

Clinical Trials Design and Management Certificate

Planned course offerings by quarter for this certificate are listed below. Please refer to the certificate page to verify available sections and to enroll. Once enrolled in a certificate, visit myextension.ucsd.edu to track your progress and view your required and elective courses. All courses applied to the certificate must be completed within five years of certificate enrollment.

| Prerequisites | | | | | |
|--|-------|-------------|--------|--------|--------|
| TITLE & COURSE NUMBER | UNITS | FALL | WINTER | SPRING | SUMMER |
| <u>Medical Terminology: An Anatomy and Physiology Approach</u> FPM-40632 | 1.5 | Online | Online | Online | Online |
| Required Courses | | | | | |
| TITLE & COURSE NUMBER | UNITS | FALL | WINTER | SPRING | SUMMER |
| <u>CT: Drug Development Process</u> FPM-40173 | 3.0 | Online | Online | Online | Online |
| <u>CT: Good Clinical Practices</u> FPM-40204 | 3.0 | Online | Online | Online | Online |
| <u>CT: Human Subjects Protection and IRBs</u> FPM-40388 | 2.0 | Online | Online | Online | Online |
| Electives <small>14 units are required</small> | | | | | |
| Clinical / Scientific Topics | | | | | |
| TITLE & COURSE NUMBER | UNITS | FALL | WINTER | SPRING | SUMMER |
| <u>CT: Science of Clinical Trials Design</u> FPM-40205 | 3.0 | Online | Online | | Online |
| <u>CT: Comprehensive Approaches to Monitoring Clinical Trials</u> FPM-40725 | 3.0 | Online | Online | Online | Online |
| <u>CT: Practical Clinical Statistics for the Non-Statistician</u> FPM-40233 | 2.0 | Online | Online | Online | Online |
| <u>CT: Documents in Drug Development: Writing Protocols, Reports, Summaries, Submissions, and Disclosures</u> FPM-40685 | 3.0 | Online | | Online | Online |
| <u>CT: Understanding Oncology</u> FPM-40493 | 3.0 | Online | Online | Online | Online |
| <u>CT: Monitoring Oncology Trials</u> FPM-40494 | 3.0 | Online | Online | Online | Online |
| <u>CT: Drug Safety: Surveillance and Reporting</u> FPM-40206 | 2.0 | Live Online | | | |
| Regulatory Topics | | | | | |
| TITLE & COURSE NUMBER | UNITS | FALL | WINTER | SPRING | SUMMER |
| <u>CT: Regulation of Drugs, Biologics, Devices, and Diagnostics</u> FPM-40189 | 3.0 | Online | Online | Online | Online |
| <u>CT: Prospective Preparation for Internal and External Audits</u> FPM-40207 | 1.0 | Online | Online | Online | Online |
| <u>Good Manufacturing Practices</u> BIOL-40000 | 3.0 | | Online | | Online |
| <u>Good Laboratory Practices</u> BIOL-40085 | 2.0 | | Online | | Online |

Project Management topics for sponsors of clinical trials

| TITLE & COURSE NUMBER | UNITS | FALL | WINTER | SPRING | SUMMER |
|---|-------|--------|--------|--------|-------------|
| <u>CT: Project Management in Clinical Trials</u> FPM-40656 | 3.0 | Online | Online | Online | Online |
| <u>CT: Clinical Research Fundamentals: Implementation to Practice</u> FPM-40717 | 3.0 | Online | Online | Online | Online |
| <u>CT: Site and Investigator Recruitment</u> FPM-40208 | 1.0 | Online | Online | Online | Online |
| <u>CT: Data Management Systems for Sponsors of Clinical Trials</u> FPM-40218 | 2.0 | | | | Live Online |

Topics related to the environment surrounding clinical trials

| TITLE & COURSE NUMBER | UNITS | FALL | WINTER | SPRING | SUMMER |
|--|-------|--------|--------|--------|--------|
| <u>CT: Financial Management of Clinical Trials</u> FPM-40338 | 1.0 | Online | Online | Online | Online |

Certificate Requirements

You are expected to complete the minimum certificate requirements, i.e., all approved required courses and the minimum number of required elective units, in effect at the time of registration regardless of any requirement changes at a later date. Prerequisite courses are not considered part of the minimum credit unit requirements of a certificate. All certificate courses must be enrolled in for credit (with a letter grade or pass/no pass grading option) and, unless the certificate program states otherwise, with a passing grade of at least a C- or better to earn the certificate.

While all courses must be successfully completed with a passing grade, the Extension academic department responsible for the certificate has the discretion to elevate the minimum grade you must earn and/or specify that courses (elective and/ or required) be taken for a letter grade. A third party, e.g., employer, Workforce Partnership, credentialing authority, also has the right to increase the minimum certificate requirements by increasing the minimum acceptable grade and time to complete the certificate program. In those cases, the minimum certificate requirements, as specified by the third party, supersede the above.

Transfer Credits

In order to receive a certificate at UC San Diego Extension, you must fulfill all minimum unit requirements of a certificate with transcribed, credit-bearing coursework from an accredited institution. The number of units that can be transferred, however, varies depending on where the academic credit was received. Non-transcribed continuing education courses or courses from a non-accredited institution are not accepted for transfer.

Units of courses completed at educational institutions operating on the semester system should be converted to a value consistent with the quarter system, i.e., one semester unit is equivalent to two-thirds of a quarter unit. The number of units of the course completed outside of Extension must be at least equal to the unit value of the certificate course you are petitioning to transfer. Similarly, the number of units that can be transferred is determined by the number of units associated with the Extension certificate course and not the unit value granted elsewhere.

If you have successfully completed comparable courses at another accredited college or university within five years certificate coursework began at UC San Diego Extension, and you earned at least a "C-" in each, you may petition to transfer up to a third of the certificate program units, not to exceed two courses for professional certificates and one course for specialized certificates. If you have successfully completed courses at a UC campus within five years certificate coursework began at UC San Diego Extension, you may petition to transfer up to half of the units required for a certificate program. To request transfer credit, please submit a written petition, including an official transcript and course descriptions (with syllabus) to the academic department listed in the certificate description for consideration.

Course Substitutions

Only approved courses count toward your certificate program. Due to the post-baccalaureate level of Extension coursework and the intent of many certificate program students to further specialize and develop their current careers, you may have acquired industry knowledge outside of the classroom. If you can demonstrate mastery of the knowledge imparted in a required certificate course through personal or professional experiences, you may petition to substitute a course. In that case, you may have the option to take another Extension course as determined by the academic department in lieu of the required course. You may waive the course requirement but not the unit requirement. Because of the curricular importance of required certificate coursework, you can only petition to substitute up to half the total required course units. To request a substitution, please submit a written petition, including evidence of your knowledge, to the academic department listed in the certificate description for consideration.

Certificate Completion

Once all certificate requirements have been successfully completed, please request a certificate audit through the student portal, My Extension, at <https://myextension.ucsd.edu>. Once you have logged in to My Extension, go to the "My Courses" tab and click on the program under "My Certificate Programs". From there, click on "Request Certificate Audit" and complete the form.