Lessons learned from COVID-19 vaccine development and future pandemic preparedness

Regulatory Perspective: Brazil

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Regulatory Affairs
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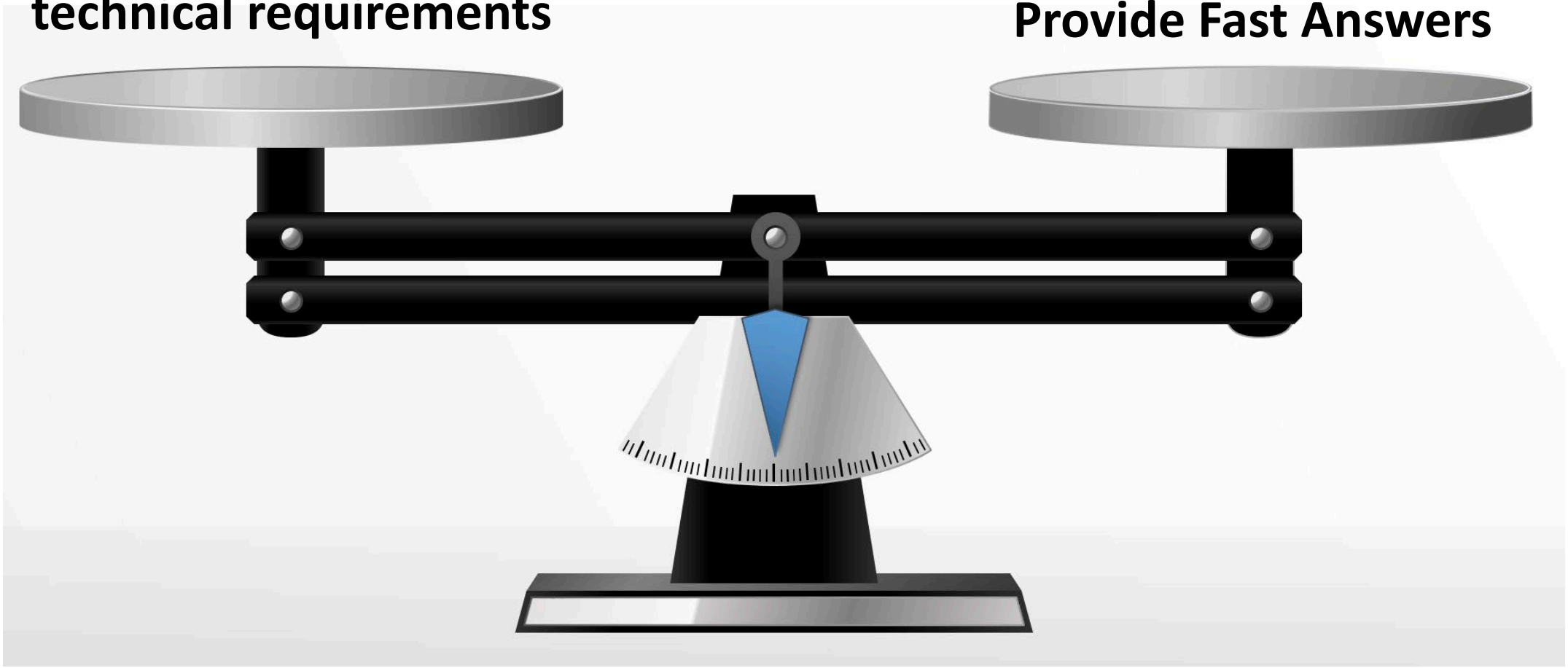
IVI International Vaccine Institute

Regulators Challenge During Pandemic

Verify compliance of all technical requirements

Provide Fast Answers



Why Brazil is a Good Example?

1. Middle-income country severely affected by COVID
2. Regional Reference Regulatory Authority
3. National Scientific capacity for clinical trials hosting, local vaccine development and tech transfer.
4. Political Scenario

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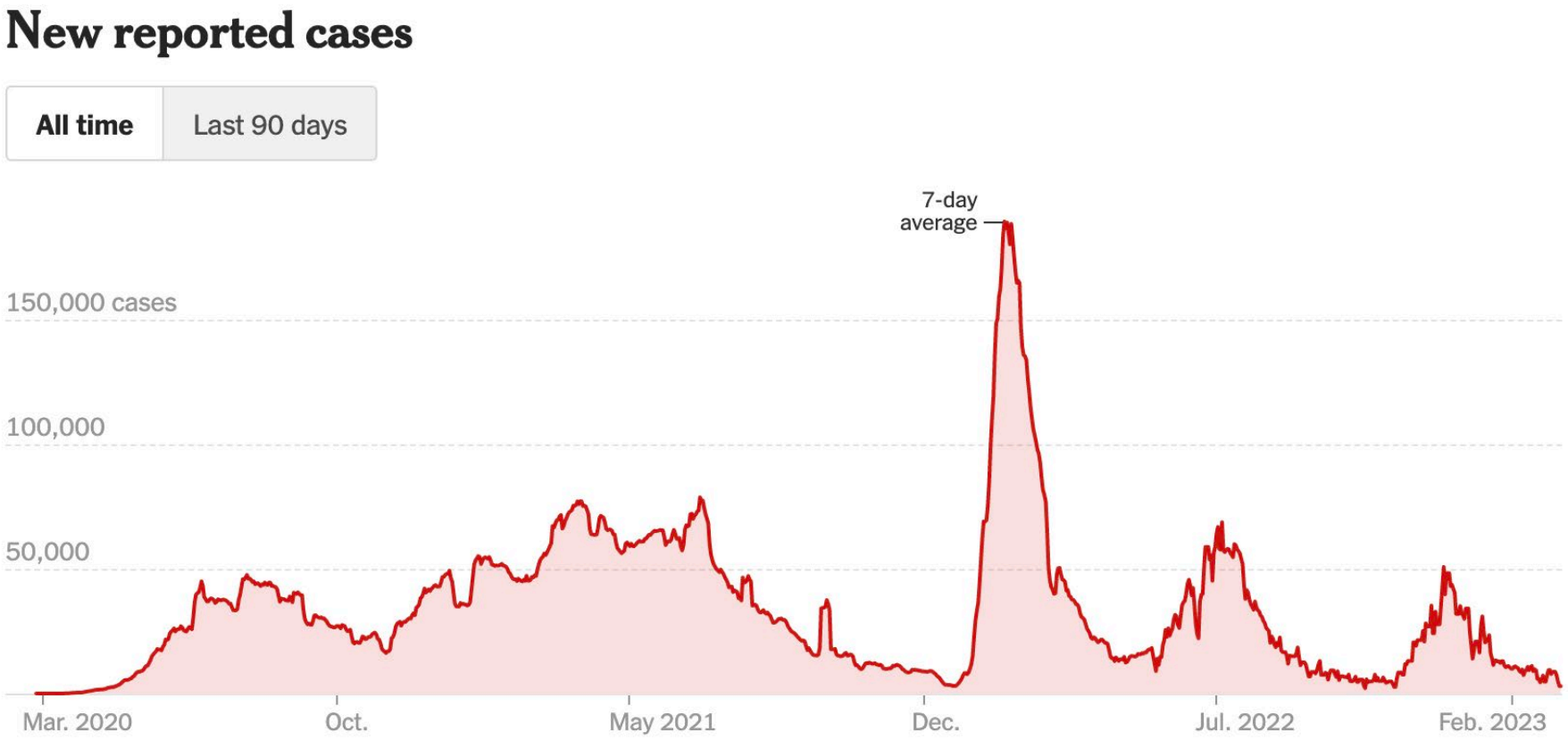
Middle-income country severely affected by COVID

In **Brazil**, from **3 January 2020** to **6:06pm CET, 21 March 2023**, there have been **37,145,514 confirmed cases** of COVID-19 with **699,634 deaths**, reported to WHO. As of **10 March 2023**, a total of **506,003,123 vaccine doses** have been administered.



Source: https://www.nytimes.com/interactive/2021/world/brazil-covid-cases.html

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Brazilian Health Regulatory Agency (Anvisa)

Administrative independence

Reference Authority for Medicines and Biologicals (PAHO)

Management Committee Member (ICH)

PICs member

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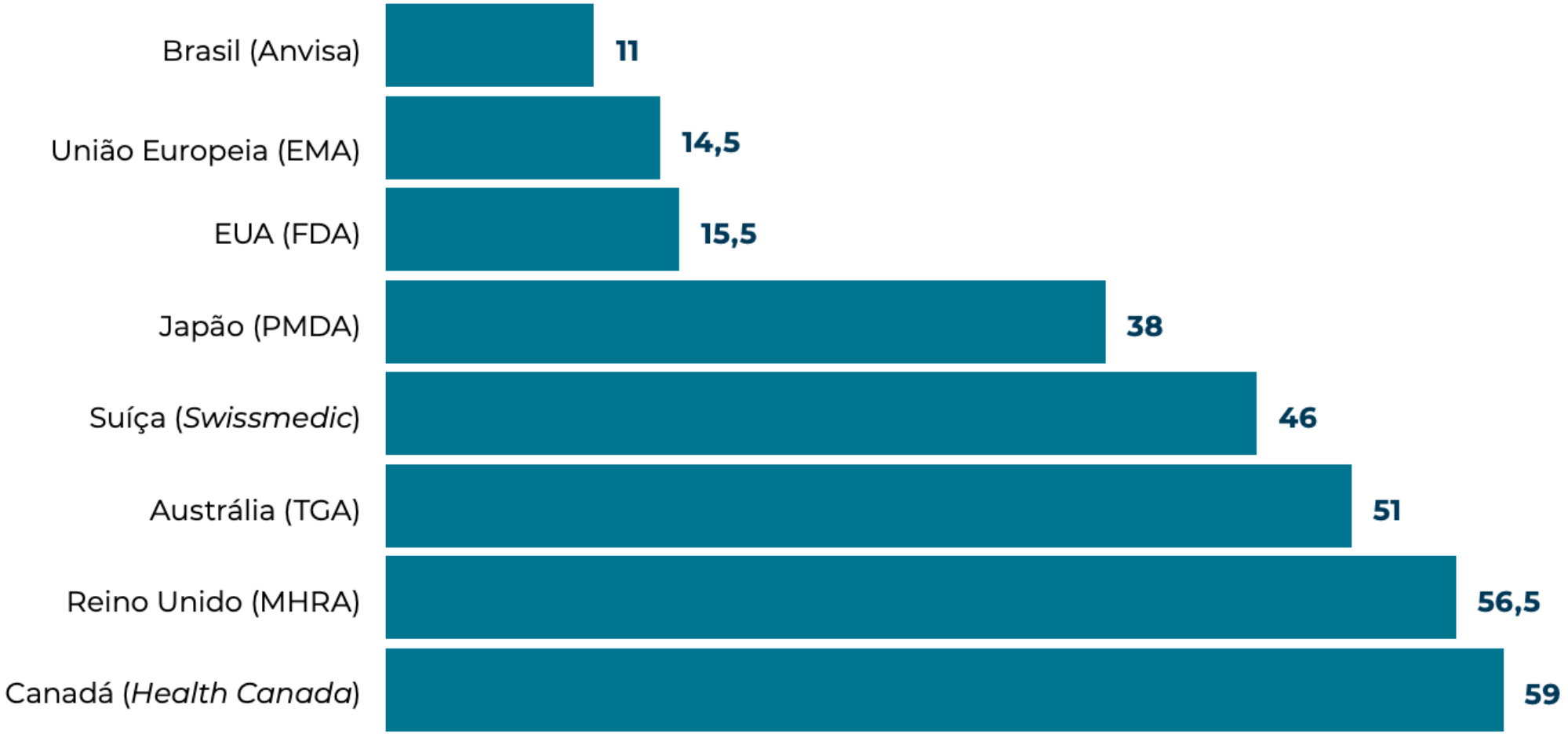
Comparative Timeline for Covid-19 vaccines regulatory analysis



Source: https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/gestao/relatorio-sobre-os-500-dias-de-acoes-da-anvisa-no-enfrentamento-a-covid-19

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Covid-19 Vaccines Clinical Trials Approved by Anvisa

Chadox 1 NCOV 19 * (Astrazeneca)	Coronavac (Butantan) *	Comirnaty (Pfizer/Wyeth) *	INO-4800 (Icon plc)
Janssen Vaccine (Janssen-Cilag) *	AZD2816 (AstraZeneca)	Butanvac (Butantan)	COVLP (Medicago)
Inativada contra Sars-CoV-2 (IMBCAMS)	SCB-2019 (Clover)	Vacina de RNAm para Sars-CoV-2 (Sanofi Pasteur)	Vacina de RNA MCTI Cimatec HDT (HDT...
Ad26.COV2.S (Janssen)	Covaxin (Precisa) - Estudo cancelado	SpiNTec (UFMG)	

15 vaccines in different phases

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Covid-19 Vaccines Authorized by Anvisa

Comirnaty (Pfizer/Wyeth)	Comirnaty bivalente (Pfizer)	Coronavac (Butantan)	Janssen Vaccine (Janssen-Cilag)	Oxford/Covishield (Fiocruz e...

Sputnik	Covaxin (SUSPENSA)

Different pathways:

- Marketing Authorization
- Emergency Use Authorization
- Exceptional Importation

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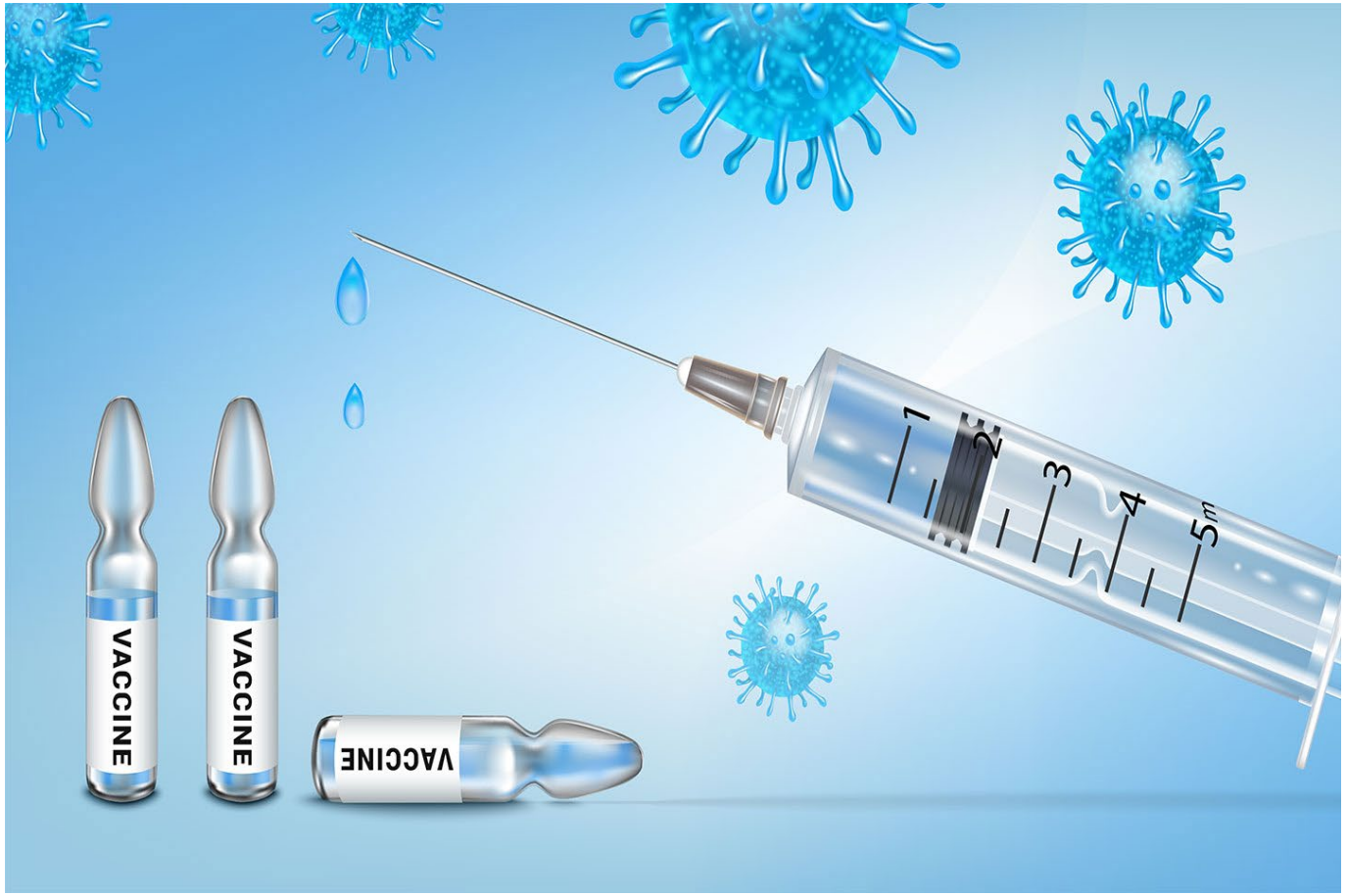
Brazilian Scientific Capacity



Source: https://www.gavi.org/vaccineswork/4-our-greatest-achievements-vaccine-science-led-covid-vaccines

159 Covid-19 clinical trials approved (medicines and vaccines)

5 local early developments (vaccines)

Vaccine Manufacturing Capacity (public and private sectors)

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GLOBAL PUBLIC HEALTH
https://doi.org/10.1080/17441692.2021.1945123

Political discourse, denialism and leadership failure in Brazil's response to COVID-19

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COVID-19 Lessons Learned on Regulatory Strategies

- **Allowing parallelization of preclinical studies:** experience with preclinical studies on efficacy with tox screening and DMPK proved to save time on therapeutic development of medicines and vaccines.

- **Remote site inspection mechanisms:** regulatory mechanisms were developed to allow remote inspections both for GCP and GMP, facilitating data integrity evaluation and reliability on data generated during studies.

- **Acceleration of clinical phase progression**: interim read-out or reduced data for clinical phase progression were accepted by many regulators as a strategy to accelerate clinical development.

COVID-19 Lessons Learned on Regulatory Strategies – Cont'd

- **Rolling Review**: regulators implemented and improved rolling review mechanisms for continuous review around new data without pre-defined submission deadlines. This helped to accelerate review timelines.

- **Continuous Developer – regulator communication:** enhanced mechanisms for better communication and rapid advice from regulators help to avoid queries and delays in development and review processes.

- **Regulatory flexibility and risk-based post-authorization requirements:** emergency use authorization mechanisms were established to meet urgent public health needs. Post-authorization commitments were defined as an important regulatory tool for rapid decisions and engagements between regulators and developers.

Final Messages

Source: https://sites.psu.edu/mromeorclblog/2020/02/21/bureaucrats-what-are-they-and-what-do-they-do/

Brazilian case of regulatory preparedness serve as examples for other LMICs

Collaborative effort from different stakeholders is one of the biggest lesson for future health emergency

Regulatory Strategy is fundamental for vaccine development and eventual approval success

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Thank YOU!