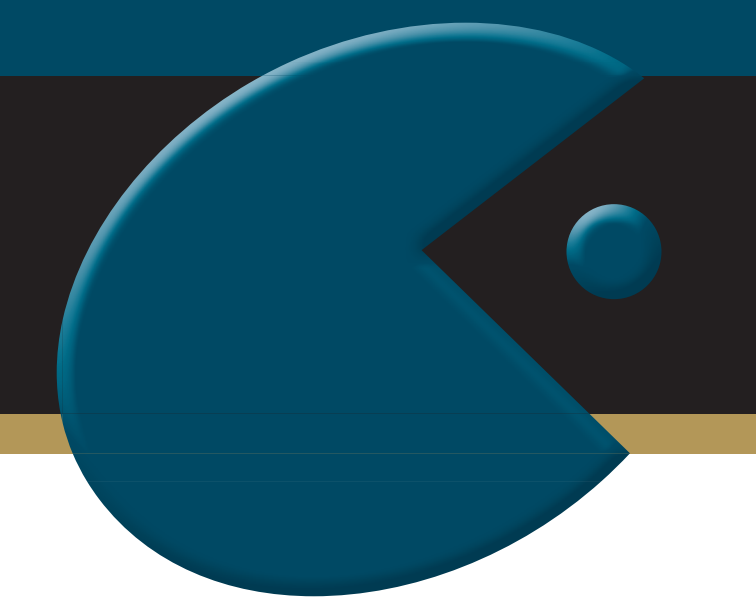
CROS NT
CONTRACT RESEARCH ORGANISATION

YOUR GATEWAY TO

EXPERIENCE, QUALITY & FLEXIBILITY



DATA MANAGEMENT SERVICES

The quality of your data define the success of your trial, therefore proper handling of data is fundamental. Our Data Management department can support you with both Electronic and Conventional Data Capture.

We perform Data Management activities on paper CRFs using Oracle Clinical™, in compliance with regulatory requirements, providing a fully validated Data Management process.

We run "Oracle Clinical Remote Data Capture" in a validated, 21 CFR part 11 compliant environment. With our Oracle Clinical experience of data managers, database developers, and programmers, CROS NT is able to host any EDC trial within your clinical program.

Our department is also very flexible in order to implement process specification from the client.

Data Management services include:

- CRF design (Page Maker, Teleform, Word, etc)
- DB design (Oracle Clinical, Teleform)
- Data Management Manual
- Data review and data Coding (MEDDRA, Costart, WHO, ICD9, etc.)
- Data Entry
- Fax-Scanner Data Entry (Teleform)
- Data Validation
- EDC (Oracle RDC Onsite 4.5.3)
- Data Management Report
- Insourcing of Data Managers at client site
- CDISC Compliant Datasets

CROS NT is a Contract Research Organization specializing in statistics and biometry, clinical data management, clinical research report writing, pharmacovigilance and life science application hosting.

STATISTICAL SERVICES

Our statistical department has wide ranging experience in study design and analysis, including pharmacokinetic, pharmacoeconomics and Health-related quality of life studies. All our Biostatisticians and SAS® programmers have a degree in Statistics. Experienced and well trained biostatisticians can support you in critical choices such as study design, sample size, and statistical methodologies.

Statistical services include:

- Study Design
- Sample size calculation
- Randomization Schedules, lists and envelopes
- Statistical consulting on protocol
- Protocol and CRF Review
- Statistical Analysis Plans
- Interim Analysis
- Blind review document
- Statistical programming (SAS)
- Statistical analysis
- Statistical report
- Data listing
- Statistical results presentation
- Statistic training

Furthermore we offer:

- Clinical Development Planning
- Exploratory Analysis
- Data Intergration
- Integrated Safety and Efficacy Analyses (ISS/ISE/CTD)
- Data Monitoring Committee Support
- Independment Programming Verification
- Manuscript and Presentation Preparation

CROS NT has more then 15 years experience in clinical research, adding up to more than 700 studies for which we managed Data management and Statistical activities. CROS NT provide its services in all therapeutic areas, with special excellence in the fields of respiratory, cardiovascular, HIV, Oncology and Infectious Diseases.

PHARMACOVIGILANCE SERVICES

CROS NT provides an approach to managing your pre- and post-marketed product safety program. We understand that accurate reporting is essential to your safety program and have validated the Oracle safety software solution AERS. We work at the highest technical level to ensure the regularity of your critical data.

These services include:

SAE/AE Data Processing

- AE and SAE logging, tracking, coding and case processing
- MedDRA and WHO-DD coding
- Medical assessment
- CIOMS generation

Reporting

- Preparation of periodic safety update reports (PSUR)
- EU Annual Report (ASR) – Listing
- EU ASR – Medical review
- End-of-study listing for reconciliation
- Unexpected serious adverse reaction (SUSAR) reports
- Submission of individual case safety reports (ICSRs)

QUALITY SYSTEM

Our working practices are governed by a full set of SOPs to ensure consistency and documentary evidence of quality at every point in a project. A series of milestones during the development of our activities control the processes in order to achieve quality in respect of deadlines. Our computer systems are fully Validated in accordance with 21 CFR part 11 rules.

CROS NT is ISO 9001:2000 certified: These globally accepted standards ensure that our services meet or exceed customer requirements and expectations.

TECHNOLOGY SERVICES

CROS NT strives to acquire and master tools of recent technological advances to make clinical trials run faster, more secure and more efficient. CROS NT runs the Oracle Life Science Application Suite:

Oracle Clinical® for Data Management activities, maintaining the most current, technologically advanced data management system.

Oracle Remote Data Capture (RDC): RDC helps R&D departments in pharmaceutical or Biotech Industries launch and conduct clinical trials more efficiently and effectively even with high regulatory complexity.

Oracle Adverse Event Reporting System (AERS): AERS is an Oracle software solution for Product Safety Monitoring and Compliance. With its integration in Oracle Clinical AERS provides the highest quality and the most functionality of any adverse event reporting system. The solution supports data handling, reports and analysis of Serious Adverse Event and Product Compliance from all clinical and spontaneous sources.

Technology Oracle Life Science Application services include:

- Hosting & housing of Pharma Life Science Solution in a secure Physical / technical infrastructure
- Help desk
- Training to Oracle Clinical and RDC software end-users

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GENERAL INFORMATION

CROS NTs Headquarters is located in Verona (Italy). We also have an office in Milan, and work with experts in Germany (Munich/ Darmstadt).
The Verona Headquarters is approx. 15 minutes drive from Verona airport. Our Verona office is designed for a complete physical security policy featuring.

With CROS NT you work with a team of professionals who deliver quality results on-time and within budget.

CROS NT
CONTRACT RESEARCH ORGANISATION

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