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.\(^1,2\)
  - Including costs to build a vaccine manufacturing facility and maintain equipment, that figure can rise to well over USD 1 billion.\(^3\)
- 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.

2. Pronker ES. Plos One: https://doi.org/10.1371/journal.pone.0057755
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
- Biosearch monitoring
- Review of label
- Presentation to advisory committee

→ Postapproval
- Lot-release testing
- Biannual or annual facility inspection
- Postmarketing surveillance

Discovery, test-tube 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

Vaccine development pathway

Pre-IND
Identification of product, components, antigen
Development of manufacturing process
Preclinical studies
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
BLA and BLA supplements
Preapproval lot release testing and inspection
Bioresearch monitoring
Review of label
Presentation to advisory committee

Industry; FDA Consultation and Review and approval (?)

Postapproval
Lot-release testing
Biannual or annual facility inspection
Postmarketing surveillance

FDA; Industry
Continuous quality improvement, and Phase 4 studies

Vaccines Present a Unique Need for Continuous Investment

Graphic courtesy of Biotechnology Industry Organization
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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