EU Big Data Stakeholder Forum Opportunities, Challenges, Priorities, Risks & Collaboration.

EMA Big Data Stakeholder Forum Virtual Meeting

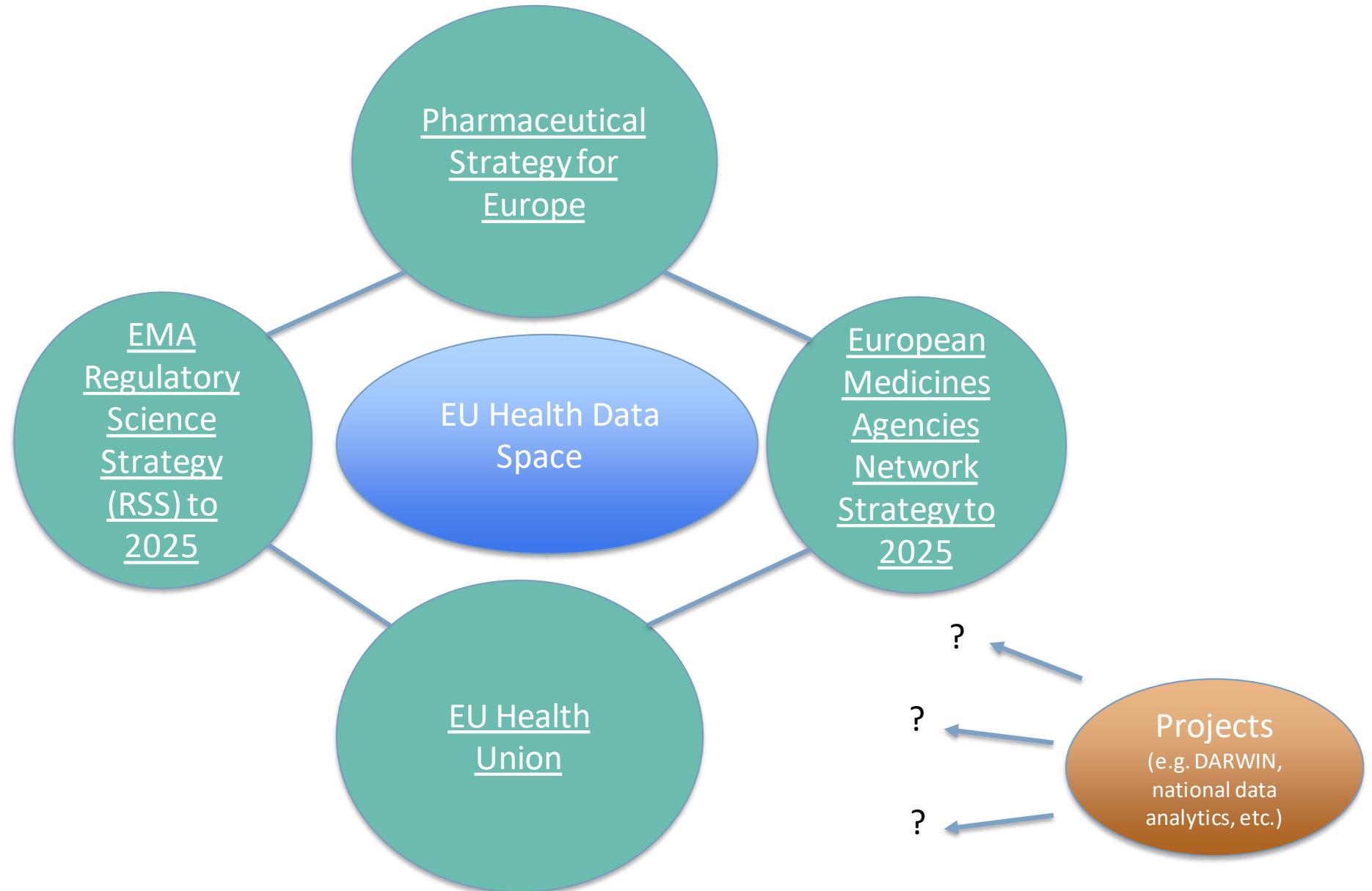December 15th, 2020
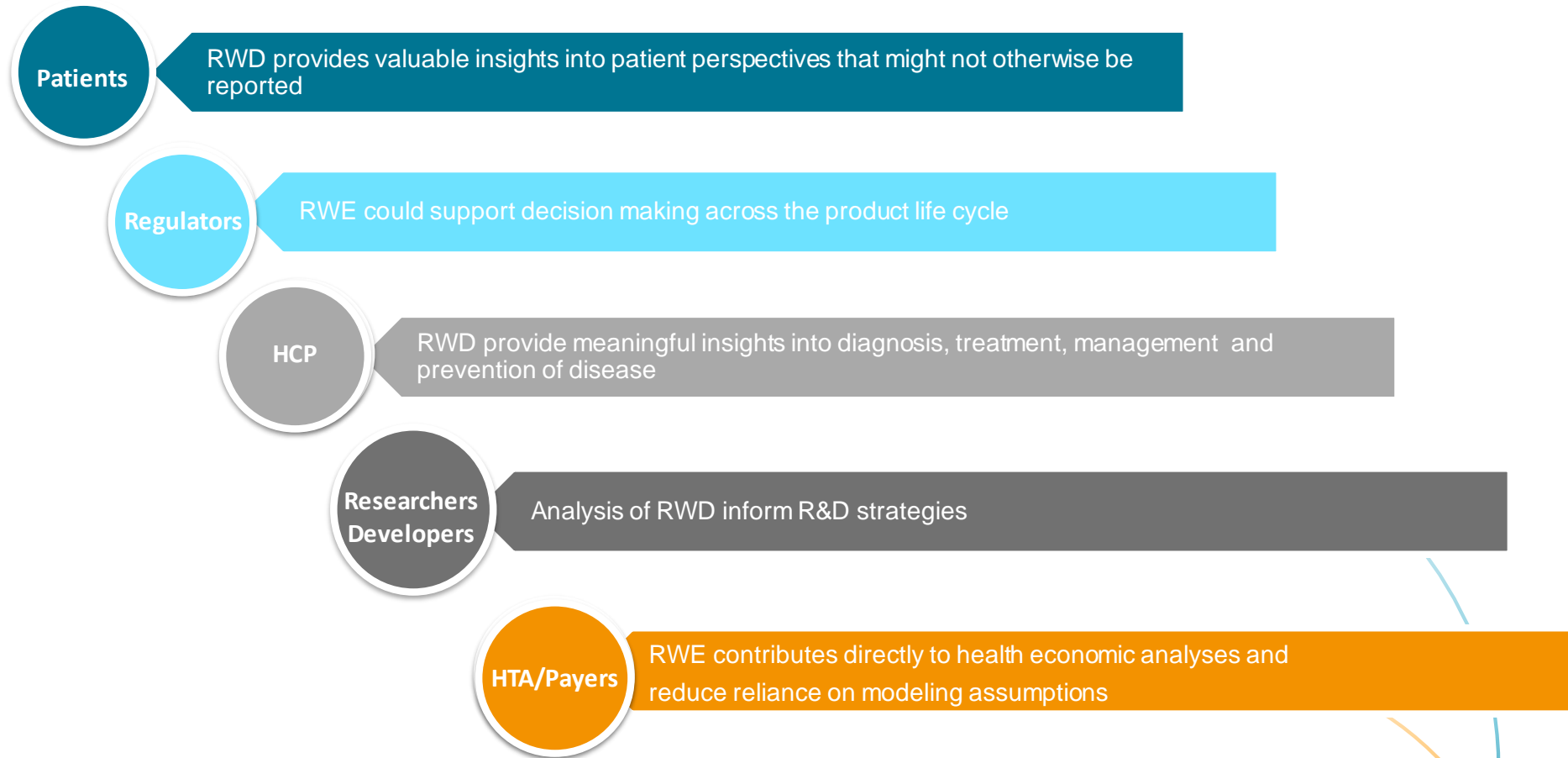
Álmath Spooner on behalf of

Review of European Regulatory Ecosystem to be Fit-For-Future

Opportunities - Value for stakeholders

Patients — RWD provides valuable insights into patient perspectives that might not otherwise be reported

Regulators — RWE could support decision making across the product life cycle

HCP — RWD provide meaningful insights into diagnosis, treatment, management and prevention of disease

Researchers Developers — Analysis of RWD inform R&D strategies

HTA/Payers — RWE contributes directly to health economic analyses and reduce reliance on modeling assumptions

And many more credible evidence and insights

Challenges for RWD /RWE

HC System Data Definition and Collection → **Access to Fit for Purpose RWD (direct or indirect)** → **Robust Study Design and Data Analysis** → **Acceptance of Evidence**
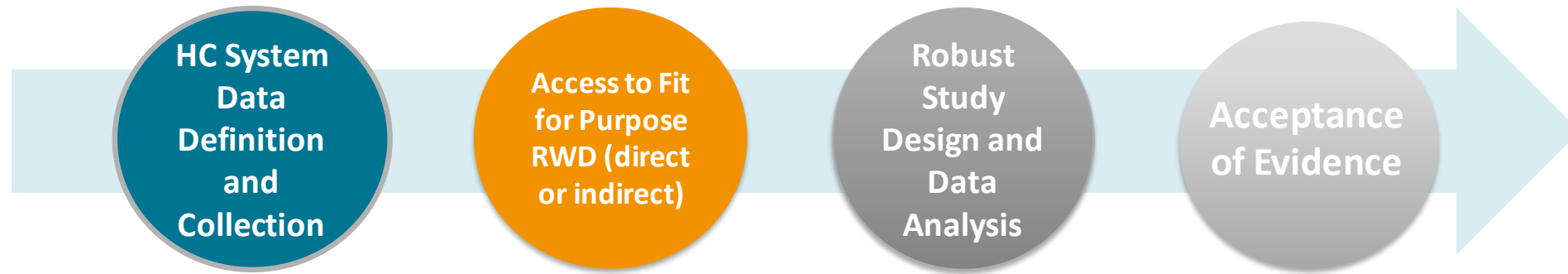
Challenges

Major questions around relevance, depth and quality of source data	Data privacy and access issues	Familiarity with and acceptance of study designs & robust analytical methods	

How to address challenges and strengthen the use of RWD/RWE

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Improve the quality, relevance and interoperability of RWD source	Achieve sustainable, appropriate access and use of RWD addressing data privacy concerns (e.g. GDPR)	Develop best practices regarding study design and analytical approaches. Define plans prospectively	Drive acceptance through multi-stakeholder interactions, discussion on use cases and development of guidance

efpia
European Federation of Pharmaceutical Industries and Associations

EMA/HMA Big Data SG workplan – Transparency & Timelines
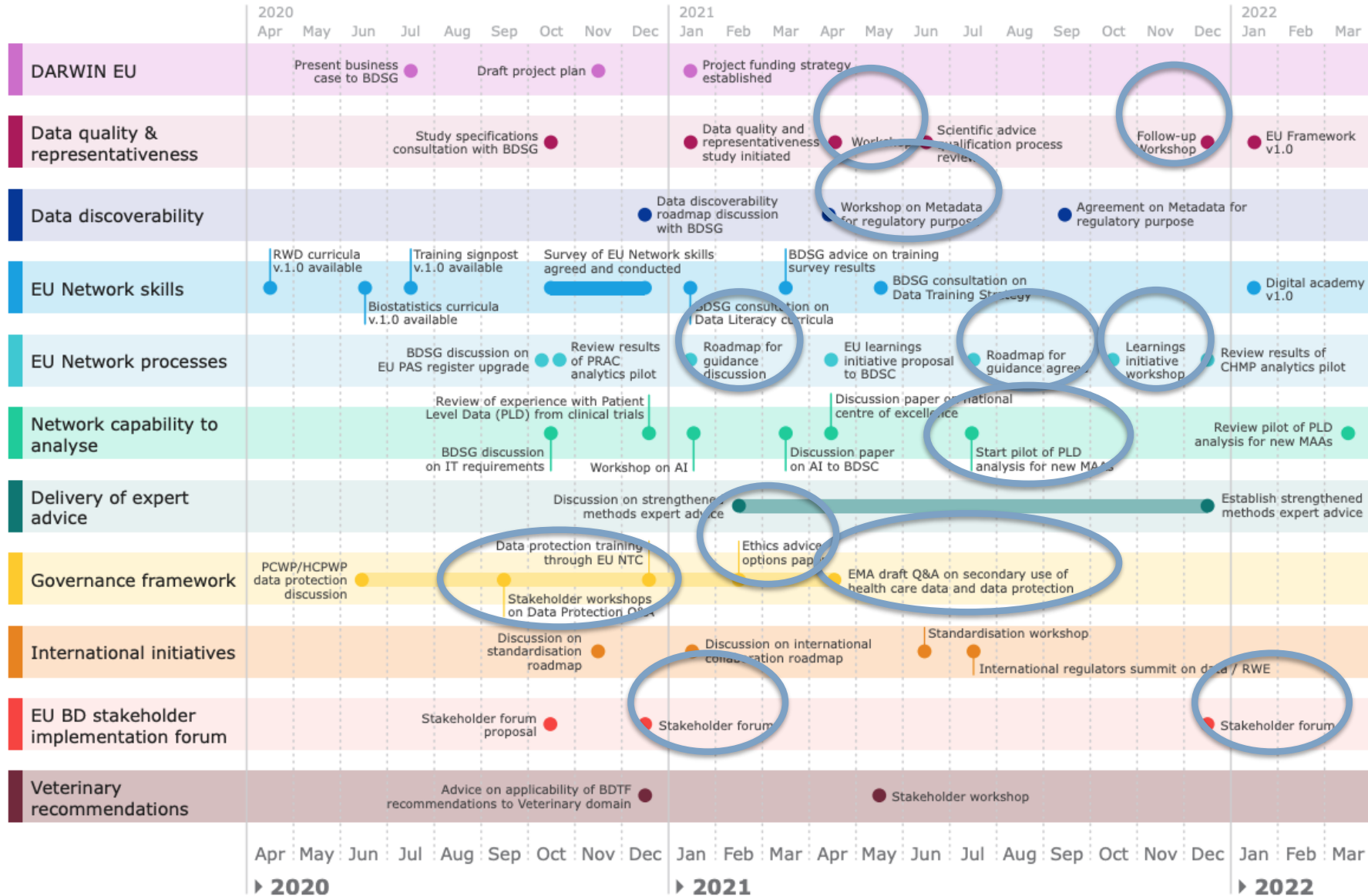
Priorities

- Establish an EU framework for **data quality and representativeness**: Develop guidelines, a strengthened process for data qualification through Scientific Advice and promote Member State uptake of EHRs, registries, genomics data, and secure data availability.

- Ensure data are managed and analysed within a **secure and ethical governance framework**: Engage with initiatives on the *harmonisation* of EU data protection regulations, engage with *medicines developers*, patients and healthcare professionals on data governance, establish an Ethics Advisory Committee.

- Modernise the **delivery of expert advice**: Establish a Methodologies Working Party (RWD, epidemiology, advanced analytics, etc). This can be supported by the conduct of **pilots** and **learning from national and global experience**.

- Deliver a **sustainable platform to access and analyse EU healthcare data** (DARWIN) including developing EU **network capability** for big data analysis. Equitable access a priority.

Areas for Collaboration

Common understanding of what constitutes fit for the intended purpose

Demonstration by case studies and share learnings

Development of guidance and best practices

Striving for internationally harmonised approaches & agreement on standardised outcomes

Extensive stakeholder interaction

How to move forward?

RWD / RWE has **great potential to improve patient lives their experience of care and to increase the efficiency of the healthcare system**.

Everything needs to be **connected and aligned or we risk not having:**
- well-resourced healthcare organisations designed to enhance delivery of quality care and to provide high quality RWD to accessible research platforms
- the necessary collaboration to develop high quality data and research networks that allow the integration and interoperability of data from a wide range of sources
- the capacity to generate evidence and insights based on RWD using a variety of designs and methodologies which are fit for purpose and accepted by relevant stakeholders

We stand ready to collaborate with all stakeholders to ensure the best expertise and experience can support timely implementation of the Task Force objectives.

Thank you !