Centre for Innovation in Regulatory Science (CIRS)

2020 Annual Report

CIRS
CENTRE FOR INNOVATION IN REGULATORY SCIENCE

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Foreword

From the CIRS Director

“Stay safe”, “you are on mute” – two phrases you would not have considered part of your vocabulary at the beginning of 2020. However, these phrases underlie the enormity of change seen during 2020 due to the COVID-19 pandemic.

It was a year of both challenges and opportunities for global healthcare systems; on the one hand the growing cost, both economic and human, and on the other, the ability to adapt to a ‘new normal’. For those working within companies and agencies involved in pharmaceuticals, this meant rethinking ways of working, accelerating ideas being piloted and embracing flexible development and regulatory pathways. This prompted increased stakeholder collaboration, reliance and trust within and across jurisdictions, as well as the ability to consider redundancy within development and regulatory systems to ensure potential new treatments and vaccines reached patients as quickly as possible.

At CIRS we were similarly challenged to rethink our established model based on face-to-face interactions with our stakeholders, bringing them together in a neutral setting to identify key issues. Our staff rose to the challenge of not just working from home, but also rethinking how we could drive the CIRS 2020 agenda whilst adding value to the changing needs and priorities of CIRS members. We looked specifically at the way we communicated and interacted with our stakeholders in a virtual setting, learning as we went and ensuring activities were prioritised that would resonate with the challenges being faced, such as a briefing on Emergency Use Pathways (EUPs) and a workshop on “Reimagining medicine regulatory models”.

The changes of 2020 are also reflected in the new CIRS 2021-2023 strategy, which was developed in line with feedback from our stakeholders and Scientific Advisory Council (SAC). We will look to build on areas in which CIRS has traditionally been strong, such as evaluating regulatory and HTA process and practices though metrics, improving decision making processes and promoting alignment of stakeholder priorities to accelerate patient access, but with the background of the changes made or accelerated during the pandemic that facilitate medicines development, review and reimbursement. There will be a specific focus on new ways of working that deliver regulatory and HTA grade evidence generation; utilising outcome metrics to measure the changing global regulatory and HTA landscape; and how companies and agencies are evolving their process and practices to ensure sustainability in terms of approval/access to new medicines.

As we drive forward our agenda for 2021 and look forward to a return to normality, CIRS will continue to meet its mission and ensure that it is not “on mute” to its stakeholders’ needs.

Stay safe,

Dr Neil McAuslane
Director, CIRS

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 medicinal 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, related activities 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 and HTA bodies. 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** setting 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 strive to make these publicly available though 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.

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 lifecycle

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.

Our strategy

CIRS sets a rolling three-year strategy with input from the Scientific Advisory Council and HTA Steering Committee. Our 2021-2023 programme, which will be achieved through workshops, fora and research projects, is grouped around 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. Topics include regulatory strengthening, re-imagined regulatory frameworks and the alignment of regulatory and HTA.
- **Outcome metrics -** CIRS has the experience of benchmarking metrics going back decades and this theme aims to continue and extend that solid foundation. The focus so far has been on outcome measures such as probability of success and access as well as the identification and codification of metrics to measure impact. A new element 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, the Cloud and digital health – and new product focus including Advanced Therapy Medicinal Products (ATMPs).

CIRS Centre for Innovation in Regulatory Science

2020 in numbers

15
Journal publications*

5
CIRS R&D Briefings*

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

9
Conference presentations*

Insight meetings

25
For companies

27
For agencies

684
New LinkedIn followers

4
PhD students supported by CIRS

*Listed on p14-15

Roadmap for regulatory performance

Dr Andrea Keyter, a CIRS-supervised student, successfully passed her PhD viva and published her thesis entitled 'Roadmap for regulatory performance: South Africa's experience in enhancing the pharmaceutical review process'. This is a valuable resource for regulatory agencies, particularly in emerging markets, as it provides practical solutions to support initiatives for regulatory reforms, such as the use of tools from the CIRS Optimising Efficiencies in Regulatory Agencies (OpERA) programme.

Deep dive on ATMPs

We took a closer look at the regulatory and HTA landscape for ATMPs in our 2020 HTA agency benchmarking study (see CIRS R&D Briefing 78). Our analysis showed that HTA agencies have various ways of dealing with the uncertainty associated with ATMPs, such as through HTA assessment procedures, orphan drug-related pathways and managed entry agreements. For a more detailed case study on our benchmarking studies of HTA agencies, please see p12-13.

2020 highlights

Aligning HTA committee deliberative processes

As part of our research programme on quality decision making, we worked closely with Canadian HTA agency CADTH to run a study assessing the decision-making practices of CADTH's expert review committees using the Quality of Decision-Making Orientation Scheme (QoDoS) tool. This study is part of a wider piece of work being conducted by the agency to assess its committees' deliberative processes and frameworks to identify if there are opportunities for improvement or alignment. We presented the results of the QoDoS study to CADTH Board members at their 2020 annual meeting.

New project for ICH

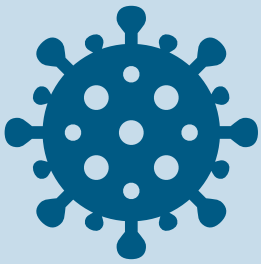
CIRS was selected by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) to undertake an assessment of regulatory agencies' and companies' perspectives on the implementation and adherence to ICH guidelines. This study builds on the methods developed in a previous study we conducted on behalf of ICH, with the additional objective to assist the ICH Management Committee in determining whether regulatory members meet the eligibility criteria for upcoming committee elections.

Initiation of Africa advisory committee

The creation of the CIRS African Regulatory Advisory Committee was an important step in ensuring that our advocacy work continues to strengthen and meet the needs of African regulatory systems. The committee, which is made up of representatives of regulatory agencies and regional regulatory initiatives, advises us on priority regulatory issues to be addressed in Africa. We are delighted to have Gugu Mahlangu, Former Director-General of the Medicines Control Authority of Zimbabwe, and Dr Boitumelo Semete-Makokotlela, Chief Executive Officer of the South African Health Products Regulatory Authority, serving as its Chair and Vice-Chair, respectively.

Virtual working

Despite the challenges posed by the COVID-19 pandemic**, 2020 has been a year of learning and evolution** for CIRS. Like many other organisations, our staff had to quickly transition to work from home and find new ways to stay connected with each other as well as with CIRS stakeholders. As travel was restricted for most of the year, we increased the number of webinars for our member companies and agency participants so that they could continue to benefit from insights from CIRS research, and in turn, we could keep listening to their needs and priorities.



One of our biggest challenges was how to move our multi-stakeholder workshops to a virtual meeting platform, while maintaining their intimacy and productivity in producing recommendations to move important topics forward. After much research and testing of different platforms, we ran our first virtual workshop in September 2020, running the same programme on two consecutive days so that different geographies/times zones could participate. We were delighted to receive very positive feedback following the meeting, which demonstrated that the virtual format – including the virtual breakout groups - worked well. Building on this success, we ended the year with another virtual workshop in December, which again was very well received.

While 2020 demonstrated the many advantages of virtual meetings, such as increased attendance and wider stakeholder and geographical reach, it also highlighted the importance of those ‘corridor conversations’ that facilitate informal learning and networking. We certainly look forward to the day that we can facilitate cross-stakeholder meetings in person once again.

CIRS virtual workshop, 15-16th September 2020

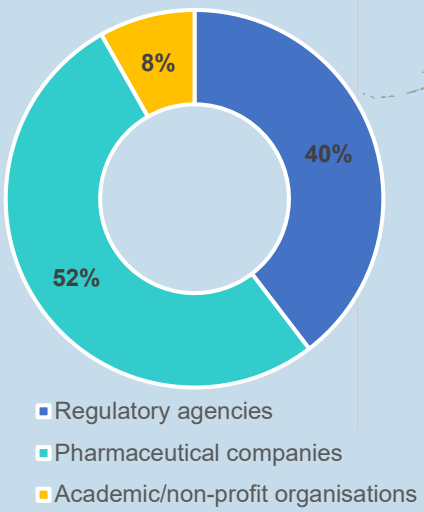
Effectiveness of the regulatory approval process – moving from measuring performance to operational excellence

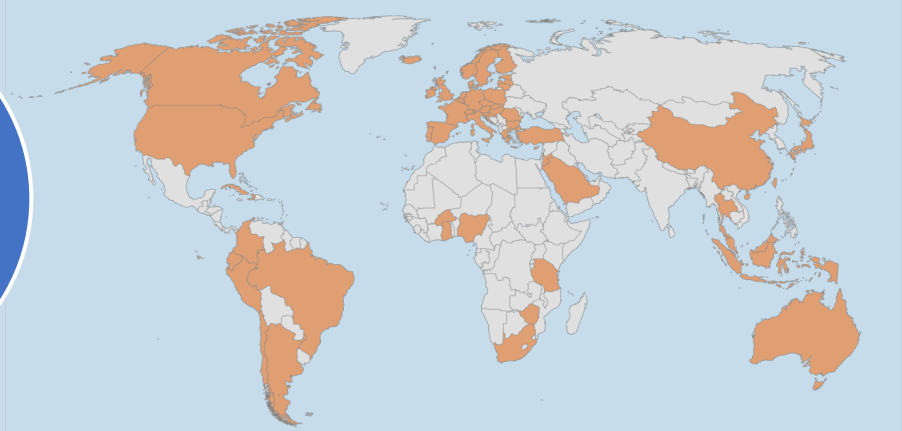
This workshop was part of a series of global development workshops that brought together mature and maturing regulatory agencies. These workshops successively built on one another and evolved from focusing on review efficiency ("doing things right") to review effectiveness ("doing the right things"). The use of reliance models was a common theme across these workshops, as agencies looked to leverage other agencies' reviews to conserve resources (find out more about CIRS' work to promote reliance on p11).

The virtual breakout groups from the September 2020 workshop produced valuable outputs that we hope can help guide both agencies and companies on how they can improve review effectiveness. These outputs will be used within the OpERA programme to enable agencies to embed a performance driven culture to measure not only efficiency but also effectiveness.

A copy of the workshop report is available here.

200+ attendees from multiple stakeholders and geographies





Workshop feedback:

"Great presentations, very informative and implementable content shared." - Regulatory 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

4.6 out of 5 value rating

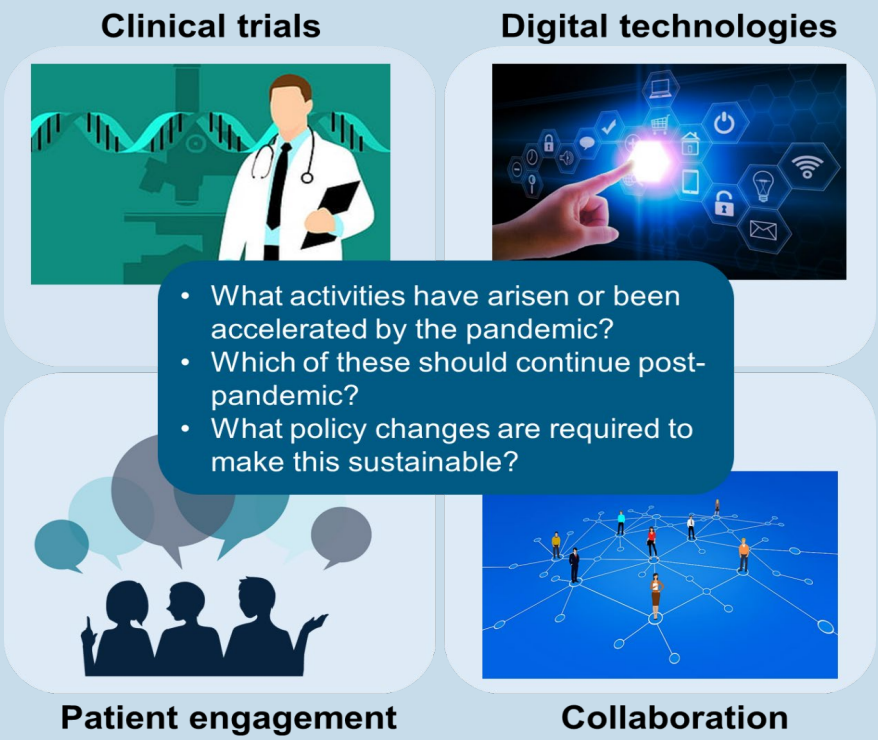
CIRS virtual workshop, 8-9th December 2020

Re-imagining medicines regulatory models: implementing fit-for-purpose sustainable activities for patient access

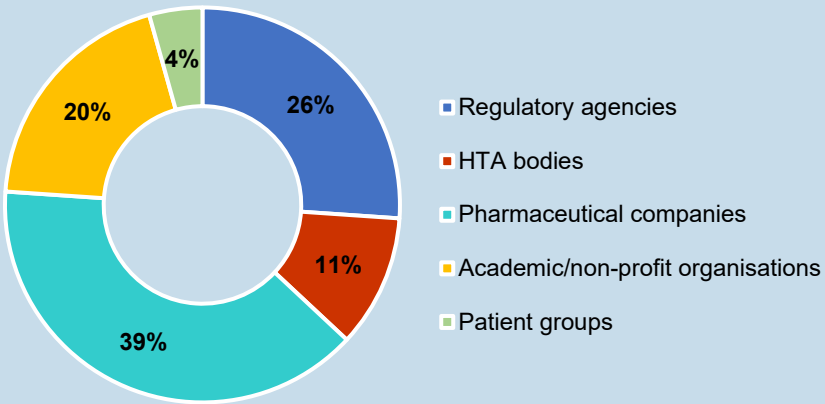
This workshop was held in memory of world-leading regulatory expert and former Chair of CIRS' Scientific Advisory Council, Prof Sir Alasdair Breckenridge. Prior to his death in December 2019, Prof Sir Breckenridge had challenged CIRS to consider the topic of "Are medicines regulatory models fit for purpose today?", a question that became even more pertinent with the COVID-19 pandemic.

A key objective of the workshop was to make recommendations on activities that should be considered to evolve a fit-for-purpose regulatory model for the development, review and access of new medicines. This was facilitated through breakout groups during which workshop participants discussed lessons learned from four areas (opposite) that had to fundamentally change because of the pandemic.

You can read more about the outputs of this workshop in our R&D Briefing.



110+ attendees from multiple stakeholders



Workshop feedback:

4.7 out of 5 value rating

Impact case study: promoting regulatory reliance

Many regulators around the world are turning to reliance and work sharing mechanisms as a way to conserve resource and become more efficient and effective in their reviews. CIRS has played a key role in promoting understanding and use of reliance through its research activities and workshops across various regions (below), as well as on a global scale that has included:

- Development of a framework for the use of Facilitated Regulatory Pathways (2018)
- Series of workshops focused on reliance (2017-2019)
- Survey on agencies' use of abridged reviews (presented at the 2019 Workshop in Singapore)
- Participation in WHO consultative meeting on Good Regulatory Practices (2019)
- Input into WHO Good Reliance Practices public consultation (2020)
- Focus study on companies' use of reliance pathways in emerging markets (2020)
- Evaluation of agency processes including reliance in the Optimising Efficiencies in Regulatory Agencies (OpERA) programme (ongoing).
- Monitoring the use and impact of cooperative procedures and work sharing initiatives in USA, Canada, Europe, Australia and Japan (ongoing in our annual six-agency R&D Briefing).

Middle East & Africa

- Studies with agencies in Saudi Arabia, Jordan and Turkey – a common recommendation was to introduce a risk stratification approach (2016-2020).
- Report for South African regulatory agency, SAHPRA, to support the implementation of reliance (2020).
- Publication on ZaZiBoNa work sharing initiative (2020).
- Educational conference on tools for effectiveness and efficiency, where 135 participants from 23 agencies took part.

Latin America

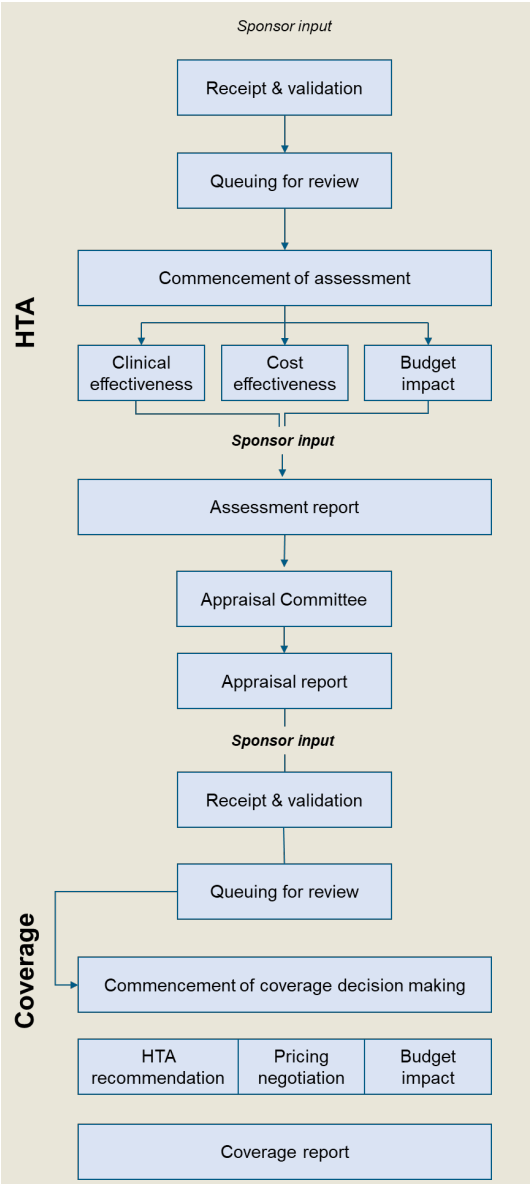
- Latin American Systems to Encourage Reliance (LASER) project to identify and categorise reliance characteristics for 20 agencies in the region and investigate the practicalities around the use of reliance (ongoing).
- Two virtual OpERA Forums for Latin American regulatory agencies in 2020, both of which included topics on reliance.
- Publication on the Caribbean Regulatory System centralised assessment process (2020).

Asia

- Presentation at the ASEAN Regulator's Roundtable focused on Good Reliance Practices (2018).
- Ongoing collaboration with Duke-NUS Centre of Regulatory Excellence (CoRE) through a Memorandum of Understanding (2020); we hope to explore new opportunities for joint working in the reliance space.
- Study with Malaysian agency NPRA as part of the OpERA programme – a key recommendation was for the agency to place greater emphasis on risk-based approaches (2020).

Impact case study: benchmarking HTA agency performance

Metrics is a key focus for CIRS and underpin the organisation's role in providing independent, evidence-based insights on the performance of companies, regulators and HTA agencies. Here we describe our annual metrics study of HTA agencies called HTADock and the impact it has had in the HTA landscape.



Common milestones in the HTA process

What is HTADock?

HTADock is an annual CIRS metrics study aiming to facilitate performance improvement in HTA agencies and increase transparency of the outcomes and timelines of HTA assessments. The HTADock database collects data from the public domain on new active substances (NASs) appraised by agencies in Europe, Canada and Australia since 2014. This includes information on first HTA recommendations, time from regulatory submission to first HTA recommendation, characteristics of products, regulatory pathways used and HTA implementation.

The findings of the HTADock study are published annually in an R&D Briefing (see R&D Briefing 78 for the latest study).

How was it developed?

HTADock was derived from a collaborative project carried out in 2013/14 with ten HTA agencies, which identified common milestones in the HTA process and mapped jurisdiction-specific processes against the agreed metrics.

The benchmarking methodology was recently published in *International Journal of Technology Assessment in Health Care*, to demonstrate the feasibility of benchmarking HTA performance metrics.

What has been the impact of HTADock?

Supporting discussions within HTA agencies: CIRS has utilised HTADock R&D Briefings over the years to stimulate interactions with HTA agencies, some of whom have then used these insights to support internal discussions on performance improvement. We also know of HTA agencies that have utilised HTADock data to demonstrate their assessment timelines with their Ministers of Health.

What has been the impact of HTADock? (continued)

Informing on regulatory-HTA alignment: Regulatory agencies have expressed interest in HTADock data showing the synchronisation of regulatory and HTA decisions.

Further research on HTA trends: CIRS member companies have used the HTADock Briefings for their own research purposes, for example, to commission follow-up projects that help to inform company strategy. CIRS has also built upon HTADock findings to answer the following research questions:

- Does FDA Breakthrough Designation affect HTA recommendation in terms of timing and outcome?
- Do conditional regulatory pathways affect HTA recommendation?
- Do parallel regulatory-HTA reviews affect time to HTA decision?

New ways of working: ATMPs

In recognition of the challenges of Advanced Therapy Medical Products (ATMPs), which fall under our 'new ways of working' research theme, we recently performed an analysis on the regulatory and HTA landscape of ATMPs. This showed that HTA agencies in Australia, Canada and Europe have various ways of dealing with the uncertainty associated with ATMPs, such as through HTA assessment procedures, orphan drug-related pathways and managed entry agreements (see below).

The full analysis - including case studies on Kymriah and Yescarta - can be found in R&D Briefing 78.

HTA landscape of ATMPs

		HTA							© CIRS, *R&D Briefing 78*
Type	**Brand Name**	**AUS**	**CAN**	**ENG**	**FRA**	**GER**	**SCO**	**SWE**	**POL**
Cell therapies	Alofisel						Orphan		
	Zalmoxis								
Gene therapies	Imlygic			PAS				HE	
	Kymriah			MAA	MEA		Ultra-Orphan; PAS	HE	
	Luxturna			HST; PAS				HE	
	Strimvelis			HST					
	Yescarta	2020		MAA	MEA		Ultra-Orphan; PAS	HE (2020)	
	Zynteglo				MEA (2020)	2020			
Tissue-based therapies	Holoclar			PAS					
	Spherox								

First HTA recommendations (data collected up to June 2020):
PAS: Patient Access Schemes; MAA: Managed Access Agreement; HST: Highly-Specialised Technologies; HE: Health Economic Assessments

Positive Restriction Negative Different HTA committee

2020 journal publications

- Koyuncu O, Gursoz H, Alkan A, Cetintas HC, Pasaoglu T, Mashaki Ceyhan E & Walker S (2020) Evaluation of the performance of the Turkish regulatory agency: recommendations for improved patients' access to medicines. *Front. Pharmacol.*10:1557.
- Mashaki Ceyhan E, Walker S & Salek S (2020) Patients' perspectives of the pharmaceutical regulatory and reimbursement systems in Istanbul, Turkey. *Ther Innov Reg Sci.*
- Keyter A, Salek S, McAuslane N, Banoo S, Azatyan S & Walker S (2020) Implementation of a framework for an abridged review using good reliance practices: optimising the medicine regulatory review process in South Africa. *Ther Innov Reg Sci.*
- Sithole T, Mahlangu G, Salek S & Walker S (2020) Evaluating the success of ZaZiBoNa, the Southern African development community collaborative medicines registration initiative. *Ther Innov Reg Sci.*
- Sani NM, McAuslane N, Kasbon SH, Ahmad R, Yusof FA & Patel P (2020) An evaluation of Malaysian regulatory process for New Active Substances approved in 2017 using OpERA methodology. *Ther Innov Reg Sci.*
- Patel P, Cerqueira DM, Santos GML, Soares RL, Sousa VD, Liberti L & McAuslane N (2020) A baseline analysis of regulatory review timelines for ANVISA 2013-2016. *Ther Innov Reg Sci*. 54, 1428-1435.
- Bujar M, McAuslane N, Connelly P & Walker S (2020) Quality decision-making practices in pharmaceutical companies and regulatory authorities: current and proposed approaches to its documentation. *Ther Innov Reg Sci*. 54, 1404-1415.
- Keyter A, Salek S, Banoo S & Walker S (2020) Can standardisation of the Public Assessment Report improve benefit-risk communication? *Front. Pharmacol.* 11:855
- Rodier C, Bujar M, McAuslane N, Patel P & Liberti L (2020) Use of the Certificate for Pharmaceutical Products (CPP) in 18 maturing pharmaceutical markets: comparing agency guidelines with company practice. *Ther Innov Reg Sci.*
- Bujar M, McAuslane N, Walker S & Salek S (2020) A process for evaluating quality decision-making practices during the development, review and reimbursement of medicines. *Int. J. Health Policy Manag.*
- Giaquinto AR, Grignolo A, Liberti L, Lim JCW, Salmonson T, Sauer F & Ukwu H (2020) Improving access to quality medicines in East Africa: an independent perspective on the East African Community Medicines Regulatory Harmonisation initiative. *PLoS Med.* 17(8):e1003092.
- Wang T, Lipska I, McAuslane N, Liberti L, Hovels A & Leufkens B (2020) Benchmarking Health Technology Assessment agencies – methodological challenges and recommendations. *International Journal of Technology Assessment in Health Care, 36*(4), 332-348. doi:10.1017/S0266462320000598
- Liberti L, Extavour R, Patel P & McAuslane N (2020) Evaluation of the Caribbean Regulatory Ssytem centralised assessment process. *Journal of Pharmaceutical Policy and Practice* 13, 56.
- Keyter A, Salek S, Banoo S & Walker S (2020) A proposed regulatory review model to support the South African Health Products Regulatory Authority to become a more efficient and effective agency. *Int J Health Policy Manag.*
- Wang T, McAuslane N, Liberti L, Gardarsdottir H, Goettsch W & Leufkens H (2020) Companies' Health Technology Assessment strategies and practices in Australia, Canada, England, France, Germany, Italy and Spain: an industry metrics study. *Front. Pharmacol.* 11:594549. doi: 10.3389/fphar.2020.594549

2020 R&D Briefings

- R&D Briefing 74 - Measuring process and performance in regulatory agencies: the OpERA Programme. 8 January 2020.
- R&D Briefing 75 - Emergency Use Pathways (EUPs): applying regulatory flexibility in the age of COVID-19. 6 May 2020.
- R&D Briefing 76 – The impact of recent regulatory developments on the Mexican therapeutic landscape. 13 May 2020.
- R&D Briefing 77 – New drug approvals in six major authorities 2010-2019: focus on Facilitated Regulatory Pathways and internationalisation. 15 May 2020.
- R&D Briefing 78 – Review of HTA outcomes and timelines in Australia, Canada and Europe 2015-2019. 11 August 2020.

2020 conference presentations

- **RAPS webcast** - Aligning regulatory and access expectations: driving towards optimum outcomes for the key stakeholders
- **DIA** – Leading through complexity: opportunities, pitfalls and best practice for managing successful partnerships
- **DIA** – Approaches for cross-functional teams to enhance quality of decision making during the development and review of medicines
- **DIA Europe** – How regulatory science shapes policy
- **DIA Europe** [poster] - How can regulatory policy functions in pharmaceutical companies measure their value and impact?
- **RAPS Convergence** – ICH, ICMRA and other global health authority collaboration – exemplified by COVID-19 and other innovative enhancements from AI to AMR and beyond
- **RAPS Convergence** – LATAM Forum: Driving regulatory convergence, optimising regulatory capacities and innovation
- **RAPS webcast** – Challenges and opportunities for using Facilitated Regulatory Pathways in mature and emerging markets
- **Asia Regulatory Conference** - OpERA Initiative: Progressing Regulatory Reliance in the Asia Region by Identifying Efficient Regulatory Processes

Thank you to those we work with

CIRS' achievements would not have been possible without the commitment and dedication of its advisory committees; we thank them for the invaluable support and direction they have provided. We would also like to thank our member companies and the Bill and Melinda Gates Foundation for its continued support.

2020 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, Senior Medical Officer, EMA

Deborah Autor, Global Head of Regulatory Excellence, AstraZeneca, USA
Dr Fabio Bisordi, Global Head International Regulatory Policy, F.Hoffmann-La Roche Ltd
Dr Claus Bolte, Head of Sector Marketing Authorisation, Swissmedic
Dr Harald Enzmann, Chair, CHMP/EMA
Dr Tim Garnett, CMO, SVP, Eli Lilly
Adrian Griffin, Vice President for HTA Policy, Johnson & Johnson
Dr Peter Honig, Senior Vice President and Head of Worldwide Safety and Regulatory, Pfizer
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Dr Sabine Luik, Chief Medical Officer and SVP, Global Medical, Regulatory and Quality, GlaxoSmithKline
Dr Theresa Mullin, Director, Office of Strategic Programs, US FDA, CDER
Dr Brian O'Rourke, Former CEO and President, CADTH, Canada
Dr Junko Sato, Office Director, Office of International Program, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
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Dr John Patrick Stewart, Director General, Therapeutic Products Directorate, Health Canada
Dr Roopal Thakkar, Vice President, Regulatory Affairs and R&D Quality Assurance, Abbvie
Prof Stuart Walker, Founder, CIRS
Dr Max Wegner, Head Regulatory Affairs PH & CH, Bayer AG

2020 Specialist Advisors

Dr Thomas Lönngren, 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

2020 HTA Steering Committee

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Vice-Chair: Prof Adrian Towse, Director Emeritus and Senior Research Fellow, OHE
Dr Nick Crabb, Programme Director, Scientific Affairs, NICE
Prof Hans-Georg Eichler, Senior Medical Officer, EMA
Dr Wim Goettsch, Associate Professor HTA, Utrecht University; Special Advisor HTA, ZIN
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
Niklas Hedberg, Chief Pharmacist, TLV
Evert Jan van Lente, Director EU-Affairs, AOK-Bundesverband
Prof Finn Børlum Kristensen, Former EUnetHTA Executive Committee Chairman and EUnetHTA Secretariat Director, Faculty of Health Sciences, University of Southern Denmark
Dr Maria Kubin, Head of MACS TA Cardiovascular, Bayer
Andrew Mitchell, Strategic Adviser, DoHA
Dr Vanessa Elisabeth Schaub, Global Access Senior Health Systems Strategy Leader HTA & Reimbursement, Roche
Dr Sean Tunis, Principal, Rubix Health and Senior Advisor, FDA

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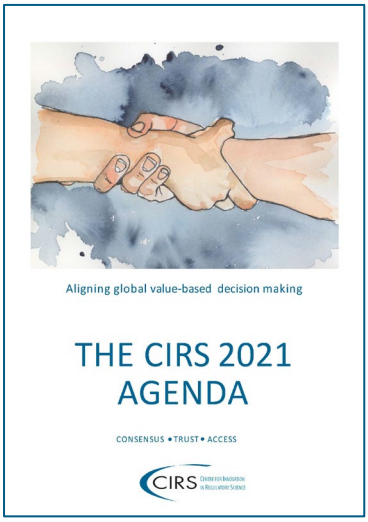

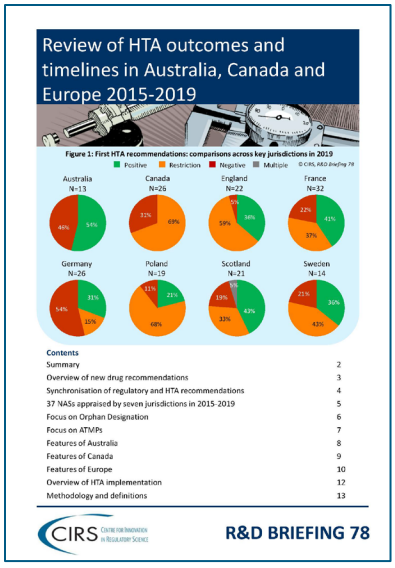

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