

Building National Regulatory Capacities: Bridging Gaps with the WHO Global Benchmarking Tool

April 21, 2020

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USAID MEDICINES,
TECHNOLOGIES, AND
PHARMACEUTICAL SERVICES
(MTaPS) PROGRAM

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Building National Regulatory Capacities: Bridging Gaps with the WHO Global Benchmarking Tool

April 21, 2020

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Special Guest

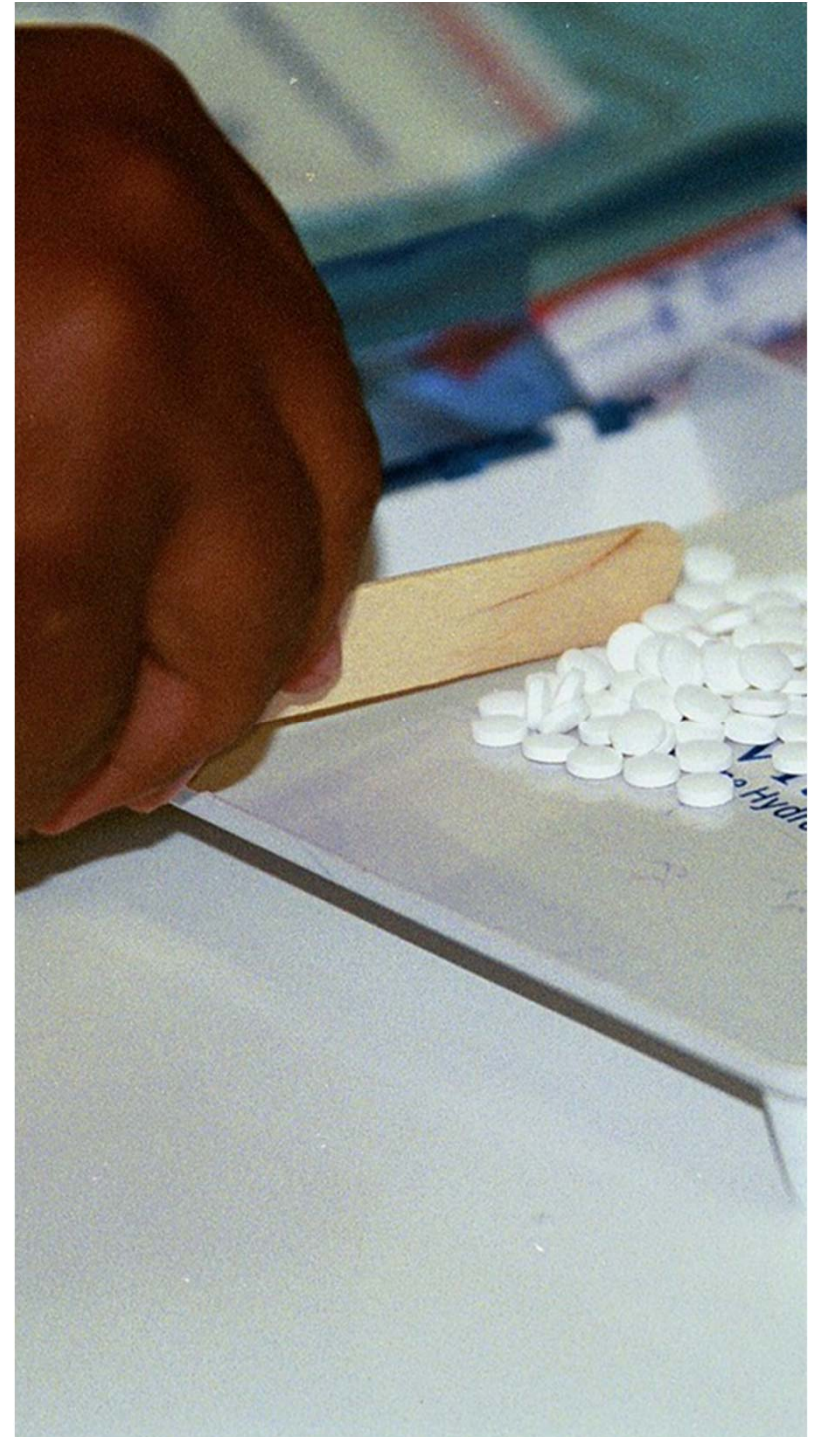
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Presentation Outline

- Why Regulation is an Essential Public Health Need?
- WHO Response, including the Coalition of Interested Partners (CIPs)
- What is WHO's Global Benchmarking Tool (GBT) for Evaluating Regulatory Systems?
- GBT Benchmarking Process
- GBT Outcomes
- Country Examples
- Conclusion



Why Regulation is an Essential Public Health Need?



SDG – 3.8

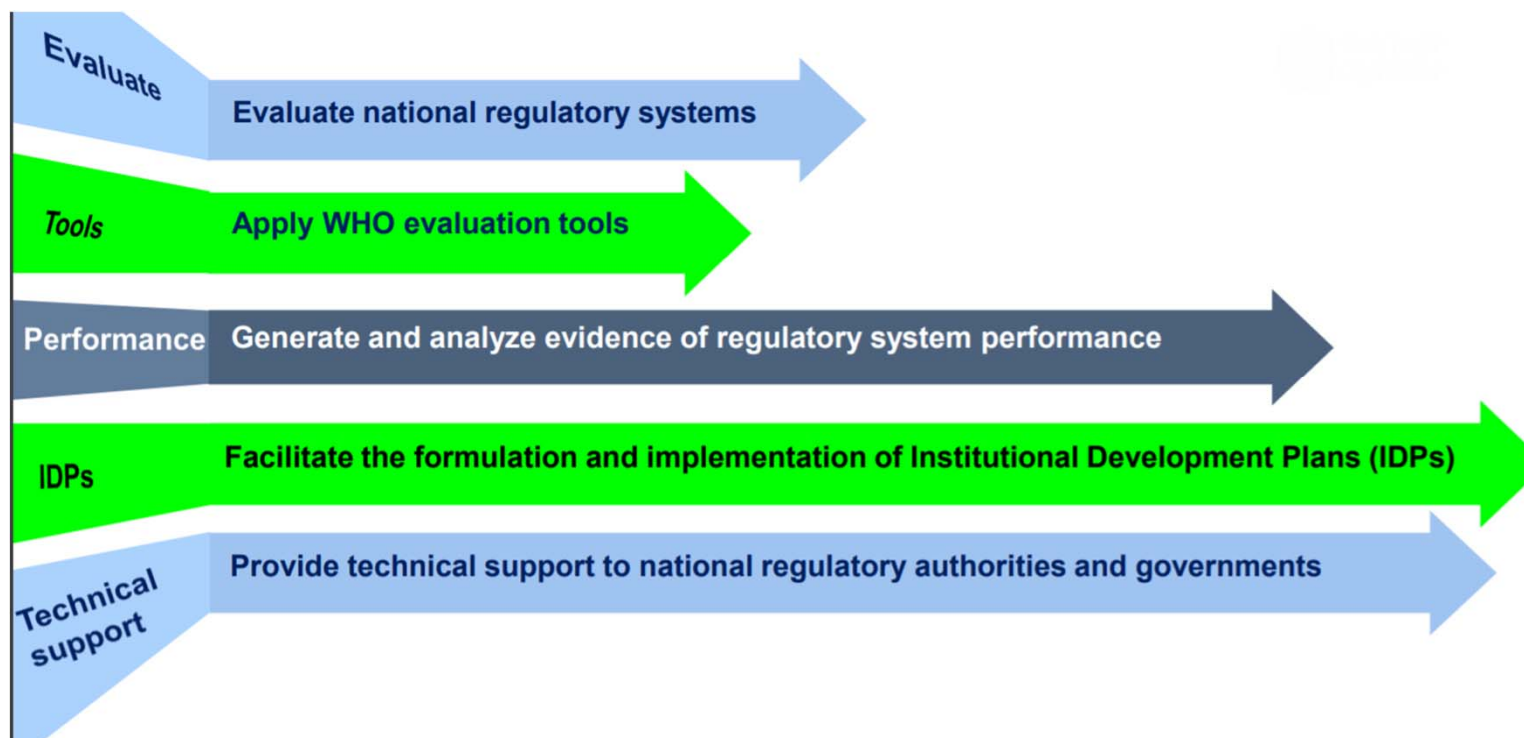
Achieve universal health coverage, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all

- Only 30% of National Regulatory Authorities (NRAs) had the capacity to regulate medical products on their markets in 2018
- At least one in ten medical products are substandard or falsified
- For health services to improve health outcomes and not cause harm, quality, safe, and effective medical products are needed
- Functioning NRAs are vital to achieving USAID goals

Sources: WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products and WHO's five-year plan to help build effective and efficient regulatory systems 2019–2023

WHO Response, including the Coalition of Interested Partners (CIPs)

- WHO mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products
- Supporting Member States to:



WHO National Regulatory Authorities Global Benchmarking Tool (GBT) and pathway for regulatory systems strengthening

What is WHO's Global Benchmarking Tool (GBT) for Evaluating Regulatory Systems?

First globally agreed-upon tool and methodology to objectively evaluate regulatory systems, formulate development plans, build capacity, and monitor achievements

Features:

- Indicator-based maturity benchmarking across 9 regulatory functions (maturity level 1=low, maturity level 4=high)
- Institutional Development Plan (IDP) allows for coordinated support
- GBT Revision VI published in Dec 2018
- Current scope: medicines and vaccines; inclusion of medical devices and blood products in progress
- Available in English, French, Spanish, and soon Russian

WHO National Regulatory Authorities Global Benchmarking Tool (GBT) and pathway for regulatory systems strengthening

Global Benchmarking Tool Modules



Home Health Topics ▾ Countries ▾ Newsroom ▾ Emergencies ▾

Essential medicines and health products

- Medicines and health products
- About us
- Access and innovation
- Regulation**
- Publications
- News
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WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems

Regulatory systems play a key role in assuring the quality, safety, and efficacy of medical products. Effective regulatory systems are an essential component of health systems and contribute to desired public health outcomes and innovation.

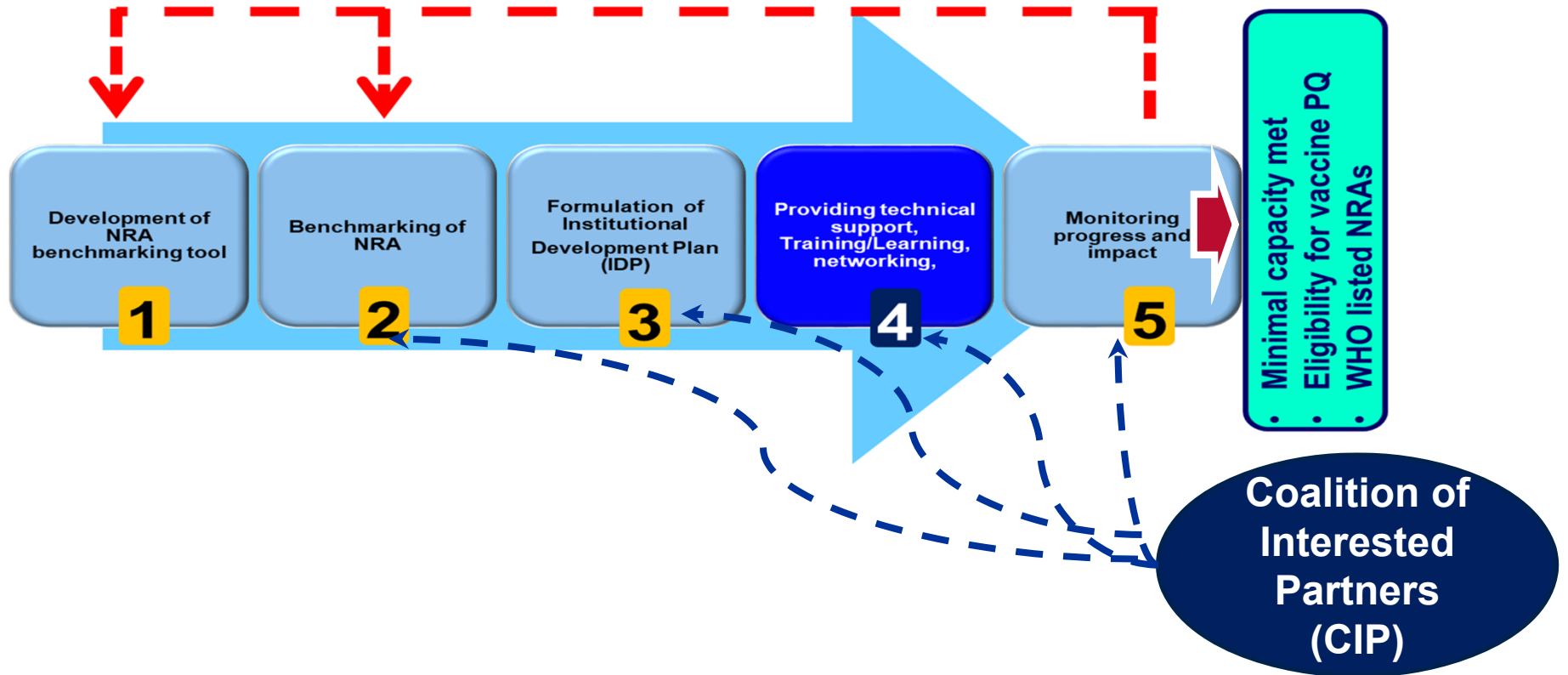
The Global Benchmarking Tool (GBT) represents the primary means by which the WHO objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The tool and benchmarking methodology enables the WHO and regulatory authorities to:

- identifies strengths and areas for improvement;
- facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps;
- prioritize IDP interventions; and
- monitor progress and achievements.

The World Health Organization (WHO) began assessing regulatory systems in 1997 using a set of indicators designed to evaluate the regulatory programme for vaccines. Since that time, a number of tools and revisions were introduced. In 2014 work began on the development of a unified tool for evaluation medicines and vaccines regulatory

- ↓ National Regulatory Systems (RS) fact sheet pdf, 1.37Mb
- ↓ Registration and Marketing Authorization (MA) fact sheet pdf, 1.09Mb
- ↓ Vigilance (VL) fact sheet pdf, 1.01Mb
- ↓ Market Surveillance and Control (MC) fact sheet pdf, 1.02Mb
- ↓ Licensing Establishments (LI) fact sheet pdf, 938kb
- ↓ Regulatory Inspection (RI) fact sheet pdf, 1.03Mb
- ↓ Laboratory Testing (LT) fact sheet pdf, 1.02Mb
- ↓ Clinical Trials Oversight (CT) fact sheet pdf, 1.03Mb
- ↓ NRA Lot Release (LR) factsheet pdf, 911kb

WHO Five-Step Capacity Building Model for National Regulatory Authorities (NRAs)



Coalition of Interested Partners (CIP)

- Global coordination effort led by WHO, with partners including Gates Foundation
- First started in Bangladesh in 2016
- Aims to coordinate support of development agencies to achieve effective regulatory strengthening in countries
- Voluntary participation of partners
- Partners may be state or non-state actors
- USAID and both MTaPS and PQM+ participate in the CIP


Benefits of GBT and CIP to Regulatory Systems

- Is globally accepted
- Offers systematic approach to assess regulatory capacity, including key regulatory functions
- Establishes a formal plan to build upon strengths and address the identified gaps, encouraging continuous improvement
- Builds trust, confidence and reliance – efficient use of regulatory resources
- Supports regulatory systems with NMRA at the driver's seat without duplication of effort from development partners

GBT Benchmarking Process in Countries

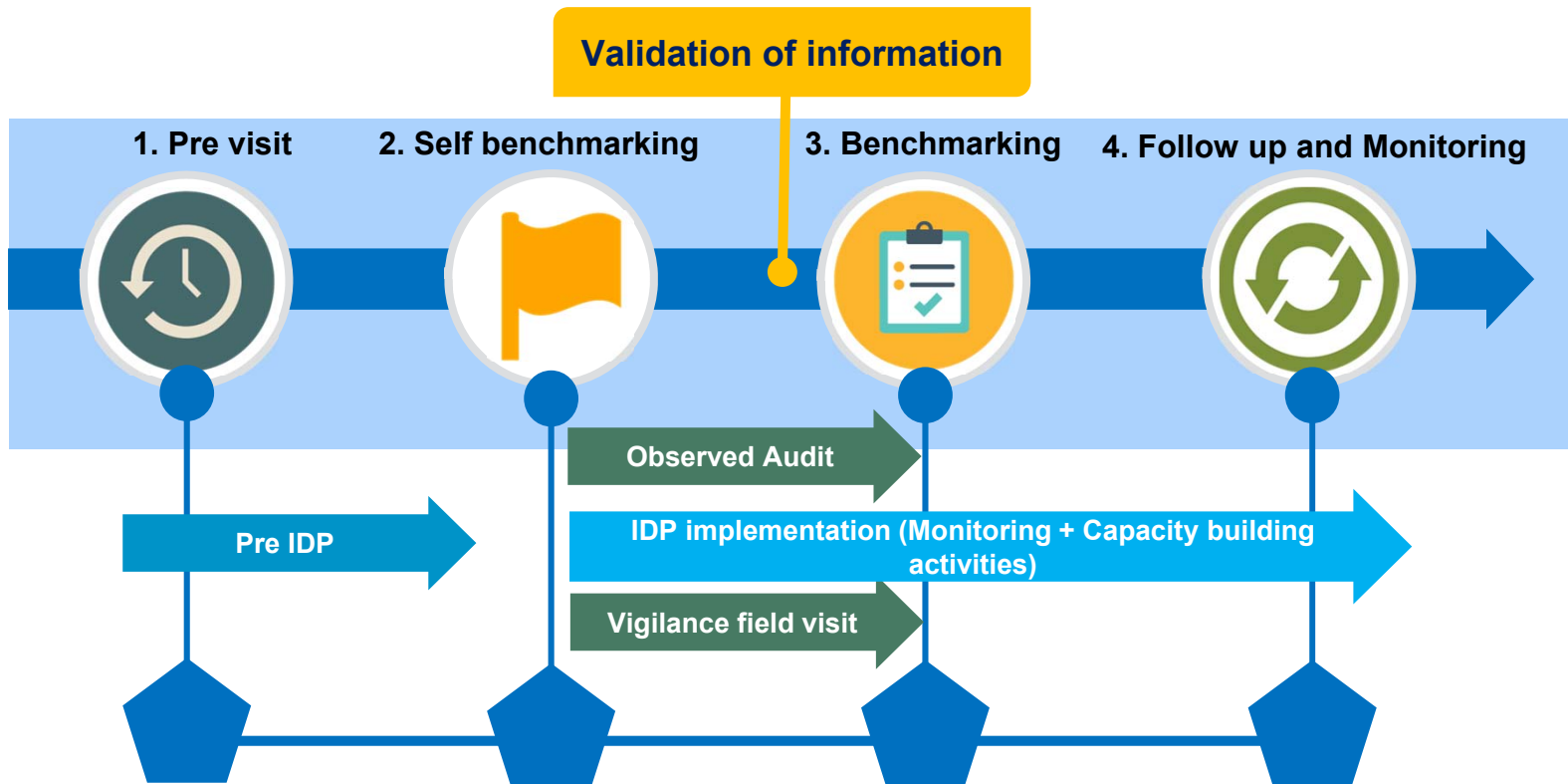


▶ Self benchmarking

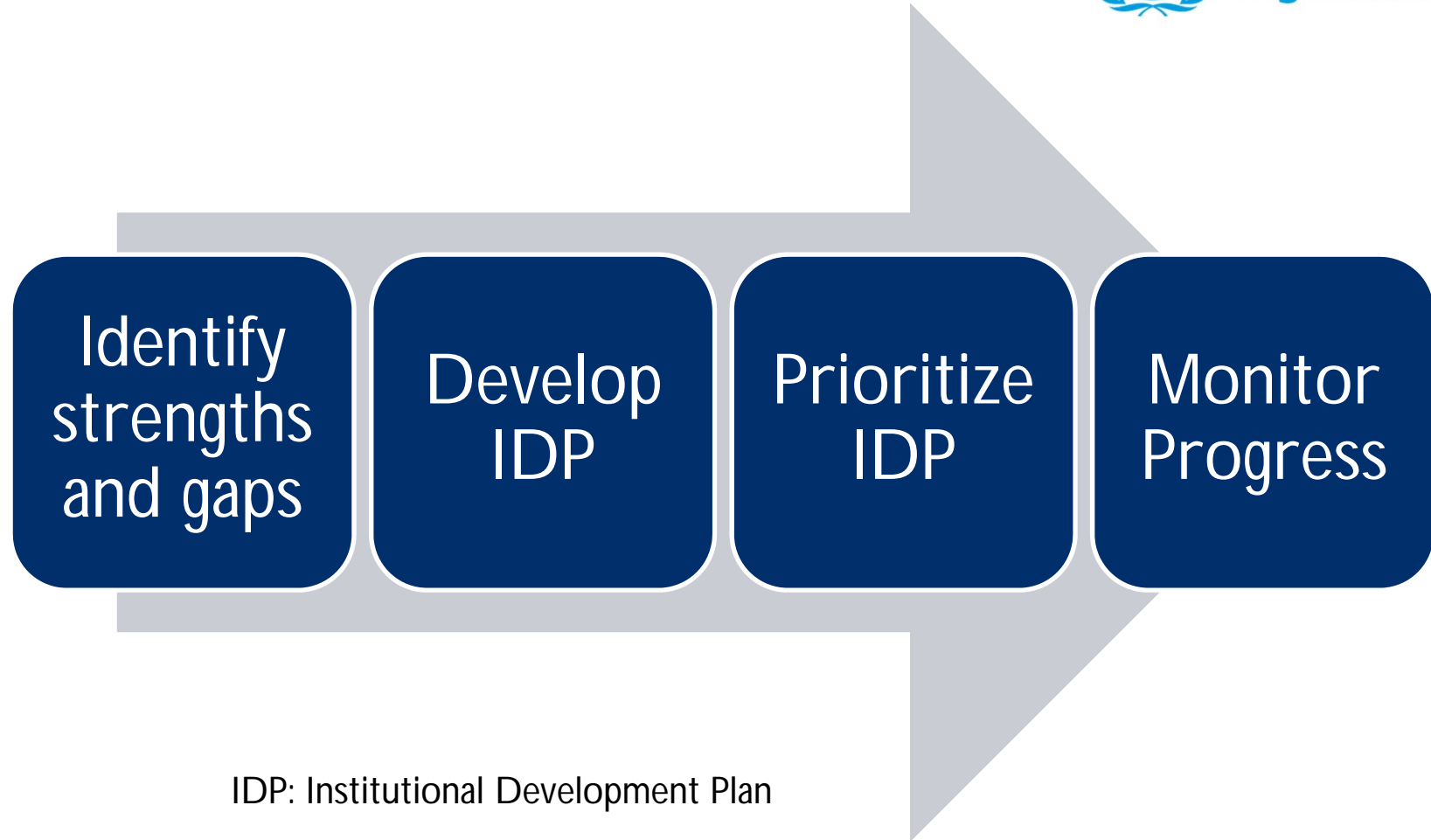


▶ Formal benchmarking

GBT Benchmarking Process

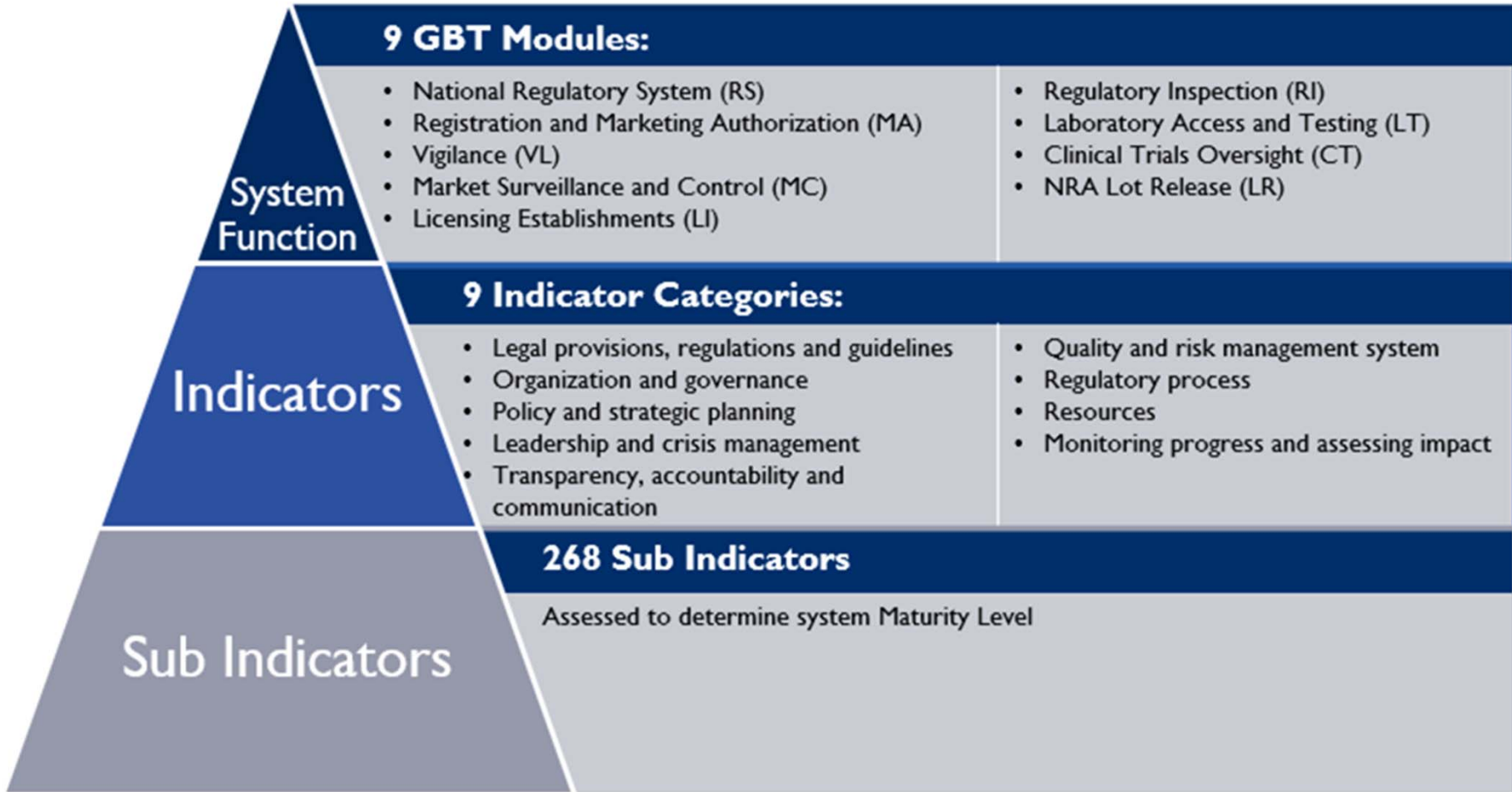


GBT Benchmarking Process



IDP: Institutional Development Plan

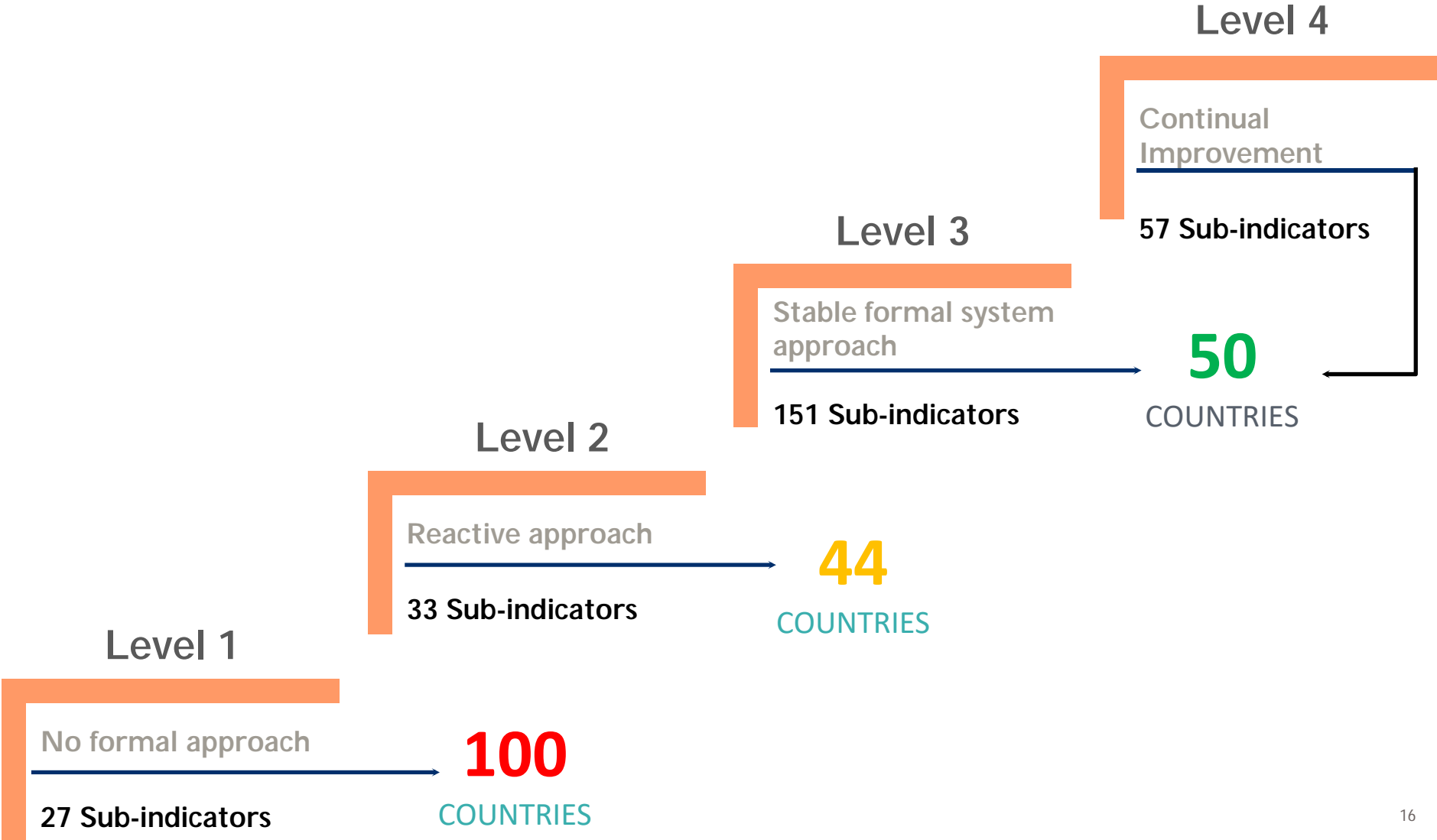
What GBT Assesses?



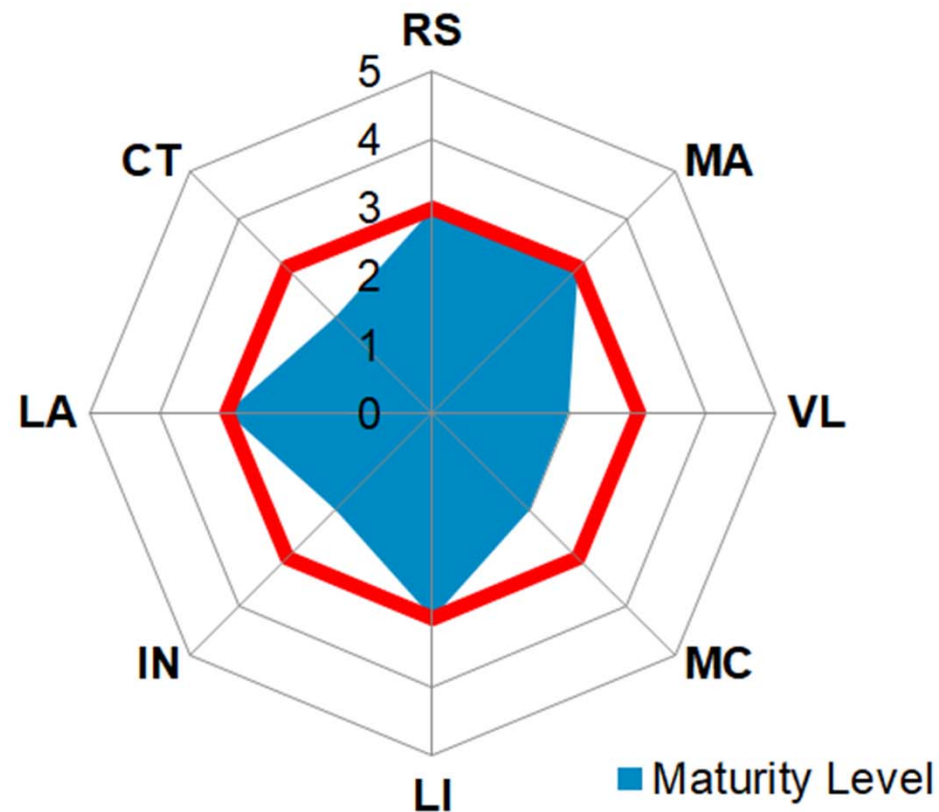
Global Benchmarking Tool Sub-Indicators

Indicator Categories	Regulatory Systems (RS)	Marketing Auth (MA)	Vigilance (VL)	Market Surv. & Control (MC)	Licensing (LI)	Regulatory Inspection (RI)	Laboratory Testing (LT)	Clinical Trials (CT)	Lot Release (LR)	Grand Total
Leadership and crisis management	5									5
Legal provisions, regulations and guidelines	9	13	7	7	5	5	2	11	2	61
Monitoring progress and assessing impact	2	2	2	3	2	5	4	4	4	28
Organization and governance	4	2	2	2	2	2	2	2	2	20
Policy and strategic planning	5						7			12
Quality and risk management system	14									14
Regulatory process		10	8	8	4	6	6	7	3	52
Resources	12	4	4	4	4	4	6	4	4	46
Transparency, accountability, communication	9	4	3	3	2	4	1	2	2	30
Grand Total	60	35	26	27	19	26	28	30	17	268

Global Benchmarking Tool Maturity Levels



Result from GBT: Visualizing Regulatory Capa



WHO National Regulatory Authorities Global Benchmarking Tool (GBT) and pathway for regulatory systems strengthening
Ref: Slide from WHO presentation

Sample Country Status

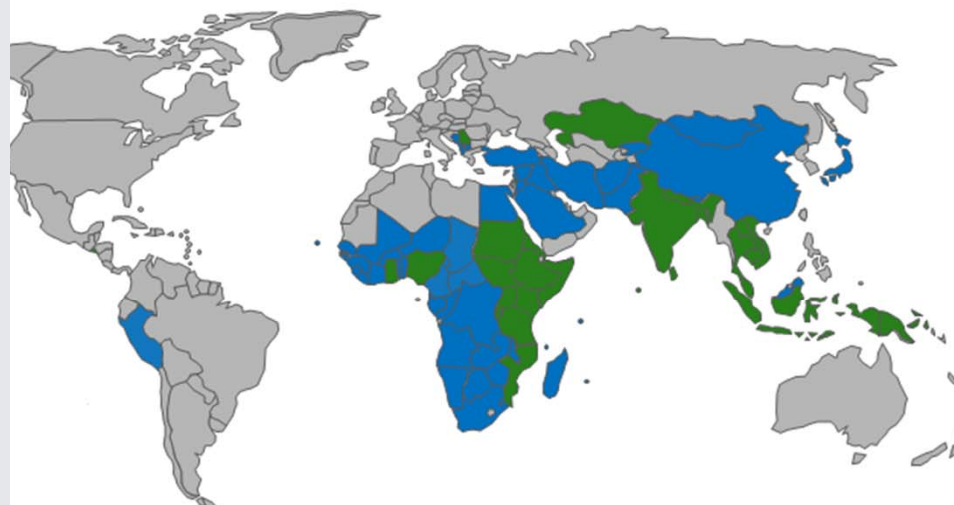
NRA Function	Country A May 2019	Country B August 2019	Country C Nov 2018
National Regulatory System (RS) 9 Legal indicators	1	1	1
Registration and Marketing Authorization (MA) 13 Legal indicators	2	2	1
Vigilance (VL) 7 Legal indicators	1	1	1
Market Surveillance and Control (MC) 7 Legal indicators	1	1	1
Licensing Establishment (LI) 5 Legal indicators	2	1	1
Regulatory Inspection (RI) 5 Legal indicators	2	1	1
Laboratory Testing (LT) 2 Legal indicators	1	1	1
Clinical Trials Oversight (CT) 11 Legal indicators	1	1	1
NRA Lot Release (LR) 2 Legal indicators		1	

Globally, 82 Countries Benchmarked with GBT (2016-2020)



Self Benchmarking

- | | |
|------------------------------|-----------------------|
| 1. Afghanistan | 29. Kyrgyzstan |
| 2. Albania | 30. Lebanon |
| 3. Angola | 31. Liberia |
| 4. Benin | 32. Madagascar |
| 5. Bhutan | 33. Malawi |
| 6. Bosnia and Herzegovina | 34. Malaysia |
| 7. Botswana | 35. Maldives |
| 8. Burkina Faso | 36. Mali |
| 9. Cameroun | 37. Mauritius |
| 10. Cape Verde | 38. Mongolia |
| 11. Central African Republic | 39. Montenegro |
| 12. Chad | 40. Namibia |
| 13. China | 41. Nepal |
| 14. Comoros | 42. Niger |
| 15. Congo DR | 43. North Macedonia |
| 16. Cote d'Ivoire | 44. Pakistan |
| 17. Djibouti | 45. Peru |
| 18. Egypt | 46. Republic of Congo |
| 19. Equatorial Guinea | 47. Saudi Arabia |
| 20. Eswatini | 48. Senegal |
| 21. Gabon | 49. Seychelles |
| 22. Gambia | 50. Sierra Leone |
| 23. Guinea | 51. South Africa |
| 24. Guinea-Bissau | 52. Syrian Arab Rep. |
| 25. Iraq | 53. Togo |
| 26. Islamic Rep. of Iran | 54. Turkey |
| 27. Japan | 55. Zambia |
| 28. Jordan | 56. Zimbabwe |



Benchmarking

1. Bangladesh
2. Burundi
3. Cambodia
4. El Salvador
5. Eritrea
6. Ethiopia
7. Ghana
8. India
9. Indonesia
10. Kazakhstan
11. Kenya
12. Lao People's Dem Rep
13. Mozambique
14. Nigeria
15. Papua new guinea
16. Rwanda
17. Serbia
18. Somalia
19. South Sudan
20. Sri Lanka
21. Sudan
22. United Rep. of Tanzania
23. Thailand
24. Timor-Leste
25. Uganda
26. Vietnam

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization (WHO) concerning the legal status of any country, territory, city or area of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on map represent approximate border lines for which there may be not yet be full agreement.

In Africa, 47 Countries Benchmarked with GBT (2016-2020)

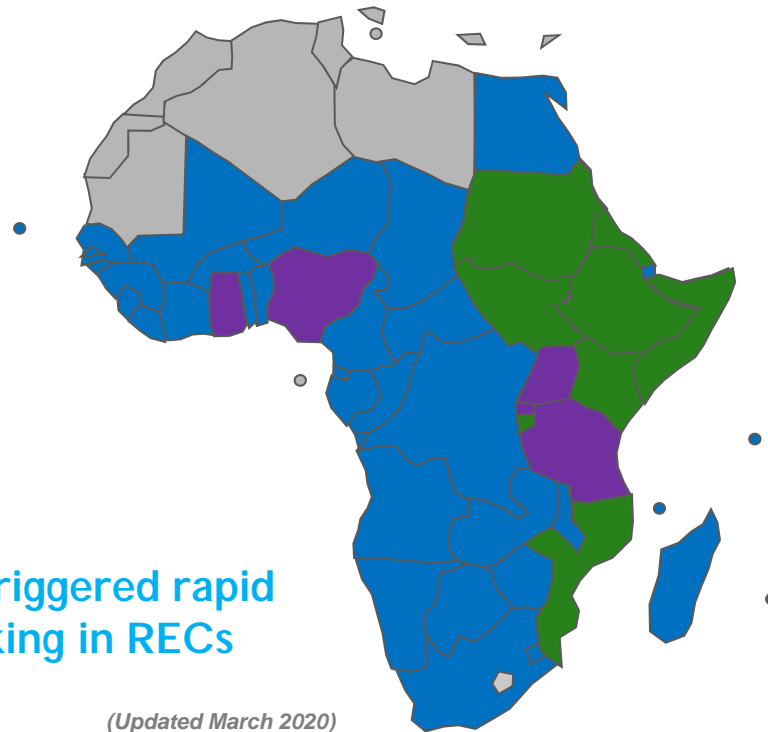


Formal Benchmarking (5)

- United Rep. of Tanzania
- Rwanda
- Nigeria
- Ghana
- Uganda

Rapid Benchmarking (8)

- Burundi
- Eritrea
- Ethiopia
- Kenya
- Mozambique
- Somalia
- South Sudan
- Sudan



Self Benchmarking (34)

- Angola
- Benin
- Botswana
- Burkina Faso
- Cameroun
- Cape Verde
- Central African Republic
- Chad
- Comoros
- Congo DR
- Cote d'Ivoire
- Djibouti*
- Equatorial Guinea
- Egypt*
- Eswatini
- Gabon
- Gambia
- Guinea
- Guinea-Bissau
- Liberia
- Madagascar
- Malawi
- Mali
- Mauritius
- Namibia
- Niger
- Republic of Congo
- Senegal
- Seychelles
- Sierra Leone
- South Africa
- Togo
- Zambia
- Zimbabwe

AMRH Programme triggered rapid and self-benchmarking in RECs

(Updated March 2020)

*EMRO countries

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PQM+ and MTaPS Supported Countries

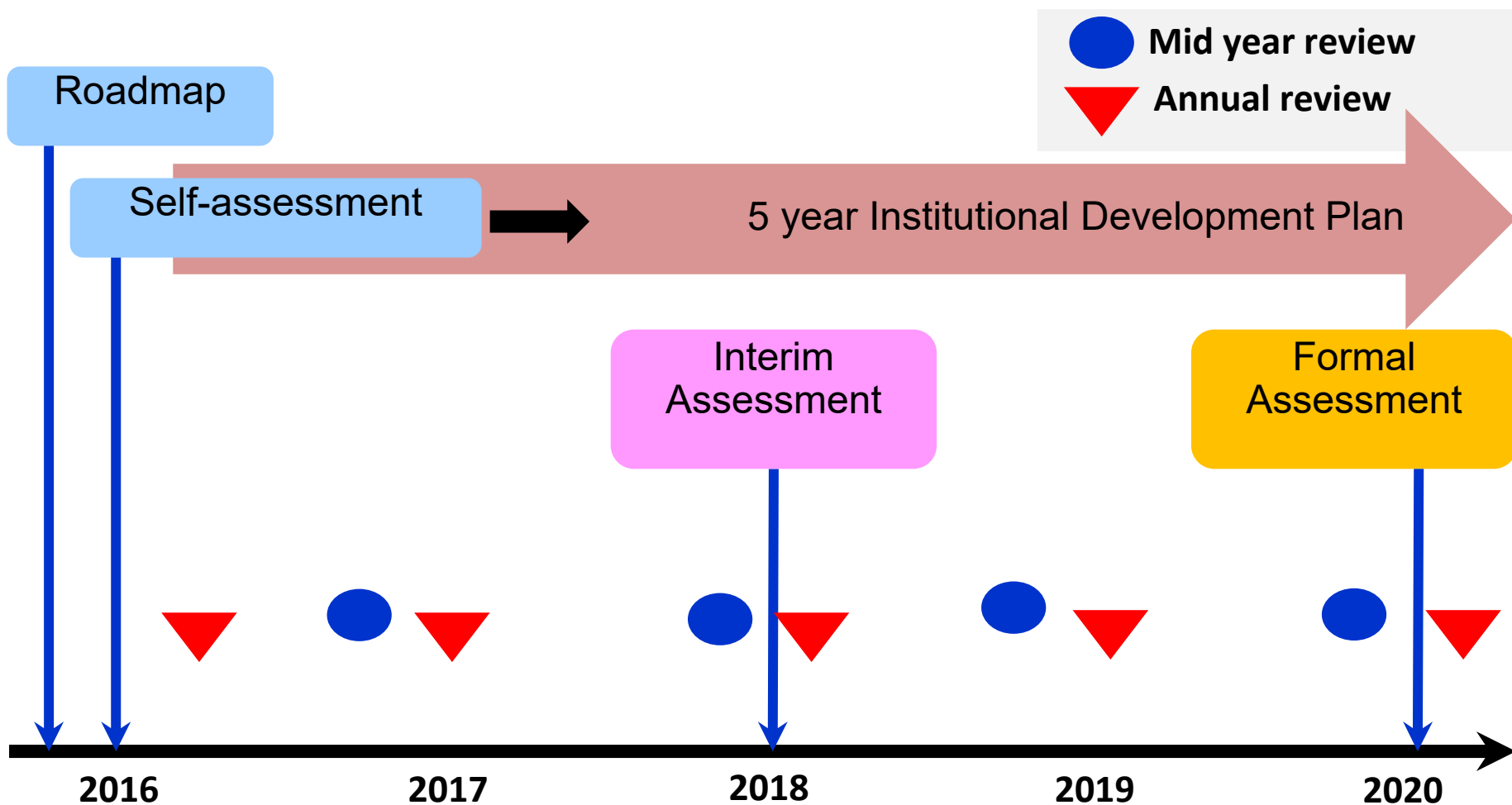
Countries	Self-Assessment and/or Formal Benchmarking	Institutional Development Plans	CIP/TWG	IPs Assigned Roles
Bangladesh	PQM+/MTaPS	PQM+/MTaPS	PQM+/MTaPS	PQM+/MTaPS
Mozambique	MTaPS			MTaPS
Nepal	PQM+/MTaPS	PQM+/MTaPS	PQM+/MTaPS	MTaPS
Nigeria	PQM+			
Pakistan	PQM+	PQM+		
Philippines	MTaPS			
Rwanda	MTaPS	MTaPS	MTaPS	MTaPS

Bangladesh: CIP*

- First country to use CIP for WHO GBT
- MSH, USP and WHO – CIP members for DGDA GBT
- PQM (PQM+ predecessor program) supported the following areas:
 - Regulatory Inspection System
 - Laboratory Access and Testing
 - Clinical Trials' Oversight
 - NRA Lot Release
- SIAPS (MTaPS predecessor program) supported the following areas:
 - Regulatory Systems
 - Marketing Authorization/Product Registration
 - Pharmacovigilance

*CIP: Coalition of Interested Partners

Bangladesh Roadmap (2016-2020)



Last benchmarking: 16-20 September, 2018

Conclusion

- Strong regulatory capacity is an essential component of a well-functioning healthcare system – a critical path to ensuring access to safe and quality-assured medical products and innovation.
- Regulatory capacity plays a significant role in achieving UHC and SDG 3 (target 3.8).
- WHO GBT offers a unique opportunity to the global community to strengthen NRAs:
 - Guides strategic investments in regulatory systems strengthening
 - Promotes good regulatory practices, flexible regulatory frameworks, reliance, collaboration and networking

References

- Presentation on WHO Benchmarking of Regulatory Systems – Updated slides received from Hiiti Sillo, Unit Head, Regulatory Systems Strengthening, RSS/REG/RPQ/MHP/WHO
- Presentation by WHO on Coalition of Interested Partners (CIP) 5th AMRC, October 2019, Victoria Falls, Zimbabwe
- WHO GBT website
https://www.who.int/medicines/regulation/benchmarking_tool/en/



Thank You!
Questions?

USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

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Learn more: www.mtapsprogram.org

USAID Promoting the Quality of Medicines (PQM+) Program

Prime: U.S. Pharmacopeia (USP)

AOR: Alison Collins, alcollins@usaid.gov

Learn more: www.usp.org/global-public-health/promoting-quality-of-medicines