CIRS Centre for Innovation in Regulatory Science

www.cirsci.org

CIRS Company

Membership

Advancing regulatory and HTA policies and processes

CIRS Membership

Membership to the CIRS Regulatory and Access programme is open to all pharmaceutical companies, particularly those engaged in research and development of new active substances, prescription medicines, devices and biologics with a view to global product development, regulatory affairs and market access.

By becoming a member, your company can support CIRS' mission to advance regulatory and HTA policies and processes; participate in multi-stakeholder activities such as workshops, research and benchmarking metrics projects; benefit from priority access to CIRS publications; and become part of an international community to help shape major policy topics. These benefits are described in more detail on the next page.

If your company would like to find out more about becoming a CIRS member, please contact Gill Hepton: ghepton@cirsci.org

Why become a CIRS member?	Membership deliverable
 Be part of a **global network** The CIRS community involves regulators, HTA agencies, payers, industry, patient groups and academia from around the world. By becoming a CIRS member, you can interact with these stakeholders at small, productive meetings.	**Four multi-stakeholder workshops** Registration and accommodation (excluding travel) for two participants per workshop.
	Two industry-focused Technical Forums (regulatory and HTA) Registration for one person to each of the annual forums (accommodation not included).
	Industry-focused webinars Organised on an ad-hoc basis on hot topics
 Access **insights & knowledge** CIRS members have exclusive access to the results of research that your company has contributed to and more.	**CIRS members website** Designed to be a 'one-stop shop' for CIRS resources including workshop slides, R&D Briefings and open access publications.
	CIRS Regulatory & Reimbursement Atlas™ An online tool that maps regulatory, HTA and payer pathways for more than 70 jurisdictions around the world.
	Insight seminars Organised specifically for your company on topics of mutual interest.
	Early access to CIRS R&D Briefings Including two annual Briefings focusing on regulatory and HTA agency benchmarking of new active substances. Additional benefits include: • Exclusive access to the slides from the Briefing • Exclusive analysis of your company's performance compared to overall benchmarks (on request) • Industry-wide webinar to review key findings
 Participate in **research & metrics** CIRS membership offers several opportunities to participate in research that gives unique insights into the regulatory and access landscape.	**Annual focus studies** Industry study on a hot topic of interest to members, with results fed back through a report and/or presentation.
	Eligibility to participate in the Growth and Emerging Markets and HTA Metrics Programmes (additional fee applies – see opposite page for more information)
	Special projects CIRS has worked with various organisations on ad hoc projects that answer short business questions or facilitate advocacy efforts.
 Contribute to **research & advocacy to advance regulatory/HTA policy** CIRS membership helps to support the CIRS research programme, including PhD projects and the development of tools, as well as the organisation of multi-stakeholder meetings and workshops.	By being a member, you can **contribute to the direction of CIRS advocacy and research** and put forward subjects for discussion at workshops, as well as topics for surveys and studies. Individuals from CIRS member companies are also eligible to be nominated to join CIRS advisory committees.

Join our Industry Metrics Programmes

As well as the **Regulatory and Access Programme**, CIRS offers two industry metrics programmes that are available as add-on benefits to CIRS members. Annual deliverables of each programme include:

- Company-specific report
- Executive summary
- Country-specific summaries
- Results of a focused study on a topic of interest to participant companies
- Industry Discussion Meeting to review trends and discuss new analyses
- Periodic updates on the programme and CIRS advocacy activities

Growth and Emerging Markets Metrics (GEMM) Programme

Each pharmaceutical market is unique, but all share complexity, dynamism, and a rapid pace of change. As opportunities in developed markets may decline, companies increasingly incorporate growth and emerging markets into their strategies. The globalisation of pharmaceutical markets drives a demand for high-quality information to support clinical development and the registrations of new medicines, helping companies secure timely market access in these regions.

The GEMM Programme provides comparative data and insights on the evolving regulatory environment in growth and emerging markets. It collects company data on submission, approval and rollout times in 19 countries and one regional alignment initiative across Asia, Latin America, Europe, Middle East and Africa.

The data is anonymised, analysed and aggregated to create an industry-wide view of the regulatory landscape, enabling participants to compare their performance against broader trends. Participants also have access to an online analysis tool that allows for secure and confidential interrogation of the programme dataset.

If your company would like to find out more about joining the GEMM Programme, please contact Magda Bujar: mbujar@cirsci.org

Join our Industry Metrics Programmes

HTA Metrics Programme

The global HTA landscape is rapidly evolving, driven by improvements in processes and methodologies, as well as policy changes such as the EU HTA Regulation. Over the years, the role of HTA has shifted from a post-approval assessment for reimbursement to an integral part of the entire lifecycle of new medicines.

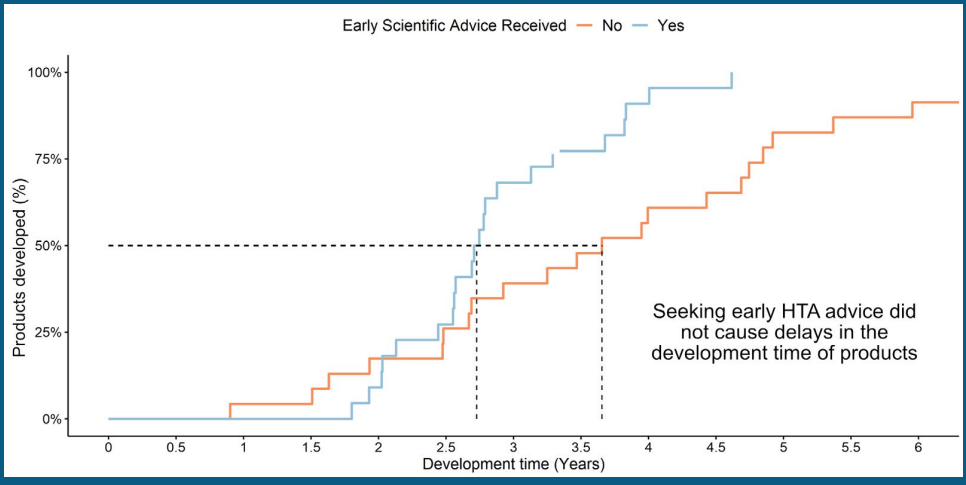
CIRS has been collaborating with companies through its industry metrics programme to examine the impact of HTA on jurisdictional rollout and during development. Insights gathered from our members help ensure that HTA considerations are embedded into the value proposition throughout a medicine's lifecycle. A key interest for both companies and agencies is the provision of early HTA advice.

In 2025, the programme will focus on analysing the current landscape of early HTA advice. It will collect data from companies, using consolidated and anonymised information to provide insights into the national dynamics of early HTA advice and establish a baseline to track the evolution of Joint Scientific Consultation (JSC) under the EU HTA Regulation. The aim to generate actionable insights that can support decision-making processes related to early HTA.

Key research questions include:

- How many early advice applications were accepted by JSC vs national agencies?
- What types of products undergo early HTA advice?
- Why is early HTA advice not sought for some products?
- Which agencies provide early HTA advice?
- Which agencies are most commonly approached for JSC?
- What topics are typically covered in early HTA advice meetings?
- What are key feedback points regarding process and procedures?

Example analysis: Comparison of development time with and without early HTA advice (HTA recommendations 2018-2023)



Time from pivotal dose to first regulatory authority submission

If your company would like to find out more about joining the HTA Metrics Programme, please contact Dr Tina Wang: twang@cirsci.org

Frequently asked questions (FAQ)

What is CIRS?

The Centre for Innovation in Regulatory Science (CIRS) is a neutral research organisation that provides a 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 regulation and HTA. CIRS works collaboratively with stakeholders worldwide and its activities are underpinned by three key pillars: metrics, quality and alignment (see 'About CIRS' for more information).

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.

We annually review our achievements and publish these in an Annual Report, which is shared with CIRS members before being released more widely.

How is the CIRS research programme governed?

CIRS has its own dedicated advisory committees made up of external international experts from academia, industry, regulatory agencies, HTA bodies and payers, which help to ensure neutrality and that the CIRS research programme meets all stakeholder needs. CIRS sets its three-year research strategy with formal input from the Scientific Advisory Council (SAC) and HTA Steering Committee, as well as ad hoc feedback from companies and agencies. For more information on our 2024-2026 research plan, please see the CIRS '**Research Agenda**'.

How is CIRS funded?

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

What is CIRS' relationship with Clarivate?

CIRS is a neutral, independent UK-based subsidiary of Clarivate plc. It is governed and operated by Clarivate for the sole support of its members' activities.

How does CIRS work with agencies?

As well as collaborating on research projects, CIRS works directly with regulatory and HTA agencies to facilitate change, either within their organisations or more widely in the regulatory and HTA landscape. For example, through the **Optimising Efficiencies in Regulatory Agencies (OpERA) programme**, CIRS is helping regulatory agencies around the world to integrate a practice of performance tracking and to promote review efficiency as well as effectiveness.

Who can become a CIRS member?

CIRS membership is open to all pharmaceutical companies, particularly those engaged in research and development of new active substances, prescription medicines, devices and biologics with a view to global product development, regulatory affairs and market access.

How is CIRS different to other membership organisations?

CIRS is unique in its ability to bring global industry, regulators, HTA bodies, payers and academics together in a neutral atmosphere to identify and address key issues in the development, licensing and reimbursement of new medicines. We have been doing this for over 30 years through focused meetings and research projects, which are often conducted in collaboration with agencies and/or industry.

How are CIRS meetings different from other professional conferences?

CIRS meetings are usually small and focused to facilitate discussion among multiple stakeholders. Our workshops also include breakout sessions, which are key to producing recommendations to move important topics forward.

What does a typical year as a CIRS member look like?

CIRS members participate in meetings and research projects and receive outputs from those throughout the year. CIRS meetings include four multi-stakeholder workshops (two in H1 and two in H2); two industry Technical Forums in H2; ad-hoc webinars to update members on CIRS activities, such as the results of our annual regulatory and HTA agency benchmarking studies; and insight seminars for individual companies, organised on request. CIRS members also receive invitations throughout the year to participate in surveys, the results of which are often presented at CIRS meetings and external conferences and are used to inform specific research projects.

How much time/resource is required as a CIRS member?

Participation in CIRS activities is completely optional, but the more active your company is within CIRS, the greater the benefits will be. For CIRS workshops and forums, companies can expect a minimum of eight days out of the office for up to two employees per meeting. These meetings are a key way to integrate the industry perspective into multi-stakeholder discussions, so we very much encourage our members to attend. Surveys are also an important way for us to gather insights from our members on issues in the regulatory and HTA landscape; these are designed according to the research questions being asked, while ensuring that they are manageable in length and not too frequently sent out.

What sort of communications can my company expect to receive from CIRS?

CIRS sends out regular communications by email to key contact persons within member companies. These include invitations to workshops, webinars and other meetings as well as surveys and updates on research projects and new publications. As a member you will receive early access to CIRS R&D Briefings and workshop reports before they are published publicly.

Regulatory-HTA alignment workshop, October 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 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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Publication date: April 2025