CIRS Centre for Innovation in Regulatory Science

www.cirsci.org

2023 Annual Report

INSIGHTS | NETWORK | ADVOCACY

Foreword

It is my pleasure to present you with our 2023 Annual Report, which encapsulates our endeavors throughout the year, showcasing a plethora of publications, workshops, and collaborative meetings that have furthered our mission.

This past year has been particularly rich, with many activities to close off our 2021-2023 Research Agenda and at the same time a lot of co-development work to shape our robust **2024-2026 Research Agenda**. I want to start by thanking the wonderful CIRS team who have again accomplished so much. Their dedication and hard work, especially in the face of challenges, have been nothing short of exemplary.

Three extremely successful multi-stakeholder workshops in Singapore, the US and UK finished off our 2021-2023 Research Agenda. We also held our Industry Discussion Meetings for our Growth and Emerging Market Metrics (GEMM) and HTA Metrics Programmes, as well as our regulatory and HTA Technical Forums. The insights from all these interactions are invaluable as we continuously strive to refine and advance these offerings. As highlighted in a case study in this report, our metrics remain an impactful cornerstone of our research.

Another focal point throughout 2023 was the formulation of our research agenda for the 2024-2026 period. This strategic planning was a comprehensive process, beginning with the Topic Groups initiative, which engaged representatives from member companies, regulatory and HTA agencies, and academic institutions. These groups provided invaluable contributions, suggesting targeted research initiatives that align with our overarching goals in patient engagement, the utilisation of expedited pathways in regulatory and the impact this has on HTA, and the enhancement of our metrics collection. The outcomes of this exercise are detailed within the pages of this report; I want to thank all contributing stakeholders, including the Scientific Advisory Council, HTA Steering Committee, member companies, participating agencies and other institutions.

On a personal note, my maternity leave gave me a unique opportunity to observe all of this great work from a distance, and also to reflect on how we can continue and build on the success and impact of CIRS in the years to come. My conclusion was as simple as it was clear: it is all about the people and the trust between them as they combine their ideas and efforts toward common goals. CIRS is nothing without its team, its members, without you.

In closing, therefore, my thanks go to you. As we look to the future, I feel excited by all of us working together in trust to advance standards and practices in our field.

Anna Somuyiwa
Head of CIRS

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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.

We serve patients, agencies and medical developers by focusing on improvements in policies and processes for regulation and HTA. CIRS also supports 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'**.

In 2023 **CIRS** continued to deliver for its stakeholders

7
Journal publications*

4
CIRS R&D Briefings*

4.7
Out of 5 feedback score for multi-stakeholder workshops**

23
Conference presentations*

INSIGHT MEETINGS

22
For companies

30
For agencies

649
New LinkedIn followers

4
PhD students supported by CIRS

4
Advisory board meetings

*Listed on p14-15 ** Listed on p6-7

Highlights in 2023

Linking CIRS tools to WHO indicators

Over the last 20 years, CIRS has been developing regulatory science tools to increase transparency of processes, support quality regulatory decision making, and provide global advocacy in support of regulatory strengthening. These tools form part of a comprehensive toolkit to support agencies participating in the Optimising Efficiencies in Regulatory Agencies (OpERA) programme.

In 2023, in order to help support agencies in their goals relating to the World Health Organisation (WHO) Global Benchmarking Tool (GBT), CIRS produced an R&D Briefing demonstrating how CIRS tools help to identify or support practices in line with the WHO GBT. This work has been presented to regulators from around the world, including at the 2023 CIRS Regulatory Forum in Singapore, and a meeting with the heads of African agencies, which was held in Rwanda in August 2023.

NICE-CIRS Insight Day

CIRS insight seminars offer a tailored platform for individual agencies and member companies to discuss how CIRS research helps to address crucial business questions. The UK National Institute for Health and Care Excellence (NICE) has participated in CIRS activities for many years, and is represented on the HTA Steering Committee by Dr Nick Crabb, Interim Director, Science, Evidence and Analytics. The 2023 CIRS-NICE Insights Day brought together CIRS and NICE senior management to discuss NICE's priorities and strategise how CIRS research can further support advancing HTA processes and policy.

New analysis tool for industry metrics

In 2023, CIRS developed and piloted an online analysis tool with companies participating in the Growth and Emerging Markets Metrics (GEMM) Programme. The tool, which allows GEMM Programme participants to interactively interrogate the GEMM database in a secure and confidential format, was developed using participant feedback. Following the success of the pilot, the tool has been integrated into the GEMM Programme's annual reporting cycle and is accessible to all participating companies.

Enhancing HTA decision making in Asia

In April 2023, CIRS organised an HTA Agencies Forum in Singapore on enhancing HTA decision-making processes in Asia. Participants included senior representatives from the Health Intervention and Technology Assessment Program (HITAP), Thailand; Center for Drug Evaluation (CDE), Chinese Taipei; the Ministries of Health in Malaysia and Indonesia; and NICE, who shared their experience of collaborative HTA practices. Discussions focused on the current HTA environment in Asia, how to grow capacity in the region and recent CIRS HTA research projects and workshops.

New ways of working agency survey

CIRS has been actively monitoring changes to the regulatory environment across new product types, sources of evidence and digital technologies. Building on the findings of a company survey, in 2023 CIRS conducted an agency survey to understand how agencies are evolving to these new ways of working, including what systems they have in place and what they view as challenges and opportunities going forward. 20 agencies globally (Africa, Australia, Asia, Americas, Europe, Middle East) responded to the survey; the findings were presented at a CIRS multi-stakeholder workshop in Singapore in April 2023, alongside the company survey results. The results of both surveys were used as a basis for discussion in the workshop breakout sessions (see the workshop report).

Deeper insights on early HTA scientific advice

The 2023 CIRS HTA Industry Technical Forum built on previous CIRS work to give deeper insights into the evolving field of early scientific advice from HTA agencies. The results of a CIRS member survey, which gathered companies' perceptions and experiences of seeking HTA advice, were presented at the Forum, in addition to high-level insights from the CIRS HTA Industry Metrics Programme. This research helped to inform discussions during the Forum and will be written up for publication in a peer-reviewed journal in 2024. Following participant feedback, the CIRS Industry Metrics Programme has also evolved to focus only on early advice in 2024 (see HTA Early Advice Metrics Programme).

2023 Workshops and Technical Fora

APRIL 2023 WORKSHOP, SINGAPORE

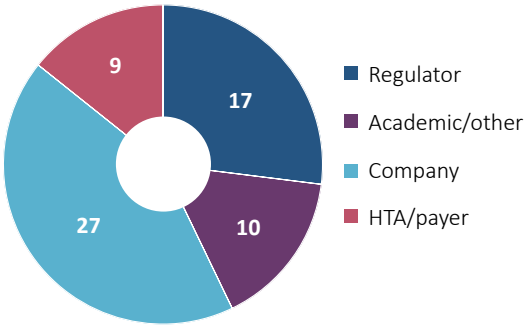
New ways of working for medicine development - How is the regulatory and HTA landscape evolving in maturing countries?

This workshop provided a platform for discussing how regulatory and HTA agencies are adapting to new technologies and evidence generation methodologies, particularly advanced therapy medicinal products (ATMPs), digital health technologies (DHTs) and real-world data/evidence (RWD/E). The discussions were informed by pre-workshop surveys of CIRS member companies and agencies, which identified several challenges across the regulatory and HTA landscape for ATMPs, DHTs and RWD/E, including a lack of guidelines and technical knowledge.

Recommendations were made on how the global landscape for ATMPs, DHTs and RWD/E should evolve to enable development and registration of new medicines. These included multi-stakeholder activities to facilitate learning of best practices, exchange of experiences and to identify training needs.

Download the workshop report

60+ ATTENDEES FROM 22 COUNTRIES



"It was a great learning experience. Particularly, I liked the content of the workshop and the clarity of discussions in the syndicate groups. Thanks to CIRS for bringing a safe space to share thoughts from multiple stakeholders."

Regulatory agency

JUNE 2023 WORKSHOP, WASHINGTON DC, USA

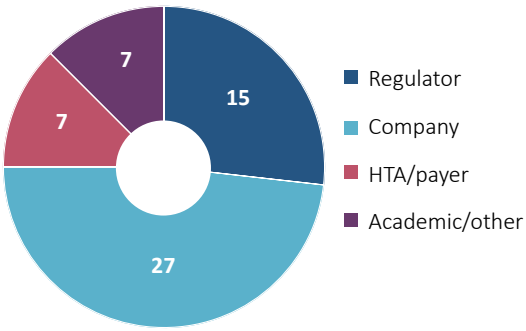
Uncertainty in the development of new medicines – How should clinical development, regulatory and HTA uncertainties be managed, or mitigated?

This workshop built on the outcomes of previous CIRS workshops conducted between 2017 and 2019, which identified a need to better understand the types of uncertainty facing different stakeholders. Therefore, this workshop aimed to discuss sources and grading of uncertainty and to recommend approaches to manage uncertainty in regulatory and HTA decision making.

The workshop recommendations were centred on the management of uncertainty in three scenarios: drugs that go through an accelerated/priority or provisional/conditional approval; drugs trialled in small populations; and drugs where there are differences between efficacy observed in clinical trials and effectiveness in the real world. Further work should focus on knowledge sharing and collaboration across stakeholders, evaluating existing tools to manage uncertainty, and promoting the inclusion of underserved populations in trials or post-marketing studies.

Download the workshop report

50+ ATTENDEES FROM 12 COUNTRIES



"Very valuable workshop, excellent cross-experience attendees."

Pharmaceutical company

OCTOBER 2023 WORKSHOP, UK

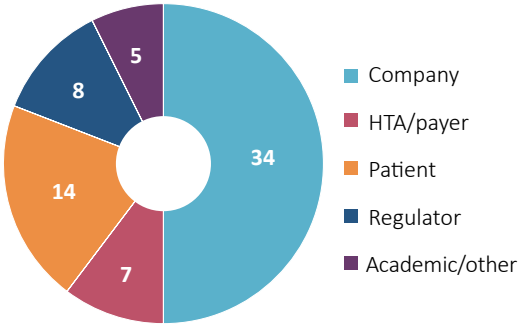
Do development, review and reimbursement frameworks need adapting to improve evidence generation and financially sustainable access for rare disease products?

Given the challenges arising from a small patient population, R&D for rare diseases often needs to use alternative clinical trial and evidence generation techniques, and acceptability of these can vary between regulatory and HTA agencies. This workshop aimed to identify challenges and opportunities for adapting regulatory or reimbursement frameworks for rare disease products, and to develop recommendations on how these can improve to best support stakeholder evidence needs.

The workshop recommendations were focused on evolving incentives, improving evidence generation and better managing uncertainty. This included further work to explore different incentive models for treatments for ultra-rare diseases, developing structured checklists for pre- and post-approval evidence generation and bringing together best practices for rare disease registries.

Download the workshop report

65+ ATTENDEES FROM 22 COUNTRIES



"I see the CIRS workshop as a valuable tool to engage with various stakeholders and consider perspectives from regulators, HTA bodies, industry and patient groups to drive drug development and access."

Pharmaceutical company

Technical Forums for CIRS Member Companies

Right information in the right place at the right time – What is needed to enable risk-based reviews?

24TH OCTOBER 2023

This meeting brought together 19 CIRS member companies to discuss the use of risk-based models and recommend best practices. Companies shared insights and case studies on collaboration and work-sharing models as well as the role of documentation in enabling reliance.

To help inform discussions, CIRS presented results from surveys and studies evaluating the use of different types of assessment reports. Roundtable discussions focused on identifying success elements of risk-based review models, key challenges and how to improve and measure success.

"Excellent content, lives up to expectation as always."

Company participant

Enhancing development strategies through early scientific advice from HTA agencies

30TH NOVEMBER 2023

This forum provided a platform for 17 CIRS member companies to share experiences of seeking early HTA advice during development. Companies discussed challenges and opportunities for HTA advice as well as how to measure its impact.

Roundtable discussions focused on identifying internal and external considerations for seeking early HTA advice. Preparation for the EU HTA Regulation, including Joint Scientific Consultation (JSC), was highlighted as a key challenge for both industry and HTA agencies.

CIRS is looking to build on this topic through its HTA Early Advice Metrics Programme and HTA Regulation Workshop in 2024.

Find out about **CIRS Membership**

Topic Groups

As part of a revamp of ways of working, CIRS initiated three Topic Groups to provide opportunities for focused discussions on the following topics: metrics; expedited pathways and HTA; and patient engagement. These topics were agreed by the CIRS Scientific Advisory Council (SAC) and HTA Steering Committee, with a mandate to develop recommendations for potential research activities.

The Topic Groups comprised CIRS committee members and other selected experts, with CIRS staff to support activities. The Topic Groups met initially at the September 2022 SAC meeting in Washington DC, with further online meetings through to May 2023. The outcomes and recommendations of each Topic Group were presented to the SAC in June 2023 and have helped to inform CIRS' 2024-2026 Research Agenda (key research priorities are outlined in the graphic below).

Enabling decision-making frameworks for new ways of working and evidence generation technologies -

Moving implementation from concept to practicality

Defining and promoting good practices for regulatory and HTA collaborative models of review and assessment

Metrics on new ways of working and evidence generation and their impact on decision making

Strategic insights and impact measures

NEW FOCUS: VACCINES, PATIENT ENGAGEMENT, HIGH IMPACT CHRONIC DISEASES

Metrics Topic Group

Chair: Dr Max Wegner, Senior Vice President, Head of Regulatory Affairs, Bayer

Vice Chair: Dr Claus Bolte, Chief Medical Officer, Swissmedic

Vice Chair: Adrian Griffin, Vice President for HTA Policy, Johnson & Johnson

Metrics is one of the three pillars of CIRS, where the goal is to provide evidence-driven insights into the performance of companies, regulators and HTA agencies in developing and facilitating access to pharmaceutical products. This Topic Group focused on reviewing CIRS metrics activities on regulatory and HTA agency benchmarking (the six agency and HTADock studies), including the scope of the collected metrics. There was agreement that metrics is a key pillar of CIRS work and that the annual six agency and HTADock R&D Briefings should continue, albeit with some evolution.

Recommendations for CIRS:

- Have earlier and more interactive outputs, in addition to the two annual R&D Briefings.
- Benchmark more countries and ensure a like-with-like comparison of the measured milestones.
- Ensure CIRS metrics are relevant, like-with-like (HTA in particular; context is key), and provide valuable insights in line with emerging trends, for example:
  - New characteristics e.g. inclusion of real-world data
  - Connecting better HTA and regulatory datasets e.g. how does the use of regulatory pathways or collaborative models impact HTA recommendations?
  - First launch analyses e.g. what are the relevant comparisons, what is the impact of access on launch?

Expedited Pathways and HTA Topic Group

Chair: Dr Harald Enzmann, Chair, EMA Committee for Medicinal Products for Human Use (CHMP)

Vice Chair: Dr Nick Crabb, Interim Director of Science, Evidence and Analytics, National Institute for Health and Care Excellence (NICE)

Vice Chair: Natalie Tolli, Vice President, Regulatory Affairs (Regulatory International, Regulatory Policy & Intelligence), Abbvie

Expedited regulatory pathways can accelerate and increase the availability of new treatments but increase uncertainty for HTA agencies and payers. To better understand harmonisation opportunities for regulation and HTA in this context, this Topic Group examined case studies of three expedited products where there were divergences in regulatory and HTA decision making. The rationale for divergencies was identified by building upon information available in CIRS databases. The case studies demonstrated the importance of the distinct roles and responsibilities of regulatory and HTA agencies and helped to generate recommendations for future CIRS research.

Recommendations for CIRS:

- Establish best practice recommendations for the use of expedited regulatory pathways, such as a best practice toolbox. Key considerations include how to promote early scientific advice, close the gap between regulatory approval and HTA submission and solutions to address uncertainty.
- Examine the potential impact on low- and middle-income countries (LMICs). This could involve choosing a pathway example that illustrates which good reliance mechanisms could be used by HTA agencies in LMICs.
- Define recommendations for work-sharing or reliance processes for HTA agencies. CIRS may have a role in enhancing regulatory reliance programmes as well as acting as a convenor, acknowledging existing work in this area.

Patient Engagement Topic Group

Chair: Prof John Lim, Executive Director of Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School and Chairman, Consortium for Clinical Research & Innovation, Singapore

Vice Chair: Dr Fabio Bisordi, Global Head International Regulatory Policy, Roche

Vice Chair: Dr David Jefferys, Senior Vice President, Head of Global Regulatory, Eisai Europe

While not a new topic for CIRS, recent growth and advancement in the patient engagement space have highlighted the need for CIRS to undertake research on this topic. Therefore, this Topic Group reviewed the current patient engagement landscape to identify where CIRS can add the most value. There was agreement that CIRS should leverage its strengths of cross-stakeholder learning and metrics to measure impact.

Recommendations for CIRS:

- Define impact measures of patient engagement on regulatory and HTA decision making – surrogate measures of how patient engagement is built into decision making may be needed.
- Survey regulatory and HTA agencies to understand
  (a) patient engagement perspectives,
  (b) impact on decision making,
  (c) how this is measured,
  (d) needs, challenges and opportunities.
- Focus on patient engagement in specific therapeutic areas, e.g. oncology, central nervous system, respiratory.
- Use survey findings to inform a potential CIRS workshop in the next research cycle (2024-2026). Consider involving patients in developing the meeting by inviting patient group comments or co-designing the meeting with an international patient organisation.

CIRS is grateful to all Topic Group Chairs, Vice-Chairs and participants for their invaluable input into the discussions, which have provided CIRS with many ideas for research in the coming years. CIRS will continue to update its stakeholders on progress made based on the research suggestions from the Topic Groups.

Impact case study

CIRS metrics

A longstanding history

Metrics is one of the three pillars of CIRS, 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. CIRS has over 25 years of experience in regulatory performance and, more recently, HTA benchmarking initiatives (see the CIRS 2019 Annual Report for a detailed timeline).

CIRS has been benchmarking major regulatory agencies since 2002 using a mutually-agreed methodology. CIRS metrics provide insights into regulatory processes, identify where improvements can be made and help to inform company and agency strategies. The current CIRS Regulatory Review Times Database (RRTD) tracks new active substance (NAS) approvals by six regulatory agencies: the US Food and Drug Administration (FDA), European Medicines Agency (EMA), Japanese Pharmaceuticals and Medical Devices Agency (PMDA), Health Canada, Swissmedic and Australian Therapeutic Goods Administration (TGA). Data is collected from the public domain and/or directly from the agencies and input into RRTD. The findings of the RRTD benchmarking study have been published annually in an R&D Briefing since 2012 (see R&D Briefing 88 for the latest study).

In recognition of the growing importance of HTA in the drug development landscape, CIRS began an HTA agency benchmarking study in 2012 to identify the processes and performance of HTA agencies. This led to the development of HTADock, an annual CIRS metrics study aiming to facilitate improvement in HTA agencies and increase transparency of HTA processes and timelines. The HTADock database collects data from the public domain on NASs appraised by nine agencies in England, France, Germany, the Netherlands, Poland, Scotland, Sweden, Canada and Australia. This includes information on first HTA recommendations, time from regulatory submission to HTA recommendation, characteristics of products, regulatory pathways used and HTA implementation. The findings of the HTADock study are published annually in an R&D Briefing (see R&D Briefing 89 for the latest study).

How agencies and companies use CIRS metrics

As the results of CIRS metrics studies are neutral and independent, they have been endorsed and quoted by agencies in their annual reports (e.g. Swissmedic 2022 Annual Report) and conference presentations (e.g. PMDA Townhall at DIA Europe 2023). Agencies utilise CIRS metrics to evaluate their own performance, make process improvements and monitor the success of these improvements. In addition, companies employ CIRS benchmarking metrics to better understand the regulatory and HTA landscape to inform decision making, as well as their policy positions and advocacy efforts.

Examples of how agencies and companies use CIRS metrics

Evaluation of the Swissmedic regulatory framework for new active substances

CIRS worked closely with Swissmedic to better understand the agency's review times and examine whether measures introduced to accelerate the review process were effective. Results from this study have recently been published (available here).

Addressing medicine unavailability and delays in Europe

Regulatory benchmarking data from CIRS R&D Briefing 81 was cited by the European Federation of Pharmaceutical Industries and Associations (EFPIA) in a report that examined the cause of unavailability and delays to innovative medicines in Europe. This helped to inform the policy solutions put forward by industry, such as proposals to speed up the European regulatory process.

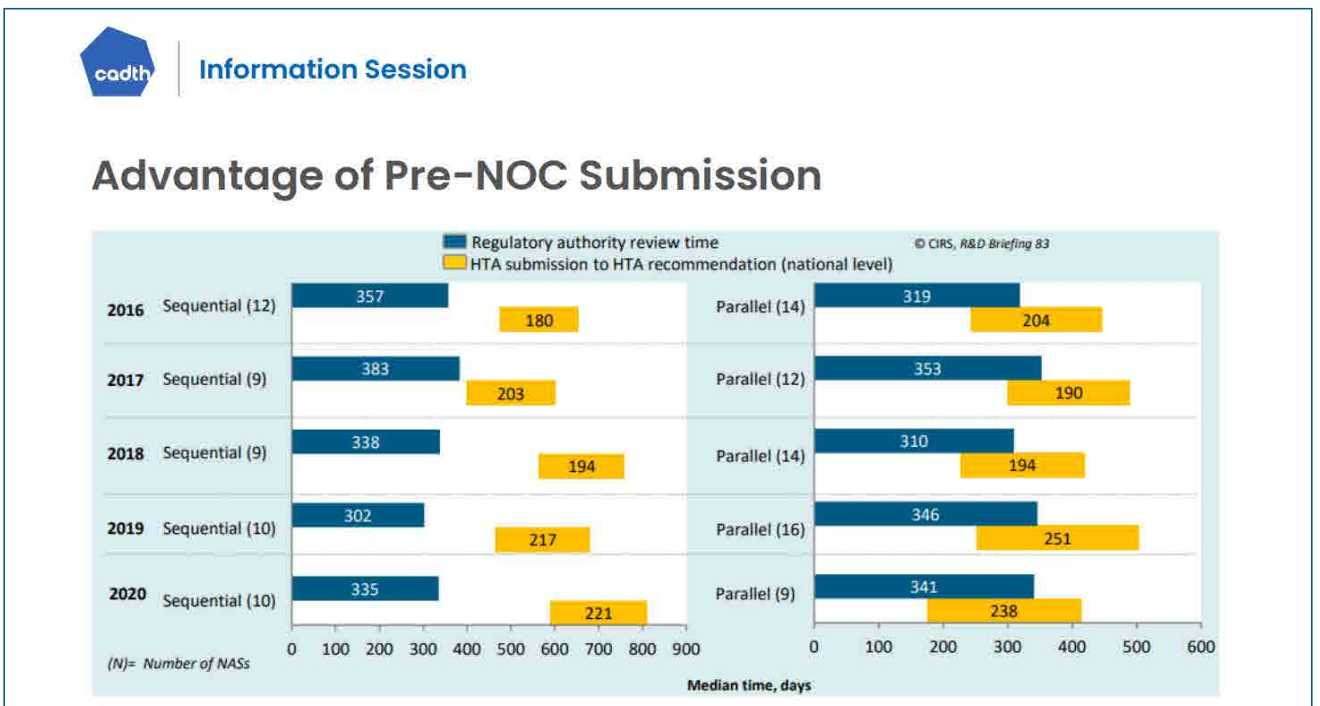
Australian HTA Policy and Methods Review

Data from HTADock (CIRS R&D Briefing 89) was presented by the Australian Department of Health and Aged Care in a paper on Australian market authorisation, funding and assessment pathways and timelines. This paper is part of a collection of expert papers that informed the recent HTA Policy and Methods Review in Australia, which is expected to make recommendationso the Australian Government in May 2024.

Data from HTADock (R&D Briefing 83) was cited by Brent Fraser, Vice President of Pharmaceutical Reviews, Canadian Agency for Drugs and Technologies in Health (CADTH), at the CADTH 2022 Information session.

This demonstrated the accelerated rollout time under the Health Canada/CADTH parallel review process compared to sequential review.

cadth | Information Session



CIRS metrics and the policy landscape

CIRS metrics have been used to track the impact of legislative changes and to inform the pharmaceutical policy landscape in several ways. Examples include:

- **Brexit**- CIRS data was used to inform important policy analysis on the implications of the UK leaving the EU (see this report by the Office of Health Economics (OHE) and its Technical Annex). CIRS has continued assessing the landscape of regulatory and HTA decision making following the exit of the UK from the EU through its HTADock database; an analysis of 'HTA Timelines and Outcomes for MHRA-Approved New Active Substances in the Post-Brexit UK via Reliance/Work-sharing Routes' was presented as a poster at ISPOR Europe 2023.
- **Orphan drug regulatory and HTA frameworks**- As the European Commission (EC) is currently reforming the legislative framework for the pharmaceutical industry, including regulatory incentives for orphan drugs, CIRS felt it timely to bring drug stakeholders together in a workshop to evaluate review and reimbursement frameworks for rare disease treatments. CIRS metrics illustrating the international rollout of orphan medicines as well as HTA processes, recommendations and funding for orphan medicines, were presented during the workshop, helping to set the scene for discussions around how to improve development, regulatory and reimbursement frameworks for rare disease products (see the workshop report).
- **Orphan drug regulation** - CIRS is currently supporting the National Academy of Sciences, Engineering and Medicines on a study on processes for evaluating the safety and efficacy of drugs for rare diseases or conditions in the US and the EU. This study was commissioned by the US Food and Drug Administration in response to a Congressional request. The resulting report is expected to form the basis of recommendations for future legislative changes and collaborative regulatory efforts.

Other metrics programmes by CIRS

CIRS collects metrics relating to company performance through two industry benchmarking programmes focusing on growing and emerging regulatory agencies, as well as major HTA agencies, where confidential reports containing unique insights are delivered to company participants. In addition, with support from the Bill and Melinda Gates Foundation and US Pharmacopeia, CIRS is facilitating global regulatory strengthening through the Optimising Efficiencies in Regulatory Agencies (OpERA) programme. This helps regulators of any size or maturity to integrate a practice of tracking their performance metrics and promoting continuous improvements while ensuring safety, efficacy and quality.

Future metrics work

CIRS will continue and extend its solid foundation in metrics for the 2024-2026 research cycle. This includes expanding CIRS metrics to other agencies globally (where public data is available); assessing the impact of new ways of working, such as novel methods of evidence generation and digital health technologies; the impact of legislative changes, such as the EU HTA Regulation and US Inflation Reduction Act; and identifying metrics for a potential research programme on vaccines.

2023 Journal Publications

1. **Wang T, McAuslane N**, Goettsch WG, Leufkens HGM, De Bruin ML. Regulatory, health technology assessment and company interactions: the current landscape and future ecosystem for drug development, review and reimbursement. Int J Technol Assess Health Care. 2023;39(1):e20. Published 2023 Apr 11.

   https://cirsci.org/publications/regulatory-hta-and-company-interactions-the-current-landscape-and-future-ecosystem-for-drug-development-review-and-reimbursement/

2. Owusu-Asante M, Darko DM, **Walker S**, Salek S. Assessment of the effectiveness and efficiency of the economic community of West African States Medicines Regulatory Harmonization initiative by the pharmaceutical industry. Front Pharmacol. 2023;14:1184108. Published 2023 May 9. doi:10.3389/fphar.2023.1184108

   https://cirsci.org/publications/assessment-of-the-effectiveness-and-efficiency-of-the-west-africa-medicines-regulatory-harmonization-initiative-by-the-pharma-industry/

3. Mashingia J, Ngum N, Ndomondo-Sigonda M, **Kermad A, Bujar M**, Salek S, **Walker S**. Regulatory performance of the East African Community joint assessment procedure: The way forward for regulatory systems strengthening. Regul Toxicol Pharmacol. 2023;140:105383. doi:10.1016/j.yrtph.2023.105383

   https://cirsci.org/publications/regulatory-performance-of-the-east-african-community-joint-assessment-procedure-the-way-forward/

4. **McAuslane N, Bujar M**, Sithole T, Ngum N, Owusu-Asante M, **Walker S**. Evaluation of Risk-Based Approaches to the Registration of Medicines: Current Status Among African Regulatory Authorities. Pharmaceut Med. 2023;37(3):251-260. doi:10.1007/s40290-023-00472-0

   https://cirsci.org/publications/evaluation-of-risk-based-approaches-to-the-registration-of-medicines-current-status-among-african-regulatory-authorities/

5. Rohr UP, Iovino M, Rudofsky L, Li Q, Juritz S, Gircys A, Wildner O, **Bujar M**, Bolte C, Dalla Torre di Sanguinetto S, Wolfer A. A decade comparison of regulatory decision patterns for oncology products to all other non-oncology products among Swissmedic, European Medicines Agency, and US Food and Drug Administration. Clin Transl Sci. 2023;16(9):1569-1581. doi:10.1111/cts.13567

   https://cirsci.org/publications/a-comparison-of-regulatory-decision-patterns-for-oncology-products-to-all-other-non-oncology-products-among-swissmedic-ema-and-fda/

6. Danks L, Semete-Makokotlela B, Otwombe K, Parag Y, **Walker S**, Salek S. Evaluation of the impact of reliance on the regulatory performance in the South African Health Products Regulatory Authority: implications for African regulatory authorities. Front Med (Lausanne). 2023;10:1265058. Published 2023 Oct 23. doi:10.3389/fmed.2023.1265058

   https://cirsci.org/publications/impact-of-reliance-on-the-regulatory-performance-of-the-south-african-health-products-regulatory-authority/

7. **Bujar M**, Dalla Torre di Sanguinetto SA, **Kermad A**, Bolte C, **McAuslane N**. An Evaluation of the Swissmedic Regulatory Framework for New Active Substances. Ther Innov Regul Sci. 2024;58(1):153-165. doi:10.1007/s43441-023-00581-7

   https://cirsci.org/publications/evaluation-of-the-swissmedic-regulatory-framework-for-new-active-substances/

2023 R&D Briefings

1. CIRS (2023) R&D Briefing 87 – A roadmap for regulatory strengthening: CIRS tools for measuring and optimising regulatory performance to support practices in line with the World Health Organization (WHO) Global Benchmarking Tool (GBT) indicators. Centre for Innovation in Regulatory Science (CIRS), London, UK.

   https://cirsci.org/publications/cirs-rd-briefing-87-a-roadmap-for-regulatory-strengthening-cirs-tools-for-measuring-and-optimising-regulatory-performance/

2. CIRS (2023) R&D Briefing 88 – New drug approvals in six major authorities 2013–2022: Focus on orphan designation and facilitated regulatory pathways. Centre for Innovation in Regulatory Science (CIRS), London, UK.

   https://cirsci.org/publications/cirs-rd-briefing-88-new-drug-approvals-in-six-major-authorities-2013-2022-focus-on-orphan-designation-and-facilitated-regulatory-pathways/

3. CIRS (2023) R&D Briefing 89 – Review of HTA outcomes and timelines in Australia, Canada and Europe 2018 -2022. Centre for Innovation in Regulatory Science (CIRS), London, UK.

   https://cirsci.org/publications/cirs-rd-briefing-89-review-of-hta-outcomes-and-timelines-in-australia-canada-europe-and-the-uk-2018-2022/

4. CIRS (2023) R&D Briefing 90 – Challenges and opportunities for orphan medicines availability in Mexico. Centre for Innovation in Regulatory Science (CIRS), London, UK.

   https://cirsci.org/publications/cirs-rd-briefing-90-challenges-and-opportunities-for-orphan-medicines-availability-in-mexico/

2023 conference presentations

6th – 8th March 2023, DIA Latin America Regulatory Conference

1. Dr Lawrence Liberti - Speaker – Latin American Systems to Enable Reliance (LASER-II) project
2. Dr Mario Alanís Garza - Speaker – The journey of ICH implementation in LATAM and opportunities for further harmonisation

22nd – 24th March 2023, DIA Europe

3. Dr Magda Bujar and Dr Neil McAuslane – Facilitators – Pre-Conference Workshop on "Regulatory System Innovation through Collaboration and Reliance"
4. Dr Neil McAuslane – Speaker - International Collaboration: Reliance in Action
5. Dr Neil McAuslane – Speaker - Expedited pathways, will Europe and UK be part of Innovation?
6. Dr Tina Wang – Chair - Utilisation of RWE/RWD in Regulatory and HTA Decision Making For Early Access Medicine: Learnings and Opportunities

10th-12th May 2023, RAPS Euro Convergence

7. Dr Magda Bujar - Chair – Regulatory policies and guidelines – are these enabling timely development of Orphan medicines globally?

25th – 29th June 2023, DIA Global Annual Meeting

8. Dr Neil McAuslane - Panelist - Regulatory Reliance: Addressing Gaps to Harmonise and Enhance Uptake Globally
9. Adem Kermad - Poster – Measuring time to market for new medicines in 7 Asian countries between 2016-21, following review by US FDA or EMA
10. Prof Stuart Walker – Poster - A comparison of the Regional Medicines Regulatory Harmonisation Projects in East, West and Southern Africa
11. Lorraine Danks – Poster - Evaluation of the impact of reliance on the regulatory performance in the South African Health Products Regulatory Authority
12. Mercy Owusu-Asante – Poster - Evaluation of the Regulatory Review Process of the FDA Ghana: Challenges and Opportunities for Improvement
13. Nancy Ngum – Poster - Evaluation of the Effectiveness and Efficiency of Ten Years' Experience with the East Africa Community Joint Assessment

24th – 28th June 2023, HTAi Annual Meeting

14. Dr Tina Wang - Speaker – A comparison of HTA recommendations in Australia, Canada and England: Is there opportunity for further alignment?

23rd-24th August 2023, 9th African Medicines Regulators Conference (AMRC)

15. Prof Stuart Walker – Speaker – CIRS Studies in Africa: Challenges and Opportunities

12th-15th September 2023, 5th Africa Regulatory Conference

16. Prof Stuart Walker – Chair - Navigating the Maze: simplifying the path to efficient national registration of medicinal products

23rd – 25th October 2023, TOPRA Annual Symposium

17. Dr Tina Wang – Speaker - Health Technology Assessments: the new EU regulation

8th – 10th November 2023, Asian Federation for Pharmaceutical Sciences

18. Dr Magda Bujar – Speaker - Approaches to implementing reliance to ensure timely availability of medicines: What is the role of regulatory science and collaboration in shaping policies and regulations?

12th- 15th November 2023, ISPOR Europe

19. Dr Belén Sola - Poster - Study of HTA Timelines and Outcomes for MHRA-Approved NASs in the Post-Brexit UK via Reliance/Worksharing Routes

5th - 7th December 2023, 6th Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA VI)

20. Prof Stuart Walker – Speaker - Evaluation of Risk-Based Approaches to the Registration of Medicines: Current Status Among African Regulatory Authorities
21. Dr Tariro Sithole – Speaker - A Comparison of the Regional Medicines Regulatory Harmonisation Projects in East, West and Southern Africa
22. Lorraine Danks – Speaker - Evaluation of New Medicines in SAHPRA's Backlog Clearance Project: The Impact of Reliance on Regulatory Performance
23. Mercy Owusu-Asante – Speaker - Evaluation of the Regulatory Review Process of FDA Ghana: Challenges and Opportunities for Improvement

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.

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