



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

THE EU INNOVATION NETWORK (EU-IN)

EU-Innovation Network workshop with academia
16.11.2018

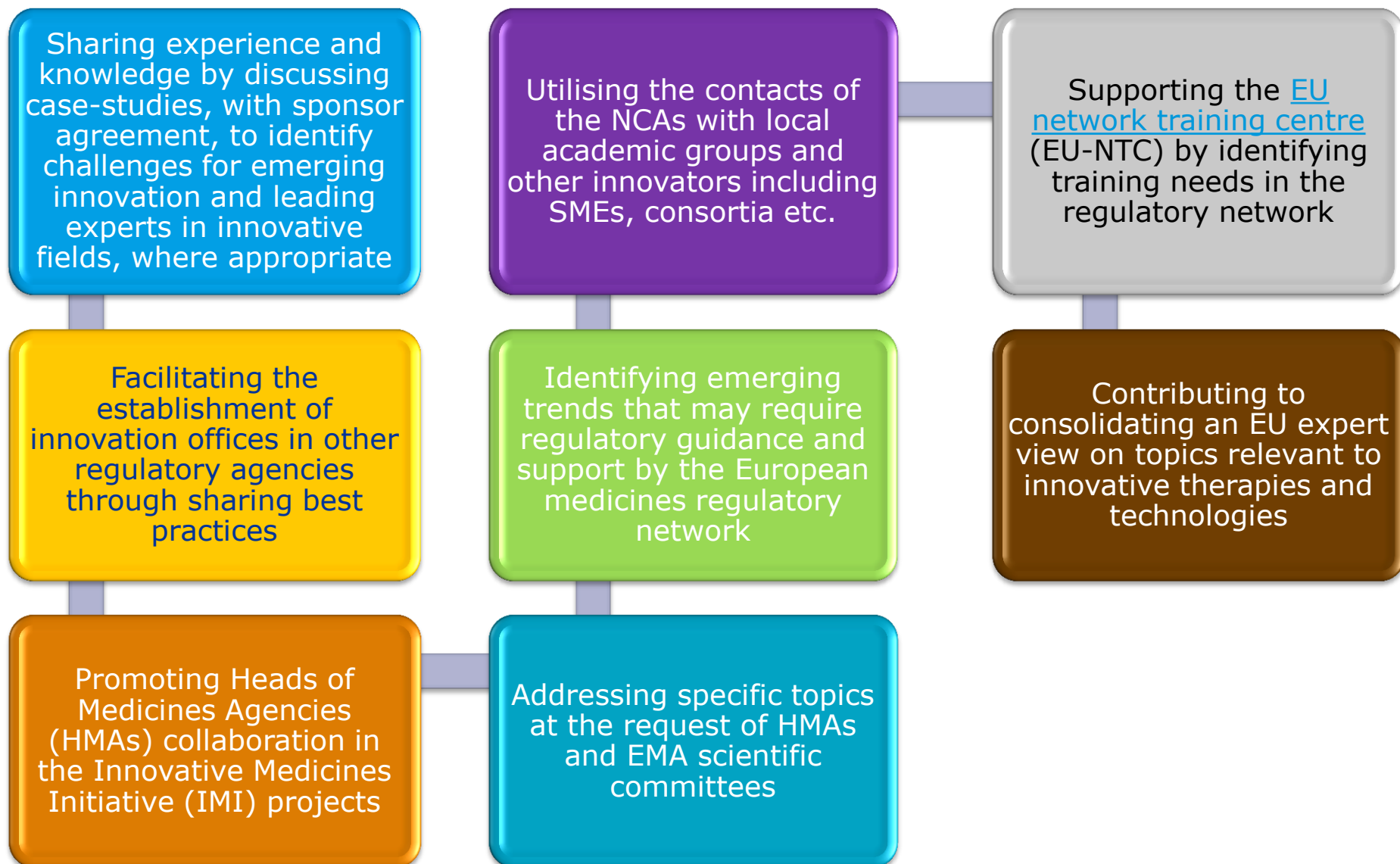
Esa Heinonen, MD, PhD, Co-chair of the EU IN
Finnish Medicines Agency (Fimea)

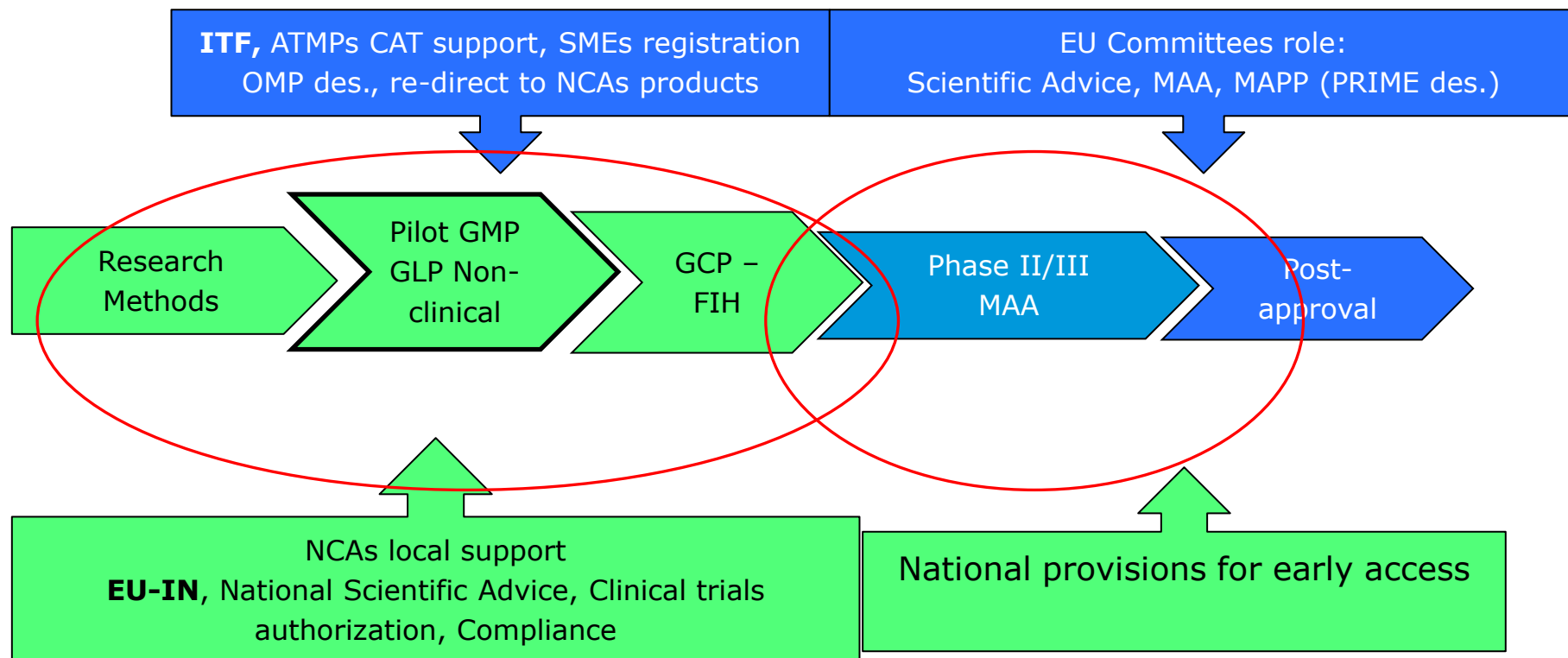


In 2015, EMA and the EU national competent authorities strengthened their collaboration to support medicine innovation and early development of new medicines in the EU by establishing the EU innovation network.



EMA and the HMAs adopted the **mandate** of the
EU Innovation Network in October 2016





- The EU-IN is composed by representatives nominated by the interested NCAs as well as of the EMA ITF.
 - HMA and EMA have the oversight of the EU-IN. Members from participating NCAs will be joining on a voluntary basis.
 - The EU-IN is co-chaired for a term of three years by a NCA senior official nominated by the HMA (currently Esa Heinonen, Fimea) and an EMA's senior staff member (currently Marisa Papaluca).
 - The EMA staff, in close collaboration with participating officials and scientific committees, will provide administrative and scientific secretariat to the EU Innovation Network.



Chairs

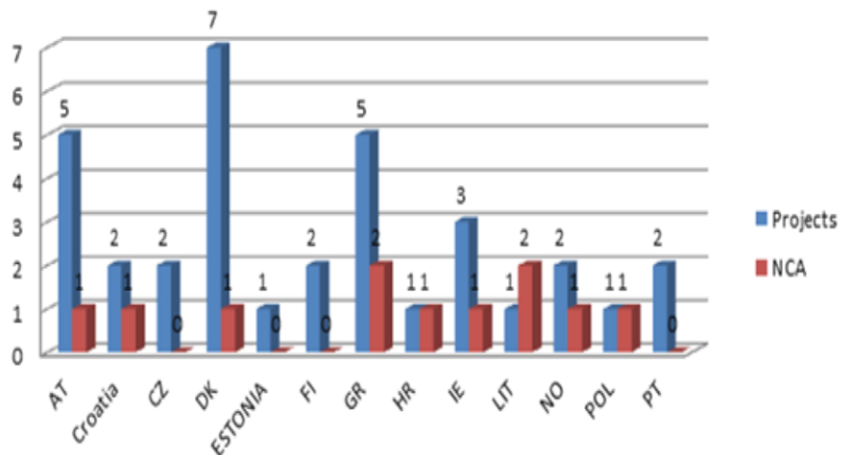
The services of the Innovation Support Offices are directed to hospitals, academic groups and SMEs, research foundations, consortia.

Some have also expressed their willingness to hear from Patient interest groups and or funding/networking organisations.

The scope is wide and includes along the lifecycle of products manufacturing processes, redaction of documents, facilities, GMP, import/export issues, antimicrobials, biostatistics, preparations for scientific advice meetings, Pharmacovigilance, and HTA/Payers interactions

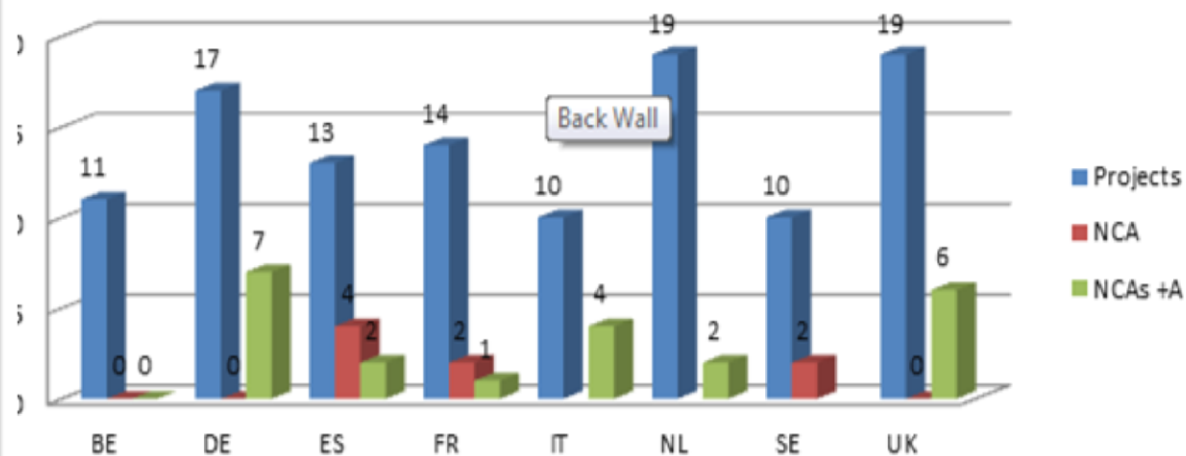
- List of emerging challenges from innovative products discussed
- Identified regulatory science topics which require NTC training coordination
 - A preliminary list of emerging challenges and interesting cases have been already identified
 - Further case studies to be done (when more detailed data would be provided by the customers)
 - Nanomedicine and novel manufacturing strategies (e.g. 3D printing) have been flagged
 - More structured horizon scanning is being planned

**EU MSs involvment
<10 IMI Projects**



Pilot map of engagement being analyzed.

**EU MSs involvment
>10 IMI Projects**



Get in touch with us! > National innovation offices:

EU-IN	European Innovation Network / Secretariat@ema.europa.eu
EMA	European Medicines Agency (EMA) / itfsecretariat@ema.europa.eu
Belgium	Federal Agency for Medicines and Health Products (FAMHP) innovationoffice@fagg-afmps.be
Czech Republic	Státní ústav pro kontrolu léčiv (SUKL) innovation@sukl.cz
Denmark	Danish Medicines Agency (DKMA) innovation@dkma.dk
Germany	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) innovation@bfarm.de
Germany	Paul-Ehrlich-Institut (PEI) innovation@pei.de
Estonia	State Agency of Medicines innovatsioon@ravimiamet.ee
Ireland	An tÚdarás Rialála Táirgí Sláinte / Health Products Regulatory Authority (HPRA) innovationoffice@hpra.ie
Spain	Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) innov_spain@aemps.es
France	Agence nationale de sécurité du médicament et des produits de santé (ANSM) innovation@ansm.sante.fr
Croatia	Agencija za Lijekove i Medicinske Proizvode (HALMED) innovation@halmed.hr
Italy	Agenzia Italiana del Farmaco (AIFA) innovation.office@aifa.gov.it
Luxemburg	Division de la Pharmacie et des Médicaments jacqueline.genoux-hames@ms.etat.lu
Hungary	Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (OGYEI) innovation.office@ogyei.gov.hu
Malta	Awtorità dwar il-Medicini (Medicines Authority) innovation.medicinesauthority@gov.mt
Netherlands	College ter Beoordeling van Geneesmiddelen (MEB) _Dienstpostbus_Innovation@cbg-meb.nl
Austria	Bundesamt für Sicherheit im Gesundheitswesen (BASG-AGES) innovation@ages.at
Poland	Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych innowacjaPL@urpl.gov.pl
Portugal	Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (INFARMED) garc@infarmed.pt
Finland	Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA) innovation.office@fimea.fi
Sweden	Läkemedelsverket (MPA) Registrator@mpa.se
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA) innovationoffice@mhra.gov.uk
Norway	Statens legemiddelverk (NOMA) ask-us@legemiddelverket.no

9 EU-IN workshop with academia 16.11.2018

Innovators meet regulators

EU-IN event at the EMA Annual SMEs
Workshop 17 Nov 2017



> Welcome to the EU
Innovation Network // EU-IN

Horizon 2020, DG Research and Innovation: Strengthen *Regulatory Sciences* and support for regulatory *Scientific Advice*

EU Innovation Network





Overview

Research and development

Adaptive pathways

Advanced therapies

Clinical trials

Compassionate use

Compliance

Data on medicines
(ISO IDMP standards)

Geriatric medicine

Innovation in
medicines

Non-pharmaceutical
products

Orphan designation

Paediatric medicines

Pharmacovigilance

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Innovation in medicines

This content applies to human and veterinary medicines.

One of the European Medicines Agency's strategic goals is to foster research and the uptake of innovative methods in the development of medicines. This helps to make safe and effective innovative medicines available to patients in a timely manner.

In order to ensure access to new medicines for patients it is essential for Europe to have a regulatory environment that understands and facilitates innovation. The Agency and the European medicines regulatory network support the development of innovative methodologies by fostering greater collaboration across the regulatory network and with academia.

EU Innovation Network

Innovation offices in national regulatory agencies have been working informally with the EMA's Innovation Task Force (ITF) on matters relating to emerging therapies and technologies since 2011. In 2015, EMA and the EU national competent authorities (NCAs) strengthened their collaboration to **support medicine innovation and early development of new medicines** in the EU by establishing the EU innovation network.

EMA and the HMAs adopted the **mandate** of the EU-Innovation Network in October 2016:

[Mandate of the European Innovation Network](#)

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Oversight Group](#)

[European Surveillance
Strategy Working
Group](#)

[EU Network Training
Centre \(EU-NTC\) -
former OTSG](#)

**EU-Innovation
Network (EU-IN)**



EU-INNOVATION NETWORK (EU-IN)

[EU-IN Introduction and Overview](#)

[EU-IN Members and Representatives](#)

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[Key documents list](#)

- We are strengthening the EU-IN in order to:
 - Share knowledge between the various Innovation Offices of NCAs and the EMA
 - Develop best practices for horizon scanning
 - Flag regulatory issues to be discussed at the EMA level
 - Discuss about the training needs of assessors with the EU Network Training Center
 - Improve our capabilities to help innovators – academic groups, SMEs, larger companies – to bring innovations forward from national level to the EU level



Thank you for your attention !

