4th November 2020

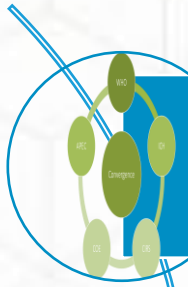
OpERA Initiative: Progressing Regulatory Strengthening in the Asia Region by Identifying Efficient Regulatory Processes

Neil McAuslane
Director
Centre for Innovation in Regulatory Science

Disclaimer

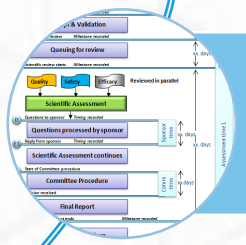
The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to IFPMA, its directors, officers, employees, volunteers, members, chapters, councils, communities or affiliates, or any organization with which the presenter is employed or affiliated.

Presentation - Agenda



Regulatory strengthening- facilitating regulatory pathways

Optimising performance in context

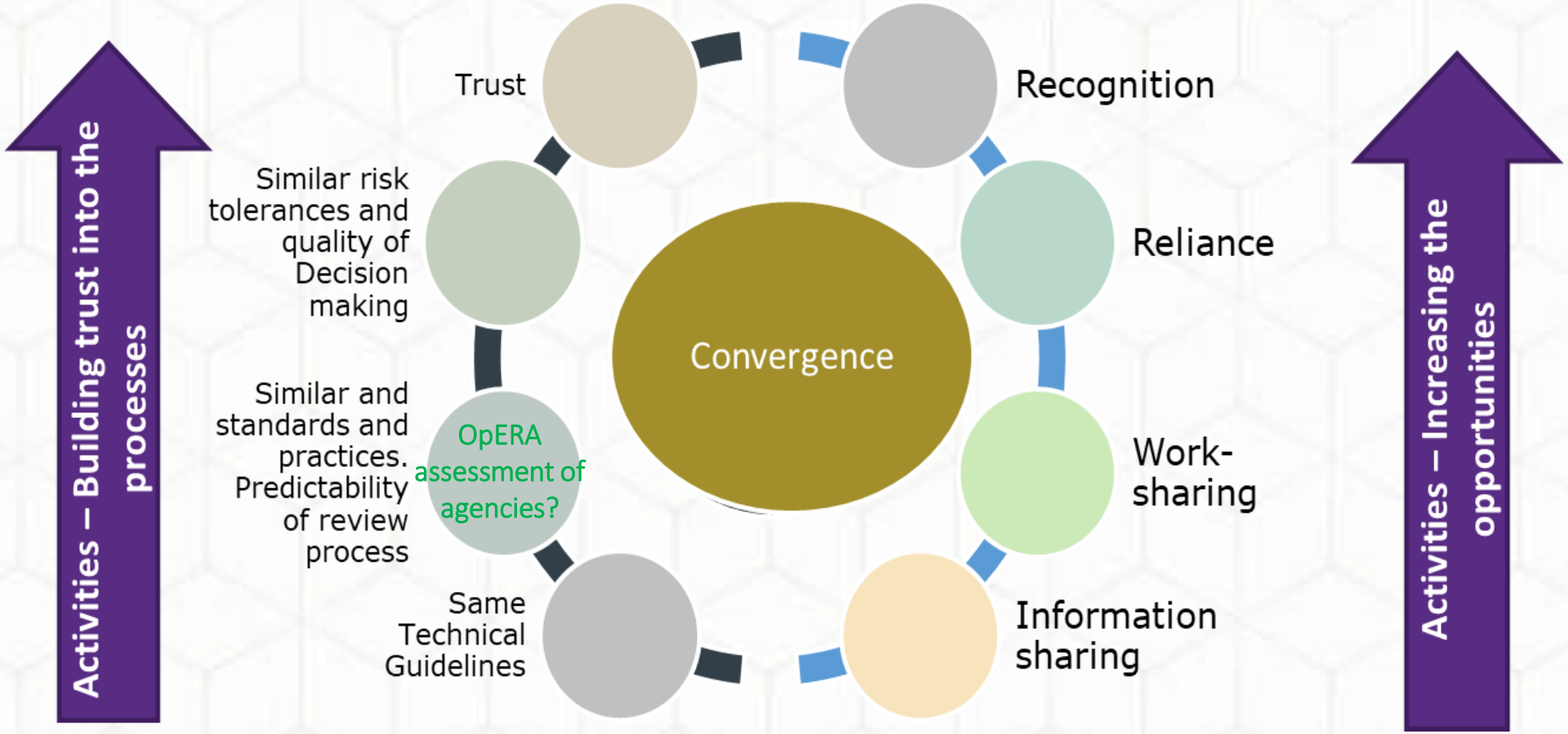


Case studies - progressing regulatory strengthening

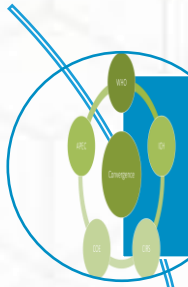
Regulatory Strengthening: Importance for all agencies

- **The role of medicines regulators** - To protect and promote public health.
  - risk-based and smart regulation
  - require to continually review and strengthen
- **National regulatory authorities** have responsibility to ensure :
  - robust regulatory system
  - timely access to innovative, effective and safe therapies,
- **Regulatory strengthening occurs through such activities as:**
  - capacity development within agencies,
  - regulatory convergence across agencies,
  - Reliance and or work sharing amongst agencies,

Enabling Regulatory System Strengthening

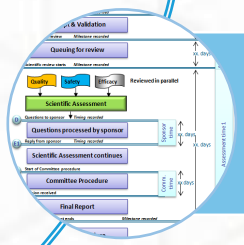


Presentation - Agenda



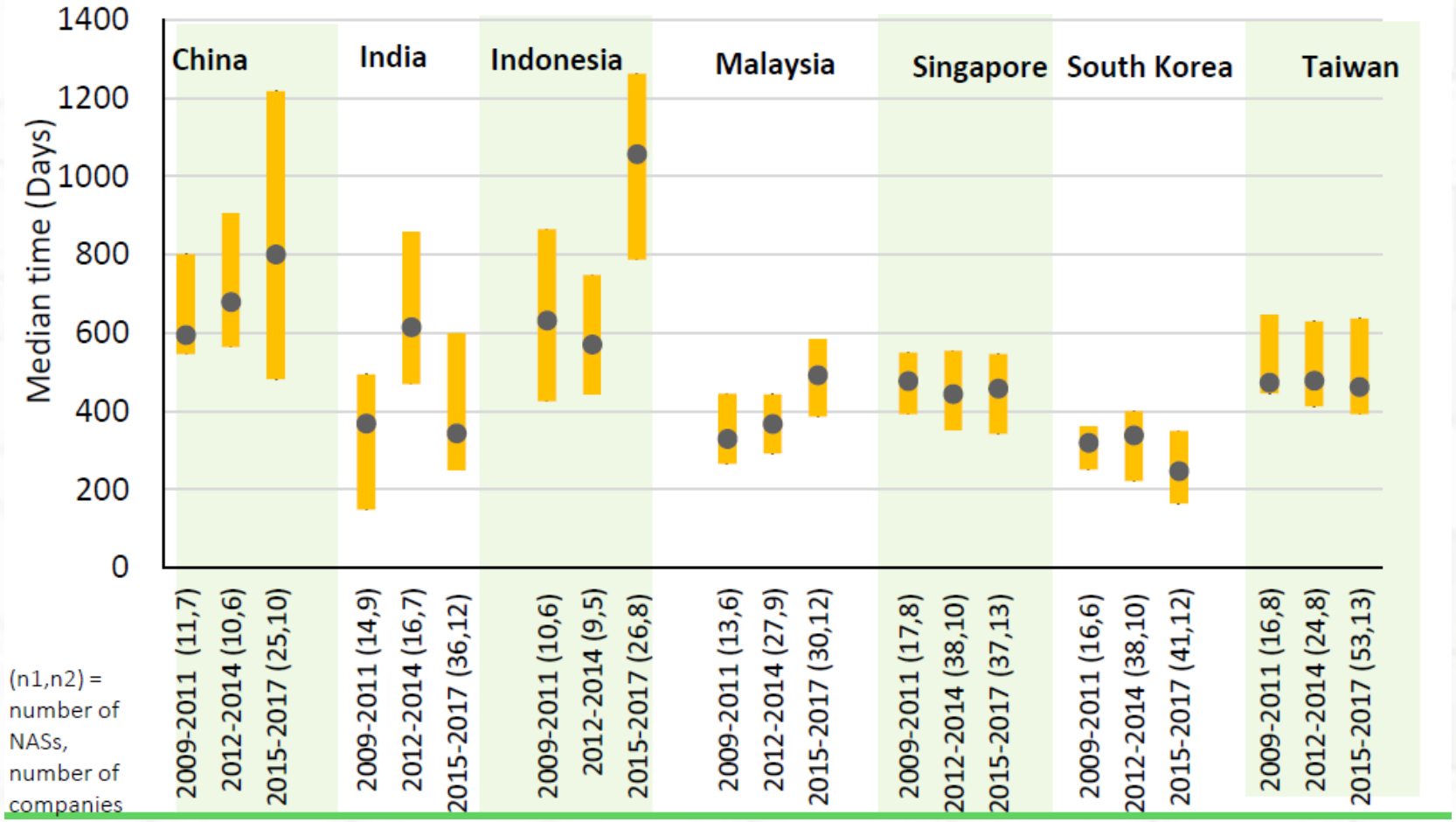
Regulatory strengthening- facilitating regulatory pathways

Optimising performance in context



Case studies - progressing regulatory strengthening

Asia Approval Times 2009-2017
Median, 25 and 75 Percentile



Timelines by themselves provide a crude perspective of Industry and Regulatory Authority performance

Key to understanding and improving is the underlying Regulatory Authority legal mandates, processes practices and capacity (Resources)

Source:: CIRS R&D Briefing 74: The OpERA programme: Measuring process and performance in regulatory agencies. Rodier C, Patel P, McAuslane N, Liberti L. 2019. Centre for Innovation in Regulatory Science. London, UK.

What is the OpERA Programme

A **multi-year** project initiated by CIRS in 2013

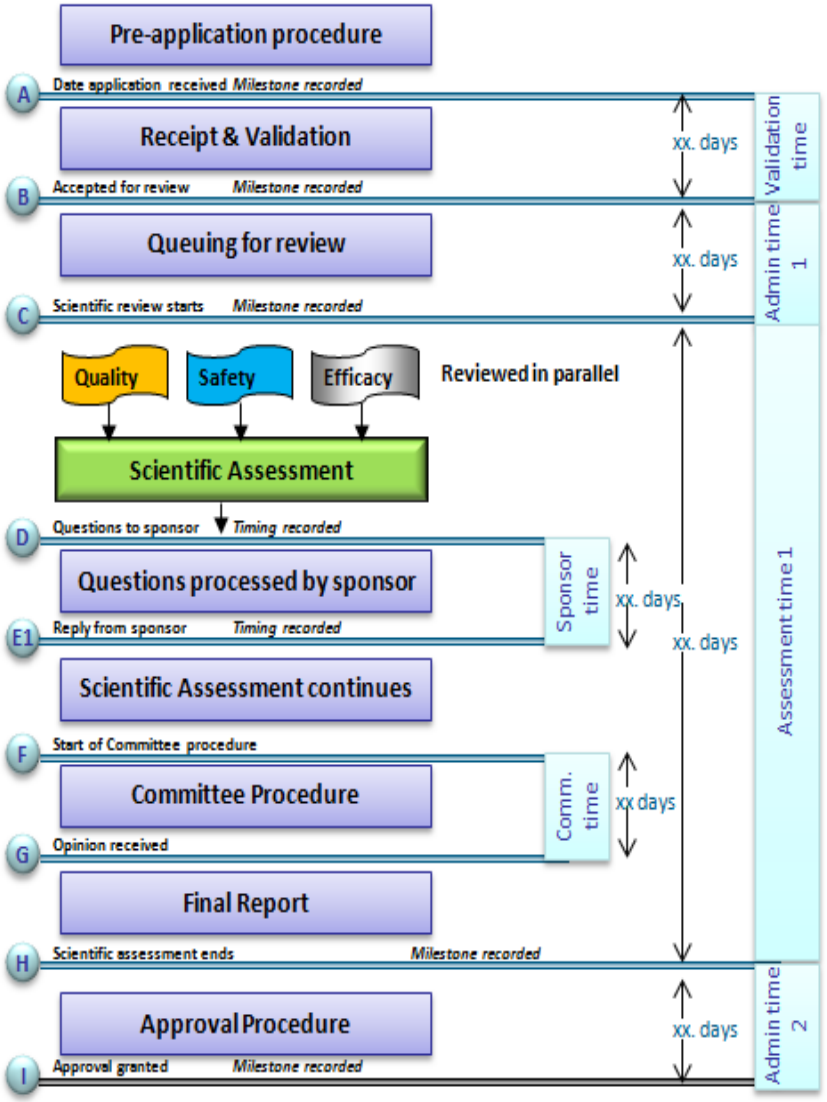
Provides the **tools** that help regulators integrate a practice **of tracking and measuring** regulatory **performances** within their agencies

Is a **global programme**, available to all regulatory agencies irrespective of their size, mission or maturity

The programme is funded by CIRS with the support of long-term grant from the BMGF.

Type of Information Collected – Systematic approach

Performance Metrics – Country Specific



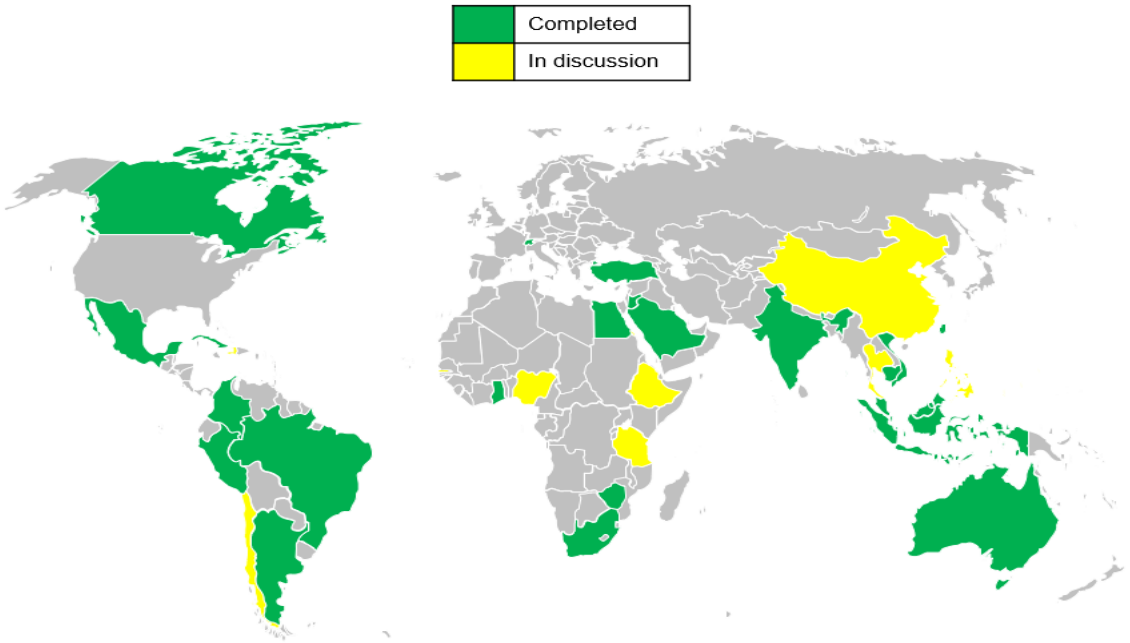
Country Reports – How the Agency Works

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

Source:: CIRS R&D Briefing 74: The OpERA programme: Measuring process and performance in regulatory agencies. Rodier C, Patel P, McAuslane N, Liberti L. 2019. Centre for Innovation in Regulatory Science. London, UK.

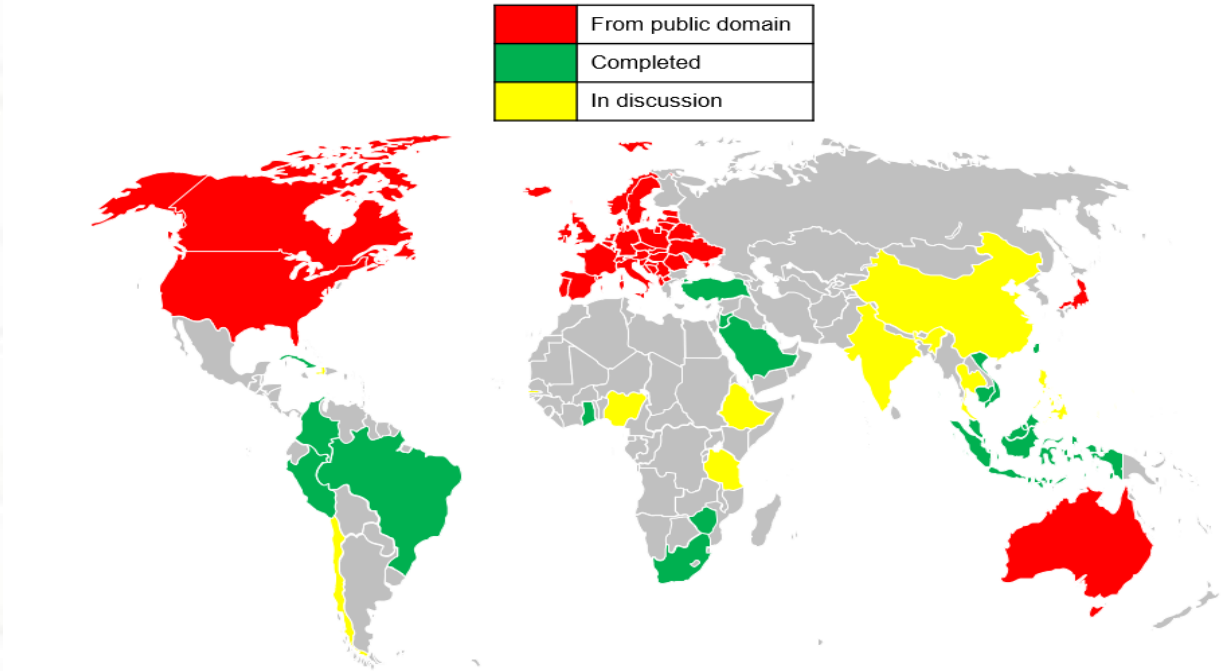
OpERA Data Collection – Status 2019

Countries covered in country reports



Regional Regulatory Initiatives:
- completed: Caribbean Regulatory System, Gulf Health Cooperation
- In discussion: ZAZIBONA (Zambia, Zimbabwe, Botswana, Namibia)

Countries engagement in performance metrics



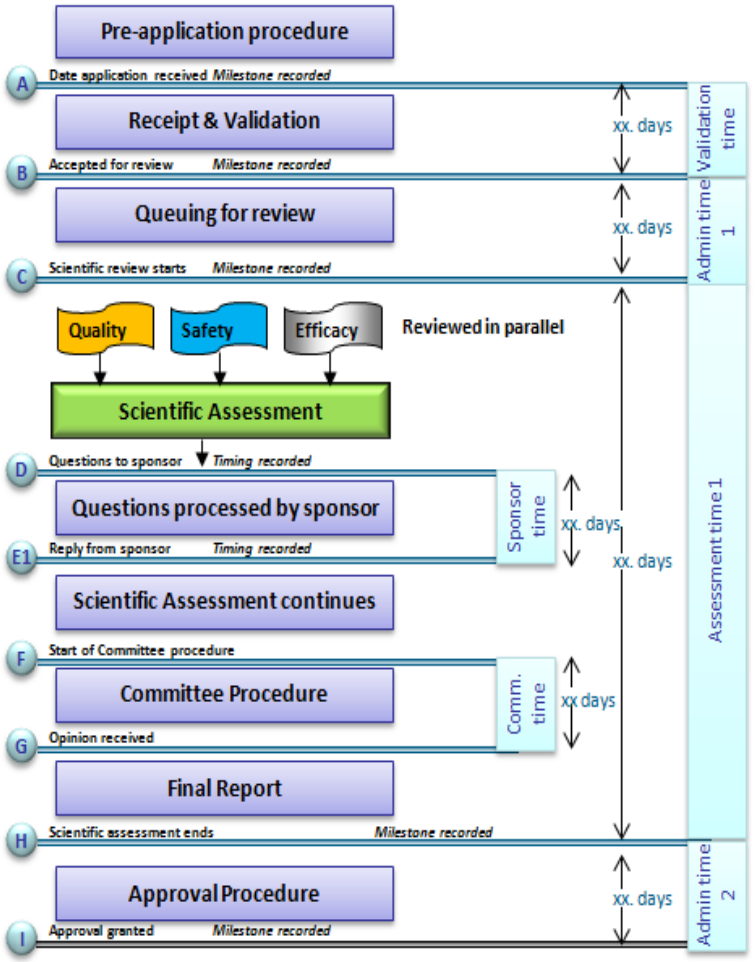
Regional Regulatory Initiatives:
- completed: Caribbean Regulatory System, Gulf Health Cooperation
- In discussion: ZAZIBONA (Zambia, Zimbabwe, Botswana, Namibia)

Source:: CIRS R&D Briefing 74: The OpERA programme: Measuring process and performance in regulatory agencies. Rodier C, Patel P, McAuslane N, Liberti L. 2019. Centre for Innovation in Regulatory Science. London, UK.

OpERA enables questions to be asked where time is spent in the process and why

ASIA REGULATORY CONFERENCE 2020

Performance Metrics



Total Time: How much of this is Agency time – scientific versus administrative and Company Time?

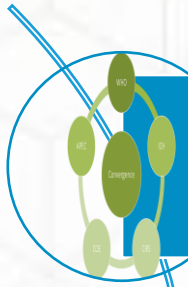
Pick Up time: How much of this is Validation versus Queue? - Quality of submission or resource constraints

Scientific Assessment: Agency time versus company time – Review cycles; External reviewer timelines

Other activities prior to approval; Advisory committees; Label negotiations; Pricing

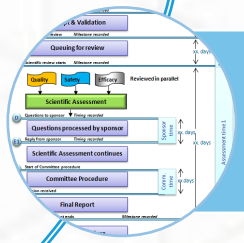
Drivers for time – Capacity issues, redundancy, (in)effective practices

Presentation - Agenda



Regulatory strengthening- facilitating regulatory pathways

Optimising performance in context



Case studies - progressing regulatory strengthening

Case Study- Saudi Arabia – Gap analysis

ASIA REGULATORY CONFERENCE 2020

Internally utilisation of country report → Gap analysis → Publication- recommendations → Introduction to risk stratification routes

SFDA, TGA, HC and HSA

Measure	Regulatory Authority			
	Saudi Arabia (5/9)	Australia (9/9)	Canada (8/9)	Singapore (6/9)
Feedback to industry on submitted dossiers	✗	✓	✓	✗
Details of technical staff to contact	✗	✓	✓	✓
Pre-submission scientific advice to industry	✓	✓	✓	✓
Official guidelines to assist industry	✓	✓	✓	✓
Industry can track progress of applications	✓			
Summary of the grounds on which approval was granted	✗			
Approval times	✓			
Advisory committee meeting dates	✗			
Approval of products	✓			

Pharm Med (2016) 30:37-47
DOI 10.1007/s40290-015-0124-4

ORIGINAL RESEARCH ARTICLE

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

Hajed Hashan[1] · Ibrahim Aljuffali[2,3] · Prisha Patel[4] · Stuart Walker[5,6]

Published online: 6 November 2015
© Springer International Publishing Switzerland 2015

Abstract

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

الموضوع: تسجيل المستحضرات بالتجسير والتوثيق

سلمه الله
السادة شركات الأدوية المحترمين
السادة وكلاء شركات الأدوية المحترمين

السلام عليكم ورحمة الله وبركاته،،،

وتقبلوا أطيب التحية و التقدير ،،،

نائب الرئيس التنفيذي لقطاع الدواء
د. ابراهيم بن عبدالرحمن الجفالي

- **Exploring a risk-stratification approach**
- Replacing the requirement for a legalised CPP
- Investigating the separation of pricing negotiations from the review process
- Publishing a Summary Basis of Approval or other document that transparently communicates decisions
- Introducing a feedback process to industry on the quality of the dossier to improve submissions

Saudi: Oct 2016
Egypt: Nov 2016
Jordan: Feb 2017
UAE: Jan 2018

Case Study – Agency Utilisation of Milestone data

NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH MALAYSIA

ANVISA

Process identification and improvement

- Identify key milestones in the approval process and time spent for each step- **NAS approved 2017**
- **Areas identified by agency**
  - Late start of scientific review
  - no. of correspondence to applicant delayed the approval
  - Applicant taking too long to provide complete response
- **Informed measures for improvement**
  - Target time for scientific assessment after filing – no more than 100 days
  - Reduction in number of cycles </ 5
  - Maximum duration of applicant response time- 6 months
- Set a baseline to measure change

Supporting policy change – delivering policy needs

- Compare timelines with those of other regulatory agencies,
- Comparative data used to establish strategic plans,
- to improve the timelines of specific types of products
- evaluate the success of facilitated pathways established in 2017.
- These data have been used to justify ANVISA results to Congress and citizens

Case studies to describe involvement in Optimising Efficiencies in Regulatory Agencies (OpERA), what has been learned and how this is informing change – Presented at the CIRS workshop Singapore 2019

OpERA Methodology Published

Therapeutic Innovation & Regulatory Science (2020) 54:1215–1224
https://doi.org/10.1007/s43441-020-00140-4

DIA

ORIGINAL RESEARCH

An Evaluation of Malaysian Regulatory Process for New Active Substances Approved in 2017 Using the OpERA Methodology

Noraisyah Mohd Sani, MSc, B. Pharmacy (Hon)[1] · Neil McAuslane, PhD[2] · Siti Hidayah Ka... (Hon)[1] · Rosilawati Ahmad, MSc, B. Pharmacy (Hon)[1] · Faridah Aryani Md. Yusof, PhD, M... Prisha Patel, MSc[2]

Received: 20 February 2020 / Accepted: 4 March 2020 / Published online: 28 March 2020
© The Author(s) 2020

Abstract

Introduction The National Pharmaceutical Regulatory Agency (NPRA) embarked on a regulat... is evaluating its processes. Optimising Efficiencies in Regulatory Agencies (OpERA) is a reg... that provides benchmarking data that can define performance targets and focus performance ... this study was to use OpERA methodology to determine where time is spent in the NPRA a... baseline to measure the performance improvements.

Methods The OpERA tool was used to collect specific milestone data that identify time pe... points for new active substances and biosimilars approved by NPRA in 2017.

Results In 2017, 25 new active substances and 1 biosimilar were approved by NPRA in a me... both agency and applicant time. The median time between dossier receipt and the initiation ... was 135 days, but there was a wide variation in queuing time. The median total assessment t... applicant timing). NPRA took a median of 166 days; applicants took a median of 131 days ...

https://link.springer.com/article/10.1007/s43441-020-00140-4

Therapeutic Innovation & Regulatory Science
https://doi.org/10.1007/s43441-020-00169-5

DIA

ORIGINAL RESEARCH

A Baseline Analysis of Regulatory Review Timelines for ANVISA: 2013–2016

Prisha Patel, MSc[1] · Daniela Marreco Cerqueira, PhD[2] · Gustavo Mendes Lima Santos, MSc[2] · Renata de Lima Soares, PGDip[2] · Varley Dias Sousa, PhD[2] · Lawrence Liberti, PhD[1] · Neil McAuslane, PhD[1]

Received: 22 January 2020 / Accepted: 18 May 2020
© The Author(s) 2020

Abstract

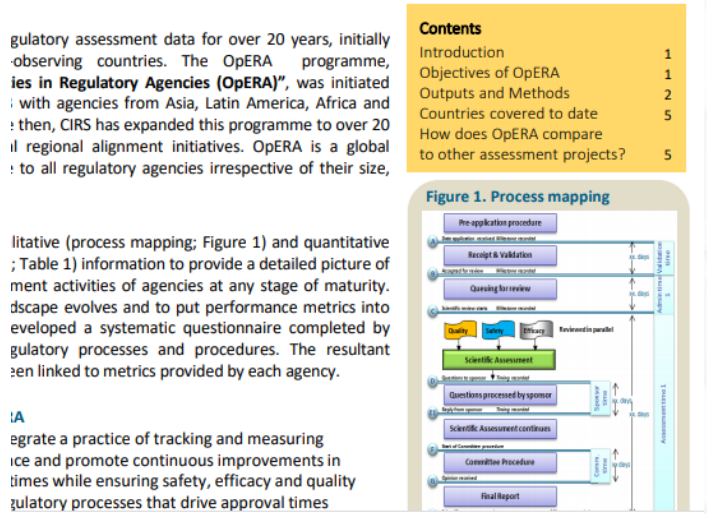
Background The Brazilian health regulatory agency (Agência Nacional de Vigilância Sanitária, ANVISA) has embarked on transformational initiatives to fulfill its mandate to provide timely access to safe, effective, and quality therapeutics. A new Brazilian law was enacted to provide the agency with greater flexibility. Optimizing Efficiencies in Regulatory Agencies (OpERA) is a regulatory-strengthening program that seeks to provide benchmarking data that can be used to define performance targets and focus performance improvement. The objective of this study was to use OpERA methodology to undertake a retrospective analysis of the timelines associated with important components of the ANVISA regulatory review process to establish a baseline against which the influence of the new law could be measured.

Methods The OpERA tool was used to collect specific milestone data that identify time periods, review stages, and data points for products approved by ANVISA 2013–2016.

Results For the 138 products approved in this cohort, the overall median approval time was 795 days. ANVISA and submitting companies will need to reduce their review and response times by approximately half in order to meet the total time goal of 365 days.

https://link.springer.com/article/10.1007%2Fs43441-020-00169-5

Measuring process and performance in regulatory agencies:
The OpERA Programme



Contents

Introduction 1
Objectives of OpERA 1
Outputs and Methods 2
Countries covered to date 5
How does OpERA compare to other assessment projects? 5

gulatory assessment data for over 20 years, initially observing countries. The OpERA programme, ies in Regulatory Agencies (OpERA)", was initiated with agencies from Asia, Latin America, Africa and then, CIRS has expanded this programme to over 20 l regional alignment initiatives. OpERA is a global to all regulatory agencies irrespective of their size,

litative (process mapping; Figure 1) and quantitative ; Table 1) information to provide a detailed picture of ment activities of agencies at any stage of maturity. dscape evolves and to put performance metrics into eveloped a systematic questionnaire completed by gulatory processes and procedures. The resultant en linked to metrics provided by each agency.

egrate a practice of tracking and measuring ice and promote continuous improvements in times while ensuring safety, efficacy and quality gulatory processes that drive approval times

Figure 1. Process mapping

https://www.cirsci.org/wp-content/uploads/2020/02/CIRS-RD-Briefing-74-OpERA-programme.pdf

OpERA: Progressing Regulatory Strenthening in the Asia Region by Identifying Efficient Regulatory Processes .

Asia Facilitated Regulatory Pathways

	Verification route	Abridged route	Priority review	Expedited/ rolling submission	Conditional approval
China			■		
India					
Indonesia		■			
Malaysia	■	■			
Philippines					
Singapore	■	■			
South Korea			■	■	■
Chinese Taipei		■	■		
Thailand		■			
Vietnam			■		

OpERA Current Status - Asia

- Chinese Taipei, Malaysia and Singapore – monitoring timelines – assessing change
- Indonesia, Vietnam – Workplan in discussion
- Philippines, Thailand and China – in discussion

Source:: CIRS R&D Briefing 74: The OpERA programme: Measuring process and performance in regulatory agencies. Rodier C, Patel P, McAuslane N, Liberti L. 2019. Centre for Innovation in Regulatory Science. London, UK.

Conclusion

- Regulatory System Strengthening and convergence is imperative for all agencies irrespective of maturity
- **Agencies in Asia are proactively evaluating and strengthening the review process** through a number of approaches
  - Initiation of formal reliance pathways
  - Evaluating their process through a number of activities including OpERA
- The OpERA system provides agencies a **simple systematic structured starting point** to assess key granular milestones and agency process. Agencies are using it to:
    - help optimise their review process and measure implemented changes
    - compare and learn off other agencies
    - provide agencies with factual results that can be used to convey their mission and needs to policy makers.

Terima Kasih
Thank you!

#ARC2020

10th Asia Regulatory Conference 2020

Building Trust & Partnership to Deliver UHC in Asia