Development of a Target Product Profile – EUA Issues

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Vaccines, from concept to implementation

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I am a paid member of the Pfizer COVID-19 vaccine Data Monitoring Committee

TPP – Element 14

Registration and Prequalification

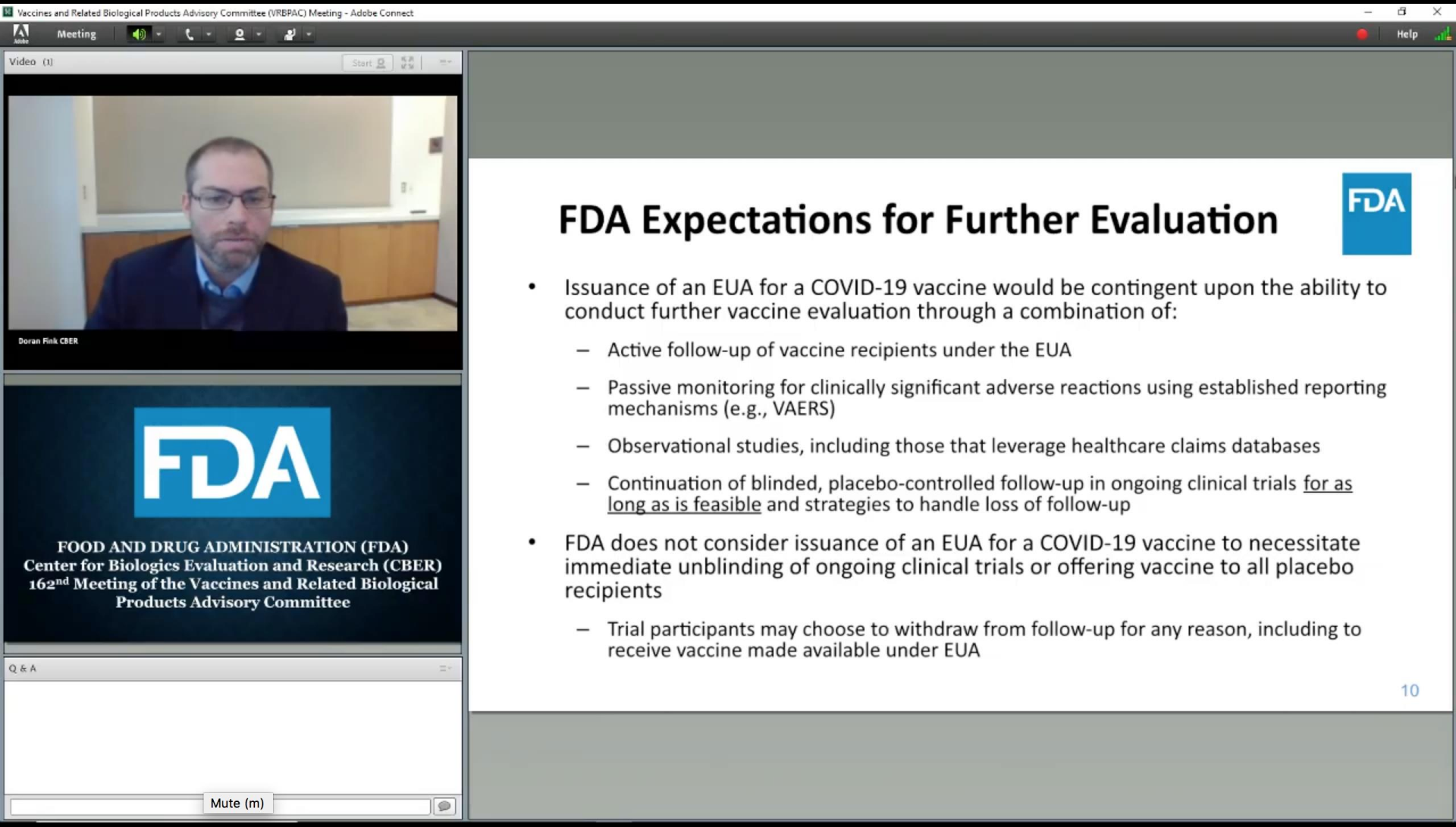
Type of license- e.g. is it experimental

WHO	US FDA
WHO prequalified and/or meets criteria for EUAL (Emergency Use Assessment & Listing Procedure.	Emergency Use Authorization, Expanded Access Program.

EUA requires detailed information on efficacy, short term safety and manufacturing processes.

Vaccines and Related Biological Products Advisory Committee December 10, 2020

- https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement



FDA Meeting December 10, 2020

Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting - Adobe Connect

Meeting

Help

Video (1)

Start

FDA

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
162nd Meeting of the Vaccines and Related Biological Products Advisory Committee

Q & A

What is "owed" to placebo participants.

- Accurate information about the EUA, if granted.
- Freedom to withdraw.
- That they won't be <u>denied</u> vaccine if it becomes otherwise available to them through societal prioritization and local availability.
- <u>Not</u> immediate vaccination in the trial before their turn is called outside of the trial.
- Not necessarily unblinding on demand.
- Potentially, higher priority for vaccine *within their societal prioritization group.*

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Q & A

Cisco Webex Meetings

Pfizer proposal re continuation

- **Offer vaccination to placebo participants > 16 who become eligible for receipt of BNT162b2 according to local or national recommendations. Unblind upon request, and offer vaccine as part of the study.**
- **Regardless of unblinding, all placebo recipients to be offered vaccination at 6 months and followed for 18 mos.** [FDA brief]
- **Pharmocovigilance: HERO, DOD, VA, Health care workers, VAERS**

"We have an ethical responsibility to inform all ongoing study participants of the availability and eligibility criteria of any COVID-19 vaccine made available under an EUA. We will appeal to participants to remain in the ongoing Phase 3 study as originally randomized for as long as possible, ideally until a COVID-19 vaccine has full regulatory approval following the accumulation of 6 months of safety follow-up data after Dose 2. The study team responsible for study conduct would remain blinded …"

But unblinding participants destroys the randomization…..

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Questions?