REAL WORLD EVIDENCE
RWE4Decisions Symposium

Real-World Evidence for HTA Bodies & Payers' Decision-Making

POLICIES & PARTNERSHIPS

24 November 2022

Scotland House Brussels

www.rwe4decisions.com

#PoliciesPartnerships @RWE4Decisions

09.30 CET

Introductory remarks

Jo De Cock

Administrateur Général Honoraire,
Belgian Institute for Health and
Disability Insurance (INAMI-RIZIV)

RWE4Decisions: A payer-led initiative, a multi-stakeholder learning network about use of RWE for highly innovative technologies

What?	Pragmatic and agile Learning Network about use of Real-World Evidence (RWE) to inform HTA/Payer Decisions
Why?	Highly innovative technologies often have accelerated development pathways and immature clinical evidence - could robust RWE fill the gaps to help demonstrate value?
How?	Payer-led, multi-stakeholder Built on principles of Collaboration and Transparency
Added Value?	'Learning by doing' approach ➢ share experience, pool resources ➢ sandbox approach - real problems, light-touch solutions ➢ build trust Public outputs and events Policy engagement – CAPR, Nordic Alliance, BENELUXAI, EU and beyond

RWE4Decisions REAL WORLD EVIDENCE Steering Group 2022

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Adviser to
RIZIV-INAMI

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President of the Commission of Drugs Reimbursement,
RIZIV-INAMI

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Chief Pharmacist,
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Chief Specialist,
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Public Affairs Director,
EURORDIS – Rare Diseases Europe

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Hans-Georg Eichler
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Insurer

Matti Aapro
Director at the
Genolier Cancer Centre

Clinician

Entela Xoxi
Pharmacologist,
Università Cattolica del Sacro Cuore, Italy

Academia

Karen Facey
Consultant to FIPRA

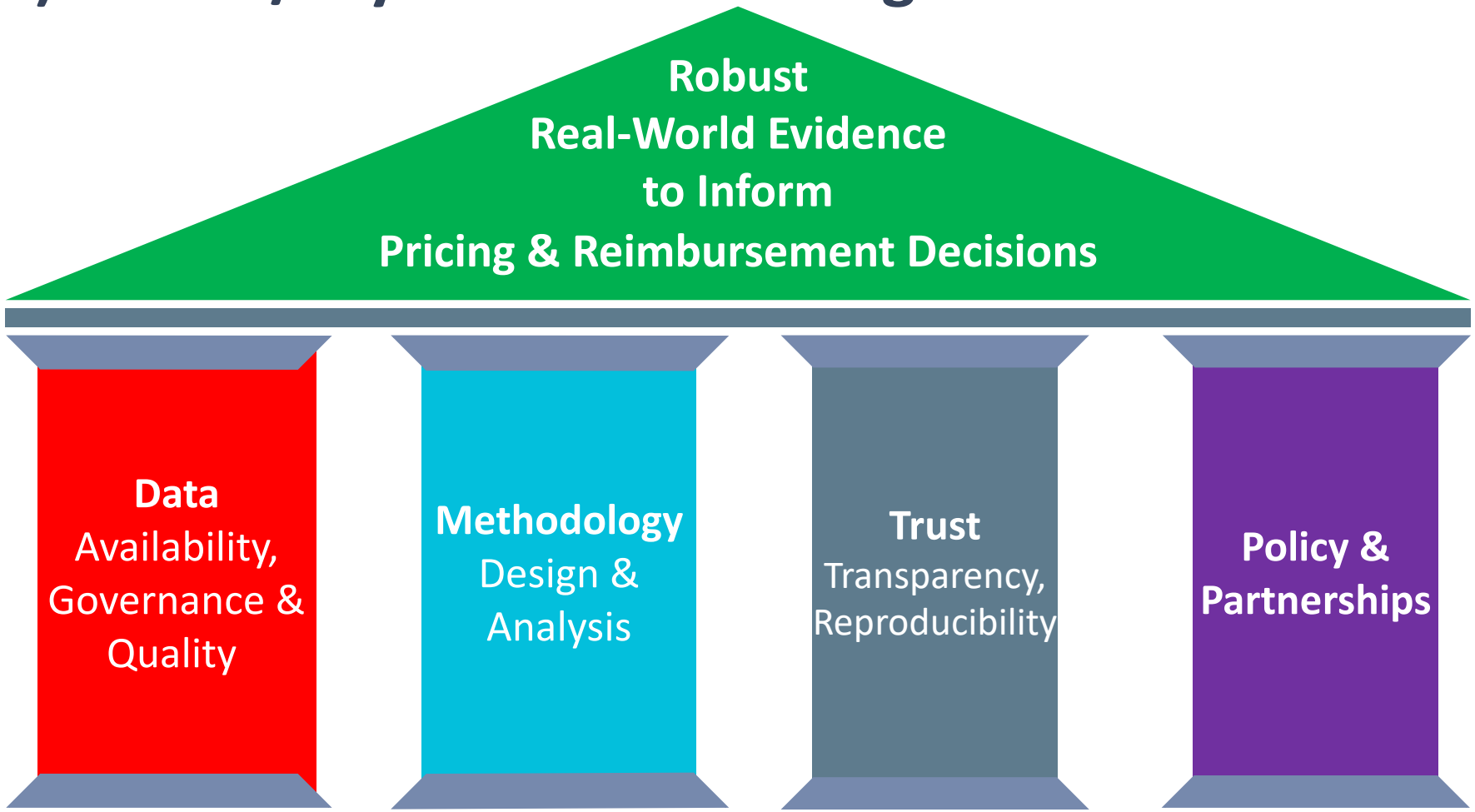
EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

AstraZeneca
BAYER
NOVARTIS
Boehringer Ingelheim
Roche
Takeda

Industry

RWE4Decisions Secretariat (FIPRA) funded by EUCOPE and member companies

Four pillars to support development of robust Real-World Evidence (RWE) for HTA/Payer decision-making (2021)



+ Management support to provide resources and upskill

Capkun, G., Corry, S., Dowling, O., Asad Zadeh Vosta Kolaei, F., Takyar, S., Furtado, C., . . . Facey, K. (2022). Can we use existing guidance to support the development of robust real-world evidence for health technology assessment/payer decision-making? *IJTACC, 38*, E79. doi:10.1017/S0266462322000605

09:40 CET

Keynote presentations

Real-world data, the implementation of the European Health Data Space (EHDS) and HTA Regulations

Video intervention

Andrzej Rys

Principal Scientific Adviser,
DG SANTE, European Commission

09:40 CET

Keynote presentations

DARWIN EU
Progress update and deliverables

Xavier Kurz

Head of Data Analytics Workstream, Data Analytics and Methods Task Force, European Medicines Agency (EMA)

DARWIN EU®

Progress update and Deliverables

RWE4Decisions Symposium

Brussels, 24 November 2022

Presented by Xavier Kurz
Data Analytics and Methods Taskforce, European Medicines Agency

Content

- Reminder: Use of RWE and the DARWIN EU® network
- List of DARWIN EU® Data Partners onboarded in phase I
- List of studies to be conducted via DARWIN EU® in phase I
- Involvement of HTA bodies and payers

Three main areas for which RWD analyses can support EMA scientific committees for decision-making

1 Support the planning and validity of applicant studies

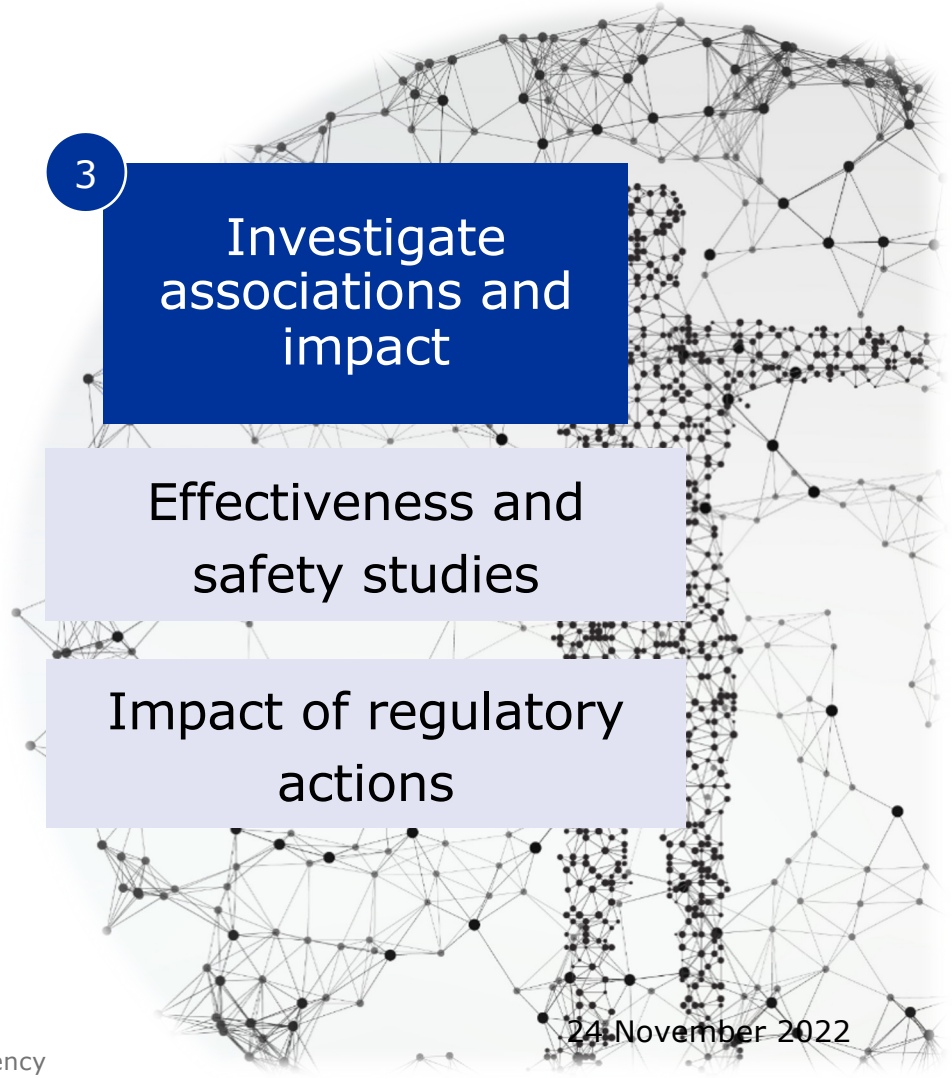
- Design and feasibility of planned studies
- Representativeness and validity of completed studies

2 Understand the clinical context

- Disease epidemiology
- Clinical management
- Drug utilisation

3 Investigate associations and impact

- Effectiveness and safety studies
- Impact of regulatory actions



How does EMA generate Real-World Evidence

EMA studies using in-house databases

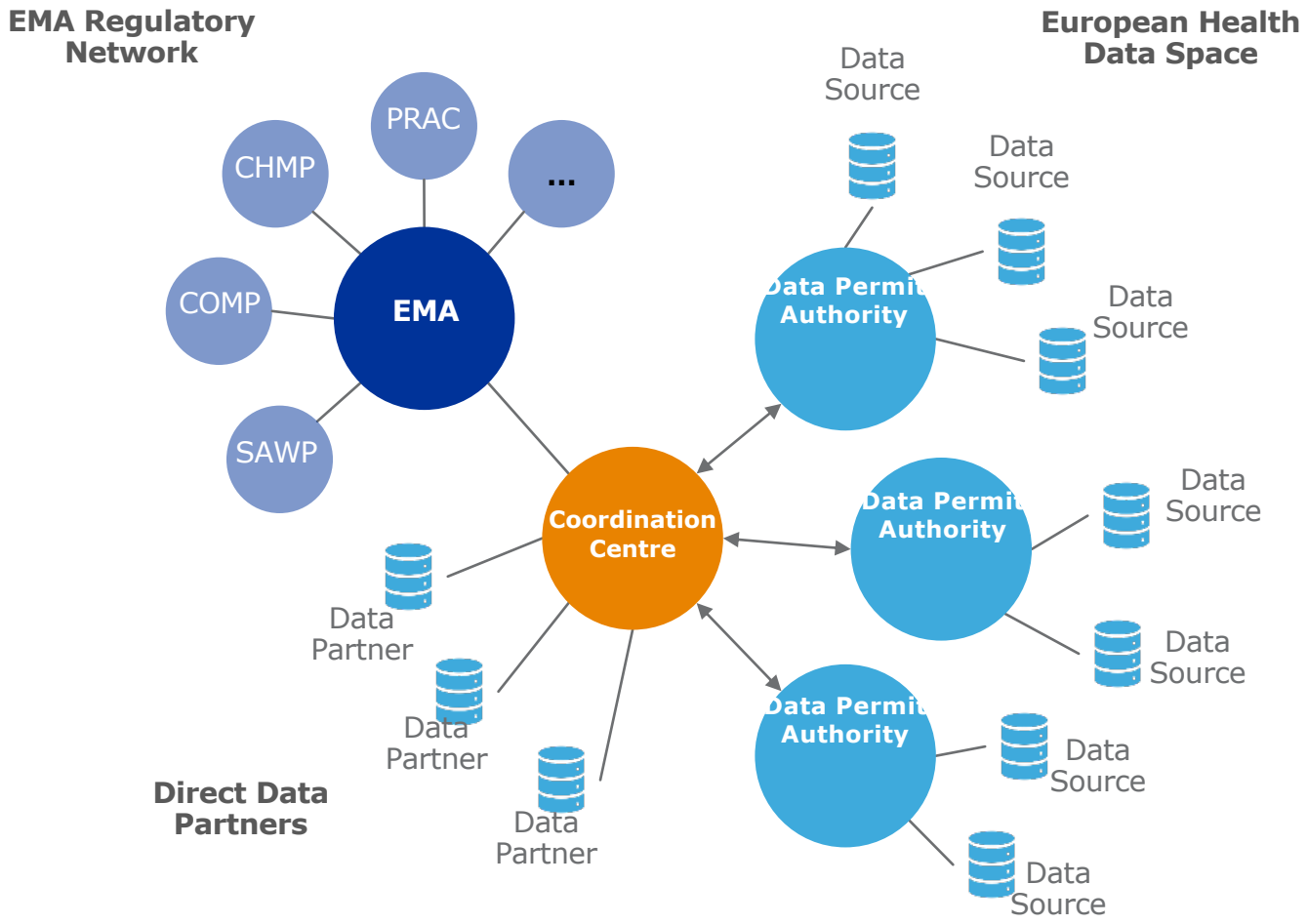
- Primary care health records from the **UK, France, Germany, Italy, Spain and Romania**
- By Q3 2022 hospital prescribing from **France** and hospital data from the **UK**

Studies procured through EMA FWCs

- New framework contract (FWC) since September 2021: services of **8 research organisations** and academic institutes
- Access to **wide network of data sources**: 59 data sources from 21 EU countries
- Ability to leverage external **scientific expertise**

DARWIN EU®

DARWIN EU® is a federated **network** of **data**, **expertise** and **services** that supports better decision-making throughout the product lifecycle by generating reliable **evidence from real world healthcare data**



FEDERATED NETWORK PRINCIPLES

- Data stays **local**
- **Use of Common Data Model** to perform studies in a timely manner and increase consistency of results

Coordination centre : Erasmus University Medical Centre Rotterdam

Implementation roadmap

Phase I - 2022

- Start running pilot studies to support EMA committees – **first benefits delivered**
  - Coordination Centre set-up
  - Data Protection Impact Assessment
  - Start recruiting and onboarding 10 data partners
  - Pilot with the EHDS model and existing Data Permit Authorities
- Consultation of stakeholders

Phase II - 2023

- Support the majority of Committees in their decision-making with reliable RWE by 2023

Phase III - 2024

Up scale delivery and capacity to routinely support the scientific evaluation work of EMA's scientific committees and NCAs by delivering studies and maintaining data sources.

Operation - 2025/2026

- DARWIN EU® to be fully operational and yearly evolves to meet the needs from the EU Regulatory Network
- **Integration with the EHDS**

- Total of 40 databases are foreseen to be recruited in 4 years
- Over 5 years, ~380 studies will be conducted

Data Partners – Phase I

UK

1. Clinical Practice Research Datalink (CPRD GOLD)

Belgium

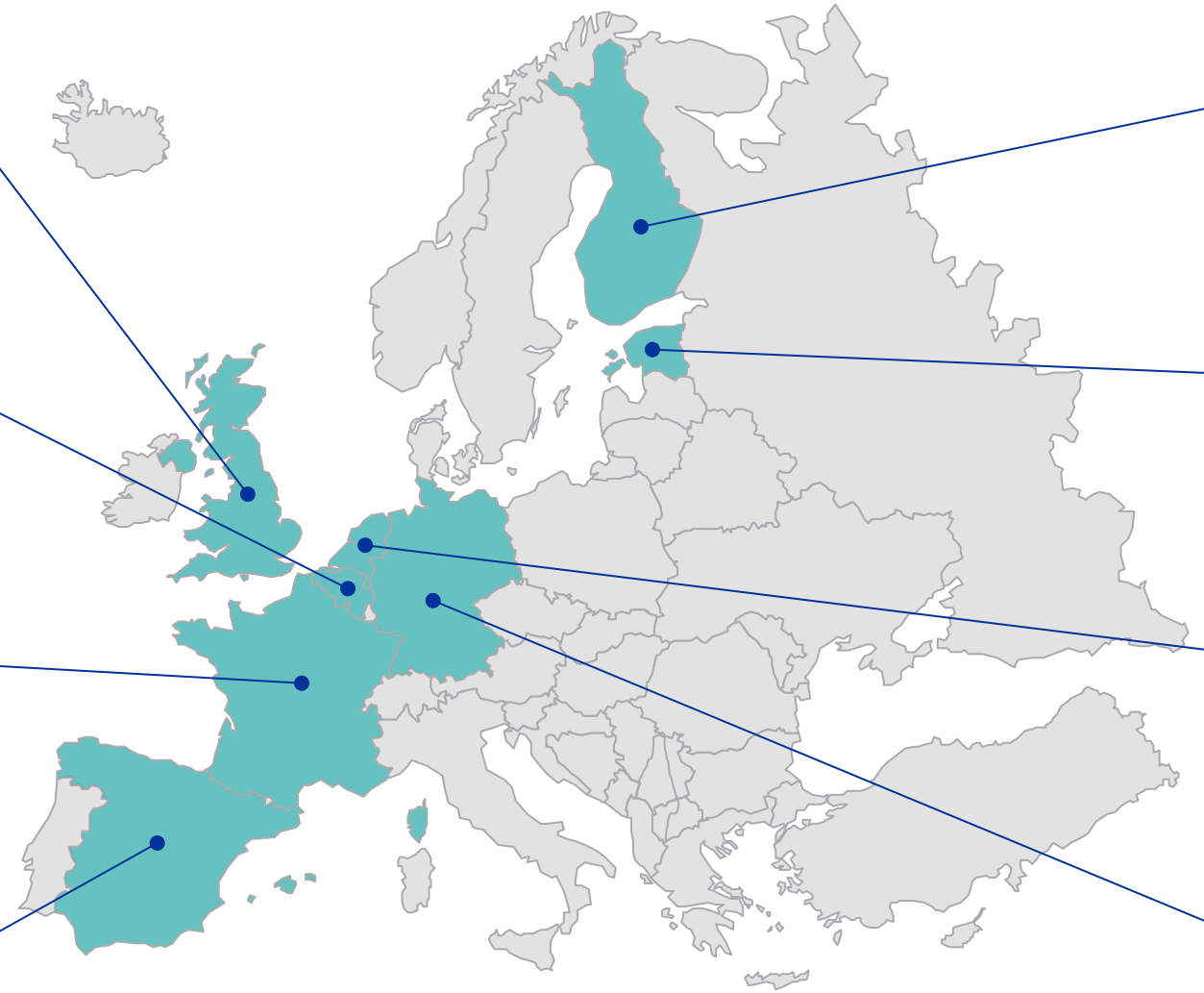
2. IQVIA Belgium Longitudinal Patient Data

France

3. Bordeaux University Hospital

Spain

4. IDIAPJGol
5. Parc Salut Mar Barcelona, Hospital del Mar (IMIM)



Finland

6. Auria Clinical Informatics at Hospital District of Southwest Finland (HDSF)

Estonia

7. University of Tartu (Biobank)

Netherlands

8. Integrated Primary Care Information
9. Netherlands Comprehensive Cancer Organisation

Germany

10. IQVIA Germany Disease Analyser

~26 million active patients

What analyses and studies will DARWIN EU® deliver?

Category of observational analyses and studies	Description
Routine repeated analyses	Routine analyses based on a generic study protocol • Periodical estimation of drug utilisation • Safety monitoring of a medicinal product • Estimation of the incidence of a series of adverse events
Off-the-shelf studies	Studies for which a generic protocol is adapted to a research question • Estimate the prevalence, incidence or characteristics of exposures • Estimate the prevalence, incidence or characteristics of health outcomes • Describe population characteristics
Complex Studies	Studies requiring development or customisation of specific study designs, protocols and Statistical Analysis Plans (SAPs), with extensive collection or extraction of data • Etiological study measuring the strength and determinants of an association between an exposure and the occurrence of a health outcome considering sources of bias, potential confounding factors and effect modifiers
Very Complex Studies	Studies which cannot rely only on electronic health care databases, or which would require complex methodological work • Studies where it may be necessary to combine a diagnosis code with other data such as results of laboratory investigations, or studies requiring additional data collection

DARWIN EU® Studies – Phase I

Type	Studies	Data Partners	Planned RWE use	Committee	
OTS	**Population level epidemiology** study on prevalence of **rare blood cancers** from 2010.	NL, ES, UK, BE, DE	Support COMP in orphan designation decision making	COMP	Ongoing
OTS	Patient level **drug utilisation** study of **valproate-containing medicinal products** in women of childbearing potential from 2010	NL, ES, UK, BE, DE, FI	Assess the use of valproate after safety referral	PRAC	
OTS	Patient level **drug utilisation** study of **antibiotics** on the Watch list of the WHO AWaRe classification, 2010-2021	NL, FR, ES, DE, UK	Inform PRAC/CHMP decision making	PRAC – CHMP AMR strategy	
Complex	Background all-cause **mortality rates in patients with severe asthma aged ≥12 years** old		Support CHMP evaluation and post-authorisation informing future decision making	CHMP	Feasibility assessment ongoing

Involvement of HTA bodies and payers
(discussion at the DARWIN EU workshop with HTA/Payer representatives, 6th October 2022)

- Need to understand how DARWIN EU® will work in practical terms, what type of data are being onboarded, who can request RWE studies (and how), what kind of evidence will be provided, how the evidence will be made available, among others.
- RWD are important to HTA appraisals for effectiveness, safety, utility etc. but there is a need to overcome scepticism/reluctance of HTA/Payers with respect to use of RWD for decision making – RCTs are preferred.
- Part of this scepticism is due to concerns with the quality of RWD – concern could be addressed through EMA metadata catalogues, data quality frameworks and feasibility analyses in DARWIN EU
- Are data needed to support HTA/Payers' decision making collected in RWD from routine clinical databases (e.g. PROs)?
- Disease registries may be better suited for decision making by HTA/Payers – but they may lack maturity and perhaps quality.
- Type of data available will drive the type of research questions that can be addressed (*but, conversely, HTA/Payers should provide use cases to understand which data partners need to be onboarded in the establishment phase*)
- Protocols and study reports for all studies to be made available via the EU PAS register.

Involvement of HTA bodies and payers
(discussion at the DARWIN EU workshop with HTA/Payer representatives)

Suggested domains of interest

- Natural history of disease, which allows to validate the assessment of the control arm, are of interest.
- RWD on chronic diseases based on remote patient monitoring
- Current standard of care – different lines of treatment and follow-up data on long-term effects
- Effects of new drugs – importance of data collection in registries
- Effectiveness studies

Suggested topics

Orphan Medicinal Products (OMPs), Advanced therapy medicinal products (ATMPs), therapies for rare cancers (e.g. multiple myeloma) and blood disorders

Discussion to be continued, e.g. through EuNetHTA

Good Practice Guide – Scope and Table of Contents

EUROPEAN MEDICINES AGENCY

Scope

- Provides **recommendations for the use of the new EMA catalogue** of data sources to identify real-world data sources for assessing the suitability of data sources for specific studies
- Provides a **detailed description of all the metadata elements** as envisaged to be used in the EMA catalogue of data sources
- Guides the user on **adding new data and maintenance** of data in the catalogue.

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Any questions?

Further information

[Data Analysis and Real World Interrogation Network (DARWIN EU) | European Medicines Agency (europa.eu)]

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Send us a question Go to www.ema.europa.eu/contact

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10:10 CET

Recap of RWE4Decisions work in 2022

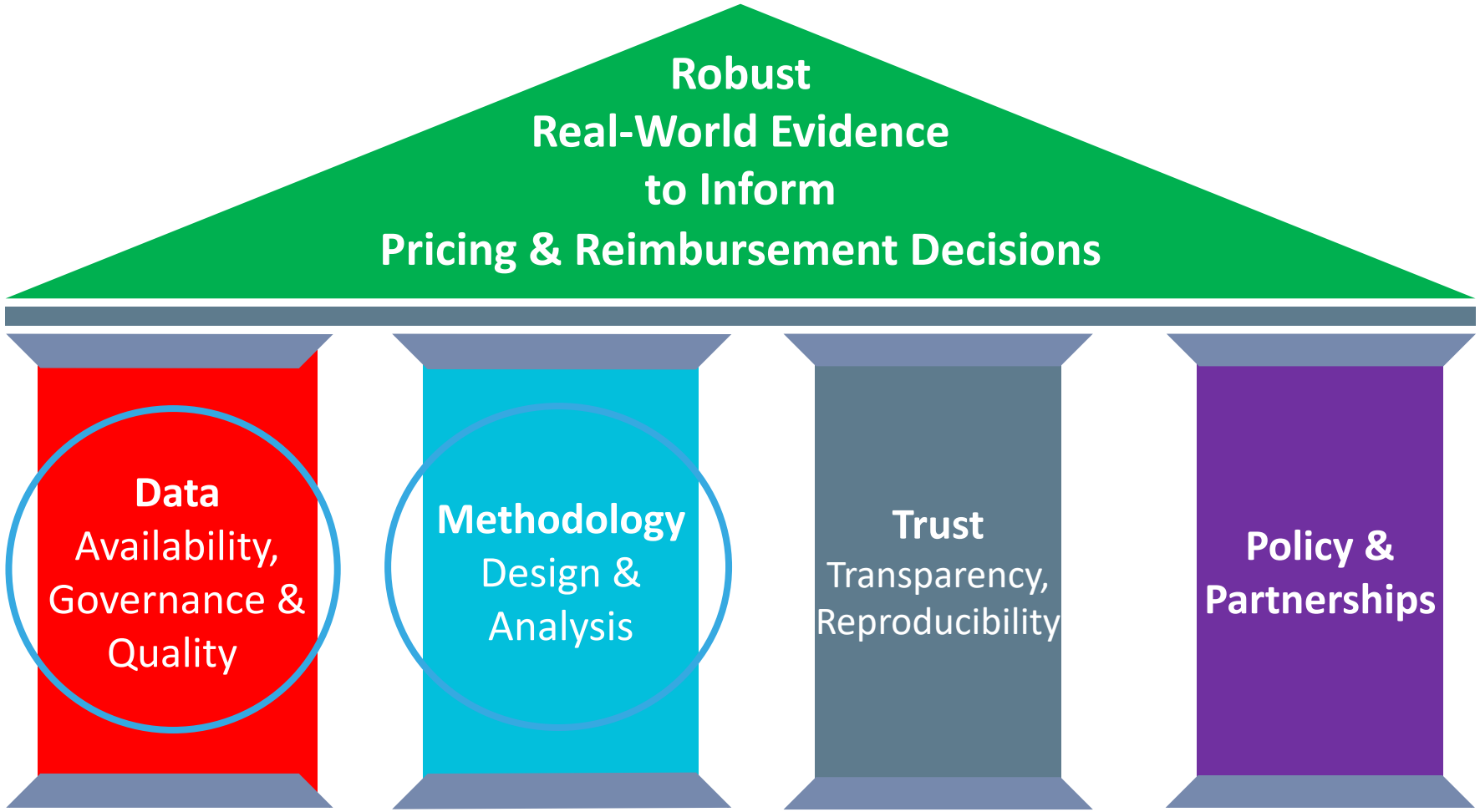
Stakeholder views on the potential for policy to support development of real-world evidence (RWE) for decision-making

Q&A with the audience

Karen Facey

Evidence Based Health Policy
Consultant, RWE4Decisions Secretariat

Four pillars to support development of robust RWE for HTA/Payer decision-making



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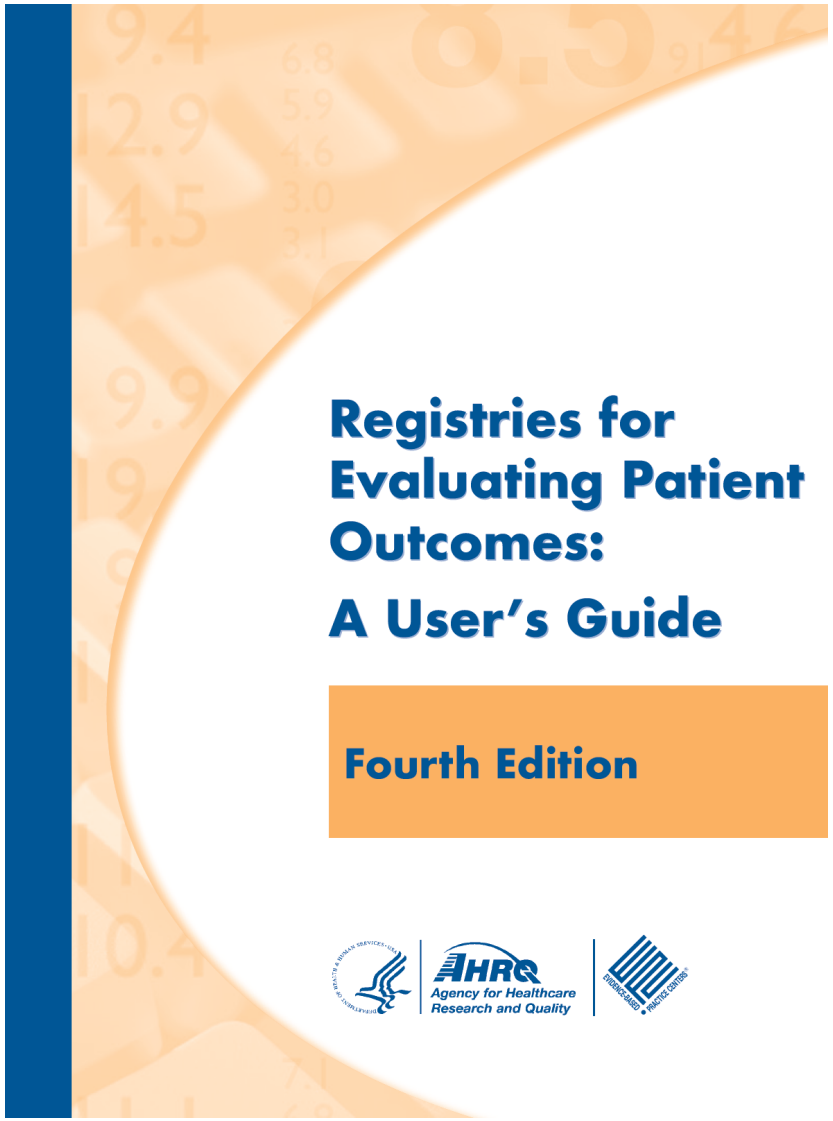
RWE4Decisions 2022 – Learning by Sharing

Just a few people named!



IQWiG

IQWiG Reports – Commission No. A19-43

Concepts for the generation of routine practice data and their analysis for the benefit assessment of drugs according to §35a Social Code Book V (SGB V)[1]

Rapid report

[1] Translation of the rapid report A19-43 *Konzepte zur Generierung versorgungsnaher Daten und deren Auswertung zum Zwecke der Nutzenbewertung von Arzneimitteln nach §35a SGB V* (Version 1.0; Status: 10 January 2020). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

HAS
HAUTE AUTORITÉ DE SANTÉ

ASSESS
HEALTH TECHNOLOGIES

METHODOLOGICAL GUIDE

Real-world studies for the assessment of medicinal products and medical devices

10 juin 2021

NICE National Institute for Health and Care Excellence

NICE real-world evidence framework

Corporate document
Published: 23 June 2022
www.nice.org.uk/corporate/ecd9

Canadian Guidance on use of RWE in Decision making

November 10, 2022

Laurie Lambert

Today, CADTH, on behalf of the **Real-World Evidence Steering Committee**, launched a public consultation to solicit feedback on a pan-Canadian guidance document that will inform the use of real-world evidence (RWE) that may be submitted for consideration in regulatory and reimbursement decision-making.

Regulators and health-technology assessment (HTA) agencies have recognized the need to integrate high-quality RWE to help address evidence gaps for decision-making. However, as capacity and expertise in the generation of RWE increase, there is a need to standardize reporting for RWE studies that are submitted to inform regulatory and HTA decision-making.

A key component of CADTH's 3-year strategic plan is to be a leader in evidence appraisal and to optimize the integration of RWE into our work. Several **projects** are underway to help us "learn by doing" and deliver on this ambition. Our goals are to facilitate multi-stakeholder dialogue, examine ways to generate and access real-world data, engage in collaborative partnerships, and develop RWE reporting guidance in collaboration with the national and international experts who form the **RWE Guidance Working Group**. CADTH's lessons learned will be shared broadly to inform the development of a framework that will optimize the integration of RWE into decision-making.

European Health Data Space

Jerome de Barros, EC

Use of data for healthcare (primary)

Sharing of health data for healthcare

Problems

- Limited control of patients over their health data
- Limited interoperability between health care providers

Areas of work

- Control of patients over their data
- Interoperability
- Role of e-health agencies
- Reinforced EU governance (eHealth Network)
- Reinforced MyHealth@EU

Single market for digital health products and services

Problems

- Uneven national legislative frameworks
- Uneven quality framework
- Uneven procedures for prescriptions, reimbursement, liability

Areas of work

- Eliminate barriers to free movement
- Labelling
- Interoperability
- Reimbursement
- Liability

Re-use of health data (secondary)

Access to health data for research, innovation, public health policy making

Problems

- Low re-use of health data
- Cumbersome cross-border access to health data
- Fragmented digital infrastructures

Areas of work

- Governance and rules for access to health data
- Data FAIR-ification
- Digital infrastructure (EHDS2)

AI

Problems

- Limited provision of data for training of AI
- Difficulties for regulators to evaluate AI algorythms
- Uncertainty on AI liability in health

Areas of work

- Support for development and rollout of AI
- Data for AI
- Support for regulators

EUROPEAN
COMMISSION

Strasbourg, 3.5.2022
COM(2022) 197 final

2022/0140 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Health Data Space

(Text with EEA relevance)

{SEC(2022) 196 final} - {SWD(2022) 130 final} - {SWD(2022) 131 final} -
{SWD(2022) 132 final}

RWE4Decisions welcomes the Commission's EHDS proposal: it is an ambitious step forward that can contribute to a sustainable real-world data (RWD) ecosystem by addressing the current fragmentation and lack of health data infrastructure within and across Member States, making sure the data are interoperable and of high-quality.

We encourage policy-makers to take into account the following aspects in the negotiations:

1. In the interests of patients and citizens, strong safeguards for security and privacy must be in place and the EHDS should look to reconcile the fragmented and differing interpretation of GDPR rules, which are blocking secondary use of RWD in some jurisdictions. The format and context of so-called 'one-time consent' needs to be worked out to enable people to indicate what they want to share and when. To tackle the fragmentation and differing interpretations, it must be assured that EHDS legislation is uniformly implemented.
2. The value of health data for patient safety, regulatory purposes and policy-making is highlighted, and of high importance, but we feel that use by healthcare payers is missing throughout the proposal…..

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space/F3325859_en

WP5 Governance: Barriers to secondary use of health data

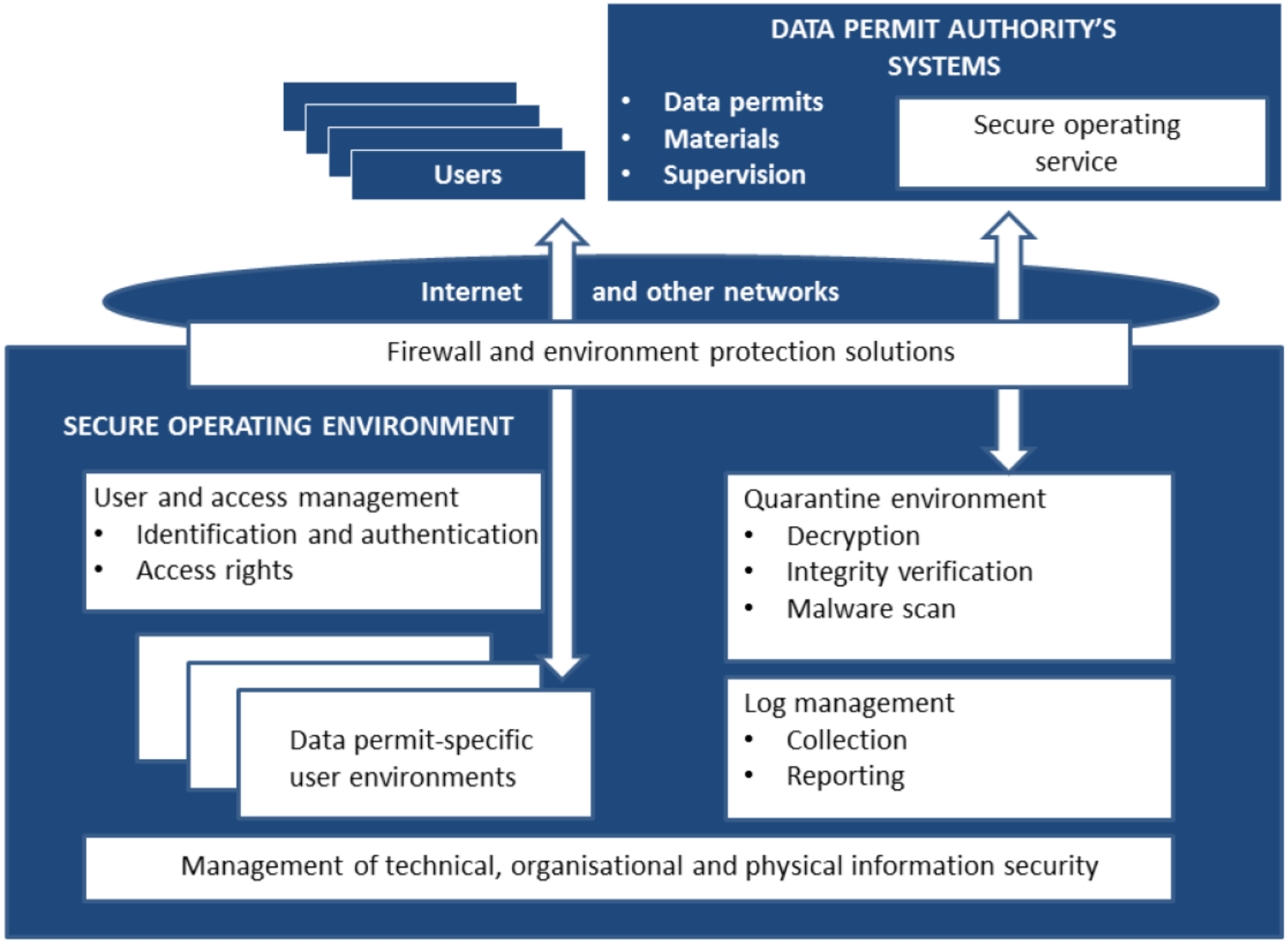
Rank	Barrier description	Theme
A	There are differences in governance and health data systems in Europe	Infrastructure
B	A lack of a common European interpretation of what constitutes 'sufficient anonymisation' to transform personal data to non-personal data	Legal
C	A lack of a common European interpretation of what constitutes 'pseudonymisation'	Legal
D	A lack of a common European interpretation of what is and is not 'secondary use' of data	Legal
E	European countries have national laws/rules on health and research data in addition to the GDPR	Legal
F	European countries can set different derogations under the General Data Protection Regulation	Legal
G	European countries have different preferences as to the choice of legal basis for processing under the GDPR	Legal
H	Health data is considered sensitive data e.g., special category data under the GDPR, and is treated differently from other types of data when it comes to health data ethics, management, and use	Data
I	A lack of standardised data sharing agreements for products developed by private sector providers using public health data to facilitate safe data sharing and protect public investment	Trust and Transparency
J	The use of different interoperability standards across Europe makes comparisons and sharing data and research results challenging	Data
K	Poor data management procedures reduce the ability to reuse data	Data

And solutions

Co-funded by The Health Programme of the European Union

FINDATA

Heikki Lanu



Secure operating environment

The figure shows the principal system architecture of a secure operating environment.

The purpose is to clarify what functions constitute a secure operating environment and how it is related to other key functions under the Act on Secondary Use.

RWE4Decisions REAL WORLD EVIDENCE

National Health Data Spaces


Austria


Belgium


Denmark


England


Finland


Norway


Scotland


Spain


Sweden

Launched today:


Germany

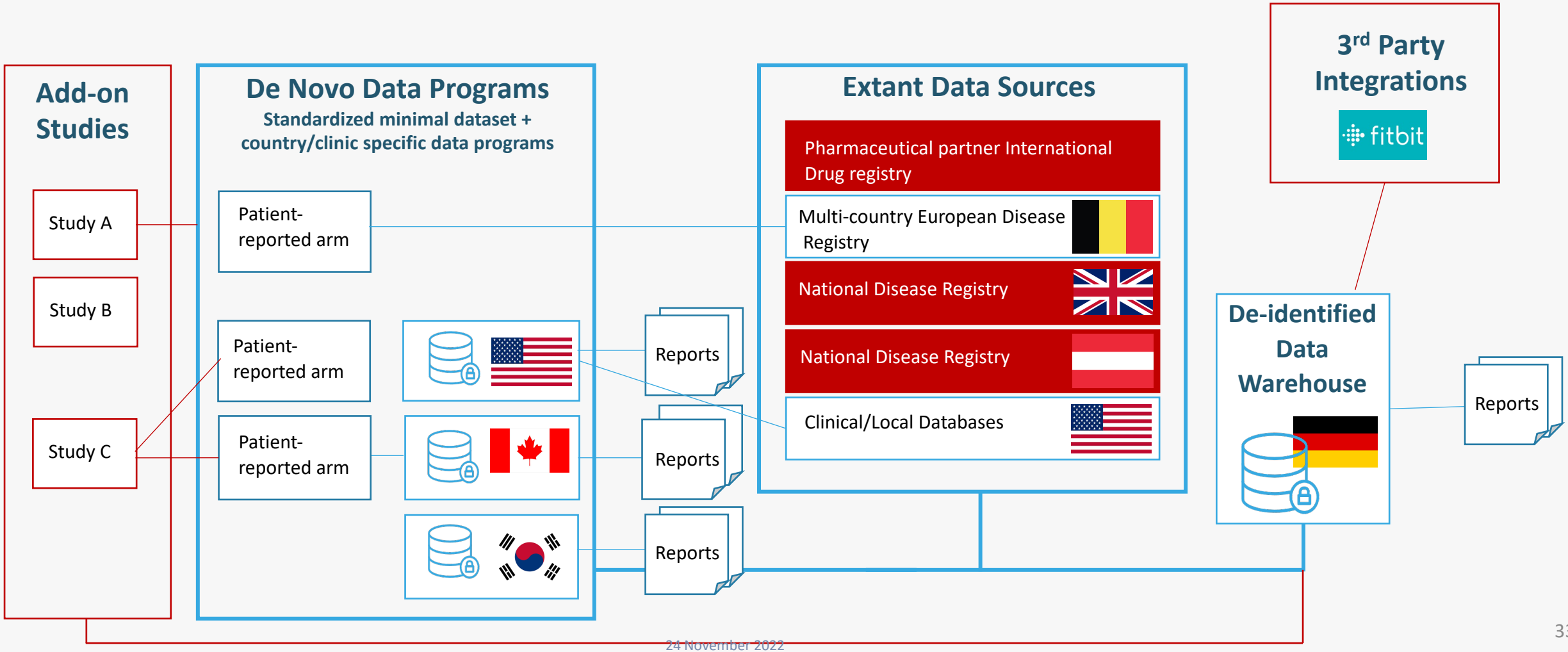

Italy


The Netherlands

https://rwe4decisions.com/documents/country-responses/

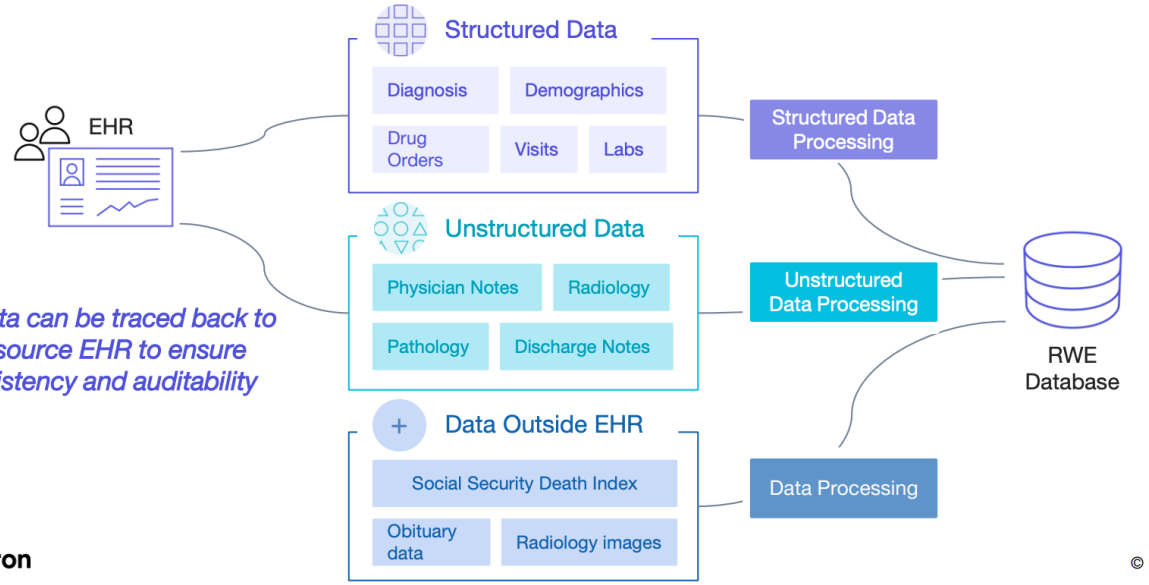
Case Studies

Global Acromegaly Registry Data Architecture



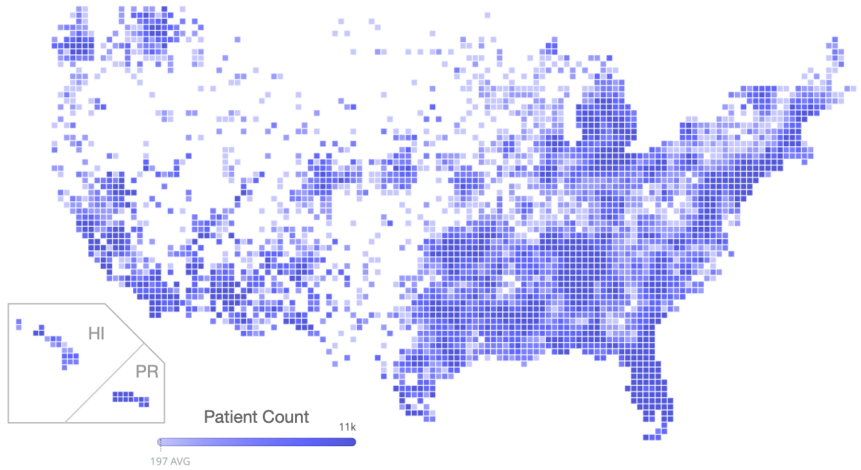
ALK+ RWD cohort created using RWD from Flatiron Health, Roche

We combine structured and unstructured data in our real-world database to capture cancer patients' experience



Our data can be traced back to the source EHR to ensure consistency and auditability

The Flatiron Network



2.5M+ Patients

2,600+ Clinicians

280 Cancer Clinics

7 Academic Medical Centers

800+ Unique Sites of Care

flatiron

flatiron

Valtermed protocols and reports Carlos Martin Saborido

https://www.sanidad.gob.es/en/profesionales/farmacia/valtermed/home.htm

GOBIERNO DE ESPAÑA MINISTERIO DE SANIDAD

› Protocolos Farmacoclínicos:

- Tisagenlecleucel en leucemia linfoblástica aguda de células B **Escuchar** (versión en inglés **Escuchar**)
- Tisagenlecleucel y axicabtagén ciloleucel en linfoma B difuso de células grandes **Escuchar** (versión en inglés **Escuchar**)
- Inotuzumab ozogamicina en leucemia linfoblástica aguda **Escuchar** (versión en inglés **Escuchar**)
- Darvadstrocel en fístulas perianales complejas en enfermedad de Crohn **Escuchar** (versión en inglés **Escuchar**)
- Lumacaftor/ivacaftor y tezacaftor/ivacaftor en el tratamiento de la fibrosis quística **Escuchar** (versión en inglés **Escuchar**)
- Dupilumab en el tratamiento de la dermatitis atópica grave en pacientes adultos **Escuchar** (versión en inglés Will open in a new window to the page docs/20200131_Protocolo_dupilumab_dermatitis_atopica__grave_adultos.pdf
- Remdesivir en el tratamiento de la enfermedad por COVID-19 **Escuchar** (versión en inglés **Escuchar**)
- Burosumab en el tratamiento del raquitismo hipofosfatémico ligado al cromosoma X **Escuchar** (versión en inglés **Escuchar**)
- Voretigén neparvovec en el tratamiento de la distrofia retiniana asociada a la mutación *RPE65* bialélica **Escuchar** (versión en inglés **Escuchar**)

Legislation enables G-BA to request routine practice data collection (AbD) to inform benefit assessment, Antje Behring

- Can be used when major uncertainties exist that could be resolved by data collection within a specified timeframe
- May be considered for certain types of medicines
- Necessity and feasibility subject to IQWiG review & stakeholder consultation
- Health technology developer must create protocol and statistical analysis plan for approval by G-BA and duration of data collection is agreed
- Monitoring of data collection expected at 18-month intervals

Learnings

HTA bodies

- RWD quality is the challenge
  - Routine practice data is never go to be of the same quality of a clinical trial
  - Fitness for purpose/data suitability?
  - Missing data
- Robustness of RWE
  - Existing guidances are consistent about need for protocols, analysis plans, transparency, need to address confounders etc
  - Each assessment is different as each product has its own uncertainties and issues – there are always trade-offs related to the context and data available (unmet need, severity, nature of uncertainties, endpoint availability, provenance, completeness, etc)
- Nothing explicitly in EUnetHTA21 guidelines about RWE

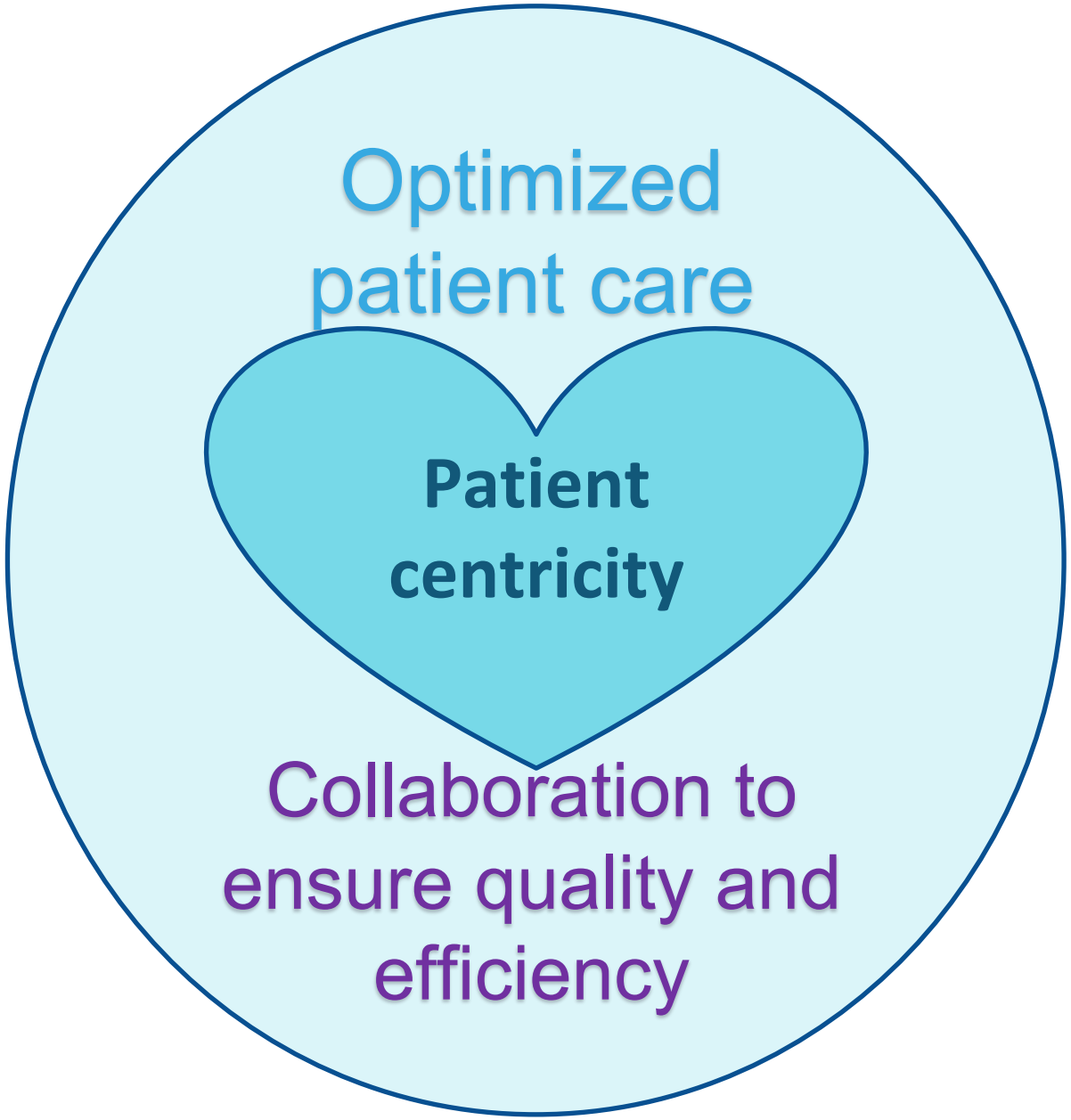
Health Technology Developers

- Want predictability about what will happen later in the life cycle of the medicine, what RWE will be acceptable, particular issues around transferability of evidence
- Need to agree and document when an RCT is not appropriate, or when an external comparator is acceptable *(case studies to discuss rationales?)*
- RWE studies are complex – need a harmonized guideline or roadmap of existing guidelines, or consistent assessment approach is needed

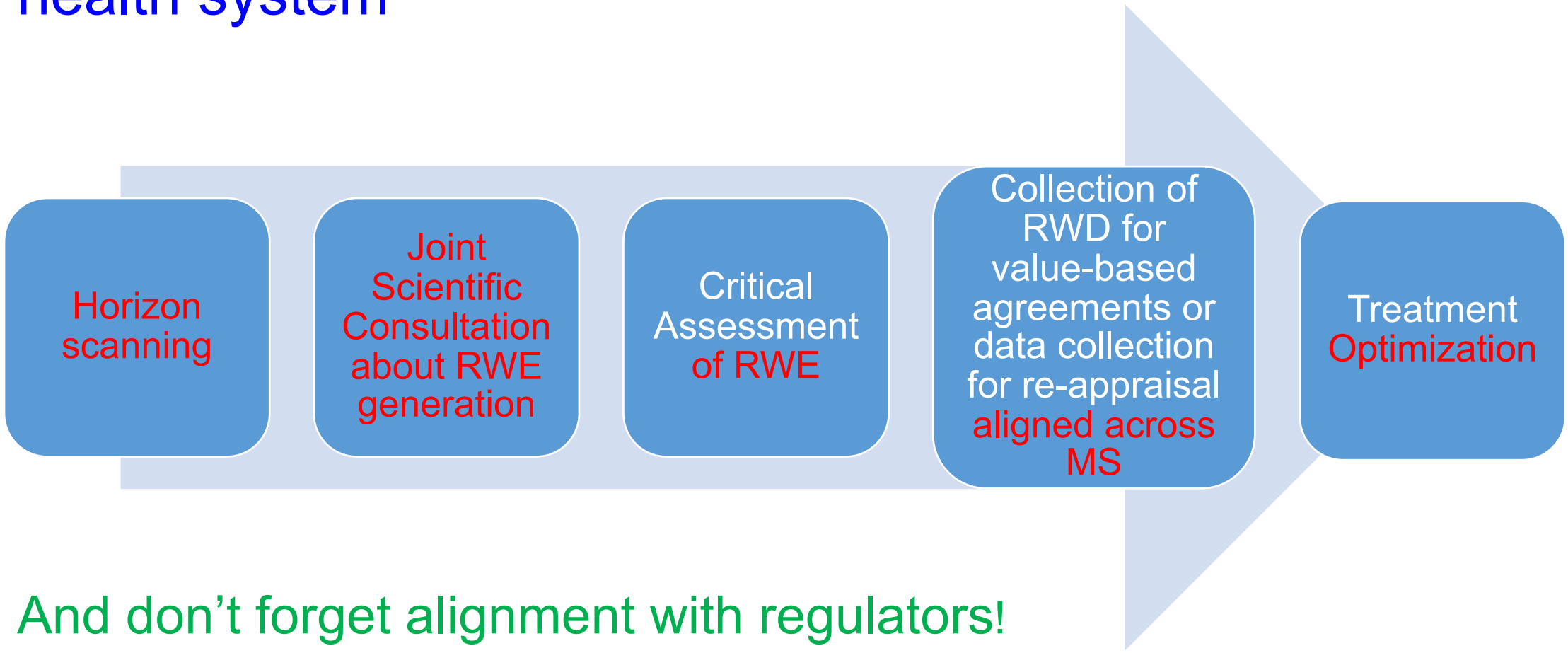
Registry holders

- Keen to understand HTA bodies needs, but it sometimes difficult to understand what the HTA requirements are, given this is real-world data, not clinical research
- It takes resources to develop good quality data and this needs to be funded
- Need to minimize burden on clinicians entering and cleaning data, and incentivize them?
- EUnetHTA REQUesT helpful for benchmarking registry and quality improvement

Patients

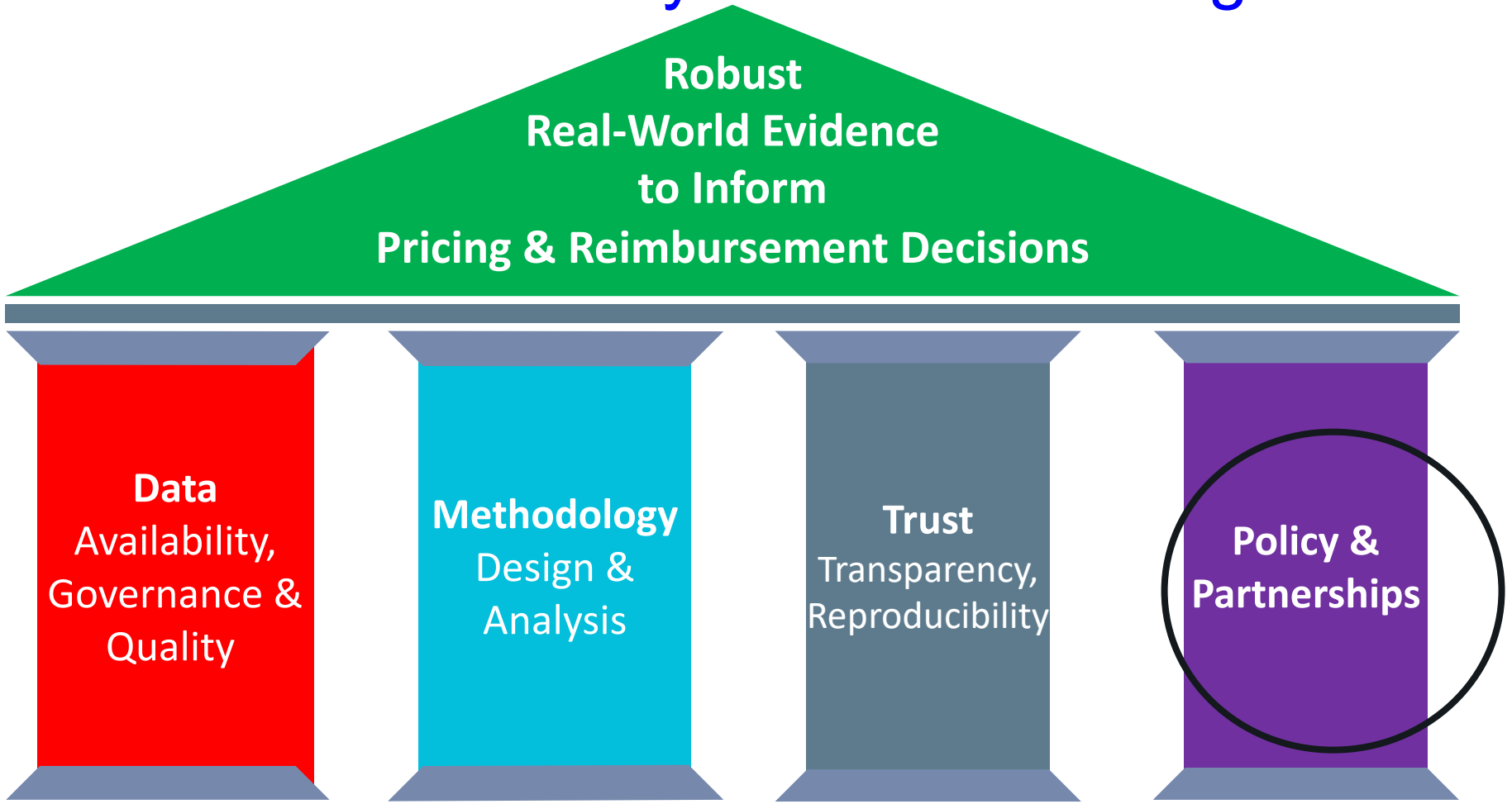

Optimized patient care
Patient centricity
Collaboration to ensure quality and efficiency

Our current vision?
The life cycle of RWE generation to create a learning health system



And don’t forget alignment with regulators!

Four pillars to support development of robust RWE for HTA/Payer decision-making



+ Management support to provide resources and upskill

10:20 CET

Panel discussion: Will health data initiatives in the EU mean that payers and HTA bodies have better real-world evidence for decision-making?

Stakeholder reactions: Opportunities and challenges

Discussion with the audience

CO-MODERATOR

Matti Aapro

Director at the Genolier Cancer Center, Switzerland

Gözde Susuzlu Briggs

Coordinator of "Data Saves Lives", European Patients' Forum

Alexander Natz

Secretary-General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

Cláudia Furtado

Head of the Health Technology Assessment, Pricing and Reimbursement Division, Portuguese Authority of Medicines and Health Products (INFARMED)

Robert Sauermann

Deputy Head of Department of Pharmaceutical Affairs, Association of Austrian Social Insurance and Chair of the Medicine Evaluation Committee (MEDEV)

11:20 CET

Interactive breakout room discussions

How do we work together to generate better real-world evidence for HTA bodies and Payers?

Moderated by RWE4Decisions Steering Group members

#PoliciesPartnerships

RWE4Decisions REAL WORLD EVIDENCE Symposium

After the coffee break… see you in the breakout rooms

1

LEAD: SIMONE BOSELLI

How can patients and patient groups support generation of RWE for HTA/Payer purposes?

2

LEAD: DIANE KLEINERMANS

How can we get timely and robust RWE that can be used for reimbursement decisions?

3

LEAD: CARLOS MARTÍN SABORIDO

How can we work in partnership to support RWE generation post-HTA?

4

LEAD: TOON DIGNEFFE

Partnerships for RWE generation: what are the roles and responsibilities for each stakeholder?

5

LEAD: KAREN FACEY

Partnerships for RWE generation

Online

Format for Online Breakout Room

15 minutes

Examples of where stakeholders have worked together to produce robust RWE4Decisions that has been used in HTA/Payer decision making

10 minutes

Examples where RWE generation has not been as anticipated, but where we learnt from it and enacted changes

15 minutes

What should RWE4Decisions do in future?

12.15 CET

Panel discussion with the RWE4Decisions Steering Group:
Where does RWE4Decisions go from here?

Plenary feedback from breakouts and discussion

CO-MODERATOR

Piia Rannanheimo

Chief Specialist, Finnish Medicines Agency (Fimea)

Diane Kleinermans

President of the Commission of Drugs Reimbursement, Belgian Institute for Health and Disability Insurance (INAMI-RIZIV)

Carlos Martín Saborido

Health Economist Advisor, Spanish Ministry of Health

Simone Boselli

EU Public Affairs Director, EURORDIS-Rare Disease Europe

Toon Digneffe

Head Public Affairs & Partnerships, Europe and Canada, Takeda

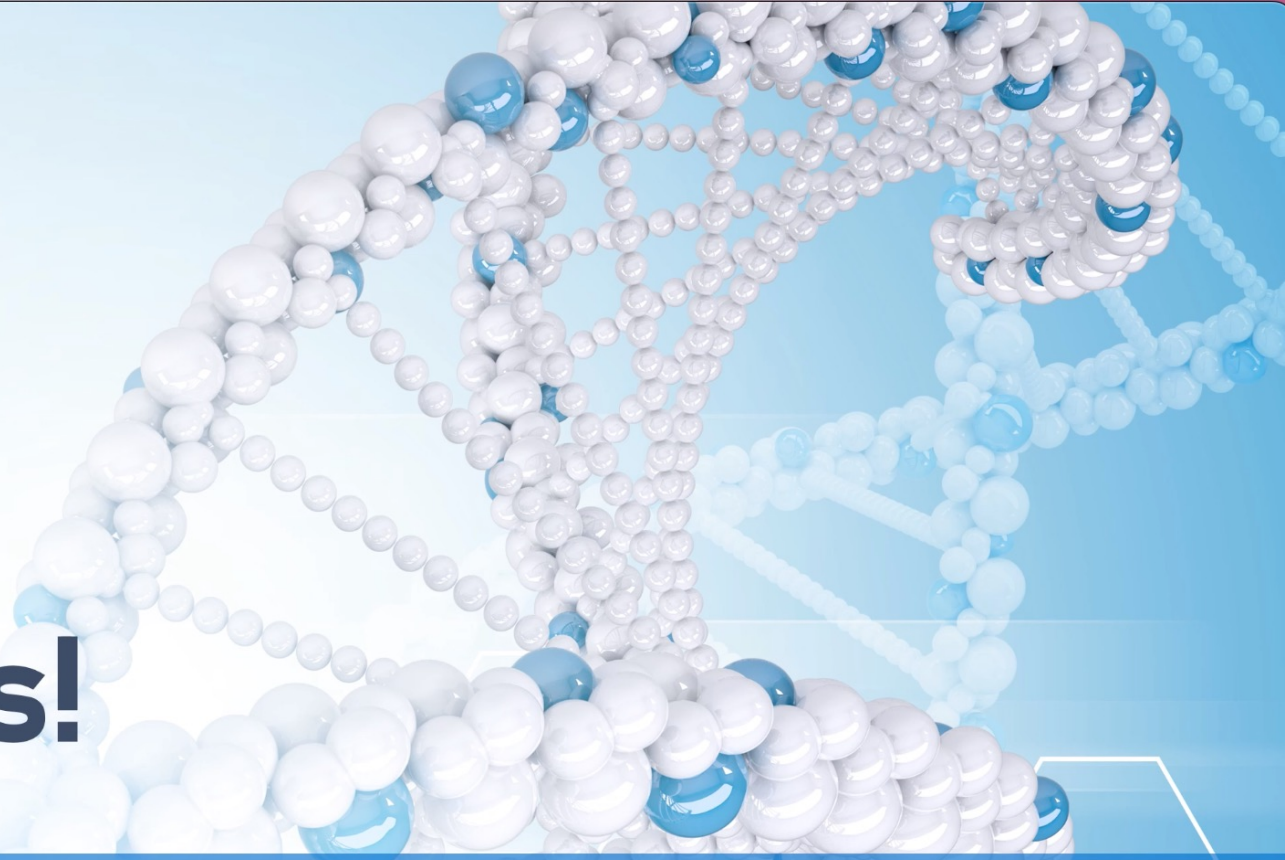
12.55 CET

Concluding remarks and next steps

Jo De Cock

Administrateur Général Honoraire,
Belgian Institute for Health and
Disability Insurance (INAMI-RIZIV)

RWE4Decisions
REAL WORLD EVIDENCE
Symposium



Thank you for your contributions!

The recording will be available at
www.rwe4decisions.com/event/rwe4decisions-symposium-policies-partnerships

For any questions or suggestions please get in touch:
secretariat@rwe4decisions.com

Check our website to stay up-to-date on our upcoming activities:
www.rwe4decisions.com