

# About CIRS

Advancing regulatory and  
HTA policies and processes

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# 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**

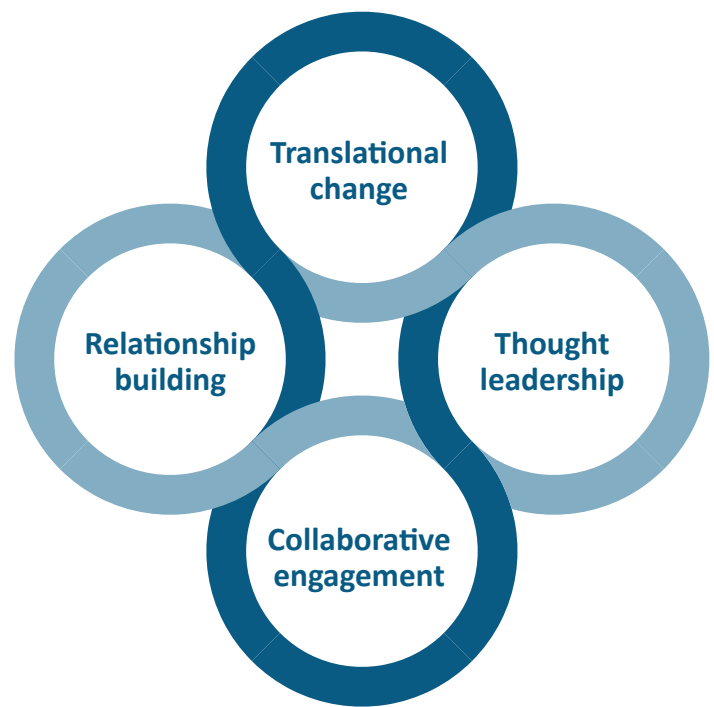
Through collaborative research projects and multi-stakeholder workshops, CIRS promotes harmonisation and alignment across HTA agencies and regulators and between HTA agencies and regulators themselves. Not only does this facilitate capacity building but also helps to enable more efficient and effective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

# 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 key recommendations from the CIRS workshop, '**Vaccines – Are regulatory and funding approaches fit for purpose for the next decade?**' held in June 2024.

CIRS brought together pharmaceutical companies, regulatory agencies, National Immunisation Technical Advisory Groups (NITAGs), HTA agencies, payers and academia to make recommendations on how to address policy challenges in the development, regulation, HTA and funding of vaccines.



Vaccines are under valued

### Key recommendations:



International collaboration on evidence generation



Evolution of regulatory, HTA and NITAG frameworks



Common lexicon of definitions



Clear and consistent communication of value to society



Increased vaccine confidence and uptake

# 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	MoH
Belgium	INAMI; KCE	Netherlands	ZIN
Brazil	CONITEC	Norway	NoMA
Bulgaria	NCPR	Poland	AOTMiT
Canada	CDA-AMC; INESSS; Alberta Health Services	Portugal	INFARMED
China	National Centre for Medicine and Technology Assessment	Romania	NAMMDR
Chinese Taipei	Division of HTA, CDE, Taiwan	Scotland	SMC
Colombia	IETS	Singapore	ACE
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

## 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: 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:**

**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, 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 Tulli**, 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 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

**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

**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](mailto:ghepton@cirsci.org)**



# Meet the CIRS team



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Head



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Scientific Director



**Dr Magda Bujar**

Associate Director,  
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**Dr Tina Wang**

Associate Director,  
HTA Programme and  
Strategic Partnerships



**Dr Jenny Sharpe**

Communications  
Manager



**Adem Kermad**

Principal 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

## 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.

## Contact Us

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