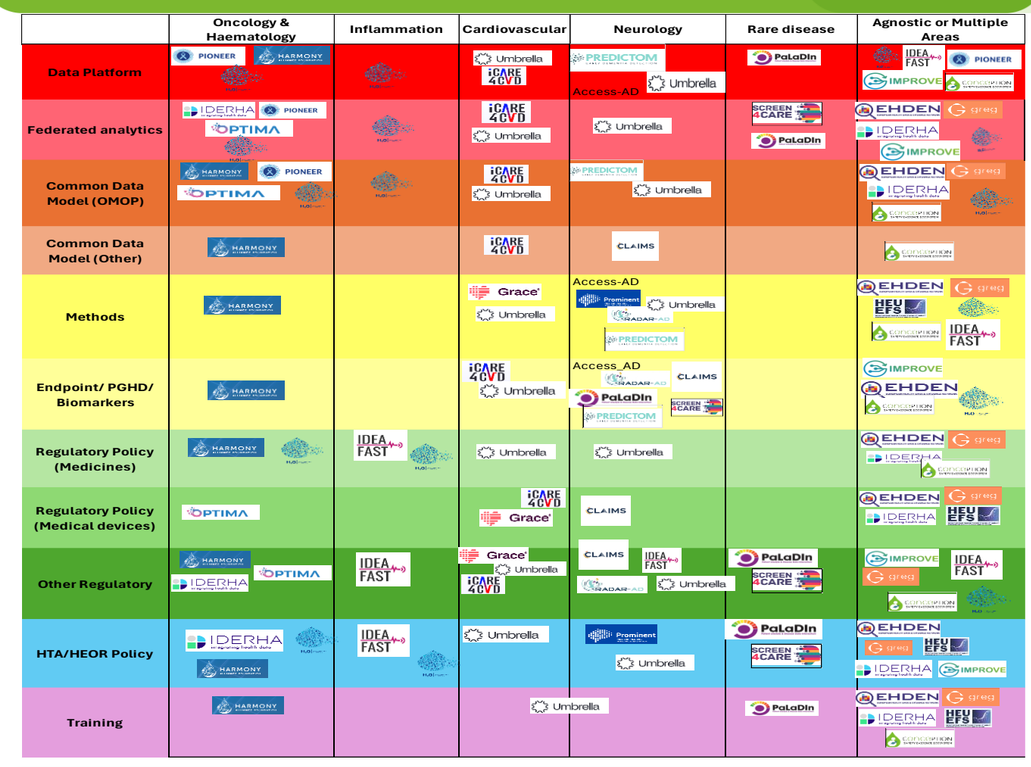
Connecting IHI Projects to Shape the Future of Good RWE Research Practices in Europe

- Rasmus M. Hansen, Camilla P. Nielsen, Heather Colvin, Rita Peeters, Philip Gribbon, and Lotte G. Jensen

FACTS & FIGURES



CHALLENGE

IHI projects are investing heavily in real-world data platforms, methods and evidence generation. Yet **fragmented regulatory and HTA expectations across Europe still limit the acceptance**, reuse and impact of RWE.

Projects repeatedly hit the same barriers: harmonised evidence requirements, data quality, governance, interoperability, and regulatory/HTA acceptance.

Projects are also tackling similar policy and methodological questions in parallel.

A cross-project mechanism is needed to reduce duplication, share reusable outputs and coordinate engagement with regulators and HTA bodies**, turning individual project learning into a sustained European RWE policy effort.**

APPROACH & METHODOLOGY

Connecting IHI projects working on RWD/RWE policy, bringing together expertise from research, industry, regulatory, HTA and patient communities.

The approach combines three elements:

- **Portfolio mapping and knowledge sharing** to identify existing tools, outputs, overlaps and gaps across IHI projects.
- **Working groups for joint action** focused on portfolio conscientiousness, collaborative policy development, and sustainability through shared impact and growth.
- **Coordinated stakeholder engagement** with regulators, HTA bodies and other experts to align priorities, refine outputs and strengthen policy uptake.

These priorities were identified by participants at the IHI Cross-Project RWE Policy Collaboration Workshop, Brussels, October 2025.

RESULTS

The IHI Cross-Project RWE Policy Collaboration Workshop (Brussels, October 2025) confirmed strong interest in continued collaboration and set a shared direction for the network.

Since then, the collaboration has taken shape through the **IHI RWE Alliance for Impact** and its **three working groups: portfolio conscientiousness, collaborative policy development, and sustainability through shared impact and growth.**

Work is now progressing toward concrete pan-European outputs: stronger alignment across projects, coordinated engagement, and a common European policy direction for RWE.



VALUE OF IHI COLLABORATION

IHI is uniquely placed to connect projects addressing similar RWD/RWE policy questions across different diseases, technologies and stages of development.

Through the Alliance, participants share methods and tools, reuse existing outputs, identify gaps and overlaps, and coordinate engagement with regulators and HTA bodies, building on what the different projects has already developed instead of duplicating it.

It also **creates value beyond the lifetime of individual projects, supporting continuity, uptake and sustainability of assets such as methodologies, guidance and data resources.**

And it gives IHI projects a stronger **collective platform for turning project-level experience into shared policy lessons and coordinated input into European RWE decision-making.**

CAREER IMPACT

Participation builds experience across research, industry, regulatory, HTA and patient perspectives, strengthening multi-stakeholder collaboration and policy development skills. **It develops practical capability** in cross-project coordination, regulatory and HTA engagement, consensus building, and translating RWD/RWE research into policy-relevant outputs.

Additionally, it strengthens connections across IHI projects, creating **a foundation for future partnerships and new joint projects.**

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