CURRICULUM VITAE

First Name/ Last Name	**DUMITRU - EMANUEL DOGARU**
Address	
Telephone	**+40 724 345 115**
E-mail	dogaru@operacro.com
Nationality	Romanian
Date and place of birth	27 October 1991, Târgu-Jiu, Romania

Professional Experience:

Clinical Project Manager at OperaCRO – Timisoara, Romania
August 2016 - Present

Responsibilities:

•Serving as primary point-of-contact liaison with Sponsor to provide outstanding customer service, including participation in proposal activities and client presentations.
•Overseeing and managing all aspects of a clinical research trial
•Preparing project status updates for customer and Sr. Management
•Serving as a member of the Project Team with the goal to contribute towards efficient management of trials.
•Preparing and reviewing of protocols and other study documentation (CRF, ICF, IB, operating manuals, monitoring guidelines, etc.).
•Establishing, updating, tracking and maintaining study specific trial management tools/systems, and status reports.
•Managing site start up procedures (recruitment of potential investigators, preparation of EC/IRB submissions and notifications, organization of meetings)
•Conducting all forms of monitoring visits, including pre-study, initiation, routine, and final monitoring visits, in accordance with the protocol, local laws, ICH-GCP and CRO/Clients SOPs.
•Preparing accurate and timely visit reports from all monitoring visits.
•Developing and maintaining good working relationship with investigators and study staff, serving as an ambassador to promote CRO/Clients high quality and ethical image.
•Maintaining study tracking, in accordance with the demands of the study.
•Identifying and processing Serious Adverse Events according to the procedures defined by the study team, writing narratives and follow-up on SAEs
•Mentoring, training, and supervising staff at a functional level.
•Assisting with review of clinical study reports.
•Conducting feasibility work when requested.
•Interacting with internal work groups to evaluate needs, resources and timelines.
•Initiating payment requests for investigators.
•Developing SOPs when required.
•Performing other duties as assigned by management.
•Management of Sr. CRAs, junior CRAs and administrative aspects according to CRO SOPs
•Monitoring and Performance Assessment

Clinical Research Associate at OperaCRO - Timisoara, Romania
March 2016 - Present

Responsibilities:

•Acting as primary point of contact for vendors, investigational sites and cross functional teams and escalates to the study lead as necessary
•Supporting and occasionally leading the development/review of clinical study plans, presentations or project/study-related documents including contracts/site payments Supports in the development and design of CRFs.
•Responsible for oversight and mentoring of junior team members
•Performing and leading in-house review of clinical data listings for completeness and accuracy and escalating issues to the CTM or above as needed
•Managing clinical monitoring activities and the overall site management ensuring compliance with Good Clinical Practices (GCP) and applicable regulations and tracking of site performance metrics
•Responsible for the development and distribution of study newsletters, tracking and reporting of recruitment updates
•Participating in the selection, training, and evaluation of study personnel (contractors, CRO, internal)

•Assisting with providing oversight of CROs, independent CRA and vendors including managing cross-functional teams
•Reviewing monitoring visit reports and track resolution of all action items
•Participating in site visits as needed or accompany junior team members for training purposes

•Collaborating with internal cross functional teams (i.e., Clinical Science, Biometrics, Regulatory Affairs, etc.), to ensure effective delivery of the assigned project milestones
•Organizing and managing internal team meetings, investigator meetings, and other trial-specific meetings as required

•Providing support to the CTM in the development and management of vendor scope of work (SOW) per contract, quality, budget, and detailed timelines including investigator and vendor payments

Medical writer at OperaCRO - Timisoara, Romania
March 2016 - Present

Responsibilities:

• Protocol Development (and protocol related documents: informed consent form, amendments, study concept sheets, as appropriate)
• Lead the clinical trial protocol development process in collaboration with CPO or Region representative (Medical Advisor, statistician, DRA responsible as appropriate)
• Responsible, in collaboration with the clinical trial team, for preparation of high quality clinical study reports
• Participate in planning of analysis, meetings and data presentations to be used in the study report
• Responsible for the clarification of requirements from the customer prior to start protocol/concept sheet/ study report development
• Incorporate input from experts (Medical Advisor, Statistician, Safety, DRA as appropriate) while ensuring that feasibility at site level, patient safety and trial objective (i.e. publications) are considered when developing the document(s)
• Coordination of the protocol, study report versions reviews and approval processes

Education:

2013-2015 - University „Politehnica" Timisoara – Master program on Implants, prosthesis and biomechanical evaluation
Master Degree

2010-2013 - "Victor Babes" University of Medicine and Pharmacy, Timisoara
Bachelor Degree

2006-2010 – „Tudor Vladimirescu" College – Biochemistry Profile
High School Diploma
English Language Competence Diploma
IT Competence Diploma

Languages:

•English (Professional working proficiency);
•Italian (Elementary proficiency);
•Romanian (Mother language)

Clinical Study Experience

•Phase III interventional study, indication Cataract and Presbyopia - CPM
•Phase III study, indication Acute Low Back Pain - Lead CRA
•Phase III interventional study, indication Cataract and Presbyopia - Lead CRA
•Phase III interventional study, indication Osteoarthritis of the Great Toe - Lead CRA
•Phase III study, indication Recurrent Bacterial Vaginosis - Back-up CRA
•Phase III retrospective study, indication Cataract and Presbyopia - CRA
•Phase IV study, indication Pediatric Functional Constipation - CRA

Trainings:

August 2016 – Specific Training for Clinical Project Managers – OperaCRO**:**

- IMP development process
- Clinical Research
- Understanding of project management terms
- Role of the project manager
- Project life cycle
- Project scope and objective
- Project constraints
- Common and critical parameters needing management and tracking
- Project planning methodology
- Tools and Techniques for modifying the project plan
- Feasibility studies, risk assessment, risk planning and management
- Making a work breakdown structure, a task network and schedule
- Additional Challenges with Global Trials
- Project schedules and critical path analysis
- Managing the project team
- Communication and Stakeholder Management
- Clinical Trials Timelines, Budgets, Resource Management & Scope Management
- Project tracking and dealing with variance
- Managing change
- Project close-out

January 2015 – Specific training for Clinical Research Associates – OperaCRO:

- Document Management TMF Global Archiving Procedures
- Sponsor Monitoring and Audits
- Process for the Management and Tracking of Urgent Safety Measures
- Communication, Implementation and Compliance Monitoring of Safety Risk Management Plan Commitments
- Recruitment and Selection
- Trial Feasibility, Allocation and Subject Recruitment
- Defining, Processing and Reporting Protocol Deviations
- Archiving of Clinical data from Clinical and EDC Databases
- Management of Health Authority Inspections
- Site Management
- Investigational Medicinal Product (IMP) Supply
- Premature Termination of a Trial or Development Project
- Clinical Aspects of Safety Management
- Handling of Technical Complaints for IMPs at local country level

Additional trainings:

March 2017 - GCP Certificate NIDA Trial Network
October 2016 - Certificate of Completion – Actide e-CRF Training Nubilaria
May 2016 - GCP Certificate Roche/Genetech - TransCelerate Biopharma INC
April 2016 - GCP Certificate NIDA Trial Network
May 2014 - GCP Certificate Pierrel Research
April 2012 - GCP Certificate Pierrel Research

Skills:
Coordination & Team Management,
Problem Analysis and Problem Solving,
Clinical Monitoring,
Knowledge of Pharmaceutical Law & ICH GCP,
Regulatory Requirements,
Taking initiative,
Pressure resistant,
Customer satisfaction oriented,
Intuitive,
Solution and target-focused,
Resourceful,
Active listening,
Team-player,
Committed.

Driving licence: B category

PC skills: IT literate
Microsoft Office Suite (Word, Outlook, Excel, Access, Powerpoint)
Adobe Suite (Photoshop, Lightroom, Illustrator, Premiere Pro, Acrobat DC/Reader)
Strong general knowledge of PC functions