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# Life Sciences Caucus Meeting
April 17, 2025
7:30am

Co-chairs:
Senator Chaudhuri
Representatives White and Reives

Meeting will begin shortly

NovaQuest Capital Management

# Drug Development and Vaccines Overview

NC General Assembly Life Sciences Caucus
April 17, 2025

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# Bio

Devin Rosenthal, Principal & Head of Due Diligence at NovaQuest Capital Management, has broad operational and strategic experience across a range of therapeutic areas, stages of development, and company types within the biopharmaceutical industry. As a member of the NovaQuest investment team, he is responsible for deal sourcing, structuring, due diligence, negotiation, and post-close investment management.

Prior to NovaQuest, Devin was a Senior Consultant at Triangle Insights Group, a boutique life sciences strategy consulting firm, where he focused on corporate strategy, due diligence, mergers and acquisitions, and commercial forecasting. His earlier experience includes work in integrated product development and regulatory affairs at Rho, a mid-size contract research organization; companion diagnostics at Novartis Oncology; and clinical development at Boston Biomedical Inc, all following postdoctoral training at Tufts University's Molecular Oncology Research Institute.

In addition to NovaQuest, Devin also serves as an Advisor to local biotech startups as part of the UNC KickStart Advisory Group. Devin holds a PhD in cellular and molecular biology from the University of Michigan, an executive MBA from the Kenan-Flagler Business School at the University of North Carolina at Chapel Hill (finance concentration), and a BS in biology from the University of North Carolina at Wilmington.

**Devin Rosenthal PhD, MBA**
Principal & Head of Due Diligence
*NovaQuest Capital Management*

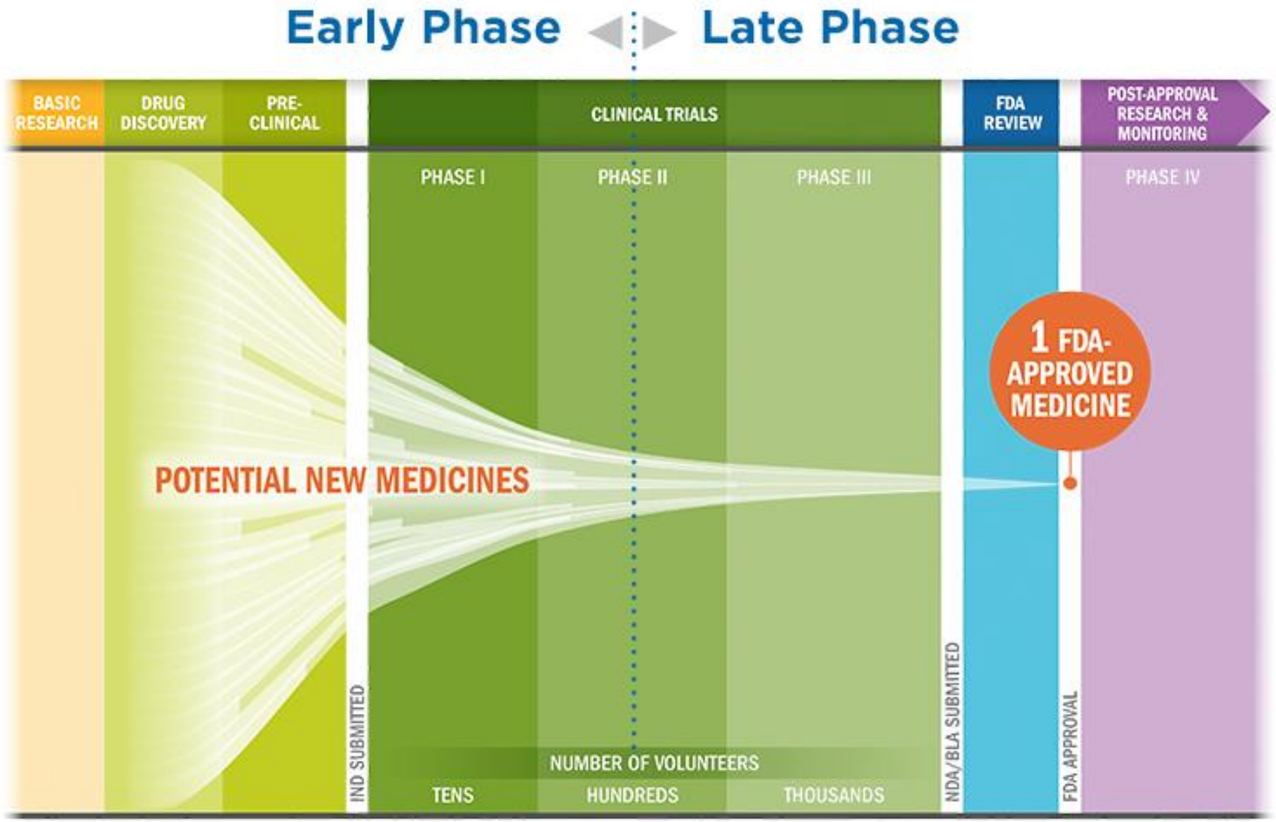
**Education**

UNCW · University of Michigan · UNC Kenan-Flagler Business School

**Professional Experience**

Boston Biomedical (Sumitomo Dainippon Pharma Global Oncology) · NIH National Institute on Aging · Rho · Triangle Insights Group by mercalis · Novartis · Tufts University · NovaQuest Capital Management

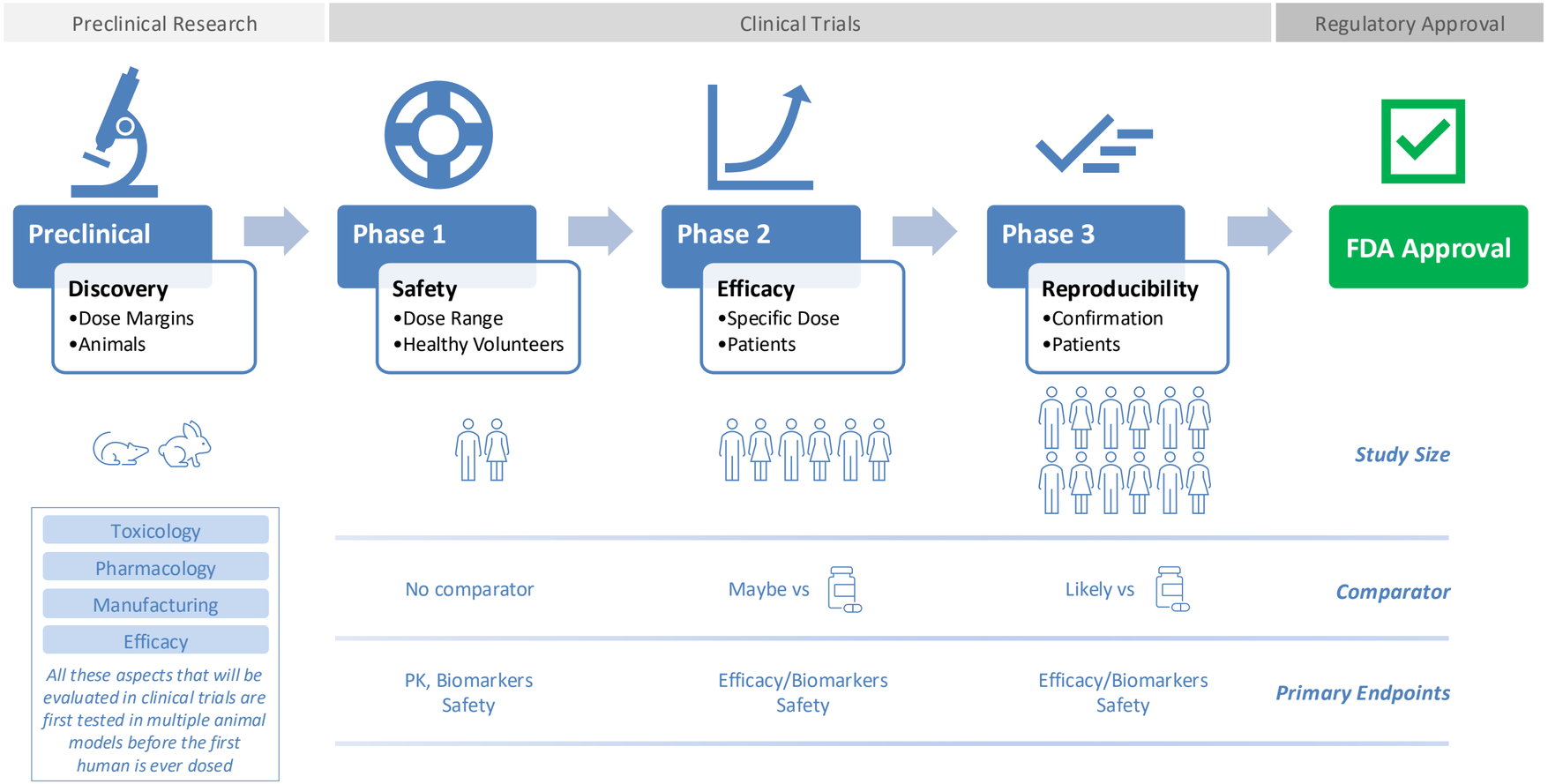
# Drug Development Process Overview




Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

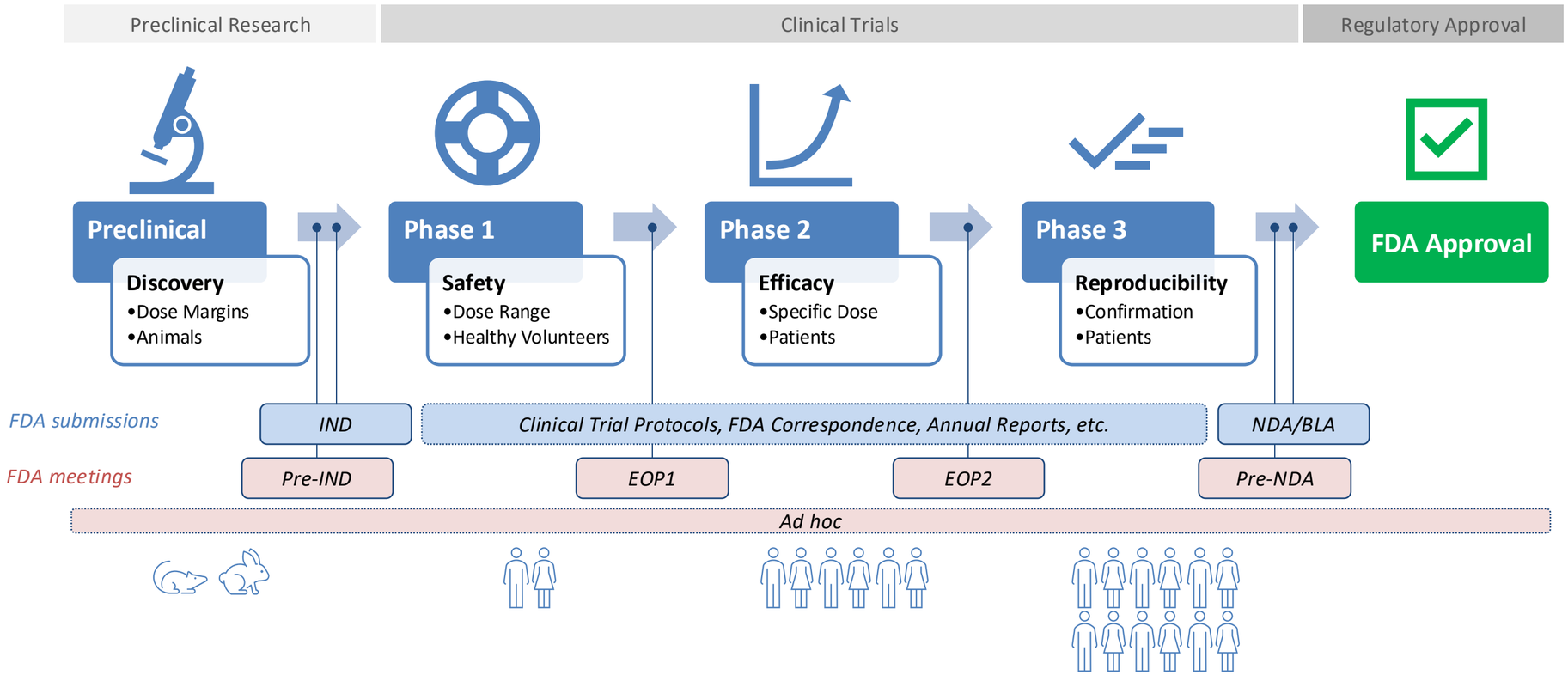
**Graphic Source: http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf**

# Drug Development by Phase – Overview




PK = Pharmacokinetics

# Drug Development by Phase – FDA Involvement




BLA = Biologics Licensing Application; EOP = End of Phase meeting; IND = Investigational New Drug Application; NDA = New Drug Application

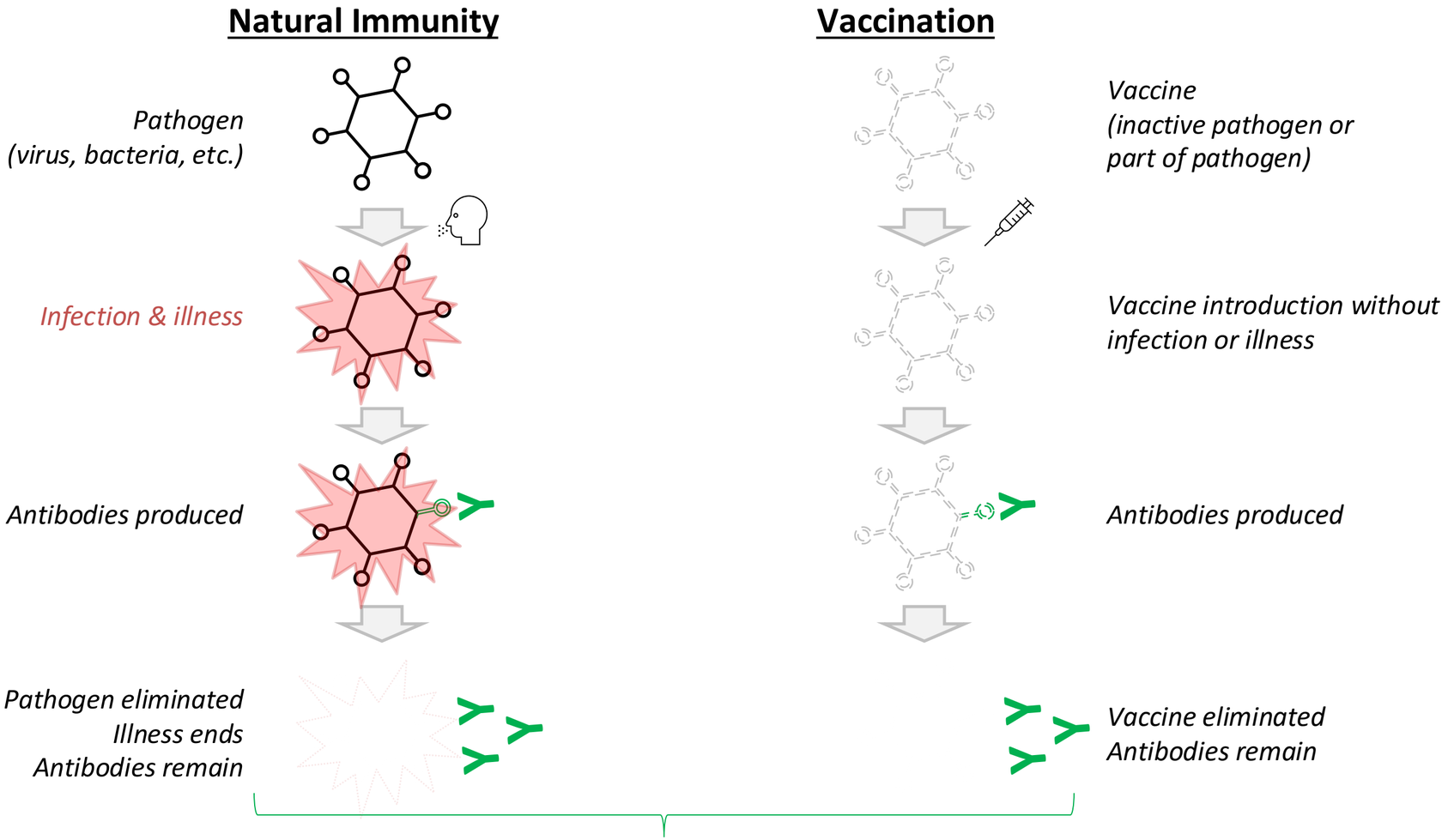
# Drug Development by Phase – Figures & Statistics

| | DRUG RESEARCH | CLINICAL TRIALS | | | REGULATORY APPROVAL |
|---|---|---|---|---|---|
| | **Pre-Clinical** | **Phase I** | **Phase II** | **Phase III** | **Regulatory Approval** |
| Probability Of Phase Success | 35% | 52% | 29% | 58% | 91% |
| Overall Likelihood of Approval | <3% | 8% | 15% | 52% | 91% |
| Time | ~5 – 7 Years | ~2 – 4 Years | ~2 – 3 Years | ~2 – 3 Years | ~1-2 Years |
| Cost ($MM) | -* | $85 | $62 | $470 | $7 |

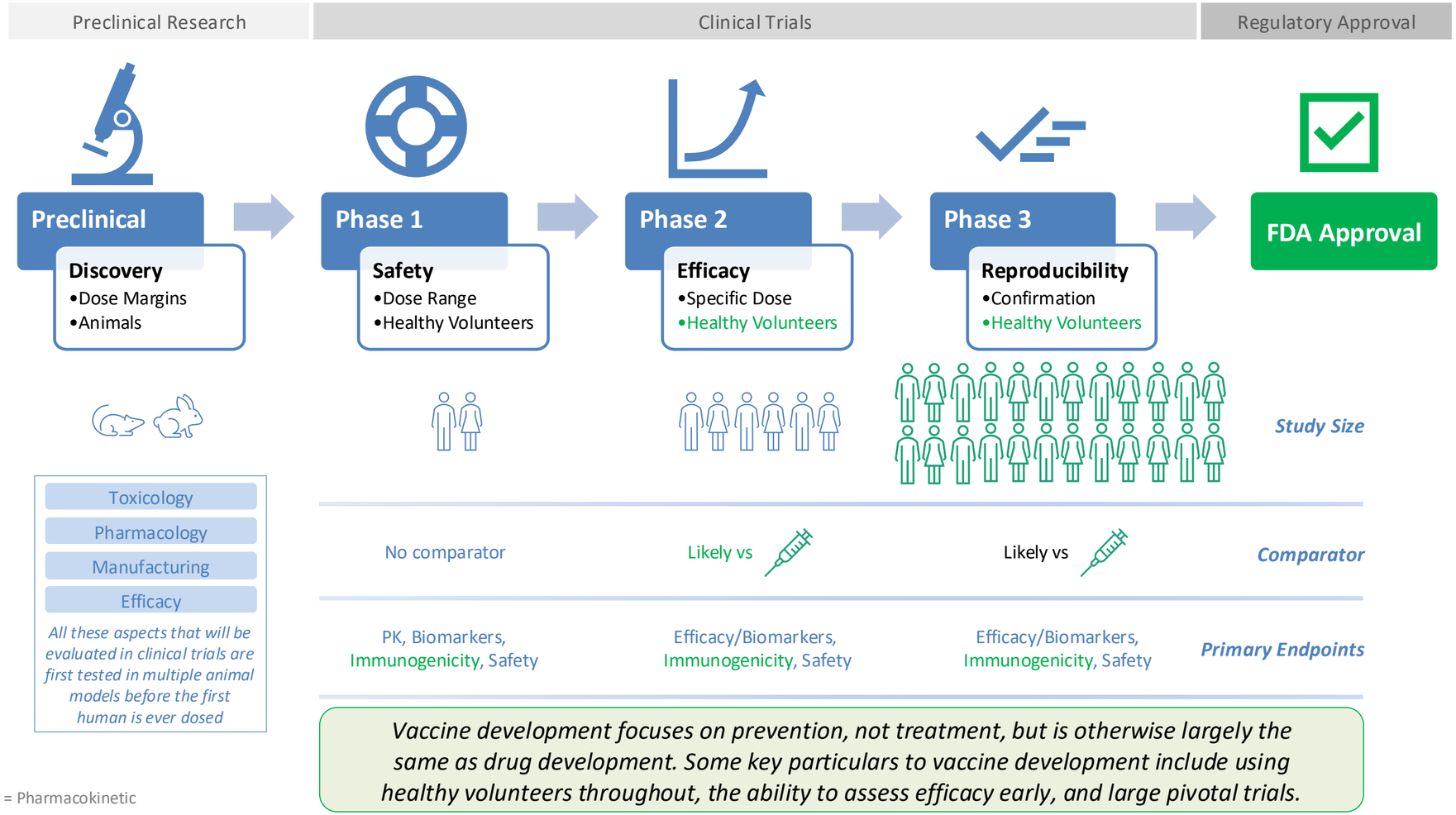
*Biopharmaceuticals is the most R&D-intensive industry in the US, investing six times more on average (as a % of sales) than all other manufacturing industries. There are more than 5,500 medicines in clinical development around the world.*

*Preclinical expenses are difficult to directly account for—estimates range from $10-100m+
Source: PhRMA, Bio, JAMA, Alacrita Consulting

# Vaccines Overview



# Drug Development by Phase – Vaccines

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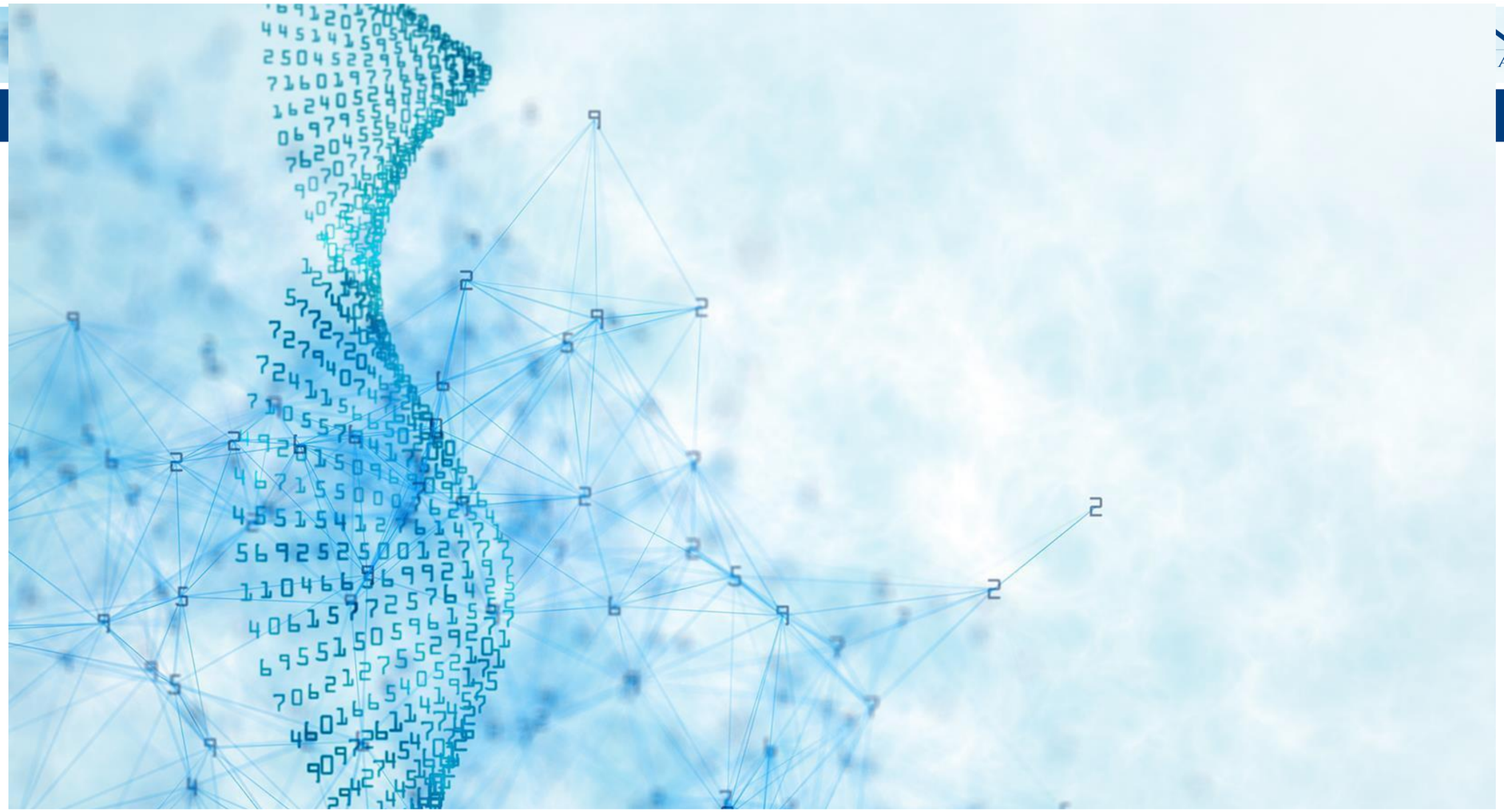

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# Session Bill review

NC Life Sciences Organization

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# Economic Development

- S267: 2025 Appropriations Act (Sen. Jackson)
  - One NC Small Business Fund
  - NC Biotechnology Center
  - Community College funding (PROPEL)
- H154: Reclaim State Assets from NC Innovation (Rep. Warren)
- H283: Small Business Investment Grant (Rep. Reives)
- H365: Workforce Education Act (Rep. Reives)
- H694: Study Water/Wastewater Regionalization (Rep. Warren, Rep. Ross)

# Patient-Related Bills

- H67/S336: Interstate Medical Licensure Compact/Internal Phys (Rep. Reeder/Sen Sawrey)
- H297/S553: Breast Cancer Prevention Imaging Parity (Rep. Belk/Sen. Batch)
- H525: Reorganize and & Fund Rare Disease Adv. Council (Rep. Carney)
- H555/S369: Medicaid Telehealth Services (Rep. Lambeth/Sen. Galey)
- H567: Ensure Access to Biomarker Testing (Rep. Wheatley)

# Pharmaceutical Industry

- H75: Pharmaceutical Disclosure Act (Rep. Warren)
- H163: Pharmacy Benefit Managers Provisions (Rep. Rhyne)
- H460: Medical Equipment Right to Repair (Rep. Belk)
- H592: Toxic-Free Medical Devices (Rep. Reeder)
- H624: Prescription Drug Pricing (Rep. Crawford)
- S479: SCRIPT Act (Sen. Sawrey)

# Vaccine-Related Bills

- H89: University Vaccination Freedom Act (Rep. Gable)
- H380: Conscientious Objection to Vaccine Mandates (Rep. Almond)
- H440: Healthy Food, Healthy Bodies (Rep. Winslow)
- H803: 3-Year FDA Approval for New Childhood Vaxx (Rep. Blackwell)