

Vaccine Production Cycle – COVID -19 implications?

Litjen (L.J) Tan, MS, PhD
Chief Strategy Officer, Immunization
Action Coalition
Co-Chair, National Adult and Influenza
Immunization Summit

April 17, 2020

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

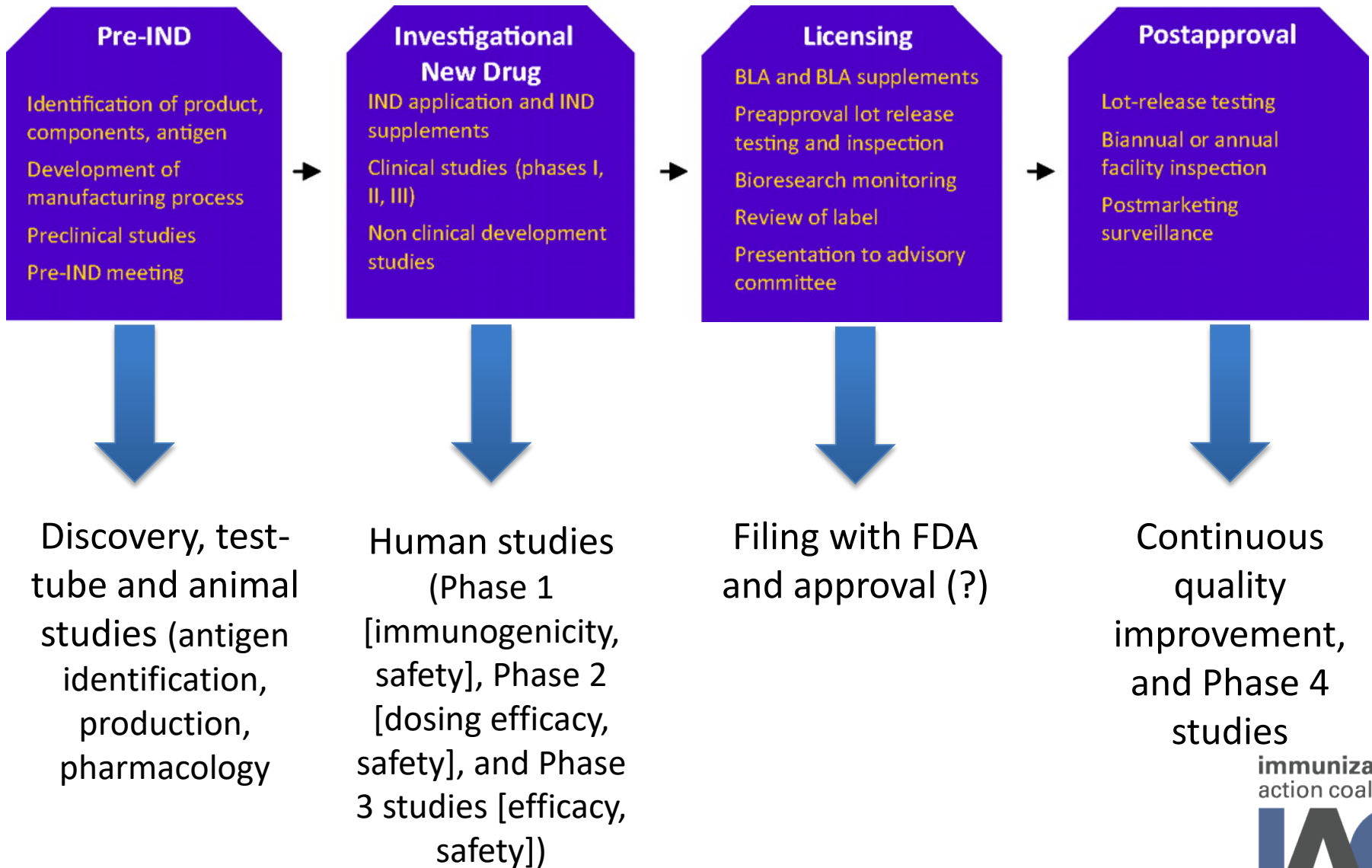
- Vaccine development can take from 10 - 15 years and cost as much as US\$800 million or more, with substantial risk.^{1,2}
 - Including costs to build a vaccine manufacturing facility and maintain equipment, that figure can rise to well over USD 1 billion.³
- Clinical development involves a large number 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.

1. Plotkin SA. Health Aff. 2005;24(3):631–634.

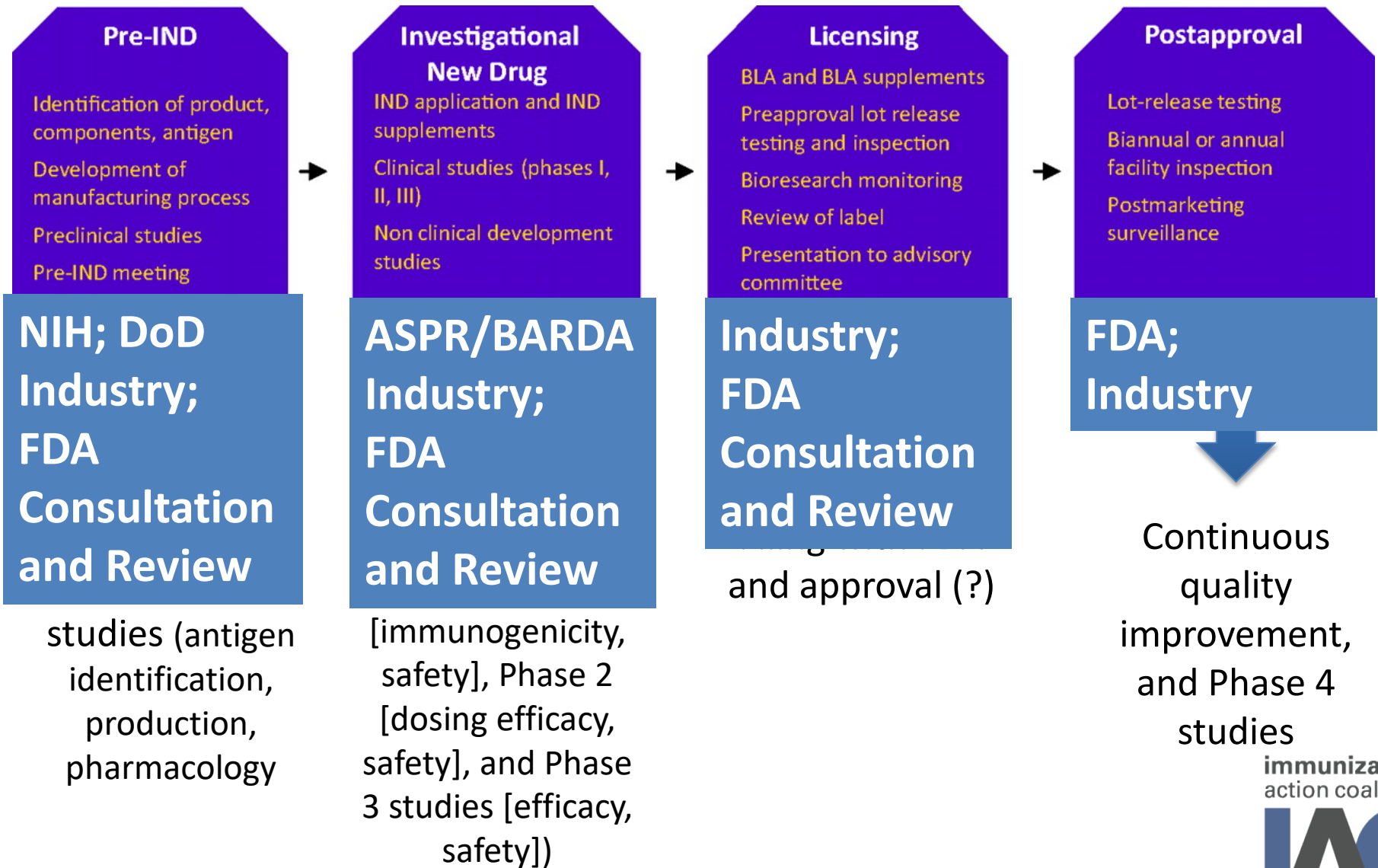
2. Pronker ES. Plos One: <https://doi.org/10.1371/journal.pone.0057755>

3. Center for Global Development. Making Markets for Vaccines: Ideas to Action. Center for Global Development; 2005.

Vaccine development pathway

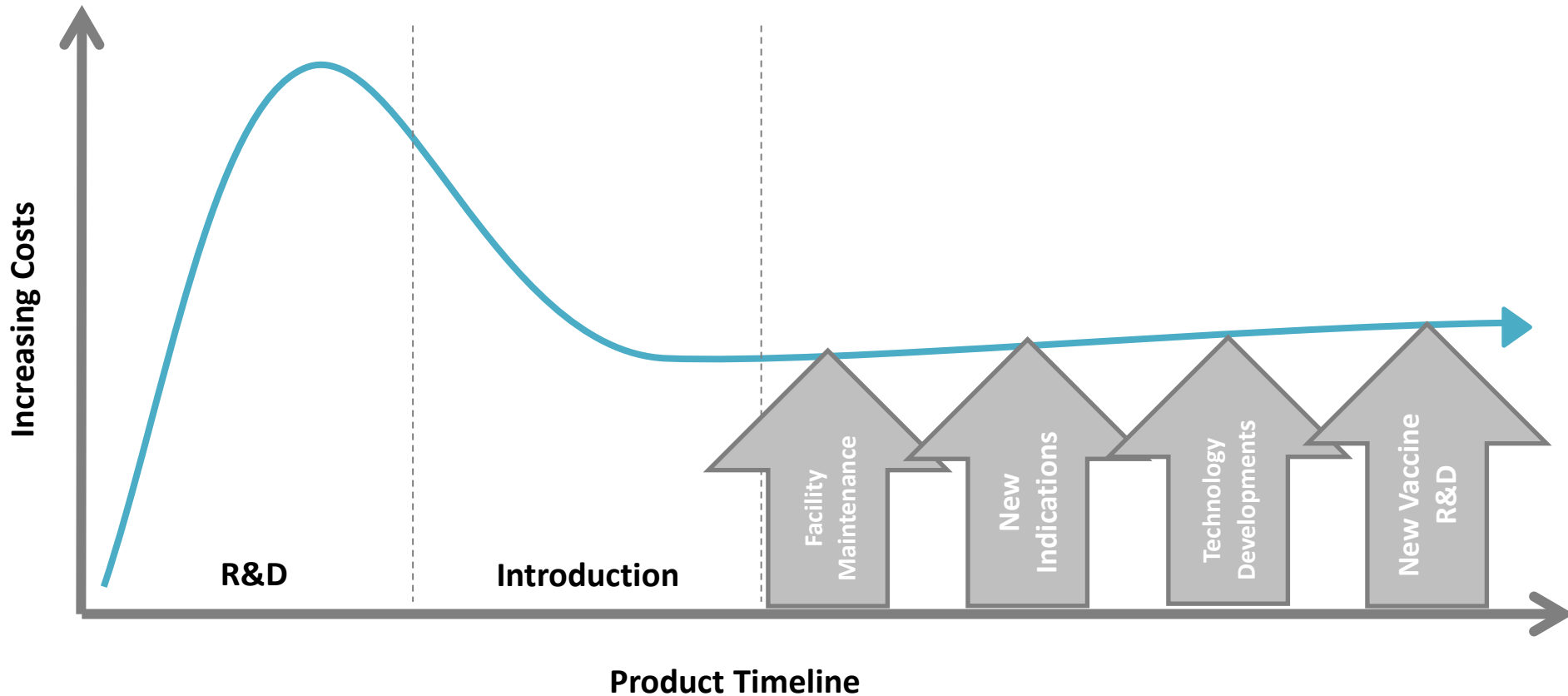


Vaccine development pathway



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

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

Adapted from: Mayhew, S. et al, 2020: [doi: 10.1038/d41573-020-00073-5](https://doi.org/10.1038/d41573-020-00073-5); Berkley, S. 2020: [doi: 10.1126/science.abb8654](https://doi.org/10.1126/science.abb8654); and Lurie, N. et al, 2020: [doi: 10.1056/NEJMp2005630](https://doi.org/10.1056/NEJMp2005630).

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

Adapted from: Mayhew, S. et al, 2020: *doi: 10.1038/d41573-020-00073-5*; Berkley, S. 2020: *doi: 10.1126/science.abb8654*; and Lurie, N. et al, 2020: *doi: 10.1056/NEJMp2005630*.

Visit IAC Resources!

- Read our publications!
 - <http://www.immunize.org/publications/>
- Visit our websites!
 - www.immunize.org
 - www.vaccineinformation.org
 - www.standingorders.org
 - www.izcoalitions.org
 - www.izsummitpartners.org (Summit)
- Stay ahead of the game! Subscribe to our updates!
 - <http://www.immunize.org/subscribe/>

Thank You!