THE VACCINE LIFE CYCLE: SAFETY AT EVERY PHASE

VACCINE DEVELOPMENT

- **Phases**:
  - **Pre-Clinical Studies**: Learning Safety and Efficacy
  - **Clinical Studies/Trials**: Learning Safety and Efficacy
  - **FDA Review**: Confirming Safety and Efficacy
  - **ACIP Review**: FDA Approval of New Vaccine
  - **Post-Approval Monitoring + Research**: Continuous safety monitoring and reporting to FDA occurs along with post approval research

**Sponsors closely monitor and report adverse events**

- **Basic Research**
- **Discovery**
- **Pre-Clinical Studies**
- **Clinical Studies/Trials**
- **FDA Review**
- **ACIP Review**
- **Post-Approval Monitoring + Research**

**GUIDE**

- **ACIP**: Advisory Committee on Immunization Practices, part of the CDC (Reviews to inform recommendations for vaccine use in the U.S.)
- **BLA**: Biologics License Application
- **CDC**: The U.S. Centers for Disease Control and Prevention (Supports medical use and access recommendations and a communication network for vaccine information.)
- **FDA**: U.S. Food and Drug Administration (Reviews to inform recommendations for vaccine use in the U.S.)
- **IND**: Investigational New Drug Application

Source: [https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html](https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html)