# Vaccine Production Cycle – COVID -19 implications?

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## **Disclosures**

• I have no conflicts of interests.



### Disclaimer

The opinions expressed in this presentation are solely those of the presenter and do not necessarily represent the official positions of the Immunization Action Coalition, or the National Adult and Influenza Immunization Summit



## Vaccine development is not simple

- Vaccine development can take from 10 15 years and cost as much as US\$800 million or more, with substantial risk.<sup>1,2</sup>
  - Including costs to build a vaccine manufacturing facility and maintain equipment, that figure can rise to well over USD 1 billion.<sup>3</sup>
- Clinical development involves a large number of subjects.
  - Vaccines must meet a high threshold of efficacy and safety.
- Manufacturing processes must meet stringent quality control criteria.
- Final filing initiates an in-depth evaluation by governmental regulatory authorities.
- 1. Plotkin SA. Health Aff. 2005;24(3):631-634.
- 2. Pronker ES. Plos One: https://doi.org/10.1371/journal.pone.0057755
- Center for Global Development. Making Markets for Vaccines: Ideas to Action. Center for Global Development; 2005.



## Vaccine development pathway

#### Pre-IND

Identification of product, components, antigen

Development of manufacturing process

Preclinical studies

**Pre-IND** meeting

## Investigational New Drug

IND application and IND supplements

Clinical studies (phases I, II, III)

Non clinical development studies

#### Licensing

**BLA and BLA supplements** 

Preapproval lot release testing and inspection

Bioresearch monitoring

Review of label

Presentation to advisory committee

**Postapproval** 

Lot-release testing

Biannual or annual facility inspection

Postmarketing surveillance









Discovery, testtube and animal studies (antigen identification, production, pharmacology Human studies
(Phase 1
[immunogenicity,
safety], Phase 2
[dosing efficacy,
safety], and Phase
3 studies [efficacy,
safety])

Filing with FDA and approval (?)

Continuous
quality
improvement,
and Phase 4
studies
immunization



Adapted from: Marshall and Baylor. 2011. *Pediatrics:* 127:S23-S30; and Kovacs, GR, 2017. Presentation to ACIP, February 2017.

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**Pre-IND** meeting

#### NIH; DoD Industry; FDA Consultation and Review

studies (antigen identification, production, pharmacology

### Investigational New Drug

IND application and IND supplements

Clinical studies (phases I, II, III)

Non clinical development studies

#### ASPR/BARDA Industry; FDA Consultation and Review

[immunogenicity, safety], Phase 2 [dosing efficacy, safety], and Phase 3 studies [efficacy, safety])

#### Licensing

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# Industry; FDA

Consultation and Review

and approval (?)

#### **Postapproval**

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#### FDA; Industry

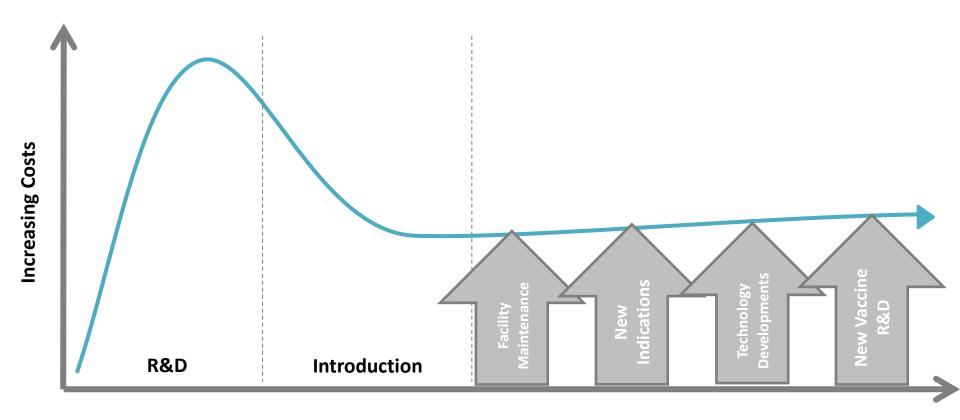
Continuous quality improvement, and Phase 4 studies



immunization

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# Vaccines Present a Unique Need for Continuous Investment



**Product Timeline** 



#### What will acceleration look like?\*

- Simultaneous, rather than sequential, clinical trials
  - Optimized for multiple target populations
  - In multiple countries with different socio-economic standing
- Adaptive trial designs: results gathered in the trial are used to modify the trial's course according to pre-specified rules
- Run trials where results are most likely, so in areas with high outbreaks, regardless of location



#### What will acceleration look like?\*

- Continuous, and early, collaboration with regulatory agencies to ensure rapid appropriate approval process
- Discussions on how to incentivize the scaling up of production; to distribute fairly across globe should happen early
- ALL this needs strong global coordination and collaboration



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# **Thank You!**

