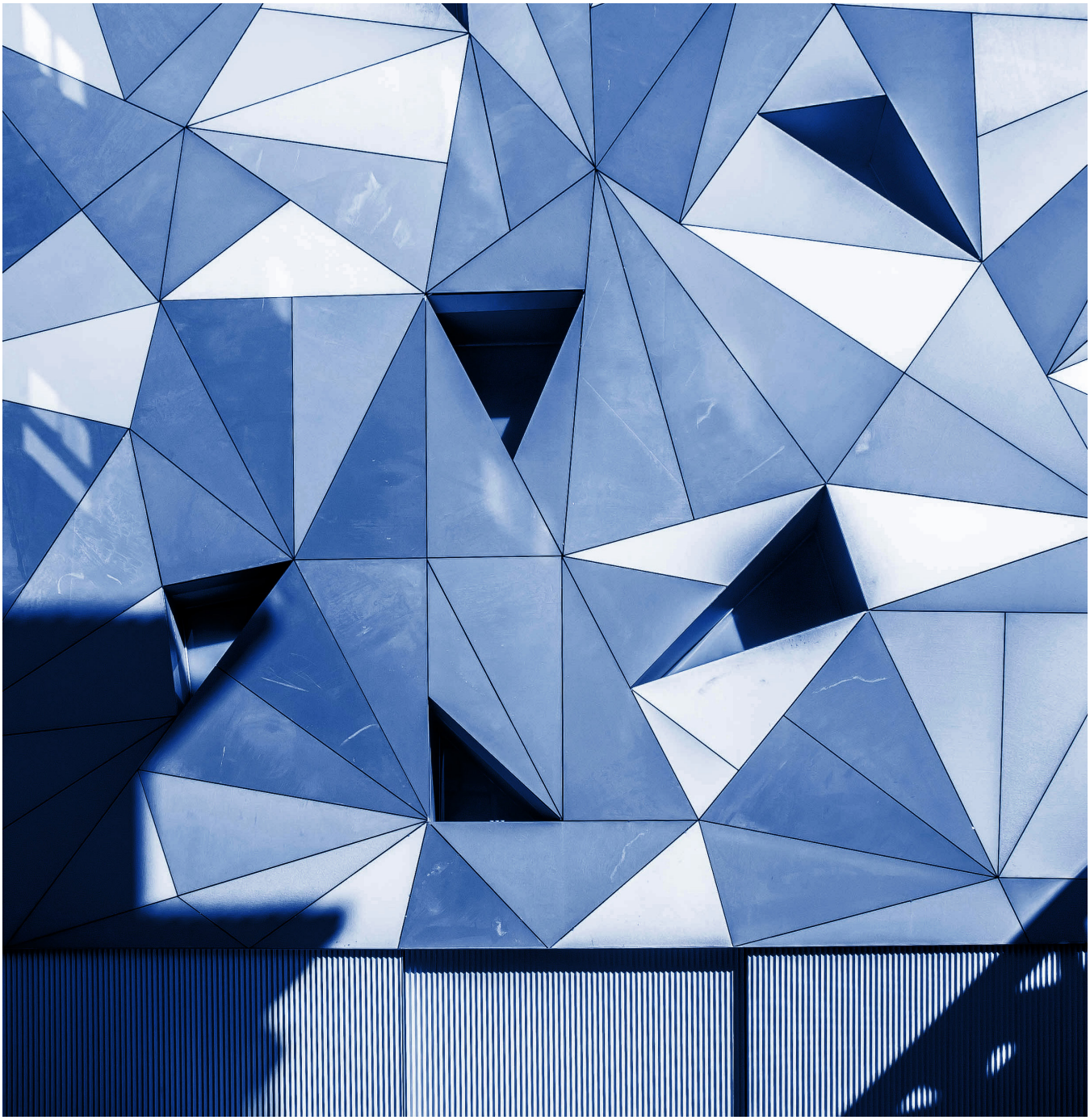
WORKSHOP DEEP DIVE

# RWE Case Studies for HTA Decision-Making

**5 DECEMBER 2023 | 15:00 -17:00 CEST**



**GETREAL INSTITUTE'S SHARED LEARNING FORUM**

GETREAL INSTITUTE | PUTTING REAL WORLD EVIDENCE INTO PRACTICE

# Background

In the dynamic landscape of healthcare, the pursuit of well-informed, evidence-based decision-making is more imperative than ever. The GetReal Institutes' "Shared Learning Forum" aims to cultivate the development and dissemination of generalisable learnings surrounding the opportunities and limitations of using Real-World Real-World Data (RWD) / Real-World Evidence (RWE) in defined decision contexts, while drawing insights from case study applications of RWE in supporting regulatory, reimbursement, and payment decisions. The Forum aspires to reshape the paradigm of healthcare decision-making where RWD/RWE would be accepted as evidence with the potential to improve patient outcomes and accelerate acess to medicines.

GetReal Institute brings together a diverse spectrum of stakeholders, including Health Technology Assessment (HTA) bodies, Regulatory authorities, industry experts, and patient advocates. For the first iteration of the "Shared Learning Forum", we were pleased to introduce general research inquiries stemming from a genuine RWE case study using registry data, as a starting point of the discussion, paving a way forward for informed decisions about treatment effectiveness, safety, and reimbursement.

# Session Highlights

## WELCOME AND INTRODUCTIONS

Dr Shahid Hanif, GetReal Institute Managing Director, kicked off the Shared Learning Forum, emphasising its primary objective: "We want to learn from the ins and outs of using Real World Evidence (RWE) in decision-making to help provide strategic support for regulatory, reimbursement and payment decisions, driven by a retrospective analysis of both successful and unsuccessful applications."

For our inaugural session, we were delighted to present a background on data registries followed by a generalised RWE case study devised from genuine industry experience, as a foundation for leveraging the discussions, paving a way forward for informed decisions about treatment effectiveness, safety, and reimbursement.  Three critical topics were explored:

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| Crafting Registries for HTA Excellence: Key Design Considerations | Navigating Time Constraints: Data Submission and Reimbursement Impact | Unlocking the Potential Overcoming Challenges in Registries Implementation |

# Comprehensive Overview of Existing Registry Data

Antonia Panayi, on behalf of European Federation of Pharmaceutical Industries (EFPIA), presented a comprehensive analysis of existing registries, emphasising the necessity of explicit acceptance of registry data as evidence for enhanced patient outcomes. She highlighted that "Until now there has only been a limited number of published examples, probably outside of oncology, available on the use of registries by HTA organisations in Europe."

### KEY GUIDELINES AND/OR RECOMMENDATIONS INTRODUCED INCLUDE:

## REGISTRIES LANDSCAPE OVERVIEW


**EUnetHTA:** The Registry Quality Evaluation and Standards Tool (REQueST)

**EUnetHTA:** Cross Border PAtient Registries iNiTiative (PARENT)

**Health Canada-CADTH**: Guidance for Reporting Real-World Evidence (2023)

**EMA**: Guideline on registry-based studies (2021)

**FDA:** Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry (2021)

**AHRQ:** Registries for Evaluating Patient Outcomes: A User's Guide, 4th Edition (2020)

**REGISTRIES**: Storehouses of RWD

**BENEFITS:**
Wide variety of data

Linked across nations - perspective on changing trends

Holistic view of collected data: disease particularities, efficacy, safety, economic value, etc

Detailed view on: morbidity, mortality & resource utilization

**LIMITATIONS:**
Data collection, validation

Data quality, Costs

- **EUnetHTA REQueST Tool (Registry Evaluation and Quality Standards Tool)**[1] which aims to support HTA organisations and other actors in guiding and evaluating registries for effective usage in HTA. The tool has been developed to be a comprehensive resource that covers all important aspects relating to the quality of registries. The standards set out in the tool are universal and are essential elements of good practice relevant for different types of registries.

- **PARENT, the Cross Border PAtient REgistries iNiTiative**[2] by the Joint Action EU Health programme 2008-2013, that was later adopted by the EUnetHTA with the overall objective to support member states in developing comparable and coherent patient registries in field. PARENT aims to rationalise and harmonise the development and governance of patient registries, thus enabling analyses of secondary data for public health and research purposes.

- **Canadian Agency for Drugs and Technologies in Health ("CADTH"), in collaboration with Health Canada and the Institut national d'excellence en santé et en services sociaux ("INESSS"), has published guidance on reporting real-world evidence ("RWE")**[3] The guidance defines RWE as evidence surrounding the use, safety, efficacy, and cost of a health product, derived from analysis of real-world data. According to CADTH, the guidance harmonises principles for the use of RWE in regulatory approval and health technology assessments in Canada and prioritises transparent reporting while maintaining alignment with international standards.

- **EMA Guidance on Registries to Support Regulatory Decision-making for Drug and Biological Products Guidance for Industry**[4] which addresses the methodological, regulatory and operational aspects involved in using registry-based studies to support regulatory decision-making.

- **FDA Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry**[5] which provides sponsors and other stakeholders with considerations when either proposing to design a registry or using an existing registry to support regulatory decision-making about a drug's effectiveness or safety.

- **The 4th edition of Patient Registries for evaluating patient outcomes, as user guide, by the Agency of Healthcare Research and Quality (AHRQ)**[6] underlining governance issues such as data access, sharing, and funding, in addition to methods and operational aspects for the use of registries for regulators providing best practices to guide design, operation, analysis, and evaluation of patient registries.

Ms. Panayi showcased the myriad advantages of registries, encompassing diverse data sets that facilitate safety monitoring, care quality assessment, and an in-depth understanding of the history of diseases. "These registries play a crucial role in determining clinical effectiveness, comparative effectiveness, and cost effectiveness of healthcare products and clinical practices across a more heterogeneous population. Furthermore, they offer the ability to monitor safety and gauge the quality of care," she added.

The EMA defines Patient Registries as organised systems that use observational methods to collect uniform data on a population defined by a particular disease, condition or exposure,

and that is followed over time.[7] Patient registries are classified based on the definition of their populations, while Product registries includes patients who have been exposed to a specific pharmaceutical product.

By generating RWD, Patient registries enable the creation of RWE, providing crucial insights for regulatory decision-making. The RWD collected from Patient registries play a pivotal role in addressing research queries through studies. These inquiries can span essential areas such as deciphering the natural progression of a disease, exploring variations in treatment and outcomes, outlining care patterns, gauging effectiveness, and monitoring safety. Although, regulatory bodies typically favour randomised controlled trials (RCTs) for endorsing marketing authorisations, situations may arise where RCT data is limited, unethical, or impractical, in such instances, Patient registry data becomes invaluable for supporting regulatory decision-making

# OVERVIEW OF A GENERAL RWE CASE STUDY USING REGISTRY DATA TO CONFORM TO HTA REQUIREMENTS AND INFORM TREATMENT EFFECTIVENESS, SAFETY, AND DETERMINE REIMBURSEMENT DECISIONS

A generalised case study devised from a combination of industry experiences involving "Product X" seeking HTA approval was presented by Antonia Panayi, on behalf of European Federation of Pharmaceutical Industries (EFPIA), revealing uncertainties in efficiency and safety from pivotal trials. This was followed by comments from François Houÿez, representing the European Organisation for Rare Diseases (EURORDIS), Niklas Hedberg, from The Dental and Pharmaceutical Benefits Agency (TLV), Stephen Duffield, from the National Institute for Health and Care Excellence (NICE), and Denise Umuhire, from the European Medicines Agency (EMA).

Setting the scene, the team at EFPIA sought to present a case framing the current stance on leveraging registry data for Health Technology Assessment. However, it is vital to underscore that beyond oncology there is a scarcity of published examples in this realm, and consequently, the scenario discussed was largely hypothetical, yet derived from collective experience representative of a typical scenario.

Initially, "Product X" received conditional reimbursement decision from the HTA body in Europe due to uncertainties in initial study design emanate from the pivotal trials, influenced by factors such as the number of patients in the clinical study, limited follow-up duration, scarcity of medium and long-term effectiveness and safety data, and restricted number of Patient Report Outcomes (PROs).

To address these uncertainties, a Patient Registry was established by the Haemophilia Research Institute and funded by the Applicant Sponsor(s), focusing on capturing short, mid,

and long-term effectiveness and safety data with both retrospective and prospective components. It was also highlighted that the presented case study was a disease registry designed for a particular disease and can be extended to other therapeutic areas.

This was part of the conditional reimbursement decision with the HTA body. Upon reassessment of "Product X", the HTA body reviewing the product considered the real-world observational data as consistent with the clinical trials, providing a favourable opinion for reimbursement maintenance. However, the HTA body concern highlighted that the registry data are still immature, prompting a recommendation for further follow-up.

# INSIGHTS FROM THE EXPERT PANEL

Analysis by François Houÿez, from the European Organisation for Rare Diseases (EURORDIS), provided valuable insights into the complexities of the case study, emphasising the need for a multi-perspective approach, addressing challenges in data collection, considering both data quality and analytic methods, and highlighting the crucial role of patient organizations in informing the HTA process providing:

- **Perspectives on Haemophilia Treatment:** Mr. Houÿez suggested that for a case study like this, it's crucial to rely on perspectives and detailed data collection, especially in the context of haemophilia. He pointed out that haemophilia is a typical case study, but it is particularly challenging due to variations in treatment approaches (on demand prophylaxis versus systematic prophylaxis) that may not be clearly identified in retrospective data.
- **Challenges with Registry Data and Perspectives:** Mr. Houÿez underlined governance issues such as data access, sharing, and funding. He mentioned operational aspects for the use of registries for regulators and noted that relying on a single source for data may lead to challenges in interpretations. Moreover, developers might choose to set up their own product registry due to difficulties in adapting existing ones.
- **Data Quality vs. Analytic Methods in Rare Diseases:** Mr. Houÿez mentioned a trend in rare diseases where there is an increasing ability to collect high-quality data. However, he pointed out a growing concern about the adequacy of analytic methods used to analyse the data rather than the quality of the data itself.
- **Patient Community Engagement:** "The patient community in Haemophilia is well-organised, many members of whom are health economists and have been actively involved in publishing studies on the economic aspects of severe haemophilia and treatment," Mr. Houÿez was quoted. The patient community is experienced in organising surveys to collect data on patient-reported outcomes, demographics, and economics related to the cost of drugs and treatment impacts.

François Houÿez concluded by emphasising the importance of researchers collaborating with patient organisations to determine how to collect patient input and information crucial for assessing the real impact of treatment on patients' lives.

Niklas Hedberg from The Dental and Pharmaceutical Benefits Agency (TLV) proceeded to

provide comprehensive comments on the case study, focusing on the data collection for haemophilia treatment, acknowledging "the mix of impressions in the presented in the case study, particularly with such a well-established disease that has previous treatments."

- **Existing Data vs. Quality:** Mr. Hedberg noted that, despite a restricted number of patients and practitioners, in the presented case study, that it was a good starting point for collecting high-quality data.
- **Sweden Case Example:** Data on drugs dispensed at pharmacies. in the Swedish Health System which allows for a good follow-up, enabled the examination of consumption patterns, especially with the new wave of advanced therapies and longer half-life.
- **Cost Analysis:** In the Swedish example, two specific scenario cases were presented, the first where the prolongation in time between doses led to a prolonged time between drug administrations, while in the other, dosing regimen remained the same and hence costs increased due to assumptions about prolonged half-life not aligning with the actual dispensing intervals.
- **Data Needs for Health Economics:** Mr. Hedberg emphasised the importance of distinguishing between data needs, when building a case, based on the assumption of superior effectiveness versus cost minimisation analysis. The former requires effectiveness data, while the latter focuses on proving that the new treatment is not worse than existing options and is not more expensive.
- **Challenges and Completeness of Data:** Mr. Hedberg raised concerns about the completeness of data, particularly for new therapeutic agents that offer one-off treatments. He acknowledged the challenge of assessing long-term effectiveness and the necessity of modelling assumptions despite the lack of complete data.
- **Need for Work on Multiple Levels:** Mr. Hedberg emphasised the need to work on three levels simultaneously from conducting pilots, managing infrastructure (data access and completeness), to refining methods. He stressed that scientific work is still required to enhance the methods used in assessing the effectiveness and cost-effectiveness of treatments.

Niklas Hedberg concluded that haemophilia is a favourable therapeutic area but requires comprehensive efforts on multiple fronts to address data challenges including data completeness, data access, and additional methodological advancements.

Dr. Stephen Duffield, from the National Institute for Health and Care Excellence (NICE) discussed the familiar scenario in the UK involving the Cancer Drugs Fund and the Innovative Medicines Fund, which support early access to innovative products for a limited period of time. Key points from Dr. Duffield's comments are:

- **Managed Access Agreements in the UK:** Dr. Duffield highlighted the established practice of entering managed access agreements, where conditional recommendations allow for the use of innovative treatments at a cost-effective price while remaining evidence gaps are addressed.

- **Timing of Data Collection:** Since conditional recommendations are usually based in part on ongoing trials, Real-World Data collection in these scenarios often starts at a later stage than ongoing trials, resulting in Real-World Data being less mature compared to RCT data.
- **Supportive Role of Real-World Data:** Real-World Data is seen as playing a supportive role, contextualising and providing reassurance for outcomes observed in trials, helping compare effects and estimate outcomes in the target population.
- **Challenges of Multiple Reappraisals:** Dr. Duffield raised a question about the practicality of multiple reappraisals, considering the potential burden on Health Technology Assessment (HTA) agencies. Managing numerous reappraisals may not align with typical practices, especially at agencies like NICE (National Institute for Health and Care Excellence).
- **Preference for Real Data in Certain Cases:** Committees may prefer real data over trial data, especially in cases where single-arm trials contribute the main data. "Real-world data is advantageous for its external validity in scenarios characterised by greater heterogeneity and long-term uncertainty, such as in rare diseases," he asserted.

Finally, Dr. Stephen Duffield suggested the potential use of patient registries for providing real-world comparative effects estimation alongside trial data that could offer a more comprehensive view of relative treatment outcomes in real-world settings.

Denise Umuhire from the European Medicines Agency (EMA) provided concise but valuable comments, highlighting important considerations when setting up disease registries, while expressing alignment with the comments made by other colleagues in the discussion.

- **Focus on Study Design:** Ms. Umuhire emphasised the importance of carefully considering study design in the context of registry data. She mentioned the importance of leveraging existing guidelines and tools such as the EMA's guideline on registry-based studies.
- **Challenges in Rare Diseases:** Ms. Umuhire highlighted the challenges in studying rare diseases, where data is often fragmented. She acknowledged that studies on rare diseases may need to be conducted cross-country, introducing further challenges related to data standardisation and other sources of heterogeneity such as coding systems, healthcare systems, clinical practices, etc.
- **HTA Challenges in Cross-Country Data:** Ms. Umuhire pointed out that HTA bodies may prefer to see data specific to their own country, reflecting local practices, which might limit the possibilities of standardisation across countries.
- **Frequency of Reassessments in Different Countries:** Reassessment frequency for Health Technology Assessments (HTAs) and payer evaluations varies across countries, and are dependent on product characteristics and levels of uncertainty. On the level of uncertainty for HTAs and payers, reassessments are often required, almost every two years in some countries and depending on products. Seeking early scientific advice from regulators and HTA in the design of registries and registry-based studies was highlighted as a recommended process to help anticipate and plan evidence needs.

Denise Umuhire concluded by acknowledging that there are many considerations involved in the process, suggesting the multifaceted nature of dealing with evidence planning and generation to address HTA needs, taking into account data validation, and reassessments.

An intervention by the Canadian Agency for Drugs and technologies in Health (CADTH) emphasised the need for clarity on the purpose of using RWE, the challenge of proving its value compared to existing options, and the consideration of whether it significantly impacts decision-making processes in the HTA context.

Niklas Hedberg interjected and highlighted the multifaceted nature of ensuring reliable data, the limitations of traditional statistical approaches, the importance of answering meaningful questions, and the collective responsibility of stakeholders in planning for the long-term acceptance of data results.

# MODERATED DISCUSSION WITH QUESTIONS ADDRESSED TO THE AUDIENCE

**I. Crafting Registries for HTA Excellence: Key Design Considerations - What factors should be considered when designing registries to meet HTA requirements and effectively inform reimbursement decisions?**

Dr. Stephen Duffield, mentioned in considering NICE's perspective, key elements involve data suitability, the use of NICE tools, which priorities data source agnosticism, emphasizing good data provenance and effective governance despite potential challenges in data suitability. The concept of "fitness for purpose" is highlighted, indicating the necessity to anticipate evidence gaps, with early scientific advice playing a pivotal role in this process.

Dr Duffield added that for NICE, grasping the key factors influencing health state transition probabilities is crucial in evaluating the value of a given treatment, maintaining a balance is essential, considering the trade-offs against the burden of data collection. To ensure meaningful gap coverage without overwhelming data collection, the inclusion of patients and clinicians in the design of datasets is emphasised.

In the context of medical technology, obtaining evidence, particularly through RCTs, may be challenging. Therefore, NICE takes a proactive approach to stimulate evidence generation for med tech, recognising the unique feasibility challenges in this area. Overall, the NICE perspective involves a strategic and nuanced consideration of various factors to make informed decisions about the value and effectiveness of healthcare interventions.

A noteworthy intervention brought forward the Italian experience in designing registries, involves parallel development alongside assessments from scientific committees. This strategy is distinctively aimed at informing reimbursement decisions, specifically addressing price and reimbursement issues. This practice is crucial, particularly in the context of certain countries, and is rooted in the regulations and legislations governing HTA and payers in Europe. In essence, Italian registry design not only serves as a comprehensive data collection tool but also aligns with reimbursement considerations, ensuring a prag-

matic and informed approach to healthcare interventions.

Advocating for the patient voice, François Houÿez, underscored the importance of engaging various stakeholders in registry design to ensure diverse perspectives and improve decision-making. Patient organisations can be engaged early in the development to discuss data needs, including patient experience and daily life impact.

**II. Navigating Time Constraints: Data Submission and Reimbursement Impact - What is the accepted setting timeframe from both industry and HTA body perspectives to provide data and how will the timeframe influence reimbursement decisions?**

Niklas Hedberg, from The Dental and Pharmaceutical Benefits Agency (TLV), advised on investing in existing patient registries to facilitate the collection of historical datasets. This approach is crucial for drawing conclusions about treatment effectiveness in the future. To achieve meaningful insights, it's essential to initiate this investment well in advance—ideally, four to five years before your product launch.

Considering the significant timespan associated with modulating lifetime effectiveness and the duration of a treatment's impact, the critical question arises: when should we commence this investment? Typically, companies recognise the need for follow-up data after product launch, often when time and resources are limited. At this juncture, building a new registry tailored for this purpose may be challenging. Instead, leveraging existing registries is a pragmatic solution, feasible in both time and cost. While this may not directly answer the question, it provides important context.

François Houÿez further highlighted the challenge of dealing with a competitor's Patient Registry evolving into a Product Registry as such engagement with competitors becomes essential to determine the optimal use of the registry for future clinical trials, emphasizing the intricacies involved in managing and accessing such data.

**III. Blocking the Potential: Overcoming Challenges in Registries Implementation - What are some of the key considerations and challenges that need to be addressed in implementing registries for HTA and reimbursement purposes, i.e., data quality and how might registration requirements be refined over time?**

The European Medicines Agency (EMA) and the European Medicines Regulatory Network established Data Analysis and Real-World Interrogation Network (DARWIN EU) to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the European Union.

Mr. Houÿez emphasized the importance of collecting patient-reported outcomes and using the same outcome measures in both clinical trials and patient registries. He highlighted challenges in obtaining consent for secondary data use, particularly for historical data, and suggested seeking ethics committee advice or direct consent from participants when possible. Mr. Houyez added that scientific advice may not always suffice, and multi-stakeholder workshops as organized by GetReal is essential. Moreover, collaborating with clinicians necessitates grasping the nature of the data they collect.

While it is crucial to align patient registries with the outcome measures used in clinical trials, complications may arise due to historical data lacking patient consent for second-

ary purposes. Engaging with patients, community advisory boards, and competitors helps gather insights on patient experience and facilitates collaboration. Considering societal impact, feedback from patients becomes crucial. HTx, a Horizon 2020 project. aims to create a framework for the Next Generation Health Technology Assessment to support patient-centred, societally oriented, real-time decision-making on access to and reimbursement for health technologies throughout Europe.

Representing NICE, Dr. Stephen Duffield stressed the significance of incentivizing and streamlining data collection in healthcare. This involves engaging both patients and clinicians. Clinicians may be incentivised by experiencing the positive impact of data input through benchmarking their clinical practice. Patients should be involved in defining meaningful outcomes and their data input can be supported through technology.

He expanded to the evolving trend of linking existing data resources in the UK, from secure data environments and potentially moving towards federated data networks. HTA bodies can play a pivotal role in influencing and steering these trends to ensure they align with the objective of delivering more beneficial services. Moreover, Dr. Duffield highlighted the transformative shift of HTA bodies from traditional gatekeeping roles to more proactive stewardship. In NICE's Early Value Assessment programme, NICE have developed evidence generation plans to support conditional recommendations in health tech and can guide research funders and evidence developers to reduce research waste. These are crucial steps in advancing both data collection and evidence generation in the healthcare landscape.

From The Dental and Pharmaceutical Benefits Agency (TLV), Mr. Hedberg interjected, adding that there's a perception among patients, partners, and prescribers that HTA intends to use data to restrict product usage and reduce costs. However, in most cases, it is the opposite. Broad access is granted when there's assurance of additional information availability for payers to rectify any mistakes. Changing the overall perception is crucial to ensure that well-covered products in patient registries stand a higher chance of receiving comprehensive treatment, even for expensive products. This positive impact was observed with TNF alpha inhibitors in Sweden 25 years ago, demonstrating the importance of utilizing such motivators for broader access and usage.

# Stakeholder Recommendations

## 1. REGISTRY DESIGN

a. Emphasise strategic design considerations for crafting registries for Health Technology Assessment (HTA) excellence and underscore the importance of early engagement with diverse stakeholders for improved decision-making in healthcare interventions.

b. Prioritise data source agnosticism, good data provenance, and effective governance. Engage patients and clinicians in dataset design to ensure relevance and fitness for purpose.

## 2. REGISTRY ADOPTION

a. Promote widespread understanding of registry data as valuable evidence for health outcomes and healthcare decisions.

b. Utilise registries for historical data collection, ensuring meaningful insights into treatment effectiveness and facilitating regulatory and reimbursement decisions.

## 3. MULTI-STAKEHOLDER COLLABORATION

a. Facilitate multi-stakeholder collaborations to address challenges related to data quality, implementation, and ethical considerations.

b. Address perceptions and misconceptions regarding registry data utilisation.

## 4. GUIDANCE & STANDARDS

a. Champion the adoption of international guidelines and standards, leveraging comprehensive frameworks, to ensure transparent and globally aligned regulatory and HTA decision-making.

b. Identify challenges and provide support towards implementing and adhering to standards.

## 5. FUNDING & STABILITY

a. Support early investment in patient registries and their development to address evidence gaps in healthcare, and advocate for incentives to streamline data collection processes.

b. Recognize the dynamic nature of registry implementation and address challenges related to data quality, consent for secondary data use, and ensure adaptability to evolving healthcare landscapes.

These recommendations collectively aim to foster a collaborative, evidence-driven approach to registry development and utilisation, ultimately contributing to more informed decision-making in healthcare.

## ADDITIONAL INSIGHTS:

The complexity of rare disease studies and the need for cross-country collaboration.

The importance of distinguishing between disease and product registries.

Overall, the forum provided valuable insights into the evolving landscape of RWE acceptance, emphasizing collaboration, transparency, and proactive engagement for informed decision-making in healthcare.

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1 https://eunethta.eu/request-tool-and-its-vision-paper/

2 https://www.eunethta.eu/parent/

3 https://www.cadth.ca/real-world-evidence-decision-making

4 https://www.ema.europa.eu/en/guideline-registry-based-studies-scientific-guideline

5 https://www.regulations.gov/document/FDA-2021-D-1146-0043

6 https://www.ncbi.nlm.nih.gov/books/NBK562575/

7 https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/patient-registries#:~:text=Patient%20registries%20are%20organised%20systems,monitoring%20the%20safety%20of%20medicines.

# Annex

## GETREAL INSTITUTE'S SHARED LEARNING PLATFORM PARTICIPANTS LIST

| # | STAKEHOLDER | NAME | ROLE | ORGANISATION |
|---|---|---|---|---|
| 1 | GetReal Institute | Shahid Hanif | Managing Director | GetReal institute |
| 2 | GetReal Institute | Isabelle Manneh | Projects Manager | GetReal institute |
| 3 | Academia | Lysbeth Bakker | Researcher | UMC Groningen / More- EUROPA |
| 4 | Academia | Fabian Windfuhr | Researcher | UMC Groningen / More- EUROPA |
| 5 | Academia | Entela Xoxi | Senior Scientific Advisor | ALTEMS Università Cattolica del Sacro Cuore (formerly AIFA) |
| 6 | Academia | Seamus Kent | Assistant Professor | Erasmus School of Health Policy & Management |
| 7 | Academia | Nitzan Arad | Policy Advisor & Researcher | Duke-Margolis Centre for Health Policy |
| 8 | HTA Body | Páll Jónsson | Programme Director - Data and RWE | NICE |
| 9 | HTA Body | Stephen J. Duffield | Associate Director | NICE |
| 10 | HTA Body | Niklas Hedberg | Chief Pharmacist | TLV |
| 11 | HTA Body | Farah Husein | Director, Science & Methods Evidence Standards | CADTH |
| 12 | Industry - Biotech | Irene Nunes | VP, Head of Global Regulatory Affairs | GenMab |
| 13 | Industry - Data Science/HEOR | Sreeram Ramagopalan | Principal | Lane Clark & Peacock |
| 14 | Industry - Data Science/HEOR | Jennifer Gaultney | Director in Health Economics and HTA | IQVIA |
| 15 | Industry - Health Tech | Laura Roe | Clinical Studies Platforms | Verily Life Sciences |
| 16 | Industry - Pharma | Jing Wang-Silvanto | Senior Director, HEOR Oncology | Astellas Europe |

| # | STAKEHOLDER | NAME | ROLE | ORGANISATION |
|---|---|---|---|---|
| 17 | Industry - Pharma | Ariadna Juarez | Director, WW HEOR, Real World Evidence Strategy | BMS |
| 18 | Industry - Pharma | Elena Popa | Regulatory Policy & Innovation Lead | Bayer |
| 19 | Industry - Pharma | Bart Barefoot | Senior Director and Head, Europe Regulatory Policy | GSK |
| 20 | Industry - Pharma | Antonia Panayi | Head Global Medical Evidence, GMA | Takeda |
| 21 | Industry - Trade Association | Aneta Tyszkiewicz | Associate Director Data Digital | EFPIA |
| 22 | Patient Organisation | François Houŷez | Treatment Information & Access Director / Health Policy Advisor Policy and Communications Manager | EURORDIS |
| 23 | Patient Organisation | Lidia Salvatori | Policy and Communications Manager | Cystic Fibrosis Europe |
| 24 | Regulatory | Denise Umuhire | Pharmacoepide-miology & RWE Specialist | EMA |