Cmed

An Aixial Group Company

Data science and analytics solutions to fit your needs perfectly

Expertise and experience, Trusted delivery,
Complex trials, Third generation technologies

aixial GROUP
AN ALTEN COMPANY

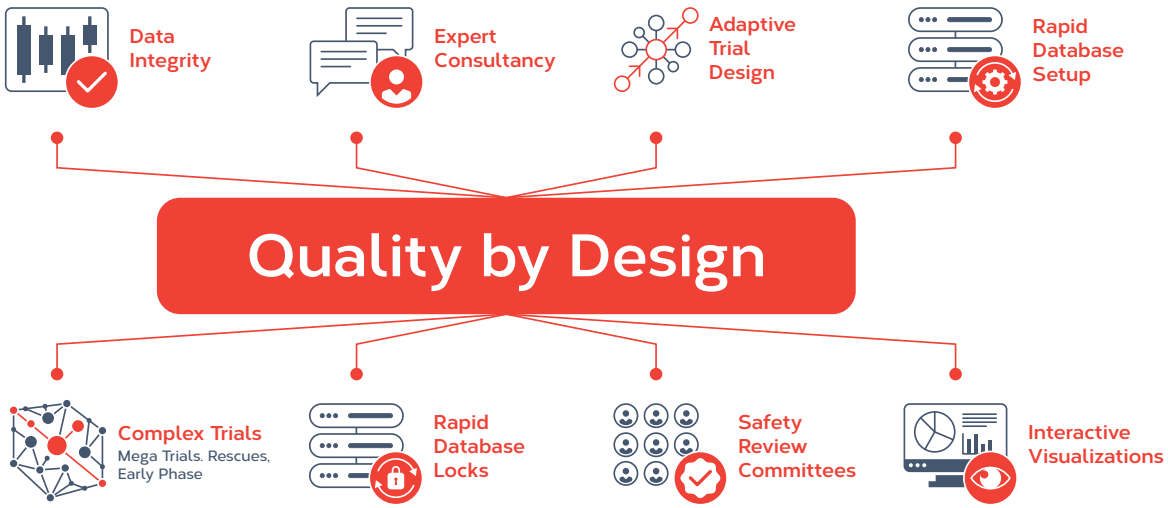
Where technology meets expertise

cmedresearch.com

Enhance the power of your trials

Quality clinical data is vital in any clinical study. Cmed has the expertise, systems, processes and resources to ensure we deliver your results to the highest quality.

Our approach is to design each trial database and dataflow with flexibility to achieve the end result while adapting to any unforeseen changes in the trial lifecycle.



Cmed delivers precise data for complex trials

Cmed Data and Analytics services will help you to make fast, accurate deliveries despite the increasing volumes, types, and sources of data of today's clinical trials. Our goal is to support you by understanding and using all data most effectively.

Cmed's Services:

- Data Management, Statistical Programming, Biostatistics and Project Management
- Large scale Functional Service Provision (FSP)
- Statistical Consultancy
- ISS/ISEs
- Systems development and integration

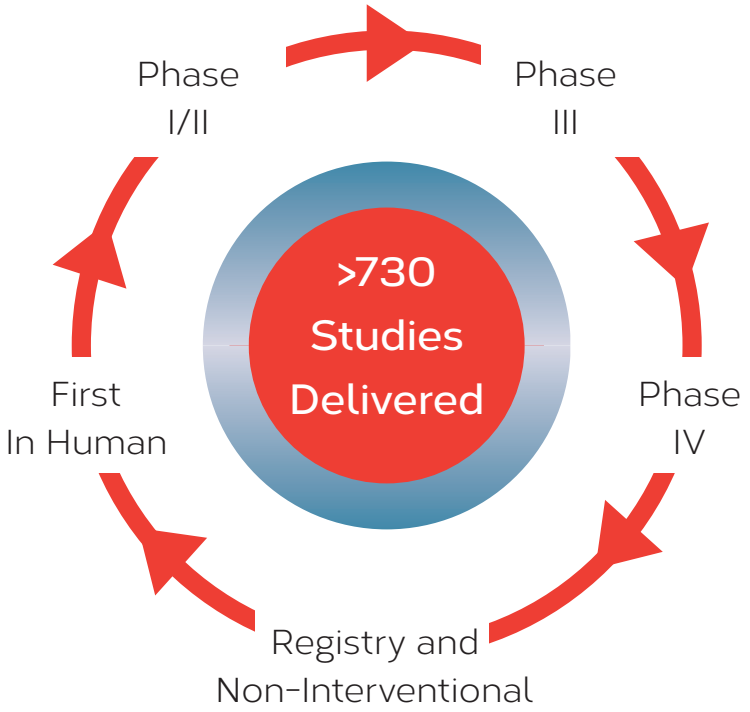
Our Experience and Resources

TOP 10
CMED WORKS WITH 5 OF THE TOP 10 PHARMA COMPANIES

25+
SMALL BIOPHARMA USE CMED

180
DATA SPECIALISTS WORLDWIDE

19 YEARS
AVERAGE STAFF EXPERIENCE



Clinical Data Management

Cmed provides end to end services that facilitate the efficient collection and management of clinical data. Through our clinical data science expertise and a focus on solutions, we combine the latest technologies, robust processes, and a flexible approach to ensure data quality and integrity.

Cmed's Services:

- Database design for eCRF and eSource
- Validation and maintenance of your database to meet protocol needs
- Creation, maintenance, and governance of sponsor-specific eCRF libraries
- Data validation specifications, programming, and testing
- Data loading and/or integration with IRT and other external systems for efficiency and data consistency
- Comprehensive data management planning and documentation
- Medical coding using standard dictionaries including MedDRA and WHODRUG
- Reconciliation of SAE and external data
- Clinical data quality review for inconsistencies, trends, and outliers
- Production and review of live clinical trial metrics

Key experience

12+ Years
AVERAGE EXPERIENCE OF LEAD DATA MANAGERS

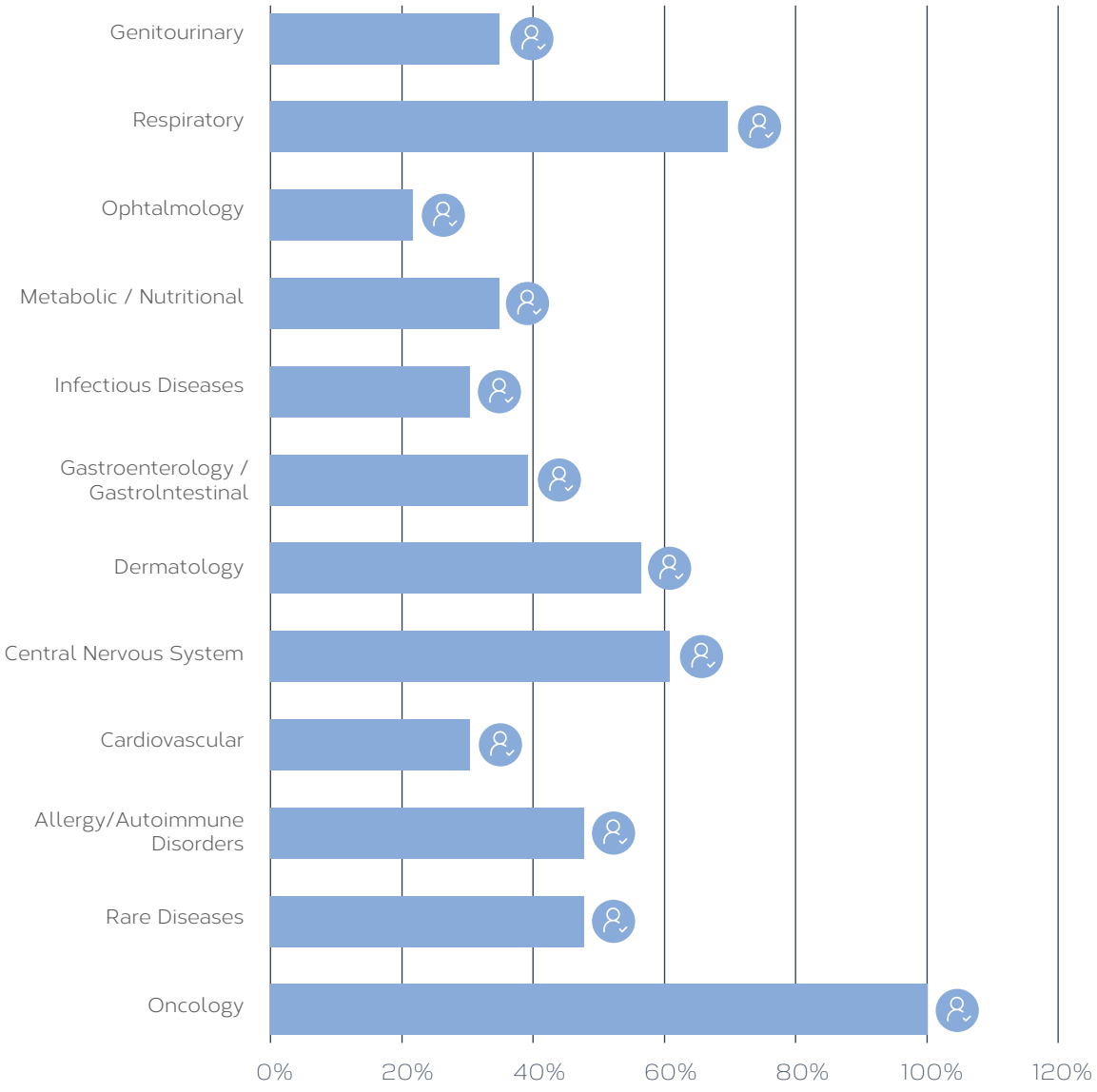
- Experience across Phases I - IV extending to registries and observational studies
- >95% databases have external third-party data integrated with clinical data
- Long term studies (up to 12 years) with annual interim analyses
- Experience of a range of EDC systems including encapsia, Medidata Rave, and Oracle InForm

Cmed manages critical deliveries within tight timelines:

8 Weeks
DATABASE RELEASES WITH ALL EDIT CHECKS

3 Weeks
DATABASE LOCK

Lead DM Experience by Therapeutic Area



> "We have a very efficient collaboration because you know and understand the study very well and can translate our needs into data."

Clinical Project Manager in Biotechnology Company

Biostatistics

Our Biostatistics Team adds value to your project with strong expertise in clinical study design and data analysis. We provide high quality CDISC compliant datasets together with insightful statistical analysis.

Core Services:

- Statistical input to trial design and protocols, including sample size calculations
- Randomization strategies and treatment allocation lists
- CDISC compliant SDTM domains, ADaM datasets and additional eCRT package supporting documents
- Statistical analysis plans
- Programming and production of interim and final tables, figures, and listings
- Statistical consultancy, including publication/abstract support, ISS and ISE delivery
- SMCs and the provision of independent statisticians for IDMCs

Key Experience:

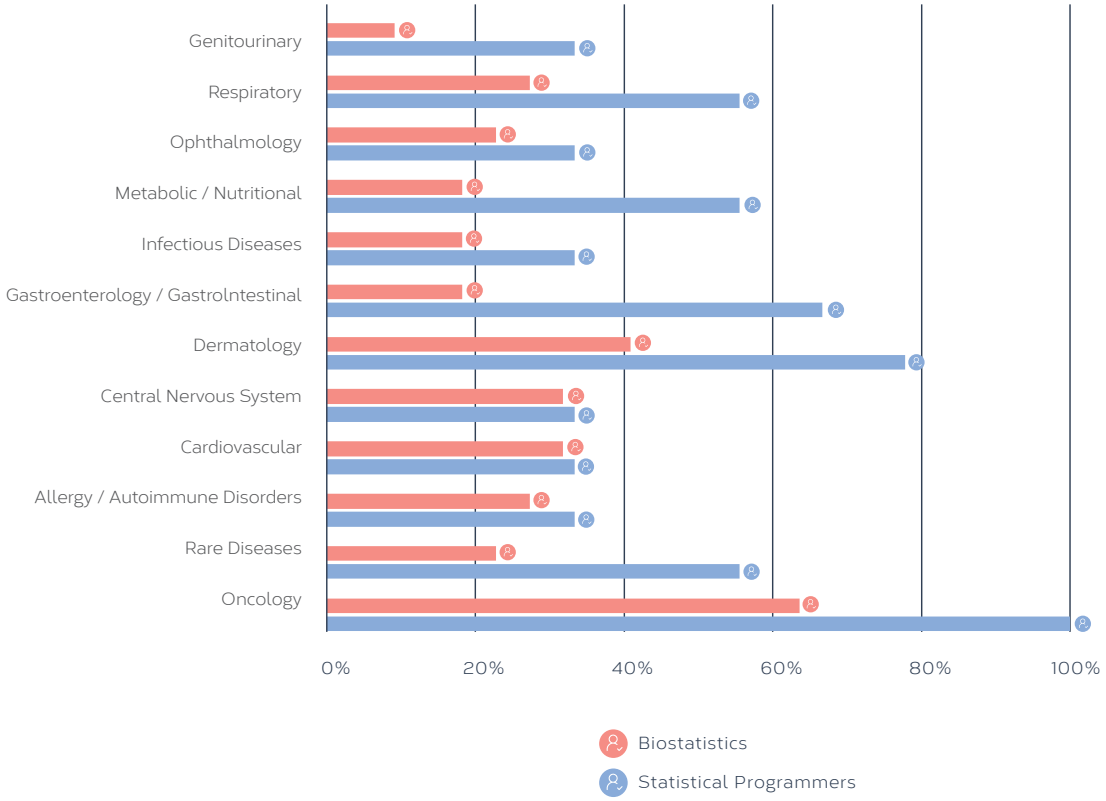
- Biostatisticians have on average > 15 years industry experience
- Senior statistical programmers have on average > 10 years industry experience
- Experience across Phases I - IV and all therapeutic areas
- Experienced in complex and adaptive study designs
- Experienced in programming with SAS and R
- CDISC conversion experience

Cmed manages critical deliveries within tight timelines:

100%
INTERIM AND FINAL DELIVERIES ARE EARLY OR ON-TIME

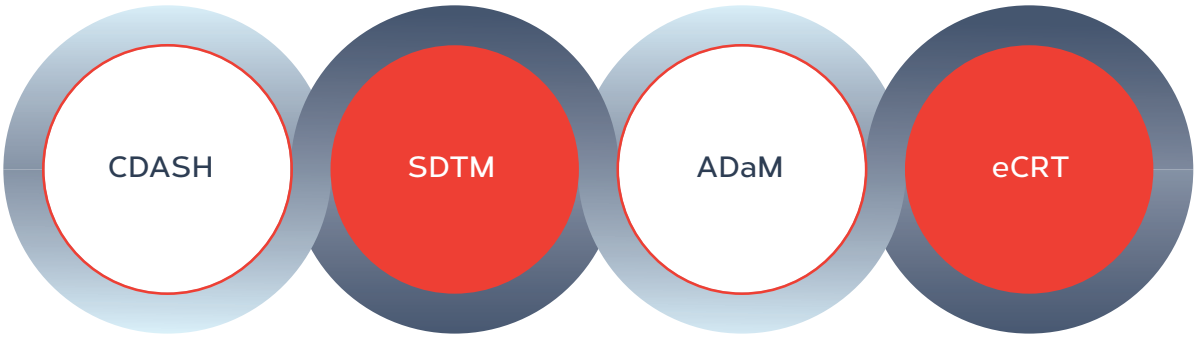
5 Days
FROM DATABASE LOCKS TO TOP LINE RESULTS

Biostatistics staff experience by therapeutic area



Ensuring Regulatory Compliance With CDISC

Adhering to industry standards



- eCRFs and databases built according to CDASH
- Client specific CDASH based libraries defined and built

- Data extraction and mapping to SDTM from CDASH
- Programming and validation of SDTM domains
- Conversion of non-CDISC studies to SDTM

- Programming and validation of ADaM datasets

Provision of:

- SDTM annotated eCRF
- Define .xml for SDTM and ADaM with reviewers guides

Proven scalability and management of large data volumes

Cmed routinely works with both large data or programs of studies

Large Data Volumes:

- Single large studies with thousands of patients
- Registries
- Observational studies
- Real World Data
- Prospective and retrospective collection of data

Key Success Factors:

- Flexible team structures adapt to study design changes and sponsor needs
- Powerful modern system architecture designed for speed and scalability
- Rapid incorporation of multiple data sources (e.g., ePRO, Laboratory Data, IRT)
- Key progress updates and summarization of study metrics for easy oversight
- Real time visibility of clinical data and status
- System adaptability (e.g., study vs country vs site access management)

> "I would like to express our thank you for your hard and smart work, professionalism and that the team always strived to give the best on the project."
>
> *Chief Medical Offi cer & EVP*
> *Leading biopharmaceutical company*

Functional Service Provision

We have extensive experience in governance, management, and partnership as a Functional Service Provider for both pharma and biotech companies. Our approach is tailored to your requirements and adapted as the partnership evolves.

Key Success Factors:

- Flexible team structures
- Governance model with clear leadership, goals, and implementation strategies
- Customized partnership approach
- Proven project control with key progress updates for easy oversight

ORGANIZATIONAL SET-UP

- GOVERNANCE IMPLEMENTATION
- RESOURCE MODELS
- ROLES & RESPONSIBILITIES

FUNCTIONAL EXPERIENCE

- MATURE PROCESSES AND TRAINING
- COMPLEX DESIGNS AND UPGRADES
- EXPEDITED DELIVERIES

PROJECT CONTROL AND MANAGEMENT

- PROJECT PLANNING
- TEAM COORDINATION
- FOCUS ON DELIVERY

TECHNOLOGY AND SYSTEMS

- RANGE OF EDC PLATFORMS
- DATA INTEGRATION AND REPORTING
- SCALABILITY AND PERFORMANCE

Systems and technologies

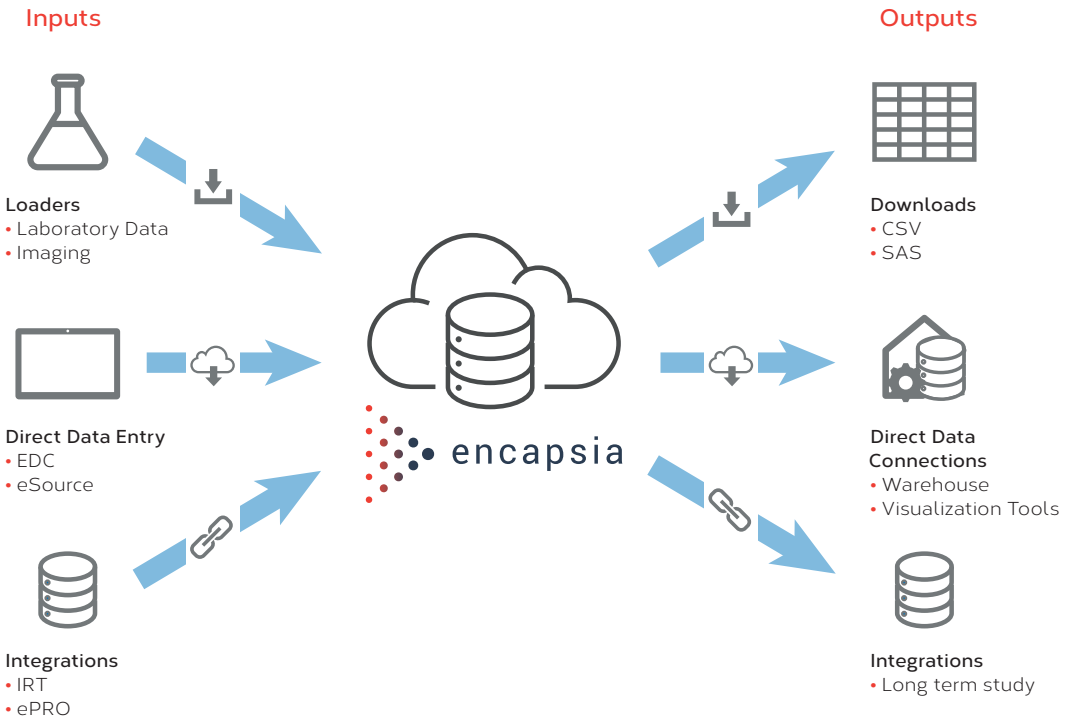
Our teams have developed, customized, and integrated multiple technologies for fast, quality deliveries for 22 years. All our solutions are fully validated and have been successfully audited multiple times.

System Experience:

- Encapsia – the only holistic clinical data platform
- Medidata Rave
- Oracle InForm
- SAS
- IBM Cognos BI
- Microsoft Power BI
- TIBCO SpotFire

Our preferred clinical data system is encapsia. Designed to incorporate data quickly from multiple external sources using various methods including integrations, uploads and direct entry, encapsia allows Cmed teams collate and visualize all data, in one single database.

With a powerful system like encapsia, we can provide flexible options in terms of data output including integrations, direct data connections (for data streaming), and downloads.



Live data visibility

Our use of encapsia means you'll have instant access to a library of data visualizations for effective data and medical review. Through interactive and actionable insights, the whole study team will be empowered to monitor, comment, and react to the same set of live data from within the same system.

Examples include:

- SAE/AE Timelines and interactive reports for detailed review by Safety Review Committees
- Site scoring dashboards support risk-based monitoring
- Online patient profiles allow immediate medical and data-driven decisions
- Visualizations support detailed review of data trends, outliers, and patterns
- Study metrics and timelines for close sponsor oversight

Bring your data to life with interactive, actionable visualizations

Standard library of >50 clinical data visualizations and reports

Standard visualizations are applied to your study and available immediately from database release

Cmed Data and Analytics services offer

- Experience and expertise across therapeutic areas and study phases
- Professional, dependable, and cost effective customer service that builds long term relationships
- Rapid deliveries with a focus on data quality and integrity
- Powerful and innovative technology to make the best of your data
- Loyal, stable team with high staff retention

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Let's Talk

Get in touch with us today to discuss your upcoming clinical trial needs and how our experts can help.

We anticipate. We adapt. We embrace every challenge. We are where you want to be.

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