

The Drug Development Process and the Role of Statisticians

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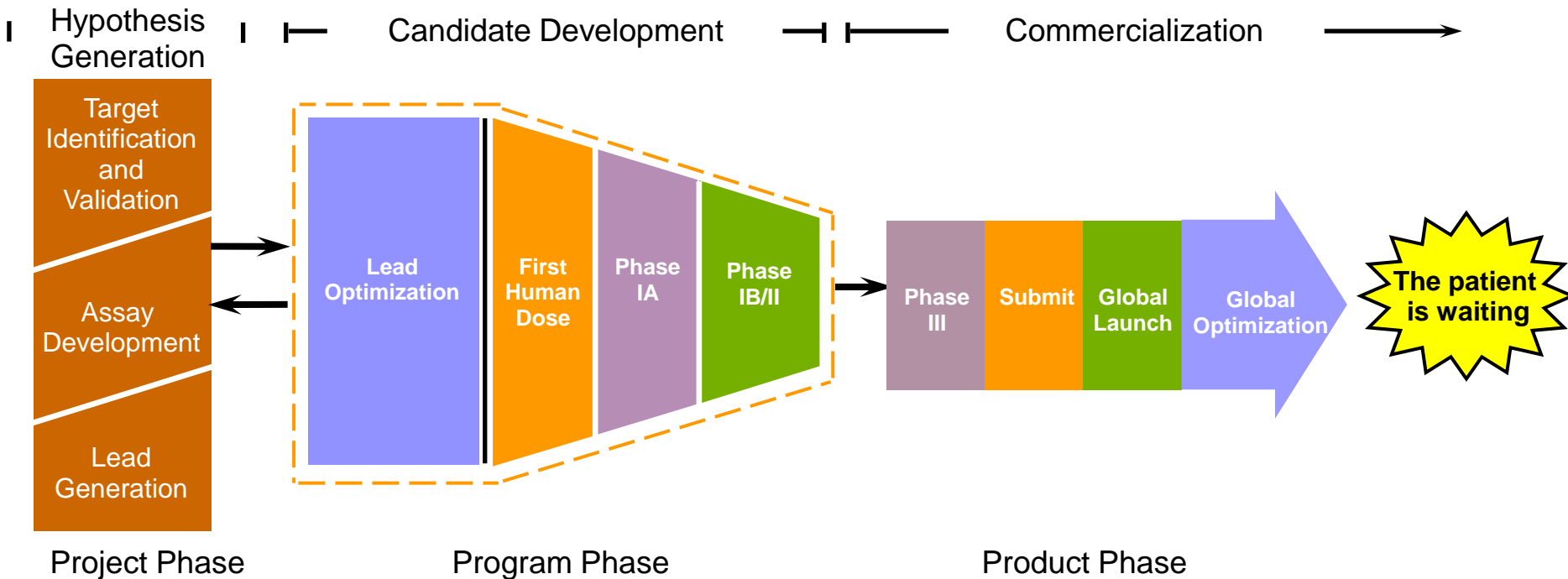
Eli Lilly and Company

Industry Overview

- **4300 companies in drug research**
- **261 companies (6%) have had a drug approved by FDA**
- **32 have been in business since 1950**
- **20 companies produced approx ½ the approvals**
- **Companies with most approvals**
 - **Merck 56**
 - **Lilly 51**
 - **Roche 50**
 - **Pfizer 45**
 - **Wyeth 43**
 - **Abbot 38**

Munos, Nature Reviews, 2009

Drug Discovery and Development Process



Cost of a new pharmaceutical

- Average cost to discover/develop a new drug = \$800 million to approximately \$1.2 billion
- Average length of time from discovery to patient = 10 to 15 years
- Only one new chemical entity (NCE) out of 10,000 candidates will make it to launch.

Type of Statistical Positions

•Project Statistician

- Ph.D. preferred
- Study design, data analysis methods, results interpretation, learning/applying new methods, improving existing methods

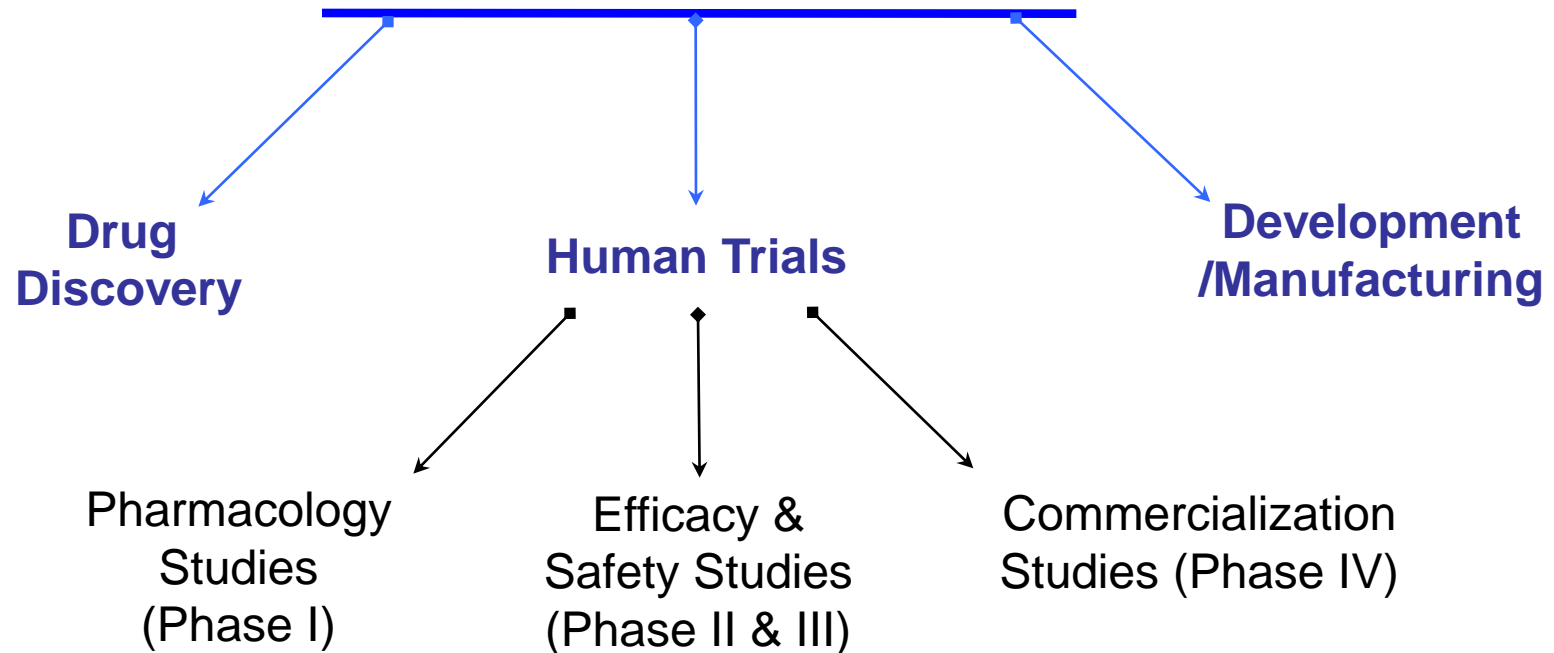
•Statistical Analyst

- Master preferred
- Emphasis on SAS/programming & implementation of analyses

•Career Paths

- Technical
- Administrative
- Combination of two

Statistical Support in Different Phases



Statistical support Areas

- **Oncology**
- **Diabetes**
- **Biomedicine: Autoimmune, Cardiovascular, Bone/Muscleskeletal/Joints, Urology**
- **Neuroscience**
- **Discovery/Development/Manufacturing**
- **Advanced Analytics Hub**