Texas Biomedical Research Institute

OPTIMIZING VACCINE DEVELOPMENT TIMELINES: THE TEXAS BIOMED DIFFERENCE

THE RIGHT RESOURCES:

The functionality of highly integrated BSL-3/BSL-4 laboratory capacity, multiple nonhuman primate (NHP) species co-located on campus, and scientific and animal care staff highly experienced at pre-clinical science is unmatched.

OPERATIONAL AGILITY:

Highly networked with sponsors, donors, and the NIH, we coordinate agreements, navigate complex regulatory and compliance processes, and initiate studies faster than traditional commercial or academic R&D organizations.

LASER FOCUS ON EVIDENCE-BASED SCIENCE, SAFETY, AND EFFICACY:

With a secure facility, more than 50 years of infectious disease experience, and the credentials and grit that FDA review and approvals demand, we move quickly and unencumbered through clinical trial phases without sacrificing evidence-based science, the safety of patients, or efficacy of therapeutics.

5-15 YEARS

STEP 1

Basic Discovery Research

- Understand the virus: Virologists study the virus through a variety of methods — from genomics to biology.
- Understand the immune response: Immunologists look at how our bodies respond to a virus by searching for immune response drivers.
- Determine whether the immune response is protective: Researchers perform in vitro (cell culture) and in vivo (animal model) studies to test whether antibodies produced protect the immune system and block virus replication.

Texas Biomed has a team of more than 75 PhD scientists focused on infectious disease research and the intersection of infection and chronic diseases, such as diabetes, heart disease and even aging. This focus enables Texas Biomed to speed the rate of discovery and contribute to greater scientific understanding of the interactions between microbes and humans. This research is the foundation for the medicines we take and the technologies that save human lives.

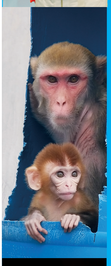
STEP 2

Pre-clinical Development

PART 1: ANIMAL MODEL DEVELOPMENT

- **Why animal models?**
  - Only humans and other primates are susceptible to many of the infectious diseases that threaten human populations.
  - Nonhuman primate models allow investigation of physiological characteristics shared only by humans and other primates.

Texas Biomed addresses research questions using cell cultures, tissue studies and computer models, but research with animals is critical for the advancement of human health. Complex disease processes involve multiple physiological processes and organ systems and require the use of complex models.



PART 2: VACCINE DEVELOPMENT

- Scientists take components of the virus that provide protective immune response and assemble them together, usually one of two ways: 1) using the whole virus (if it is killed to make it noninfectious) or 2) using proteins, RNA or DNA of the virus to make it recognizable.
- They then may incorporate adjuvants to see which drive the best immune response. Typically, only a few work in humans, so those are tested first.
- The vaccine is then designed and screened through a small animal (like rodents, guinea pigs, ferrets, or rabbits) to determine effectiveness. This is usually conducted several times using control animals to ensure the data is repeated and accurate.
- Studies then progress to larger animal models like non-human primates to test safety and efficacy ahead of human clinical trials.

PART 3: FDA SUBMISSION REQUIREMENTS TO MOVE TO HUMAN CLINICAL TRIALS

- Drug developers, or sponsors, must submit an Investigational New Drug (IND) application to FDA before beginning clinical research. In the IND application, developers must include:
  - Animal study data and toxicity (side effects that cause great harm) data
  - Manufacturing information
  - Clinical protocols (study plans) for studies to be conducted
  - Data from any prior human research
  - Information about the investigator
- These plans must adhere strictly to quality control and assurance standards, and provide proof of scientific validity and reproducibility.
- The FDA team requires a 30-day timespan for review in an effort to keep volunteers safe and avoid significant risk.

Texas Biomed is home to the Southwest National Primate Research Center, one of seven national centers in the U.S. dedicated to research with nonhuman primates (monkeys). Texas Biomed is also home to rodent and other animal species research and is the only place in the world to combine these animal research resources with the highest biosafety containment labs and regulated study procedures, which enable the Institute to move through pre-clinical development seamlessly and comprehensively, so as to move therapeutics and vaccines through this part of the pipeline faster.

2-5 YEARS

STEP 3

Clinical Development

PART 1: CLINICAL TRIALS

Over the course of several years, thousands of human patients must be tested before the FDA will grant national approval for a commercialized pharmaceutical product, based on the following phases:

- Phase 1: 20-119 volunteers with no underlying health conditions are tested to find the best dose of a new drug with the fewest side effects. This phase is largely focused on safety for use.
- Phase 2: 100-500 volunteers with the disease or condition being studied are tested to determine the drug's effectiveness and to outline the common short-term adverse effects and risks associated with the drug.
- Phase 3: 1000-5000 volunteers with the disease or condition being studied are tested to evaluate how the new medication works in comparison to existing medications for the same condition. Trials in this phase can last for several years.

PART 2: FDA APPROVAL PROCESS

The FDA's drug approval process includes:

- Analysis of the target condition and available treatments
- Assessment of benefits and risks from clinical data
- Strategies for managing risks
- Approvals can be expedited for serious and life-threatening conditions; however, approvals generally take between 6 and 10 months

1-2 YEARS

STEP 4

Commercial Phase

Before commercialization of a vaccine can begin, the FDA requires:

- FDA approval of the drug for commercialization based upon pre-clinical and clinical study data
- Production of label and description
- Regulatory review & approval, including fair market pricing
- Submission of a Biologics License Application (BLA), a request to introduce or deliver a biologic product into interstate commerce, which takes 6-10 months for approval

From there, companies may commercially market their release of the vaccine.

STEP 5

Manufacturing Scale-up

The fastest a vaccine has ever been made is 5 years, and the manufacturing process typically takes between 6 and 36 months.

The process includes propagation of virus in bulk, purification, clarification, formulation (adding safe stabilizers and preservatives), and quality control through several hundred test processes.

STEP 6

Distribution to Providers & Patients

Once large-scale manufacturing is established, the vaccines can then be packaged, batch released, transported and distributed/shipped to healthcare providers.