IncreaseNET: A Two-Year Progress Overview

The European Medicines Regulatory Network (EMRN) plays a central role in protecting public health by ensuring that medicines in Europe meet high standards of quality, safety, and efficacy. Rapid scientific and technological advances are reshaping the pharmaceutical landscape, creating new opportunities while also exposing knowledge and capacity gaps that can challenge timely and well-informed regulatory decision making. In this context, regulatory systems must evolve continuously to remain effective.

Since its launch on 1 January 2024, the **EU4Health Joint Action IncreaseNET** has made tangible progress in strengthening the EMRN by identifying gaps in capacity, competences, and frameworks, while developing targeted strategies to address them. By leveraging existing resources and initiatives, and fostering new concepts, **IncreaseNET aims to build a sustainable framework for regulatory training, professional development, and modern regulatory practice**.

HIGHLIGHTS

- A **comprehensive and structured project framework** has been successfully established through clear **coordination, evaluation, dissemination and communication structures**, securing successful implementation of project activities, effective collaboration among partners, and ensuring visibility and impact of the project.
- The project has delivered meaningful advances in identifying gaps and opportunities in regulatory training and capacity building, leading to the development of **structured learning approaches** and **modern training methodologies** tailored to both new and experienced assessors.
- In parallel, the **IncreaseNET on-the-job training and coaching programme** is providing practical learning opportunities and directly strengthening expertise across the network.
- Significant progress has also been achieved in **fostering collaboration between National Competent Authorities (NCAs)** and exploring more **efficient ways of managing workload**, including resource sharing and reducing duplication of effort.
- Engagement with academia and innovators has been actively approached, supporting the **integration of emerging scientific knowledge into regulatory practice**.

Overall, IncreaseNET is successfully building a **stronger, more connected, and future-ready regulatory network**, better positioned to address emerging scientific and regulatory challenges in Europe.

ADDRESSING KNOWLEDGE GAPS IN A FAST-MOVING SCIENTIFIC ENVIRONMENT

Recognising that continuous professional development is essential for keeping pace with an evolving scientific and regulatory environment, IncreaseNET has taken a strategic and comprehensive approach to strengthening expertise across the network, focusing on **identifying learning needs and enhancing training systems**.

From the outset, IncreaseNET has collaborated closely with the **European Medicines Agency (EMA) expert committees and working groups** and gathered input through **comprehensive surveys of NCAs** across Europe. This combined approach brought together different perspectives and real-world experience, providing a clear picture of current NCAs strengths and identifying areas where additional expertise is urgently needed. **Key priority areas are**: advanced therapies (ATMPs), biological active substances, clinical trials, modelling and simulation, pharmacokinetics, and statistics.

The analysis also revealed **common challenges in capacity development**, such as limited time for training due to heavy workloads, uneven distribution of expertise across NCAs, and difficulties in recruiting experts. In addition, approaches to identifying and addressing learning needs vary across the network, pointing to the need for a more standardised yet flexible framework.

From the start of the project, IncreaseNET joined forces with the **EU Network Training Centre (EU NTC)** to avoid duplication of efforts, make better use of existing resources, and ensure that training activities reflect real-world regulatory needs. Guided by a formal collaboration plan, this partnership also focuses on enhancing the usability and practical application of the EU-NTC Learning Management System (LMS) and exploring expanded learning opportunities through cooperation with external sources, such as academia.

IncreaseNET conducted a **detailed mapping of existing training resources** to support targeted development in priority areas. Drawing primarily on EU NTC and ICH (the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) training materials, and supplemented by NCA contributions, this assessment confirmed a solid foundation of high quality content. However, it also revealed uneven coverage across scientific domains, limited availability of advanced and specialised training, and inconsistent structuring of materials, which complicates alignment with identified learning needs.

Together, these findings provide a clear **direction for future action**: targeted development of advanced training, improved organisation and accessibility of materials, and stronger knowledge sharing across the network.

DRIVING CONTINUOUS LEARNING ACROSS THE EMRN

Building on these findings, IncreaseNET has established a modern, structured approach to regulatory training, evolving from initial concepts to a coherent portfolio of high quality digital learning material and a practical training programme.

A standardised methodology now underpins the development of all training modules, guiding the process from defining target audiences and learning objectives to content development, peer review, and digital delivery. This streamlined approach reduces the time required from experts while maintaining high standards of quality. It integrates scientific expertise with pedagogical design, supported by educational specialists and advanced digital tools, including AI, to ensure material is accurate, clear, and easy to follow. Training is delivered through **flexible, self-paced eLearning**, enabling learners to engage with the content according to their individual needs.

Substantial progress has been made in addressing gaps in priority areas and building capacity for content developers. Twenty training curricula have been identified for scientific topics, along with four "Becoming a Regulatory Trainer" modules. Scripting of seven training courses has already been completed, with six currently under development. **All IncreaseNET training materials are hosted on the EU NTC platform** (access restricted to NCAs and EMA staff) and will remain available beyond the end of the project.

To date, three **trainings** have been successfully **delivered by EMRN Experts**: the **Induction Programme for New Assessors**, providing a foundation in EU regulatory assessment; **E-Learning for EMRN Topic Experts**, supporting e-learning development and instructional design; and **Fundamentals of Biostatistics 1**, an introductory course for non-statistical assessors.

In parallel, IncreaseNET is expanding the EMRN training portfolio through **targeted collaboration with academia**, focusing on high-priority innovation topics. The first courses, covering Organ-on-Chip technologies and RNA therapeutics, are expected to launch in mid-2026. To support this, academic partners were selected through a public call to European universities and research institutes to **co-develop specialised e-learning modules tailored to regulatory needs**.

Recognising that effective learning is closely linked to practical experience, IncreaseNET has initiated **the first-ever programme within the network** to systematically integrate hands-on learning into assessor development. The **On-the-Job Training and Coaching Programme**, developed in collaboration with the Committee for Medicinal Products for Human Use (CHMP), the Pharmacovigilance Risk Assessment Committee (PRAC), and the EMA, places assessors in real assessment settings, where they gain practical insight while building confidence. It enables progression from introductory to more advanced responsibilities through flexible learning pathways. To date, more than 100 assessors from multiple NCAs have participated, demonstrating strong engagement across the network and the programme's value. Ongoing refinements focus on improving onboarding processes, managing time demands, and enhancing opportunities for direct interaction.

Collectively, these activities are shaping a **coherent and evolving training ecosystem** that **integrates structured learning with practical experience**. This approach strengthens capacity across the network and ensures that training remains relevant, sustainable, and responsive to emerging scientific and regulatory needs.

PRACTICAL APPROACHES TO RESOURCE OPTIMISATION ACROSS THE EMRN

Over the past two years, IncreaseNET has delivered a comprehensive assessment of how to **optimise regulatory resources across the EMRN**. This work combines insights from a **network-wide capacity survey** with **in-depth analyses,** drawing on input and experience from across the network, as well as discussions with key stakeholders. It reflects both operational experience and strategic priorities, while close collaboration with the **Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh)** ensures alignment with ongoing initiatives and real-world regulatory practice.

The analysis identified **key challenges affecting efficiency**, including unpredictable submission timelines, high administrative burden, uneven distribution of expertise across Member States, limitations in coordination mechanisms, varying quality of applications, and repeated assessment of the same data.

To address these challenges, IncreaseNET explored **practical measures to improve coordination and reduce avoidable workload** while maintaining assessment quality. The findings emphasise clearer expectations, proportionate and risk-based approaches, simplifying processes and better use of available expertise.

A key focus was on **strengthening collaboration** across the network. Existing approaches enabling experts from different NCAs to work together have proven valuable and could be expanded in a flexible and practical way. In this context, the feasibility of **extending the Multinational Assessment Team (MNAT) concept to Decentralised Procedures** was assessed, with a case-by-case approach identified as the most feasible option.

Reducing duplication of work is another priority, with analysis supporting reusing assessment outputs and improved information exchange between NCAs. This was illustrated through the exploration of the feasibility of **work-sharing in the assessment of bioequivalence studies**.

Overall, the findings favour **incremental and flexible improvements** over “one-size-fits-all” structural changes. **Building on existing tools and encouraging informal sharing practices** are seen as more effective than introducing complex new systems. Digital tools – including enhanced IT systems and emerging AI tools – are expected to play an important supporting role. Sustained collaboration across the network will be essential to ensure that these approaches remain practical, scalable, and aligned with ongoing changes in pharmaceutical legislation.

SHAPING AN INNOVATION-READY REGULATORY ECOSYSTEM

IncreaseNET promotes a regulatory environment in which **innovation support is embedded, visible, and delivered consistently** across the network. By strengthening early dialogue and coordinated action, it aims to reduce uncertainty for innovators while improving regulatory preparedness.

Building on existing European initiatives and projects, including the **EU Innovation Network (EU-IN)**, IncreaseNET consolidates and advances previously fragmented efforts into a more coherent EU-level approach. This reflects a shared commitment to accessible, consistent, and effective innovation support, with EU-IN acting as a key partner in shaping and implementing these activities.

Within this continuum, IncreaseNET supports the refinement of collaborative concepts, SNSA and PGRSA. **Simultaneous National Scientific Advice (SNSA)**, developed within EU-IN, has demonstrated its value by improving consistency and resource efficiency through coordinated multi-NCA advice, particularly at early development stages, and is now undergoing targeted refinements to enhance feasibility and sustainability. Similarly, **Pre-Grant Regulatory and Scientific Advice (PGRSA)**, initiated under the STARS project, is being further explored to integrate regulatory input earlier in the research lifecycle. IncreaseNET survey results indicate strong demand from academia for such early guidance, particularly in areas such as clinical trial design and data requirements.

IncreaseNET has conducted a **systematic mapping of innovation support practices** across the network. While organisational models vary, the findings show convergence around core practices, increased collaboration, stronger engagement with academia and SMEs (small and medium-sized enterprises), and the use of data-driven approaches.

Building on these insights, IncreaseNET has developed an Impact Assessment Chart to support proactive organisational readiness for innovation. This tool helps NCAs assess the operational implications of emerging technologies and reinforces the need to address innovation preparedness beyond scientific assessment alone.

These efforts are complemented by the IncreaseNET Innovation Toolkit, which provides practical guidance to strengthen early interaction between regulators, academia and experts. The toolkit helps build a shared understanding of early advice, supports the development of innovation offices, and increases the visibility of EU-level regulatory support services, with a strong focus on clear and transparent communication with stakeholders.

Together, these activities contribute to a more coherent and forward-looking regulatory ecosystem, better equipped to evolve alongside scientific and technological progress and to support innovation across Europe.

A STRONG FOUNDATION FOR THE FUTURE

In just two years, IncreaseNET has moved from vision to tangible impact, **laying the foundations for a more adaptive, skilled, and connected European Medicines Regulatory Network**. By addressing critical knowledge gaps, modernising training, strengthening collaboration, and promoting innovation, the project is not only responding to today's challenges but actively preparing the network for those ahead.
The journey is well underway, but the momentum built so far signals even greater impact ahead, ultimately ensuring timely access to safe, effective, and innovative medicines for patients across Europe.

All **documents and materials addressed** in this article are available on the restricted **IncreaseNET SharePoint**. NCA staff interested in accessing these resources should contact their IncreaseNET consortium representative for more information.

A **selection of documents** produced within the IncreaseNET project is **publicly available** and can be accessed freely via the IncreaseNET webpage.

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