

HELEN CRANMER

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PROFILE

An experienced, results focused, freelance Project Manager seeking dynamic and challenging assignments.

EDUCATION AND EMPLOYMENT

Clinical Research Consultant Current assignment Senior Clinical Project Manager at a biopharmaceutical company	Oct 2006 - Present
Senior Project Manager INC Research, Maidenhead (Field based in Cambridge)	Jul 2005 – Oct 2006
Senior Project Manager PRA International, Reading (Field based in Cambridge)	Nov 2004 – Jul 2005
Project Manager PRA International, Reading (Office based for 8 months then field based in Cambridge)	Jan 2003 – Oct 2004
Project Manager (Clinical Research Scientist) Napp Pharmaceuticals Ltd, Cambridge	Jan 2000 – Jan 2003
Project Manager (Clinical Research Scientist) SmithKline Beecham, Harlow	Apr 1998 – Dec 1999
Clinical Trials Assistant MRC, Cancer Trials Office, Cambridge	May 1997 – Apr 1998
BSc (Hons) Upper Second Class, in Environmental Biology and Combined Studies Oxford Brookes University, Oxford	1992-96

GCE `A' Levels: French, and Social Biology

GCSEs: Eight subjects, including Biology, English, French, Chemistry, and Mathematics

CURRENT THERAPEUTIC AND STUDY EXPERIENCE:

- Asthma, cancer pain, chronic non-malignant pain (osteoarthritis, and neuropathic pain), chronic wound healing, oncology (including breast, bladder, brain, colorectal, head and neck, lung, Non-Hodgkins Lymphoma, prostate, renal, and testicular cancer), ophthalmology (glaucoma, & age related macular degeneration), type 2 diabetes, and urology (overactive bladder & BPH).
- Experience of managing phase I studies through to post-marketing observational cohort studies.
- Experience of trials using monoclonal antibodies and medical devices.
- Experience of trials using electronic data capture.
- Project management of international studies.
- Project management of a medical review of study data pre-database lock.
- MAA submission team member.

CURRENT THERAPEUTIC AND STUDY EXPERIENCE CONTINUED:

- Experience of an MHRA mock inspection.

INC ROLE AND RESPONSIBILITIES:

- Report to the senior director of project management (former director of project management at PRA International)
- Act as project manager on a study and oversee another project manager's work on a small programme of studies with full responsibility for programme issues with the expectation that the role would be extended if additional work was awarded by the client.
- Primary liaison between the company and the Customer to ensure study launch, conduct and closeout according to the Customer's and the company's contractual agreement. Ensures the study is progressing according to internal and Customer quality standards, SOPs, GCPs and ICH guidelines to fulfil all federal and local regulations.
- Manage projects ranging in size and complexity from single service studies to full scope or multiple protocol projects. Including management of resources, tasks, risk and quality.
- Manage contract and financial aspects of assigned projects. Review study budgets and expenses and ensures all study related contractual and budgeting issues are upheld and performed.
- Develop knowledge of current therapeutic environment and drug development trends as needed. Facilitate team training in accordance with protocol and/or project requirements including therapeutic, protocol specific, and process training.
- Reviews protocol and CRF for consistency within each document.
- Maintain and evaluate project progress by maintaining timelines and other tracking/analysis tools. Produce and distribute status, resourcing and tracking reports, and functional area plans, to appropriate team members and senior management.
- Perform on-going review of project financial status of studies; alerting senior management to potential issues and ensure necessary corrective action is taken.
- Support Business Development Department by providing information on company capabilities, patient populations, etc. Presents company capabilities as well as project management specific responsibilities at Customer proposal defence meetings.

PRA ROLE AND RESPONSIBILITIES:

- Schedule and supervise projects, providing leadership in the delivery of services to clients; review work produced by the project team; ensure staff fulfil their responsibilities in accordance with project contract and company policies, procedures and Standard Operating Procedures (SOPs).
- Share responsibility for growing the company's business with existing clients and for identifying and closing projects with new clients; participating in presentations to the client and providing input to the project bid process.
- Management of a full service studies, ensuring that the project is delivered on time, within budget and according to client expectations.
- Development, review, and critique of key documents such as protocols, project plans, investigator brochures CRFs, analysis plans, reports, and regulatory submissions, and ensure review of same by appropriate team member(s).
- Efficient and effective planning, implementation, and monitoring of project status to ensure optimal utilization of billable staff.
- Appropriate escalation of issues to senior management team; and take steps to resolve issues.

NAPP CRS ROLE AND RESPONSIBILITIES:

- Study design, feasibility, and protocol writing involving contact with key opinion leaders.
- To oversee and co-ordinate CRAs, trials administrators, Clinical Supplies, Data Management, Statistics, QA, Medical Affairs, Pharmacovigilance, Regulatory Affairs, and other departments.
- CRO leader responsible for the development of request for proposals, co-ordination of the CRO selection process, CRO handover meetings and managing the successful CRO(s) for part and full service contracts.
- Plan study budgets and track study costs.

- To review and approve data management plans, validation plans, statistical analysis plans and CRF completion guidelines.
- Present at investigator, and advisory board meetings.
- Mentor less experienced clinical research scientists and clinical trials administrators.
- Write and update SOPs and departmental templates.
- Clinical member of a clinical trial database project team. Responsible for setting up a project planning template for clinical studies and training colleagues in the Medical Department.
- Business area specialist and departmental trainer for a new regulatory document management system.

SMITHKLINE BEECHAM CRS ROLE AND RESPONSIBILITIES:

- Study design, and protocol writing.
- To oversee and co-ordinate CRAs, trials administrators, Clinical Supplies, Data Management, Statistics, QA, Medical Affairs, Pharmacovigilance, Regulatory Affairs, and other departments.
- To co-monitor at study sites to ensure consistent monitoring standards are maintained and ensure consistency across sites.
- Plan study budgets and track study costs.
- To review and approve data management plans, validation plans, statistical analysis plans, CRF, and, CRF completion guidelines.
- Present at investigator, and monitors meetings.
- Assist Pharmaceutical Technologies with designing the packaging and labelling for clinical trial supplies and documentation for IVRS.
- Set up contracts with central and local laboratories as required.
- Contribute to clinical reports and produce scientific presentations.

CTA ROLE AND RESPONSIBILITIES:

- Sole responsibility for a European trial in non-Hodgkin's lymphoma.
- Conducting feasibility work.
- Setting up a trial database, validation checks, and data entry.
- Follow up of serious adverse event reports.
- Completing ethics submissions.
- Randomisations and drug ordering.
- Setting up and maintaining a database of trial and investigator information.
- Administration of conferences.

ACHIEVEMENTS

- 2003 PRA New Business Award.
- 1998 SmithKline Beecham Team Silver IMPACT Award for an outstanding contribution in the area(s) of: Innovation, creativity, and technical excellence, measuring and delivering results, customer focus, taking initiative and extraordinary effort.

TRAINING COURSES

Analgesics & Palliative Care	Effective Project Teams	Medical Writing
Cardiovascular Course	Presentation Skills	Statistical Thinking
Wound Healing (WHRU, Cardiff)	MS Project	ICH GCP
Diabetes Mellitus (Healthcare)		Ethics/GCP forum
EORTC oncology course		Successful Research Ethics Committee Applications
Medical Device Studies (ICR)		
Chest Radiographs: identification, technique, and anatomy (Addenbrooke's Hospital, Cambridge)		

PRESENTATIONS

- Current Clinical Trials, European Experts Group on Appropriate Use of Opioids, Bruges, December 2002
- Rosiglitazone is Effective in Both Obese and Non-Obese Patients with Type 2 Diabetes. European Association for the Study of Diabetes Annual Meeting, 1999.

PUBLICATIONS

H. Cranmer, N.P. Jones and R. Patwardan. Rosiglitazone is Effective in Both Obese and Non-Obese Patients with Type 2 Diabetes. 1999

INTERESTS

Horse riding, IT, photography, and travel.