Study Population and Study Design in Clinical/Translational Research, Session 2

This course outlines basic concepts and terminology in the design of clinical/translational research projects targeting specific populations, and discusses methods to identify useful study populations within large and diverse cities. These online video lectures prepare students for course in-class sessions.

**About this Resource**

In this 50-minute video lecture -- an accompaniment to the short course "Study Population and Study Design in Clinical/Translational Research, Session 2" -- an ECDE lecturer introduces fundamental terms and concepts of study design that apply to research within populations. The ECDE lecturer familiarizes clinical/translational researchers with fundamental concepts and guidelines, such as Study Populations, Target Populations, and Source populations. The lecturer also discusses the challenges unique to research in diverse "mega-cities" such as Los Angeles, including ethnic and cultural differences, how to define subpopulations meaningfully, and other factors that can bias findings and impair the overall ability to generalize research findings to broader target populations.

Researchers learn about the basic types of population studies -- Experimental and Observational (including cohort, cross-sectional, and case-control studies) -- and how to use each to study different types of interventions or exposures. Viewers learn how to identify representative source and study populations, how to develop of inclusion/exclusion criteria, about the benefits and limits of randomization, and other concepts that contribute to clinical/translational study design.

**Course Syllabus/Topics**

Populations

Name the Populations

Study Design is Easy! Experimental vs. Observational

Why Randomize?

When to Use a Case-Control Design

**Recommended background**

Please complete the following prior to attending the short course, "Study Population and Study Design in Clinical/Translational Research, Session 2."

Pre-test on Clinical Translational Research

View the two-part video resource

Participant Break-out Session Guide

Read the four articles listed below

**Suggested Readings**

[Liu R](http://www.ncbi.nlm.nih.gov/pubmed?term=liu%2520r%255bauthor%255d&cauthor=true&cauthor_uid=17229949)1, [Wang X](http://www.ncbi.nlm.nih.gov/pubmed?term=Wang%2520X%255BAuthor%255D&cauthor=true&cauthor_uid=17229949), [Chen GY](http://www.ncbi.nlm.nih.gov/pubmed?term=Chen%2520GY%255BAuthor%255D&cauthor=true&cauthor_uid=17229949), [Dalerba P](http://www.ncbi.nlm.nih.gov/pubmed?term=dalerba%2520p%255bauthor%255d&cauthor=true&cauthor_uid=17229949), [Gurney A](http://www.ncbi.nlm.nih.gov/pubmed?term=Gurney%2520A%255BAuthor%255D&cauthor=true&cauthor_uid=17229949), [Hoey T](http://www.ncbi.nlm.nih.gov/pubmed?term=hoey%2520t%255bauthor%255d&cauthor=true&cauthor_uid=17229949), [Sherlock G](http://www.ncbi.nlm.nih.gov/pubmed?term=Sherlock%2520G%255BAuthor%255D&cauthor=true&cauthor_uid=17229949), [Lewicki J](http://www.ncbi.nlm.nih.gov/pubmed?term=lewicki%2520j%255bauthor%255d&cauthor=true&cauthor_uid=17229949), [Shedden K](http://www.ncbi.nlm.nih.gov/pubmed?term=shedden%2520k%255bauthor%255d&cauthor=true&cauthor_uid=17229949), [Clarke MF](http://www.ncbi.nlm.nih.gov/pubmed?term=Clarke%2520MF%255BAuthor%255D&cauthor=true&cauthor_uid=17229949). [The prognostic role of a gene signature from tumorigenic breast-cancer cells.](http://www.ncbi.nlm.nih.gov/pubmed/?term=The+prognostic+role+of+a+gene+signature+from+tumorigenic+breast-cancer+cells) [N Engl J Med.](http://www.ncbi.nlm.nih.gov/pubmed/17229949) 2007 Jan 18;356(3):217-26.

[Slamon DJ](http://www.ncbi.nlm.nih.gov/pubmed?term=Slamon%2520DJ%255BAuthor%255D&cauthor=true&cauthor_uid=11248153)1, [Leyland-Jones B](http://www.ncbi.nlm.nih.gov/pubmed?term=Leyland-Jones%2520B%255BAuthor%255D&cauthor=true&cauthor_uid=11248153), [Shak S](http://www.ncbi.nlm.nih.gov/pubmed?term=shak%2520s%255bauthor%255d&cauthor=true&cauthor_uid=11248153), [Fuchs H](http://www.ncbi.nlm.nih.gov/pubmed?term=Fuchs%2520H%255BAuthor%255D&cauthor=true&cauthor_uid=11248153), [Paton V](http://www.ncbi.nlm.nih.gov/pubmed?term=Paton%2520V%255BAuthor%255D&cauthor=true&cauthor_uid=11248153), [Bajamonde A](http://www.ncbi.nlm.nih.gov/pubmed?term=bajamonde%2520a%255bauthor%255d&cauthor=true&cauthor_uid=11248153), [Fleming T](http://www.ncbi.nlm.nih.gov/pubmed?term=Fleming%2520T%255BAuthor%255D&cauthor=true&cauthor_uid=11248153), [Eiermann W](http://www.ncbi.nlm.nih.gov/pubmed?term=eiermann%2520w%255bauthor%255d&cauthor=true&cauthor_uid=11248153), [Wolter J](http://www.ncbi.nlm.nih.gov/pubmed?term=wolter%2520j%255bauthor%255d&cauthor=true&cauthor_uid=11248153), [Pegram M](http://www.ncbi.nlm.nih.gov/pubmed?term=pegram%2520m%255bauthor%255d&cauthor=true&cauthor_uid=11248153), [Baselga J](http://www.ncbi.nlm.nih.gov/pubmed?term=baselga%2520j%255bauthor%255d&cauthor=true&cauthor_uid=11248153), [Norton L](http://www.ncbi.nlm.nih.gov/pubmed?term=Norton%2520L%255BAuthor%255D&cauthor=true&cauthor_uid=11248153). [Use of chemotherapy plus a monoclonal antibody against HER2 for metastatic breast cancer that overexpresses HER2](http://www.ncbi.nlm.nih.gov/pubmed/?term=Use+of+chemotherapy+plus+a+monoclonal+antibody+against+HER2+for+metastatic+breast+cancer+that+overexpresses+HER2). [N Engl J Med.](http://www.ncbi.nlm.nih.gov/pubmed/?term=Slamon+D+Use+of+Chemotherapy+plus+a+monoclonal+antibody) 2001 Mar 15;344(11):783-92.

Pritchard KI, Shepherd LE, O'Malley FP, Andrulis IL, Tu D, Bramwell VH, Levine MN; National Cancer Institute of Canada Clinical Trials Group. [HER2 and responsiveness of breast cancer to adjuvant chemotherapy](http://www.ncbi.nlm.nih.gov/pubmed/16707747). N Engl J Med. 2006 May 18;354(20):2103-11.

[Stark A](http://www.ncbi.nlm.nih.gov/pubmed?term=Stark%2520A%255BAuthor%255D&cauthor=true&cauthor_uid=15557362)1, [Kucera G](http://www.ncbi.nlm.nih.gov/pubmed?term=kucera%2520g%255bauthor%255d&cauthor=true&cauthor_uid=15557362), [Lu M](http://www.ncbi.nlm.nih.gov/pubmed?term=Lu%2520M%255BAuthor%255D&cauthor=true&cauthor_uid=15557362), [Claud S](http://www.ncbi.nlm.nih.gov/pubmed?term=claud%2520s%255bauthor%255d&cauthor=true&cauthor_uid=15557362), [Griggs J](http://www.ncbi.nlm.nih.gov/pubmed?term=Griggs%2520J%255BAuthor%255D&cauthor=true&cauthor_uid=15557362). [Influence of health insurance status on inclusion of HER-2/neu testing in the diagnostic workup of breast cancer patients](http://www.ncbi.nlm.nih.gov/pubmed/?term=Influence+of+health+insurance+status+on+inclusion+of+HER-2%2Fneu+testing+in+the+diagnostic+workup+of+breast+cancer+patients). [Int J Qual Health Care.](http://www.ncbi.nlm.nih.gov/pubmed/?term=stark+A+influence+of+a+health+insurance+status) 2004 Dec;16(6):517-21.

**FAQ**

**Will I receive a Certificate of Completion after completing this course?** Yes. Participants who complete the course receive a Certificate. Participants must watch the videos and attend the in-person session.

**Do I need to be a K Scholar to take this course?** No. In addition to K Scholars, this course is open to faculty, clinicians, community health workers, fellows, post-docs, TL1 and F trainees, as well as medical, OT/PT, pharmacy and other students who intend to conduct clinical and translational research.