CIRS Centre for Innovation in Regulatory Science

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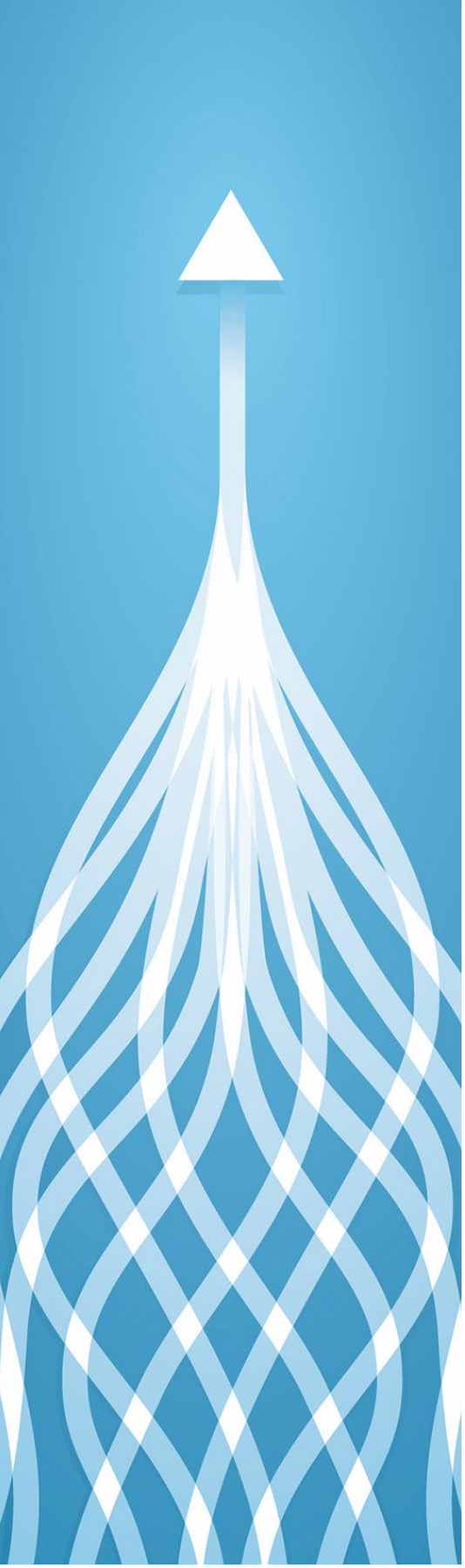
CIRS 2026 Research Agenda

Advancing regulatory and HTA policies and processes



CIRS Centre for Innovation in Regulatory Science

Table of **Contents**

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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 regulation 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'.

Research Agenda 2024-2026

Executive Summary

CIRS generated its 2024-2026 research agenda with significant input from its Scientific Advisory Council and HTA Steering Committee. Priorities were identified and thoroughly reviewed through meetings of Topic Groups in 2022-2023, which focused on patient engagement; expedited pathways in regulation and HTA; and metrics.

Feedback from these groups, careful review of the landscape as well as conversations with various CIRS member companies, agencies and other stakeholders, were reviewed and organised into the following research agenda. This will be achieved through research projects, workshops and other meetings.

CIRS Research Agenda 2024 - 2026

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

Research Agenda 2024-2026

Themes

Decision-making frameworks for new ways of working and evidence generation techniques: Moving implementation from concept to practicality

Faced with increasingly complex technologies and novel evidence generation techniques, regulatory and HTA agencies are being challenged to work in new ways. There is pressure on them to be agile and effective in their processes and more efficient with their resources. While risk-based decision making and regulatory reliance are well-developed concepts for agencies, how to implement these in practice is not always clear.

This research area builds on previous CIRS work in the areas of advanced therapy medicinal products (ATMPs), digital health technologies, real-world data/evidence (RWD/E), risk-based decision making (reliance models) and the use of public and non-public assessment documentation. The overall aim is to shift regulatory and HTA frameworks and models in these areas from concept to practicality, so companies and agencies are supported to better implement these models.

Good practices for regulatory and HTA collaborative models of review and assessment: Sharing learnings and experiences

A growing number of regulatory and HTA agencies are collaborating at a national, regional and/or international level as well as across disciplines. The impact of these collaborations, however, is still largely unknown. There is uncertainty around the operationalisation of the EU HTA Regulation, which is formalising collaboration between EMA and HTA bodies and between individual EU HTA bodies through Joint Scientific Consultation (JSC) and Joint Clinical Assessment (JCA). The assessment and funding environment for health products is also changing in other countries, for example with the passage of the US Inflation Reduction Act (IRA) and Most Favoured Nation (MFN) policy.

This research area assesses the impact of regulatory and HTA collaborative models in both mature and growth markets, in order to share learnings and identify best practices. Collaborative models of interest are those that bring together regulators, HTA agencies, and both regulators and HTA agencies. Examples include Project Orbis, the Access Consortium, regional regulatory collaborations, the UK Innovative Licensing and Access Pathway (ILAP) and the EU JSC.

Metrics on new ways of working and evidence generation and their impact on decision making: Strategic insights and impact measures

CIRS' experience in benchmarking metrics goes back two decades. This research area for 2024-2026 continues and extends that solid foundation, with a focus to identify qualitative and quantitative metrics on the efficiency and effectiveness of regulatory review and HTA assessment. This includes assessing the impact of new ways of working, including novel methods of evidence generation and digital health technologies, and the impact of legislative changes such as the EU HTA Regulation and US IRA and MFN.

5

New research topics:

Patient engagement in regulatory and HTA decisions

Patients are increasingly involved in regulatory and HTA assessments, however, the impact that their input has on regulatory and HTA decision making is not well defined. In 2025, CIRS conducted a stakeholder survey and workshop to further understand this impact, how it is measured and articulated, and the needs, challenges and opportunities for patients, companies and agencies going forward. A second patient engagement workshop in 2026 will build on these efforts, with a focus on building capacity in Asia.

Vaccines

Interest in vaccines is growing from a public health, commercial, regulatory and HTA perspective, in part due to the COVID-19 pandemic, advances in vaccine technologies and the development of a significant number of new vaccines for adult use. In 2024, CIRS convened a multi-stakeholder workshop to discuss the evolving vaccine landscape and how this can be better supported. A Task Force has since been set up to help direct future research efforts, such as a potential metrics study, for CIRS' 2027-2029 research cycle.

High public health impact medicines for chronic diseases

Common chronic diseases such as cardiovascular, metabolic and neurological diseases, are major contributors to declining life expectancy, yet there are limited new drug development incentives for these diseases. In 2025, CIRS held a multi-stakeholder workshop to identify key challenges and explore solutions for improving the drug development paradigm for common chronic diseases. The CIRS Summit in May 2026 will assess whether chronic diseases should continue to be a research theme for CIRS going forward for 2027-2029.

Artificial intelligence

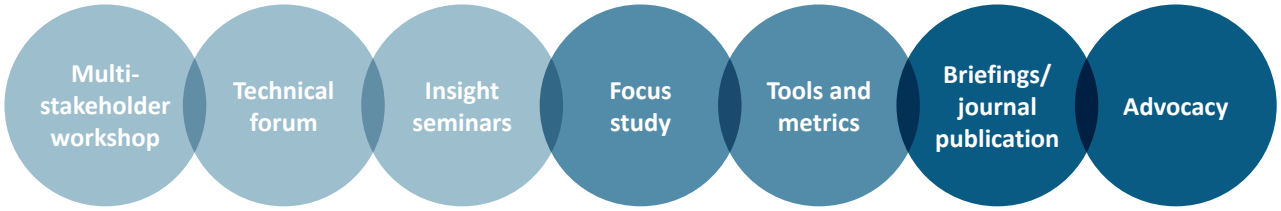
Artificial intelligence (AI) is being used by pharmaceutical companies, regulators and HTA/coverage bodies in a growing number of ways. In 2024 CIRS set up a Task Force to help design a stakeholder survey and AI Roundtable meeting on the use of AI in regulation and HTA, which took place in 2025. A workshop is planned for 2026 to explore the ongoing evolution of AI in regulatory, HTA and payer processes and inform future CIRS research for 2027-2029.

Rare diseases

Rare diseases are increasingly seen as a large group of diseases that have common challenges and require a global response to accelerate drug development. In addition to annual publication of insights on orphan drug approvals and HTA recommendations, CIRS conducted metrics research in 2024/25 that informed recommendations made to the FDA by a National Academies Committee on regulatory processes for rare disease drugs in the US and EU. 2026 activities include continued participation in the Rare Diseases International-Lancet Commission on Rare Diseases (RDI-LCRD) and World Economic Forum Rare Diseases Affinity Group.

2026 Workstreams and Workshops

Outputs of the Regulatory and Access Programme (RaAP) span from multi-stakeholder workshops, to focus studies to advocacy activities:



CIRS members can participate in multi-stakeholder activities such as workshops, research and benchmarking metrics projects, benefit from priority access to CIRS publications and are part of an international community helping to shape major policy topics.

More information can be found in '**CIRS Company Membership**'.

The next sections outline the workplans for the CIRS Regulatory and HTA teams in 2026.

Global Development Workshop, February 2025

2026 Workstreams and Workshops

Regulatory Workstream for 2026

GOAL

Provide a neutral forum for the evolution of the global regulatory environment by facilitating the advancement of regulatory science concepts, tools and policies that improve the effectiveness, efficiency and decision making of companies and regulatory agencies in the development of safe and effective medicines.

PRIORITIES

TIME

Increase transparency of regulatory performance through timely, relevant metrics.

QUALITY

Enable development and implementation of good regulatory practices.

RISK-BASED

Promote the use of risk-based reviews (reliance, worksharing) and facilitated pathways.

TRANSPARENCY

Increase information sharing and transparent documentation of decision making

NEW MODELS

Evaluate new ways of working and support opportunities for alignment

2026 Workstreams and Workshops

Regulatory 2026 Workstream

Priority area	Outputs
 1. Time	• R&D Briefing with updated metrics on mature regulatory agency benchmarking • R&D Briefing with updated metrics on Project Orbis and Access Consortium collaborations – with more comprehensive analysis on MHRA, HSA and ANVISA timelines for non-Orbis/Access products • R&D Briefing and publication on regulatory performance in other major markets including China and Brazil • Growth and Emerging Markets Metrics (GEMM) programme – new streamlined core report, analysis tool, Industry Discussion Meeting, and deep dive analyses driven by customer interest e.g. therapy area or facilitated regulatory pathways • Publication assessing the link between CPP submission timing and medicine rollout, using statistical analysis on the GEMM dataset • Metrics reports and publications focusing on agencies participating in the Optimising Efficiencies in Regulatory Agencies (OpERA) Programme (Africa, Latin America, Asia) • R&D Briefing comparing regulatory performance of African WHO ML3 countries • Forum for regulatory agencies on 'Making Reliance Work: Practical Approaches and Tools for Effective Regulatory Collaboration' and a new Africa-focused Regulators' Forum
 2. Quality	• Evaluation of regulatory practices and processes within target OpERA agencies using CIRS tools to ensure quality of process, practices and decision making - Publication comparing the performance of WHO Maturity Level 3 African regulatory agencies, using CIRS OpERA Country Reports - Training, education and publications with OpERA agencies and regional bodies (e.g. in Africa – AMA; Asia – ASEAN) on implementation of benefit-risk frameworks, good review practices and quality decision making (e.g. Ghana, Zambia, Zimbabwe)
 3. Risk-based	• Evaluation and support for the implementation and operationalisation of the African Medicines Agency (AMA) using OpERA - Publication evaluating regulatory outcomes of the AMRH pilot project - Publication analysing the structure and performance of Technical Committees - Publication assessing stakeholder perspectives on the effectiveness and efficiency of the AMA framework • Training on benefit-risk assessment in selected countries and supporting implementation of reliance – including publication of case studies (e.g. Vietnam, Mexico, Jordan) • Establishing a mechanism to continuously monitor use of regulatory reliance in line with WHO Good Reliance Practices- new project supported by FIFARMA producing comprehensive report country white papers, external presentations - Mapping the use of reliance and assess implementation in selected LATAM countries - Identifying barriers and enablers for effective implementation of reliance - Assessing the extent to which current reliance practices reflect global standards
 4. Transparency	• Monitoring use of regulatory reliance- proposal for an online interactive monitoring platform as part of the FIFARMA project • Interactive online repository of CIRS OpERA outputs and deliverables by country (publications, country reports, metrics)
 5. New models	• R&D Briefing evaluating the utilisation and embeddedness of artificial intelligence within regulatory review processes in agencies using OpERA country reports • Multi-stakeholder workshop: AI in Regulatory and HTA/Pricing Submission and Review • Multi-stakeholder workshop: Policy to Practice: Strategic Implications of HTA and Regulatory Changes Worldwide
+ Regulatory Technical Forum for CIRS member companies (Topic tbc)	

2026 Workstreams and Workshops

HTA Workstream for 2026

GOAL

Provide a neutral forum for the evolution of the global HTA environment by advancing the process and policies that improve the effectiveness, efficiency and decision making of companies and HTA agencies in improving access to new medicines.

PRIORITIES

PERFORMANCE
Increase HTA performance and transparency through timely, relevant metrics.

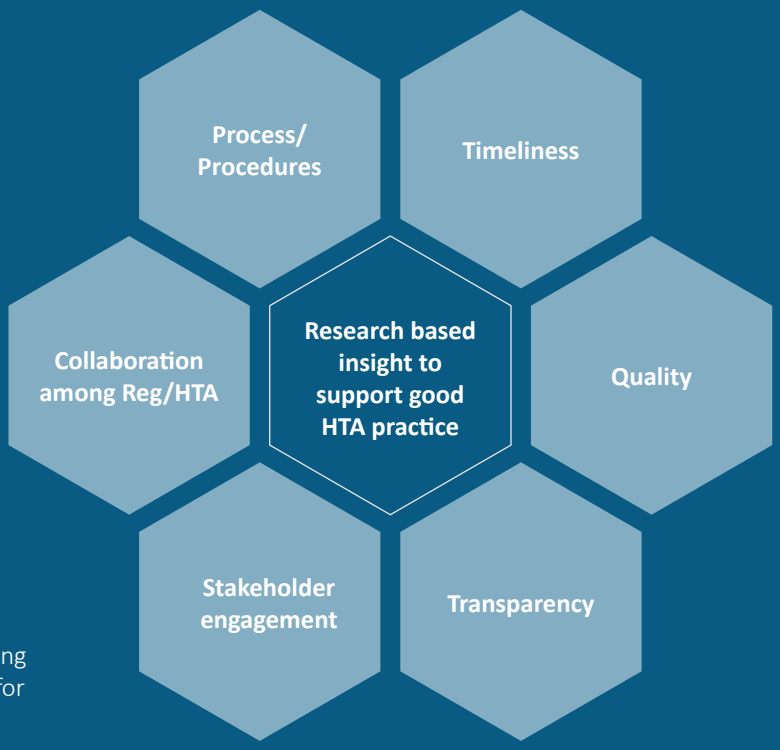
EARLY INSIGHT
Identify opportunities and challenges with early HTA advice and enhance development strategies and upstream communication, including with regulatory agencies

COLLABORATION
Promote international engagement and strategic policy discussion

QUALITY
Advance the development of good HTA practices

TRANSPARENCY
Increase information sharing and transparent documentation of decision making

NEW MODELS
Evaluate new ways of working and support opportunities for collaboration



2026 Workstreams and Workshops

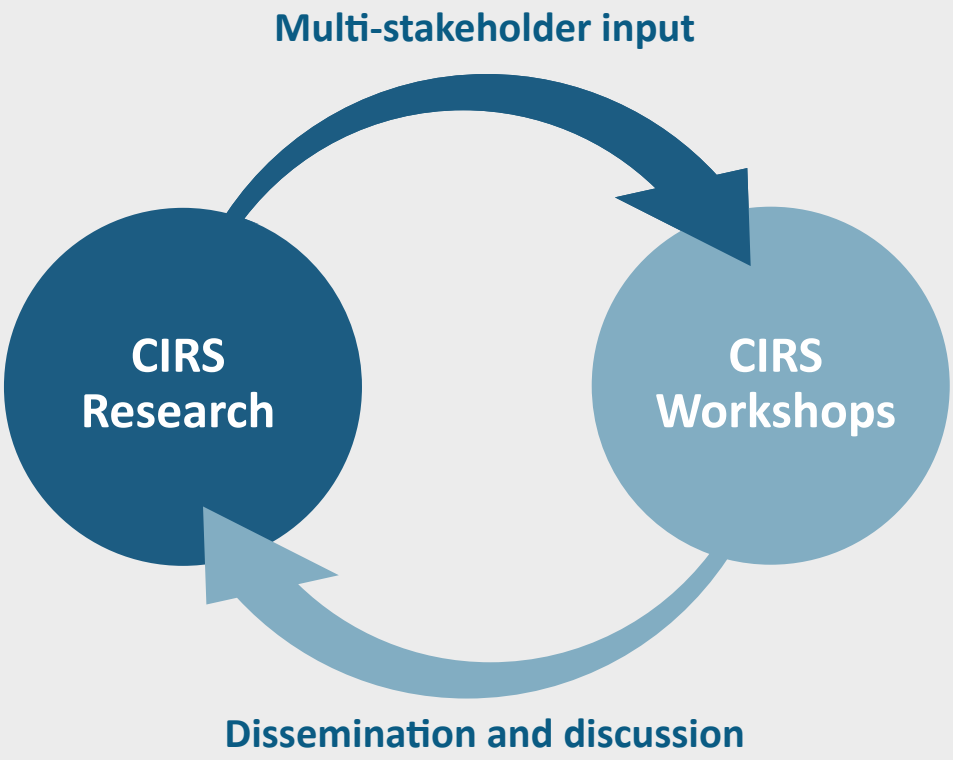
HTA 2026 Workstream

Priority area	Outputs
1. Performance	• HTADock annual briefing tracking regulatory and HTA decision making for new active substances across Australia, Canada, the UK and Europe (12 HTA agencies) • Comparative assessment across jurisdictions of regulatory–HTA timing alignment, the impact of regulatory pathways on HTA outcomes, and the use of flexible HTA processes and managed access arrangements • Additional analysis on time from regulatory submission to reimbursement across key jurisdictions, highlighting time to patient access
2. Early insight	• Member Focus Study 2026, building on the 2025 early advice metrics, co designed with member companies • Quantitative/qualitative research providing insights into Joint Scientific Consultation (JSC) and national early advice, Joint Clinical Assessment (JCA) and implications for future considerations • Multi-stakeholder workshop reflecting on the first year of HTAR implementation, discussing JCA and JSC from both company and agency perspectives.
3. Collaboration	• Multi-stakeholder workshop: Regulatory and HTA Building Capacity for Patient Involvement in Regulatory and HTA Decision Making in the Asia-Pacific: Focus on Rare Diseases and Precision Medicine • HTA Agency Forum: The Next Generation of HTA: Challenges and Opportunities for Asia
4. Quality	• Publications supporting improved HTA practice, including: - Literature review mapping current HTA patient involvement approaches - Comparative review of HTA governance and lifecycle processes across 10 countries - Review of orphan drug decisions at EMA and reimbursement conditions in Turkey, Germany and Poland
5. Transparency	• Regulatory & Reimbursement Atlas, providing transparent, stakeholder accessible process maps for EU 27 regulatory and HTA pathways, reflecting post HTA Regulation processes • Comparative benchmarking of HTA processes across the EU 27, delivered as Atlas R&D Briefing • R&D Briefing on China innovative medicines, comparing approval and reimbursement processes for international and domestic products across key jurisdictions
6. New models	• Examination of HTA flexible pathways, new initiatives, stakeholder engagement, and managed access arrangements through HTADock and publications • Publication on parallel submissions in Australia and Canada, including contributing factors • Publication summarising outputs from the 2025 HTA Regulation workshop • Multi-stakeholder workshop: AI in Regulatory and HTA/Pricing Submission and Review • Multi-stakeholder workshop: Policy to Practice: Strategic Implications of HTA and Regulatory Changes Worldwide
+ HTA Technical Forum for CIRS member companies (Topic tbc)	

2026 Workstreams and Workshops

2026 Workshops

CIRS workshops provide a forum for the dissemination and discussion of CIRS research through structured sessions and breakout groups that enable companies, agencies and other participants to shape CIRS research projects. A synopsis and report are published following each workshop to help disseminate the learnings and recommendations from the meeting.




Regulatory-HTA Alignment Workshop, October 2024

2026 Workshops

Building Capacity for Patient Involvement in Regulatory and HTA Decision Making in the Asia-Pacific: Focus on Rare Diseases and Precision Medicine

4-5th March, Kuala Lumpur, Malaysia

Objectives:

- Identify current practices for patient involvement across the Asia-Pacific, identifying barriers, enablers, and culturally relevant approaches to integrating patient voices and data into development and regulatory and HTA decision making.
- Explore strategies to build capacity for patient engagement and evaluation of patient experience data within regulators and HTA agencies in the Asia-Pacific, including training, infrastructure, and insights from agencies with already established practices.
- Highlight the role of patient engagement and patient experience data in regulatory and HTA policy for precision medicines and rare diseases, exploring how these areas present unique challenges and opportunities for inclusive and impactful decision making in the Asian context.
- Recommend practical steps, tools, and frameworks to support sustainable patient engagement and use of patient experience data, aligned with local health system priorities and economic contexts.

AI in Regulatory and HTA/Pricing Submission and Review

2nd September, USA

Objectives:

- Understand how AI is currently being applied in regulatory and HTA/pricing submissions and reviews.
- Evaluate the implications of AI for review and reimbursement processes, timelines, and patient access.
- Discuss transparency and oversight mechanisms to support responsible use of AI.
- Identify areas where regulatory, HTA, and payer alignment on AI would provide system-wide benefit.

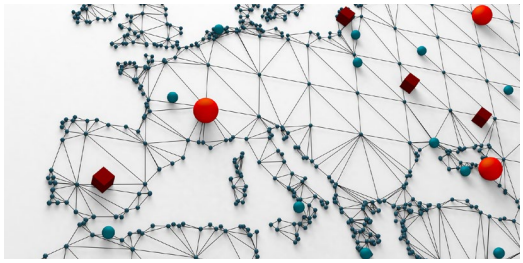
2026 Workshops

Policy to Practice: Strategic Implications of HTA and Regulatory Changes Worldwide

14-15th October, Amsterdam, The Netherlands

Objectives:

- Provide an overview of the recent and upcoming legislative changes affecting the regulatory and HTA/payer landscape in Canada, Europe, the UK, USA, and Australia.
- Discuss the implications of these changes for the development, review, and reimbursement of new medicines and their implications for innovation and patient access.
- Identify key areas of focus and recommendations for stakeholders to navigate the evolving regulatory and HTA environment.



Multi-stakeholder workshop on the first year of HTA Regulation implementation

w/c 23rd November, UK/Europe

CIRS Summit – Shaping the 2027-2029 Research Agenda

6-7th May, UK

Key focus areas:

- System co-design across development, regulatory review, HTA, and access
- Evidence evolution and decision making under uncertainty
- Post-HTA implementation and access to medicines
- Metrics to better reflect outcomes beyond regulatory and HTA decisions

The CIRS Summit will provide a forum for strategic discussion to inform the evolution of the CIRS research agenda. It will bring together regulators, HTA agencies, payers, industry, and other stakeholders to explore a small number of cross-cutting themes across the development–regulatory–HTA–access lifecycle. The Summit will adopt a workshop-based format to support structured discussion, share perspectives and experiences, and identify priority areas for further research. The outcomes will inform the development of CIRS' longitudinal research programme and research priorities for 2027–2029.

More About CIRS and How We Work

Collaborations

CIRS has a rich history of collaboration with various groups on topics of mutual interest. In the near past and present, these have included:

- Gates Foundation
- National Academies of Sciences, Engineering, and Medicine
- Rare Diseases International-Lancet Commission on Rare Diseases
- World Economic Forum Rare Disease Affinity Group
- International Coalition of Medicines Regulatory Authorities (ICMRA)
- World Health Organization (WHO)
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals (ICH)
- United States Pharmacopoeia (USP)
- Office of Health Economics (OHE)
- African Union Development Agency- New Partnership for Africa's Development (AUDA-NEPAD)
- Centre of Regulatory Excellence, Singapore (CoRE)
- University of Hertfordshire
- University of Hong Kong
- Utrecht University
- University of Southern California

Collaborations on Regulatory Strengthening

CIRS is currently working with 35+ regulatory authorities globally through the Optimising Efficiencies in Regulatory Agencies (OpERA) programme, which is supported by the Gates Foundation.

A key activity of the OpERA programme is to promote the use of CIRS tools that help regulators to implement WHO indicators and sub-indicators as part of the WHO Global Benchmarking Tool assessment programme. This ultimately helps regulators to become more effective, efficient, predictable, accountable, and high-performance based.

For more information about CIRS, please see 'About CIRS'.

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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