.
- **Quality Management Plan:** Defines quality requirements and establishes quality assurance and control measures.
- **Sustainability Plan:** Elaborates the operational approach and framework to ensure long-term project viability and integration.

### Leveraging Existing Resources

At the project's outset, existing training materials and other relevant documents were collected from consortium members. This effort culminated with a report summarizing the collected resources, which will serve as a foundation for developing further training materials for NCAs staff.

## Progress in Technical Work Packages

Several key milestones and deliverables have been achieved within the technical work packages:

- 1. Collaboration Plan with EU Network Training Centre (EU NTC):** The EU NTC is a platform that provides training for staff in the EMRN and is overseen by the EMA and Heads of Medicines Agencies (HMA). A plan was developed to define actions and processes for collaboration between IncreaseNET and the EU NTC throughout the project.
- 2. Report on analysis of gaps in the learning possibilities in EMRN:** To identify missing or incomplete training materials within prioritized learning areas in the EMRN, mapping of existing training resources against learning needs was performed. The report provides concrete findings, lessons learned, and recommendations to guide future training development within the IncreaseNET.
- 3. Induction Program for Newly Recruited Assessors:** An induction program was created to help new assessors start their employment effectively. The program consists of a series of regulatory-focused trainings, covering technical assessment skills and regulatory decision-making. The training is available through the EU NTC portal on the following [link](#) (access restricted to NCAs and EMA staff).
- 4. Report on Optimal Methodologies for Education of Regulatory Assessors:** Based on a literature review, survey, and focus groups, the most effective and current methodologies for educating regulatory assessors were outlined. This report will guide the development of new training materials within the project. The full report is available at this [link](#).
- 5. Outline of the Learning Curricula:** Areas of high-priority learning needs in the EMRN have been identified: ATMPs, Biological Active Substances, Clinical Trials, Modelling & Simulation, Pharmacokinetics, and Statistics. Topic experts (TEs) have been recruited from the EMRN, and dedicated TEs groups formed to create focused training curricula for each area. These curricula will serve as the foundation for the next phase: training development. The full report is available at this [link](#).
- 6. On-the-Job Learning and Coaching Program:** In collaboration with the Committee for Medicinal Products for Human Use (CHMP) and EMA, the project initiated a pilot on-the-job learning and coaching program. This program is designed to not only provide education on specific topics but also to prepare assessors for involvement in Centralised Procedures. Bite size videos describing the roles, responsibilities and process for involvement in the program are available through the EU NTC portal on the following [link](#) (access restricted to NCAs and EMA staff). Briefing packages with instructions and templates for each role have been developed and are continuously updated based on feedback from program participants.

7. **NCA Capacity Survey:** A survey was conducted to map and determine the capacities and skills of NCAs in various areas, as well as to identify potential resource needs and knowledge gaps. Preliminary results were presented in December 2024 at the HMA dedicated meeting on resourcing issues. Further dissemination of the results is planned for 2025.
8. **Inventory of existing processes for managing MNATs:** A review of existing processes for managing Multinational Assessment Teams (MNATs) was conducted to promote smooth and effective cooperation within these teams. As part of this work, up-to-date developed instructions, best practice guides, templates, and tools were revisited and clarified in a report, contributing to a better understanding of current practices.
9. **Criteria grid for assessing the impact of innovative technologies on NCAs organisation:** “Impact Assessment Chart” has been developed as a tool to provide a structured approach to evaluating how new technologies may affect various sectors of an NCA’s activities, with the aim to support NCAs in proactively addressing necessary organizational changes. The full document is available at this [link](#).
10. **Questionnaire on best practices in innovation support:** A questionnaire was developed to collect best practices from NCAs regarding innovation support activities. It aims to not only identify current activities but also explore future plans. The feedback analysis will aim to provide recommendations for enhancing innovation support across the network.

All documents and materials mentioned in the article are available on the restricted IncreaseNET SharePoint. NCA staff interested in accessing these resources should reach out to their IncreaseNET consortium representative for more information.

As it moves forward, IncreaseNET is well-positioned to drive impactful regulatory training and capacity-building enterprises. By shaping a more cohesive and adaptable learning framework for NCAs, IncreaseNET’s focus remains on equipping regulatory professionals with the tools and expertise necessary to navigate the evolving pharmaceutical landscape, ensuring that regulatory excellence across Europe is both maintained and advanced.