THE CIRS 2015 AGENDA

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 Best International 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.

MEMBER COMPANIES AND PARTICIPATING REGULATORY AUTHORITIES

Member Companies

USA	Europe	Japan
AbbVie	Actelion	Astellas
Allergan	AstraZeneca	Daiichi-Sankyo
Amgen	Bayer	Eisai
Biogen-Idec	Boehringer Ingelheim	Takeda
Celgene	GlaxoSmithKline	Zeria
Eli Lilly and Company	Merck Serono	
Johnson & Johnson	Novartis	
Merck	Novo Nordisk	
Pfizer	Roche	
Shire	Sanofi	
	Servier	

HTA and Coverage Bodies

Country	Organisation
Australia	PBAC
Belgium	INAMI; KCE
Brazil	CONITEC
Canada	CADTH; DSEN, Canadian Institutes of Health Research, INESSS, Alberta Health 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

Country	Authority
Argentina	ANMAT
Australia	TGA
Brazil	ANVISA
Canada	Health Canada
Chile	ANAMED
China	SFDA; CDE
Chinese Taipei	TFDA; CDE
Colombia	INVIMA
Egypt	DPPC
EU	EMA
India	CDSCO
Indonesia	NAFDC
Israel	MoH
Japan	MHLW, PMDA
Jordan	JFDA
Kuwait	KDFC
Malaysia	NCPB
Mexico	COFEPRIS
Oman	MoH
Peru	DIGEMID
Philippines	DOH, FDA
Qatar	SCH
Saudi Arabia	SFDA
Singapore	HSA
South Africa	MRA
South Korea	MFDS
Sweden	MPA
Switzerland	Swissmedic
Turkey	MARA
United Arab Emirates	MoH
United Kingdom	MHRA
United States	FDA

ADVISORY NETWORKS

Scientific Advisory Council

Chair: Professor Sir Alasdair Breckenridge, Former Chairman, MHRA, UK
Vice Chair: Barbara J. Sabourin, Director, TPD, Health Canada
Dr Petra Dörr, Deputy Exec. Dir., Swissmedic
Prof Hans-Georg Eichler, Senior Medical Officer, EMA
Dr John Lim, Deputy Director of Medical Services, MOH, Singapore; Executive Director, Centre of Regulatory Excellence, Duke-NUS, Singapore
Dr Richard Moscicki, US FDA
Prof Robert Peterson, Exec. Dir. DSEN, Canadian Institutes of Health Research
Dr John Skerritt, National Manager, TGA,
Tomas Salmonson, Chair, CHMP/EMA

Dr Mary Baker, Pres., European Brain Council
Dr Murray Lumpkin, Senior Fellow, Bill and Melinda Gates Foundation
Prof Stuart Walker, Founder, CIRS
Dr Stephane Andre, Head of EU/ROW Reg. Affairs, F. Hoffmann-La Roche Ltd
Dr Jay T. Backstrom, SVP, Regulatory Affairs and Pharmacovigilance, Celgene Corporation
Adrian Griffin, Vice President for HTA Policy Johnson & Johnson
Dr Tim Garnett, CMO, SVP, Eli Lilly
Dr Edmund Harrigan, SVP, Worldwide Regulatory and Safety Strategy, Pfizer
Dr Paul Huckle, Chief Regulatory Officer and SVP, GlaxoSmithKline
Dr David Jefferys, SVP, Head of Global Regulatory, Eisai Europe Ltd
Dr Ronald Robison, VP, Reg Affairs, Medical Services, R & D, AbbVie
Dr Joseph Scheeren, Head of Global Reg Affairs, Bayer Healthcare Company Ltd

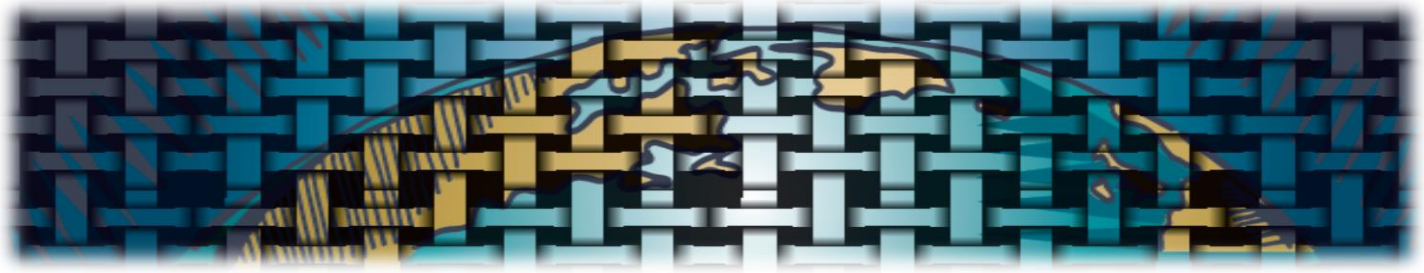
Advisory Management Committee

Chair: **Prof Robert Peterson**, Exec. Dir, DSEN, Canadian Institutes of Health Research
Dr Carmen Bozic, SVP, Clinical and Safety Sciences, Biogen-IDEC
Robin Evers, SVP, NovoNordisk
Paul Huckle, Chief Regulatory Officer and SVP, GlaxoSmithKline
Dr Hilary Malone, Head, Global Reg Affairs, Sanofi
Dr Ronald Robison, VP, Reg Affairs, Medical Services, R & D, AbbVie
Dr Joseph Scheeren, Head of Global Regulatory Affairs, Bayer Healthcare Company
Lawrence Liberti, Executive Director, CIRS
Dr Neil McAuslane, Director, CIRS
Prof Stuart Walker, Founder, CIRS

Specialist Advisors to the Executive Director

Professor Bruno Flamion, Professor of Pharmacology, University of Namur
Dr Thomas Lönngren, Independent Strategy Advisor, Pharma Executive Consulting
Prof Mamoru Narukawa, Associate Professor Pharmaceutical Medicine, Kitasato University Graduate, School of Pharmaceutical Sciences

TRACKS AND THEMES



Medicine development in the 21st century requires a globally coordinated development, regulatory and access effort. To address the key topics that will impact global medicines development and access, CIRS has organised its activities into two Tracks.

The Global Development Track: Designed to address the challenges posed by the need to align global submissions and to fulfil requirements for regulatory reviews across mature and developing jurisdictions.

The Health Technology Assessment and Market Access Track: As HTA assessments inform and influence market access, the need to identify the factors that can be built into early medicine development, conducted in concert with regulatory requirements, and that characterise the value of new therapies will be the focus of this track.

CIRS will address three overlapping themes within these two tracks.

METRICS

Theme: Managing uncertainty and improving predictability

Goal: To undertake the collection, curation and analysis of data, information and processes to provide insights into the performance of companies and agencies in the development, review and access of new medicines. These activities are supported by company- and agency-led metrics programmes, topic-specific focused surveys, and collation of supportive public domain information. Findings are communicated through CIRS confidential reports and R&D briefings to enable a clearer understanding of the regulatory and HTA environment for medicines development.

QUALITY OF PROCESS

Theme: Improving development and regulatory processes and ultimately, the quality of decision making

Goal: Building on CIRS' considerable experience in refining a benefit-risk framework, these activities will focus on developing a framework for a structured, transparent and logical approach to quality decision making. This will be applicable throughout all stages of medicine development and review, including the regulatory and HTA review processes.

ALIGNMENT

Theme: To promote convergence within and across organisations and stakeholders.

Goal: Activities will assess approaches and identify the building blocks to help regulatory and HTA agencies best use and share resources between and among them. With the participation of the industry in developing these best practices we envision promoting activities that result in more efficient and timely development and access to medicines. Accelerating access while managing the uncertainty associated with medicine development will be a key aspect of these activities. We will work toward an agreement for a flexible, risk-based approach to the development and assessment of innovative therapies.

2015 WORKSHOPS

2-3 February, Chinese Taipei

Utilisation of a common benefit-risk framework: Can it facilitate decision-making and improve communication within and across agencies?

Benefit-risk assessment is the cornerstone of every regulatory decision, irrespective of the type of review and in the future, the use of a benefit-risk framework will be part of good review practices. This Workshop will build on the work that has been accomplished in mature markets and through the ongoing activities of the CIRS *international Summary Approach to Benefit-Risk Evaluation* (iSABRE).

OBJECTIVES

- **Consider how utilisation of a structured systematic benefit-risk framework and its documentation can aid both the process and communication within and across agencies**
- **Recommend how a benefit-risk framework can best be used to optimise internal decision making and external communication**

Key discussion points

What are the processes, procedures and considerations that agencies undertake to make benefit- risk decisions for their jurisdictions and how this process is documented?

OBJECTIVES

- **Discuss the potential influences on good decision making, both at the review team- and senior-management level**
- **Identify considerations for companies and agencies when applying or embedding decision frameworks within decision-making processes**

Key discussion points

How are the structured approaches to evaluating the evidence in balancing benefit-risk undertaken within companies and agencies? How are these approaches incorporated into the broader key decision-making processes?

11-12 June, Washington, DC, USA

Exploring approaches to decision making

Over the last three years, in addition to work to develop a systematic structured approach to benefit risk, CIRS has undertaken a project to identify the important issues that influence quality decision making from both individual and organisational perspectives. As a result of this background research, a draft framework for good decision making in the development and review of medicines has been developed.

7-8 October, UK

Patient's role in informing the decision process for approval and reimbursement of new medicines

The patient's role in the development, regulation and health technology assessment processes for new medicines continues to grow in importance to all stakeholders. This Workshop will build on CIRS Workshops on this topic conducted during 2012-2014.

OBJECTIVES

- **Improve understanding of the importance of patient involvement**
- **Identify best practices in the acquisition of patient input**
- **Recommend methods for leveraging the same patient input for both health technology assessment and regulation**

Key discussion points

What are the learnings from current practices for patient involvement from different HTA and regulatory agencies? How can industry and agencies identify truly representative patient viewpoints? How do reviewers use the various inputs from patients and what weights to patients' perspectives have on final decisions?

2015 CIRS ACTIVITIES CALENDAR

Date	Activity	Venue
1 February	**6th Annual Regulators Forum**	**Chinese Taipei**
2-3 February	**Workshop: *Utilisation of a common benefit-risk framework: Can it facilitate decision-making and improve communication within and across agencies?***	**Chinese Taipei**
11-12 June	**Contemporary Insights Workshop: *Exploring approaches to decision making***	**Washington, DC, USA**
7-8 October	**Workshop: *Patient's role in informing the decision process for approval and reimbursement of new medicines***	**UK**
17 November	**Emerging Markets Industry Discussion Meeting**	**Heathrow, UK**
18 November	**Global Development Technical Forum**	**Heathrow, UK**
19 November	**HTA Industry Discussion Meeting**	**Heathrow, UK**
20 November	**HTA Technical Forum: *How does the effective use of various kinds of scientific advice support access success?***	**Heathrow, UK**

TENTATIVE WORKSHOPS FOR 2016-2017

Date	Workshop	Venue
January/February 2016	**Workshop: *Building trust across agencies: what activities support alignment of activities?***	**TBD**
June 2016	**Contemporary Insights Workshop: *Communication and social media***	**USA**
October 2016	**Workshop: *Commonality in evidentiary requirement across stakeholders. Has the gap between HTA and Regulatory evidence requirements closed?***	**UK**
February 2017	**Workshop: *Risk-based decision making –What does this mean and what are the underpinning requirements?* (Ties in with quality decision making and comparison of various regional (EAC, GCC, APAC) activities for better access to priority medicines)**	**TBD**
June 2017	**Contemporary Insights Workshop: *Post approval pharmacovigilance using innovative data sources***	**USA**
October 2017	**Workshop: *Flexible regulatory/access pathway; are we there yet? How does this tie in with personalised medicine and adaptive management?* Or *Sharing assessment reports and other regulatory or HTA data to expedite reviews and access to medicines***	**UK**

BENEFITS OF MEMBERSHIP

Membership 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 up to three participants at each Workshop (two from the Global Development Track and one from the HTA Track).
- 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
  - Full 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 each Track entitles the member organisation to all of the benefits of membership described in this brochure and the annual *Agenda*; this includes the full registration and accommodation (excluding travel) for two participants at each Workshop (Global Development Track) and one participant (HTA Track). Additional participants may attend Workshops (space permitting) and will be assessed a registration fee, to cover direct participation costs (conference rate, meals and accommodations, administration and overhead; travel excluded).

CIRS - The Centre for Innovation in Regulatory Science - is a neutral, independent UK-based subsidiary company, forming part of the Intellectual Property and Science business of Thomson Reuters. The mission of CIRS 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. It is governed and operated 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)
The Johnson Building, 77 Hatton Garden, London, EC1N8JS, UK
Email: cirs@cirsci.org
Website: www.cirsci.org

Lawrence Liberti, Executive Director	LLiberti@cirsci.org
Neil McAuslane, Director	nmcauslane@cirsci.org
Prisha Patel, Manager, Emerging Markets Programmes	ppatel@cirsci.org
Tina Wang, Portfolio Manager, HTA Programme	twang@cirsci.org
Gill Hepton, Administrator	ghepton@cirsci.org

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