
The ACS Clinical Trials Methods Course: Overview and assessment

by Kamal M. F. Itani, MD, FACS



Participants, faculty, and ACS staff at the 2009 CTM Course.

The Clinical Trials Methods (CTM) Course was established in 1997 by the late Olga Jonasson, MD, FACS, and Timothy J. Eberlein, MD, FACS, Editor-in-Chief of the *Journal of the American College of Surgeons*, in conjunction with the late Shukri Khuri, MD, and William Henderson, PhD. The course was modeled after a similar course offered by the U.S. Department of Veterans Affairs

(VA) office of research in collaboration with the VA Cooperative Study Program (CSP). The VA course was offered to VA faculty and was funded by their respective institutions. Each participant was nominated and supported by their respective chief and facility director, and was accepted into the course on competitive grounds based on qualifications and availability, taking into consideration

geographic distribution of course participants.

The vision, enthusiasm, and dedication of Drs. Jonasson, Eberlein, Khuri, and Henderson allowed for the VA experience represented by Drs. Khuri and Henderson to be translated into a course designed specifically for the American College of Surgeons (ACS). It is this same energy and collaboration among Drs. Jonas-

son, Khuri, and Henderson and many of the faculty participants in the CTM Course that started the ACS National Surgical Quality Improvement Program (ACS NSQIP®), as a mirror image of the VA NSQIP, through the Study in Patient Safety funded by the Agency for Healthcare Research and Quality.*

The first course was chaired by Dr. Eberlein and took place in 1997 at the Westfields International Conference Center in Chantilly, VA. The course was repeated in 1999, and every year afterward until 2003. With the introduction of the outcomes course in 2004, the CTM course was offered every other year starting in 2005, alternating with the outcomes course. This year, the course is scheduled for December 2–6. The course currently takes place at the ACS headquarters in Chicago, IL.

Dr. Eberlein chaired the course until 2000, at which point Robin McLeod, MD, FACS, took over until 2005. I have had the privilege of being the Course Chair since 2007.

Mary Fitzgerald, an ACS staff member, was the course coordinator beginning in 2002 until she retired in 2010. Alexandra Marchel has taken over and is coordinating all preparations for the course in December.

Course overview

The course is limited to 50 participants and takes place in the fall, in November or December of every other year (odd year), and, as previously stated, alternates with the outcomes course. Participants

*Khuri SF, Henderson WG: The patient safety in surgery study. *J Am Coll Surg.* 2007;204(6):1087-1088.

Topics and faculty: 2009 ACS clinical trials methodology course

Topic	Faculty*
Basic biostatistics	William Henderson, PhD, Domenic Reda, PhD
Design options for clinical trials	Mary Hawn, MD, FACS
The question and the end points	Peter Nelson, MD, FACS
Patient selection	Lawrence Kim, MD, FACS
Experimental design for a randomized clinical trial	Robert Anderson, PhD
Statistical inference, hypothesis, testing, and sample size	Dorothy Dunlop, PhD
Interventions	David Ota, MD, FACS
Statistical concepts in clinical trials	Joseph Collins, PhD
Ethics of clinical trials	Kamal Itani, MD, FACS
Clinical trials analysis methods	Domenic Reda, PhD
How to get a clinical trial paid for	Eric Lazar, MD, FACS
Trial management and planning measurements	William Clarke, PhD
Mistakes in clinical trials	William Henderson, PhD
Publication and results	Layton Rikkers, MD, FACS

*Other faculty participants in courses from 1997 to 2007 include the following: Brent Blumenstein, PhD; Henri Buchwald MD, FACS; Raphael Bueno, MD, FACS; Timothy Eberlein, MD, FACS; Aaron Fink, MD, FACS; Mary P. Fitzgerald, MD, FACS; Lawrence Friedman, MD, FACS; Stephen George, PhD; Sylvan Green, MD; John Henderson, MB, CHB, FACS; Robert Hobson, MD, FACS; Olga Jonasson, MD, FACS; John Kestle, MD; Shukri Khuri, MD, FACS; George Lundberg, MD; Robin McLeod; Jonathan Meakins, MD, FACS; Michael Mulholland, MD, FACS; Leigh Neumayer, MD, FACS; Reza Rostami, PhD; Valerie Rusch, MD, FACS; Gulshan Sethi, MD, FACS; David Sugarbaker, MD, FACS; Larissa Temple, PhD; Lee Wilke, PhD; Ian Witterick, MD; and Robert Woolson, PhD.

are largely composed of staff surgeons from all surgical specialties, along with the occasional fellow and/or residents.

The course is designed to take place over the course of five days covering a weekend and consists of a didactics and hands-on approach to a prospective randomized clinical trial.

Before noon, over the course of four days, didactics are covered by faculty members in various areas of clinical trials methodology (see table, this page). In the afternoon, the students are divided

into groups of eight or nine based on areas of common interest, with one faculty surgeon and biostatistician assigned to each group. Over the course of four afternoons, each team selects a topic, performs an extensive review of the literature, and develops a full clinical trial proposal, including a budget. The faculty surgeon and biostatistician serve as advisors throughout the course of each afternoon. On the evening of the fourth day, the proposals are circulated to all the students and faculty for review in preparation for the

last day of the course. On that last day, each team gives a 10-minute PowerPoint presentation followed by a 15-minute discussion. After each presentation, the faculty goes into recess, critiques the proposals, and scores them. Proposals are also scored by the students based on the NIH scale. At the end of the session on the fifth day, an overall score, faculty score, and student score are tallied and presented in conjunction with the critiques from the faculty. Needless to say, the groups go out of their way to perfect their written and oral presentations in order to compete for the best possible scores. In addition, this educational and review process has allowed for the development of long-lasting relationships among students and faculty, that have, in turn, led to the development and funding of other proposals.

Assessment of CTM Course

In order to determine the impact of the CTM Course on participants' research involvement and success in research, a survey was administered to all past participants of this course.

The survey was designed with input from all the CTM Course faculty participating in the 2009 course. The survey looked specifically at the following areas:

- Participation in clinical trials, level of participation, type of funding
 - Current academic position
 - Type of research currently conducted
 - Time commitment to research
 - Impact of the course on participants (research, academics, interpretation of literature, and so on)

- Barriers encountered in pursuing surgical research

The survey was sent electronically in 2010 to all participants in CTM Courses conducted between 1997 (the year of the inaugural course) and 2007.

In all, 345 students participated in the eight courses conducted between 1997 and 2007 (with an average of 43 students per year). A total of 314 electronic addresses were known, with a total of 15 failed message transmissions, likely due to incorrect or outdated e-mail addresses. In all, 14 past participants opted out of the survey, for a total of 284 available past participants who participated in the survey. (A follow-up e-mail was sent to those who did not respond initially.)

The total number of respondents was 90 (31.7 percent). Respondents were evenly distributed among the years with the exceptions of 1997 and 2005, which had five and four respondents, respectively.

The results of the survey—based on the seven areas addressed in the questionnaire—are very telling and are outlined in the following bullet points:

- *Participation in clinical trials, level of participation, and type of funding:*
 - 61 percent of respondents received NIH or other peer-reviewed funding for a clinical trial (40 percent of those were principal investigator)
 - 63 percent participated in an industry-sponsored trial
 - 50 percent were investigators in a non-funded trial
 - 48 percent published the results of their trial in a peer-reviewed journal

—5 percent did not pursue clinical trials

- *Current academic position of past participants:*

—84 percent of respondents are affiliated with an academic practice (University Hospital, VA)

—10 percent are in private practice with a university affiliation

—6 percent are in private practice with no academic affiliation

- *Type of research currently conducted by past participants:*

—77 percent of respondents stated that they perform clinical trials or other type of clinical research

—30 percent are involved in translational research

—29 percent are in health services/outcomes research

—23 percent are involved in educational research

—21 percent are involved in basic science research

- *Time commitment to research:*

—80 percent of respondents spend more than 50 percent of their time in research

—52 percent spend between 10 and 30 percent of their time in research

—40 percent spend less than 10 percent of their time in research

- *Impact of the course on participants:*

—For 81 percent of the participants, the CTM Course fostered an interest and facilitated involvement in clinical trials. For at least two-thirds of the respondents, the course helped in establishing a network of experts and collaborative relationships and assisted in a better interpretation of the literature. Seventy-seven percent have recommended the course to others.

—A total of 12 (13 percent) of

respondents decided that clinical trials were too complex (five respondents), were of little use in their career (five respondents) or that the course did not meet their expectations (two respondents).

- *Barriers encountered in pursuing surgical research:*

—Inadequate protected time (79 percent) and excessive clinical demands (77 percent) were the most common barriers to pursuing research. Other factors included lack of mentorship (36 percent), inadequate support (30 percent), and lack of appropriate collaborators (15 percent).

- *Comments received:*

Many positive comments were received, while a few negative comments dealt with the complexity of trials, the statistical portion, barriers to research, and the need for experienced personnel.

Although the response rate to the survey was low, it was not different from response rates to similar surveys. Based on the responses obtained, the CTM

Course provided participants with an opportunity to become involved in clinical trials, obtain funding, and publish in that area. Barriers consist of the usual lack of protected time, support, and complexity of this type of research.

Present, future of CTM Course

The course has constantly evolved to take into consideration past participants' feedback. For example, two hours of basic statistics were added to the first day of the course—starting in 2009—based on participants' suggestions. For seasoned participants, these sessions represented a review, and for those attendees with little statistical knowledge, they provided the building blocks for more advanced biostatistics presented throughout the course.

The faculty also decided that, starting in 2009, all didactics will be framed around four clinical trials published in the literature. Those trials are provided to participants ahead of the course,

presented on the first day, and discussed at length throughout the course. This setup has provided a more tangible sense of some of the concepts presented by the faculty during the didactics.

In an era where the highest level of evidence is needed for improved outcome, quality, and cost-effectiveness, the CTM Course provides participants with the perfect opportunity to learn how to conduct credible and high-level comparative effectiveness research to reach such evidence. It is imperative that we, as surgeons, identify the areas in need of further investigation and conduct credible research in those areas. Funding of such research remains difficult, but the opportunities to conduct comparative effectiveness research and, specifically, clinical trials have never been better.

Dr. Itani is chief of surgical service, VA Boston (MA) Health Care System, and professor of surgery at Boston University.

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Topics addressed include the following: Ambulatory Surgical Centers; Assistants at Surgery; Cancer Issues; Emergency Medical Treatment and Labor Act (EMTALA); Graduate Medical Education; Health Information Technology; American Recovery and Reinvestment Act of 2009; Health Insurance Portability and Accountability Act and Medical Records Confidentiality; ICD-10; Inpatient Prospective Payment System (IPPS) Rule; Medicare Coverage Issues; Medicare Physician Fee Schedule for 2009, 2010, and 2011; Medicare Payment Advisory Commission (MedPAC); Medicare Payment Reform—Budget-Neutral Bonus Payments for Primary Care, Berkley-Kirk Letter Supporting Increased Medicare Payments and Medicare Payment Reform, EMTALA-Related Tax Deduction, Hospital Payment, Medicare Physician Payment Reform Act of 2007, Medicare Reform Proposals, Pay for Performance, and Sustainable Growth Rate; Office-Based Surgery, Organ Transplants; Patient Safety; Physician Self Referral Law; Access to Imaging Services; Scope of Practice; Specialty Hospitals; State Children's Health Insurance Program; Trauma and Emergency Medical Services; Veterans Affairs; and Workforce.