Centre for Innovation in Regulatory Science (CIRS)

A Proposal for 2022

Outline

Overview of 2022 programme and research plan

Achievements for 2021 and plans for Q3/4

Appendix – general background to CIRS

Three pillars of CIRS activities – foundation of CIRS research themes

Evidence-driven insights into company and agency performance

Improving decision-making processes during the medical product life cycle

Converging stakeholder priorities and processes to accelerate patient access

CIRS research themes 2021-2023
Globalisation: Regionalisation - Reliance - Trust
New 'ways of working': New product focus - Evidence generation techniques - Post-marketing activities
Outcome metrics: Efficiency and effectiveness of process; Patient involvement and decision making

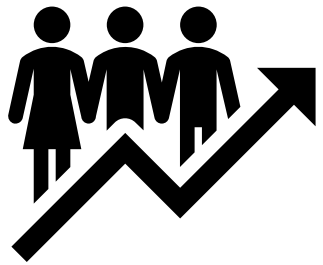
Research strategy 2021-2023

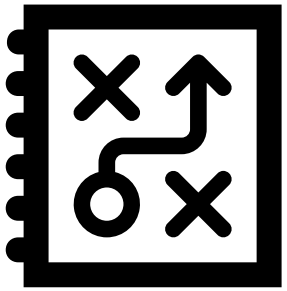
Research themes 2021-2023	2021 Workshop Theme	2022 Theme	2023 Theme	2023 Vision
Globalisation/ Regionalisation, Reliance, Trust	The regulatory and reimbursement landscape in maturing markets: how are these aligning to ensure access to new medicines?	Reimagined regulatory frameworks	Return On Investment of regulatory systems strengthening	**Frameworks and policies to enable sustainable and aligned regulatory/access**
New 'ways of working'/ • **New product focus** • **evidence generation techniques** • **Post-marketing activities**	Digital Technologies: enabling evidence generation in clinical development for regulatory and reimbursement decisions – how are the regulatory and HTA landscapes adapting?	Real world data	Lifecycle approach to optimise regulatory & HTA effectiveness	**Policies to promote transparent decision-making and public communication**
Outcome metrics • **Efficiency and effectiveness of process** • **Patient involvement in decision-making**	Regulatory, HTA and Payer Interactions and collaborations – is this enabling better evidence generation, improved probability of success and patient access?	Multi-stakeholder representation in regulatory and HTA decision-making	Keeping stakeholders informed	**Identification and codification of metrics to measure impact**

2022 Multi-stakeholder Workshops (draft)

Q1 (March): How is utilisation of RWE changing the regulatory and HTA landscape and approach post-pandemic? ***Suggested discussion topics:***

- Life cycle approach to regulation and HTA - building on its March 2021 workshop, CIRS could carry out a deeper dive into certain aspects e.g. joint scientific advice, parallel review, collection/analysis of RWE, reassessments etc.
- Use of RWD e.g. to what extent were vaccine approvals driven by RWD?
- RWE readiness/infrastructure – interoperability and standardisation of measurements





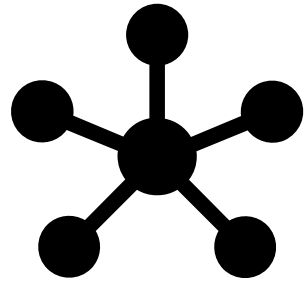
Q2 (June): Building on regulatory and HTA agilities for high unmet need - Has the development review and HTA assessment for priority medicines and vaccines changed? ***Suggested discussion topics:***

- Lessons learned from the pandemic on development review and roll out of vaccines/COVID therapeutics and how to capitalise on success and extrapolate to other disease areas
- Impact of FDA Cures 2.0 and FRP on regulators – enhancement of Breakthrough designation and Accelerated Assessment
- MHRA ILAP approach - increased connection pre-approval by stakeholders
- Role of RWE and endpoints of importance to patients and Cloud based submissions and digital data structures

Q4 (October): Collaborative, work sharing, information sharing and regionalisation models.

Suggested discussion topics:

- How do these fit into the regulatory toolkit post-pandemic; do they enable earlier availability of medicines for unmet need?
- Current regulatory frameworks for registration of medicines that enable collaboration - lessons learned from the pandemic but also the challenges and opportunities around regionalisation
- Work-sharing and regional models that enable agencies to increase efficiency/effectiveness - what frameworks need to be in place to enable success both with internal staff as well as externally with stakeholders?
- What frameworks/policies will enable sustainable information sharing/work-sharing/regional regulatory processes?



NOTE: Participants include those from member companies; regulatory and HTA agencies/payers, patient groups and academia; 2022 Workshops are planned in-person and/or hybrid depending on travel policies

2022 Projects (draft)

CIRS will continue with the following research activities in 2022:

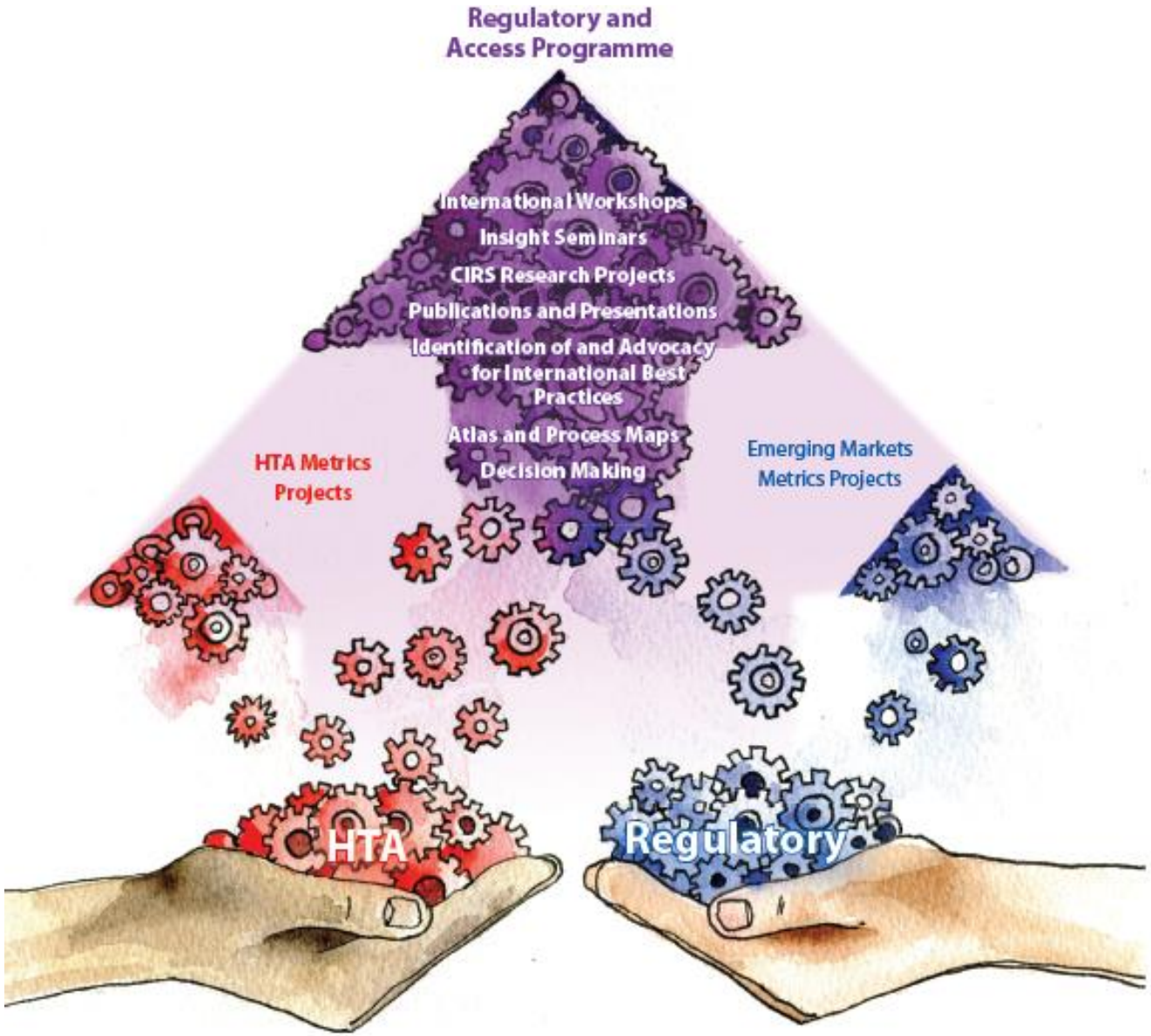
	HTA	Regulatory
Agency projects	HTA agency benchmarking (HTA Dock)	Optimising Efficiencies in Regulatory Agencies (OpERA)
Industry projects	Benchmarking of major HTA agencies	Benchmarking of key Emerging Markets
Research and multistakeholder projects	**New ways of working:** New product types (ATMP) • New evidence generation (RWD/RWE) • Digital health technologies • Impact and lessons learned from COVID-19 **Measuring and promoting information sharing, reliance, regionalization:** How this enables transparency, convergence and trust • Ensuring reliance throughout the lifecycle of medicines **HTA-regulatory interactions:** • Alignment of evidence requirements and generation • Use and impact of facilitated regulatory and access pathways • Mapping of regulatory and reimbursement landscape and processes **Stakeholder involvement and collaboration:** • Defining an ideal ecosystem to ensure early access to medicines for unmet need • Assessing the value of early scientific advice • Promoting patient involvement and measuring its impact on decision making	

Output: R&D Briefings; Publications, Webinars and Fora

CIRS Regulatory and Access Programme (RaAP)

CIRS RaAP programme open to all pharmaceutical companies particularly those engaged in R&D of new active substances

with HTA Metrics and Emerging Markets Metrics available as add-on projects



Why become a CIRS member ?

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.

Be part of a global network

- Multi-stakeholder workshops
- Industry-focused technical forums
- Industry-focused webinars

Access insights & knowledge

- CIRS Members website
- CIRS Regulatory and Reimbursement Atlas
- Early access to R&D Briefings

Participate in research & metrics

- Annual focus studies
- Emerging Markets Metrics programme
- HTA Metrics Metrics Programme
- Special Projects

Contribute to research & advocacy

- Support CIRS research & advocacy activities
- Put forward topics for workshops & studies
- Potential to join CIRS committees

Membership deliverables

Deliverables	Membership
Meetings – including exclusive access to slides and early access to meeting reports - 3 Multistakeholder Workshops - Annual industry-focused Technical Fora - Ad hoc industry-wide focused Webinars	Full registration for **two** colleagues
Insight seminars organised for your company on topics of mutual interest	✓
Eligibility to participate as a member of the SAC, HTA Steering Committee or other committees or Working Parties	✓
Access insights & knowledge • CIRS Members website – access to CIRS workshop slides, R&D Briefings and open access publications • CIRS Regulatory and Reimbursement Atlas with maps of 70+ jurisdictions	✓
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 • Annual Focus Study • Eligibility to participate in HTA and EM Metrics (additional fee applies) • Special Projects – CIRS has worked with companies on ad hoc projects that answer short business questions, produce strategy documents or facilitate external advocacy	✓

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2021 CIRS Workshops - March 10th and 11th, Virtual Regulatory, HTA and payer interactions and collaborations

Objectives:

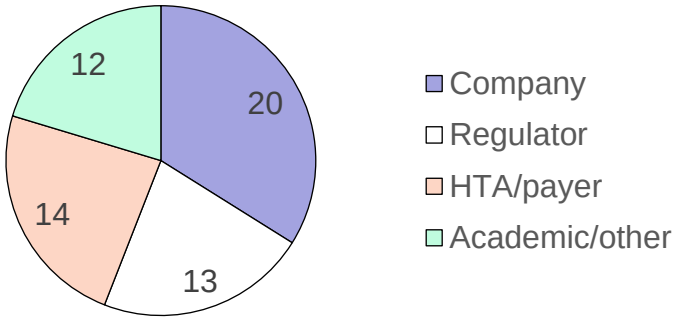
- Discuss the current and future of regulatory, HTA and payer initiatives within and across jurisdictions
- Identify through case studies the key areas and types of interactions and collaborations that are seen as effective models
- Understand the benefit these interactions between stakeholders bring to enabling improved decision making by different stakeholders and what can be learnt across jurisdictions

130+
attendees

22
countries

4.5/5
Feedback score

Who took part?



Output
- Report, slides and summaries available to members and participants
- Report will be published on CIRS website later in the year
- Publication

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

2021 CIRS Workshops - June 24th and 25th, Virtual
Digital Technologies – Enabling evidence Generation in Clinical Development

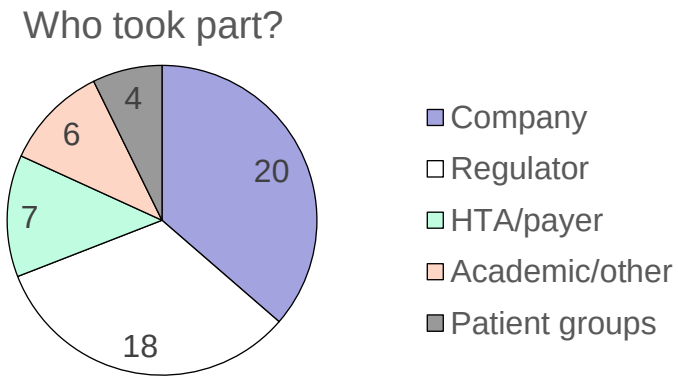
Objectives:

- Discuss how agencies and companies are currently developing the role of digital technology for evidence generation in clinical development for regulatory and HTA decision making.
- Identify the opportunities and how to reduce potential barriers going forward for evidence generated by digital technologies for use in the review and reimbursement of medicines.
- Recommend areas of work/research that could facilitate alignment across jurisdictions to ensure digital technologies maximize their potential within a fit for purpose regulatory and HTA environment.

170+
attendees

30
countries

4.5/5
Feedback score



Output
- Slides and summaries available to members and participants
- Report to be shared with members/participants later in the year and thereafter published on CIRS website

"The delay for this meeting I think made it a better meeting given the experience this past year during the pandemic, and it was terrific to have the broad stakeholders participating including regulators and HTA assessors. "

2021 CIRS Workshops - November 25th & December 9th, Virtual
The regulatory and reimbursement landscape in maturing markets: how are these aligning to ensure both availability and access to new medicines?

Objectives:

- Discuss the current and future regulatory and HTA landscape within maturing jurisdictions and how or if these are aligned.
- Identify through case studies different models and maturity of systems within countries as well as the challenges and opportunities.
- Make recommendations on what can be learnt across jurisdictions from the current initiatives so as to inform the future evolution of the regulatory-HTA landscape in maturing countries.

Format:
The workshop will be held virtually, over two days, as follows:

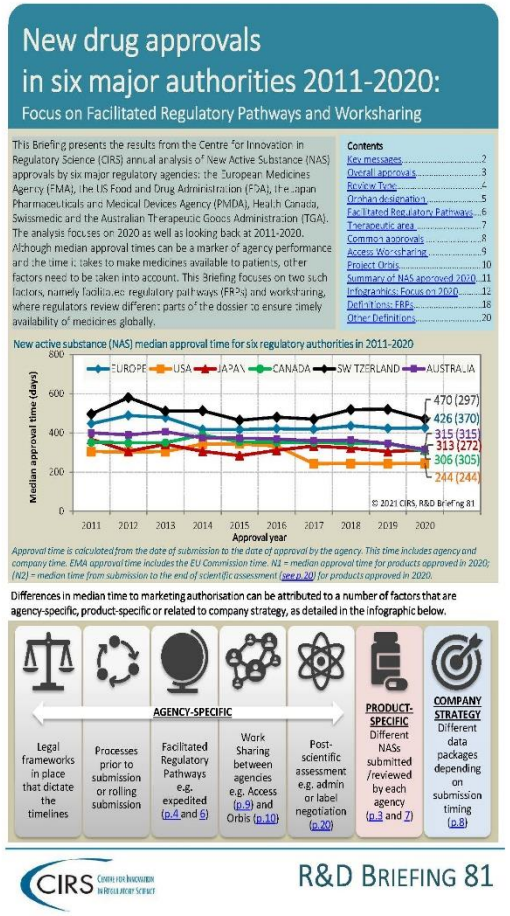
Date – Asia – 25th November 2021
The Americas – 9th December 2021

Annual CIRS R&D Briefing and member webinar: Regulatory approvals of new medicines in 6 agencies

- **Focus on Facilitated Regulatory pathways in Europe, USA, Japan, Canada, Switzerland and Australia; and Worksharing (Project Orbis; Access Consortium)**
- **Initially shared with CIRS member companies and participating agencies in June. Other member benefits:**
  - **Copy of ppt slides**
  - **Ad hoc/company specific analyses on request**
  - **Webinar,** which enabled a discussion with senior executives from 15 CIRS member companies,

4.5/5
Feedback score

"Excellent meeting, good value of the metrics shared including the good proposal to continue building up on this area. Thanks" Senior Director, Pharma Company

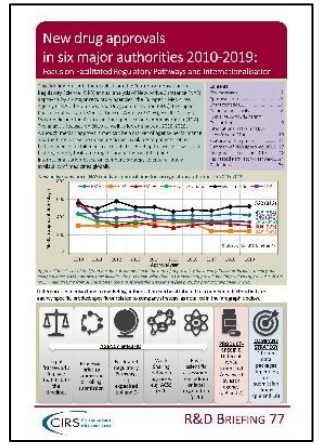


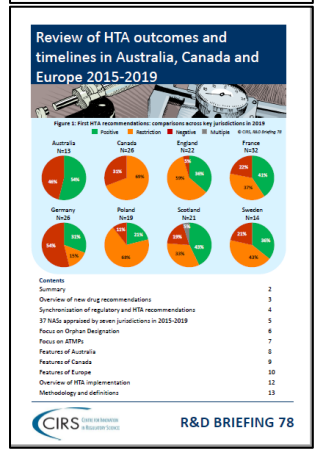
- **Published widely on CIRS website in July (most downloaded Briefing)**
- **Results endorsed and quoted by regulatory authorities** through their annual reports, conference presentations; as well as data used by **external stakeholders like the OHE** for UK Brexit scenarios planning
- A similar R&D Briefing focusing on **HTA** and alignment with regulatory planned for Q3

Publications – delivered so far in 2021

Journal manuscripts:

1. Sithole, T et al. Evaluation of the **Regulatory Review Process in Zimbabwe**: Challenges and Opportunities. Ther Innov Regul Sci (2021). https://cirsci.org/publications/sithole-et-al-2021-regulatory-review-process-in-zimbabwe/
2. Bujar, M et al. The Qualitative Value of **Facilitated Regulatory Pathways** in Europe, USA, and Japan: Benefits, Barriers to Utilization, and Suggested Solutions. Pharm Med (2021). https://cirsci.org/publications/bujar-et-al-2021-value-of-facilitated-regulatory-pathways/
3. Bujar M. et al. **Transparency in European Medicines Agency and US Food and Drug Administration Decision Making**: Is It Possible to Identify the Rationale for Divergences in Approved Indication From Public Assessment Reports? Clinical Therapeutics (2021). https://cirsci.org/publications/bujar-et-al-2021-transparency-in-ema-and-fda-decision-making/
4. Keyter A et al. **South African Regulatory Authority: The Impact of Reliance** on the Review Process Leading to Improved Patient Access. Front Pharmacol. 2021;12:699063. https://cirsci.org/download/keyter-et-al-2021-impact-of-reliance-on-south-african-review/
5. Sithole T et al. **Evaluation of the Good Review Practices of Countries Participating in the Southern African Development Community**: Alignment and Strategies for Moving Forward. Front Med (Lausanne). 2021;8:742181. Published 2021 Aug 27. https://cirsci.org/download/good-review-practices-in-sadc-sithole-et-al-2021/
6. Sithole T et al. **Evaluation of the Review Models and Approval Timelines of Countries Participating in the Southern African Development Community**: Alignment and Strategies for Moving Forward. Front Med (Lausanne). 2021;8:742200. Published 2021 Aug 27. https://cirsci.org/download/models-and-timelines-in-sadc-sithole-et-al-2021/
7. Wang T et al. Building HTA insights into the drug development plan: **current approaches to seeking early scientific advice from HTA agencies**. Drug Discovery Today. Journal pre-proof available online 28th September 2021. https://doi.org/10.1016/j.drudis.2021.09.014
8. Liberti L & Wang T. The regulatory-HTA decision-making interface: What the medical writer should know. Medical Writing 2021; 30(3):50-55. https://cirsci.org/download/liberti-wang-2021-medical-writing/
9. Sithole T et al. **Comparison of the registration process of the medicines control authority of Zimbabwe with Australia, Canada, Singapore, and Switzerland**: benchmarking best practices [published online ahead of print, 2021 Oct 20]. Expert Rev Clin Pharmacol. 2021;1-11. https://cirsci.org/publications/comparison-of-the-registration-process-of-zimbabwe-with-australia-canada-singapore-and-switzerland/





Publications – delivered in 2021

R&D Briefings:

- CIRS R&D Briefing 79 – Practical application of regulatory science by Latin American regulatory agencies: optimising the use of **advisory committees in the Colombian regulatory environment**. https://cirsci.org/publications/cirs-rd-briefing-79-use-of-advisory-committees-in-colombia/
- CIRS R&D Briefing 80 – CIRS Workshop: **Reimagining medicines regulatory models – outputs from multistakeholder discussions**. https://cirsci.org/publications/cirs-rd-briefing-80-reimagining-medicine-regulatory-models/
- CIRS R&D Briefing 81 – New drug **approvals in six major authorities 2011-2020**: focus on Facilitated Regulatory Pathways and work sharing. https://cirsci.org/download/rdb-81-six-agency-benchmarking/
- CIRS R&D Briefing 82 – **Regulatory reliance pathways**: what are the opportunities and barriers? https://cirsci.org/download/rdb-82-regulatory-reliance-pathways/
- CIRS R&D Briefing 83 - **Review of HTA outcomes and timelines** in Australia, Canada and Europe 2016-2020 https://cirsci.org/download/rdb-83-review-of-hta-outcomes-and-timelines-2016-2020/

Reports: delivered in 2021

- 2020 Technical Forum Report - Regulatory and HTA policy groups – how can their value be maximised to improve access to medicines? [Member publication – not publicly available]
- 2020 Workshop Report – Effectiveness of the regulatory approval process – moving from measuring performance to operational excellence. 15-16th September 2020. https://cirsci.org/download/2020-effectiveness-workshop-report/
- 2020 Workshop Report - Re-imagining medicines regulatory models: implementing fit-for purpose sustainable activities for patient access. 8-9 th December 2020. https://cirsci.org/download/2020-workshop-report-reimagining-regulatory-models/
- **2020 CIRS Annual Report** https://cirsci.org/publications/cirs-2020-annual-report
- 2021 Workshop Report – Regulatory, HTA and Payer Interactions and Collaborations: Optimising their Use and Outcome Success. 10-11th March 2021 [not yet publicly available]
- 2021 Project report – Monitoring the adequacy of implementation and adherence to ICH guidelines. https://cirsci.org/download/2021-ich-implementation-report/
- 2021 Workshop Report - Digital Technologies: enabling evidence generation in clinical development for regulatory and reimbursement decisions - how are the regulatory and HTA landscapes adapting? 25-26th June 2021 [not yet publicly available]

15
Journal publications

5
CIRS R&D Briefings

4.6
Out of 5 feedback score for virtual multi-stakeholder workshops

9
Conference presentations

**Figures from 2020*

Insight meetings

25
For companies

27
For agencies

684
New LinkedIn followers

4
PhD students supported by CIRS

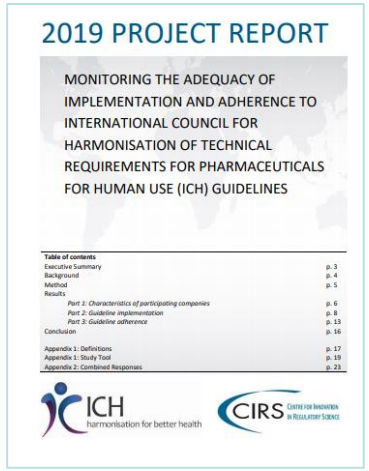
2021 Conferences

Completed presentations:

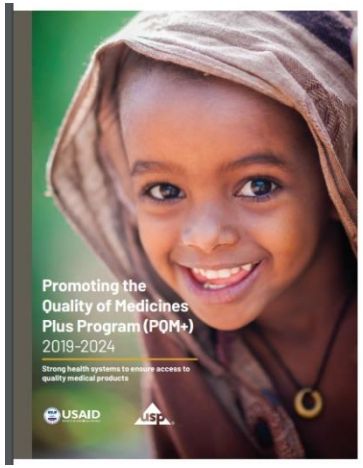
- 22nd February, **HTAi Policy Forum** - Developing a framework for HTA management of uncertainty: feedback from CIRS multi-stakeholder workshops
- 22nd February, **DIA Latin America Regulatory Conference** – Results of CIRS reliance study for Latin America
- 20-23rd May, **DIA China** - The importance of international standards, guidelines and regulatory science for building trust and competency
- 19th-23rd June**, HTAi annual meeting -** Challenges and opportunities of building value into development for innovative technologies: a multi-stakeholder perspective.
- 27th June – 1st July**, Annual DIA**
    - Panel - Value-Based Evidence Generation: What are the Regulatory and HTA Strategies that Companies Could Take in Development?
    - Panel - Trends in Regulatory Reliance: will the COVID-19 experience accelerate implementation?
    - Panel - Emergency Use Pathways: What Learnings from COVID-19 Can be Generalized to Address Unmet Medical Needs?
    - Poster - Facilitated Regulatory Pathways (FRPs) - Their value and how it could be maximised to ensure timely availability of medicines
- 29th June – 2nd July**, National Congress of Professionals in Sanitary Regulation (AMEPRES), Mexico**
    - Roundtable - Regulatory reliance and its impact on the pharmaceutical industry in the Americas
- September - **INTERFARMA** webinar on use of reliance pathways within the context of the Brazilian regulatory system
- 12th October – AFIDRO/FIFARMA meeting - Best Practices and Convergence in Latin America
- 18th November – National Chamber of Commerce Bolivia meeting -The use of regulatory decisions of other jurisdictions in Latin America: current situation and expectations

Multi-stakeholder International Collaborations

- **CIRS completed Phase 2b of its work with ICH on monitoring the implementation of ICH guidelines**. The report has been presented at the ICH Management Committee meeting on 11th May 2021 and the Assembly on 2nd June. The report is available on both ICH and CIRS websites.



- CIRS to further promote regulatory capacity and strengthening in lower and middle income countries, having been selected as a Technical Resource Partner for the Promoting the **Quality of Medicines Plus (PQM+) programme** led by **US Pharmacopeia** and funded by **USAID**



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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

35+ yrs experience in bringing **global** industry, regulators, HTA bodies, payers, academics and others together in a **neutral** atmosphere to identify and address key issues in the development, licensing and reimbursement of medicines.

Subsidiary of Clarivate plc – **operate independently** as a non-profit. Financed by industry membership fees, special projects, grants e.g. from regulators, HTA bodies, Bill and Melinda Gates Foundation

See CIRS Agenda: https://cirsci.org/download/agenda-2022/

CIRS Member companies

20+ Global R&D Companies		
USA	**Europe**	**Japan**
AbbVie	AstraZeneca	Astellas
Amgen	Bayer	Eisai
Biogen	GlaxoSmithKline	Takeda
Biomarin	Ipsen	
BridgeBio	Leo	
Bristol Myers Squibb	Lundbeck	
CSL Behring	Novartis	
Eli Lilly and Co.	Roche	
Johnson & Johnson	Sanofi	
Merck & Co		
Pfizer		

Participants: Regulatory Agencies

Americas- Country	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

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

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	MoH
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
Zambia	ZAMRA
Zimbabwe	MCAZ
Regional Initiatives	AMRH-EAC Zazibona/SADC WAHO

Participants: 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, AOK-Bundesverband

Country	Organisation
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

CIRS Scientific Advisory Council (SAC)

Chair: Adjunct Prof John Skerritt, Deputy Secretary for Health Products Regulation, Department of Health, Canberra, 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, CHMP/EMA
Dr Ian Hudson, Senior Advisor, Integrated Development, Global Health, Bill & Melinda Gates Foundation, UK
Dr John Lim, Executive Director of CoRE, Duke-NUS Medical School and Chairman, Consortium for Clinical Research & Innovation Singapore
Dr Theresa Mullin, Director Office of Strategic Programs, CDER, US FDA
Dr Brian O'Rourke, Former CEO and President CADTH
Dr Junko Sato, Office Director, Office of International Program, PMDA, Japan
Dr Xie Songmei, Deputy Director of Clinical Department Center for Drug Evaluation, NMPA, China
Dr John Patrick Stewart, Director General, Therapeutic Products Directorate, Health Canada

Deborah Autor, Global Head of Regulatory Excellence, AstraZeneca, USA
Dr Fabio Bisordi, Global Head International Regulatory Policy, F.Hoffmann-La Roche Ltd
Dr Carlos Garner, Vice President, Global Regulatory Affairs, Eli Lilly and Co
Adrian Griffin, Vice President for HTA Policy Johnson & Johnson
Dr David Jefferys, SVP, Head of Global Regulatory, Eisai Europe Ltd
Dr Sabine Luik, Chief Medical Officer and SVP, Global Medical, Regulatory & Quality, GlaxoSmithKline
Jerry Stewart, Vice President, Global Regulatory Policy and Intelligence, Pfizer
Dr Roopal Thakkar, Vice President, Regulatory Affairs and R&D Quality Assurance, Abbvie
Dr Max Wegner, Head Regulatory Affairs PH & CH, Bayer AG
Prof Stuart Walker, Founder, CIRS

Specialist Advisors:
Dr Thomas Lonngren, 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, Associate Professor Pharmaceutical Medicine, Kitasato University Graduate School of Pharmaceutical Sciences, Tokyo, Japan
Dr Tomas Salmonson, Former Chair, CHMP/EMA
Dr Joseph Scheeren, Former President and CEO, Critical Path Institute

CIRS HTA Steering Committee

Chair: Dr Brian O'Rourke, Former CEO and President, CADTH, Canada

Vice-Chairman: Prof Adrian Towse, Director Emeritus and Senior Research Fellow, OHE

Dr Nick Crabb, Programme Director, Scientific Affairs, NICE

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

Dr Wim Goettsch, Associate Professor HTA, Utrecht University; Special advisor HTA, ZIN

Niklas Hedberg, Chief Pharmacist, TLV

Suzanne McGurn, CEO and President, CADTH

Andrew Mitchell, Strategic Adviser, DoHA

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

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 Maria Kubin, Head, Integrated Evidence Planning for Cardiovascular TA, Bayer

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

Dr Sean Tunis, Principal, Rubix Health

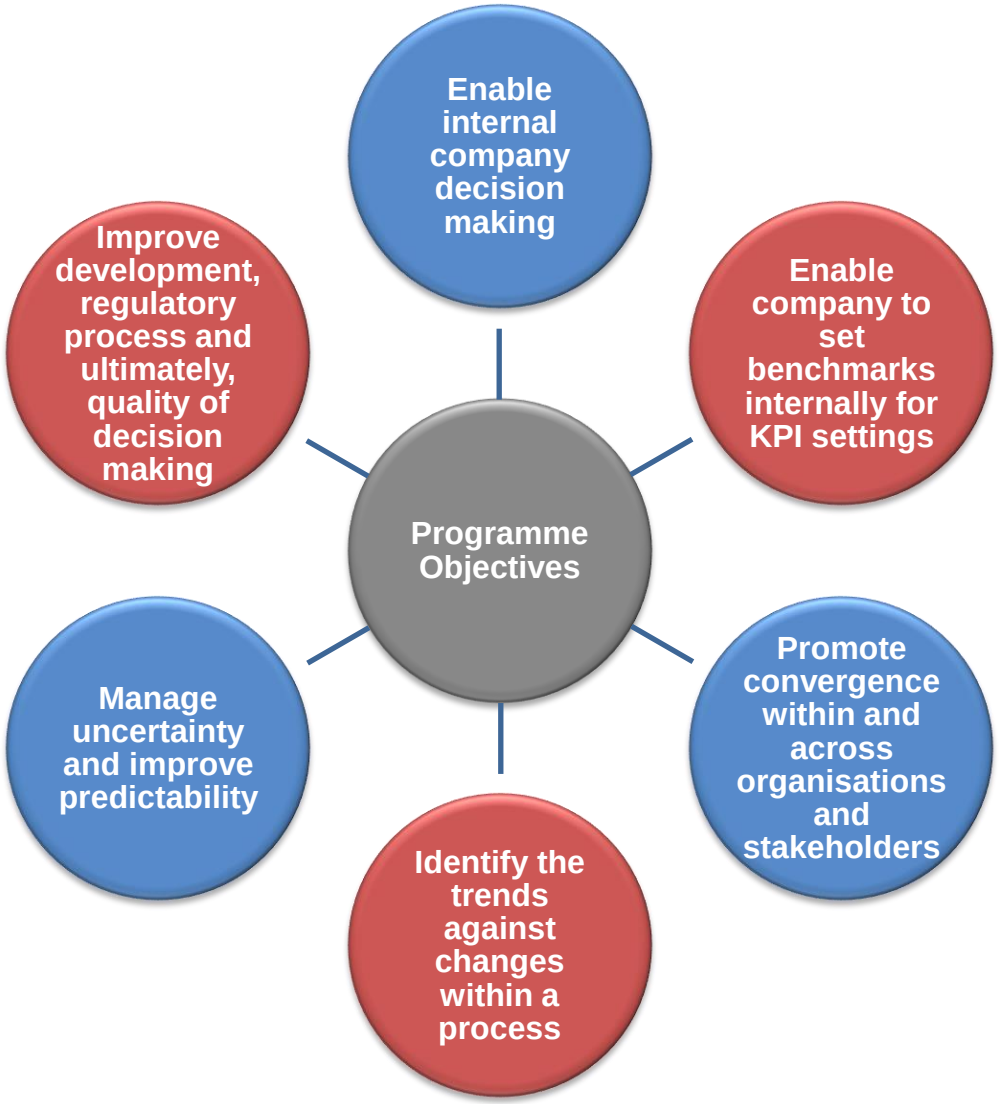
Prof Finn Børlum Kristensen, Former EUnetHTA Executive Committee Chairman and EUnetHTA Secretariat Director, Faculty of Health Sciences, University of Southern Denmark

Emerging Markets (EM) Metrics Programme

The Programme collects company data on submission, approval and rollout times in 18 countries and one regional alignment initiative 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.

Annual deliverables of the Programme:

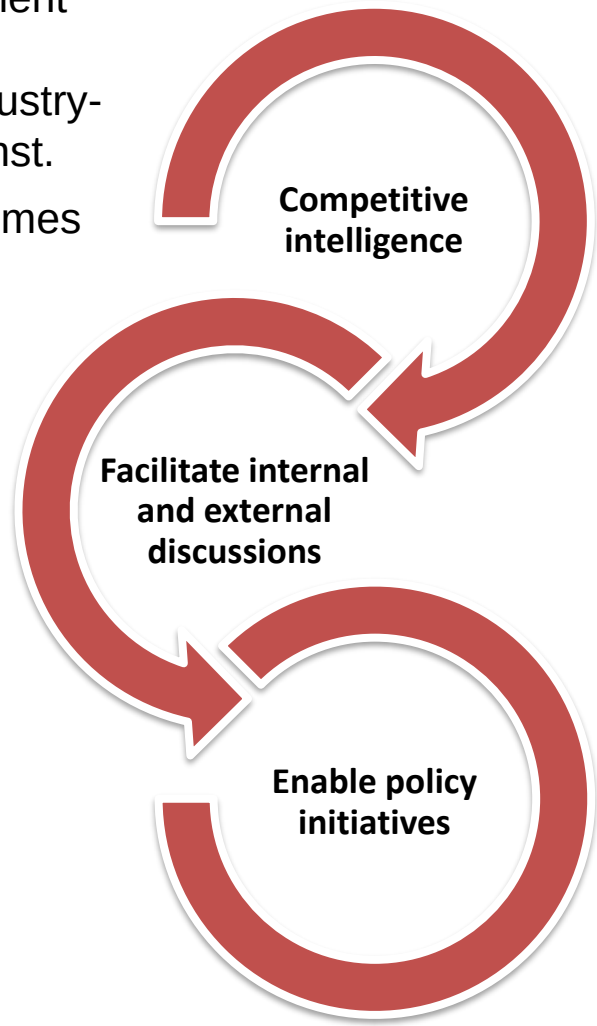
- Main report, aimed at Global Regulatory Leads, Policy and Intelligence
- Executive summary, aimed at Management and Policy and Intelligence
- Country-specific summaries, aimed at Regional Affiliates
- Results of a focused study on a topic of interest to participant companies
- Industry Discussion Meeting to review trends and discuss new analyses
- Periodic updates on the Programme and CIRS advocacy activities



HTA Metrics Programme

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.



Annual deliverables of the Programme:

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

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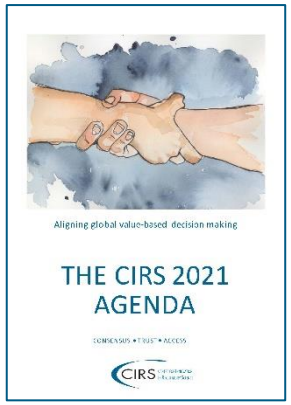

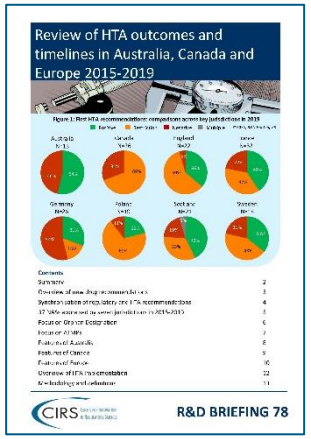

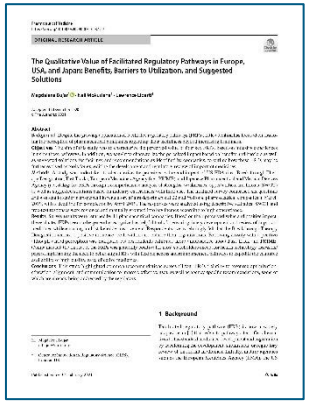

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