Aligning global value-based decision making

# CIRS 2023 Agenda

**CONSENSUS ● TRUST ● ACCESS**

CIRS Centre for Innovation in Regulatory Science

# 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

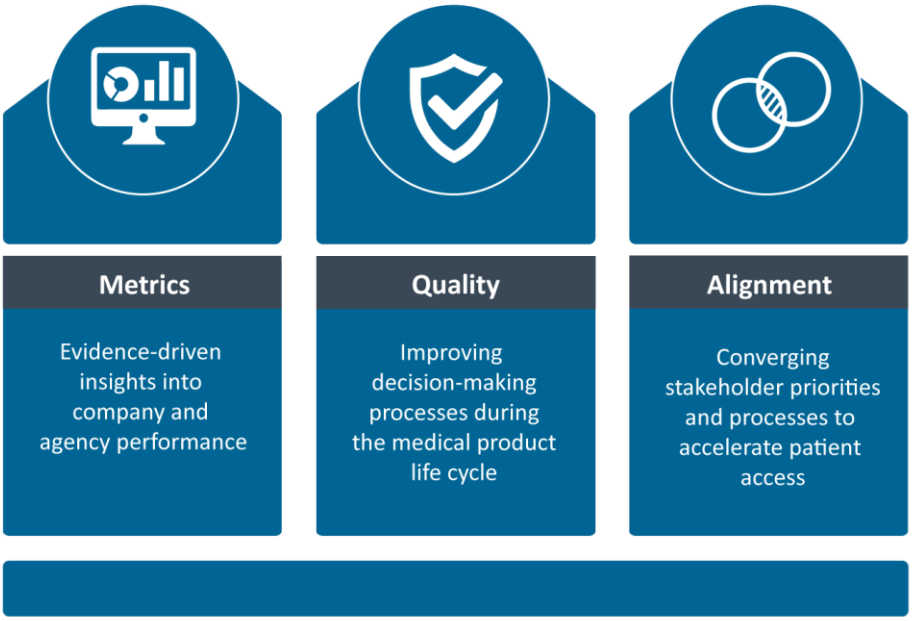
What sets us apart is our ability to bring **global** industry, regulators, HTA bodies, payers and academics together in a **neutral** atmosphere to identify and address key issues in the development, licensing and reimbursement of new medicines. We have been doing this for over 35 years through **focused**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

# 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*

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

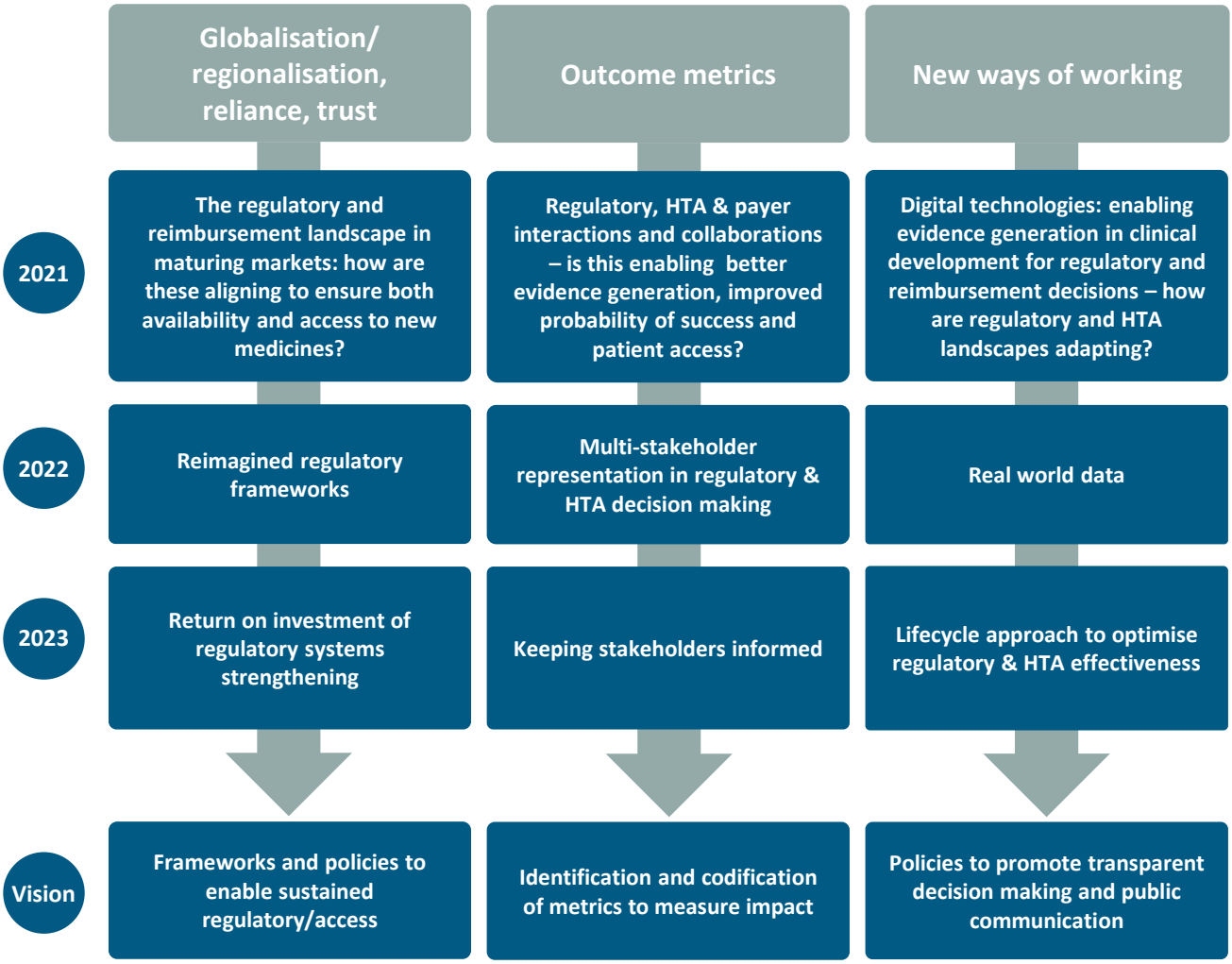
# Research strategy 2021-2023

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 2021-2023 programme, which will be achieved through workshops, fora and research projects, is grouped into three strategic themes:

**Globalisation/regionalisation, reliance, trust** - This theme is focused upon how organisations are evolving in order to ensure sustainability in terms of approval/access to new medicines. As well as ensuring a performance management culture, this theme incorporates a number of inter-related aspects such as regulatory strengthening, re-imagined regulatory frameworks and the alignment of regulatory and HTA.

**Outcome metrics** - CIRS has the experience of benchmarking metrics going back two decades and this theme aims to continue and extend that solid foundation. This will contain outcome measures as well as the identification and codification of metrics to measure impact. A key focus for 2021-2023 will be developing and utilising metrics on efficiency and effectiveness of process and patient involvement in regulatory and reimbursement decision making.

**New ways of working** - The COVID-19 pandemic has not only challenged regulatory and HTA systems globally to work in new ways but has also accelerated changes in the digital space. We will examine these new ways of working across industry, regulatory and HTA with an emphasis on digital – notably evidence generation (real world data/evidence), the Cloud and digital health – and new product focus including advanced therapeutic medicinal products.



# Member companies and participating agencies

## Member companies

| USA | Europe | Japan |
|---|---|---|
| AbbVie | AstraZeneca | Astellas |
| Amgen | Bayer | Eisai |
| Biogen | Boehringer-Ingelheim | Takeda |
| Biomarin | GlaxoSmithKline | |
| BridgeBio | 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 |
| Netherlands | ZIN |
| Norway | NoMA, NOKC |
| Poland | AHTAPol |
| Portugal | INFARMED |
| Scotland | SMC |
| Singapore | ACE |
| Spain | CAHIAQ, Osteba |
| 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 - Americas | Authority |
|---|---|
| Argentina | ANMAT |
| Brazil | ANVISA |
| Canada | Health Canada |
| Chile | ANAMED |
| Colombia | INVIMA |
| Cuba | CECMED |
| Dominican Republic | DIGEMAPS |
| Ecuador | ARCSA |
| El Salvador | DNM |
| Haiti | DPM/MT-MSPP |
| Mexico | COFEPRIS |
| Peru | DIGEMID |
| USA | FDA |
| Regional initiatives | CARICOM-CRS, PAHO, SICA |

## 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 *(and at member state level)* | Zazibona/SADC, EAC, ECOWAS |

# 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, Australia and 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

**Dr Claus Bolte**, Chief Medical Officer, Swissmedic

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

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

**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)

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

**Karen Reynolds** Director General, Pharmaceutical Drugs Directorate, Health Canada

**Dr Junko Sato**, Office Director, Office of International Program, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

**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

**Anna Somuyiwa,** Head, CIRS

**Dr Neil McAuslane,** Director, CIRS

**Prof Stuart Walker**, Founder and Senior Advisor, CIRS

**Dr Fabio Bisordi**, Global Head International Regulatory Policy, Roche

**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

**Judith Macdonald**, Head of International Regulatory Policy, Pfizer

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

**Eddie Reilly**, Chief Regulatory Officer, Sanofi

**Jerry Stewart**, VP 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: Prof Adrian Towse**, Director Emeritus and Senior Research Fellow, Office of Health Economics (OHE), UK

**Dr Michael Coory**, Medical Advisor, Technology Access and Assessment Division, Commonwealth Department of Health, Australia

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

**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 Michael Happich**, Senior Director HTA, International markets, Eli Lilly and Co

**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

**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

# African Regulatory Advisory Committee

The CIRS African Regulatory Advisory Committee was to act as an advisory group to provide recommendations on and guide the strategic planning process for CIRS activities with African regulatory agencies, regional regulatory initiatives, as well as continental regulatory initiatives.

**Chair: Gugu Mahlangu**, Former Director General, Medicines Control Authority of Zimbabwe (MCAZ)

**Vice-Chair: Dr Tumi Boitumelo Semete**, CEO, South African Health Products Regulatory Authority (SAHPRA)

**Prof Coulibaly Assane**, Director General, Directorate of Pharmacy and Medicines, Ivory Coast

**Mimi Darko**, CEO, Ghana Food and Drug Authority

**Adam Fimbo**, Director General, Tanzania Medicines and Medical Devices Authority (TMDA)

**Heran Gerba**, Director General, Ethiopian Food and Drug Administration (EFDA)

**Markieu Janneh Kaira**, CEO, Gambia Medicines Control Agency

**Dr Charles Karangwa**, Director General, Rwanda Food and Drugs Administration

**Prof Cristianah Mojisola Adeyeye**, Head of Nigeria National Agency for Food and Drug Administration and Control (NAFDAC)

**Bernice Mwale**, Head of Zambia Medicines Regulatory Authority (ZAMRA)

**Dr David Nahanya**, Head of Uganda National Drug Authority

**Margareth Ndomondo-Sigonda**, Co-Ordinator, Health Programmes, New Partnership for Africa's Development (NEPAD)

**Dr Fred Siyoi**, Head of Kenya Food and Drugs Authority

**Prof Stuart Walker**, Founder and Senior Advisor, CIRS

# 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 (see page 3) 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

*"Important topic addressed by broad range of relevant stakeholders. The very high CIRS standard is being maintained in the virtual world."*

**HTA agency**

*"The breakout session I joined was very well run – we managed to have a good discussion and heard from many of the group. Overall, this workshop exceeded my expectations."*

**Pharmaceutical company**

**4.7/5**

Our workshops receive consistently high feedback scores (averaged 4.7/5 in 2022)

# 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 virtual CIRS workshop, **Digital technologies: Enabling evidence generation in clinical development for regulatory and reimbursement decisions – how are the regulatory and HTA landscapes adapting?** which was held on 24-25th June 2021.

## What are the key challenges to ensure an efficient and effective digital ecosystem through a common digital infrastructure?

The group agreed that the overarching goals of a common digital infrastructure are to enable:

- Trust and transparency
- Access to the same data at the same time, enhancing collaboration and allowing for simultaneous submission and review
- Collaboration and data analysis – an example case study from the real-world data (RWD) perspective is the European Health Data & Evidence Network (EHDEN).

# 2023 Workshops

## 25 & 26 April 2023, Asia

**New product focus and evidence generation techniques – how is the regulatory landscape evolving in maturing countries?**

### Objectives

- Discuss the changing regulatory landscape for new products and ways of working both challenges and opportunities
- Identify through specific areas such as Advanced Therapy Medicinal Products (ATMP) review and use of Real World Evidence (RWE) and Digital Health Technologies (DHT), how agencies are adapting their requirements to enable the development and review so as to ensure efficient, effective and sustainable system
- Make recommendations on how these areas should evolve to enable global development and registration of medicines, as well as what should be considered in regard to convergence, regulatory alignment and harmonization.

## 22 & 23 June 2023, Tysons Corner, Virginia, USA

**The changing development evidence generation landscape for new medicines – What are the regulatory and HTA uncertainties and how should they be identified, managed or mitigated?**

### Objectives

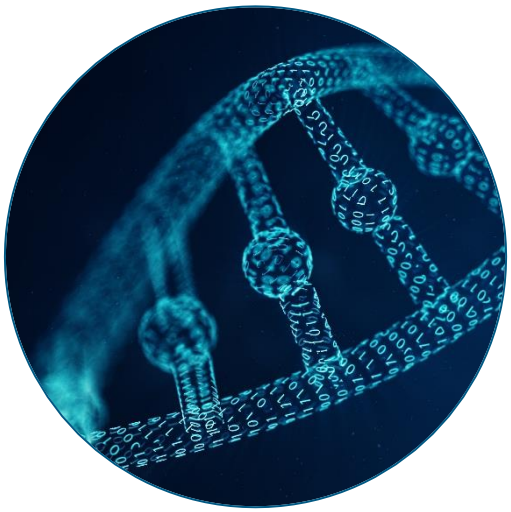
- Discuss the source of regulatory and HTA uncertainties [being built into the review and reimbursement of new medicines] arising from new ways of working and evidence generation during development
- Identify what strategies, tools, criteria are utilized to grade or reduce uncertainties within drug development, review and reimbursement as well as what can also be learnt from other industries
- Make recommendations on the role of uncertainty in regulatory and HTA decision making for innovative medicines and how to these can be managed or mitigated pre or post approval.

## 4 & 5 October 2023, United Kingdom

**Do development, review and reimbursement frameworks need adapting to enable fit-for-purpose evidence generation and financially sustainable access for rare disease products?**

### Objectives

- Identify the perspectives from the different stakeholders on the challenges and opportunities for rare disease products
- Discuss how best to align evidence generation in the development space to meet the different needs and remits, what upstream input will aid downstream decision making
- Recommendations on how best to support evidence generation and particularly focused on pre assessment evidence generation versus post approval to meet regulatory and HTA needs so as to enable financially sustainable access to rare disease products

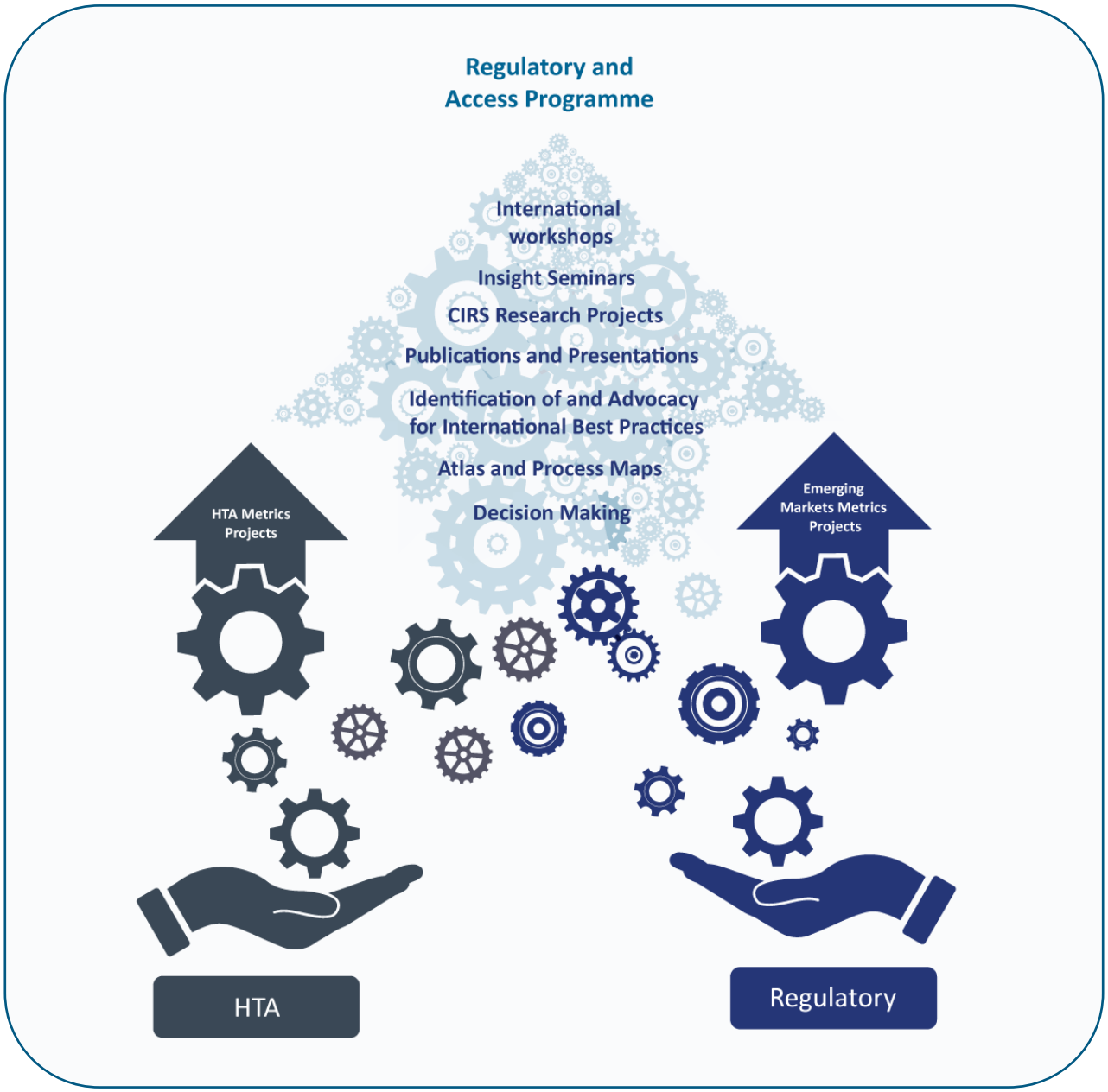


# CIRS Memberships

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**



# Why become a CIRS member?

## Be part of a **global network**

The CIRS community involves regulators, HTA agencies, payers, industry and academia from around the world.

By becoming a CIRS member, you can interact with these stakeholders at small, productive meetings* including:

- Multi-stakeholder workshops (see **p12-13**)
- Annual industry-focused technical forums
- Ad hoc industry-focused webinars

## Participate in **research & metrics**

CIRS membership offers several opportunities to participate in research that gives unique insights into the regulatory and access landscape, including:

- Annual focus studies e.g. **Evaluation of landscape China**
- **Growth & Emerging Markets Metrics Programme (additional fee)** – through this annual study, CIRS analyses company-provided data on product characteristics, country characteristics, registration and rollout timelines, and factors influencing patient access to medicines in 19 countries and two regional alignment initiatives. More information can be found on p17.
- HTA Metrics Programme (additional fee) – through this annual study CIRS tracks company-provided data to quantify the impact of addressing HTA requirements on clinical development programmes, reimbursement timing and outcomes in Europe, Australia and Canada. More information can be found on p18.
- Special Projects – CIRS has worked with various organisations on ad hoc projects that answer short business questions or facilitate advocacy efforts. To find out more, please contact **asomuyiwa@cirsci.org**

## Access to **insights & knowledge**

As well as gaining exclusive access to the results of research that your company has contributed to, as a CIRS member you will also be able to access:

- **CIRS Members website** - designed to be a 'one-stop shop' for CIRS resources including workshop slides, R&D Briefings and open access publications
- **CIRS Regulatory & Reimbursement Atlas™** - an online tool that maps regulatory, HTA and payer pathways for more than 70 jurisdictions around the world.

In addition, CIRS members have early access to R&D Briefings including two annual Briefings focusing on **regulatory** and HTA agency benchmarking of new active substances. Additional benefits include:

- Exclusive access to the slides from the Briefing
- Exclusive analysis of your company's performance compared to overall benchmarks (on request)
- Industry-wide webinar to review key findings

## Contribute to **Research & advocacy** to advance regulatory/HTA policy

CIRS membership helps to support the CIRS research programme, including PhD projects and the development of tools, advocacy through the **Optimising Efficiencies in Regulatory Authorities (OpERA) programme** as well as the organisation of multi-stakeholder meetings and workshops.

By being a member, you can contribute to the direction of CIRS advocacy and research and put forward subjects for discussion at workshops, as well as topics for surveys and studies. Individuals from member companies can also be nominated to join CIRS committees (see **p9-11**).

*Full registration and accommodation (excluding travel) for two participants at each workshop and registration for one person to each of the annual forums (accommodation not included).

# Join our Industry Metrics Programmes

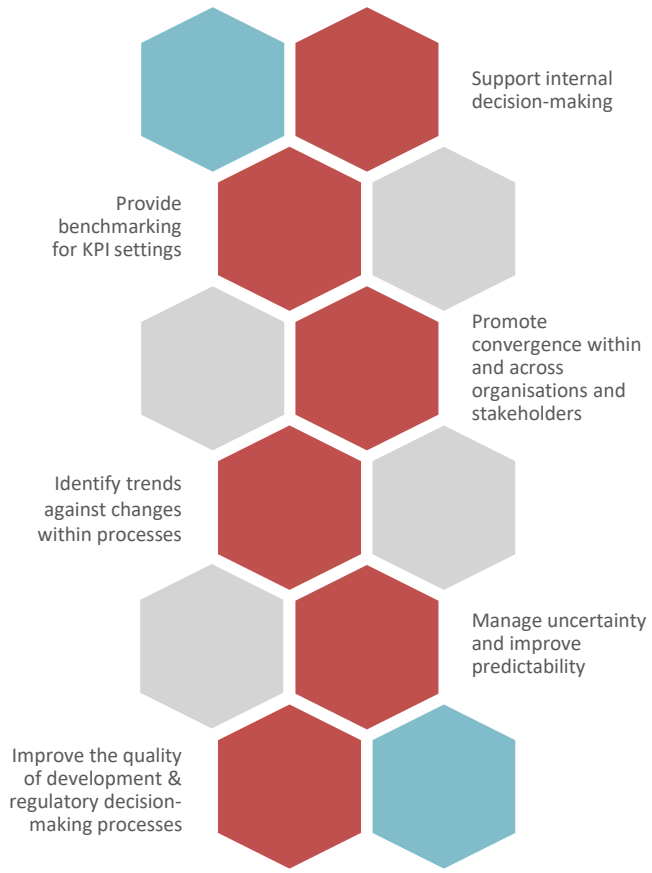
As well as the Regulatory and Access Programme, CIRS offers two industry metrics programmes that are available as add-on benefits to CIRS members. Annual deliverables of each programme includes:

- 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 two regional alignment initiatives 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.



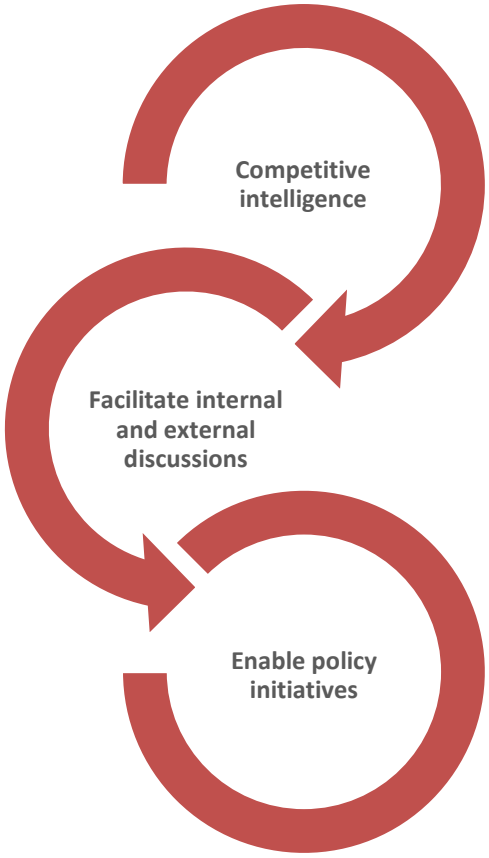

**If your company would like to find out more about joining the GEMM Programme, please contact Dr Magda Bujar: mbujar@cirsci.org and Adem Kermad: akermad@cirsci.org**

# 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**

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 Magda Bujar, Senior Manager, Regulatory Programme and Strategic Partnerships | mbujar@cirsci.org |
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| Dr Jenny Sharpe, Senior Scientific Writer | jsharpe@cirsci.org |
| Anna Somuyiwa, Head | asomuyiwa@cirsci.org |
| Dr Belén Sola Barrado, Research Analyst | bsola@cirsci.org |
| Dr Tina Wang, Senior Manager, HTA Programme and Strategic Partnerships | twang@cirsci.org |
| Prof Stuart Walker, Founder and Senior Advisor | swalker@cirsci.org |

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

**Email:** cirs@cirsci.org

**Website:** www.cirsci.org

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