I
phase

rheumatology

48
subjects enrolled

Test case 2

A randomized, single-blind clinical study in two parallel groups to compare the pharmacokinetics, safety and tolerability of the study drug product vs. known drug product formulation.
Therapeutic area: rheumatology, rheumatoid arthritis.

The study was conducted under very tight deadlines for collection, processing and submission of data. Data MATRIX successfully completed this task and now continues to provide its support for the drug development program.

Study description

Solution from Data MATRIX

Randomization strategy: no randomization numbers, involvement of an unblinded employee

MATRIX IWRS

Configuration of the MATRIX IWRS provided for completion of a number of mandatory forms in CRF prior to randomization which was carried out by an unblinded employee. CRF required specification of treatment group only without randomization number.

The MATRIX IWRS added an additional classification of users by their roles and blinding levels.

Special study questionnaires

External data sources

Individual start dates and duration of the study

Requirements for the number of follow-up queries

MATRIX EDC

Patient questionnaire data collection forms were added to the MATRIX EDC.

Analyses of blood samples collected from subjects during the study were conducted by an external central laboratory. The MATRIX EDC was configured to provide for central laboratory data import which was done successfully.

The duration of the startup phase was reduced from 2.5 to 1 month due to project-specific factors and upon the customer's request. The data were exported to a biostatistician 2 weeks after the last patient's last visit .

Due to the use of built-in checks and the lab module, the number of created data correction queries was reduced by 15 % as compared to the expected number.

Additional services related to study design, biostatistics and preparation of documents

MATRIX EDC Medical Writing

Two biostatisticians and one SAS programmer were involved in the project to prepare the statistical analysis plan of pharmacokinetic and drug safety data, and writing of relevant reports.

Regulatory submissions

Timely and successful regulatory submission to the Ministry of Healthcare of Russia Data MATRIX is involved in the next phase of the clinical development program.