CIRS Centre for Innovation in Regulatory Science

www.cirsci.org

Aligning global value-based decision making

About CIRS

CONSENSUS | TRUST | ACCESS

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

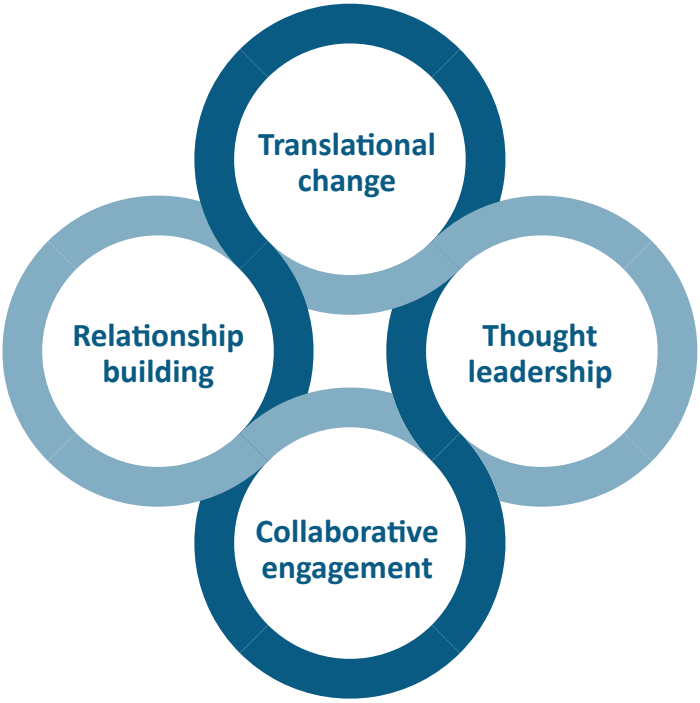
Through collaborative research projects and multi-stakeholder workshops, CIRS promotes harmonisation and alignment across HTA agencies and regulators and between HTA agencies and regulators themselves. Not only does this facilitate capacity building but also helps to enable more efficient and effective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

For more information, please see the CIRS 'Research Agenda'.

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

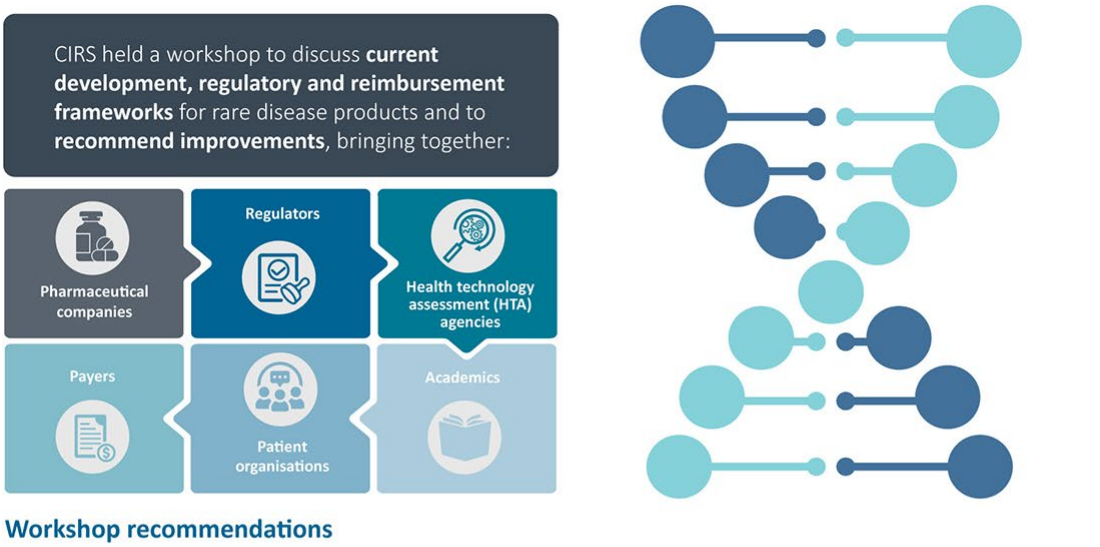
4.7/5

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

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

Evolving incentives

Explore different incentive models for **treatments for ultra-rare diseases**

Investigate which regulatory and HTA approaches improve the probability of **successful review and reimbursement**

Leverage learnings from **managed entry agreements**

Improve evidence development

Multi-stakeholder engagement
Earlier/more opportunities

Shift mindsets on patient input
Reduce perception that patients who work with industry have a conflict of interest when interacting with regulatory/HTA agencies

Develop structured checklists for pre-/post-licensing evidence generation
Increase alignment on stakeholder needs

Better manage uncertainty

Rare disease registries
Establish best practice

Rare disease products
Develop integrated value framework utilising research and an experimental 'sandbox' approach

Rare disease space
Examine the extent of post-licensing evidence generation; how much is happening and what is working well?

Member companies and participating agencies

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

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	AOTMiT
Bulgaria	NCPR	Portugal	INFARMED
Canada	CADTH; DSEN, Canadian Institutes of Health Research, INESSS, Alberta Health Services	Romania	NAMMDR
		Scotland	SMC
Chinese Taipei	Division of HTA, CDE, Taiwan	Singapore	ACE
Croatia	AAZ	Spain	MoH
Denmark	DKMA	Sweden	TLV
England, Wales	NICE	Switzerland	BAG
Finland	THL	Thailand	HITAP
France	HAS	USA	UnitedHealth Group; TEC, Blue Cross/Blue Shield Association; Kaiser Permanente Institute for Health Policy; AHRQ; OPTUM
Germany	G-BA, DAK-Gesundheit		
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 *(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

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

Prof Stuart Walker, Founder and Senior Advisor, CIRS

Agencies:

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

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)

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

Dr Eveline Trachsel, Head of Authorisation, 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

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

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 Finn Børlum 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

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

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

Dr Sean Tunis, Principal, Rubix Health

Agencies & coverage bodies:
Dr Michael Coory, Medical Advisor, Technology Access 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

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

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

Lucia D'Apote, Executive Director ELMAC & JAPAC, Global Regulatory and R&D Policy, Amgen

Adrian Griffin, Vice President for HTA Policy, Johnson & Johnson

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

Dr Antonia Morga, Senior Director, Global Health Economics and Outcomes Research (HEOR) and HTA Strategy Lead, Astellas

Dr Vanessa Elisabeth Schaub, Global Access Chapter Lead for Evidence, Roche

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

Anna Somuyiwa

Head

Dr Neil McAuslane

Scientific Director

Dr Magda Bujar

Associate Director, Regulatory Programme and Strategic Partnerships

Dr Tina Wang

Associate Director, HTA Programme and Strategic Partnerships

Dr Jenny Sharpe

Communications Manager

Adem Kermad

Senior Research Analyst

Juan Lara

Senior Research Analyst

Gill Hepton

Administrator

Dr Belén Sola

Research Analyst

Penelope Cervelo

Research Analyst

Prof Stuart Walker

Founder and Senior Advisor*

Dr Mario Alanis

Senior Consultant*

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

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Contact Us

Anna Somuyiwa, Head of CIRS	asomuyiwa@cirsci.org
Dr Mario Alanis, Senior Consultant	marioalanisgarza@cirsci.org
Dr Magda Bujar, Associate Director, Regulatory Programme and Strategic Partnerships	mbujar@cirsci.org
Penelope Cervelo Bouzo, Research Analyst	pcervelo@cirsci.org
Gill Hepton, Administrator	ghepton@cirsci.org
Adem Kermad, Senior Research Analyst	akermad@cirsci.org
Juan Lara, Senior Research Analyst	jlara@cirsci.org
Dr Neil McAuslane, Scientific Director	nmcauslane@cirsci.org
Dr Jenny Sharpe, Communications Manager	jsharpe@cirsci.org
Dr Belén Sola, Research Analyst	bsola@cirsci.org
Prof Stuart Walker, Founder and Senior Advisor	swalker@cirsci.org
Dr Tina Wang, Associate Director, HTA Programme and Strategic Partnerships	twang@cirsci.org

Centre for Innovation in Regulatory Science (CIRS)

70 St Mary Axe, London EC3A 8BE, UK

cirs@cirsci.org

www.cirsci.org

www.linkedin.com/company/centre-for-innovation-in-regulatory-science-ltd/

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