

Aligning global value-based
decision making

About CIRS

Introduction

Who we are

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 also supports 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

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 in developing and facilitating access to pharmaceutical products.

Three pillars of CIRS activities



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

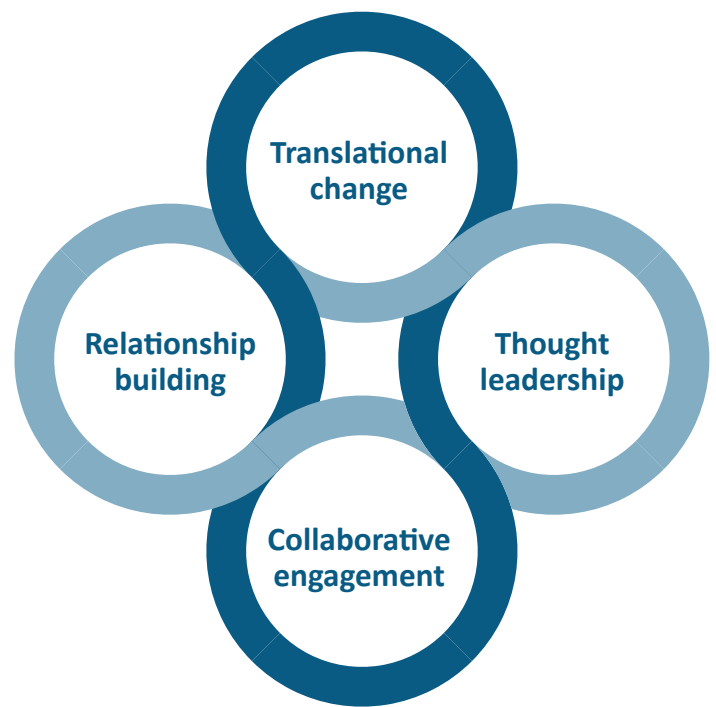
Through collaborative research projects and multi-stakeholder workshops, CIRS promotes harmonisation and alignment across HTA agencies and regulators and between HTA agencies and regulators themselves. Not only does this facilitate capacity building but also helps to enable more efficient and effective 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**
2. **Current 'hot' topic e.g. digital, real-world 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

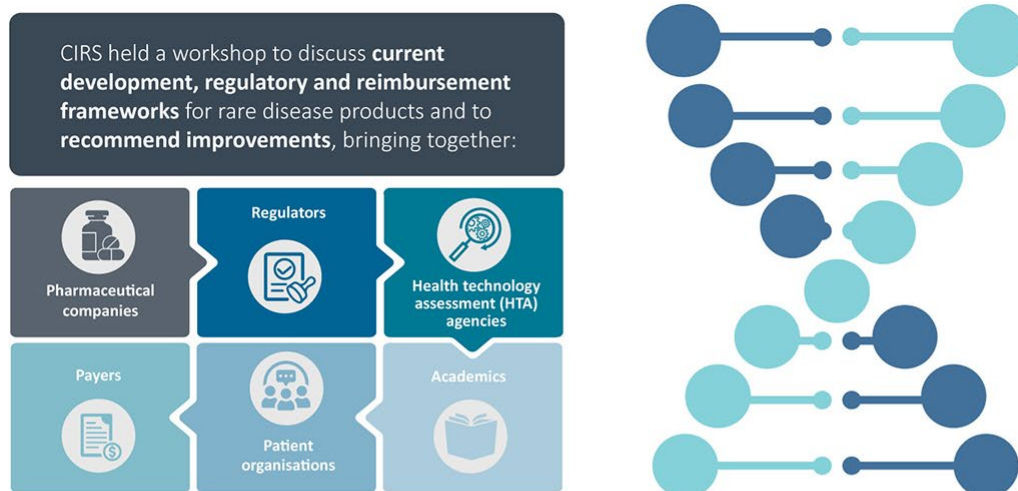
Our workshops receive consistently high feedback scores (averaged 4.7/5 in 2023)



CIRS Workshops

All our workshops feature interactive breakout sessions that result in a set of recommendations.

Here's an infographic summarising the outputs from the breakout sessions at the CIRS workshop, [Do development, review and reimbursement frameworks need adapting to improve evidence generation and financially sustainable access for rare disease products?](#) which was held in the UK on 4-5th October 2023.



Workshop recommendations



Member companies and participating agencies

Member companies		
USA	Europe	Japan
AbbVie	AstraZeneca	Astellas
Amgen	Bayer	Eisai
Biogen	GlaxoSmithKline	Takeda
Biomarin	Ipsen	
CSL Behring	Leo	
Eli Lilly & Company	Novo Nordisk	
Johnson & Johnson	Roche	
Merck & Co	Sanofi	
Pacira	UCB	
Pfizer		
Regeneron		
Ultragenyx		

Participating HTA and coverage bodies			
Country	Organisation	Country	Organisation
Australia	PBAC	Malaysia	MoH
Austria	Association of Austrian Social Insurance Institutions	Netherlands	ZIN
Belgium	INAMI; KCE	Norway	NoMA, NOKC
Brazil	CONITEC	Poland	AHTAPol
Canada	CADTH; DSEN, Canadian Institutes of Health Research, INESSS, Alberta Health Services	Portugal	INFARMED
Chinese Taipei	Division of HTA, CDE, Taiwan	Scotland	SMC
Croatia	AAZ	Singapore	ACE
Denmark	DKMA	Spain	MoH
England, Wales	NICE	Sweden	TLV
Finland	THL	Switzerland	BAG
France	HAS	Thailand	HITAP
Germany	G-BA, DAK-Gesundheit	USA	UnitedHealth Group; TEC, Blue Cross/Blue Shield Association; Kaiser Permanente Institute for Health Policy; AHRQ; OPTUM
Ireland	NCPE		

Member companies and participating agencies

Participating regulatory agencies	
Country - EMEA	Authority
Denmark	DKMA
EU	EMA
Ireland	HPRA
Israel	MoH
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

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 (<i>and at member state level</i>)	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	MINSAL
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: Adjunct Prof John Skerritt, Enterprise Professor, Health Research Impact at the University of Melbourne, and an Adjunct Professor, Faculty of Medicine and Health of the University of Sydney, Australia

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

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

Dr Charles Preston, Senior Program Officer, Regulatory Affairs, Bill and Melinda Gates Foundation, USA

Anna Somuyiwa, Head, CIRS

Dr Neil McAuslane, Director, CIRS

Prof Stuart Walker, Founder and Senior Advisor, CIRS

Dr Claus Bolte, Chief Medical Officer, Swissmedic

Dr Harald Enzmann, Chair, European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP)

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)

Karen Reynolds Director General, Pharmaceutical Drugs Directorate, Health Canada

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

Prof Steffen Thirstrup, Chief Medical Officer, EMA

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

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 David Jefferys, Senior Vice President, Head of Global Regulatory, Eisai Europe

Dr Jacques Mascaro, Senior Vice President, Oncology Regulatory Science, Strategy and Excellence, AstraZeneca

Eddie Reilly, Chief Regulatory Officer, Sanofi

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

Specialist Advisors

Dr Thomas Lönngren, Independent Strategy Advisor, PharmaExec Consulting Filial SE, Sweden, and Former Executive Director, EMA

Dr Murray Lumpkin, Deputy Director, Integrated Development, and Lead for Global Regulatory Systems Initiatives, Bill and Melinda Gates Foundation

Prof Mamoru Narukawa, Professor, Pharmaceutical Medicine, Kitasato University Graduate School of Pharmaceutical Sciences, Japan

Dr Tomas Salmonson, Partner, Consilium Salmonson & Hemmings and Former Chair, CHMP/EMA

Dr Joseph Scheeren, Former President and CEO, Critical Path Institute

HTA Steering Committee

Chair: Dr Brian O'Rourke, Former CEO and President, CADTH, Canada

Vice-Chair: Dr Nick Crabb, Interim Director, Science, Evidence and Analytics, National Institute for Health and Care Excellence (NICE), UK

Prof Finn Børllum Kristensen, Professor of Health Services Research and HTA, Faculty of Health Sciences, University of Southern Denmark and Former Director and Chair of EUnetHTA Executive Committee

Prof Andrew Mitchell, Honorary Professor, The Australian National University

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Dr Tina Wang, Senior Manager, HTA Programme and Strategic Partnerships, CIRS

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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*working on a contractual basis on region-specific CIRS projects

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 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 and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to pharmaceutical products. 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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