THE CIRS 2018 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 AUTHORITIES

Member Companies

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

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
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	MCC/SAHPRA
South Korea	MFDS
Sweden	MPA
Switzerland	Swissmedic
Turkey	TITCK
United Arab Emirates	MoH
United Kingdom	MHRA
United States	FDA

Scientific Advisory Council

DRIVING THEMES

BENEFITS OF MEMBERSHIP

2018 represents the culmination of a seven-year plan directed by the Scientific Advisory Council to more fully align CIRS' activities in the regulatory and access arenas. Because of CIRS' special ability to coordinate the input and activities of multiple stakeholders from a global perspective, the new "Regulatory and Access Programme" will, starting in 2018, address our activities in this holistic manner.

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 2018 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).

2018 WORKSHOPS

7-8 March, Johannesburg, South Africa

Practical implementation of reliance models: What are the barriers and facilitators to successful application of these models for innovative medicines, generics and variations

OBJECTIVES

- **Understand how to practically implement reliance models for decision making in the review of medicines, variations and generics and how agencies/consortia can overcome implementation hurdles and focus on the benefits of utilising these approaches**
- **Recommend practical and acceptable reliance models for evaluating new medicines, variations and generics and how to ensure the success of these as approaches to decision making that allow agencies to focus on value-added activities and provide timely patient availability to good quality medicines that are safe and effective**

Key discussion point

When can and should reliance models be used (by design or default) and what data and trust need to be in place to enable their effective and efficient use?

OBJECTIVES

- **Identify which strategies, systems and technologies may provide the evidence agencies will be willing to consider to meet the growing demand for a life cycle approach to medicines evaluation**
- **Recommend how post-approval evaluations need to develop to ensure that they are fit for purpose to meet the evidence demands of different stakeholders**

Key discussion point

How can post-approval evaluations be used to generate not just safety information but better information around effectiveness and value of treatment?

21-22 June, Tysons Corner, Virginia, USA

Advancing the on-market evaluation of medicines: Evolving post-approval assessments for a life cycle approach to medicine evaluation

26-27 September, Surrey, UK

Enabling innovation – Early upstream partnering to enhance downstream innovation and decision making

OBJECTIVES

- **Identify which types of early upstream interactions or partnering are considered able to provide the right environment for developing innovative medicines**
- **Recommend ways in which early upstream partnering can enhance downstream innovation and what developments are necessary to ensure that early interactions are fit for purpose to meet the demands of different stakeholders**

Key discussion point

How can companies and regulatory and HTA agencies utilise early interactions to enable the development and review of new innovative medicines?

The 2018 Programme of Work: Evolution of the deliverables

2015-2017		For 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 Focused 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 sligned projects** • **Regulatory: iSABRE** • **Aligned projects: 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**
---	Access to Regulatory and Reimbursement Atlas	**Access to Regulatory and Reimbursement Atlas**
Communications: Global R&D Briefings; publications; meeting presentations	Communications: Global R&D Briefings; publications; meeting presentations	**Communications: Advance access to Global R&D Briefings; meeting presentations; workshops slides through members only site; CIR*Spotlight* app to disseminate publicly available communications**
Company Insight Seminars	Company Insight Seminars	**Company Insight Seminars (focused on regulatory and access as requested)**
Regional Insight Seminars for affiliates	--	**Aligned Regional Insight Seminars for affiliates**

CIRS - The Centre for Innovation in Regulatory Science - is a neutral, independent UK-based subsidiary company, forming part of Clarivate Analytics. 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.

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