VACCINE DEVELOPMENT

STANDARD STEPS

- Exploratory Phase
- Pre Clinical Phase
- Investigational New Drug Application
- Phase Ⅰ Vaccine Trials
- Phase Ⅱ Vaccine Trials
- Phase Ⅲ Vaccine Trials
- Phase Ⅳ Vaccine Trials

EXPLORATORY PHASE

- Basic laboratory research
  - Lasts 2-4 years
- Academic and governmental scientists identify natural or synthetic antigens
- Antigens include virus-like particles, weakened viruses or bacteria, weakened bacterial toxins, or other substances derived from pathogens

PRE CLINICAL PHASE

- Uses tissue-culture/cell-culture systems and animal testing to assess safety and ability to provoke an immune response
- Animal subjects may include mice and monkeys
- From this phase researchers get an idea of the cellular responses to expect in humans and a safe starting dose
- Many vaccines do not progress as they fail to produce the desired immune response
- This stage lasts 1-2 years

INVESTIGATIONAL NEW DRUG APPLICATION

- Sponsor submits an application for an IND
  - They describe the manufacturing and testing processes, summarizes the laboratory reports, and describes the proposed study
- Once the IND is approved, the vaccine is subject to three phases of testing

PHASE Ⅰ VACCINE TRIALS

- This first attempt to assess the vaccine in humans involves a small group of adults (20-80)
- If the vaccine is intended for children, researchers will first test adults, then gradually step down the age until they reach their target

Goals:

- Assess safety
- Determine the type and extent of immune response that the vaccine provokes

Phase II Vaccine Trials

- A larger group of several hundred individuals participates
- Some of the individuals may belong to groups at risk of acquiring the disease
  - These trials are randomized and well controlled, and include a placebo group

Phase II Vaccine Trials

Goals

- Vaccine’s safety
- Immunogenicity
- Proposed doses
- Schedule of immunizations
- Method of delivery

Phase III Vaccine Trials

- Involve thousands to tens of thousands of people
- The experimental vaccine being is tested against a placebo (saline solution/vaccine for another disease, or some other substance

Goal

- Assess vaccine safety and efficacy in a large group of people
- Rare side effects may show up in this group

Approval and Licensure

- After a successful Phase III trial, a Biologics License Application is submitted
- Factory inspection of vaccine production is done and if satisfactory, approval is granted

Phase IV trial

- This is an optional phase that drug companies may conduct after a vaccine is released
- The manufacturer may continue to test the vaccine for safety, efficacy, and other potential uses

VACCINE ADVERSE EVENT REPORTING SYSTEM

- Anyone, such as a parent, a health care provider, or friend of the patient, who suspects an association between a vaccination and an adverse event may report that event and information about it to VAERS
- The CDC then investigates the event and tries to find out whether the adverse event was in fact caused by the vaccination

CONCLUSION

- Vaccines are developed, tested, and regulated in a very similar manner to other drugs
- Vaccines are more thoroughly tested than non-vaccine drugs because the number of human subjects in vaccine clinical trials
- There is post-licensure monitoring of vaccines by regulatory bodies

VACCINE 101


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