MARIANA D'ERAMO

Born July 7, 1982
Based in Buenos Aires, Argentina

SUMMARY

MD, supporting Medical Affairs' strategy as Medical Manager for Neurology and Immunology in Argentina coordinating a team of 3/2 direct reports since 2017. Experience in Clinical Research since 2006. Directly managed 14 Global Project Managers based in Europe, US and Latin America, each of them responsible for global studies since 2016 through 2017. Strong background in clinical monitoring and in project management coordinating and overseeing international studies and monitoring teams across different regions in global trials. Experience in Neuroscience/ Inflammatory disorders, Endocrinology, Cardiovascular, Ophthalmology and Oncology clinical research.

EDUCATION

2010	University of Buenos Aires, School of Medicine, Argentina ***Medical Specialist Degree* in *Pharmaceutical Medicine***
2007	Austral University, Buenos Aires, Argentina Diploma, Clinical Research Monitoring
2006	Austral University, Buenos Aires, Argentina ***Doctor of Medicine***

PROFESSIONAL EXPERIENCE

June2017-Present

Medical Manager Neurology and Immunology, Medical Affairs
Merck: Buenos Aires, Argentina

Purpose: Medical Administrator and Scientific enabler to design and drive Medical alignment within the Business Unit partnering and collaborating with Market Access and Commercial teams. Accountable to guarantee effective and successful Medical Governance in the Business Unit by translating local strategy into specific plans, management of KTLs, ensuring appropriate Medical Capabilities for the Business Unit (Training & education) and direct MSL management.

Responsibilities:

• Responsible for medical, technical and scientific information related to specific Therapeutic Area.
•Supports the development of regulatory dossiers and medical review of SmPc's for assigned products
•Responsible for the execution of MASP tactics and medical TA budget.
•Build and develop a local KTL network with country field force.
•Own the relationships with selected local KTLs and develop the value needed to support educational programs, studies, expert meetings and academic events.
•Assists in the selection process of clinical study sites for Company-sponsored clinical trials, in collaboration with R&D and GCO

June2017-Present

•Coordinates with Clinical Development and Medical Affairs providing field support for local research studies
•Communicates information to HCPs regarding Company-sponsored Medical initiatives and research opportunities (Medical programs, sponsorships, grants, etc.)
•Maintains and demonstrates comprehensive and in-depth scientific knowledge of an assigned TA, including disease principles, therapeutic approach, research advances and investigational therapies.
•Gathers relevant opinions, expert knowledge, competitive insights and research and development concepts from KTLs, to advance and influence the strategic direction of the Medical Affairs-Business Unit ensemble.
•Starting from the local MASPs, executes assigned tactics to fulfill Medical Affairs strategies in the field, making a positively impact on KTL perceptions and knowledge, regarding the company, Company initiatives and associated products.
•Leads Medical Affairs activities in assigned territory, coordinating with internal departments and external HCPs
•Supports the designing of data generation plans (studies, publications, medical education, congress, summits and advisory boards, commercial materials)
•Ensures compliant use of field material and conduct of activities and acts as a respected and highly regarded representative of the Medical Affairs department and Company.
•Liaises with the medical, commercial and access departments, on the development and implementation of the country and territory specific Medical Affairs strategies and initiatives.
•As applicable, assists in the development of educational and training material and conducts medical training for internal colleagues.
•Provides training to HCPs (i.e. contracted speakers) as needed.
•Participates in the selection and onboarding process for new MSLs by conducting candidate review and leading interviewing, selection and onboarding process.
• Manages the quality of assigned staff's clinical work through regular review and evaluation of work product.
• Identifies quality risks and issues and creates appropriate corrective action plans to prevent or correct deficiencies in performance of staff.
• Ensures that staff are meeting defined workload and quality metrics through regular review and reporting of findings as outlined by clinical operations management.
•Presents Medical Affairs strategy to global and regional TA Heads

2016-Jun2017

CPM Direct Line Manager, *Global Functional Resourcing*
QuintilesIMS based in Buenos Aires, Argentina

Purpose: Manage a team of 14 staff in accordance with organization's policies and applicable regulations. Responsibilities include planning, assigning, and directing work; appraising performance and guiding professional development; rewarding and disciplining employees; addressing employee relations issues and resolving problems. Approve actions on human resources matters.

Responsibilities:
• Participates in the selection and onboarding process for new Clinical Project Managers by conducting candidate review and participating in the interviewing process. Conducts onboarding training for new staff in conjunction with Human Resources and Learning and Development training programs.
• Ensures that staff has the proper materials, systems access and training to complete job responsibilities. Provides oversight for the execution of the training plan, SOP review and mentored training experiences, as applicable.
• Participates in the allocation of resources to clinical research projects by assigning staff to clinical studies that are appropriate to their experience and training.
• Manages the quality of assigned staff's clinical work through regular review and evaluation of work product.
• Identifies quality risks and issues and creates appropriate corrective action plans to prevent or correct deficiencies in performance of staff.
• Ensures that staff are meeting defined workload and quality metrics through regular review and reporting of findings as outlined by clinical operations management.
• May fill in as a PM for a defined project or to assist with milestone achievement on a temporary basis.
• May participate in clinical operations quality or process initiatives

Apr2015-Aug2015

Medical Scientist**,** Medical Department.
mAbxience, Chemo Group biotech, Buenos Aires, Argentina/ Madrid, Spain

Purpose: Support operational and marketing areas in medical related affairs. Interact with opinion leaders, MoH authorities, partner companies and internal teams.

Responsibilities:

Marketing department Medical Support:

- Development and execution of molecule training module and coordination of disease training module development with specialists.
- Scientific advice to commercial areas based on best available scientific evidence.

Clinical/Regulatory departments Medical Support:

- Data safety monitoring board member selection and meeting coordination.
- Ongoing patient profile medical reviews. Protocol medical issues consultation and amendment medical review.
- Disease and molecule Internal staff training.
- Attends Ministry of Health meetings.

Jan2015- March2015 ***Clinical Project Manager***, Clinical Department.
mAbxience, Chemo Group biotech, Buenos Aires, Argentina/ Madrid, Spain

Purpose: Manage the execution of global clinical studies from planning through to closeout. Ensure clinical study management deliverables on time, within budget and in accordance with SOPs, policies and GCPs.
Responsibilities:

- Manage and co-ordinate efforts of different vendor project teams to support milestone achievement and to manage study issues and obstacles and ensure consistent compliance with processes, policies and procedures.
- Develop study management plans, monitoring plans and tools, protocol amendments, ICF templates, database design, recruitment strategies. Coordinate distribution and execution of Confidentiality disclosure agreements, contracts and final approval of site visit reports.
- Vendors and site/country selection, internal team assignments and oversight of database maintenance. Serve as primary project contact to vendors and coordinate vendors and site payments.
- Prepare and present project information at internal, external meetings.
- Ensure high performance and efficiency of the multi-company-team through the scheduling of meetings, training, accompanied site visits and ongoing mentoring of CRA team.

2011 –Jan 2015 ***Clinical Project Manager*** *(CPM) / Global Functional Resourcing*
Quintiles Buenos Aires, Argentina

Purpose: Manage the execution of the assigned clinical studies per Contract, from initiation through to closeout. *Global* Team leader on assigned complex global trials. Ensure that project deliverables are completed to the Sponsor's satisfaction, ensuring quality deliverables on time and within budget and in accordance with SOPs, policies and practices.

Responsibilities:

- *Global* Team leader on assigned global trials. Acts as coordinator of regional CPMs to ensure similar and correct project execution throughout the different regions managed by Quintiles. Supervise regional project teams' quality deliverables across the participating regions.
- Manage and co-ordinate efforts of cross-functional project teams to support milestone achievement and to manage study issues and obstacles and ensure consistent use of study tools and training materials and compliance with standard processes, policies and procedures.
- Develop study management plans, together with team assignments and accountabilities and oversight of database maintenance.
- Serve as primary project contact with Sponsor to ensure communication is maintained and reporting schedules are adhered to. Prepare and present project information at internal and external meetings.
- Risk management, contingencies and issue resolution.
- Identify quality issues within the study to implement appropriate corrective action plans. Escalate findings and action plans to appropriate parties.
- Provide input for the development of proposals for new work and manage project budgets.
- Provide input to line managers of their project team members' performance relative to project tasks.
- Ensure high performance and efficiency of the clinical team through the scheduling of co-monitoring/accompanied site/visits and ongoing mentoring of CRA team.
- Serve as coordinator along with Quality during project Audits or Regulatory inspections, preparation, onsite support and CAPA.

2010 – 2011 ***Sr. Clinical Research Associate*** *(LCRA) / Global Functional Resourcing*
Quintiles Buenos Aires, Argentina

Responsibilities:

Assures adherence to Good Clinical Practices (GCPs), SOPs, and study protocols. Review regulatory documents as required and prepare site visit reports. Responsible for multiple projects and must work both independently and in a team environment. Organizes and presents at investigator meetings, working with management on monitoring strategy, and/or developing project-specific CRA training. Acts as Lead CRA coordinating study conduct regionally.

2007 – 2010 ***Clinical Research Associate - Regional project coordinator***
Kendle Argentina, Buenos Aires, Argentina

Responsibilities:

-Site selection, pre-study visits and evaluation, clinical trial initiation, monitoring and close-out activities while adhering to all applicable regulatory procedures. Submissions to Ethics Committees.
Ensures proper storage, dispensation, and accountability of all Investigational Product(s) and trial-related materials. Source data verification to ensure the integrity of clinical data and appropriate follow up procedures, including Serious Adverse Events (SAE) reporting in accordance with the project plan. Completes in-house monitoring activities. Continuous training on drug development process, Good Clinical Practices (GCP), and any applicable local regulatory requirements.
-TMF Quality assurance project.
Ensure quality deliverables on time and within budget and in accordance with SOPs, policies and practices.
Define project workloads and assignments. Develop and maintain internal databases. Maintenance of project management information and tracking systems

2006 – 2007 **Glaucoma Research Unit, Moorfields Eye Hospital**, London, United Kingdom
Research Fellow and Study Coordinator
Responsibilities:

Sub investigator in Clinical Trials: Patient recruitment, clinical/ imaging evaluation including the performance of direct & indirect ophthalmoscopy, IOP check, perimetry and BCVA –ETDRS-, Fundus Photography- OCT- GDx- HRTIII, treatment and medical follow up.
Performed Study specific procedures, completion of CRFs, and resolution of DCFs, Safety reporting, general study coordination and regulatory file maintenance, IRB submissions.

2006 ***Study Coordinator***
Clinical Research Dep., Austral Academic Health Center, Buenos Aires, Argentina

Clinical histories review and CRF completion with data entry / analysis for the liver-transplant database for a late phase registry.

2005 ***Research assistant,***
Basic Research Department, Austral Academic Health Centre.

Macular degeneration induced by light research project.

THERAPEUTIC EXPERIENCE

Endocrinology

- Diabetes Type I — (2) Phases 2 and 3
- Diabetes Type II — (4) Phase 3
- Hypogonadism — Phase 3

Neuroscience/ Inflammatory disorders

- Major Depressive Disorder — Phase 3
- Rheumatoid Arthritis — (3) Phase 3
- Multiple Sclerosis — Medical Affairs

Cardiovascular

- Peripheral Arterial Disease — Phase 2

- Arterial Hypertension — Phase 3

Ophthalmology

- Glaucoma studies — Phase 4
- Macular Degeneration — Phase 3
- Imaging device normative database generation

Oncology

- Lymphoma — Phase 3
- Colo-Rectal Cancer — Phase 1

LANGUAGES

Spanish: Native speaker
English: Fully bilingual
French: Proficient