StatistX EDC

ELECTRONIC DATA CAPTURE FOR CLINICAL TRIALS

Clinical data, right the first time.

A complete, validated EDC for clinical trials, with randomization, ePRO and safety reporting built in. Designed, hosted and supported by StatistX.

- Built for 21 CFR Part 11
- Randomization
- ePRO
- SAE reporting
- CDISC SDTM export



Fast study setup

Send us the protocol: we **draft the whole study design**, you review it and try it in a test copy before going live.

Changes without drama

Protocol amendments become **new design versions**; the data follows, and every step stays in the audit trail.

Monitoring at a glance

Reports on **enrollment, overdue visits, open queries, SDV and signatures** by site, in Excel or PDF.

Support and training

Training for your team, a built-in help center with required reading and training records, and fast answers.

Everything a trial needs, in one system

No separate tools to connect

Study design

Visual form and visit-schedule builder, standard CDASH forms, skip logic, calculations and edit checks. Versioned releases and test copies.

Easy data entry

Subject page and visit grid, checks as you type, lab results flagged against each site's normal ranges, adverse event and medication logs.

Clean data

Automatic and manual queries, source data verification, MedDRA and WHODrug coding, investigator signatures, and locks from a form to the whole study.

Randomization

Your lists, per study or per site, with stratification and eligibility checked from the forms. Blinded or open-label, with emergency unblinding.

ePRO portal

Diaries and questionnaires on the subject's phone, in multiple languages, with reminders, compliance tracking and safety alerts to the site.

SAE reporting

Serious adverse events reported from the AE log, with the 24-hour clock, the investigator's signature and the sponsor's distribution list.

Analysis-ready exports

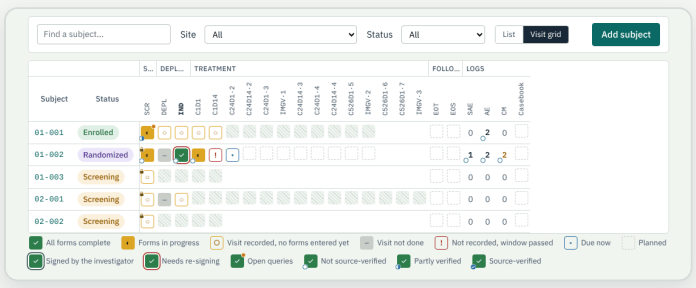
Excel, CSV, SAS, SPSS and R files with labels and formats, and CDISC SDTM with define.xml.

Compliance by design

An audit trail kept by the database itself, electronic signatures, reasons for change, roles per study and site, two-factor login.

Hosted and validated

On Amazon Web Services, with nightly backups and monthly restore tests. IQ and OQ reports with every release.



The visit grid: every subject's visits and forms at a glance.

A partner, not just a vendor.

You work directly with the experienced biostatistician and data manager who built the system, from the first draft of the study to the final export. No call centers, no ticket queues: your questions reach someone who knows your trial.

Planning a trial?

Let's talk about your protocol, timelines and data needs.

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