WHO Listed Authorities Framework

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Objectives of the WHO regulatory system strengthening programme

1. build regulatory capacity in Member States consistent with good regulatory practices

2. promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance

Mandate

- **WHA Resolution 67.20 (2014)**
  - Recognizes the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC

- **SDG 3 – Target 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

WHO benchmarking of NRAs

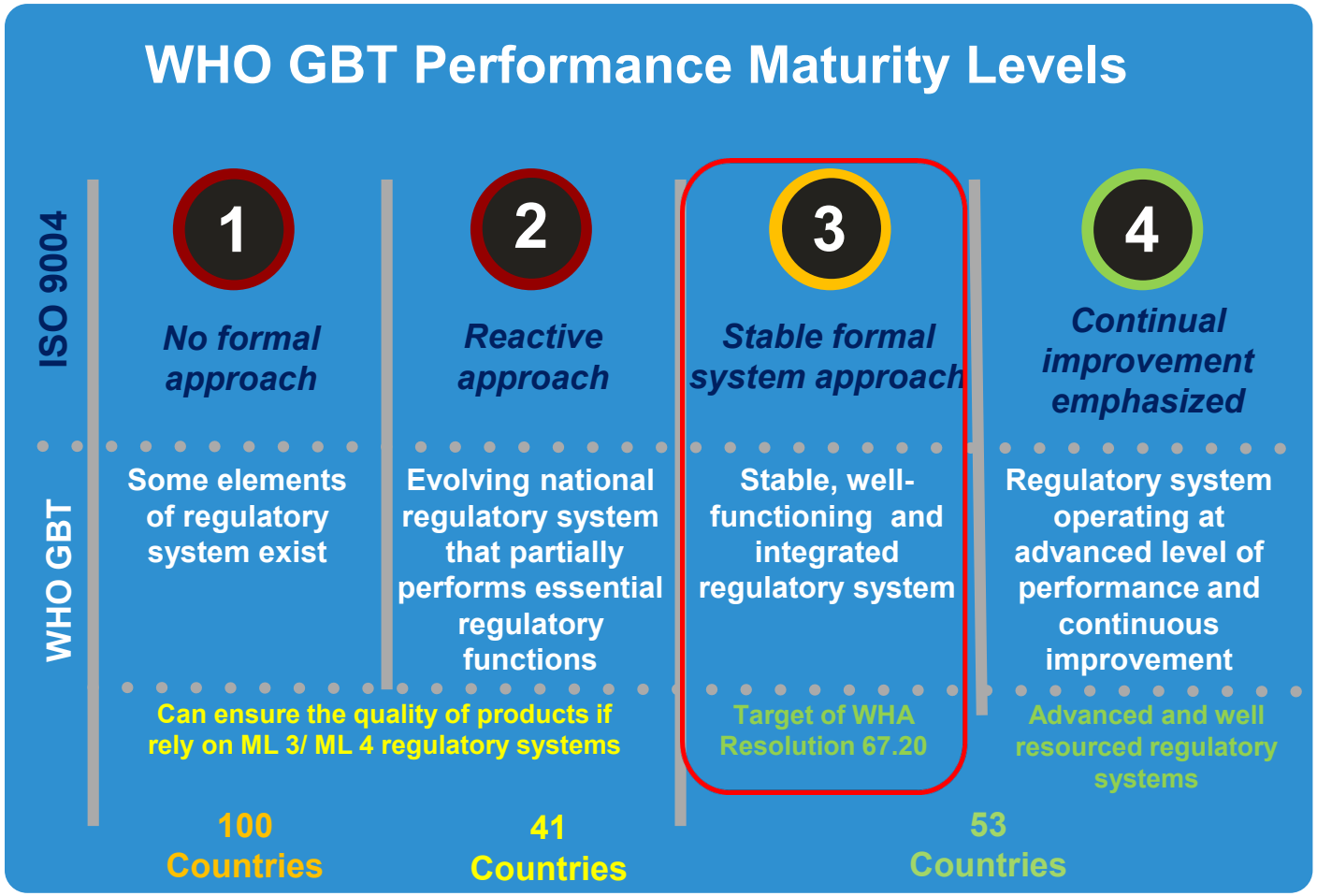
- WHO has been benchmarking regulatory systems since 1997 using an established set of indicators
  - ✓ to identify gaps and improve capacity to regulate medical products in an efficient, effective and transparent manner

- However, for vaccine manufacturers seeking WHO prequalification an NRA must be considered **'functional'** following WHO benchmarking as a pre-condition for application

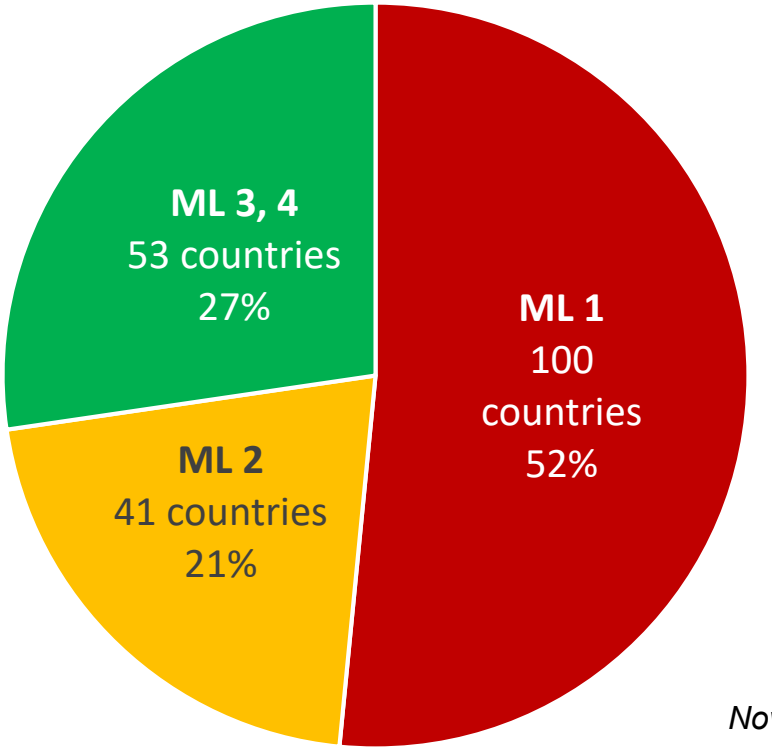
- 2016: introduction of harmonized medicines & vaccines 'Global Benchmarking Tool' (GBT) and categorization of NRAs based on **maturity levels** instead of "functionality"

- A unified WHO GBT Revision VI was published in December 2018 (https://www.who.int/medicines/regulation/benchmarking_tool/en/)

WHO GBT Performance Maturity Levels



Global status following WHO benchmarking of National Regulatory Authorities (NRAs)



November 2020

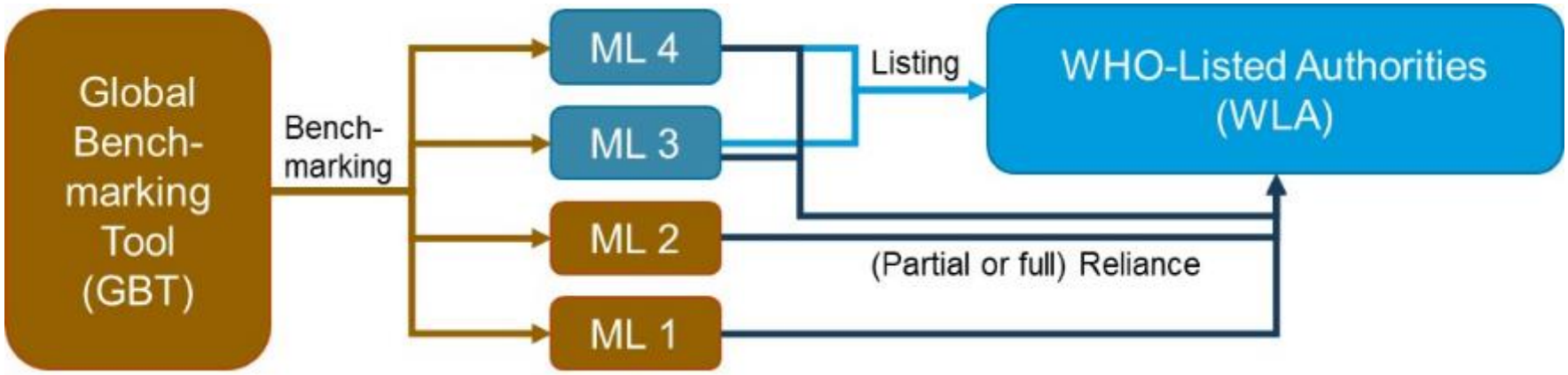
WHO Listed Authorities Framework

Adopting a smart regulatory approach

- Strengthening regulatory systems (to ML 3) remains the primary focus of WHO efforts – the baseline for effective regulation.
- However, the principle of reliance is central to WHO's approach to regulatory system strengthening and effective regulation regardless of the size and maturity of the authority.
- It represents a vital strategy in confronting the challenges posed by global regulatory environment.
- Regulatory cooperation and reliance are built on trust and confidence.
- A framework for designating regulators as WHO Listed Authorities (WLAs) will provide a transparent and evidence-based pathway to be globally recognized.

Regulatory capacity building consistent with good regulatory practices

Benchmarking and listing of regulatory authorities



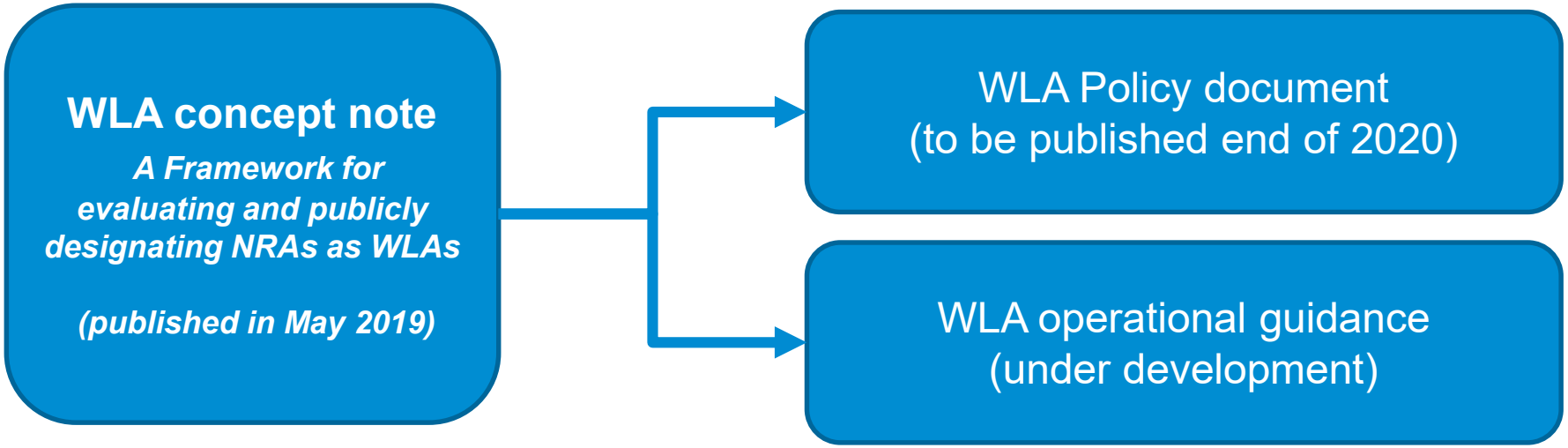
What's different from current practice?

- WHO GBT represents primary means by which the WHO evaluates regulatory systems
  - ✓ GBT designed to provide a structured approach to analyzing the **inputs, regulatory processes** and intended **outputs** that together determine how well a regulatory authority is configured
- Benchmarking process incorporates elements of performance measurement - but the challenge has been time required to fully evaluate consistent performance during benchmarking.
- WHO intends to address this challenge **through an expansion of performance measurement**
- Positive outcome would result in a public listing as a WLA

Performance evaluation process

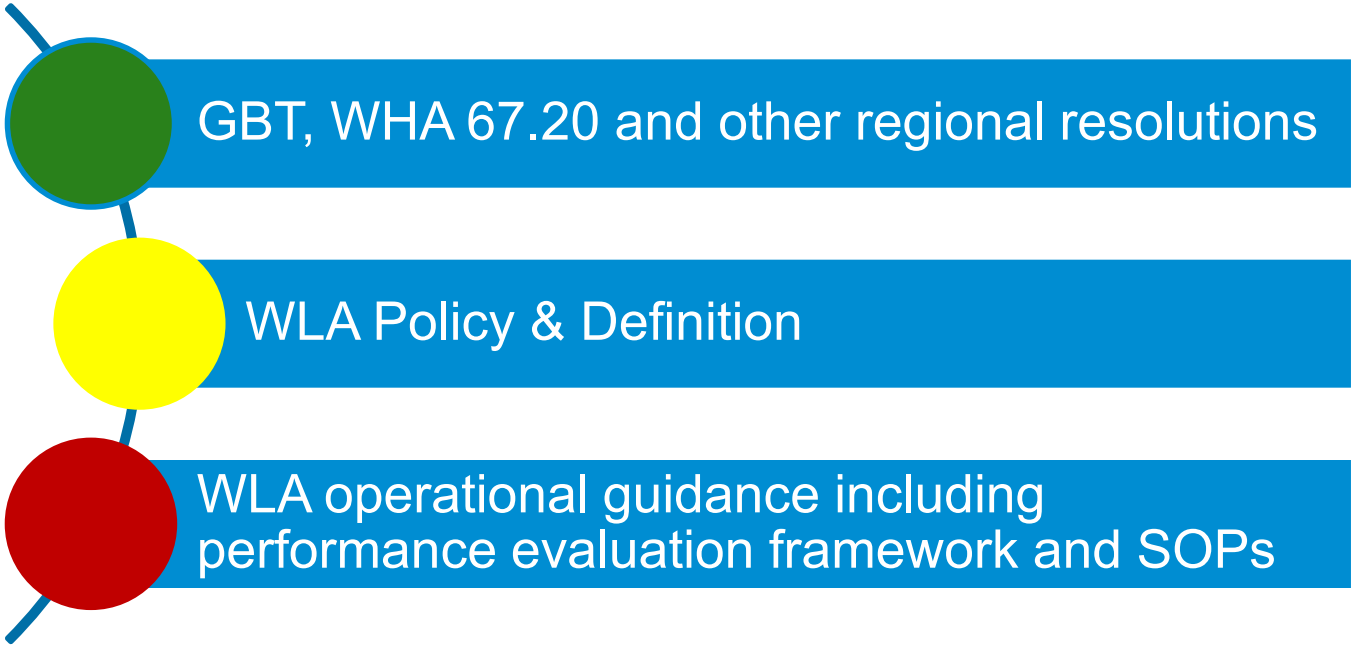
- Performance evaluation activity is expected to provide a more detailed picture of how a regulatory system operates
- Will serve to document **consistency** in adherence to procedures and in producing outputs - consistent with international regulatory requirements and best practices.
- WLA Framework will consider the nature and extent of evaluation required to provide a high degree of confidence in an authority's performance
- Regulatory outputs will serve as a proxy for regulatory competencies

The WLA Framework



The WLA framework (policy and operational guidance) is envisaged to be operational in 2022

WLA framework

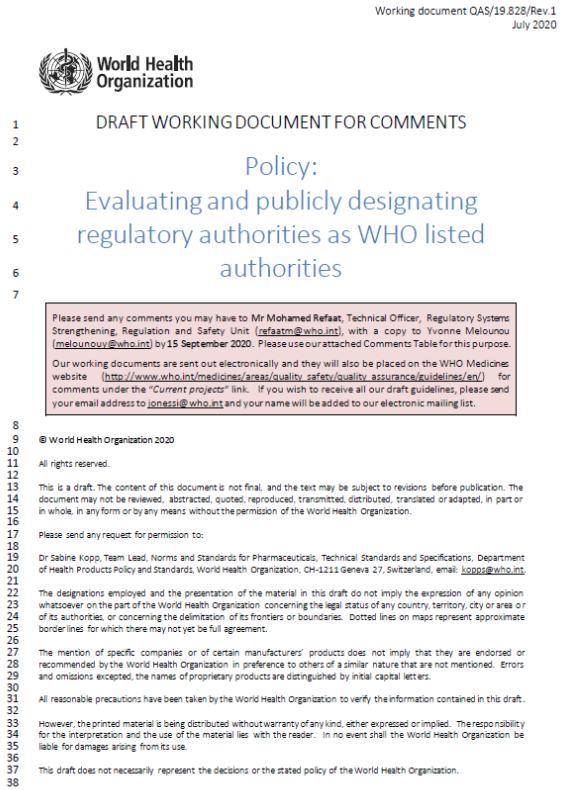


Available

Endorsed by 55th ECSPP, Oct 2020

Under development

WLA Policy



Working document QAS/19.828/Rev.1
July 2020

World Health Organization

DRAFT WORKING DOCUMENT FOR COMMENTS

Policy:
Evaluating and publicly designating regulatory authorities as WHO listed authorities

Please send any comments you may have to **Mr Mohamed Refaat**, Technical Officer, Regulatory Systems Strengthening, Regulation and Safety Unit (refaatm@who.int), with a copy to Yvonne Melounou (melounouy@who.int) by **15 September 2020**. Please use our attached Comments Table for this purpose.

Our working documents are sent out electronically and they will also be placed on the WHO Medicines website (http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/) for comments under the *"Current projects"* link. If you wish to receive all our draft guidelines, please send your email address to jonessi@who.int and your name will be added to our electronic mailing list.

1. Introduction
2. Context
3. Purpose
4. Scope
5. Policy statement
6. Definition
7. Operating principles
8. Glossary

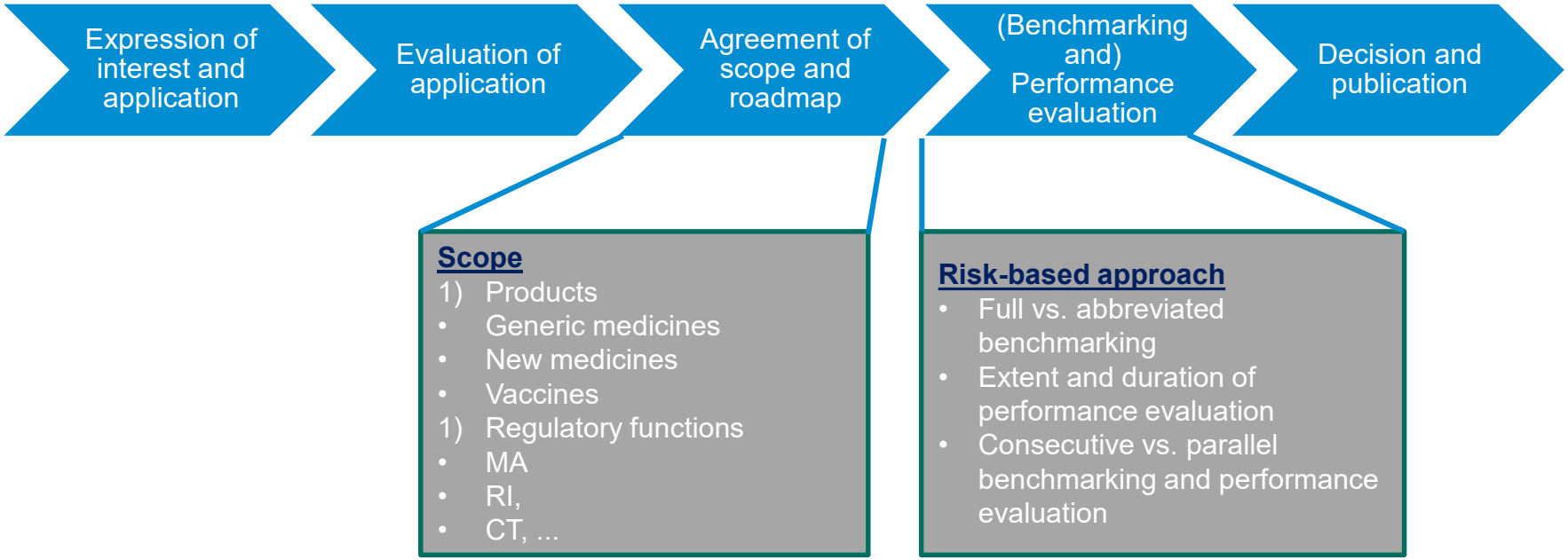
References

Definition of a WHO Listed Authority

Adopted by the ECSPP in October 2020

A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process

Proposed listing process



Interim list of NRAs be published on WHO website

https://www.who.int/medicines/regulation/wla_introduction/en/

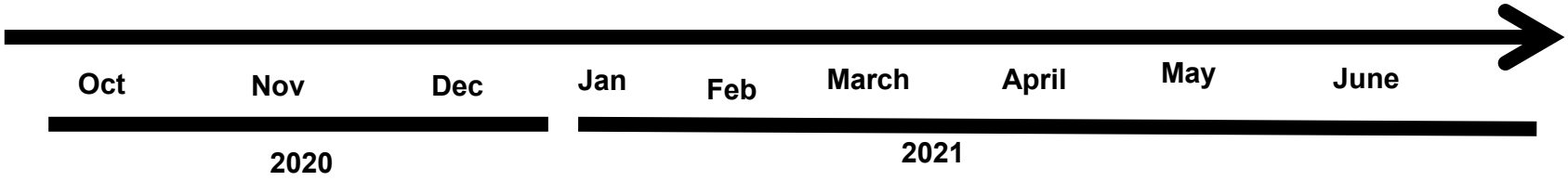
SRAs	NRAs of regional reference (WHO/PAHO)	WHO functional NRAs (vaccines)	NRAs at ML3 and ML4
• Based on ICH membership (2015)	• Based on WHO/PAHO tool	• Based on vaccine assessment tool	• Based on WHO GBT (after 2016)

Roadmap for developing Operational Guidance (OpG) and Performance Evaluation Framework (PEF)

- Virtual meetings of Working Groups (WGs) to develop methodology and tools
  - Representing NRAs, technical partners from across 6 WHO regions
- Generate PEF as part of OpG

- Publish OpG including PEF for public consultation

Compile comments, update the OpG and PEF and discussion with WGs



Composition of WGs for development of PEF & progress

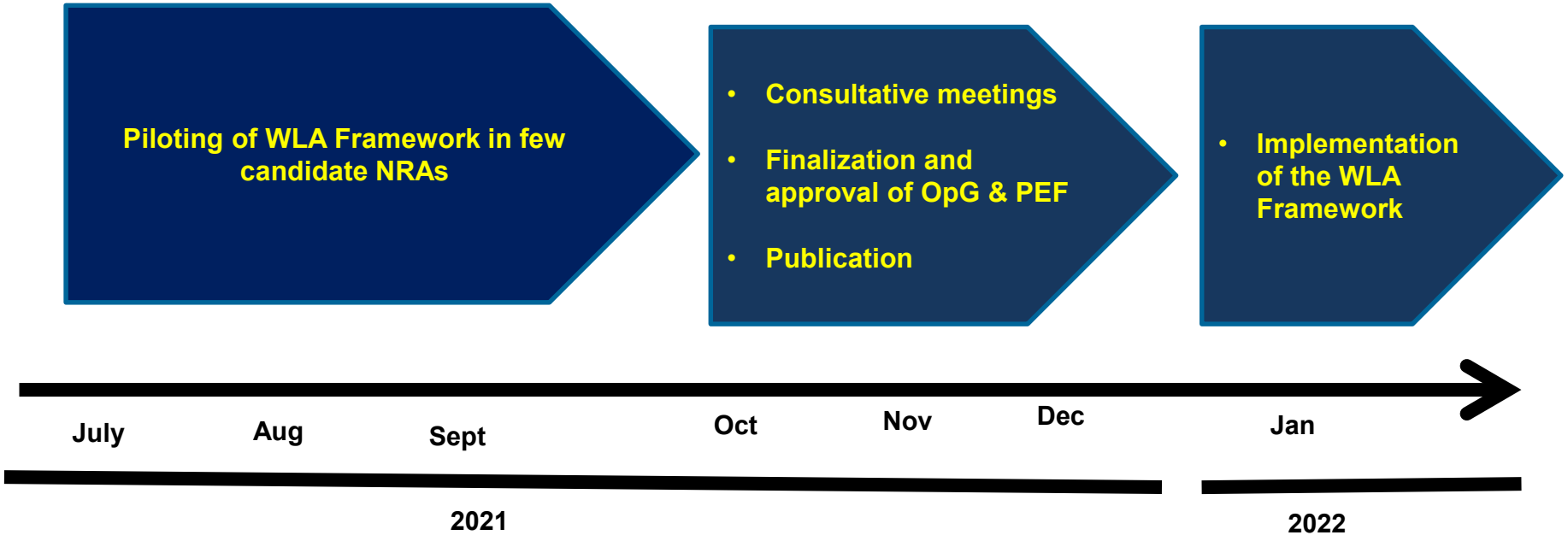
Working group	Regulatory functions
WG 1	Cross Cutting (including Regulatory Systems (RS) and Market Surveillance (MC))
WG 2	Registration and Marketing authorization (MA)
	Clinical Trials oversight (CT)
WG 3	Vigilance (VL)
WG 4	Licensing premises (LI)
	Regulatory inspection (RI)
WG 5	Laboratory access and testing (LA)
	NRA lot release (LR)

Composition and Progress

- Members
  - Regulatory experts nominated by the Member States (NRAs)
  - Specialists nominated by Technical/Specialized Agencies involved in performance evaluations e.g. HMA/BEMA, EDQM, CIRS
  - WHO staff from HQ and ROs nominated by the appropriate units and teams for the specific regulatory functions

- Progress as of 27 November 2020
  - Each WG held 10 meetings
    - ✓ 2 sessions/day/week
  - Average 50% work completed (30% - 80%)
  - WG 4 (RI & LI) will complete work in 2020

Roadmap for developing Operational Guidance (OpG) and Performance Evaluation Framework (PEF)



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Thank you