ROLE OF RELIANCE, RE-ENGINEERING, AND REGIONALIZATION IN THE OPTIMIZATION OF REGULATORY SYSTEMS

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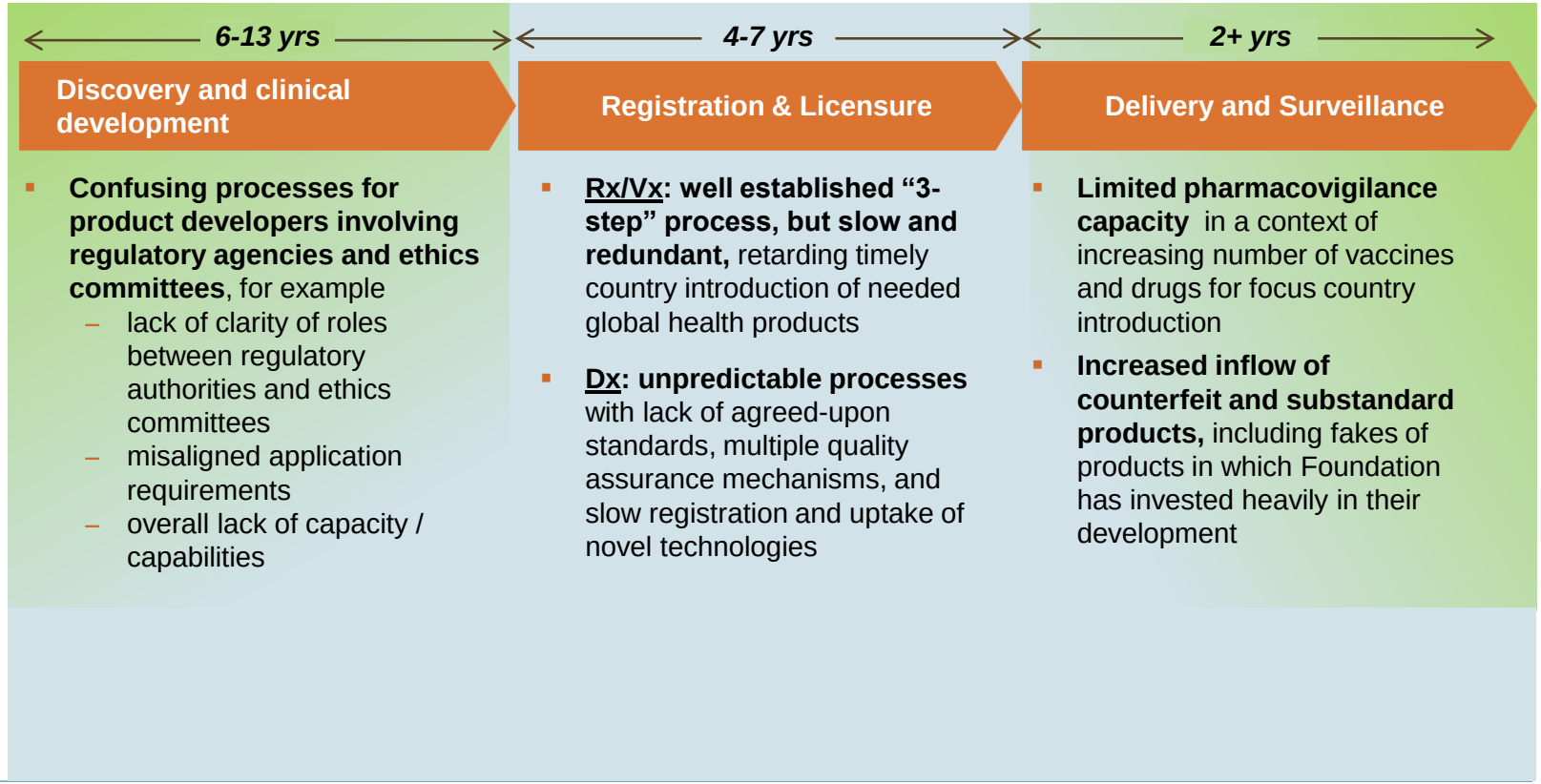
REGISTRATION ACTIVITIES ARE KEY STEPS IN GLOBAL HEALTH PRODUCT ACCESS – NECESSARY BUT NOT SUFFICIENT

To introduce a vaccine or drug in many LMICs

- The product must usually be **registered with the country's NRA**
- The product typically **needs WHO-PQ to meet quality requirements** of donors and procurers – helps assure LMIC suitability
- Before that, the **product generally needs a first registration**, usually in the country of origin, or a recognized Stringent Regulatory Authority (SRA) (often needs Certificate of Pharmaceutical Product – "CPP")

Major focus thus far
Current expansion

THE REGULATORY SYSTEMS PROBLEMS WE FOCUS ON



BASELINE FOR MEDICINES AND VACCINES REGISTRATION

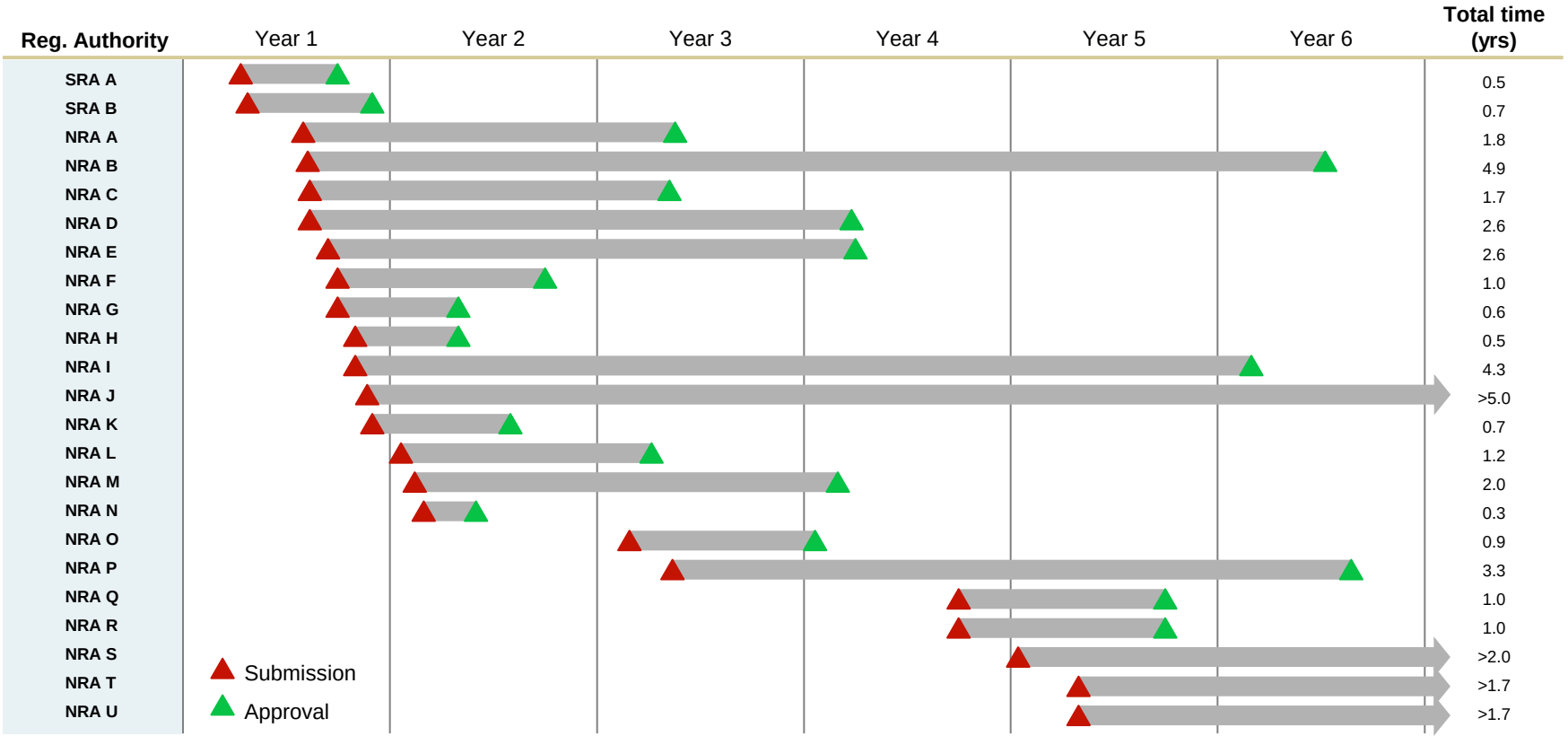
2009-2012 timelines

Median (months)		1st RA approval time	PQ approval time	Spread in RA submissions	Local NRA approval time
Medicines	SRA	10 months	4	52	11
	NRA	~12	27	~24	~18
Vaccines	SRA	15	16	78	16
	NRA	~12	16	N/A	N/A

A, B, C, D

SRA: Stringent Regulatory Authority (e.g. Canada, Europe, Japan, Switzerland, USA); NRA: National Regulatory Authority (e.g. India CDSCO, China FDA)

EXAMPLE OF LONG SUBMISSION SPREADS



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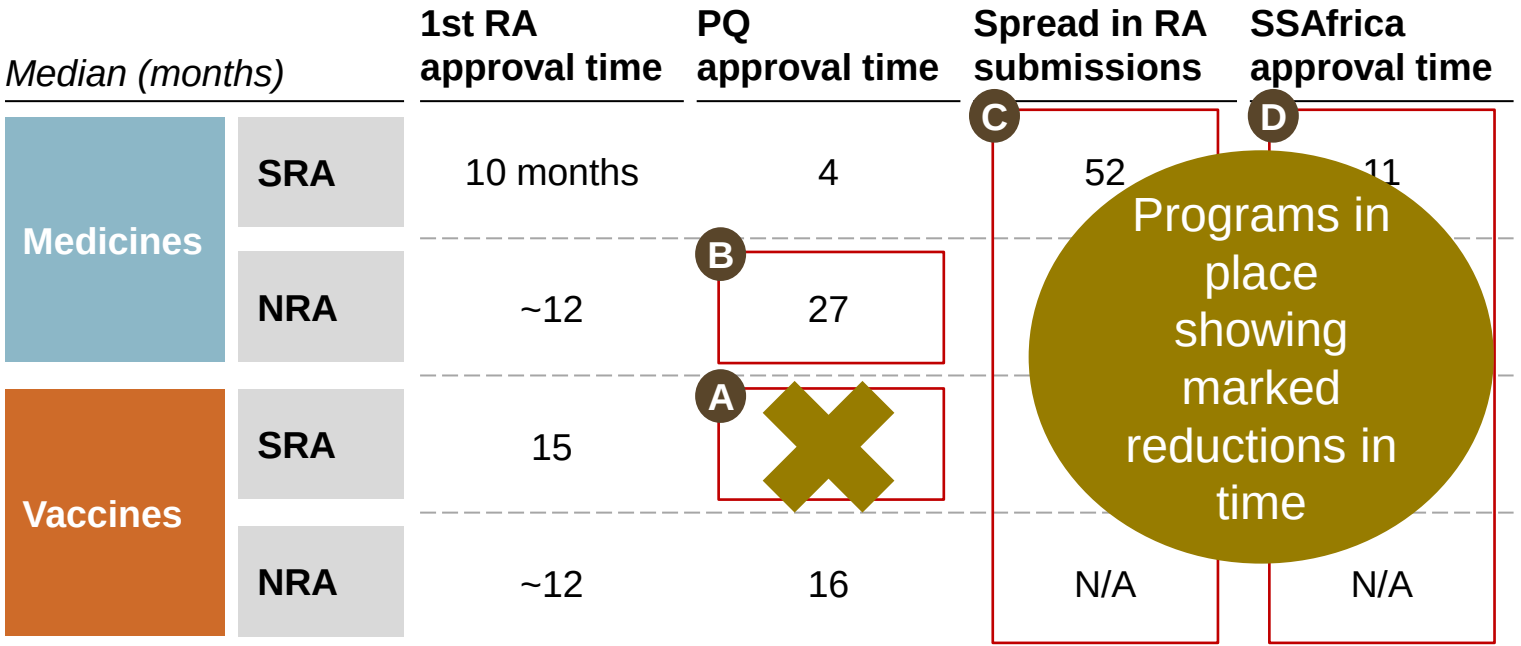

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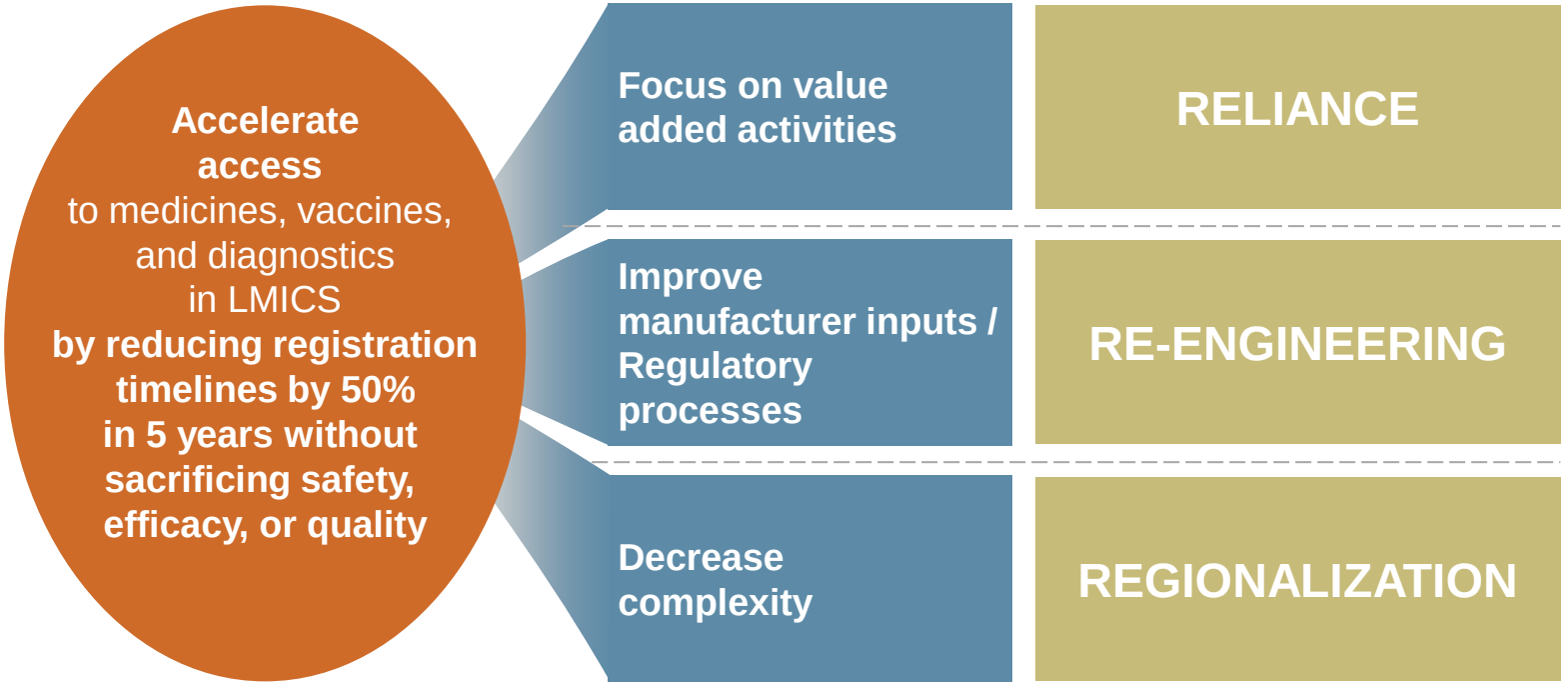
VISION AND KEY STRATEGIC PARTNERSHIPS



Major focus thus far
Current expansion

THE INITIATIVES WE FOCUS ON (GRANTS)

Discovery and clinical development

- Regional approach to **clinical trial and ethics committee authorization and oversight** in Africa (AVAREF)
- Developing WHO **Guidance** on local Clinical Trial Requirements

Registration & Licensure

First Registration

- Optimizing **PQ processes** to be predictable, accountable, and transparent (Medicines, Vaccines, Diagnostics, Vector Control)
- Expanding PQ **Collaborative Procedure, including into the Americas**
- Supporting regulatory **regionalization** (AMRH - Africa, **CARICOM – Caribbean**, ASEAN)
- Monitoring NRA and REC **performance** metrics, **including WHO/PAHO assessments**

WHO Prequalification

- Strengthening **NRA value added capacity** in targeted countries
- Developing WHO **Guidance** on Good Reliance Practices (annex to Good Regulatory Practices)
- Global regulatory **communication**, **training**, and **best practices** sharing

NRA Registration

Delivery and surveillance

- Improving **safety & surveillance activities** in LMICs
- Regulatory components of **supply chain** integrity (SSFFCs)
- Regulatory oversight of **vaccine CMC variations**

COLLABORATIVE PROCEDURES - RELIANCE

Reliance on work products of trusted agency/WHO to inform own regulatory decision
Not Recognition (mutual or unilateral)
Allows resources to be used in areas where only that NRA can do it

- Regulatory Agency of Regional Reference
  - PAHO

- COFEPRIS
  - Reliance on work products of several trusted agencies to make own regulatory decisions on pending applications and clear their backlog and focused own resources on activities that only they could do

- WHO PQ – NRA Collaborative Procedure

STATISTICS ON PQ COLLABORATIVE PROCEDURE (MEDICINES)

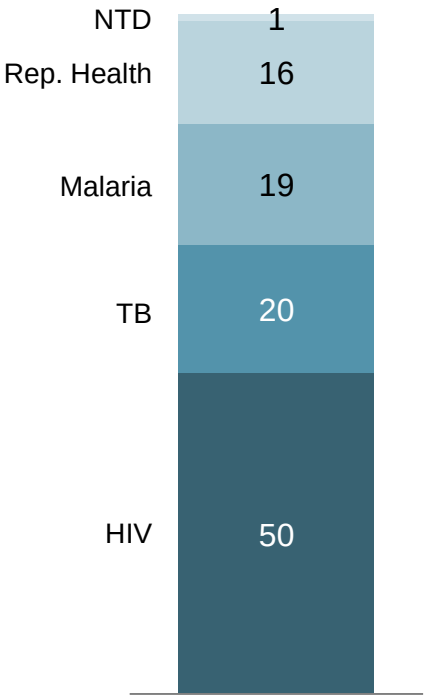
Key facts

- **28 countries** enrolled in the collaborative procedure
- **43 medicines** registered
- **106 registrations**
- **74 days** as a median time for local registration

Country	# of registrations
Nigeria	16
Tanzania	13
Ghana	11
Botswana	10
Zimbabwe	10
Zambia	9
Namibia	8
Ethiopia	5
Uganda	5
Ukraine	5
Kenya	4
Madagascar	3
Cameroon	2
Kyrgyzstan	2
Malawi	2
Burkina Faso	1

Manufacturer	# of registrations
Macleods Ph.	45
Hetero Labs	19
Famy Care	15
Cipla	12
Strides Arcolab	4
Mylan Lab.	3
Cadila Ph.	2
DNDi*	2
Ajanta Ph.	1
Dong-A ST Co	1
Eisai Co	1
Ranbaxy Lab.	1

Therapeutic area



*Cipla Ltd is the supplier and is responsible for the product

MUCHAS GRACIAS

MUITO OBRIGADO

MERCI BIEN

MANY THANKS

