CIRS Centre for Innovation in Regulatory Science

2022 Annual Report

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CIRS Centre for Innovation in Regulatory Science

Contents

Glossary

ARCSA	Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (Ecuador's medicine regulatory agency)
ANVISA	Agência Nacional de Vigilância Sanitária (Brazilian health regulatory agency)
ATMPs	Advanced therapy medicinal products
BMGF	Bill & Melinda Gates Foundation
CADTH	Canadian Agency for Drugs and Technologies in Health
CARPHA	Caribbean Public Health Agency
CIRS	Centre for Innovation in Regulatory Science
CRS	Caribbean Regulatory System
DHTs	Digital health technologies
DIA	Drug Information Association
GBT	Global Benchmarking Tool
HTA	Health technology assessment
HTAi	Health Technology Assessment International
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultations
NAS	New active substance
OpERA	Optimising Efficiencies in Regulatory Agencies
PAHO	Pan American Health Organization
PBAC	Pharmaceutical Benefits Advisory Committee (Australia)
RAPS	Regulatory Affairs Professionals Society
RWD	Real-world data
RWE	Real-world evidence
R&D	Research and development
SAC	Scientific Advisory Council
TGA-PBAC	Therapeutic Goods Administration (Australia)
TOPRA	The Organisation for Professionals in Regulatory Affairs
WHO	World Health Organization
UMBRA	Unified Methodologies for Benefit-Risk Assessment

Foreword

Welcome to the Annual Report for my first full year of service as Head of the Centre for Innovation in Regulatory Science (CIRS). What a year it has been! The degree to which I have been warmly welcomed into this community has been overwhelming, and I appreciate every interaction I've had since joining in July 2021.

In 2022, CIRS has continued to deliver on its 2021–2023 Agenda, applying our pillars of Metrics, Quality, and Alignment to the topics of Globalisation, New Ways of Working, and Outcome Metrics. As the world moves on beyond the COVID pandemic and back to in-person meetings, I have had the opportunity to engage with many of our stakeholders from companies and Regulatory/HTA agencies during my first Scientific Advisory Council (SAC) Meeting and Multi-stakeholder Workshop in Washington DC, as well as our Regulatory and HTA Fora and Industry Discussion Meetings in London. The passion and energy during these meetings can only be properly experienced with everyone in the same room!

As the pandemic abates (we hope!), the landscape has evolved and provided ample novel opportunities for all players in the ecosystem. CIRS is well placed to help stakeholders maximise the positive changes that have been catalysed by this unexpected event.

This Annual Report provides a brief snapshot of our work in the Regulatory and HTA policy space. It includes details of our Multi-stakeholder Workshops, Technical Fora, Industry Discussion Meetings, Impact Case Studies from Regulatory and HTA workstreams, as well as highlights of new initiatives such as the SAC Topic Groups, which have been instituted temporarily to generate ideas for the upcoming 2024–2026 CIRS Research Agenda. Our focus for 2023 is to formalise and communicate the future Agenda – many of our present areas of research will continue, as well as bringing in some new areas of interest that are relevant to all our stakeholders.

As we approach the end of Q1 2023, I am full of hope and excitement for the future and CIRS' continued role in shaping it. I would like to encourage all our participating Agencies and Member Companies to continue to engage with our research and events in 2023, as well as reaching out to our Senior Leadership, two of whom have a spotlight in the Annual Report, to share insights and ideas on how CIRS can support your organisational goals and objectives going forward.

I am hugely grateful to my staff and contractors, our Committees, participating Agencies/Academic Groups, and Member Companies for your continued trust, investment, support and collaboration over the last year, and look forward to our continued success in 2023.

Anna Somuyiwa
Head of CIRS

asomuyiwa@cirsci.org

Spotlight on Senior Managers

Dr Magda Bujar, Senior Manager, Regulatory Programme and Strategic Partnerships

Background: Magda is a scientist by background and received her BSc in Biochemistry from the University of Bristol and MSc in Biochemical Engineering from UCL. She joined CIRS in 2013 and is now responsible for developing a strategy for the regulatory programme, overseeing its implementation through projects and interactions with pharmaceutical companies and regulatory authorities. She also received a PhD from the University of Hertfordshire, which was co-supervised by CIRS, and focused on quality decision-making during the lifecycle of medicines.

Interests: Magda's interests include evidence- and metric-driven regulatory strengthening to decrease health inequalities, improving decision-making transparency, as well as supporting regulatory harmonisation. She feels passionate about scientific communication and has co-authored articles in over 20 peer-reviewed journals, books, briefings and reports. At CIRS she supports the organisation of workshops and fora and is also a member of the RAPS Euroconvergence Committee. She enjoys presenting her research and has chaired and spoken at DIA and TOPRA conferences, as well as presenting to the ICH Management Committee on a study undertaken for ICH on Guideline Implementation. She has also lectured at the University of Hertfordshire on decision-making science, strategy and quality, and presented on regulatory science trends and professional experiences at the University of Freiburg and University Paris Saclay.

Fun fact: Magda is Polish, grew up in Belgium for a few years before moving to the UK. She is an adventurer at heart and loves to swim in icy pools and ponds in London, and dive with tropical fish on exotic holidays.

Dr Tina Wang, Senior Manager, HTA Programme and Strategic Partnerships

Background: Tina received her BSc in Chemistry from the Beijing University of Technology, and MSc in Pharmaceutical Analysis and Quality Control from King's College London. Tina joined CIRS in 2010, initially working in the regulatory sector, but soon moved into supporting the establishment of the new HTA programme. Tina now leads the CIRS HTA programme and is responsible for the development of research projects, stakeholder interactions and HTA strategies. Tina recently received her PhD from Utrecht University, focusing on "The evolution of practice and approaches for Health Technology Assessment".

Interests: Tina's main field of interest is international HTA policy and intelligence. Tina is passionate about bringing multiple stakeholders together to discuss, debate and advance healthcare policy. She has developed/co-developed numerous multi-stakeholder workshops to ensure alignment between the overarching regulatory and HTA vision, presenting at external conferences, engaging with industry members and leading strategic partnerships with agencies globally. Her approach is evidence-based, metrics and research-driven, to provide insight on policy changes and global initiatives. Tina is a member of longstanding international scientific societies and is a frequent speaker at various international conferences such as HTAi, ISPOR, and DIA.

Fun fact: Tina grew up in Wuhan near to the river Yangtze. When she first moved to London, she lived near the river Thames, which has a similar river scenery, and soon became her second home. Tina lives with her husband and two daughters in London. Having recently finished her PhD, she has more time for music (she plays the piano, guitar and Guzheng and is learning the harp), reading Kung-Fu novels and traveling with her family.

About CIRS

Mission

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 in developing and facilitating access to pharmaceutical products.

How we operate

CIRS is a neutral, independently managed UK-based subsidiary of Clarivate plc. We operate as a not-for-profit organisation, deriving funding from membership dues, related activities and grants to cover our operating and research costs.

We are governed by our own dedicated advisory boards made up of external international experts from academia, industry, regulatory agencies and HTA bodies. Our Scientific Advisory Council (SAC) and HTA Steering Committee advise on workshop topics and content as well as our research programme.

What makes us unique

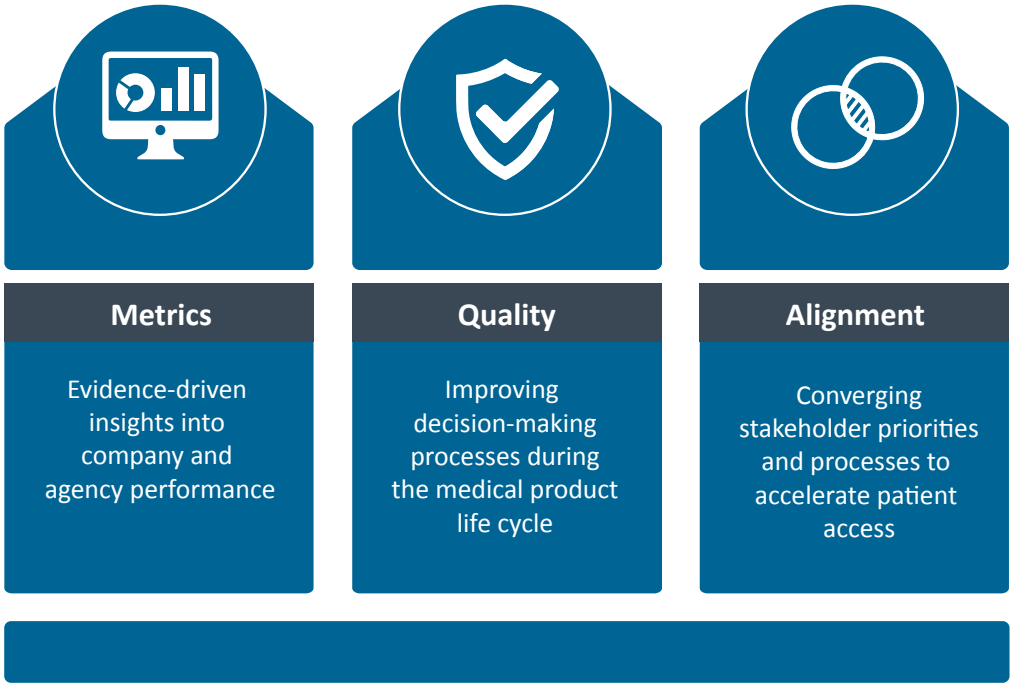
What sets us apart is our ability to bring **global** industry, regulators, HTA agencies, payers, patients and academics together in a **neutral** setting to identify and address key issues in the development, licensing and reimbursement of new medicines. We have been doing this for over 35 years through **focused** meetings and collaborative research.

Our workshops have consistently received positive feedback ratings of over 90% and resulted in recommendations that inform strategic and policy-level thinking. The strong support for our research as well as attendance in meetings demonstrates the trust and confidence our stakeholders have in us.

We are also **evidence-driven** and **transparent** in our work. The data we collect are used to support our workshops and we endeavour to make these publicly available through peer-reviewed journals or our R&D Briefings.

Our small but dedicated team of experienced scientists strive to ensure that the needs and priorities of our stakeholders are at the heart of CIRS activities. Our door is always open to new ideas and suggestions that fit with our mission.

Three pillars of CIRS activities



Metrics – evidence-driven insights into company and agency performance

CIRS provides unique insights and an independent viewpoint on the performance of companies, regulatory and HTA agencies through its metrics programmes. Data are collected and analysed to give a better understanding of regulatory and HTA assessment times and evidentiary requirements. This form of benchmarking details regulatory and HTA processes and practices, identifies where improvements can be made and informs company and agency strategies.

Quality – improving decision-making processes during the medical product life cycle

CIRS works with companies and agencies to evaluate the quality of their processes, identify challenges, and implement best practices. Tools developed from these projects support decision-making practices and their documentation in general or are specific to areas such as benefit-risk assessment. The aim is to foster learning and improve transparency, predictability and consistency of critical decisions during development, regulatory review and health technology assessment.

Alignment – converging stakeholder priorities and processes to accelerate patient access

Through collaborative research projects and multi-stakeholder workshops, CIRS promotes harmonisation and alignment across HTA agencies and regulators, as well as between HTA agencies and regulators themselves. Not only does this facilitate capacity building but also helps to enable more efficient and effective development of medicines.

Our Strategy

CIRS sets a rolling three-year strategy with input from the SAC and HTA Steering Committee. Our 2021-2023 programme, which will be achieved through workshops, fora and research projects, is grouped around three strategic themes:

- **Globalisation/regionalisation, reliance, trust**
- **Outcome metrics**
- **New ways of working**

Find out more about our strategy and plans for 2023 in the CIRS Agenda

CIRS Centre for Innovation in Regulatory Science

In 2022 **CIRS** continued to deliver for its stakeholders

8
Journal Publications

3
CIRS R&D Briefings*

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

* Listed on p16
** Listed on p10

18
Conference presentations

Insight meetings

30
For companies

24
For agencies

613
New LinkedIn followers

4
PhD students supported by CIRS

CIRS Centre for Innovation in Regulatory Science

2022 highlights

Assessing new ways of working industry survey

CIRS has been actively monitoring the changes to the regulatory environment across new product types, sources of evidence and digital technologies, focusing on 12 major agencies in Asia, Africa, the Americas, Europe and the Middle East. In 2022, 18 member companies responded to a CIRS survey on this topic, with results presented at the CIRS Regulatory Technical Forum, to gather company perceptions on the evolving landscape that are taking place across ATMPs, DHTs and RWD/RWE globally as well as capture how companies are adapting and addressing current and future challenges. CIRS also initiated a work on a parallel survey of regulators with main study and findings planned in 2023.

Engaging HTA agencies in performance metrics for decision-making

CIRS continued working with the global HTA community to support an effective and efficient decision-making process. In 2022, CIRS actively engaged with HTA agencies from Australia, Canada and Europe to update and review the methodology of the annual benchmarking study: HTADock. The output from the HTA agency discussion meeting led to the refinement of our **2022 HTA Briefing**, which assessed the impact of regulatory review type on HTA, and the resubmission status of HTA for new medicines.

CIRS HTA Industry Metrics programme marks its 12th anniversary

Initiated 12 years ago in collaboration with CIRS Member Companies, the CIRS HTA Industry Metrics Programme addresses key business questions for HTA strategy from development through to market access. This annual programme tracks over 200 compounds during their life cycle and provides insight on the impact of HTA in the development and jurisdictional roll-out strategy.

The 2022 study shed light on the current approaches of seeking early HTA advice, and utilising RWE in HTA submissions. The ongoing metrics programme also provides a framework to assess the impact of future HTA policy changes, such as EU HTA Regulation.

CIRS global regulatory strengthening OpERA programme marks its 10th anniversary

2022 marked the 10th anniversary of the CIRS Optimising Efficiencies in Regulatory Agencies (OpERA) programme and the end of the second three-year grant from the BMGF to support this work. Between 2020 and 2022, OpERA has supported 35+ authorities, with more than 20 publications, which can be found here, five CIRS-led regulators' fora, as well as presentations at over 15 major scientific conferences. In 2022, BMGF also renewed the support for the OpERA 2023–2025 programme with a focus on publishing CIRS metrics and tools to improve national and regional processes, support implementation of risk-based approaches and demonstrate compliance with specific WHO GBT indicators.

Risk-based approaches agency survey

CIRS has played a key role in supporting the implementation of risk-based approaches such as reliance, work-sharing and collaborative projects to facilitate approval of medicines. In 2022, CIRS undertook a study across 32 regulatory authorities in Asia, Africa, the Americas and Middle East to identify which risk-based models agencies have been using, determine what frameworks and approaches agencies have in place to enable a risk-based approach and provide insight into the future direction for risk-based models. The results were shared with participants and CIRS member companies at a CIRS workshop in 2022 and a publication was submitted to a journal.

SAC Topic Groups pilot

In 2022, our advisory committees saw the introduction of Topic Groups. These are temporary, time-limited groups of 10 or fewer members from the SAC, HTA Steering Committee or Member Companies, tasked with reviewing the landscape for Expedited Pathways and HTA, Patient Engagement and the CIRS Metrics Pillar to generate ideas for our 2024–2026 Agenda. The output of these groups will be shared with the membership and other stakeholders in due course.

CIRS Virtual Workshop 9th – 10th March 2022

How has the pandemic accelerated the acceptance and utility of RWD/RWE in regulatory/HTA decision making?

This workshop provided a platform for discussion on the changing data landscape and provision of fit-for-purpose data for regulatory and HTA decision making, with a focus on use of RWD/RWE. The aim was to recommend stakeholder and collaborative activities to enable both alignment and utilisation of RWD/RWE by HTA agencies, regulators and payers for decision making during a medicine's life cycle.

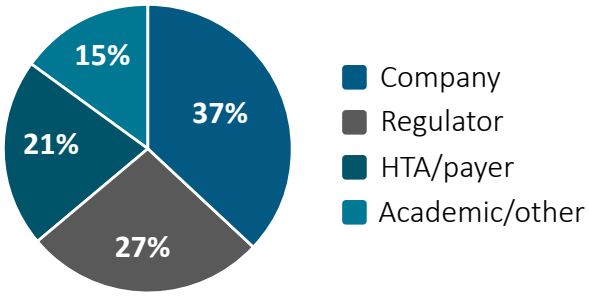
The recommendations and feedback from the multi-stakeholder workshop can be amalgamated into three potential roles for CIRS: Research that supports RWD/RWE definitions, standards, methodologies, usability by different stakeholders and jurisdictions; Multi-stakeholder engagement to increase alignment, capacity and learning; and case studies/monitoring/metrics on the utilisation of RWD/RWE.

Download the workshop report

"Great range of speakers and well selected topics for the breakout sessions. Breadth and depth of the workshop was impressive. Created real dialogue."

Industry participant

150+ attendees from 26 countries



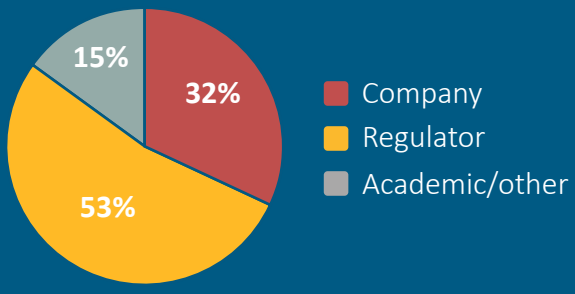
CIRS Virtual Workshop 5th – 6th July 2022

Collaborative models: How do these fit into the regulatory agency toolkit?

Collaborative models, including information sharing, work sharing and regionalisation, can add value as agencies are challenged, not just with the learnings from the last two years but also with the pace of change with new technologies, innovations and increasingly complex products. The aim of this workshop was to discuss how collaborative models add value to a jurisdiction's regulatory toolkit. In addition, understanding the challenges and how such models need to evolve to ensure timely patient availability of medicines for unmet need were addressed during this workshop.

The outcomes include discussions on the future regulatory toolkit: it must be collaborative, with reliance in action to promote better use of global regulatory resources and should evolve to include a wide range of models, next-level collaboration and technology to unlock efficiencies. Further research should focus on successes and barriers to date; defining and obtaining consensus on the principles of risk-based approaches.

150+ attendees from 46 countries



"The workshop was very stimulating and has provided tremendous insight into the landscape of risk-based regulatory registration; approaches, models, benefits, shared successes, challenges and the way forward."

Regulatory agency participant

CIRS Washington DC Workshop 22nd – 23rd September 2022

Building on the Regulatory and HTA agilities for high unmet need: Has the development, review and HTA assessment for priority treatments changed?

Regulatory and HTA agilities deployed during the pandemic to ensure the continued smooth functioning of regulatory and reimbursement systems should be built on in order to reduce redundancies. The aim of this workshop was to discuss which processes and practices instigated during the pandemic, in the development, regulatory review and HTA assessment of COVID-19 treatments are sustainable. The key question is whether they can be extrapolated to treatments for high unmet need within other disease areas.

Outcome of discussions were focused in three key areas; retainment of enhanced communication between sponsors and agencies using structured pathways for iterative communication; changes to clinical trial design and conduct and areas that worked well; and regulatory and operation efficiencies identified which included value of engaging the public and use of reliance / facilitated pathways. All these activities helped to build flexibility into the process while maintaining public engagement and confidence.

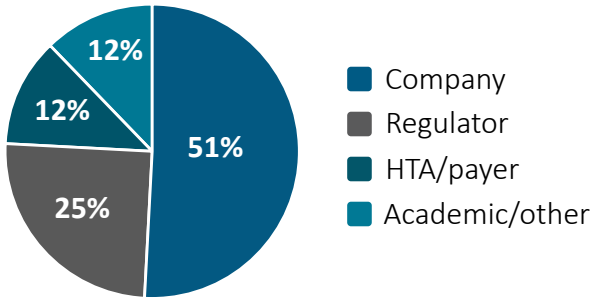
"It was an outstanding event, one of the best i've been at in years!"

Agency participant

"The meeting was exceptional. Timely and well run. Engagement was high, and a lot of side bar sessions that were very valuable. Many great ideas to advance."

Industry participant

62 attendees from 15 countries



Technical Forums for CIRS Member Companies

New product focus and evidence generation techniques – how are companies adapting to the evolving regulatory landscape and ensuring future convergence?

2nd November 2022

This meeting brought together 19 CIRS member companies to discuss the changes to the regulatory environment across ATMPs, DHTs and RWD/RWE globally. Companies shared insights and case studies on how they are integrating new sources of data and implementing novel evidence generation techniques, but also advocating for best practice and international convergence.

To help inform the forum discussions, CIRS presented the results of a pre-meeting survey, and held roundtable discussions to address future challenges and solutions for ATMPs, RWD and DHT.

"Very useful discussion & the insights into future state were very welcome"

Company participant

New ways of working for HTA agencies: Work-sharing, collaborations, reliance, and the policy implications for companies

15th December 2022

This forum provided a platform for 17 CIRS member companies to discuss the new ways of working for HTA agencies. Companies shared their current and future development of working with the European HTA Regulation: JSC, JCA, and jurisdictional implementation, as well as the recent initiatives outside Europe.

The meeting also discussed the potential influence on the companies' HTA strategy, how companies can proactively engage in the new ways of working, and how this collaboration can enable better evidence generation, HTA efficiency as well as improved outcomes for patient access.

Impact case study: Influence of regulatory initiatives on HTA decision making

CIRS has been actively monitoring the synchronisation of regulatory and HTA decision-making process. In response to the increasing demand for new medicines to address unmet medical need, regulatory agencies have developed flexible pathways to speed up the review process. In addition, regulators have begun working together to promote greater collaboration and alignment of regulatory process. Therefore, in 2022 CIRS reviewed the timing and HTA decisions outcomes for products which underwent two global regulatory initiatives: Access Consortium and Project Orbis.

The Access Consortium is a medium-sized coalition, which was formed by 'like-minded' regulatory agencies (Australia, Canada, Singapore, Switzerland, UK) to promote greater collaboration and alignment of regulatory requirements.

- As part of the work-sharing process, the regulatory agencies review different parts of the dossier.
- Each regulator makes an independent decision regarding market authorisation.

- This model of work-sharing is being monitored to determine if this could be a working model for other like-minded agencies to share resource both within and across regions

The **2022 HTA Briefing** provides more detail on metrics for parallel review in Australia and Canada, how it was operationalised within the context of Access, and the impact of Access on HTA decision making.

NASs approved by the Access Consortium and reviewed by national HTA agencies in Australia and Canada between 2018-2021

Product name	Therapeutic area	TGA-PBAC submission sequence	PBAC initial recommendation	Health Canada - CADTH submission sequence	CADTH initial recommendation
abemaciclib	Anti-cancer and immuno-modulators	Parallel	Positive	Parallel	Positive with restrictions
apalutamide	Anti-cancer and immuno-modulators	Sequential	Negative	Parallel	Positive with restrictions
avalglucosidase alfa	Alimentary and metabolism	Parallel	Negative	Parallel	Positive with restrictions
darolutamide	Anti-cancer and immuno-modulators	Sequential	Negative	Parallel	Positive with restrictions
isatuximab	Anti-cancer and immuno-modulators	Not reviewed as Access	Not reviewed as Access	Sequential	Positive with restrictions
niraparib	Anti-cancer and immuno-modulators	Sequential	Negative	Sequential	Positive with restrictions
tafamidis meglumine	Nervous system	Sequential	Negative	Not reviewed as Access	Not reviewed as Access

In Australia, Access products showed faster regulatory review whilst the HTA timing is fixed to committee meeting schedule. In Canada, the Access NASs were more likely to be submitted in parallel to HTA agencies during regulatory review

Proportionally, the Access NASs presented a lower percentage of NASs that received a positive/positive with restrictions recommendation by PBAC compared to non-Access, but received a higher percentage of positive/positive with restrictions when reviewed by CADTH

CIRS strategic pillar addressed:

Project Orbis is an initiative of the US FDA Oncology Center of Excellence that aims to give patients faster access to promising cancer treatments across the globe.

Project Orbis partners (Australia, Brazil, Canada, Israel, Singapore, Switzerland, UK) work together on the review of submissions for cancer drugs.

Orbis Type A:
where submission is largely concurrent with FDA

Orbis Type B:
where there is a >30-day delay from FDA to partner submission

Orbis Type C:
where submission occurs once FDA has already taken regulatory action

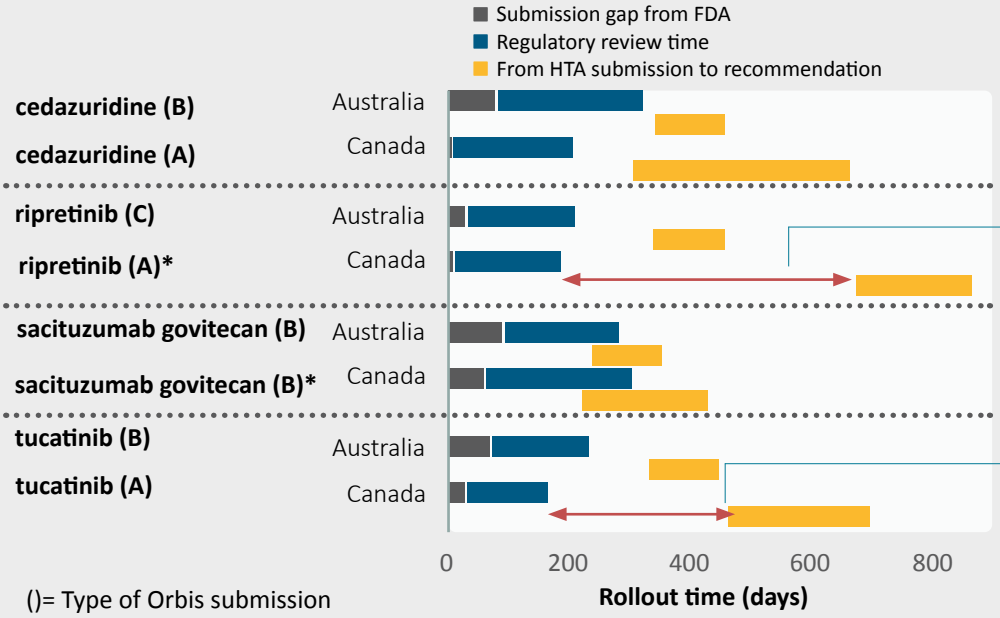
The **2022 HTA Briefing** analyses the products that underwent Project Orbis in Australia and Canada, in terms of the submission type, rollout time and their first HTA recommendation outcome.

In Australia, Orbis type B was most used, while in Canada, Orbis type A was used for 3 out of 4 products

All 4 Orbis products received a negative decision at the initial PBAC review in Australia, compared to restrictive HTA recommendation at Canada.

A long gap between regulatory approval to HTA submission was observed for Orbis type A products.

The regulatory approval and HTA recommendation for NASs approved by Project Orbis between 2018–2021



()= Type of Orbis submission

Longer submission gap for Orbis A products may suggest that companies were not ready to submit to HTA agencies when receiving the market authorisation.

Supporting Regulatory System Strengthening in Latin America

The Latin American (LatAm) region, encompassing Central America, the Caribbean, Mexico and South America, is seeing the growth and strengthening of its regulatory systems, however the process is hampered by slow movement towards regional and international alignment, heterogenous levels of competency and manpower, and limitations in implementing efficient reliance mechanisms.

CIRS has implemented a successful, bespoke strategy to address the diverse needs of the agencies in the region by implementing a variety of projects with participation from agencies and companies designed to highlight opportunities for regulatory system strengthening and process optimisation. These include:

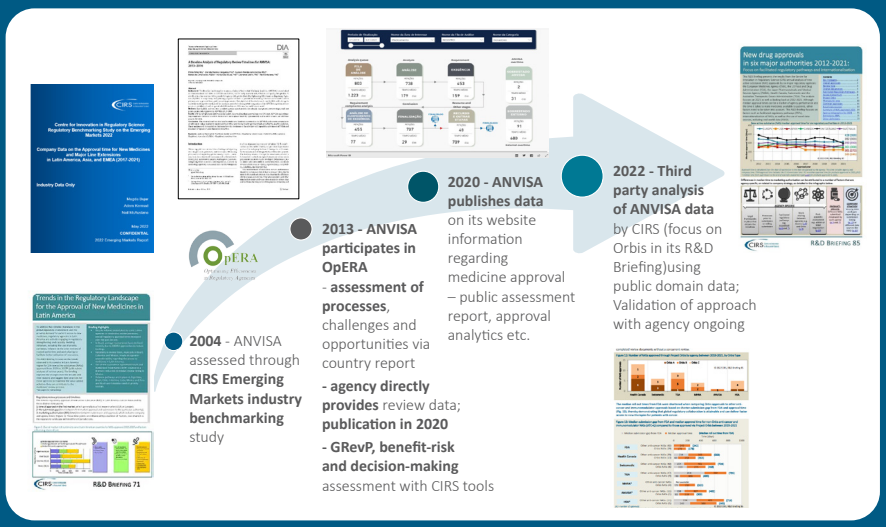
The LASER Project (Latin American Systems to Enable Reliance): Now in its third year, CIRS has, with the detailed input and contributions of the research-based industry, landscaped the LatAm regulatory agencies to understand their capacity, capabilities and willingness to implement and use reliance pathways for the authorisation of medicines. Based on the findings of LASER-1, LASER-2 has been designed and completed and is identifying the barriers and facilitators to using reliance across 13 LatAm countries. Results will be shared with the agencies to highlight opportunities for optimisation.

Optimising Efficiencies in Regulatory Agencies (OpERA) programme
CIRS has played a key part in this by giving the LatAm regulators and regional regulatory initiatives the tools to measure efficiency and effectiveness of national agencies and regional bodies. This has allowed barriers and opportunities for improvement to be identified and helped to embed a culture of ongoing performance monitoring and self-assessment in ways that are consistent with and supportive of the agencies' efforts to comply with WHO GBT indicators and subindicators.

OpERA national example: ANVISA: CIRS has worked with the Brazilian agency to analyse processes, and timelines and support the agency in ensuring transparency. In 2022 the focus was on utilising Brazil's publicly available information to evaluate their performance.

OpeRA regional example: (CRS)/ CARPHA: Building on the ongoing OpERA annual assessment of CRS, which is published in the PAHO Annual Report, CIRS initiated a project to evaluate barriers to member state uptake of centrally approved products in the CRS. Working with the CRS in 2022, CIRS has developed a protocol which we hope to implement in 2023 that will seek input from Caribbean member states to understand what barriers are limiting the widespread use of the centralised CRS decisions.

Case study: Brazil's progress on transparency and optimising its regulatory efficiencies



OpERA regional example: Central American Reliance: A centralised reliance joint registration process is available in the region; however, it has been met with limited success. This is in part due to a confusing mix of organisations that are seeking to impact the process. CIRS sees an opportunity to help align and accelerate the reliance process in the region based on interactions started in 2022.

LatAm impact case study: supporting the establishment of reliance and capacity training in Ecuador

The health emergency caused by COVID-19 led to a deep recession that had a major impact on growing poverty levels in Ecuador. Since mid-2021, the new government has initiated reforms aimed at returning Ecuador to a path of growth and shared prosperity.

Supporting the medicines regulatory environment of Ecuador could improve the availability of medicines for the Ecuadorian population. Better access to medicines can lead to a more prosperous, peaceful and healthier people.

Over the past two years, CIRS has worked on projects designed to help Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA, Ecuador's medicine regulatory agency) strengthen their regulatory systems and to optimise the use of reliance-based assessment procedures to facilitate availability of innovative medicines. The agency currently has limited resources and does not have a robust complement of regulatory procedures, skills and capabilities in place to provide the most effective and efficient regulatory support. This has resulted in delays in medicines reviews and approvals, an increased likelihood of poor-quality medicines entering the market, and delays in patient access to critical medicines.

The first project CIRS undertook (2021) focused on reviewing the regulations for the registration of biological medicines in LatAm and other key countries. Through this landscaping activity, CIRS used its OpERA tools to develop a comprehensive plan for how the agency could use regulatory reliance as an accelerated pathway to introduce innovative drugs and treatments.

The second phase of CIRS' ARCSA interaction (2022) provided capacity building and training sessions focused on regulatory reliance as an agency-wide efficiency tool. The programme aimed to promote efficiency thereby reducing timelines resulting in more timely access to medicines and treatments. By providing capacity-building plans the agency looks to improve their registration process of medicines by assessing and revising their internal procedures. The training addressed the following topics:

1. Regulatory optimisation, following international standards, priority pathways.
2. Reliance pathways and how to use them.
3. Benefit-risk assessment using the UMBRA tool.
4. Good review practices and the embeddedness survey.
5. Good manufacturing practices and their relationship to reliance.

Work is underway in 2023 to deliver capacity building sessions focused on the review of a case study on how to register an innovative biologic drug using a reliance and homologation as an optimised pathway to be used routinely by ARCSA.

Specific objectives:

1. Develop guidelines in Spanish containing technical approaches based on tools and experiences that will serve as a template focused on how to register the innovative biologic using reliance.
2. Promote the use of the guidelines as a reference by ARCSA staff.
3. Develop a training slide deck to support the understanding and use of the guidelines.

2022 journal publications

1. Sithole T, Mahlangu G, Walker S and Salek S (2022) Regulatory Authority Evaluation of the Effectiveness and Efficiency of the ZaZiBoNa Collaborative Medicines Registration Initiative: The Way Forward. Front. Med. 9:898743. https://cirsci.org/publications/regulatory-evaluation-of-the-efficiency-and-effectiveness-of-zazibona/

2. Sithole T, Mahlangu G, Walker S and Salek S (2022) Pharmaceutical Industry Evaluation of the Effectiveness and Efficiency of the ZaZiBoNa Collaborative Medicines Registration Initiative: The Way Forward. Front. Med. 9:898725. https://cirsci.org/publications/industry-evaluation-of-the-efficiency-and-effectiveness-of-zazibona/

3. Hashan HM, Al-Muteb SK, Alismail IA, Alsaleh ON, Alkherb ZM, McAuslane N, Walker SR. Evaluation of the Performance of the Gulf Cooperation Council Centralised Regulatory Review Process: Strategies to Improve Product Authorisation Efficiency and Quality [published online ahead of print, 2022 Jun 29]. Pharmaceut Med. 2022;10.1007/s40290-022-00432-0. https://cirsci.org/publications/evaluation-of-the-performance-of-the-gulf-centralised-registration-procedure/

4. Ngum N, Mashingia J, Ndomondo-Sigonda M, Walker S and Salek S (2022) Evaluation of the Effectiveness and Efficiency of the East African Community Joint Assessment Procedure by Member Countries: The Way Forward. Front. Pharmacol. 13:891506. https://cirsci.org/download/evaluation-of-eac-joint-assessment-by-member-states-ngum-2022/

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6. Owusu-Asante M, Darko DM, Asamoah-Okyere KD Asante-Boateng S, Kermad A, Walker S and Salek S (2022) Evaluation of the Food and Drugs Authority, Ghana Regulatory Review Process: Challenges and Opportunities. Ther Innov Regul Sci. doi.org/10.1007/s43441-022-00478-x https://cirsci.org/wp-content/uploads/dlm–uploads/2022/11/ GHANA-FDA-TIRS-PUBLICATION.pdf

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2022 R&D Briefings

1. CIRS (2022) R&D Briefing 84 – China's evolving regulatory landscape: what are the opportunities and challenges? Centre for Innovation in Regulatory Science (CIRS), London, UK. https://cirsci.org/publications/cirs-rd-briefing-84-chinas-evolving-regulatory-landscape/

2. CIRS (2022) R&D Briefing 85 – New drug approvals in six major regulatory authorities 2012-2021: Focus on facilitated regulatory pathways and internationalisation. Centre for Innovation in Regulatory Science (CIRS), London, UK. https://cirsci.org/publications/cirs-rd-briefing-85-new-drug-approvals-in-six-major-authorities-2012-2021/

3. CIRS (2022) R&D Briefing 86: Review of HTA outcomes and timelines in Australia, Canada and Europe 2017-2021. Centre for Innovation in Regulatory Science. London, UK. https://cirsci.org/publications/cirs-rd-briefing-86-hta-outcomes-in-australia-canada-and-europe-2017-2021/

2022 conference presentations

15th March 2022, DIA Latin America Regulatory Conference

1. Dr Mario Alanís Garza – Speaker – LatAm Systems to Enable Reliance: Best Practices and Recommendations
2. Dr Lawrence Liberti – Speaker – Opportunities for Greater Convergence in Latam

29th - 31st March 2022, DIA Europe

3. Dr Jenny Sharpe – Chair – Identifying and Managing Uncertainty During Drug Development to Improve Predictability of Regulatory and HTA Outcomes

6th – 13th April 2022, Global Pharmaceutical Regulatory Affairs Summit

4. Dr Mario Alanís Garza – Speaker – Pandemic Readiness: Lessons Learned from COVID-19 in Ensuring Regulatory Agility
5. Dr Mario Alanís Garza and Dr Lawrence Liberti – Speakers – Updates on Convergence & Reliance Efforts for LatAm

25th – 29th April 2022, BioHabana 2022 Congress

6. Dr Mario Alanís Garza – Speaker – Latin American Experience of Reliance: Challenges and Opportunities

10th – 12th May 2022, RAPS Euro Convergence

7. Dr Magda Bujar – Chair – Global Facilitated Regulatory Pathways for COVID-19
8. Dr Magda Bujar – Chair – Global Regulatory Outlook: How Will the Landscape Evolve and How Should Regulatory Professions Prepare?

19th – 23rd June 2022, DIA Global Annual Meeting

9. Dr Jenny Sharpe – Speaker – Meeting Regulatory Expectations: What Needs to be Considered When Using Digital Technologies to Generate Clinical Evidence
10. Dr Magda Bujar – Speaker – Regulatory Convergence Successes and Opportunities
11. Dr Magda Bujar – Chair – Approaches to Health Authority Collaboration – Are They Fit For Purpose and Should They Evolve Post Pandemic?
12. Dr Magda Bujar and Dr Lawrence Liberti – Poster – Relianomics: A Proposed Approach to the Assessment of the Societal, Economic, and Regulatory Impacts of Reliance Pathways

25th – 29th June 2022, HTAi Annual Meeting

13. Dr Belen Sola-Barrado, Dr Tina Wang, and Dr Neil McAuslane – Poster – Associations of orphan designation and other drug development-related factors on rollout time and health-technology-assessment recommendations of new-active-substances
14. Dr Belen Sola-Barrado, Dr Tina Wang, and Dr Neil McAuslane – Poster – The impact of parallel submission on the rollout time and health-technology- assessment recommendations of new- active-substances
15. Dr Tina Wang – Speaker – Interactions between regulatory, HTA and companies: A multi-stakeholder survey on the current experiences and future landscape evolvement

2022 APEC Good Registration Management Training Program

17th – 19th October 2022, TOPRA Annual Symposium

16. Dr Tina Wang – Speaker – Assessing the value of Innovative Therapies: Trends, Challenges, and Learnings
17. Dr Lawrence Liberti – Speaker – Using FRPs for Special Case Authorizations

8th – 11th November 2022 Mexican Association of Regulatory Affairs Professionals, A.C. (AMEPRES)

18. Dr Mario Alanís Garza and Dr Lawrence Liberti – Speakers – The Evolution of Reliance during COVID and on Regional Alignment Initiatives

Thank you to those we worked with in 2022

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About CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. CIRS provides an international forum for industry, regulators, Health Technology Assessment (HTA) and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to pharmaceutical products. 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, special projects and grants.

Keep in touch

Anna Somuyiwa, Head of CIRS — **asomuyiwa@cirsci.org**

Dr Magda Bujar, Senior Manager, Regulatory Programme and Strategic Partnerships — **mbujar@cirsci.org**

Gill Hepton, Administrator — **ghepton@cirsci.org**

Adem Kermad, Senior Research Analyst — **akermad@cirsci.org**

Juan Lara, Research Analyst — **jlara@cirsci.org**

Dr Neil McAuslane, Director — **nmcauslane@cirsci.org**

Dr Jenny Sharpe, Senior Scientific Writer — **jsharpe@cirsci.org**

Dr Belén Sola, Research Analyst — **bsola@cirsci.org**

Prof Stuart Walker, Founder and Senior Advisor — **swalker@cirsci.org**

Dr Tina Wang, Senior Manager, HTA Programme and Strategic Partnerships — **twang@cirsci.org**

Centre for Innovation in Regulatory Science (CIRS)
70 St Mary Axe, London EC3A 8BE, UK
Email: cirs@cirsci.org
Website: www.cirsci.org
www.linkedin.com/company/centre-for-innovation-in-regulatory-science-ltd/

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