National Center for the Biotechnology Workforce

From "Bench to Bedside"

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June 23, 2014

Forsyth Tech Community College

c3bc Community College Consortium for Bioscience Credentials

#TC-23761-12-60-A-37

BioNetwork NC Community Colleges Creating Success in Life Science

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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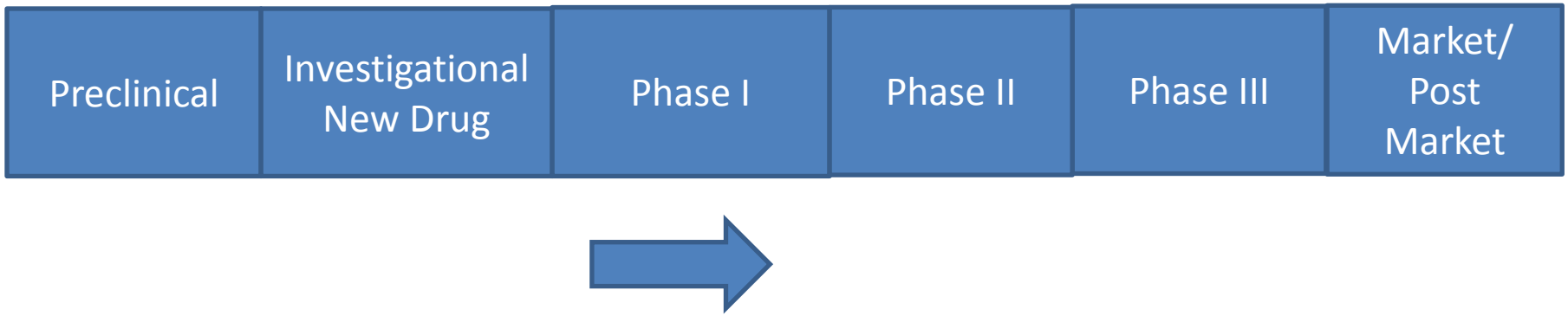
Drug Development Process



First entry into man - Clinical Phase

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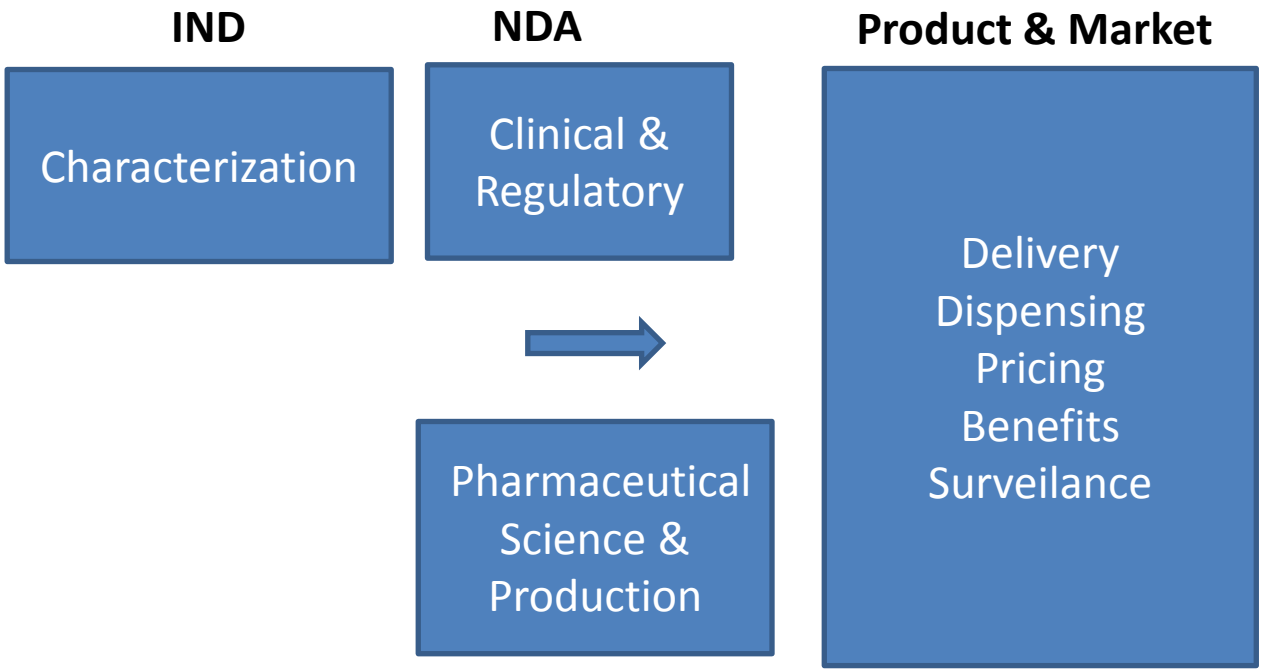
Process Summarized



The Drug Discovery, Development and Approval Process for Biopharmaceuticals (Biologics)

DISCOVERY DEVELOPMENT LAUNCH

Testing Phase	Discovery / Preclinical Testing
Test Population	Laboratory and animals studies
Purpose	Assess safety biological activity and formulations
Success Rate	5,000 compounds evaluated
Manufacturing Activities	Cell line construction, Cell banking
Years	6.5
Approximate	$350M

File IND at FDA

Clinical Trials		
Phase I	Phase II	Phase III
20 to 100 healthy volunteers	100 to 500 patient volunteers	1,000 to 5,000 patient volunteers
Determine safety and dosage	Evaluate effectiveness, look for side effects	Confirm effectiveness, monitor adverse reactions from long-term use
5 enter trials		
Process development, assay development, process optimization, scale-up, cGMP manufacture		
1.5	2	3.5
$70M	$100M	$200M

File NDA at FDA

File application	Phase IV
Review process / approval	Additional post-marketing testing required by FDA
1 approved	
Commercial manufacture	
1.5	=15
$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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Thank You

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