2021 Annual Report

CIRS
Centre for Innovation in Regulatory Science

Contents

Foreword

From the Head of CIRS

I'm pleased to present CIRS' Annual Report for 2021. In the pages that follow, we update you on the headway we have made over the year to execute our goal of informing the regulatory and access landscape through our three pillars of metrics, quality, and alignment. We have also outlined the steps we took to extend our global outreach in regulatory sciences, despite the challenges we have all faced lately.

The past two years have precipitated unprecedented changes in the pharmaceutical policy landscape, leading to increased international collaboration and opportunities for accelerating policies that will enhance product development, registration and reimbursement. The pandemic was and still is a pressure test for all the institutions involved in the delivery of healthcare worldwide. CIRS' role as a global forum for industry, regulators, HTA agencies, and other healthcare stakeholders, has never been this critical.

While CIRS' operations were predominantly delivered virtually in 2021, they were very well received by our stakeholders. Our Q4 workshop on the regulatory and HTA landscape in Asia and Latin America was a particular highlight as it included HTA agencies who were new to CIRS. Our Optimising Efficiencies in Regulatory Agencies (OpERA) forums brought together regulators from Africa, Asia and Latin America to share their experiences and similarly our industry Technical Forums brought CIRS member companies together to discuss the impact of evolving areas such as patient engagement and regulatory reform in China. 2021 also featured the inaugural meeting of the CIRS Africa Regulatory Advisory Committee, an advisory group set up to provide recommendations on and guide strategic planning of CIRS activities with African regulatory agencies, regional regulatory initiatives, as well as continental regulatory initiatives.

I feel extremely honoured to be leading this fine institution with such a global remit, influential stakeholders and unmatched legacy. I began my tenure as Head of CIRS in July of 2021, and very quickly established communication channels with members of the Scientific Advisory Council and HTA Steering Committee, as well as key contacts from our member companies and other participating organisations. One theme ran through each of the 70+ stakeholder meetings that I have held in the past few months: your support of CIRS and its mission is overwhelming and energising! I look forward to working with our stakeholders in 2022 and to discussing areas for consideration for 2023 and beyond.

Happy reading!

Anna Somuyiwa

Head of CIRS

Welcome to new CIRS staff

Anna

HEAD OF CIRS

Anna Somuyiwa leads CIRS on its mission to maintain a leadership role in identifying and applying scientific principles to advance regulatory and HTA policies and processes. Before joining CIRS in July 2021, Anna was International Operations Lead at Guidehouse, where she oversaw the European team of regulatory consultants working for small to medium sized pharmaceutical and biotechnology companies.

Adem

SENIOR RESEARCH ANALYST

Adem Kermad is responsible for the operation of the Emerging Markets Industry Metrics Programme and provides analytical support for the Optimising Efficiencies in Regulatory Agencies (OpERA) programme and other regulatory projects. Prior to joining CIRS in June 2021, Adem was Senior Research Executive at Ipsos MORI.

Juan

RESEARCH ANALYST

Juan Lara supports the delivery of regulatory research projects as well as the OpERA programme. Prior to joining CIRS in June 2021, Juan was Consulting Analyst at IQVIA and before that, worked at the Mexican regulatory agency COFEPRIS.

Belen

RESEARCH ANALYST

Dr Belen Sola supports core HTA projects, such as the annual HTA agency and industry benchmarking studies, as well as other research projects and meetings/workshops. Prior to joining CIRS in May 2021, Belen completed her PhD in Drug Delivery at University College London.

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 pharmaceutical 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 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 agencies, 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 endeavour 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, regulators 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 life cycle

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 agencies and regulators, as well as between HTA agencies 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**
- **Outcome metrics**
- **New ways of working**

Find out more about our strategy and plans for 2022 in the CIRS Agenda

2021 in numbers

9 Journal publications*

5 CIRS R&D Briefings*

4.5 Out of 5 feedback score for multi-stakeholder workshops**

13 Conference presentations*

Insight meetings

28 For companies

40 For agencies

601 New LinkedIn followers

6 PhD students supported by CIRS

* Listed on p16-17
** Listed on p10-11

2021 highlights

Improving access to biologics in Ecuador

CIRS met with the Ecuadorian regulatory agency ARCSA to discuss the recommendations of a report developed in collaboration with the British Embassy in Quito. The report provided a detailed analysis of the current authorisation process for biologics and ATMPs in Ecuador and identified opportunities for ARCSA to align with international best practices. ARCSA posted a summary of the meeting on its website.

Engaging with the global HTA community

CIRS continued working with the global HTA community to improve understanding of HTA processes and decision making. In addition to presenting at the HTAi 2021 Annual Meeting, we gave input into the HTAi Global Policy Forum on uncertainty. Our 2021 Q4 workshop also featured presentations from the HTAi Policy Forum Chairs for Latin America and Asia and from the Chair of the International Network of HTA (INAHTA).

Mapping regulatory and HTA systems in Latin America and Asia

CIRS conducted systematic mapping of regulatory and HTA systems in Asia and Latin America, which showed varying levels of HTA involvement; four archetypes of regulatory-HTA system were identified in Asia and five in Latin America. These findings were an important discussion piece at our 2021 Q4 workshop, helping to inform the direction of regulatory-HTA interactions in Asia and Latin America. The generated maps are available in the CIRS Regulatory and Reimbursement Atlas.

Bringing regulators together to learn about reliance practices

In 2021, over 100 representatives from 34 regulators in Latin America, Africa, Middle East and Asia participated in our regional OpERA Forums and shared their experiences with one another. A common focus point in these meetings was how to support the use of reliance, work sharing and regionalisation initiatives. CIRS was also delighted to be involved in a virtual workshop for regulators in Asia, which was organised by the Centre for Regulatory Excellence (CoRE) in Singapore and focused on the implementation of Good Reliance Practices.

Monitoring work sharing

CIRS has been actively monitoring the impact of the Access Consortium and Project Orbis work-sharing initiatives on the approvals of new medicines. Key findings were published in our annual regulatory benchmarking briefing, which focuses on approvals by six major regulators.

Our Q1 2021 workshop also featured presentations on Project Orbis and new collaborative ways regulators and HTA agencies are working together, including the UK Innovative Licensing and Access Pathway (ILAP).

Assessing implementation of ICH guidelines

CIRS was selected by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) to undertake an assessment of regulators' and companies' perspectives on the implementation and adherence to ICH guidelines. The findings highlighted the progress made by regulators in implementing and adhering to ICH Guidelines since the 2019 assessment, and will be used to support training needs and ICH membership-related activities.

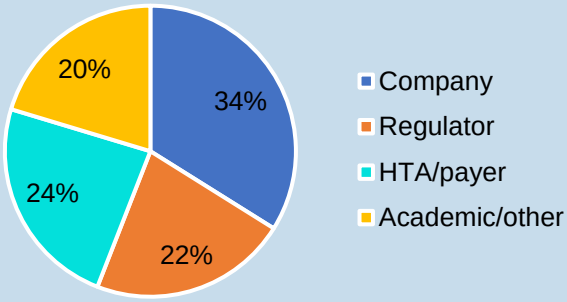
CIRS virtual workshop - 10-11th March 2021

Regulatory, HTA and payer interactions and collaborations: optimising their use and outcome success

This workshop provided a platform for discussion on the current and future landscape for interactions and collaborations between and within different stakeholders. The aim was to assess the value and impact of these interactions on development, regulatory review and reimbursement and to make recommendations on an ideal ecosystem for multi-stakeholder interactions.

Prior to the workshop, CIRS conducted a multi-stakeholder survey that mapped current interactions between companies, regulators and HTA agencies, and determined each stakeholder's perception of the value and future evolution of these interactions. The survey findings were presented at the workshop to inform the discussions and are currently being prepared for publication in a peer-reviewed journal.

130+ attendees from 22 countries



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

Agency attendee

Download the workshop report

CIRS virtual workshop, 24-25th June 2021

Digital technologies: enabling evidence generation in clinical development

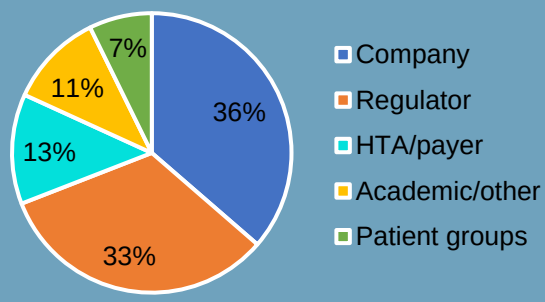
As regulatory and HTA agencies adapt to the use of digital technology in clinical development, which has been accelerated by the ongoing pandemic, it is important to understand how aligned their requirements are across jurisdictions as well as the opportunities for both stakeholders going forward. The aim of this workshop was to provide a platform to discuss the utilisation of digital technologies for evidence generation in the clinical development space for regulatory and HTA decision making. The discussions resulted in several recommendations to facilitate alignment across jurisdictions to ensure the potential of digital technologies are maximised within a fit-for-purpose regulatory and HTA environment.

"I particularly appreciated the breakout sessions, which allowed for brainstorming in real time and arriving at some actionable proposals for CIRS to help advance the field."

Company attendee

Download the workshop report

170+ attendees from 30 countries



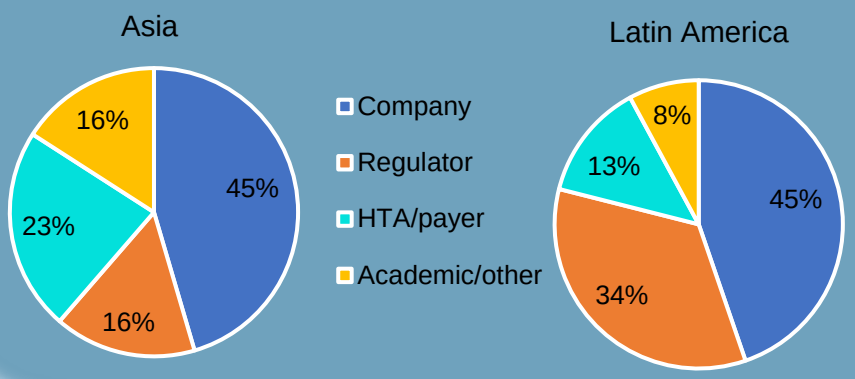
CIRS virtual workshop, 25th November & 9th December 2021

Regulatory and HTA landscape in Asia/Latin America: How are these aligning to ensure availability and access to new medicines?

This workshop provided a platform for discussion of the changing regulatory/HTA environment within Asia and Latin America. Both mature and maturing agencies as well as companies working in each region shared experiences and discussed challenges and opportunities for aligning regulatory and HTA needs. Some of the participating HTA agencies were new to CIRS so it was great to have their input and we look forward to growing our relationships with them.

We hope that the learnings from this meeting can help to inform the direction of regulatory-HTA interactions in Asia and Latin America. A report of the workshop will be published in 2022.

250+ attendees from 50 countries



"CIRS must be commended for putting together industry, HTA and regulatory agencies in a continuing dialogue."

Agency attendee

Virtual Technical Forums for CIRS member companies

Evolving regulatory landscape in China: challenges and opportunities to ensure timely availability of medicines

3rd November 2021

This meeting allowed CIRS member companies to discuss the impact of recent regulatory reforms in China and to learn from one another about monitoring the evolving China regulatory landscape. There was agreement that the changes in China's regulatory landscape have been generally positive, though there are still some challenges and areas for improvement.

To help inform the forum discussions, CIRS presented the results of a pre-meeting survey, the findings of which are currently being prepared for publication in an R&D Briefing.

Ensuring meaningful patient engagement: how can companies align internal and external stakeholder expectations during development to support review and reimbursement?

15th December 2021

This allowed CIRS member companies to discuss the value of engaging patients early in development to enable downstream stakeholder decision making. Experiences and learnings were shared by a patient group as well as CIRS member companies.

Key challenges highlighted included the difficulty in measuring return on investment of patient engagement and differences in the way regulators and HTA agencies use patient-relevant data.

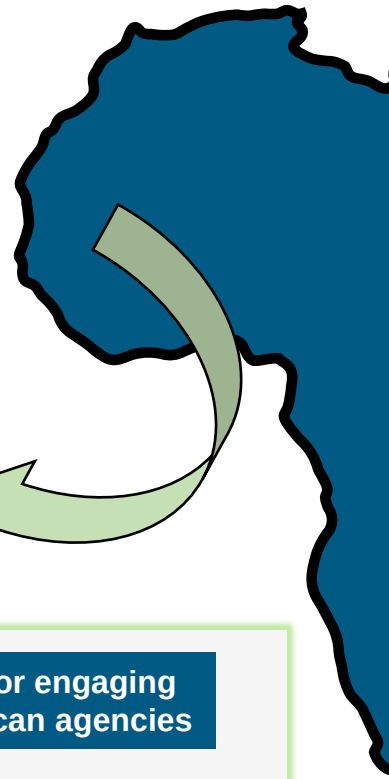
Find out more about CIRS membership

Impact case study: supporting the establishment of the African Medicines Agency through performance metrics

There are 55 regulatory agencies that govern medicines regulation across Africa. Many of these agencies have limited resources and do not have a robust complement of systems, skills and capabilities in place to provide effective and efficient regulatory support. This results in delays in medicines reviews and approvals, an increased likelihood of poor-quality medicines entering the market, and delays in patient access to critical medicines.

Over the last decade, much work has been done to improve regulatory capacity, capability and collaboration across Africa. CIRS has played a key part in this by giving African regulators and regional regulatory initiatives in the Optimising Efficiencies in Regulatory Agencies (OpERA) programme the tools to measure their efficiency and effectiveness. This has allowed barriers and opportunities for improvement to be identified and helped to embed a culture of ongoing performance monitoring and self-assessment.

The overall aim of the OpERA programme within Africa is to evaluate the regulatory performance of agencies and regional assessment initiatives to support the treaty for the establishment of the African Medicines Agency.



West African Health Organisation (WAHO)

Work is underway to evaluate the effectiveness and efficiency of seven agencies who are active in the Economic Community of West African States (ECOWAS). Similar to the studies in the EAC and ZaZiBoNa regions, companies' perspectives of the WAHO joint assessment will also be investigated.

PhD student: Mercy Acquaye Owusu-Asante, Ghana Food and Drug Authority

Model for engaging with African agencies

Agency contact — CIRS initially identifies and works with a PhD student and/or champion within the agency, who is able to obtain the data needed

OpERA Country Report — Agency's regulatory processes and practices are mapped and analysed using the OpERA questionnaire

OpERA Metrics Report — Regulatory review dates are collected from the agency to identify where time is spent and embed a culture of tracking performance

Peer-reviewed publication — Baseline measurements, areas for improvement and strategic recommendations are identified and published in a journal publication co-authored with the agency

CIRS strategic pillars addressed:

East African Community (EAC)

Seven agencies in the region have completed a questionnaire that rates their efficiency and effectiveness. These data have been analysed and are currently being put into a manuscript for publication, which will include recommendations for the region to improve its performance. In 2022, CIRS hopes to investigate what companies think of the efficiency and effectiveness of the EAC joint assessment by asking them complete a modified version of the agency questionnaire.

PhD student: Nancy Ngum, New Partnership for Africa Development

Southern African Development Community (SADC)

ZaZiBoNa - six agencies who are active in ZaZiBoNa, the Southern African Development Community (SADC) collaborative medicines registration initiative, have been evaluated in terms of their Good Review Practices, review models and approval timelines, resulting in two peer-reviewed publications. A further study of all nine active ZaZiBoNa agencies is currently being prepared for publication; this evaluated the region's efficiency and effectiveness, both from the agencies' perspective and from the perspective of companies. This is the first time ZaZiBoNa has been evaluated in such a way by both stakeholders.

PhD student: Tariro Sithole, Medicines Control Authority of Zimbabwe

Zimbabwe – In 2021 two peer-reviewed publications on Zimbabwe were published; the first assessed OpERA-collected metrics from the Zimbabwe agency for 2017-2019, while the second compared the Zimbabwe agency with the agencies in Australia, Canada, Switzerland and Singapore. Both publications included recommendations for improvement, such as developing a decision-making framework and enhancing transparency.

South Africa – a key aspect of CIRS' work with South Africa has been around the implementation of reliance pathways. The introduction of abridged and verification reliance pathways has successfully helped the South African agency to address its backlog of marketing authorisation applications, reducing approval timelines for these applications by 68%. CIRS continues to work closely with the South African agency on various aspects of its performance as it looks to achieve the next maturity level of the WHO Global Benchmarking Tool (GBT) indicator.

Impact case study: promoting stakeholder interactions to facilitate regulatory-HTA alignment

CIRS has been actively promoting and monitoring multi-stakeholder interactions involving HTA agencies since 2009 (see below). Greater engagement between regulators and HTA agencies is facilitating alignment in requirements, while greater engagement between companies and HTA agencies through early scientific advice is helping to integrate HTA considerations into development plans.

Over the last five years, regulatory and HTA interactions, as well as multi-HTA and multi-regulatory interactions, have evolved in thinking and mutual activities, both at a product level as well as at a policy level, spanning both national and cross-jurisdictional systems. In addition, the COVID-19 pandemic has tested channels of communication and networks for interactions, creating challenges but also opportunities for change.

Therefore 2021 seemed like an ideal time for CIRS to review the current ecosystem of interactions and collaborations and the future direction this may move in through a multi-stakeholder research survey and workshop. Key findings from the pre-workshop survey and the workshop breakout discussions are currently being prepared for publication in a peer-reviewed journal.

2009

Multi-stakeholder survey

Highlighted need for alignment of regulatory and HTA requirements and joint scientific advice.

2010

Multi-stakeholder workshop

Examined how to align review and reimbursement needs and requirements in clinical development

2011

Industry HTA metrics study established

Collecting HTA-related data on individual products from development through to rollout.

2012

HTA agency metrics study piloted

Benchmarking HTA agency processes to facilitate performance improvement and enhance transparency of HTA outcomes and timelines

2013

Multi-stakeholder workshop

Discussed whether there is commonality across structured decision frameworks used by HTA and regulatory agencies

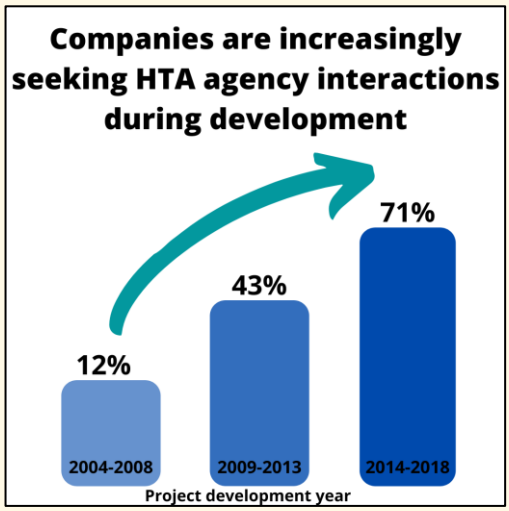
2014

4th Annual industry discussion meeting

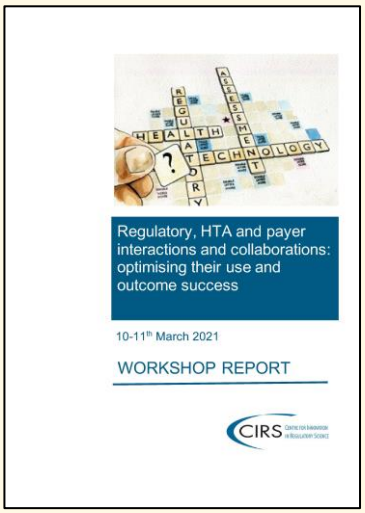
Discussed the impact of HTA on drug development and market access

Evolution of CIRS' work promoting

CIRS strategic pillars addressed:



Wang et al. 2021



2021 Workshop report

2015

Industry survey and Technical Forum

Identified optimal approaches to seeking and implementing early HTA advice

2016

Multi-stakeholder survey and workshop

Showed increasing regulatory-HTA interactions and company support for joint scientific advice

2017

HTA agency survey

Evaluated the return on investment for early scientific advice

Multi-stakeholder workshop

Discussed alignment of flexible regulatory/access pathways

2018

Multi-stakeholder workshop

Discussed how early upstream interactions can enhance downstream innovation and decision making

2021

Journal publication

Showed companies' approaches to seeking early scientific advice from HTA agencies

Multi-stakeholder survey and workshop

Assessed the current and future landscape for multi-stakeholder interactions and collaborations

stakeholder interactions and alignment →

2021 journal publications

1. Sithole T, Mahlangu G, Salek S, Walker S. Evaluation of the Regulatory Review Process in Zimbabwe: Challenges and Opportunities. Ther Innov Regul Sci. 2021;55(3):474-489.
2. Bujar M, McAuslane N, Liberti L. The Qualitative Value of Facilitated Regulatory Pathways in Europe, USA, and Japan: Benefits, Barriers to Utilization, and Suggested Solutions. Pharmaceut Med. 2021;35(2):113-122.
3. Bujar M, Ferragu S, McAuslane N, Liberti L, Kühler TC. 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?. Clin Ther. 2021;43(5):888-905.
4. Keyter A, Salek S, Danks L, Nkambule P, Semete-Makokotlela B and Walker S (2021) South African Regulatory Authority: The Impact of Reliance on the Review Process Leading to Improved Patient Access. Front. Pharmacol. 12:699063.
5. Sithole T, Mahlangu G, Capote V, 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.
6. Sithole T, Mahlangu G, Capote V, 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.
7. Wang T, McAuslane N, Gardarsdottir H, Goettsch WG, Leufkens HGM. Building HTA insights into the drug development plan: Current approaches to seeking early scientific advice from HTA agencies [published online ahead of print, 2021 Sep 28]. Drug Discov Today. 2021;S1359-6446(21)00408-6.
8. Liberti L & Wang T. The regulatory-HTA decision-making interface: What the medical writer should know. Medical Writing 2021; 30(3):50-55.
9. Sithole T, Salek S, Mahlangu G, Walker S. 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.

2021 R&D Briefings

1. 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.
2. R&D Briefing 80 – CIRS Workshop: Reimagining medicines regulatory models – outputs from multistakeholder discussions.
3. R&D Briefing 81 – New drug approvals in six major authorities 2011-2020: focus on Facilitated Regulatory Pathways and work sharing.
4. R&D Briefing 82 – Regulatory reliance pathways: what are the opportunities and barriers?
5. R&D Briefing 83 - Review of HTA outcomes and timelines in Australia, Canada and Europe 2016-2020.

2021 conference presentations

1. 22nd February, **HTAi Policy Forum** - Developing a framework for HTA management of uncertainty: feedback from CIRS multi-stakeholder workshops

2. 22nd February, **DIA Latin America Regulatory Conference** – Results of CIRS reliance study for Latin America

3. 20-23rd May, **DIA China** - The importance of international standards, guidelines and regulatory science for building trust and competency

4. 19th-23rd June**, HTAi Annual Meeting -** Challenges and opportunities of building value into development for innovative technologies: a multi-stakeholder perspective.

5-8. 27th June – 1st July**, DIA Annual Meeting**

   - 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

9. 29th June – 2nd July**, AMEPRES National Congress of Professionals in Sanitary Regulation -** Regulatory reliance and its impact on the pharmaceutical industry in the Americas

10. 31st August, **INTERFARMA** webinar on use of reliance pathways within the context of the Brazilian regulatory system

11. 12th October, **AFIDRO/FIFARMA** meeting - Best Practices and Convergence in Latin America

12. 9-12th November, **AMEPRES 6th International Meeting on Health Regulation** – Good Regulatory Practices and Reliance

13. 18th November, **National Chamber of Commerce Bolivia** meeting -The use of regulatory decisions of other jurisdictions in Latin America: current situation and expectations

Thank you to those we worked with in 2021

CIRS' achievements in 2021 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 (BMGF) for its continued support.

Scientific Advisory Council (SAC)

Chair: Adjunct Prof John Skerritt, Deputy Secretary for Health Products Regulation, Department of Health, Australia
Vice-Chair: Prof Hans-Georg Eichler, Consulting Physician of the Association of Austrian Social Insurance Institutions

With special thanks to retiring members:
Dr Tim Garnett, Former Chief Medical Officer, Senior Vice President, Eli Lilly
Dr Peter Honig, Former Senior Vice President and Head of Global Regulatory Affairs, Pfizer

Deborah Autor, Global Head of Regulatory Excellence, AstraZeneca, USA
Dr Fabio Bisordi, Global Head International Regulatory Policy, Roche
Dr Claus Bolte, Head of Sector Marketing Authorisation, Swissmedic
Dr Harald Enzmann, Chair, European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP)
Dr Carlos Garner, Vice President, Global Regulatory Affairs, Eli Lilly
Adrian Griffin, Vice President for HTA Policy, Johnson & Johnson
Dr Ian Hudson, Senior Advisor, Integrated Development, Global Health, BMGF, UK
Dr David Jefferys, Senior Vice President, Head of Global Regulatory, Eisai Europe
Prof John Lim, Executive Director of Centre for Regulatory Excellence (CoRE), Duke-NUS Medical School and Chairman, Consortium for Clinical Research & Innovation, Singapore
Dr Sabine Luik, Chief Medical Officer and Senior Vice President, Global Medical, Regulatory and Quality, GlaxoSmithKline
Dr Theresa Mullin, Director, Office of Strategic Programs, US Food and Drug Administration (FDA) Centre for Drug Evaluation and Research (CDER)
Dr Brian O'Rourke, Former CEO and President, Canadian Agency for Drugs and Technologies in Health (CADTH)
Dr Junko Sato, Office Director, Office of International Program, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Dr Xie Songmei, Deputy Director of Clinical Department Centre for Drug Evaluation, National Medical Products Administration (NMPA), China
Jerry Stewart, Vice President, Global Regulatory Policy and Intelligence, Pfizer
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, Senior Vice President, Head of Regulatory Affairs, Bayer

Specialist Advisors

Dr Thomas Lönngren, Former Executive Director, EMA
Dr Murray Lumpkin, Deputy Director, Integrated Development, and Lead for Global Regulatory Systems Initiatives, BMGF
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

HTA Steering Committee

With special thanks to retiring members: Evert Jan van Lente, Former Director EU-Affairs, AOK-Bundesverband

Chair: Dr Brian O'Rourke, Former CEO and President, CADTH, Canada
Vice-Chair: Prof Adrian Towse, Director Emeritus and Senior Research Fellow, Office of Health Economics (OHE), UK
Dr Nick Crabb, Programme Director, Scientific Affairs, National Institute for Health and Care Excellence (NICE), UK
Prof Hans-Georg Eichler, Consulting Physician of the Association of Austrian Social Insurance Institutions
Dr Wim Goettsch, Associate Professor HTA, Utrecht University, and Special Advisor HTA, National Health Care Institute (ZIN), The Netherlands
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
Niklas Hedberg, Chief Pharmacist, Dental and Pharmaceutical Benefits Agency (TLV), Sweden
Prof Finn Børlum Kristensen, Professor of Health Services, Faculty of Health Sciences, University of Southern Denmark and Former Director and Chair of EUnetHTA Executive Committee
Dr Maria Kubin, Head, Integrated Evidence Planning, Cardiovascular Therapy Area, Bayer
Suzanne McGurn, CEO and President, CADTH, Canada
Andrew Mitchell, Strategic Adviser, Department of Health Australia
Dr Detlev Parow, Head, Department of Medicines, Medical Remedies and Selective Contracts, DAK – Gesundheit, Hamburg, Germany
Dr Vanessa Elisabeth Schaub, Global Access Chapter Lead for Evidence, Roche
Dr Sean Tunis, Principal, Rubix Health

African Regulatory Advisory Committee

Chair: Gugu Mahlangu, Former Director General, Medicines Control Authority of Zimbabwe (MCAZ)
Vice-Chair: Dr Tumi Boitumelo Semete, CEO, South African Health Products Regulatory Authority (SAHPRA)
Prof Coulibaly Assane, Director General, Directorate of Pharmacy and Medicines, Ivory Coast
Mimi Darko, CEO, Ghana Food and Drug Authority
Adam Fimbo, Director General, Tanzania Medicines and Medical Devices Authority (TMDA)
Heran Gerba, Director General, Ethiopian Food and Drug Administration (EFDA)
Markieu Janneh Kaira, CEO, Gambia Medicines Control Agency
Dr Charles Karangwa, Director General, Rwanda Food and Drugs Administration
Prof Cristianah Mojisola Adeyeye, Head of Nigeria National Agency for Food and Drug Administration and Control (NAFDAC)
Bernice Mwale, Head of Zambia Medicines Regulatory Authority (ZAMRA)
Dr David Nahanya, Head of Uganda National Drug Authority
Margareth Ndomondo-Sigonda, Co-ordinator, Health Programmes, New Partnership for Africa's Development (NEPAD)
Dr Fred Siyoi, Head of Kenya Food and Drugs Authority

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About CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. CIRS provides an international forum for industry, regulators, Health Technology Assessment (HTA) and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to pharmaceutical products. It is governed and operated by Clarivate 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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