

Innovation and Development Accelerator

EMA Veterinary Medicines Info Day
12-13 March 2026

Falk Ehmann
Regulatory Science and Innovation Task Force

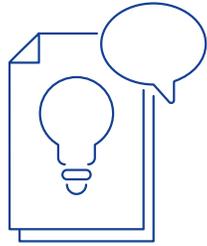


Aim: Support a fast path from innovation to safe and effective medicines

Working streams:

- Innovation Task Force (ITF)
- Portfolio and Technology meetings (PTMs)
- Horizon Scanning
- EU Innovation Network

What is the role of the Innovation Task Force?



Medicine & technology development

- Support drug development via early informal dialogue on scientific, legal and regulatory issues
- Preparing for formal procedures (e.g., scientific advice, qualification)



Agency & network development

- Address impact of emerging therapies and technologies on the regulatory system
- Identifying emerging trends that may require regulatory support
- Collaboration with the national innovation offices (EU Innovation Network) to address gaps in regulatory support to innovation

Innovation Task Force (ITF) briefing meetings

Early informal dialogue on
innovative methods,
technologies and medicines



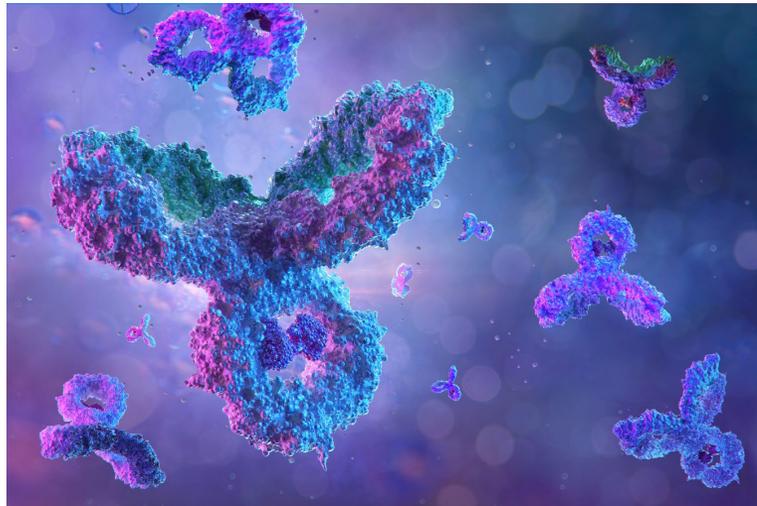
Informal scientific and regulatory dialogue
with EU network regulators. Experts express
their personal opinion

1,5-hour discussion – Free of charge

Open to any type of applicant

Innovation Task Force (ITF) briefing meetings

Examples of developments discussed



Emerging therapies

- Cell & gene therapies
- Nanomedicines
- Bioprinted tissues

Emerging technologies

- Digital technologies
- ATMP manufacturing
- Artificial intelligence



Emerging methods

- Novel approach methodologies & 3Rs
- Clinical trial methodology

Veterinary ITF briefings

Topics discussed during recent veterinary ITF briefing meetings:

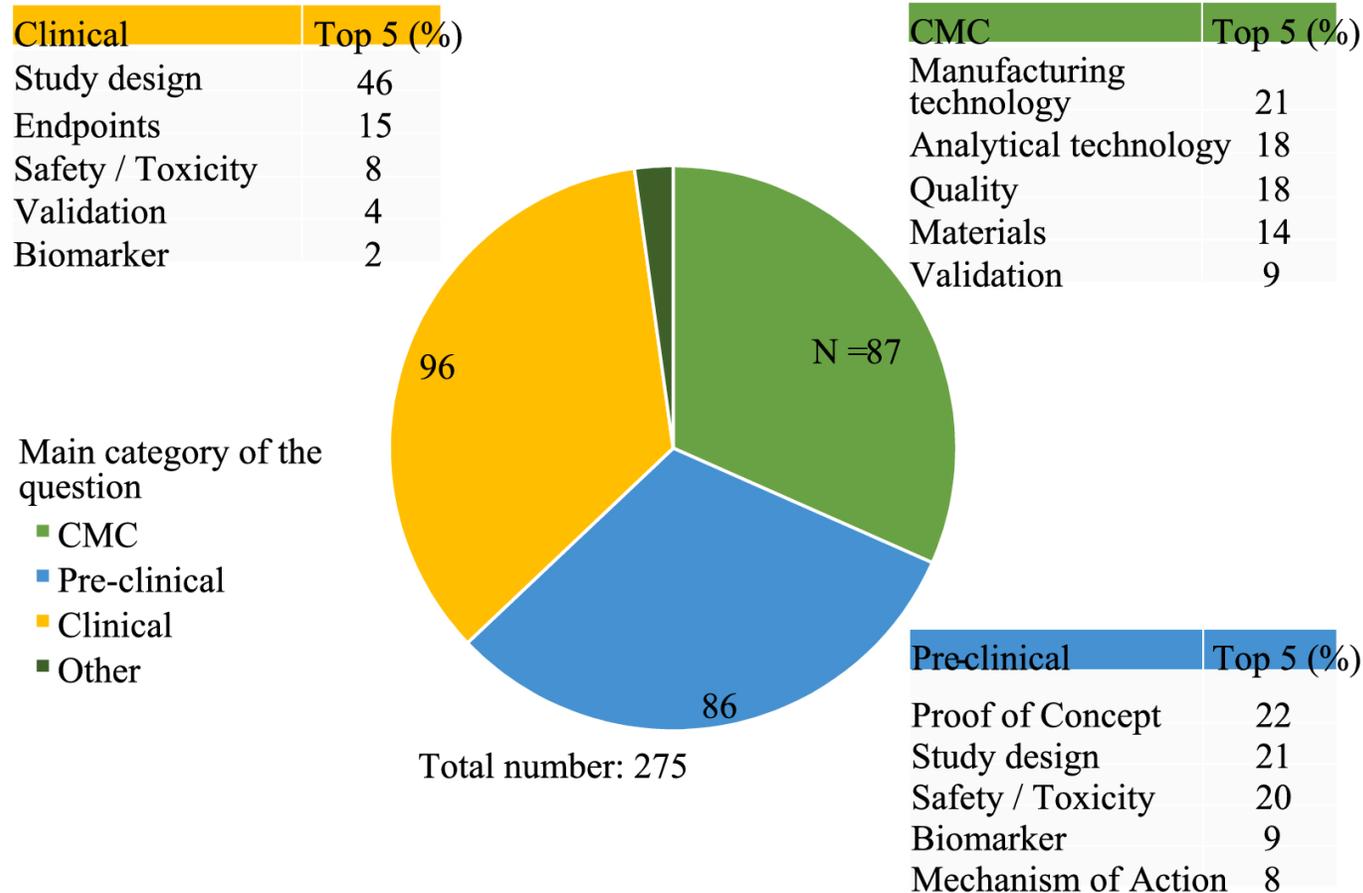
Novel **insecticides** derived
from **fungi**

Mesenchymal **cell-based**
therapies

Genetically modified living
bacteria

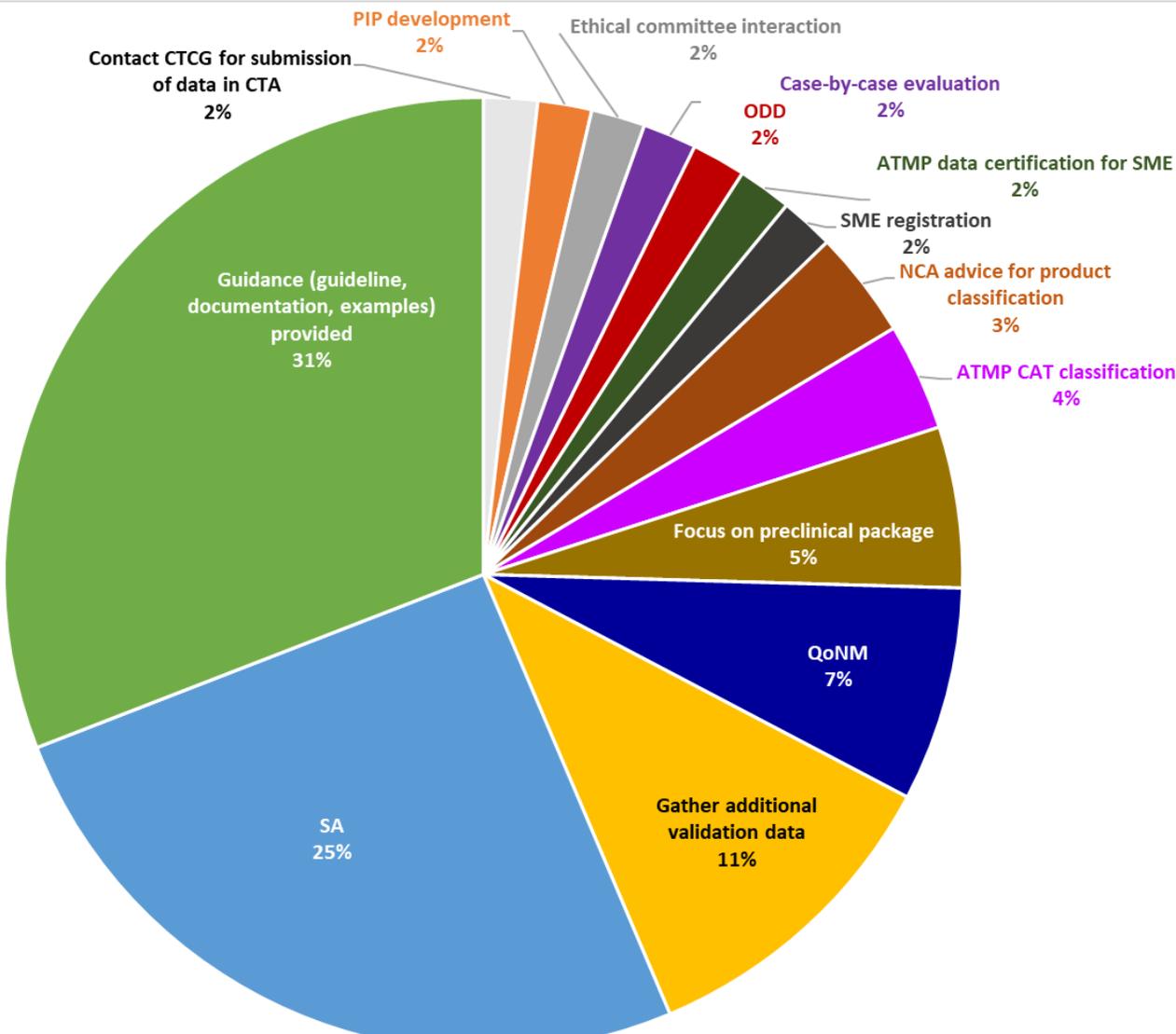
Bacteriophage-based
therapy for MRSI (Methicillin-
Resistant Staphylococcus
Infections)

What type of questions are asked?



Classification of questions asked during ITF meetings

What type of feedback / recommendations are provided?



More than one feedback or action can be provided during an ITF BM

SA: Scientific Advice

QoNM: Qualification of Novel Methodologies

ODD: Orphan Drug Designation

PIP: Pediatric Investigation Plan





Portfolio and Technology Meetings (PTMs)

- 3 meetings with industry stakeholders (2024/2025)
- Topics discussed included:
 - Marine aquaculture parasiticides
 - Classification criteria for veterinary medicinal products
 - Plasmid-DNA (pDNA) technology
 - Usage of antibiotic resistance genes
- New call for H2 2026 meetings launched ([EMA website](#)).

Horizon Scanning (HS)

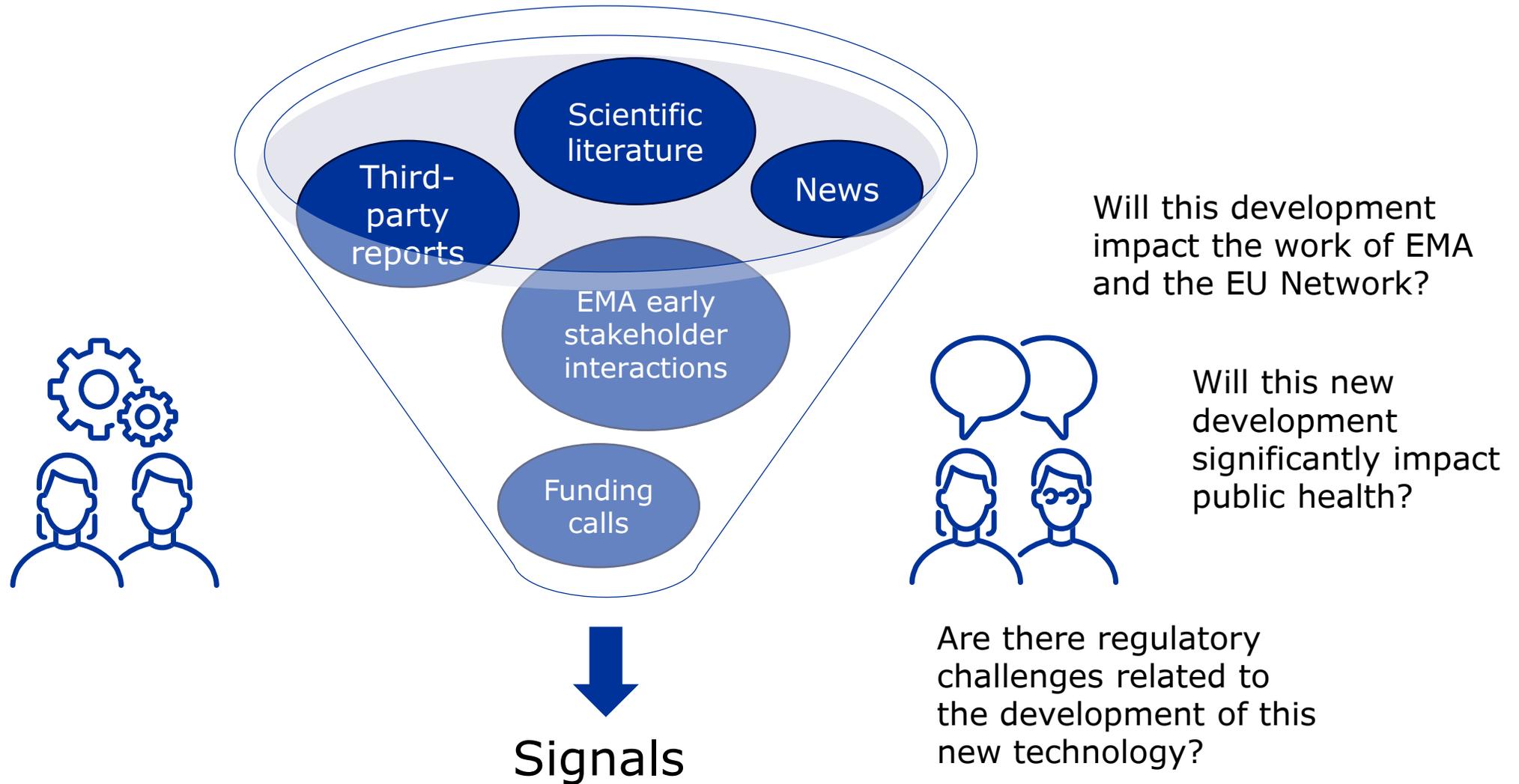
Horizon Scanning attempts to predict trends and developments, ie Innovation, anticipates what change it will bring, prepare for it and turn it into opportunities

Proactive vs passive approach to prepare for the future to:

- inform developers, regulators and other key stakeholder
- accelerate translation of innovation
- HS translates into competitiveness



Screening of information & signal identification



Published HS reports and anticipated Impact

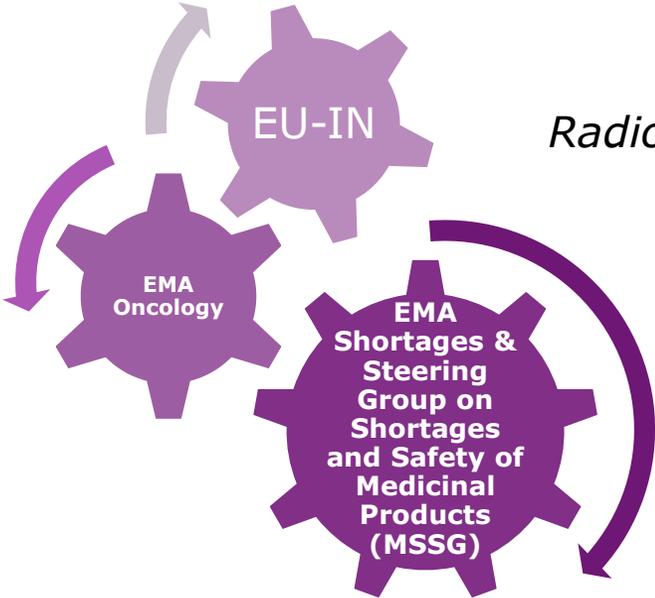
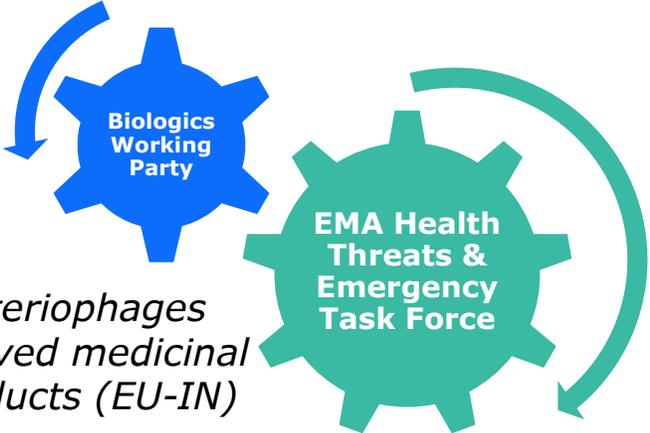
| Reports published | Anticipated Impact |
|---|--|
| ELMs: Engineered living materials | <ul style="list-style-type: none"> • Increased EU attractiveness for ELMs related R&D, CT, SA, MAA and manufacturing |
| AI in medicine lifecycle | <ul style="list-style-type: none"> • Inform strategy and priorities |
| NAMs (3Rs) New Approach Methodologies | <ol style="list-style-type: none"> 1. Creation of validated in vitro, in silico, and organ-on-chip systems for regulatory use 2. Accelerated transition to animal-free science |
| FMT Faecal Microbiota Transplantation | <ol style="list-style-type: none"> 1. Expansion to other microbiome diseases (IBD, metabolic, neuroimmune) 2. Use of omics and AI tools to characterise microbiota composition |
| Alzheimer disease, age-related dementias | <ol style="list-style-type: none"> 1. Cross-disease data pooling enabling trans-diagnostic therapeutics 2. Development of AI-driven diagnostics (early detection) 3. Preventive or disease-modifying trials at prodromal stages |

Ongoing work

Climate change & regulatory response (EU-IN)



Future exchange with Quality Innovation Group (QIG) on green manufacturing & sustainability



Radiopharmaceuticals



- And more:
- Precision medicines & companion diagnostics
 - Healthy ageing
 - Targeted protein degradation

Conclusions

- **Innovation Task Force (ITF)**
→ platform for early informal dialogue on innovative medicine developments and technologies
- **Portfolio and Technology meetings (PTMs)**
→ to discuss issues impacting the progress of product portfolios and assist successful developments
- **Horizon Scanning (HS)**
→ Proactive approach to predict trends and developments and prepare for the future



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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Annex

Collaboration, Dissemination, Recommendation, Impact

| Reports published | Collaboration | Dissemination and Publication | Recommendation | Anticipated Impact |
|--|--|---|---|---|
| ELMs: Engineered living materials | <ul style="list-style-type: none"> EIC Joint EMA-EIC webinar | <ul style="list-style-type: none"> EIC-ELMS portfolio meeting LinkedIn post shared on official EIC site | <ol style="list-style-type: none"> Definitions and Classification GMP standards, potency and release specifications | <ul style="list-style-type: none"> Increased EU attractiveness for ELMs related R&D, CT, SA, MAA and manufacturing |
| AI in medicine lifecycle | <ul style="list-style-type: none"> AI-CG | <ul style="list-style-type: none"> HMA and NDSG presentation Published as part of AI observatory | <ul style="list-style-type: none"> Provide guidance on AI in drug life-cycle | <ul style="list-style-type: none"> Inform AI CG priorities and strategy |
| NAMs (3Rs) New Approach Methodologies | <ul style="list-style-type: none"> 3RWP, H-EG-TRA | <ul style="list-style-type: none"> New approach methodologies: EU regulatory horizons Insights into new approach methodology innovation: an EMA perspective | <ol style="list-style-type: none"> Develop harmonised global acceptance criteria via ICH/IMRWG3Rs Encourage safe-harbour data submission Expand training, funding, and regulatory capacity building for NAM assessment | <ol style="list-style-type: none"> Creation of validated in vitro, in silico, and organ-on-chip systems for regulatory use Accelerated transition to animal-free science |
| FMT Faecal Microbiota Transplantation | <ul style="list-style-type: none"> EC SoHO EDQM | Joint webinar EMA – EC SoHO | <ol style="list-style-type: none"> EMA, EDQM and SoHO collaboration Encourage clinical data sharing and registries | <ol style="list-style-type: none"> Expansion to other microbiome diseases (IBD, metabolic, neuroimmune) Use of omics and AI tools to characterise microbiota composition |
| Alzheimer disease and other age-related dementias | <ul style="list-style-type: none"> H-NEU, CNS-WP | EU regulatory horizons for Alzheimer's disease - ScienceDirect | <ol style="list-style-type: none"> Increase targeted EU funding for biomarker Support international data sharing Encourage multi-stakeholder collaboration (EMA, HTA, payers, academia) | <ol style="list-style-type: none"> Cross-disease data pooling enabling trans-diagnostic therapeutics Development of AI-driven diagnostics (early detection) Preventive or disease-modifying trials at prodromal stages |

| Forthcoming Reports | Collaboration | Recommendation | Anticipated Impact |
|----------------------|-------------------|--|---|
| Radiopharmaceuticals | MSSG WP, NCAs | Aligned with MSSG vulnerability exercise | |
| Healthy Aging | upcoming EIC call | | Increase outcome of funded EIC projects |