

Mads Tarring Jensen
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41 yrs, Danish
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Languages:
Danish, French, German, English

Senior Project Manager International clinical trials management

Experience

Experience with global clinical trials

Clinical Project Management:

- Client management and relationships: Analysis of client needs – bid defense presentations and proposals
- Definition and start up of clinical studies as well as monitoring and close out phase. Organizing the development of study related material accordingly to SOPs (Standard operating procedures)
- Preparation of and participation and presentation at IMs (Investigator meetings)
- Study set up and training of teams; Project team (PIs – Principal Investigator and CRAs – Clinical Research Associate), lab team as well as the data management and scientific team
- Monitoring of studies in order to ensure all study data is delivered to (and received from) study sites and clients. -
- Ongoing data check and analysis of reported results. Monitoring of study sites in order to ensure a correct flow of the study.
- Close out phase; database cleaning and transfers to clients accordingly to the clients needs. Close teamwork with bio statisticians and data management teams, in order to ensure a clean data base.
- Monthly activity reports, workload estimation
- ***Therapeutic areas: Cardio- & neurovascular, endocrinology, CNS and oncology – Phase II & III as well as late phase trials – Total trial budget responsibilities up to Euro 40M***

Q & A:

- Reviewing of study data in order to ensure proper results are delivered to and by sites and to sponsor
 - Ensuring all study related documents created by study teams are accordingly to related SOPs
 - Ensuring all procedures and activities during the study time is performed accordingly to SOPs as well as GCP
 - Closely monitor timelines in order to ensure proper database lock
 - Review of and development of new SOPs
 - Assisting the QA team in the preparation and assisting in client audits as well as audits conducted by international organizations (FDA – Federal Drug Administration (USA), EMEA – European Medicine Agency, etc)
 - Monitoring and management of external vendors and contracts with them
- Solid knowledge of the conducting of international clinical trials

Management:

- Being the head of a global orchestra for all studies, means a.o. making sure all global teams are working properly accordingly to international regulations and within correct timing
- Coordination of all departments involved in a given study
- Collection of study performance metrics from internal departments to support client needs
- Collection of quality metrics and adjustment of process in order to improve outcome and quality
- Monthly activity report: achievements, workload estimation on future projects,
- Responsible of training and integration of new staff members
- Responsible for personnel training of a study team by conducting regular team meetings and communication sessions. Provide coaching to all members of the team.
- Responsibility for any other duties when delegated by the VP of Project Management
- Responsible for all clients' related communication mainly with the outsourcing team as well as the project team in order to guarantee a service of high quality is delivered
- Improve business processes with Global needs and take into account the Global services in all decision making.
- Ensure communications with global teams as well locally with the Operations Management Team
- Responsible for client budgets and MSA's (Master Service Agreement)

Professional Experience

11.2007- 08.2009



MDS PHARMA SERVICES – CENTRAL LABORATORY (France)

International Senior Project Manager

Direct staff responsibility: 12 PMs and CRAs – further there were global study teams under my responsibility for all studies (flat hierarchy structure)

Therapeutic areas: Cardio- & neurovascular, endocrinology, CNS and oncology – Phase II & III as well as late phase trials – Total budget responsibilities up to Euro 40M

01.2005 – 11.2007



SYNARC Inc

2006 – 2007 Synarc Paris (Paris, France)

International Project Manager

Direct staff responsibility: 8 CRAs and assistants – further there were global study teams under my responsibility (flat hierarchy structure)

2005 – 2006 Synarc Denmark (Copenhagen, Denmark)

International Project Manager

Direct staff responsibility: 8 CRAs and assistants – further there were global study teams under my responsibility (flat hierarchy structure)

Therapeutic areas: Cardio- & neurovascular, endocrinology – Phase II & III, total budget responsibilities up to Euro 20M

2004



STATENS SERUM INSTITUTE (Denmark)

Export Consultant – Set up and putting in place for the export of Salmonella and E-Coli antiserum to the North American market. The two products had obtained an FDA approval, and the lab wanted to move into the US market

1998 - 2003



PCA A/S – ERNST & YOUNG (Copenhagen, Denmark)

Consultant Microsoft and SAP Business Solutions

1997



KMC Management Consultants (Recklinghausen, Germany)

Marketing Consultant

1996



MACONOMY (Copenhagen, Denmark)

IT Consultant Business Solutions

Education

1995

MBA – European Business School (Lausanne – Switzerland)

1994

BBA – European Business School (Brussels – Belgium)

1988

GCE A-level – European School (Luxembourg)

IT knowledge: MSOffice, SAP, Lotus Notes, Microsoft Business Solutions, Navision, Sigma Stat and Plot

Languages: Danish, French, German, English - fluent

Hobbies and interests

Music: Jazz & Rock, Art's in France and abroad: Galleries, museums, art fairs