CIRS Centre for Innovation in Regulatory Science

CIRS Newsletter - July 2025

Artificial Intelligence (AI) Roundtable

June was an extremely productive month for CIRS, with several internal and external meetings in the Washington area in the USA, the first being our AI Roundtable focusing on optimising its use in company-regulator-HTA agency interactions throughout the drug product lifecycle. Our research set the stage for this Roundtable, where our brief pre-meeting survey demonstrated that AI is either being used or plans are in place for its use across the ecosystem.

Our AI Taskforce were instrumental in crafting the programme, which included a series of excellent presentations and case studies from the FDA, MHRA, Swissmedic, TLV, NICE and several member companies, with panel discussions on AI use cases across development, regulatory review, HTA/payer assessment and post-licensing surveillance. Interactive breakout sessions then discussed key AI-related challenges and provided excellent recommendations on future CIRS research as this space continues to evolve.

Workshop on Incentivising Medicines for Chronic Diseases

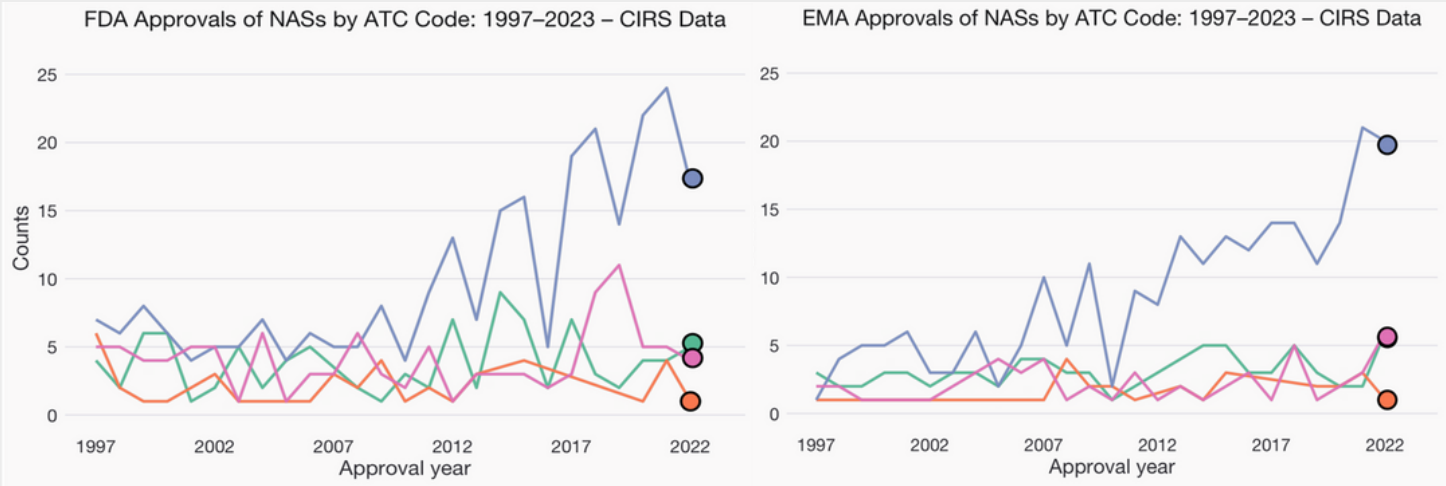
Our June workshop convened industry, regulators, HTA agencies, payers and patient organisations to discuss how to incentivise development of high public health impact medicines for common chronic diseases.

We kicked off the meeting by presenting CIRS metrics on the registration and reimbursement of medicines intended for the treatment of chronic diseases over the last 25 years. For example, trend analysis showed a divergence in the number of new active substance (NAS) approvals for anti-cancers and immunomodulators compared to elementary metabolism, cardiovascular, and nervous system NASs since 2011 (see below), suggesting more incentives or facilitated regulatory pathways in oncology.

Workshop sessions explored the impact of chronic disease on health systems and life expectancy, flexibility in clinical trials, considerations for adapting regulatory and HTA/payer frameworks, followed by syndicate sessions focusing on priority research areas. The learnings and recommendations from this meeting will help address policy challenges in the development, regulation and reimbursement of treatment for chronic diseases.

Keep an eye out for the workshop synopsis, when it is published in the coming months.

Are approvals skewed towards cancer due to facilitated development and regulatory pathways and incentives?



Source: CIRS RRTD Database

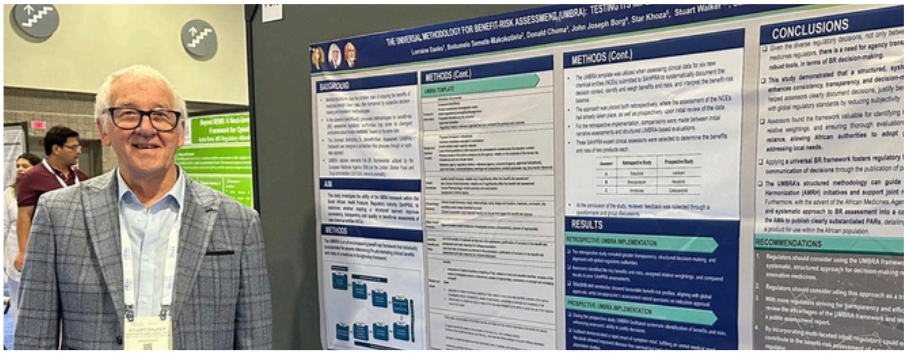
Sharing Insights from CIRS Research at the DIA Global Annual Meeting

Anna, Neil, Magda and Stuart attended the DIA Global Annual Meeting in Washington DC, which featured numerous sessions on AI, patient engagement, collaborative models and rare diseases, topics which closely align with CIRS' research agenda.

Magda contributed to a stimulating panel discussion, sharing insights from CIRS metrics on the effectiveness of global regulatory collaborations and how those principles could be applied to chronic diseases outside of oncology. The panel included experts from the FDA, MHRA, Health Canada and CIRS member companies.

Stuart presented several posters sharing insights from CIRS regulatory strengthening research in Africa. These posters are now available to download from the CIRS website.

In addition, the team was able to connect and re-connect with global regulators, further strengthening our collaborative ties as we look to continue to influence regulatory policy worldwide.



Latest publications

- Wang T & McAuslane N. 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 2025, 13, 9.

- CIRS Workshop Report – Working across regulatory and HTA agencies: collaborative, work-sharing and reliance models – what are the policy implications?

- CIRS Workshop Synopsis - Regulatory agency collaboration and system strengthening – How is this enabling national, regional and continental models and improving medicines availability for patients?

Stay tuned for our regulatory and HTA agency benchmarking briefings that will be published very soon!

Where to meet us

- DIA Singapore Annual Meeting, 15-16th July, Singapore
  - Neil will be presenting on "Advancing regulatory practices and processes globally: Insights, new ways of working and impact" as part of the Plenary session

- DIA Asia Meeting, 17th July, Singapore

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