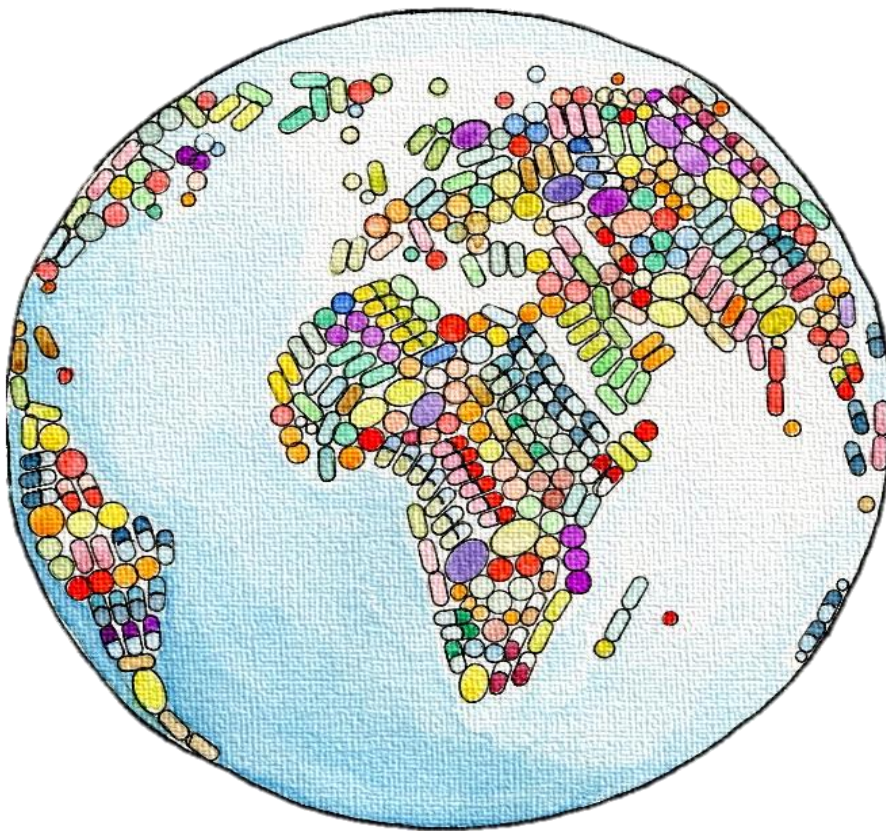


# CIRS Growth & Emerging Markets Metrics Programme

## 2025 Programme Brochure



## CIRS Contacts

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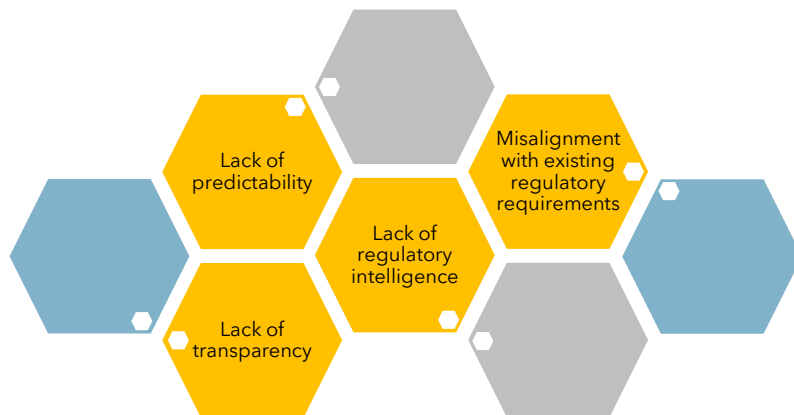
The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. Its mission is to identify and apply scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes in developing and facilitating access to pharmaceutical products. CIRS provides an international forum for industry, regulators, HTA bodies and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy. 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, and grants.

## Background

Each pharmaceutical market is unique, but all share complexity, dynamism, and a rapid pace of change. As opportunities in developed markets may decline, companies increasingly incorporate growth and emerging markets into their strategies. The globalisation of pharmaceutical markets drives a demand for high-quality information to support clinical development and the registrations of new medicines, helping companies secure timely market access in these regions.

The Emerging Markets Metrics Programme, launched in 2004, aimed to help companies and regulatory agencies address the major challenges in these markets, foster innovation, and strengthen regulatory systems. As many of these markets have matured and their national agencies have become more established, the Programme was renamed the Growth & Emerging Markets Metrics (GEMM) Programme in 2023. Today, the Programme leverages comparative data on regulatory landscape in 20 jurisdictions across LatAm; the Middle East, Africa, Russia, and Turkey; and Asia. The jurisdictions covered within these regions represent high-growth and prominent 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 in growth/emerging markets
- Expand understanding of the regulatory processes with these markets and identify areas for improvement
- Bring together stakeholders for opportunities to discuss and debate topics focussed on the regulatory environment in these markets

## Programme Components

### Programme Database

The Programme 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

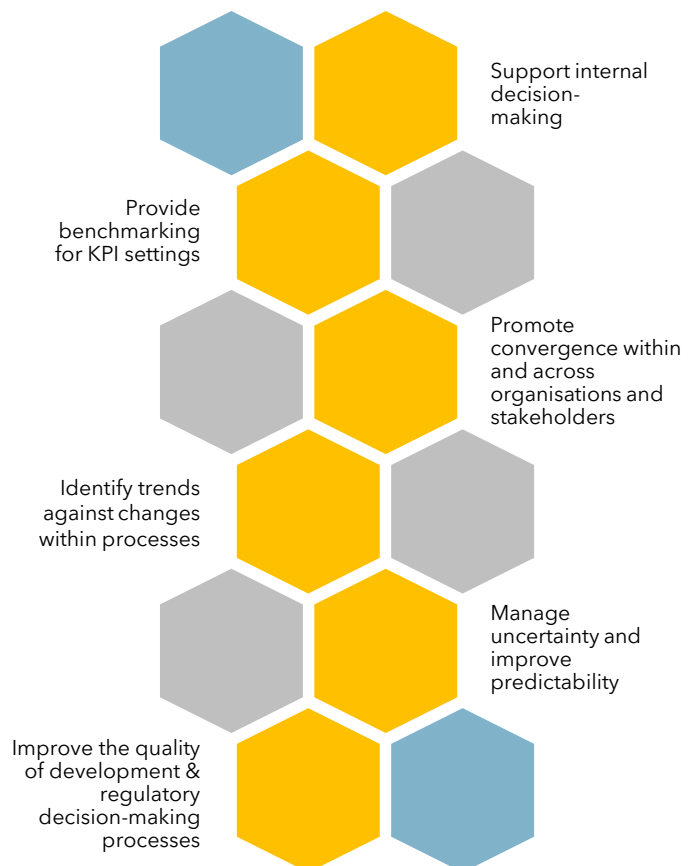
CIRS can produce bespoke analyses to meet participants' specific reporting needs (upon request and subject to availability).

### Insight Seminars

CIRS can organise a bespoke seminar to provide an update on CIRS activities to the interested company, followed by a discussion on a topic of mutual interest related to the GEMM Programme (i.e., available upon request).

### Analysis Tool

CIRS provides access to an online analysis tool that enable interactive interrogation of the Programme database in a secure, instant, and confidential format. The tool is available to all participating companies, is refreshed on an annual basis with the most recent data collected, and is updated based on participant feedback.



## The Growth & Emerging Markets Metrics Programme Database

The database contains regulatory submission and approval data provided annually by participating companies. It consists of 10,000 NAS & MLE submissions to growth and emerging markets across 20 jurisdictions in LatAm; Middle East, Africa, Russia, and Turkey; and Asia (see 'Jurisdictions Covered' below).

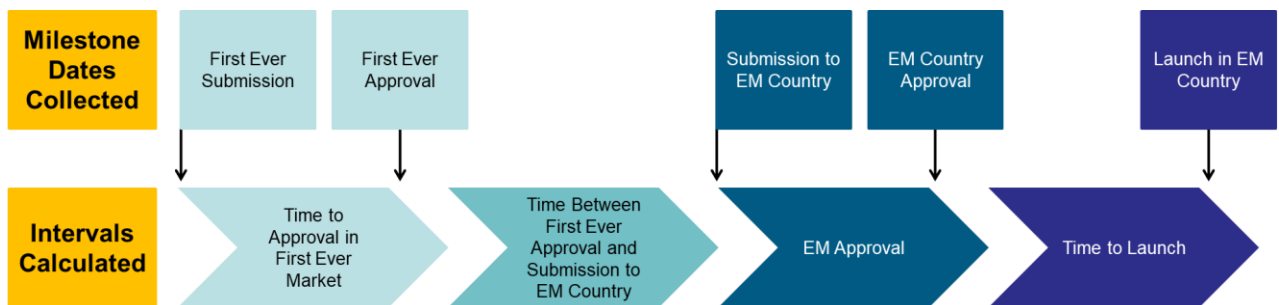


Data captured in the database includes:

- General application details, e.g., assessment route, review status, Certificate of Pharmaceutical Product (CPP) and assessment report utilisation, priority review, and orphan designation
- Country-specific application processes, e.g., China IND submission and approval dates
- Application milestones (see 'Milestones Captured for Metrics' below)
- Factors influencing patients' access to medicines, such as company strategy, and reason(s) for delays launching a product

The database enables CIRS to produce and provide access to aggregated metrics for NASs & MLEs, at both an industry and company level.

### Milestones Captured for Metrics



### Jurisdictions Covered

Latin America (LatAm)	Middle East, Africa, Russia, and Turkey	Asia
Argentina Brazil Colombia Mexico	Algeria Egypt Israel Russia* Saudi Arabia South Africa Turkey United Arab Emirates (new for 2025)	China Chinese Taipei India Indonesia Malaysia Singapore South Korea Vietnam

\* With consideration to submissions made to Russia via the Eurasian Economic Union (EAEU).

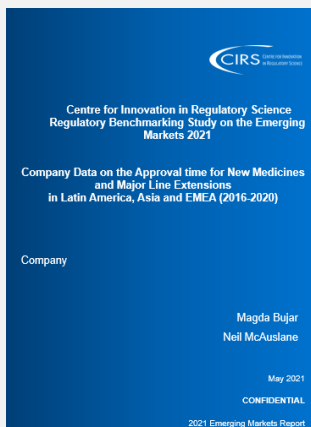
## Programme Reports

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 concise 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 2025 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.

### **Analysis Tool**

CIRS provides access to an online analysis tool that enable interactive interrogation of the Programme database in a secure, instant, and confidential format. The tool is available to all participating companies and is refreshed on an annual basis with the most recent data collected. Development of the content and functionality of the tool is driven by feedback provided by participants over the course of the year.

\* Each participant is responsible for travel and accommodation.

Please refer to page 2 for CIRS' contact details.