Developing a Career in Clinical and Translational Research

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Course Objectives

- Identify a research question
- Pick a study design
- Recruit subjects
- Collect and manage data
- Analyze data
- Write an abstract
- Present a poster
- Publish a paper
- Prepare a grant

- Identify institutional resources
- Appreciate the ethical, legal and regulatory issues in human subjects research
- Understand the multidisciplinary nature of research
- Recognize career opportunities in clinical and translational research
Audience participation

- Faculty
- Staff
- Fellows
- Residents
- Graduate Students
- Professional Students
- Undergraduate Students
- Other?
- Multiple?
My Typical Collaborations

- ID Physician and Clinical Researcher
- Biostatistician
- Genomics scientist
- Clinical and Research Microbiologist
Clinical Research Team

- Project Manager
- Regulatory Specialist
- Recruiter
- Research assistant

- Quality control coordinator
- Data manager and analyst
- Budget administrator
Careers in Clinical Research

- **Industry**
  - Pharmaceutical, Biotechnology and Medical Device

- **Government Service**
  - Regulatory
  - Public Health

- **Academic Research**
  - Faculty and Staff
The drug discovery and development pipeline

- **Target identification**
- **Hit generation**
- **Lead generation**

**Clinical development phase**
- Early-stage research and discovery
- Preclinical studies in animal models
- Phase I: safety; 20–80 healthy individuals (~1–2 years)
- Phase II: efficacy, safety; 100–300 patients (~1–2 years)
- Phase III: efficacy, safety; 1,000–3,000 patients (~2–3 years)
- FDA review and approval (~1–2 years)

**Approval phase**
- Post approval

**% compounds advanced at each stage**
- ~5%
- ~2%
- ~20%

**Cost**
- $335 million
- $467 million
- $96 million
# Clinical Research Positions in Industry

<table>
<thead>
<tr>
<th>Positions</th>
<th>Backgrounds</th>
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</thead>
<tbody>
<tr>
<td>- Pharmaceutical development</td>
<td>- Basic science</td>
</tr>
<tr>
<td>- Manufacturing</td>
<td>- Chemistry</td>
</tr>
<tr>
<td>- Medical writers</td>
<td>- Medicine and Nursing</td>
</tr>
<tr>
<td>- Medical monitors, clinical research associates, project managers</td>
<td>- Engineering</td>
</tr>
<tr>
<td>- Data management, statisticians</td>
<td>- Pharmacy</td>
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<tr>
<td>- Regulatory</td>
<td>- Statistics, computer science</td>
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<tr>
<td></td>
<td>- Patent law</td>
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<td></td>
<td>- Business</td>
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</table>
Careers in Clinical Research

- **Industry**
  - Pharmaceutical, Biotechnology and Medical Device

- **Government Service**
  - Regulatory
  - Public Health

- **Academic Research**
  - Faculty
  - Staff
**Government: Department of Health & Human Services**

- 27 Institutes and Centers
- Intramural research
- Scientific Review Officers, Program Officers

**Environmental Protection Agency**: Epidemiologists, toxicologists, microbiologists

**Department of Energy**: Los Alamos, Sandia, Brookhaven, Lawrence Livermore, Argonne, Oakridge
Government: Department of Defense

Biological defense and infectious diseases research:
• U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) @Ft. Detrick - vaccine and antiviral drug development
• Aberdeen Proving Ground (APG) - critical reagents programs (biological detection assays and reagents)

Naval Medical Research Center (Silver Spring),
Research to develop solutions to combat issues (TBI, PTSD, biological agents, etc.)

Allied Healthcare careers - public health officers, pharmacists, clinical psychology, etc.
www.airforce.com/opportunities/healthcare/careers/allied-health
Careers in Clinical Research

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- **Academic Research**
  - Faculty
  - Staff
Classic academic research career path

Graduate student
↓
Postdoctoral fellow
↓
Assistant Professor
↓
Associate Professor
↓
Professor

Develop original research ideas, write grants, publish, write grants, mentor, write grants, publish, write grants, write grants, write....
# Clinical Research Education Options at UMB

<table>
<thead>
<tr>
<th>Investigators</th>
<th>Other team members</th>
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<tbody>
<tr>
<td>• Selected coursework</td>
<td>• <em>Depending on role and background</em></td>
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<tr>
<td>• 6 credits</td>
<td>• Certificate in Research Ethics</td>
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<tr>
<td>• Certificate in Clinical Research</td>
<td>• Certificate in Clinical Research</td>
</tr>
<tr>
<td>• 12 credits</td>
<td>• Masters in Public Health</td>
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<tr>
<td>• Masters in Clinical Research</td>
<td>• 42 credits</td>
</tr>
<tr>
<td>• 30-36 credits</td>
<td>• Masters of Regulatory Science</td>
</tr>
</tbody>
</table>
M.D. Track- When to add clinical research training

Ph.D. Track - When to add clinical research training
Resources

- Clinical Research Education and Training Program
  - medschool.umaryland.edu/K30/default.asp