Institute of Biostatistics and Analyses

CLINICAL DATA SERVICES FOR MDR COMPLIANCE

ENSURING COMPLIANCE AND IMPROVING QUALITY

BIOSTATISTIKA.CZ

MDR and Clinical Data

Ensuring clinical data compliance with the latest Medical Device Regulation (MDR) is critical for medical device manufacturers to maintain their ability to market and sell their devices in Europe. Our Clinical Data Services are designed to help medical device manufacturers achieve and maintain MDR compliance with ease and confidence.

We offer complex project management from clinical data collection to data analysis

Our Services

Clinical Data Collection

Our clinical data collection services include protocol design, site selection, and patient recruitment to ensure efficient data collection. We work with you to design a study that meets your needs and the requirements of MDR.

Clinical Data Management

Our experienced team provides comprehensive data management services, including data entry, cleaning, validation, and storage. We use industry-standard tools and processes to ensure that clinical data is of high quality and meets regulatory standards.

Clinical Data Analysis

Our team of experienced statisticians can assist with statistical analysis and report generation, providing insights into the data and supporting regulatory submissions. We use the latest techniques and methods to ensure accurate and reliable results.

We are committed to providing you with comprehensive support and guidance

PMCF step by step

Planning
PMCF plan outlines the objectives, scope, and methods of the PMCF program, as well as the resources required to carry it out. The PMCF plan must be submitted with the Clinical Evaluation Report (CER) as part of the regulatory approval process for medical devices.

Implementation
Our experienced team provides comprehensive data management services, including data entry, cleaning, validation, and storage. We use industry-standard tools and processes to ensure that clinical data is of high quality and meets regulatory standards.

Data Collection
The PMCF program must include the collection of data from a variety of sources, including clinical studies, adverse event reporting, literature reviews, and other relevant sources. The data must be collected in a systematic and comprehensive manner and must be kept up-to-date.

Post-Market Clinical Follow-up (PMCF)

PMCF is a systematic process that involves planning, implementation, data collection, analysis, and reporting. PMCF is an essential component of the ongoing evaluation of the safety and performance of medical devices in Europe and must be carried out in accordance with the relevant provisions of the Medical Device Regulation (MDR).

Data Analysis
The data collected as part of the PMCF program must be analyzed to identify any trends, patterns, or concerns related to the safety and performance of the device. The results of the data analysis must be used to inform the ongoing evaluation of the device and to make any necessary changes to the PMCF program.

Reporting
The results of the PMCF program must be reported in a timely manner to the relevant authorities, as well as to the manufacturer's customers and other stakeholders. The PMCF report must include a summary of the findings, any recommendations for further action, and a plan for ongoing monitoring of the device.

Clinical Study

Clinical study is a controlled investigation of a medical device in human subjects to gather data on its safety, performance, and effectiveness. The results are documented in a Clinical Evaluation Report and must demonstrate compliance with MDR requirements. Clinical studies must be conducted in accordance with Good Clinical Practice and approved by an ethics committee.

You can rely on our years of expertise conducting clinical studies.

Clinical Study step by step

Planning
Developing a comprehensive plan that outlines the objectives, design, methods, and timeline of the study. The plan must also include a description of the population to be studied, the inclusion and exclusion criteria, and the methods of data collection and analysis.

Ethics Approval
Before a clinical study can be conducted, it must be approved by an ethics committee. The ethics committee will review the study design, informed consent procedures, and any potential risks to the study participants.

Implementation
Once the clinical study has been approved, it must be implemented in accordance with the study plan. The study must be carried out by appropriately qualified and trained personnel, and must be conducted in accordance with the principles of Good Clinical Practice (GCP).

Data Collection
Data must be collected systematically and accurately throughout the study, using validated methods and tools. Data must be recorded in a manner that ensures the confidentiality and privacy of the study participants.

Data Analysis
Once the data collection is complete, the data must be analyzed to determine the safety and performance of the medical device. The results of the data analysis must be used to support the regulatory approval of the device.

Reporting
The results of the clinical study must be reported in a comprehensive and transparent manner, including the study design, methods, results, and conclusions. The results of the study must be included in the Clinical Evaluation Report (CER) and must demonstrate that the device meets the applicable requirements of the MDR and is suitable for its intended use.

Institute of Biostatistics & Analyses

IBA is a CRO with extensive experience in clinical data collection and analysis, completing 300+ projects in 25 countries. We partner with medical societies, pharma, medical device and IVD manufacturers, and grant teams. We have our own web-based systems for data collection, validation, and analysis. We offer services in clinical research, clinical trials, non-interventional studies, medical device registries, and real-world evidence projects. Our focus is on data management, data collection, and communication with regulators, data analysis and interpretation.

Our services are flexible and customizable to meet your specific needs

Specific service for each part of your project

- Clinical trial design and management
- Patient recruitment and management
- Data management and statistical analysis
- Regulatory affairs and compliance support
- Medical writing and report preparation
- Monitoring of clinical studies including RBM
- Quality assurance and quality control
- Medical device registry services
- Post-market surveillance (PMCF) support
- Real-world evidence (RWE) studies
- Electronic Data Capture (EDC) system for Medical Device

CLADE-IS

CLADE-IS represents an information system for clinical data warehousing. Researchers in health and life sciences industry use this EDC platform (Electronic Data Capture) for secure and intuitive data management. CLADE-IS is in compliance with ISO 13 485.

Comparison of Electronic Data Collection (EDC) System vs. Paper Data Collection

CLADE-IS ✔

- Faster data collection and entry
- Real-time data availability and analysis
- Reduced errors and improved data accuracy
- Improved data management and security
- Better ability to monitor data quality
- Reduced paper usage and waste.

Paper Forms ✘

- Slower data collection and entry
- Delayed data availability and analysis
- Increased errors and data inaccuracies
- Poor data management and security
- Limited ability to monitor data quality
- Increased paper usage and waste

CLADE-IS
CLINICAL DATAWAREHOUSE

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