CLINICAL DATA FOR PHARMACEUTICAL RESEARCH

Tools and Services for Clinical Trials

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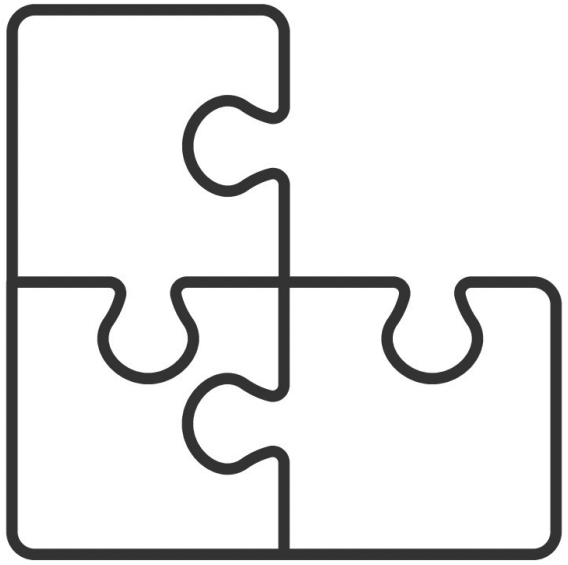
CLINICAL DATA FOR PHARMACEUTICAL RESEARCH

TECHNOLOGY, STATISTICS & DATA MANAGEMENT FOR CLINICAL TRIALS



We assist clinical trial teams in the pharmaceutical industry to collect, manage and analyse their data by offering an integrated, coordinated suite of tools and services.

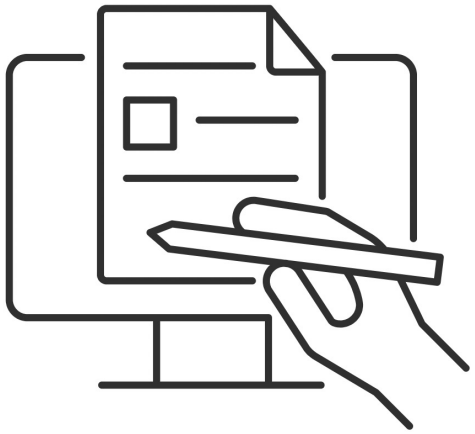
TECHNOLOGY, STATISTICS & DATA MANAGEMENT FOR CLINICAL TRIALS

CLOUD SOFTWARE AS A SERVICE FOR CLINICAL DATA

We have developed a flexible clinical data collection & data management system that can be easily adapted to complex requirements, allows the quick set-up of a trial's database and forms, and offers monitoring of trial progress and of data quality. Offered as Cloud SaaS.

CLOUD SOFTWARE FOR CLINICAL DATA

CLINICAL DATA COLLECTION, MANAGEMENT, MONITORING AND REPORTING

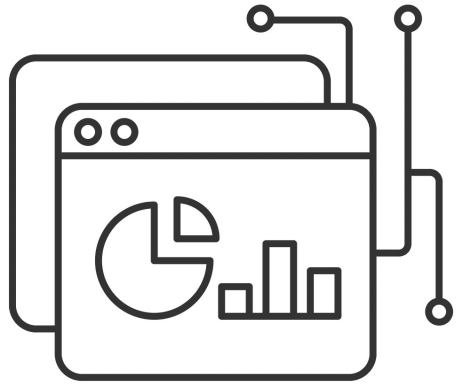


✓*Security*:	Secure Cloud data hosting in segregated study databases
✓*Collection*:	Dynamic eCRF, ePRO/COA, data entry validation, AE/SAE submission and PV notifications,
✓*Complex data*:	Medical imaging data, interactive image-based data entry, lab and PK data, device data
✓*Process*:	Subject enrolment, e-Signatures, secure audit trail, data export and archiving
✓*Monitoring*:	DCF/SDV, monitoring dashboards, study progress indicators, Safety Data Management and Reconciliation
✓*Documents*:	Trial document repository, eCRF document attachments and uploads

CLOUD SOFTWARE FOR CLINICAL DATA

SPECIALISED CLINICAL TRIAL SOFTWARE TOOLS

- ✓*IWRS*: Single and double blind interactive subject randomisation
- ✓*Adjudication*: Blind clinical image examination assessment and adjudication
- ✓*Visualisation*: Interactive real-time visualisation charts and tables for study endpoints, adverse events
- ✓*ePROs*: Controlled distribution of multilingual PRO questionnaires to subject mobile devices
- ✓*Scoring*: Automated scoring algorithms (e.g. QoL questionnaires)
- ✓*Custom Tools*: Design and development of custom features or tools to meet complex requirements



TECHNOLOGY, STATISTICS & DATA MANAGEMENT FOR CLINICAL TRIALS

STATISTICAL ANALYSIS AND CLINICAL DATA REPORTING

Statistical analysis for each stage of a trial, from inception, study design and protocol review, to statistical analysis plans, to conclusive statistical analysis and reports.

✓*Study Design:* Sample size calculation, statistical review of protocols and CRFs, controlled randomisation lists

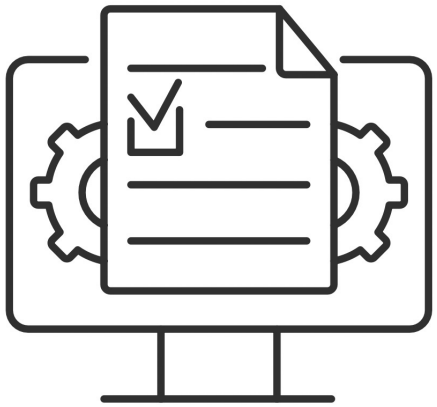
✓*SAP/CSR:* Statistical Analysis Plans and Statistical Efficacy and Safety Reports according to ICH guidelines, statistical review of Clinical Study Reports

✓*Reporting:* Statistical programming for the consistent production of TLFs and quality statistical reports

✓*Exploratory:* Advanced data analysis methods for clinical data exploration

TECHNOLOGY, STATISTICS & DATA MANAGEMENT FOR CLINICAL TRIALS

CDISC STATISTICAL PROGRAMMING



cdisc

✓*CDASH*:	CDASH coding of CRFs, CDASH annotated CRFs
✓*SDTM*:	Production and validation of CDISC/SDTM tabulation of clinical data
✓*ADAM*:	Statistical programming for the production and validation of CDISC/ADAM analysis files
	Analysis and regulatory submission level reporting based on ADAM files

TECHNOLOGY, STATISTICS & DATA MANAGEMENT FOR CLINICAL TRIALS

ENSURING DATA QUALITY AND REGULATORY COMPLIANCE FOR CLINICAL DATA MANAGEMENT

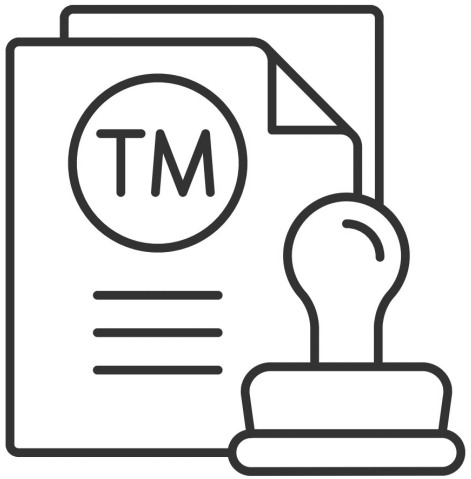
We manage our clinical trial databases, from routine and planned data management tasks to ad hoc reporting and risk assessment, using documented and controlled GCP compliant standard procedures.

✓*Planning*: Data Management Planning, Data Validation Plans

✓*Monitoring*: Data Quality monitoring tools and reports for risk assessment

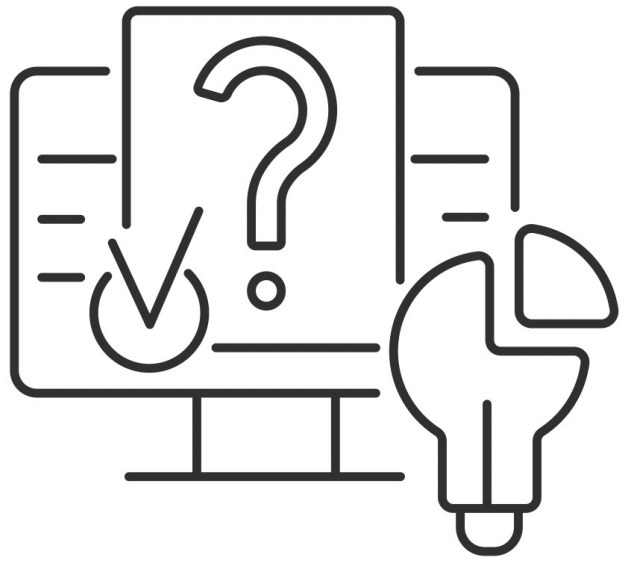
✓*Support*: Training and support for investigators, CRAs and monitors

✓*Data Tasks*: eCRF setup, study initiation to DCF/SDV monitoring to DB lock & unblinding



CLINICAL DATA FOR PHARMACEUTICAL RESEARCH

EXPERIENCE AND KNOW-HOW



✓ *A stable management team of highly qualified software engineers and biostatisticians that have worked together in clinical trials for many years.*

✓ *We have worked for specialized CROs, sponsors, including most major multinational pharmaceuticals and innovative biotechs, research institutes and academia, international organizations and government bodies*

✓ *From small-scale but complex Phase I and II clinical studies, to demanding Phase III and meta-analyses for regulatory submission, to large scale, multi-centre, multi-country multilingual post marketing trials and patient registries*

EXPERIENCE
& KNOW-HOW

SHOWCASE PROJECTS: Clinical Trial Software

✓ A coordinated post-marketing clinical trial in more than a dozen countries for a major multinational pharmaceutical, including multilingual ePROs sent to patient mobile devices

✓ A system for blind clinical assessments and adjudication of scintigraphy medical images for a major multinational pharmaceutical

✓ Real-time monitoring of critical endpoints and vital signs through interactive & dynamic charts and data tables for a Phase III trial of a COVID-19 therapy for a US/GR biopharma

✓ eCRF with interactive image-based data entry of exact body locations of symptoms for a dermatological patient registry

✓ eCRF with medical image upload and display for eye-surgery

EXPERIENCE
& KNOW-HOW

SHOWCASE PROJECTS: Biostatistics & Statistical Programming

✓ Meta-analysis of pooled data from Phase I/II and Phase III clinical studies for efficacy and safety analysis for a new drug for a Swiss pharmaceutical. Preparation of CDISC/ADAM files and analysis programs for regulatory submission all studies and meta-analysis

✓ CDASH eCRF coding and SDTM & ADAM CDISC data files for a Phase I trial for a Swedish biopharma

✓ Statistical analysis of clinical assessment discrepancies in a blind adjudicated clinical assessment process of medical imaging in a Phase IV clinical study for a Greek pharmaceutical

✓Exploratory data analysis of pooled data from past trials for dosage optimization and target patient cohort specification for a multinational pharma and medical device manufacturer.

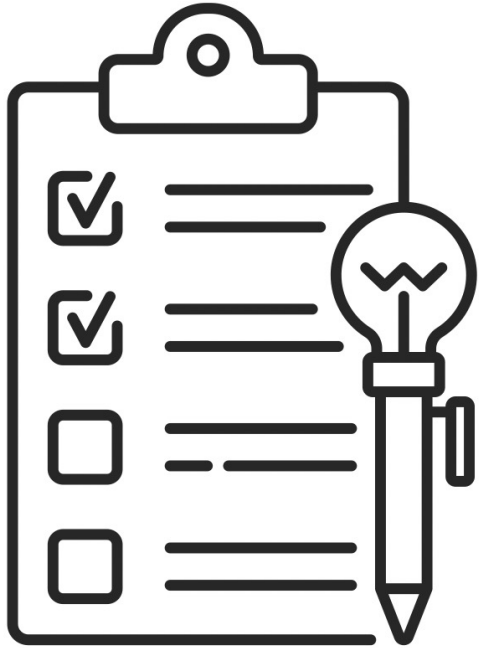
CLINICAL DATA FOR PHARMACEUTICAL RESEARCH

STANDARDS, QUALITY & COMPLIANCE

✓ Committed to apply applicable international and industry standards in all aspects of our work. From ICH E3 for statistical reporting and SCDM's GCDM practices to GAMP for software validation and Agile Software Development Life Cycle. And of course, CDISC.

✓ Operating under a certified ISO9001:2015 Quality Management System.

✓ Controlled and audited SOPs to ensure GCP compliance.



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AGILIS

Agilis has been founded in 1998 with a strong commitment in technology and statistics. Since then we have developed innovative technological solutions for data intensive applications and provided in-depth statistics consulting to international organisations.

Our involvement with technology and statistics for clinical trials started more than ten years ago out of academic research and since then clinical trials have become our primary business and the focus of our technological and scientific strategy.

We have provided high quality services in dozens of countries in four continents, we have actively participated in international standardisation initiatives and we know how to become team members in the teams of our customers, rather than mere vendors or suppliers.

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