CIRS Centre for Innovation in Regulatory Science

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CIRS

Membership

INSIGHTS | NETWORK | ADVOCACY

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 following 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 and academia from around the world. By becoming a CIRS member, you can interact with these stakeholders at small, productive meetings.	**Three 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 Early Advice 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 multistakeholder 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

Globalisation of pharmaceutical markets means that quality information for development and registration of new medicines in emerging markets is more important than ever before. The CIRS GEMM Programme can help you to get ahead in these fast-growing markets by providing comparative data and information on the evolving regulatory environment at the country and regional level.

The GEMM Programme 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 analysed, aggregated and anonymised, resulting in an industry-wide picture of the regulatory landscape in each country, which you can then compare your company against. As a participant of the Programme, you will also have access to an online analysis tool that allows interactive and secure 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 Early Advice Metrics (HEAM) Programme

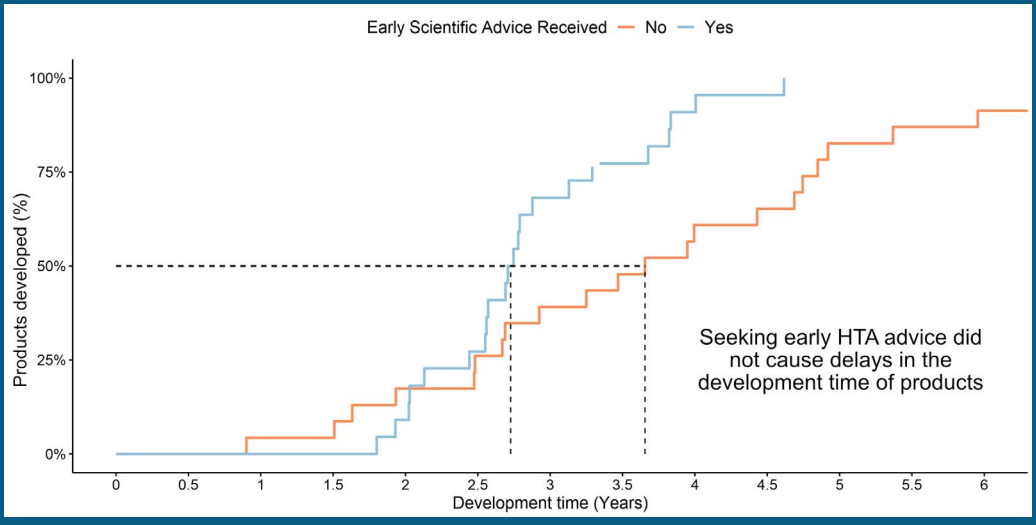
The landscape of early HTA scientific advice is rapidly evolving, emphasising collaborative engagement with various stakeholders. The CIRS HTA Early Advice Metrics (HEAM) Programme builds on previous CIRS work to offer companies unique insights into the early advice landscape and its potential impact on HTA outcomes in key markets.

Conducted in collaboration with participating companies, this study systematically follows individual products, offering an understanding of the dynamics of early HTA advice and providing a baseline to capture the evolvement of Joint Scientific Consultation under the EU HTA Regulation. The study's findings aim to contribute actionable insights that can inform decision-making processes related to early HTA, ultimately enhancing the strategic approach of companies.

Key research questions include:

- What type of products undergo early HTA advice?
- What are the reasons behind some products opting not to seek early advice?
- Which agencies are offering early HTA advice?
- Which agencies are commonly approached for EU Joint Scientific Consultation?
- What topics are covered in early HTA advice meetings?
- When is early advice typically sought, and how does it impact the development plan?

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 Early Advice Metrics Programme, please contact Tina Wang: twang@cirsci.org

Frequently asked questions (FAQ)

What is CIRS?

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, scientific and independently run global forum for policy leaders from government regulators, health technology assessment (HTA) agencies, the pharmaceutical industry, and other stakeholders in healthcare, such as patient organisations and academia. We serve patients, agencies and medical developers by focusing on improvements in policies and processes for regulation and HTA. CIRS' 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 three multistakeholder workshops (two in H1 and one 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 multistakeholder 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.

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: May 2024