

Case Study: Data MATRIX EDC for an NIS Study

To meet their study demands the Sponsor has chosen Data MATRIX EDC to deliver flexible, intuitive, cost-effective and bespoke solutions for its NIS (Non Interventional Study). Using Data MATRIX EDC enabled the Sponsor to build and manage the study with ease and efficiency, to programme edit checks effortlessly, and deliver valid data without 100% SDV. Data MATRIX solutions facilitated effortless deployment of mid-study changes whilst keeping within study timelines and budget.

We are happy we took this step and partnered with Data MATRIX on this NIS project. We improved our operational performance by leveraging custom functionality within Data MATRIX EDC. Adoption of Data MATRIX EDC has given us control and flexibility in data management.

Sponsor's testimonial

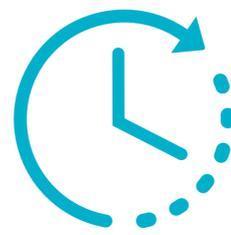
Multicenter Retrospective Study in Population of HIV-1 Infected Patients in Routine Clinical Settings of the Russian Federation



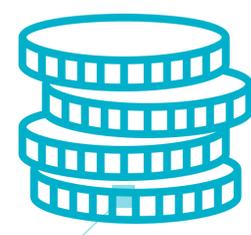
900 patients



6 sites



15 month



LOW budget

Practice shows, that clinical NIS are often accompanied by a variety of issues and complexities. The ones raised and addressed in this particular case are in the following content block.



Challenge

1 Low budget. Customarily, both the requirements and the budgets for NIS studies are low in Russia. Therefore, as a rule, sponsors are not inclined to use EDC for this type of studies, deeming them unnecessary. Even nowadays, a lot of NIS studies of the local market are still conducted on paper

2 Platform vs Language barrier. Since the investigators working on the NIS cases are regular doctors, unlike the ones conducting clinical trials, and considering that data should have been collected in English, a Sponsor was worried that not all investigators would be comfortable operating on the electronic solution, and on the English-based platform, in particular

3 Low quality data. NIS cases tend to be run on a limited budget, causing situations when there are hundreds of patients to just one monitor. Such conditions increase the risk of receiving low-quality data, especially in the absence of a unified approach and common standards

4 Mid-study changes. The most important challenges, quite common for NIS studies, are were the unforeseen mid-study changes that occurred during the project and were not provided by the Medical research plan. It requires a lot of time and effort to deal with these matters and discuss them within the team.

■ **D drug.** During the study an unpredictable and crucial finding has revealed — a D drug, the fourth drug, which can be included in the therapy originally intended as an A-C therapy. These updates required multiple system cleanings and separate discussions on each amendment with the Sponsor. This resulted in an additional block being included CRF

Solution

Quick lock of Database. The DB lock process was executed 3 times faster than if run with paper CRFs. With the large number of subjects we were able to speed up the process and lower the costs. With EDC there is also room to cut back on Data Entry tools

Bilingual CRFs. Bilingual Case Report Forms obviated the need for translation of table titles for regular doctors
Online staff training — the project participants are granted access to the live environment only after having completed basic online training and having gone through a practice course in the training environment within a special application

Electronic Data Capture allows us to obtain high quality data: 97 automatic edit checks were configured by data managers during the project. Data MATRIX track record and high level of professionalism among its staff members allowed the harmonization of procedures and data within the shortest time

Rapid response to **mid-study changes:**
 A system update was immediately configured as a part of a CRF update, saving both time and money

Results

- ✓ **Valid data even without 100% SDV**
- ✓ **Short study timeline** — Data MATRIX's solution allows the shortening of the timeline for double data entering, and as a result, cuts back on labor costs. Unlike a paper-based approach, having a modern EDC system to bring data together will be key to instant access to CRFs for all participants and the acceleration of all processes
- ✓ **No need to archive the paper CRFs for 1000 patients (electronic format)**
- ✓ **Quick mid-study changes** — deployed within one CRF update, saving both time and money
- ✓ **Cost reduction: logistics** (sending of CRFs to sites and back) **and CRF printing** (in the case of a paper-based approach. CRFs must be printed in triplicate in accordance with all standards on special self-copying paper). Using EDC makes it possible to reduce all these costs
- ✓ **Effective staff work the electronic solutions** — due to Data MATRIX's training even the regular doctors were able to operate the EDC

The Sponsor decided to go with Data MATRIX EDC for collecting and conducting data for the NIS study, and here is what they ended up with as a result: The Sponsor improved their operational performance by leveraging custom functionality within Data MATRIX EDC. Adoption of EDC has given the Sponsor control and flexibility in data management. This model has reduced costs on several budget articles, which allowed them to cut the final budget for data management by 20% and shorten the timeline by 5 months. Most importantly, the Sponsor has seen the impact of increased data quality as a result of implementing an ongoing data review process