CIRS Centre for Innovation in Regulatory Science

NEWSLETTER
WINTER 2024

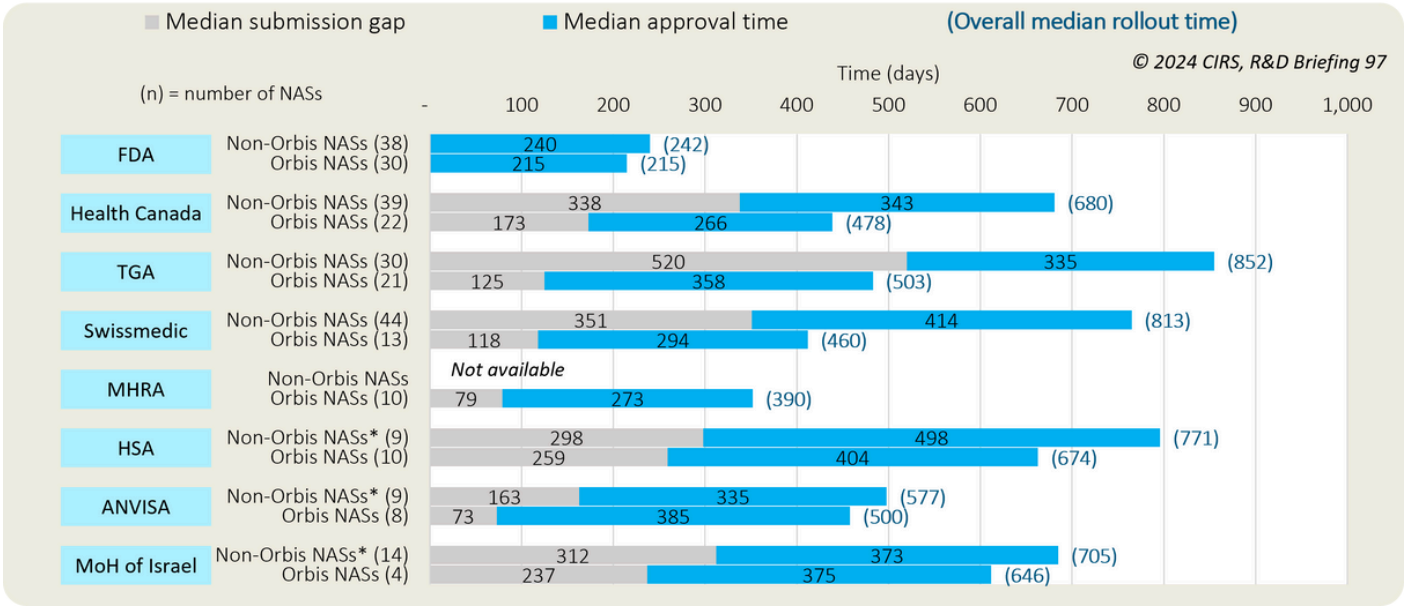
Before everyone signs off for the festive season, we'd like to share a few things that CIRS has been up to recently, as well as a summary of our publications this year.

We hope that you find this of interest and would like to wish you a very **happy holiday!**

FDA MEETING

In November, Anna and Neil met with representatives of the FDA Oncology Centre of Excellence (OCE) at the US Embassy in London to share some of CIRS' research outputs, in particular our annual benchmarking studies that collect publicly available data on FDA outcomes and timelines. This was a great opportunity to discuss our methodologies and insights on Project Orbis regulatory timelines and the impact on HTA.

Comparison of median submission gap, approval time and rollout time for new active substances (NASs) approved via Project Orbis vs Non-Orbis NASs (2019-2023)



Non-Orbis NASs: ATC L01 NASs approved outside Project Orbis. For the FDA, only those ATC L01 NASs reviewed by the OCE were considered. Submission gap is calculated as the time from the date of submission at the first regulatory agency (out of EMA, FDA, PMDA, Health Canada, Swissmedic and TGA) to the date of regulatory submission to the target agency. Two products were considered MLEs to FDA and NASs to other agencies within Project Orbis; for these cases, the submission date of FDA was used instead of the date of submission at the first regulatory agency. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. Rollout time is calculated from the date of submission at the first regulatory agency to the date of regulatory approval at the target agency.

** The timelines for other Non-Orbis NASs were obtained from industry via the CIRS Growth and Emerging Markets Programme.*

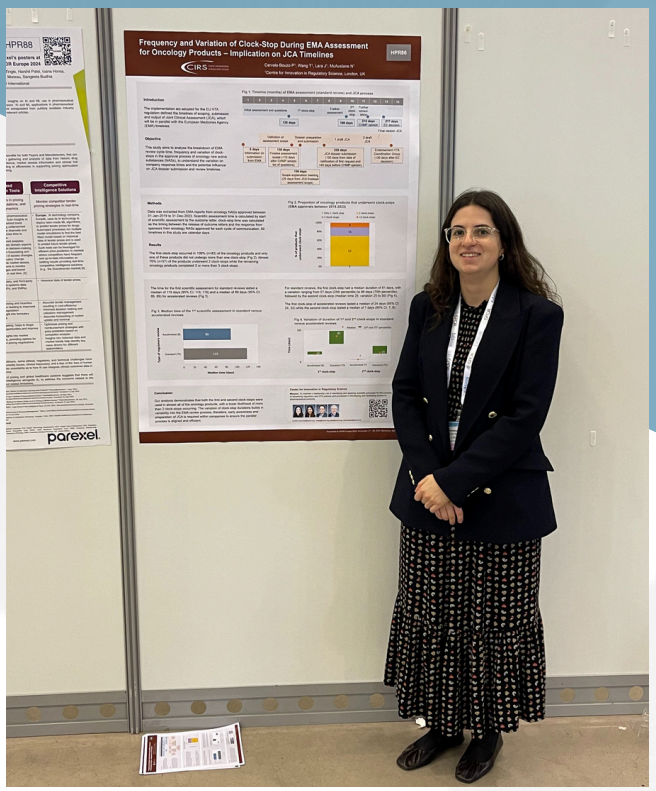
Look out for R&D Briefing 97 on Orbis and Access in January!

ISPOR EUROPE

Anna and the HTA team (Tina, Belen and Penelope) attended the ISPOR Europe conference in Barcelona in November. It was great to meet familiar faces and connect with new ones from the market access/HEOR area.

Well done to Research Analyst Penelope on her first poster presentation for CIRS, featuring EMA stop-clock data for oncology products to give initial insight into how the parallel joint clinical assessment (JCA) and EMA timelines may impact one another.

DOWNLOAD POSTER



COLLABORATIVE MODELS WORKSHOP

We had our final workshop of the year in October, which brought together regulators, HTA agencies, companies, payers, academics and patient organisations to discuss the impact of regulatory and HTA collaborative models.

A series of excellent presentations and panel discussions highlighted the benefits and challenges of different ways of collaborative working between and among regulatory and HTA agencies.

We hope that the learnings and recommendations from this meeting can help to inform the evolution of these collaborative models.

DOWNLOAD SYNOPSIS

PUBLICATIONS

Workshop synopses and reports:

- New ways of working - enabling patient access through reliance or regional review models
- Vaccines - Are regulatory and funding approaches fit for purpose for the next decade?
- Facilitating joint clinical assessment (JCA) implementation, utilisation and timely patient access
- Working across regulatory and HTA agencies: Collaborative, work-sharing or reliance models

CIRS R&D Briefings:

- 91 – Approaches to implementing regulatory reliance: Considerations for agencies
- 92 – Appraisal of public assessment reports (PARs) as tools to guide reliance decision making by regulatory agencies
- 93 – New drug approvals by six major authorities 2014-2023: Changing regulatory landscape and facilitated regulatory pathways
- 94 – The value of reference agency assessment reports in enabling regulatory reliance
- 95 – CIRS HTADock Project: Review of HTA outcomes and timelines in Australia, Canada, Europe and the UK 2019-2023
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Project reports with external partners:

- Monitoring implementation and adherence to ICH Guidelines
- Regulatory processes for rare disease drugs in the United States and European Union

Peer-reviewed journal publications:

- Comparison of Three Regional Medicines Regulatory Harmonisation Initiatives in Africa: Opportunities for Improvement and Alignment
- Evaluation of good review practices in member authorities of the East African Medicines Regulatory Harmonisation initiative: Strategies for alignment with African medicines agency
- Evaluation of the Review Models and Approval Timelines of Agencies, participating in the East African Medicines Regulatory Harmonisation Initiative: Alignment and Strategies for Moving Forward

PhD thesis:

- The role of regional initiatives in the operationalisation of the African Medicines Agency: Contribution of the EAC-MRH initiative

External online articles/blogs:

- Minding the Gap: CPP Utilisation Practices and the Impact on Submission Gap in Growth and Emerging Markets. DIA Global Forum article
- Regulatory and Access Approaches for Vaccines: Recommendations from an Expert Workshop. DIA Global Forum article
- Is collaboration between and across regulatory and HTA agencies the answer to access challenges? OHE Insights Blog

Take a look at CIRS publications

READ MORE

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