Development of a Target Product Profile – EUA Issues

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Vaccines, from concept to implementation
(GLHL 7209) – January 19, 2021
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

<table>
<thead>
<tr>
<th>WHO</th>
<th>US FDA</th>
</tr>
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<tbody>
<tr>
<td>WHO prequalified and/or meets criteria for EUAL (Emergency Use Assessment &amp; Listing Procedure).</td>
<td>Emergency Use Authorization, Expanded Access Program.</td>
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EUA requires detailed information on efficacy, short term safety and manufacturing processes.
Vaccines and Related Biological Products Advisory Committee December 10, 2020

FDA Expectations for Further Evaluation

- Issuance of an EUA for a COVID-19 vaccine would be contingent upon the ability to conduct further vaccine evaluation through a combination of:
  - Active follow-up of vaccine recipients under the EUA
  - Passive monitoring for clinically significant adverse reactions using established reporting mechanisms (e.g., VAERS)
  - Observational studies, including those that leverage healthcare claims databases
  - Continuation of blinded, placebo-controlled follow-up in ongoing clinical trials for as long as is feasible and strategies to handle loss of follow-up

- FDA does not consider issuance of an EUA for a COVID-19 vaccine to necessitate immediate unblinding of ongoing clinical trials or offering vaccine to all placebo recipients
  - Trial participants may choose to withdraw from follow-up for any reason, including to receive vaccine made available under EUA
What is “owed” to placebo participants.

- Accurate information about the EUA, if granted.
- Freedom to withdraw.
- That they won’t be denied vaccine if it becomes otherwise available to them through societal prioritization and local availability.
- Not 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.
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]

- Pharmacovigilance: 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…..
Questions?