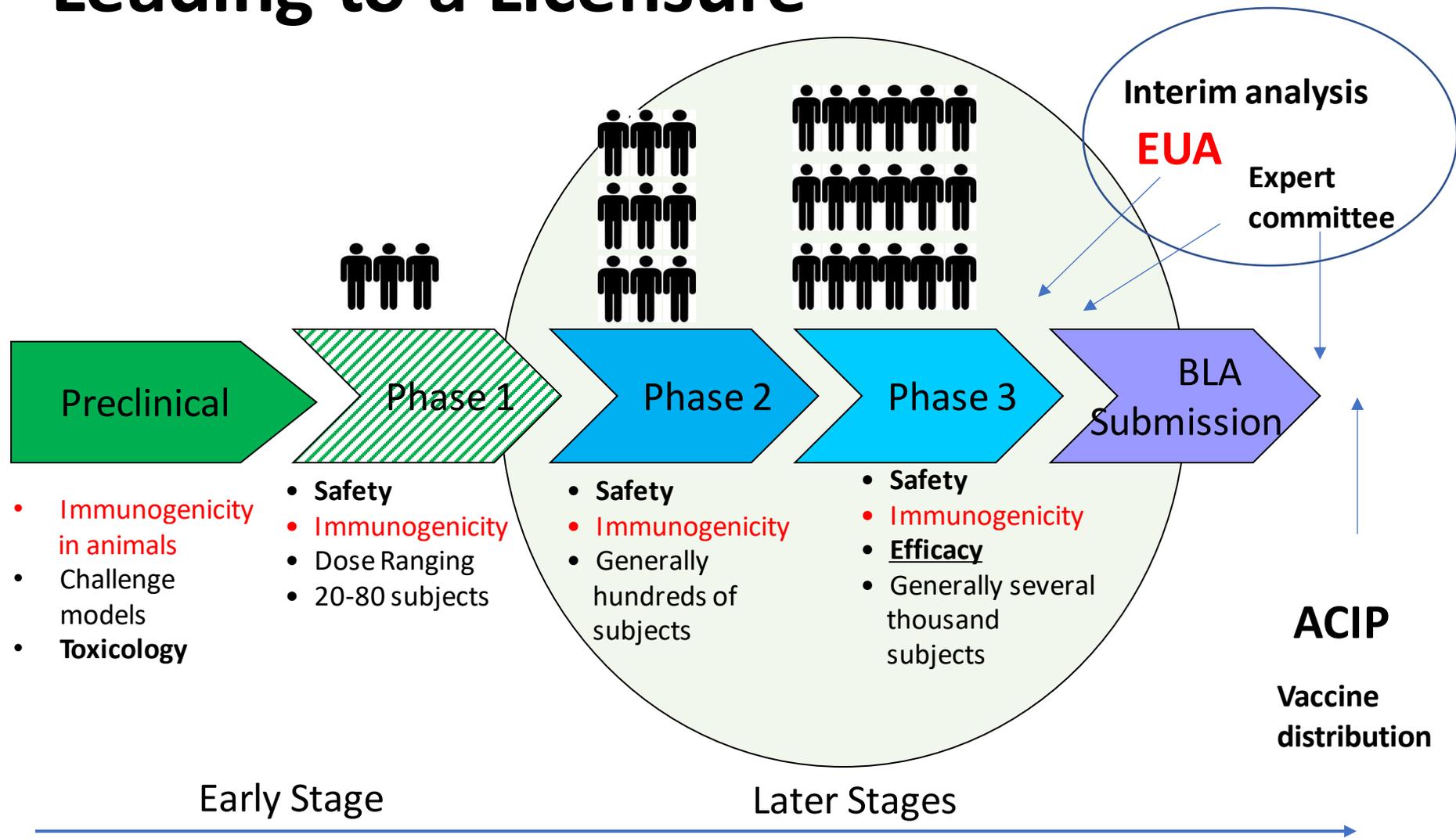


COVID-19 Vaccine  
Efficacy & Safety  
DHS CCICADA WORKSHOP  
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*The view points in this presentation have not been formally disseminated by the FDA and should not be construed to represent any Agency determination or policy*

# Phases of Vaccine Development Leading to a Licensure



**BLA application: Manufacturing (small->large scale); consistency; stability; assay validation; correlates of protection; extended safety and efficacy data (6-12 months)**

# Potential Benefits/Risks of Vaccines

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## Benefits

- **Protect individual against infection**
- Protect individual against severe disease / mortality
- Protect individual against emerging variant strains
- Elicit “long-term” immune memory/protection
- **Reduce transmission to household and community**
- Shield highly susceptible individuals from exposure

## Risks

Reactogenicity (common/transient)

- Local: pain, edema, rash
- Systemic: fever, myalgia, headache, chills, fatigue

Rare

- **Nonspecific immune activation**
- **Autoimmune and other diseases of special interest.**
- **Vaccine Associated Enhanced Disease**

# Points for discussion: gaps in knowledge

## 1. Vaccine Efficacy:

Correlates of protection from infection vs. disease.

- How to capture asymptomatic infections?
- Immune parameters post one vs. two vaccinations
- Longevity of protection
- Impact of spike mutations on neutralization/protection
- Quality of antibodies post infection vs. vaccination (specificity, isotypes, affinity maturation)

## 2. Vaccine Safety:

- Potential mechanisms of hyperactivity (anaphylaxis)
- Potential mechanisms of autoimmunity (mimicry? bystander effects? Polyreactivity?)
- How to identify VAERD – in animal models and humans

# Immune Enhancement of human viral diseases

