Covid-19 vaccines: factors that enabled unprecedented timelines for clinical development and regulatory authorisation

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Vaccine Development 2019

Understanding inefficiencies in the vaccine development ecosystems

Research Goal

- Identify challenges impacting clinical development decisions
- Identify solutions to create a more effective vaccine development ecosystem

Research Focus

Development programmes from Phase 2 to market roll-out and focusing on vaccines against:

- Emerging epidemic, infectious diseases
- Diseases disproportionally affecting low income countries
- Diseases contributing to the growth of antimicrobial resistance

Research questions

1. How do developers make decisions related to vaccine development?
2. What are the most relevant challenges from Phase 2 clinical development to initial in-country use?
3. Which challenges, if addressed, could significantly improve the vaccine development ecosystem?
4. What are the current and potential solutions?
5. Which challenges require additional solutions and what should Wellcome Trust invest in?

Conclusions

These actions must be tackled in a systemic fashion to build a fairer and more effective vaccine ecosytem.

New clinical trials and models to make vaccine development more efficient and effective, but require regulatory acceptance and incentives for use.

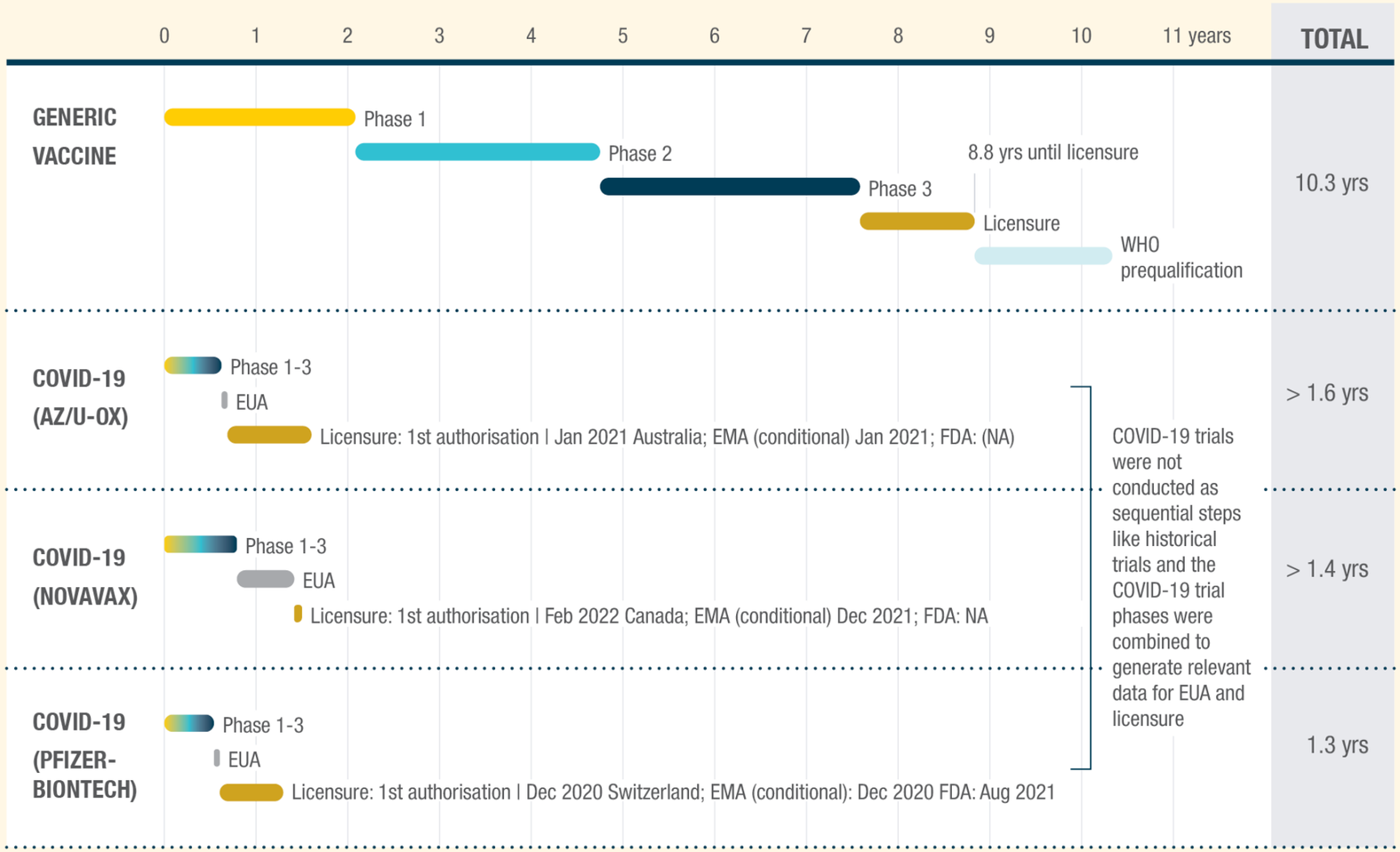
Regulatory capacity is an important enabler to widen improvements.

Innovation and more diversity in manufacturing could mitigate costs related to development

A radical rethink of the conventional models for vaccine development financing to address the investment opportunity costs

wellcome

Introduction: Comparison of historical and COVID-19 vaccine development and authorization timelines



Commissioned Work:

“Analysis of the Factors Enabling the Rapid Development of Covid-19 Vaccines”

Aims

1. **Identify** the factors that enabled the rapid development of Covid-19 Vaccines globally and their varying impact. Scope also includes factors impeding development and any **missed opportunities**, drawing on lessons from other **modalities** (e.g. adaptive/platform trials).
2. Understand if any of the above factors are **sustainable** for future vaccine development (in or outside of a pandemic context), particularly those which do not require unprecedented financial investment.
3. Publish and promote a **report** with recommendations to the community on future action to increase the speed of vaccine development, based on lessons learned.

Read the report here: https://wellcome.org/reports/covid-19-vaccines-factors-enabled-unprecedented-timelines-clinical-development

Insights captured with a mixed methods approach and validation

Output: Reviewed 683 articles and identified potential factors which may have impacted the timelines for COVID-19 vaccine development and approval

Output: Validated the identified factors, determined the role and impact of each factor, and find any factors not identified in the rapid assessment of literature

Output: Prioritized factors based on replicability for future vaccine development and identified actions and investment to enable replicability

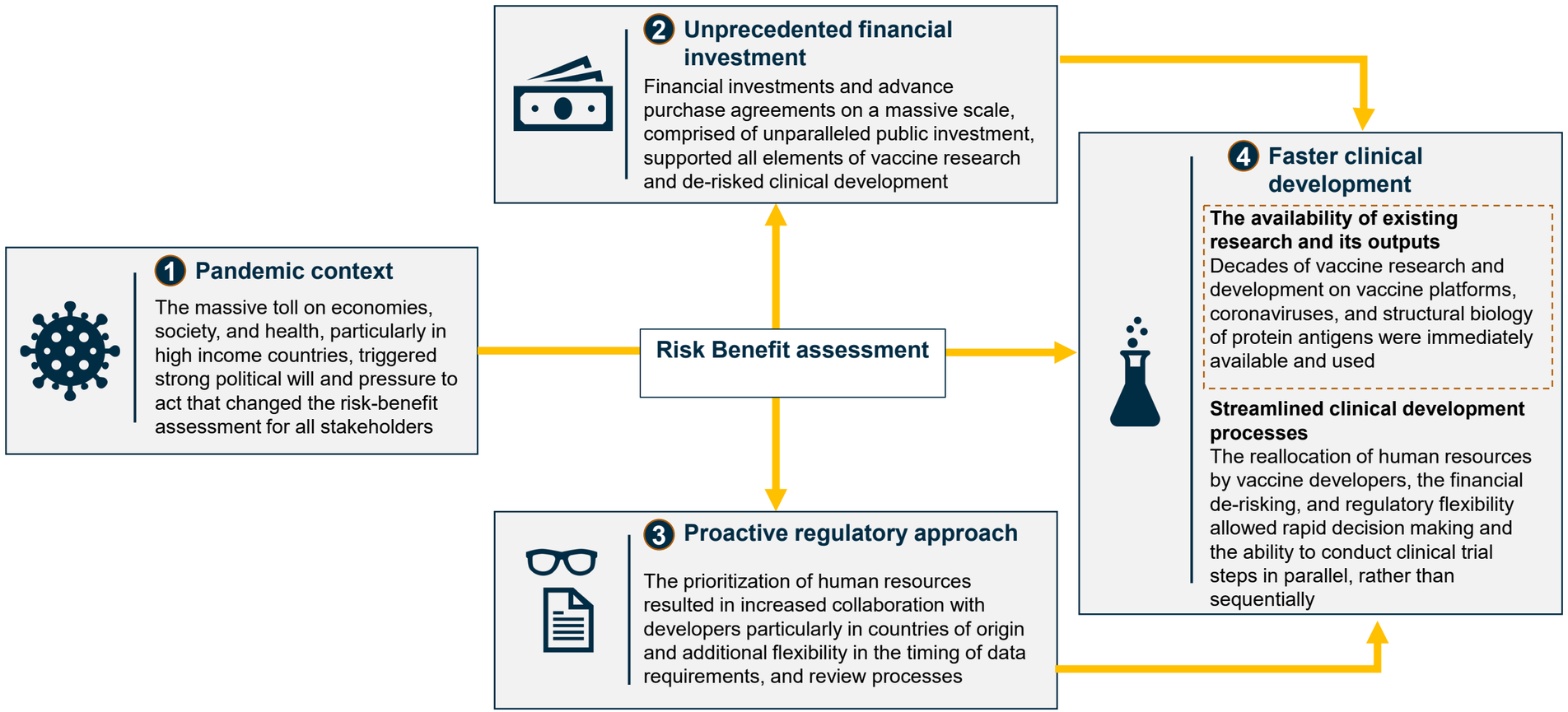
Comparator vaccines

Output: Contextualized COVID-19 vaccine development timelines, financing and regulatory pathways against benchmark licensed and candidate vaccines – PCV, TB, H1N1

Factorial regression model

Output: Identified the factors that correlated with progression through clinical development phases for currently licensed or candidate COVID-19 vaccines using WHO landscape of COVID-19 vaccine clinical trials

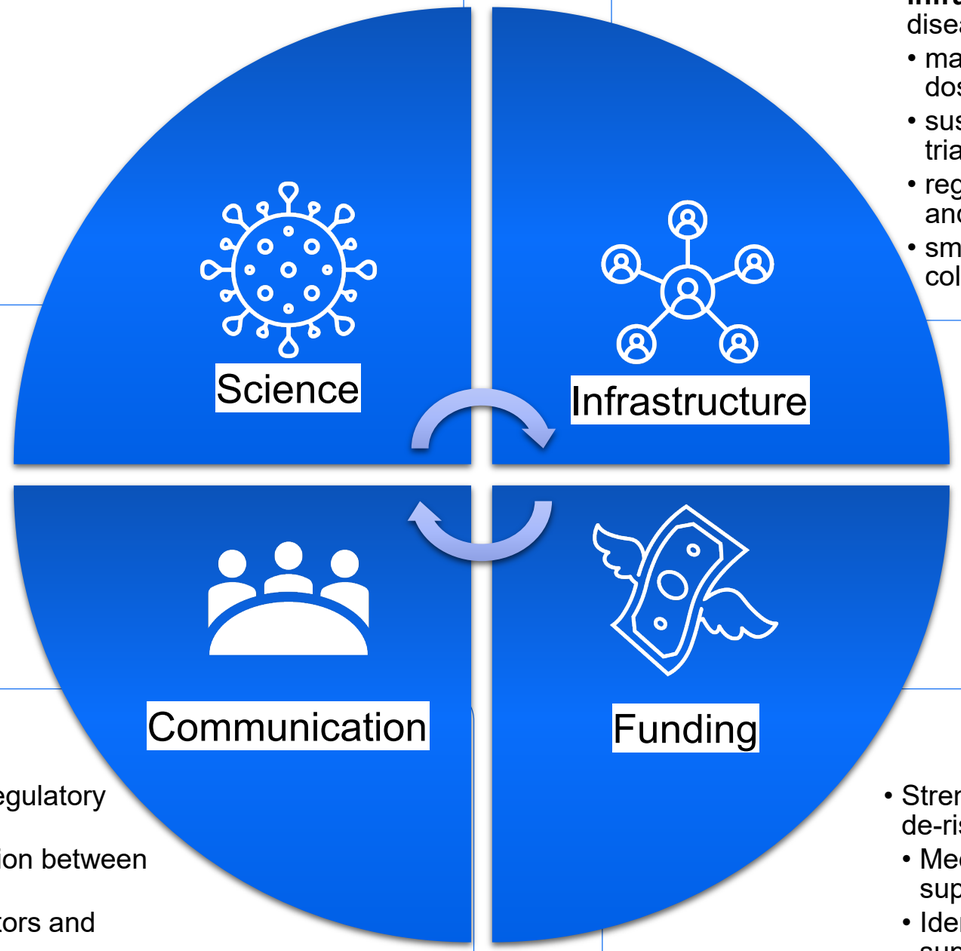
Interacting factors which resulted in rapid development of vaccines for COVID-19



Applying lessons learned to the vaccine development ecosystem

- Commit **sustained financial support** for scientists and foundational science
  - Pathogen biology
  - Predictive models
  - Vaccine technology platforms

- Establish **strong clinical trial infrastructure** in regions of infectious disease burden
  - manufacturing capacity for clinical trial doses
  - sustainable capacity to conduct vaccine trials
  - regulatory capacity to support, conduct and approve clinical trial processes
  - smarter surveillance to improve data collection, sharing and analytics



- Facilitate **communication** between regulatory authorities and other stakeholders
  - Promote discussion and harmonization between regulators
  - Promote discussion between regulators and developers
  - Develop guidance documents

- Strengthen **global funding mechanisms** to de-risk and advance vaccine development
  - Meet CEPI's $3.5bn replenishment target to support its "100 days" mission
  - Identify effective funding mechanisms to support early stage R&D and guarantee demand

Thank you!

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Findings of COVID-19 Vaccine Development report

Actions

- Advocate for sustained investment in vaccine science
- Strengthen global surveillance, manufacturing and clinical trial infrastructure
- Strengthen regulatory capacity and harmonization
- Strengthen global funding mechanisms to de-risk and advance vaccine development
- Read the report here.