EMA
EUROPEAN MEDICINES AGENCY

Horizon Scanning activities at EMA

14th Industry Stakeholder Platform on R&D

3 July 2025

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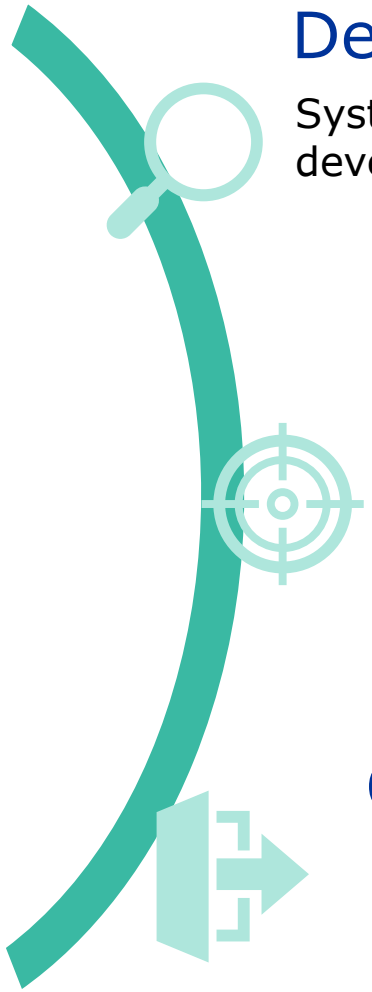
Innovation & Development Accelerator

Regulatory Science and Innovation Task Force

What is Horizon Scanning?



Definition

Systematic examination of information to detect early signs of scientific and technological developments with previously unknown regulatory challenges or public health opportunities

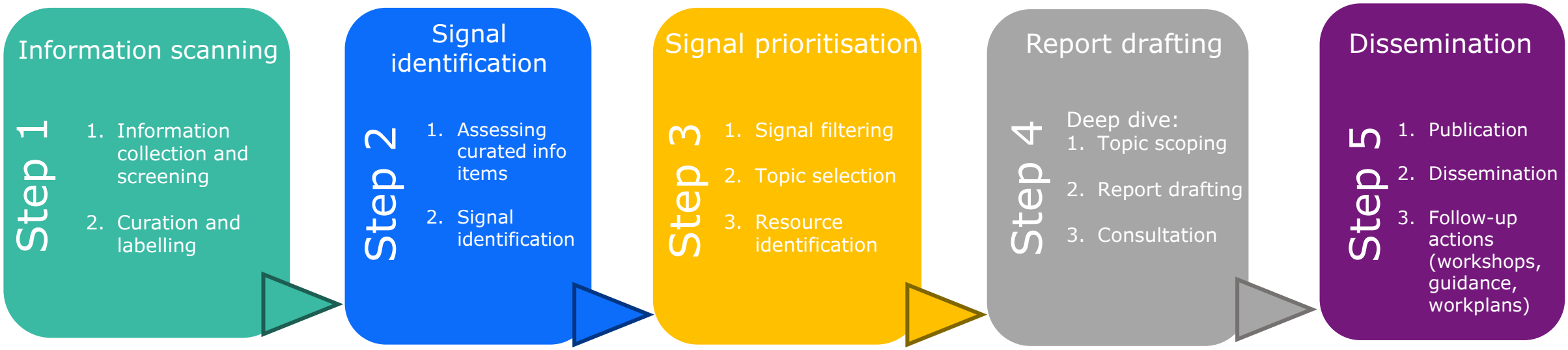
Objectives

- Enable EU Medicines Regulatory Network (EMRN) to proactively prepare for forthcoming challenges and opportunities
- Future-proofing the EMRN in next 5 – 10 years
- Fostering high-quality development and ensuring innovation reaches patients

Output

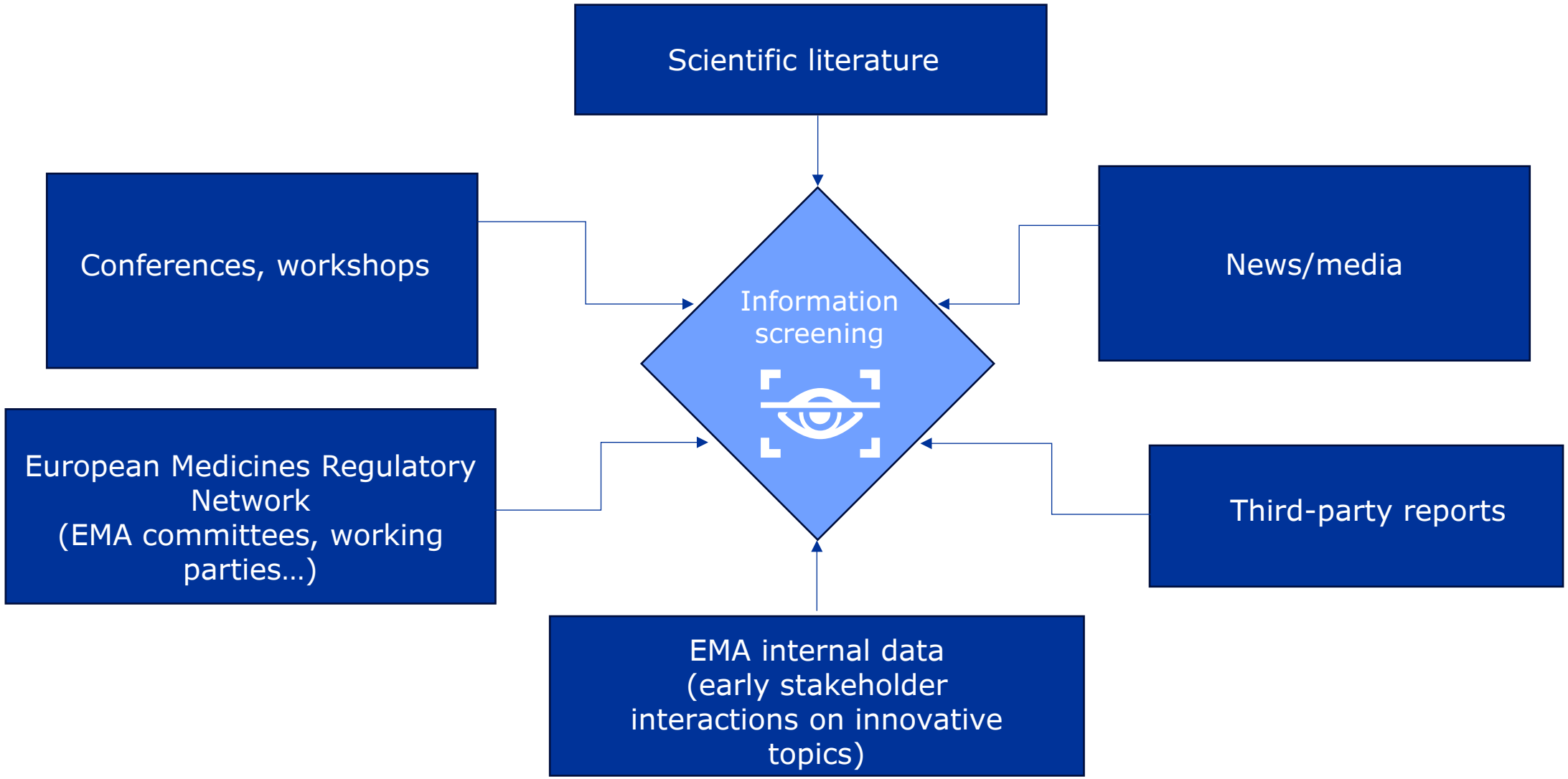
Topic-specific reports that explore challenges and opportunities in the identified areas from a regulatory perspective. The reports include recommendations for action aimed at the EMRN and stakeholders.

Horizon Scanning workflow



Information scanning

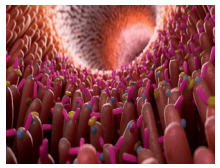
SOURCES



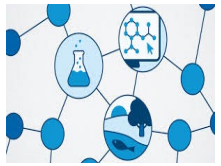
Output

Deep-dive reports

Genome Editing

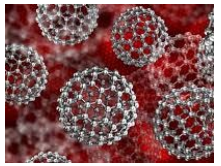


Faecal microbiota transplants



New Approach Methodologies

Alzheimer's disease



Nanotechnology-based MP

EMRN

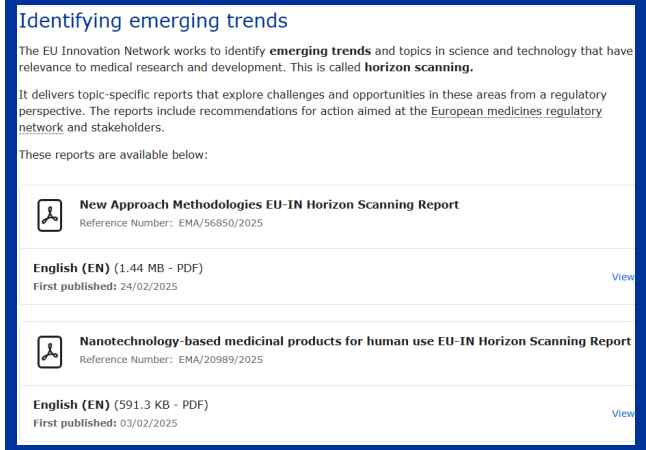
- EMA
- Committees & working parties
- EU-IN
- EC

International

- National policy makers
- WHO
- ICMRA

Stakeholders

- Medicines developers
- Technologies developers
- Healthcare professionals
- Patients
- Funders



Identifying emerging trends

The EU Innovation Network works to identify **emerging trends** and topics in science and technology that have relevance to medical research and development. This is called **horizon scanning.**

It delivers topic-specific reports that explore challenges and opportunities in these areas from a regulatory perspective. The reports include recommendations for action aimed at the European medicines regulatory network and stakeholders.

These reports are available below:

New Approach Methodologies EU-IN Horizon Scanning Report
Reference Number: EMA/56850/2025

English (EN) (1.44 MB - PDF)
First published: 24/02/2025 View

Nanotechnology-based medicinal products for human use EU-IN Horizon Scanning Report
Reference Number: EMA/20989/2025

English (EN) (591.3 KB - PDF)
First published: 03/02/2025 View

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BIOBUSINESS BRIEFS | 24 March 2025

Insights into new approach methodology innovation: an EMA perspective

By Mariana Edwards, Oriane Blanquie & Falk Ehmann

Follow-up actions:

- Stakeholder workshops
- Contribution to EMA working parties workplans
- Drafting of new guidance

Webinar on Horizon Scanning methodologies (20 May 2025)

Participants:

- International agencies and non-profit organisations performing Horizon Scanning (EMA, JRC/EC, EFSA, WHO, Newcastle University/NIHR IO, EUDA)

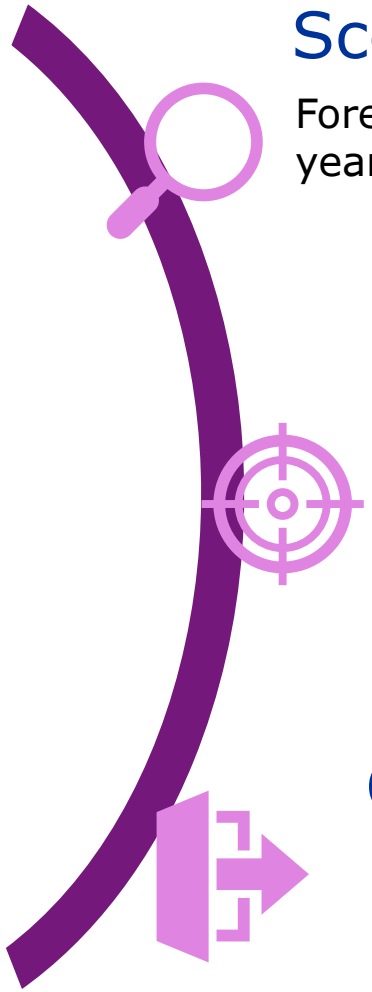
Objectives:

- Share best practices on horizon scanning methodologies and outputs
- Discuss the impact of horizon scanning activities and how to optimise them
- Discuss challenges and opportunities arising from Horizon scanning activities
- Explore potential synergies and collaborations among institutions

Main points:

- *Different activities (signal detection, trends and technology monitoring, foresight, forecast) can fall under the Horizon Scanning umbrella term*
- *Horizon scanning is a continuous process and experts' consultation is needed*
- *Workflows and methodologies can vary according to the target audience for the activities*

Business Analysis & Forecasting



Scope

Forecast and business intelligence on marketing-authorisation applications with a three years time window

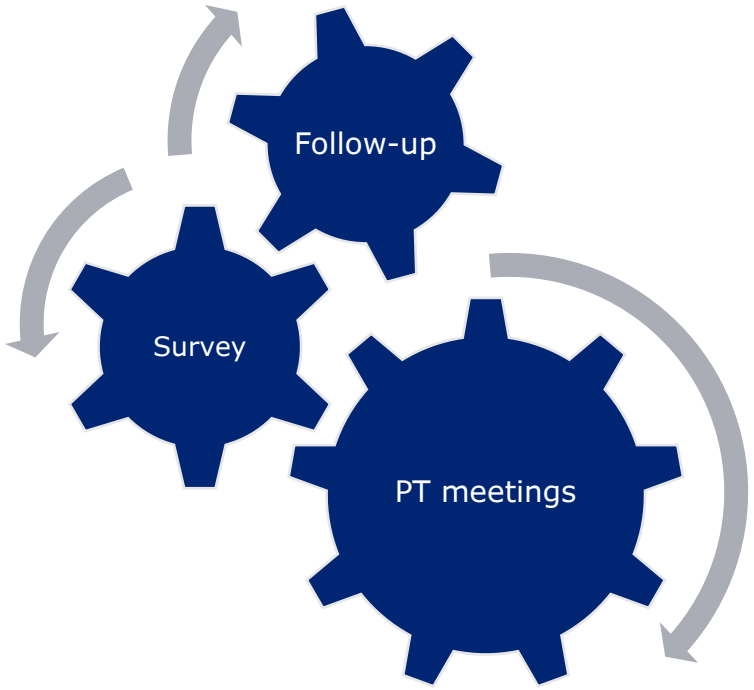
Objectives

- Enables accurate budgeting
- Workload planning & identification of the most appropriate resources and scientific expertise
- Facilitate development
- Support medicines availability

Output

Reports regularly to EMA, HMA, NCAs and EHTSG

Intel gathering from developers
Portfolio & Technology Meetings (PTMs)[1]



- Identify issues impacting the progress of product portfolios and assist successful development
- Capture innovative and disruptive technologies
- Anticipate the scientific and regulatory expertise needed to assess future applications
- Facilitate exchange on European Medicines Agencies Network strategy e.g., NAMs, AI, RWE

Survey
On pipeline submission plans (e-update)

1. Portfolio and technology meetings

Intel gathering output

Top 5 discussion topics

- Methodology of clinical trials
- Novel ways of evidence generation / data sources
- Digital technologies
- Medical devices associated with medicines and treatments

Current* topics of special interest

- NAMs
- AI
- WoCBP
- ODD
- Shortages
- Sandbox

ARTICLE

Queries Raised During Oncology Business Pipeline Meetings at the European Medicines Agency: A 5-Year Retrospective Analysis

C. Mircea S. Tesileanu[1,2], Francesco Pignatti[1], Enrico Tognana[3,*] and Anthony Humphreys[3]

The European Medicines Agency (EMA) offers guidance and support to pharmaceutical companies through bilateral discussions called business pipeline meetings (BPMs). An analysis of BPMs in oncology over a 5-year period was conducted to identify common topics and recurring queries. The documents of all BPMs available at the EMA regarding the field of oncology from January 1, 2018, to Decemer 31, 2022, were reviewed. For every query, a main category was assigned, and in case of multiple relevant topics, a secondary category was appointed too. For all queries, the follow-up offered by the EMA was documented, and whether the requested information was available. Subsequently, all queries were scanned for overlapping topics between meetings. From 2018 to 2022, 31 BPMs were held between the EMA and pharmaceutical companies to discuss oncology-related questions, for a total of 397 queries raised. They were classified into 24 topics, of which 15 were common topics ($n \geq 10$ queries) with regulatory pathways/guidelines and trial design having the most queries. Post-BPM actions were taken or recommended by the EMA for 41.3% of queries, such as referrals to scientific advice or published guidelines. Forty-three queries were raised at more than one BPM. Targeted therapy, companion diagnostics, institutional collaboration, trial design, and regulatory pathways/guidelines were the most discussed topics in oncology BPMs, with molecular developments being the common denominator. Creating Q&A documents, publishing new guidelines, providing a framework for discussions, and questionnaire-based follow-up research can improve the quality of BPMs, and the accessibility of the information requested during the BPMs.

Study highlights

WHAT IS THE CURRENT KNOWLEDGE ON THIS TOPIC?
☑ This is the first published analysis of the business pipeline meeting platform offered at the European Medicine Agency.

WHAT QUESTION DID THIS STUDY ADDRESS?
☑ The study addresses the value of the business pipeline meeting platform as a tool to support the development and evaluation of new and innovative medicinal products.

WHAT DOES THIS STUDY ADD TO OUR KNOWLEDGE?
☑ The study shows how the business pipeline meeting platform represents a valuable tool for the developers of medicinal products and provide insight on key challenges in the development of oncology medicines.

HOW MIGHT THIS CHANGE CLINICAL PHARMACOLOGY OR TRANSLATIONAL SCIENCE?
☑ The business pipeline meeting is a further layer of interaction the developer can have with the regulators to initiate early-stage dialogue on their pharmaceutical development, in preparation for subsequent product-specific and multi-stakeholder discussions.

The European Medicines Agency (EMA) is a medicine regulatory authority which aims to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union.[1,2] A regulatory environment that supports innovation is necessary to achieve these goals. Pharmaceutical companies can obtain guidance and support for the development of medicinal products through different modalities.[1,3–11] For instance, one of the core responsibilities of the EMA is to offer scientific advice to pharmaceutical companies on individual medicinal products before their respective marketing authorization applications are submitted.[1,7,11] Furthermore, the EMA holds bilateral discussions with applicants of marketing authorization in so-called "business pipeline meetings" (BPMs) as part of its business analysis and forecasting strategy.[9,12]

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* NAMs = New Approach Methodologies; AI = Artificial intelligence; WoCBP = Women of Childbearing Potential; ODD = Orphan Drug Designation

Points for discussion

What is the industry view on Horizon Scanning?

How can we increase the impact of Horizon Scanning activities?

Is there any convergence/room to optimise (EU) preparedness?

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