Clinical data science services

By leveraging cutting-edge AI and machine learning capabilities, Cognizant revolutionizes the landscape of clinical trials and brings unparalleled value to its clients.

Our bespoke Functional Services Partnership (FSP) solutions, augmented by our partner's innovative technologies, enable intelligent connectivity between data, analytics and operational expertise.

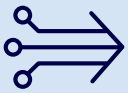
This synergy allows us to effectively address complex clinical trial challenges, craft patient-centric trials, and enhance data transformation, integrity and quality to achieve maximum efficiency.

End-to-End capabilities in Clinical Data Management

Consulting

Study set-up

Study conduct



Study closeout

End-to-end capabilities in CDM

CDM services across diversified customer portfolio - Pharmaceuticals, Devices, Consumer Health, Biologics & Vaccine

Digital Clinical Platform, eCOA & IRT support, Product Customization & Validation, Application Support, R&D, Reporting & Analytics, Integrations & Migrations, Standards Library management, Domain Consulting & Business Analysis

Consulting

- Clinical Data Business Strategy
- Business Process Transformation
- Automation and Optimization of Process
- Center Of Excellence (CoE)
- Data Migration
- Clinical Data Scientist (CDS)
- Data Standards Standardization/mapping support
- Global library streamlining for existing, new Standards and components
- Quality Framework
- Training Services

Study set-up

- Clinical Protocol Review
- Paper/Electronic case report form Build
- CRF/eCRF Specifications & Annotation
- Data Management & Review Plan
- Edit Checks specification & Programming
- EDC Report setup
- User Acceptance Testing
- Third Party Data Specification creation and Set-up
- ePRO (electronic Patient Reported Outcome) validation and setup
- Dictionary Set up
- Risk Based Quality Management

Study conduct

- Third Party Data Transfer & reconciliation
- Data Review and Query/Discrepancy Management
- Medical Coding
- Serious Adverse Event Reconciliation
- Medical Data Listings
- Quality Control Plan
- Database amendments/Migrations
- Dictionary update and UAT

Study closeout

- Interim Database Closure
- Pre-lock Checklist
- Database Lock
- Relevant project closure documentation, Database Archival/Decommissioning
- Record Retention
- Study Data Transfer
- eTMF Filing of CDM documents

"Ready to go"

Global delivery infrastructure	Program change & communication management	Quality & audit compliance management	Transformation & innovation management

Our end-to-end capabilities in biostatistics & statistical programming

01

Inputs to protocol design

- Contribution to Protocol Synopsis & Final Protocol
- Sample Size calculations
- Contribution/Authoring of Statistical section of the Protocol
- CRF review & inputs to CRF Design

02

Randomization

- Executed 80+ randomizations on sponsor systems
- Review of IVRS/IWRS specifications
- Support for blinded and un-blinded IDMC/DSMB

03

SAP

- Created SAP templates aligned to processes & TA
- Inclusion of sample SAS code for statistical model Till date we have authored 65+ Statistical Analysis Plans.
- Typically, we aim to finalize SAP within three to four weeks post receiving finalized protocol or synopsis

04

Mock shells

- Created guidance document for mock shells
- Created template repository to streamline process and increase efficiency
- SAP, Mock Shells and Programming Specification activities run in parallel to save

05

Programming specification

- Automated predefined mapping rules for SDTM & ADaM
- Metadata mapping specs used directly to generate Define.XML

06

SDTM/ADAM

- Mapping CDASH to SDTM for standard SDTM modules
- Developed Safety SDTM, ADaM mapping standard
- Submission Package
- Submission Packages including SDRG/ ADRG, Annotated CRF and Define
- SDTM conversion for legacy Raw or ADS datasets

07

TFLS

- Created utility Macros for quality and efficiency for reporting
- Creation of customizable reports as per customer requirements
- TLFs creating with R

08

CSR

- Front loading CSR creation before DBL - Draft CSR within 2 weeks from SAS output
- Finalization of CSR within 30 days of SAS output (section 11 & 12) Creation of Web Synopsis & abstract within 01 week of Final CSR

Project Level

ISS / ISE	Pooling of data	DSMB / DMC Support	Data Conversions	Meta Analysis
DSUR / PSUR	HEOR	Independent Statisticians / Programmers	Adjudication Committee support	Genomics / Proteonomics

Process Consulting

TA guidelines / TA specifications

SOP development

Standard for reporting

Clinical Data Management, Biostats & Statistical Programming Services Capabilities

10	Global delivery locations across EU, Latam, US, Apac	50+	Biostatisticians	100+	Associates trained on DCT platforms
20+	Supporting Global to Bio Pharma & Med Techs for Clinical Data	200	Statistical Programmers	2600+	Studies mapped to CDISC standards
19+	Years of rich Clinical Data Management	800	Rave Certified Professionals	30+	Trained professionals
2700	Clinical studies supported till date	1000+	Veeva trained Professionals	80+	Trained professionals on CDISC standards
15+	Supporting projects for Biostats & Statistical Programming	100+	Internal certification on Demystifying Clinical Data Science		
9000	Resources Globally across	200+	SAS certified professionals		
1300+	CDS Expert	220+	Python certified professionals		
06+	EDC platforms for end-to-end	40+	Unique Indications Expertise across multiple		

Tools and Accelerators

CCMH Clinical Study Build Solution

CCMH (Cognizant Clinical Metadata Hub) 20-25% potential reduction in cost, cycle time & risk using proactive performance mgmt. hub for study build

CARE

20-25% potential cycle time reduction through automated analytics and reports in biostats

Similarity Tool

Python enabled tool to compare similarities between SAS codes and compare changes in RTF outputs file or datasets

Data Anonymization Tool

Python enabled Data Anonymization for SAS data bases to share with other institutions as per data privacy rules

Data Quality and Testing

Automated Test Data Creation & loading in EDC for efficient & effective Testing

Rapid Pro®

Content migration solution for clinical systems like eTMF and CTMS

Value Proposition and Advantages of our FSP model

Integrated best in class modular solution with established technology partners

Program Governance

- Ownership / accountability of defined tasks
- Alignment between Client and Cognizant on expected outcomes

Proven Expertise

- Core team of experts for operational synergies and efficiencies
- Expertise in implementation and support of proven solutions and emerging technologies

Accountability

- Cognizant to own end-to-end process management, technology stack, resources and business outcomes
- Cognizant is responsible for oversight of its partners

Risk Free & Faster Transition

- Minimal Disruption
- Experience of complex and time bound transitions
- Migration of legacy cases

End-to-end customizable tech enabled Biometric solutions

- Power of automation with industry established partners
- Modular, pre-validated, customizable, plug and play Technology ecosystem

Focus on Quality and Compliance

- Robust Risk and Quality management and Audit Readiness
- Monitor regulatory requirements warranting additional controls and reports

Flexibility & Transparency

- Agile and Modular solutions catering to client specific requirements
- Operational transparency & client centric approach

Cost Saving

- Cost efficient operations
- Leveraging low-cost delivery locations

Our deep experience and expertise in domain services

To multitude of clients across major TAs & rare diseases portfolio over 19 years

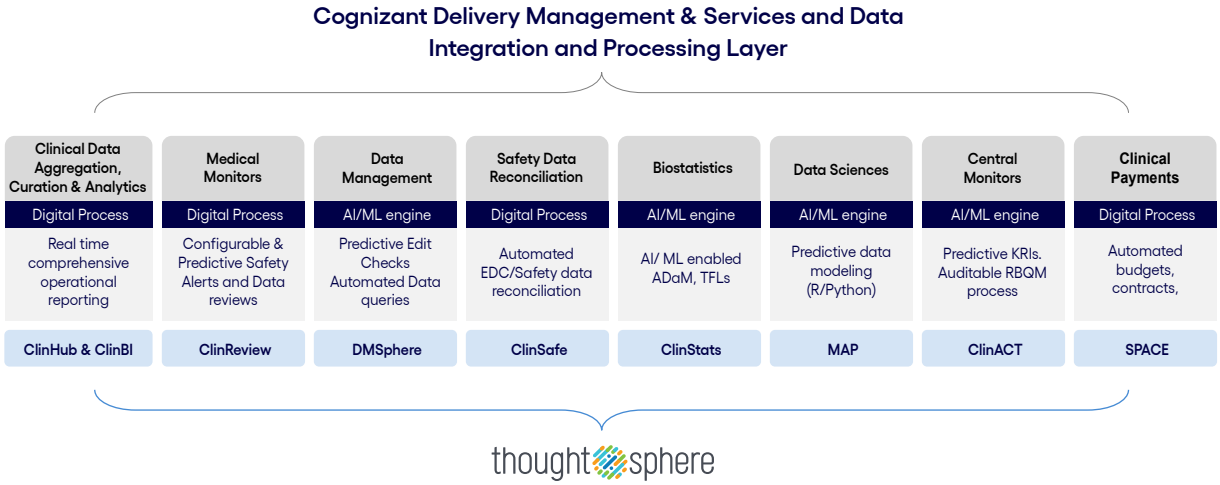
Next Gen Technology ecosystem

Bringing best in class domain Tools enabled with Next Gen technology, GenAI and Hyperscalers covering all aspects of CDM, Biostats life cycle

Full Accountability

Of business services and technology to drive innovation, automation and efficiency

Intelligent Integration_Enabling the End-to-End CDS Delivery Model



EDC & Key Database Partnerships

MEDIDATA viedoc Veeva

Medable medrio ORACLE ARGUS SAFETY

sas yseop

Leverage Hyperscalers for building custom CDS solutions using Gen AI

Google Microsoft aws

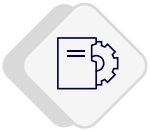
A Unique Proposition For CDS Strategy

Unified platform
for comprehensive Data Cleaning, Aggregation & Processing

Adaptive study design set up
Experience in Medical Device, Decentralized trials

Superior study monitoring
data insights hence faster time to market

eCOA Platform
Development, Implementation, Testing, Validation and Helpdesk support



RBQM Support
Risk Assessment, QTLs & KRI Set up, Centralized Monitoring

Database migration & integration
support and customization

eTMF Expertise
TMF Management and Oversight

Decentralized Clinical Trials
with Unified Clinical Platform

Multiple Clinical Data Repository
Set Up & Customisation

Dedicated CoE model
UAT, Spec Writing, Report Development, Lab Data & Project Management

IRT Capabilities
Helpdesk support, UAT and End-to-End Services

Partnership
with leading EDC providers **Veeva, Medidata RAVE & Oracle**

Powered By

Proven Established Global delivery

Proven Expertise & Trusted Partner

Leadership - Domain & Life Sciences Industry

Industry leading training framework

Global talent acquisition expertise

Our Industry Leading & Award-Winning Competency

Industry Recognitions

Key Recognitions

- Leader in Intelligent Process Automation (IPA) Solutions PEAK Matrix® Assessment 2024
- LEADER in Avasant's Clinical Data Management BPT Services 2024 RadarView™
- Leader in MedTech Operations PEAK Matrix® Assessment 2023
- Leader in Life Sciences Operations PEAK Matrix® Assessment 2023
- LEADER in IDC LS R&D ITO & BPO Capabilities (2021 - 2022)
- LEADER in Life Sciences Veeva services (2021)

International Awards for human capital management

Key Recognitions

- Fortune America's Most Innovative Companies 2024
- America's Greatest Workplaces for Diversity 2024
- LinkedIn Top Employer in India
- Best Employer for Excellence in Health & Well-being by the Business Group on Health.

International Awards for Excellence in Talent Development

Key Recognitions

- 12 Golds, 2 Silver, 2 Bronze from Brandon Hall
- 3 Excellence in practice from ATD
- Best Certification training program (2024, 2023, 2022, 2018)
- Best Certification Program for Clinical Data Sciences (2022)
- Therapeutic Areas training strategy, Campus training (2022)
- Learning culture at Life Sciences (2022)
- Best Learning and Development team (2019)
- Unique / Innovative

cognizant

Cognizant (Nasdaq-100: CTSH) engineers modern businesses. We help our client to modernize technology, reimagine process and transform experiences so they can stay ahead in our fast-changing world. Together, we're improving everyday life. See how at **www.cognizant.com** or **@Cognizant.**

World Headquarters
300 Frank W. Burr Blvd.
Suite 36, 6th Floor
Teaneck, NJ 07666 USA
Phone: +1 201 801 0233
Toll Free: +1 888 937 3277

European Headquarters
1 Kingdom Street
Paddington Central
London W2 6BD England
Phone: +44 (0) 20 7297 7600

France Headquarters
5 place de la Pyramide
92800 Puteaux
France
Phone: +33 1 70 36 56 57
Email: Contact-France@cognizant.com

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