Newly approved medications offer the promise of safer and more effective treatments for patients than currently exist today. The path to approval of new medications and devices is long and formidable. Central to that process is the clinical research trial. Clinical trials can take months or years of careful investigation and evaluation. They must be implemented carefully and ethically to ensure the protection of their human subjects, and they must adhere to the ever-growing complexity of laws and regulations.

A multitude of well-trained professionals are needed to appropriately implement a clinical trial. Personnel such as clinical research coordinators, regulatory affairs specialists, project and data managers, auditors, and more, each execute functions important to the success of the clinical investigation.

There were over 7,000 clinical trials in 2010—a nationwide increase of over 500% from 2000. Data supports a bright outlook for clinical research-related positions. The U. S. Bureau of Labor Statistics (BLS) expects continued national job growth in the 2008-2018 period. The addition of new laws by the Food and Drug Administration is increasing the demand for professionals capable of navigating this changing regulatory landscape. Consequently, the BLS predicts the positions of regulatory affairs specialists and compliance officers to have a 31% increase in jobs.

Graduate Certificate in Clinical Research Trials Management

Michigan State University (MSU) and Grand Valley State University (GVSU) have teamed up to help prepare a clinical research workforce ready to meet these growing market needs by offering a joint certificate program, the Graduate Certificate in Clinical Research Trials Management (CRTM). The certificate program is designed to expand the knowledge of current clinical research professionals who are seeking to further their careers, and to give students the skills and education to prepare for entry-level to mid-level positions in a clinical research setting.

The certificate facilitates the understanding of the roles and responsibilities of all personnel involved with a clinical research trial. It covers data collection, management, analysis, interpretation and dissemination of results. The certificate covers the variety of possible research designs. It investigates the ethical principles, regulatory codes and policies involved in research trials. Students look at the governing agencies and institutions which provide for the protection of human and animal subjects.
**Required Online Courses**

- **PHM 659 (MSU) Regulatory Affairs & Project Management in Clinical Research (MSU Fall: Aug-Dec)**
  
  This course addresses the principles and activities involved in drug development and the regulatory process for obtaining marketing authorization. It also covers the fundamental aspects of project management, including work breakdown structure, scheduling, earned value analysis, and risk management.

- **HM 868 (MSU) Integrated Research Study Design & Informatics (MSU Spring: Jan-May)**
  
  This course is an introduction to clinical trial phases, research design, informatics aims, informatics platforms and datum lifecycle.

- **PSM 650 (GVSU) Ethics and Professionalism in Applied Science (GVSU Winter: Jan-May)**
  
  This course covers ethical and professional issues and problems facing practicing scientists. It emphasizes the role of scientists in the public and private sectors, their responsibilities, and emerging ethical and professional issues.

Choose one of the following classes offered through GVSU:

- **AHS 692 (GVSU) Clinical Research Trials Practicum**
  
  AHS 692 is recommended for students who have less than two years of related professional experience.

- **PA 535 (GVSU) Grant Writing (GVSU Fall: Aug-Dec)**
  
  This course offers instruction in finding grant sources, writing grants, developing grant budgets and evaluating grant proposals. As part of this course, students will be expected to write and submit at least one actual grant proposal.

- **STA 610 (GVSU) Applied Statistics for Health Professions**
  
  This course offers a project-oriented overview of major statistical techniques commonly used in problems encountered in health professions. Students will learn to use a major statistical computer package. It covers hypothesis testing, t-tests, regression, analysis of variance, analysis of covariance categorical data analysis, and non parametric statistics.

**Application**

The Program in Public Health offers two forms of Graduate Certificates. The first, which is transcriptable, allows students to earn college credits while concentrating on a particular area of study. The second is for Lifelong Learners (professionals and others) who may be interested in learning more in a concentrated area of study without a need or desire for earning college credits.

**ALL Graduate Certificates Require:**
- Appropriate application
- Supplemental Information Form
- Personal essay describing interest/experience in public health discipline and career goals
- Resume or CV
- Official test scores of English Language Proficiency Exam (TOEFL, MELAB, MSUELT or IELTS) Institute Code: 1465.

**TRANSCRIPTABLE Graduate Certificates Also Require:**
(Materials are submitted electronically through GIMS)
- Bachelor's degree from an accredited college or university
- MSU Graduate Certificate Application ($50)
- Official copies of transcripts from all post-secondary institutions attended
- Three letters of recommendation

**NON-TRANSCRIPTABLE Graduate Certificates Also Require:**
Completion of MSU Lifelong Education Application. Print a copy and submit all materials to: Program in Public Health, 909 Fee Road Room 519, East Lansing, MI 48824

**ALL MSU and GVSU Students:**
MSU and GVSU students must complete the MIGS (Michigan Intercollegiate Graduate Studies) application for enrollment in each partner institute’s courses.

**MSU students:** Please contact the graduate school for a MIGS application. See www.grad.msu.edu/migs.

**GVSU students:** Please contact your advisor for a MIGS application.

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<th>SEMESTER</th>
<th>CLASSES BEGIN</th>
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<tr>
<td>FALL</td>
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*Admission is done on a rolling basis. Apply early when possible.

Visit [www.publichealth.msu.edu](http://www.publichealth.msu.edu) to begin your application.

If you need additional information, please contact the Program Office at 517.353.4883 or info@publichealth.msu.edu

MSU is an affirmative-action, equal-opportunity employer.