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Horizon scanning of innovative medicines, devices, diagnostics and digital technologies for stakeholders in England

NIHR Innovation Observatory, UK

Saturday 19th June 2021

Disclaimer

This project is funded by the National Institute for Health Research (NIHR) [HSRIC-2016-10009/Innovation Observatory]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Learning objectives

- To gain an understanding of horizon scanning in the context of HTA
- To provide an overview of key elements for consideration in a horizon scanning process/system
- To discuss challenges and opportunities (present and future) arising from horizon scanning of pharmaceutical and non-pharmaceutical health technologies

HTAi 2021 Contributions from NIHR Innovation Observatory

Pre-Annual Meeting Workshops:

- WS07: Horizon Scanning of New and Emerging Health Technologies (Medicines, Devices, Diagnostics and Digital) For HTA Stakeholders **Day 1: Saturday, June 19, 2021 - Half Day Session from 12:00 to 15:00 (UTC)**
- WS13: Simplifying horizon scanning with the use of digital solutions (ScanMedicine) **Day 2: Sunday, June 20, 2021 - Half Day Sessions from 08:00 to 11:00 (UTC)**
- WS18: Providing intelligence to support an accelerated innovation pathway: A UK COVID-19 Story **Day 2: Sunday, June 20, 2021 - Half Day Sessions from 17:00 to 20:00 (UTC)**

Oral presentations:

- A semi-automated tool for horizon scanning preprint repositories to support decision-making
- Exploring the value of soft-intelligence: a case study using Twitter to track mental health during the COVID-19 pandemic
- **Identification of COVID-19 diagnostics using horizon scanning approaches to inform decision making***
- **A semi-automated process to monitor the clinical development and regulatory approval pathway of innovative medicines***
- Tracking global views on COVID-19 vaccines: a case study deploying machine learning to analyse public insights from Twitter

Poster presentations:

- A pipeline analysis of Tumour Agnostic Therapies (TATs) in clinical development

***shortlisted for HTAi Oral Presentation Award**

Welcome & Introduction

Workshop Panel

Dr Anne Oyewole
Programme Manager – Healthcare Innovations (Devices, Diagnostics and Digital)

Sonia Garcia Gonzalez-Moral
Horizon Scanning Specialist

Sarah Khan
Horizon Scanning Specialist

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Presenter: Anne Oyewole

NIHRIO – Who we are and what we do

- Funded by the National Institute for Health Research (NIHR)
- Horizon scanning centre based at Newcastle University
- We identify and track health innovations (e.g. medicines, devices, diagnostics and digital)
- We work closely with our stakeholders to deliver timely intelligence on health innovations in the pipeline
- We also engage in active research to advance horizon scanning methods and tools to identify emerging health innovations and current/future trends
- Core activities:
  - ❖ **Topic selection and prioritisation for HTA stakeholders**
  - ❖ **Building advanced Horizon Scanning Tools**
  - ❖ **Patient and Public Involvement** through **VOICE** (Valuing Our Intellectual Capital and Experience)
  - ❖ **Bespoke Intelligence Reports**

Question to audience

Please tell us about yourself:

- Name
- Job role
- Organization you work for

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Horizon Scanning in the Context of HTA

Presenter: Sonia Garcia Gonzalez - Moral

Question to audience

What is your level of experience and or knowledge on horizon scanning?

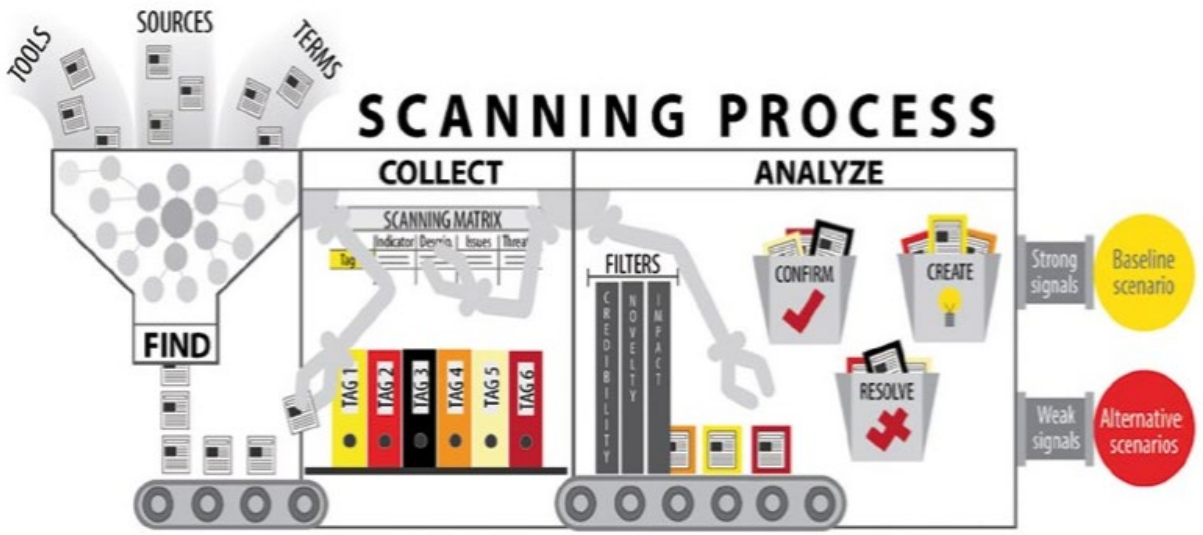
A. Novice/Beginner

B. Intermediate

C. Experienced

Horizon scanning

- What is horizon scanning?
- Why is it necessary?
- Elements of a horizon scanning system



Horizon scanning: definition

- "The systematic examination of potential (future) problems, threats, opportunities and likely future developments, including those at the margins of current thinking and planning. Horizon scanning may explore novel and unexpected issues, as well as persistent problems, trends and weak signal." (van Rij, 2010)

- "Timely information on the impact on the health technologies to decision makers in health care." (Douw, et al. 2003)

What is horizon scanning?

- **Analytical method** used to describe an **organized formal process**
- detect and assess **emerging threats and opportunities**
- use in guiding decision- and policy-making, and risk management **ahead of actual events**

Image courtesy of: Vecteezy.com

Horizon Scanning is NOT about predicting the future like this…

Image courtesy of: Vecteezy.com

It is about detecting signals and exploring possibilities for the future to ensure that your strategies are robust

Image courtesy of: Vecteezy.com

Why horizon scan?

Horizon scanning is a **crucial component** of the HTA system

- ✓ Topics identified and sent for evaluation at the right time
  - evaluation prior to widespread use
  - protects patients
  - supports innovation
- ✓ Alerts policy-makers/health service organisations to innovations that will:
  - Change current options/decisions
  - Change current guidance/guidelines
  - Require further planning or commissioning activity
- ✓ Monitor key products through clinical development
- ✓ Facilitates adoption of 'lower-profile' technologies

Used by policy-makers **to identify** and **assess** new, or a new use of existing healthcare technologies:

- ✓ Therapeutic technologies – **new medicines**

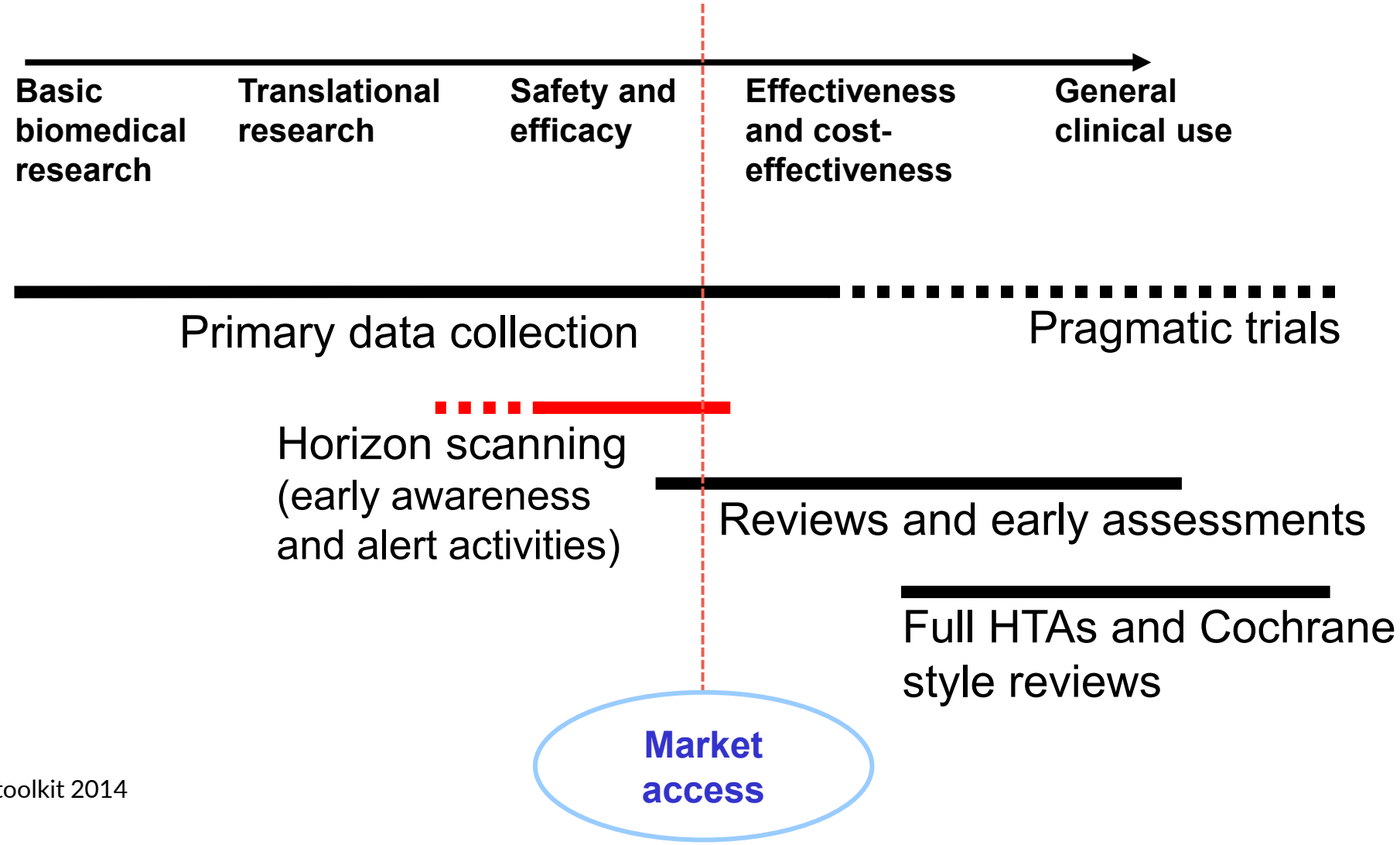
- ✓ Medical Technologies – **devices, diagnostics, digital interventions**

- ✓ Public health interventions – **vaccines, screening programs, etc.**

Assessment at an early stage enables health authorities and health services to make the necessary preparations for the introduction of new health technologies

Key Elements of the HTA System

Role of horizon scanning in the HTA process



Source: EuroScan toolkit 2014

Other roles of horizon scanning

Horizon scanning builds health system resilience….

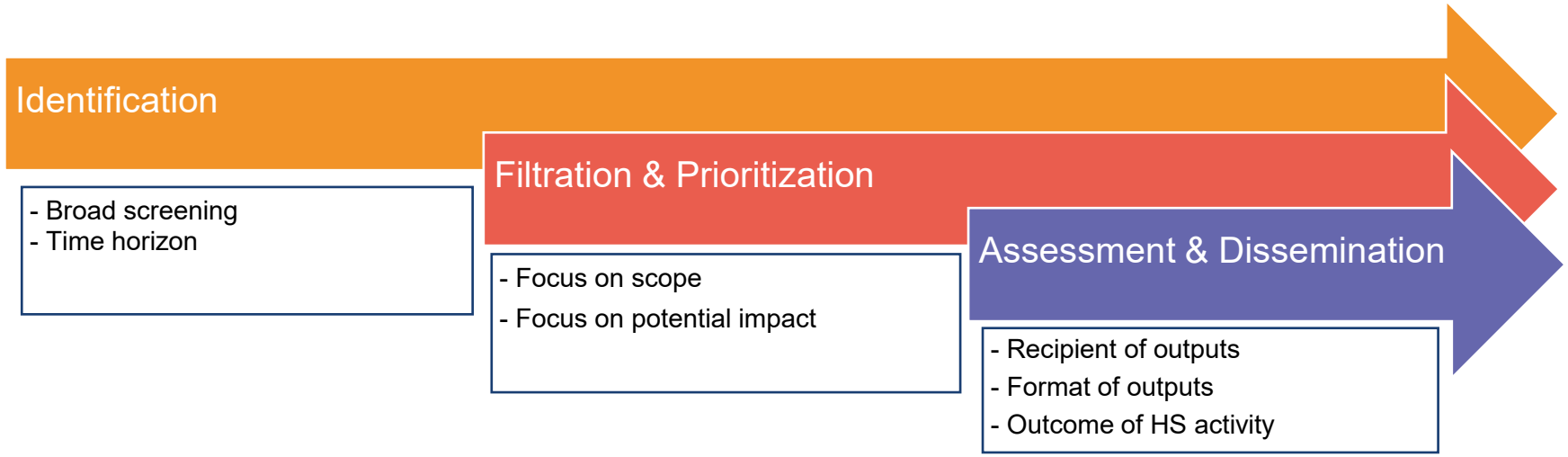
- Manage budgets
- Anticipate pressures (financial and service delivery - new and redesign)
- Identify areas for disinvestment/ reassessment
- Manage entry of new healthcare innovations
- Identification of areas of unmet need
- Identifies areas for further R&D

Being prepared, it's better than fire fighting!

Preparedness should lead to improved patient care through timely access to new innovations

Horizon scanning process - Overview

Horizon scanning generally follows a process of signal detection, filtration, prioritisation, assessment and dissemination



Question to audience

Do you have a formal process for horizon scanning? (Please choose one response)

A. Yes

B. No

C. Unsure

Question to audience

What is your perception of the level of maturity of your horizon scanning process/system? (Please choose one response)

A. Highly developed

B. Developed

C. Developing

D. Least developed

The structure of a Horizon Scanning system will depend on several factors…….

Things to consider for a horizon scanning system

HS Timeline

- What is the expected time-horizon for technologies entering the health service?
- What is the furthest point in the future you are considering? E.g. 1-2; 3-5; 5-10 or 10-20 years
- Are you considering scanning multiple horizons?

HS Scope

- What type of technology do you want to identify and assess? E.g. devices, drugs, procedures
- What stage of development do you want to cover?

HS Purpose

- What is the scope of your HS system?
- When will you conduct horizon scanning? E.g. on-going basis, as needed etc.

Stakeholders

- Who will the HS system inform? E.g. Health department policy-makers, Hospital managers, Regulatory agencies, Clinicians, Patients/consumer groups
- What type of information will they need?
- Which sources will you need to gather data/information from?
- How will you collate data and information emerging from HS?
- How will they use it?

Healthcare System

- How is it funded?
- Coverage: National/Regional

Regulatory Jurisdiction

- Coverage: National and or International

Question to audience

Whether your horizon scanning process is formal or emergent, please share with us what your horizon scanning supports decisions on? (Please select all that apply)

A. Technology assessment
B. Disinvestment
C. Managed entry of new healthcare innovations (medicines and/or medical devices)
D. Identification of unmet needs
E. Research prioritisation
F. Other

Question to audience

Please tell us what your horizon scanning activity focusses on? (Please select all that apply)

A. Medicines
B. Medical Devices
C. Diagnostics
D. Digital interventions/applications
E. Other (surveillance, public health, procedures, etc.)

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Horizon Scanning for 'Innovative' Medicines

Presenter: Sarah Khan

Question to audience

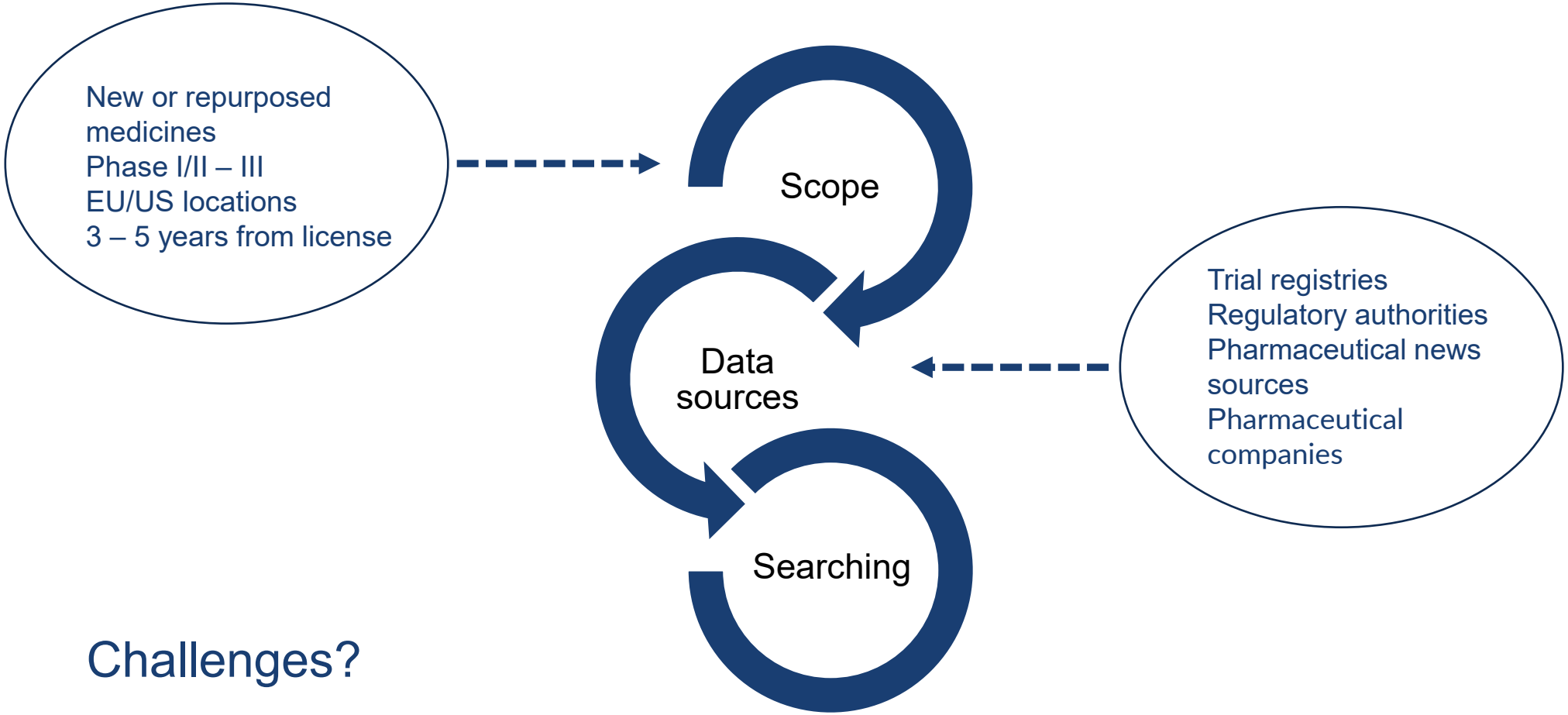
How would you describe an innovative medicine? (Please choose one response)

A. New class of drug
B. New indication
C. New route of administration
D. New combination of drugs
E. All of the above

Our definition of innovative medicine

- New medicinal product
- New biosimilar
- New prophylactic vaccine
- New indication
- New formulation/route of administration
- New fixed-dose combination
- New combination
- New subgroups / mutations
- New stage of disease
- New line of treatment
- New population – age group
- New population - comorbidity

NIHRIOs horizon scanning process: Medicines



Challenges?

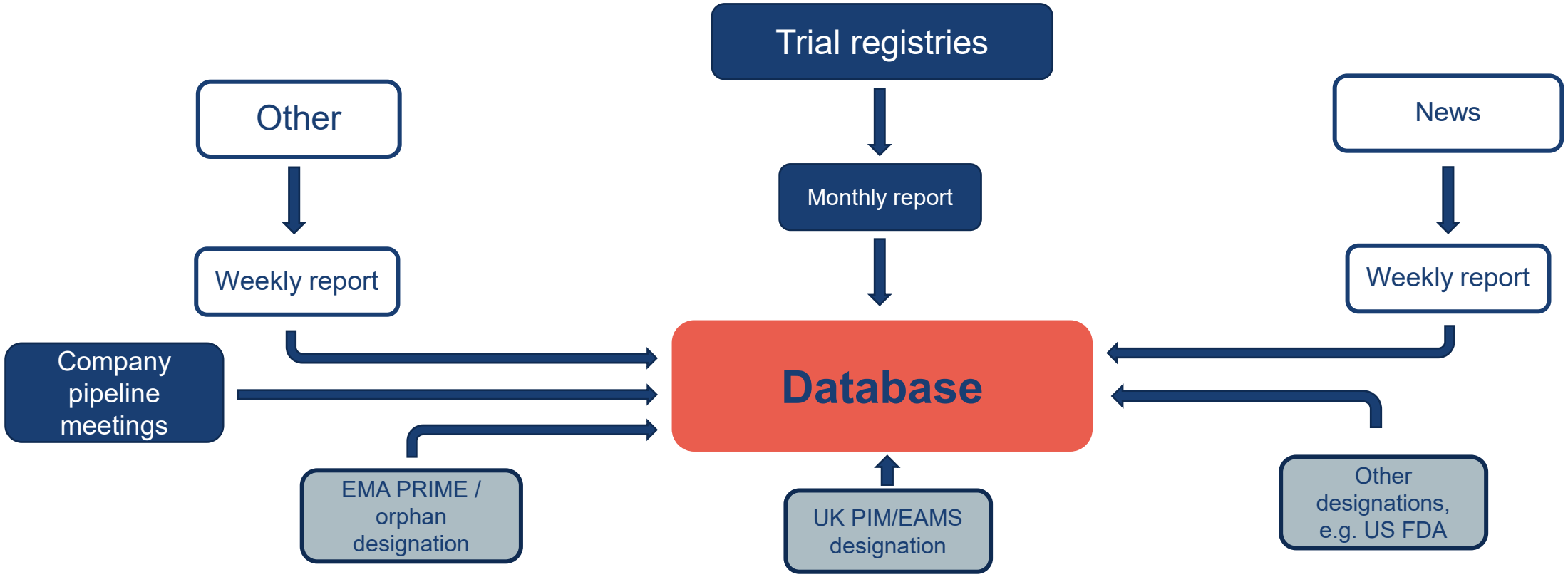
Question to audience

Where do you collate data and information emerging from horizon scanning (medicine)?

Horizon scanning database

- Different pieces of horizon scanning work require a particular database
- Our innovation database has a very specific purpose geared towards producing particular outputs, however, it is not malleable enough to produce some ad hoc outputs (COVID-19 therapeutics scan)
- Excel is customizable, however handling large amounts of data becomes challenging

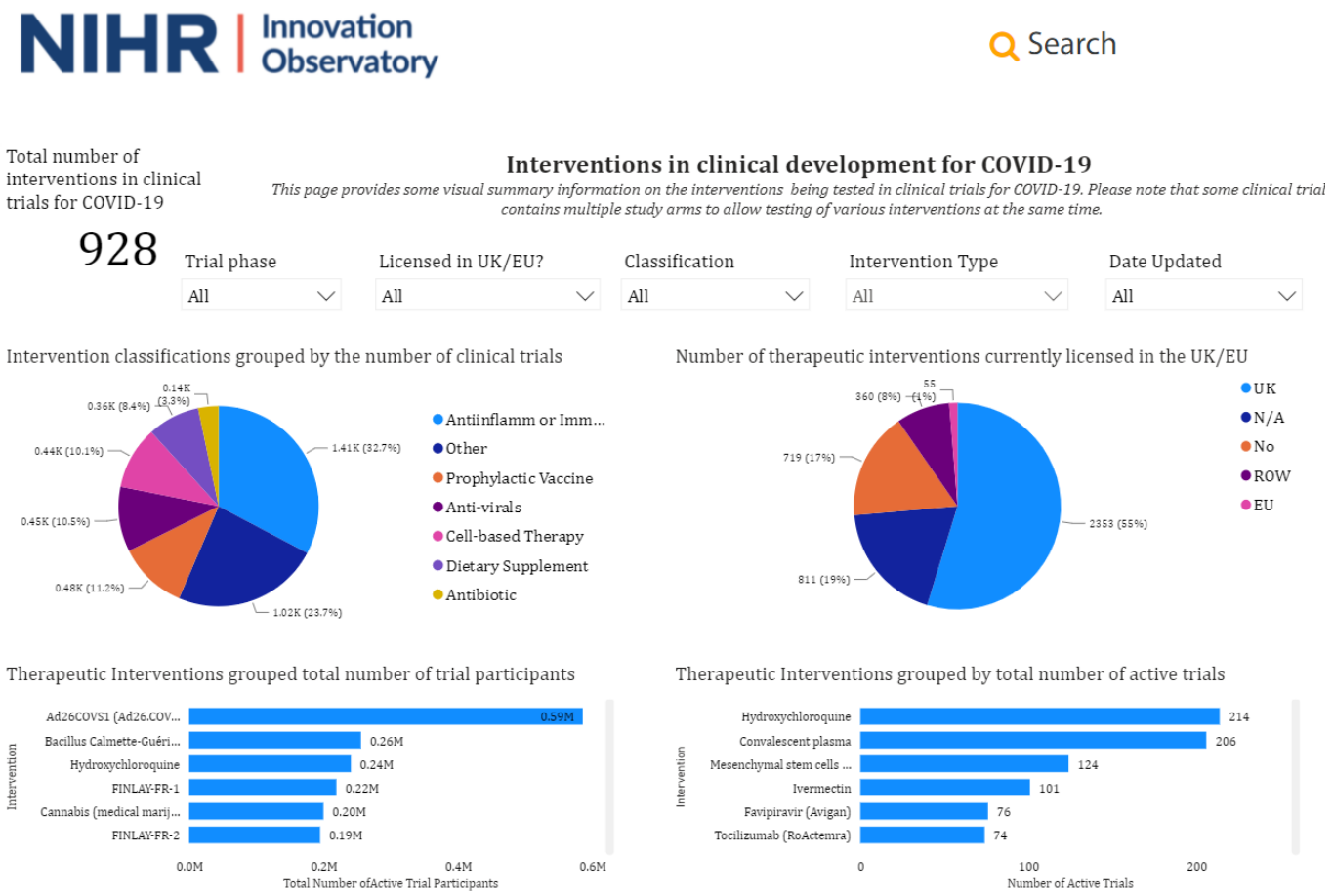
NIHRIOs horizon scanning intelligence gathering



Horizon scanning outputs

- Filtration forms
- Briefing documents
- Dashboards
- Datasets
- Bespoke reports

http://www.io.nihr.ac.uk/covid-19-updates/



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Case Study 1: Tumour Agnostic Therapies (TATs) Horizon Scan

Why horizon scan for TATs?

- TATs also referred to as histology-independent therapies, are recent innovations, wherein treatment is based on the cancer's genetic or molecular alterations rather than cancer type and/or site of origin

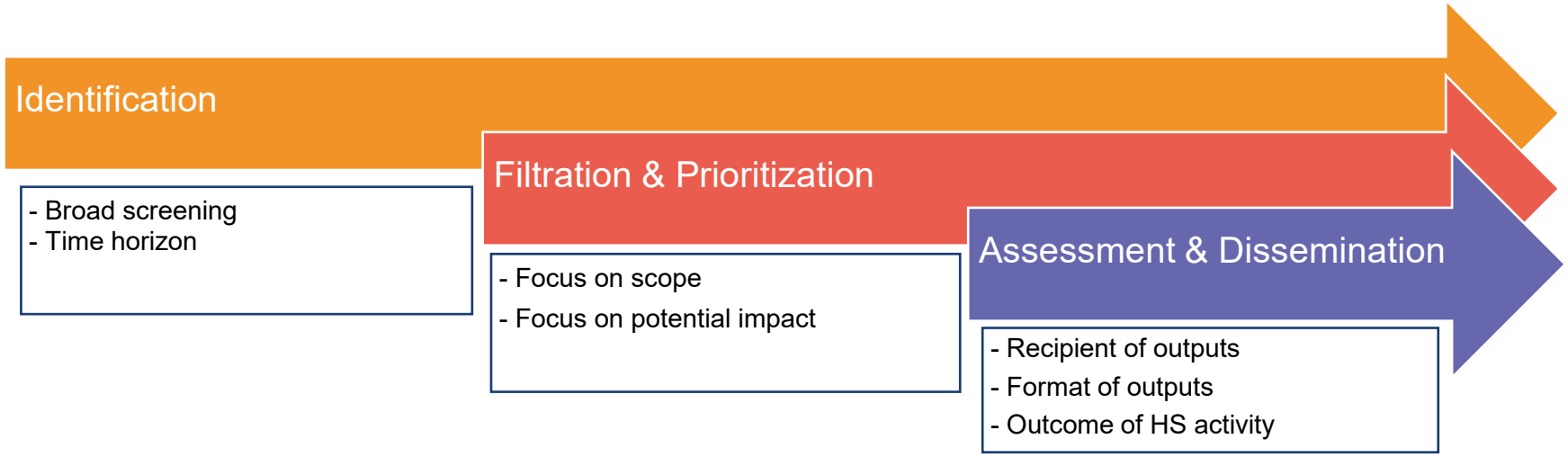
- TAT as an emergent innovation can change genetic testing and treatment pathways in oncology – preparedness for appraisal and adoption into the NHS

- It is a challenge for HTA bodies to appraise TATs due to:
  - 'Immature' clinical data from trials with small populations (mostly from 'single-arm' basket trials)
  - Limited evidence for robust cost-effectiveness assessment

Project objectives & scope

- This scan was undertaken to update a previous scan in order to:
  1. Inform the early products work stream of a HTA Stakeholder (AAC)
  2. Support the development of the national genomic test directory of another HTA stakeholder (NHSE Genomics and Commercial Unit)
- The scan was scoped to ensure that the requirements of the 2 different stakeholders were addressed using a single 'spine' of data
- Active 'stakeholder engagement' was employed to address this via –
  - Setting up a 'working group' with all relevant parties
  - Agreeing a project brief / scoping document
  - Regular interim meetings to address any challenges
  - Agreeing delivery timelines and dissemination strategy

Horizon scanning process - Overview



Identification

- The innovation database was queried for this purpose

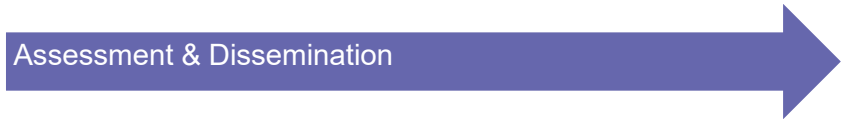
- True TATs are not always simple to identify as such therapies may begin development as histology-independent *or* tumour-specific, open to subsequent change

Filtration and prioritisation

- For this scan, the following criteria were applied:
- Inclusion
  - All technology records for solid tumours + genetic/biomarker subgroup
  - All technology records with multiple cancer indications + genetic/biomarker subgroup
  - Technology records with ≥ phase I/II trials
- Exclusion criteria
  - Technology records with solid tumour indications with no genetic/biomarker subgroup
  - Technology records with single cancer indications + genetic/biomarker subgroup
  - Technology records with no associated clinical trial
  - Technology records with already approved TATs being developed as line extensions in the same genetic mutation subgroup (i.e., pembrolizumab, larotrectinib, or entrectinib)

- Type of therapy, combination/monotherapy
- Genetic mutations/biomarkers presence
- Manufacturer, clinical trial details
- Regulatory data e.g. Orphan awards, MA/MAA estimates

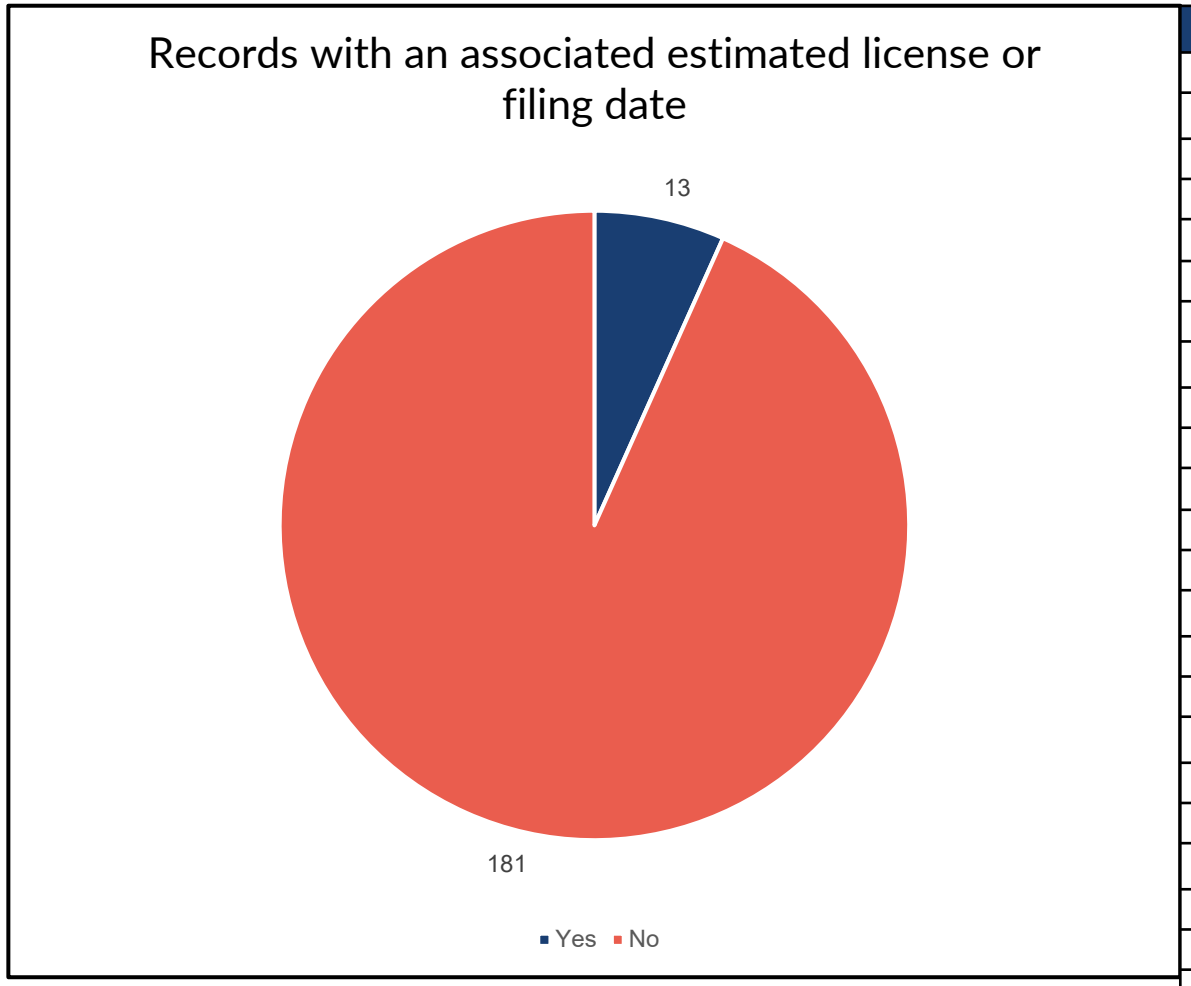
Dissemination



Dissemination strategy was determined before carrying out the scan

- Timelines for delivery
- Interim reporting
- Final outputs (reports/dataset)
- Follow-up/feedback

Outcome: Exemplar of key data for HTA stakeholders



Associated biomarkers in CTs		
AKR1C3	EphA2	Mesothelin expression
AKT2	FANCA	MRE11A
ATR	FANCC	MSS
AXL	FANCE	MTOR
BARD1	FANCF	MYC/N
BRIP1	FANCL	NBN
CCNE1	FANCM	Nectin-4 (PVRL4)
CCR5+	GNAQ/11	NTSR1
CD123+	GRPR	NY-ESO-1
CD19+	HER2/ERBB2	PALB2
CD22+	HLA-A	PD-L1
CD20+	HLA-A2	PD-L2
CD30+	HPV	PPP2R2A
CDK4	HRD+	PRAME
CDK6	IFNG	PSCA
CEACAM5	INT1	RAD51
CHEK1	KEAP1	SETD2
CLDN18.2	LAG-3	SSTR2
CLDN6	LAGE-1A	STK11
CLEVER-1	MAGE-A4	TMB-H
CYP2D6	MAP2K2	TROP2
dMMR	MAPK1	VEGFR
	MAPK3	Virus-associated*

Value for HTA stakeholders

- Informed AAC of TATs in development that might proceed to HTA assessment
- Informed the NHSE Genomics and Commercial Unit of genetic biomarkers not on the National Genomics Testing Directory

Reflections on the case study

- This scan provided an initial ‘spine’ of data to support different HTA stakeholders; further enrichment and/or ‘deep dives’ may be necessary
- Subject matter expertise (e.g. oncologists, genomics) will add value to horizon-scanning and HTA decisions
- Clinical trial descriptions (e.g. trial design, genetic testing information) are often unstructured, making horizon scanning and data extraction challenging
- Data sharing / confidentiality considerations are important part of horizons-scanning and should be addressed early on
- Disseminating horizon-scanning intelligence to stakeholders; 'snap-shot' vs 'real-time' data?

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Horizon Scanning for Devices, Diagnostics and Digital Technologies (DDD)

Presenter: Sarah Khan

Medical Devices, Diagnostics & Digital Technologies (DDD)

Medical devices....products, services or solutions that prevent, diagnose, monitor, treat and care for human beings by physical means

In vitro diagnostics ....non-invasive tests used on biological samples to determine the status of one's health

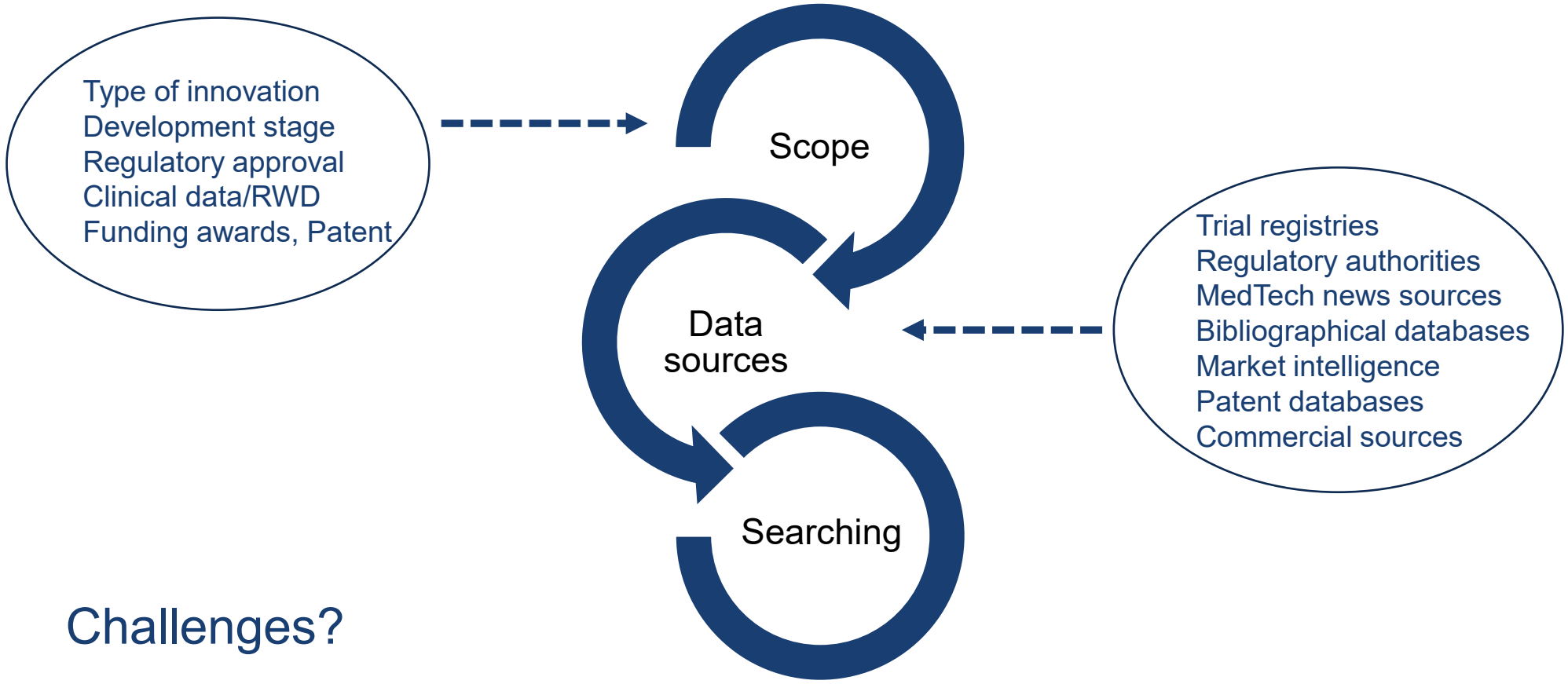
Digital health...tools and services that use information and communication technologies to improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle

Image courtesy of: freepik.com

NIHRIOs horizon scanning process: DDD

- Innovation pathway for DDD is less clearly defined than for medicines ….. development, clinical validation and regulatory approval
- Horizon scanning principles being applied to develop relevant methodologies, tools, techniques and systems
- Development of proactive approaches to identify early signals of new technological innovations
- Provision of intelligence on specific areas of technological innovations to inform health authorities and health services to enable them to:
    - Evaluate potential impact of these technologies
    - Anticipate some of the consequences for the care pathway

NIHRIOs horizon scanning process: DDD



Challenges?

Question to audience

Where do you collate data and information emerging from horizon scanning (DDD)?

Horizon scanning outputs

- Dashboards
- Datasets
- Bespoke reports

http://www.io.nihr.ac.uk/covid-19-updates/

COVID-19 Diagnostic Test Landscape

The interactive map provides an overview of the global scale of diagnostic tests that have been developed for COVID-19.

Total Number of COVID-19 Diagnostics

2328

Country of Development

All

Number of Commercialized tests

2074

Number of Tests in Development

254

To tailor the countries displayed on our interactive map, select the country of interest from the 'Country of Development' drop-down menu.

To select multiple countries, press and hold CTRL on the keyboard whilst clicking country names from the menu.

To remove a country from the selection, press and hold CTRL whilst clicking on the country a second time.

To stop viewing specific countries that are selected from the drop-down, click 'Select all' in the drop-down menu.

Development Status Commercialized In development

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Case Study 2: Artificial Intelligence (AI) Horizon Scan

Why AI?

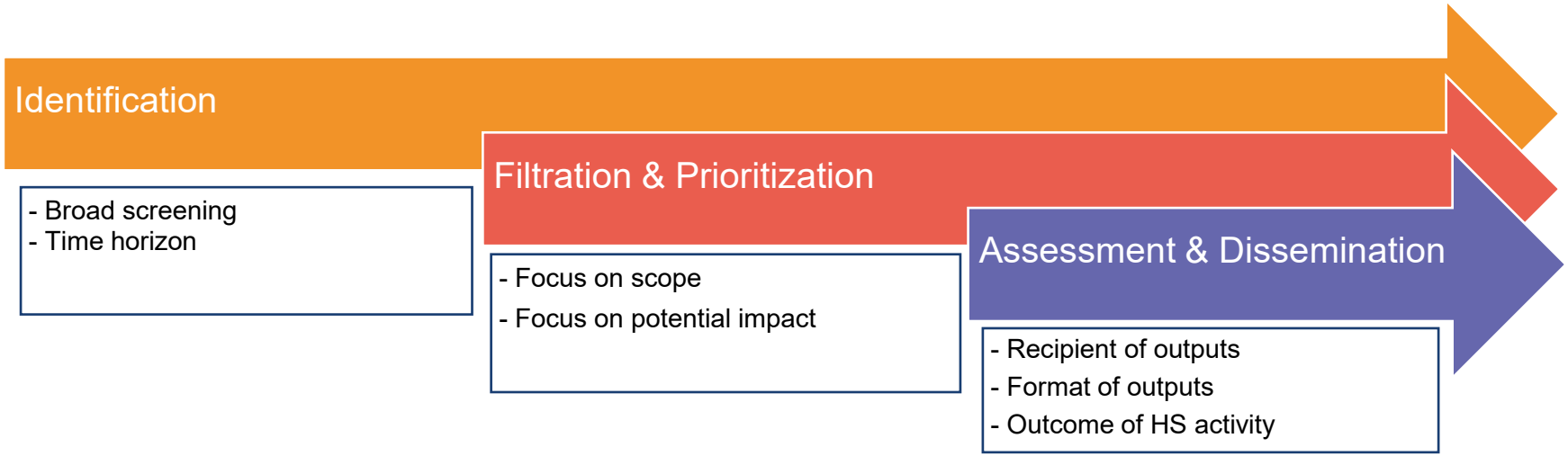
- Umbrella term to classify technology that mimics human intelligence, which can be used to automate, predict and optimise everyday human tasks
- Application: Early detection and diagnosis, treatment, outcome prediction and prognosis evaluation, administrative tasks
- Likely to have a significant impact on important aspects of UK policy and service delivery across a wide range of clinical areas
- Enormous potential for improving the delivery of healthcare
- Associated with challenges e.g. displacement of traditional technologies/human processes, lack of regulatory framework and policy guidelines

Project scope

- Scan requested by NHSX and also reviewed by wider HTA stakeholders (AAC and NICE)
- This scan was undertaken in order to:
  - Inform stakeholders of pipeline of development of AI technologies in healthcare (all stages of development)
  - Allows stakeholder to evaluate the potential impact of these technologies
  - For strengthening negotiation position between health services and companies
  - To improve patient care through timely access
  - To facilitate the managed entry of new technologies in the next 12-18 months

- Active 'stakeholder engagement' was employed to address this via –
  - Setting up a 'working group'
  - Agreeing a project brief / scoping document
  - Regular interim meetings to address any challenges
  - Agreeing delivery timelines and dissemination strategy

Horizon scanning process - Overview



Criteria for signal identification

Sources:

- ScanMedicine (clinical trial information)
- MedTech online news
- Bibliographic databases e.g. PubMed, EMBASE
- Commercial websites and market reports
- Press releases and academic institution webpages
- Conferences and competition awards
- Patent databases

Regulatory Jurisdiction:

- Europe (CE mark); UK (MHRA); USA (US FDA)

Scope:

- All areas of healthcare

Stage of Development:

- Early - late stage including prototype and mature (e.g. product ready to launch/ regulatory approved)

Filtration and prioritisation

- Filtration/prioritisation criteria and methods adapted based on data source in order to discard irrelevant signals
  - Bibliographical scan: Prioritisation was based on the strength of the signal

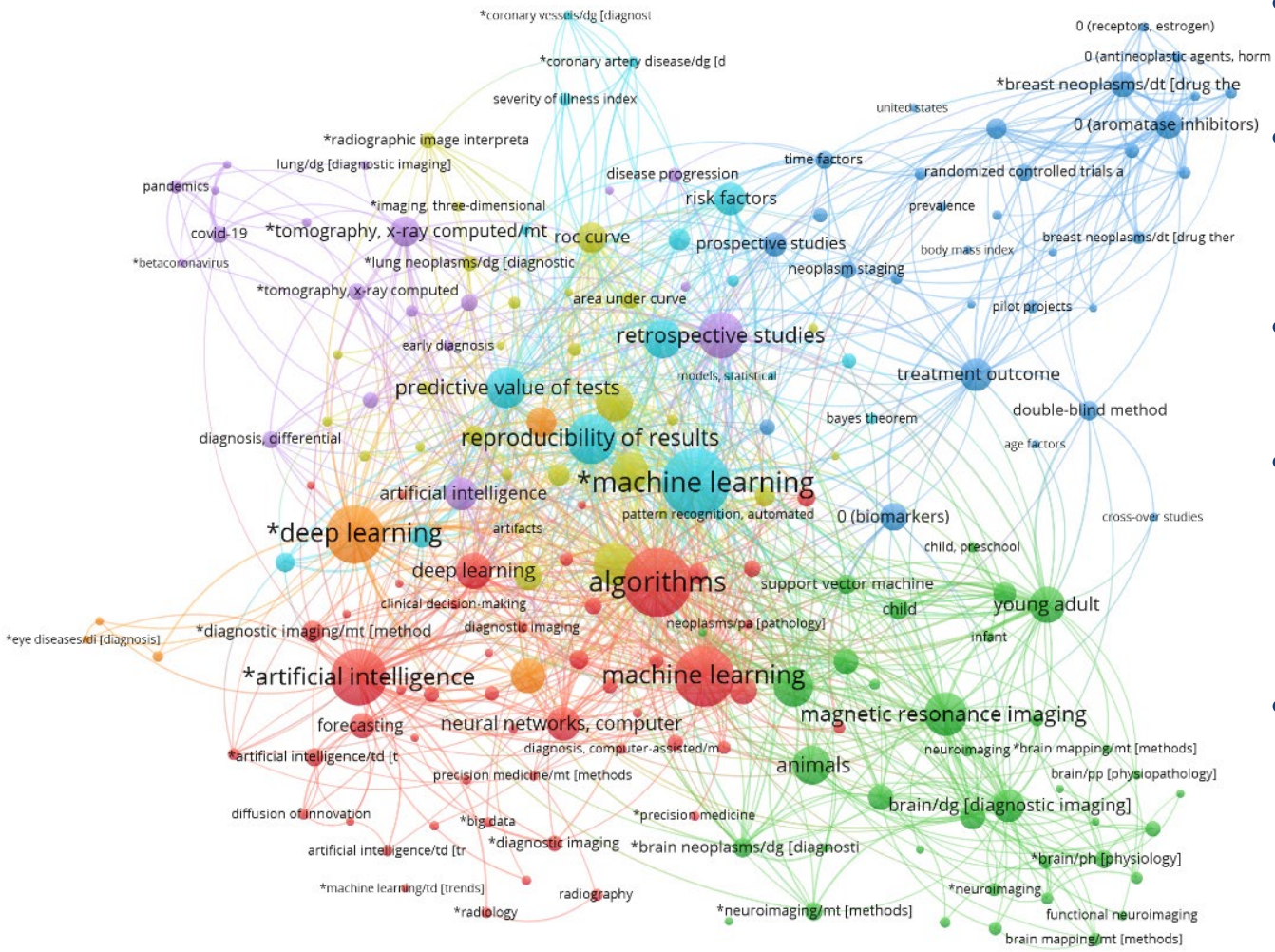
- Classification of Technology: Diagnosis and treatment, Prevention and health promotion or Intelligence operational automation
- Clinical Condition
- Country of Development
- Development Stage: 1) concept, 2) prototype, 3) product validated/ demonstrated in relevant environment/ clinical study, 4) product ready to launch/ regulatory approved
- Regulatory approval (e.g. CE Mark, US FDA, Health Canada, China etc.)
- Additional information: patent, funding/competition awards

Dissemination

Dissemination strategy was determined before carrying out the scan

- Timelines for delivery
- Interim reporting
- Final outputs (reports/dataset)
- Follow-up/feedback
- Manuscript in preparation

Horizon scanning outcome for AI



- 800+ technological innovations for AI identified from across 46 countries
- Most common indications: oncology (e.g. breast cancer, melanoma, and lung cancer), cardiology and neurology
- Majority of AI utilised imaging for diagnosis and treatment
- SMEs most dominant type of developer, others included large enterprises and academic institutions, based predominately across North America and Europe
- Pipeline information coupled with business insights provided valuable insights into:
  - Global scale and activity surrounding the use and development of AI technologies
  - Identified emerging clusters (i.e. themes)

Value for HTA stakeholders

Early warning of transformative technologies assisted with:

- Informed strategic prioritisation of AI interventions identified for adoption into health service for 2021-22
- Informed future 'AI' funding streams to accelerate the most promising AI technologies that meet the strategic aims of health service (i.e. address prioritised health challenges)

Reflections

- Lack of centralised repositories (i.e. traditional sources) that capture information along the entire development stage of a technology
- Combinations of manual and semi-automated techniques implemented due to heterogeneity of data sources and large amount of data to process
- Data sources: heterogeneous, often unstructured and or incomplete data.
- Lack of open source regulatory information on approved technologies in UK/EU
- Developing new horizon scanning approaches (methods and tools) and training staff in scanning for AI/DDD

Finding the right information from various sources and integrating this diverse intelligence is challenging and time consuming

Horizon Scanning - Recap

- Systematic approach
- Adaptability
- Complex 'not a one size fits all approach'
- Changing innovation landscape impacting scanning approach
- Horizon scanning framework
- Stakeholder engagement is key
- Complex due to the diversity of innovations and less defined innovation pathway
- The identification process for TATs was different from AI technologies

Activity

Your reflections on horizon scanning

Based on your reflections on successful and unsuccessful experiences in horizon scanning, what are your top three critical success factors for horizon scanning?

Your reflections on horizon scanning

How do you see horizon scanning developing in the future?

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Closing Summary

Presenter: Anne Oyewole

Things to consider for a horizon scanning system

HS Timeline

- What is the expected time-horizon for technologies entering the health service?
- What is the furthest point in the future you are considering? E.g. 1-2; 3-5; 5-10 or 10-20 years
- Are you considering scanning multiple horizons?

HS Scope

- What type of technology do you want to identify and assess? E.g. devices, drugs, procedures
- What stage of development do you want to cover?

HS Purpose

- What is the scope of your HS system?
- When will you conduct horizon scanning? E.g. on-going basis, as needed etc.

Stakeholders

- Who will the HS system inform? E.g. Health department policy-makers, Hospital managers, Regulatory agencies, Clinicians, Patients/consumer groups
- What type of information will they need?
- Which sources will you need to gather data/information from?
- How will you collate data and information emerging from HS?
- How will they use it?

Healthcare System

- How is it funded?
- Coverage: National/Regional

Regulatory Jurisdiction

- Coverage: National and or International

Summary

- Horizon scanning is a method used for future forecasting new and innovative health technologies
- Challenges:
  - Time constrains
  - Lack of defined scope
  - Handling large amount of data and information
- Strategic tool that facilitates:
  - Timely access to medicines and medical technologies to patients
  - Healthcare planning (budgets, pathways, supply, policies)
  - Builds organisational resilience
- Automation is fundamental to develop a sustainable system

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Thank you for your participation!

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