



Clinical Site Coordinator / Manager Workshop
*GCP For Coordinators, Research Associates,
Study Nurses, Site Managers*

Day 1

8:00-8:15 *Registration and Continental Breakfast (provided)*

8:15-9:30 **The Regulatory Environment (9:15-9:30 Health Canada)**

All aspects of clinical trials are governed by regulations and guidelines. This session will discuss the various regulatory agencies and their respective guidelines in terms of their impact on the clinical trial site.

9:30-12:00 **Good Clinical Practice at the Research Site (Break 10:00-10:15)**

This session will consider the basic philosophy and guiding principles of clinical research GCP. GCP is a standard for the conduct and performance of clinical trials that provides assurance that the data is credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected.

12:00-12:30 **Informed Consent Process**

The elements of the Informed Consent Form (ICF) will be discussed in relation to applicable regulatory requirements. These requirements adhere to GCP and to the ethical principles originating in the Declaration of Helsinki. The participants will have the opportunity to identify specific elements of the ICF. Course leaders will also discuss various aspects of the informed consent process and those special considerations that may impact the process.

12:30-1:15 *Lunch (provided)*

1:15-2:30 **Informed Consent Process (Continued)**

2:30-4:30 **Safety for the Research Subject (Break 3:00-3:15)**

It is incumbent upon the investigator to protect the safety of the research participant and this module will review the various aspects of human research protections. Course leaders review the ICH definitions of AEs (adverse events) and SAEs (serious adverse events) and describe the reporting requirements common to all sponsors. Participants also review unexpected adverse drug reactions and the appropriate procedures for informing IRBs/IECs.

Day 2

8:00-8:15 *Continental Breakfast (provided)*

8:15-10:00 **Study Implementation**

This module reviews the role of the Study Coordinator. Course leaders discuss the following issues: submitting a protocol to the IRB; setting up local procedures; and source documentation management and control. Through use of a practical exercise, participants will have the opportunity to critique documentation of a simulated study.

10:00-10:15 *Break and Opportunity for Discussion*

10:15-11:30 **Monitoring Exercise and Discussion**



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11:30-12:30 Monitoring Visits

High quality clinical research is an essential component of the development of new medical treatments. Participants will discuss the rationale and issues surrounding the monitoring visit from a site, a sponsor, and a regulatory perspective. Course leaders provide tips to help participants prepare for a successful relationship with a study monitor.

12:30-1:15 Lunch (Provided)

1:15-2:30 Audits and Inspections

This module will consider the essence of the audit and the inspection. Discussion will include a review of the purpose of an audit; the documents, policies and procedures open to audit; the mechanisms of audit; various outcomes; and the site's opportunities to respond. Course leaders provide tips to help site personnel prepare for an audit or inspection.

2:30-3:00 Continuous Quality Improvement

In this session, the participants will discuss responses to inspection findings and the current trend of regulators and sponsors to request Corrective Action Plans (CAPA) and Standard Operating Procedures (SOPs).

3:00-3:15 Break and Opportunity for Discussion

3:15-4:30 Continuous Quality Improvement (Continued)

Using a group exercise, attendees will evaluate a case study and complete root cause analysis, develop a CAPA and corresponding SOP.

4:30 Adjournment



Course Leader – Helen R. Darwin, CCRP

Helen is President of Darwin Site Management Services, Ltd. She has 20 years experience in clinical research, having worked as an independent monitor and previously as a senior regional monitor in Western Canada for Janssen-Ortho Inc, a unit of Johnson & Johnson. Prior to that she worked as a CRA for a contract research organization. Before joining industry, she was employed for five years as a study coordinator. Helen joined SoCRA in 1991 and was the first Canadian member. She was elected to the Board of Directors in 1995 and was Chair of the Certification Committee from 1996 to 1998 and again from 1999 to 2000. Since that time, she has served on the Board as a Director and as President of the Society.



Course Leader - Jacqueline Busheikin, RN, CCRP

Jacqueline Busheikin is President of JANA Research Corporation, an independent clinical research consulting/monitoring organization established in 2001. She is a registered nurse and had been working in the field of clinical trials since 1989 as a study coordinator - specializing in Mental health, mainly schizophrenia, at the University of Calgary/Foothills Medical Centre. She was the first research coordinator at the Foothills Medical Centre and was responsible for establishing all standard operating procedures and for organizing the functioning of the unit. Ms. Busheikin has also presented numerous training and educational programs for site coordinators and clinical research monitors.