

eDiary App customization



Techorizon is a worldwide provider of technology advanced solutions and services for the healthcare and life sciences industry.





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Case Study



A European biotech company operating in the healthcare industry was performing a phase II, randomized, double-blind clinical study on a drug to evaluate pain relief, safety and tolerability in patients with osteoarthritis.

The study involved six sites in two European countries with a total of 250 patients, for a period of 12 months

The client was looking for an EDC solution, integrated with an eDiary (focused on the collection of pain relief data) and a randomization system for the study drug assignment.

The aim was to provide investigators only with one tool for managing the study data collection.

This system should allow patients to fill in the questionnaire independently, not only at the site but also at home, in online and offline mode, within tight timelines.

This data collection had to take place according to a very precise hourly schedule (in minutes) and the patient's response time had to be a few seconds before moving to the next question.

THE CHALLENGE

The client's need was to carry out real-time data collection from patients (eg. pain intensity via VAS scales and pain relief), starting from the visit at the site and continuing at home. The data should have been integrated with the EDC system.

The client was also aware that there were not many integrated eCRF system and eDiary solutions available on the market.

Another request from the client was to prevent the patient from forgetting to fill in the eDiary at the requested study timelines. Therefore, the patient had to be alerted by a sound system to allow the compilation in a timely and precise manner.

The diary was very complex due to a very demanding data collection flow, therefore it was necessary to understand how to manage this diary which had a straight answer window of few seconds.

Finally the data collected within the eDiary had to be analyzed and compared to the data collected by the investigator during the study visits (entered in the EDC system).

THE SOLUTION

As no standard App on the market could satisfy the client's needs for this study, **Techorizon** proposed a solution based on the integrated database between THeCRF and THeDiary with the development of a customized diary application (**THeDiary** App customization).

THeDiary App customization allowed (with a time frame of seconds) the collection of information to be scheduled and requested from the patient through an alarm system (sound and/or vibration) and implemented a dynamic list of questions, based on the answers received from the patient.

Considering that the VAS scale had to be displayed to all of the patients in a fixed way with a well-defined and restrictive criteria of 10 cm length, it was decided to use and provide patients with a tablet of a specific size that would allow them to view the VAS scales of the same size according to the mandatory parameters of the study.

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THE RESULT

The VAS scales, thanks to the App customization and the fixed-size device provided by **Techorizon**, were successfully compiled in compliance with the restrictive requirements of the study, allowing for very accurate and effective data collection of the patient's pain evaluation.

All clinical tools used in this study were integrated together (THeCRF, THeDiary, randomization tool). This allowed the client to view and process the data, via web, from **THeCRF** and **THeDiary**, within the same application throughout the entire study.

The client not only had the study progress always available for early review and rapid decisionmaking, but also had all of the data for the ad interim statistical analysis in real time.

CONCLUSION

Thanks to the innovative approach and attention to the client's needs, Techorizon was able to implement and develop the right custom App to make the trial a success.

Furthermore, a single application for eCRF and eDiary means a single source for clinical data. This helps to cut integration cost with external applications, optimize time management and keeps study data safe, in one place and immediately available.



About Techorizon

Techorizon is a worldwide provider of technology solutions for the Life Sciences. Founded in 2009 as a spin-off of the IT department of CROMSOURCE, an international Contract Research Organization, Techorizon supplies advanced solutions and services to the healthcare environment.

Techorizon is an ISO certified Italian company that has been repeatedly ahead of its time when it began helping providers in the healthcare sector with their technology needs.

Techorizon's products and services are tailored to offer the best technological solutions for sponsors, CROs and academic and non-profit organizations so that they can focus on their core activities and achieve a perfect balance between budget requirements, functionality and quality data management.

In addition to EDC and related services Techorizon, as an IT company can also offer high level enterprise IT services such as networking consultancy, hosting and data center provision and many others.

With an expertise of more than 10 years in the Microsoft environment, Techorizon is in the position to provide high level consultancy in many areas including but not limited to MS SharePoint.

With more than 15 years of experience in the life sciences sector and the proven satisfaction of our clients, we are confident that we can find and tailor a technological solution to help you with your project! Contact us for more information on how Techorizon can help you with your technology needs.

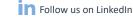
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