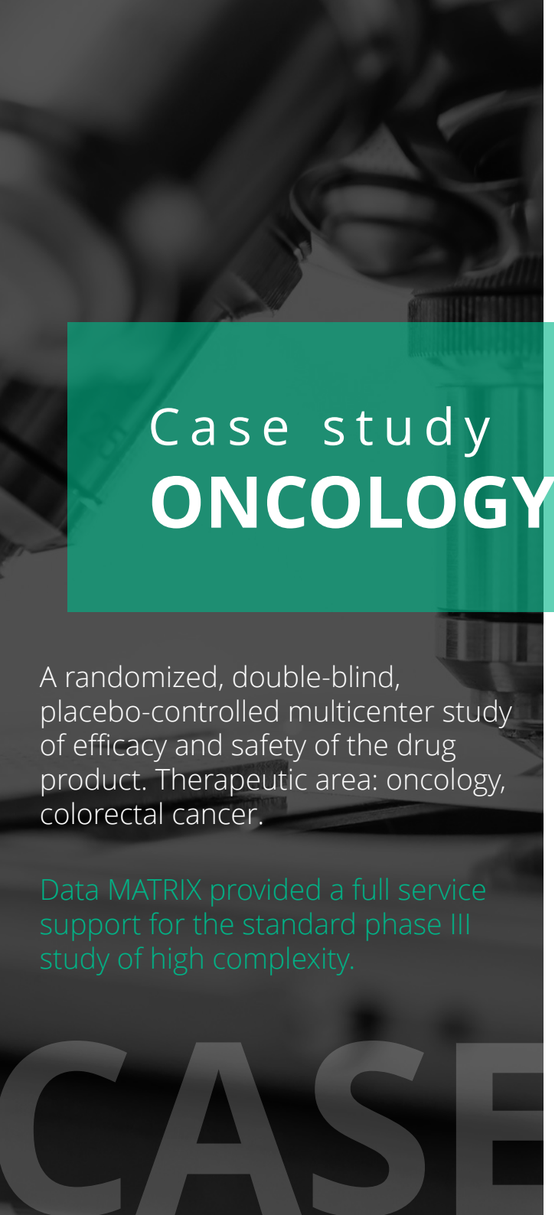

Case study
ONCOLOGY

A randomized, double-blind, placebo-controlled multicenter study of efficacy and safety of the drug product. Therapeutic area: oncology, colorectal cancer.

Data MATRIX provided a full service support for the standard phase III study of high complexity.

CASE

Study description		Solution from Data MATRIX
▪ Complicated randomization strategy: blocked randomization, 3 treatment groups; stratification by presence of neutropenia at the time of enrollment into the study. Tumor growth assessment performed by a central assessor.	**MATRIX IWRS**	▪ IWRS is programmed in accordance with the requirements of the Protocol. An “Independent Assessor” role is added to the MATRIX EDC/IWRS: the user may only see the results of tumor measurement and add findings of tumor assessment to CRF. Forms to be filled out by the Independent Assessor have limited view access for investigators.
▪ Absence of investigational drug products in stock	**MATRIX Trial Supply**	▪ The Data MATRIX Trial Supply system is programmed to prevent overconsumption of drug products and any irregularities, as well as to minimize costs of drug supply to study sites.
▪ External data sources ▪ Need for intermediate reporting ▪ Study start dates and duration ▪ Requirements for the number of follow-up queries	**MATRIX EDC**	▪ Data import configuration: lab results successfully imported to clinical database several times in the course of the project (before intermediate and final statistical reports). ▪ It took exactly 2.5 months to start up the applications and 30 calendar days (from the last patient’s last visit) to clean and lock the database. ▪ Due to the use of built-in checks and the lab module, the number of created data correction queries was reduced by 10 % as compared to the expected number.
▪ Additional services related to study design, biostatistics and preparation of documents ▪ Regulatory submissions	**Medical Writing** **Biostatistics** **Data Management**	▪ Data MATRIX also performed the following project activities: ▫ Preparation and approval of the study design ▫ Preparation of synopsis and protocol ▫ Determination of sample size, writing of statistical parts of the protocol, SAP and study reports with the involvement of a biostatistician ▫ MedDRA and WHO Drug coding ▫ Verification of intermediate and final statistical reports ▫ Preparation of intermediate and final study reports. ▪ Timely and successful regulatory submission to the Ministry of Healthcare of Russia.

Data MATRIX