



Aligning global value-based  
decision making

# CIRS 2024 Agenda

CONSENSUS • TRUST • ACCESS

# About CIRS

## 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

## How we operate

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independently managed UK-based subsidiary of Clarivate plc. We operate as a not-for-profit organisation, deriving funding from membership dues, special projects and grants to cover our operating and research costs.

We are governed by our own dedicated advisory boards made up of external international experts from academia, industry, regulatory agencies and HTA bodies. Our Scientific Advisory Council (SAC) and HTA Steering Committee advise on workshop topics and content, as well as our research programme.

## What makes us unique

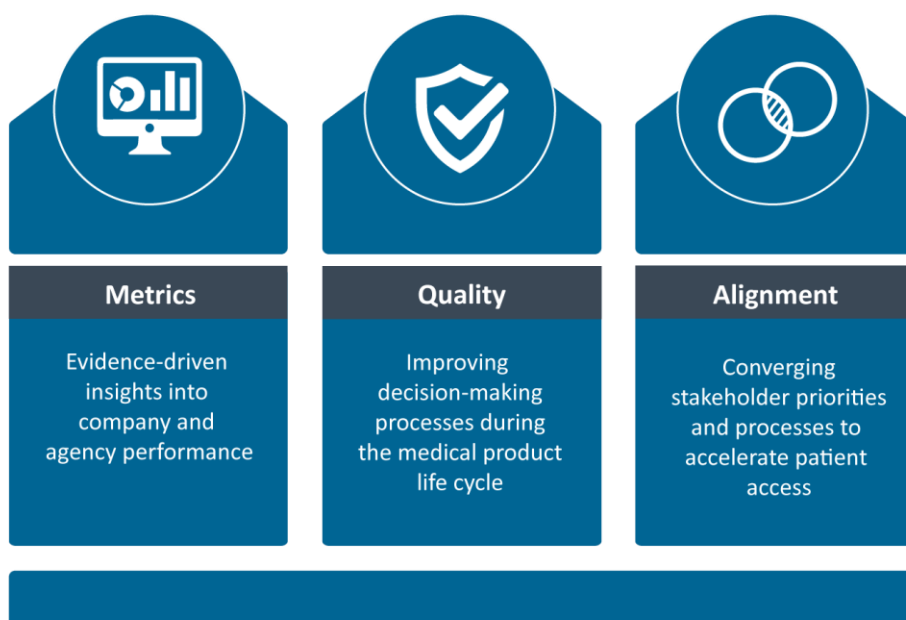
What sets us apart is our ability to bring **global** industry, regulators, HTA bodies, payers and academics together in a **neutral** atmosphere to identify and address key issues in the development, licensing and reimbursement of new medicines. We have been doing this for over 35 years through **focused** meetings and collaborative research.

Our workshops have consistently received positive feedback ratings of over 90% and resulted in recommendations that inform strategic and policy level thinking. The strong support for our research as well as attendance in meetings demonstrates the trust and confidence our stakeholders have in us.

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 of experienced scientists 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.

# 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 during the medical product life cycle**

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 health technology assessment.



## **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, as well as 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.

# Research Strategy 2024-2026

CIRS sets its three-year research strategy with formal input from the Scientific Advisory Council (SAC) and HTA Steering Committee, as well as ad hoc feedback from companies and agencies. Our 2024-2026 programme, which will be achieved through workshops, fora and research projects, is grouped into three strategic themes:

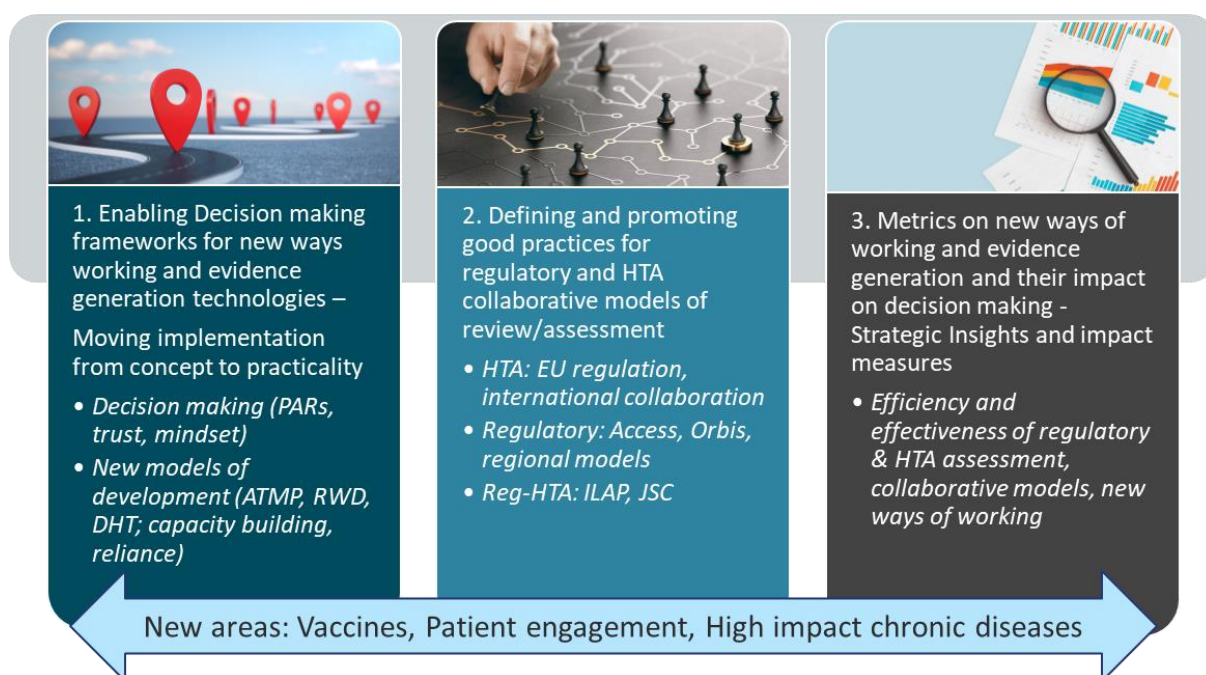
**Theme 1: Enabling decision-making frameworks for new ways of working and evidence generation techniques.** This theme is focused on moving the implementation of regulatory and HTA frameworks and models from concept to practicality. Topic areas include the transparency and utilisation of public and non-public assessment documentation, ATMPs, digital health technologies, real-world data/evidence and risk-based decision making (reliance models).

**Theme 2: Defining and promoting good practices for risk-based, collaborative models of review and HTA assessment.** We will assess the impact of regulatory/regulatory, regulatory/HTA and HTA/HTA collaborations in mature and growth markets, in order to share learnings and identify best practices. Collaborative models of interest include Project Orbis, the Access Consortium, regional regulatory collaborations, the UK Innovative Licensing and Access Pathway and the EU Joint Scientific Consultation.

**Theme 3: Metrics to generate strategic insights that influence decision making.** CIRS has the experience of benchmarking metrics going back two decades and this theme aims to continue and extend that solid foundation. A key focus for 2024-2026 will be identifying qualitative and quantitative metrics on the efficiency and effectiveness of regulatory review and HTA assessment, new ways of working including novel methods of evidence generation and digital health technologies, and the impact of legislative changes such as the revised EU General Pharma Legislation, EU HTA Regulation and US Inflation Reduction Act.

In addition, new areas of focus will be incorporated into the three research themes:

- **Patient engagement in regulatory & HTA decisions:** Workshop and stakeholder surveys to understand the impact of patient engagement on agency decision making, including how this is measured and the needs, challenges and opportunities going forward.
- **Vaccines** (therapeutic vaccines): Workshop and evaluation of existing CIRS metrics databases to identify what is available and of value to collect in the future as part of a potential research programme in this area.
- **High public health impact medicines for chronic diseases:** These diseases drive life expectancy down (e.g. cardiovascular, metabolic and neurological diseases) but have limited new drug development incentives. Work will focus on how such medicines could be incentivised and what learnings from other areas can be harnessed. Discussion on high impact medicines for chronic disease will be introduced as part of existing topics and workshops during this research cycle.



# Member companies and participating agencies

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

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

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

# Member companies and participating agencies

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 at 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 Thstrup**, 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

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

**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

**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**, Programme Director, Scientific Affairs, National Institute for Health and Care Excellence (NICE), UK

**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

**Dr Wim Goettsch**, Professor 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, CADTH, Canada

**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)

**Dr Indranil Bagchi**, Global Head, Pricing & Market Access, GSK

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

**Ramiro Gilardino**, Global HTA & Access Policy Lead – Global Market Access, MSD

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

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

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

**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

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

**Dr Sean Tunis**, Principal, Rubix Health

**Anna Somuyiwa**, Head, CIRS

**Dr Neil McAuslane**, Director, CIRS

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



# 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 our research priorities and frequently build on the recommendations of previous meetings to continue 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, decision making, 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 example output from one of the breakouts at the CIRS workshop, [\*New ways of working for medicines development: How is the regulatory and HTA landscape evolving?\*](#), which was held in Singapore on 25-26th April 2023.

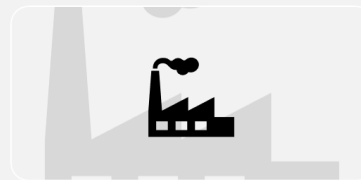
## Breakout Topic: How does the global landscape for ATMPs need to evolve to ensure availability and access in maturing countries?

### Challenges for the development, review and reimbursement of ATMPs



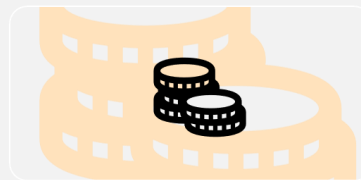
#### Clinical development

- Lack of established clinical development methods and guidelines
- Limited resources to execute robust clinical trials
- Evolving regulatory approval process



#### Manufacturing

- Limited manufacturing hubs and local manufacturing
- GMP requirements at local vs large-scale sites
- Chain of custody and quality control
- Lack of technical knowledge across stakeholders



#### Socioeconomic/ patient access

- Funding to elevate healthcare, research and administration infrastructure
- Identifying appropriate patient populations
- Mitigating pricing and clinical uncertainty

Potential solutions for these challenges were summarised by the breakout group in order of priority:

- 1) Establish a regional multi-stakeholder working group to facilitate learning, sharing of experiences and promotion of best practices.
- 2) Build infrastructure such as training personnel who can manufacture ATMPs and facilitating clinical trial readiness.
- 3) Establish commercialisation roadmap and criteria, including domains such as investment needs, patient population, affordability, infrastructure (clinical, manufacturing and commercial).
- 4) Establish pricing and reimbursement frameworks, for example adapting existing cost-effectiveness models or developing risk-sharing reimbursement models.

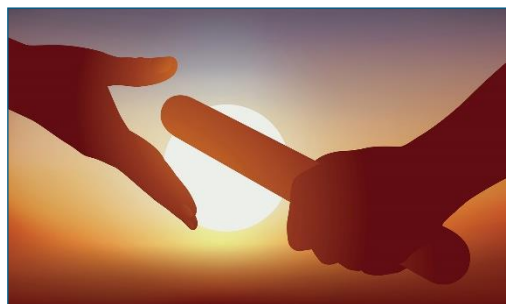
# 2024 Workshops

## 28-29<sup>th</sup> February 2024, Sao Paulo, Brazil

**New ways of working - enabling patient access through reliance or regional review models**

### Objectives

- Identify current risk-based prioritisation evaluation models of decision making being used for the review of medicines, and the benefits and hurdles of utilising these in the review of new medicines.
- Discuss frameworks and decision-making practices that need to be in place to move from concept to practical implementation for both unilateral and regional reliance models.
- Make recommendations on practical considerations and current best practices for both unilateral and regional models of reliance, discussing what is necessary to allow agencies to focus on value-added activities in order to provide timely patient availability to good quality, safe and effective medicines.



## 13-14<sup>th</sup> June 2024, Tysons Corner, Virginia, USA

**Vaccines – Are regulatory and HTA approaches fit for purpose for the next decade?**

### Objectives

- Review and discuss the changing vaccine landscape and what the opportunities and challenges are within and across development, regulatory and HTA.
- Identify critical information gaps and how regulatory and HTA systems need to evolve to accommodate new vaccine technologies.
- Propose options and make recommendations on how to address policy challenges in the development, regulation, HTA and funding for vaccines.



## September/October, UK or Europe

**New ways of working across regulatory and HTA agencies: collaborative, work-sharing or reliance models - what are the policy implications for companies, HTA and regulatory agencies?**

### Objectives

- Assess the impact of different regulatory and HTA collaborative models on development, regulatory review and HTA assessment.
- Understand the experiences and learnings from current regulatory/regulatory, HTA/HTA and regulatory/HTA collaborative models - what can be learnt at local, regional, national, and international levels? How do these models influence companies' development strategy and jurisdictional roll out?
- Make recommendations on the current and future development of regulatory and HTA collaboration, such as the EU HTA Regulation and its jurisdictional implementation, international initiatives outside of Europe and cross-continent partnerships.



# CIRS Memberships

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 on the following page.

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)



Why become a CIRS member?	Membership deliverable
<p><b>Be part of a global network</b></p>  <p>The CIRS community involves regulators, HTA agencies, payers, industry and academia from around the world.</p> <p>By becoming a CIRS member, you can interact with these stakeholders at small, productive meetings.</p>	<p><b>Three multi-stakeholder workshops</b> Registration and accommodation (excluding travel) for two participants per workshop.</p> <p><b>Two industry-focused Technical Forums (regulatory and HTA)</b> Registration for one person to each of the annual forums (accommodation not included).</p> <p><b>Industry-focused webinars</b> Organised on an ad-hoc basis on hot topics</p>
<p><b>Access insights &amp; knowledge</b></p>  <p>CIRS members have exclusive access to the results of research that your company has contributed to and more.</p>	<p><b>CIRS Members website</b> Designed to be a 'one-stop shop' for CIRS resources including workshop slides, R&amp;D Briefings and open access publications.</p> <p><b>CIRS Regulatory &amp; Reimbursement Atlas™</b> An online tool that maps regulatory, HTA and payer pathways for more than 70 jurisdictions around the world.</p> <p><b>Insight seminars</b> Organised specifically for your company on topics of mutual interest.</p> <p><b>Early access to CIRS R&amp;D Briefings</b> Including two annual Briefings focusing on regulatory and HTA agency benchmarking of new active substances. Additional benefits include:</p> <ul style="list-style-type: none"> <li>➤ Exclusive access to the slides from the Briefing</li> <li>➤ Exclusive analysis of your company's performance compared to overall benchmarks (on request)</li> <li>➤ Industry-wide webinar to review key findings</li> </ul>
<p><b>Participate in research &amp; metrics</b></p>  <p>CIRS membership offers several opportunities to participate in research that gives unique insights into the regulatory and access landscape.</p>	<p><b>Annual focus studies</b> Industry study on a hot topic of interest to members, with results fed back through a report and/or presentation.</p> <p><b>Eligibility to participate in the Growth and Emerging Markets and HTA Metrics Programmes</b> (additional fee applies – see opposite page for more information)</p> <p><b>Special projects</b> CIRS has worked with various organisations on ad hoc projects that answer short business questions or facilitate advocacy efforts.</p>
<p><b>Contribute to Research &amp; advocacy to advance regulatory/HTA policy</b></p>  <p>CIRS membership helps to support the CIRS research programme, including PhD projects and the development of tools, as well as the organisation of multistakeholder meetings and workshops.</p>	<p>By being a member, you can <b>contribute to the direction of CIRS advocacy and research</b> and put forward subjects for discussion at workshops, as well as topics for surveys and studies.</p> <p>Individuals from CIRS member companies are also eligible to be nominated to join CIRS advisory committees.</p>

# Join our Industry Metrics Programmes

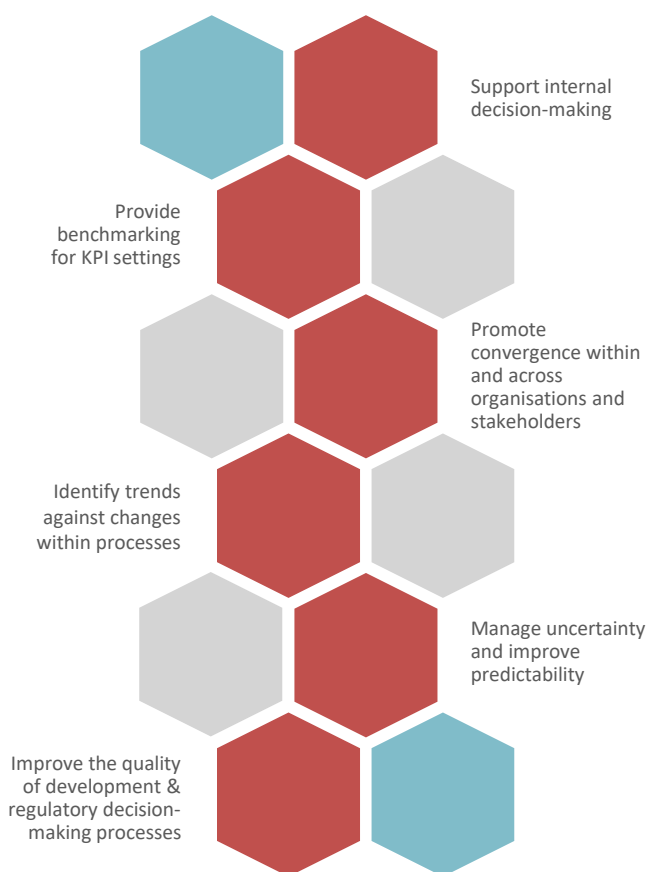
As well as the Regulatory and Access Programme, CIRS offers two industry metrics programmes that are available as add-on benefits to CIRS members. Annual deliverables of each programme includes:

- Company-specific report
- Executive summary
- Additional ad hoc analyses and special studies
- Industry Discussion Meeting to review trends and discuss new analyses
- Periodic updates on the Programme and CIRS advocacy activities

## GROWTH & EMERGING MARKETS METRICS (GEMM) PROGRAMME

Globalisation of pharmaceutical markets has accelerated the rising need for quality information on the development and registration of new medicines in growth and emerging countries. CIRS' GEMM Programme can help you to progress in these fast-growing markets by providing comparative data and information on the evolving regulatory environment.

The Programme collects company data annually on product characteristics, country characteristics, registration and rollout timelines, and factors influencing patient access to medicines in 19 countries and one regional alignment initiative across Asia, Latin America, Europe, the Middle East, and Africa. The data is anonymised, aggregated, and analysed, resulting in an industry-wide picture of the regulatory landscape in each country against which your organisation can be benchmarked. As a participant of the Programme, you will also have access to an online analysis tool that allows interactive and secure interrogation of the Programme dataset.



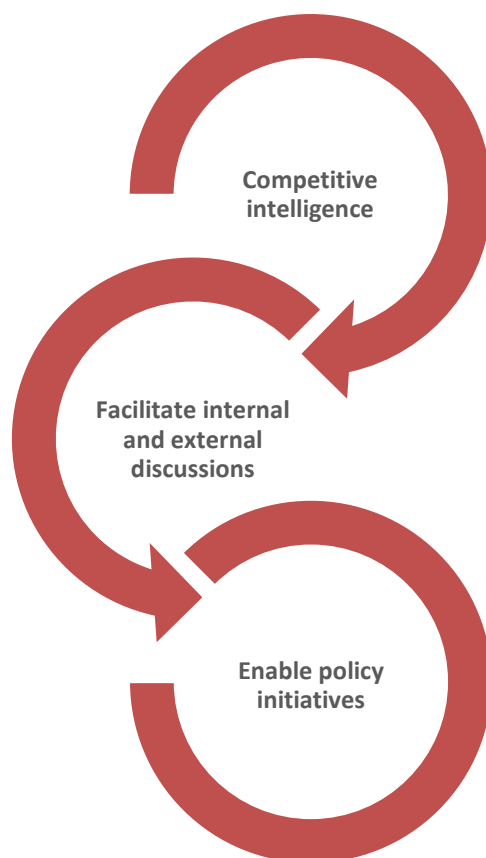
**If your company would like to find out more about joining the GEMM Programme, please contact Dr Magda Bujar: [mbujar@cirsci.org](mailto:mbujar@cirsci.org) and Adem Kermad: [akermad@cirsci.org](mailto:akermad@cirsci.org)**

# Join our Industry Metrics Programmes

## HEALTH TECHNOLOGY ASSESSMENT (HTA) METRICS PROGRAMME

HTA is a major challenge in drug development and market access, as requirements vary by jurisdiction and there is an overall lack of predictability and transparency in the HTA process. The CIRS HTA Metrics Programme can help your company to mitigate these risks and plan for success by providing unique insights and actionable benchmarks.

The Programme collects company data on individual products from development through to rollout in Australia, Canada, England, France, Germany, Italy and Spain. The data is analysed, aggregated and anonymised, resulting in an industry-wide picture of the HTA landscape that you can compare your company against. Key analyses address important business questions such as types and outcomes of early HTA-related advice and inclusion of active comparators during development and the acceptance by HTA agencies.



**If your company would like to find out more about joining the HTA Metrics Programme, please contact Dr Tina Wang: [twang@cirsci.org](mailto:twang@cirsci.org)**



# Meet the CIRS team



**Anna Somuyiwa**

Head



**Dr Neil McAuslane**

Director



**Dr Magda Bujar**

Senior Manager,  
Regulatory Programme  
and Strategic Partnerships



**Dr Tina Wang**

Senior Manager,  
HTA Programme and  
Strategic Partnerships



**Dr Jenny Sharpe**

Communications Manager



**Adem Kermad**

Senior Research  
Analyst



**Juan Lara**

Senior Research  
Analyst



**Dr Belén Sola Barrado**

Research Analyst



**Gill Hepton**

Administrator



**Prof Stuart Walker**

Founder and Senior  
Advisor\*



**Dr Mario Alanis**

Senior Consultant\*



**Penelope Cervelo Bouzo**

Research Analyst

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



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.

Dr Mario Alanis, Senior Consultant

[marioalanisgarza@cirsci.org](mailto:marioalanisgarza@cirsci.org)

Dr Magda Bujar, Senior Manager, Regulatory Programme and Strategic Partnerships

[mbujar@cirsci.org](mailto:mbujar@cirsci.org)

Penelope Cervelo Bouzo, Research Analyst

[pcervelo@cirsci.org](mailto:pcervelo@cirsci.org)

Gill Hepton, Administrator

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

Adem Kermad, Senior Research Analyst

[akermad@cirsci.org](mailto:akermad@cirsci.org)

Juan Lara, Senior Research Analyst

[jlara@cirsci.org](mailto:jlara@cirsci.org)

Dr Neil McAuslane, Director

[nmauslane@cirsci.org](mailto:nmauslane@cirsci.org)

Dr Jenny Sharpe, Communications Manager

[jsharp@cirsci.org](mailto:jsharp@cirsci.org)

Anna Somuyiwa, Head

[asomuyiwa@cirsci.org](mailto:asomuyiwa@cirsci.org)

Dr Belén Sola Barrado, Research Analyst

[bsola@cirsci.org](mailto:bsola@cirsci.org)

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

[twang@cirsci.org](mailto:twang@cirsci.org)

Prof Stuart Walker, Founder and Senior Advisor

[swalker@cirsci.org](mailto:swalker@cirsci.org)

### Centre for Innovation in Regulatory Science (CIRS)

Email: [cirs@cirsci.org](mailto:cirs@cirsci.org)

Website: [www.cirsci.org](http://www.cirsci.org)



[www.linkedin.com/company/centre-for-innovation-in-regulatory-science-ltd/](https://www.linkedin.com/company/centre-for-innovation-in-regulatory-science-ltd/)