Aligning global value-based decision making

THE CIRS 2022 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, HTA bodies and payers. 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 | Quality | Alignment

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 and regulatory agencies, as well as between HTAs 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
Manager, Strategic Development


Tina Wang
Senior Manager, HTA Programme and Strategic Partnerships


Gill Hepton
Administrator


Dr Jenny Sharpe
Senior Scientific Writer


Adem Kermad
Senior Research Analyst


Juan Lara
Research Analyst


Dr Belén Sola Barrado
Research Analyst


Prof Stuart Walker
Founder*


Dr Lawrence Liberti
Senior Advisor*


Dr Mario Alanis
Senior Consultant*

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

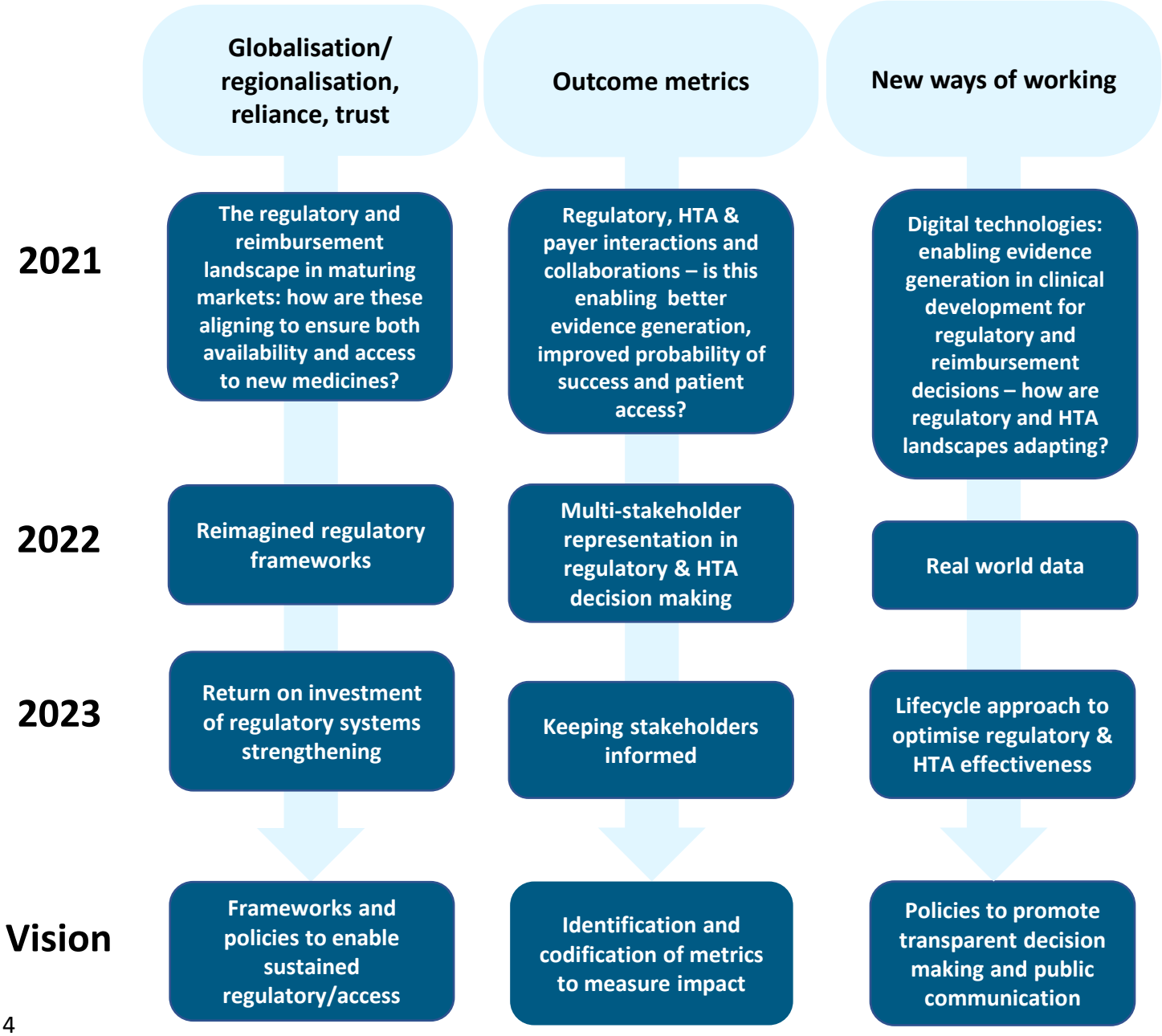
Research strategy 2021-2023

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	GlaxoSmithKline	Takeda
Biomarin	Ipsen	
BridgeBio	Leo	
Bristol Myers Squibb	Lundbeck	
Eli Lilly and Co.	Novartis	
Johnson &Johnson	Novo Nordisk	
Merck &Co	Roche	
Pfizer	Sanofi	

Participating HTA and coverage bodies

Country	Organisation
Australia	PBAC
Belgium	INAMI; KCE
Brazil	CONITEC
Canada	CADTH; DSEN, Canadian Institutes of Health Research, INESSS, AlbertaHealth Services
Croatia	AAZ
Denmark	DKMA
England, Wales	NICE
Finland	THL
France	HAS
Germany	G-BA, DAK-Gesundheit
Norway	NOKC
Poland	AHTAPol
Portugal	INFARMED
Scotland	SMC
Singapore	ACE
Spain	CAHIAQ, Osteba
Sweden	TLV
Switzerland	BAG
The Netherlands	ZIN
United States	UnitedHealth Group; TEC, Blue Cross/Blue Shield Association; Kaiser Permanente Institute for Health Policy; AHRQ;OPTUM

Participating regulatory agencies

Asia - Country	Authority
Australia	TGA
China	NMPA
Chinese Taipei	TFDA; CDE
India	CDSCO
Indonesia	NADFC
Japan	MHLW, PMDA
Malaysia	NPRA
Philippines	PFDA
Singapore	HSA
South Korea	MFDS
Thailand	Thai FDA
Vietnam	DAV
Regional initiatives	APEC

Participating regulatory agencies

Americas - Country	Authority
Argentina	ANMAT
Brazil	ANVISA
Canada	Health Canada
Chile	ANAMED/ISP
Colombia	INVIMA
Cuba	CECMED
Dominican Republic	DIGEMAPS
Ecuador	ARCSA
El Salvador	DNM
Haiti	DPM/MT-MSPP
Mexico	COFEPRIS
Peru	DIGEMID
United States	FDA
Regional initiatives	CARICOM-CRS/PAHO

EME - Country	Authority
Denmark	DKMA
EU	EMA
Ireland	HPRA
Israel	MoH
Jordan	JFDA
Kuwait	KDFC
Oman	MoH
Qatar	SCH
Saudi Arabia	SFDA
Sweden	MPA
Switzerland	Swissmedic
The Netherlands	MEB
Turkey	TITCK
United Arab Emirates	MoH
United Kingdom	MHRA
Regional initiatives	GHC

Africa - Country	Authority
Botswana	BoMRA
Burkina Faso	DGPML
Ethiopia	EFDA
Gambia	MCA
Ghana	FDAG
Ivory Coast	AIRP
Kenya	PPB
Malawi	PMRA
Mozambique	MoH
Namibia	NMRC
Nigeria	NAFDAC
Rwanda	RFDA
Senegal	MoHP
South Africa	SAHPRA
Tanzania	TMMDA
Uganda	NDA
Zambia	ZAMRA
Zimbabwe	MCAZ
Regional initiatives	AMRH-EAC, Zazibona/SADC, WAHO

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, Deputy Secretary for Health Products Regulation, Department of Health, Australia

Vice-Chair: Prof Hans-Georg Eichler, Consulting Physician of the Association of Austrian Social Insurance Institutions

Dr Claus Bolte, Head of Sector Marketing Authorisation, Swissmedic

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

Dr Ian Hudson, Senior Advisor, Integrated Development, Global Health, Bill and Melinda Gates Foundation, UK

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

Dr Xie Songmei, Deputy Director of Clinical Department Center for Drug Evaluation, National Medical Products Administration (NMPA), China

Dr John Patrick Stewart, Director General, Therapeutic Products Directorate, Health Canada

Anna Somuyiwa, Head, CIRS

Dr Neil McAuslane, Director, CIRS

Prof Stuart Walker, Founder, CIRS

Dr Fabio Bisordi, Global Head International Regulatory Policy, Roche

Dr Carlos Garner, Vice President, Global Regulatory Affairs, Eli Lilly

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

Dr David Jefferys, Senior Vice President, Head of Global Regulatory, Eisai Europe

Dr Sabine Luik, Chief Medical Officer and Senior Vice President, Global Medical, Regulatory & Quality, GlaxoSmithKline

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

Jerry Stewart, Vice President, Global Regulatory Policy and Intelligence, Pfizer

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 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, Associate 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

Andrew Mitchell, Strategic Adviser, Department of Health Australia

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

Dr Indranil Bagchi, Senior Vice President and Worldwide Head of Value and Access, Novartis

Dr Melinda Goodall, Director, HTA Policy Research, Policy Evidence Research, Centre for Observational and Real World Evidence (CORE), MSD

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

Dr Michael Happich, Director, BioMed HTA, Eli Lilly and Co

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

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

Dr Sean Tunis, Principal, Rubix Health

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

Anna Somuyiwa, Head, CIRS

Dr Neil McAuslane, Director, CIRS

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, CIRS

The **CIRS Latin American Regulatory Reflection Group** is also being set up to facilitate open discussion and reflection on issues within the Latin America region.

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 4) 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

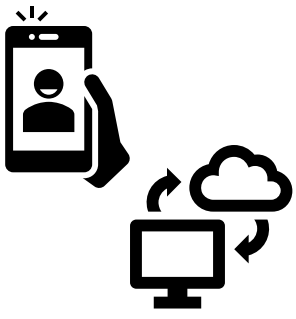
Our workshops receive consistently high feedback scores (averaged 4.5/5 in 2021)

All our workshops feature interactive breakout sessions that result in a set of recommendations.

Here's an example from one of the breakouts* at the virtual CIRS workshop *Reimagining medicine regulatory models: implementing fit-for-purpose sustainable activities for patient access*, which was held in memorial of Professor Sir Alasdair Breckenridge on 8-9th December 2020.

Recommendations on digital technologies that should be retained post pandemic:

- Enablers of virtual or decentralised clinical trials and associated tools, including **electronic Patient Reported Outcomes, telehealth, apps and site monitoring**
- Use of apps (especially for the collection of safety data), **digital tools, wearables, devices with digital software** for pre/post authorisation utilisation
- **Common digital infrastructure** and platforms for collaboration and work-sharing during the review, including Cloud submissions.

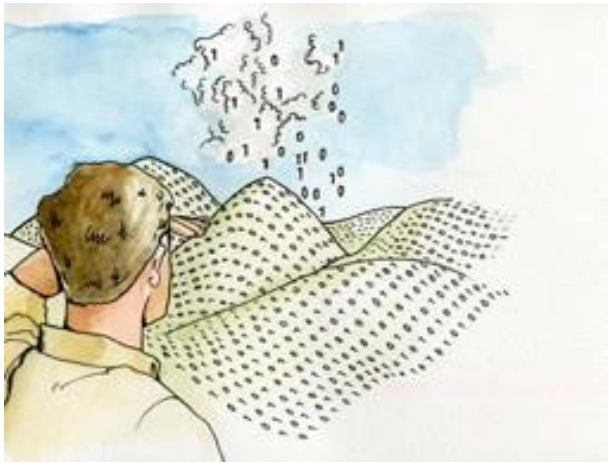


**The recommendations from all four breakout groups can be found in CIRS R&D Briefing 80.*

2022 Workshops

9-10th March, virtual

How has the pandemic accelerated the acceptance and utility of RWD/RWE in regulatory/HTA decision making?



Objectives

- Discuss the changing data landscape and provision of fit-for-purpose data for regulatory and HTA decision making, with a focus on use of RWD/RWE.
- Identify through case studies how RWD/RWE has or could be used to enable regulatory and reimbursement decisions through the life cycle of a medicine.
- Recommend stakeholder and collaborative activities to enable both alignment and utilisation of RWD/RWE by HTA agencies, regulators and payers for decision making during a medicine's life cycle.

June (date, location/format TBC)

Building on regulatory and HTA agilities for high unmet need – has the development, review and HTA assessment for priority medicines and vaccines changed?

Objectives

- Identify how well regulatory and HTA agilities post pandemic have been extrapolated to other disease areas in the development and rollout of medicines/vaccines for high unmet need.
- Discuss the impact of initiatives to facilitate medicines development as well as access to medicines of high unmet need, such as FDA Cures 2.0 and the UK Innovative and Licensing and Access Pathway (ILAP) approach.
- Make recommendations on areas that are enabling regulatory and HTA agility to be built into today's development review and reimbursement of new medicines such as RWE, patient-relevant endpoints, cloud submission and digital data structures.

October (date, location/format TBC)

Collaborative, work sharing, information sharing and regionalisation models - how do these fit into the regulatory toolkit post pandemic and are they adding value by enabling earlier patient availability of medicines for unmet need?

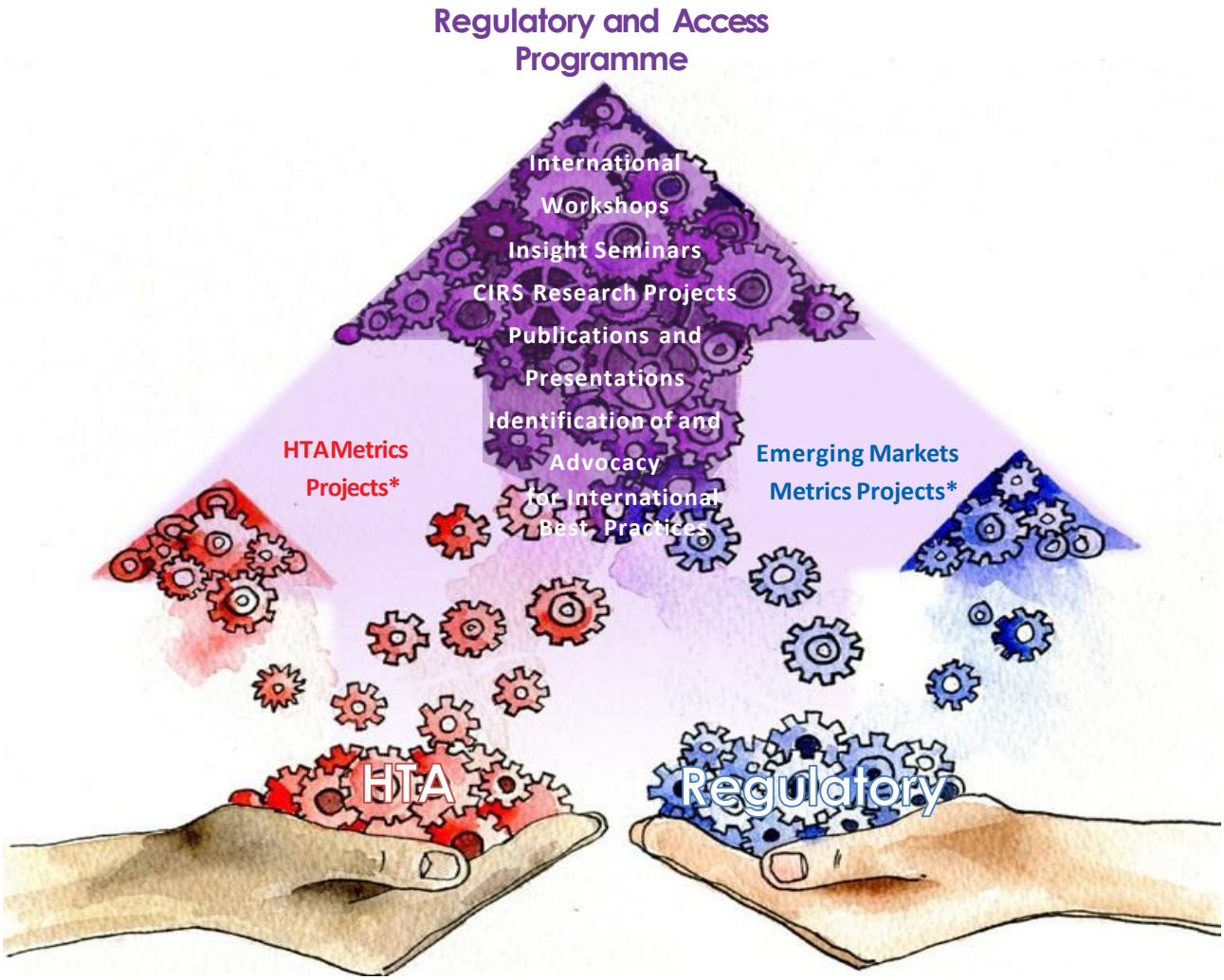
Objectives

- Discuss regulatory frameworks for registration of medicines which enable collaborative models, lessons learned from the pandemic but also the challenges and opportunities around regionalisation.
- Identify different work-sharing and regional models being utilised to enable agencies to increase efficiency and effectiveness and which frameworks need to be in place to enable success both with internal staff as well as externally with stakeholders.
- Make recommendations on frameworks and/or policies that will enable sustainable information sharing/work-sharing/regional regulatory processes for review of new medicines.

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



*Add on programmes (for an additional fee)

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 p8-9)
- Annual industry-focused technical forums
- Ad hoc industry-focused webinars

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

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
- Emerging Markets Metrics Programme (for an additional fee) – through this annual study CIRS analyses company-provided data on time to submissions and approvals for 18 Emerging Market regulatory authorities. More information can be found on p12.
- HTA Metrics Programme (for an 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 p12.
- 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 mbujar@cirsci.org

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, 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 p6-7).

*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

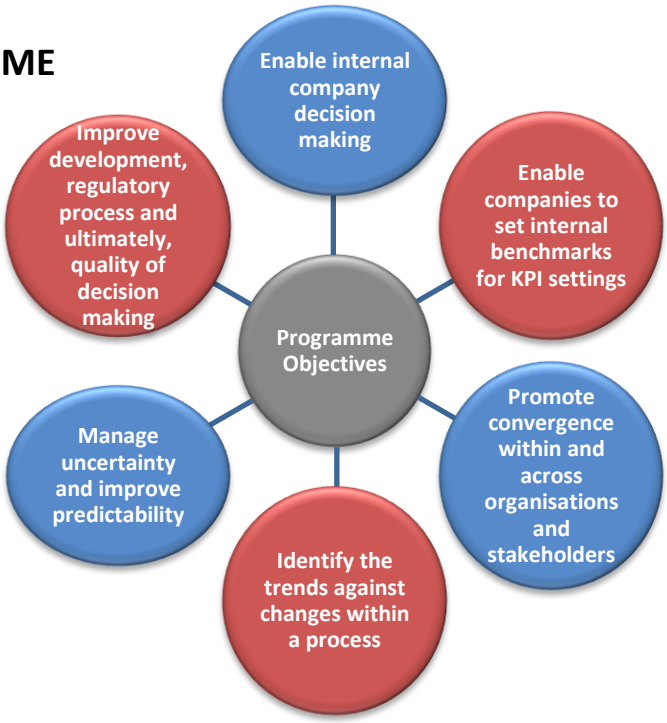
As well as the **Regulatory and Access programme,** CIRS offers two industry metrics programmes that are available as add-on benefits to CIRS members. Annual deliverables of each programme includes:

- Company-specific report
- Executive Summary
- Country-specific summaries
- Results of a focused study on a topic of interest to participant companies
- Industry Discussion Meeting to review trends and discuss new analyses
- Periodic updates on the Programme and CIRS advocacy activities

EMERGING MARKETS (EM) METRICS PROGRAMME

Globalisation of pharmaceutical markets means that quality information for development and registration of new medicines in EM countries is more important than ever before. The CIRS EM Metrics Programme can help you to get ahead in these fast-growing markets by providing comparative data and information on the evolving regulatory environment at the country and regional level.

The Programme collects company data on submission, approval and rollout times in 18 countries and two regional alignment initiatives across Asia, Latin America, Europe, Middle East and Africa. The data is analysed, aggregated and anonymised, resulting in an industry-wide picture of the regulatory landscape in each country, which you can then compare your company against.

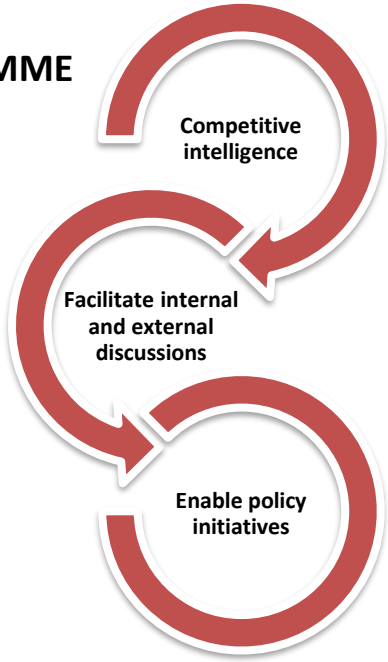


If your company would like to find out more about joining the EM Metrics Programme, please contact Magda Bujar: mbujar@cirsci.org

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 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.

Centre for Innovation in Regulatory Science (CIRS)

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CIRS Centre for Innovation in Regulatory Science