



Education and Training Directory

Clinical research professionals now have more training options than ever.

Academic degree programs

AA and certificates (Level I and Level II) for clinical trials research associates

Durham Technical Community College. Durham, NC, and online. Ongoing.

Length of course/program. Certificates: 4 semesters; AA: 7 semesters (72 credit hours).

Who would benefit. AA: Persons with high school diploma, GED or college coursework/degree who meet administration criteria and have a strong interest in the clinical research industry.

Certificates: clinical trials personnel in need of clinical research education or who have the desire to advance their professional careers.

Program goals. To prepare students for a career as a CRA/monitor, study coordinator, data manager or other entry level clinical research profession. During the programs, students obtain theoretical knowledge of basic drug development, federal regulations, GCP and processes necessary to conduct a research study. Clinical rotations offer the opportunity to gain field experience.

Fees. Instate: Approx. \$38.50 per credit hour (approx. total program costs: AA \$2850, Certificate \$595, plus books and fees). Out-of-state: \$197 per credit hour.

Contact. Melissa Oakley Ockert, MS, Program

Director, Durham Technical Community College, 1637 Lawson St., Durham, NC 27703, (919) 686-3309, fax (919) 686-3705, email: ockertm@gwmail.dtcc.cc.nc.us, www.durhamtech.edu.

BS in clinical research administration

George Washington University. Washington, DC. Spring and Fall.

Length of course/program. 124 credit hours (may transfer 90 credits).

Who would benefit. Those interested in participating in clinical research prepared at the BS level.

Program goals. To prepare professionals in organizations such as Pharma, CROs, SMO's academic medical centers, and as independent consultants in clinical research.

Fees. \$306 per credit hour.

Contact. Margaret Ann Skelton, Director, Clinical Research Programs, George Washington University, 900 23rd St. NW, Suite 6173, Washington, DC 20037, (202) 994-0844, fax (202) 994-0181, email: icrmas@gwumc.edu.

e Certificate of advanced study

MGH Institute of Health Professionals. Boston, MA or online. Rolling admissions.

Length of course/program. 15 credit hours.

Who would benefit. Postgraduate science and/or healthcare professionals seeking knowledge and credentials to advance their career goals.

Program goals. To prepare clinical research professionals for a variety of roles in the design and implementation of clinical trials. A rigorous academic curriculum provides a core of courses including patient-oriented research methodologies, regulatory law, policy and administration, and the ethical considerations critical for a leader in the field of clinical investigation.

Fees. \$667 per credit hour.

Contact. Heather Duram, Program Manager, MGH Institute of Health Professionals, 36 1st Avenue, Boston, MA 02129, (617) 724-6362, fax (617) 726-8022, email: hduram@mghihp.edu, www.mghihp.edu.

Clinical research design and statistical analysis

University of Michigan School, Horace H. Rackham Graduate School. Ann Arbor, MI.

Begins in October of odd-numbered years.

Length of course/program. Two-year Master's

program; students meet four days a month for 18 months (five terms); 50.25 CME credits available.

Who would benefit. Faculty and researchers employed by medical, dental, pharmaceutical, and nursing schools, teaching hospitals, and research divisions of pharmaceutical and medical firms.

Program goals. To improve the quality of clinical research and to address the shortage of persons with clinical expertise who are trained in research methods.

Fees. \$3973.80 per term (MI residents) or \$8050.20 per term (nonresidents).

Contact. Amanda Ring, Student Services Assistant, Biostatistics Dept., 1420 Washington Heights, Ann Arbor, MI 48109-2029, (734) 615-9817, fax (734) 763-2215, email: cumminga@umich.edu, www.sph.umich.edu/biostat/programs/clinical-stat.

Clinical trial management

Boston University School of Management. Boston, MA. January–May.

Length of course/program. 14 weeks.

Who would benefit. Clinical research personnel at investigative sites or sponsors. Bachelor's degree and at least two years of experience in a clinical research setting required.

Program goals. Part of a Masters degree in clinical investigation, this program prepares the student for managing a clinical research site or sponsor.

Fees. \$3200.

Program Finder

Programs are listed alphabetically, most by course or program title. Those available online as distance learning are marked with an e.

Academic degree programs	62
Certificate programs	64
Short courses/workshops/conferences	68
DIA events	70
Onsite/customized training	72
Self-study materials	76

Contact. Nicole Pirani, Boston, MA, (617) 414-1329, email: pirani@bu.edu, www.bu.edu/maci.

Database design and implementation in clinical research

Johns Hopkins University School of Medicine Graduate Training Programs in Clinical Investigation. Baltimore, MD. July–August.

Length of course/program. Two evenings a week × four weeks; 16 CME credits available.

Who would benefit. Scientists, clinicians, and other health professionals fully engaged in clinical investigation.

Program goals. To enhance the theoretical and practical skills of clinical scientists in the design, implementation, analysis, and interpretation of data from clinical investigators.

Fees. \$1176 per course.

Contact. Mary Jeter, CME Conference/Course Coordinator, Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Turner 20, 720 Rutland Ave., Baltimore, MD 21205, (410) 955-3988, fax (410) 614-7302, email: www.hopkinscme.org/cme/events/SciClinInvest.html.

Design & conduct of clinical trials

Boston University. Boston, MA. Fall.

Length of course/program. 15 weeks.

Who would benefit. Health professionals with a degree in the natural sciences, pharmacy and other allied health fields; physicians, research nurses, study coordinators, managers in clinical research and site management, professionals working in the pharmaceutical, biotechnology, medical device industries as well as CRO and SRO organizations.

Program goals. Covers the history and current methodologies used in the design and conduct of clinical trials. Topics include sample selection, data forms and management, patient recruitment, enrollment and compliance, cost measures and effectiveness.

Fees. \$3200.

Contact. Nicole Pirani, Boston University, 715 Albany St., 560-300, Boston, MA 02118, (617) 414-1329, fax (617)-358-1961, email: maci@bu.edu, www.bu.edu/maci.

Design of clinical studies

Johns Hopkins University School of Medicine Graduate Training Programs in Clinical Investigation. Baltimore, MD. September–October.

Length of course/program. One evening a week × seven weeks; 21 CME credits available.

Who would benefit. Scientists, clinicians, and other health professionals fully engaged in clinical investigation.

Program goals. To enhance the theoretical and practical skills of clinical scientists in the design, implementation, analysis, and interpretation of data from clinical investigators.

Fees. \$1764 per course.

Contact. Mary Jeter, CME Conference/Course Coordinator, Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Turner 20, 720 Rutland Ave., Baltimore, MD 21205, (410) 955-3988, fax (410)

614-7302, email: www.hopkinscme.org/cme/events/SciClinInvest.html.

Ethical and regulatory issues in clinical research

Johns Hopkins University School of Medicine Graduate Training Programs in Clinical Investigation. Baltimore, MD. March–May.

Length of course/program. One evening a week × eight weeks; 24 CME credits available.

Who would benefit. Scientists, clinicians, and other health professionals fully engaged in clinical investigation.

Program goals. To enhance the theoretical and practical skills of clinical scientists in the design, implementation, analysis, and interpretation of data from clinical investigators.

Fees. \$1764 per course.

Contact. Mary Jeter, CME Conference/Course Coordinator, Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Turner 20, 720 Rutland Ave., Baltimore, MD 21205, (410) 955-3988, fax (410) 614-7302, email: www.hopkinscme.org/cme/events/SciClinInvest.html.

Good clinical practice

Boston University. Boston, MA. July/August.

Length of course/program. Six weeks.

Who would benefit. Health professionals with a degree in the natural sciences, pharmacy and other allied health fields; physicians, research

nurses, study coordinators, managers in clinical research and site management, professionals working in the pharmaceutical, biotechnology, medical device industries as well as CRO and SRO organizations.

Program goals. Introduces regulatory responsibilities of sponsors, monitors, and investigators conducting clinical trials. Practical information and exercises are designed on GCP compliance from an industrial perspective.

Topics include: selecting qualified investigators; obtaining ethical approval for patients; and initiating sites successfully.

Fees. \$3200.

Contact. Nicole Pirani, Boston University, 715 Albany St., 560-300 Boston, MA 02118, (617) 414-1329, fax (617)-358-1961, email: maci@bu.edu, www.bu.edu/maci.

Master of statistics

North Carolina State University, Department of Statistics. Raleigh, NC. August 2004–May 2006.

Length of course/program. Four semesters.

Who would benefit. Those interested in working in a pharmaceutical company, CRO or clinical research company. BS degree required.

Program goals. To provide training in statistical methods useful in the design and analysis of studies conducted in medical research, the pharmaceutical industry, and the public health area. Students will learn fundamentals of clinical

trials and epidemiological studies and will be exposed to recent advances in statistical methods for the analysis of time-to-event, categorical, and longitudinal data. Specialized training in these areas will be complemented by courses in advanced linear models, classical design of experiments, and supporting electives in areas such as quantitative genetics, biomathematics, and pharmacology.

Fees. \$1600 per semester (North Carolina residents).

Contact. Dr. William Swallow, Director of Graduate Programs, Department of Statistics, North Carolina State University, Box 8203, Raleigh, NC 27695-8203, (919) 515-1916 or (919) 515-1901, fax (919) 515-7591, email: stat_dgp@stat.ncsu.edu, www.stat.ncsu.edu.

MS in clinical research

American Institute of Health Sciences. Long Beach, CA. Ongoing.

Length of course/program. 24 months; 89 credits.

Who would benefit. The program is open to anyone who believes that quality of life is something that should be assured to all men and women. It is designed for students who have a BA or BS degree in the sciences, nursing, pharmacy, allied health fields, or liberal arts.

Program goals. The two-year program competency equips clinical trial personnel with comprehensive knowledge and training contributing to the design, conduct, analysis, and management of clinical trials.

Fees. \$18,900 (entire program).

Contact. Gregory Johnson, Chief Operating Officer/Vice President for Affiliation Development, American Institute of Health Sciences, 4300 Long Beach Blvd., Ste. 400, Long Beach, CA 90807, (562) 728-1989, fax (562) 728-4159, email: gjohnson@aihs.edu, www.aihs.edu.

Msc in clinical research

Liverpool John Moores University, School of Pharmacy and the Institute of Clinical Research (ICR). Liverpool and Southeast UK. Ongoing enrollment.

Length of course/program. Two years, part time.

Who would benefit. CRAs, senior clinical research personnel.

Program goals. To educate clinical research personnel in the organization, execution, management, and scientific clinical rationale of clinical research/trials to ICH/GCP standards.

Fees. \$6000.

Contact. Louise Galvin, Course Administrator, School of Pharmacy, Liverpool John Moores University, Byrom St., Liverpool L3 3AF, UK, +44 151 231 2248, email: l.galvin1@livjm.ac.uk.

MS in clinical research administration

George Washington University. Washington, DC. Spring and Fall.

Length of course/program. 36 credit hours.

Who would benefit. Those interested in participating in the clinical research industry utilizing a graduate education.

Program goals. To prepare professionals in organizations such as Pharma, CROs, SMO's academic medical centers, and as independent

consultants in clinical research.

Fees. \$406 per credit hour.

Contact. Margaret Ann Skelton, Director, Clinical Research Programs, George Washington University, 900 23rd St. NW, Suite 6173, Washington, DC 20037, (202) 994-0844, fax (202) 994-0181, email: icrmas@gwumc.edu.

MS in pharmacology, clinical research scientist track

Thomas Jefferson University, College of Graduate Studies. Philadelphia, PA. Rolling admissions.

Length of course/program. 40 credits (2-4 years part-time to completion).

Who would benefit. Study coordinators, clinical trial center staff, physicians, medical directors, biomedical scientists, research scientists, nurses and allied health professionals, statisticians, pharmacists, IRB monitors, and others seeking to enhance or develop their clinical and research skills.

Program goals. Students will be trained in initiation, administration, coordination, and management of clinical research studies for the development of new drugs, clinical products, and treatment programs.

Fees. \$675 per credit.

Contact. Georganne K. Buescher, Associate Dean, College of Graduate Studies, Thomas Jefferson University, 1020 Locust St., Philadelphia, PA 19107, (215) 503-5799, fax (215) 503-3433, email: Georganne.Buescher@jefferson.edu, www.jefferson.edu/jcgs/mssci/pharm.cfm.

MS in quality assurance/regulatory affairs

Temple University School of Pharmacy. Fort Washington, PA. Spring, Summer, and Fall.

Length of course/program. Twelve 3-credit courses.

Who would benefit. Industry professionals seeking career development.

Program goals. Provides knowledge of the pharmaceutical industry, quality principles and practices, and regulations to foster professional development and prepare students for supervisory and managerial positions.

Fees. \$2337 per 3-credit course (non-PA residents). \$1767 per 3-credit course (PA residents).

Contact. Wendy Lebing, Assistant Dean, Temple University School of Pharmacy, 425 Commerce Dr., Ste. 175, Ft. Washington, PA 19034, (215) 591-2333, fax (215) 591-2334, email: qara@temple.edu.

MS in regulatory affairs administration: protection of human subjects

George Washington University. Washington, DC. Fall 2004 and Spring 2005.

Length of course/program. 36 credit hours.

Who would benefit. Those interested in participating in the clinical research industry utilizing a graduate education.

Program goals. To prepare professionals to function as thought leaders in organizations such as Pharma, CROs, SMOs, academic medical centers, and as independent consultants, in

relation to regulatory affairs and protection of human subjects.

Fees. \$406 per credit hour.

Contact. Margaret Ann Skelton, Director, Clinical Research Programs, George Washington University, 900 23rd St. NW, Suite 6173, Washington, DC 20037, (202) 994-0844, fax (202) 994-0181, email: icrmas@gwumc.edu.

e MS nursing in clinical research management

Duke University. Durham, NC, or online.

Semesters begin August, January, and May.

Length of course/program. Minimum of 39 semester hours.

Who would benefit. Registered nurses interested in obtaining a graduate degree while furthering their knowledge and career development in the field of clinical research management.

Program goals. Develop expertise in the design and management of complex clinical research trials, develop expertise in the regulatory and ethical issues in research, and develop understanding of business and financial aspects of clinical trials.

Fees. \$672 per semester hour.

Contact. Elizabeth E. Hill, Assistant Professor and Director, CRM Program, Box 3322, DUMC, Duke University, Durham, NC 27710, (919) 681-0230 or (877) 415-3853, fax (919) 668-6120, email: liz.hill@duke.edu, www.nursing.duke.edu.

e MS in clinical investigation

MGH Institute of Health Professionals. Boston, MA or online. Rolling admissions.

Length of course/program. 36 credit hours.

Who would benefit. Candidates with a Bachelor's or higher degree interested in a strong academic and clinical research experience essential to the development of a leader in the field of clinical investigation.

Program goals. To prepare clinical research professionals for a variety of roles in the design and implementation of clinical trials. A rigorous curriculum encompassing academic and clinical research experience, providing a core of courses including: scientific, patient-oriented research methodologies; regulatory law; policy and administration; and a comprehensive coverage of the ethical considerations critical for a multi-skilled leader in the field of clinical investigation.

Fees. \$667 per credit hour.

Contact. Heather Duram, Program Manager, MGH Institute of Health Professionals, 36 1st Avenue, Boston, MA 02129, (617) 724-6362, fax (617) 726-8022, email: hduram@mghihp.edu, www.mghihp.edu.

Certificate programs

Biotechnology project management

Massachusetts Biotechnology Council's MassBioEd. Cambridge, MA. Spring and Fall.

Length of course/program. Three days.

Who would benefit. Anyone who wants to learn the essentials of project management in a biotechnology company.

Program goals. Provides a comprehensive overview of the project management process in a

biotechnology company.

Fees. \$1350.

Contact. Amy Goodman, MBC, One Cambridge Center, 9th Floor, Cambridge, MA 02142, (617) 577-8198, fax (617) 577-7860, email: amy_Goodman@massbio.org, www.massbio.org/education.

e Business and financial practices of clinical research

Duke University, School of Nursing, Durham, NC, or online. On campus August–December; online January–April.

Length of course/program. 12–13 weeks.

Who would benefit. Individuals interested in furthering their knowledge and career development through graduate-level education in the business and financial aspects of conducting clinical research.

Program goals. Develop expertise and leadership skills in the business and financial practices followed during the conduct of clinical research. Presented by experts from industry and academia.

Fees. \$672 per semester hour.

Contact. George H. Turner III, Assistant Clinical Professor, Box 3322, DUMC, Duke University, Durham, NC 27710, (877) 415-3853 or (919) 668-5108, fax (919) 668-6120, email: george.turner@duke.edu, www.nursing.duke.edu.

Certificate of professional development in clinical research

Liverpool John Moores University, School of Pharmacy and the Institute of Clinical Research (ICR), Liverpool, UK. Program starts in September.

Length of course/program. One year, part time. 48 UK undergraduate credits.

Who would benefit. Study site coordinators, research nurses, pharmacology nurses.

Program goals. To educate study site personnel in the organization, execution, management, and scientific clinical rationale of clinical research/trials to ICH/GCP standards.

Fees. \$2500.

Contact. Louise Galvin, Course Administrator, School of Pharmacy, Liverpool John Moores University, Byrom St., Liverpool L3 3AF, UK, +44 151 231 2248, email: l.galvin1@livjm.ac.uk.

Certificate in clinical research

Thomas Jefferson University, College of Graduate Studies, Philadelphia, PA. Rolling admissions.

Length of course/program. One year (15 credits).

Who would benefit. Graduates of baccalaureate programs in basic sciences, nursing, health professions, engineering, or business. Graduates of professional programs in medicine, dentistry, veterinary medicine, or law. Graduates of doctoral or postdoctoral programs.

Program goals. To introduce the roles and responsibilities of investigators and sponsors, educate students on the regulations governing clinical research, and train them for the management of clinical trials.

Fees. \$675 per credit.

Contact. Georganne K. Buescher, Associate Dean, College of Graduate Studies, Thomas

Jefferson University, 1020 Locust St., Philadelphia, PA 19107, (215) 503-5799, fax (215) 503-3433, email: Georganne.Buescher@jefferson.edu, www.jefferson.edu/jcgs/mssci/pharm.cfm.

Post-baccalaureate Certificate in clinical research administration

Eastern Michigan University, Ypsilanti, MI. Year-round.

Length of course/program. One year (certificate) and 2 years (MS).

Who would benefit. Individuals interested in upward mobility from their current position or entry into the field of drug/device development.

Program goals. To provide an opportunity for professionals participating in the drug/device development process to increase their knowledge base and research/creative skills.

Fees. \$270 per credit hour.

Contact. Stephen A. Sonstein, Coordinator, Clinical Research Administration, 318 Marshall Building, Eastern Michigan University, Ypsilanti, MI 48197, (734) 487-1238, fax (734) 487-4095, email: stephen.sonstein@emich.edu, www.emich.edu/public.dahp/cra.html.

Certificate program in clinical trials design and management

University of California, Santa Cruz Extension, Cupertino and Sunnyvale, CA. Ongoing.

Length of course/program. Approx. 210 hours—

typically 1 year, part-time, evenings and weekends. Academic credit and RN CE units available.

Who would benefit. CRAs, CRCs, physicians, research scientists, statisticians, nurses, and allied health professionals.

Program goals. Designed for the career advancement of working professionals, this academically rigorous and practical certificate program facilitates an understanding of the clinical trials process and the drug and device development industry.

Fees. \$3900–\$4600, depending on electives chosen.

Contact. Jim Kostecka, UCSC Extension, 10420 Bubb Rd., Cupertino, CA 95014, (408) 861-3863, fax (408) 342-0164, email: jkostecka@ucsc-extension.edu, www.ucsc-extension.edu.

Certificate in clinical trials management

University of Chicago, Graham School of General Studies, Chicago, IL. Throughout the academic year.

Length of course/program. Eight 3-day seminars. CEU nursing credits available.

Who would benefit. CRAs, study coordinators, regular nurses, bench scientists.

Program goals. The Certificate in Clinical Trials Management will help to meet the demand of training professionals working for pharmaceutical companies, CRO's, and clinical

study sites.

Fees. \$1250.

Contact. Matthew Cherry, Program Manager, Graham School of General Studies, University of Chicago, 1427 E. 60th St., 2nd Floor, Chicago, IL 60637, (773) 834-3310, fax (773) 702-6814, email: mcherry@uchicago.edu, www.grahamschool.uchicago.edu.

Clinical research associate, clinical research coordinator, and clinical data monitor certificate program

Rutgers University, Center for Professional Development, Newark, NJ. Saturdays (CRA/CRC: 7 February–20 March and 5 June–17 June; CDM: 3 April–8 May).

Length of course/program. Six days (36 contact hours).

Who would benefit. Nurses and others with a science background.

Program goals. The courses provide a comprehensive overview of either the role(s) of the CRA, CRC, or CDM. Course content provides the key aspects of these roles and prepares the individual to enter these fields.

Fees. \$1650.

Contact. Gayle Person, Assistant Dean, Center for Professional Development, 175 University Avenue, Conklin Hall, Room 244, Newark, NJ 07102, (973) 353-5895, fax (973) 353-1700, email: cpd@nursetech.rutgers.edu, www.nursing.rutgers.edu/cpd.

Clinical research certificate program

University of Cincinnati, Raymond Walters College. Cincinnati, OH. Quarters begin in September, January, and March.

Length of course/program. Three quarters. CNE credit available.

Who would benefit. Individuals with a bachelor's degree who are interested in a career as a clinical research professional.

Program goals. To provide information on GCP and the drug, device, and biologic approval processes. Paid internship options are available.

Fees. \$112 per credit hour.

Contact. Karen King, Coordinator, Clinical Research Certificate Program, University of Cincinnati, Raymond Walters College, 9555 Plainfield Rd., Cincinnati, OH 45236, (513) 745-5617, fax (513) 936-7113, email: karen.king@uc.edu, biology.rwc.uc.edu/homepage/programs/crpg.html.

e Clinical research design and management

Duke University, Graduate School of Nursing. Durham, NC, or online. On campus August–December; online January–April.

Length of course/program. 12–13 weeks.

Who would benefit. Individuals interested in furthering their knowledge and career development through graduate-level education in clinical research design and management.

Program goals. Develop expertise and leadership skills in the design and management of clinical research through a comprehensive course presented by experts from industry and academia.

Fees. \$672 per semester hour.

Contact. George H. Turner III, Assistant Clinical Professor, Box 3322, DUMC, Duke University School of Nursing, Durham, NC 27710, (877) 415-3853 or (919) 668-5108, fax (919) 668-6120, email: george.turner@duke.edu, www.nursing.duke.edu.

Clinical research postgraduate certificate

Humber College, Institute of Technology and Advanced Learning. Toronto, ON, Canada. September–August (including coop May–August).

Length of course/program. One year (3 semesters) full time, 3 years part time (3 semesters, 2–3 evening courses per semester).

Who would benefit. Admission requirements include a university degree in the health sciences. Preference given to those with a Master's degree.

Program goals. The program prepares candidates to conduct clinical trials. Graduates will obtain different positions in the biopharma industry and at hospitals. The training has an international focus.

Fees. CDN\$10,000 per year for Canadians, CDN\$15,000 per year for non-Canadians.

Contact. Urszula Kosecka, Program Coordinator, Humber College, Institute of Technology and Advanced Learning, 205 Humber College Blvd., Toronto, ON M9W 5L7, Canada, (416) 675-6622 x4843, fax (416) 675-2015, email: urszula.kosecka@humber.ca, www.healthsciences.humberc.on.ca/crra.

e Clinical research regulatory affairs

Duke University, School of Nursing. Durham, NC, or online. On campus May–August; online August–December.

Length of course/program. 12–13 weeks.

Who would benefit. Individuals interested in furthering their knowledge, leadership skills, and career development through graduate-level education in regulatory affairs.

Program goals. Develop expertise in regulatory affairs and oversight of clinical research through a comprehensive course presented by experts from industry and academia.

Fees. \$672 per semester hour.

Contact. George H. Turner III, Assistant Clinical Professor, Box 3322, DUMC, Duke University School of Nursing, Durham, NC 27710, (877) 415-3853 or (919) 668-5108, fax (919) 668-6120, email: george.turner@duke.edu, www.nursing.duke.edu.

Clinical trial management certificate

Temple University School of Pharmacy. Fort Washington, PA. Spring, Summer, and Fall.

Length of course/program. Five courses for certificate; 36 hours per course.

Who would benefit. Pharmaceutical and healthcare professionals involved in the clinical trial process.

Program goals. This certificate reviews new drug discovery, the design and implementation of protocols, effective monitoring strategies, and

data auditing to ensure the integrity of clinical trials.

Fees. \$2337 per 3-credit course (non-PA residents). \$1767 per 3-credit course (PA residents).

Contact. Wendy Lebing, Assistant Dean, Temple University School of Pharmacy, 425 Commerce Dr., Ste. 175, Ft. Washington, PA 19034, (215) 591-2333, fax (215) 591-2334, email: qara@temple.edu.

Clinical trials administration

University of California—San Diego Extension. La Jolla, CA. 22–26 March, November.

Length of course/program. 110 hours. CME and BRN, NSWC credits available.

Who would benefit. Research scientists, research associates and coordinators, managers in training, physicians, nurses, allied health professionals. BA/BS degree preferred.

Program goals. Provides a solid foundation in the principles upon which clinical trials are based. Covers drug development process, GCP, CRE design, IRBs, trial design and protocol, site and study management, monitoring, regulatory responsibilities, setting up a new clinical study, working with CROs, and more.

Fees. \$1795.

Contact. Donna Stern, Manager Clinical Trials Programs, UCSD Extension, 9500 Gilman Drive, Dept. 0170E, La Jolla, CA 92093-0170, (858) 748-5580 or (858) 964-1010, fax (858) 964-1018, email: dmstern@ucsd.edu, www.extension.ucsd.edu.

Clinical trials: medical device and drug development

University of California—Irvine Extension. Variable locations in Orange County, CA. January.

Length of course/program. 16.5 units.

Program goals. Comply with GCP requirements, design and manage a clinical trial, develop a clinical data management process, apply knowledge of GCP regulations in preparation for an FDA inspection, apply principles of human subject safety in clinical trials.

Contact. Rogelio Rodriguez, Director of Engineering and Science Programs, (949) 824-5380, www.unex.uci.edu.

Clinical trials: medical device and drug development

University of California—Irvine Extension. Variable locations in Orange County, CA. January.

Length of course/program. 16.5 units.

Program goals. Comply with GCP requirements, design and manage a clinical trial, develop a clinical data management process, apply knowledge of GCP regulations in preparation for an FDA inspection, apply principles of human subject safety in clinical trials.

Contact. Rogelio Rodriguez, Director of Engineering and Science Programs, (949) 824-5380, www.unex.uci.edu.

Drug development certificate

Temple University School of Pharmacy. Fort Washington, PA. Spring, Summer, and Fall.

Length of course/program. Four courses for

certificate; 36 hours per course.

Who would benefit. Industry professionals.

Program goals. This certificate reviews new drug discovery, industry good practices, and FDA regulation, enabling students to explore quality assurance and regulatory affairs issues.

Fees. \$2337 per 3-credit course (non-PA residents). \$1767 per 3-credit course (PA residents).

Contact. Wendy Lebing, Assistant Dean, Temple University School of Pharmacy, 425 Commerce Dr., Ste. 175, Ft. Washington, PA 19034, (215) 591-2333, fax (215) 591-2334, email: qara@temple.edu.

European diploma of pharmaceutical medicine—EUDIPHARM

Pharmaceutical industry: Pfizer, Merck, Sanofi-Synthelabo, European programs: Socrates-Erasmus. Lyon, France; Paris, France; Brussels, Belgium. 19–24 January, 16–21 February, 15–20 March, 19–23 April, 10–15 May, 14–17 June.

Length of course/program. Eight weeks (two semesters).

Who would benefit. Basic training is organized for doctors, post-graduate students, or students following their residency, with a background in human medicine, dentistry, veterinary medicine, or pharmacy. Candidates for the Diploma must have a background in pharmacology and methodology in clinical research, and a good command of the English language. Continuing education is aimed at physicians, pharmacists, dentists, veterinarians or other scientists with current or past positions in research, development, registration, evaluation, and post-monitoring of medicines.

Program goals. The Diploma is aimed at preparing students who want to become professionals in the healthcare industry, CROs, or regulatory bodies, or to work as faculty members or researchers in higher education or as principal investigators in private or public practice.

Fees. \$2500 for students. \$5000 per year for physicians, officers in drug regulation agencies, CROs. Continuing education: \$460 per day for seminars/\$460 per basic module.

Contact. Françoise Dürr, Pharmacy Doctor, +33 (0) 4 78 78 5774, email: registration@eudipharm.net, www.eudipharm.net.

Introduction to clinical research

Villanova University, College of Nursing, Villanova, PA. March.

Length of course/program. Five weeks (Saturdays 9 am–4 pm).

Who would benefit. Nurses and other professionals interested in moving into the field of clinical research monitoring.

Program goals. To explore the multiple roles/responsibilities of those involved in managing clinical trials and to discover regulations and controls that influence clinical research.

Fees. \$1495.

Contact. Louisa Zullo, Program Assistant, 800

Lancaster, Avenue, St. Mary's Hall, Villanova, PA 19085, (610) 519-4930, fax (610) 519-6780, email: louisa.zullo@villanova.edu, www.nursing.villanova.edu/cont_ed.

Post-baccalaureate certificate for CRAs/CRCs

American Institute of Health Sciences. Long Beach, CA. Ongoing.

Length of course/program. 18 months; 74.5 credit hours.

Who would benefit. The certificate program is designed for students who have a BA or BS degree, preferably in the science or allied health fields, who meet the admissions criteria. Open to anyone interested in performing clinical research or working in drug development, and those working in the field of biotechnology who want to increase their knowledge and skill-sets.

Program goals. The certificate program will provide the foundation needed to become a clinical research associate/coordinator with the knowledge and comprehensive training contributing to the design, conduct, analysis, and management of clinical trials.

Fees. \$15,329 (entire program).

Contact. Gregory Johnson, Chief Operating Officer/Vice President for Affiliation Development, American Institute of Health Sciences, 4300 Long Beach Blvd., Ste. 400, Long Beach, CA 90807, (562) 728-1989, fax (562) 728-4159, email: gjohnson@aihs.edu, www.aihs.edu.

Post-graduate certificate in clinical trial administration

Liverpool John Moores University, School of Pharmacy and the Institute of Clinical Research (ICR). Liverpool, UK. Ongoing enrollment.

Length of course/program. 18–24 months, part-time. 60 UK undergraduate credits.

Who would benefit. Clinical research and clinical trial administrators at study sites, in sponsor companies, or at research institutes.

Program goals. To educate clinical research administrators in the organization, execution, management, and tracking of scientific clinical research/trials to ICH/GCP standards.

Fees. \$3500.

Contact. Louise Galvin, Course Administrator, School of Pharmacy, Liverpool John Moores University, Byrom St., Liverpool L3 3AF, UK, +44 151 231 2248, email: l.galvin1@livjm.ac.uk.

Outcomes and effectiveness research

Johns Hopkins University School of Medicine Graduate Training Programs in Clinical Investigation. Baltimore, MD. January–March.

Length of course/program. One evening a week × eight weeks; 21 CME credits available.

Who would benefit. Scientists, clinicians, and other health professionals fully engaged in clinical investigation.

Program goals. To enhance the theoretical and

practical skills of clinical scientists in the design, implementation, analysis, and interpretation of data from clinical investigators.

Fees. \$1764 per course.

Contact. Mary Jeter, CME Conference/Course Coordinator, Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Turner 20, 720 Rutland Ave., Baltimore, MD 21205, (410) 955-3988, fax (410) 614-7302, email: www.hopkinscme.org/cme/events/SciClinInvest.html.

Overview of clinical research

Massachusetts Biology Council's MassBioEd. Cambridge, MA. 5 February–20 May and 9 September–16 December.

Length of course/program. 14 weeks.

Who would benefit. Anyone who wants an introduction to clinical research: executives, government employees, laboratory and preclinical, entry-level clinical research staff, those intending to change careers.

Program goals. Provides a comprehensive overview of the clinical research process, including the regulatory and business backdrop, and explores the process from Investigator identification through final report.

Fees. \$1350 per semester.

Contact. Amy Goodman, MBC, One Cambridge Center, 9th Floor, Cambridge, MA 02142, (617) 577-8198, fax (617) 577-7860, email: amy_Goodman@massbio.org, www.massbio.org/education.

Physicians in clinical research

Massachusetts Biotechnology Council's MassBioEd and Massachusetts Medical Society. Waltham, MA. 12–13 March.

Length of course/program. 1.5 days. 15 CME credits available.

Who would benefit. Anyone who wants to learn the essentials of project management in a biotechnology company.

Program goals. Provides a comprehensive introduction to the clinical research process from the physician's perspective. Attendees participating in this course include potential clinical investigators, current clinical investigators who need to learn GCPs, and potential industry physicians.

Fees. \$1250/25% discount for MMS members.

Contact. Amy Goodman, MBC, One Cambridge Center, 9th Floor, Cambridge, MA 02142, (617) 577-8198, fax (617) 577-7860, email: amy_Goodman@massbio.org, www.massbio.org/education.

e Post-MS certificate in clinical research management

Duke University, Durham, NC, or online. Semesters begin August, January, and May.

Length of course/program. Minimum of 19 semester hours.

Who would benefit. Individuals interested in furthering their knowledge and career development in the field of clinical research management.

Program goals. Develop expertise and understanding in design and management of complex clinical research trials, regulatory and

ethical issues in research, and the business and financial aspects of clinical trials.

Fees. \$672 per semester hour.

Contact. Elizabeth E. Hill, Assistant Professor and Director, CRM Program, Box 3322, DUMC, Duke University School of Nursing, Durham, NC 27710, (919) 681-0230 or (877) 415-3853, fax (919) 668-6120, email: liz.hill@duke.edu, or George H. Turner III, Assistant Clinical Professor, Duke University School of Nursing, Box 3322, DUMC, Durham, NC 27710, (877) 415-3853 or (919) 668-5108, fax (919) 668-6120, email: george.turner@duke.edu, www.nursing.duke.edu.

Quantitative analysis of clinical data

Johns Hopkins University School of Medicine Graduate Training Programs in Clinical Investigation. Baltimore, MD. October–December.

Length of course/program. One evening a week × eight weeks; 24 CME credits available.

Who would benefit. Scientists, clinicians, and other health professionals fully engaged in clinical investigation.

Program goals. To enhance the theoretical and practical skills of clinical scientists in the design, implementation, analysis, and interpretation of data from clinical investigators.

Fees. \$1764 per course.

Contact. Mary Jeter, CME Conference/Course Coordinator, Johns Hopkins University School of Medicine, Office of Continuing Medical Education, Turner 20, 720 Rutland Ave., Baltimore, MD 21205, (410) 955-3988, fax (410) 614-7302, email: www.hopkinscme.org/cme/events/SciClinInvest.html.

Regulatory affairs postgraduate certificate program

Humber College, Institute of Technology and Advanced Learning. Toronto, ON, Canada. September–August (including coop May–August).

Length of course/program. One year (3 semesters).

Who would benefit. Admission requirements: a university degree in health sciences. Preference given to those with a Master's degree.

Program goals. The program prepares candidates to conduct regulatory affairs in biopharma, medical devices industry, government and regulatory CROs. The training covers international and country-specific regulations to allow graduates to work anywhere in the world.

Fees. CDN\$5000 per year for Canadians, CDN\$15000 for non-Canadians.

Contact. Urszula Kosecka, Program Coordinator, Humber College, Institute of Technology and Advanced Learning, 205 Humber College Blvd., Toronto, ON M9W 5L7, Canada, (416) 675-6622 x4843, fax (416) 675-2015, email: urszula.kosecka@humber.ca, www.healthsciences.humberc.on.ca/crra.

Short courses/workshops/conferences

AAPP 11th Annual Meeting

American Academy of Pharmaceutical Physicians (AAPP). Atlanta, GA. 4–6 November.

Length of course/program. Three days, 12 CME

credits available.

Program goals. The AAPP Annual Meeting is an invaluable pharmaceutical medicine conference that focuses on issues relating to clinical investigators and physicians involved in industry.

Fees. \$695 for early bird registration. \$795 for regular registration.

Contact. Heidi Bergs, Education Programs Coordinator, AAPP, 1031 Pemberton Hill Road, Suite 101, Apex, NC 27502, (919) 355-1003, fax (919) 355-1010, email: hbergs@aapp.org, www.aapp.org.

Achieving and maintaining 21 CFR Part 11 compliance

Validation Associates, Inc. 2 February: Baltimore, MD; 29 March: New Orleans, LA; 22 June: Toronto ON, Canada; 27 September:

Albuquerque, NM; 30 November: Princeton, NJ.

Length of course/program. Two days.

Who would benefit. This workshop is appropriate for anyone who needs to ensure that their automated systems are compliant with the Electronics Records; Electronic Signature regulation.

Program goals. This one-day workshop reviews 21 CFR Part 11 requirements, and FDA and industry positions and guidance on the regulation. The session focuses on how to evaluate new and existing systems for compliance, and how the rule impacts the implementation and use of automated systems.

Fees. \$575.

Contact. Danielle C. Mongiello, Validation Associates, Inc., 305 E. Pennsylvania Blvd., Feasterville, PA 19053-7846, (215) 354-1720, ext. 201, fax (215) 354-1725, email: info@validassoc.com, www.validassoc.com.

Adverse events: managing and reporting

Barnett International, Inc. Locations throughout the United States. 4–6 times annually.

Length of course/program. Two days; CE credits available through the American Council on Pharmaceutical Education (ACPE) and the New Jersey State Nurses Association.

Who would benefit. Safety surveillance personnel responsible for the acquisition, classification, entry, analysis, and reporting of marketed product and investigational trial adverse events; regulatory affairs personnel responsible for submitting safety reports to FDA or other health authorities; medical affairs personnel responsible for safety-related decisions regarding product labeling, regulatory interactions, or customer communication; quality control personnel involved in the investigation of adverse event reports; and CRAs and CRCs responsible for collecting, reviewing, and reporting investigational adverse events for new and marketed products.

Program goals. This course provides an introduction for newcomers to the field of drug and biologic product pharmacovigilance, a comprehensive overview of current approaches and regulations for professionals in the field, and challenging questions and ideas for the experienced safety information scientist.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., Rose Tree Corporate Center, 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

11th Annual Applied Clinical Trials European Summit

Advanstar Communications, Inc. Europe, Munich, Germany. 12–14 May.

Length of course/program. Three days.

Who would benefit. Directors, heads, managers, and team leaders in clinical research, clinical trials/studies, clinical operations, data management/E-trials, regulatory affairs, project management, quality assurance, drug safety, corporate management, business development, and research and development.

Program goals. Devising and implementing successful drug development strategies and procedures under the EU GCP Directive.

Fees. TBD.

Contact. Sián Winston, Advanstar Communications, Park West, Sealand Road, Chester CH1 4RN, UK, +44 1244 393 159 or +44 1244 393 158, fax +44 1244 370 560, email: swinston@advanstar.com, www.appliedclinicaltrials.co.uk.

Auditing computer system providers

Validation Associates, Inc. 5 February: Baltimore, MD; 30–1 April: New Orleans, LA; 25 June: Toronto ON, Canada; 30 September: Albuquerque, NM; 3 December: Princeton, NJ.

Length of course/program. One day.

Who would benefit. This workshop is appropriate for anyone who needs to understand how to evaluate documentation supporting the development of automated systems.

Program goals. This one-day workshop focuses on the activities associated with planning and completing audits of computerized system providers. The session includes practical techniques for evaluating the quality of validation deliverables, and is applicable to both internally developed and vendor-supplied systems. In-class inspection activities reinforce completing the audit tasks.

Fees. \$550.

Contact. Danielle C. Mongiello, Validation Associates, Inc., 305 E. Pennsylvania Blvd., Feasterville, PA 19053-7846, (215) 354-1720, ext. 201, fax (215) 354-1725, email: info@validassoc.com, www.validassoc.com.

Auditing techniques for clinical research professionals

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. Clinical quality assurance professionals, CRAs, managers, project leaders, medical monitors, regulatory affairs professionals, investigators, trial center managers, and study coordinators.

Program goals. This workshop teaches practical, immediately usable techniques that are

employed by top-notch GCP auditors and FDA Investigators, including techniques used when auditing clinical trials that use electronic medical records and/or Electronic Data Capture (EDC). When monitors apply these techniques, they can better detect, correct, and prevent clinical study performance deficiencies at clinical sites and within their organizations.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Basic training for clinical research coordinators

The Walter B. Morley Research Foundation and the University of Wisconsin Medical School. Ongoing.

Length of course/program. Two days. 14 CNE credits and 14 CPE credits available.

Who would benefit. Research coordinators with less than three years of experience and individuals interested in becoming research coordinators.

Program goals. Participants will receive information and materials necessary to conduct successful clinical trials and to prepare for certification exams, including; GCPs, understanding basic regulatory requirements,

source documentation practices, and recruitment strategies.

Fees. €595.

Contact. Lisa Blandford, Program Manager, The Walter B. Morley Foundation, Fusion Medical Education, 800 Township Line Rd., Yardley, PA 19067, (215) 550-8150, ext. 8503, fax (215) 550-8160, email: morleyfoundation@fusionmed.com, www.morleyfoundation.org.

Biologic approval process: preparation and processing of INDs and BLAs

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. This course is intended for regulatory, technical, and quality personnel who require an understanding of the biologic approval system. This course will also benefit management and other personnel who must be familiar with the essentials of the biologic approval system and submission of related documents.

Program goals. This course provides an overview of the FDA system for approval of biologic products. Participants will receive a foundation of knowledge about the biologic approval process and the scientific and regulatory principles involved. Guidelines for each aspect of research will be provided along with information

DIA clinical trials events

This is a small fraction of the Drug Information Association (DIA)'s workshops and conferences. For the complete schedule, visit the association's Web site.

Contact. 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, (215) 442-6100, fax (215) 442-6199, e-mail: dia@diahome.org, www.diahome.org. DIA European Bureau, Postfach, CH-4002 Basel, Switzerland, +41 61 225 51 51, fax +41 61 225 51 52, e-mail: dia@diaeurope.org, www.diahome.org.

5th Annual Workshop on Pharmaceutical Outcomes Research

January 21–23: Westin La Paloma, Tuscon, AZ

Emerging Clinical Trials Regions: Central & Eastern Europe and Asia on the Forefront

January 27–28: Grand Hyatt, Washington DC

European Regulatory Affairs Training Course

February 2: Hyatt, San Francisco, CA

Project Management and Finance

February 8–10: Hyatt Regency, Fort Lauderdale, FL

Chemistry, Manufacturing & Controls Regulatory and Technical Strategies

March 1–3: Hyatt Regency, Bethesda, MD

Pharmacokinetic and Pharmacodynamic Application in the Drug Development Process

March 3–5: Park Hyatt, Washington DC

Investigational Supply Process Training Course

March 15–19: Hyatt Regency, New Orleans

15th Annual Workshop for Medical Communications

March 21–25: Marriott Waterside, Tampa, FL

Assessing Treatment impact Using PROs: Challenges in Study Design, Conduct and Analysis

May 10–11: Hotel Sofitel, Paris

Fundamentals of Clinical Research Monitoring Training Course

May 17–19: Chicago

DIA 40th Annual Meeting

June 13–17: Washington Convention Center, Washington DC

Fundamentals of Clinical Research Monitoring Training Course

August 16–18: Langham Hotel, Boston

Computer Validation

October 12–14: Renaissance Hotel, Prague

on submissions and postapproval documents. The course will enable the professional to provide the FDA with necessary information and obtain product approval.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Biometrics in practice

Kendle, Munich, Germany or onsite. Spring and Fall.

Length of course/program. Two days.

Who would benefit. Individuals from the pharmaceutical industry (clinical research/medical science/biometrics) involved in the planning and evaluation of clinical trials.

Program goals. This two-day seminar concentrates on presenting basic descriptive and inferential statistics. The relevant ICH regulations are used as a guideline.

Fees. €1090.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

Building a clinical research business: financial management

The Walter B. Morley Research Foundation and the University of Wisconsin Medical School. Ongoing.

Length of course/program. One day. 6 CNE credits and 6 CPE credits available.

Who would benefit. All individuals with accountability for the financial management of a research site.

Program goals. Participants will receive information and materials necessary to maximize the budget and profitability of a research site, including: contract evaluation and

negotiation, marketing strategies, key regulatory and legal requirements, staffing, and hidden or unexpected protocol costs.

Fees. €479.

Contact. Lisa Blandford, Program Manager, The Walter B. Morley Foundation, Fusion Medical Education, 800 Township Line Rd., Yardley, PA 19067, (215) 550-8150, ext. 8503, fax (215) 550-8160, email: morleyfoundation@fusionmed.com, www.morleyfoundation.org.

Clinical data: the guidelines for today

Association for Clinical Data Management (ACDM). London, UK. 23 June, 1 December.

Length of course/program. One day.

Who would benefit. Those with at least three years of experience handling clinical data.

Program goals. To emphasize the impact of new legislation and regulations affecting clinical data and discuss the ground rules on which the handling of clinical data is based.

Fees. \$635.

Contact. ACDM Administrator, Association for Clinical Data Management, PO Box 129, Macclesfield, Cheshire, SK11 8FG, UK, +44 1625 511818, fax +44 1625 267879, email and Web site: acdm.org.uk.

Clinical data management

Kendle, Munich, Germany or onsite. Spring and Fall.

Length of course/program. One day.

Who would benefit. Individuals involved in clinical data management or interested in an overview of the tasks of clinical data management.

Program goals. The aim of this seminar is to explain the role played by clinical data management in the field of clinical research.

Fees. €575.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

Clinical investigator workshop for clinical investigators and key research staff

Society of Clinical Research Associates (SoCRA). 9–10 December (Washington, DC).

Length of course/program. 1.5 days; 12.9 CNE contact hours, 12 CME contact hours.

Who would benefit. Investigators and key research staff members.

Program goals. Attendees will be able to describe the drug development process, investigator and site responsibilities, source documentation and record management requirements, adverse event reporting, audits, execution of clinical studies, investigator-initiated research, and financial management of study funds.

Fees. \$525. Nonmembers of SoCRA must purchase annual membership for \$75.

Contact. SoCRA, P.O. Box 101, Furlong, PA 18925, (800) 762-7292 or (215) 345-7749, fax (215) 345-7369, email: SoCRAmail@aol.com, www.SoCRA.org.

Clinical project management

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. 2 days; CE credits available through the ACPE.

Who would benefit. New project managers with less than one year of experience; project managers who have little or no drug development or clinical trial experience; staff from pharmaceutical companies or CROs who will be involved with the management of clinical trials; new clinical or other project team leaders who will be managing projects; managers who are unfamiliar with clinical project management; new clinical, regulatory, and development staff who design clinical trial programs.

Program goals. This course is an introduction to clinical project management in the pharmaceutical industry. The focus will be on individuals who want to learn basic management skills and how they can be applied to the drug

Onsite and customized training

Halloran Consulting Group, Inc.

Laurie Halloran, President, 54 Kenrick St., Boston, MA 02135, (617) 842-2306, fax (617) 254-7850, email: halloran@halloranconsultinggroup.com.

Good Clinical Practice Customized. This two- to four-day workshop is designed for physicians, research nurses, study coordinators, managers in clinical research, and site management professionals in the pharmaceutical and biotechnology industries. Introduces regulatory responsibilities of sponsors, monitors, and investigators conducting clinical trials. Practical information and exercises are designed on GCP compliance from an industry perspective. Topics include: selecting qualified investigators; obtaining ethical approval for patients; and initiating sites successfully.

Kendle

Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

Biometrics in practice. This two-day seminar concentrates on presenting basic descriptive and inferential statistics. The relevant ICH regulations are used as a guideline.

Clinical data management. The aim of this seminar is to explain the role played by clinical data management in the field of clinical research.

Clinical trials with special reference to the German Drug Law and ICH-GCP. The two-day seminar aims to give a comprehensive overview of methods for planning, conducting, and analyzing clinical trials. Participants are shown how good study design can lead to high quality.

EU clinical trials directive and its implementation to the German Drug Law. In this seminar, the EU clinical Trials directive is presented as well as implementation to national law of member states, with a focus on Germany.

GCP for project assistants and study coordinators. In this 1.5-day workshop, participants will learn about the legal basis for clinical trials, according to both German law and the international GCP standard.

Integrated study reports according to ICH. The one-day seminar deals with final reports for clinical studies. It also covers the presentation of data in tables and graphs in the study report.

Monitoring clinical trials with special reference to the 12th version of the German Drug Law and to ICH-GCP. Participants in this two-day workshop will learn which activities are necessary in the pharmaceutical company and at the study site to ensure monitoring of a clinical trial according to the international GCP standard.

Monitoring workshop with special reference to the 12th version of the German Drug Law and to ICH-GCP. The three-day workshop covers the basics required of a monitor and then goes into the details of national and international regulations.

Pharmacoeconomics in practice. The seminar presents the basic principles of pharmacoeconomics and also deals with selected topics in depth.

Postmarketing surveillance studies with reference to the German Drug Law. The one-day seminar aims to point out the possibilities and limitations of post-marketing surveillance (PMS) studies.

Project management of clinical trials. The seminar presents the tasks and responsibilities of a project manager for clinical trials. The initiation of a project is covered, and the main focus is on how to manage a running project.

Polaris Clinical Research Consultants

Celine M. Clive, President, Polaris Clinical Research Consultants, Inc., 130 Iowa Lane, Ste. 103, Cary, NC 27511, (919) 463-0003, fax (919) 463-0004, email: CMclive@aol.com, www.polarisconsultants.com.

Customized clinical research training. The company provides one- to four-day, interactive, customized training that is developed to meet clients' needs and participants' experience, and which can be tailored for any of the following groups: beginning, intermediate or advanced CRAs; beginning or intermediate CRCs, clinical investigators; and IRB members and administrators. Programs are available on such topics as basic GCP, adverse experiences, the role and responsibilities of the IRB, informed consent, drug accountability, site visits, and regulatory documents. CME credits are available, depending on the specific program.

Detecting fraud in clinical research. These workshops provide an awareness of what clinical research fraud is and how it can be detected. Cases of investigators who have been convicted of fraud are discussed. Students will participate in an exercise to develop their skills in detecting fraud. Half- or full-day programs with or without CME credits are available.

development process, especially management of clinical trials.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063-2043, (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Clinical project management: advanced

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. 2 days; CE credits available through the ACPE.

Who would benefit. Clinical project managers who have mastered project management basics; experienced project managers with limited drug development or clinical trial experience; team leaders or managers with a basic knowledge of clinical project management; staff from pharma, biotech or CROs who want to learn more about the clinical trial process; clinical, regulatory, and development staff who design clinical trial programs.

Program goals. This course builds on project management basics to examine some of the more difficult issues encountered by clinical project managers. It examines approaches for

optimizing clinical trial conduct and includes discussion of current hot-button concerns facing clinical project managers.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063 (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Clinical project management: running a clinical trial

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. One day; CE credits available through the ACPE.

Who would benefit. New project managers or project managers with less than two years of experience; project managers who have little or no drug development or clinical trial experience; clinical research associates, data managers or others interested in transitioning into clinical trial management; project team leaders with limited direct clinical trial experience who will be managing drug development programs and supervising project managers; managers who are unfamiliar with clinical project management; others involved in the drug development process who are interested in learning more about

managing clinical trials.

Program goals. This course extends the project management basics addressed in Clinical Project Management. It addresses the needs of relatively new project managers not familiar, or experienced, with specific technical tasks involved in clinical trial management. Specifically, it focuses on the need to anticipate, understand, and implement detailed project management activities in a proactive manner. The course is structured around a highly detailed and fully developed clinical trial management process map. Discussions are practically oriented with emphasis given to useful advice that, when implemented, will assist with trial management.

Fees. \$699.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063-2043, (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Clinical research monitoring course for site coordinators, monitors, and auditors

Society of Clinical Research Associates (SoCRA). 18–19 March (Chicago, IL); 15–16 July (San Diego, CA).

Research Dynamics Consulting Group, Ltd.

Jeanne Koepke, Administrative Assistant, Sales and Marketing, 1250 Pittsford-Victor Road, Bldg. 100, Ste. 110, Pittsford, NY 14534, (585) 381-1350 x221, fax (585) 381-4032, email: www.resdyncc.com.

GCPs for clinical research professionals: conducting a clinical research study. This course reviews the basic requirements for conducting clinical trials at investigator sites. The training is based on FDA requirements and ICH GCP guidelines.

Managing a clinical research business. This class addresses critical clinical research management issues in a comfortable environment, allowing clinical research professionals to talk, network, and learn about managing the many aspects of their professional business.

The RAN Institute

Karen Longley, Educational Products Manager, The RAN Institute, Inc., 21907 Bell Lake Rd., Land O Lakes, FL 34639, (813) 929-9269, email: www.raninstitute.com.

Custom GCP training. GCP training appropriate to the experience and level of understanding of the participants.

Clinical monitor training. Programs can include basic to advanced skills and US or ICH GCPs and SOPs. Case studies and problem-solving exercises available.

Validation Associates

Danielle C. Mongiello, Validation Associates, Inc., 305 E. Pennsylvania Blvd., Feasterville, PA 19053-7846, (215) 354-1720, ext. 201, fax (215) 354-1725, email: info@validassoc.com, www.validassoc.com.

Computer system validation overview. This half-day introductory seminar overviews the regulatory and business requirements for computer system validation. The session includes a discussion of the related issues and regulations, and reviews the scope and management of the required activities.

The Walter B. Morley Research Foundation and University of Wisconsin Medical School

Lisa Blandford, Program Manager, The Walter B. Morley Foundation, Fusion Medical Education, 800 Township Line Rd., Yardley, PA 19067, (215) 550-8150, ext. 8503, fax (215) 550-8160, email: morleyfoundation@fusionmeded.com, www.morleyfoundation.org.

In cooperation with the University of Wisconsin Medical School, The Morley Foundation offers a variety of cost-effective educational programs for professionals involved in clinical research that can be customized for individual institutions, research sites, and companies. In addition to fully customized programs, The Morley Foundation's scheduled course topics are available for onsite implementation, including:

Responsible conduct for research: clinical investigator training. The core curriculum of this one-day course complies with GCP training requirements, providing a certificate of evidence of training and preparation for certification exams. Additional topics focus on business opportunities and responsibilities from ethical, legal, and regulatory perspectives.

Basic training for clinical research coordinators. Participants in this two-day program will receive information and materials necessary to conduct successful clinical trials and to prepare for certification exams, including: GCPs, understanding basic regulatory requirements, source documentation practices, and recruitment strategies.

Clinical research site management training. Participants in this two-day program will receive information and materials necessary to successfully manage a clinical research site, including privacy laws, informed consent, regulatory issues, budgeting, internal quality assurance, patient recruitment and retention, and expansion tips for growing a research program.

Building a clinical research business: financial management. Participants in this one-day program will receive information and materials necessary to maximize the budget and profitability of a research site, including contract evaluation and negotiation, marketing strategies, key regulatory/legal requirements, staffing, and hidden or unexpected protocol costs.

Length of course/program. Two days; 19.2 CNE contact hours.

Who would benefit. All clinical researchers.

Program goals. Although designed with all research professionals in mind, this program is ideal for research study coordinators who want to improve their understanding of their responsibilities and interactions with their clinical research monitors, and for monitors or auditors with fewer than five years of monitoring experience who want to increase their knowledge and understanding of monitoring responsibilities.

Fees. \$510. Nonmembers of SoCRA must purchase annual membership for \$75.

Contact. SoCRA, P.O. Box 101, Furlong, PA 18925, (800) 762-7292 or (215) 345-7749, fax (215) 345-7369, email: SoCRAmail@aol.com, www.SoCRA.org.

Clinical research professional certification preparation and review course

Society of Clinical Research Associates (SoCRA). 20 February (Philadelphia, PA), 11 June (Denver, CO), and 12 November (San Francisco, CA).

Length of course/program. One day; 6.6 SoCRA and CNE contact hours.

Who would benefit. Clinical researchers seeking

certification or regulatory review.

Program goals. To assist participants in preparing for the SoCRA examination for the Certified Clinical Research Professional. Information will be presented and discussed regarding the conduct of clinical trials, regulatory guidelines regarding IRB oversight and human research protections, and ethical issues in clinical research. Workshops will stress the ability to follow directions and practice activities related to abstracting information and completing case report forms and other records.

Fees. \$250. Nonmembers of SoCRA must purchase annual membership for \$75.

Contact. SoCRA, P.O. Box 101, Furlong, PA 18925, (800) 762-7292 or (215) 345-7749, fax (215) 345-7369, email: SoCRAmail@aol.com, www.SoCRA.org.

Clinical research site management training

The Walter B. Morley Research Foundation and the University of Wisconsin Medical School. Ongoing.

Who would benefit. Directors or site managers, administrators, lead coordinators, finance managers or accountants or those responsible for establishing a research program for a group of physicians. 14 CME credits, 14 CNE credits available.

Program goals. Participants in this program will receive information and materials necessary to successfully manage a clinical research site, including privacy laws, informed consent, regulatory issues, budgeting, internal quality assurance, patient recruitment and retention, and expansion tips for growing a research program.

Fees. €649.

Contact. Lisa Blandford, Program Manager, The Walter B. Morley Foundation, Fusion Medical Education, 800 Township Line Rd., Yardley, PA 19067, (215) 550-8150, ext. 8503, fax (215) 550-8160, email: morleyfoundation@fusionmeded.com, www.morleyfoundation.org.

Clinical research symposium/career fair

Northwestern University and ACRP. Chicago, IL. 26 March, 2004.

Length of course/program. One day.

Who would benefit. Clinical trials professionals and individuals interested in the field. No degree or experience required.

Program goals. Provides an opportunity for clinical research professionals and those interested in breaking into the field to hear lectures from noted professionals, network with one another, and interact with companies interested in hiring clinical research staff.

Fees. No cost.

Contact. Northwestern Center for Clinical Research, 710 N. Lake Shore Dr., 10th Floor, Chicago, IL 60611, (312) 503-7952, fax (312) 503-1505, email: nccr@northwestern.edu, www.nccr.northwestern.edu.

Clinical science course for clinical research professionals

Society of Clinical Research Associates (SoCRA). 23–27 February (Philadelphia, PA), 14–18 June (Denver, CO), and 15–17 November (San Francisco, CA).

Length of course/program. Full course: 5 days; 42 CNE contact hours. Regulatory/procedural module: 3 days. Medical/scientific module: 2.5 days.

Who would benefit. All clinical researchers.

Program goals. This course has been established to develop an internationally accepted standard of knowledge and understanding of the research process and related regulations, as well as medical and scientific areas related to clinical research.

Fees. Five-day program \$1150, regulatory module \$750, medical module \$600. Nonmembers of SoCRA must purchase annual membership for \$75.

Contact. SoCRA, P.O. Box 101, Furlong, PA 18925, (800) 762-7292 or (215) 345-7749, fax (215) 345-7369, email: SoCRAmail@aol.com, www.SoCRA.org.

Clinical materials education forum

International Society for Pharmaceutical Engineering (ISPE), Clinical Materials Committee. San Antonio, TX. October.

Length of course/program. Two days; CE credits available.

Who would benefit. Clinical trials materials professionals.

Program goals. Provides delegates the opportunity to discuss issues of common interest and propose solutions to problems facing the industry.

Fees. Inquire.

Contact. Customer Service Department, 3109 W. Dr. Martin Luther King, Jr. Blvd., Suite 250, Tampa, FL 33607, (813) 960-2105, fax (813) 264-2816, email: customerservice@ispe.org, www.ispe.org.

Clinical materials manufacturing

International Society for Pharmaceutical Engineering (ISPE), Clinical Materials Committee. Durham, NC. 20–21 September.

Length of course/program. Two days; 1.2 CE credits available through the ACPE.

Who would benefit. Professionals involved in the manufacture, testing, review, and packaging of clinical trial materials.

Program goals. Outlines the requirements for the production of bulk finished products for use in clinical trials.

Fees. Inquire.

Contact. Customer Service Department, 3109 W. Dr. Martin Luther King, Jr. Blvd., Suite 250, Tampa, FL 33607, (813) 960-2105, fax (813) 264-2816, email: customerservice@ispe.org, www.ispe.org.

Clinical trials: design and development

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. Staff from pharmaceutical companies or CROs who will be involved in the design of clinical trials and have responsibility for protocol development; project managers who have little or no clinical trial experience; project team leaders who will be designing clinical trials; clinical, regulatory, and development staff who would like to learn how to design a clinical trial program; investigators who would like to learn how to design a clinical trial and about protocol development.

Program goals. This course addresses the practical issues in the design of clinical trials and protocol development, as well as the broader issues relating to the interface of clinical trial design with overall drug development.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063 (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Clinical trial materials operation: production, QA, and packaging processes

International Society for Pharmaceutical Engineering (ISPE), Clinical Materials Committee. Providence, RI. 21–22 June.

Length of course/program. Two days; 1.2 CE credits available through the ACPE.

Who would benefit. Clinical trials materials professionals new to the CTM area who are involved in the manufacture, review, packaging and labeling of clinical trial materials.

Program goals. Provides an overview of the manufacture of bulk finished products for clinical supplies, protocol review, packaging and labeling requirements and issues, outsourcing, and regulatory requirements for clinical trial materials.

Fees. Inquire.

Contact. Customer Service Department, 3109 W. Dr. Martin Luther King, Jr. Blvd., Suite 250, Tampa, FL 33607, (813) 960-2105, fax (813) 264-2816, email: customerservice@ispe.org, www.ispe.org.

Clinical trials with special reference to the 12th version of the German drug law and to ICH-GCP

Kendle. Munich, Germany or onsite. Spring and Fall.

Length of course/program. Two days.

Who would benefit. Employees in clinical research and medical sciences and those interested in acquiring basic knowledge for planning, conducting, and evaluating clinical trials.

Program goals. The seminar aims to give a comprehensive overview of methods for planning, conducting, and analyzing clinical trials. Participants are shown how good study

design can lead to high quality.

Fees. €1090.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

Comprehensive CRC training

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE and the New Jersey State Nurses Association.

Who would benefit. Clinical research coordinators with limited experience in managing industry-sponsored investigational drug studies; experienced coordinators seeking a greater understanding of federal regulations and ICH requirements and wanting to enhance their skills to more efficiently and effectively manage their studies, as well as those interested in sharing experiences and ideas with other workshop participants.

Program goals. This course provides an in-depth survey of the roles and responsibilities of the clinical research coordinator and is designed for CRCs with less than one year of experience. CRCs with some experience may also find this course valuable for refining their skills and sharing experiences and helpful techniques with their colleagues. The course incorporates the updated ICH GCP guidelines.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063 (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Comprehensive monitoring for clinical trials research: beginner

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE and the New Jersey State Nurses Association.

Who would benefit. Clinical research professionals; clinical research associates, in-house; medical monitors and associates; anyone who is seeking a career change and is interested in clinical research and monitoring.

Program goals. This is a basic, how-to course with a main focus on current regulatory requirements and an introduction to clinical research.

Designed mainly for entry-level monitors and clinical research associates with less than one year of experience and for those seeking a career change.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063 (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Comprehensive monitoring for medical devices

Barnett International, Inc. Locations throughout

Self-study materials

Foundations of clinical research, 2nd ed.

Center for Clinical Research Practice (CCRP).

Length of course/program. 16 CME or CNE credits available.

Who would benefit. Anyone requiring a basic understanding of the clinical research process. Also ideal for clinical research exam prep.

Program goals. An independent study course designed to teach principles and practices of clinical trials. Includes textbook, workbook, annotated answer key, and medical record and source documentation.

Fees. \$180; \$250 with 16 CNE credits; \$295 with 16 CME credits.

Contact. Eileen Rusnack, New Business Development, CCRP, 40 Washington St., Wellesley, MA 02481, (781) 431-6466, fax (781) 237-0330, email: info@ccrp.com, www.ccrp.com.

Foundations of human subject protection

Center for Clinical Research Practice (CCRP).

Length of course/program. 15 CME or CNE credits available.

Who would benefit. Institutional review board members and their staff.

Program goals. An independent study course that covers the basic ethical concepts and regulatory requirements of human subject research. Includes complete regulatory references on CD.

Fees. \$125; \$175 with 15 CNE credits; \$225 with 15 CME credits.

Contact. Eileen Rusnack, New Business Development, CCRP, 40 Washington St., Wellesley, MA 02481, (781) 431-6466, fax (781) 237-0330, email: info@ccrp.com, www.ccrp.com.

GCPs made easy, USA and ICH edition flashcards

The RAN Institute, Inc.

Who would benefit. Clinical research professionals studying the ICH GCP guideline. This has helped thousands of candidates prepare for the ACRP, SoCRA, RAPS, and SQA certification exams.

Program goals. Self-paced study aids.

Fees. \$99 each edition.

Contact. Karen Longley, Educational Products Manager, The RAN Institute, Inc., 21907 Bell Lake Rd., Land O Lakes, FL 34639, (813) 929-9269, email: www.raninstitute.com.

Scientific writing

Hurley TechComm, Inc. Online.

Who would benefit. Those interested in publishing a scientific paper or those who write scientific reports.

Program goals. This course focuses on helping writers understand the theoretical and practical aspects of scientific writing and applying those concepts. The heart of the course is helping writers develop the tools they need to write concisely, coherently, and clearly. All participants receive professional feedback on their writing.

Fees. \$649.

Contact. Pam Hurley, 6812 Hardscrabble Court, Wilmington, NC 28409, (910) 233-7670 or (919) 749-4446, fax (910) 791-4673, email: pam@hurleytechcom.com, www.hurleytechcom.com.

The ultimate step-by-step guide to conducting pharmaceutical clinical trials in the USA (sponsor/monitor and investigator/CRC editions).

The RAN Institute, Inc. Two books: one is for monitors and other personnel at sponsor organizations who are involved in clinical research; the second book is oriented toward investigators and clinical research coordinators and other site personnel.

Who would benefit. Anyone involved with clinical trials seeking a detailed and cross-referenced understanding of the responsibilities of investigators and clinical research coordinators, or of sponsors and monitors.

Program goals. Comprehensive step-by-step guide, including specific actions of the researcher, the regulatory basis (both US and ICH), documentation standards, and hints for optimal success. Also included are descriptions of study phases, a glossary of terms and abbreviations, extensive sample documents and forms, and a useful list of industry resources.

Fees. \$149 each.

Contact. Karen Longley, Educational Products Manager, The RAN Institute, Inc., 21907 Bell Lake Rd., Land O Lakes, FL 34639, (813) 929-9269, fax (813) 929-0125, email: klongley@raninstitute.com, www.raninstitute.com.

the United States. Four–six times annually.

Length of course/program. Three days; CE credits available through the ACPE and the New Jersey State Nurses Association.

Who would benefit. CRAs with 1–2 years of experience, engineers and other device industry professionals responsible for the placement and monitoring of clinical trials who want a practical, hands-on introduction to monitoring medical device studies according to GCP. This course is ideal for CRAs new to the device industry, as well as experienced CRAs who are transitioning from monitoring drug studies to monitoring device studies.

Program goals. An in-depth overview of the medical device development process and the role of the CRA in managing and monitoring medical device studies.

Fees. \$1495.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063 (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Computer system validation in FDA-regulated industries

Validation Associates, Inc. 3–4 February:

Baltimore, MD; 30–31 March: New Orleans, LA; 23–24 June: Toronto ON, Canada; 28–29 September: Albuquerque, NM; 1–2 December: Princeton, NJ.

Length of course/program. Two days.

Who would benefit. This workshop is appropriate for anyone who needs to understand what is required to validate a system, as well as individuals who are participating in the validation, and those who are auditing the validation effort.

Program goals. This two-day workshop combines an overview of computer system validation requirements with an emphasis on how to complete related tasks. The course content focuses on activities required by FDA regulations and guidelines, and the use of hands-on activities and practical learning (computers provided) emphasizes these areas.

Fees. \$1125.

Contact. Danielle C. Mongiello, Validation Associates, Inc., 305 E. Pennsylvania Blvd., Feasterville, PA 19053-7846, (215) 354-1720, ext. 201, fax (215) 354-1725, email: info@validassoc.com, www.validassoc.com.

Computer system validation overview

Validation Associates, Inc. Onsite.

Length of course/program. Four hours.

Who would benefit. This workshop is appropriate for individuals who have not previously participated on validation activities, and for organizations that are coordinating computer system validation activities among various departments.

Program goals. This half-day introductory seminar overviews the regulatory and business requirements for computer system validation. The session includes a discussion of the related issues and regulations, and reviews the scope and management of the required activities.

Fees. Based on number of attendees.

Contact. Danielle C. Mongiello, Validation Associates, Inc., 305 E. Pennsylvania Blvd., Feasterville, PA 19053-7846, (215) 354-1720, ext. 201, fax (215) 354-1725, email: info@validassoc.com, www.validassoc.com.

Computer systems validation in clinical research

Association for Clinical Data Management. Oxford, UK. 3–4 November.

Length of course/program. Two days.

Who would benefit. Anyone using or introducing computer systems in clinical research to process data for regulatory submission.

Program goals. Participants will understand validation requirements, risks, benefits and

principles and discuss the application of good validation practices.

Fees. \$1015.

Contact. ACDM Administrator, Association for Clinical Data Management, P.O. Box 129, Macclesfield, Cheshire SK11 8FG, UK, +44 1625 511 818, fax +44 1625 267879, email and Web site: acdm.org.uk.

Conducting clinical trials under ICH GCP

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. Clinical, regulatory, and quality personnel who require an understanding of the GCP regulations and requirements. This course will also benefit other personnel who must be familiar with the essentials of the clinical process and requirements.

Program goals. This course provides a comprehensive overview of GCP and FDA regulations and requirements. Participants will receive knowledge about GCP, practical examples, and the scientific and regulatory principles involved. Guidelines for each aspect of research will be provided, as well as information on the structuring and preparation of protocols, consent forms, and investigator brochures.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

CRA and CRC training

Northwestern University, Chicago, IL. February–May and September–November.

Length of course/program. 36 hours (12 modules); 43.2 contact hours.

Who would benefit. Individuals interested in entering the field of clinical research as a CRA or CRC. Healthcare degree or equivalent training recommended.

Program goals. The program provides an in-depth overview of the roles and responsibilities of the CRA and CRC, including clinical research trial conduct, GCPs, and the federal regulations governing research, as well as the drug development process, data management, and other important topics.

Fees. \$1750.

Contact. Northwestern Center for Clinical Research, 710 N. Lake Shore Dr., 10th Floor, Chicago, IL 60611, (312) 503-7952, fax (312) 503-1505, email: nccr@northwestern.edu, www.nccr.northwestern.edu.

CRA manager course

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. Learn your new role in managing clinical research associate/clinical research project teams. The focus of this workshop is to address the skills in our work

that affect the work of others. This course is a must for new and aspiring managers. Sharpen your people skills.

Program goals. Managers, clinical project coordinators, or newly promoted project team leaders who are responsible for managing clinical personnel; experienced CRAs who are becoming involved, or hope to become involved, in managing projects and/or people; technically trained staff with little or no management experience.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

CRC training

Northwestern University, Chicago, IL. Monthly.

Length of course/program. Three days.

Who would benefit. New or inexperienced coordinators.

Program goals. This intensive 3-day program is designed for clinical research coordinators and other healthcare professionals who need a fast, thorough introduction to clinical research conduct. Designed to get the new coordinator “up and running” in minimal time.

Fees. \$900.

Contact. Northwestern Center for Clinical Research, 710 N. Lake Shore Dr., 10th Floor, Chicago, IL 60611, (312) 503-7952, fax (312) 503-1505, email: nccr@northwestern.edu, www.nccr.northwestern.edu.

Customized clinical research training

Polaris Research Consultants, Inc. Onsite at variable times per client's request.

Length of course/program. One–four days; CME credits available.

Who would benefit. Programs can be customized to meet the needs of any of the following groups: beginning, intermediate or advanced CRAs, beginning or intermediate CRCs, clinical investigators, IRB members and administrators.

Program goals. Interactive, customized training developed to meet clients' needs and participants' experience. Programs include: basic GCPs, adverse experiences, role and responsibilities of IRBs, informed consent, drug accountability, site visits, regulatory documents.

Fees. Varies with program.

Contact. Celine M. Clive, President, Polaris Clinical Research Consultants, Inc., 130 Iowa Lane, Suite 103, Cary, NC 27511, (919) 463-0003, fax (919) 463-0004, email: CMClive@aol.com, www.polarisconsultants.com.

Detection and prevention of clinical research fraud and misconduct

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. CRAs and research coordinators responsible for reviewing and collecting clinical research data from

investigational sites; quality assurance professionals responsible for auditing clinical trial quality. Participants should be knowledgeable of 21 CFR-GCP requirements.

Program goals. This course provides a comprehensive summary of clinical research fraud and misconduct. In-depth background, history, and laws are discussed. Participants will gain understanding and skills for detecting, monitoring, and auditing suspect and poor quality data.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., Rose Tree Corporate Center, 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Detecting fraud in clinical research

Polaris Research Consultants, Inc. Onsite at variable times per client's request, often in association with investigator's meetings.

Length of course/program. One-half to one day; CME credits available.

Who would benefit. CRAs and project managers.

Program goals. Provides an awareness of what clinical research fraud is and how it can be detected. Cases of investigators who have been convicted of fraud are discussed. Students will participate in an exercise to develop their skills in detecting fraud.

Fees. Varies with program.

Contact. Celine M. Clive, President, Polaris Clinical Research Consultants, Inc., 130 Iowa Lane, Suite 103, Cary, NC 27511, (919) 463-0003, fax (919) 463-0004, email: CMClive@aol.com, www.polarisconsultants.com.

Developing clinical data management skills

Northwestern University, Chicago, IL. February–May and September–November.

Length of course/program. 36 hours (12 modules).

Who would benefit. Individuals interested in working in clinical data management. Healthcare background helpful.

Program goals. Provides basic preparation for entering the pharmaceutical research field as a clinical data manager, with primary responsibilities for data management, including clinical data review, coding, and data editing/clarification.

Fees. \$1750.

Contact. Northwestern Center for Clinical Research, 710 N. Lake Shore Dr., 10th Floor, Chicago, IL 60611, (312) 503-7952, fax (312) 503-1505, email: nccr@northwestern.edu, www.nccr.northwestern.edu.

Developing clinical study budgets

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. One day; CE credits available through the ACPE.

Who would benefit. Clinical trial personnel (clinical research coordinators, investigators) responsible for preparing and implementing study budgets.

Program goals. This course provides the practical skills needed to construct and negotiate study budgets that appropriately compensate investigative sites for resource needs required as a result of clinical research protocols.

Fees. \$699.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Drug approval process: submission, preparation, and processing of INDs and NDAs

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. This course is intended for regulatory, technical, and quality personnel who require an in-depth understanding of the drug approval system. The course will also benefit management, legal, and other personnel who must be familiar with the essentials of the drug approval system and the preparation and submission of related documents.

Program goals. Participants will receive knowledge about the drug approval process, submission preparation, and the scientific and regulatory principles involved. Guidelines for each aspect of research will be provided, as well as information on the structuring and assembly of INDs, NDAs and post-approval documents.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556 x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Drug development and FDA regulations: a regulatory overview

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. CRAs and auditors who want a greater understanding of the drug development process and their role in it; regulatory affairs professionals who may be new to their positions or want a more complete understanding of how FDA regulates new drug development; study coordinators who want to learn about the drug development process.

Program goals. A perfect introduction for all new industry professionals who want a greater understanding of the drug development process—a good regulatory overview.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556, x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

EU clinical trials directive and its implementation in the German Drug Law (12th version)

Kendle. Munich, Germany or onsite. Spring and Fall.

Length of course/program. One day.

Who would benefit. This seminar is aimed at persons who want an overview of the EU GCP standard.

Program goals. The EU Clinical Trials directive is presented as well as its implementation to the national law of member states, with a focus on Germany.

Fees. €575.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

European course in pharmaceutical medicine

European Confederation of the Upper Rhine Universities (EUCOR). Basel, Switzerland. September 2005–July 2007 (2003–2005 course fully enrolled).

Length of course/program. 24 days over two years; 192 CME credits available.

Who would benefit. Postgraduate scientists who are involved in the drug development process.

Program goals. To provide a sound background in applied knowledge and skills in global drug development, including the framework of healthcare systems.

Fees. 6'833 Euros, including meals, documentation, and examination fee.

Contact. Annette Mollet, Program Director, Isagelle Steiger, Administrator, +41 61265 7650, fax +41 61265 7655, email: ecpm@unibas.ch, www.ecpm.ch.

GCP and clinical trial introduction for physician investigators

The RAN Institute. Onsite. Throughout the year.

Length of course/program. One–two days. CE and CME credits available.

Who would benefit. Physicians desiring to conduct clinical trials in compliance with all federal and international regulations.

Program goals. Covers the foundations of research, investigator regulatory and ethical responsibilities, IRB review, informed consent, handling investigational supplies, adverse event reporting, and GCP documentation requirements, including surviving a regulatory audit.

Fees. Per person/per day with a minimum of 10 participants at your site.

Contact. Karen Longley, Educational Products Manager, The RAN Institute, Inc., 21907 Bell Lake Rd., Land O Lakes, FL 34639, (813) 929-9269, email: www.raninstitute.com.

GCP course for industry-sponsored clinical trials: preparing the physician and research team for clinical research

American Academy of Pharmaceutical Physicians (AAPP). Various: 7–8 February, Phoenix, AZ; 1–2 May, Providence, RI; 11–12

September, Denver, CO; 6–7 November, Atlanta, GA; 4–5 December, Richmond, VA.

Length of course/program. 1.5 days. 11 CME credits available.

Who would benefit. All clinical research professionals, including physicians, study coordinators, site managers, study monitors, IRB professionals, and anyone just beginning a career or considering a career in clinical research.

Program goals. This course comprises lectures and hands-on exercises that will provide registrants with a basic understanding of the structure and conduct of clinical research studies.

Fees. \$800 early bird registration. \$900 regular registration. Discounts for groups, students, and AAPP members available. On-site seminars also available.

Contact. Heidi Bergs, Programs Coordinator, AAPP, 1031 Pemberton Hill Rd., Suite 101, Apex, NC 27502, (919) 355-10003, fax (919) 355-1010, email: hbergs@aapp.org, www.aapp.org.

GCP for project assistants and study coordinators

Kendle. Munich, Germany or onsite. Spring and Fall.

Length of course/program. 1.5 days.

Who would benefit. Individuals within a study team who deal with the administrative aspects of clinical trials.

Program goals. Participants will learn about the regulatory basis for clinical trials, according to both German law and the international GCP standard.

Fees. €815.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

GCPs for clinical research professionals: conducting a clinical research study

Research Dynamics Consulting Group, Ltd. Orlando, FL; Las Vegas, NV; Atlanta, GA; Washington, DC; Philadelphia, PA; Tampa, FL; and onsite. Inquire.

Length of course/program. CME and CEU credit available.

Who would benefit. Investigators, coordinators, pharmacists, data managers, and new clinical research professionals.

Program goals. This course reviews the basic requirements for conducting clinical trials at investigator sites. The training is based on FDA requirements and ICH GCP guidelines.

Fees. \$895.

Contact. Jeanne Koepke, Administrative Assistant, Sales and Marketing, 1250 Pittsford-Victor Road, Bldg. 100, Ste. 110, Pittsford, NY 14534, (585) 381-1350 x221, fax (585) 381-4032, www.resdynycg.com.

Human research protections regulatory workshop

Society of Clinical Research Associates (SoCRA). Washington, DC. 15–16 April.

Length of course/program. Two days plus half-day postconference workshops; 18 CNE contact hours.

Who would benefit. All clinical researchers.

Program goals. To discuss the roles of the FDA, ICH, and OHRP as they affect recordkeeping, investigator responsibilities, IRB management issues, audits, the informed consent process, and administrative activities falling under FDA and OHRP guidelines. Attendees will understand the responsibilities of FDA and OHRP and the complementary role of the clinical researcher as a fundamental contributor to successful clinical research and the protection of research subjects.

Fees. Workshop \$515; half-day sessions \$250. Nonmembers of SoCRA must purchase annual membership for \$75.

Contact. SoCRA, P.O. Box 101, Furlong, PA 18925, (800) 762-7292 or (215) 345-7749, fax (215) 345-7369, email: SoCRAmail@aol.com, www.SoCRA.org.

Integrated study reports according to ICH overview of the Common Technical Document (CTD)

Kendle. Munich, Germany or onsite. Spring and Fall.

Length of course/program. One day.

Who would benefit. Aimed at persons who prepare study reports (medical writers, project managers), who work with study reports in connection with clinical trials, or who are responsible for quality assurance of study reports.

Program goals. The seminar deals with final reports for clinical studies. It also gives an overview of the Common Technical Document.

Fees. €575.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

International drug approval regulatory procedures

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. Project leaders, medical monitors, CRAs, and MRAs who must be familiar with the various international clinical research regulations and practices; regulatory affairs professionals responsible for the preparation of global regulatory submissions; newly hired or transferred regulatory affairs professionals concerned for the first time with international registrations; regulatory affairs and product development managers seeking an overview of the international situation; top managers of small- to medium-sized companies active in the international market; marketing managers with international responsibilities.

Program goals. This course will cover the evolving regulatory environment and its impact on international drug development registration, with special concentration on Europe.

Fees. \$1345.

Contact. Eric Bradson, Customer Service

Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556, x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Introduction to clinical data management

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. Staff of pharmaceutical companies or contract or independent research organizations whose function is to review, correct, enter, or manage data, with less than one year of experience in that function; individuals who desire a basic understanding of the function of clinical data management in the drug development process.

Program goals. An introduction to clinical data management in the pharmaceutical industry. Its focus on processes and their rationale renders it ideal for the new data manager and for other individuals who wish to learn basic clinical data management skills as well as the function of clinical clinical data management in the drug development process.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556, x2200,

fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Investigational site symposium for site coordinators, research associates, study nurses

Society of Clinical Research Associates (SoCRA). 22–23 January (Nashville, TN), 13–14 May (Vancouver, British Columbia), and 21–22 October (Boston, MA).

Length of course/program. Two days; 12 SoCRA and CNE contact hours.

Who would benefit. Site coordinators, research associates, study nurses, and other clinical researchers.

Program goals. This program is designed to address all functions of the research site related to U.S. and ICH GCP. This goal will be accomplished through lectures and practical application facilitated by clinical research professionals with a combined industry experience of more than 20 years. Topics will include administration of clinical trials according to FDA regulations and ICH guidelines as well as practical procedures and site/sponsor/CRO relationships.

Fees. \$525. Nonmembers of SoCRA must purchase annual membership for \$75.

Contact. SoCRA, P.O. Box 101, Furlong, PA 18925, (800) 762-7292 or (215) 345-7749, fax (215) 345-7369, email: SoCRAmail@aol.com, www.SoCRA.org.

Managing a clinical research business

Research Dynamics Consulting Group, Ltd. Orlando, FL; Las Vegas, NV; Atlanta, GA; Washington, DC; Philadelphia, PA; Tampa, FL; and onsite. Inquire.

Length of course/program. CME and CEU credit available.

Who would benefit. Anyone interested in starting or improving a clinical research business, and clinical research professionals who want to manage the business side better.

Program goals. This class addresses critical clinical research management issues in a comfortable environment, allowing clinical research professionals to talk, network, and learn about managing the many aspects of their professional business.

Fees. \$1995.

Contact. Jeanne Koepke, Administrative Assistant, Sales and Marketing, 1250 Pittsford-Victor Road, Bldg. 100, Ste. 110, Pittsford, NY 14534, (585) 381-1350 x221, fax (585) 381-4032, www.resdyncc.com.

Medical device GCP overview

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. CRAs who want a greater understanding of the medical device clinical trial process and their role in it. Clinical project managers who are taking on wider ranging responsibilities and need to gain a wider understanding of the regulatory and practical issues involved in medical device clinical trials. Regulatory affairs professionals new to the device industry or new to the trials process. Clinical investigators and study coordinators interested in gaining a broader understanding of their role and responsibilities and how these tasks relate to the research process.

Program goals. Provides information across the full range of medical device clinical trial activities. Ideal for those new to clinical research and those requiring information specifically relating to regulatory and practical aspects of medical device clinical research.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556 ext. 2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Monitoring clinical drug studies: intermediate

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE and the New Jersey State Nurses Association.

Who would benefit. Experienced CRAs and MRAs seeking to update their knowledge of the GCP regulations and guidelines and fine-tune their site management and monitoring skills.

Program goals. Updated to include ICH GCP

guidelines and to reflect current trends and challenges facing clinical research associates.

Includes an expanded section on FDA audits and emphasizes techniques to optimize the sponsor–CRO–site–subject relationship.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556, x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Monitoring of clinical trials with special reference to the 12th version of German drug law and ICH-GCP

Kendle, Munich, Germany or onsite. Spring and Fall.

Length of course/program. Two days.

Who would benefit. Persons responsible for monitoring clinical trials in the company and at the study site.

Program goals. Participants will learn which activities are necessary in the pharmaceutical company and at the study site to ensure monitoring of a clinical trial according to the international GCP standard.

Fees. €1050.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

Monitoring workshop with special reference to the 12th version of German drug law ICH-GCP

Kendle, Munich, Germany or onsite. Spring and Fall.

Length of course/program. Three days.

Who would benefit. Newcomers to clinical trials who are soon to be involved in monitoring at a study site, and experienced monitors who would like to brush up their knowledge.

Program goals. The workshop covers the basics required of a monitor and then goes into the details of national and international regulations.

Fees. €1540.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

New directions Coordinator training program

Endpoint Research Ltd. Toronto, ON, Canada, and western Canada. May in Toronto; February and September in western Canada.

Length of course/program. Three days; 20.5 CE credit hours available through SoCRA.

Program goals. Designed for Canadian clinical research coordinators working in a hospital, private clinic, emergency room or critical care setting, the course covers budgets, communication, the drug development process, ethics, GCP, and more.

Fees. CDN\$1300.

Contact. Betty Cuffy, CTP Coordinator, Endpoint Research Ltd., 2595 Skymark Ave., Mississauga, ON L4W 4L5, Canada, (416) 626-0299 or (905)

282-8884, fax (416) 626-2063, email, Web site: www.endpoint.ca.

Pharmacoeconomics in practice

Kendle, Munich, Germany or onsite. Spring and Fall.

Length of course/program. 1.5 days.

Who would benefit. Individuals from the pharmaceutical industry and manufacturers of diagnostic or medical technology (e.g. in the fields of health economics, public health, clinical research, scientific research, and marketing) who want to gain an insight into the subject of pharmacoeconomics.

Program goals. The seminar presents not only the basic principles of pharmacoeconomics but also deals with selected topics in depth.

Fees. €905.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

Postmarketing surveillance studies with reference to the 12th version of the German Drug Law

Kendle, Munich, Germany or onsite. Spring and Fall.

Length of course/program. One day.

Who would benefit. Employees in the pharmaceutical industry involved in planning, initializing, administration and coordination, AEs/ADRs, statistical analysis or reporting of PMS studies (e.g. in clinical research, medical science, marketing, biometrics, drug safety).

Program goals. The seminar aims to point out the possibilities and limitations of postmarketing surveillance (PMS) studies.

Fees. €605.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

Project management of clinical trials

Kendle, Munich, Germany or onsite. Spring and Fall.

Length of course/program. One day.

Who would benefit. Anyone who would like to be a project manager or who is already working as one. Assistants to project managers will also benefit from this seminar.

Program goals. The seminar presents the tasks and responsibilities of a project manager for clinical trials. The initiation of a project is covered, and the main focus is on how to manage a running project.

Fees. €575.

Contact. Petra May, Kendle, Stefan-George-Ring 6, Munich 81929, Germany, +49 89 99 39 13 0, fax +49 89 99 39 13 160, email: info.muc@kendle.com, www.kendle.com.

Research ethics course for clinical research coordinators (CRCs)

University of Virginia School of Nursing, various U.S. locations, throughout the year.

Length of course/program. Six 1-week modules.

Who would benefit. Clinical research coordinators.

Program goals. The continuing education course is composed of a series of 6 modules, 2 in traditional classroom format and 4 using Web-based technology. The 2 scheduled meeting days are the first and the last class, and the rest of the course takes place over the Web, on participants' own time. Courses are limited to 25–30 participants and are scheduled in various regions of the United States. Each module is designed to examine current ethical issues in clinical research with a focus on issues most pertinent to the role of the CRC.

Fees. \$200 registration fee; National Institutes of Health reimburses all lodging, travel, and other expenses upon successful completion of the course.

Contact. Ann Baile Hamric, Associate Professor, University of Virginia School of Nursing, McLeod Hall, P.O. Box 800782, Charlottesville, VA 22908-0782, (434) 924-0112, fax (434) 982-1809, email: abh4f@virginia.edu, ethics.nursing.virginia.edu.

Responsible conduct for research: clinical investigator training

The Walter B. Morley Research Foundation and the University of Wisconsin Medical School. Ongoing.

Length of course/program. One day. 7 CME credits, 7 CNE credits, and 7 CPE credits available.

Who would benefit. All individuals involved in Phase I–IV clinical or device research.

Program goals. The core curriculum of this program complies with GCP requirements, providing a certificate of evidence of training and preparation for certification exams. Additional topics focus on business opportunities and responsibilities from ethical, legal, and regulatory perspectives.

Fees. €599.

Contact. Lisa Blandford, Program Manager, The Walter B. Morley Foundation, Fusion Medical Education, 800 Township Line Rd., Yardley, PA 19067, (215) 550-8150, ext. 8503, fax (215) 550-8160, email: morleyfoundation@fusion-med.com, www.morleyfoundation.org.

SoCRA—13th annual conference

Society of Clinical Research Associates (SoCRA). Montreal, Quebec, Canada. 23–24 September.

Length of course/program. 2.5-day conference preceded by 6 concurrent half-day seminars; up to 22.4 CNE contact hours.

Who would benefit. Clinical research professionals, including investigators, research coordinators, research associates, research nurses, project managers, consultants, educators, and administrators.

Length of course/program. Sessions will include: good clinical practice policy and initiatives at FDA as they relate to clinical researchers, GCP objectives at the Inspectorate of the Health Products and Food Branch of Health Canada, how FDA approaches their audit program, monitoring and auditing—how they are similar and how they differ, IRB organizational requirements and audit

practices, organizational requirements for investigator-initiated research, effective data management implementation and audit practices, implementation of audit guidelines among various NIH cooperative groups, development of clinical research agreements and contracts, issues involved in electronic data capture programs implementation, ethical issues in clinical research including patient care and informed consent, GCP requirements for clinical researchers, clinical research monitoring and its objectives, mechanisms for incorporating quality assurance into the clinical research process, quality of life issues in clinical research and patient care, implementation of standard operating procedures for the research site, statistical issues for meeting clinical research objectives, initiatives in chemoprevention, predictors of conversion from mild cognitive impairment to alzheimer's disease.

Fees. \$495. Nonmembers of SoCRA must purchase annual membership for \$75. Preconference seminars \$150 each.

Contact. SoCRA, P.O. Box 101, Furlong, PA 18925, (800) 762-7292 or (215) 345-7749, fax (215) 345-7369, email: SoCRAMail@aol.com, www.SoCRA.org.

Statistical concepts for non-statisticians

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. Monitors who will assist in designing and evaluating studies; CRAs who will be communicating with statisticians; clinical project leaders who will be designing and evaluating studies; regulatory professionals who utilize statistical concepts in their reports; medical writers who must interpret statistical reports.

Program goals. This is a basic statistical concepts workshop with direct applicability to clinical research. This is not a course on statistical formulas or computations.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556, x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Working with CROs: building a partnership for project success

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. CRAs, data management, or project managers who are changing roles from in-house study management to outsourcing projects with CROs; personnel who have significant interactions with CRO staff. This course is ideal for those who have less than two

years of experience managing CROs.

Program goals. This course provides an in-depth overview of CRO management, starting with reviewing of bids through follow-up analysis and debriefing of the CRO partnership.

Fees. \$1345

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556, x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com.

Writing for clinical research

Barnett International, Inc. Locations throughout the United States. Four–six times annually.

Length of course/program. Two days; CE credits available through the ACPE.

Who would benefit. New medical writers, clinical research associates, medical monitors, biostatisticians, clinical scientists, and other clinical research professionals who want to learn practical techniques for more powerful writing.

Program goals. This course provides the practical skills needed to write better sentences and paragraphs, which are the building blocks of protocols, reports, and manuscripts. Participants discover how to improve their writing skills and to create documents that meet regulatory requirements and are reader-friendly. References used include the Code of Federal Regulations and the ICH Guidelines for the Structure and Content of Clinical Study Reports, and participants gain practical experience applying the rules of grammar and punctuation.

Fees. \$1345.

Contact. Eric Bradson, Customer Service Representative, Barnett International, Inc., 1400 N. Providence Rd., Ste. 2000, Media, PA 19063, (800) 856-2556, x2200, fax (610) 565-4584, email: customer.service@parexel.com, www.barnettinternational.com. □

Is your program missing?

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Call (732) 346-3035, e-mail rdavidson@advanstar.com, or fax (732) 596-0003.