

North West Data Center



Clinical Research Data Center of the North West Cancéropôle granted by French National Cancer Institute since 2007 and by French National League against Cancer since 2006

MISSIONS

DATA MANAGEMENT

Data managers have knowledge and experience in electronic CRF development (design and preparation), data base design (standard database such as CDISC), data management plan development, quality checks (queries), database quality control, traceability (audit trail), data security, freeze of database and export.

DATA ENTRY

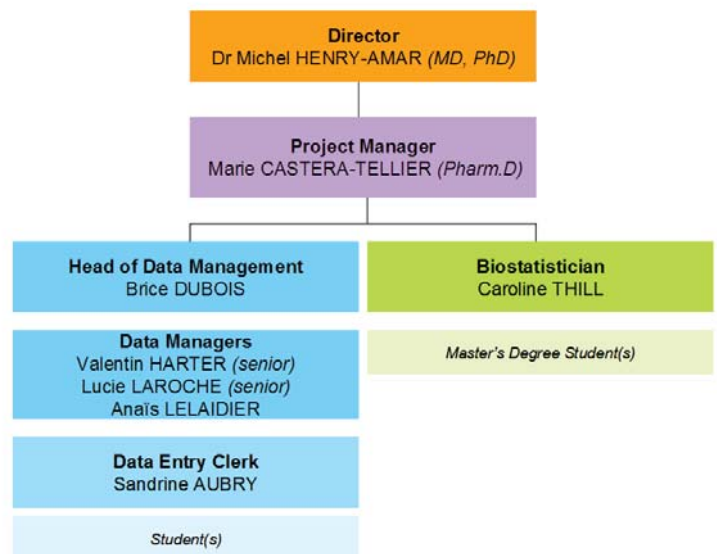
The data entry clerk is dedicated to data entry and quality check assistance.

METHODOLOGY and BIOSTATISTICS

Methodologist and biostatistician can provide advice and assistance in the design of studies, statistical planning, analysis and results publication.

PROJECT MANAGEMENT and AE CODING

Chemist has experience in project management, coding adverse events using MedDRA and can help in regulatory affairs, pharmacovigilance and AE qualification (unexpectedness, causality).



TOOLS

Resources include on-line data base management software (ClinSight ®; CLINSIGHT, 33155 Cenon, France) which complies with the EMEA/FDA requirements regarding IT systems as well as electronic signature and various international norms. It is particularly suitable for data management and monitoring; DC develops e-CRF which can be completed online (via CSONline) from any computer equipped with internet navigator and data transfer is encrypted by SSL (SSL certificate validated annually). Data entry and coding can also be performed by DC Staff.

Resources also include standard statistical softwares: SAS ® 9.2 ; Stata ® 12.1 ; Cytel Studio ® 9.0.0 : StatXact, LogXact, Crossover ; nQuery Advisor ® 7.0 ; nTerim ® 2.0 Resources include updated MedDRA dictionary (version 16).

CONTACT

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