





Introduction

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.

What makes us unique

What sets us apart is our ability to facilitate safe harbour discussions between multiple stakeholders involved in drug development and patient access to medicines. CIRS meetings are usually small, focused and build on discussions from previous meetings to enable continuous evolution of a topic. They also include breakout sessions, which are key to producing recommendations to help effect change.

We are also evidence-driven and transparent in our work. The data we collect are used to support our workshops and we endeavour to make these publicly available through peer-reviewed journals or our R&D Briefings.

Our small but dedicated team strive to ensure that the needs and priorities of our stakeholders are at the heart of CIRS activities. Our door is always open to new ideas and suggestions that fit with our mission.



Mission

Identify and apply scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes in developing and facilitating access to pharmaceutical products.



Three pillars of CIRS activities



METRICS

Evidence-driven insights into company and agency performance



OUALITY

Improving decision-making processes



ALIGNMENT

Converging stakeholder priorities and processes to accelerate patient access



Metrics – evidence-driven insights into company and agency performance

CIRS provides unique insights and an independent viewpoint on the performance of companies, regulatory and HTA agencies through its metrics programmes. Data are collected and analysed to give a better understanding of regulatory and HTA assessment times and evidentiary requirements. This form of benchmarking details regulatory and HTA processes and practices, identifies where improvements can be made and informs company and agency strategies.



Quality – improving decision-making processes

CIRS works with companies and agencies to evaluate the quality of their processes, identify challenges, and implement best practices. Tools developed from these projects support decision-making practices and their documentation in general or are specific to areas such as benefit-risk assessment. The aim is to foster learning and improve transparency, predictability and consistency of critical decisions during development, regulatory review and HTA.



Alignment – converging stakeholder priorities and processes to accelerate patient access

Through collaborative research projects and multi-stakeholder workshops, CIRS promotes harmonisation and alignment across HTA agencies and regulators and between HTA agencies and regulators themselves. Not only does this facilitate capacity building but also helps to enable more efficient and effective development of medicines.

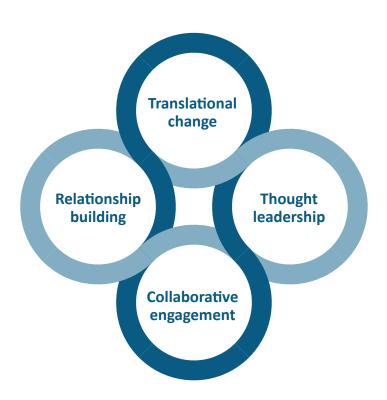


CIRS Workshops

Our workshops are small, international meetings that provide exceptional learning and networking opportunities. Participants can interact with peers from industry, agencies and academia in a neutral atmosphere of informed and productive discussion to produce recommendations to move important topics forward in the development, regulation and reimbursement of medicines.

Workshop topics are aligned with CIRS' research priorities and frequently build on CIRS research as well as the recommendations of previous meetings to develop strategic and policy-level thinking. We usually hold three workshops a year, with each one addressing one of the following areas:

- 1. Global development e.g. reliance, effectiveness, efficiency
- Current 'hot' topic e.g. digital, realworld data, new ways of working
- 3. Regulatory-HTA alignment e.g. early scientific advice





What our stakeholders say

"I see the CIRS workshop as a valuable tool to engage with various stakeholders and consider perspectives from regulators, HTA bodies, industry and patient groups to drive drug development and access."

- Pharmaceutical company

"It was a great learning experience. Particularly I liked the content of the workshop and the clarity of discussions in the syndicate groups. Thanks CIRS for bringing a safe space to share thoughts from multiple stakeholders."

- Regulatory agency



4.7/5

Our workshops receive consistently high feedback scores (averaged 4.7/5 in 2024)





CIRS Workshops

All our workshops feature interactive breakout sessions that result in a set of recommendations. Here's an infographic summarising the key recommendations from the CIRS workshop in June 2025, High public health impact medicines for chronic diseases – Do regulatory, HTA and payer paradigms need to change?



A CIRS workshop involving















Calls for new adaptive, collaborative, patient-centered approaches to chronic disease treatment development, review and reimbursement.

What needs to change?

- Improve clinical trial efficiencies through novel trial designs and digitalisation.
- · Promote company-regulator-HTA collaboration through early scientific advice and data sharing initiatives.
- · Establish stakeholder expectations around the strength of the relationship between surrogate endpoints and clinical outcomes.
- · Implement incentives for R&D in neglected chronic disease areas.
- · Explore adaptive regulatory pathways and innovative pricing and payment models for common chronic diseases.



Member companies and participating agencies

Member companies			
AbbVie	Chiesi	Pacira Biosciences	
Amgen	CSL Behring	Pfizer	
Astellas	Eli Lilly and Company	Regeneron	
AstraZeneca	GlaxoSmithKline	Roche	
Bayer	Ipsen	Sanofi	
Biogen	Johnson & Johnson	Takeda	
Biomarin	Merck	UCB	
Boehringer Ingelheim	Moderna	Ultragenyx	
Bristol Myers Squibb			

Participating HTA and coverage bodies				
Country	Organisation	Country	Organisation	
Argentina	IECS	Germany	G-BA; DAK-Gesundheit	
Australia	PBAC	Ireland	NCPE	
Austria	Association of Austrian Social Insurance Institutions	Malaysia	МоН	
Belgium	INAMI; KCE	Netherlands	ZIN	
Brazil	CONITEC	Norway	NoMA	
Bulgaria	NCPR	Poland	AOTMIT	
(anada	CDA-AMC; INESSS;	Portugal	INFARMED	
	Alberta Health Services	Romania	NAMMDR	
China	National Centre for Medicine	Scotland	SMC	
	and Technology Assessment	Singapore	ACE	
Chinese Taipei	Division of HTA, CDE, Taiwan	Spain	AEMPS; MoH	
Colombia	IETS	Sweden	TLV	
Croatia	AAZ	Switzerland	BAG	
Denmark	DKMA	Thailand	HITAP	
England, Wales	NICE	USA Cross/Blue Shield Associ Kaiser Permanente Institu	UnitedHealth Group; TEC, Blue	
Finland	THL		Cross/Blue Shield Association;	
France	HAS		Health Policy; AHRQ; OPTUM	

6



Member companies and participating agencies

Participating regulatory agencies		
Country - EMEA	Authority	
Denmark	DKMA	
EU	EMA	
Ireland	HPRA	
Israel	МоН	
Jordan	JEDA	
Saudi Arabia	SEDA	
Sweden	MPA	
Switzerland	Swissmedic	
The Netherlands	MEB	
Turkey	TITCK	
United Arab Emirates	MOHAP	
United Kingdom	MHRA	
Regional initiatives	GHC	

Participating regulatory agencies		
Country - Asia	Authority	
Australia	TGA	
China	NMPA; CDE	
Chinese Taipei	TFDA; CDE	
India	CDSCO	
Indonesia	NAFDC	
Japan	MHLW, PMDA	
Malaysia	NPRA	
Philippines	PFDA	
Singapore	HSA	
Thailand	TFDA	
Vietnam	DAV	
Regional initiatives	APEC, ASEAN	
Thailand Vietnam	TFDA DAV	

Participating regulatory agencies		
Country - Africa	Authority	
Egypt	EDA	
Ethiopia	EFDA	
Ghana	FDAG	
Kenya	PPB	
Mali	DPM	
Liberia	LMHRA	
Nigeria	NAFDAC	
Rwanda	RFDA	
Senegal	MoHP	
South Africa	SAHPRA	
Tanzania	TMMDA	
Zambia	ZAMRA	
Zimbabwe	MCAZ	
Regional initiatives (and at member state level)	Zazibona/SADC, EAC, ECOWAS	

Participating regulatory agencies		
Country - Americas	Authority	
Argentina	ANMAT	
Bolivia	AGEMED	
Brazil	ANVISA	
Canada	Health Canada	
Chile	ANAMED	
Colombia	INVIMA	
Costa Rica	MINSA	
Cuba	CECMED	
Dominican Republic	DIGEMAPS	
Ecuador	ARCSA	
El Salvador	DNM	
Guatemala	MSPAS	
Haiti	DPM/MT-MSPP	
Mexico	COFEPRIS	
Peru	DIGEMID	
USA	FDA	
Regional initiatives	CARICOM-CRS, PAHO, SICA	



CIRS Committees

CIRS is governed by its own dedicated advisory boards made up of external international experts from academia, industry, regulatory agencies and HTA bodies. The Scientific Advisory Council (SAC) and HTA Steering Committee advise CIRS on workshops, special projects, publications as well as the research programme, to ensure neutrality and that the areas are unbiased and the programme meets the needs to all stakeholders. The selection of Committee Members and Chairs is set out in each committee's Terms of Reference.

Scientific Advisory Council

Chair: Prof John Skerritt,

Enterprise Professor of Health Research Impact, University of Melbourne, Australia

Vice-Chair: Prof Hans-Georg Eichler, Consulting Physician of the Association of Austrian Social Insurance Institutions

Academic/Other:

Prof John Lim, Executive Director of Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School and Chairman, Consortium for Clinical Research & Innovation, Singapore

Prof Stuart Walker, Founder and Senior Advisor, CIRS

Agencies:

Julian Beach, Interim Executive Director, Healthcare Quality & Access, Medicines Healthcare Products Regulatory Agency (MHRA)

Prof Tony Lawler, Deputy Secretary, Health Products Regulation Group, Australian Government Department of Health and Aged Care

Dr Theresa Mullin, Associate Center Director - Strategic Initiatives, US Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER)

Dr Brian O'Rourke, Former CEO and President, Canadian Agency for Drugs and Technologies in Health (CADTH)

Kelly Robinson, Director General, Pharmaceutical Drugs Directorate, Health Canada

Prof Bruno Sepodes, Chair, European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP)

Dr Xie Songmei, Director of Clinical Department Center for Drug Evaluation, National Medical Products Administration (NMPA), China

Prof Steffen Thirstrup, Chief Medical Officer, EMA

Dr Eveline Trachsel, Head of Authorisation and Vigilance, Swissmedic

Naoyuki Yasuda, Associate Executive Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Industry:

Dr Fabio Bisordi, Global Head International Regulatory Policy, Roche

Donna Boyce, Senior Vice President, Global Regulatory Sciences, Pfizer

Jeffery Francer, Vice President, Head of Global Regulatory Policy & Strategy, Eli Lilly & Company

Dr Amy McKee, Senior Vice President, Oncology Regulatory Science, Strategy and Excellence, AstraZeneca

Dr Katrin Rupalla, Global Head Regulatory Affairs, J&J Innovative Medicines, USA

Jerry Stewart, Vice President, Regulatory Policy & Advocacy Head, GlaxoSmithKline

Natalie Tolli, Vice President, Regulatory Affairs (Regulatory International, Regulatory Policy & Intelligence), AbbVie

Dr Max Wegner, Senior Vice President, Head of Regulatory Affairs, Bayer



CIRS Committees

Pictured from left to right: Prof Hans-Georg Eichler, CIRS SAC Vice Chair; Anna Somuyiwa, Head of CIRS; Prof John Skerritt, Chair of CIRS SAC; Dr Brian O'Rourke, Chair of CIRS HTA SC; Dr Tina Wang, Associate Director of CIRS' HTA Programme; and Dr Nick Crabb, Vice-Chair of CIRS HTA SC.



HTA Steering Committee

Chair: Dr Brian O'Rourke, Former CEO and President, CADTH, Canada Vice-Chair: Dr Nick Crabb, Chief Scientific Officer, National Institute for Health and Care Excellence (NICE), UK

Academic/Other:

Prof Andrew Mitchell, Honorary Professor, The Australian National University

Dr Dan Ollendorf, Chief Scientific Officer and Director of HTA Methods and Engagement, Institute for Clinical and Economic Review (ICER), USA

Dr Detlev Parow, Former Head, Department of Medicines, Medical Remedies and Selective Contracts, DAK – Gesundheit, Germany

Prof Lotte Steuten, Deputy Chief Executive, Office of Health Economics (OHE), UK

Dr Sean Tunis, Principal, Rubix Health

Agencies & coverage bodies:

Dr Michael Coory, Medical Advisor, Technology Assessor and Assessment Division, Commonwealth Department of Health, Australia

Prof Hans-Georg Eichler,

Consulting Physician of the Association of Austrian Social Insurance Institutions

Prof Wim Goettsch, Professor of HTA, Utrecht University and Special Advisor HTA, National Health Care Institute (ZIN), The Netherlands

Niklas Hedberg, Chief Pharmacist, Dental and Pharmaceutical Benefits Agency (TLV), Sweden

Suzanne McGurn, CEO and President, Canada's Drug Agency

Yannis Natsis, Director, European Social Insurance Platform (ESIP), and Board Member of the European Health Forum Gastein

Dr Anja Schiel, Special Adviser, Lead Methodologist in Regulatory and Pharmacoeconomic Statistics, Norwegian Medicines Agency (NoMA); Vice-Chair JSC (EUnetHTA21)

Industry:

Dr Indranil Bagchi, Global Head,

Pricing & Market Access, GSK

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Melinda Hanisch, Director, Evidence Policy, Science and Regulatory Policy, Merck

Dr Adam Heathfield, Senior Director, Patient and Health Impact Innovation Centre, Pfizer

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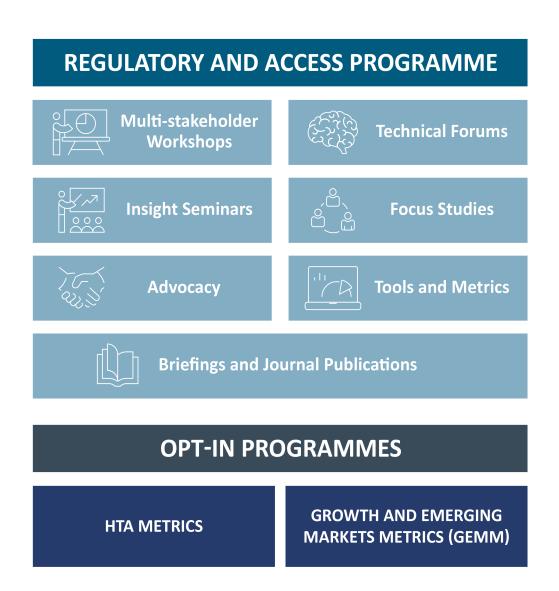


CIRS Membership

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, 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 in 'CIRS Membership'.

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





Meet the CIRS team



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Penelope Cervelo

Research Analyst



Founder and
Senior Advisor*



Dr Mario AlanisSenior Consultant*



About CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independently managed 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 in developing and facilitating access to pharmaceutical products. CIRS provides an international forum for industry, regulators, HTA 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, special projects, and grants.

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