EMA Support to Innovation: Operation of the EU Innovation Network

2nd International Awareness Session - The EU medicines regulatory system and the European Medicines Agency

Presented by Marisa Papaluca on 8 March 2018
Co-Chair of the EU Innovation Network

Early development services at EU level

- SMEs office* regulatory and scientific support for protocol assistance, fee reductions, training, workshops etc.
- Innovation task force (ITF) safe harbour*
- Qualification of novel methodologies
- Scientific advice

- Advanced therapy medicinal product classification*
- Paediatric investigation plan*
- Orphan medicine designation*
- PRIME scheme(PRIority Medicines)*
- **EU-Innovation Network**(EU-IN)(H)*

Keep in mind: **time** and potential fees (Note on fees payable to EMA and exemptions)

* **No fee**
* Fee reduction for academics

Why an EU-Innovation offices Network?

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


HMA

30 September 2016

Mandate of the European Innovation Net
6 September 2016

1. Background

Innovative medicines development projects emerge throughout Europe
Medium-Sized Enterprises (SMEs), hospitals and academia. The Innovat
European Medicines Agency (EMA) and innovation offices of National Co
important role in supporting innovation in an early phase of de
, dialogue and understanding of regulatory requirements.

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

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/03/WC500223627.pdf

Support to medicines innovation at National level

National Competent Authorities (NCAs) responsible for key tasks, including

- Authorisation and Good Manufacturing and Lab Practices
- Clinical trial authorisation
- ATMPs Hospital Exemption
- Compassionate use
- NCAs scientific advice (fees might apply)
- NCA's Innovation Offices: specific schemes/services (fees might apply) including decision on applicable framework (e.g. device or medicine)

EU-IN Composition – March 2018

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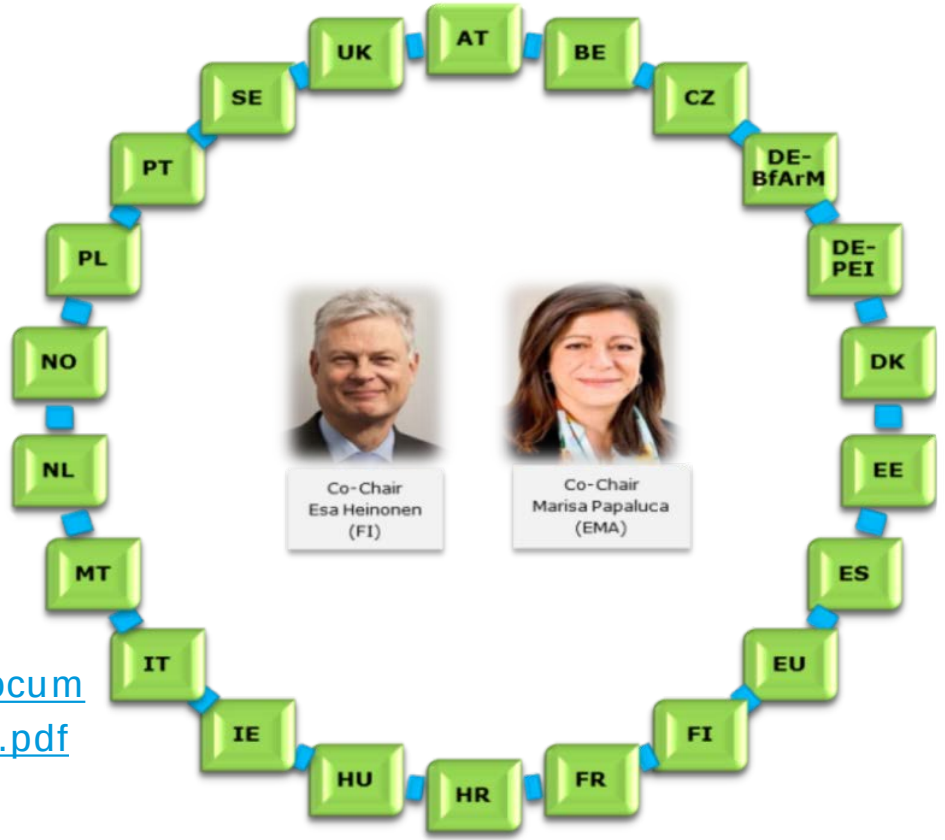
AT	FI	FR	PL	PT
BE	EMA	HR	NO	SE
CZ	ES	HU	NL	UK
DE (BfArM)	EE	IE	MT	23 offices
DE (PEI)	DK	IT	LUX	

Chairs

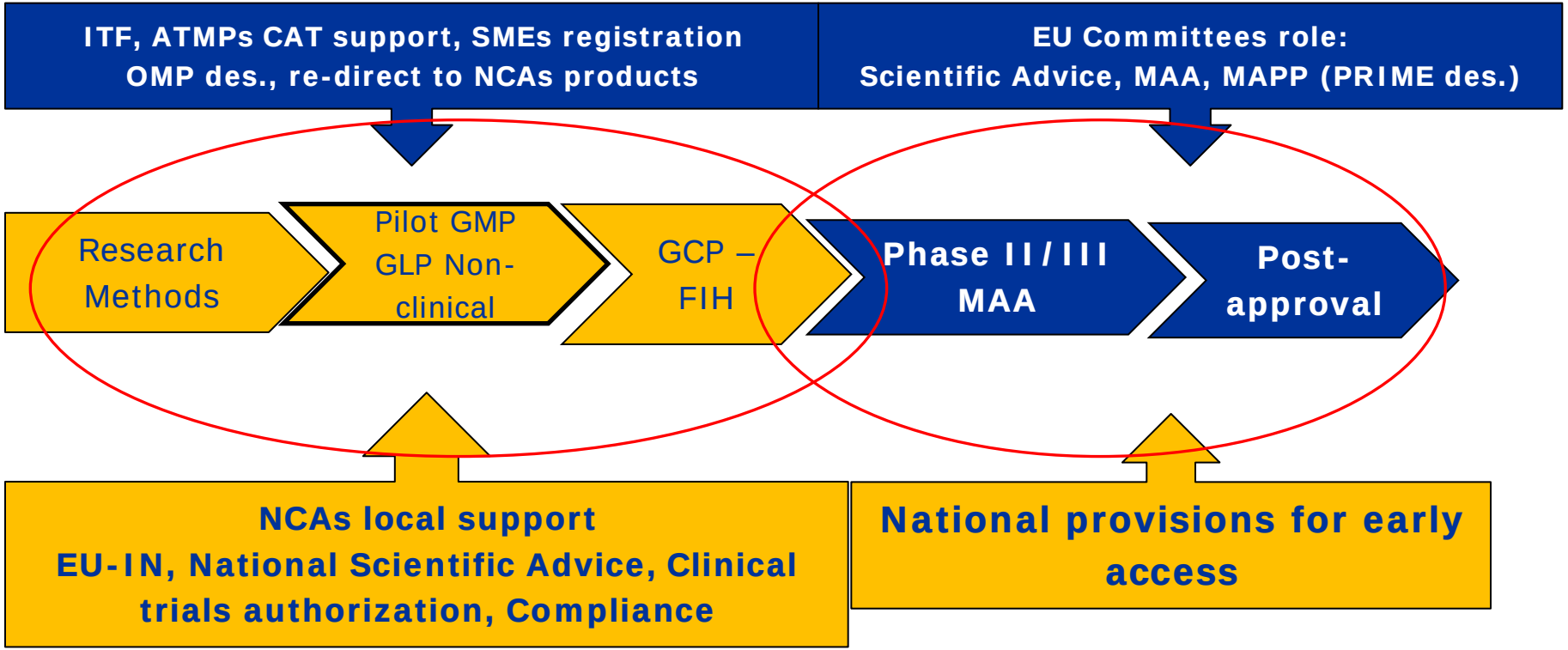


E-mail addresses for users

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500228157.pdf

EU-IN Mission

Addressing gaps: seamless support to Innovation at local and EU level



EU-IN core business

Innovation Offices join on a voluntary basis

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

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

The scope is wide and includes 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

Current EU-IN Activities – Management

Methodology for fast response to queries raised by members within the network

Promote core EU-IN innovation horizon scanning methodology

Review impact of Innovation offices on products development

Continue sharing and promote best practices across the Innovation Offices

Revise format and pilot process for planning and reporting on activities

Current EU-IN Activities – Knowledge

Develop methodology to share as appropriate information and data on Innovative products identified within the Agency and the network with the EMA Scientific Committees

- Develop methodology to share as appropriate information and data on Innovative products identified within the Agency, the network and with the EMA Scientific Committees
  - Consolidate **criteria** in the NCAs to consider products and/or developments as ‘innovative’ for the purpose of discussing and bring forward case-studies.
  - Discuss innovative products identified at EMA and at national Innovation offices level as **case-studies** to promote harmonisation, consistency and resolution of regulatory bottlenecks.
  - **Flag priority innovation areas** (therapeutic areas, technologies, other) where there is a need for the EMRN **to develop new tools.**

Current EU-IN Activities – Knowledge

Flag to the Network Training Centre identified emerging topics from innovative medicines which require training action to increase capacity and capability of the EMRN.

Keep the EU-IN updated on the progress of the H2020 CSA for Regulatory Science training of Innovators in Academia.

Current EU-IN Activities – Communication

Announce EU-IN relevant news within the EMA, the individual Innovation Offices, and the HMA websites.

Promote the concept and the usefulness of the EU-IN.

Strengthen the interaction with academia, hospitals and groups that could benefit most of the innovation offices regulatory support

Enhance visibility of the EU-IN via appropriate communication tools

Deliverables 2018

1. • Pilot tracking the companies' journey in the national and EU regulatory pathway
2. • Finalise a core EU-IN horizon scanning methodology
3. •List emerging challenges from selected innovative products discussed
   •Identify regulatory science topics which require NTC training coordination
4. • Map the areas of current mayor interest across the EU-IN to facilitate communication

Deliverables 2018

5

- Increase public dissemination of information and deliverables of the EU-IN and of the Innovation Offices activities

6

- Meetings: Web-sharing meetings in 2018 of plenary EU-IN (Jan, March, May, July, September) and drafting groups; a plenary Face-to-face meeting will take place once a year Q4.

7

- Maintain the EU-IN updated on the progress of the H2020 CSA for Regulatory Science training of Innovators Academic centres

Thank you for your attention

Further information

Heads of Medicines Agencies www.hma.eu

European Medicines Agency www.ema.europa.eu

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001768.jsp&mid=WC0b01ac0580b18a3a

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SCIENCE MEDICINES HEALTH

The EMA Regulatory Science Observatory and Horizon Scanning

An European and International Prospective

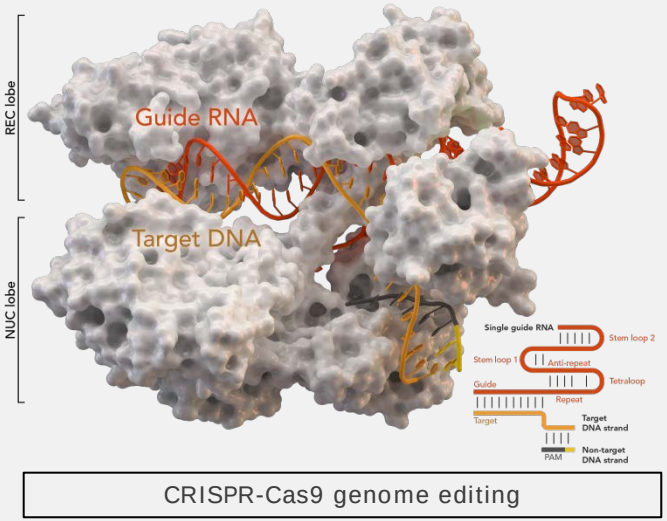
2nd International Awareness Session - The EU medicines regulatory system and the European Medicines Agency

Presented by Tony Humphreys on 8 March 2018
Scientific Committees Regulatory Science Strategy

An agency of the European Union

Innovation landscape: what we see

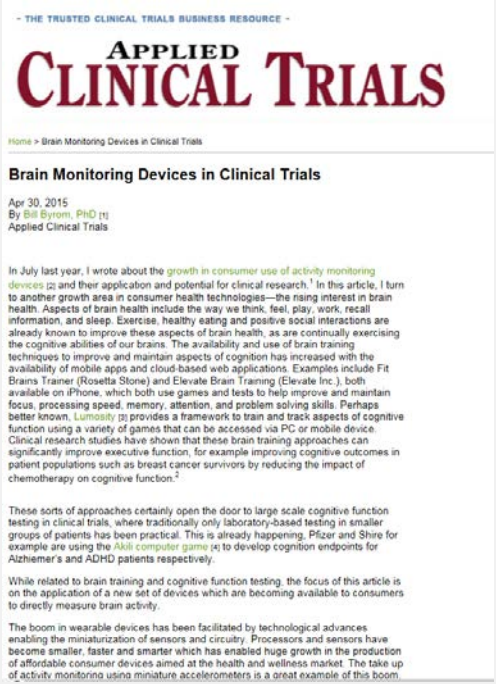
- New development paradigms are progressing with unprecedented speed
- Complex and challenging products to develop, manufacture, evaluate and make available to patients



CRISPR-Cas9 genome editing

Opportunistic Innovation Landscape

- Medical research and technological innovation are both advancing at an exponential pace, rapidly integrating each other
- Research and technology meet when there is a market opportunity, sometimes at unexpected moments and places
- This often brings radical systemic changes



- THE TRUSTED CLINICAL TRIALS BUSINESS RESOURCE -

APPLIED CLINICAL TRIALS

Home > Brain Monitoring Devices in Clinical Trials

Brain Monitoring Devices in Clinical Trials

Apr 30, 2015
By Bill Byrom, PhD [1]
Applied Clinical Trials

In July last year, I wrote about the growth in consumer use of activity monitoring devices [2] and their application and potential for clinical research.[1] In this article, I turn to another growth area in consumer health technologies—the rising interest in brain health. Aspects of brain health include the way we think, feel, play, work, recall information, and sleep. Exercise, healthy eating and positive social interactions are already known to improve these aspects of brain health, as are continually exercising the cognitive abilities of our brains. The availability and use of brain training techniques to improve and maintain aspects of cognition has increased with the availability of mobile apps and cloud-based web applications. Examples include Fit Brains Trainer (Rosetta Stone) and Elevate Brain Training (Elevate Inc.), both available on iPhone, which both use games and tests to help improve and maintain focus, processing speed, memory, attention, and problem solving skills. Perhaps better known, Lumosity [3] provides a framework to train and track aspects of cognitive function using a variety of games that can be accessed via PC or mobile device. Clinical research studies have shown that these brain training approaches can significantly improve executive function, for example improving cognitive outcomes in patient populations such as breast cancer survivors by reducing the impact of chemotherapy on cognitive function.[2]

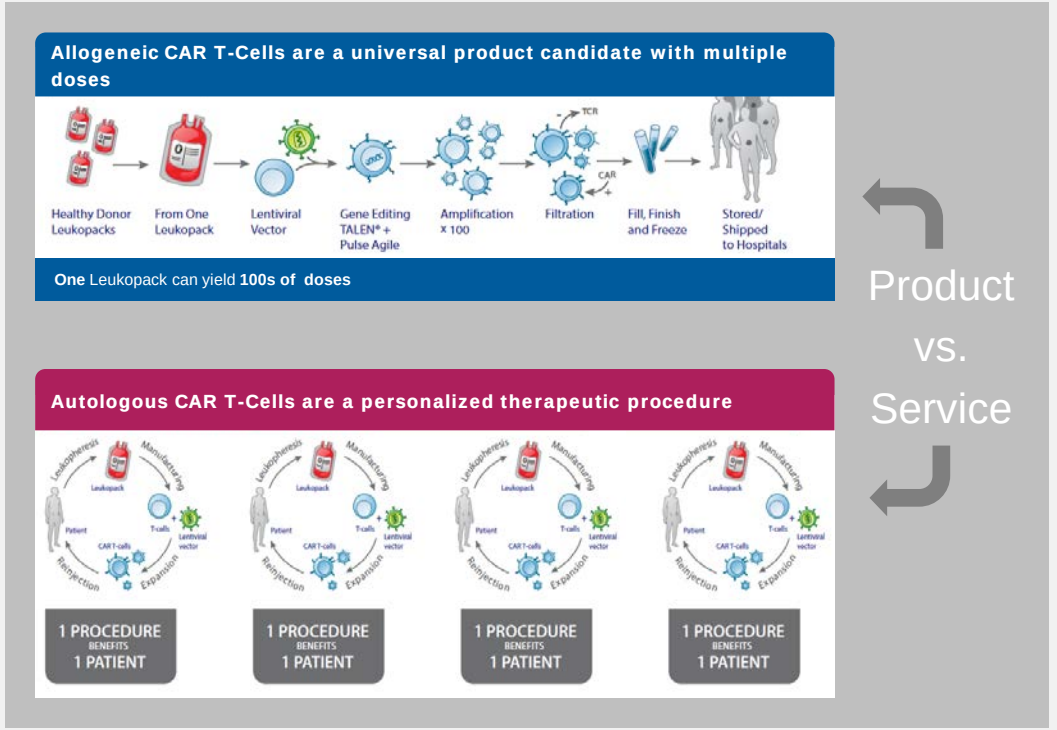
These sorts of approaches certainly open the door to large scale cognitive function testing in clinical trials, where traditionally only laboratory-based testing in smaller groups of patients has been practical. This is already happening, Pfizer and Shire for example are using the Akili computer game [4] to develop cognition endpoints for Alzhiemer's and ADHD patients respectively.

While related to brain training and cognitive function testing, the focus of this article is on the application of a new set of devices which are becoming available to consumers to directly measure brain activity.

The boom in wearable devices has been facilitated by technological advances enabling the miniaturization of sensors and circuitry. Processors and sensors have become smaller, faster and smarter which has enabled huge growth in the production of affordable consumer devices aimed at the health and wellness market. The take up of activity monitoring using miniature accelerometers is a great example of this boom.

Emerging business models

- Innovative industry is increasingly transforming itself into a service provider
- Industry needs also to train specialised medical staff for delivering innovative therapies to patients



Emerging business models: HTAs and payers

- Highly innovative, potentially curative medicines require re-definition of value
- Emerging business models are driving need to improve cooperation between EU Member States on a key element of drug-pricing decisions


POLICY PRIMER

Brussels gets into drug business

2018 is make-or-break for push to get countries to join up on prices.

By SARAH WHEATON AND CARMEN PAUN | 1/8/18, 1:30 PM CET | Updated 1/7/18, 7:45 PM CET

47

Few topics are more taboo in Brussels than the EU getting involved in drug pricing.

Yet that's exactly what the European Commission is doing.

MOST READ ARTICLES

1 Hungary has arrest warrant out

Why we need a new approach to innovation

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- **New competences** for the regulatory and public health systems, both for the evaluation and for the delivery to patients
- To **build expertise** to evaluate increasingly complex products, Regulators need to **reach out to many stakeholders** and **interact with new players** outside the health arena
- Shift from treatment to potentially curative medicines require **new approaches to value assessment, payment and financing**
- Constraints driving strategic allocation of resources

New role for regulators

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*"Regulators need to take a **new role** at the **crossroads between science and national healthcare systems**: in order to promote public health in the current environment, they can no longer be just a gateway between those two worlds; they need to become a catalyst, an enabler for science to be translated into patient-centred healthcare and fit in the reality of healthcare systems."*

Regulators as **enablers** between science and healthcare systems

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Scanning the horizon

Identifying the main gaps

Connecting various stakeholders together, in order to bridge gaps

EMA Regulatory Science Observatory: a collaborative approach

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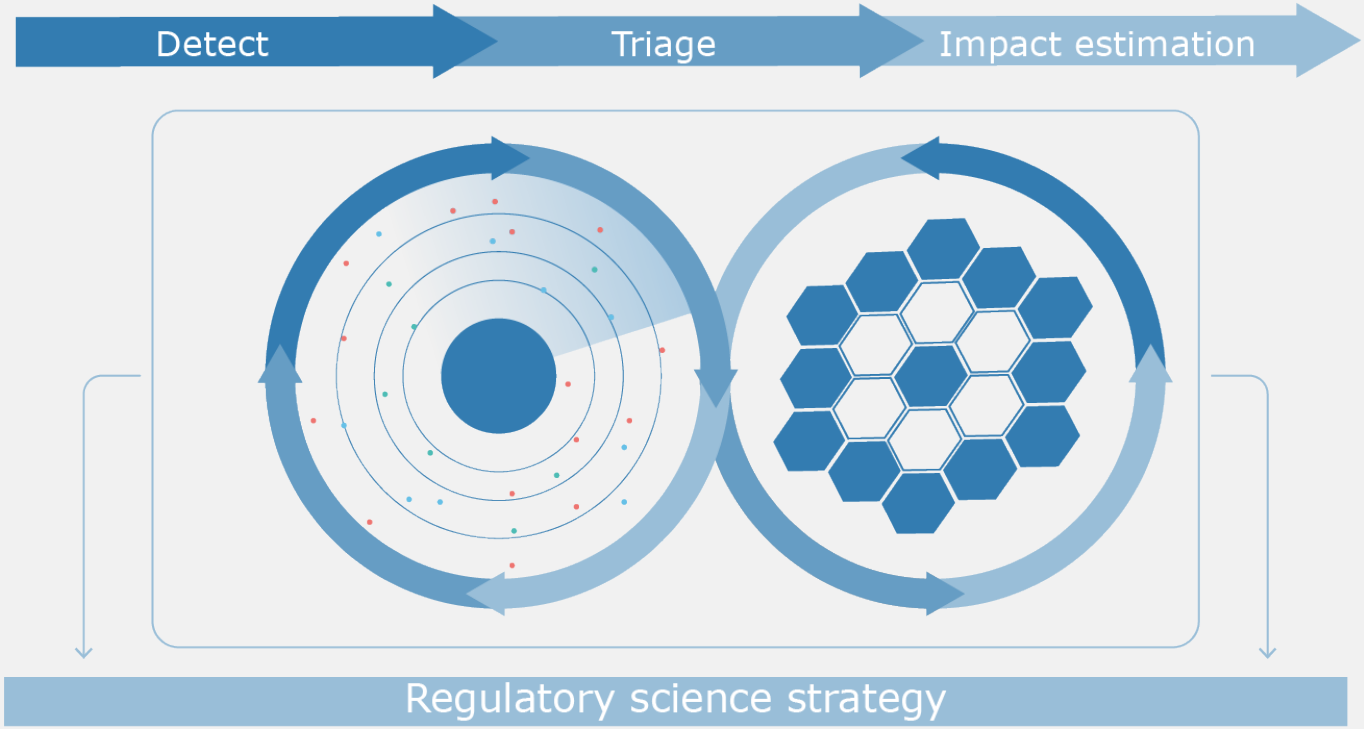
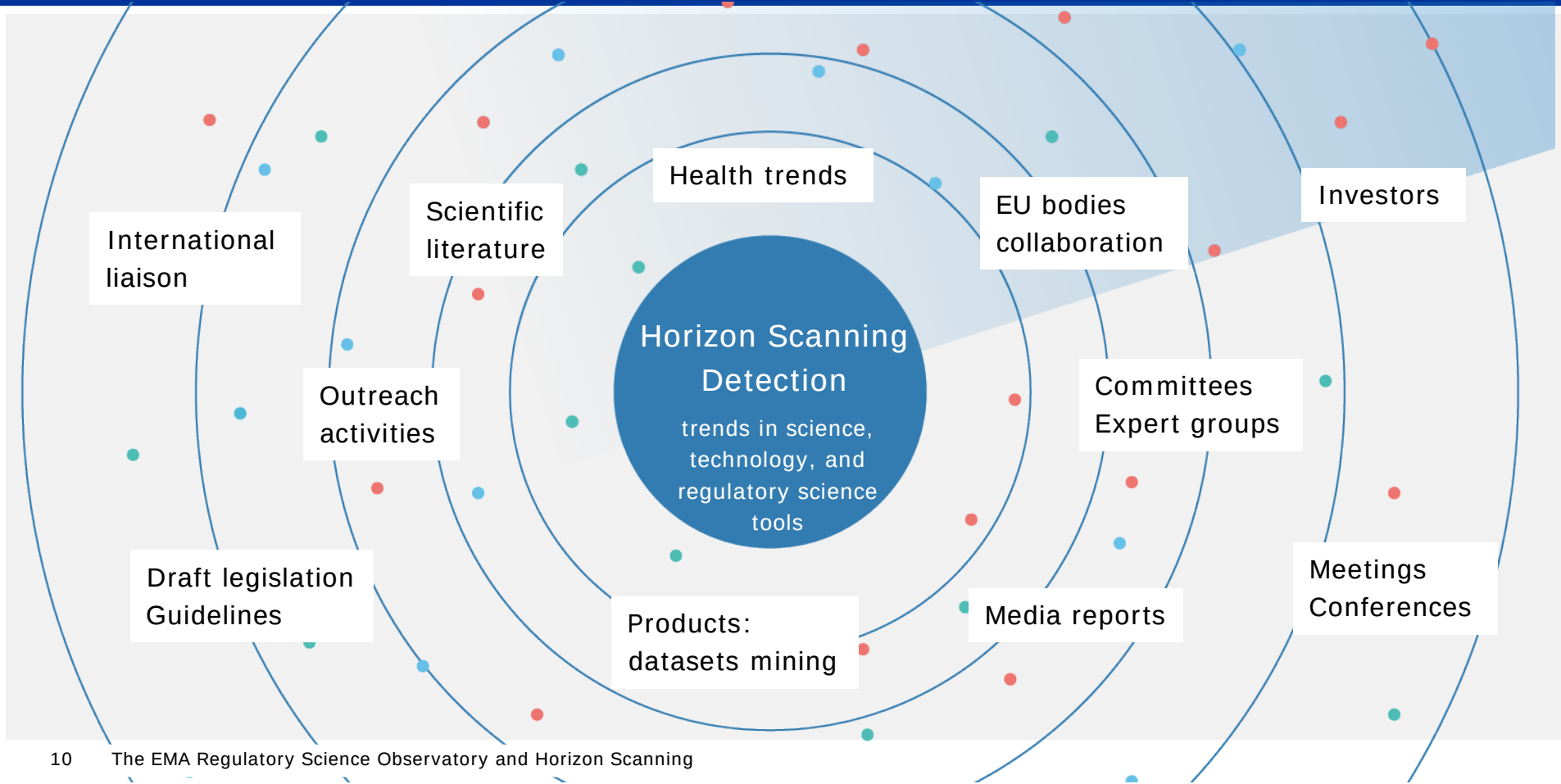


Informing the Regulatory Science Strategy



Identifying the main gaps: EMA baseline report

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Trends in science and technology

Therapeutic area diseases

Oncology/CNS neurodegenerative diseases Diabetes/ Obesity/ HIV/ Vaccines/ Immunotherapies

Gene therapy and regenerative medicine

Gene therapy/ cells and tissues based products
New materials

Personalised medicines

Personalised medicine/ Biomarkers

Methods, technologies and other trends

Nanotechnology/ New Omics (e.g. microbiomics)
Taxonomy of the disease/ Digital health and wearable technology/ Novel manufacturing and 3D printing

Special populations

Pregnancy/ Paediatric/ Geriatric/ Health threats (science)
Anti-microbial resistance

Trends in Regulatory Science tools

Access pathways

PRIME/ Adaptive pathways/ Biosimilars

HTAs' and Payers' collaborative activities

Synergies with HTA/payers activities

Non-clinical methodology

Novel non-clinical models

Clinical methodology

Modelling and simulation/ Extrapolation
Patient reported outcomes (PROs)/ New endpoints
Bayesian methods

Risk/benefit evaluation

Risk benefit project

Big data and e-health

Big data/ Real world evidence
E-health/ EU strategy and regulatory tools

EMA Horizon Scanning: specifications

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Working definition: Horizon scanning is a systematic examination of information to detect early signs of important and potentially disruptive developments impacting on public health.

Objective: This enables the Agency to build the capacity, capability and collaboration it needs to leverage potential opportunities and address threats. By informing decision making, it influences policy-making in science and health. Clarifying the system in which the Agency operates it guides its evolution to improve access to innovative medicines in Europe

Stakeholders: EMA executive bodies, EU institutions, Network, Non-EU Regulators, developers, Academia, HCPs

Time to Horizon: Systematic: 3-10 years before MAA; Periodically: 3-20 years before MAA

EMA Horizon Scanning: Process

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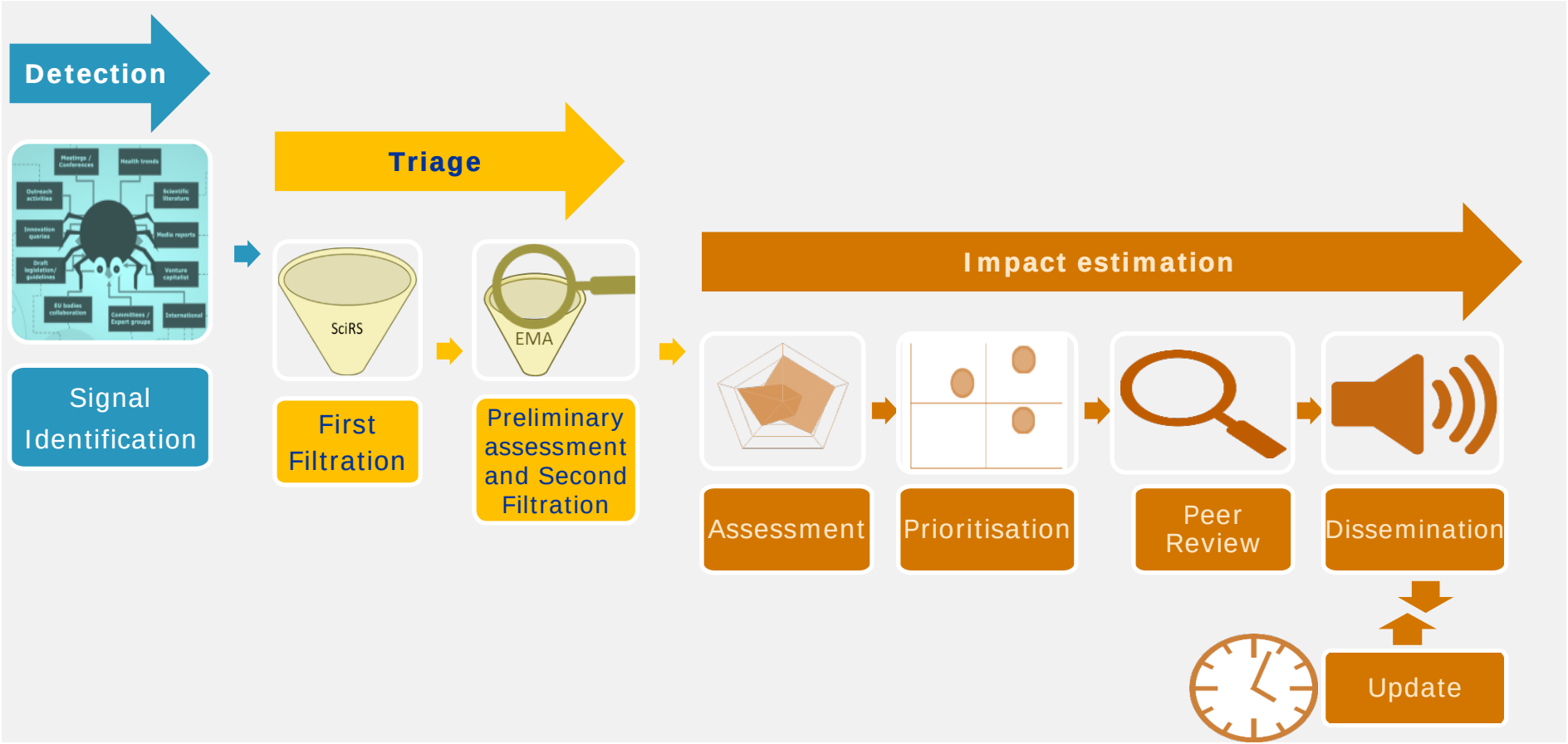
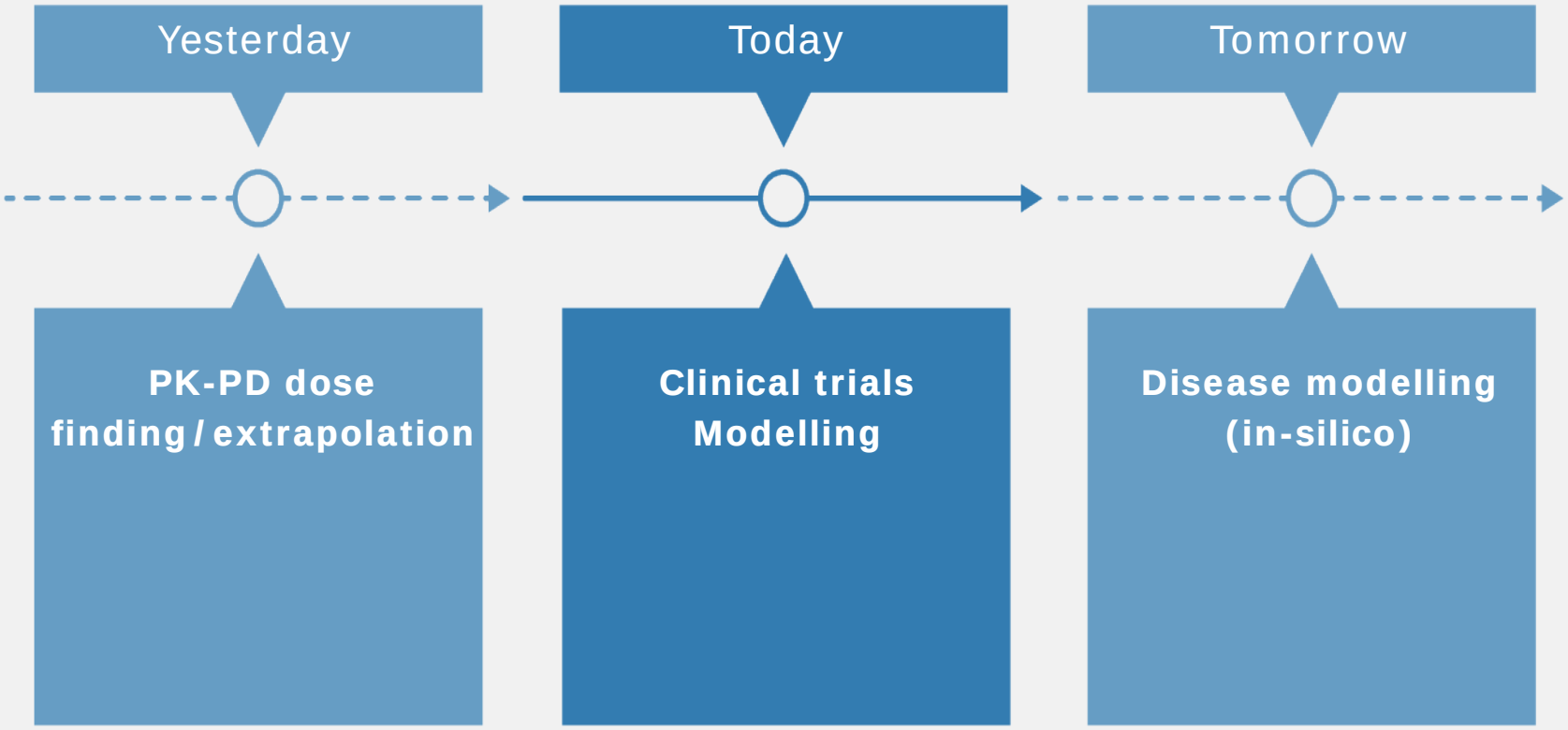


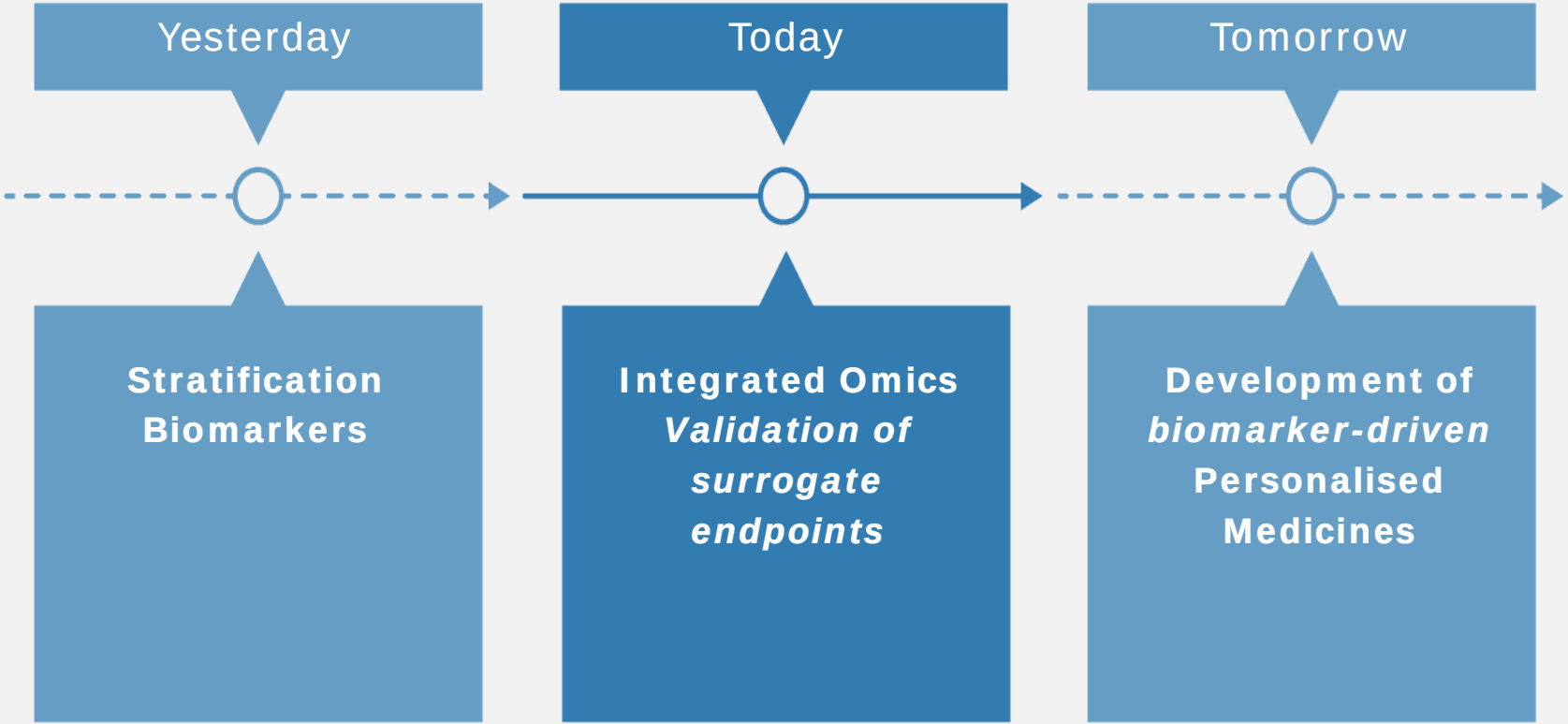
Engaging with partners and stakeholders

- Leveraging collaboration at EU and international level with partners
- Stakeholder engagement to avoid self-referential outcomes
- Identification of hotspots in the current regulatory science discussions

How are we impacting on science



How we can impact on science



Proposed Projects and Outcomes

Project 1:

Analysis of global best practices in horizon scanning methodologies

- Analysis of existing methodologies and approaches
- Identification of best practices

Project 2 Part 1:

Leveraging outcomes of Horizon Scanning

- Critical Innovation (products and technologies)

- Identification of product and technologies, where regulatory science approaches are required or could be of benefit
- Leveraging from ICMRA leadership to engage with policy/key decision makers

Project 2 Part 2:

Leveraging outcomes of Horizon Scanning

- Expertise and Skills

- Identification of future expertise requirements and potential opportunities for collaboration and capacity building to support innovation

Project 3:

Novel Approaches to Licencing/ Early Access Schemes

- Analysis of barriers to early access approaches
- Detail how barriers can be overcome using regulatory science initiatives
- Leveraging from ICMRA leadership to engage with policy/key decision makers

21st century model healthcare – data-driven, patient-centred

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21st century model regulator?

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Questions