CIRS Centre for Innovation in Regulatory Science

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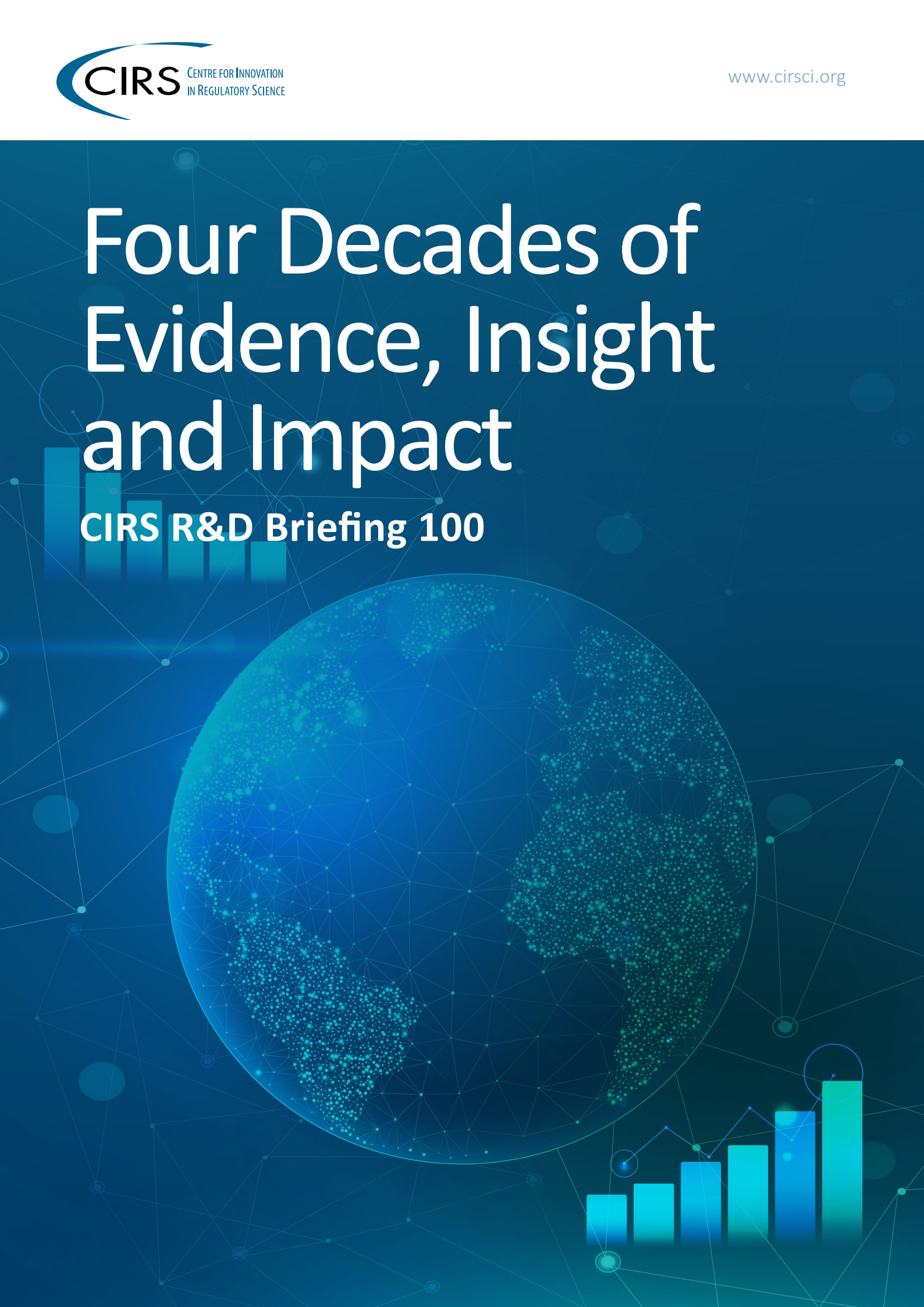
# Four Decades of Evidence, Insight and Impact

## CIRS R&D Briefing 100



# Introduction

## What are CIRS R&D Briefings?

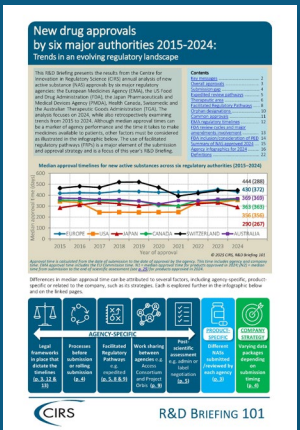
First published in the 1990s, R&D Briefings are independent publications by CIRS that distil the findings from our research —alongside journal articles, posters and workshop reports—into strategic insights that inform policy and support decision making across the regulatory and HTA landscape. Several R&D Briefings are published each year, covering a range of topics aligned with our three pillars and Research Agenda.

Our benchmarking R&D Briefings spotlight the findings from our annual regulatory and HTA agency metrics studies, also known as the 'six agency' and 'HTADock' studies, respectively. They provide comparative insights into the performance of selected agencies with similar mandates and processes.

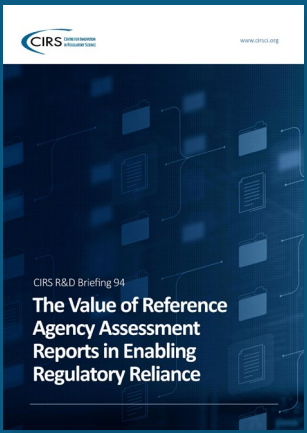
Other R&D Briefings identify and explore emerging regulatory and HTA trends, challenges, opportunities and best practices at national, regional and global levels.

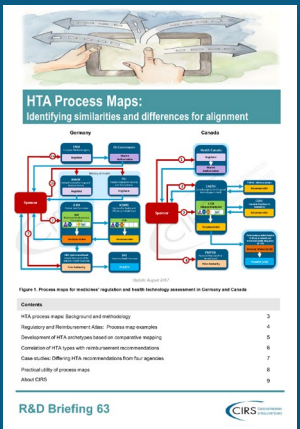
These studies may involve desk-based research, such as examining agency policies, guidance and procedures (e.g. R&D Briefing 92 on 'Appraisal of public assessment reports (PARs) as tools to guide reliance decision making by regulatory agencies'), as well as surveys to gather the perspectives and experiences of our stakeholders (e.g. R&D Briefing 94 on 'The value of reference agency assessment reports in enabling regulatory reliance').

Outputs from our workshops have also formed the basis of earlier briefings (e.g. R&D Briefing 80 on the CIRS workshop, 'Reimagining medicine regulatory models on learnings from the COVID-19 pandemic') and other CIRS meetings (e.g. R&D Briefing 60 on 'Early scientific advice from HTA agencies', based on a CIRS Company Technical Forum).







# Why do CIRS R&D Briefings matter?

CIRS R&D Briefings are more than research publications—they are strategic tools that inform, influence, and catalyse action across the global medicines development ecosystem. Their value lies in their ability to translate complex data into meaningful insights that support evidence-based decision making across stakeholders.

## STRATEGIC MONITORING AND INTELLIGENCE

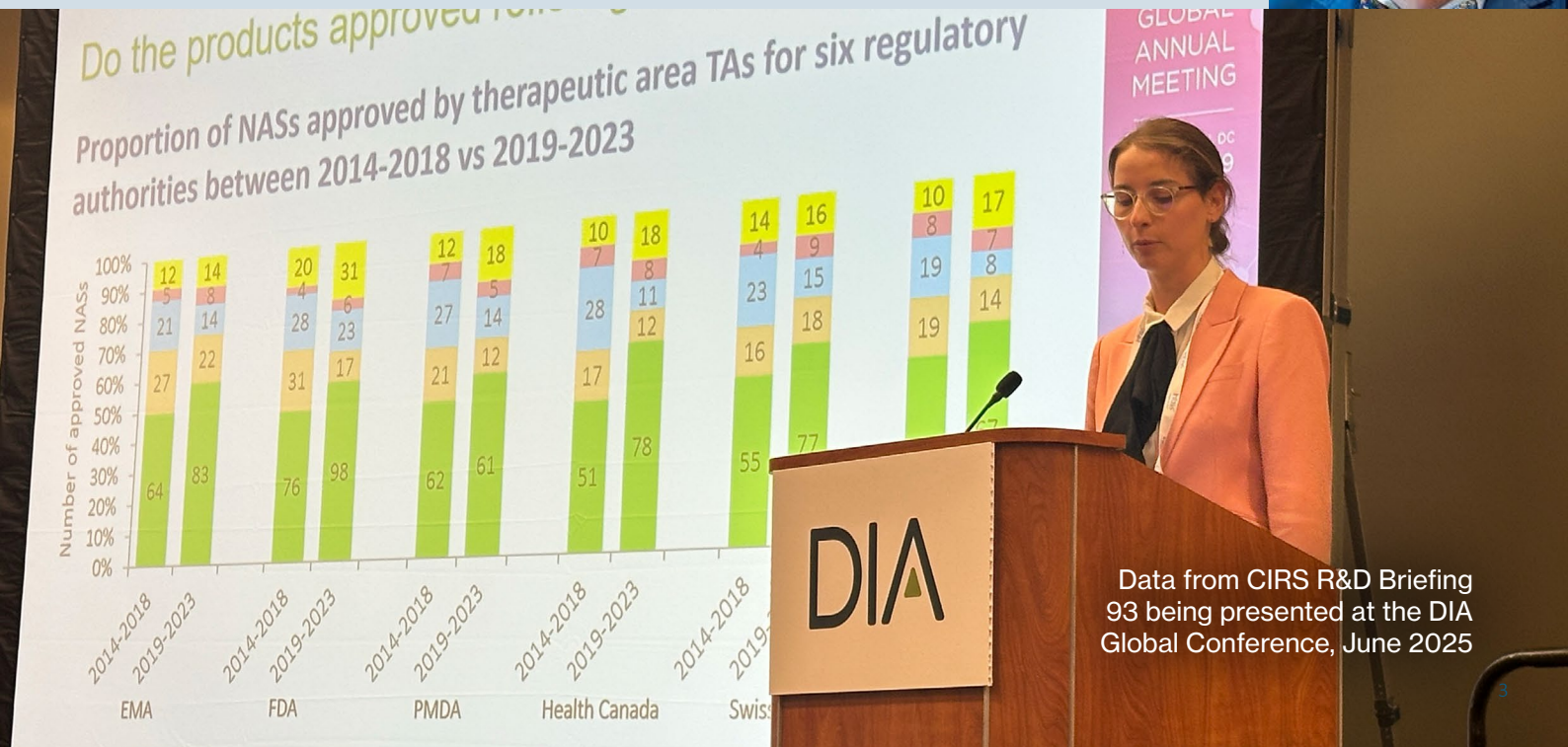
CIRS R&D Briefings offer a panoramic view of the regulatory and HTA landscape, helping stakeholders anticipate shifts, benchmark performance, and identify emerging trends. By bringing together data across jurisdictions and timeframes, they enable:

- **Comparative analysis** of agency performance and timelines
- **Identification of best practices** and areas for improvement
- **Early signal detection** for policy and procedural changes.

These insights empower regulators, HTA bodies, and industry leaders to make informed decisions that align with evolving global standards and patient needs.

*"The annual six agency CIRS R&D Briefing is always scrutinised with interest. Its comparative nature gives valuable insight into EMA's global performance, and any impact regulatory/procedural changes may have on this."*

**Dr Steffen Thirstrup, Chief Medical Officer, European Medicines Agency (EMA), and member of the CIRS Scientific Advisory Council**




Data from CIRS R&D Briefing 93 being presented at the DIA Global Conference, June 2025

## POLICY DEVELOPMENT AND ADVOCACY

CIRS R&D Briefings are frequently cited in national and international policy documents, demonstrating their influence in shaping regulatory and HTA reform. They provide a neutral, evidence-based foundation for:

- **Advocating** for streamlined processes and accelerated access
- **Supporting** reliance and collaborative review models
- **Informing** legislative and procedural updates.

*"CIRS R&D Briefings have consistently provided a robust, independent evidence base that supports the evolution of HTA policy and practice. Their insights have helped inform national and international discussions on streamlining processes and legislative reform. As HTA continues to evolve, these briefings remain a vital resource for policy makers seeking to ensure that access pathways meet healthcare needs."*

**Dr Nick Crabb, Chief Scientific Officer, National Institute for Health and Care Excellence (NICE), and Vice-Chair of the CIRS HTA Steering Committee**

## CROSS-SECTORAL DIALOGUE AND ALIGNMENT

By convening stakeholders through workshops and forums and sharing the resulting insights in publications such as R&D Briefings, CIRS fosters a shared understanding across regulators, HTA bodies, industry, and academia. Our data provide a neutral basis to support evidence-based discussions, allowing for best practices to be identified. Our collaborative approach:

- **Bridges silos** between regulatory and HTA communities
- **Promotes harmonisation** of standards and practices
- **Encourages innovation** while safeguarding public health.

CIRS R&D Briefings help provide a common perspective for policy professionals navigating complex, multi-jurisdictional environments.

*"These publications serve as a critical bridge across the R&D ecosystem — bringing stakeholders together around a neutral, rigorous foundation of evidence. They enable our regulatory decision makers to collaborate deeply, uncover new perspectives and, ultimately, advance our goal of bringing safe, effective treatments to patients more efficiently."*

**Dr Katrin Rupalla, Global Head Regulatory Affairs, J&J Innovative Medicines, and member of the CIRS Scientific Advisory Council**

# What impact have CIRS R&D Briefings had?

CIRS R&D Briefings have become a recognised source of independent evidence cited by our stakeholders globally. Insights from our R&D Briefings have helped shape national policies, inform strategic reforms and catalyse cross-sector global dialogue.

## AGENCY RECOGNITION AND INTEGRATION

Our benchmarking R&D Briefings are routinely referenced by the agencies they evaluate – this demonstrates the rigor and trust in our methodology and neutrality. For example:

- **Swissmedic** issued a press release summarising the findings of R&D Briefing 101 to contextualise its performance.
- **Japan's PMDA** featured CIRS data in its 2025 summer newsletter, highlighting the value of international benchmarking in shaping domestic regulatory strategy.
- **Australia's Department of Health and Aged Care** incorporated HTA benchmarking data from CIRS R&D Briefing 89 into a government report examining Australia's approach to HTA, which informed recommendations for reforming Australia's HTA processes.

## INDUSTRY ADVOCACY AND POLICY REFORM

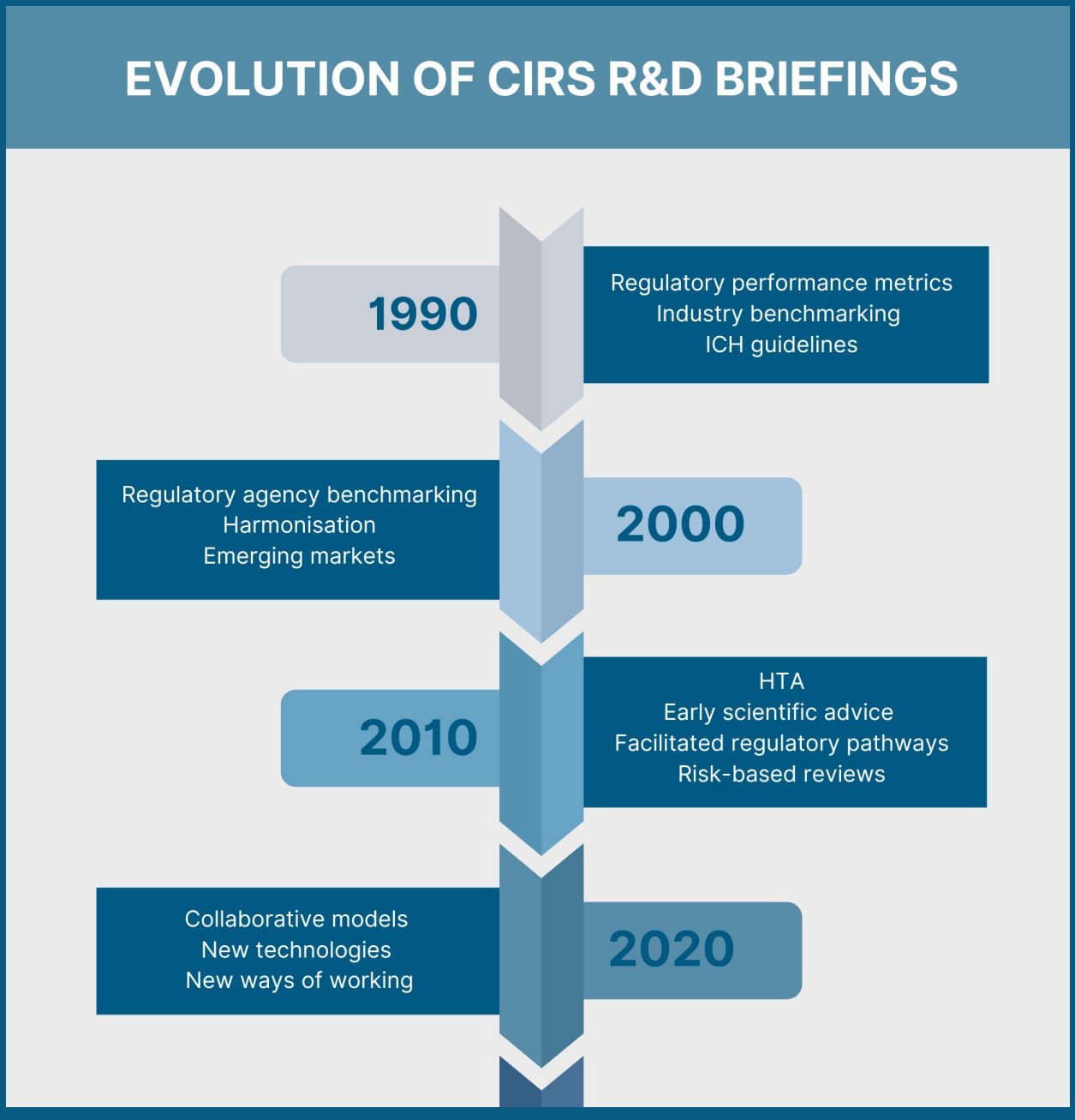
CIRS R&D Briefings are used by pharmaceutical companies and industry associations to support advocacy efforts aimed at improving the regulatory and HTA environment, empowering stakeholders to make the case for change. For example, the **European Federation of Pharmaceutical Industries and Associations** (EFPIA) cited data from regulatory benchmarking CIRS R&D Briefing 81 in their report on unavailability and delay to innovative medicines in Europe. The insights informed the policy proposals by industry to accelerate the European regulatory process.

Beyond industry, CIRS data has also informed high-level policy discourse. The **European Commission (EC)** cited regulatory benchmarking data from CIRS R&D Briefing 88 in Part B of the Draghi Report on the future of European competitiveness, noting the differing approval timelines for Europe against regulatory agencies in other regions. This recognition underscores the broader influence of CIRS benchmarking in shaping strategic reform across both industry and governmental stakeholders.

# History

For over 30 years, CIRS R&D Briefings have provided insights into the evolution of regulation, and more recently, HTA of novel medical products. While performance benchmarking has remained a constant focus topic, the evolution into broader topics over the years reflects how the priorities of stakeholders in medicines policy have shifted (see below).

This progression underscores our commitment to staying ahead of the curve—ensuring that our research remains relevant, responsive, and impactful.

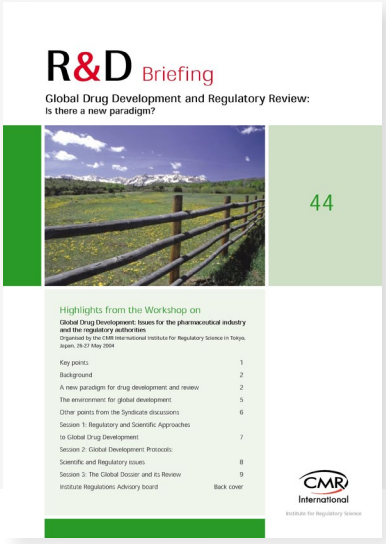


# From vision to reality:

## Two decades of progress in global drug development

CIRS R&D Briefing 44 summarised discussions and recommendations from the May 2004 CMR International Institute for Regulatory Science (now CIRS) forward-looking workshop in Tokyo, Japan, which brought together senior representatives from regulatory agencies and the pharmaceutical industry. The discussions centred on the need for a new paradigm in global drug development and regulatory review, one that would better align with evolving patient needs, and the increasing complexity of emerging technologies.

Twenty years on, many of its recommendations have been implemented in today's regulatory landscape, while others continue to inspire innovation and reform.




### FACILITATED REGULATORY PATHWAYS: FROM CONCEPT TO PRACTICE

Rolling reviews with early regulatory engagement were among the most forward-thinking proposals from this workshop; participants envisioned a model where scientific advice is sought at the beginning of clinical development, with regulatory agencies evaluating data earlier and on a continuous basis, rather than assessing the full dossier at the completion of phase III. This model also explored the potential for early marketing of a novel medicine addressing unmet medical needs under controlled conditions when sufficiently robust supporting data was confirmed at the end of phase II. The medicine would then move to a full marketing authorisation under normal conditions based on fulfilment of an agreed post-marketing programme.

Over the last two decades since the workshop, major regulatory agencies globally have established facilitated regulatory pathways (FRPs) to accelerate product development, market authorisation application submissions, or regulatory reviews.

Data from our agency benchmarking R&D Briefings show that FRPs are currently integral to regulatory strategies, particularly for products addressing serious conditions and unmet medical needs. The workshop's vision of more flexible and adaptive approvals with real-world data collection is now reflected in the increased use of FRPs and post-marketing evidence generation.

### CENTRAL DATA STORAGE FOR REAL-TIME ACCESS

The vision for a centralised data warehouse—an electronic platform enabling real-time access to product dossiers —has become partly become a reality through cloud-based platforms, such as the Accumulus platform. This was recently discussed at our collaborative models workshop in South Africa. Several proof-of-concept projects across multiple jurisdictions demonstrate support for regulatory reliance by facilitating real-time collaboration between industry and regulators, as well as among regulators. Scaling this model globally could unlock unprecedented efficiencies in regulatory collaboration and reliance.

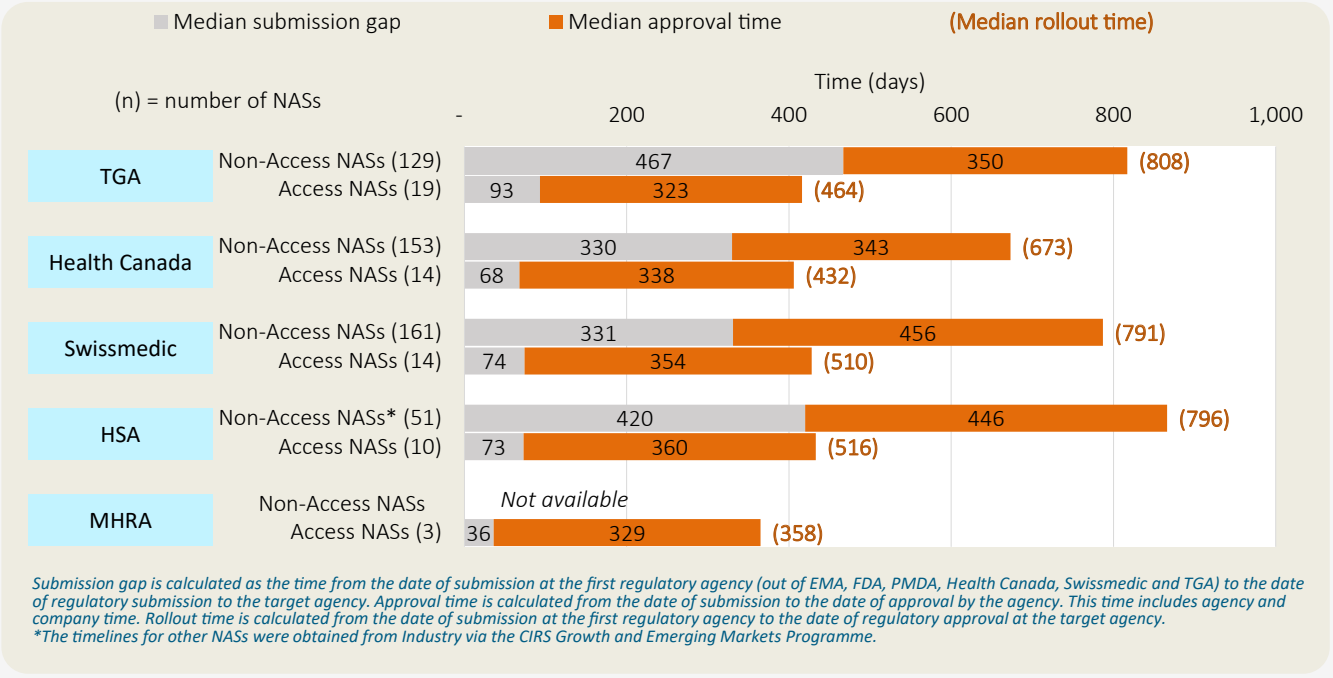
## COLLABORATIVE REVIEWS

The 2004 workshop advocated for joint coordinated reviews with the potential for recognition of the assessment of Chemistry, Manufacturing and Controls (CMC) and nonclinical data across agencies. As regulatory standards have become increasingly harmonised and trust has been built between regulators, the concept of collaborative review gained traction and has become reality in the form of initiatives such as:

- 2007- **Access Consortium**, now facilitating work sharing among five regulatory authorities (Australia, Canada, Singapore, Switzerland and UK).
- 2009- **African Medicines Regulatory Harmonisation initiative**, supporting regional joint assessments in Africa and laying the groundwork for the African Medicines Agency established in 2021.
- 2016- **Caribbean Regulatory System**, providing recommendations for market authorisation, rational use, and quality and safety monitoring of medical products in the Caribbean.
- 2017 - **ASEAN Joint Assessment**, enabling collaborative product evaluations across ASEAN member states (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam).
- 2019- **Project Orbis**, enabling concurrent submission and review of oncology products across multiple countries (currently Australia, Brazil, Canada, Israel, Singapore, Switzerland, and UK) led by the US FDA.

Collaborative regulatory models – including reliance, work sharing and collaborative review- are now a standard part of the regulatory toolkit and have reshaped how agencies work together to evaluate and approve medicines. Many of our workshops and R&D Briefings over the last decade have focused on understanding the impact of these models and sharing best practices. For example, new active substance (NAS) data from R&D Briefing 97 shows that Access work sharing is helping to reduce submission gaps to participating regulatory agencies, suggesting that there are efficiency gains (see below).

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




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

## SINGLE GLOBAL DEVELOPMENT AND SUBMISSION

The aspiration for a single integrated development programme that allows simultaneous global submission remains a work in progress. While harmonisation efforts via the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (as shown in this 2024 CIRS study commissioned by ICH) have contributed a great deal to the achievement of this vision, regulatory requirements, processes and timelines still vary globally. Our data shows that company submission strategies continue to prioritise the FDA followed by EMA, with increasing integration of growth and emerging markets, such as China and Brazil, reflecting a shift towards truly global development planning.

## SUSTAINING THE VISION: CIRS' COMMITMENT TO COLLABORATIVE POLICY MAKING

The 2004 Tokyo workshop laid out a bold vision for the future of drug development and regulatory review, with emphasis on collaboration, flexibility and data-driven decision making. Many of its recommendations including rolling reviews, facilitated pathways, joint assessments, and real-time data sharing, have since been realised or are actively shaping current practices. Yet the aspiration for a truly integrated, globally harmonised development and review process remains a work in progress, particularly as emerging markets and new technologies reshape the regulatory landscape.

As the regulatory environment continues to evolve, CIRS remains committed to facilitating forward-thinking dialogue through multi-stakeholder workshops informed by our collaborative research. By fostering shared understanding and alignment, we help to identify policy solutions such as those articulated in R&D Briefing 44 that can be implemented or further refined to support responsive, forward-looking, and patient-focused medicines development globally.

CIRS Global Development Workshop, February 2025

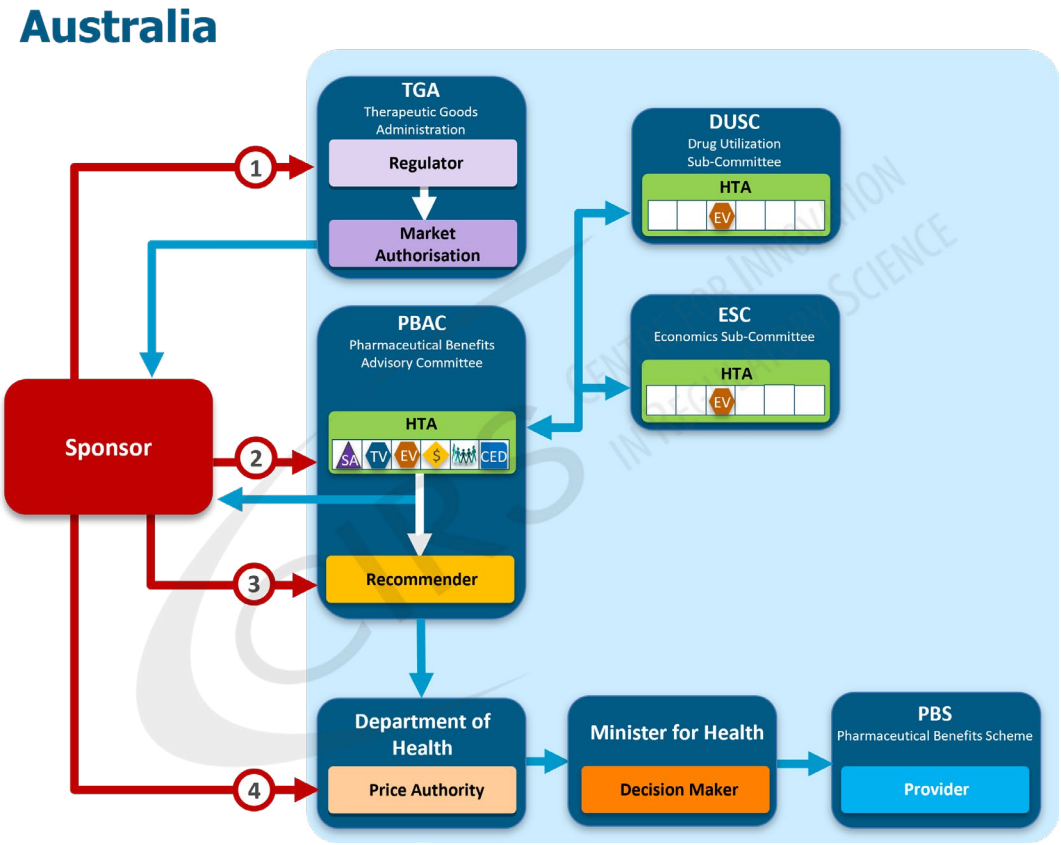
# From downstream decision maker to early stream enabler:

## The role of HTA in the healthcare ecosystem

Over the past decade, HTA has evolved from a traditionally downstream decision maker focused on reimbursement to an increasingly upstream enabler shaping evidence generation and development strategy. Through its research and convening power, CIRS has tracked and supported this evolution, highlighting how HTA agencies are embedding themselves earlier in the development process, engaging in scientific advice, and collaborating more closely with regulatory counterparts. This section explores the changing role of HTA, drawing on insights from CIRS R&D Briefings to illustrate how HTA is becoming a proactive force in enabling timely and patient-focused access to medicines.

### MAPPING PROCESSES TO DRIVE EFFICIENCY

CIRS R&D Briefing 63 in 2017 built on academic research using systematic mapping methodology to understand the processes and procedures of HTA decision making globally (see example map below). The study highlighted both divergences and similarities in how HTA systems are structured, from their functions and methodologies to their position within national healthcare systems. The research introduced an archetype model that illustrates how HTA fits into pricing and reimbursement pathways for new medicines, how decision criteria are set, and how HTA is embedded with broader functions such as early scientific advice and coverage with evidence development. A recurring theme of this research was the need for deeper collaboration and stronger interactions among HTA stakeholders.




CIRS HTA Regulation Workshop, November 2025

Eight years on, the implementation of Regulation (EU) 2021/2282 on health technology assessment (HTAR) has marked a milestone for collaborative clinical assessment of medicines in the EU. This initiative aims to reduce duplication, improve consistency, and enhance efficiency across Member States, representing a significant step forward in embedding HTA as a driver of collective decision making within healthcare systems.

Process mapping enables developers and decision makers to plan strategies by identifying potential roll out steps. For example, the various regulatory pathways available in the UK after Brexit—such as the MHRA national route, work-sharing pathway of the Access Consortium, collaborative review through Project Orbis, or European Commission Decision Reliance Procedure (ECDRP)—have been evaluated using metrics on HTA timelines and outcomes described in R&D Briefing 96.

## FROM REGULATORY APPROVAL TO HTA DECISION MAKING

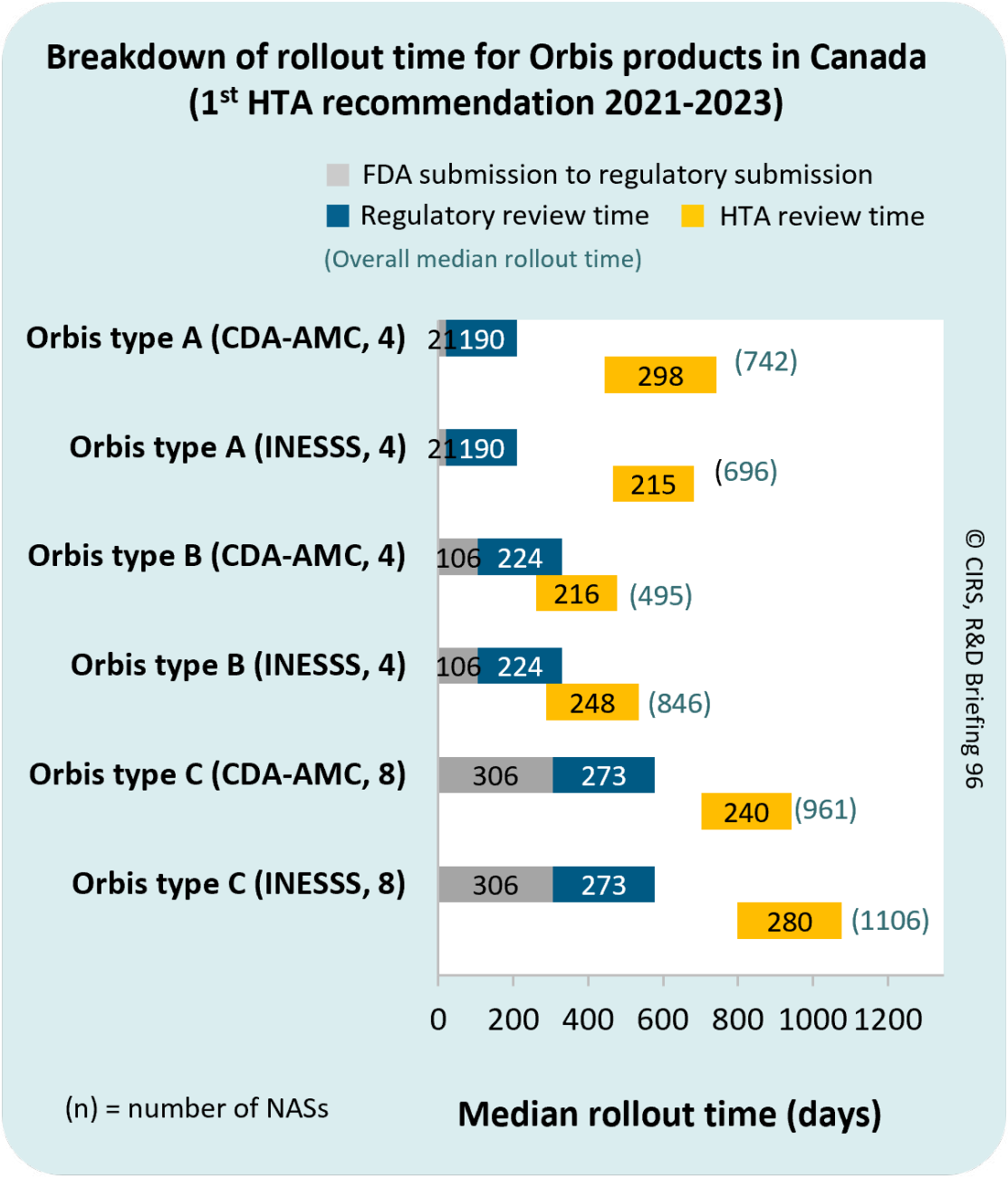
CIRS' benchmarking of industry, regulatory and HTA performance against peers with similar mandates has created opportunities to encourage good practices and to promote timeliness, predictability, transparency, efficiency and quality in decision making. The HTADock R&D Briefing series – beginning with R&D Briefing 64- has been central to this work. The annual HTADock study examines the timeline from regulatory submission to the first HTA recommendation, shedding light on how regulatory and HTA agency performance, as well as company submission strategy collectively shape the pace of patient access. This analysis has shown that the pathway from regulatory approval to first HTA recommendation is not only based on assessment timelines but also by company submission strategies, including the sequence and timing of submissions across jurisdictions.

Understanding the broader context behind the rollout of medicines requires a view that extends beyond regulatory review times- something CIRS is well placed to assess given its neutrality, strength in metrics research, and unique role as a multi-stakeholder convener. CIRS research has demonstrated that variation exists not only in the performance of regulators and HTA bodies but also in company approaches to submission. As shown in R&D Briefing 99, some HTA agencies assess all new medicines, while others focus on outpatient medicines, leading to further differences in scope and remit.

At the same time, regulators are increasingly adopting flexible pathways such as conditional approvals, expedited reviews and collaborative mechanisms including the Access Consortium and Project Orbis. These developments inevitably affect the submission process to HTA agencies and highlight the importance of greater awareness and coordination between regulatory and HTA stakeholders. R&D Briefing 96 looked specifically at HTA timelines and outcomes in Australia, Canada and the UK, countries whose regulators are involved in the Access and Orbis collaborations. While there seemed to be efficiency gains from these collaborative

models due to smaller submission gaps to the participating regulatory agencies, preliminary data for Project Orbis suggested that the expedited regulatory timelines meant a longer submission gap to HTA agencies in certain jurisdictions. This was particularly evident with product approvals granted Orbis Type A in Australia and Canada (see figure below), where the regulatory review is concurrent with FDA, with simultaneous submission (less than 30 days from FDA submission).

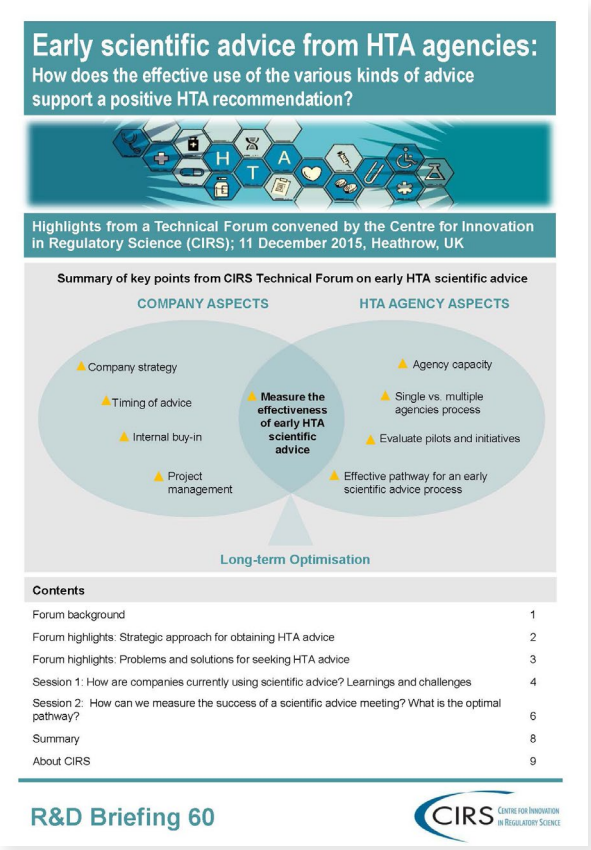
New initiatives such as the parallel review process of Health Canada and Canadian HTA agencies, or collaborative approaches between the MHRA and NICE in the UK, illustrate how joint efforts can enable more coherent and efficient submission strategies while respecting the distinct remits of each decision maker. For example, R&D Briefing 103 found that products submitted between 2020-2024 to either Canada's Drug Agency (CDA-AMC) or l'Institut national d'excellence en santé et en services sociaux (INESSS) through the parallel regulatory/HTA process had a faster median rollout time than those submitted sequentially.



## SUPPORTING UPSTREAM DECISION MAKING: EARLY HTA SCIENTIFIC ADVICE

The past decade has witnessed a significant evolution in the role of HTA, with agencies increasingly shaping upstream decision making in drug development. Early HTA scientific advice has become a formalised process that allows companies to identify potential data gaps, refine and 'stress test' study designs, and align evidence generation with the requirements of HTA bodies. By fostering collaboration between developers, agencies, payers and patients, this process supports a more evidence based and predictable approach to development planning.

R&D Briefing 60, based on a CIRS industry forum in 2015, scoped the landscape of early advice by mapping three primary pathways: advice from a single HTA agency, parallel advice from regulatory and HTA agencies, and simultaneous advice from multiple HTA bodies. Although voluntary and non-binding, these interactions increasingly shape development strategies and provide valuable insight into evidentiary expectations.




Ten years after this forum, the Joint Scientific Consultation (JSC), introduced in January 2025 under the EU HTAR, represents a further milestone in institutionalising early advice. Outside Europe, similar initiatives are expanding. The UK has established parallel scientific advice involving the MHRA and NICE, while Canada has created collaborative pathways between its regulatory and HTA agencies. In 2019, Canada's Drug Agency and NICE launched a joint programme to provide simultaneous advice to developers. These examples illustrate a growing international trend towards earlier, coordinated multi-stakeholder engagement that reduces uncertainty and increases efficiency in evidence planning.

## SUSTAINING THE VISION: EMBEDDING HTA AS AN ENABLER

The evolution of HTA reflects a broader shift from a role centred on downstream reimbursement decisions to one that is increasingly focused on shaping the upstream design of evidence generation. The past decade has delivered important milestones, including collaborative clinical assessments under the EU HTAR, national and international pilots of regulator/HTA advice and aligned processes, and the establishment of early HTA scientific advice as a core feature of the development strategy.

CIRS has played a key role in this journey—providing a neutral platform for multi-stakeholder dialogue, generating independent evidence through its HTADock and mapping studies, and supporting the development of practical policy solutions. The R&D Briefings have been an important tool in this effort: distilling complex data into accessible insights that inform strategy, benchmark performance, and guide policy development. As HTA continues to evolve, CIRS remains committed to enabling timely, transparent and patient-focused access to medicines through collaborative dialogue and research.

# Looking ahead:

## Shaping the next era of medicines policy

The future of global medicines development is being redefined by technological innovation, regulatory convergence, and a renewed commitment to patient-centred outcomes. The next decade will demand bold thinking, agile collaboration, and evidence-led leadership—principles that have guided CIRS for over 40 years. As we begin crafting our Research Agenda for 2027-2029, we will continue to build on a legacy of evidence-based insight and collaborative engagement, as illustrated through our R&D Briefing series. Our activities and outputs in 2026 will continue to align with our research pillars, themes and topics outlined below.

### CIRS Research Agenda 2024 - 2026

| | | | |
|---|---|---|---|
| **Pillars** | **Metrics**<br>Evidence-driven insights into company and agency performance | | |
| | **Quality**<br>Improving decision-making processes | | |
| | **Alignment**<br>Converging stakeholder priorities and processes to accelerate patient access | | |
| **Themes** | Decision-making framework for new ways of working and evidence generation technologies | Good practices for regulatory and HTA collaborative models of review and assessment<br><br>Sharing learnings and experiences | Metrics on new ways of working and evidence generation and their impact on decision making<br><br>Strategic insights and impact measures |
| **New Topics** | Vaccines \| Artificial Intelligence \| Patient Engagement \| High Impact Chronic Diseases \| Rare Diseases | | |

### AI – FROM PROMISE TO PRACTICE

The integration of artificial intelligence (AI) into drug development and regulatory/HTA review is beginning to revolutionise how data is generated, analysed, interpreted, and acted upon. As shared by various stakeholders at our AI Roundtable meeting in June 2025, companies, regulators and HTA agencies are already exploring and benefitting from the applications of AI at various stages in the medicines' lifecycle; however, to realise its full potential, stakeholders must co-create harmonised standards, governance models and ethical frameworks through cross-sectoral dialogue in order support both innovation and oversight of this transformative technology.

## CLOUD-BASED COLLABORATION AND THE GLOBAL DOSSIER

Cloud-based platforms are laying the groundwork for a future where real-time data sharing and collaborative review are the norm, accelerating decisions and enhancing transparency. As these technologies mature and trust is enhanced, we may see the emergence of a truly global dossier accessible to multiple regulators simultaneously; the possibility of adopting a similar approach for HTA bodies' review could enable more coordinated and timely decision making across jurisdictions.

## REGIONAL HARMONISATION AND JOINT PROCEDURES

Collaborative models will also continue to evolve. The implementation of the EU HTAR and the establishment of the African Medicines Agency mark significant steps toward joint procedures and regional harmonisation. These initiatives, alongside models like Project Orbis and the Access Consortium, signal a growing appetite for cooperation and collaboration between stakeholders —a trend we will continue to monitor to assess its impact.

## OUR CONTINUED COMMITMENT

CIRS will remain at the forefront of these transformative developments – serving as a neutral convener, a trusted source of evidence, and a catalyst for policy innovation. As we enter our next research cycle, we reaffirm our commitment to enabling smarter, faster, and more equitable access to medicines worldwide. Through rigorous benchmarking, forward-thinking workshops, and collaborative research, we will continue to illuminate pathways for regulatory and HTA systems to evolve in step with scientific progress and societal needs.

The next decade will demand not only technical excellence but also visionary leadership. It will require us to embrace complexity, foster global alignment, and ensure that innovation translates into real-world impact for patients. CIRS stands ready to support this journey—by connecting stakeholders, shaping policy discourse, and delivering insights that matter.

**Together, we can shape a future where regulatory and HTA systems are not only aligned and efficient, but also inclusive, adaptive, and deeply responsive to the health challenges of tomorrow.**

CIRS Team, 2024

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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*Publication date: December 2025*