Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

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Upcoming Advisory Committee

- The Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet on December 10, 2020.
  - To discuss the request for emergency use authorization (EUA) of a COVID-19 vaccine from Pfizer, Inc. manufactured in partnership with BioNTech Manufacturing GmbH.
- The meeting will be videocast with specific details forthcoming:
  - https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/2020-meeting-materials-vaccines-and-related-biological-products-advisory-committee

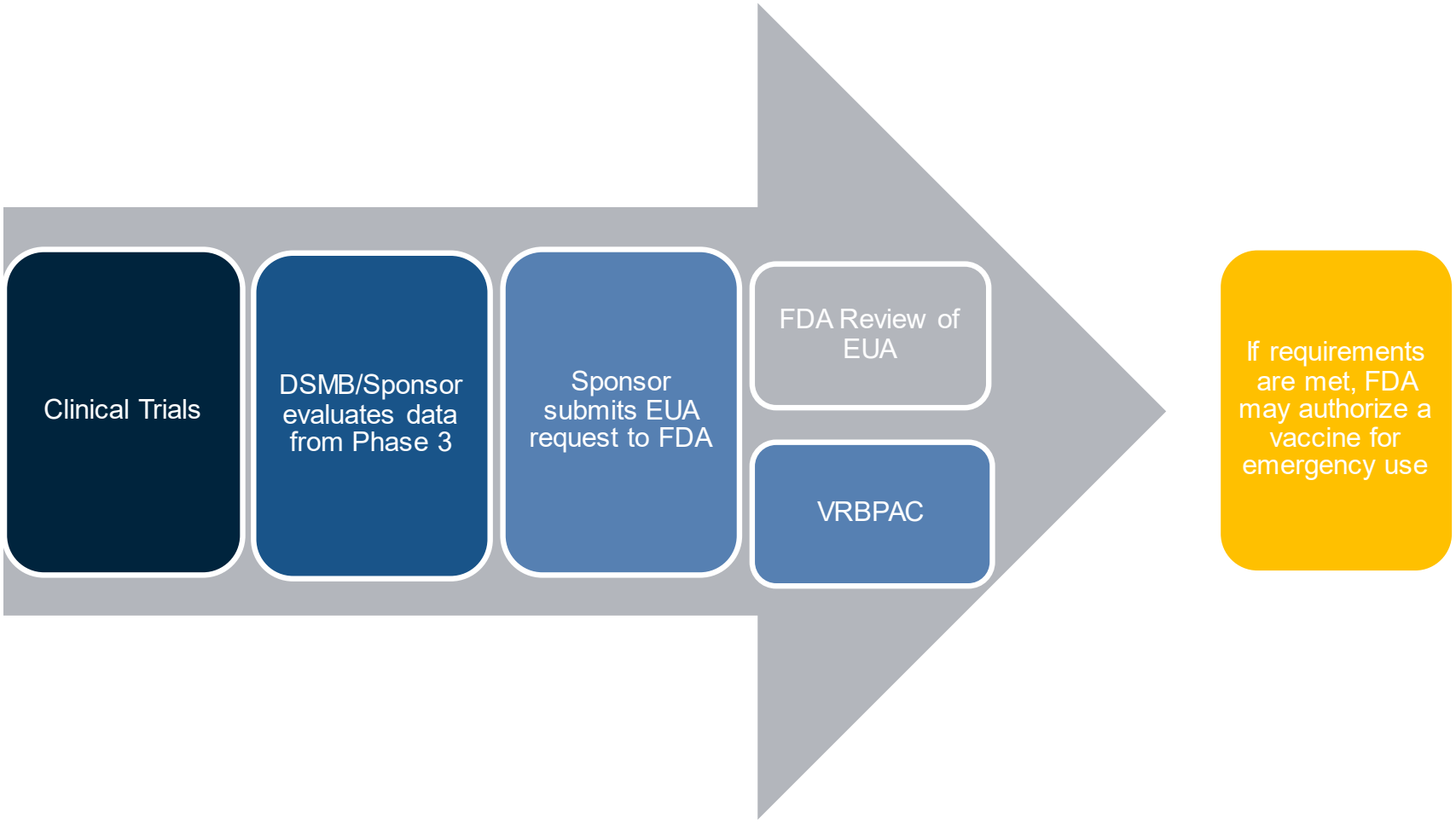
Emergency Use Authorization for Vaccines

- An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic.
- Under an EUA, the FDA may allow the use of unapproved medical products to prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.
  - Taking into consideration input from the FDA, manufacturers decide whether and when to submit an EUA request to FDA.
- Once submitted, FDA will evaluate an EUA request and determine whether the relevant statutory criteria are met, and review the scientific evidence about the vaccine that is available to FDA.
- COVID-19 vaccines are undergoing a rigorous development process that includes tens of thousands of study participants to generate the needed non-clinical, clinical, and manufacturing data.

Requirements for the EUA

- FDA will evaluate nonclinical, clinical, and manufacturing data submitted by a vaccine manufacturer.
- For an EUA to be issued for a vaccine:
  - Adequate **manufacturing** information ensures quality and consistency
  - Vaccine benefits outweigh its risk based on data from at least one well-designed Phase 3 clinical study that in a compelling manner demonstrates:
    - **Safety**
    - **Efficacy**

EUA Process


Clinical Trials
DSMB/Sponsor evaluates data from Phase 3
Sponsor submits EUA request to FDA
FDA Review of EUA
VRBPAC
If requirements are met, FDA may authorize a vaccine for emergency use

Plans for continued monitoring of COVID-19 vaccines authorized by FDA

- **Manufacturer** will submit plans for active follow-up
- **USG Systems**:
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD),
  - Biologics Effectiveness and Safety (BEST) Initiative
  - Medicare Claims Data.

FDA Websites

- **Vaccine Development 101**
  - https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101
- **Emergency Use Authorization for Vaccines Explained**
  - https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

Thank you!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