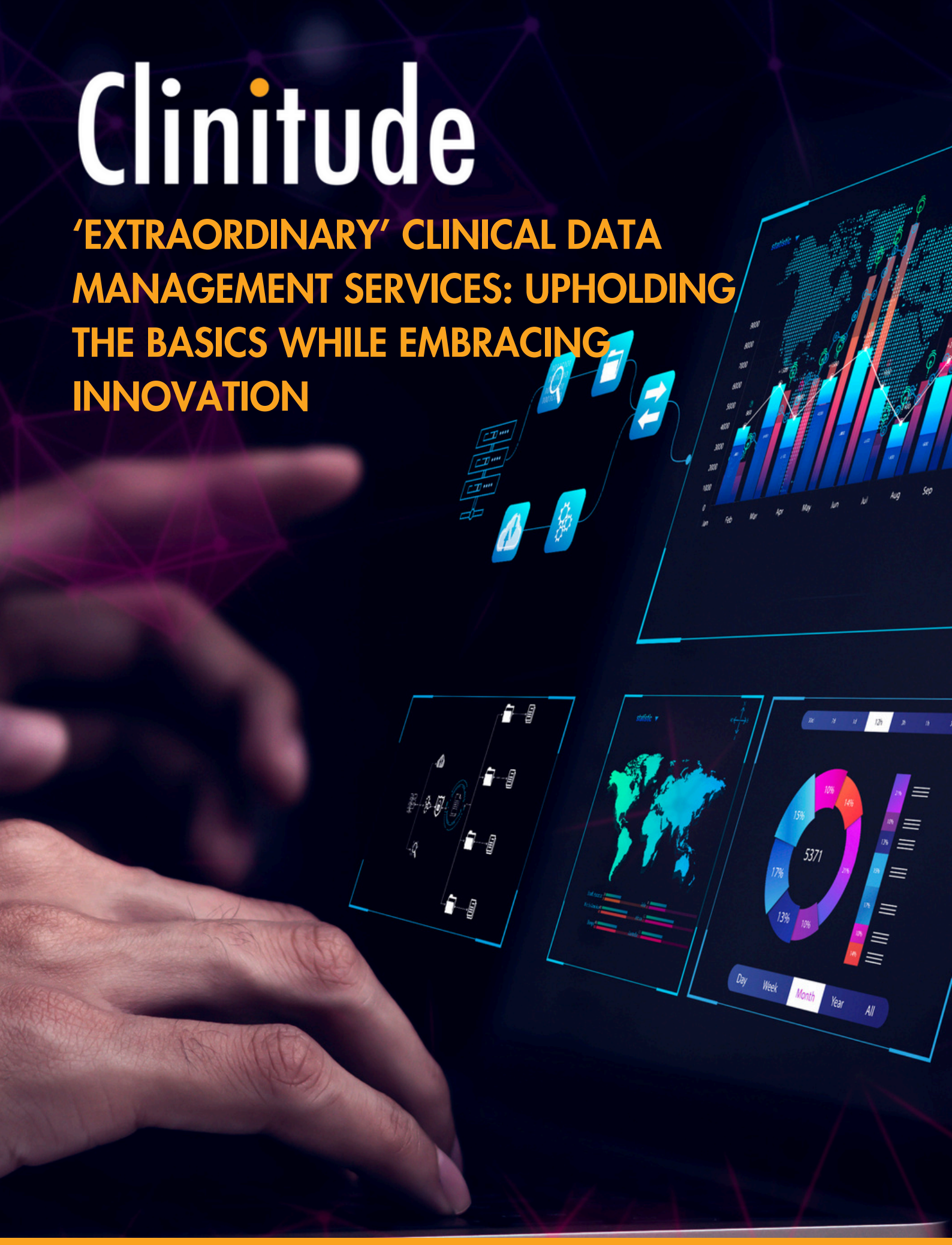
Clinitude

‘EXTRAORDINARY’ CLINICAL DATA MANAGEMENT SERVICES: UPHOLDING THE BASICS WHILE EMBRACING INNOVATION



Phone
+32 (0) 16 58 19 84

Email
info@clinitude.com

Website
www.clinitude.com

INTRODUCTION

Clinical Data Management (CDM) is the bedrock of successful clinical trials, securing the accuracy, integrity, and reliability of clinical trial data. This whitepaper presents a detailed overview of Clinitude's CDM services, highlighting its comprehensive and tailored solutions, and its strong commitment to uphold the foundation of data management while embracing technological innovations, ensuring data quality and regulatory compliance. By understanding the core principles, capabilities, and case studies of Clinitude, potential clients and stakeholders can make informed decisions about partnering with the organization.

The realm of clinical data management stands at an exciting era, where tradition and innovation converge to shape the future of clinical research and drug development. The very essence of clinical data management is rooted in safeguarding the integrity and quality of data collected during clinical trials. At the same time, the field is experiencing a remarkable influx of innovative technologies and innovative methodologies that promise to revolutionize how clinical data is collected, processed, and analyzed. This dynamic environment creates synergy, thus striking a balance between embracing these advancements and safeguarding the foundational principles becomes crucial as ever.

OUR **PURPOSE**

Clinitude Clinical Data Management team's mission is to provide tailored data management solutions that bridge the gap between traditional practices and cutting-edge technologies, ensuring that data integrity and quality remains the cornerstone of our endeavors. We stand apart with our customer-focused, site-centric, and innovative approach, and strong commitment to collaborative excellence. We offer a new dimension to clinical data management, focused on understanding the unique requirements of each clinical trial. Data Integrity, Quality and Traceability are our 3 main pillars within our team.

DATA MANAGEMENT CORE SERVICES

STUDY SETUP

- e-CRF and Database Design and Validation (based in CDASH)
- Edit Checks Programming
- Creating essential CDM Documents
- User Acceptance Testing (UAT)
- User Account Management

DATA VALIDATION

- Double Data Entry
- Data Review and Cleaning
- Query Management
- Coding (WHODrug & MedDRA)
- SAE Reconciliation
- Protocol Deviation Reconciliation
- Data Listings and Progress Reports

EXTERNAL DATA MANAGEMENT

- Vendor Coordination
- Data Transfer Specification
- External Data Reconciliation
- eCRF Integration

RANDOMIZATION AND TRIAL SUPPLY MANAGEMENT (RTSM)

- Set-up, Validation and Maintenance

DATABASE LOCK AND CLOSEOUT

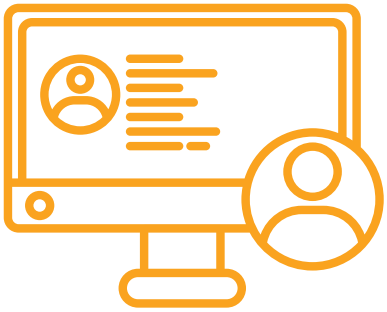
- Data Review Meetings
- Transfer of Final Datasets
- CRF PDF Generation
- Oversight of conversion of raw datasets to SDTM with our trusted partner
- Support in the preparation of DM submission package

FUNCTIONAL SERVICE DATA MANAGEMENT

- Qualified and dedicated team who will be integrated into your workflow.

LEVERAGING INNOVATIONS

While traditional principles serve as the foundation, advancements in technology and methodologies are reshaping the landscape of CDM:



CLINICAL DATA MANAGEMENT SYSTEMS

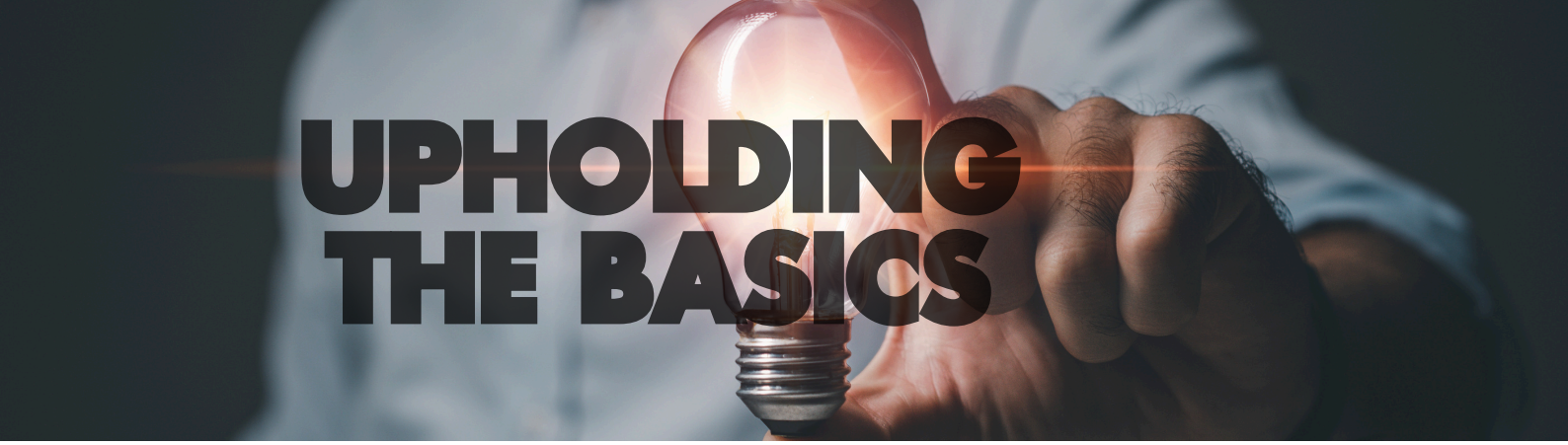
Clinitude excels in managing various data collection systems in clinical research, including EDC, RTSM, ePRO, and eSource from different partners which allows us to offer our clients a diverse range of choices to meet their specific study needs and budget constraints. Furthermore, Clinitude's team can seamlessly adapt to client's preferred systems, ensuring flexible approach to clinical data management.

OPTIMIZING DATA VALIDATION USING OPEN-SOURCE TOOLS (E.G., R, PYTHON)

This is a cost-effective way to semi-automate data cleaning and help streamline data validation processes, enhancing data integrity and improving overall trial efficiency.

PRE-VALIDATED CASE REPORT FORMS (CRF) AND EDIT CHECKS LIBRARIES

Clinitude has developed CRF Library which is aligned with CDISC standards. Subsequently, Edit Checks Library is also created based on these forms. These integrated libraries come pre-validated and ready to be customized according to protocol requirements. Utilizing these libraries will shorten the time of UAT, thus accelerating the deployment of the study to production.



"Upholding the foundational principles while integrating cutting-edge technologies and methodologies results in a dynamic and effective approach to clinical data management."

At Clinitude, we implement strategies to find balance between adhering to conventional practices and embracing innovation:

CUSTOMIZED IMPLEMENTATION

Adapt advancements to fit the specific needs of each trial. Not all innovations are universally applicable.

QUALITY ASSURANCE

Regular quality checks are embedded in our standard procedures.

STREAMLINED COLLABORATION

Clinitude fosters collaborative environment both internally and towards external parties. Together, we work as a team to deliver the best outcomes for your clinical trials.

COMBINATION OF SEASONED HEALTHCARE AND IT PROFESSIONALS

As most of our associates have backgrounds in healthcare, our constant effort is to design our eCRF to be as site-centric as possible, ensuring that our forms are clear and straightforward, facilitating quicker data entry. Our philosophy is "to query what matters" avoiding unnecessary and duplicate queries to the site.

CASE STUDY

MEDICAL DEVICE
REAL WORLD EVIDENCE (RWE) STUDY

CHALLENGE

Retrospective Data Collection comparing 2 Treatment arms from different EU sites and validating these data within a short timeframe.

SOLUTIONS

- Clinitude launches its Integrated Site Support services to streamline data collection processes among the sites.
- Optimize the functionality of the EDC platform to import data from external sources for quick validation.
- Leverages Python software for complex edit checks to enhance data cleaning.

RESULT

High quality data is delivered within the agreed budget and timelines.

CLIENT TESTIMONIAL

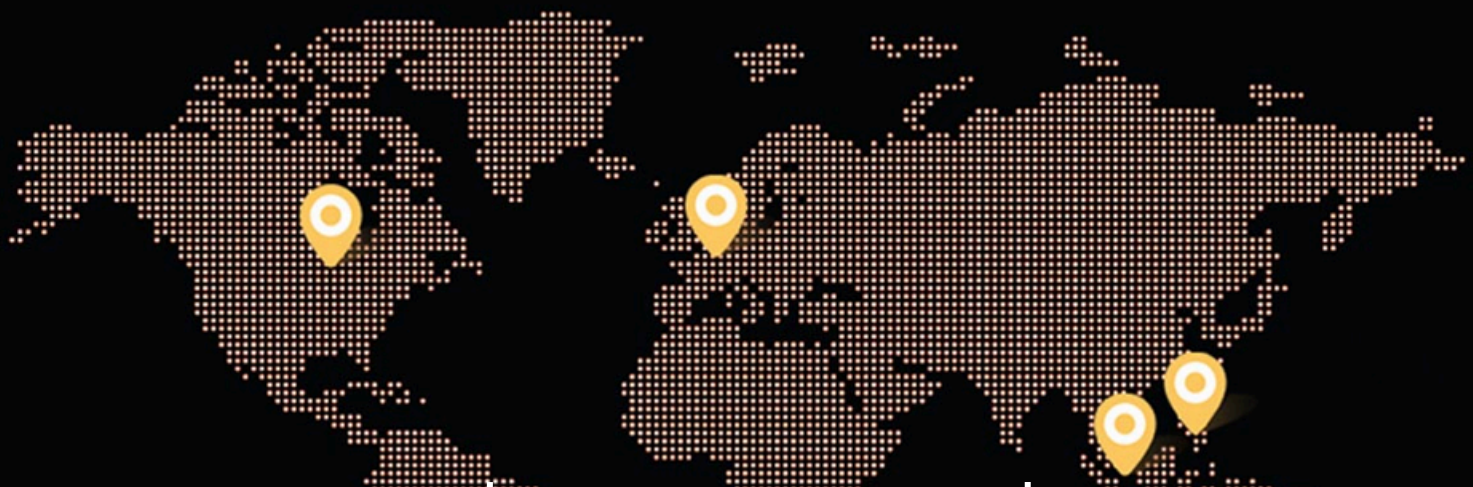
"The Statistics team are hard at work on performing the analysis, and we are incredibly happy to see that the data is of high quality and has not found anything amiss so far. We indeed solved the pending questions thanks to your record keeping. We want to thank you and congratulate you for your efforts to achieve this!"
– Sponsor

CONCLUSION

Clinitude's commitment to data quality and innovation is unwavering. Furthermore, the CDM team is well-versed in the latest guidelines, regulations and best practices set forth by respected CDM organizations (SCDM, ACDM) and regulatory agencies like the US FDA and EMA. This expertise ensures that all data management processes adhere to the highest standards, mitigating the risk of regulatory issues and ensuring a smooth path toward market approval.

In conclusion, Clinitude represents a cornerstone of excellence in the clinical research industry. By offering comprehensive solutions, balancing between innovation and traditions, and demonstrating an unyielding commitment to data quality and regulatory compliance, Clinitude stands as a trusted partner for organizations seeking top-notch clinical data management services.

Contact Us!



US Office

Chicago

10 South West Loop, Riverside Plaza
Suite 875, Chicago, Illinois, 60606
United States
Tel.: +1 312 474 6080
Fax: +1 312 474 6099

Europe Office

Belgium (HQ)

Kempische Steenweg 309 bus 2.09
3500 Hasselt
Belgium
Tel.: +32 (0) 16 58 19 84
Fax: +32 (0) 16 46 55 52
Email: info@clinitude.com

Asia Office

The Philippines

Cebu Ayala Business Park
IT Tower 1
14B, Arch Reyes Str. & Bohol Ave.
6000 Cebu City, The Philippines

"Don't settle for ordinary. Choose extraordinary. It's always a choice."

Phone
+32 (0) 16 58 19 84

Email
info@clinitude.com

Website
www.clinitude.com