




**Your gateway to  
experience, quality  
& responsiveness**

## **Experience, quality & responsiveness**

CROS NT is a Contract Research Organisation specialising in Statistics, Data Management and clinical research report writing. Established in 1992, we have completed over 200 studies in a wide range of therapeutic areas of clinical and observational studies. Our reputation has been built on experience, quality of performance, responsiveness to our client needs and a passion to achieve the highest performance of our clients need.

## Therapeutic Areas

CROS NT has experience in the following areas:

|  |              |
|--|--------------|
| Anaesthesiology  | Imaging      |
| Cardiovascular   | Oncology     |
| Dermatology  | Pain         |
| Endocrinology  | Psychiatry   |
| Gastrointestinal   | Respiratory  |
| Genetics  | Rheumatology |
| Gynaecology  | Urology      |
| Infectious diseases  | Virology     |

## Protocol Development

CROS NT has been involved in the development of several study protocols, from safety and efficacy studies to pharmacokinetics and pharmacoeconomic studies.

The following services are at our client disposal:

- Sample size calculations
- Randomisation list
- Power Calculation
- Case Report Form design
- CRF Completion guidelines

## Data Management

The quality of your clinical data defines the success of your trial, therefore proper handling of data is fundamental. CROS NT is a specialized data management CRO with experienced people and advanced computerised systems. Our Data Management department work fast and accurately in compliance with client requirements and standards.

The following is a summary of our data management services and procedures:

- Data Management Plan
- Database Design
- Data Entry (Manual, TELEFORM)
- CRF medical review
- SAE reconciliation
- Medical Coding
- Data validation and Query management
- Central Lab Database import
- Database quality control
- Database lock and database release
- Database Documentation (export, audit trail)

## **Biostatistics**

Our statistical department has experience in the design and analysis of several clinical trials, from parallel or cross-over designs to complex pharmacokinetic studies. All statistical analyses are performed by well trained SAS programmers. Senior statisticians can support our clients in the design and analysis plan (SAP), also providing them with help in investigator's meetings

The following is a summary of our biostatistics services:

- Sample size calculation
- Randomisation list and envelopes
- Statistical consulting on protocol
- Statistical Analysis Plan
- Blind review document
- Statistical programming (SAS)
- Statistical analysis
- Statistical report
- Data listing
- Statistical results presentation
- Statistical training

## **Clinical Research Report**

In order to provide you with the final activity related to the clinical trial, our medical writing staff can offer you the following services:

- Protocols
- Clinical Research Report (ICH compliant)
- Abstract and Manuscript

## **Contact Information**

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