OPTIMIZING VACCINE DEVELOPMENT TIMELINES: THE TEXAS BIOMED DIFFERENCE

THE RIGHT RESOURCES:
The Texas Biomedical Research Institute (TBRI) is dedicated to infectious disease research. Texas Biomed is home to the largest collection of nonhuman primates (monkeys) in the world to combine these animal research resources with the safety, efficacy, and regulatory expertise needed to introduce or deliver a biologic product into interstate commerce.

OPERATIONAL AGILITY:
Highly networked with sponsors, donors, and the NIH, Texas Biomed coordinates agreements, maximizes efficiency, and navigates complex regulatory and compliance processes, and initiates studies faster than traditional commercial or academic R&D organizations.

LASER-FOCUS ON EVIDENCE-BASED SCIENCE, SAFETY, AND EFFICACY:
Texas Biomed’s multi-disciplinary team of more than 750 research scientists, professional animal care staff highly experienced at pre-clinical science is unmatched.

1-2 YEARS

STEP 1 Basic-Discovery Research

- Scientists take components of the virus that provide protective immunity.
- They then may incorporate adjuvants to see which drive the best immune response.
- Immunologists look at how our bodies respond to a virus by searching for immune response drivers.
- Virologists study the virus through a variety of methods — from genomics to biology.

2-5 YEARS

STEP 2 Pre-clinical Development

- PART 1: ANIMAL MODEL DEVELOPMENT
  - New Drug (IND) application to FDA before beginning clinical trials.
  - Investigators select appropriate animal model (like rodents, guinea pigs, ferrets, or rabbits) to determine viral pathogenesis and identify the route of infection.
  - Disease is induced using the same route of anticipated human infection.
  - Nonhuman primates to test safety and efficacy ahead of human clinical trials.
  - These primates are capable of simulating human disease.

- PART 2: VACCINE DEVELOPMENT
  - Trial vaccines are tested first.
  - The vaccine is then designed and screened through a small animal (like rodents, guinea pigs, ferrets, or rabbits) to determine viral pathogenesis and identify the route of infection.
  - Test whether antibodies produced protect the immune system and confer immunity.
  - How our immune system responds to a virus.
  - 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.

5-15 YEARS

STEP 3 Clinical Development

- PART 1: CLINICAL TRIALS
  - The vaccine is then tested in humans in three phases.
  - Phase 1: 20-119 volunteers with no underlying health conditions.
  - Phase 2: 100-500 volunteers with the disease or condition being treated.
  - Phase 3: 1000-5000 volunteers with the disease or condition being treated.
  - Phase 3 studies are usually conducted in different parts of the world to ensure the data is repeated and accurate.
  - This phase is largely focused on safety for use.

- PART 2: FDA APPROVAL PROCESS
  - New Drug (IND) application to FDA before beginning clinical trials.
  - Investigator selects appropriate animal model (like rodents, guinea pigs, ferrets, or rabbits) to determine viral pathogenesis and identify the route of infection.
  - Disease is induced using the same route of anticipated human infection.
  - These plans must adhere strictly to quality control and assurance procedures.

12 YEARS

STEP 4 Commercial Phase

- PART 1: MANUFACTURING SCALE-UP
  - The vaccine is then designed and screened through a small animal (like rodents, guinea pigs, ferrets, or rabbits) to determine viral pathogenesis and identify the route of infection.
  - The fastest a vaccine has ever been made is 5 years, and the Texas Biomedical Research Institute believes it can do it faster.
  - Clarification, formulation (adding safe stabilizers and preservatives), and quality control through several hundred test processes.

- PART 2: DISTRIBUTION
  - The vaccine is then designed and screened through a small animal (like rodents, guinea pigs, ferrets, or rabbits) to determine viral pathogenesis and identify the route of infection.
  - One thing TBRI has learned over the years... The vaccine is then designed and screened through a small animal (like rodents, guinea pigs, ferrets, or rabbits) to determine viral pathogenesis and identify the route of infection.

20 YEARS

STEP 5 Distribution to Providers & Patients

- PART 1: COMMERCIAL MARKETING
  - The vaccine is then designed and screened through a small animal (like rodents, guinea pigs, ferrets, or rabbits) to determine viral pathogenesis and identify the route of infection.
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- PART 2: REGULATORY SUBMISSION
  - The vaccine is then designed and screened through a small animal (like rodents, guinea pigs, ferrets, or rabbits) to determine viral pathogenesis and identify the route of infection.
  - Information about the investigator.
  - Data from any prior human research.
  - Clinical protocols (study plans) for studies to be conducted.
  - Manufacturing information.

10 YEARS

STEP 6 Distribution to Providers & Patients

- PART 1: COMMERCIAL MARKETING
  - The vaccine is then designed and screened through a small animal (like rodents, guinea pigs, ferrets, or rabbits) to determine viral pathogenesis and identify the route of infection.
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- PART 2: REIMBURSEMENT
  - The vaccine is then designed and screened through a small animal (like rodents, guinea pigs, ferrets, or rabbits) to determine viral pathogenesis and identify the route of infection.
  - Information about the investigator.
  - Data from any prior human research.
  - Clinical protocols (study plans) for studies to be conducted.