FULL NAME:	**Arthur Steinmann**
DESIGNATION:	**Clinical Project Manager / Senior Clinical Research Associate**
PROFESSIONAL ADDRESS:	**Germany (Hessen)**
CONTACT DETAILS:	Mobile: +49 176 476 333 80 Email: arthur.steinmann@posteo.de Web: http://www.clintrial-services.de

ACADEMIC QUALIFICATIONS:

DATE (YR)	DEGREE/CERTIFICATION	INSTITUTION/UNIVERSITY
2000	**Diploma Biology**	**Johann Wolfgang Goethe Universität Frankfurt am Main, Germany**

CURRENT ACTIVITY:

Organization	**Freelancer**
Designation	**Senior Clinical Research Associate / Consultant**
Time period	**AUG 2013 – PRESENT**

Key Responsibilities

Monitoring and coordinating activities including

- set up activities
- feasibility conducts
- performance and maintenance of regulatory submissions to competent RAs / ECs / BfS
- monitoring (pre-trial, initiation, interim and closeout visits)
- TMF maintenance and audit preparation
- handling and negotiation of site agreements
- handling of patient reimbursements and site payments
- preparation amd generation of status reports
- assistance in medical review (if requested)
- Generation, translation & adaptation of study documents (e.g. Informed consent forms)
- handling of IP and non IP shipments
- coordination of general task to support the PM
- remote monitoring
- query handling

Project description				**Scope of Responsibilities**
Phase	**Indication**	**Duration**	**Sponsor**	
I	Monotherapy / combined therapy in advanced-stage, relapsed / refractory cancer	Nov 2019 - present	Pharm. Industry	Clinical Monitoring / Project Coordination
Ib / IIa	Acute Ischemic Stroke	Aug 2019 - present	Pharm. Industry	Clinical Monitoring Oversight
III	Colorectal Cancer	Jan 2018 - present	Pharm. Industry	Clinical Monitoring / Consulting
IIb	Colorectal Cancer (Surgery)	Jan 2018 - present	Pharm. Industry	Clinical Monitoring / Consulting
Late Phase	Radioactive MD Treatment of Hepatic Carcinoma (Oncology)	Germany Feb 2016 – Oct 2019 (project cancelled by sponsor)	Medical Device Industry	Clinical Monitoring / Consulting
II	Breast Cancer (Oncology)	Dec 2017 – Apr 2018 (project cancelled by sponsor)	Pharm. Industry	Clinical Monitoring / Consulting
IIb	NSCLC (Oncology)	Germany Aug 2013 – Apr 2017	Pharm. Industry	Clinical Monitoring / Consulting
IIT	Cardiac Arrest / Medical Device	Germany Jan 2015 – Jan 2017	Medical Device Industry	Clinical Monitoring / Consulting
Late Phase	Venous Thrombosis / Non-Interventional	Germany Nov 2015 – Mar 2016	Pharm. Industry	Site Identification / Site Selection
NI Late Phase	Non-Interventional / Data Collection	Germany and Austria Sep 2016 – Dec 2016	Medical Device Industry	Consulting / Ethics Submissions

PREVIOUS RELEVANT POSITION(S) AND EXPERIENCE:

Organization	**Omega Mediation Clinical Research Services GmbH (Name change since May 2013) -> closed due to Insolvency**
Designation	**Clinical Project Manager II**
Time period	**OCT 2012 – AUG 2013**

Key Responsibilities

- Coordination and development of trial projects regarding agreed defaults and timelines
- Coordination of budgets, time lines, quality guidelines for projects, delivery of clinical trial supplies, payment of clinical grants etc.
- Supervision and coordination of submissions to authorities and IRBs/IECs, ensuring the accuracy and quality of regulatory data
- Tracking project activities and delegation to members of the project team
- Risk analysis of projects and making recommendations to improve time lines for project completion
- Compilation and maintenance of documentation for the project, e.g. Trial Master File, Management Plans
- Organising project meetings, e.g. investigator meeting, kickoff meeting, project meetings, teleconferences
- Coordination of collaboration among different departments involved in the project

  Safeguard the compliance to international regulations and safety standards, e.g. ICH / GCP, safety reporting timelines etc.

Experience

Project description

Phase	**Indication**	**Submission**	**Sponsor**	**Scope of Responsibilities**
II	COPD	Estonia	Pharm. Industry	Project Management
III	Renal dysfunction	France, UK	Pharm. Industry	Project Management (admin. / finance)
Non Interventional	Renal dysfunction	Spain, UK	Pharm. Industry	Project Management (admin. / finance)
II	Gastric Adenocarcinoma	Spain	Pharm. Industry	Project Management (admin. / finance)

Designation	**Clinical Project Manager I**
Time period	**JUN 2010 – OCT 2012**

Key Responsibilities

- Coordination and development of trial projects regarding agreed defaults and timelines
- Coordination of budgets, time lines, quality guidelines for projects, delivery of clinical trial supplies, payment of clinical grants etc.
- Supervision and coordination of submissions to authorities and IRBs/IECs, ensuring the accuracy and quality of regulatory data
- Tracking project activities and delegation to members of the project team
- Risk analysis of projects and making recommendations to improve time lines for project completion
- Compilation and maintenance of documentation for the project, e.g. Trial Master File, Management Plans
- Organising project meetings, e.g. investigator meeting, kickoff meeting, project meetings, teleconferences
- Coordination of collaboration among different departments involved in the project

  Safeguard the compliance to international regulations and safety standards, e.g. ICH / GCP, safety reporting timelines etc.

Experience

Project description				**Scope of Responsibilities**
Phase	**Indication**	**Submission**	**Sponsor**	
II	COPD	Estonia	Pharm. Industry	Project Management
III	Renal dysfunction	France	Pharm. Industry	Project Management (admin. / finance)
Non Interventional	Renal dysfunction	Spain, UK	Pharm. Industry	Project Management (admin. / finance)
II	Gastric Adenocarcinoma	Spain	Pharm. Industry	Project Management (admin. / finance)
I	Transdermal patches	Germany	Pharm. Industry	Project Management
I / IIa	Type 2 Diabetes Mellitus	Germany, Switzerland	Pharm. Industry	Project Management
IV	Treatment of Actinic Keratoses	Germany and Austria	Pharm. Industry	Project Management
IV	Scars after caesarean section	Mexico	Pharm. Industry	Project Management
IV	Treatment of Cervical Dystonia	Germany	Pharm. Industry	Project Management

Organization	**SIRO Clinpharm Germany GmbH, Offenbach, Germany**
Designation	**Senior Clinical Research Associate**
Time period	**JAN 2010 - JUN 2010**

Experience

Monitoring and coordinating activities in neurology, dermatology and oncology fields, including

- set up activities
- feasibility conducts
- assistance in IRB / IEC submissions
- monitoring (pre-trial, initiation, interim and closeout visits)
- TMF maintenance and audit preparation
- handling of patient reimbursements and site payments
- preparation of status reports
- assistance in medical review
- assistance in compilation of the final study report
- handling of IP and non IP shipments
- coordination of general task to support the PM
- conduct of trainings for employees

Project description

Phase	**Indication**	**Submission**	**Sponsor**	**Scope of Responsibilities**
IV	Scars after caesarean section	Mexico	Pharm. Industry	Senior CRA / Study Coordinator
IV	Treatment of Cervical Dystonia	Germany	Pharm. Industry	Senior CRA / Study Coordinator
III	Feasibility Indolent Hodgkin Lymphoma	Europe	Pharm. Industry	Senior CRA
III	Feasibility Microbial reduction within surgical wound treatment	Europe, Baltic States	Pharm. Industry	Senior CRA
III	NSCLC Stage IIIB “wet” and Stage IV	Europe, Baltic States, Israel, India	Pharm. Industry	Senior CRA
IV	Feasibility Treatment of Actinic Keratoses	Germany, Austria	Pharm. Industry	Senior CRA

Organization	**Omega Mediation GmbH & Co. KG, Clinical Research Services, Offenbach, Germany**
Designation	**Senior Clinical Research Associate**
Time period	**JUL 2008 - DEC 2009**
Experience and Study Projects: please refer to previous Page	

Organization	**Omega Mediation GmbH & Co. KG, Clinical Research Services, Offenbach, Germany**
Designation	**Clinical Research Associate**
Time period	**JUN 2004 - JUL 2008**

Experience

- set up activities
- feasibility conducts
- assistance in IRB / IEC submissions
- monitoring (pre trial, initiation, interim and closeout visits)
- TMF maintenance
- coordination of general task to support the PM, preparation for site audits

Project description				**Scope of Responsibilities**
Phase	**Indication**	**Submission**	**Sponsor**	
III	Active ankylosing spondylitis	Germany and Europe	Pharm. Industry	CRA
IV	Acute bacterial sinusitis	Germany	Pharm. Industry	CRA
IV	Percutaneous coronary intervention	Germany and France	Pharm. Industry	CRA

Organization	**Chiltern International GmbH, Bad Homburg, Germany**
Designation	**Clinical Research Associate**
Time period	**JUL 2003 - NOV 2003**

Experience

- set up activities
- feasibility conducts
- assistance in IRB / IEC submissions
- TMF maintenance
- coordination of general task to support the PM
- documentation

Project description

Phase	**Indication**	**Submission**	**Sponsor**	**Scope of Responsibilities**
III	Renal transplantation	Germany, Switzerland	Pharm. Industry	CRA
III	Diabetic neuropathy	Germany, UK	Pharm. Industry	CRA
epidemiological study	Aconuresis, menopause	Germany	Pharm. Industry	CRA

TRAINING:

Please refer to training records filed separately

SOFTWARE SKILLS:

Microsoft Office (Outlook, Word, Excel, Power Point)
Microsoft Windows Operating Systems
Basic knowledge in HTML

EDC EXPERIENCE (most recent)

Datatrak (Datatrak Solutions)
Inform (Oracle Inc.)
Viedoc (Viedoc Technologies AB)
Clindex (Fortress Medical)

LANGUAGES:

German (native),
English (fluent),
Russian (intermediate),
French (basic)

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Signature with date