EMA
EUROPEAN MEDICINES AGENCY

# Horizon scanning at EMA

## Emerging trends in innovation

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Regulatory Science and Innovation Task Force



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# Our mission

## Science, Medicines, Health.

To foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the EU.



Ekaterina Pokrovsky – stock.adobe.com

# Our regulatory network



**4000**

Experts



**50+**

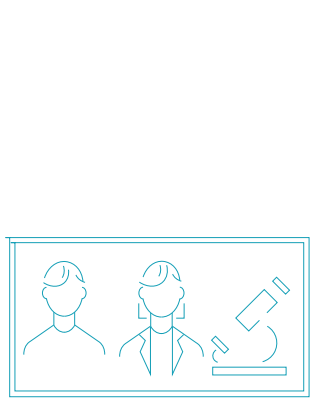
NCAs



**24**

Official languages

# EMA interactions along the medicine development



Dedicated **SME entry point** SME office

Dedicated **academia entry point**

**Qualification of novel methodologies**

**Scientific Advice** (SA) / **Protocol Assistance** (PA)

**EU Health Technology Assessment** (HTA)

Submission of **Marketing Authorization Application**

**Innovation Task Force** (ITF)

**Orphan Drug** Designation

**PRIME scheme** (PRIority MEdicines)

**Eligibility to the centralized procedure**

**Paediatric Investigation Plan** (PIP)



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# Horizon scanning pillars

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## Forecasting

**Forecast of MAA submissions** for workload, rapporteurs and support to **Emerging Health Technology Subgroup** (HTA coordination group)

**Portfolio & Technology meetings**

## Reports

**Latest published reports**

Targeted protein degradation

Microgravity-enabled development and manufacturing

Radiopharmaceuticals

**New topics:**

Climate change & regulatory response

Bacteriophages

Healthy ageing

Precision medicines and companion diagnostics

## *HORIZON SCANNING*

**Implementation of the collaborative system for horizon scanning**

**Identification of new signals**






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# Horizon scanning

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

Fostering high-quality development

## Partners and Stakeholders



EU institutions

National competent authorities

Non-EU regulators

Researchers

Medicine developers

## Time Horizon



~3-10 years

before marketing authorization application



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# Forecasting

Provides the Agency and the regulatory network with forecast and business intelligence on marketing authorisation applications

## Objectives



Enable accurate budgeting, workload planning, identification of the most appropriate resources and scientific expertise needed

## Sources of information



Internal databases, external sources and direct interactions with developers

## Time Horizon



~0-3 years

before marketing authorization application



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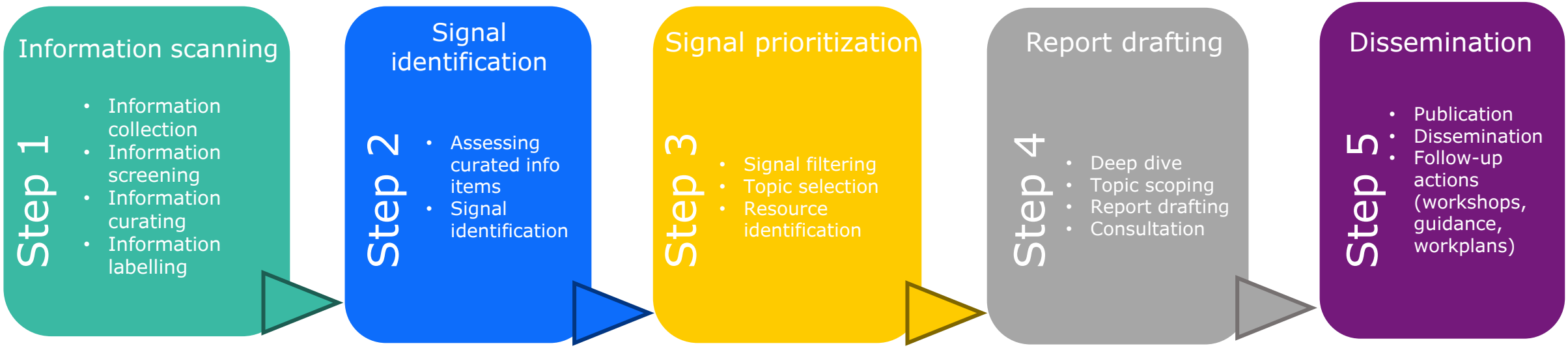
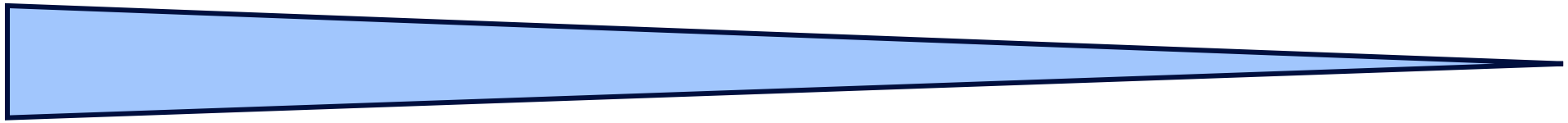
# Horizon Scanning workflow



EMA interactions
~40k info items

10-20 innovation signals

3-5 reports per year



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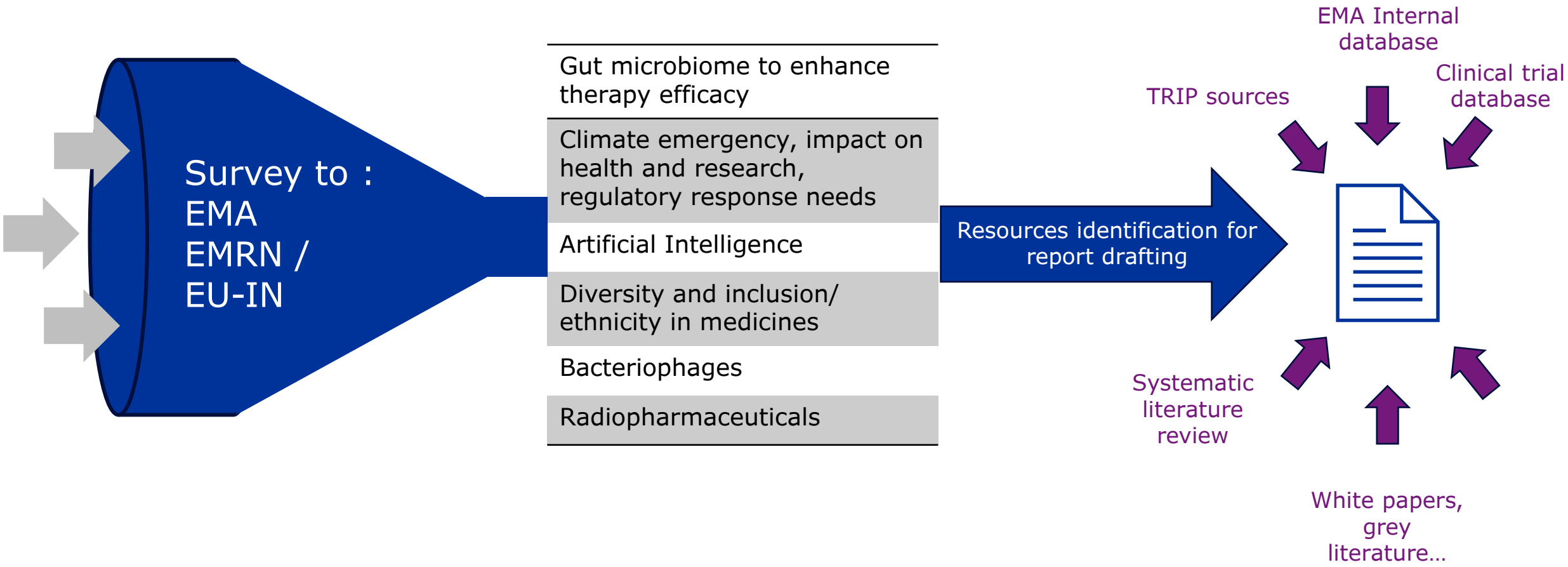
# Signal prioritization and report drafting



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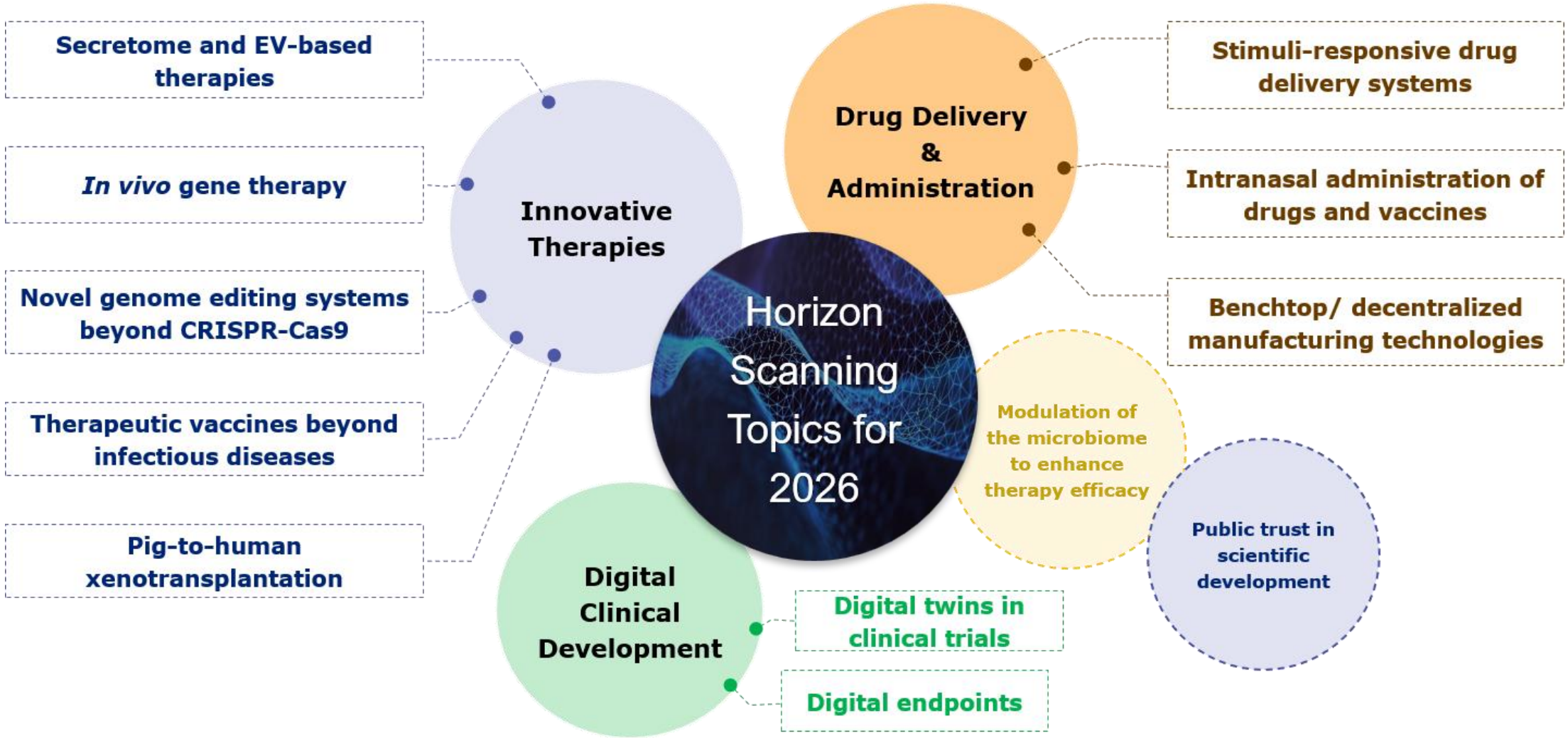
# What comes next: Horizon scanning priority topics



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# Published reports

**Targeted Protein Degradation (July 2026)**

**Microgravity-enabled medicinal product research, development and manufacturing (July 2026)**

**Radiopharmaceuticals *(April 2026)***

**Engineered living materials for in situ production of therapeutics *(September 2025)***

**New Approach Methodologies *(February 2025)***

**Nanotechnology-based medicinal products for human use *(January 2025)***

Horizon scanning: Identifying emerging trends

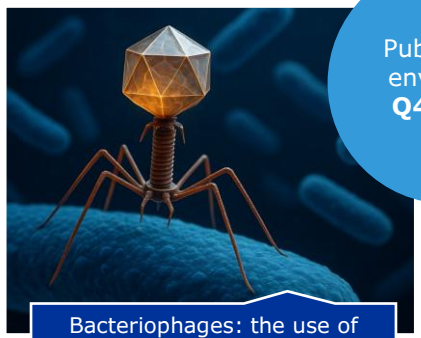
# Ongoing reports

Publication envisaged **Q4 2026**



Climate change and regulatory response (e.g. pharmaceutical carbon footprint and green manufacturing)

Publication envisaged **Q4 2026**



Bacteriophages: the use of specific viruses to eliminate bacteria and potentially fight antibiotic resistance

Publication envisaged **H1 2027**



Precision medicines and companion diagnostics

Publication envisaged **H1 2027**



Healthy ageing

And more:

- Digital twins/Digital endpoints
- Cancer immunotherapy/RNA therapeutics



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# Thank you

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