From “Bench to Bedside”

Russ H. Read

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Talent Required

Scientists, clinicians, **technicians**, chemists, biologists, pharmacologists, toxicologists, **research associates**, regulatory experts, manufacturing & production teams, packaging, ancillary support teams etc.,
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Work up of a bench molecule may be summed up as:

**Preclinical Testing**

Process includes:

- Chemistry - design and synthesis
- Quality of pharmaceutical
- Predictability of pharmacology
- Cellular efficacy
- Cellular toxicity
- Absorption, Metabolism, Efficacy, Safety & Toxicity in an animal model
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Preclinical

• The goal is to get the most predictable, efficacious and safe candidate into animal experimentation.
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Preclinical Jobs

- Research & Analytical Technician - Chemistry, Pharmacology, Quality, Microbiology, Production, Regulatory
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Drug Development Process

Preclinical | Investigational New Drug | Phase I | Phase II | Phase III | Market/Post Market

First entry into man - Clinical Phase
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Process Summarized

IND

Characterization

NDA

Clinical & Regulatory

Pharmaceutical Science & Production

Product & Market

Delivery
Dispensing
Pricing
Benefits
Surveillance
# The Drug Discovery, Development and Approval Process for Biopharmaceuticals (Biologics)

## DISCOVERY

<table>
<thead>
<tr>
<th>Testing Phase</th>
<th>Discovery / Preclinical Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Population</td>
<td>Laboratory and animals studies</td>
</tr>
<tr>
<td>Purpose</td>
<td>Assess safety, biological activity and formulation</td>
</tr>
<tr>
<td>Success Rate</td>
<td>5,000 compounds evaluated</td>
</tr>
<tr>
<td>Manufacturing Activities</td>
<td>Cell line construction, Cell banking</td>
</tr>
<tr>
<td>Years</td>
<td>6.5</td>
</tr>
<tr>
<td>Approximate Cost</td>
<td>$350M</td>
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</tbody>
</table>

## DEVELOPMENT

### Clinical Trials

<table>
<thead>
<tr>
<th>Phase</th>
<th>Purpose</th>
<th>Test Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Determine safety and dosage</td>
<td>20 to 100 healthy volunteers</td>
</tr>
<tr>
<td>Phase II</td>
<td>Evaluate effectiveness, look for side effects</td>
<td>100 to 500 patient volunteers</td>
</tr>
<tr>
<td>Phase III</td>
<td>Confirm effectiveness, monitor adverse reactions from long-term use</td>
<td>1,000 to 5,000 patient volunteers</td>
</tr>
</tbody>
</table>

### Manufacturing Activities

- Process development, assay development, process optimization, scale-up, cGMP manufacture

<table>
<thead>
<tr>
<th>Year</th>
<th>Cost</th>
</tr>
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<tbody>
<tr>
<td>1.5</td>
<td>$70M</td>
</tr>
<tr>
<td>2</td>
<td>$100M</td>
</tr>
<tr>
<td>3.5</td>
<td>$200M</td>
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</table>

## LAUNCH

### File IND at FDA

- 5 enter trials

### File NDA at FDA

- 1 approved

### File NDA at FDA for Phase IV

- Additional post-marketing testing required by FDA
- Commercial manufacture
- 1.5 years
- $80M
- = $1B
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Clinical Research Jobs

• Assist in conducting clinical trials at research sites

• Monitor clinical trials for pharmaceutical, biotechnology, and medical device companies and CROs

• Manage data for companies developing drug and medical devices as well as the biotechnology industry and CROs
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Skill Sets

• Regulatory foundational knowledge
• Understanding of industry standards for documentation
• IT use
• People skills
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Clinical Trials Research Programs- Durham Tech

Associate in Applied Science(Degree) includes heavy science component and internship

CTRA - Certificate Level 1 - 4 semesters (first 4 courses) and one full year of Clin. Research Exp.

CTRA - Certificate Level II - 4 semesters (second 4 courses) requires Level I or two years of Clin. Research Exp.

Data Management Certificate - Completion of Level I or Level II or BS or Grad. Degree or data management exp.

Program Manager: Bill Gluck PhD- gluckw@durhamtech.edu

http://www.durhamtech.edu/health/clintrials.htm

Special thanks to Bill Gluck (Durham Tech), Sengyong Lee (Ivy Tech) and William Lee (Cato Research) for technical assistance.
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Technician & Research Associate Jobs

• **Analytical Phase** - Chemistry, Lab, Quality, Microbiology, Production, Regulatory

• **Clinical Phase** - Regulatory, Data, Research, Production, Commercial, Outcomes

• **Clin. Research Jobs** - medical monitor, In house monitor, clinical or site monitor (CRA)
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<th>Phase II</th>
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Thank You
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