CIRS Centre for Innovation in Regulatory Science

CIRS Newsletter - March 2025

Regulatory strengthening and collaborative models workshop

In February, CIRS hosted a workshop in Johannesburg that brought together industry, regulators, academics and non-profit organisations from 20 countries worldwide to discuss success factors for strengthening regulatory systems to support the implementation of collaborative models.

A series of excellent presentations and panel discussions highlighted the opportunities, challenges and best practices for implementing collaborative regulatory models. We hope that the learnings and recommendations from this meeting can help to inform the progression of efficient and effective regulatory systems around the world, particularly as Africa moves forward with the African Medicines Agency.

The workshop was preceded by a forum for regulatory agencies only, where practical examples of regulatory system strengthening were presented and learnings shared across agencies.

Stay tuned for a synopsis of the workshop, set to be published in May 2025.

2025 Research Agenda Launched

CIRS has published its 2025 Research Agenda, which outlines its research priorities for 2024-2026 as well as plans for our Regulatory and HTA workstreams for 2025.

CIRS generated its 2024-2026 Research Agenda with significant input from its advisory committees, CIRS member companies, agencies and other stakeholders. This feedback was organised into three research themes, with new topics of focus.

Themes	Decision-making frameworks for new ways of working and evidence generation technologies Moving implementation from concept to practicality	Good practices for regulatory and HTA collaborative models of review and assessment Sharing learnings and experiences	Metrics on new ways of working and evidence generation and their impact on decision making Strategic insights and impact measures
New Topics	Vaccines | Artificial Intelligence | Patient Engagement | High Impact Chronic Diseases | Rare Diseases		

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Sharing insights at DIA Europe

Anna and Magda recently attended DIA Europe in Basel, where the focus was on sustainability, innovation and collaboration. The conference featured numerous sessions on AI, patient engagement and collaborative models, which closely align with CIRS' research agenda.

Magda contributed to a stimulating panel discussion, sharing insights from CIRS research on the challenges and potential of cloud technology in advancing regulatory harmonisation and industry digitalisation. The panel included experts from various companies and the MHRA, who also shared their perspectives.

Participation in the RDI-Lancet Commission on Rare Diseases

CIRS is participating in the Rare Diseases International-Lancet Commission on Rare Diseases (RDI-LCRD), which aims to catalyse global recognition and action for people living with a rare disease, driving systemic change to achieve Global Health 2035 goals and Universal Health Coverage.

The RDI-LCRD brings together 27 Commissioners from six continents with a broad range of expertise from fields including academia, clinical practice, health economics, and patient advocacy. As one of the Commissioners, Anna will provide CIRS insights on the regulatory and HTA landscape for rare diseases, including the views of CIRS stakeholders, into the Commission's work.

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Latest publications

- CIRS R&D Briefing 97 – Access Consortium and Project Orbis new active substance approvals across eight national regulatory authorities: A five year comparative study
- CIRS R&D Briefing 98 – European HTA trends: HTA outcomes and timelines across seven markets 2019-2023
- Owusu-Asante M et al. Comparison of good review practices of seven countries participating in the ECOWAS medicines regulatory harmonisation initiative: identifying opportunities for improvement. Front Med. 2025;11:1520892. Published 2025 Jan 10.
- Danks L et al. The Economic Impact of Reliance on an African Medicines Regulatory Authority. Pharm Med (2025).
- Ngum N et al. 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. Pharm Med (2025).

Stay tuned for our regulatory and HTA agency benchmarking briefings that will be published in the coming months!

Where to meet us

- Access Academy Spring Convention, 3rd April, Berlin, Germany
- Patients as Partners Europe, 20th–21st May, London, UK
- DIA China, 22-25th May, Shanghai, China
- DIA Global, 15-19th June, Washington DC, USA

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