Review of 2025

Key research outputs and meetings

In 2025 CIRS continued to deliver for its stakeholders

12

Journal publications

6

CIRS R&D Briefings

4.8

Out of 5 feedback score for multi-stakeholder workshops

18

Conference presentations

104K+

Website downloads

Regulatory and HTA Research Programmes

2025 Regulatory Research Outputs

Time 	• R&D Briefing with updated metrics on mature regulatory agency benchmarking and CIRS member webinar to share findings • Exploratory analysis on regulatory performance in other major markets – China R&D Briefing • Growth and Emerging Markets Metrics (GEMM) programme reports, analysis tool and Industry Discussion Meeting • Metrics reports from agencies participating in the Optimising Efficiencies in Regulatory Agencies (OpERA) Programme ○ Publications on Africa (South Africa, Zimbabwe, Ghana, Zambia), Asia (Malaysia) and reports delivered to LATAM agencies directly (CARICOM, Ecuador) • Forum for regulatory agencies on 'Advancing performance of regulatory systems and enabling continuous improvement within agencies'
Quality 	• Evaluation of practices and processes within target OpERA agencies using CIRS tools to ensure quality of process, practices and decision making ○ Training and education for OpERA agencies and regional bodies on implementation of benefit-risk frameworks, good review practices and quality decision making (Ghana, South Africa, Zambia)
Risk-based 	• Report from the Latin American Systems to Enable Reliance (LASER-2) project • Study of review models, timelines and Good Review Practices for the African ECOWAS region • Publication on the economic impact of reliance review in South Africa • Initiation of a project on monitoring regulatory reliance in LATAM
Transparency 	• Agency survey and multi-stakeholder workshop on 'Meaningful patient engagement in regulatory and HTA decision making – What are current practices and what impact does this have on the final assessment?'
New Models 	• Technical Forum for Industry 'Navigating Global Regulatory and HTA Changes: Challenges, Opportunities, and Implications for Innovation' • Multi-stakeholder Roundtable on 'AI – Optimising company-regulator-HTA agency interactions through the drug product lifecycle' • Multi-stakeholder workshop on 'High public impact medicines for chronic diseases – Do regulatory, HTA and payer paradigms need to change?' • Multi-stakeholder workshop on 'Regulatory agency collaboration and system strengthening – How is this enabling national, regional and continental models and improving medicines availability for patients?'

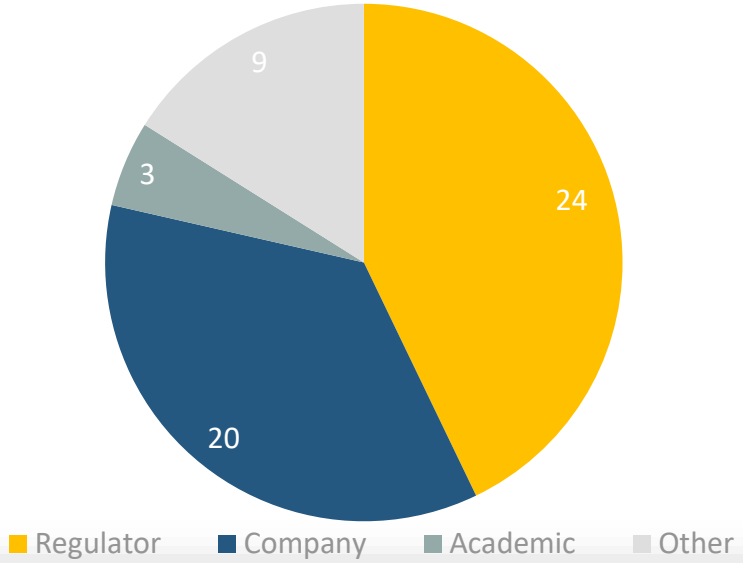
2025 HTA Research Outputs

Performance	• HTADock annual briefing tracking HTA outcomes and timelines for new active substances in 12 key jurisdictions. • HTADock briefing on Europe first HTA recommendations and rollout timelines, including for oncology products, ATMPs, products using EMA accelerated assessment and PRIME priority medicines • HTADock briefing tracking first HTA outcomes and timelines for EMA-approved oncology medicines, setting baseline for measuring the impact of JCA
Early insight	• Publication on enhancing development strategies through early scientific advice • HTA Industry Metrics Study: Early HTA Advice Survey 2025
Collaboration	• Multi-stakeholder workshop on 'Navigating national decision making post Joint Clinical Assessment (JCA): Enablers, barriers and the path forward' • Publication on ensuring efficiency and effectiveness of JCA in national HTA decision making
Quality	• Publications supporting improved HTA practice, including: • Literature review mapping HTA patient involvement approaches
Transparency	• Agency survey and multi-stakeholder workshop on 'Meaningful patient engagement in regulatory and HTA decision making – What are current practices and what impact does this have on the final assessment?'
New Models	• Technical Forum for Industry 'Navigating Global Regulatory and HTA Changes: Challenges, Opportunities, and Implications for Innovation' • Multi-stakeholder Roundtable on 'AI – Optimising company-regulator-HTA agency interactions through the drug product lifecycle' • Multi-stakeholder workshop on 'High public impact medicines for chronic diseases – Do regulatory, HTA and payer paradigms need to change?'

Workshops and Meetings

Workshop 26-27th February 2025 - Regulatory agency collaboration and system strengthening – How is this enabling national, regional and continental models?

- Identified critical success factors and national/regional activities that help agencies strengthen their regulatory systems for the registration of medicines.
- Discussed lessons learned from current initiatives and practices that enable jurisdictions and regional work-sharing initiatives to move from concept to practical implementation, as well as the key challenges and opportunities.
- Made recommendations on how jurisdictional system strengthening and regulatory collaboration can drive continental models across agencies and improve medicines availability for patients globally.



56
attendees

20
countries

4.7/5
Feedback score

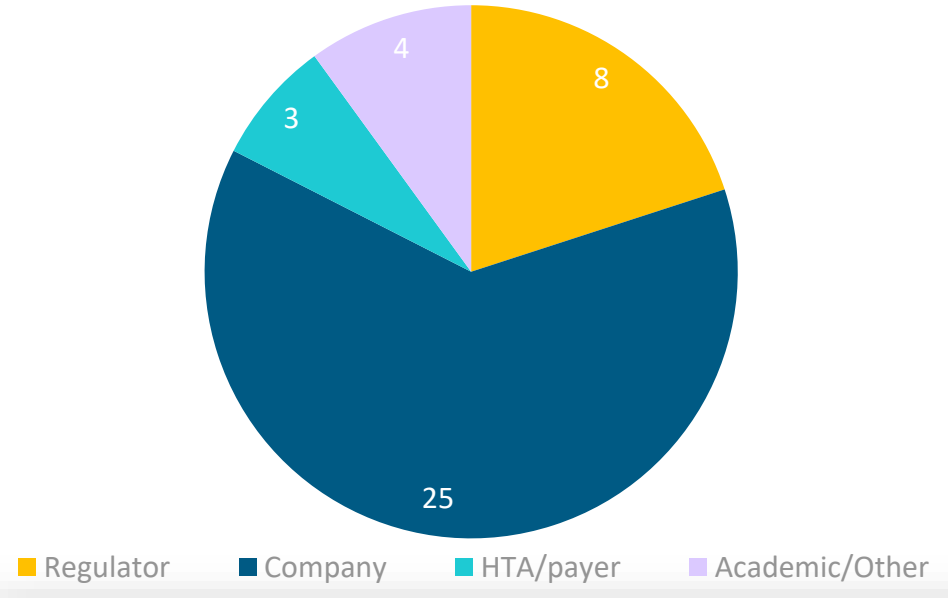
Agencies included:

- Africa: South Africa, Zambia, Tanzania, Ghana, Zimbabwe, Egypt
- EMA, Swissmedic, Health Canada, TGA, ANVISA, NPRA

LINK TO REPORT

AI Roundtable, 11th June 2025 – AI: Optimising company-regulator-HTA agency interactions through the drug product lifecycle

- In 2024 CIRS set up an AI Taskforce to help design a stakeholder survey and AI Roundtable meeting (2025) on the use of AI in regulation and HTA.
- The Roundtable meeting focused on addressing linkages that either exist or need to be strengthened between companies, regulators and HTA agencies for AI to be implemented efficiently but in a reliable, safe and effective manner.
- The roundtable also identified areas where there are gaps (e.g. lack of relevant regulatory policies or of internal agency capability) and where greater effort or investment may be required.



40
attendees

13
countries

5/5
Feedback score

"I was genuinely impressed by the way CIRS structured and facilitated the discussion. Bringing together different stakeholders and perspectives in this way is exactly what's needed to ensure safe and responsible deployment of AI."
Industry participant

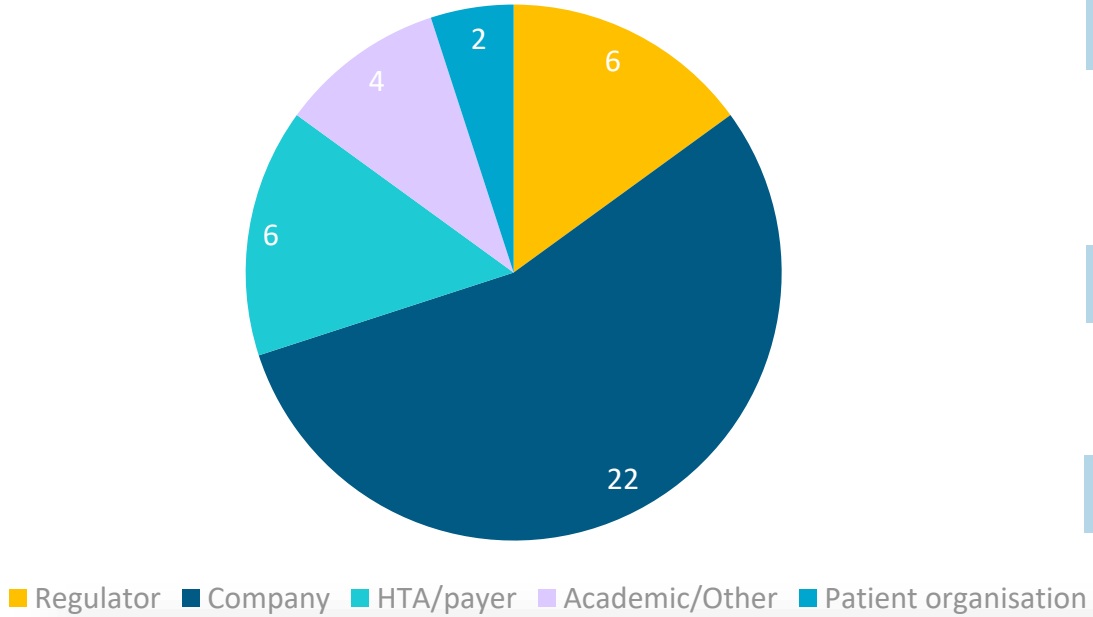
Agencies included:

- Reg: FDA, MHRA, Swissmedic, Health Canada, TGA, MEB, HSA
- HTA: NICE, TLV

(Report available for CIRS member companies)

Workshop, 12-13th June 2025 – High public health impact medicines for chronic diseases – Do regulatory, HTA and payer paradigms need to change?

- Reviewed and discussed high public health impact medicines for common chronic diseases to understand the challenges these medicines face from a regulatory, HTA, payer and patient perspective.
- Identified how to incentivise medicines which target diseases of significant public health interest that drive life expectancy down.
- Made recommendations on how to address policy challenges in the development, regulation, HTA and funding chronic diseases of high impact on health systems.



40
attendees

9
countries

4.7/5
Feedback score

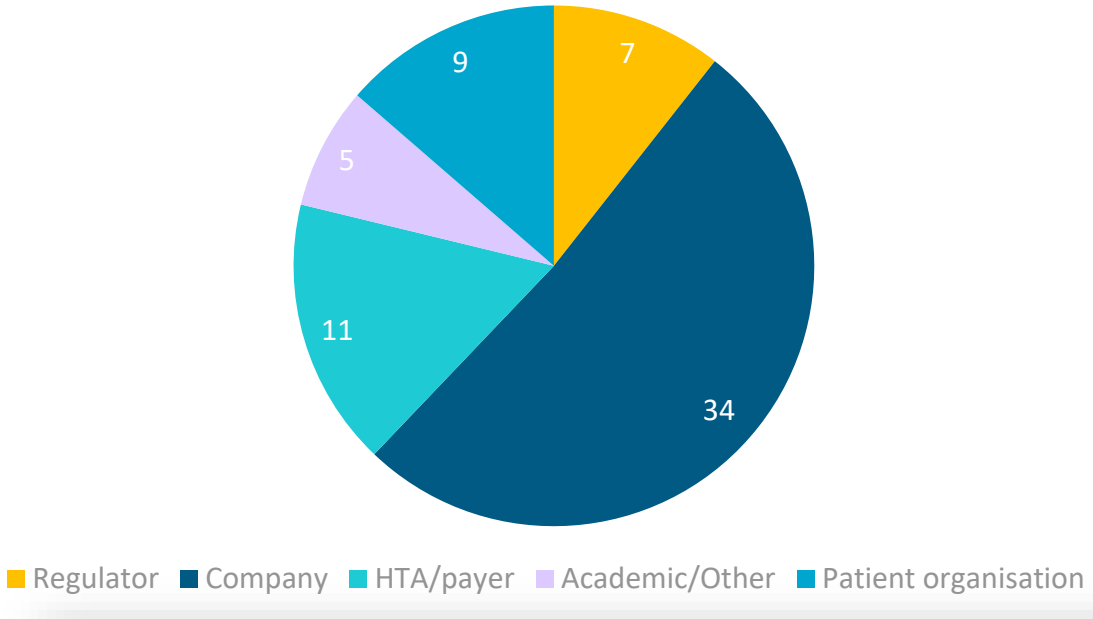
Stakeholders included:

- Reg: Health Canada, MEB, Swissmedic, TGA, HSA
- HTA/payers from USA, UK, The Netherlands, Austria
- Patient orgs: American Brain Coalition, COPD Foundation
- National Academy of Science

LINK TO REPORT

Workshop, 1-2 October 2025 – Meaningful patient involvement in regulatory and HTA decision making – Current practices and impact on final assessment

- Discussed the value of engaging patients in early development and how this aids downstream decision making.
- Clarified how regulatory and HTA agencies are utilising PE and PED within their review and assessment frameworks.
- Identified the challenges and opportunities for measuring the utilisation of patient input in the evaluation of new medicines and how this can be best articulated.
- Made recommendations on key components for a systematic structured approach to documenting how PE/PED was used during the assessment and the articulation of its influence on agency decision making.



76
attendees

17
countries

4.8/5
Feedback score

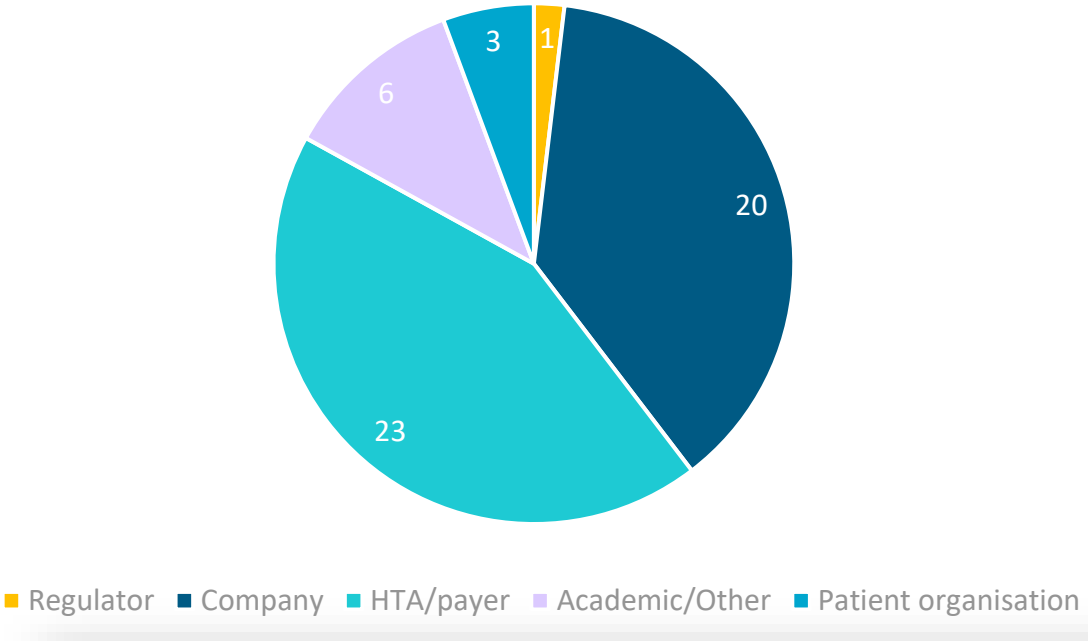
Stakeholders included:

- Reg: EMA, FDA, Health Canada, MEB, Swissmedic
- HTA/payers: UK, Canada, Sweden, Portugal, Germany, The Netherlands, Norway, Austria
- Patient orgs: EURORDIS, Parkinsons UK, Parkinsons Europe, Cancer Patients Europe, SMA Europe, PBC Foundation

LINK TO SYNOPSIS

Workshop, 27th November 2025 – Navigating national decision making post Joint Clinical Assessment (JCA)

- Examined the role of HTA agencies in the JCA process – focusing on both process inputs and outcome outputs, as well as how agencies and companies are adapting their processes to integrate JCA outputs into decision making.
- Identified key challenges and capacity-building needs for effective JCA implementation, including resource constraints, methodological and timeline alignment, and stakeholder engagement.
- Facilitated multi-stakeholder discussion and developed recommendations, bringing together HTA agencies and industry to explore practical implementation of JCA outputs and identify actions to improve efficiency and alignment in national decision making.



63
attendees

19
countries

4.9/5
Feedback score

Stakeholders included:

- European Commission, EMA
- HTA: Spain, Germany, Italy, Portugal, The Netherlands, Norway, Sweden, Denmark, Slovenia, Slovakia, Greece, Bulgaria, Romania, Ukraine
- Patient orgs: Cancer Patients Europe, EURORDIS, Dutch Federation of Cancer Patients

Regulatory and Access Programme Industry Technical Forum, 26th November 2025

Navigating Global Regulatory and HTA Changes: Challenges, Opportunities, and Implications for Innovation

- Examined global regulatory and HTA decision making in Europe, the US, and the rest of the world, and their implications for innovation and patient access.
- Explored company perspectives on how organisations are adapting to these changes, and whether certain jurisdictions risk losing ground in global competitiveness.
- Identified how CIRS can support stakeholders in scenario planning, benchmarking, and fostering cross regional and multi-stakeholder dialogue.
- Provided input into the 2026 CIRS multi-stakeholder workshop entitled *Policy to Practice: Strategic Implications of HTA and Regulatory Changes Worldwide.*

25

Attendees

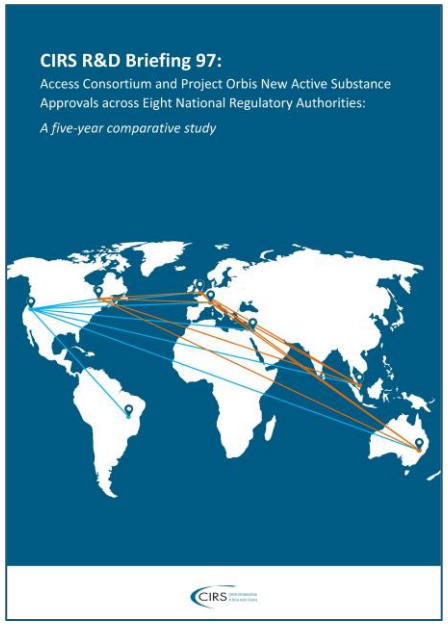
4.9/5

Feedback score

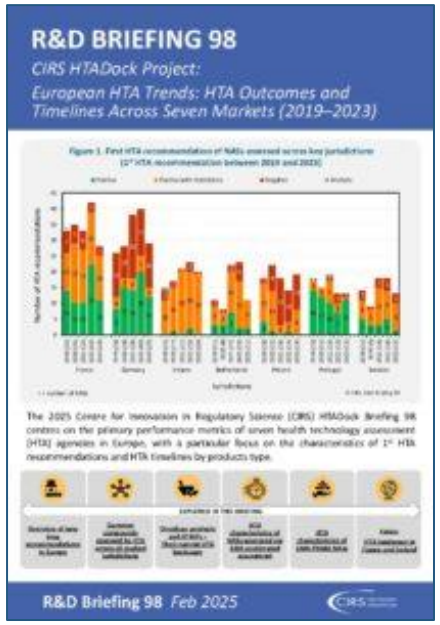
(Report available to CIRS member companies)

Publications

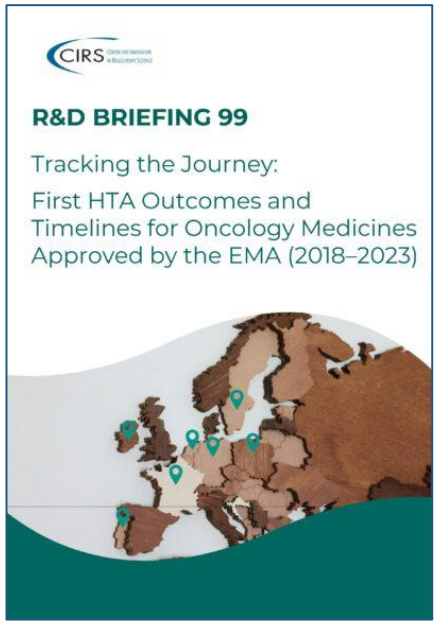
2025 R&D Briefings



CIRS R&D Briefing 97 – Access Consortium and Project Orbis new active substance approvals across eight national regulatory authorities: A five-year comparative study



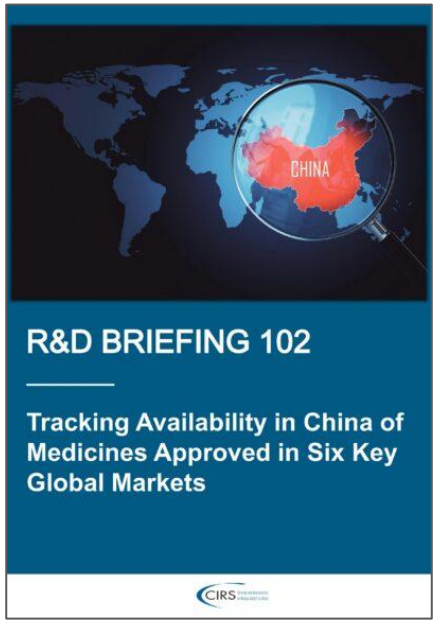
CIRS R&D Briefing 98 – European HTA trends: HTA outcomes and timelines across seven markets 2019-2023



CIRS R&D Briefing 99 – First HTA outcomes and timelines for oncology medicines approved by EMA 2018-2023

2025 R&D Briefings

CIRS R&D Briefing 101 – New drug approvals by six major authorities 2015-2024



CIRS R&D Briefing 102– Tracking availability in China of medicines approved in six key global markets

CIRS R&D Briefing 103– Review of HTA outcomes and timelines in Australia, Canada, Europe, and the UK, 2020-2024

2025 Journal Publications

- Owusu-Asante M, Darko DM, Seaneke S… **Walker S**. Comparison of the review models and regulatory timelines of seven countries participating in the ECOWAS-MRH initiative: identifying opportunities for improvement. Front Med (Lausanne). 2025;12:1587761.
- Danks L, Semete-Makokotlela B, Chuma D, Borg JJ, Khoza S, **Walker S**, Salek S. The value of a structured, systematic approach to benefit-risk assessment of medicines: A South African regulator case study. Regul Toxicol Pharmacol. 2025;162:105893.
- Owusu-Asante M, Darko DM, Seaneke S… **Walker S** and Salek S. Comparison of good review practices of seven countries participating in the ECOWAS medicines regulatory harmonisation initiative: identifying opportunities for improvement. Front Med (Lausanne). 2025;11:1520892. Published 2025 Jan 10.
- Danks L, Semete-Makokotlela B, Gouws R, Otwombe K, **Walker S** and Salek S. The Economic Impact of Reliance on an African Medicines Regulatory Authority. Pharm Med (2025).
- **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.
- Ngum N, Chamdimba C, Mbonyingingo D… **Walker S** and Salek S. 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).
- Mohd Sani N, Kasbon SH, Yap KY, Abdullah MF, Lajis R, Ramli A, **McAuslane N, Bujar M, Kermad A**. Assessing the Malaysian Regulatory Process for Medicinal Product Approval: An OpERA Methodology and Standardized Reporting Approach. Ther Innov Regul Sci (2025).
- **Wang, T., McAuslane, N.** Enhancing Development Strategies Through Early Scientific Advice from HTA Agencies–Experiences, Expectations and Best Practices from Health Technology Developers. Ther Innov Regul Sci (2025).
- Owusu-Asante M, Darko DM, Seaneke S, **McAuslane N, Walker S** & Salek S. 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. 2025; 163:105932.
- Dangy-Caye A, Mousset A, **Kermad A**, Bouché-Bazerolle L, **Bujar M**, De Lucia M-L, **McAuslane N** and Lumsden R (2025) Harmonizing health: a global analysis of pharmaceutical regulatory activities by international regulatory organizations. Front. Med. 12:1636269.
- Owusu-Asante M, Darko DM, Semete-Makokotieia B, Adeyeye CM, Fimbo AM, Rukwata R, Zaki G, **Walker S**, Salek S. Regulatory Performance of African National Medicines Regulatory Authorities Achieving WHO Maturity Level 3: Identifying Best Practices. Ther Innov Regul Sci. Published online October 27, 2025.
- Sakala Chisha C, Leigh S, Siyanga M, **McAuslane N** and **Walker S**. Assessment of compliance with good review practices by medicine assessors within the Zambia medicines regulatory authority . Front. Med. 12:1706139.

External presentations

2025 Conference presentations

DIA Europe, 18-20 March, Basel, Switzerland

- Dr Magda Bujar – Panellist – Transforming Regulatory Landscapes: Driving Regulatory Innovation via AI/Automation, Data Exchange and Harmonisation

DIA China, 22-25 May, Shanghai, China

- Dr Tina Wang – Panellist - Evidence Across the Continuum: From Discovery to Access for Innovative Medicine

DIA Global, 15-19 June, Washington DC, USA

- Dr Magda Bujar – Panellist – Applying Principles of Global Regulatory Collaboration to Address Chronic Disease
- Prof Stuart Walker – Poster – Quality of Decision Making Orientation Scheme (QoDoS): A Study to Evaluate the Quality of Decision Making within the Zambian Medicines Regulatory Authority (ZAMRA)
- Prof Stuart Walker – Poster – Assessment of Good Review Practices at the FDA Ghana
- Prof Stuart Walker – Poster – A Proposed Model for the East African Community Medicines Regulatory Harmonisation Joint Review Process
- Prof Stuart Walker – Poster – The Universal Methodology for Benefit-Risk Assessment (UMBRA): Testing its Implementation in a South African Agency

DIA Singapore, 15-16 July, Singapore

- Dr Neil McAuslane – Plenary presentation - Advancing regulatory practices and processes globally: Insights, new ways of working and impact

DIA Latin America Annual Meeting, 29 September – 1 October, Buenos Aires, Argentina

- Dr Magda Bujar – Panellist - Navigating Regulatory Reliance: Practical Insights and Applications Beyond Initial Marketing Authorisation Application

DIA Canada, 27-28 October

- Dr Neil McAuslane – Virtual presentation - Advancing Regulatory Innovation: Canadian Role in Global Collaboration – What do Metrics Tell Us?

ISPOR Europe, 9-12 November, Glasgow, UK

- Dr Tina Wang – Panellist – A New Era for EU HTA: What Can the EU HTAR Learn from the EMA's Path to Harmonisation?
- Penelope Cervelo – Poster - The HTA Landscape of Orphan Products in the UK between 2019 and 2024
- Penelope Cervelo – Poster - HTA Submission Trends for EMA-Approved Oncology NASs Prior to the EU HTA Regulation (2018-2023)
- Penelope Cervelo – Poster – The Canadian HTA Landscape (2020-2023): A Comparative Study of CDA-AMC and INESSS Recommendations

Scientific Conference on Medical Product Regulation in Africa, 11-13 November

- Prof Stuart Walker – Poster – Quality of Decision Making Orientation Scheme (QoDoS): A Study to Evaluate the Quality of Decision Making within the Zambian Medicines Regulatory Authority (ZAMRA)
- Prof Stuart Walker – Poster – Assessment of Good Review Practices at the FDA Ghana
- Prof Stuart Walker – Poster – A Proposed Model for the East African Community Medicines Regulatory Harmonisation Joint Review Process

University of Hong Kong SCAN-2030 Seminar, 4 December, Hong Kong

- Dr Tina Wang – Speaker - Value Framework for Building our NextGen HTA Mechanism

Appendix – About CIRS

CIRS is an experienced research organisation with a global remit

Mission

To identify and apply scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes in developing and facilitating access to pharmaceutical products

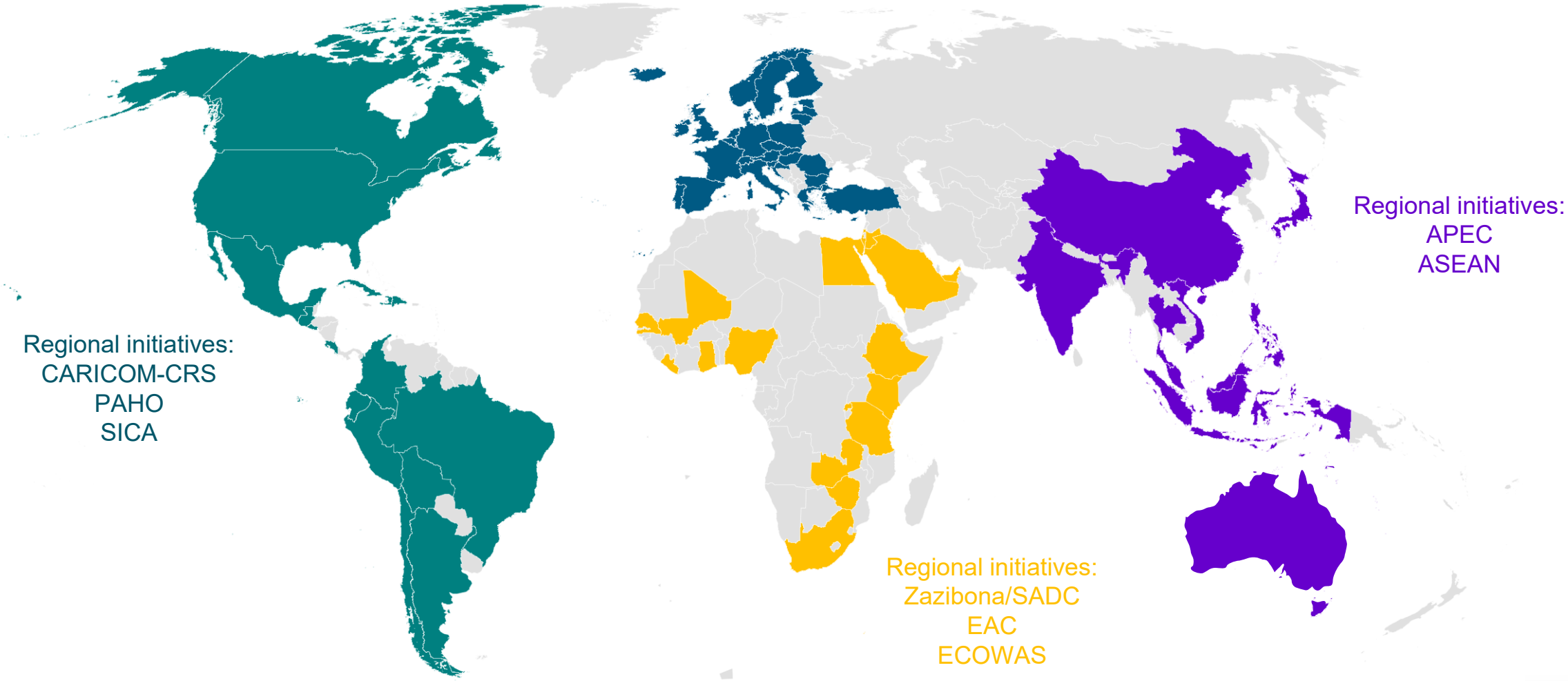
35+ yrs experience in bringing **global** industry, regulators, HTA bodies, payers, academics and others together in a **neutral** atmosphere to identify and address key issues in the development, licensing and reimbursement of medicines.

Subsidiary of Clarivate plc – **operate independently** as a non-profit. Financed by industry membership fees, special projects, grants e.g. from regulators, HTA bodies, Gates Foundation

See CIRS About Us

Companies of all sizes are CIRS members

CIRS collaborates with regulators all over the world



CIRS works with HTA/coverage bodies in many jurisdictions

Non-Europe	Organisation
Argentina	IECS
Australia	PBAC
Brazil	CONITEC
Canada	CDA-AMC; INESSS; Alberta Health Services
China	National Centre for Medicine and Technology Assessment
Chinese Taipei	Division of HTA, CDE
Colombia	IETS
Malaysia	MoH
Singapore	ACE
Thailand	HITAP
USA	UnitedHealth Group; Blue Cross/Blue Shield Association; Kaiser Permanente Institute for Health Policy; AHRQ; OPTUM

Europe	Organisation
Austria	Association of Austrian Social Insurance Institutions
Belgium	INAMI; KCE
Bulgaria	NCPR
Croatia	AAZ
Denmark	DKMA
England, Wales	NICE
Finland	THL
France	HAS
Germany	G-BA; DAK-Gesundheit
Greece	MoH
Ireland	NCPE
Italy	AIFA
Netherlands	ZIN
Norway	NoMA
Poland	AOTMiT
Portugal	INFARMED
Romania	NAMMDR
Scotland	SMC
Slovakia	NIHO
Slovenia	JAKZ
Spain	AEMPS; MoH
Sweden	TLV
Switzerland	BAG

Three pillars of CIRS activities – Foundation of CIRS research themes

For more information, see CIRS' Research Agenda

Thank you!

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