CIRS Centre for Innovation in Regulatory Science

www.cirsci.org

About CIRS

Advancing regulatory and HTA policies and processes

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

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.

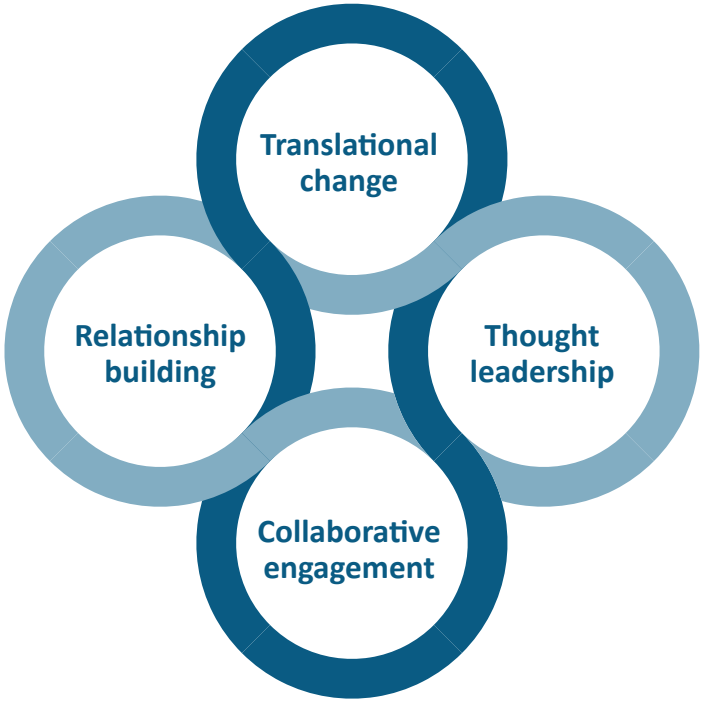
For more information, please see the CIRS 'Research Agenda'.

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."

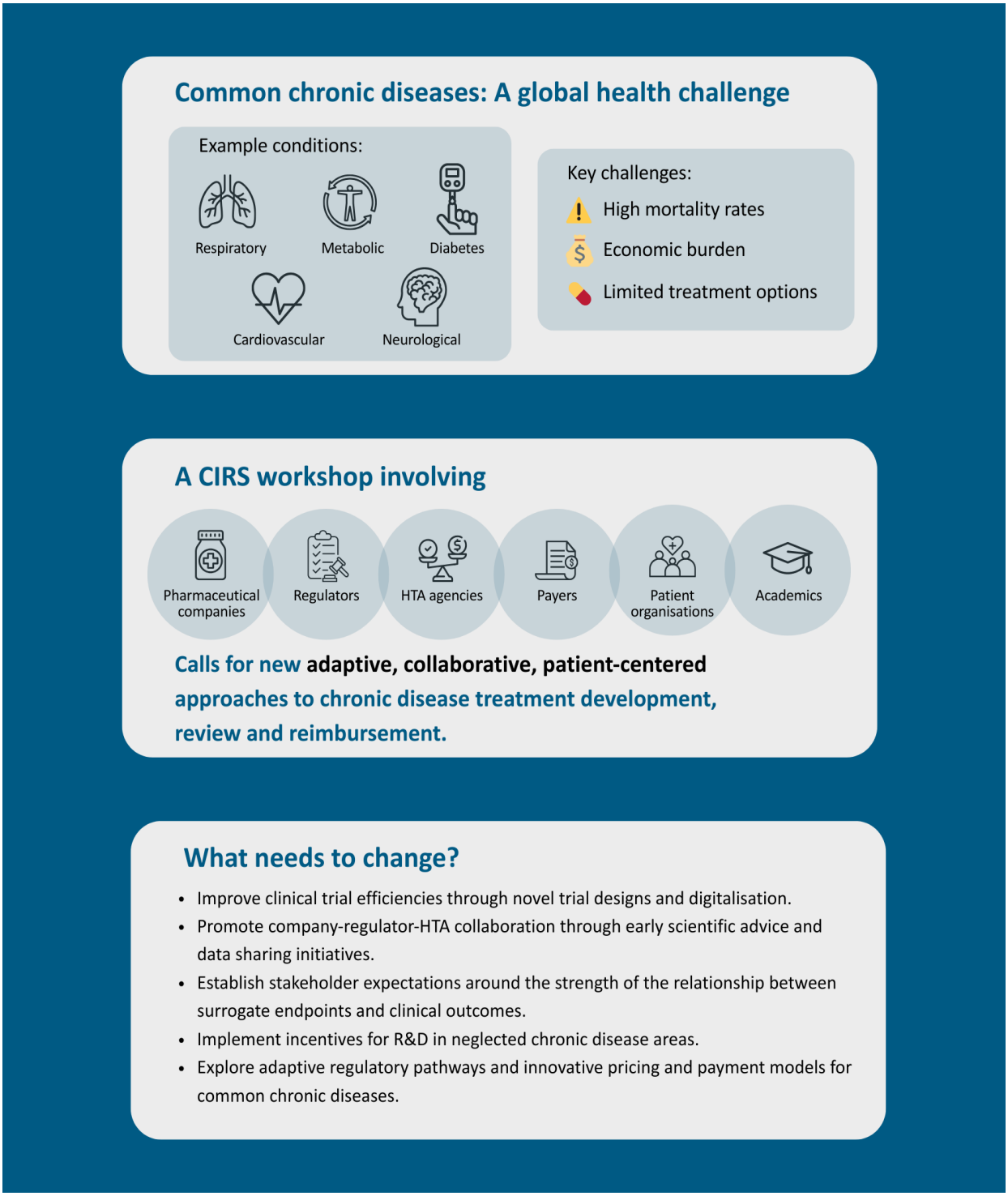
- Regulatory agency

4.8/5

Our workshops receive consistently high feedback scores (averaged 4.8/5 in 2025)

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?



Member companies and participating agencies

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

Participating HTA and coverage bodies			
Country	**Organisation**	**Country**	**Organisation**
Argentina	IECS	Ireland	NCPE
Australia	PBAC	Italy	AIFA
Austria	Association of Austrian Social Insurance Institutions	Malaysia	MoH
Belgium	INAMI; KCE	Netherlands	ZIN
Brazil	CONITEC	Norway	NoMA
Bulgaria	NCPR	Poland	AOTMiT
Canada	CDA-AMC; INESSS; Alberta Health Services	Portugal	INFARMED
		Romania	NAMMDR
China	National Centre for Medicine and Technology Assessment	Scotland	SMC
		Singapore	ACE
Chinese Taipei	Division of HTA, CDE, Taiwan	Slovakia	NIHO
Colombia	IETS	Slovenia	JAKZ
Croatia	AAZ	Spain	AEMPS; 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		
Greece	MoH		

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

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:

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 Andrew Robertson, Vice President, Head of Global Regulatory Policy and Innovation, Takeda

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

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

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

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

Shane Kavanagh, Vice President, Health Economics, Johnson & Johnson

Dr Antonia Morga, Head, New Product Planning, Global Value Evidence, Medical Affairs, Astellas Pharma Europe

Dr Vanessa Elisabeth Schaub, Access Strategy Chapter Lead, Global Access, 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

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Head

Dr Neil McAuslane

Scientific Director

Dr Magda Bujar

Associate Director, Regulatory Programme and Strategic Partnerships

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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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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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