

We are looking for a: **Senior Data Manager** For Barcelona Office

About us:

SOLTI is an academic research group that performs clinical trials of excellence in oncology. Currently, SOLTI is comprised of over 400 renowned research professionals distributed over a broad network of more than 110 leading hospitals in Spain, Portugal, France and Italy. SOLTI focuses its efforts on developing cutting-edge clinical trials with novel targeted therapeutics including innovative translational research, fostering the participation of research into cancer in international networks and promoting excellence in the management of cancer among their members.

Get to know us at: www.gruposolti.org

We are looking for an experienced Clinical Trials Data Manager/Database Developer. This role will be focused on the design, building and maintenance of study databases and coordinating data management activities for the assigned studies using an electronic case report form (eCRF) system based in OpenClinica.

Main responsibilities:

- To ensure that the SOLTI eCRF meets the data collection requirements according to the current legislation.
- To design and create a new eCRF of an assigned study through review of the protocol and other supporting documentation in close relationship with the Scientific Manager and the Medical Monitor.
- Creates and maintains documentation for the project; p.eg. Data Management Plan, Data Entry guidelines, definition and validation of the edit-checks included in the Data Validation Plan as agreed with the sponsor
- Provides support to the data preparation for reporting clinical study results for regulatory filings, publications, presentations.
- Produces data management reports, query status reports and reviews metrics reports for internal/external project team.
- Contributes to developing and implementing data management standard operating procedures.

- Works with third-party vendors to develop clinical data transfer specifications and databases finalization.
- Communicate with the sponsor and other collaborators of the project regarding data management issues.
- Offers support and training to the investigators and monitors.
- Ensures that the external data generated (Labs, SAEs, etc...) are transferred and reconciled with the clinical database.
- Perform database lock activities in close collaboration with the sponsor, Project Manager, Scientific Manager, Statistician and other parties.
- Develops and reviews the Data Management standards (templates and processes).

We are looking for:

- A bachelor's degree in computer science, or engineering or life sciences with relevant experience in building trial databases using eCRF OpenClinica.
- Experience in developing relevant data management processes and documentation, as well as a good understanding of the regulatory framework around data protection and information governance.

Should you be interested:

Please send your resume to recursos.humanos@gruposolti.org

Our team will review your application and will contact you in case your profile fits with the requirements for the position.