Measuring process and performance in regulatory agencies: The OpERA Programme

INTRODUCTION

CIRS has collected regulatory assessment data for over 20 years, initially with ICH and ICH-observing countries. The OpERA programme, **"Optimising Efficiencies in Regulatory Agencies (OpERA)"**, was initiated through CIRS in 2013 with agencies from Asia, Latin America, Africa and the Middle East. Since then, CIRS has expanded this programme to over 20 countries and several regional alignment initiatives. OpERA is a global programme, available to all regulatory agencies irrespective of their size, mission or maturity.

OpERA combines qualitative (process mapping; Figure 1) and quantitative (performance metrics; Table 1) information to provide a detailed picture of the regulatory assessment activities of agencies at any stage of maturity. As the regulatory landscape evolves and to put performance metrics into local context, CIRS developed a systematic questionnaire completed by agencies to map regulatory processes and procedures. The resultant Country Report has been linked to metrics provided by each agency.

OBJECTIVES OF OpERA

- Help regulators integrate a practice of tracking and measuring regulatory performance and promote continuous improvements in review and approval times while ensuring safety, efficacy and quality
- Understand the regulatory processes that drive approval times
- Identify qualitative and quantitative regulatory indicators of performance.

Contents

Figure 1. Process mapping

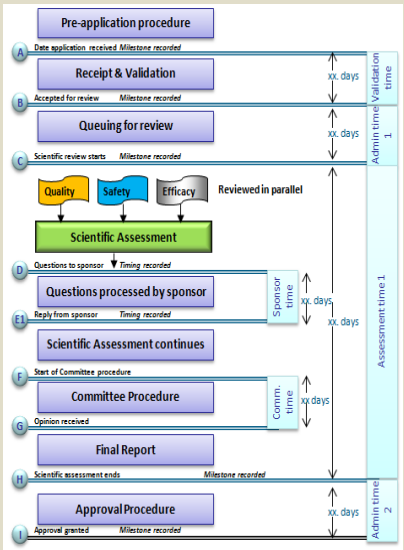


Table 1. Performance metrics

Target time	Definition
Overall Approval Time	The time between the date stamped on Receipt of Dossier when received by authority and the Date of Legal Marketing (date of the product licence)
Dossier Validation	The time between the date stamped on Receipt of Dossier when received by authority and the Date of "Acceptance (or Refusal) to File" (letter was sent)
Scientific Assessment Time	Amount of time spent actively reviewing the dossier or additional information provided
Sponsor Time	Time during which the clock was stopped during the review whilst the authority awaited additional data provision by the company
Other Regulatory Authority Time	Time taken up by the authority during the review for administration, queuing, Advisory Committee time etc.

Key Milestone Dates
1a. Receipt of the dossier
1b. Acceptance to file
2a. Start of Primary Scientific Assessment
2b. Completion of Primary Scientific Assessment Primary Scientific Assessment
3a. Primary assessment deficiency letter sent to sponsor (if applicable)
3b. Response from Sponsor (If applicable)
4. Secondary assessment following deficiency letter response (if applicable)
5. Advisory Committee Review (if applicable)
6. Completion of Scientific Assessment
7. Marketing Authorisation Granted /Rejected
For REC: Final Acceptance by member state

OUTPUTS AND METHODS

There are two components to the OpERA Programme: The **Country Report** (process) (Figure 2) and **specific metrics collections** (Figure 3).

Figure 2. Country report

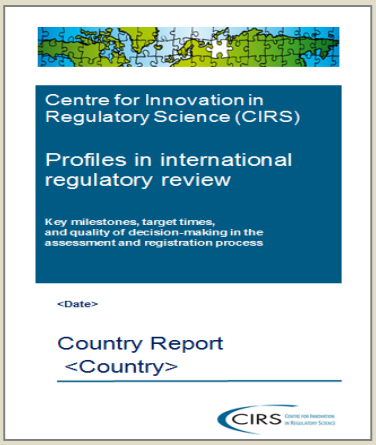
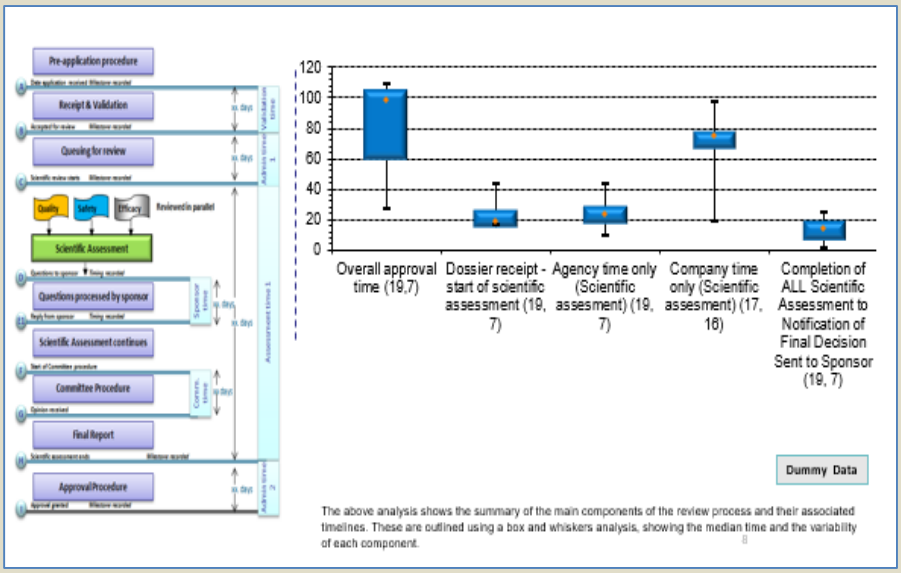


Figure 3. Key Milestones data collected & Summary of review process timelines



THE COUNTRY REPORT (PROCESS)

The Country Report is created by CIRS with information provided by each agency through the Country Questionnaire. More than 15 years ago CIRS developed a standardised reporting approach to identify key characteristics that may impact regulatory performance. Using this mature process, CIRS uses information provided by an agency via the Country Questionnaire to create the agency-specific Country Report.

This report:

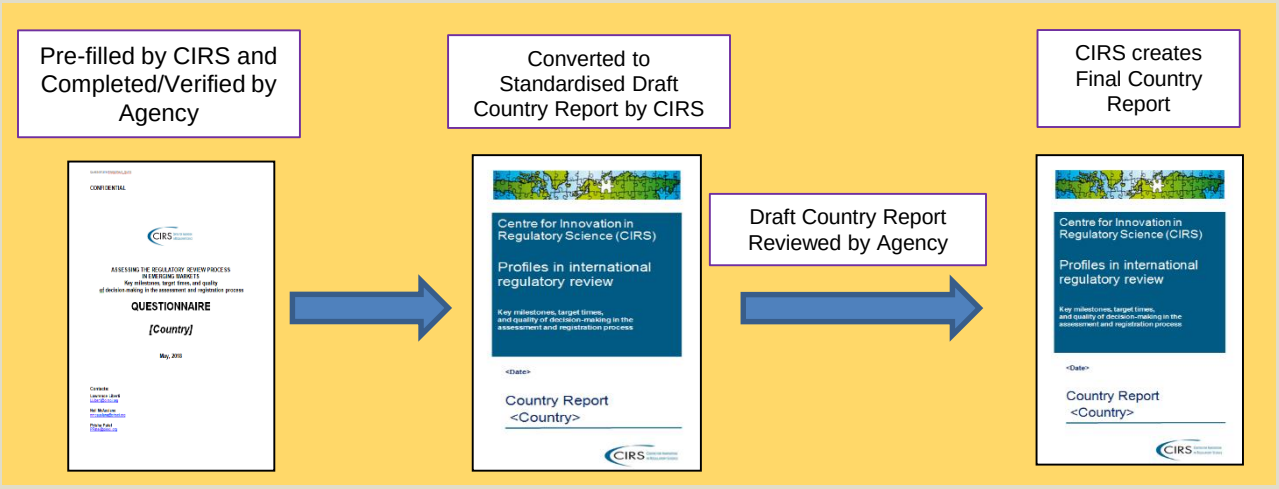
- allows **accurate interpretation** of the quantitative metrics to be evaluated according to the review process
- permits **global comparisons** to similar agencies open to sharing their profile
- encourages **sharing and adopting** of Good Review Practices.

The report captures:

Part 1	Organisation of the agency
Part 2	Types of review models
Part 3	Key milestones in the review process (Figure 1)
Part 4	Good Review Practices (GRevP)
Part 5	Quality Decision-Making Processes

CIRS works closely with each agency to verify collected data and prepare the Country Report (Figure 4).

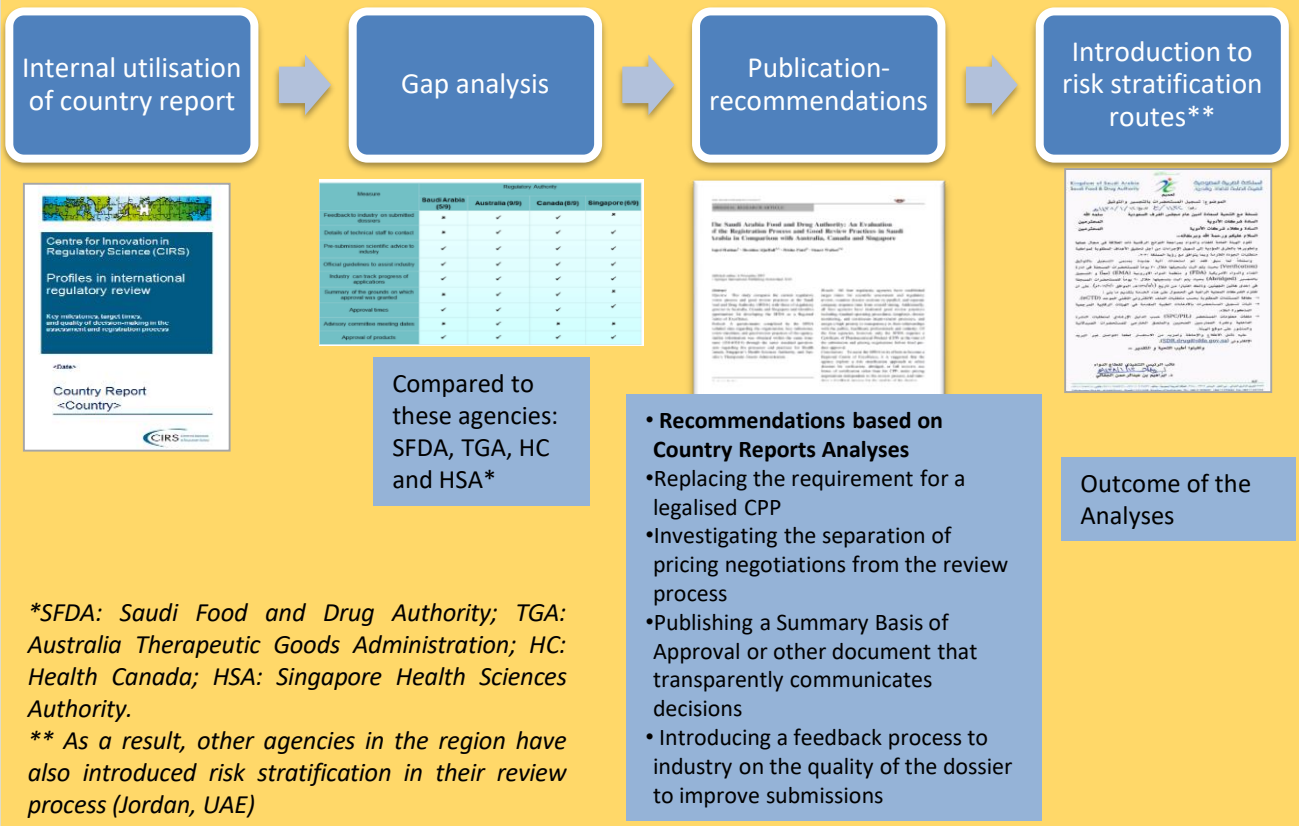
Figure 4. How the country report is produced



Practical Use of the Country Report

The Country Report can be used by the agency internally, cited within publications or to conduct a gap analysis to identify where improvements can be made. Figure 5 is a case study described in "The Saudi Arabia Food and Drug Authority: An Evaluation of the Registration Process and Good Review Practices in Saudi Arabia in Comparison with Australia, Canada and Singapore" (Hashan H., Aljuffali I., Patel P., Walker S. Pharmaceut Med. 2016; 30: 37–47).

Figure 5. Case Study – Saudi Arabia – Gap analysis (in collaboration with agency)



**SFDA: Saudi Food and Drug Authority; TGA: Australia Therapeutic Goods Administration; HC: Health Canada; HSA: Singapore Health Sciences Authority.*

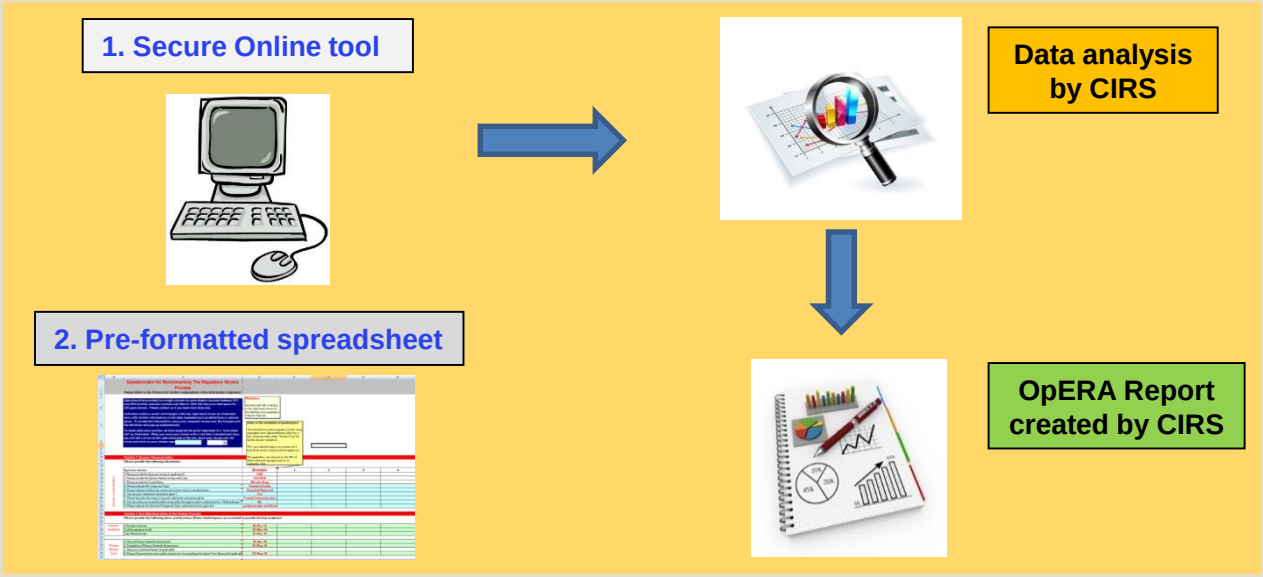
*** As a result, other agencies in the region have also introduced risk stratification in their review process (Jordan, UAE)*

REGULATORY PERFORMANCE METRICS: LINKING THE APPROVAL PROCESS TO METRICS

The product characteristics requested for each submission and key milestone dates are illustrated in Figures 2 and 3 and Table 1. Data can be provided to CIRS by the agency in two ways (Figure 6):

- Via the secure OpERA online data collection portal
- Using a password-protected Excel spreadsheet provided by CIRS

Figure 6. How the metrics report is produced



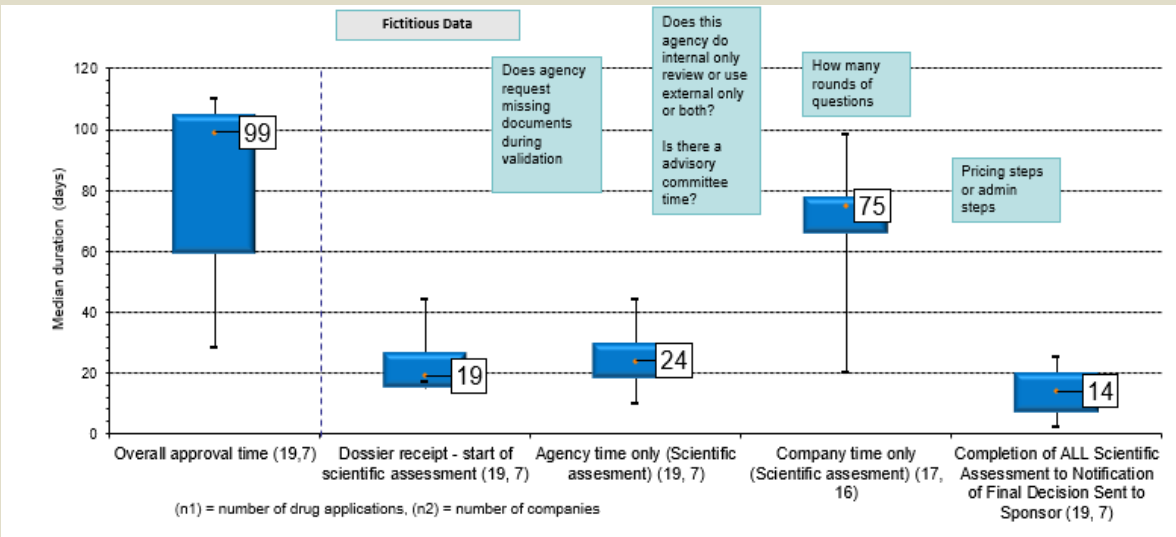
Using the OpERA Metrics Report

The metrics report helps to identify the **major components** of the Regulatory Review and opportunities for **optimisation**. Results can be used **to monitor yearly changes**.

OPERA profiles can help agencies **raise questions on their optimal process** and identify both what is working and what is not in terms of **effectiveness**. Participating agencies can also understand how they **compare** to other agencies doing similar activities, and identify **opportunities for improvement**.

The below analysis with fictitious data (Figure 7) shows the summary of the main components of the review process and their associated timelines. These are outlined using a box and whiskers analysis, with median time and variability of each component.

Figure 7. Summary of Review Process Timeline Components



COUNTRIES COVERED TO DATE

Figure 8 and 9 show countries for which data are included in the OpERA programme.

Figure 8. Countries covered in country reports

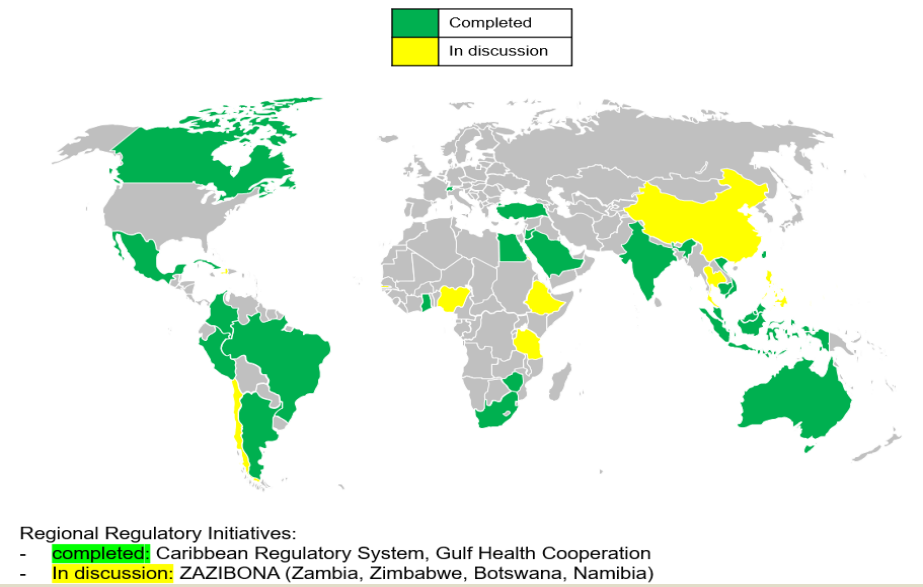
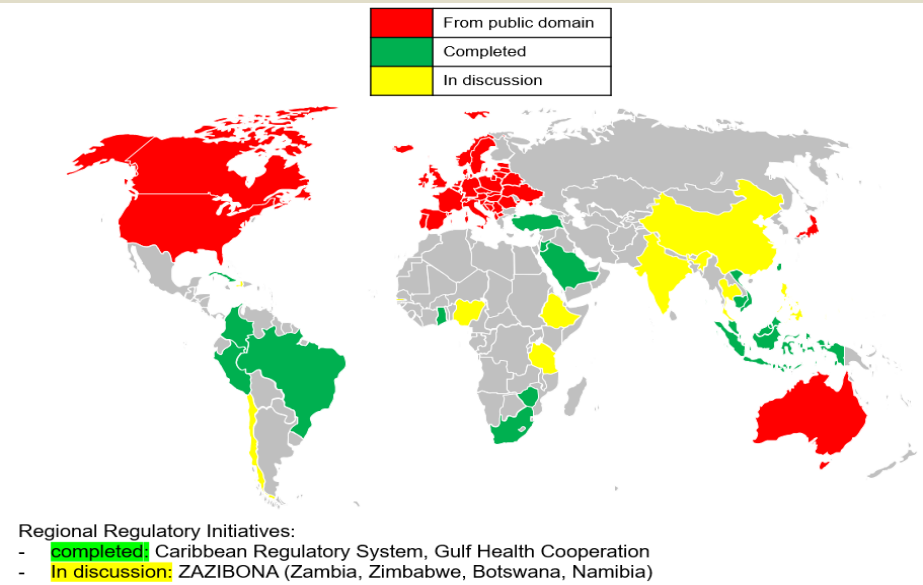


Figure 9. Countries engagement in performance metrics



HOW DOES OpERA COMPARE TO OTHER REGULATORY STRENGHTENING INITIATIVES?

The OpERA Programme is **focused on the details of marketing authorisation activities**. Therefore, it is synergistic with other regulatory strengthening projects, such as the ones listed below with their main objectives:

- **WHO Global Benchmarking Tool**: Evaluates regulatory systems across all functions within an agency
- **AMRH/NEPAD monitoring & evaluation tool:** Provides information for decision-making and program planning
- **Pan American Health Organization (PAHO) Indicators:** For the assessment of core health indicators, health analysis, and other health topics in the national regulatory systems.

OpERA is focused on the **regulatory assessment process** (including decision making and Good Review Practice indicators) and **monitoring the assessment process performance** (Table 1).

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The OpERA programme has been funded by CIRS with the support of a long-term grant from the Bill and Melinda Gates Foundation.

Report date: 08 January 2020

Please cite this report as: CIRS R&D Briefing 74: The OpERA programme: Measuring process and performance in regulatory agencies. Rodier C, Patel P, McAuslane N, Liberti L. 2020. Centre for Innovation in Regulatory Science. London, UK.

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