

## IncreaseNET: A Six-Month Progress Overview

Since its launch on January 1, 2024, the IncreaseNET project has been making steady progress, focusing on enhancing the capabilities and collaboration among European medicines regulatory authorities. In the first six months, the project has successfully established a strong operational framework and initiated several key activities that are pivotal for achieving its long-term goals. From launching training programs to conducting surveys that map the current landscape of regulatory expertise, the project has already reached significant milestones. Here's a closer look at what has been accomplished so far and the highlights of IncreaseNET's early journey.

### Highlights:

- Initiation of the **“on-the-job” learning and coaching pilot program**.
- Launch of the **NCA Capacity Survey** to map and determine National Competent Authorities' (NCAs) capacities and skills.
- Development of a **survey to collect NCAs' best practices related to innovation support**.
- Creation of an **induction program for new NCA assessors**.
- Completion of a **report on optimal methodologies for the education** of regulatory assessors.

### 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.

### 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 Content-Related Work Packages

Several key milestones and deliverables have been achieved within the content-related work packages:

1. **Collaboration Plan with EU Network Training Centre (EU NTC):** The EU NTC is an access-restricted platform that provides training for staff in the European Medicines Regulatory Network (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. **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, that should ideally be completed within the first six months of employment, 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).
3. **Report on Optimal Methodologies for Education of Regulatory Assessors:** A report was developed based on a literature review, survey, and focus groups, outlining the most effective and current methodologies for educating regulatory assessors. This report will guide the development of new training materials within the project.
4. **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 (as Trainee Assessor, Shadow Assessor or iRapporteur / iCoRapporteur) are available through the EU NTC portal on the following [link](#) (access restricted to NCAs and EMA staff).
5. **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. The results will be presented in Q4 2024.
6. **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.

The first half-year has laid a solid foundation for the IncreaseNET project, and the team looks forward to building on this momentum to further support the capacity and effectiveness of NCAs across Europe.