CIRS Centre for Innovation in Regulatory Science

EMERGING MARKETS METRICS PROGRAMME 2022

CIRS Contacts

Adem Kermad
Senior Research Analyst
akermad@cirsci.org

Dr Magda Bujar
Manager, Strategic Development
mbujar@cirsci.org

Dr Neil McAuslane
Scientific Director
nmcauslane@cirsci.org

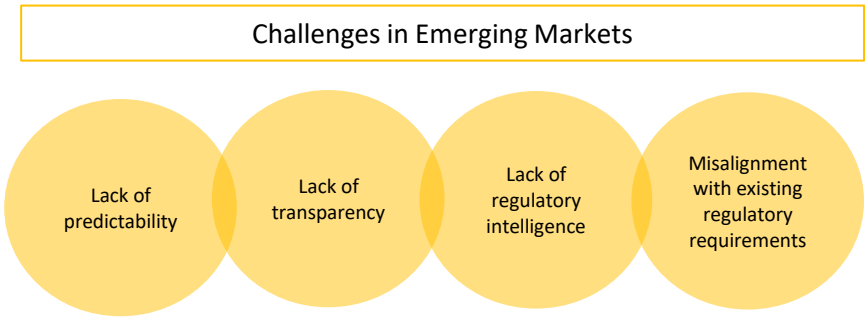
Centre for Innovation in Regulatory Science (CIRS)
Email : cirs@cirsci.org
Website: www.cirsci.org

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independently managed UK-based subsidiary company, forming part of the Clarivate Analytics group. CIRS' mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and HTA policies and processes. CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to medical products through these activities. This is CIRS' purpose. CIRS is operated solely for the promotion of its purpose. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, special projects and grants.

Background

While each pharmaceutical market is unique, they are all complex, dynamic and subject to rapid change. As growth opportunities continue to decrease in more developed markets, companies are pursuing the emerging countries in their strategic planning. Globalisation of the world's pharmaceutical markets means that quality information for clinical development and registration of new medicines for these markets is more important than ever to the various stakeholders. Establishing R&D activities in emerging market countries will help pharmaceutical companies obtain market access in a timely way.

With this tremendous progress in a short span of time, significant challenges remain for industries and authorities to overcome. As a result, the Emerging Markets Metrics Programme was established in January 2004 to meet the needs of the both companies and regulatory agencies to overcome these challenges and build on strengths by fostering innovation and process building. The programme utilises comparative data and information on the evolving regulatory environment in the emerging markets at the country and regional level. This programme focuses on 18 countries, which includes the biggest and fastest growing economies and also represent the most prominent and promising emerging markets.



To address these challenges and facilitate a streamlined regulatory process, CIRS initiated the Emerging Markets Metrics programme to

- meet needs of the pharmaceutical industry for comparative data and information on the regulatory environment

- exchange dialogue with regulatory agencies to better understand their processes and identify where improvements were required.

- bring together stakeholders at workshops to discuss and debate topics focussed on Emerging Market regulatory environment

PROGRAMME

This programme has the following key components:

The Emerging Markets Regulatory Review Times (EMaRReT) database

The EMaRReT database tracks time to submissions and approvals for new active substances (NASs) and major line extensions (MLE). Data are also analysed by:

- Therapeutic indications
- Review types and process
- Compound types

Focus study

A study focussing on a regulatory issue or emerging trend in the regulatory landscape. The purpose of the study is to gain company (and where required agency) feedback on the topic of interest. (Topic is decided by the programme participants).

Industry Discussion Meeting

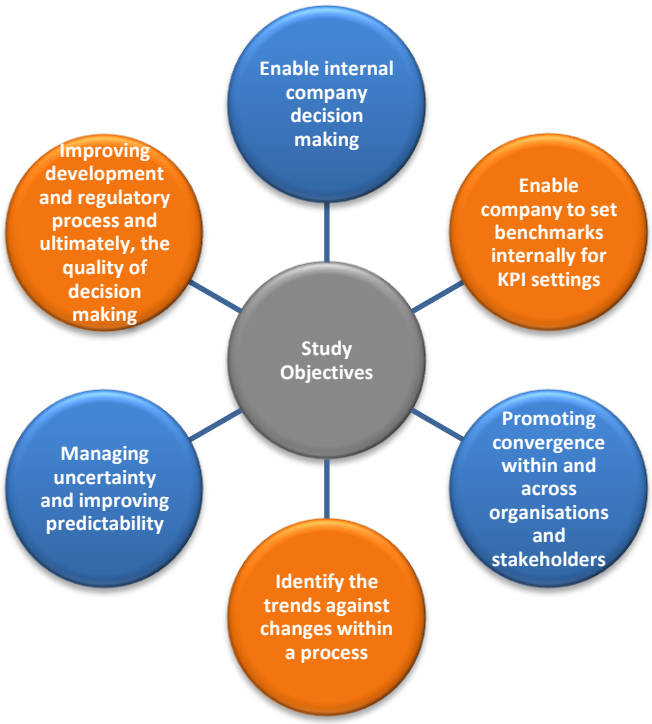
The annual Industry Discussion Meeting is held during each year of the programme. At these meetings, participating companies engage in interactive discussions regarding new data analyses, trends in the emerging markets, and, where possible, activities and results related to the Focus Study.

EMaRReT-specific teleconferences

Quarterly updates with the participating companies on the status of the activities, updates on upcoming events i.e. local company insight seminars; CIRS meetings, database deadlines etc. These teleconferences allow CIRS to stay engaged with the companies and to share any information which may help with the activities

Company- specific analyses

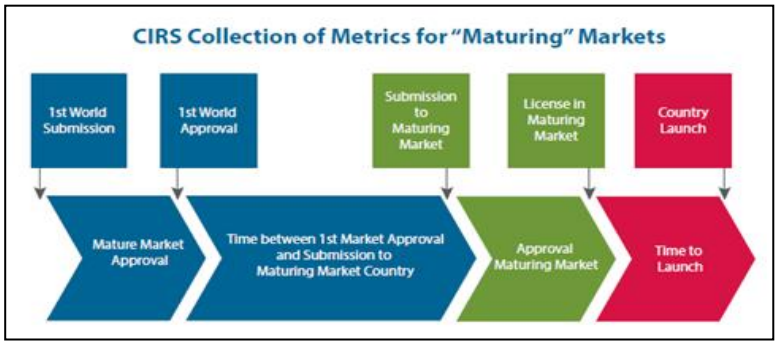
CIRS can create company-requested analyses tailored to specific needs; such as analyses of specific products, milestones or therapeutic areas.



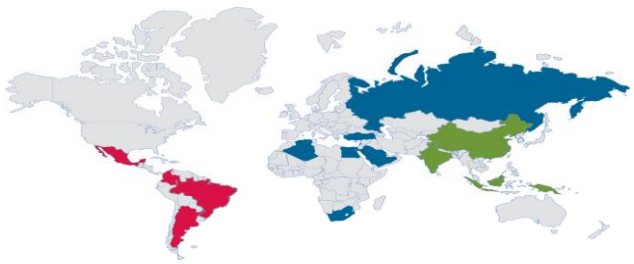
Emerging Markets Regulatory Review Times (EMaRReT) Database

- This database tracks regulatory metrics provided by companies on 18 countries and 1 regional alignment initiative
- Tracks changes in approval time milestones from first world submission to drug launch, utilisation of a certificate of a pharmaceutical product (CPP) and roll-out times from first worldwide approval to the submission and approval in the emerging market countries
- Currently contains over 7000 submissions to the emerging market countries made up of NASs and MLEs.
- The data provide company-specific trend analyses for submission, approval and roll-out times for new active substances and major line extensions within the emerging markets

Milestones collected



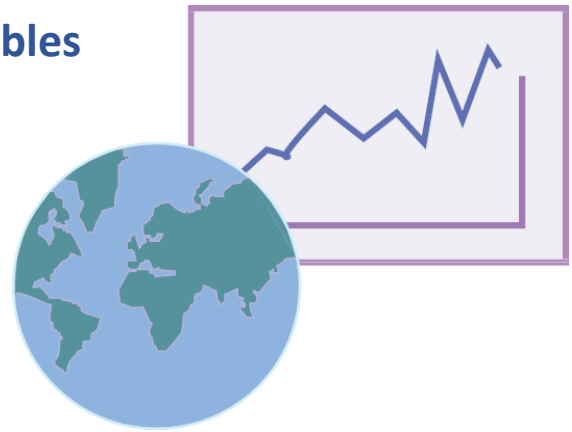
Countries of interest to the programme



Latin America	Europe, Middle East and Africa	Asia
Argentina	Algeria	China
Brazil	Egypt	Chinese Taipei
Colombia	Israel	India
Mexico	Russia*	Indonesia
	Saudi Arabia	Malaysia
	South Africa	Singapore
	Turkey	South Korea
	Gulf Health Council (GHC)	

* With additional consideration to submissions made via the EAEU

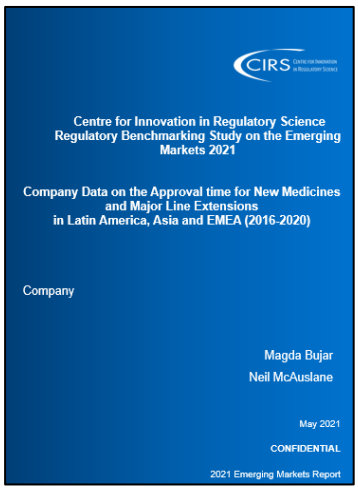
EMaRReT Database Report Deliverables



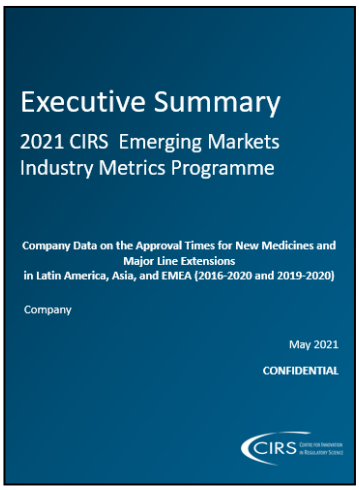
The Emerging Markets Programme reports deliver value to all levels within an organisation. Programme participants have identified the top three uses of the reports as:

- Identifying areas for improvement in company practices
- Being informed of changes/trends in emerging markets
- Benchmarking company performance and KPI setting

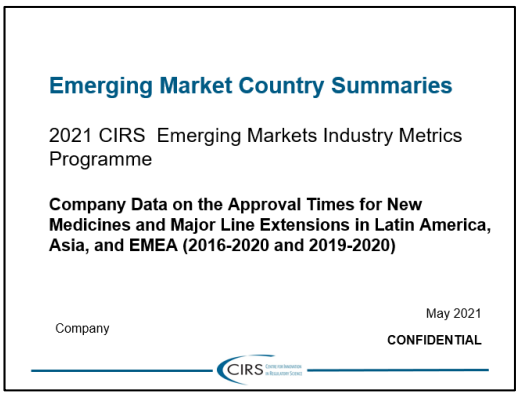
Setting strategy



Policy



Country level feedback



1. Main Report

- A comprehensive 150 page report including industry and company specific analyses as well as a description of major findings
- **Main audience**: Global regulatory leads
- **Main purpose:** Strategy, intelligence

2. Executive Summary

- A 17 page summary of the study background along with the key outcomes (industry and company specific)
- **Main audience:** Management
- **Main purpose:** Policy, advocacy

3. Country Summary

- A country-specific snapshot of the main study metrics (industry and company specific) with two high level slides per country
- **Main audience:** Regional affiliates
- **Main purpose:** Country feedback

SUMMARY OF THE DELIVERABLES OF THE 2022 EMERGING MARKETS METRICS PROGRAMME

The Emerging markets Programme package is available at a participation fee of **£17,500** for 2022.
The following summarises the deliverables for a participating company

Emerging Markets Metrics Programme: Key Deliverables
Emerging Markets Regulatory Approval Times Database (EMaRReT) database and full report
• Provision of a company-specific report including: - Current approval times, trends from 2021 and small year range cohorts, to reflect the recent environment (i.e. 2020-2021) - Company strategies for submission to emerging market countries - Role of the timing of the CPP submission - An understanding of regulatory requirements through the deficiency questions asked during review
Executive Summary
· A summary of the methodology of this long-term benchmarking project, along with the key outcomes from data analyses through 2021
Individual Country Summaries
· Concise country-specific summaries highlighting key metrics and process observations
Focus study
· Feedback analysis and insights on the outcomes on the selected focus study topic
Quarterly Teleconferences
• Update on ongoing activities relating to the data collection tool • Discussion and feedback on the changes of the data collection parameters • Update on any visits and to arrange affiliate Insight Seminar
Industry Discussion Meeting*
• A meeting will be held in 2022 to review the outputs from the data collected from the EMaRReT database • At this meeting, companies will participate in interactive discussions regarding new data analyses and trends in the emerging markets

* Industry Discussion Meeting: Each participant is responsible for travel and will be assessed a fee to cover accommodations.

Please refer to page 2

for CIRS contact details