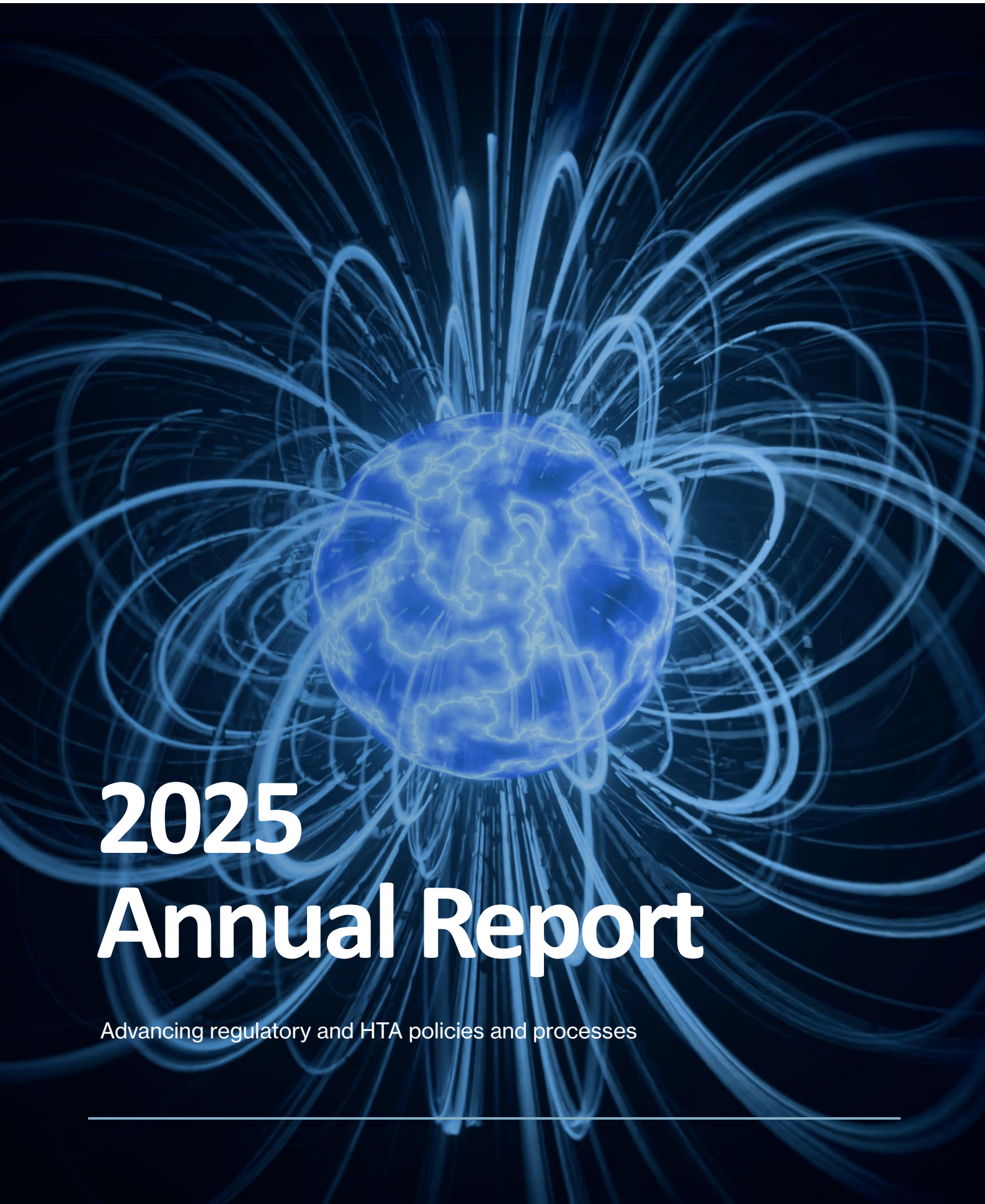
CIRS Centre for Innovation in Regulatory Science

www.cirsci.org



2025 Annual Report

Advancing regulatory and HTA policies and processes

Foreword

2025 was an important year for CIRS.

In a global environment that is becoming more complex, more connected and, in many cases, more uncertain, our focus has remained clear: to generate independent evidence, convene the right stakeholders, and help shape better thinking on how medicines are developed, reviewed and accessed.

What stands out most to me from the past year is the quality of the engagement around our work. Across our workshops, fora and roundtable discussions, we brought together regulators, HTA agencies, industry, academics and patient organisations to explore some of the most pressing questions facing the field. Those discussions were open, thoughtful and practical. They reinforced the value of CIRS as a trusted space for honest dialogue across different perspectives, particularly at a time when the systems involved in the development, review and reimbursement of medicines are under pressure to adapt and evolve.

Our research remains central to that role. In 2025, CIRS continued to produce a strong body of work across regulatory science and HTA, including R&D Briefings, peer-reviewed publications and conference presentations. These outputs matter not simply because of their volume, but because they are grounded in real policy and system-level challenges. Whether examining regulatory performance across major authorities, medicine availability in China, or the implementation of Joint Clinical Assessment in Europe, our aim has been to provide evidence that is relevant, robust and useful to decision makers.

This year also highlighted the importance of engaging seriously with emerging issues. Artificial intelligence (AI) is a clear example. AI is already beginning to influence development, review and assessment across the medicines lifecycle, but many of the governance, policy and practical questions remain unresolved. Through our Task Force and stakeholder discussions, we have seen both the potential of AI and the need for greater clarity, shared standards and cross-sector collaboration. This is an area where CIRS can continue to make a meaningful contribution.

I have also reflected on our work on patient involvement. Revisiting this topic in 2025 showed real progress over the past decade, but also clear gaps that remain. Recognition of the value of patient input has grown, but the harder questions now are about consistency, transparency and impact. How is patient input used? How is its contribution communicated? And how do we ensure that systems become more responsive in practice, not only in principle? These are important questions, and they will continue to shape our thinking.

Our international work remains a defining strength of CIRS. Through the Optimising Efficiencies in Regulatory Agencies (OpERA) Programme and our wider engagement, we have continued to support regulatory strengthening and cross-agency learning, particularly in Africa, while also deepening our engagement in other regions. This work is often gradual, but it matters. Stronger, more effective systems are built through sustained collaboration, trust and shared learning over time.

As we look ahead, my priority is to ensure that CIRS remains focused on where it can add the most value. Better evidence, better dialogue and better alignment across systems will not solve every challenge, but they do create the conditions for better decisions. And better decisions matter, because ultimately, they shape patient access to medicines.

That remains the purpose of CIRS, and it continues to guide our work.

Anna Somuyiwa, Head of CIRS

Introduction and overview

Who we are

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.

CIRS focuses on improvements in policies and processes for regulaton and HTA. We also support the development of agency capacity, including in low- and middle-income countries.

The CIRS team works internationally and is headquartered in the UK. CIRS works collaboratively with stakeholders worldwide, runs research projects internationally and conducts meetings globally to feed into and build on this research. Organisationally, CIRS is a wholly owned and independently managed UK subsidiary of Clarivate, with our funding derived from membership dues, special projects and grants from non-profits and governments.

CIRS's unique value proposition is its diverse community, with the participation of leaders from both small and large organisations in industry, regulators and HTA agencies around the world.

Three pillars of CIRS activities

For more information, please see 'About CIRS'.

Highlights in 2025

Comparing China's regulatory performance with six major regulators

In August 2025, we published R&D Briefing 102 tracking the availability in China of medicines approved in Australia, Canada, Europe, Japan, Switzerland and the US. While China has long been included in our Growth and Emerging Markets Metrics (GEMM) Programme using industry data, this was the first time we have compared public data from China with that of the six major regulators.

The briefing has been well received, highlighting the evolving role of China in global regulatory strategies. In addition, it has been translated into Chinese and published as a special feature in the China Food and Drug Administration magazine.

Understanding the landscape of AI use in medicine regulation and HTA

The CIRS AI Task Force was established in response to suggestions from CIRS' Scientific Advisory Council following AI's rapid integration into regulatory and HTA work. The Task Force helped to design a stakeholder survey and plan a roundtable meeting on the use of AI in medicine regulation and HTA, which took place in June 2025 in Washington DC US (see p11 for more detail).

The CIRS survey and roundtable meeting demonstrated that 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 to support both innovation and oversight of this transformative technology.

A follow-up workshop focusing on AI use in developing and reviewing regulatory and HTA submissions is planned for September 2026.

Completion of OpERA milestones

2025 marked the final year of a three-year grant from the Gates Foundation supporting the Optimising Efficiencies in Regulatory Agencies (OpERA) Programme. Building on the work of previous grants, a key achievement has been assisting agencies to use CIRS tools in their efforts to qualify as World Health Organization (WHO) Maturity Level 3 regulators. Having strong regulatory systems facilitates agency participation in regional and continental harmonisation initiatives, which the OpERA Programme has supported in Africa.

OpERA highlights from 2023-2025:

- Organised 3 annual fora facilitating cross-agency learning and exchange.
- Published 28 publications including peer-reviewed journals, posters, books, and R&D briefings.
- Fostered relationships with over 20 regulatory agencies in Africa with the support of three PhD students.
- Deepened connections in Latin America and Asia, supporting various countries in these regions with tools and metrics.

We have secured further funding from the Gates Foundation for the OpERA Programme for 2026-2028. This will help to support implementation of reliance-based regional and continental regulatory initiatives – particularly the African Medicines Agency (AMA) – while we continue championing regulatory strengthening and process improvements within countries.

Insights to inform EU JCA

In August 2025 we published R&D Briefing 99 reviewing EMA oncology approvals between 2018-2023 in terms of their first HTA outcomes and timelines across seven key EU jurisdictions. The insights from this briefing act as an important baseline for measuring the impact of Joint Clinical Assessment (JCA) under the EU HTA Regulation (HTAR), which is now in play for oncology products and advanced therapy medicinal products.

We shared the findings of R&D Briefing 99 with our member companies during an interactive webinar, and with a wider group of stakeholders through a poster at ISPOR Europe 2025. We also participated in a panel session at the ISPOR conference on potential learnings from the EMA's journey to harmonisation that could be applied to the HTAR, sharing insights from CIRS research and workshops.

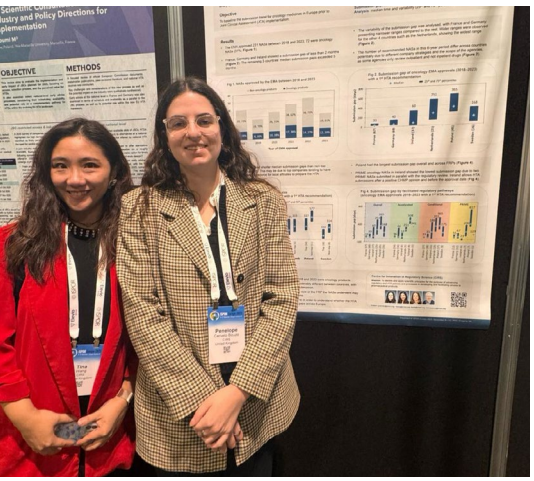
In addition, we organised a JCA workshop in Amsterdam in November 2025, co-hosted with Utrecht University (more detail on p10). This workshop was a follow-on to the CIRS JCA workshop in 2024 on assessing the efficiency and effectiveness of JCA. The 2025 workshop explored different stakeholders' experiences of early JCAs, looking deeper at the challenges of post-JCA transition at the national level.

Together, we hope that the insights from both the workshop and the briefing will help to support iterative improvement as JCA is gradually rolled out to all centrally authorised products by 2030.

Recognition of six agency benchmarking publication

Our R&D Briefings are a recognised source of independent evidence cited by our stakeholders globally. This year's mature regulatory agency benchmarking briefing was cited publicly by various stakeholders, such as:

- Swissmedic's press release summarising the findings of the briefing to contextualise its performance.
- The Swiss trade association, Interpharma, including data from the briefing in its annual Health Panorama publication on the Swiss pharmaceutical landscape.
- Japan's PMDA 2025 summer newsletter featuring data from the briefing, highlighting the value of international benchmarking in shaping domestic regulatory strategy.



2025 in numbers

Thought leadership

12
Journal publications *

6
CIRS R&D Briefings*

18
Conference presentations*

3
PhD students supported by CIRS

Stakeholder engagement

7
Workshops and fora†

4.8
out of 5 scored for multi-stakeholder workshops

INSIGHT MEETINGS

16 For companies

29 For agencies

4
Advisory board meetings

2
Webinars

100k+
Website downloads

650
New LinkedIn followers

* Listed on p17-19
† Listed on p7-11

2025 Multi-stakeholder workshops and meetings

FEBRUARY 2025 WORKSHOP, JOHANNESBURG, SOUTH AFRICA

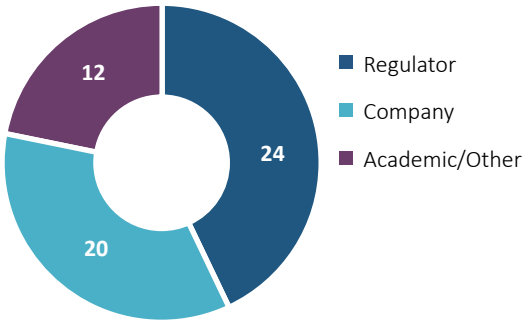
Regulatory agency collaboration and system strengthening – How is this enabling national, regional and continental models?

This workshop provided a platform for discussing success factors that support the implementation of regulatory collaborative models. Identified success factors centred around jurisdictional regulatory strengthening, measuring impact, quality decision making, reliance and work sharing, and digital solutions.

We hope that the learnings and recommendations from this meeting can help to inform the progression of efficient and effective regulatory systems around the world, particularly as Africa advances with the African Medicines Agency.

Download the workshop report

56 ATTENDEES FROM 20 COUNTRIES



"I gained a lot of knowledge from different regulator representatives and industry."

Regulatory agency

JUNE 2025 WORKSHOP, VIRGINIA, USA

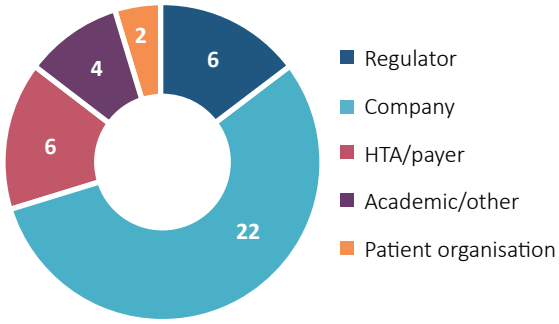
High public health impact medicines for chronic diseases – Do regulatory, HTA and payer paradigms need to change?

This workshop convened industry, regulators, HTA agencies, payers and patient organisations to explore strategies for incentivising the development of high-impact medicines for common chronic diseases. Stakeholders noted that chronic disease R&D faces limited incentives, evidence uncertainty, and few validated biomarkers or patient-relevant endpoints. The workshop highlighted the need for a new adaptive, collaborative, and patient-centered approach to chronic disease treatment development, review and reimbursement.

As part of a panel at the Drug Information Association (DIA) 2025 conference, we explored this topic further, sharing insights from CIRS metrics research and the workshop. A key theme was the potential for facilitated regulatory pathways (e.g. priority review) and collaborative pathways (e.g. Project Orbis, Access Consortium) to support more chronic disease medicines.

Download the workshop report

40 ATTENDEES FROM 9 COUNTRIES



"Thank you for bringing us together and for addressing such an underrepresented topic."

HTA/payer organisation

OCTOBER 2025 WORKSHOP, HEATHROW, UK

Meaningful patient involvement in regulatory and HTA decision making – Current practices and impact on final assessment

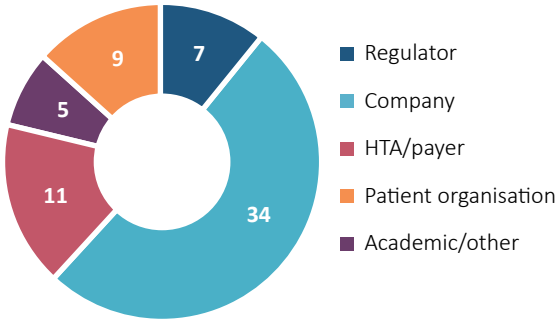
The workshop brought together multiple stakeholders to discuss challenges, opportunities, share case studies, and develop recommendations for improving the measurement and articulation of patient input in regulatory and HTA agency assessments. The findings of a CIRS survey of regulators and HTA agencies were presented to help inform the discussions among workshop participants.

The timing of the workshop coincided with the release of the EMA Patient Experience Data Reflection Paper, which was welcomed as an important step forward for the utilisation of patient input in the EU.

CIRS continues to explore patient involvement practices among regulators and HTA agencies, with another multi-stakeholder workshop – this time focusing on Asia – scheduled for 2026. We hope that the learnings and recommendations from these workshops will help to address policy barriers to the meaningful use of patient input in agency decision making.

Download the workshop report

76 ATTENDEES FROM 17 COUNTRIES



"One of the best collaborative settings I've been part of."

Anon

NOVEMBER 2025 WORKSHOP, AMSTERDAM, THE NETHERLANDS

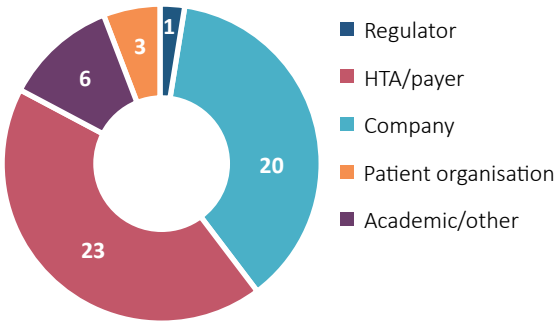
Navigating national decision making post Joint Clinical Assessment (JCA): Enablers, barriers, and the path forward

This workshop, co-hosted with Utrecht University, brought together EU HTA agencies, industry, academics, payers, patient organisations, the European Medicines Agency and European Commission to examine how HTA agencies are adapting their processes to integrate Joint Clinical Assessment (JCA) outputs into decision making. The workshop built upon the insights from the CIRS JCA workshop in 2024, exploring early learnings from JCA experiences in oncology and advanced therapy medicinal products.

Key topics of discussion were around PICO coordination, capacity building, EMA–HTA collaboration, and feedback loops. We hope that the learnings and recommendations from this meeting will help to facilitate practical implementation of JCA outputs and improve the efficiency and effectiveness of the JCA.

Download the workshop report

63 ATTENDEES FROM 19 COUNTRIES



"Nice blend of all perspectives from different stakeholders. I learned a lot!"

HTA agency

Other stakeholder meetings

Regulators' Forum - February 2025, Johannesburg, South Africa

Advancing performance of regulatory systems and enabling continuous improvement within agencies

This forum provided a platform for 12 regulatory agencies from around the world to discuss the importance of performance measurement and share best practices. Agency case studies showed the application of various tools and practices, including CIRS metrics and decision-making tools. The forum emphasised the need for regulators to focus on continuous improvement through metrics, clear communication, and leveraging assessment reports to optimise risk-based processes.

Find out how your agency can get involved with CIRS

AI Roundtable – June 2025, Virginia, USA

Artificial intelligence (AI) - Optimising company-regulator-HTA agency interactions through the drug product lifecycle

This multi-stakeholder roundtable meeting focused on addressing linkages that either exist or need to be strengthened between companies, regulators and HTA agencies for AI to be implemented responsibly and effectively. The findings of a CIRS survey of companies and regulators were presented to help inform the discussions during the meeting.

The roundtable demonstrated that while companies, regulators and HTA agencies are exploring and benefitting from AI applications, integration of AI into development, review and reimbursement processes remains an evolving endeavour. Participants underscored the importance of collaboration, transparency, shared learning, and the need for harmonised standards, cross-sectoral dialogue, and practical frameworks that support both innovation and oversight.

The insights and recommendations from the roundtable will inform the programme of a multi-stakeholder workshop in 2026 on 'AI in regulatory and HTA/pricing submission and review'.

Industry Forum for CIRS Members - November 2025, Amsterdam, The Netherlands

Navigating global regulatory and HTA changes: Challenges, opportunities, and implications for innovation

Prior to the JCA workshop, we held a Technical Forum with our member companies to explore the impact of major policy and procedural changes in the global landscape, including the US Most Favoured Nation policy, the EU Pharmaceutical Legislation reform, and the EU HTA Regulation.

Participants shared their perspectives on the implications of such changes on innovation, competitiveness and patient access globally, as well as development, regulatory and HTA strategies across industry. Importantly, recommendations were put forward for how CIRS can support industry in navigating the changing pharmaceutical landscape by conducting metrics research, facilitating collaboration and fostering dialogue.

The insights and recommendations from the forum will inform the programme of a multi-stakeholder workshop in 2026 entitled 'Policy to practice: Strategic implications of HTA and regulatory changes worldwide'.

Find out about CIRS Industry Membership

Growth and Emerging Markets Metrics (GEMM) Programme Industry Discussion Meeting (IDM) – September 2025, London, UK

This meeting provided a forum for participating companies to discuss trends in the development and registration of new medicines in growth and emerging markets, based on data from the GEMM Programme.

Find out about the GEMM Programme

Case study

Evolution of patient involvement in regulatory and HTA decision making: Insights from CIRS workshops

In October 2025, CIRS convened a multi-stakeholder workshop exploring the role of patient involvement in medicines development, regulation, and health technology assessment (HTA), a decade on from the last CIRS workshop on this topic. This article summarises insights from the two workshops, exploring how certain areas of patient involvement have evolved, and which challenges remain unresolved.

Background

CIRS has generated insights on patient involvement in medicines development, regulation, and health technology assessment (HTA) since 2012 through various stakeholder meetings and research (see timeline).

Multi-stakeholder workshops held in 2012, 2013, and 2014 drew attention to the role of patient involvement in benefit-risk decisions; stakeholders supported the inclusion of patient input into benefit-risk evaluation and decision making but acknowledged that methods to capture this input were still evolving. They highlighted the importance of clear objectives, robust methodologies, and continued multi-stakeholder dialogue to help embed the patient voice more systematically into clinical development and regulatory review.

2012 Workshop - The patient's role in the benefit-risk assessment for the submission and review of new medicines

2013 Workshop - Patient voice in clinical development: Can patients contribute to the benefit-risk assessment of new medicines?

2014 Workshop - The assessment of benefits and harms and their relative importance for patients, industry and agencies: How should they be captured?

2015 Workshop- What is the patient's role in informing the decision process for approval and reimbursement of new medicines?

2015-2025 Patient representatives share their perspectives in various workshops

2020 Research study- Patients' perspectives of the pharmaceutical regulatory and reimbursement systems in Istanbul, Turkey

2021 Industry forum- Ensuring meaningful patient engagement: How can companies align internal and external stakeholders' expectations during development to support the review and reimbursement of new medicines?

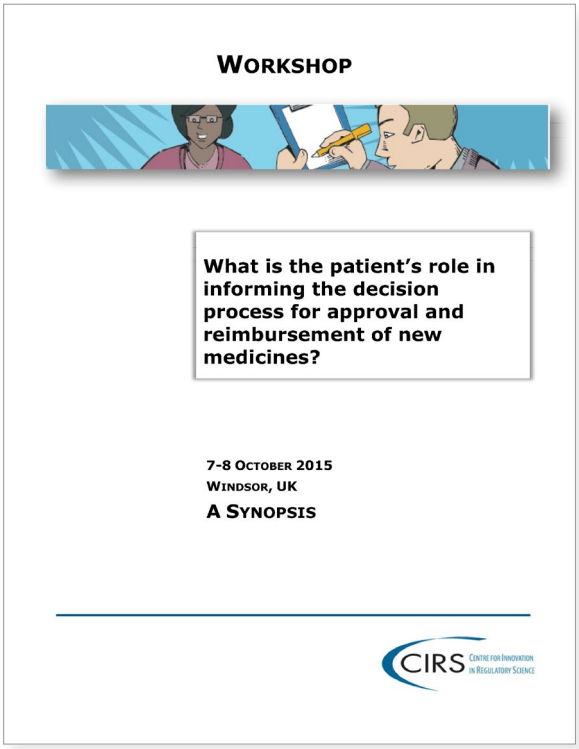
2021-2026 Metrics research tracking FDA's inclusion and consideration of PED in regulatory reviews

2022-2023 Strategic topic group on patient involvement

2024 Industry forum – Patient engagement and patient experience data: How is this supporting review and reimbursement decisions and can impact be measured?

2025 Workshop – Meaningful patient involvement in regulatory and HTA decision making: Current practices and impact on the final assessment

2026 Workshop – Building capacity for patient involvement in regulatory and HTA decision making in the Asia Pacific: Focus on rare diseases and precision medicine

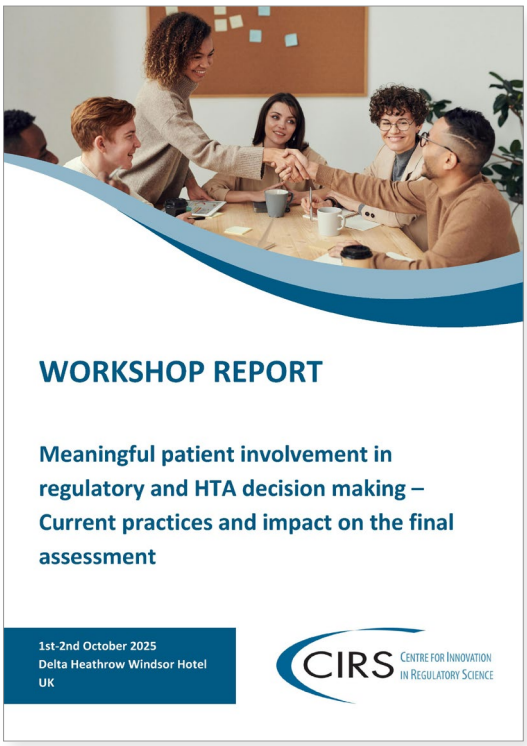


2015 workshop: Linking patient perspectives to evidence and process

Building on insights from the 2012-2014 workshops, CIRS convened another patient involvement workshop in 2015, specifically on processes for incorporating patient input into regulatory and HTA assessments and decision making. This included patient-reported outcomes and other forms of patient-derived information that were increasingly being submitted to regulatory and HTA agencies.

Participants discussed how patient input was collected and used by regulators and HTA bodies, and whether more integrated approaches could reduce duplication. Progress was noted in patient involvement across North America, Europe and Australia, but challenges remained, including identifying representative patients, limited patient capacity, and unclear evidence of impact on decisions.

A key theme was the need to move from ad hoc engagement toward more structured and transparent approaches, including better documentation and feedback on how patient input is used. Looking ahead, participants highlighted the potential of digital tools, improved training for patient contributors, and stronger cross-stakeholder collaboration.



2025 workshop: Integration, visibility, and impact

Following the 2015 workshop, CIRS invited patient representatives to various workshops to share their perspectives on certain topics, such as commonality in regulatory and HTA requirements (2016 workshop), pandemic practices and learnings (2020), rare diseases (2023), EU Joint Clinical Assessment (2024 and 2025), and chronic diseases (2025).

As recommended by a strategic Topic Group constituted of individuals from its advisory bodies, CIRS re-examined the topic of patient involvement in 2025 with an agency survey (see p14) and multi-stakeholder workshop.

The 2025 workshop revisited many of the themes raised in earlier workshops, but with a more explicit focus on how patient engagement (PE)[1] and patient experience data (PED)[1] are integrated within regulatory and HTA decision-making processes, and how their impact is measured and communicated. The findings of the CIRS survey of regulators and HTA agencies were presented to help inform the discussions among workshop participants.

1 As defined by the US Food and Drug Administration.

The workshop highlighted that PE and PED are greatly valued by regulators and HTA agencies, but their use remains inconsistent and often lacks transparency. Case studies illustrated a wide range of patient involvement models now being used by agencies, including written patient submissions, committee participation, and stakeholder networks. While examples showed that PE and PED can meaningfully influence assessments—particularly where clinical evidence is limited—participants noted that feedback to patients on how their input affected decisions is limited.

A central theme was the challenge of measuring and communicating impact of patient involvement. Harmonised terminology, structured reporting tools such as standardised PED tables, clearer rationales for accepting or excluding patient evidence, and more accessible public-facing summaries were seen as key steps toward building trust and demonstrating meaningful use of patient insights by agencies.

Looking ahead, participants agreed that progress requires cultural change, stronger infrastructures, and sustained cross-stakeholder collaboration. Increased alignment between regulatory and HTA agencies was viewed as important for reducing duplication, supporting consistent expectations, and easing the burden on patient organisations.

2025 CIRS agency survey on patient involvement

Prior to the 2025 workshop, CIRS conducted a survey of regulatory and HTA agencies to better understand their perspectives and practices for patient engagement (PE) and patient experience data (PED). The survey focused on agency-level activities related to PE and PED, metrics for measuring impact, communication/documentation, current challenges, and future thinking in this area.

The survey was completed by 13 regulatory agencies and 18 HTA agencies across North America, Europe, Asia, and Latin America.

Key findings:

- HTA agencies tend to engage more broadly in PE/PED activities and are more likely to have a formal approach to PE/PED than regulatory agencies.
- Most agencies (both regulatory and HTA) do not have impact measures or direct feedback to patients on the use of PE/PED in their deliberations and decisions.
- While agencies are challenged by concerns about biases and representativeness, they believe that patient data will have greater influence on their work over the next five years.
- Guidelines on ensuring quality, rigour, and representativeness of data, along with infrastructure and resources to support patient groups, are needed going forward.

So, what's changed?

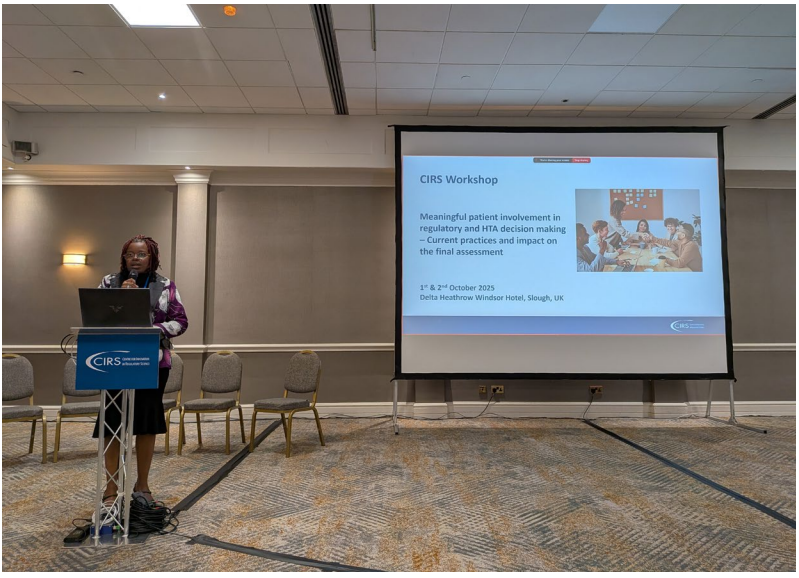
The breakout discussions during the 2015 workshop produced several recommendations about the integration of patient involvement, its impact in regulatory and HTA decisions, and how agencies can better meet the needs of patients (see table on p16). Insights from the 2025 workshop suggest that while several of these recommendations have been achieved or partly achieved, more work is needed to address integration, impact and visibility challenges.

In addition, the 2025 workshop showed that expectations placed on patients have increased faster than supporting infrastructure and guidance. Support for patient groups, including capacity-building, sustainable funding, and more flexible conflict-of-interest policies, will be necessary to ensure diverse, representative patient voices can contribute to regulatory and HTA processes effectively.

What's next for CIRS?

Through another multi-stakeholder workshop, this time focused on the Asia-Pacific region, CIRS continues to explore patient involvement practices among regulators and HTA agencies. This workshop was held in March 2026 in Kuala Lumpur, Malaysia, in collaboration with the Duke NUS Centre of Regulatory Excellence. The learnings and recommendations from this meeting will hopefully help to support capacity-building efforts for patient involvement across the Asia-Pacific.

Patient involvement was a cross-cutting theme at the CIRS Strategic Summit in May 2026 focused on receiving stakeholder input, including patient groups, for planning the next CIRS research agenda (2027-2029). The Summit outcomes will help determine the role that CIRS may play in the patient involvement space in the foreseeable future.



Progress against 2015 CIRS workshop recommendations, as evidenced by the 2025 workshop

2015 Workshop Breakout Theme	2015 Breakout Recommendation	2025 Status	What has happened since 2015?	What still needs to happen?
A. Integrated patient involvement across the product lifecycle	Develop clear definitions and frameworks for patient involvement in regulatory and HTA decision making.	Partly achieved	Definitions and frameworks for PE and PED have become clearer (e.g. US Food and Drug Administration Patient-Focused Drug Development Guidance, European Medicines Agency PED Reflection Paper).	Greater harmonisation of PE and PED definitions, and clear guidance on what constitutes high-quality PED. Common standards
	Work globally with regulators and HTA bodies to make the patient voice an integrated part of their processes.	Partly achieved	Patient involvement has become operationalised in many regulatory and HTA systems, with better understanding of good practices.	More consistent integration is still needed, with clearer links between patient input and decision processes.
B. Measuring impact of patient input in HTA decisions	Transition patient participation in HTA from consultation to partnership.	Partly achieved	Patient involvement in HTA has become broader and more formalised, with recognition of the importance of patient partners.	Patient-HTA partnerships supported by transparency, clear demonstration of impact, and sustainable funding.
	Conduct research to establish standards on quality and impact of patient involvement in HTA.	Partly achieved	Conceptual frameworks for quality and impact have been proposed, reflecting recognition of this gap (e.g. Patient Focused Medicine Development (PFMD), HTA International (HTAi) Patient and Citizen Involvement Interest Group).	Agreed, widely adopted standards to assess the quality and impact of patient involvement in HTA practice.
C. Measuring impact of patient input in regulatory decisions	Map global regulatory frameworks for patient involvement and identify gaps.	Achieved	Global landscape reviews and surveys have mapped regulatory approaches to PE and PED, identifying strengths and gaps across regions (e.g. PFMD landscape studies, CIRS survey).	Explore policy solutions to address regional gaps and repeat mapping exercises to assess future progress.
	Develop evaluation measures for patient involvement in the regulatory process.	Partly achieved	Documentation of patient input has improved, and evaluation is increasingly discussed as a regulatory science priority.	More consistent, repeatable measures of how patient input influences regulatory decision making.
D. Ensuring agencies better meet the needs of patients	Review agency conflict-of-interest (COI) policies and assess potential exclusion of patient voices.	Partly achieved	COI challenges have been highlighted in various forums (e.g. HTA Coordination Group for the EU HTA Regulation).	More flexible, proportionate COI frameworks that balance transparency with inclusion.
	Establish a consortium to review patient involvement methodologies and share best practices.	Achieved	Multiple collaborative initiatives have shared learning and methods across stakeholders (e.g. PFMD, Innovative Medicines Initiative PREFER, HTAi, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).	Continue to promote common methodological expectations and establish a best practice repository.
	Assess transferability of patient perspectives across countries.	Not achieved	Increased cross-country collaboration and use of regulatory risk-based approaches has raised awareness of this issue.	Practical mechanisms to support reuse or extrapolation of PED across jurisdictions while respecting national contexts.

Publications in 2025

CIRS R&D Briefings

Regulatory

1. R&D Briefing 97 – Access Consortium and Project Orbis New Active Substance Approvals Across Eight National Regulatory Authorities. A Five-Year Comparative Study
2. R&D Briefing 101 – New drug approvals by six major authorities 2015-2024
3. R&D Briefing 102 – Tracking availability in China of medicines approved in six key global markets

HTA

1. R&D Briefing 98 – HTADock Project: European HTA Trends: HTA Outcomes and Timelines Across Seven Markets (2019–2023)
2. R&D Briefing 99 – HTADock Project- Review of HTA Outcomes and Timelines of Oncology Products Approved by the EMA Between 2018 and 2023
3. R&D Briefing 103 – Review of HTA outcomes and timelines in Australia, Canada, Europe, and the UK, 2020-2024

Journal publications & books

Regulatory

1. Owusu-Asante M, Darko DM, Seaneke S, Nacoulma A, Traore OIO, Adeyeye CM, Akinyemi A, Assane C, Clamoungou CÉKM, Ndao OK, Kande RN, Komeh J, Mansaray S, Lamboni D, Agba M, **Walker S** and Salek S. Comparison of good review practices of seven countries participating in the ECOWAS medicines regulatory harmonisation initiative: identifying opportunities for improvement. Front. Med. 2025;11:1520892.
2. Ngum N, Chamdimba C, Mbonyingingo D, Siyoi F, Bienvenu E, Atem M, Fimbo A, Nahamya D, Simai B, **Walker S** and Salek S. Suggested Improvements to the Current East African Community Medicines Regulatory Harmonization Joint Review Process and a Proposed New Review Model for this Initiative. Pharm Med; 2025;39:125–141.
3. Danks L, Semete-Makokotlela B, Gouws R, Otwombe K, **Walker S** and Salek S. The Economic Impact of Reliance on an African Medicines Regulatory Authority. Pharm Med 2025;39:109–123 .

4. Danks L, Semete-Makokotlela B, Chuma D, Borg JJ, Khoza S, **Walker S**, Salek S. The value of a structured, systematic approach to benefit-risk assessment of medicines: A South African regulator case study. Regul Toxicol Pharmacol. 2025;162:105893.

5. Owusu-Asante M, Darko DM, Seaneke S, Nacoulma A, Traore OIO, Adeyeye MC, Akinyemi A, Assane C, Clamoungou CÉKM, Ndao OK, Kande RN, Komeh J, Mansaray S, Lamboni D, Agba M, Salek S and **Walker S**. Comparison of the review models and regulatory timelines of seven countries participating in the ECOWAS-MRH initiative: identifying opportunities for improvement. Front Med 2025;12:1587761.

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10. Sakala Chisha C, Leigh S, Siyanga M, **McAuslane N** and **Walker S.** Assessment of compliance with good review practices by medicine assessors within the Zambia medicines regulatory authority. Front. Med. 12:1706139.

11. Owusu-Asante M., Salek S, **Walker S.** The current regulatory environment in Africa and the future role of the African Medicines Agency: Contribution of the ECOWAS region. [PhD thesis]

HTA

1. **Wang T, McAuslane N**. Ensuring the Efficiency and Effectiveness of Joint Clinical Assessment in National HTA Decision-Making: Insights from the 2024 CIRS Multi-Stakeholder Workshop. J. Mark. Access Health Policy 2025, 13, 9.

2. **Wang, T., McAuslane, N.** Enhancing Development Strategies Through Early Scientific Advice from HTA Agencies–Experiences, Expectations and Best Practices from Health Technology Developers. Ther Innov Regul Sci 2025; 59:1484–1494.

Conference presentations in 2025

DIA Europe, 18-20th March, Basel, Switzerland

1. Dr Magda Bujar – Panellist- Transforming Regulatory Landscapes: Driving Regulatory Innovation via AI/Automation, Data Exchange and Harmonisation

DIA China, 22-25th May, Shanghai, China

2. Dr Tina Wang – Panellist- Evidence Across the Continuum: From Discovery to Access for Innovative Medicine

DIA Global, 15-19th June, Washington DC, USA

3. Dr Magda Bujar – Panellist – Applying Principles of Global Regulatory Collaboration to Address Chronic Disease
4. Prof Stuart Walker (on behalf of Constance Chisha) – Poster – Quality of Decision Making Orientation Scheme (QoDoS): A Study to Evaluate the Quality of Decision Making within the Zambian Medicines Regulatory Authority (ZAMRA)
5. Prof Stuart Walker (on behalf of Mercy Owusu-Asante) – Poster – Assessment of Good Review Practices at the FDA Ghana
6. Prof Stuart Walker (on behalf of Nancy Ngum) – Poster – A Proposed Model for the East African Community Medicines Regulatory Harmonisation Joint Review Process
7. Prof Stuart Walker (on behalf of Lorraine Danks) – Poster – The Universal Methodology for Benefit-Risk Assessment (UMBRA): Testing its Implementation in a South African Agency

DIA Singapore, 15-16th July, Singapore

8. Dr Neil McAuslane – Plenary presentation- Advancing regulatory practices and processes globally: Insights, new ways of working and impact

DIA Latin America Annual Meeting, 29th September – 1st October, Buenos Aires, Argentina

9. Dr Magda Bujar – Panellist- Navigating Regulatory Reliance: Practical Insights and Applications Beyond Initial Marketing Authorisation Application

DIA Canada, 27-28th October

10. Dr Neil McAuslane – Virtual presentation- Advancing Regulatory Innovation: Canadian Role in Global Collaboration – What do Metrics Tell Us?

ISPOR Europe, 9-12th November, Glasgow, UK

11. Dr Tina Wang – Panellist – A New Era for EU HTA: What Can the EU HTAR Learn from the EMA's Path to Harmonisation?
12. Penelope Cervelo – Poster- The HTA Landscape of Orphan Products in the UK between 2019 and 2024
13. Penelope Cervelo – Poster- HTA Submission Trends for EMA-Approved Oncology NASs Prior to the EU HTA Regulation (2018-2023)
14. Penelope Cervelo – Poster – The Canadian HTA Landscape (2020-2023): A Comparative Study of CDA-AMC and INESSS Recommendations

Scientific Conference on Medical Product Regulation in Africa (SCoMRA), 11-13th November

15. Prof Stuart Walker (on behalf of Constance Chisha) – Poster – Quality of Decision Making Orientation Scheme (QoDoS): A Study to Evaluate the Quality of Decision Making within the Zambian Medicines Regulatory Authority (ZAMRA)
16. Prof Stuart Walker (on behalf of Mercy Owusu-Asante) – Poster – Assessment of Good Review Practices at the FDA Ghana
17. Prof Stuart Walker (on behalf of Nancy Ngum) – Poster – A Proposed Model for the East African Community Medicines Regulatory Harmonisation Joint Review Process

University of Hong Kong SCAN-2030 Seminar, 4th December, Hong Kong

18. Dr Tina Wang – Speaker- Value Framework for Building our NextGen HTA Mechanism

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 HTA policies and processes in developing and facilitating access to pharmaceutical products. 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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