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Supporting the Increased Capacity and Competence Building of the EU Medicines Regulatory Network



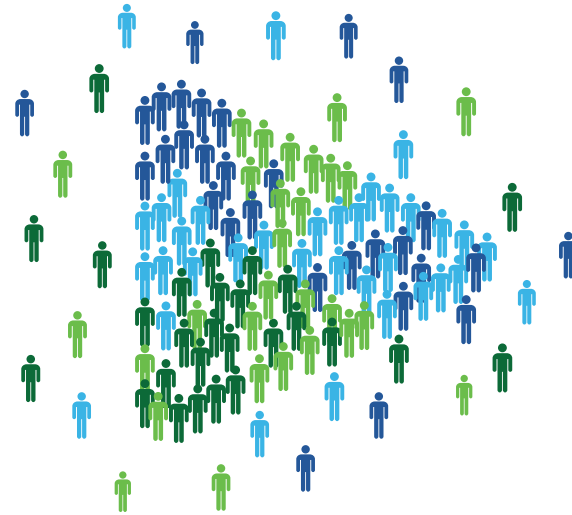
► About IncreaseNET

The Joint Action **“Supporting the increased capacity and competence building of the EU medicines regulatory network” (IncreaseNET)**, funded within **EU4Health programme 2021-2027**, aims to address the challenges faced by the **European Medicines Regulatory Network (EMRN)** due to an ever **increasing workload** (both with respect to the number and complexity of procedures) and the **rapid evolution of science**.

IncreaseNET



The overall **IncreaseNET objective** is to **increase the necessary regulatory expertise and competences in the EMRN** and **to develop additional capacities** to face the challenges represented by upcoming scientific developments. The **exchange of knowledge, ideas and good practices** will reinforce the network as well as the **training programme** for both new and experienced regulatory assessors, in particular by **optimising existing capacities and supporting innovation**.



IncreaseNET activities are carried out in close collaboration with the **European Medicines Agency (EMA)** and the **Heads of Medicines Agencies (HMA)**, primarily **EU Network Training Centre (EU NTC)**, and will complement existing similar EU initiatives, such as the **EU Innovation Network (EU IN)** and **Accelerating Clinical Trials in the EU (ACT EU)**.

The three-year project will run from **01 January 2024 till 31 December 2026** and brings together **29 partners**, mainly **National Competent Authorities (NCA)**, representing **27 EU/EEA countries and Ukraine**.

► IncreaseNET IN NUMBERS



► IncreaseNET aims to:

- Identify **capacities and knowledge** available in NCAs
- Identify gaps and solutions in the **learning possibilities** in EMRN
- Identify the **areas of most pressing needs** in relation to **available and required competences** in EMRN
- Investigate optimal methodologies and **develop a tested training program** for education of regulatory assessors
- Develop **training packages on specific topics**, where lack of competences and trainings has been identified
- Develop **on-the-job learning and on-the-job coaching program** to promote development of new assessors following a learning curve
- Facilitate **exchange of knowledge** and support better **collaboration** between NCAs
- Explore possibilities for **efficient use of resources**, such as work-sharing and avoiding duplication of work
- Collect **best practices** with regards to innovation and provide **support to NCAs** to better address **innovation, new technologies and scientific developments**
- Strengthen the **collaboration between NCAs, Academia and subject matter experts (SMEs)** to enable a flow of information with a view to enable understanding and harmonise guidance for new developments, including trainings by Academia, sharing of information amongst NCAs and innovation toolkits



“It is always great to see motivated and engaged people who want to change things in the regulatory system in order to feel the progress and go out of their comfort zone. The more you go out of your comfort zone, the bigger it gets. You are the architects of a future proof regulatory system. With you on board the future is bright!”

Momir Radulović, JAZMP Executive Director about IncreaseNET



▶ WORK PACKAGES (WP)



Delivery of training materials WP5

Seeks to determine EMRN learning needs and develop optimal learning methodologies and training programs.
WP Lead: HPRA, IE



On-the-job training program WP6

Aims to implement an on-the-job learning and coaching program for NCA assessors of centralised procedures to put theory into practice.
WP Lead: BfArM, DE



WP1

Project management and coordination

WP Lead: JAZMP, SI



WP2

Dissemination and communication

WP Lead: HALMED, HR



WP3

Evaluation

WP Lead: MMA, MT



WP4

Sustainability and collaboration with EU-NTC

Supports the maintenance and continuity of project achievements with a focus on development of a stable and futureproof EU-NTC programme.
WP Lead: DKMA, DK



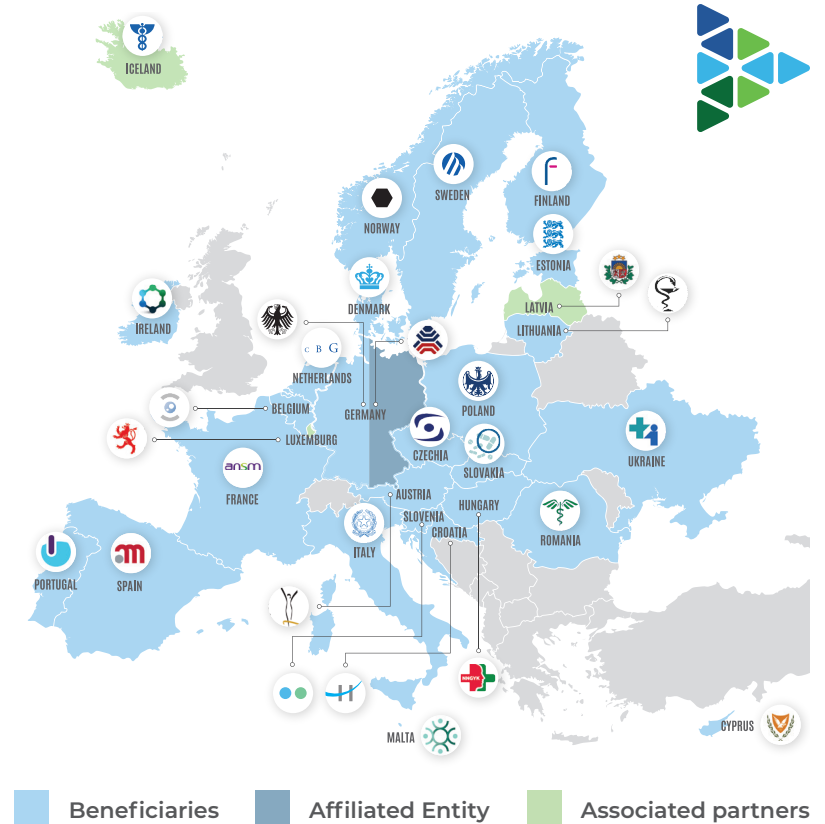
WP7 Efficient use of resources

Aims to identify capacities and expertise available in NCAs and explore possibilities for optimization of processes and efficient use of resources, such as work-sharing and avoiding duplication of work.
WP Lead: Swedish MPA, SE



WP8 Supporting innovation

Addresses strategies regarding best practices and models for interaction and training with Academia and other SMEs on innovative topics, together with sharing of workload and pooling expertise in specialised areas to overcome the impact of innovative technologies.
WP Lead: ANSM, FR



▶ PARTNERS

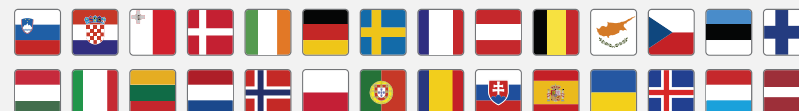
Beneficiaries (25)

Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), Slovenia
Agency for Medicinal Products and Medical Devices of Croatia (HALMED), Croatia
The Medicines Authority (MMA), Malta
Danish Medicines Agency (DKMA), Denmark
Health Products Regulatory Authority (HPRA), Ireland
Federal Institute for Drugs and Medical Devices (BfArM), Germany
Swedish Medical Products Agency (Swedish MPA), Sweden
French National Agency for Medicines and Health Products Safety (ANSM), France
Austrian Agency for Health and Food Safety (AGES), Austria
Federal Agency for Medicines and Health Products (FAMHP), Belgium
Ministry of Health of the Republic of Cyprus (MOH CY- PHS), Cyprus
State Institute for Drug Control (SÚKL), Czechia
State Agency of Medicines (SAM), Estonia
Finnish Medicines Agency (FIMEA), Finland
National Public Health and Pharmaceutical Center (NNGYK), Hungary
Italian Medicines Agency (AIFA), Italy
State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania (SMCA), Lithuania
Medicines Evaluation Board (CBGMEB), Netherlands

Norwegian Medical Products Agency (NOMA), Norway
Medical University of Lublin (MUL), Poland
National Authority of Medicines and Health Products, (INFARMED), Portugal
National Agency for Medicines and Medical Devices of Romania (NAMMDR), Romania
State Institute for Drug Control (SUKL), Slovakia
Spanish Agency of Medicines and Medical Devices (AEMPS), Spain
The State Expert Centre of the Ministry of Health of Ukraine (SECMOH), Ukraine

Affiliated Entity (1)
Paul-Ehrlich-Institute (PEI), Germany

Associated Partners (3)
Icelandic Medicines Agency (IMA), Iceland
Ministry of Health (DISA), Luxembourg
State Agency of Medicines (SAM), Latvia



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Grant Agreement No. 101124540 — EU4H-2022-JA-IBA

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.