

## 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?

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## Functional Roles for Members of a Clinical Research Team I

Role	Function
Principal investigator	Ultimately responsible for the design, conduct and quality of the study and for reporting findings
Project Director	Provides day-to-day management of all study activities
Recruiter	Ensure that desired number of participants are enrolled
Research assistant	Carries out study procedures
Quality control coordinator	Ensures that staff follow Standard Operating Procedures and oversees quality control
Data manager	Designs, tests, and implements the data entry, editing and storage system

## Functional Roles for Members of a Clinical Research Team II

Role	Function
Regulatory Specialist	Enters and tracks regulatory applications including IRB submission
Analyst	Produces study reports to describe recruitment, adherence and data quality, conduct data analysis
Statistician	Estimates sample size and power, designs analysis plan, interprets findings
Administrative Assistant	Provides clerical support, sets up meetings
Financial Manager	Prepares budget and manages expenditures
Human Resources Manager	Assists in preparing job descriptions, hiring, evaluations

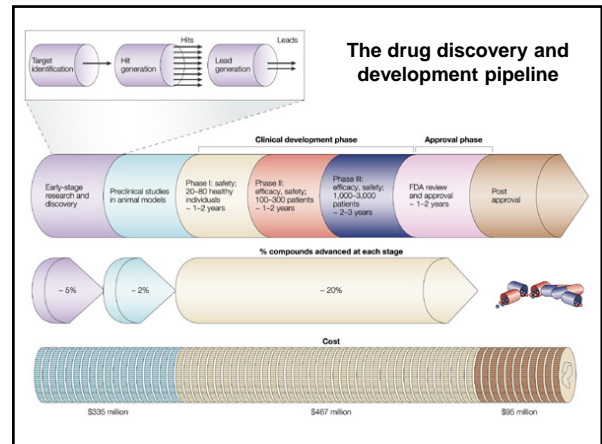
## Careers in Clinical Research

- Industry
  - Pharmaceutical, Biotechnology and Medical Device
- Government Service
  - Regulatory
  - Public Health
- Academic Research
  - Faculty and Staff

## Industry

**MULTINATIONAL PHARMA**

**BIOTECH**



## Clinical Research Positions in Industry

Positions	Backgrounds
<ul style="list-style-type: none"> <li>Pharmaceutical development</li> <li>Manufacturing</li> <li>Medical writers</li> <li>Medical monitors, clinical research associates, project managers</li> <li>Data management, statisticians</li> <li>Regulatory</li> </ul>	<ul style="list-style-type: none"> <li>Basic science               <ul style="list-style-type: none"> <li>Chemistry</li> </ul> </li> <li>Medicine and Nursing</li> <li>Engineering</li> <li>Pharmacy</li> <li>Statistics, computer science</li> <li>Patent law</li> <li>Business</li> </ul>

## Careers in Clinical Research

- Industry
  - Pharmaceutical, Biotechnology and Medical Device
- Government Service
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  - Public Health
- Academic Research
  - Faculty
  - Staff

## Federal Government Agencies involved in Clinical and Translational Research

## Government: Department of Health & Human Services

- NATIONAL INSTITUTES OF HEALTH**
  - 27 Institutes and Centers
  - Intramural research
  - Scientific Review Officers, Program Officers
- FDA**
  - Scientific Officers
  - Medical Officers
- CDC**
  - Public Health Officers
  - Epidemic Intelligence 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)

*Additional info:* [www.jpeocbd.osd.mil/packs/Default2.aspx?pg=0](http://www.jpeocbd.osd.mil/packs/Default2.aspx?pg=0)



**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](http://www.airforce.com/opportunities/healthcare/careers/allied-health)

## Government Research Divisions cont'd

### To Learn more:

- USAJobs.gov
- Washington Post jobs section
- S.T.E.M. postdoctoral conference and career fair, <http://postdoc-conference.ncet2backoffice.org/>

### NIH

- NIH Intramural Research Sourcebook, <http://sourcebook.od.nih.gov/>
- **Getting a job with the federal Government** from OITE, [www.training.nih.gov/events/view/\\_2/88/Getting\\_a\\_Job\\_with\\_the\\_Federal\\_Government](http://www.training.nih.gov/events/view/_2/88/Getting_a_Job_with_the_Federal_Government)
- **Non-bench options at NIH** from OITE, [https://www.training.nih.gov/events/view/\\_2/60/NonBench\\_Careers\\_for\\_Scientists\\_at\\_NIH](https://www.training.nih.gov/events/view/_2/60/NonBench_Careers_for_Scientists_at_NIH)

## Careers in Clinical Research

- **Industry**
  - Pharmaceutical, Biotechnology and Medical Device
- **Government Service**
  - Regulatory
  - Public Health
- **Academic Research**
  - Faculty
  - Staff

## Classic academic research career path



**Develop original research ideas, write grants, publish, write grants, mentor, write grants, publish, write grants, write grants, write....**

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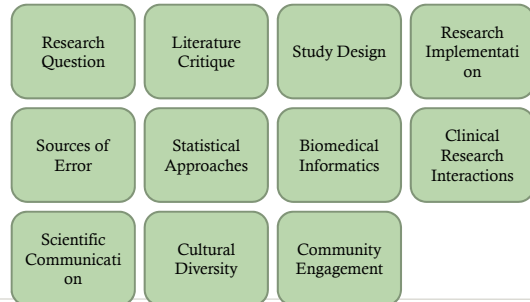
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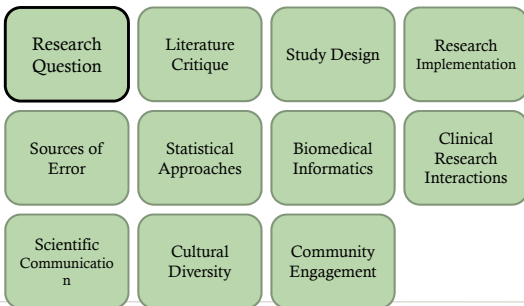
## Tools of a Clinical Investigator

Education and Training	Support Services	Physical Infrastructure
MS, Clinical Research	IRB	General Clinical Research Center
Certificate, Clinical Research	Scientific writing	Informatics
Non-degree training	Study coordinators	Imaging core
Coordinator training	Recruitment registry	Core labs
		Sample storage

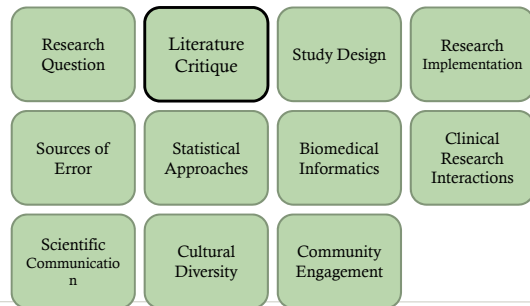
## Core competencies in Clinical and Translational Research



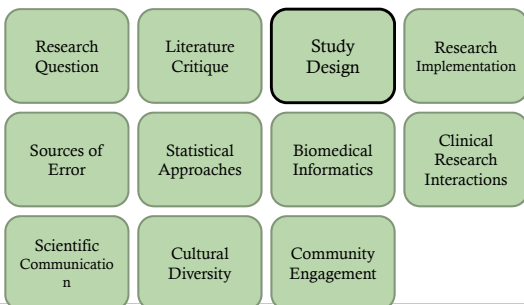
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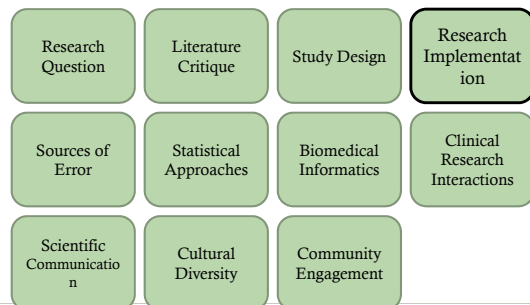
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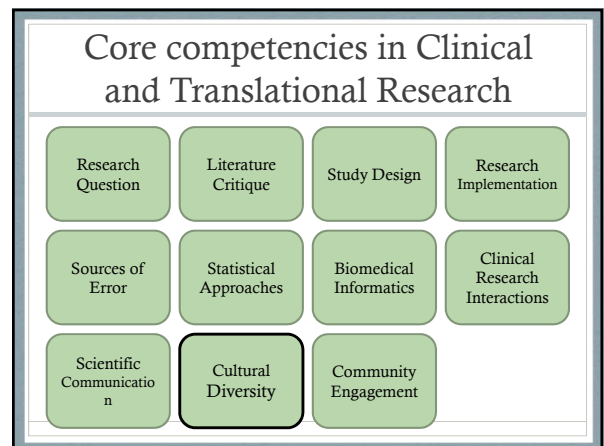
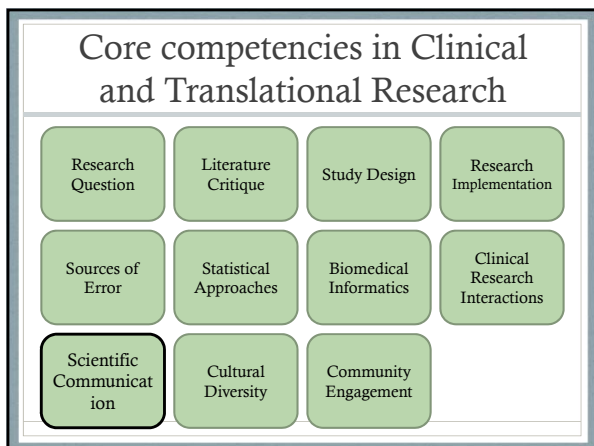
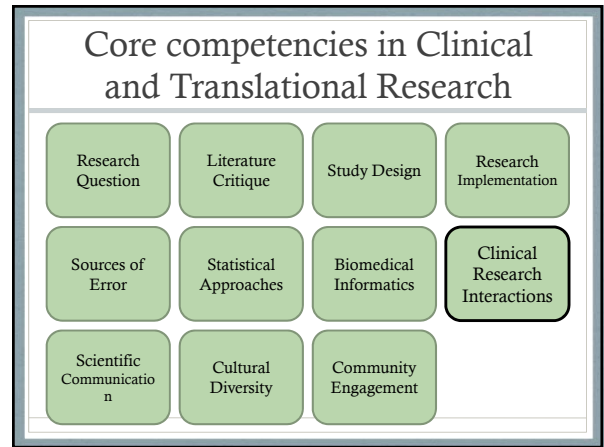
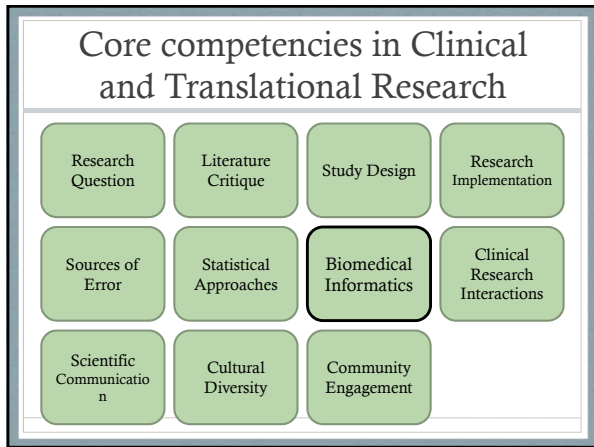
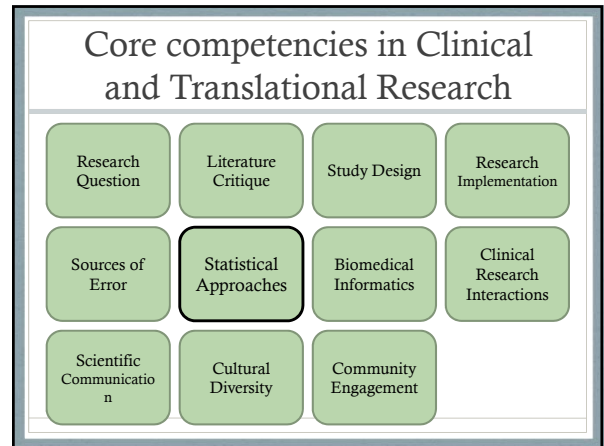
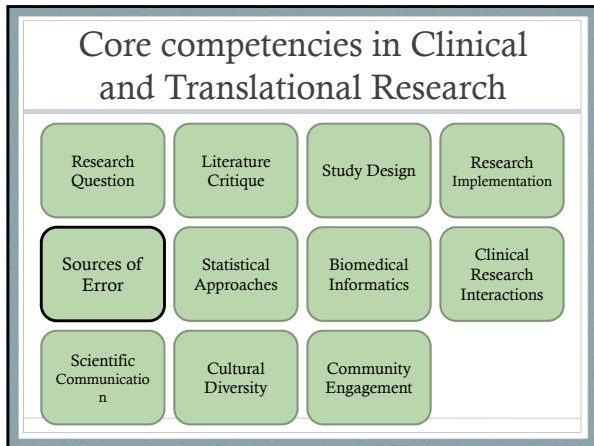


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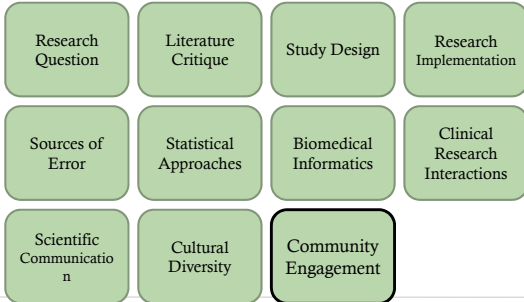


## Core competencies in Clinical and Translational Research





## Core competencies in Clinical and Translational Research



## Clinical Research Education Options at UMB

- | Investigators   | Other team members   |
|---|--|
| <ul style="list-style-type: none"> <li>Selected coursework                             <ul style="list-style-type: none"> <li>6 credits</li> </ul> </li> <li>Certificate in Clinical Research                             <ul style="list-style-type: none"> <li>12 credits</li> </ul> </li> <li>Masters in Clinical Research                             <ul style="list-style-type: none"> <li>30-36 credits</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li><i>Depending on role and background</i></li> <li>Certificate in Research Ethics</li> <li>Certificate in Clinical Research</li> <li>Masters in Public Health                             <ul style="list-style-type: none"> <li>42 credits</li> </ul> </li> <li>Masters of Regulatory Science</li> </ul> |

## Clinical Research Curriculum: Certificate Program

Course	Credits
PREV 600 Principles of Epidemiology	3
PREV 616 Introduction to Clinical and Translational Research at UMB	2
PREV 706 Research Informatics	2
PREV 633 Legal and Regulatory Issues in Clinical Research	1
CIPP 909 Responsible Conduct of Research	1
PREV 621 Biostatistical Methods	3

## Clinical Research Curriculum MS in Clinical Research

Core Courses	18 Credits
PREV 600 Principles of Epidemiology	3
PREV 616 Summer Short Course	2
PREV 619 Biostatistical computing	1
PREV 620 Principles of Biostatistics	3
PREV 720 Statistical Methods in Epi	3
PREV 706 Research Informatics	2
CIPP 633 Legal and Regulatory Issues	1
CIPP 909 Responsible Conduct of Research	1
PREV 710 Clinical Research Project Development and Implementation	2
<b>Concentration Courses</b>	<b>-12</b>
<b>Thesis (or Research Practicum)</b>	<b>5-6</b>

## Research Ethics Curriculum: Certificate Program

Course	Credits
ETHC 637 Introduction to Research Ethics	3
ETHC 638 Ethical Issues in International Research	3
ETHC 629 Introduction to Ethical Theory	2
ETHC 639 Legal and Regulatory Issues For Institutional Review Boards	2
ETHC 665 Responsible Conduct of Research in International Affairs	1
ETHC 640 Ethics of the Globalization of Research	1

## Master of Public Health

Core Courses	17 Credits
PH 600 Principles of Epidemiology	3
PH 620 OR PH 621 Principles of Biostatistics OR Biostatistical Methods	3
PH 668 Environmental and Occupational Health	3
PH 648 Health Services Policy, Management and Finance	3
PH 610 Social and Behavioral Foundations of Public Health	3
PH 623 Ethical Issues in Public Health	2
<b>Concentration Courses</b>	<b>9-10</b>
<b>Elective Courses</b>	<b>9-10</b>
<b>Field Capstone Project (240 hours)</b>	<b>6</b>

## Master of Public Health Concentrations

### Epidemiology

- PREV 619: Introduction to SAS (1)
- PREV 720: Statistical Methods in Epidemiology (3)
- PREV 803: Clinical Trials/Experimental Epidemiology (3)
- PREV 659: Observational Studies in Epidemiology (3)

### Community and Population Health

- PREV 758: Health Survey Research Methods (3)
- NURS 732: Program Planning and Evaluation (3)
- PREV 625: Community Based Participatory Research: Theories & Methods (3)

## Master of Public Health Concentrations

### Global Health

- PREV 664: Critical Issues in Global Health (3)
- PREV 749: Infectious Disease Epidemiology: A Global Perspective (3)
- NURS 732: Program Planning and Evaluation (3) OR
- PREV 625: Community Based Participatory Research: Theories & Methods (3)

## Master of Regulatory Science

UNIVERSITY OF MARYLAND  
SCHOOL OF PHARMACY

### MS IN REGULATORY SCIENCE

The Master of Science (MS) in Regulatory Science provides graduates with the knowledge and skills necessary to contribute to drug regulatory and pharmaceutical product strategies.

Information on the [graduate catalog](#) can be found at [http://www.pharmacy.umd.edu](#).

**What is Regulatory Science?**

Regulatory science is the science of drug regulation. It is the science of ensuring that drugs are safe, effective, and of high quality. The MS in Regulatory Science provides students with the knowledge and skills necessary to contribute to drug regulatory and pharmaceutical product strategies.

**Program Objectives:**

- Identify Manufacturing and Control (CMC)
- Drug Quality
- Pharmacovigilance
- Drug Development (Pharmaceuticals)
- Regulatory Science

The program is designed to provide students with a strong foundation in regulatory science and to prepare them for careers in the pharmaceutical industry.

<https://www.pharmacy.umaryland.edu/academics/regulatoryscience/>

## Resources

- Clinical Research Education and Training Program
  - [medschool.umaryland.edu/K30/default.asp](https://medschool.umaryland.edu/K30/default.asp)