

PIVOTAL : DMBS DIVISION

■ *The Team*

- Data Managers, ORACLE and SAS Programmers, Biostatisticians and Data Entry Clerk Coordinators.
- Multidisciplinary team: IT Specialist, MSc Stats, PhD Maths, MPharm, MD.
- Good combination of practical experience in Clinical Research and management of DMBS projects.
- Average years of experience in clinical research: 9,5 (0,5 – 24).

■ *Services offered*

DATA MANAGEMENT

- Randomisation
- Data Management Plan
- DATA BASES: Design / Development / Validation
- Query Plans and Edit Checks programming
- DCFs (Data Clarification Forms) Generation
- e-CRF Design

BIOSTATISTICS

- Trials sample size calculations
- Protocols statistical design sections
- Statistical Analysis Plan and Scientific Programming
- Analysis Data Base Creation
- Interim and Final Statistical Reports

■ *Validated Tools and Systems*

DATA MANAGEMENT

- Oracle Clinical. Version 4.5.3
- EDC: Electronic Data Capture (e-CRF)
- Thesaurus Management System: MedDRA, WHODrug
- MS-Office: Access, Excel

BIOSTATISTICS

- SAS Version 9.2: Scientific Programming & Statistical Analysis