CIRS Centre for Innovation in Regulatory Science

www.cirsci.org



2024 Annual Report

Advancing regulatory and HTA policies and processes



Foreword

I am proud to present the Centre for Innovation in Regulatory Science (CIRS) 2024 Annual Report, highlighting a year of remarkable progress and deepening collaboration within our ecosystem. Our commitment to advancing regulatory and HTA policies and processes has never been stronger, particularly as the political landscape necessitates amplification of our messages.

2024 marked the first year of our three-year research agenda cycle, which was developed with significant input from our advisory committees and Topic Groups, feedback from various agencies and member companies, as well as the forward looking mindset of the CIRS team.

We successfully held four multi-stakeholder workshops and two fora, fostering dialogue and collaboration among diverse groups. Our Regulators' Forum in Sao Paolo, Brazil, continued our role in promoting implementation of reliance, and for the first time we held a meeting dedicated to vaccines in Washington DC, USA, providing an opportunity for in-depth discussion on challenges facing vaccine developers, as well as health experts, regulators, National Immunisation Technical Advisory Groups (NITAGs) and payers. In addition, our inaugural workshop on the new EU Joint Clinical Assessment (JCA) procedure in Seville, Spain, was met with eager participation and positive feedback, prompting us to plan a follow-up in 2025 to facilitate the sharing of experiences from the first year of JCAs. Our final workshop on regulatory and HTA collaboration highlighted the progress made with these initiatives, where much more needs to be done to advance practices internationally.

CIRS generated relevant metrics for these meetings, supporting our mission of identifying key challenges in the regulatory and HTA landscapes and recommending potential policy solutions.

As part of our evolution to a listening organisation, we boldly conducted a comprehensive stakeholder feedback study, which provided invaluable insights to inform our future direction and transformation. We are grateful to all participants for their contributions, which were crucial in guiding our efforts to better serve the regulatory and HTA communities. Watch this space as we begin to implement the recommendations from this study!

2024 saw the launch of our first Taskforce focusing on artificial intelligence (AI), a pivotal initiative that shaped the programme for our 2025 AI Roundtable. The Taskforce's work underscores our commitment to explore new ways of working to better utilise the expertise within our network, which can help boost CIRS' capabilities to examine emerging topics in the years to come.

CIRS' increasing impact was demonstrated by our participation in three very high-profile rare diseases related projects: the National Academy of Science, Engineering Medicines study on processes for evaluating the safety and efficacy of drugs for rare diseases or conditions in the United States and the European Union, the International Coalition of Medicines Regulatory Authorities (ICMRA) Symposium and Workshop on Rare Diseases in Lugano, Switzerland, and the Rare Diseases International Lancet Commission for Rare Diseases, which continues its work into 2025 and beyond.

Reflecting on the accomplishments of 2024, I am always amazed at what we can co-create by asking the right questions and thinking outside the box. The collaborative spirit and dedication of our stakeholders, partners, and team members were the driving force behind our progress. Together, we will continue to innovate, adapt, and lead the way in regulatory and HTA policies.

Thank you for your continued support and engagement. We look forward to another year of growth, learning, and impactful contributions to the field.



Anna Somuyiwa, Head of CIRS

Introduction and overview

Who we are

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, scientific and independently run global forum for policy leaders from government regulators, health technology assessment (HTA) agencies, the pharmaceutical industry, and other stakeholders in healthcare, such as patient organisations and academia.

CIRS focuses on improvements in policies and processes for regulaton and HTA. We also support the development of agency capacity, including in low- and middle-income countries.

The CIRS team works internationally and is headquartered in the UK. CIRS works collaboratively with stakeholders worldwide, runs research projects internationally and conducts meetings globally to feed into and build on this research. Organisationally, CIRS is a wholly owned and independently managed UK subsidiary of Clarivate, with our funding derived from membership dues, special projects and grants from non-profits and governments.

CIRS's unique value proposition is its diverse community, with the participation of leaders from both small and large organisations in industry, regulators and HTA agencies around the world.

Three pillars of CIRS activities



For more information, please see 'About CIRS'.

Highlights in 2024

Informing rare disease drug policy

CIRS, commissioned by the National Academies of Sciences, Engineering, and Medicine (NASEM) Committee on Regulatory Processes for Rare Disease Drugs in the US and EU, conducted data analyses that informed recommendations made to the US FDA. These analyses used CIRS databases and validated methods, which have also been used to produce annual metrics on new active substance approvals, including for orphan products, across six major regulators. In collaboration with the NASEM Committee, we generated insights on new active substance approvals for rare diseases by the FDA and EMA between 2013-2022, which are shown in the study report. The report provides important recommendations to promote rare disease drug development and approval by improving engagement with people affected by a rare disease, advancing regulatory science, and fostering collaboration between the FDA and EMA.

In addition, the RDI-Lancet Commission on Rare Diseases was launched in 2024 to generate actionable recommendations for stakeholders, including policymakers, to improve the lives of people living with rare disease. As a member of the Commission, Anna, the Head of CIRS, will provide insights on the regulatory and HTA landscape for rare diseases - including the views of regulators, HTA agencies and pharmaceutical companies- into the Commission's work as it progresses over the next few years.

CIRS also participated in the International Coalition of Medicines Regulatory Authorities (ICMRA) Rare Disease Symposium and Workshop in Lugano, Switzerland. These meetings brought together various stakeholders to discuss the challenges and opportunities in the field of rare diseases, and identify how ICMRA could provide tangible support on a global scale.

First HTA Regulation workshop

In response to our stakeholders' need for a neutral forum to discuss the EU HTA Regulation, we conducted a multi-stakeholder workshop focused on facilitating the implementation and utilisation of joint clinical assessment (JCA) (more detail on p9). Informed by a pre-workshop stakeholder survey, the discussions highlighted the need for metrics, training and research to further support the JCA process. Following positive feedback from the workshop attendees, we decided to continue the conversation in 2025 with a follow-up workshop on JCA. This will explore the national adaptation of JCA outputs, identify gaps and capacity needs, and develop recommendations to improve the efficiency of national decision making.

Gathering stakeholder feedback

To help inform our strategy and communications development, a stakeholder study was conducted with a third party to elicit feedback on how CIRS was perceived by key audiences. In-depth interviews (21) and an online survey (106 responses) were conducted. The results show that our highest value is our convening and facilitating role, helping to generate open and productive discussions among different participants, combined with our ability to consistently produce high-quality, relevant and impactful research. We have begun implementation of several suggestions including broadening our range of stakeholders, starting with payers and patient organisations, improving our agility to incorporate high-priority topics, increasing the reach and relevance of our research outputs, using strategic Taskforces to guide us in crafting research programmes (e.g. AI Taskforce), and improving communication of our activities via quarterly email newsletters.

Insight meetings with EMA and FDA

In May 2024, we met with EMA representatives at their Amsterdam office to share insights from CIRS research and discuss how these insights can help address crucial questions for the agency. This meeting provided a valuable opportunity to discuss key topics such as facilitated, expedited, orphan and collaborative pathways, regulatory-HTA collaboration and parallel scientific advice, together with international collaboration and regulatory strengthening, enabling cross-learning for both CIRS and EMA on respective priorities.

We also met with representatives of the FDA Oncology Centre of Excellence (OCE) at the US Embassy in London in November, to share some of our research outputs, in particular our annual benchmarking studies that collect publicly available data on FDA outcomes and timelines. This was a great opportunity to discuss our methodologies and insights on Project Orbis regulatory timelines and their impact on HTA.

In addition to those two regulators, in 2024 we held insight meetings with 11 regulators across five continents. We look forward to continuing conversations with the EMA, FDA and other regulators through our research activities in 2025 and beyond.

Expansion of HTA agency benchmarking

Three new HTA agencies were added to the CIRS HTADock database in 2024: NCPE (Ireland), INFARMED (Portugal) and INESSS (Canada). This brings the total number of benchmarked HTA agencies to 12. We also developed three R&D Briefings on HTADock, each with a different focus and set of analyses. While the first briefing took a view of the global HTA landscape, the second was on Australia, Canada and the UK (including analyses on Access work sharing and Project Orbis), and the third focused on EU jurisdictions.









2024 in numbers

Thought leadership

4
Journal publications *

6
CIRS R&D Briefings*

19
Conference presentations*

3
PhD students supported by CIRS

Stakeholder engagement

6
Workshops and fora†

4.7
Out of 5 feedback score for multi-stakeholder workshops

INSIGHT MEETINGS

20 For companies
20 For agencies

4
Advisory board meetings

2
Taskforce meetings on AI

764
New LinkedIn followers

4
Webinars*

MULTI-STAKEHOLDER FEEDBACK STUDY

21
Interviewees

106
Survey respondents

* Listed on p14-15
† Listed on p8-10

High profile citations of CIRS research in 2024



Draghi Report on EU Competitiveness (Part B, p193)

Regulatory benchmarking data from CIRS R&D Briefing 88 was cited by the European Commission in a report that looks at the challenges faced by the industry and companies in the European Union. The report's findings are aiding the Commission in developing a new strategy for Europe's sustainable prosperity and competitiveness.



Australian HTA Policy and Methods Review

HTA benchmarking data from CIRS R&D Briefing 89 was presented by the Australian Department of Health and Aged Care in a report examining Australia's approach to HTA, including what works well and what doesn't. The report provided a set of recommendations to the Australian Government that are now under consideration.



Swiss Healthcare System Report

Regulatory benchmarking data from CIRS R&D Briefing 93 was reproduced in the *Health Panorama* publication by Interpharma, the trade association for the pharmaceutical industry in Switzerland. This annual statistics publication aims to contribute to a constructive discussion about the healthcare system, Switzerland as a business location and the welfare of patients.



Developing a framework for AI regulation in the UK

Regulatory benchmarking data from CIRS R&D Briefing 81 was reproduced in a case study by the Ada Love Lace Institute, an independent research institute aiming to ensure data and AI work for people and society. This work was commissioned as part of a report on lessons for AI regulation from the governance of other high-tech sectors (including the pharmaceutical industry).

2024 Multi-stakeholder workshops

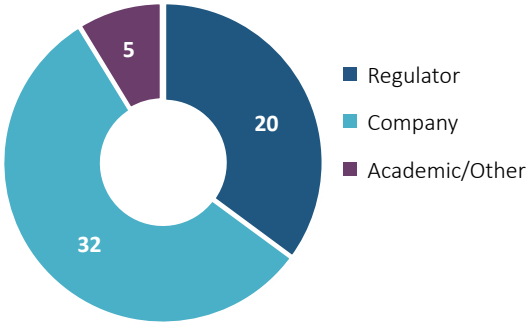
FEBRUARY 2024 WORKSHOP, BRAZIL

New ways of working: Enabling patient access through reliance or regional review models

This workshop provided a platform for identifying what is needed for reliance or regional review processes to work effectively and efficiently. Practical considerations and best practices were discussed, informed by lessons learned from various models, including collaborative reviews, worksharing and reliance, being implemented around the world. Recommendations from the interactive breakout sessions focused on enabling regional collaborations, changing mindsets and implementing good collaborative practices. We hope that the learnings from this meeting can help to inform the next steps towards the practical implementation of reliance in Latin America and beyond.

Download the workshop report

65 ATTENDEES FROM 18 COUNTRIES ACROSS 6 CONTINENTS



"An excellent forum to strengthen knowledge and share experiences about reliance."

Regulatory agency

JUNE 2024 WORKSHOP, WASHINGTON DC, USA

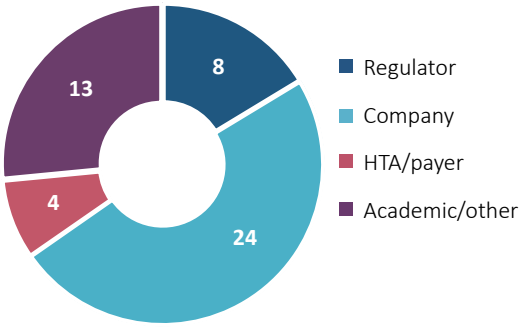
Vaccines: Are regulatory and funding approaches fit for purpose for the next decade?

Vaccines are a cornerstone of public health, yet there are just 34 pathogens that have approved vaccines. This workshop aimed to review the vaccine landscape and make recommendations were made on how to address policy challenges in the development, regulation, HTA and funding of vaccines.

The workshop highlighted the need for regulatory, HTA and National Immunisation Technical Advisory Group (NITAG) frameworks for vaccines to evolve, a common terminology for vaccines to be established, and the value of vaccines to be better communicated to society. More work needs to be done to 'derisk' vaccine development, focusing on early engagement with government and public health professionals involved in national immunisation programmes to better assess potential vaccine demand and pathways to market access.

Download the workshop report

49 ATTENDEES FROM 13 COUNTRIES



"Great experience and the perspective diverse - range of participants adds value."

Academic organisation

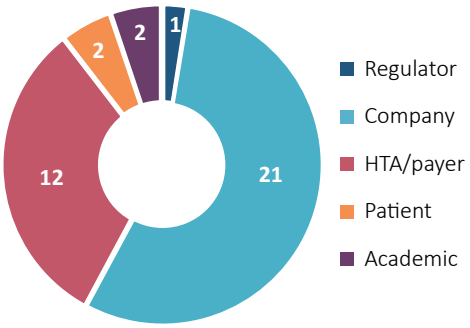
JUNE 2024 WORKSHOP, SPAIN

Facilitating joint clinical assessment (JCA) implementation, utilisation and timely patient access

This workshop provided a platform for companies and HTA agencies to discuss how the JCA can be efficiently and effectively implemented at the Member State level. A pre-workshop survey was conducted to assess company readiness for the EU HTA Regulation, which showed that companies are generally prepared for JCA but have concerns about timeline uncertainties and timely report delivery. The workshop highlighted the need for metrics to enable iterative learning among stakeholders, training programmes to support Member States and research to better understand agencies' use of JCA reports. Together, the survey and workshop recommended that a collaborative, iterative approach is used to refine the JCA process, ensuring it meets stakeholders' needs and improves access to treatments for patients.

Download the workshop report

38 ATTENDEES FROM 16 COUNTRIES



"Great topic and discussion, enabling much needed facilitation. Would welcome future sessions on this topic."

Pharmaceutical company

OCTOBER 2024 WORKSHOP, UK

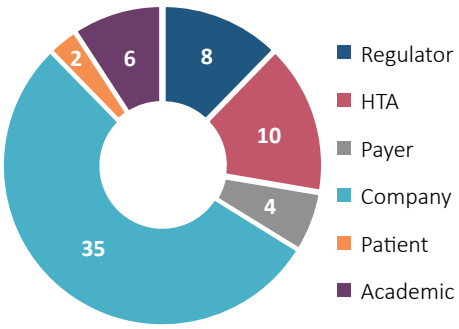
New ways of working across regulatory and HTA agencies: Collaborative, work-sharing and reliance models

This workshop aimed to explore the impact of collaborative models among regulators and HTA agencies and recommend how these models should evolve. Various dimensions of collaborative models were examined, including regulatory-regulatory, regulatory-HTA, HTA-HTA and HTA-payer collaborations.

The workshop highlighted that collaborations between regulators were relatively mature compared to collaborations between HTA agencies, which were progressing. To ensure success of a collaboration, stakeholders should 'align and define' goals early on and ensure that the collaboration is an organisational priority, with senior leadership buy-in. A recommendation for agencies was to explore opportunities to adapt other agencies' assessment reports for decision making.

Download the workshop report

65 ATTENDEES FROM 18 COUNTRIES



"Great organisation as always and a great networking opportunity."

HTA agency

2024 Forums

Regulators' Forum - February 2024, Brazil

Regulatory collaboration: How can agencies build trust and work together to ensure a fit-for-purpose toolbox? February 2024

This forum provided a platform for 14 regulatory agencies from around the world to share experiences and discuss how regulators can build trust and work together to ensure a fit-for-purpose toolbox through the implementation of risk-based reviews, including reliance and collaborative reviews.

Challenges such as legal, political, and resource constraints were highlighted, along with the importance of trust-building and transparent guidelines. The forum emphasised the need for agencies to focus on continuous improvement through metrics, clear communication, and leveraging assessment reports to optimise regulatory risk-based processes.

Find out how your agency can get involved with CIRS

Industry Forum for CIRS Members - November 2024, UK

Patient engagement and patient experience data: How is this supporting review and reimbursement decisions and can impact be measured?

This meeting brought together 14 CIRS member companies and three patient/non-profit organisations to discuss the value patient perspectives bring to regulatory and HTA decision making. Insights and case studies were shared on how to generate meaningful patient insights in development and measure their impact.

Measuring the impact of patient insights was deemed to be a key challenge, as well as the lack of transparency on how agencies consider patient insights in their decision making. CIRS will be continuing the discussion at a multi-stakeholder workshop in October 2025.

Find out about CIRS Industry Membership



Case study

Assessing the landscape and impact of regulatory and HTA collaborations

Regulatory and HTA agencies face increasing pressure to review many novel and complex interventions with robust methods, fast timelines and limited resources. Collaborations between agencies have been identified as key drivers to improving the efficiency of agency decisions and facilitating aligned thinking on requirements and processes.

CIRS has been studying the progress of such collaborations for over a decade, with the aim to share learnings among stakeholders and identify best practice. Through a series of workshops and quantitative and qualitative research studies, we have assessed the landscape of regulatory and HTA collaborations and measured their impact.

Recognising the importance of collaborative early dialogue

In the previous decade, we played an active role in bringing stakeholders together to discuss the barriers and opportunities for aligning their expectations and needs. With the growth in facilitated regulatory pathways and flexible HTA/reimbursement pathways globally, we conducted workshops in 2014 and 2017 to better define the relationship between these pathways in supporting timely availability and patient access. Early dialogue among stakeholders, including companies, regulators, HTA bodies, payers, and patients, was emphasised as the process likely to provide the greatest return on investment to identify, develop, review and recommend important new medicines, especially those addressing unmet medical needs (see McAuslane, Liberti and Connelly, 2019).

Collaboration during a global pandemic

While the COVID-19 pandemic put pressure on agency communication channels and networks, it also created opportunities for collaborative working, which were discussed during our workshop on re-imagining regulatory models in December 2020. The rise of collaborative activities using digital technologies was highlighted, as well as co-creative strategies to accelerate development and review and increased information sharing among agencies.

Mapping the interactions landscape

Building on the findings from the previous workshop, in 2021 we conducted a stakeholder survey to assess the landscape of interactions (where two or more stakeholders communicate with each other) and collaborations (where two or more stakeholders work together to achieve the same goal). The results were discussed at a multi-stakeholder workshop to better understand the value interactions and collaborations bring, as well as how they should evolve in future.

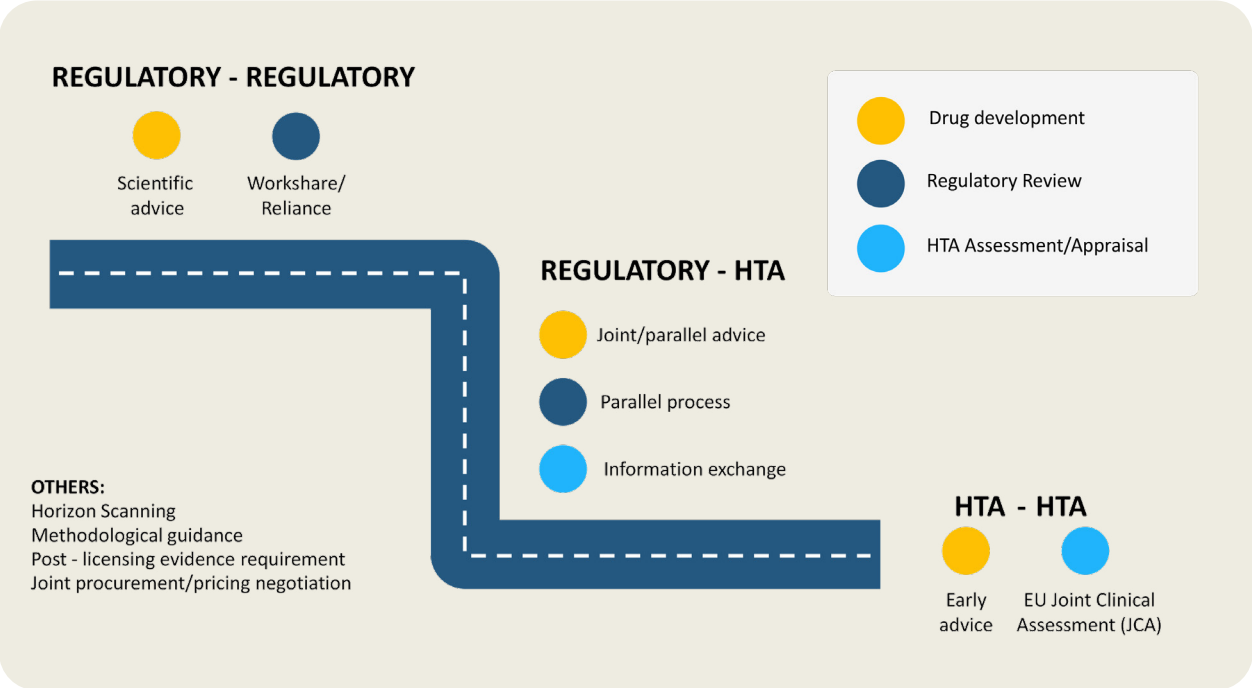
The survey and workshop showed a difference in the level of interaction between regulators compared to HTA agencies, which may be due to the longer history of regulators; more formal collaboration, such as work sharing, often occurred between regulators, whereas HTA agency interactions were usually more informal, involving exchange of information. Four principles were proposed for an ideal ecosystem of multi-stakeholder interactions: separate remit and functions between regulators and HTA agencies; aligning processes; converging evidence requirements where possible; and increasing transparency.

Honing in on collaborative models

In the years that followed, regulators gained more experience with work sharing and collaborative review, and European HTA agencies prepared for Joint Clinical Assessment (JCA) under the EU HTA Regulation. Therefore 2024 felt like the right time to hold another workshop on collaboration, this time focused on the impact of collaborative regulatory and HTA models.

The pre-workshop stakeholder survey highlighted the various dimensions of stakeholder collaboration across the medicine life cycle (see below). Timely access to medicine was seen as a measurable benefit, alongside other qualitative metrics that demonstrate the effectiveness and efficiency of collaboration. To further evolve stakeholder collaboration, respondents highlighted the need for active measures, the development of good practices and a mindset shift to enable progress.

Dimensions of Stakeholder Collaboration Across the Medicine Lifecycle



Key recommendations from the **2024 workshop**:

- **Align and define:** Start with a clear aligned vision for the collaboration, with agreement on how to measure success.
- **Changing mindsets:** Ensure the success of collaboration is an organisational priority, with senior leadership buy-in.
- **Look in your neighbourhood:** Identify opportunities to adapt regulatory and HTA assessment reports for decision making.
- **Product agnostic early dialogue:** Explore a new forum for stakeholders to discuss unmet need and national health priorities

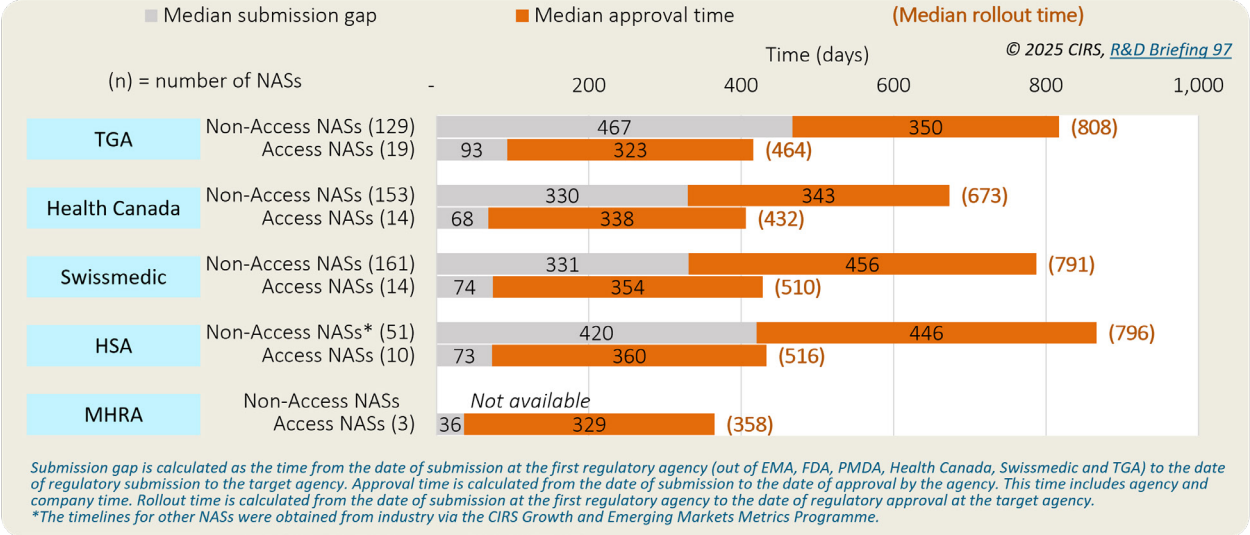
Evaluating impact with metrics

Metrics is one of our research pillars, where the goal is to provide evidence-driven insights into the performance of companies, regulators and HTA agencies in developing, reviewing and facilitating access to pharmaceutical products. We have over a longstanding history of benchmarking the performance of regulatory agencies, and more recently, HTA agencies, working collaboratively with these agencies to validate our methodologies and results.

We have been tracking new active substance approvals made through the Access Consortium work-sharing initiative and Project Orbis collaborative review pathways for oncology products to assess their impact on regulatory and HTA

timelines and outcomes. Our research shows that these collaborative models are helping to reduce submission gaps to the participating regulatory agencies, suggesting that there are efficiency gains (see below). However, preliminary data for Project Orbis suggests that the expedited regulatory timelines mean a longer submission gap to HTA agencies in certain jurisdictions. This is particularly evident with product approvals granted Orbis Type A in Australia and Canada, where the regulatory review is concurrent with FDA, with simultaneous submission (less than 30 days from FDA submission).

Comparison of median submission gap, approval time, and rollout time for NASs approved via Access Consortium vs. Non-Access NASs (2019-2023)



Submission gap is calculated as the time from the date of submission at the first regulatory agency (out of EMA, FDA, PMDA, Health Canada, Swissmedic and TGA) to the date of regulatory submission to the target agency. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. Rollout time is calculated from the date of submission at the first regulatory agency to the date of regulatory approval at the target agency.
**The timelines for other NASs were obtained from industry via the CIRS Growth and Emerging Markets Metrics Programme.*

We have also been monitoring the effect of vertical regulatory-HTA collaboration, in the form of parallel regulatory/HTA submissions. Our research shows that parallel submissions result in an overall shorter rollout timeline compared to sequential submissions, highlighting the strategic value of aligning regulatory and HTA processes.

These insights have been of particular interest to the regulatory and HTA agencies participating in these collaborative models and have been cited at major conferences and meetings. We continue to share and discuss our metrics research with agencies to better understand the context around observed trends and gather feedback for future analyses.

Where to next?

We continue to assess the impact of agency collaborations in enhancing the efficiency and effectiveness of regulatory and HTA processes. Our focus remains on promoting international engagement and strategic policy discussion, providing opportunities for cross-stakeholder learning and identification of best practices.

Activities in 2025 on agency collaborations include:

- Workshop on 'Regulatory agency collaboration and system strengthening – How is this enabling national, regional and continental models and improving patient availability to medicines?'
- Workshop on 'Navigating national decision making post-JCA: Enablers, barriers and the path forward'
- Updated metrics on mature regulatory agency and HTA agency benchmarking, including the assessment of Project Orbis and Access Consortium collaborations.
- Regulatory strengthening projects focusing on the implementation of reliance and collaborative models across Africa and Latin America.

Publications in 2024

Journal publications & books

1. Sithole T, Ngum N, Owusu-Asante M, **Walker S**, & Salek S (2024). Comparison of Three Regional Medicines Regulatory Harmonisation Initiatives in Africa: Opportunities for Improvement and Alignment. Int J Health Policy Manag. 2024;13:8070. doi:10.34172/ijhpm.2024.8070
2. Ngum N, Ndomondo-Sigonda M, Habonimana R, Siyoi F, Irasabwa C, Ojukwu J, Apolinary F, Okello A, Ahmada S, **Walker S** and Salek S (2024) Evaluation of good review practices in member authorities of the East African Medicines Regulatory Harmonisation initiative: strategies for alignment with African medicines agency. Front Med (Lausanne). 2024;11:1437970. Published 2024 Aug 29. doi:10.3389/fmed.2024.1437970
3. Ngum N, Ndomondo-Sigonda M, Habonimana R, Siyoi F, Irasabwa C, Ojukwu J, Apolinary F, Okello A, Ahmada S, **Walker S** and Salek S (2024) Evaluation of the Review Models and Approval Timelines of Agencies, participating in the East African Medicines Regulatory Harmonisation Initiative: Alignment and Strategies for Moving Forward. Front Med (Lausanne). 2024;11:1438041. Published 2024 Sep 17. doi:10.3389/fmed.2024.1438041
4. Chisha CS, Siyanga M, Leigh S, **Kermad A, Walker S**. Evaluation of the Regulatory Review Process of the Zambia Medicines Regulatory Authority: Challenges and Opportunities. Ther Innov Regul Sci. Published online December 27, 2024. doi:10.1007/s43441-024-00730-6
5. Ngum N, Salek S & **Walker, S**. (2024). The role of regional initiatives in the operationalisation of the African Medicines Agency: Contribution of the EAC-MRH initiative. [PhD thesis]

R&D Briefings

1. CIRS R&D Briefing 91 – Approaches to implementing regulatory reliance: Considerations for agencies
2. CIRS R&D Briefing 92 – Appraisal of public assessment reports (PARs) as tools to guide reliance decision making by regulatory agencies
3. CIRS R&D Briefing 93 – New drug approvals by six major authorities 2014-2023: Changing regulatory landscape and facilitated regulatory pathways
4. CIRS R&D Briefing 94 – The value of reference agency assessment reports in enabling regulatory reliance
5. CIRS R&D Briefing 95 – CIRS HTADock Project: Review of HTA outcomes and timelines in Australia, Canada, Europe and the UK 2019-2023
6. CIRS RD Briefing 96 – CIRS HTADock Project: Review of HTA outcomes and timelines in Australia, Canada and the UK 2019-2023

Online articles/external blogs

1. DIA Global Forum, September 2024 – Minding the Gap: CPP Utilisation Practices and the Impact on Submission Gap in Growth and Emerging Markets
2. DIA Global Forum, November 2024 – Regulatory and Access Approaches for Vaccines: Recommendations from an Expert Workshop
3. OHE Insights Blog – Is collaboration between and across regulatory and HTA agencies the answer to access challenges?

Project reports with external partners

1. Monitoring implementation and adherence to ICH guidelines
2. Regulatory processes for rare disease drugs in the US and EU
3. ICMRA Rare Disease Workshop Report

Conference presentations in 2024

21st February, EURORDIS Roundtable of Companies

1. Dr Tina Wang – Speaker- Do development, review and reimbursement frameworks need adapting to improve evidence generation and financially sustainable access for rare disease products?

11-15th March, DIA Europe

2. Dr Magda Bujar – Facilitator – Pre-Conference workshop on "Reliance for post-approval changes: How do we move from exceptional to routine use?"
3. Dr Magda Bujar – Speaker – Regulatory risk-based approaches: Are these enabling better availability and access to medicines globally?

1st-5th April, BioHabana Congress – Regulatory Symposium

4. Dr Mario Alanis– Speaker – Implementation of reliance

6-8th May, RAPS Euro Convergence

5. Dr Magda Bujar- Chair – Emerging advancements in eCTD: A panel discussion on cloud integration, data standards and publishing perspectives in regulatory submissions

16-19th May, DIA China – ICH Day

6. Dr Neil McAuslane – Speaker – Importance of building trust and capacity in international standards, guidelines and regulatory science

5-6th June, DIA Southeastern Europe Conference

7. Dr Magda Bujar – Speaker – Feedback from studies: Regulatory risk-based approaches – Are these enabling better availability and access to medicines globally?

15-19th June, HTAi Annual Meeting

8. Dr Belen Sola – Pre-recorded presentation – HTA timelines and outcomes of common compounds in France, Germany, Sweden and Poland from 2015-2023
9. Dr Tina Wang- Poster – Navigating HTA Requirements During Development Through Early HTA Scientific Advice: Insights From Companies' Strategies, Challenges, And Priorities
10. Dr Tina Wang – Poster- Rare Disease Product Approvals: The Changing Regulatory And HTA Landscape Between 2018-2022

16-20th June, DIA Global Annual Meeting

11. Dr Magda Bujar – Chair – What is the value of reference agency assessment reports in enabling reliance and what do relying agencies require?
12. Juan Lara- Poster – Assessing the Use of Risk-Based Approaches in Four Major Agencies – What is the Impact on the Approval of New Medicines?
13. Lorraine Danks – Poster- The Economic Impact of Reliance on a National Regulatory Authority: a SAHPRA Case Study
14. Mercy Owusu-Asante – Poster- Comparison of Regulatory Performance of WHO Maturity Level 3 National Medicines Regulatory Authorities (NMRAs) in Africa: Identifying Best Practices
15. Nancy Ngum – Poster- Evaluation of Good Review Practices in Member Agencies of the East African Medicines Regulatory Harmonisation Initiative
16. Constance Chisha – Poster- Assessment of the Regulatory Review Process of the Zambia Medicines Regulatory Authority: Opportunities and Challenges

25-26th September, DIA Latin America Annual Meeting

17. Juan Lara- Speaker- Appraisal of Public Assessment Reports (PARs) as Tools to Guide Reliance Decision Making by Regulatory Agencies

17-20th November, ISPOR Europe

18. Penelope Cervelo – Poster- Frequency and Variation of Clock-Stop During EMA Assessment for Oncology Products: Implication on JCA Timelines

25-27th November, DIA Middle East and North Africa

19. Dr Neil McAuslane – Speaker- International Collaboration, Harmonisation & Convergence: ICH Implementation Survey Results

Webinar presentations in 2024

5th April, Pharma Group Vietnam

1. Approaches to Implementing Regulatory Reliance: Considerations for Agencies

24th June, FPath Project

2. What core information is needed for a reliance decision?

28th August, CIRS

3. Utility of public and non-public assessment reports from reference agencies – What is being utilised and for what reason?

12th December, FPath Project

4. How are Reference Agencies Evolving to Meet the Needs of the Evolving Regulatory Landscape?

CIRS Centre for Innovation in Regulatory Science

About CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. Its mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes. CIRS provides an international forum for industry, regulators, HTA bodies and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science. It is governed and operated by Clarivate for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, and grants.

Contact Us

Anna Somuyiwa, Head of CIRS	asomuyiwa@cirsci.org
Dr Mario Alanis, Senior Consultant	marioalanisgarza@cirsci.org
Dr Magda Bujar, Associate Director, Regulatory Programme and Strategic Partnerships	mbujar@cirsci.org
Penelope Cervelo Bouzo, Research Analyst	pcervelo@cirsci.org
Gill Hepton, Administrator	ghepton@cirsci.org
Adem Kermad, Principal Research Analyst	akermad@cirsci.org
Juan Lara, Senior Research Analyst	jlara@cirsci.org
Dr Neil McAuslane, Scientific Director	nmcauslane@cirsci.org
Dr Jenny Sharpe, Communications Manager	jsharpe@cirsci.org
Dr Belén Sola, Research Analyst	bsola@cirsci.org
Prof Stuart Walker, Founder and Senior Advisor	swalker@cirsci.org
Dr Tina Wang, Associate Director, HTA Programme and Strategic Partnerships	twang@cirsci.org

Centre for Innovation in Regulatory Science (CIRS)

70 St Mary Axe, London EC3A 8BE, UK

cirs@cirsci.org

www.cirsci.org

www.linkedin.com/company/centre-for-innovation-in-regulatory-science-ltd/

Publication date: July 2025