CIRS Centre for Innovation in Regulatory Science

www.cirsci.org

Get Involved With CIRS

Regulatory Agencies & HTA Bodies

Introduction

The Centre for Innovation in Regulatory Science (CIRS) is an independent research organisation that provides a neutral 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 focus on improvements in policies and processes for pharmaceutical regulation and HTA. We also support the development of agency capacity.

We work collaboratively with stakeholders worldwide, running research projects and conducting meetings globally to feed into and build on this research.

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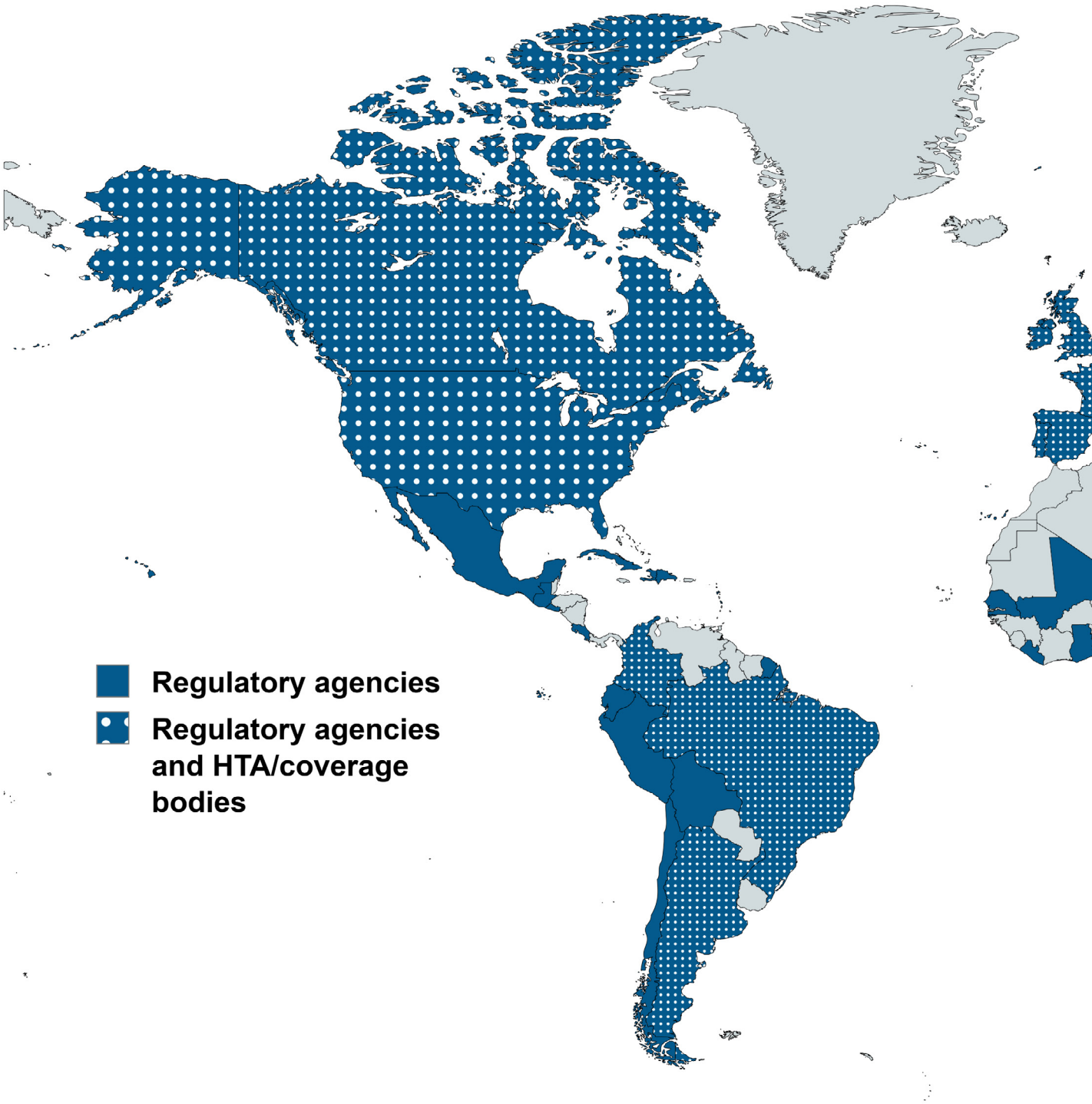
Why CIRS?

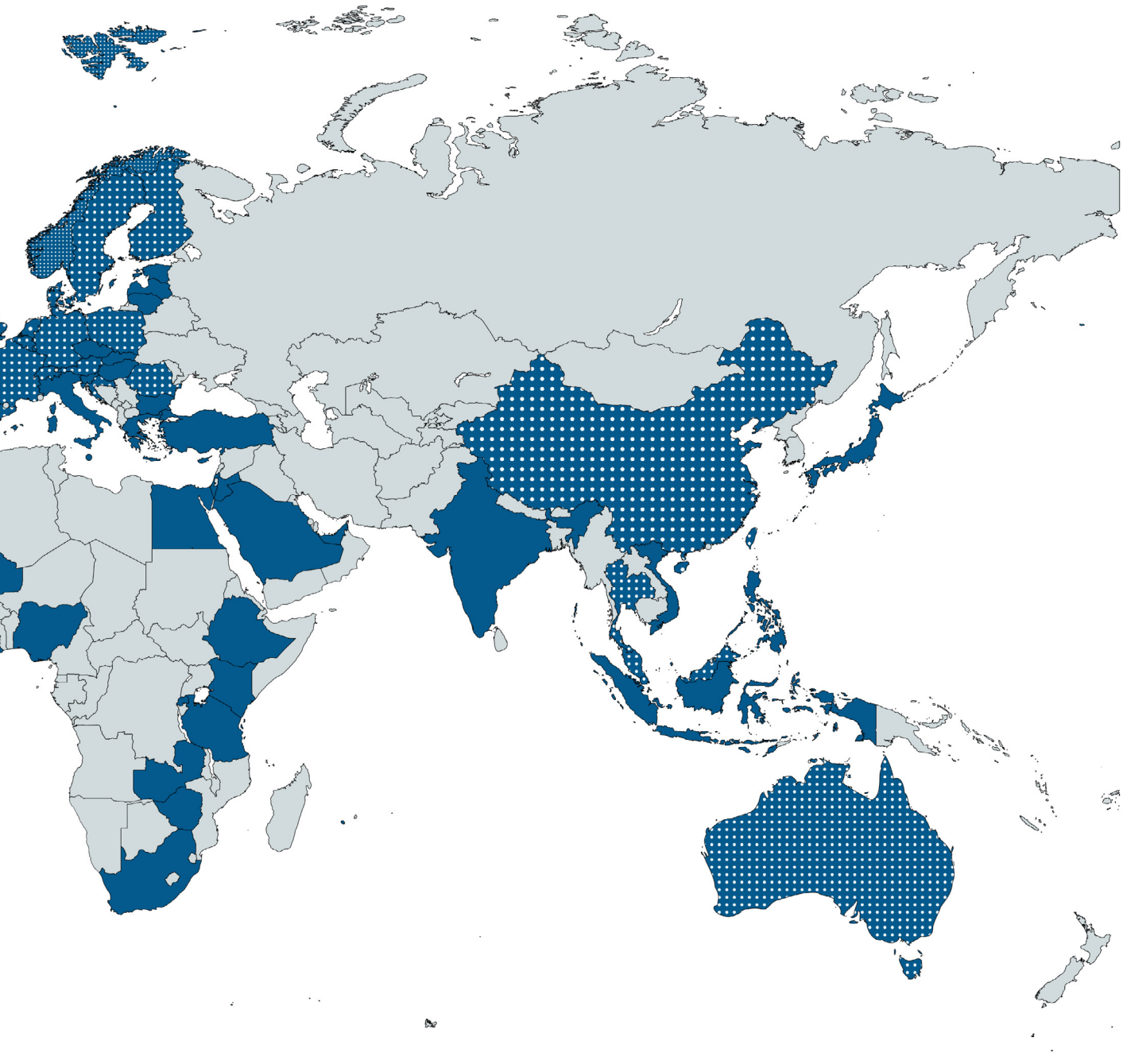
CIRS is a trusted source of regulatory and HTA insights and knowledge. For over 30 years we have worked with agencies of all sizes from around the world to facilitate change, either within their organisations or more widely in the regulatory and HTA landscape.

Agencies who engage with us become part of an international community sharing insights and knowledge through research, benchmarking metrics projects and multi-stakeholder activities such as workshops.

There is no fee for agencies to access our insights and tools, or to engage with our research activities (see CIRS Research Agenda for more information). Please note that participation in our workshops and other meetings is by invitation only.

Agencies engaging with CIRS





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May 2025

How can my agency get involved with CIRS?

Insights from CIRS research

CIRS regularly publishes insights from its research and meetings, which can help agencies to better understand the regulatory and HTA landscape and identify best practices. These insights are freely available on the CIRS website and take several forms:

- **R&D Briefings** – research papers produced by the CIRS team e.g. annual regulatory and HTA agency benchmarking briefings
- **Journal articles** – peer reviewed academic research papers (often co-authored with agencies)
- **Reports** – from CIRS workshops and externally commissioned research projects, as well as CIRS Annual Reports
- **Books** – research theses from CIRS-supported PhD students
- **Posters** – presented at external conferences

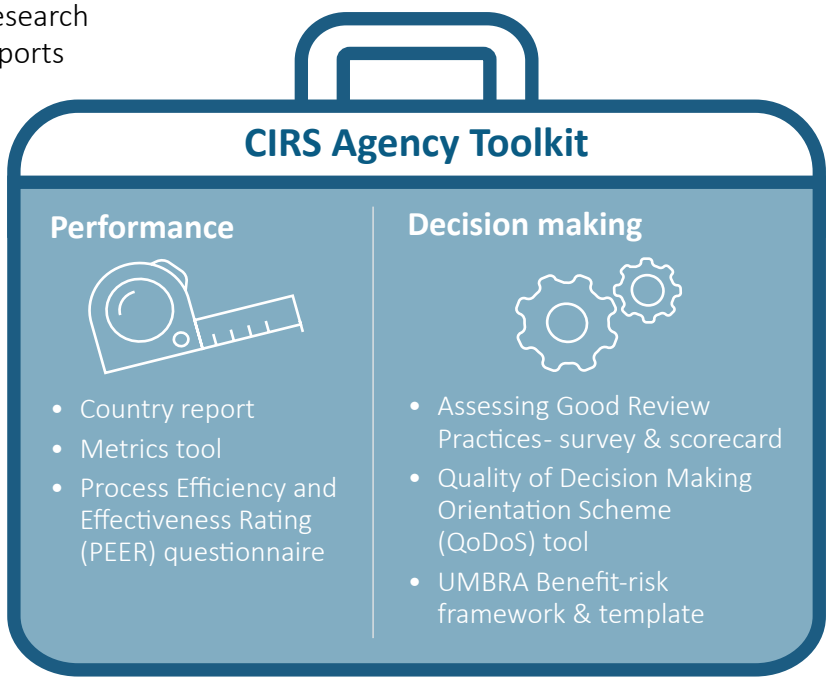
You can also be kept up to date with our latest research by signing up to our mailing list.

In addition, agencies an request access to the CIRS Regulatory and Reimbursement Atlas, which provides insights on the diverse global regulatory and reimbursement landscape.

Developed in collaboration with regulators, HTA agencies and payer organisations, Atlas illustrates the sequence of agency interactions in over 70 jurisdictions and the core functions of each agency involved.

CIRS tools to strengthen practices and processes

CIRS has developed and validated several tools in collaboration with regulatory and HTA agencies to enhance their internal practices and processes. These include metrics tools that provide evidence-based insights into agency performance, and tools to support decision making (see below). More information about these tools can be found on the CIRS website.



Participating in CIRS research

CIRS regularly conducts research using agency data, either collected from the public domain or directly from agencies. We have over 30 years' experience in doing this and where possible, work collaboratively with agencies to validate our methodologies and results.

Our metrics studies give an independent insight into agency performance and can be used to inform agency strategies and identify areas for improvement. This includes work under the Optimising Efficiencies in Regulatory Agencies (OpERA) Programme as well as our annual agency benchmarking studies that compare selected agencies with similar mandates and processes.

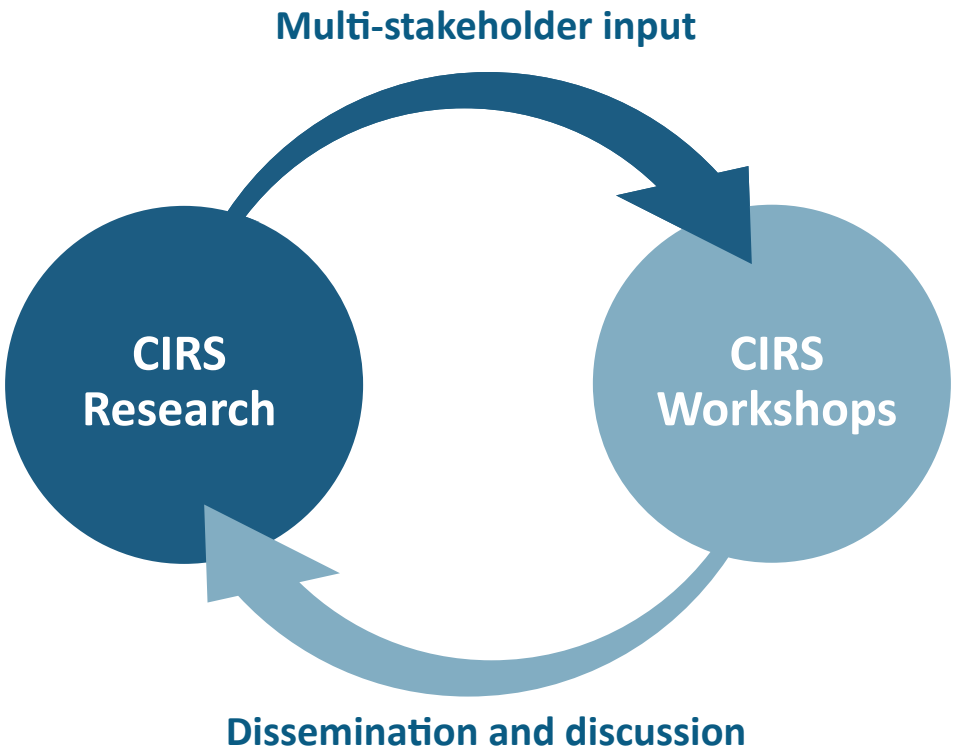
We also undertake survey-based research to understand agency perspectives and the challenges they are facing globally. This helps to inform the discussions at our workshops and meetings, as well as future research. For example, we recently surveyed agencies for their perspectives on the impact, measurement and future direction of patient engagement in regulatory and HTA decision making. Insights from this survey were shared and discussed at the October 2025 patient engagement workshop.

Participate in CIRS workshops and meetings

Engaging with other agencies and stakeholders in a safe harbour environment through CIRS workshops provides opportunities to understand the global policy landscape, raise issues and identify possible solutions. We also hold dedicated forums for only regulatory agencies and for HTA agencies.

To foster productive discussions, our meetings are kept small and focused, often featuring breakout sessions that are key to generating recommendations to help effect change in pharmaceutical policy. Due to this format, we must be selective about participants, basing invitations on the meeting topic, location and stakeholder balance. We make our workshop reports public so everyone can access the outcomes and recommendations.

Our research provides the evidence basis for our workshops and meetings, which in turn generate new ideas and areas for further research.



For information on current CIRS research activities and workshops see our Research Agenda.

Commissioning special projects

In addition to its core research activities, CIRS can be commissioned to undertake 'Special Projects' in collaboration with or on behalf of agencies. The aims, methods and outcome of each project can be adapted to meet agencies' unique needs and goals, such as to support internal strengthening efforts and promote best practices. For example, we have conducted studies in collaboration with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) to monitor the implementation and adherence to ICH guidelines by regulatory authorities.

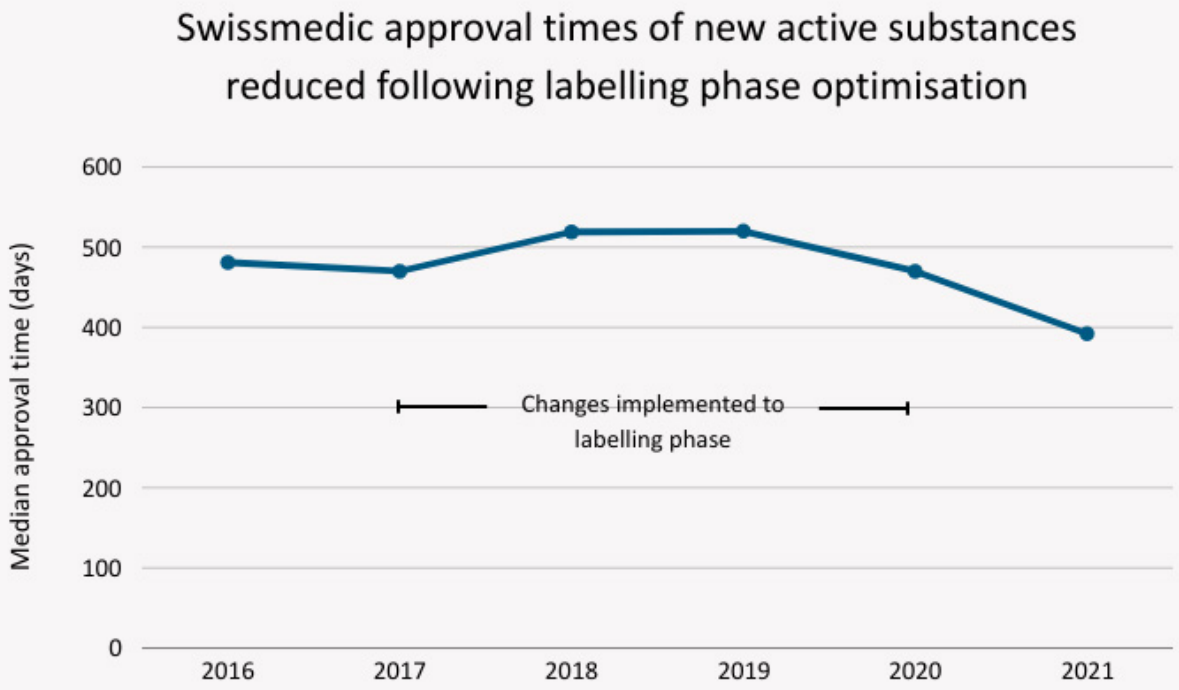
If your agency would like to get involved with CIRS, please speak to the Head of CIRS, Anna Somuyiwa: asomuyiwa@cirsci.org

CIRS Global Development Workshop, February 2025

Swissmedic case study: Performance measurement and continuous improvement

CIRS has a long-standing relationship with Swissmedic, the Swiss Agency for Therapeutic Products. From the late 1990s to early 2000s, we collaborated with Swissmedic and other major agencies to identify key milestones in the regulatory approval process and validate a benchmarking methodology that ensures like-for-like comparisons. This methodology has been refined over the years and is still used in our annual benchmarking study involving Swissmedic, the US Food and Drug Administration (FDA), European Medicines Agency (EMA), Japanese Pharmaceuticals and Medical Devices Agency (PMDA), Health Canada and Australian Therapeutic Goods Administration (TGA).

Swissmedic has an established culture of measuring its own performance through annual metrics collection and analysis. During the 2010s, Swissmedic's overall approval times were considerably longer than other those of the fastest agencies, despite similar scientific assessment times. Swissmedic was spending a relatively large amount of time in the labelling phase, which often involved multiple rounds of negotiation with applicants. To reduce time lost outside of the scientific assessment, Swissmedic made several changes between 2017-2020 to optimise and accelerate the labelling phase.



To verify whether these changes were effective, Swissmedic approached CIRS to undertake an independent evaluation of the agency's regulatory framework using CIRS tools. The retrospective analysis showed a reduction in median approval times for new active substances from 520 days in 2019 to 392 days in 2021. This was attributed to a shortening of the labelling phase, demonstrating that Swissmedic's changes were successful.

We continue to share and discuss insights from our annual benchmarking study with Swissmedic to better understand the context around observed approval trends and gather feedback for future analyses. The impact of collaborative pathways such as Project Orbis and the Access Consortium are of particular interest, as international collaboration to accelerate availability of innovative therapies is a strategic focus for Swissmedic.

In summary, performance metrics help agencies to understand their processes and identify process limitations and opportunities for improvement. Swissmedic continues to use metrics to regularly benchmark themselves and continuously improve their performance. CIRS has the tools and expertise to support agencies of any size or maturity on their metrics journey.

"Swissmedic highly appreciates the excellent collaboration with CIRS. As a regulator we play an important role in ensuring fast access for patients to innovative drugs in our country. Metrics on review times and submission gaps help us identify bottlenecks and ways to further improve our work."

Dr Eveline Trachsel, Head of Authorisation and Vigilance, Swissmedic, and member of the CIRS Scientific Advisory Council.

Pictured sharing Swissmedic's experience at the CIRS workshop in October 2024.

Frequently Asked Questions (FAQs)

How is CIRS funded?

CIRS operates as a not-for-profit organisation, deriving funding from industry membership dues, special projects, and grants from non-profits and governments to cover operating and research costs.

What is CIRS' relationship with Clarivate?

CIRS is a UK-based subsidiary of Clarivate plc and conducts research independently. We have our own dedicated management and advisory boards that provide direction for our Research Agenda. There is a firewall in place so that no confidential information, such as data, insights or contacts, is shared with Clarivate.

How does CIRS handle agency data?

CIRS understands the sensitivity of agency data and has over 30 years of experience handling such information. All data from regulatory and HTA agencies will remain strictly confidential. No identifying information will be publicly reported or shared with third parties without explicit written consent from the providing agency.

What makes CIRS unique?

What sets us apart is our ability to facilitate safe harbour discussions between multiple stakeholders involved in drug development and patient access to medicines. CIRS meetings are usually small, focused and build on discussions from previous meetings to enable continuous evolution of a topic. They also include breakout sessions, which are key to producing recommendations to help effect change.

We are 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 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.

What impact has CIRS had?

CIRS has a 30+ year history of helping to improve the regulatory and HTA landscape through its work in the areas of metrics, quality and alignment. For example, CIRS has laid the foundations for the development of practices for building quality into review and decision-making processes. This has helped to define Good Review Practices and increase the quality of processes by using structured frameworks and ensuring documentation. This is both for specific processes such as benefit-risk and for ensuring quality of decision making in general.

You can find out more about CIRS' impact in our Annual Reports.

How is the CIRS research agenda governed?

CIRS has its own dedicated advisory committees made up of external international experts from academia, industry, regulatory agencies, HTA bodies and payers, which ensure neutrality and that the CIRS Research Agenda meets all stakeholder needs. We set our three-year Research Agenda with input from the Scientific Advisory Council (SAC) and HTA Steering Committee, as well as feedback from companies and agencies. Please see the CIRS website for current lists of committee members.

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 identify and apply 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. 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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