CIRS Centre for Innovation in Regulatory Science

CIRS Q4 2025 Newsletter

Thank you for your continued interest in CIRS. From all of us at CIRS, we wish you a **happy holiday** season and look forward to sharing more insights with you in 2026!

Joint Clinical Assessment Workshop

Our November workshop in Amsterdam, co-hosted with Utrecht University, brought together EU HTA agencies, industry, academics, payers, patient organisations, the European Medicines Agency and European Commission to examine how HTA agencies are adapting their processes to integrate Joint Clinical Assessment (JCA) outputs into decision making.

The workshop built upon the insights from the CIRS JCA workshop in 2024, exploring early learnings from JCA experiences in oncology and advanced therapy medicinal products.

A series of excellent presentations and panel discussions explored the challenges and potential solutions for the JCA process and post-JCA transition at the national level. Interactive breakout sessions focused on identifying actions to align national HTA processes with JCA and to strengthen stakeholder collaboration.

📢 **What's next?** The learnings and recommendations from this meeting will help to facilitate practical implementation of JCA outputs and improve the efficiency and effectiveness of the JCA. Keep an eye out for the workshop synopsis, coming soon!

Industry Technical Forum

Prior to the workshop, we held a Technical Forum with our member companies to explore the impact (or potential impact) of major policy and procedural changes in the global landscape, including the US **Most Favoured Nation** policy, the **EU Pharmaceutical Legislation** reform, and the **EU HTA Regulation**.

Participants shared their perspectives on the implications of such changes on innovation, competitiveness and patient access globally, as well as development, regulatory and HTA strategies across industry. Importantly, recommendations were put forward for how CIRS can support industry in navigating the changing pharmaceutical landscape by conducting metrics research, facilitating collaboration and fostering dialogue.

Find out about Company Membership

📢 **What's next?** The insights and recommendations from the forum will inform the programme of a multi-stakeholder workshop in 2026 entitled ***'Policy to Practice: Strategic Implications of HTA and Regulatory Changes Worldwide'***.

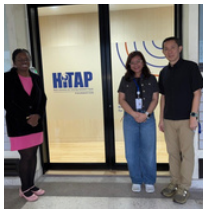
Agency meetings in Asia

Head of CIRS, Anna Somuyiwa, recently visited various regulatory and HTA agencies in Asia, including **HiTAP** (Thailand), **PMDA** (Bangkok office), and the **Hong Kong Drug Office**.

Insights from CIRS research were shared and organisational priorities exchanged. We look forward to further strengthening collaborations with these agencies and others worldwide.

While in Hong Kong, Anna also participated in the second in-person meeting of the RDI-Lancet Commission on Rare Diseases. The five working groups came together to review progress, align priorities, and ensure synergy across all streams of work.

As one of the Commissioners, Anna is providing CIRS insights on the regulatory and HTA landscape for rare diseases into the working group on care/treatment pathways.



Patient Involvement Workshop

What impact does **patient engagement (PE)** and **patient experience data (PED)** have in regulatory and HTA decision making? How is this measured and communicated?

In October we hosted a workshop near London Heathrow that brought together industry, regulators, HTA agencies, payers and patient organisations to examine these questions and more.

Presentations, case studies and panel discussions explored opportunities for involving patients in development, regulatory and HTA processes, and breakout sessions addressed challenges such as measuring the impact and visibility of PE/PED in regulatory and HTA decision making and improving cross-stakeholder alignment.

The timing of the workshop coincided with the release of the **EMA PED Reflection Paper**, which was welcomed as an important step forward for the utilisation of PED in the EU.

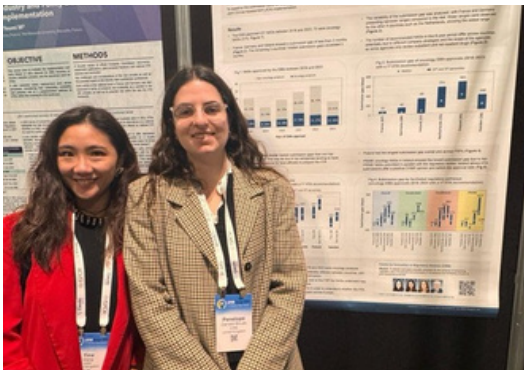
📢 **What's next?** The learnings and recommendations from this workshop will help to address policy barriers to the meaningful use of PE and PED. Look out for the workshop synopsis, landing in January!

Sharing insights from CIRS research globally

Members of the CIRS team presented insights from CIRS research and workshops at various conferences and meetings around the world (see below). These were great opportunities to connect with colleagues and partners, while contributing to discussions shaping the future of medicine regulation and HTA in different jurisdictions and regions.

Highlights included:

- September - Participation in the DIA Latin America panel on *'Navigating Regulatory Reliance: Practical Insights and Applications Beyond Initial Marketing Authorisation Application'.*
- October - Presented virtually at DIA Canada on *'Advancing Regulatory Innovation: Canadian Role in Global Collaboration – What do Metrics Tell Us?'*
- November - Participation in the ISPOR Europe panel on *'A New Era for EU HTA: What Can the EU HTAR Learn From the EMA's Path to Harmonisation?'*
- November - Posters at ISPOR Europe exploring Canadian HTA decisions, orphan product assessments in the UK, and oncology HTA submission trends prior to the EU HTA Regulation.
- December - Presented in the University of Hong Kong Faculty of Medicine Seminar on *'Value Framework for Building our NextGen HTA Mechanism'.*



Strengthening connections with MHRA and NICE

While attending the Financial Times Global Pharma and Biotech Summit in London, Anna re-connected with Lawrence Tallon, CEO of the Medicines and Healthcare products Regulatory Agency (MHRA), and Sam Roberts, Chief Executive of the National Institute for Health and Care Excellence (NICE) (pictured).

We currently have representatives from both agencies on our advisory committees, and will continue working closely them in 2026.

Journal Publications

1. Comparison of the review models and regulatory timelines of seven countries participating in the ECOWAS-MRH initiative: identifying opportunities for improvement. Front. Med.
2. The value of a structured, systematic approach to benefit-risk assessment of medicines: A South African regulator case study. Regul. Toxicol. Pharmacol.
3. Comparison of good review practices of seven countries participating in the ECOWAS medicines regulatory harmonisation initiative: identifying opportunities for improvement. Front. Med.
4. The Economic Impact of Reliance on an African Medicines Regulatory Authority. Pharm Med
5. Ensuring the Efficiency and Effectiveness of Joint Clinical Assessment in National HTA Decision-Making: Insights from the 2024 CIRS Multi-Stakeholder Workshop. J. Mark. Access Health Policy
6. Suggested Improvements to the Current East African Community Medicines Regulatory Harmonization Joint Review Process and a Proposed New Review Model for this Initiative. Pharmaceut Med.
7. Assessing the Malaysian Regulatory Process for Medicinal Product Approval: An OpERA Methodology and Standardized Reporting Approach. Ther. Innov. Regul. Sci
8. Enhancing Development Strategies Through Early Scientific Advice from HTA Agencies–Experiences, Expectations and Best Practices from Health Technology Developers. Ther. Innov. Regul. Sci.
9. Evaluation of good review practices at the Food and Drugs Authority of Ghana as it strives to become a World Health Organization-listed agency. Regul. Toxicol. Pharmacol.
10. Harmonizing health: a global analysis of pharmaceutical regulatory activities by international regulatory organizations. Front. Med.
11. Regulatory Performance of African National Medicines Regulatory Authorities Achieving WHO Maturity Level 3: Identifying Best Practices. Ther Innov. Regul. Sci.
12. Assessment of compliance with good review practices by medicine assessors within the Zambia medicines regulatory authority. Front. Med.

CIRS R&D Briefings

1. R&D Briefing 97: Access Consortium and Project Orbis New Active Substance Approvals Across Eight National Regulatory Authorities. A Five-Year Comparative Study.
2. R&D Briefing 98: European HTA Trends: HTA Outcomes and Timelines Across Seven Markets (2019–2023).
3. R&D Briefing 99: Review of HTA Outcomes and Timelines of Oncology Products Approved by the EMA Between 2018 and 2023
4. R&D Briefing 101 – New drug approvals by six major authorities 2015-2024
5. R&D Briefing 102 – Tracking availability in China of medicines approved in six key global markets
6. R&D Briefing 103 – Review of HTA outcomes and timelines in Australia, Canada, Europe, and the UK, 2020-2024

Workshop Reports

- Working across regulatory and HTA agencies: Collaborative, work-sharing and reliance models – What are the policy implications? Workshop Report
- Regulatory agency collaboration and system strengthening – How is this enabling national, regional and continental models and improving medicines availability for patients? Workshop Synopsis and Workshop Report
- High public health impact medicines for chronic diseases – Do regulatory, HTA and payer paradigms need to change? Workshop synopsis and Workshop report