2023 Growth & Emerging Markets Metrics Programme

CIRS Centre for Innovation in Regulatory Science

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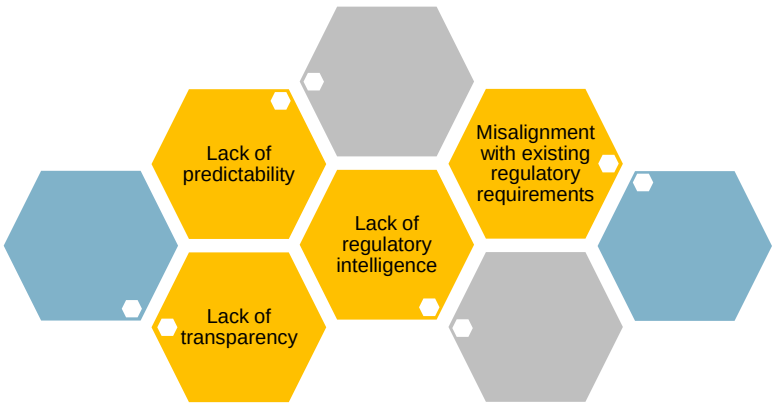
The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independently managed UK-based subsidiary of Clarivate plc. Its mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes. 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 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.

Background

While each pharmaceutical market is unique, they are all complex, dynamic and subject to rapid change. As opportunities continue to decrease in more developed markets, companies are pursuing growth and 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 growing and emerging countries will help pharmaceutical companies obtain market access in a timely way.

Despite 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 2004 to meet the needs of both companies and regulatory agencies for overcoming these challenges and building upon existing strengths by fostering innovation and strengthening regulatory systems. Recognising that many of the economies have since matured substantially and the national agencies have become more established, from 2023 onwards the Programme was retitled the Growth & Emerging Markets Metrics Programme. The Programme utilises comparative data and information on the evolving regulatory environment, and currently focuses on 19 jurisdictions across Latin America (LatAm), Europe, the Middle East, and Africa (EMEA), and Asia, in addition to two regional initiatives in EMEA. These represent fast-growing key economies in addition to recognised prominent and promising emerging markets.

Challenges in Growth & Emerging Markets



CIRS initiated the Programme in order to address these challenges and facilitate a streamlined regulatory process. The Programme seeks to:

- Meet the needs of the pharmaceutical industry for comparative data and information on the regulatory environment
- Expand understanding of the regulatory processes and identify areas for improvement
- Bring together stakeholders at meetings to discuss and debate topics focussed on the regulatory environment in growth and emerging markets

Programme Components

The Growth & Emerging Markets Metrics Database

The database is updated on an annual basis, capturing participants' submission and approval data for New Active Substances (NASs) and Major Line Extensions (MLEs) (see page 5 for more details).

Programme Reports

CIRS produce three reports analysing the data collected in the programme database. The 'Main Report' is a comprehensive set of industry and company specific analyses in addition to a account of the major findings, the 'Executive Summary Report' explains the study background along with the key outcomes, and 'Country Summary Report' offers country-specific snapshots of the main study metrics (see page 6 for more details).

Industry Discussion Meeting (IDM)

An annual Industry Discussion Meeting is held following the delivery of the programme reports. At this meeting, participating companies have the opportunity to engage in interactive discussions on trends in the key markets, new data analyses, and, the current regulatory environment within the countries of interest and how CIRS can best utilise these findings to advance best practices in these agencies.

Company-specific Analyses

CIRS can produce and/or create bespoke analyses tailored to meet participants' reporting needs (subject to availability and upon request).

Insight Seminars

CIRS can organise a bespoke seminar for interested companies to provide an update on CIRS activities followed by a discussion on a topic of mutual interest related to the Growth & Emerging Markets Programme (available upon request).

Analytics Tool Pilot Project

CIRS is currently working to produce a pilot version of an online analytics tool in order to investigate the feasibility and utility of allowing interactive interrogation of the Programme database in a secure and confidential format.

The Growth & Emerging Markets Metrics Programme Database

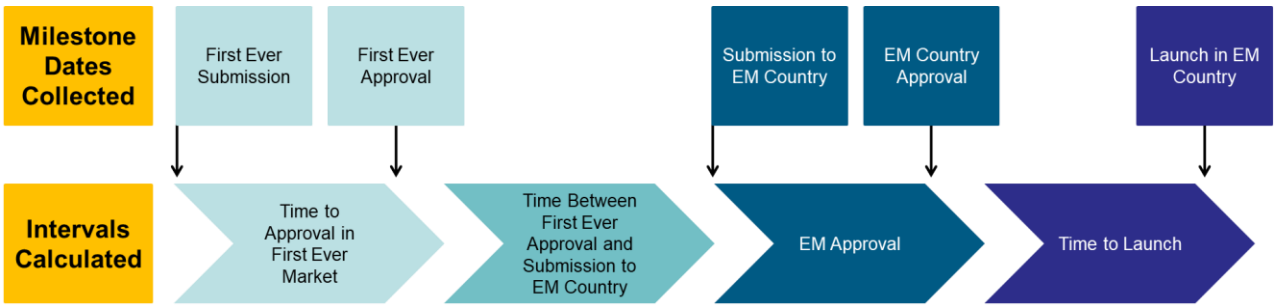
The database contains regulatory submission and approval data provided annually by participating companies for 19 jurisdictions across LatAm, EMEA, and Asia, in addition to two regional initiatives (see table below). It consists of over 8000 NAS & MLE submissions to growth and emerging markets.

Data captured in the database includes:

- General application details, such as the assessment route, review status, Certificate of Pharmaceutical Product (CPP) usage, and orphan designation
- Country-specific application processes, such as China IND submission and approval dates
- Application milestones (see below)
- Factors influencing patients' access to medicines, e.g., company and marketing strategy, and launch delays

The database facilitates analysis of numerous metrics for NASs & MLEs at both industry and company levels.

Milestones Captured for Metrics



Jurisdictions Covered

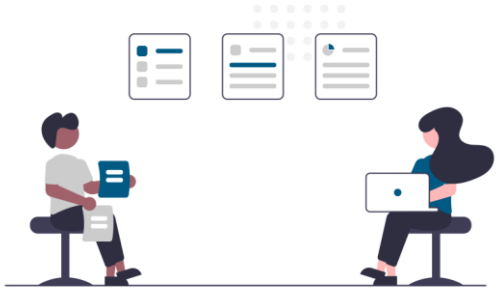
Latin America (LatAm)	Europe, Middle East, & Africa (EMEA)	Asia
Argentina	Algeria	China
Brazil	Egypt	Chinese Taipei
Colombia	Israel	India
Mexico	Russia*	Indonesia
	Saudi Arabia	Malaysia
	South Africa	Singapore
	Turkey	South Korea
	Gulf Health Council (GHC)	Vietnam

* With additional consideration to submissions made via the Eurasian Economic Union (EAEU)

Programme Reports

The Growth & Emerging Markets Metrics Programme reports provide value across all organisational levels. The top three uses of the reports, as identified by programme participants, are:

- Identifying key areas for improvement in company practices
- Staying informed of changes and trends in growth & emerging markets
- Benchmarking company performance against industry peers for Key Performance Indicator setting

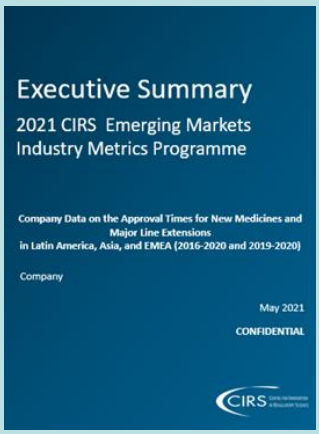


Strategy

Main Report

- A comprehensive report (over 150 pages) providing industry and company-specific analyses, and a description of major findings
- Principal audience: Global regulatory leads
- Principal purpose: Strategy and intelligence

Policy



Executive Summary Report

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

Country-level Feedback

Country Summary Report

- Country-specific snapshots of the main study metrics (both industry and company-specific) with two high-level slides per market
- Principal audience: Regional affiliates
- Principal purpose: Market-level feedback

Summary of Deliverables for the 2023 Programme

The details below represent a summary of the key deliverables for the 2023 Growth & Emerging Markets Metric Programme.

Programme Reports
CIRS deliver three reports analysing the data collected in the programme database. These are a 'Main Report', an 'Executive Summary Report', and a 'Country Summary Report' (see page 6 for more details).

Industry Discussion Meeting (IDM) *
Held following delivery of the programme reports, the IDM is a forum for participating companies to engage in interactive discussion on the analysis and insights derived from the most recent data collection period as well as the evolving regulatory landscape.

Company-specific Analyses
Upon request and subject to availability, CIRS can produce and/or create bespoke analyses to address participants' reporting needs.

Insight Seminars
Upon request and subject to availability, CIRS can deliver an insight seminar providing an update on CIRS' activities and a discussion on a topic of mutual interest related to the Growth & Emerging Markets Programme.

* Each participant is responsible for travel and accommodation.

Please contact CIRS (details on page 2) for information on the programme participation fee.