Aligning global value-based decision making

THE CIRS 2019 AGENDA

CONSENSUS • TRUST • ACCESS

CIRS Centre for Innovation in Regulatory Science

MISSION

To maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and HTA policies and processes in developing and facilitating access to medicinal products

KEY ACTIVITIES

International Workshops: Meetings for members are convened at which invited participant interactions are optimised to facilitate networking, constructive discussion, recommendations and actions.

CIRS Research Projects: Specialised research and surveys are carried out among leading pharmaceutical companies and regulatory and HTA agencies with expert analyses and interpretation of the findings.

Identification of and Advocacy for International Best Practices: Using findings from our Workshops and research projects CIRS interacts with companies, regulators, HTA agencies and other international organisations to promulgate efficiencies in global medicine development.

Publications and Presentations: Reports are prepared from Workshops and projects. Dissemination of findings and recommendations through the R&D Briefing series, conference presentations, papers in peer-reviewed journals and the CIRS website are key aspects of the CIRS educational communication mission.

CIRS: VALUE, IMPACT, RETURN

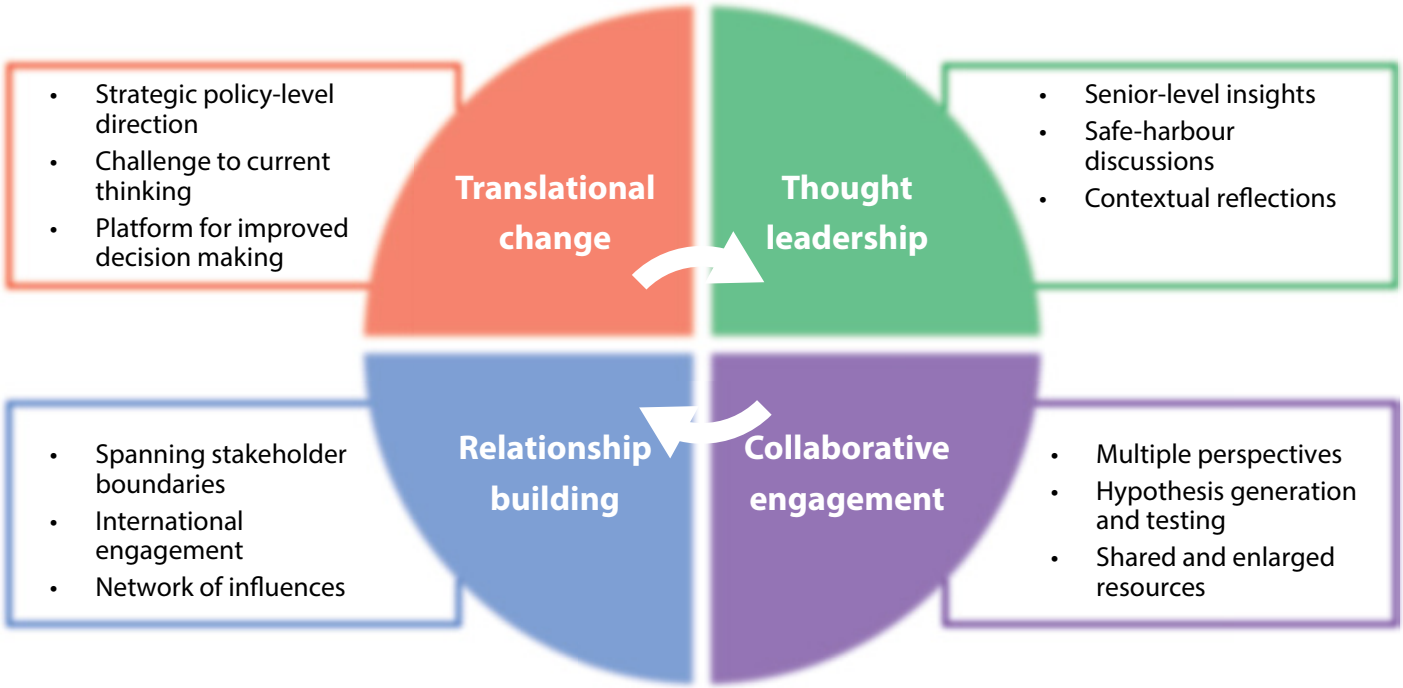
For over 25 years, the Centre for Innovation in Regulatory Science has provided a neutral forum for the evolution of the concepts, methodologies and policies that improve the effectiveness, efficiency and decision making of stakeholders in the development of and access to safe and effective medicines.

How does CIRS provide value?

- Facilitating interaction among stakeholders
- Evolving best practices
- Offering decision-making tools
- Providing data and analyses to inform policy decisions
- Demonstrating the relevant application of metrics
- Strengthening agency capacity
- Aligning regulatory and HTA needs
- Recording and communicating situational analyses

CIRS Workshops provide exceptional learning and networking opportunities where participants can interact with peers in an atmosphere of informed and productive discussion to produce recommendations to move important topics forward in the development, regulation and reimbursement of medicines.

CIRS Workshops: impact and return on investment



2019 WORKSHOPS

27-28 March, Singapore

Optimising the regulatory approval process by evaluating performance and addressing good reliance practices

OBJECTIVES

- Understand how the use of a systematic structured approach to agencies measuring their review process can enable them to focus their improvement initiatives, set realistic targets and facilitate future strategic planning and decision making
- Recommend the use of quantitative metrics that can help to optimise review performance and the constituents of good reliance practices that will enable agencies to focus on value-added activities and provide timely patient availability to good-quality, safe and effective medicines

Key discussion point: How can the development and introduction of good reliance practices provide direction and a pathway for agencies and what are the benefits of these approaches?

20-21 June, Tysons Corner, Virginia, USA

Approaches to better decision making in companies and regulatory and HTA agencies through documentation, quality decision-making practices and knowledge management

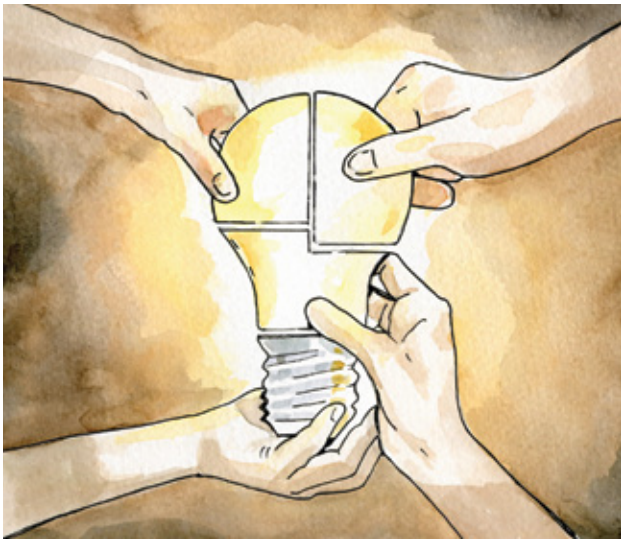
OBJECTIVES

- Ascertain how utilising structured systematic approaches applying good documentation of decision making can ensure that institutional knowledge sharing becomes an integral part of the development and review of medicines
- Recommend the processes and practices that will enable access to relevant information to inform current decision making while increasing transparency and consistency

Key discussion point: How can good knowledge management systems can make the processes more efficient, transparent, consistent and scientifically rigorous?

9-10 October, Surrey, UK

Identifying and mitigating avoidable uncertainty in the review and reimbursement of new medicines: How can this improve predictability of regulatory and HTA outcomes?



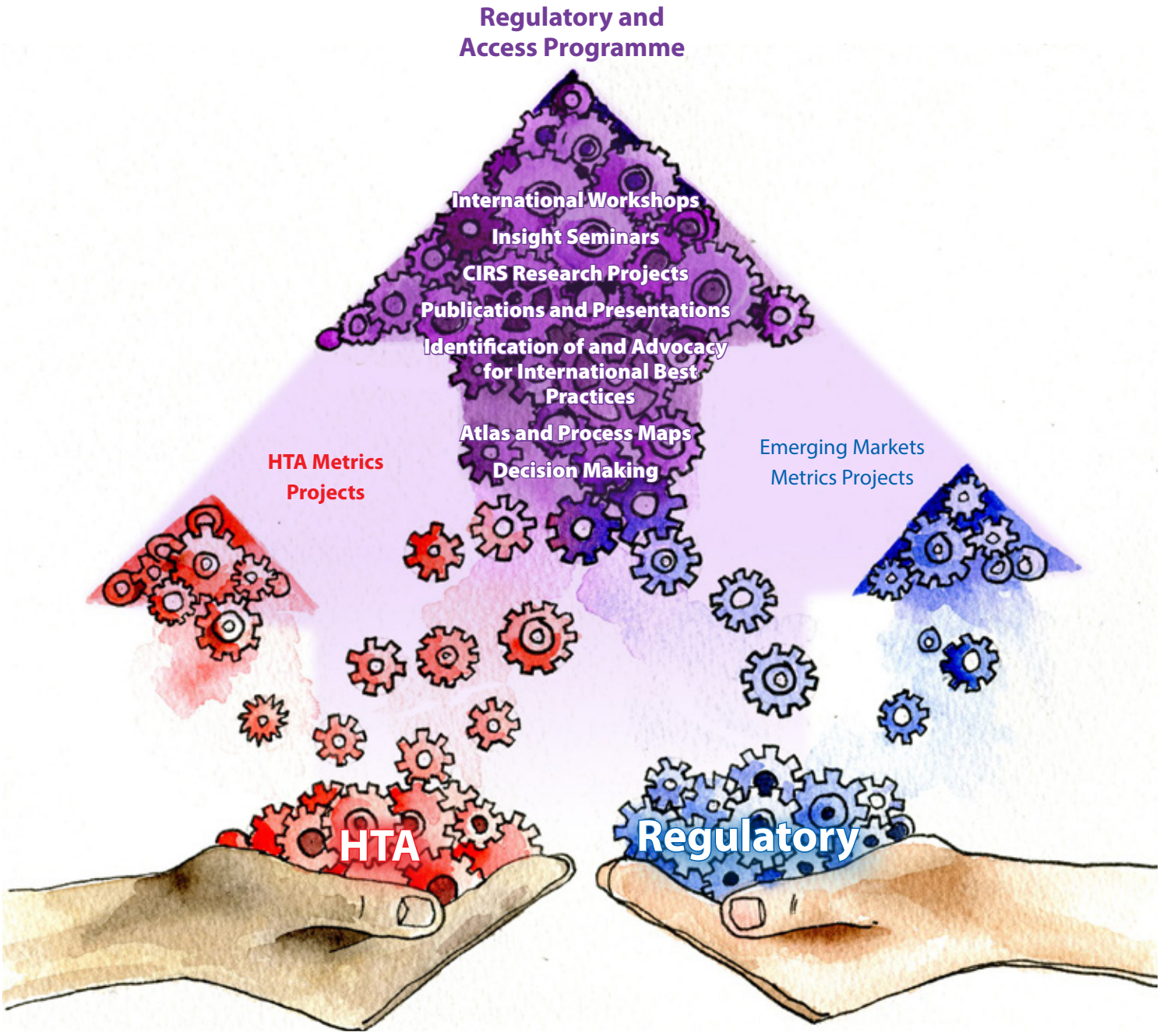
OBJECTIVES

- Identify the potential avoidable uncertainties as perceived by companies, HTA, payers, patients and regulatory agencies
- Recommend ways in which these uncertainties can best be mitigated such as alignment between regulators and health technology assessors

Key discussion point: Can knowledge and mitigation be used to improve the probability of a positive regulatory and HTA outcome and what are the key considerations?

THE CIRS REGULATORY AND ACCESS PROGRAMME

In 2019, the seven-year plan directed by the Scientific Advisory Council to more fully align CIRS activities in the regulatory and access arenas will have been fully realised. Because of CIRS' special ability to coordinate the input and activities of multiple stakeholders from a global perspective, the new "Regulatory and Access Programme" addresses our activities in this holistic manner.



DRIVING THEMES

METRICS	QUALITY OF PROCESS	ALIGNMENT
Managing uncertainty and improving predictability	Improving development and regulatory processes and ultimately, the quality of decision making	Promoting convergence within and across organisations and stakeholders

THE 2019 PROGRAMME OF WORK: EVOLUTION OF THE DELIVERABLES

2015-2017		2018-2020
GLOBAL DEVELOPMENT PROGRAMME TRACK	**HTA TRACK**	**NEW COMBINED "REGULATORY AND ACCESS PROGRAMME"**
2 paid registrations per Workshop (3 WS)	1 paid registration per Workshop (3 WS)	**Two paid registrations per Workshop (3 WS per year)**
Global Development (regulatory focused) Technical Forum (annual)		**Regulatory-focussed Technical Forum (annual) registration fee included (accommodation not included)**
Regulatory advocacy with ICH+ countries	European, Canadian and US HTA advocacy	**Aligned regulatory and access advocacy with ICH+ countries**
	HTA focussed Technical Forum (annual)	**HTA/HEOR-focussed Technical Forum (annual) - registration fee included (accommodation not included)**
Targeted international regulatory advocacy	Advocacy with access agencies in the global environment	**Aligned global international advocacy across regulatory and access agencies**
Support for the Annual Regulator's Forum		**Support for the Annual Regulator's Forum; ad hoc Agency Discussion Meetings; new periodic HTA agency webinars**
	Semi-annual HTA teleconferences	**Semi-annual teleconferences (2 regulatory focus and 2 HTA/HEOR focus)**
Focus Study participation	Focus Study participation	**Focus Study participation across regulatory and access topics**
Regulatory agency performance metrics benchmarking		**Regulatory agency performance metrics benchmarking; HTADock integrated regulatory and HTA database outcomes analyses**
Key regulatory projects: BR, iSABRE, PhD student support	Key HTA projects: Factors influencing HTA recommendations in Europe; Exploring Approaches to HEOR/HTA decision making; Commonality in evidentiary requirement across regulatory and HTA stakeholders	**Key aligned projects** • **Regulatory: iSABRE** • **Quality Scorecards/Decision Making activities; Facilitated regulatory and access pathways; Commonality in evidentiary requirement across regulatory and HTA stakeholders** • **PhD student support- regulatory and HTA thesis themes**

MEMBER COMPANIES AND PARTICIPATING AUTHORITIES

Member Companies

USA	Europe	Japan
AbbVie	AstraZeneca	Astellas
Amgen	Bayer	Eisai
Biogen	GlaxoSmithKline	Takeda
Celgene	Idorsia	
Eli Lilly and Co.	Ipsen	
Johnson & Johnson	Merck KgaA/ EMD Serono	
Merck & Co	Novartis	
Pfizer	Roche	
Vertex	Sanofi	
	UCB	

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	Danish Health and Medicines Authority
England, Wales	NICE
Europe	EUnetHTA
France	HAS
Finland	THL
Italy	AIFA
Lithuania	VASPVT
Norway	NOKC
Poland	AHTAPol
Portugal	INFARMED
Scotland	Scottish Medicines Consortium
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 Authorities

Americas - Country	Authority
Argentina	ANMAT
Brazil	ANVISA
Canada	Health Canada
Chile	ANAMED
Colombia	INVIMA
Cuba	CECMED
Mexico	COFEPRIS
Peru	DIGEMID
United States	FDA
	CARICOM-CRS/PAHO

EMEA - Country	Authority
EU	EMA
Israel	MoH
Jordan	JFDA
Kuwait	KDFC
Oman	MoH
Qatar	SCH
Saudi Arabia	SFDA
South Africa	MRA
Sweden	MPA
Switzerland	Swissmedic
Turkey	TITCK
United Arab Emirates	MoH
United Kingdom	MHRA
	AMRH –EAC
	ZaZiBoNa/SADC

ASIA - Country	Authority
Australia	TGA
China	SFDA; CDE
Chinese Taipei	TFDA; CDE
Indonesia	NAFDC
Japan	MHLW, PMDA
Malaysia	NCPB
Philippines	DOH, FDA
Singapore	HSA
South Korea	MFDS
	APEC

BENEFITS OF MEMBERSHIP

Membership to the Regulatory and Access Programme is open to all pharmaceutical companies, in particular 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.

The benefits enjoyed by members of CIRS include:

- Be part of the small interactive CIRS Workshops, which provide exceptional learning and networking opportunities where you can interact with peers from industry, regulatory authorities, HTA agencies and academia in an atmosphere of informed and productive discussion
- Full registration and accommodation (excluding travel) for two participants at each Workshop
- The opportunity to meet and network with senior regulatory personnel from government agencies, international pharmaceutical companies and academia
- The ability to contribute to the direction of the programme of work for CIRS and put forward subjects for discussion and debate at future Workshops as well as topics for surveys and studies
- The opportunity to be nominated for participation in the Advisory Management Committee or the Scientific Advisory Council, Steering Committees and Taskforces

- Exclusive, priority access to
  - Information derived from studies and surveys to which your organisation has contributed
  - Reports and slide presentations from CIRS Workshops
- Early access to
  - Reports and supportive documents from all Workshops and projects, projects highlighting regulatory and HTA developments, issues and attitudes as a unique information resource
  - Archives of all CIRS publications including survey and Workshop reports and R&D Briefings

The fee for the 2019 Regulatory and Access Programme entitles member organisations to all of the benefits of membership described in this brochure; this includes the full registration and accommodation (excluding travel) for two participants at each Workshop and registration for one person to each of the annual Forums. Additional participants may attend Workshops (space permitting) and will be assessed a registration fee (£950 per person per Workshop plus VAT where applicable), to cover direct participation costs (conference rate, meals and accommodations, administration and overhead; travel excluded).

CIRS - The Centre for Innovation in Regulatory Science Limited - is a neutral, independently managed UK-based subsidiary company, forming part of Clarivate Analytics (UK) Limited. CIRS' mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and 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 medical products through these activities. This is CIRS' purpose. CIRS is operated solely for the promotion of its purpose. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, special projects and grants.

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