Sixteen years' experience in clinical research, including six years as clinical research associate, three years as project manager and six years as manager of clinical operations. Therapeutic experience in rheumatology, cardiology, endocrinology, neurology, infection diseases, palliative care, vaccines and oncology in studies phases II and III in pharma and contract research organization environments As a manager responsible for managing resources to ensure they are consistent with clients' needs and expectations, providing flexible thinking, business solutions and teamwork environment and building good working relationships with clients.

Work History

Title Manager of Clinical Operations 2
Company/Location PRA Health Sciences, Mexico City, Mexico City, MEXICO
Dates Apr 2018 - Present 5 mos
Responsibilities

- Manages and developes company employees to ensure high quality work performance and retention of high quality employees
- Develops plans to support growth and career development of assigned clinical operations employees as well as managed the delivery of quality performance in line with their job description
- Ensures staff development and performance feedback are provided through activities such as mentorship and career development
- Communicates team and individual goals and expectations to ensure direct reports understand their responsibilities
- Manages the performance of staff, including providing input into salaries, bonuses as well as nominations for promotion.
- Promotes a positive and professional work environment that attracts and retains the best talent and delivers services that exceed customer expectations
- Conducts assessment visits with staff as required by standard operating procedures
- Manages resources and resource projections to ensure project teams were consistent with client needs, expectations and contractual expectations
- Reviews project tasks and timelines and assignes team members
- Determines level and type of employee resources to meet corporate/client/project objectives
- Schedules and reviews project tasks, provides leadership in the delivery of services to clients
- Provides guidance/insight on aspects of clinical operations, as well as contingency planning, to accommodate projects while identifying potential impacts to the budget
- Leads clinical operations employees in the delivery of services to clients
- Ensures staff fulfill their responsibilities in accordance with company policies, procedures, standard operating procedures, International Conference of Harmonization, Good Clinical Practices and other relevant regulatory requirements
- Liaises with other functional managers to ensure consistency within the company
- Maintains utilization of all clinical operations employees within department goals
- Provides leadership and implement clinical operations services and productivity improvements to ensure optimal utilization of billable staff:
- Performs metric collection and data analysis to support company continuous improvement in policies, procedures and business process
- Identifies and implements process improvements through review of clinical operations standard operating procedures processes recommending improvement plans to senior management.
- Leads task forces to implement process improvement initiatives
- Builds teamwork and improves process and productivity by working within and across functional areas
- Evaluates compliance of assigned clinical operations employees with company systems and processes
- Provides support with proposal development and participated in client presentations and/or bid defense meetings, as required
- Mentors and trains other clinical operations management level employees
- Designs and delivers relevant training to the clinical operations teams and/or management groups.
- Be a mentor and a go-to resource across all services within the clinical operations group and as a subject matter expert by the company staff outside of clinical operations.
- Leads process development / improves task force developing tool(s) to improve clinical operations processes acting as a subject matter expert for various initiatives.
- Acts as a leader on programs and/or initiatives that are increasingly complex in their scope of services, technology employed, volume, and/or revenue.
- Assists more senior clinical operations staff in the review, development and implementation of

short-term and long- term objectives, major plans and programs for each functional group within clinical operations
- Creates and maintains effective relationships between other company business units or functions
- Participates in internal/external audits and regulatory agency inspections, as required

Accomplishments
- Achieved to build and strengthen the business relationship with one of the local clients improving the customer satisfaction

Title Manager of Clinical Operations
Company/Location PRA Health Sciences, Mexico City, Mexico City, MEXICO
Dates Aug 2014 - Mar 2018 3 yrs, 7 mos
Responsibilities
- Managed and developed company employees to ensure high quality work performance and retention of high quality employees
- Developed plans to support growth and career development of assigned clinical operations employees as well as managed the delivery of quality performance in line with their job description.
- Ensured staff development and performance feedback are provided through activities such as mentorship and career development
- Communicated team and individual goals and expectations to ensure direct reports understand their responsibilities
- Managed the performance of staff, including providing input into salaries, bonuses as well as nominations for promotion.
- Promoted a positive and professional work environment that attracts and retains the best talent and delivers services that exceed customer expectations.
- Conducted assessment visits with staff as required by standard operating procedures
- Managed resources and resource projections to ensure project teams were consistent with client needs, expectations and contractual expectations
- Reviewed project tasks and timelines and assigned team members
- Determined level and type of employee resources to meet corporate/client/project objectives
- Scheduled and reviewed project tasks, provided leadership in the delivery of services to clients
- Provided guidance/insight on aspects of clinical operations, as well as contingency planning, to accommodate projects while identifying potential impacts to the budget
- Leaded clinical operations employees in the delivery of services to clients
- Ensured staff fulfill their responsibilities in accordance with company policies, procedures, standard operating procedures, International Conference of Harmonization, Good Clinical Practices and other relevant regulatory requirements
- Liaised with other functional managers to ensure consistency within the company
- Maintained utilization of all clinical operations employees within department goals
- Provided leadership and implement clinical operations services and productivity improvements to ensure optimal utilization of billable staff
- Performed metric collection and data analysis to support company continuous improvement in policies, procedures and business process
- Identified and implemented process improvements through review of clinical operations standard operating procedures processes recommending improvement plans to senior management.
- Leaded task forces to implement process improvement initiatives
- Built teamwork and improving process and productivity by working within and across functional areas
- Evaluated compliance of assigned clinical operations employees with company systems and processes
- Provided support with proposal development and participated in client presentations and/or bid defense meetings, as required

Accomplishments
- Increased the number of local contracts granted for Mexico; obtaining one for administrative services and another for site training services achieving to expand the company services portfolio
- Obtained a three-year extension to the local contract with a client obtaining higher local income for the company
- Obtained a local contract to offer monitoring and assistance services to a client, strengthening the core portfolio services of the company

Title Clinical Research Manager

Company/Location	PRA Health Sciences formerly ReSearch Pharmaceutical Services (RPS), Mexico City, Mexico City, MEXICO
Dates	Mar 2012 - Aug 2014 2 yrs, 5 mos
Responsibilities	• Interviewed and selected team members for research projects according to sponsors' needs • Reviewed and approved timesheets and expense reports for utilization and payment. • Provided overall management of clinical operations • Planned clinical resources needs and timely deploy them, upon approval • Evaluated assigned employees' needs • Developed good rapport and communicate effectively with the appropriate project manager or responsible for leading projects and programs, as required, on each project • Oversaw project and/or program deliverables for staff under their responsibilities • Provided supportive management to project managers, clinical team leaders, clinical research associates and clinical trials assistants • Evaluated employee performance through sponsor and company project managers feedback and established performance metrics. • Reviewed monitoring metrics and key performance indicators to identify performance trends • Assisted with the training of a team member • Performed co-monitoring visits as required as well as conduct periodic review of deliverables for quality • Ensured that performance assessment visits are provided to all clinical research associates under his /her responsibility annually at a minimum or according to client's specifications. • Acted as a liaison between sponsor and deployed employee/team • Assisted in the development and revision of site management and monitoring processes, standard operating procedures and guidelines • Implemented and guided activities related to process integration and improvement, best practices and strategic direction • Resolved emergent issues • Assisted strategic development assess workload for projects • Attended capabilities presentations and provided input to proposals as necessary.

Title	Project Manager
Company/Location	PRA Health Sciences formerly ReSearch Pharmaceutical Services (RPS), Mexico City, Mexico City, MEXICO
Dates	Jul 2008 - Mar 2012 3 yrs, 8 mos
Responsibilities	• Managed projects from the planning phase to the analysis phase for delivery to client • Prepared the project plan / timelines and monitored and tracked progress against plan; ensured project activity compliance with plan. Suggested and implemented alternative solutions to problems with study timelines, schedules, resources and budgets. Took corrective action where necessary • Assisted in establishing metrics for project progress and evaluated project performance to these standards • Assessed and monitored project resource needs within department and cross functionally to insure appropriate level of staffing to achieve project objectives • Managed project team members as assigned • Developed project specific procedures as necessary with responsible functional department lead • Managed third-party vendors as required • Participated in the review of the protocol and provide input from an operational perspective • Provided input and approval of study related documents • Selected and evaluated the final investigators list • Developed and maintained professional working relationship with key investigators • Ensured that investigational sites were being appropriately managed and adhered to Food and Drug Administration Regulations and International Conference of Harmonization Guidelines • Managed project financial reporting, including, project budget management and analysis, revenue recognition and profitability. Evaluated and managed project budget against project milestones to ensure project profitability. Recommended corrective measures where necessary to keep project in line with budget and profit expectations • Coordinated project organization, implementation and management activities between all functional areas and the client. Served as primary client contact for all project-related matters • Participated to regular client and project team meetings; ensured minutes were developed and distributed timely

- Prepared and presented study material at client meetings and communicated outcomes to project team
- Prepared or oversaw preparation of project status reports for client and line manager
- Identified, developed and trained project resources on project specific training requirements in collaboration with the sponsor
- Monitored sites for projects for which responsible
- Mentored other functional resources as appropriate
- Provided administrative oversight for direct reports including; approving and tracking of pay time off requests, timesheets, expense reports and confirming that all clinical staff was adhered to the company policies for reporting and submission
- Participated in scheduled project management department meeting
- Evaluated current processes for efficiency and quality and made recommendations for improvements
- Participated in the review departmental standard operating procedures and guidance
- Developed project specific procedures as necessary with responsible functional department lead
- Supported company corporate goals
- Participated in prospective study feasibility activities
- Reviewed trip reports, specially looking for issue trends that may require an action plan
- Assisted in business development activities; provided proposal input and attend bid defense meetings
- Participated in the review of departmental standard operating procedures and guidance
- Performed good clinical practices training to potential sites selected by the sponsor

Title Senior Clinical Research Associate

Company/Location PRA Health Sciences formerly ReSearch Pharmaceutical Services (RPS), Bogota, Cundinamarca, COLOMBIA

Dates Sep 2007 - Jun 2008 9 mos

Responsibilities

- Adhered with internal policies and requirements, including submission of timesheets and expense reports in a timely manner
- Applied knowledge of applicable standard operating procedures, guidelines and study procedures
- Conducted study start-up activities related to in-house monitoring activities
- Assisted with protocol and case report forms review
- Completed study feasibility and site selection activities; conducted telephone screening interviews, administered site questionnaires, collected and reviewed regulatory documents, assisted with investigator grants negotiation
- Assisted with the development of study manuals, annotated case reports forms, tracking forms, site study tools and other study materials
- Assisted with investigator meeting activities including organization, preparation and attendance
- Communicated site study issues, concerns and progress to lead clinical research associate, project manager and clinical operational manager
- Communicated sponsor management team regarding the site study issues and doubts
- Assisted with implementation of corrective actions when appropriate
- Conducted in-house review of case report forms
- Assisted with data query resolution
- Performed telephone monitoring activities in order to obtain study status information
- Gave input and maintained updated study information in tracking systems
- Provided information concerning subject status for financial reimbursement to sites
- Conducted and assisted with administrative activities as a member of the project team; attended staff /project team meetings, documented all investigator information and study contacts, gave support to investigator agreements and grant negotiations, prepared reports as defined by standard operating procedures
- Provided status of site activity to project manager
- Wrote study reports and follow-up letters within the timeline established by the applicable standard operating procedures and guidelines
- Performed site management activities; site qualification visits, site initiation visits, site training, site routine monitoring visits in Mexico and Costa Rica and close-out visits
- Established and maintained good rapport with study sites; maintained frequent telephone communication with sites, provided guidance to study coordinators and investigators as necessary and in agreement with monitoring plans

- Coordinated timely shipment of clinical supplies and study drug to sites in collaboration with regional clinical research associates
- Maintained adequate site tracking records
- Followed-up of drug safety issues and safety reports in timely manner
- Coordinated clinical research assistant activities at site
- Supported clinical research associate level 1 and level 2 on site management and other project related activities
- Conducted on the job training and formal training to other clinical research associates and project assistants
- Collaborated with clinical operations manager / study teams to resolve issues
- Reviewed study visit reports, follow-up letters and site communications generated by other clinical research asscciates for timelines, quality, consistency, and appropriate documentation and resolution of issues, with support from lead clinical research associate or manager
- Participated in routine study progress meetings, face to face or via teleconference

Title Clinical Research Associate
Company/Location MERCK, Bogota, Cundinamarca, COLOMBIA
Dates Jul 2002 - Sep 2007 5 yrs, 2 mos
Responsibilities

- Acted as the primary sponsor point of contact for the clinical research sites for all operational and routine protocol issues
- Provided communication to sites in regards issues related to protocol conduction, regulatory documents / requirements and financial payments schedule
- Recorded, monitored and tracked site metrics across protocols and sites, using metrics to guide, measure, drive and improve site performance
- Utilized knowledge and interpersonal skills to develop/optimize site relationships and ensured continuity of site relations before, during and after a clinical trial execution
- Used the core trial management systems
- Reviewed protocol design with the site and delivered the appropriate protocol specific training to site personnel
- Provided support to the sites during the transition to continuous data flow scheme and remote data capture
- Handled queries from the investigator and referred to the local or headquarters medical team based on the nature of the query.
- Discussed the need of escalation of site performance issues with the appropriate personnel in order to determine whether study activities should brought the attention of quality assurance area.
- Attended to local and international investigator meetings as needed
- Supported audit activities at the sites as needed
- Provided recruitment/retention advice and gave support to sites
- Collected, reviewed and monitored the required regulatory documentation for study start-up, study maintenance and study close-out
- Identified training needs of personal at each site and provided recommendations

Title Study Coordinator
Company/Location Instituto Nacional del Riñón / Clínica Nueva / Centro Javeriano de Oncología, Bogotá, Cundinamarca, COLOMBIA
Dates Jan 2001 - Jun 2002 1 yr, 5 mos
Responsibilities

- Acted as the site contact between principal investigator and sponsor´s clinical research associates for all operational and routine protocol issues in supporting the study protocols developed in the clinical research sites
- Assured the compliance of International Conference of Harmonization and Good Clinical Practices Guidelines and local regulations
- Performed quality assurance activities at the clinical research sites
- Supported the investigators in every operative activity; ensured they fill out the documents
- Designed recruitment strategies
- Supported the principal investigator in contacting institutional ethics committees
- Contacted subjects to schedule study visits
- Dispensed, accounted and inventored study medication

Education

- **Graduate, Bachelor of Science, Nov 1993**
  Pontifical Javeriana University, Bogota, Cundinamarca, COLOMBIA
  Laboratory

Protocol Therapeutic Experience

Therapeutic Area	Indication Group	Primary Indication	Role	Number of Studies	Duration	Phase	Subject Population
Cardio-Metabolic Diseases	Atherosclerosis	Hyperlipidemia		1	6 mos	III	ADULTS
Cardio-Metabolic Diseases	Diabetes	Diabetes Mellitus - Type II		1	11 mos	III	ADULTS
Cardio-Metabolic Diseases	Diabetes	Diabetes Mellitus - Type II		1	1 yr, 3 mos	III	ADULTS
Cardio-Metabolic Diseases	Hypertension Disorder	Hypertension		1	1 yr, 5 mos	III	ADULTS; PEDIATRICS
Cardio-Metabolic Diseases	Metabolic	Obesity		1	1 yr, 0 mos	III	ADULTS
Gastroenterology	Irritable Bowel Syndrome	IBS-Constipation		1	1 yr, 0 mos	III	ADULTS
Immunology	Autoimmune Disorders	Rheumatoid Arthritis		1	1 yr, 5 mos	III	ADULTS
Infectious Diseases	Antibacterials	Intra-Abdominal Infections		1	1 yr, 0 mos	III	ADULTS
Infectious Diseases	Antivirals	HIV		1	1 yr, 6 mos	III	ADULTS
Infectious Diseases	Antivirals	HPV		1	5 yrs, 3 mos	III	ADULTS
Infectious Diseases	Pneumonia	Vaccines		1	6 mos	III	PEDIATRICS
Neurology	Dementia	Alzheimer's Disease		1	1 yr, 0 mos	III	ADULTS
Neurology	Pain	Migraine		1	1 yr, 1 mo	III	ADULTS
Oncology	Solid Tumors	Multiple Solid Tumors		1	1 yr, 5 mos	III	ADULTS
Oncology	Supportive Care	Nausea / Vomiting		1	1 yr, 0 mos	III	ADULTS
Psychiatry	Mood Disorders	Depression		1	2 mos	III	ADULTS

Geographic Experience

Country or Region	Therapeutic Area	Role
COLOMBIA	Psychiatry, Oncology, Cardio-Metabolic Diseases, Immunology, Infectious Diseases	Clinical Research Associate
COSTA RICA	Infectious Diseases	Clinical Research Associate
MEXICO	Infectious Diseases, Neurology, Gastroenterology, Cardio-Metabolic Diseases	Project Manager
LATIN AMERICA	Oncology, Cardio-Metabolic Diseases, Infectious Diseases, Neurology	Clinical Research Associate

Drug Type Experience

Drug Type	Therapeutic Area	Subject Population
Biologic	Infectious Diseases	ADULTS

Drug Type	Therapeutic Area	Subject Population
Chemical Entity	Psychiatry, Infectious Diseases, Neurology, Gastroenterology, Cardio-Metabolic Diseases, Oncology, Immunology	ADULTS, ADULTS; PEDIATRICS
Vaccine	Infectious Diseases	PEDIATRICS

Environment Experience

Environment	Therapeutic Area	Subject Population
Doctor's Office	Psychiatry, Infectious Diseases, Neurology, Gastroenterology, Cardio-Metabolic Diseases, Immunology	ADULTS, PEDIATRICS, ADULTS; PEDIATRICS
In-patient	Infectious Diseases	ADULTS
Out-patient	Oncology	ADULTS
Surgical	Oncology	ADULTS

System Experience

Type	System Name
CDMS (Paper)	ClinTrial
Clinical Trial Management Systems	eClinical, IMPACT CTMS
EDC	Medidata RAVE, Oracle Inform

Vendor Experience

Type	Name
Central Lab Services	Covance