Climedo

Study to Analyze the Clinical Performance of an IVD Product

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Introduction

This case study outlines a clinical performance evaluation of an in vitro diagnostic device for SARS-CoV-2 according to the In Vitro Diagnostics Regulation (IVDR) 2017/746 in the Climedo platform. Over an eight-month period in 2022, CRO TRIGA-S GmbH conducted the study for an IVD manufacturer. The main objective was to assess the device's safety and performance in compliance with IVDR criteria. This case study highlights the methodology and results of a study, as well as examining the experiences and contributions of professionals involved, including Data Managers and Clinical Research Associates (CRAs), throughout the extensive study.

Starting point

The IVDR defines clear requirements for the evaluation of the performance and safety of IVD devices prior to market approval. The performance study discussed in this paper consisted of two main parts: Part I evaluated the diagnostic sensitivity and specificity compared to a CE-marked RT-PCR test, while Part II investigated the ability of laypersons to use the test correctly and interpret the results.

Project Description

Description of Product and Methodology

The study examined the effectiveness of an immunochromatographic immunoassay in identifying SARS-CoV-2 nucleocapsid antigen in human nasal secretions. The assay was classified as a Class D In-Vitro Diagnostic in agreement with the IVDR. Its purpose is to offer a quick and dependable way of identifying SARS-CoV-2 infection. The research was conducted among 431 participants at three different study sites. The methodology involved collecting data on the test's diagnostic accuracy when compared to an established RT-PCR method. Furthermore, the study included a layperson's assessment of the diagnostic accuracy compared to an established RT-PCR method.

Data Management

Study data were obtained using both paper-based Case Report Forms (CRFs) and an electronic CRF system (eCRF), as necessitated by the level of digitalization at the study sites. Every trial participant was assigned a unique study ID to pseudonymize the data. Authorized personnel collected the CRF data both electronically and manually. Questionnaires completed by the participants were also included. The eCRF contained 161 queries, 38 dependencies and 21 validations spread across nine input forms. Any

discrepancies or irregularities were recorded and corrected immediately to ensure high-quality data.

Experience of the Data Manager

When creating and using the eCRF, the following points are worth mentioning from a data management perspective:

- Intuitive system operation: The drag-and-drop feature of each input field during eCRF creation, straightforward access rights assignment and clear mask for building complex dependencies facilitated the quick and effortless development of the intricate eCRF.
- Wide functionality range: The vast array of functions and adaptable handling enabled the effortless and personalized system adjustments aligned with the study demands and in accordance with the stipulations of TRIGA-S GmbH's in-house SOPs.
- Powerful query management: The integration of query management and the range of options for creating dependencies and validations significantly improved data quality, as automated processes prevented the entry of erroneous data to a large extent.
- User support: During the study, the user support provided by Climedo played a vital role in the project's overall success. Any issues encountered were promptly and efficiently resolved to the satisfaction of all parties involved. Any recommendations for improvement from TRIGA-S GmbH were also promptly received and implemented.
- Documentation: Climedo's comprehensive documentation of safety standards, including release notes and subcontractors, along with proactive distribution of such documentation, exemplified GDPR- and GCP-compliant work by the data management team. Additionally, the capability to generate annotated eCRF printouts was instrumental during the study.

Advantages and Results

Experience of the CRAs with the eCRF-System

The CRAs were pivotal in overseeing the study on the sponsor's behalf. Their tasks included:

- Adherence to protocols: The CRAs ensured strict adherence to study protocols to maintain the integrity of the research.
- Study site support: The CRAs served as a liaison for the study sites and facilitated the seamless study implementation.
- Correct data collection: CRAs were responsible for ensuring that data collection was carried out according to the requirements.

The use of the eCRF proved to be highly beneficial:

- Real-time data access: The eCRF system allowed the CRAs to retrieve real-time data remotely at any time without the need to be physically present on-site.
- Efficient data monitoring: The software facilitated the identification of deviations thanks to its effective data monitoring.
- Early problem detection: Real-time data access allowed for the timely identification and resolution of potential issues.
- Facilitated collaboration: The platform facilitated collaboration between various stakeholders, including CRAs, study staff, data managers and sponsors.

The capacity to monitor the research's advancement and examine the information in real time has demonstrated significant utility:

- Rapid problem resolution: The team was able to identify and resolve potential bottlenecks or irregularities.
- Minimizing ambiguities: Real-time data updates reduced misunderstandings and eliminated ambiguities.
- Effective collaboration: The software facilitated communication and collaboration among different study participants.
- Improved data quality: Real-time analysis capabilities helped increase data quality.

The CRAs found that digital solutions, such as Climedo's eCRF system, contribute significantly to efficiently monitoring and coordinating complex clinical trials.

Experiences of the Study Sites

The study personnel were able to electronically document the collected data, complete digital questionnaires and track study progress in real time. Implementing electronic data collection resulted in a much more efficient study process and data collection. As a result, the study sites positively assess the use of Climedo as a substantial improvement relative to previous systems and methods.

Positive effects of the use of Climedo:

- Noticeable impact on working methods and study results (see advantages of the Climedo platform below).
- High usability and intuitive navigation for study staff.
- Smooth data collection and management processes.

Advantages of the Climedo platform:

- Electronic data capture enabled efficient and precise documentation.
- Real-time monitoring of study progress for better control.
- Increased efficiency in coordination and communication in the study team.
- Improved data quality and consistency thanks to digital data collection.

Study personnel testimonials with the Climedo platform highlight its positive impact on the seamless execution of clinical studies and the enhancement of data aggregation.

Conclusion and Prospects

The implementation of Climedo's electronic data management system has significantly increased the efficiency of data collection, monitoring and validation. The Data Manager and CRAs' results underscore the advantages of digital solutions for clinical trial implementation. This case study has showcased the potential of innovative technologies to enhance efficiency, data quality and patient safety in evaluating clinical performance.

Conducting a clinical performance evaluation study in adherence to IVDR mandates precise data management and efficient monitoring. The experiences of the data manager and CRAs in this study showcase the importance of digital solutions, such as the Climedo platform, in clinical trial management. The lessons learned contribute to the advancement of IVD products and enhance trust in their effectiveness and safety in the marketplace.

About Climedo

The leading European eCOA system for non-interventional studies, RWE and launch success

Climedo offers an all-in-one eCOA and EDC solution with hybrid capabilities for non-interventional studies and real-world evidence. By using a patient-centric approach and leveraging real-time data insights and visualizations around a study's current progress, Climedo empowers its clients to better engage with healthcare professionals and other key opinion leaders (KOLs). This boosts awareness, stimulates scientific dialogue and accelerates the launch success of new medical innovations, thus reaching more patients faster. Founded in Munich in 2017, Climedo is a leading trusted partner for pharma, medtech, CROs and academia with over 1.7 million patients enrolled to date. Learn more at www.climedo.com.

About TRIGA-S

TRIGA-S GmbH is a contract research organization (CRO) that operates an S2 laboratory. It offers customized solutions for many types of studies, from exploratory feasibility studies to analytical and clinical performance studies according to EU-IVDR. TRIGA-S was founded in 1998 by Sabine Radiske and is now a company with more than 120 employees in the areas of contract laboratory, sample management, study management, monitoring, biostatistics, data management and logistics. Over the past 25 years, TRIGA-S has expanded from a small team to a highly regarded service provider in the diagnostics industry.

For more information visit: www.triga.s-de

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