

PROFESSIONAL DEVELOPMENT PROGRAM

Clinical Trials

Design & Management

www.cel.sfsu.edu/clinical-trials/

FREE INFORMATION SESSION | WED., JAN. 11, 2012, 5-6 PM

Staff and faculty will be on hand to discuss our curriculum, certificate and program requirements, as well as the logistics of getting started.

Faculty and graduates from the program will be on hand to discuss their careers, and how to enter and advance in this industry.

RSVP at www.cel.sfsu.edu/clinical-trials/events.cfm



Clinical Trials Design & Management

Cathy Flight, Program Director, (415) 817-4226, cflight@sfsu.edu

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● Enhance
your career
opportunities,
maintain
your edge,
or transition
to a whole
new career.



What is Clinical Trials Design & Management?

Rigorous clinical trials must be conducted on pharmaceuticals, biologics and devices by sponsor organizations prior to applying for approval to market these products to the public. The work is fast-paced, and the regulations and market change constantly. The industry needs trained professionals and our program delivers the necessary skilled workforce.

We are located in the heart of San Francisco and Biotech Bay where sponsor organizations, public agencies, and clinical investigators in medical centers and private practice, care for clinical trials subjects. Enroll now to enhance your career opportunities, or transition into a whole new career.

The Program

SF State Extended Learning is dedicated to the ongoing training and development in this growing field. Our courses are taught by active industry professionals who demonstrate a deep level of commitment to their students and the industry at large.

Learn in an environment that provides valuable networking opportunities while learning the design implementation and regulation of all phases of clinical trials.

Board of Registered Nursing (BRN) Approved Classes

Selected classes have been approved for contact hours by the California Board of Registered Nursing. California BRN Provider #CEP15289. Certificate of contact hours will be retained for a period of four years after the course concludes.

How to Begin Taking Classes

- No application process to begin
- Obtain SF State Student ID and Password
- Register for classes based on individual goals
- Apply for Certificate of Completion after all classes are completed.

For registration questions, please contact Enrollment Services at (415) 405-7700, press '5' to speak with a staff person.

From the BayBio Impact Report 2011:

"Among the companies that expanded their in-state operations, the largest percentage credited the skilled workforce for that decision.

Further, companies are expecting to increase their workforces overall and across all categories. With the world's most comprehensive network of research and higher learning centers, entrepreneurs, employers, investors and suppliers in place, California is well positioned to sustain and even grow its highly specialized and well compensated workforce. The strength of the biomedical sector's contributions to the state's employment is evident in the number of jobs retained through a significant economic downturn and the need and desire of the industry's leading innovators to continue to grow their California operations."

Clinical Trials Design & Management

Intended Audience

Individuals who pursue a Clinical Trials Design & Management certificate from SF State Extended Learning are professionals, often with advanced degrees, working in science, health care, technology, or management.

Length and Cost of Program

The time it takes for participants to finish the certificate of completion varies according to students' availability and experience. The 18-CEU Certificate of Completion (180 hours) may be accomplished in as short a time as three semesters, or students may take as long as needed, up to three years.

The cost of the program is calculated on a per-class basis. Class tuition is available online at our website with each course description. Prices may vary each semester. There are no additional costs for course materials, except a certificate fee of \$50.

Location and Frequency of Classes

All classes are held at the SF State Downtown Campus at 835 Market St., 6th floor, in San Francisco. Required courses are offered three times a year, during the Spring, Summer and Fall semesters. Electives are held once or twice a year, as necessary.

Certificate of Completion

Candidates for the certificate of completion must complete all Required and necessary Elective courses (18 CEUs) in the curriculum. Once a candidate has completed the necessary coursework, an application for the certificate of completion must be submitted. Applications are due, along with a \$50 non-refundable fee and your unofficial SF State transcripts, after all grades have been submitted.

Please visit the Clinical Trials Design & Management Certificate web page to download the Graduation Application.

Open Lab (Room 611)

Students enrolled in courses receive 15 hours of free Open Lab time per hands-on class. Additional use of the lab beyond the 15 hours is subject to availability of computers. All Clinical Trials software that is used in the certificate program is installed in the Open Lab.

- Mon. - Thurs., 12 noon–9 pm
- Fri., 12 noon–5 pm
- Sat., 10 am–5 pm

Please Register Early!

To ensure you receive course materials at the first class meeting, please enroll at least THREE weeks before the start date.



About the Classes

Medical Terminology, *Introduction to The Clinical Trials Process* and *Good Clinical Practices* are the prerequisites for all other classes.

Curriculum (18 CEU)

Take the seven required classes and enough electives to complete the minimum of 180 hours (18 CEUs).

Required Courses	SP	SU	FA
• <i>Medical Terminology</i>	•	•	•
• <i>Introduction to the Clinical Trials Process</i>	•	•	•
• <i>Good Clinical Practices</i>	•	•	•
• Clinical Trials Monitoring	•	•	
• Clinical Trials Design	•		•
• Clinical Data Management	•	•	
• Biostatistics	•		•
Elective Courses			
• Case Report Form Design	•		
• Regulatory Processes and Issues		•	
• Toxicology			•
• Compliance Audits and FDA Inspections	•		
• Clinical Operations: Study Start-up	•		•
• Clinical Operations: Study Conduct	•		•
• Clinical Operations: Study Close-out	•		•
New Course			
• Clinical Trials Workshop			

Some Clinical Trials Development Online classes may be used toward Electives. Please see www.cel.sfsu.edu/clinicalonline.

spring 2012 classes

MEDICAL TERMINOLOGY (.7 CEU)

Lecture/demonstration

This course, or equivalent knowledge, is a prerequisite for the Clinical Trials Certificate. It may be taken concurrently with other courses at the discretion of the Program. This course reviews basic medical and clinical terminology necessary for team members working in clinical trials development of pharmaceuticals, biologics, and devices. It is intended to be an introduction for persons with no health care or clinical trials background or a refresher for those who have previous, but not recent, use of this terminology.

Instructor: Addy Alsumde

Schedule Number 92127 IT 9384 Section A 01

- Sat., Feb. 4, 9 am-5 pm
- SF State DTC, 835 Market, 6th Floor
- \$175

INTRODUCTION TO THE CLINICAL TRIALS PROCESS (2.1 CEU)

Lecture/demonstration

Prerequisite: Recommended: Background in a science, medical, nursing, or other health profession. Drugs, biologics, and devices require structured clinical testing in humans prior to approval for marketing and post-marketing safety surveillance. This class provides an introduction to the clinical research industry including trends and opportunities, clinical program and trial development and management, regulations, ethics, and the role of regulatory agencies, sponsors, investigators, IRBs, and the public as study subjects or patients.

Instructor: Michelle Gray

Schedule Number 92121 IT 9357 Section A 01

- Tues., Jan. 24-Mar. 6, 6:30-9:30 pm
- SF State DTC, 835 Market, 6th Floor
- \$495

GOOD CLINICAL PRACTICES (2.1 CEU)

Lecture/demonstration

Prerequisite: Recommended: Introduction to the Clinical Trials Process (may be taken concurrently). Background in a science, medical, nursing, or other health profession. Good Clinical Practices are an established industry code for the structure and conduct of effective, ethical, and compliant clinical research studies. This class will review the scientific basis of clinical drug, biologics, and device research, the regulatory basis behind human trials, and the GCPs commonly accepted in clinical research across the US and globally. We will focus on application of GCPs in sponsor companies and clinical research study sites from recruitment and consent of subjects to audit requirements. Fluency in GCPs is essential toward optimal employability, and will serve you well over the course of your career.

Instructor: Betsy Bradley

Schedule Number 92122 IT 9358 Section A 01

- Wed., Feb. 1-Mar. 14, 6:30-9:30 pm
- SF State DTC, 835 Market, 6th Floor
- \$495

CLINICAL TRIALS MONITORING (2.1 CEU)

Lecture/demonstration

Prerequisite: Introduction to the Clinical Trials Process, Good Clinical Practices. This course provides the foundation for monitoring clinical trials. Topics include roles and responsibilities of the sponsor and investigator site defined by the FDA and applied to monitoring activities from study start-up to completion. Study site selection, initiation, interim monitoring, and closeout procedures are reviewed. Regulatory documents, source documents, safety reporting of adverse events, study drug accountability, and compliance are reviewed. Principles of investigator grant budget, contract, and payment are also reviewed.

Instructor: Kristina Neal

Schedule Number 92129 IT 9387 Section A 01

- Thurs., Apr. 5-May 17, 6:30-9:30 pm
- SF State DTC, 835 Market, 6th Floor
- \$495

CLINICAL TRIALS DESIGN (2.1 CEU)

Lecture/demonstration

Prerequisite: Introduction to the Clinical Trials Process, Good Clinical Practices. This course will provide students with basic understanding of clinical trials design, and will review techniques used to prevent potential bias that could impact the approval of a new drug to the market. Topics include Phase I to IV trials, project team roles, trial methodology, and regulatory requirements. Processes and components of protocol development will include synopsis, hypothesis, scientific rationale, study objectives, sample size, endpoints, procedures, safety, ethical considerations, and analyzing and reporting the results. Quality of life, pharmacoeconomics, management of clinical supplies, and new technology will also be discussed.

Instructor: Bruno Gagnon

Schedule Number 92130 IT 9388 Section A 01

- Tues., Apr. 3-May 15, 6:30-9:30 pm
- SF State DTC, 835 Market, 6th Floor
- \$495

CLINICAL DATA MANAGEMENT (2.1 CEU)

Lecture/demonstration

Prerequisite: Introduction to the Clinical Trials Process, Good Clinical Practices (may be taken concurrently). Today's Clinical Trials depend on clean, fully integrated scientific databases, ready for statistical analysis and in full compliance with regulatory guidelines. This class teaches you to frame research questions accurately, in terms that work for the trial and for the database, to choose the most appropriate technology to capture and store the data, and to translate the data into terms understood by biostatisticians and the analysis programs most commonly used.

Instructor: Siu Po Sit

Schedule Number 92123 IT 9359 Section A 01

- Thurs., Feb. 16-Mar. 29, 6:30-9:30 pm
- SF State DTC, 835 Market, 6th Floor
- \$495

spring 2012 classes

BIOSTATISTICS IN CLINICAL TRIALS (2.1 CEU)

Lecture/demonstration

Prerequisite: *Introduction to the Clinical Trials Process*. This course provides basic statistical concepts for the non-statistician involved in clinical trial design, implementation, and report writing. Topics include the role of the statistician, statistical terms, study designs, sampling techniques, hypotheses, endpoints, data management, and analysis plans.

Instructor: Peter Shabe

Schedule Number 92128 IT 9386 Section A 01

- Mon., Mar. 26-May 7, 6:30-9:30 pm
- SF State DTC, 835 Market, 6th Floor
- \$495

CASE REPORT FORM DESIGN (.7 CEU)

Lecture/demonstration

Prerequisite: *Introduction to the Clinical Trials Process*. The case report form (CRF) is the primary data collection tool in clinical trial conduct, analysis, and reporting of results. The sponsor is responsible for development of a CRF that accurately represents the protocol, management of CRF production, monitoring, and auditing. The study site is responsible for accurate and timely completion of the CRF. This short course provides an overview of key elements in design and management of the CRF.

Instructor: Brad Fugate

Schedule Number 92132 IT 9392 Section A 01

- Sat., Apr. 21, 9 am-5 pm
- SF State DTC, 835 Market, 6th Floor
- \$175

COMPLIANCE AUDITS & FDA INSPECTIONS (.7 CEU)

Lecture/demonstration + open lab time

Prerequisite: *Introduction to the Clinical Trials Process, Good Clinical Practices*. Regulatory authorities may conduct routine or for-cause inspections of sponsor and study sites during clinical trials and routine inspections prior to product approval. This is an overview of FDA and sponsor audit procedures, roles, processes, and responses to findings.

Instructor: Michelle Gray

Schedule Number 92131 IT 9391 Section A 01

- Sat., Apr. 14, 9 am-5 pm
- SF State DTC, 835 Market, 6th Floor
- \$175

REGULATORY PROCESSES & ISSUES (1.4 CEU)

Lecture/demonstration + open lab time

Prerequisite: *Introduction to the Clinical Trials Process, Good Clinical Practices*. The FDA and other regulatory agencies establish rules and guidances for clinical development and marketing of drugs, biologics, and devices. This course provides an overview of drug development and the regulatory process that is necessary to get drugs approved. The course will provide students with a good basic understanding of the regulations involved in drug development, how the technical areas (i.e., manufacturing, pre-clinical and clinical) interact during that development, and where to find information to guide that development.

Instructor: Ursula Fritsch

Schedule Number 92133 IT 9394 Section A 01

- Sat., Mar. 10-24, 9 am-5 pm (no class Mar. 17)
- SF State DTC, 835 Market, 6th Floor
- \$335

CLINICAL TRIALS CAREER WORKSHOP (1.4 CEU)

Lecture/demonstration + open lab time

Learn about the career possibilities in Clinical Research. This workshop will run over two Saturdays and have some homework assignments in the week between classes. The workshop will focus on how to “break into” the Clinical Research Industry, different entry level jobs, and where to look for such jobs. We will work on creating “industry” style resumes, and discuss tools such as social media, personal business cards, professional organizations, and networking. We will define the differences between interviewing for information and jobs, how to prepare, and what to expect, when interviewing for a clinical research job. There will be time for group discussions, questions and answers, and hands-on exercises.

Instructor: Betsy Bradley

Schedule Number 92126 IT 9373 Section A 01

- Sat., May 5-12, 9 am-5 pm
- SF State DTC, 835 Market, 6th Floor
- \$225



“I have applied my certificate in Clinical Trials Design & Management to my ongoing responsibilities, received a promotion upon completion, and will shadow a monitor on our company’s next two studies to experience some of what I learned firsthand.

This certificate was exactly what I needed for my professional track.”

~ **Bethany S.** - Clinical Trials Design & Management Student

**CLINICAL OPERATIONS: STUDY START-UP
(2.1 CEU)**

Hybrid

Drug companies lose on average more than \$600,000 each day clinical trials are delayed. The need for clinical trials to be completed on time and within budget has never been greater. The Clinical Operations group is responsible for the planning, implementation and conduct of large, complex clinical trials or multiple smaller studies across indications or development compound(s). The Clinical Project Manager (CPM) is responsible for leading a cross-functional team to conduct a clinical trial according to its timeline, within a specified budget and define resources.

This class provides an overview of clinical operations in the study start-up phase of a clinical trial. From final protocol to first patient in, a team must be formed, vendors and sites selected and activated, processes established for data collection and reporting and regulatory approvals obtained.

Note: This class will utilize both in-class sessions as well as online project work. Online portion will be held at <http://ilearn.sfsu.edu>.

Instructor: Michelle Gray

Schedule Number 92120 IT 9350 Section A 01

- Sat., Feb. 4 & 25, 9 am-5 pm
(other classes held online)
- SF State DTC, 835 Market, 6th Floor
- \$495

**CLINICAL OPERATIONS: STUDY CONDUCT
(2.1 CEU)**

Hybrid

This class provides an overview of clinical operations in the study conduct phase of a clinical trial. Continuing where the Study Start-up class left off, we pick up with enrollment and continue through last patient out. We will explore strategies for keeping the study on-time and within budget despite recruitment challenges, protocol changes, data entry and cleaning efforts, safety events and team members coming and going.

Note: This class will utilize both in-class sessions as well as online project work. Online portion will be held at <http://ilearn.sfsu.edu>.

Instructor: Stewart Hallett

Schedule Number 92124 IT 9362 Section A 01

- Sat., Mar. 3 & 24, 9 am-5 pm
(other classes held online)
- SF State DTC, 835 Market, 6th Floor
- \$495

**CLINICAL OPERATIONS:
STUDY CLOSE-OUT (2.1 CEU)**

Hybrid

This class provides an overview of clinical operations in the study closeout phase of a clinical trial. Continuing where the Study Conduct class left off, we pick up with data entry of the last patient visit and continue through development of the study report. We will explore strategies for keeping the study on-time and within budget despite data entry issues and cleaning problems, site and vendor closeout, database review and lock and development of the clinical study report.

Note: This class will utilize both in-class sessions as well as online project work. Online portion will be held at <http://ilearn.sfsu.edu>.

Instructor: Shilpa Airy

Schedule Number 92125 IT 9364 Section A 01

- Sat., Apr. 7 & 28, 9 am-5 pm
(other classes held online)
- SF State DTC, 835 Market, 6th Floor
- \$495



Testimonials

“SF State Extended Learning’s “Clinical Trials Design & Management” program provided my career with the foundation that I needed to transition from the IT industry to Biotechnology.

With over 14 years experience in the IT industry, I decided to find a new career path. I used my transferable skills to find entry level opportunities in the Biotechnology industry. I began SF State Extended Learning’s certificate program to gain knowledge about clinical trials design and management. I was promoted to CRA after I completed my certificate. I could not have moved forward with my career without SF State Extended Learning.”

~ **Alzata H.**, Oncology Clinical Development, Student

“Clinical Trials Design & Management program is valuable to me personally and professionally. It not only taught me the principles and practices of clinical research but also supported me to build my network in the field. I am currently working in a clinical consulting company and I can relate the lectures to my work.”

~ **Agatha L.**, SF State Extended Learning graduate

Clinical Trials Faculty

Shilpa Airy, M.S., has 15 years of research experience in protein chemistry and global clinical program management for both large cap pharma and biotech start-up companies. Shilpa has managed 14 global phase II-IV clinical drug trials to successful completion in a variety of indications and actively participated in three NDA/BLA filings resulting in FDA approvals. Shilpa has a B.S. in Biochemistry from Rutgers University, and an M.S. in Biochemistry from Columbia University. Shilpa works as a Consultant in Clinical Operations to several biotech and pharma companies in San Francisco and New York City.

Dr. Addy Alsumde, M.D., Ph.D., is the CEO of Advancement in Health Profession. He has more than 23 years' experience in pharmaceutical and device clinical research and project management. He worked as investigator, monitor, trainer and manager of all aspects of numerous phase IV multi-center trials. He has an extensive background in teaching medical and clinical courses in academic and professional settings.

Betsy Bradley has worked in the clinical research industry for 15 years. She has worked for CROs, pharmaceutical and biotech companies. She has a background in monitoring, program management, and line management in clinical operations, as well as training and instructional design. Betsy has managed clinical trials and post-marketing studies in North America, European Union, and South America. She has a Master's Degree in Public Health from Yale University and a Bachelor's degree in English Literature from Smith College. Currently Betsy consults with small biotech/pharmaceutical companies.

Ursula Fritsch, PharmD, has worked in San Francisco Bay Area biotechnology and pharmaceutical companies since 1987. Dr. Fritsch has regulatory experience in drug development that spans asset acquisition through drug product approval and launch.

Brad Fugate has worked in clinical data management for 17 years. He has extensive experience with study setup, maintenance and database lock activities for all phases of clinical trials in a wide variety of therapeutic indications. He has been responsible for the lead role with data management activities for the filing of multiple new drug applications to regulatory agencies worldwide and has participated in FDA inspections.

Bruno Gagnon, B. Pharm., M. Sc. is an opinion leader in the field of Clinical Operations. He has over twelve years of drug development experience. His industry experience includes positions in big pharma, CRO and biotech. Functional areas under his responsibility have included: Medical Writing, Outsourcing and Contracts, Supply Chain Management, Clinical Systems, Document Management and SOPs & Training. Bruno has been teaching at University of San Diego, UCSD Extension and is an instructor with Barnett International for public seminars in monitoring clinical trials. He has a bachelor degree from the School of Pharmacy, Laval University and a Masters in Pharmaceutical Sciences from University of Montreal, both in Quebec, Canada.

Michelle Gray, M.H.S., has over 18 years of research experience with devices, small molecules and biologics. She has worked on US and international studies in all phases of trials for private and public organizations, and taught clinical trials classes at the university level. Michelle's focus has been on clinical operations and program management and has been part of several IND and NDA submissions. She is currently working with a small Bay Area biotech company. Michelle received her masters at John Hopkins University School Of Public Health.

Stewart Hallett has over 19 years in the pharmaceutical, biotech, and health care industries with a focus on clinical operations, infrastructure development and project management. Stewart has worked across multiple therapeutic indications including cardiovascular, pulmonary, critical care, dermatology, and oncology working with both small molecules and biologics. He has worked on all phases of research from clinical pharmacology studies to Phase IV trials in both international and domestic settings. He is currently the Senior Director of Clinical Operations at a Biopharmaceutical company in San Francisco. Stewart received his MBA from St. Mary's College and has a BS in Biology from San Francisco State University.

Véronique Lauriault, Ph.D., D.A.B.T., Toxicologist, has 16 years of toxicology experience primarily in industrial, biotechnology and pharmaceuticals. During this time she has worked for various companies in the Bay Area – Genencor International, Theravance, Inc., the Institute for OneWorldHealth and most recently Genentech. She has interacted with regulatory agencies around the world, including the FDA, EMEA and the Drug Controller General (DCG) of India. Her experience enables her to design strategic toxicology programs. She holds a Ph.D. in Biochemical Toxicology from the University of Toronto, Canada, a MSc in Toxicology from the University of Surrey in the United Kingdom and a B.Sc in Toxicology

from the University of Guelph in Canada. She is a Diplomate of the American Board of Toxicology (since 1999). She also completed a PostDoc in 1992 at the University Rene Descartes, School of Medicine in Paris, France.

Kristina Neal, CCRA, has worked in the clinical research industry for 10 years. She has worked for a large CRO as well as mid-size and small pharmaceutical and bio-tech companies. Her background is in biochemistry, monitoring, clinical trial and program management, as well as mentoring and training monitors. Kristina has been involved with development and post-marketing studies in North and South America. She is a certified CRA through ACRP. Currently Kristina is a consultant for small biotech/pharmaceutical companies.

Peter Shabe, M.S., is President of Advance Research Associates, Inc., a contract research organization (CRO) providing data management and biostatistical services to medical device, biotech and pharmaceutical industries. Prior to starting ARA, he worked as a biostatistician for several pharmaceutical and CRO companies and taught statistics courses at several universities.

S. P. Sit, M.S., Ph.D., serves as Vice President, Clinical Affairs, for Penumbra Inc. and has worked in clinical trials for more than 20 years. His work includes oversight of clinical trials of a wide variety of drugs, devices and pharmaceuticals. He is widely published and has taught at Harvard Medical School and Gwynedd-Mercy College. His advanced degrees are from Michigan State University.

Thomas Tremblay is a registered nurse with over 12 years of experience in intensive/coronary care medicine, emergency/trauma, HIV, oncology and clinical research. Thomas has over 17 years experience in industry-based clinical operations including the ethical design and implementation of Phase 1 through Phase 3 clinical trials. Thomas has worked for large as well as start-up pharmaceutical companies, and is currently working as the Senior Director of Clinical Operations for a local bay area company. ■

Clinical Development **Online** Certificate

PROFESSIONAL DEVELOPMENT CERTIFICATE

www.cel.sfsu.edu/clinicalonline/

Cathy Flight, Program Director, (415) 817-4226, cflight@sfsu.edu

Dylan Romero, Program Coordinator, (415) 817-4232, dromero2@sfsu.edu



SF State Extended Learning is offering an online certificate in Clinical Development. The program consists of eight courses specifically designed to provide an overview of regulatory and compliance issues in the drug/biologic or device development arena. All courses are online and self-paced. Each class is supported by an industry expert who will be available to answer questions during online 'classroom' time. Upon completion of the certificate, students will have reviewed current regulations and guidelines and common practical issues. The classes can be taken individually based on your goals, or towards a certificate of completion (7.8 CEU). Students may apply for the certificate after successful completion of all program requirements.

Certificate of completion: (Take all eight classes)

- Introduction to Regulatory Affairs (US)
- Overview of Drug/Biologic Development, or Overview of Device Development
- Good Clinical Practice (GCP) Part I
- Good Clinical Practice (GCP) Part II
- Good Laboratory Practice (GLP)
- Current Good Manufacturing Practices (cGMP)
- Biostatistics for Non-Statisticians
- Safety Monitoring

Once you register and pay for your course(s), you will be able to log in to our learning management system, iLearn, at: <https://ilearn.sfsu.edu/>, using your SF State ID and password. Classes will be available to you on the first scheduled date of each class. You will have one month to complete each course. This program is separate from the Clinical Trials Design and Management program, but some classes may be taken to satisfy elective requirements.

Free

Clinical Development: Online Certificate Virtual Information Session

Tues., Jan. 10, 2012, 5-6 pm

Anyone can participate in the Clinical Development Online Information Session from anywhere in the world. The event is free and held 100% online through **Blackboard Collaborate™**, the University's online collaboration software. A unique URL will be emailed to you on the day of the event.

Please visit www.blackboard.com/collaborate to make sure your computer meets all system requirements.

Please RSVP at www.cel.sfsu.edu/clinicalonline/events.cfm