NOVASYNE

STUDYPRO

User Guide

Run a clinical trial end to end — subjects, consent, recordings, signals, analysis and the money — with every change written to an audit log you can read.

Version 1.0 August 2026

Novasyne · Clinical trial management

Contents

Before you start

STUDYPRO holds a clinical trial: the people in it, what was consented, what was collected, what the signals look like, what the analysis says, and where the money went. It is one place rather than a folder of spreadsheets, and every change it accepts is written to an audit log that reads back in plain language.

Three things are worth knowing before the first screen.

Access is per study, and it is granted by email. Having an account does not give you a study. Someone who administers the study adds your email address to it, and that is what makes it appear in your list.

Nothing here is deleted quietly. Removing a subject's identifying details is a deliberate, irreversible act with its own button and its own wording, and it leaves the clinical record intact. Revoking a study is separate again, and says so.

The AI features are optional and off by default. They need an OpenAI key against the study. Everything else — import, subjects, recordings, the signal viewers, every statistical analysis in this guide, finances, export — runs without one.

What you need

The application	Running and reachable in a browser. See DEPLOYMENT.md for installation.
An account	Registered with your work email, confirmed by the link you are sent.
A study	Created by you, or one you have been added to by email.
An OpenAI key	Only for the AI analyses and the research assistant.

The study in this guide

Every figure comes from one study: **CARDIO-SLEEP: Omega-3, Sleep Quality and Cognition** — a randomised, placebo-controlled trial of omega-3 supplementation on sleep quality, cardiometabolic markers and mood. Twenty-four subjects in two arms, roughly 1,100 recordings, four study documents, and a budget of $185,000. It was itself imported from a REDCap export, which is the subject of the last part of this guide.

The public side

The front page

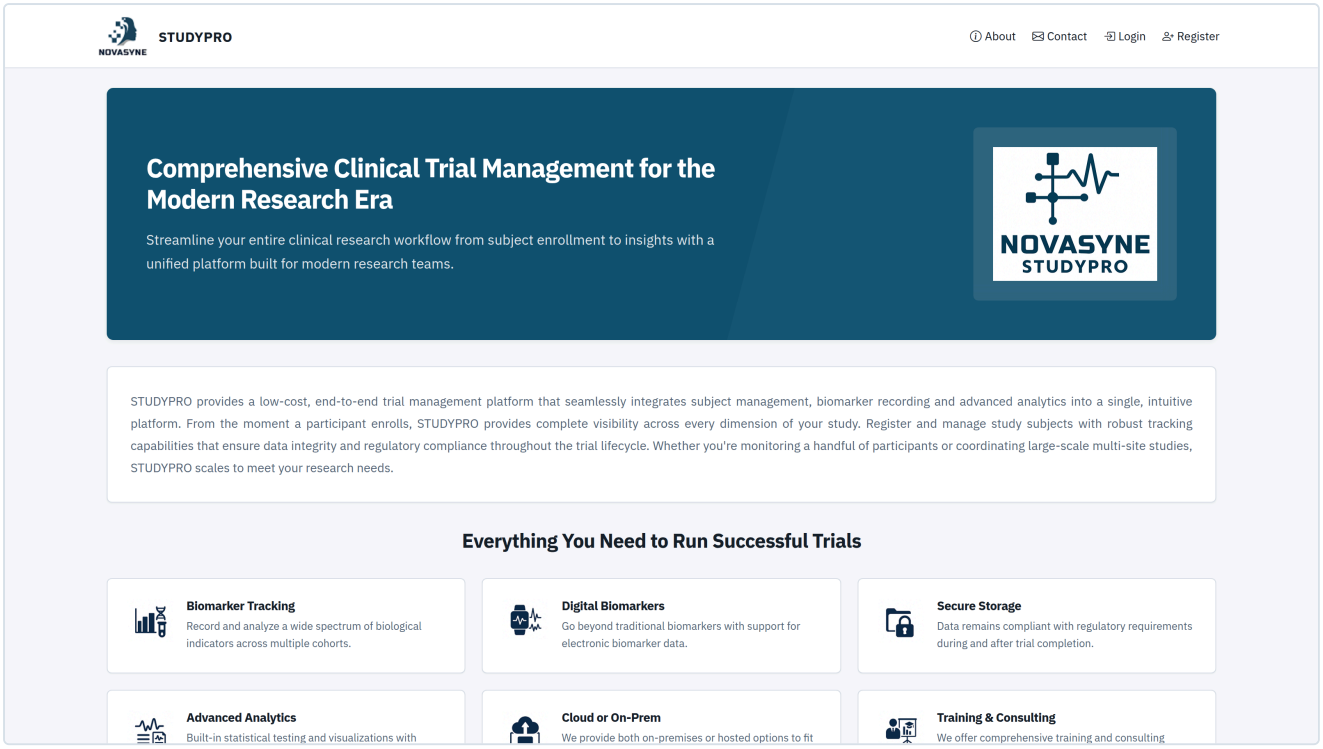


Figure 1 — The front page.

Everything before sign-in is a description of the product rather than part of it. It matters for one reason: this is what a collaborator sees when you send them a link, before they have an account.

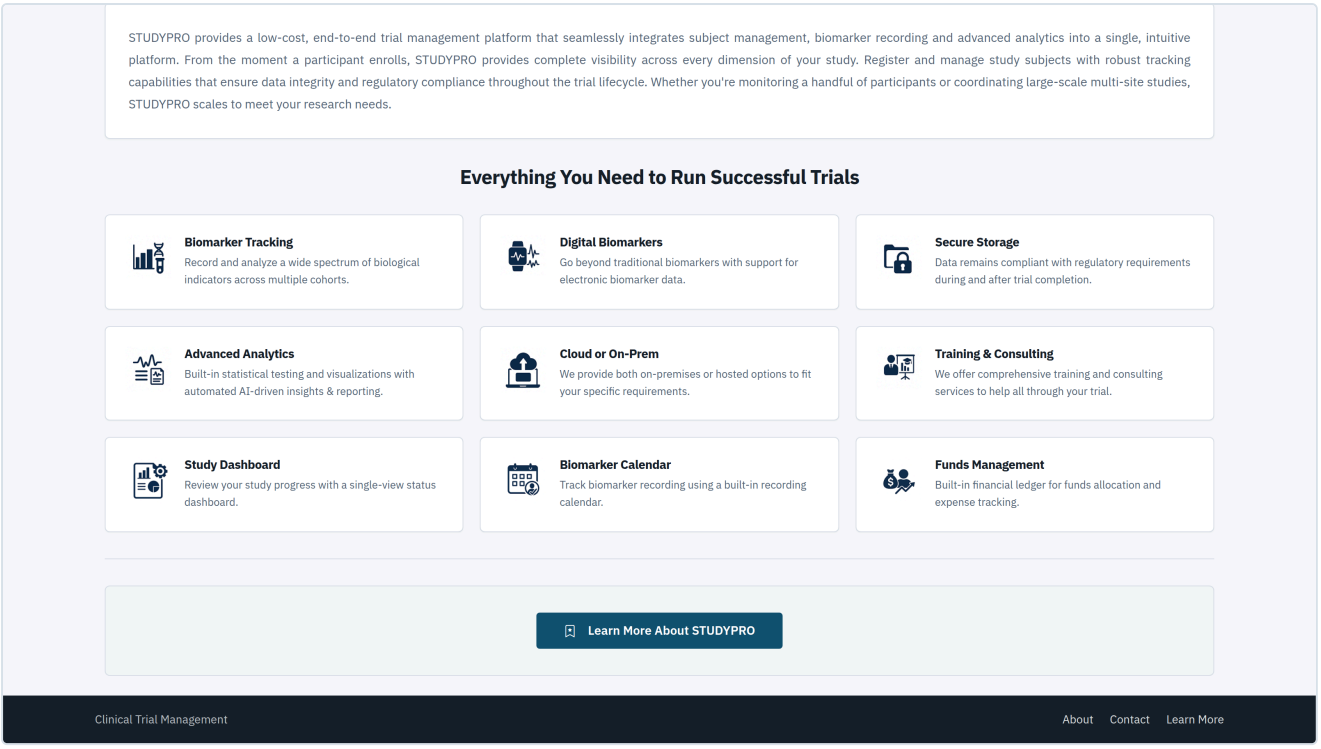


Figure 2 — What the platform claims to do.

The longer tour

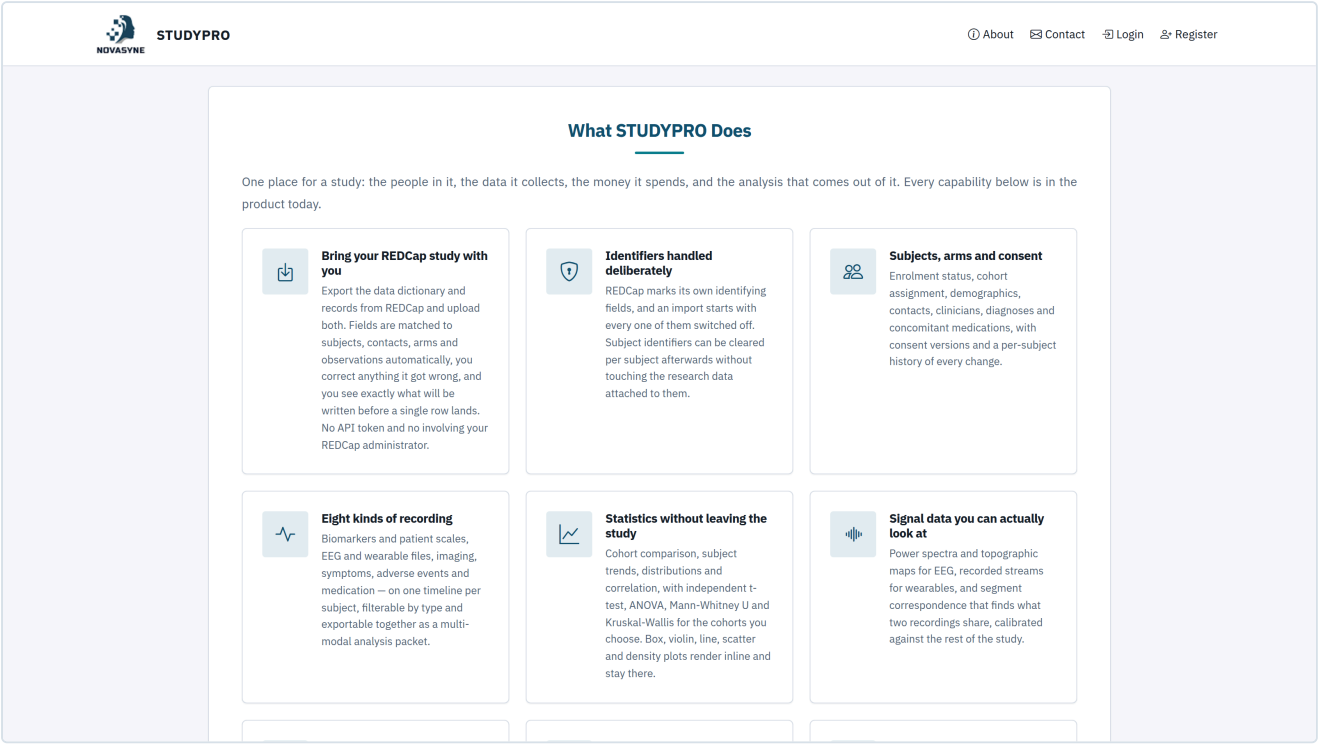


Figure 3 — The tour.

Learn more walks the same ground in more detail — what a study holds, what the analysis bench does, what the signal viewers read.

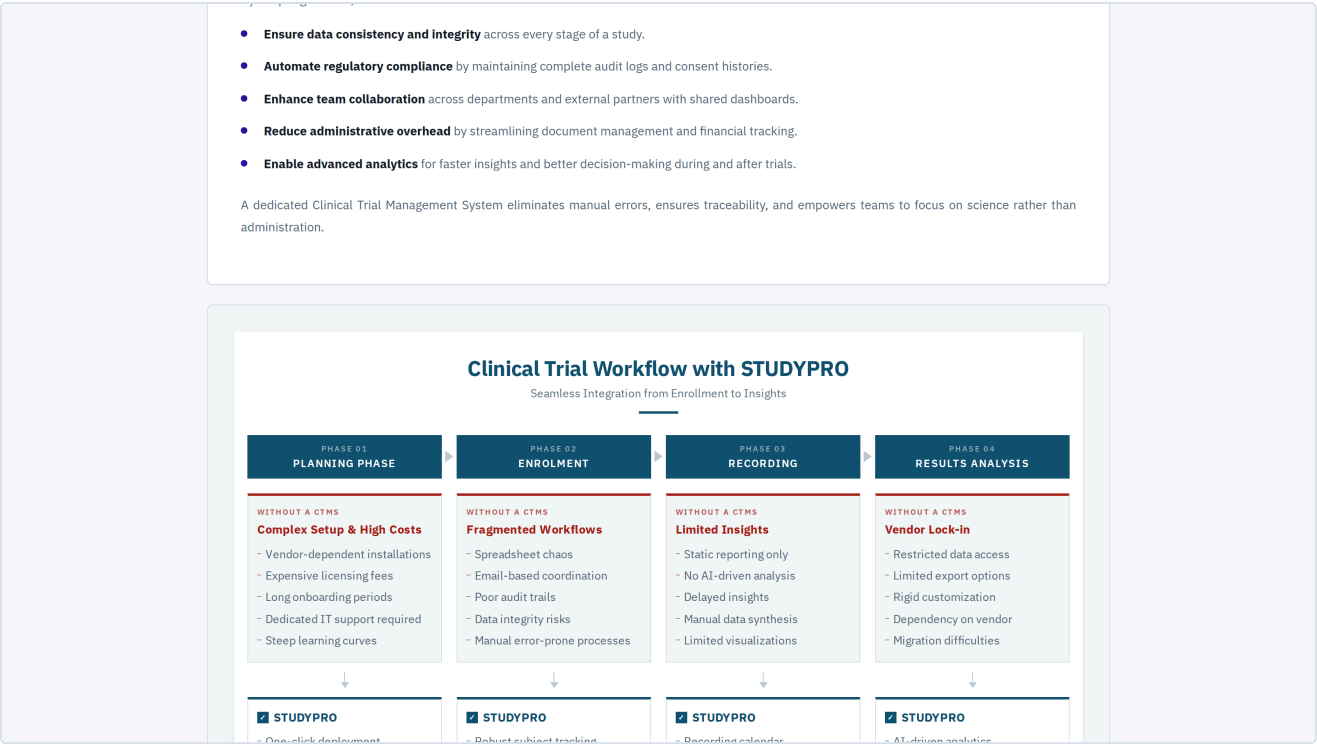


Figure 4 — Further down the same page.

The best-practice guide

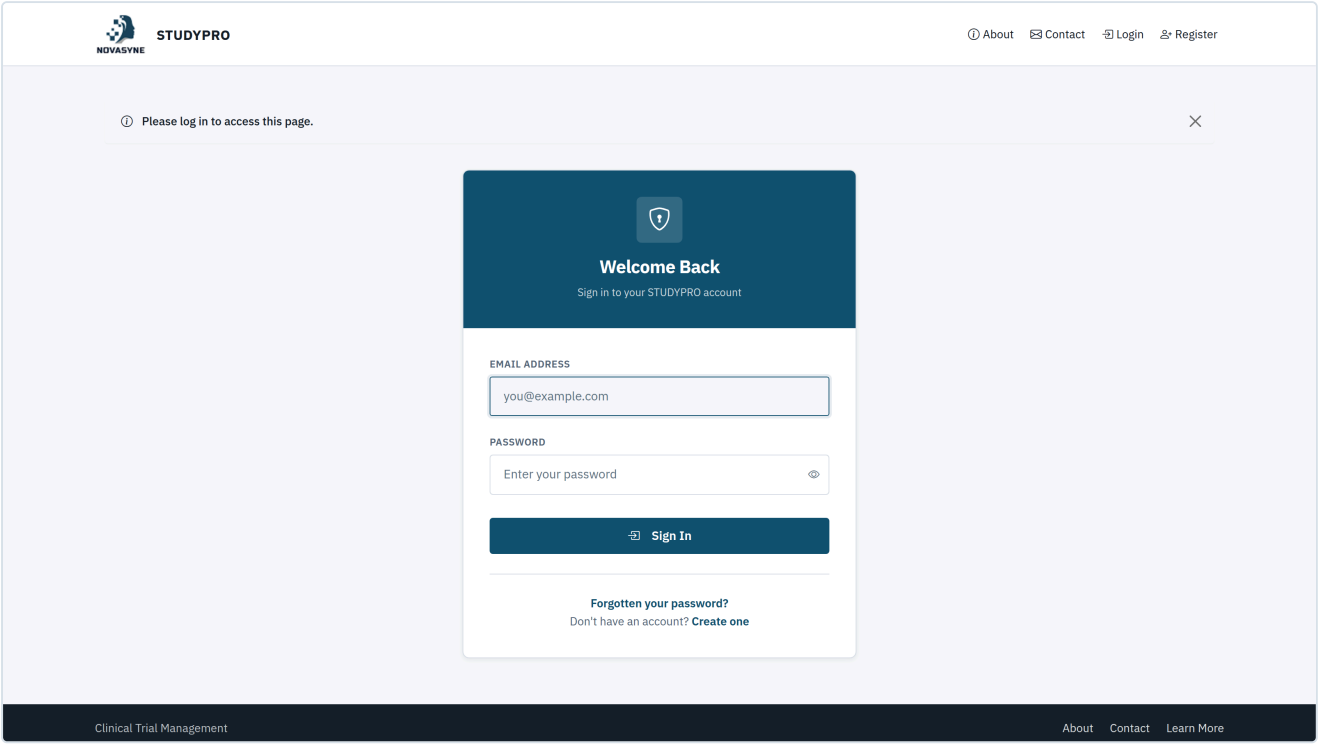


Figure 5 — Running a study well, rather than running the software.

This one is not about the software. It is about the trial: pre-registration, consent versioning, protocol deviations, keeping the analysis plan ahead of the data. Worth reading once before the first subject is enrolled.

About and contact

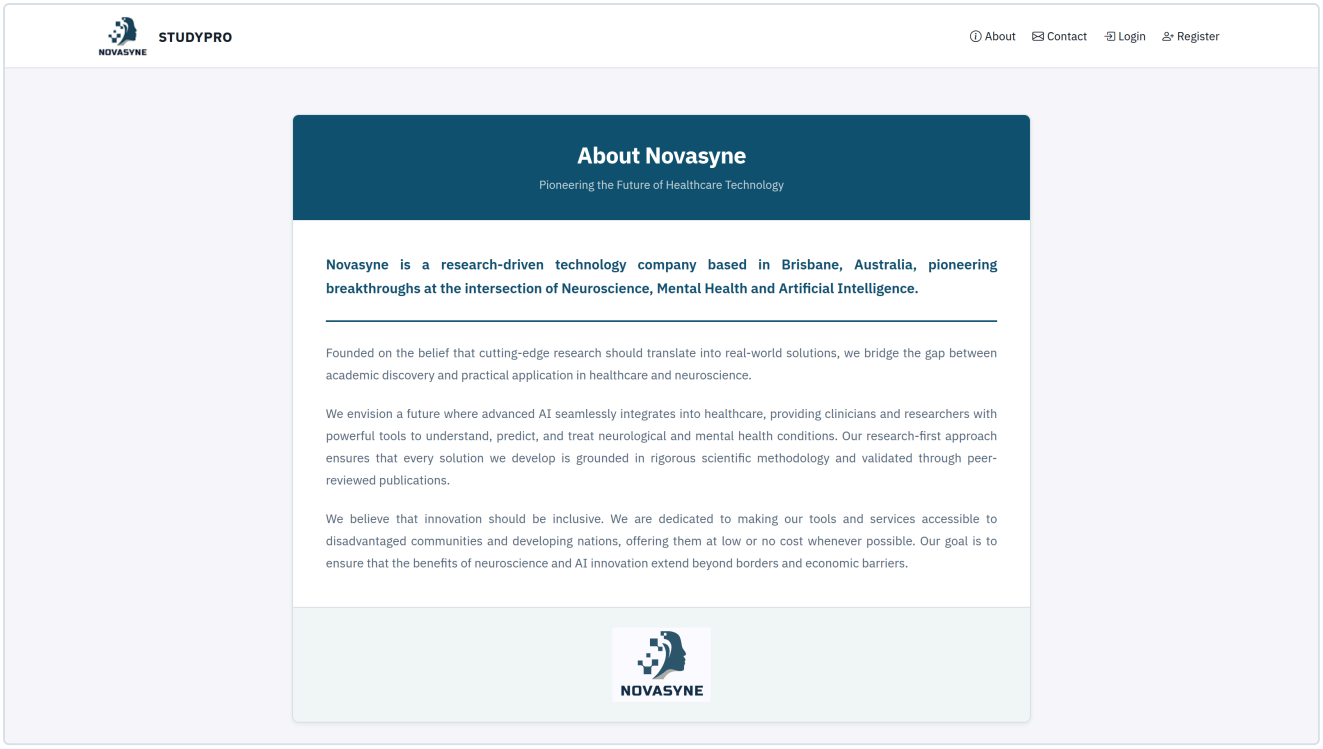


Figure 6 — About.

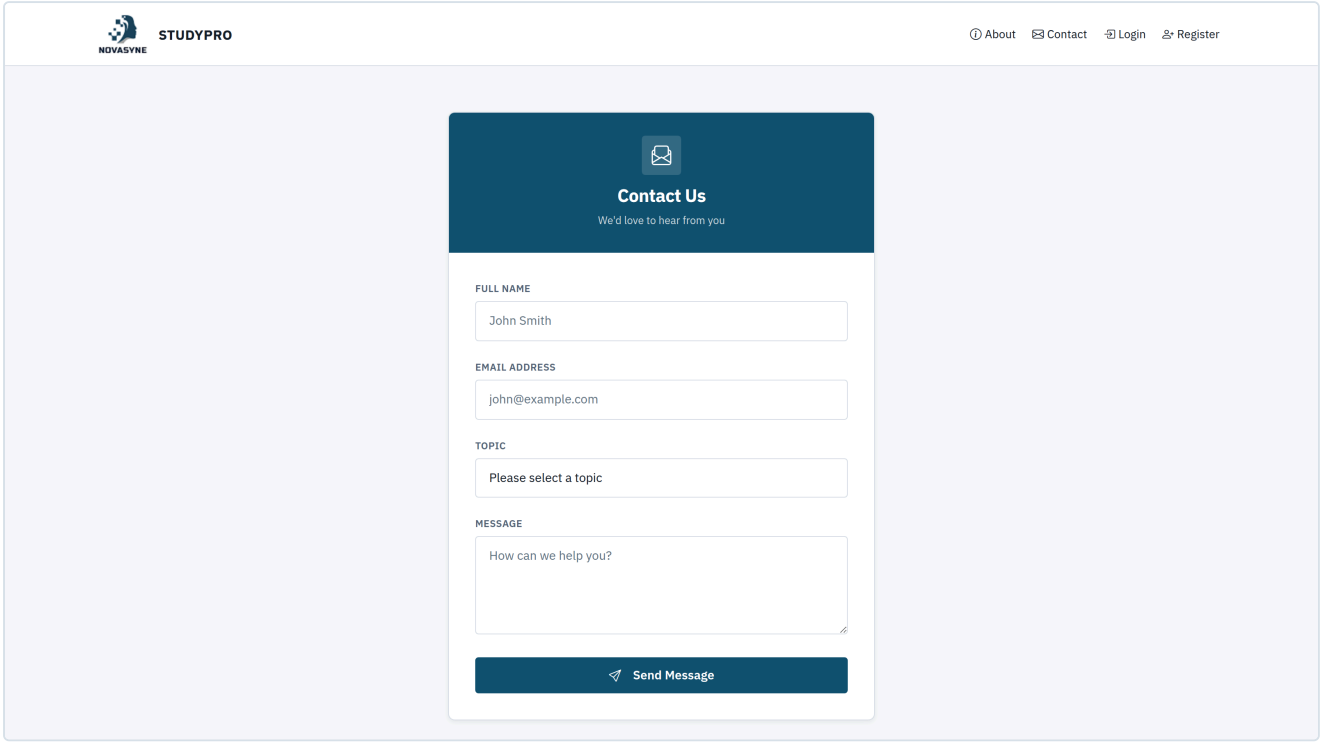


Figure 7 — Contact.

Getting an account

Registering

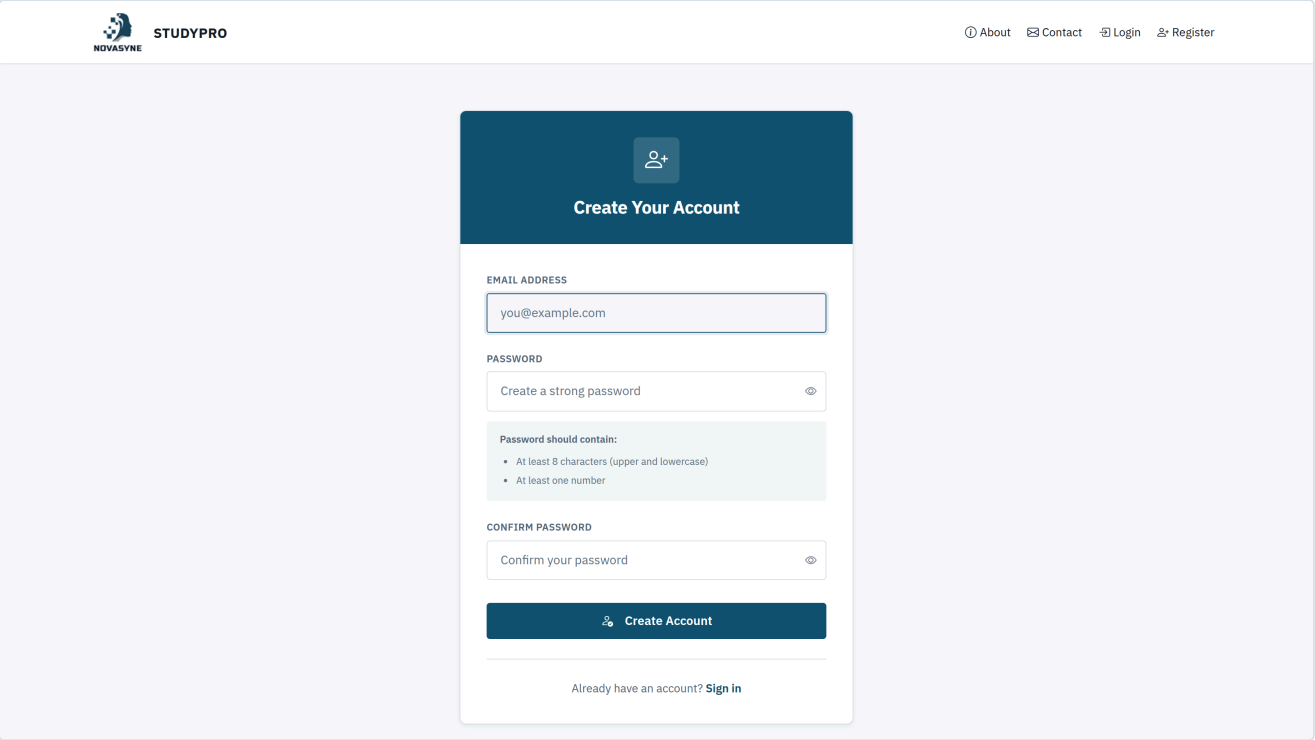


Figure 8 — Registering.

Register with the email address your colleagues will use to add you to a study. If you register with a personal address and are invited by your work address, you will have an account that can see nothing.

Registration sends a confirmation link. The account exists but cannot sign in until it is followed.

> **THE EMAIL YOU REGISTER WITH IS THE KEY TO EVERYTHING**
>
> Study access is matched on the email address, not on your name and not on an account id. Changing which address you use later means being added to every study again.

Signing in

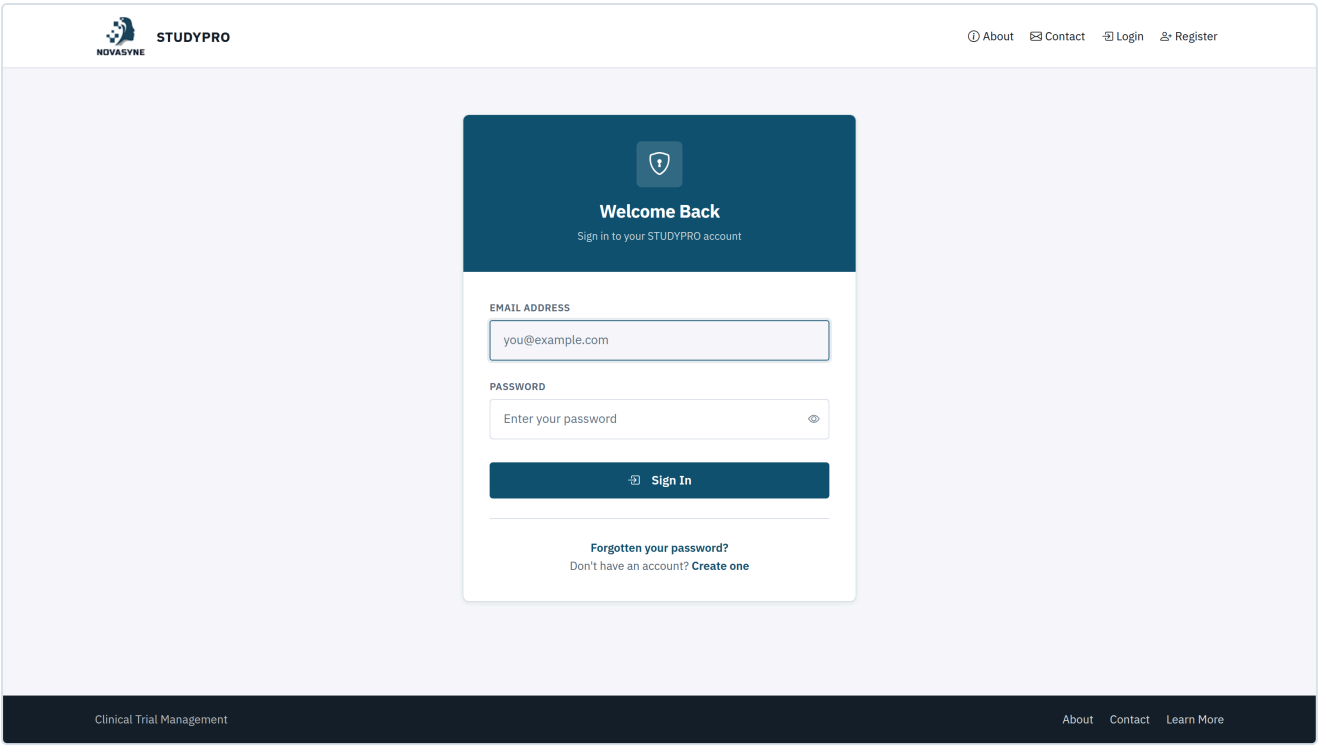


Figure 9 — Signing in.

Repeated failures are throttled rather than locked out: ten failures from one address in five minutes and it stops answering for a while, then starts again on its own. A successful sign-in clears the count.

When you have forgotten it

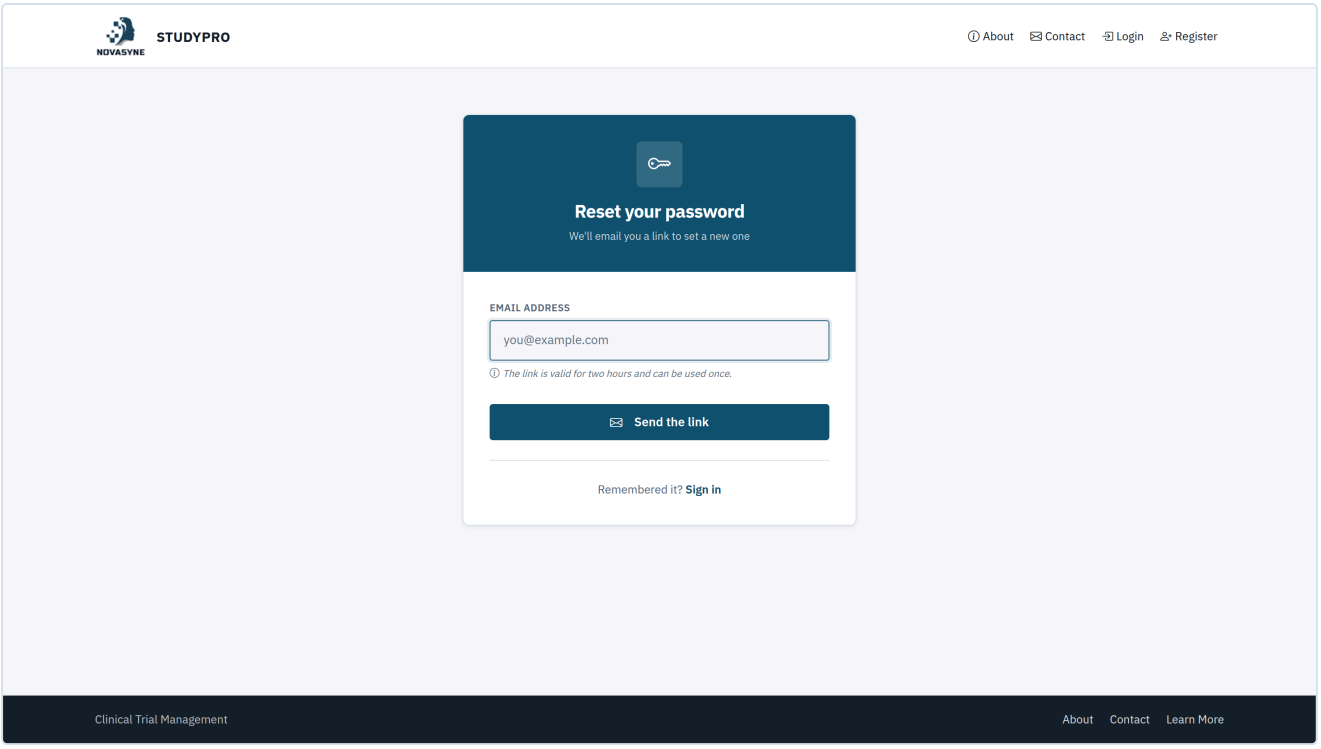


Figure 10 — Asking for a reset link.

The reply is the same whether or not the address is known to the system, which is deliberate — it is not a way to find out who has an account. The link that arrives is valid for two hours, and using it invalidates itself: it is signed with the password it is about to replace.

Your studies

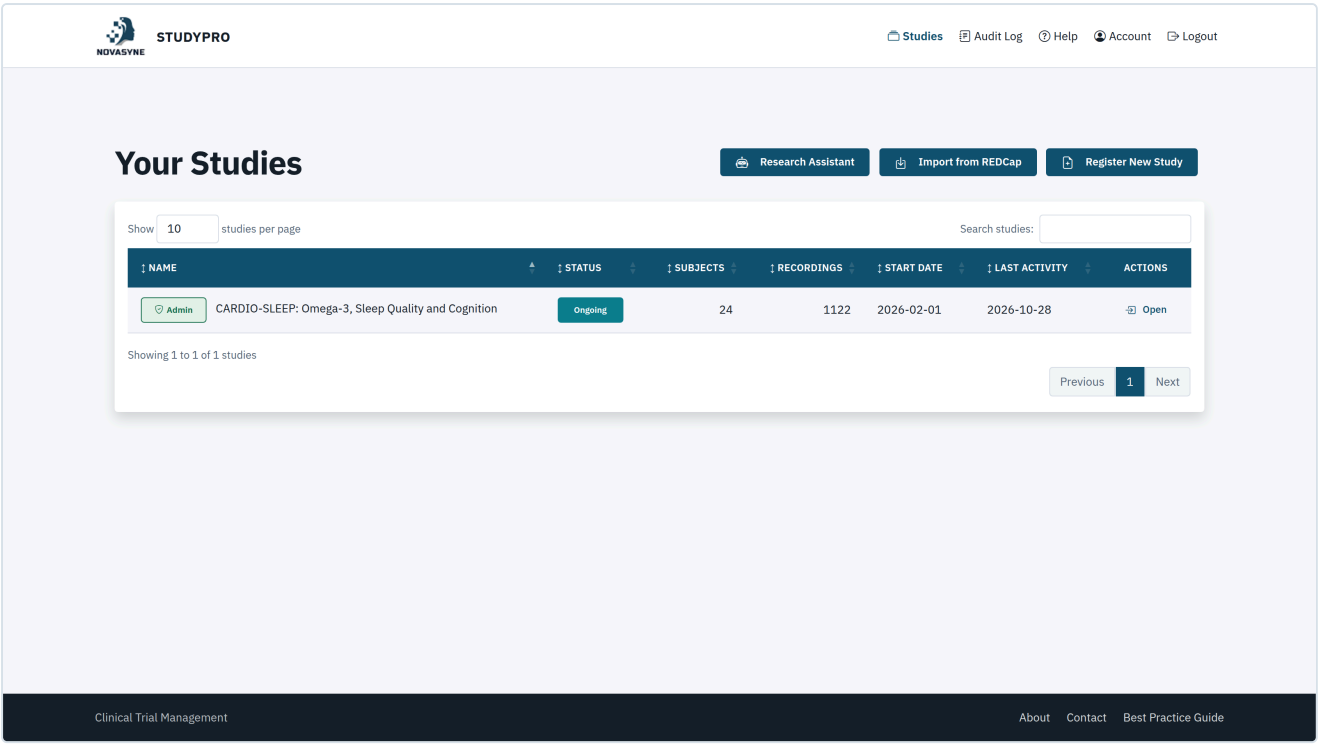


Figure 11 — Every study this account can reach.

One row per study, with the count of subjects and recordings, the status, and when it was last touched. **Admin** on a row means you can change the study itself — its settings, its participants and its money — rather than only work inside it.

Three buttons sit above the table:

Register New Study opens the three-step wizard, covered near the end of this guide.

Import from REDCap starts the same thing from an existing REDCap project.

Research Assistant is the AI assistant, and needs a key.

The study workspace

Everything inside a study is reached from one tab strip, and every page in it carries the same breadcrumb: Studies, the study, the section you are in.

Tab	What lives there
Dashboard	Status, recruitment, spend and completeness at a glance
Analytics	The analysis bench
Finances	Budget, expenses and the transaction history
Subjects	The roster, and everything held about one person
Recordings	Every observation, and the viewers
Documents	The study binder
Arms	The cohorts subjects are allocated to
Participants	Who works on the study, and who administers it
Settings	The study record itself

The dashboard

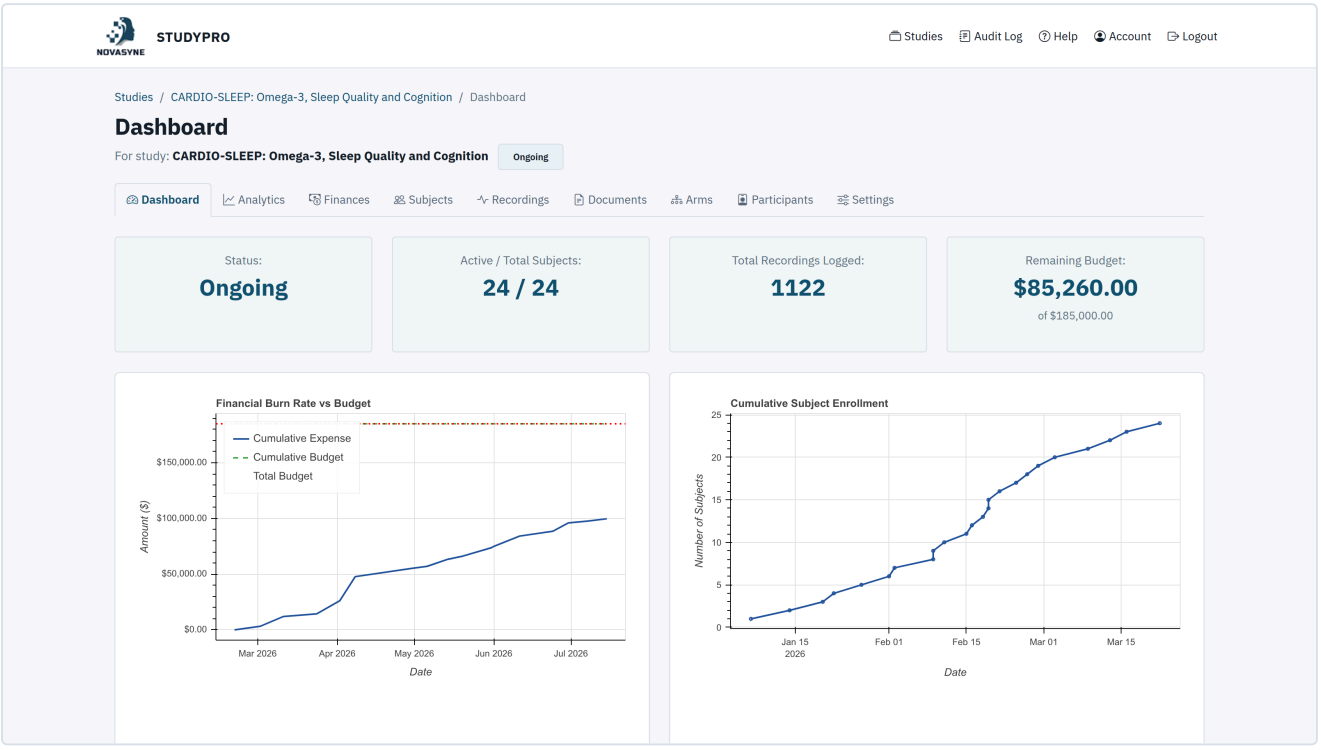


Figure 12 — The study dashboard.

Four numbers first: the status, how many subjects are active out of how many enrolled, how many recordings have been logged, and what is left of the budget.

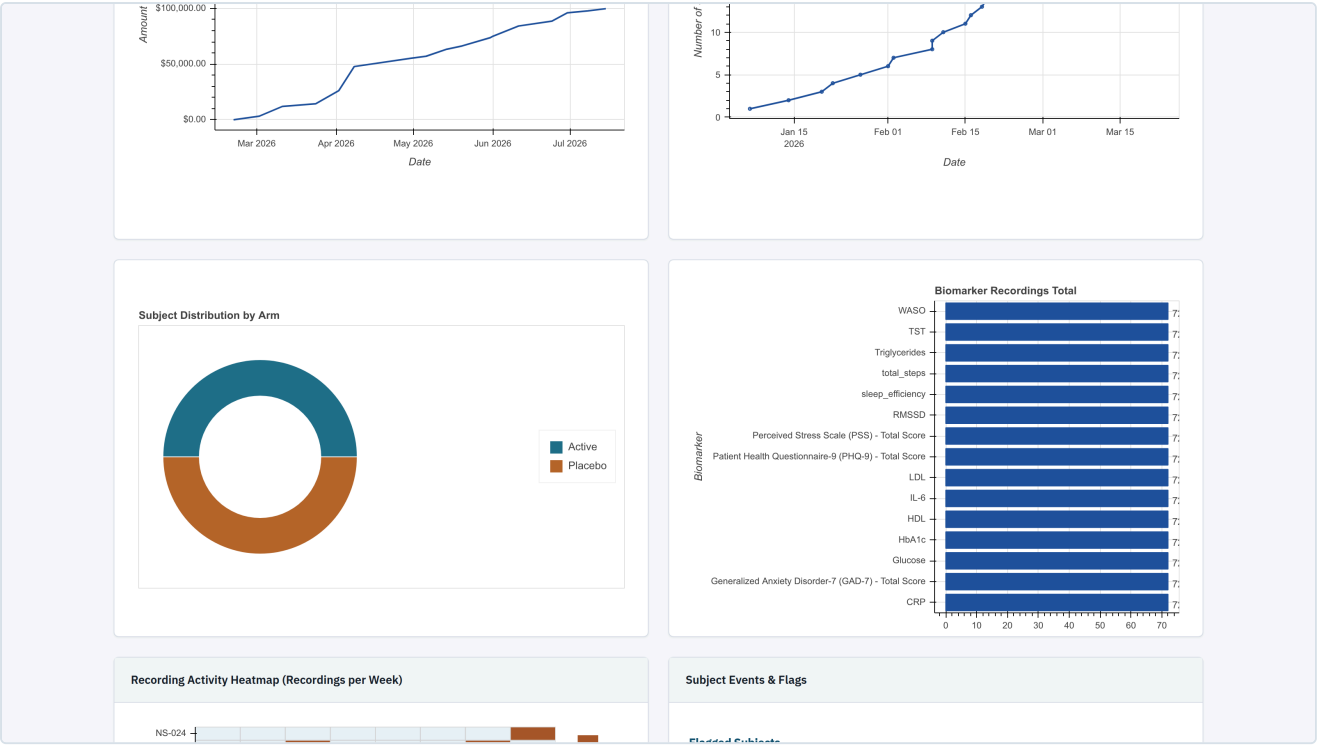


Figure 13 — Spend against budget, and recruitment over time.

Then two curves that answer the two questions a chief investigator asks between meetings: *are we recruiting fast enough?* and *are we spending faster than we are recruiting?* The budget line is the plan; the expense line is what has actually been committed.

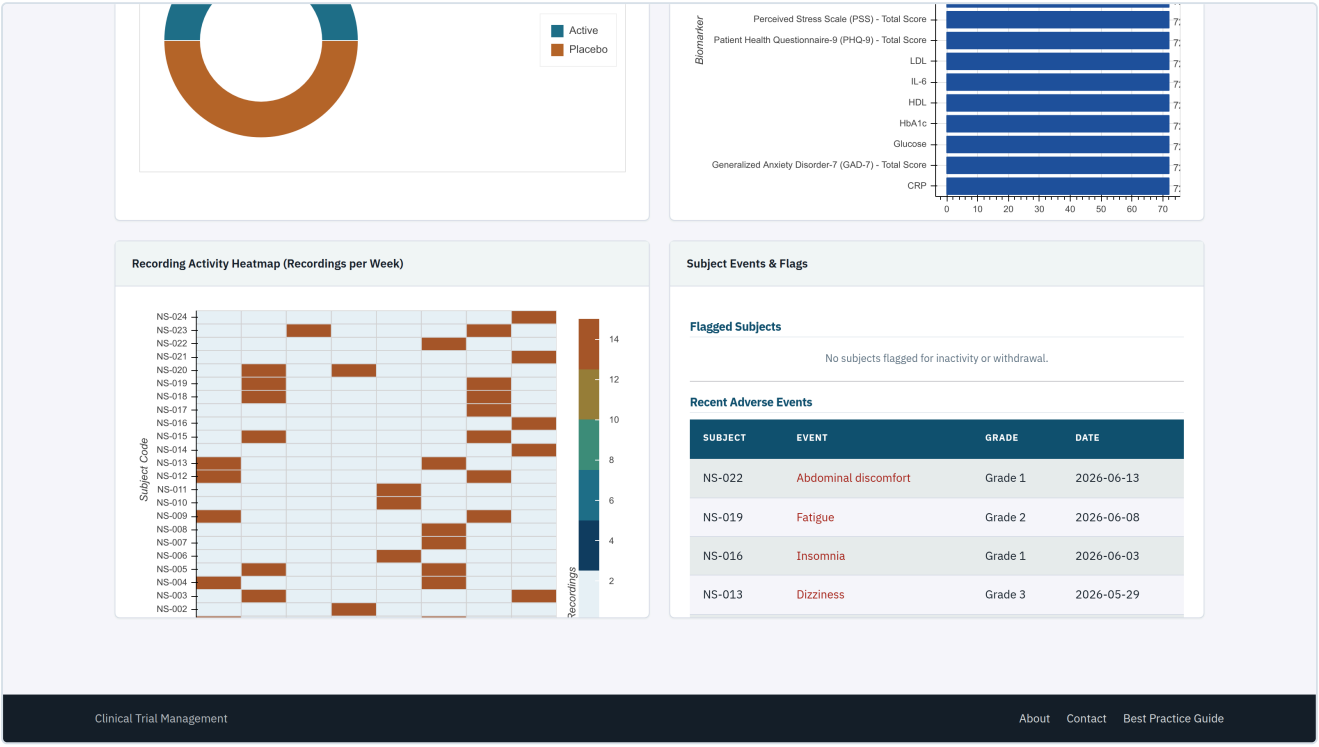


Figure 14 — What the study has collected.

Lower down, the same recording counts broken out by kind, which is the fastest way to notice that one modality has quietly stopped arriving.

Subjects

The roster

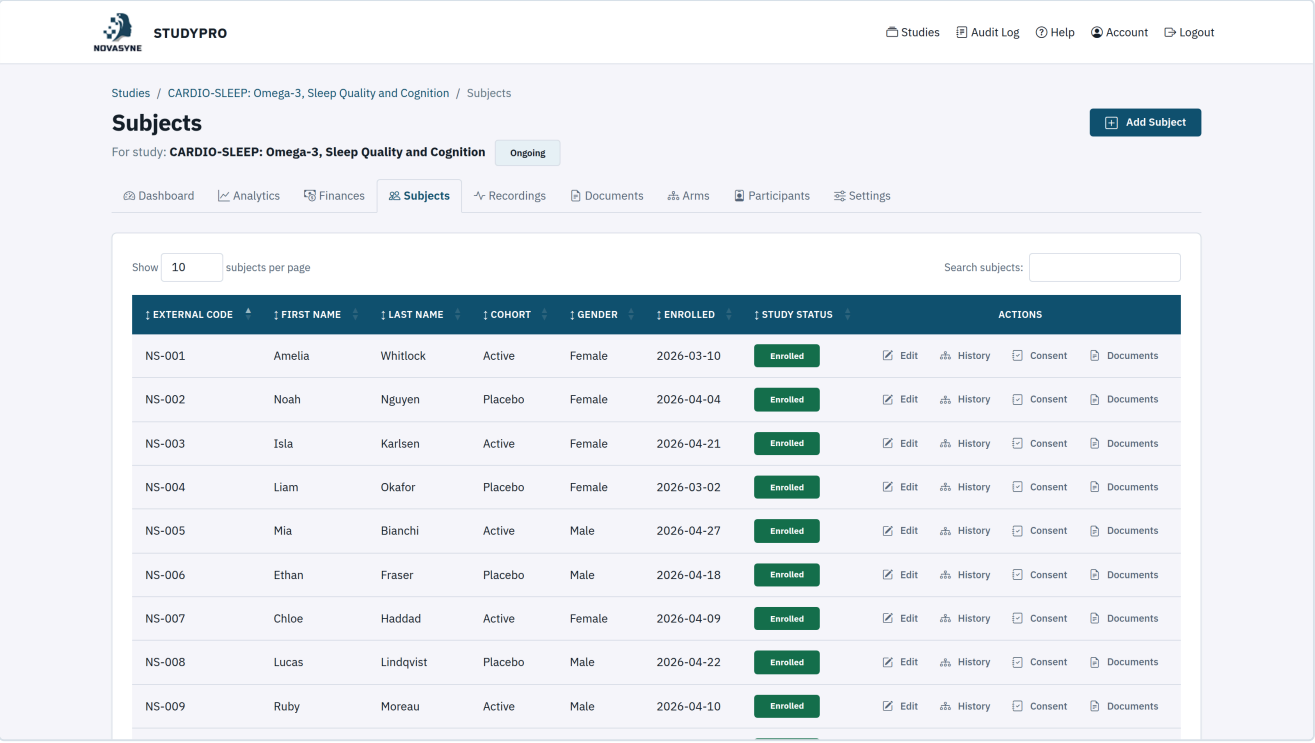


Figure 15 — The subject roster.

One row per subject: the external code you know them by, first and last name, the arm they are in, gender, when they were enrolled, and their study status.

The four buttons on each row are the whole subject record — **Edit**, **History**, **Consent** and **Documents**.

> **THE EXTERNAL CODE IS YOURS, NOT OURS**
>
> `NS-001` is whatever your protocol calls that person. It is unique within the study, and it is what appears on every recording, every export and every audit entry. Names are held for the site; the code is what travels.

Enrolling someone

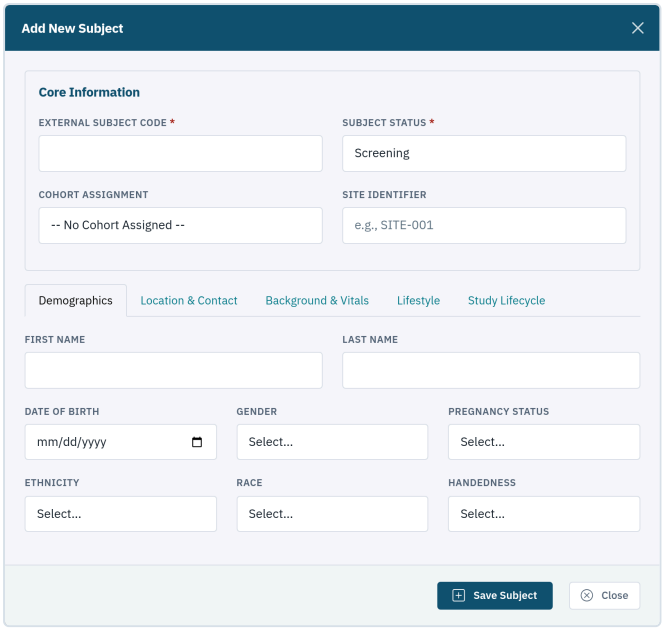


Figure 16 — What the study records about a subject.

The form is grouped into demographics, location, background, lifestyle and study lifecycle, because that is roughly the order a site collects it in. Only the external code and the arm are needed to create the record; the rest can follow.

Clinical history

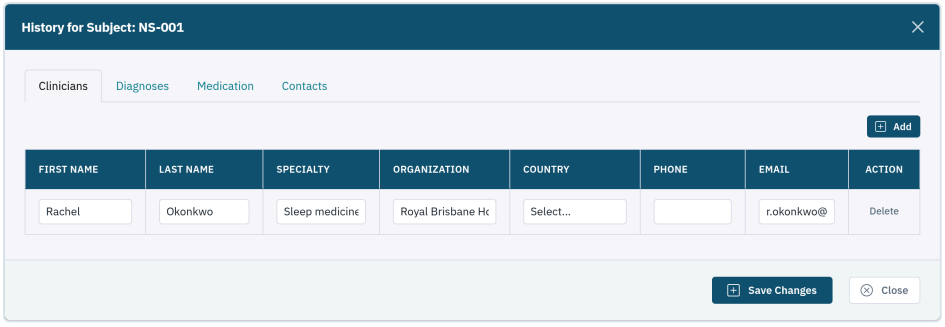


Figure 17 — Clinicians, diagnoses, medications and contacts.

Four tabs, each a table you edit in place.

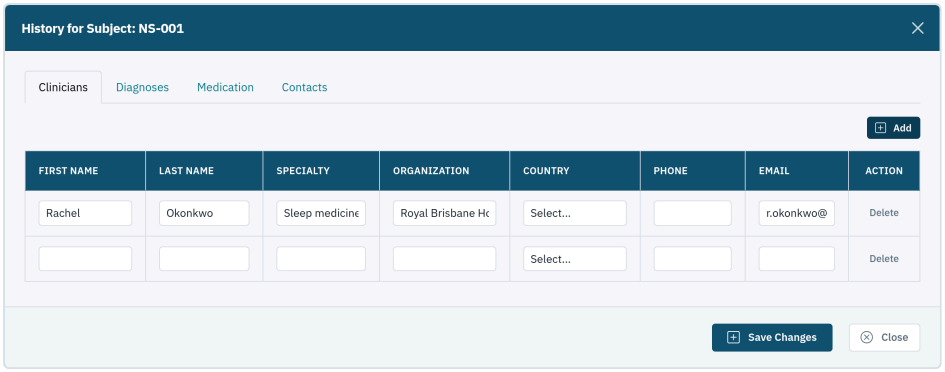


Figure 18 — A row you fill in place, rather than a form on another page.

Add appends an empty row and you type into it. Nothing is written until **Save Changes**, which writes all four tables at once.

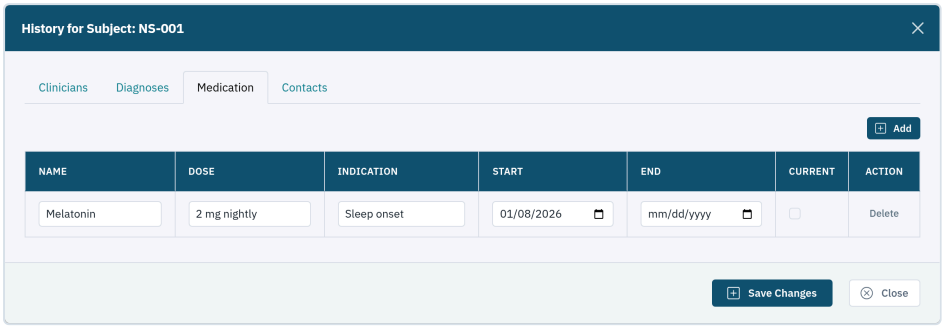


Figure 19 — Concomitant medication, which the frequency analysis counts.

Medication is not just a note: the **Concomitant Medication Frequency** analysis counts these rows across the study, so a drug typed three different ways counts as three drugs.

Consent

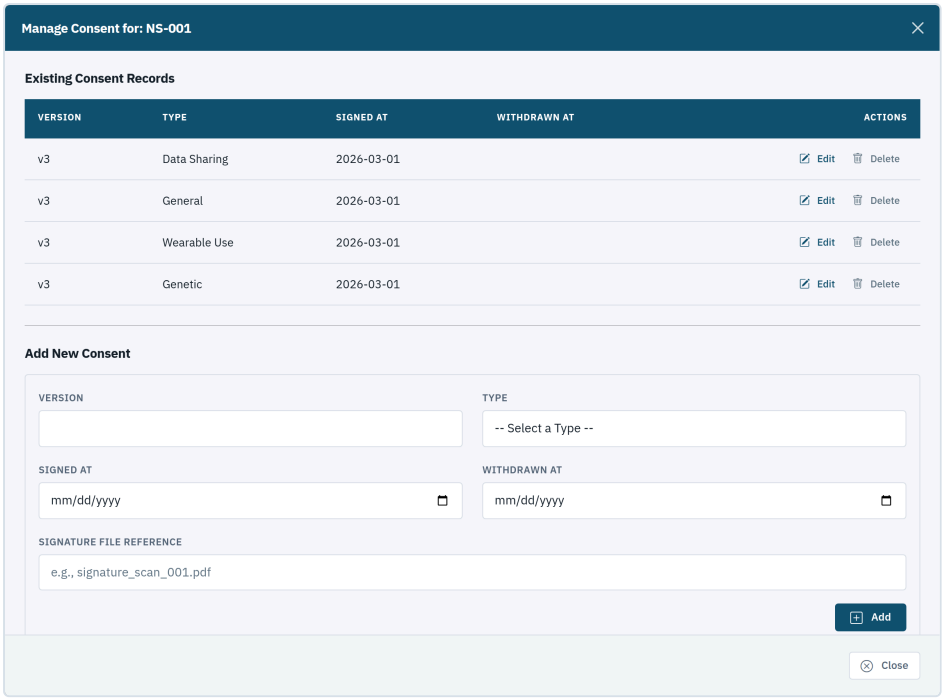


Figure 20 — Which version, signed when, withdrawn when.

Consent is versioned. Each row is a consent type and version with the date it was signed, and — if it happened — the date it was withdrawn. A withdrawal does not delete anything; it records that the permission ended, which is what an auditor will ask to see.

Documents

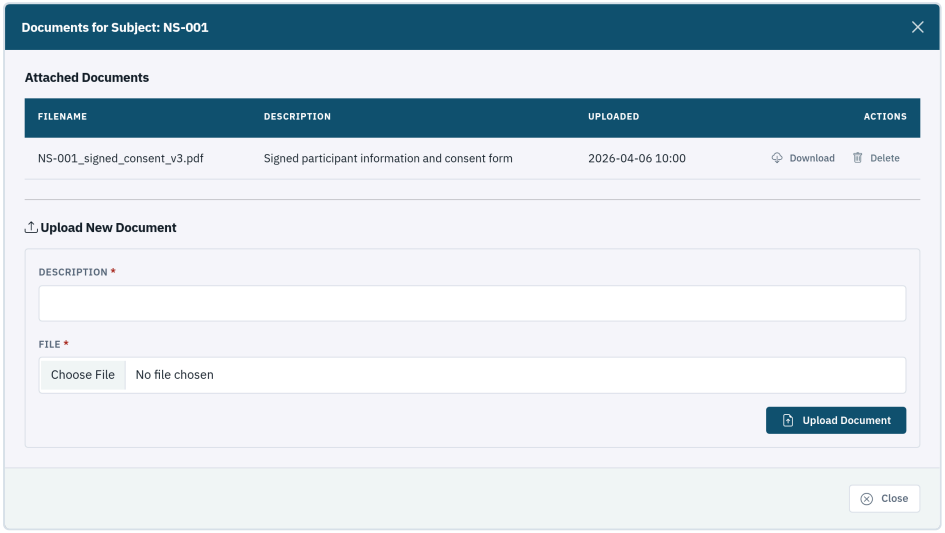


Figure 21 — Documents held against one subject.

Signed consent forms, correspondence, source documents. These are stored against the subject rather than the study, and they follow the same access rules as everything else about that person.

Releasing a subject

A subject can ask to be forgotten. **Release** does that, in the only way a trial can honour it:

- first name, last name, date of birth, city, state, postcode and site identifier are cleared on the subject record;
- their contacts and clinicians are deleted outright;
- every historical audit value naming them is overwritten with a marker saying the values were removed at their request;
- the clinical record — arm, visits, recordings, adverse events — is kept.

> **RELEASE CANNOT BE UNDONE, AND IT IS NOT DELETION**
>
> The trial keeps the data it was consented to keep; what goes is everything that ties it to a name. The action is recorded in the audit log with who did it and how many historical values were scrubbed.

Recordings

What a recording is

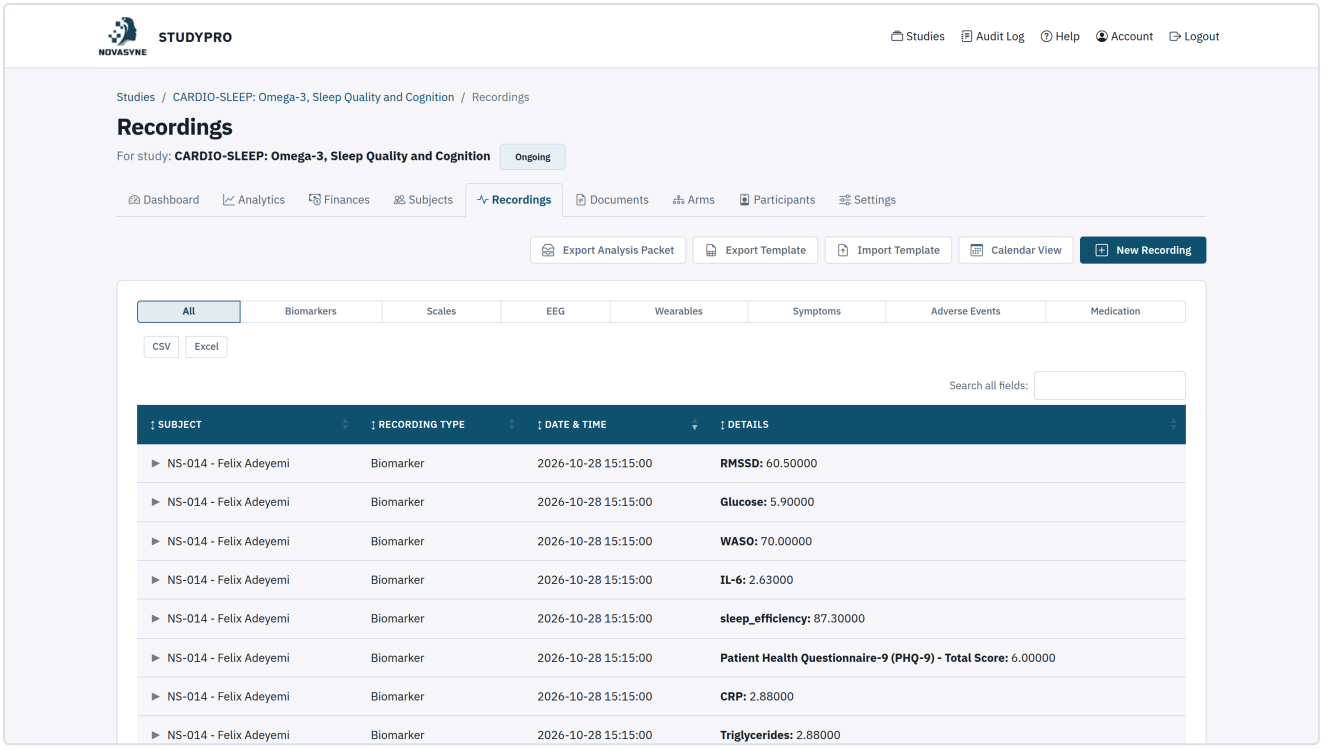


Figure 22 — Every observation the study holds.

A recording is one observation of one subject at one moment. That covers more than signals: a blood result, a questionnaire score, a symptom, an adverse event and a medication are all recordings, which is why one table can carry the whole study.

The tabs across the top filter by kind — Biomarkers, Scales, EEG, Wearables, Symptoms, Adverse Events, Medication — and **CSV** and **Excel** export whatever the table is currently showing.

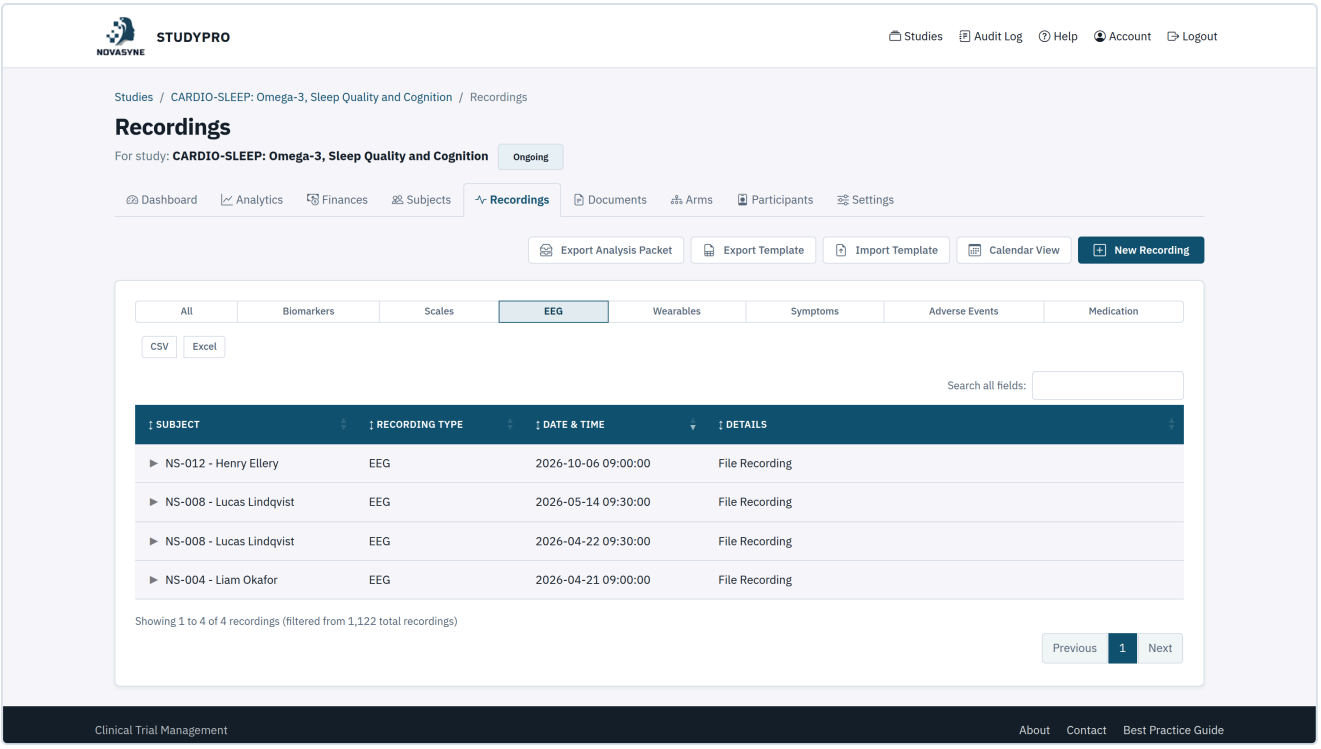


Figure 23 — Filtered to one kind of recording.

FILTER FIRST ON A LARGE STUDY

The table is paginated and only the rows on screen exist in the page. With a thousand recordings, filtering to the kind you want is faster than searching, and it is the only way to be sure the export contains what you think it does.

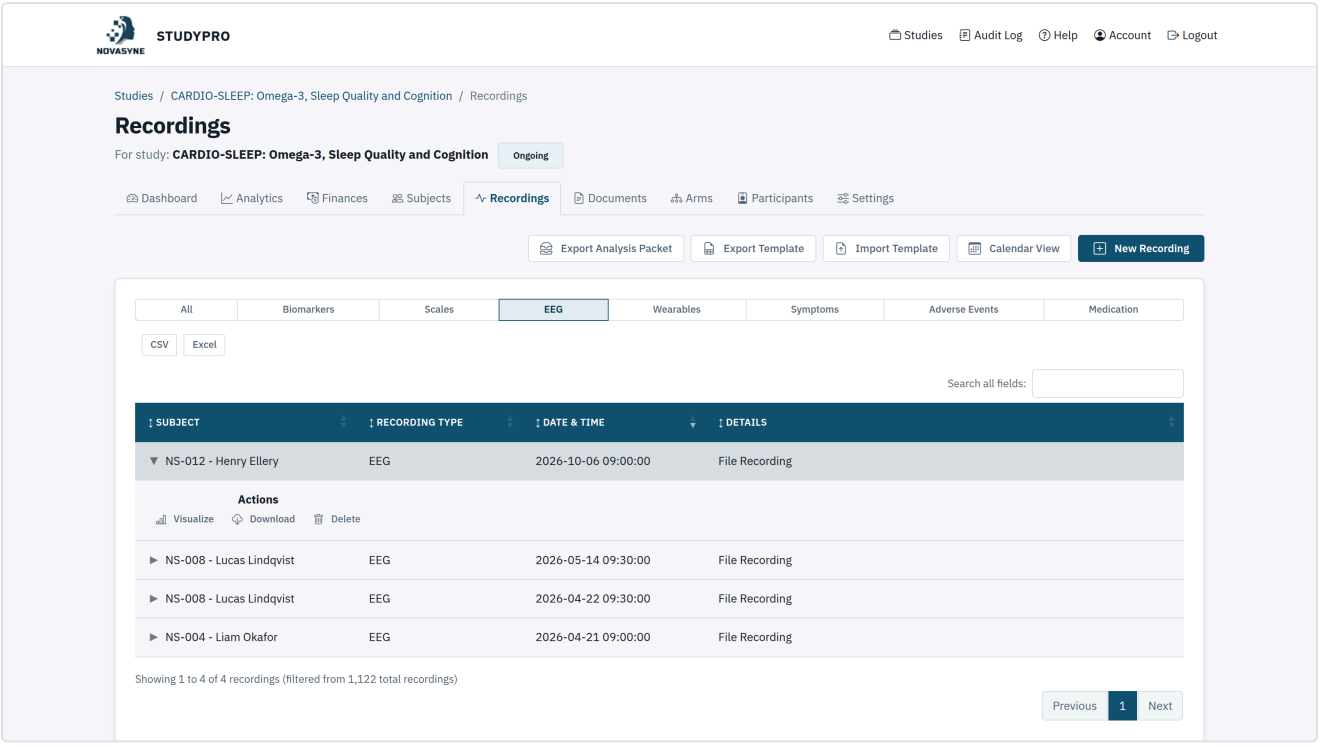


Figure 24 — A row opened for its actions.

At this width the Actions column is folded away. Click the arrow at the left of a row to open it, and the actions — including **Visualize** for a signal recording — appear underneath.

The calendar

Figure 25 — When collection actually happened.

The same recordings, by date. It opens on the current week; switch to month view and step back to the period you care about. A visit window with nothing in it is much easier to see here than in a table.

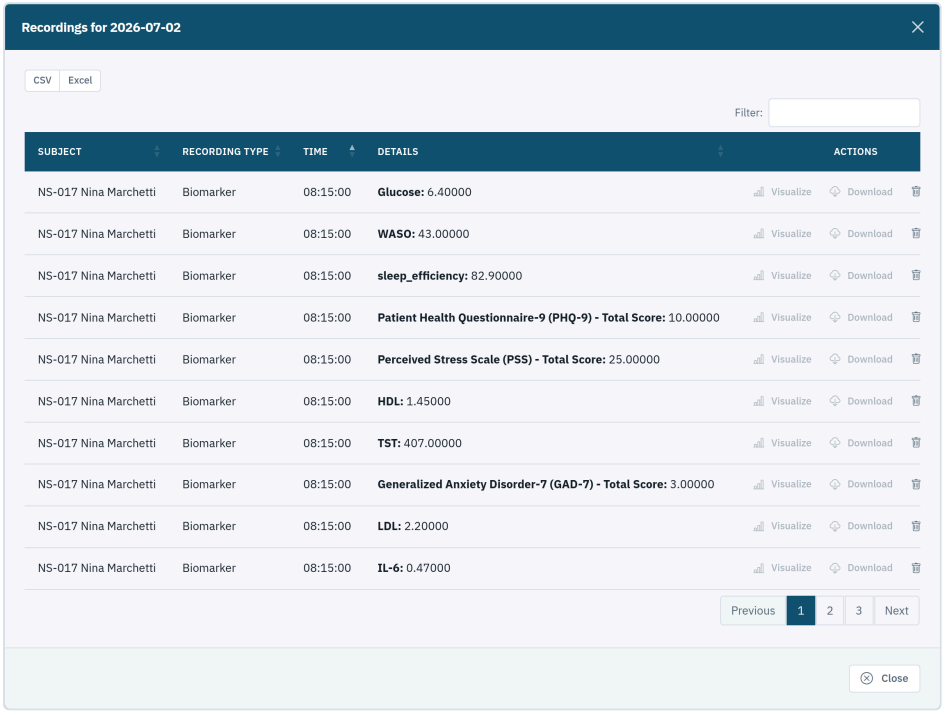


Figure 26 — One day, and everything collected on it.

Clicking a day lists what was collected on it.

Adding one by hand

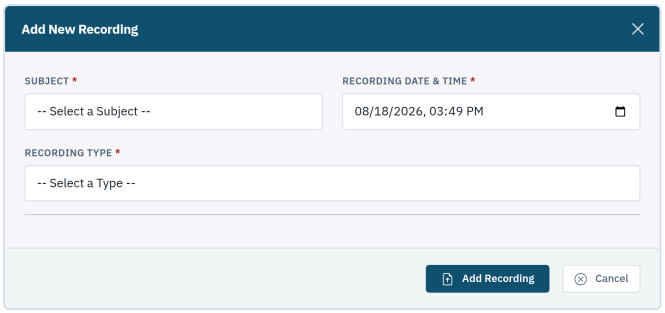


Figure 27 — Adding a recording.

Choose the subject, the kind of recording, the moment it was taken, and then whatever that kind needs — a biomarker and a value, or a file for a signal.

The spreadsheet route

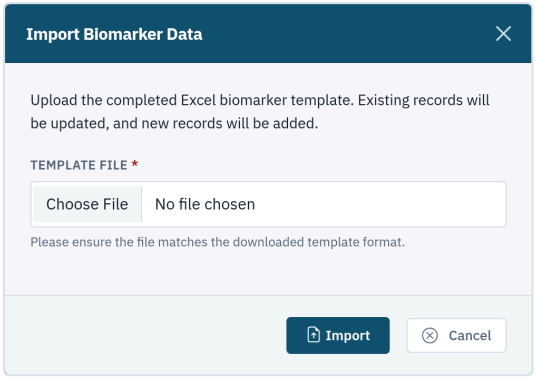


Figure 28 — The spreadsheet route in.

Export Template writes a spreadsheet shaped for this study — its subjects, its allowed biomarkers — and **Import Template** reads it back. This is the sane way to enter a visit's worth of results, and it validates every row before writing anything.

Taking data out

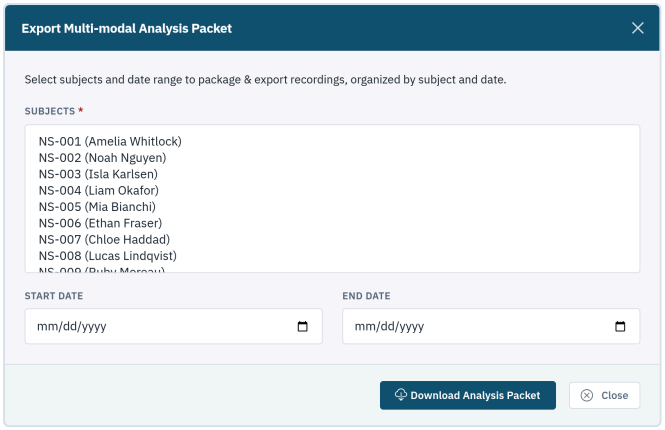


Figure 29 — Exporting an analysis packet.

The analysis packet is the export for someone doing statistics elsewhere: choose the subjects and a date range, and it builds a zip of tables plus the raw signal files.

> **RAW FILES COME FROM CLOUD STORAGE**
>
> Signals live in blob storage. If storage is not configured the packet is still written, with the tables in it and a warning that the raw files were skipped — it does not fail silently, but it also does not stop.

Signals

Signal recordings are not summarised into a number. STUDYPRO stores the file the instrument wrote and renders it on demand.

EEG

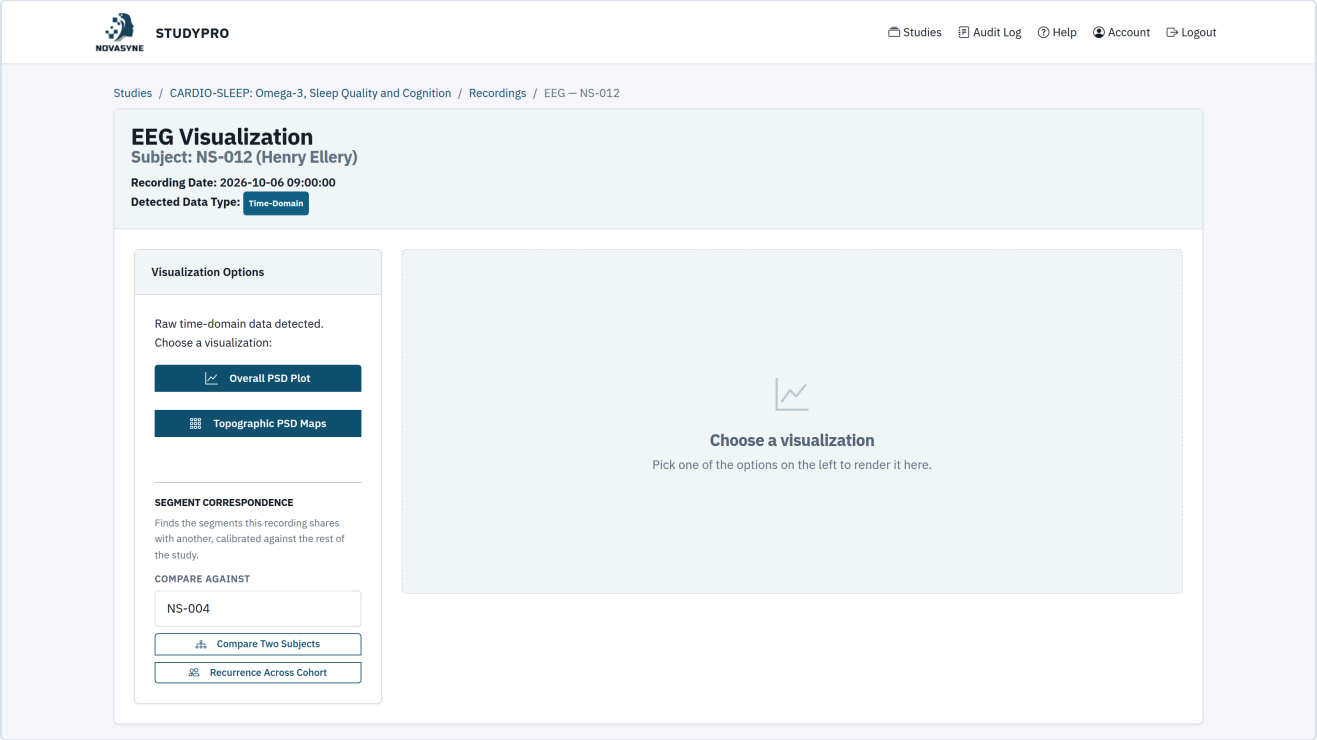


Figure 30 — A clinical EEG, read straight from the file.

The viewer reads the EDF and reports what it found — the subject, the recording date, and whether the data is time-domain or already reduced.

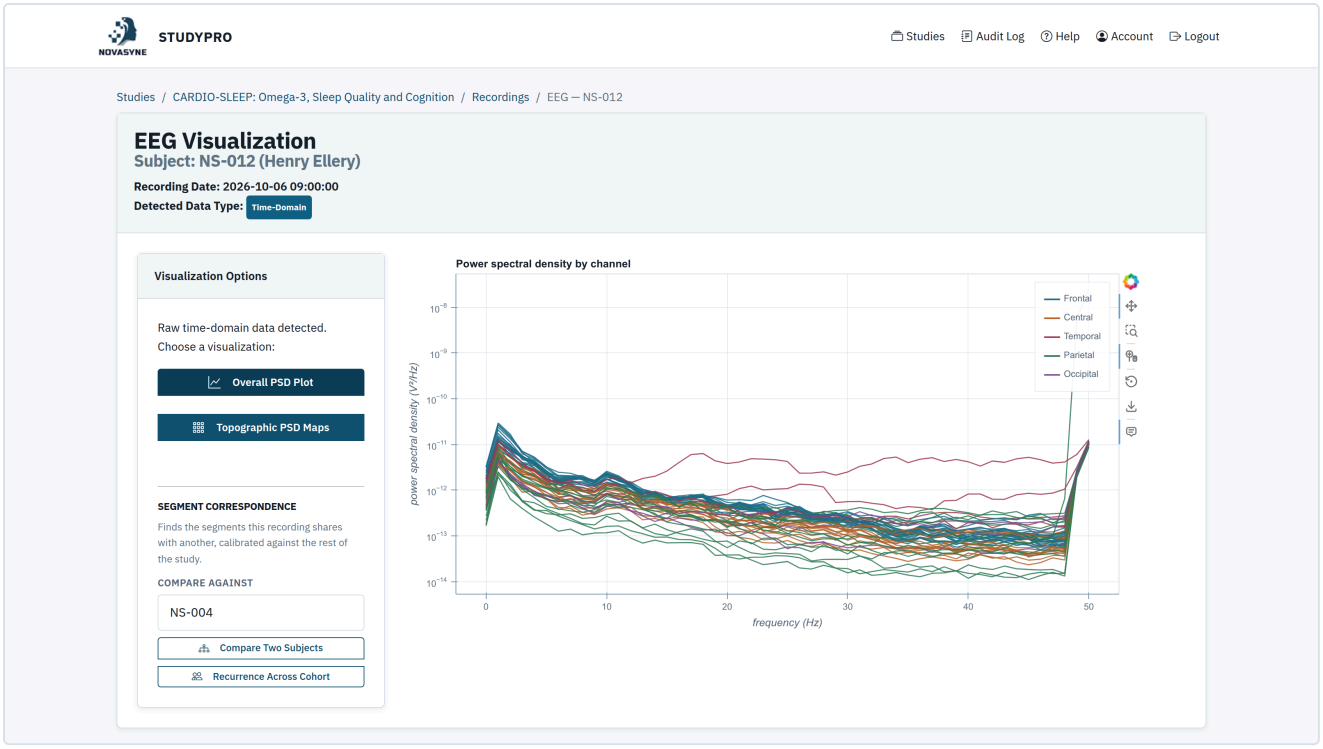


Figure 31 — Power spectrum across the montage.

Overall PSD is the spectrum per channel across the whole recording.

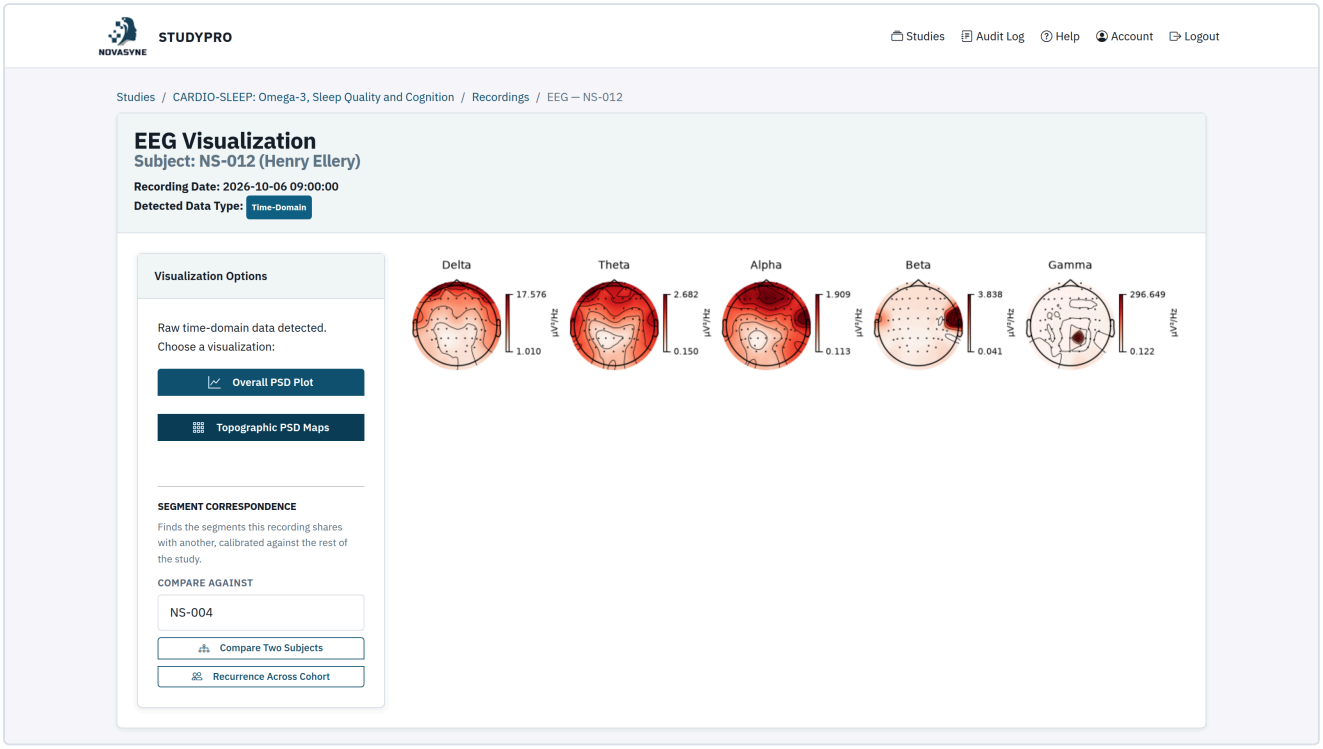


Figure 32 — Voltage across the scalp.

Topographic PSD Maps put band power where the electrodes were.

Segment correspondence is the pair of buttons below: compare this recording against one other subject, or against the rest of the cohort at once. That is the question a trial asks that a single recording cannot answer.

Wearables

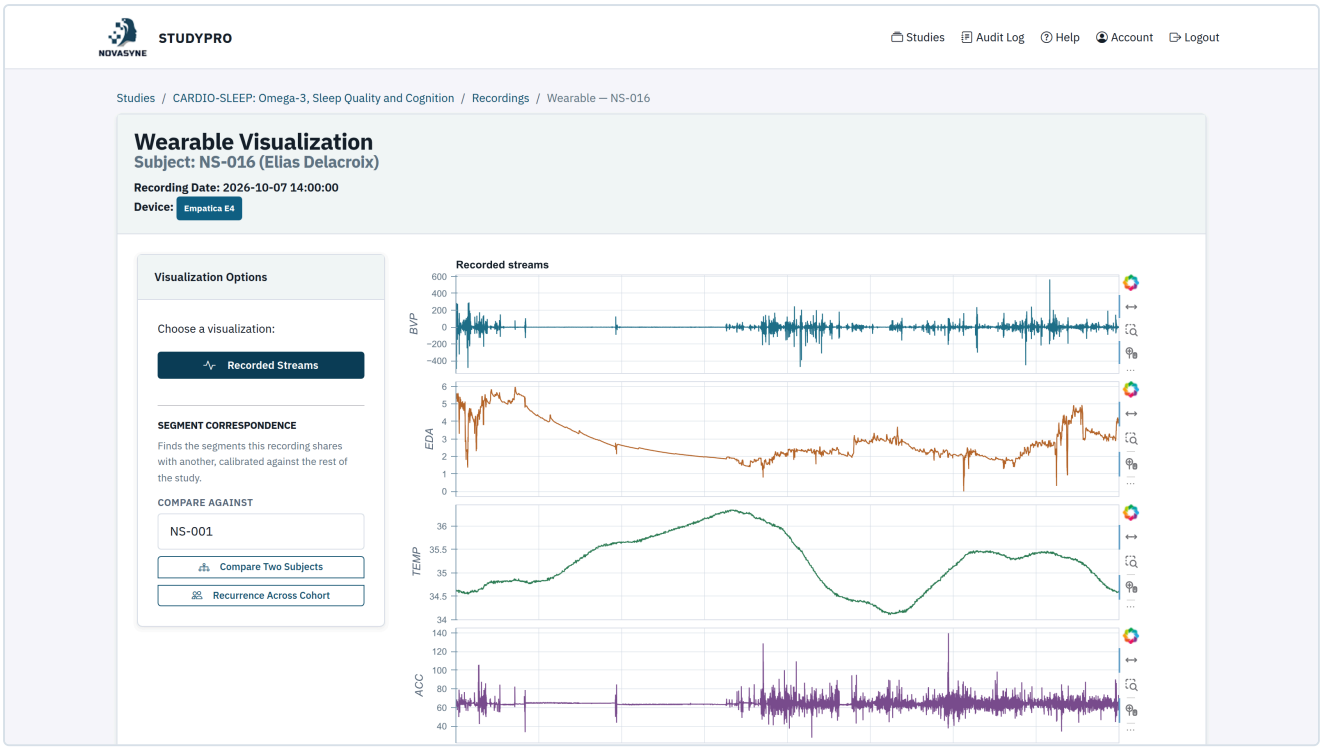


Figure 33 — Every stream on one clock.

A wrist recorder session with its streams stacked on a shared time axis — pulse, electrodermal activity, temperature, motion and heart rate.

> **THE WEARABLE VIEWER NEEDS A TIME COLUMN**
>
> It reads a flat CSV whose first column is `time` in seconds. A raw device export — an Empatica E4 zip, for instance — has a start timestamp and a sample rate per signal instead, and is refused with that reason. Convert it before uploading, or use the Wearable Workbench, which reads 23 device formats natively and exports what this viewer wants.

Analysis

The bench

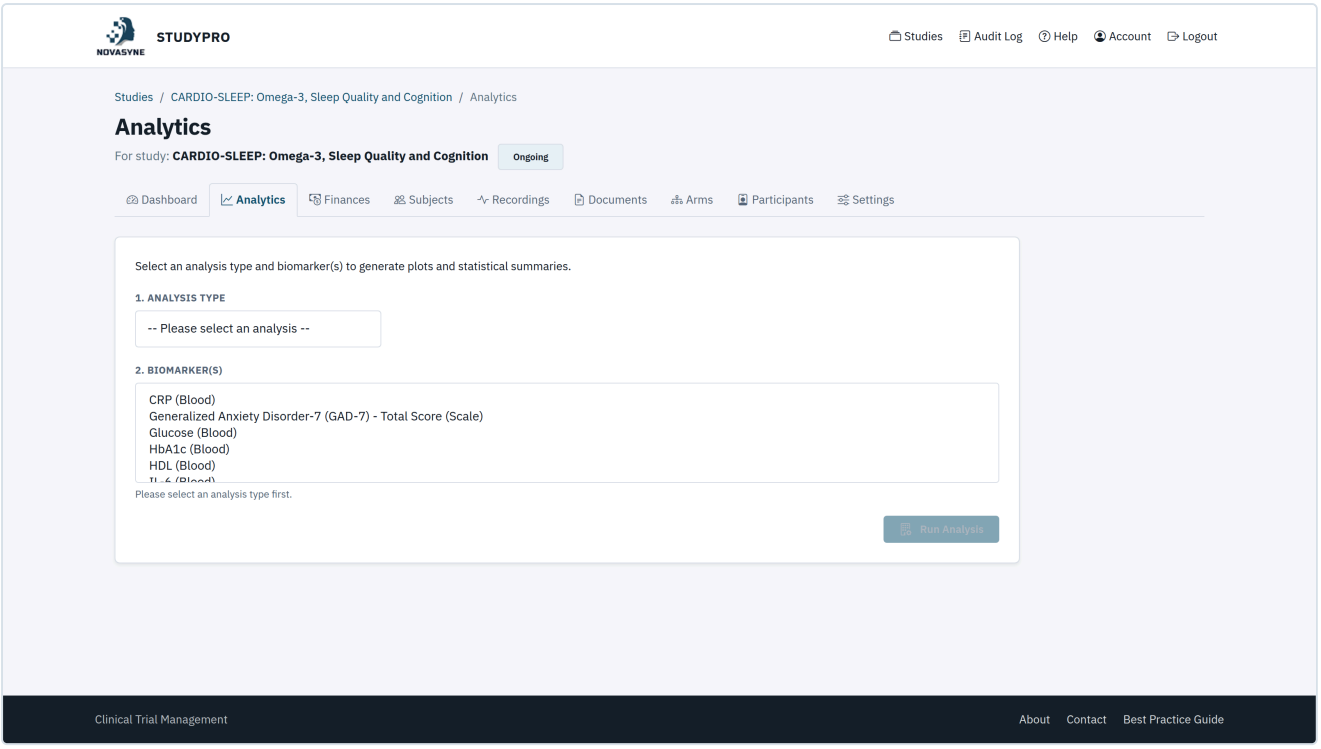


Figure 34 — The analysis bench, before a question is asked.

Choose an analysis, then what it runs on. The Run button stays disabled until the combination is one the analysis can actually perform, and the line beneath the biomarker list says what is missing.

The catalogue is in two groups. **Biomarker analyses** work on numeric series: cohort comparison, one subject over time, distribution, correlation, and a comprehensive correlation across everything. **Categorical analyses** count things: demographics, event and symptom frequency, concomitant medication frequency, and a cohort distribution report.

Comparing the arms

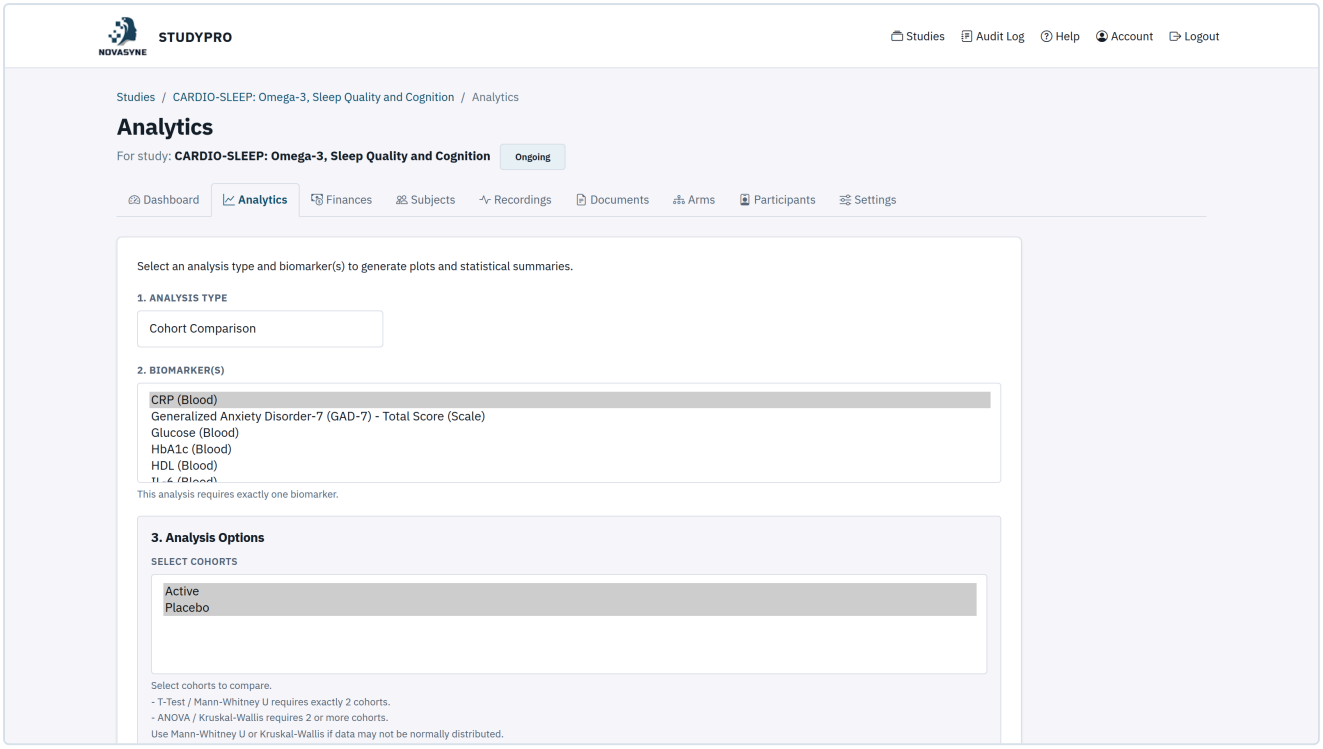


Figure 35 — Two arms, one biomarker, one test.

The question the trial exists to answer. Pick the biomarker, pick both cohorts, and pick how to show it — a box plot, or a named statistical test.

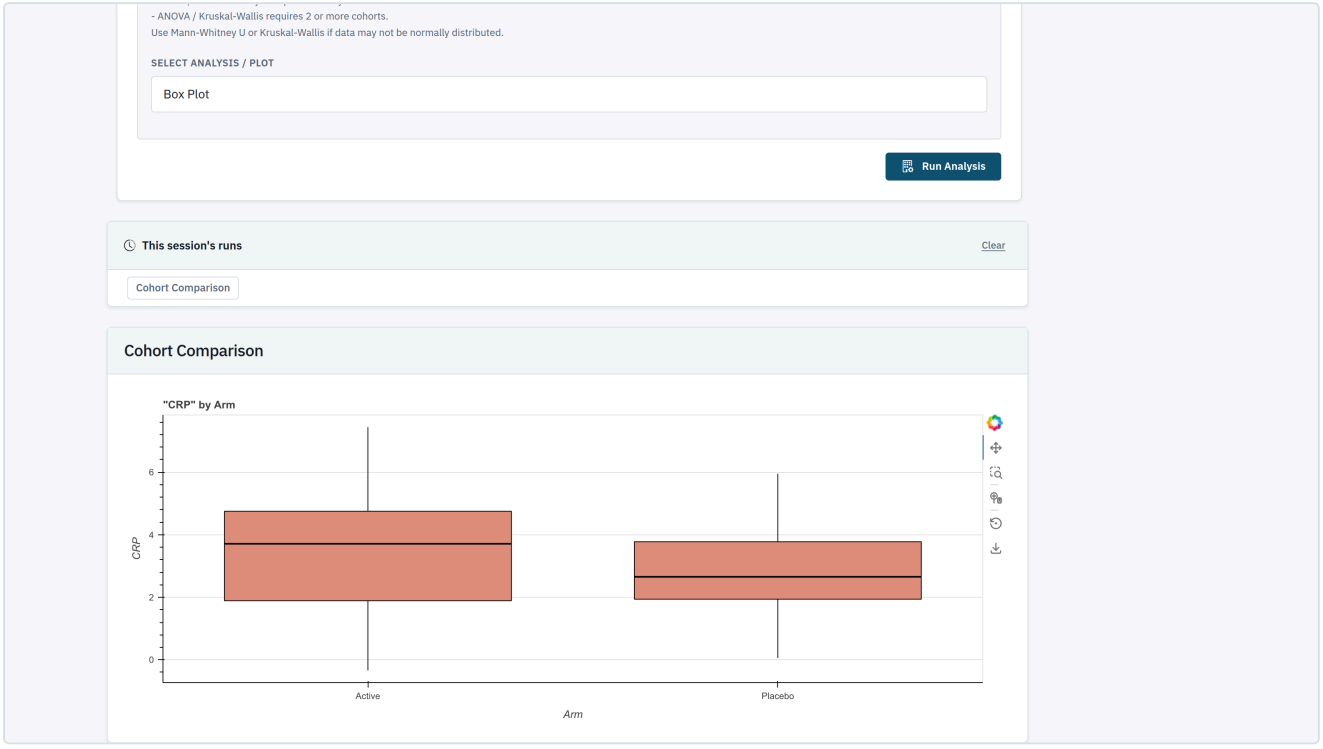
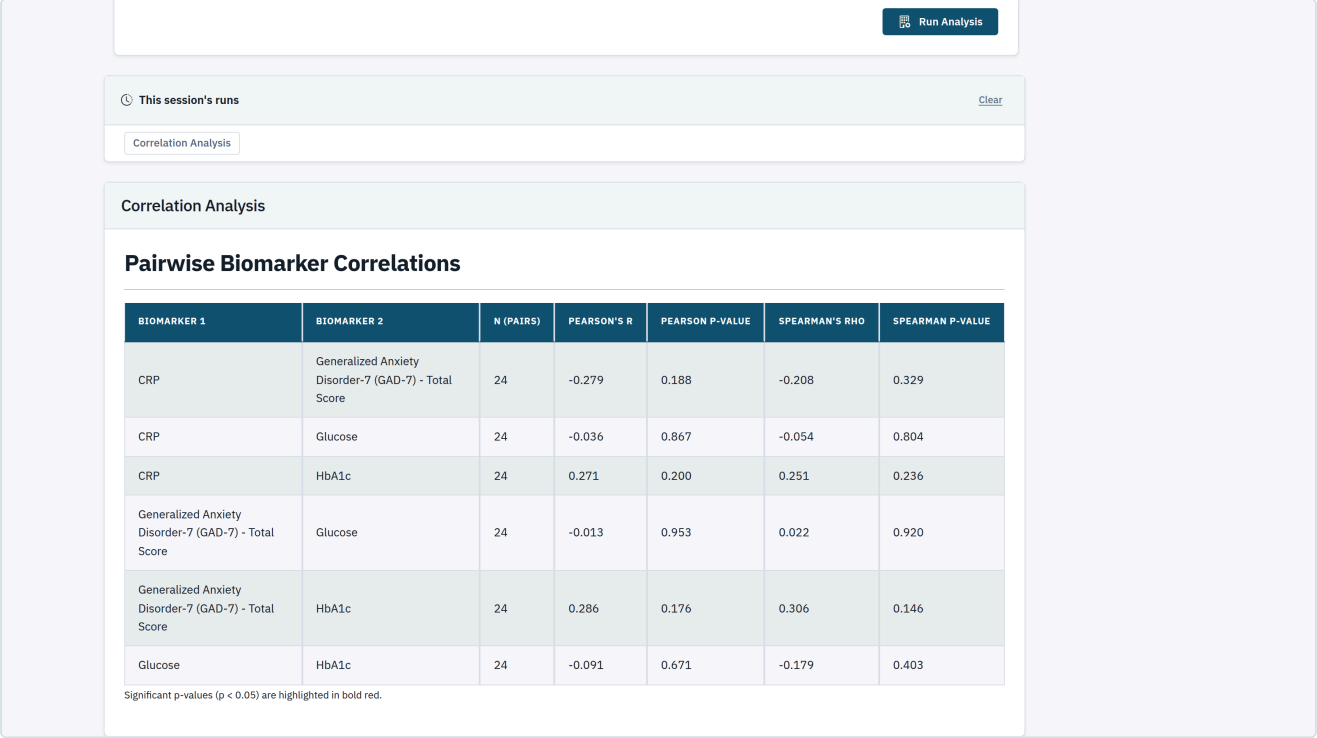


Figure 36 — Active against Placebo.

Every run is kept in **this session's runs** above the result, so you can flip between two analyses without running either again.

> **THE TEST IS YOUR CHOICE, AND THE PAGE TELLS YOU WHAT IT ASSUMES**
>
> ANOVA and Kruskal-Wallis need two or more cohorts; Mann-Whitney U and Kruskal-Wallis are the ones to reach for when the data is not normally distributed. The help text beside the selector says so, and it says it before you run rather than after.

Correlation



BIOMARKER 1	BIOMARKER 2	N (PAIRS)	PEARSON'S R	PEARSON P-VALUE	SPEARMAN'S RHO	SPEARMAN P-VALUE
CRP	Generalized Anxiety Disorder-7 (GAD-7) - Total Score	24	-0.279	0.188	-0.208	0.329
CRP	Glucose	24	-0.036	0.867	-0.054	0.804
CRP	HbA1c	24	0.271	0.200	0.251	0.236
Generalized Anxiety Disorder-7 (GAD-7) - Total Score	Glucose	24	-0.013	0.953	0.022	0.920
Generalized Anxiety Disorder-7 (GAD-7) - Total Score	HbA1c	24	0.286	0.176	0.306	0.146
Glucose	HbA1c	24	-0.091	0.671	-0.179	0.403

Significant p-values (p < 0.05) are highlighted in bold red.

Figure 37 — Four biomarkers against each other.

Correlation needs two or more biomarkers, and reports Pearson and Spearman side by side with the number of pairs each was computed from. Where a pair has too few complete observations it says so rather than printing a coefficient.

Who is in the study

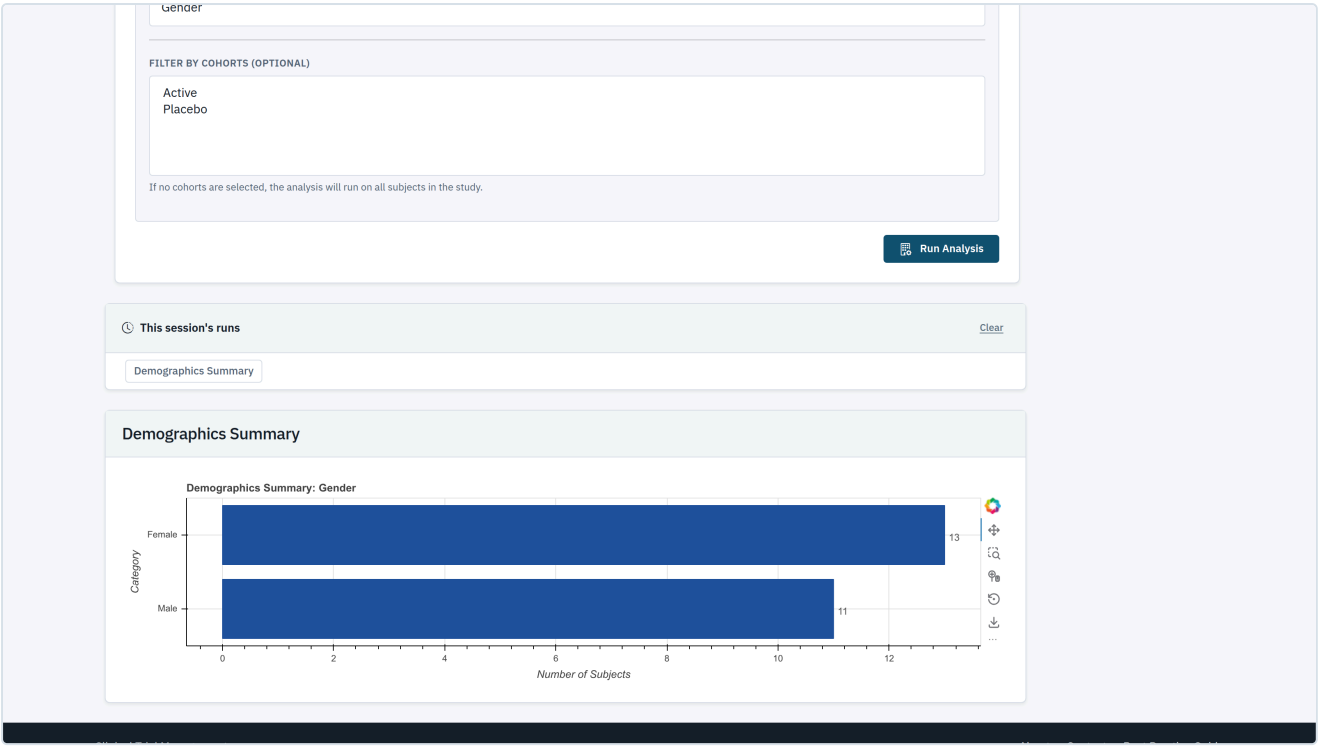


Figure 38 — Demographics, by arm.

Demographics summarise one field — gender, ethnicity, race, handedness, smoking status or alcohol intake — across the study.

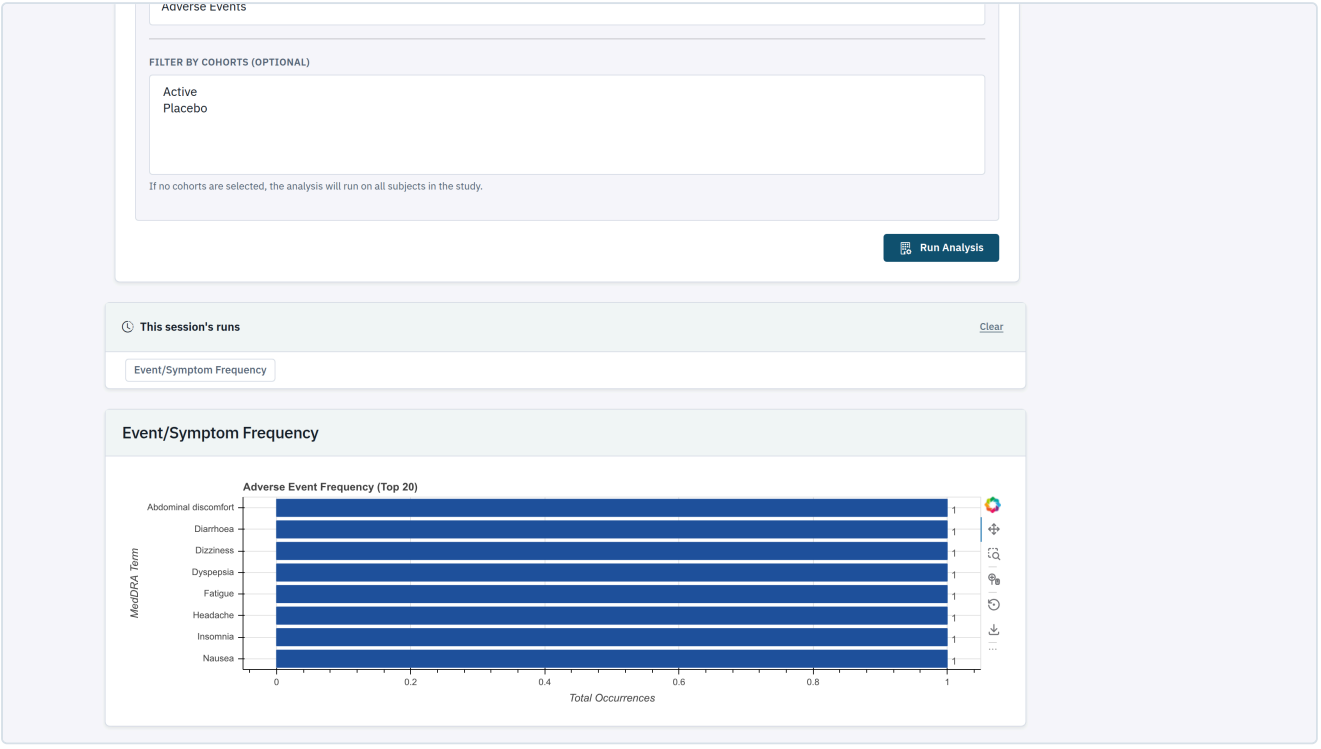


Figure 39 — Adverse events, counted by MedDRA term.

Event frequency counts adverse events or symptoms. Both are coded against MedDRA when they are entered, which is what makes counting them meaningful.

The AI analyses

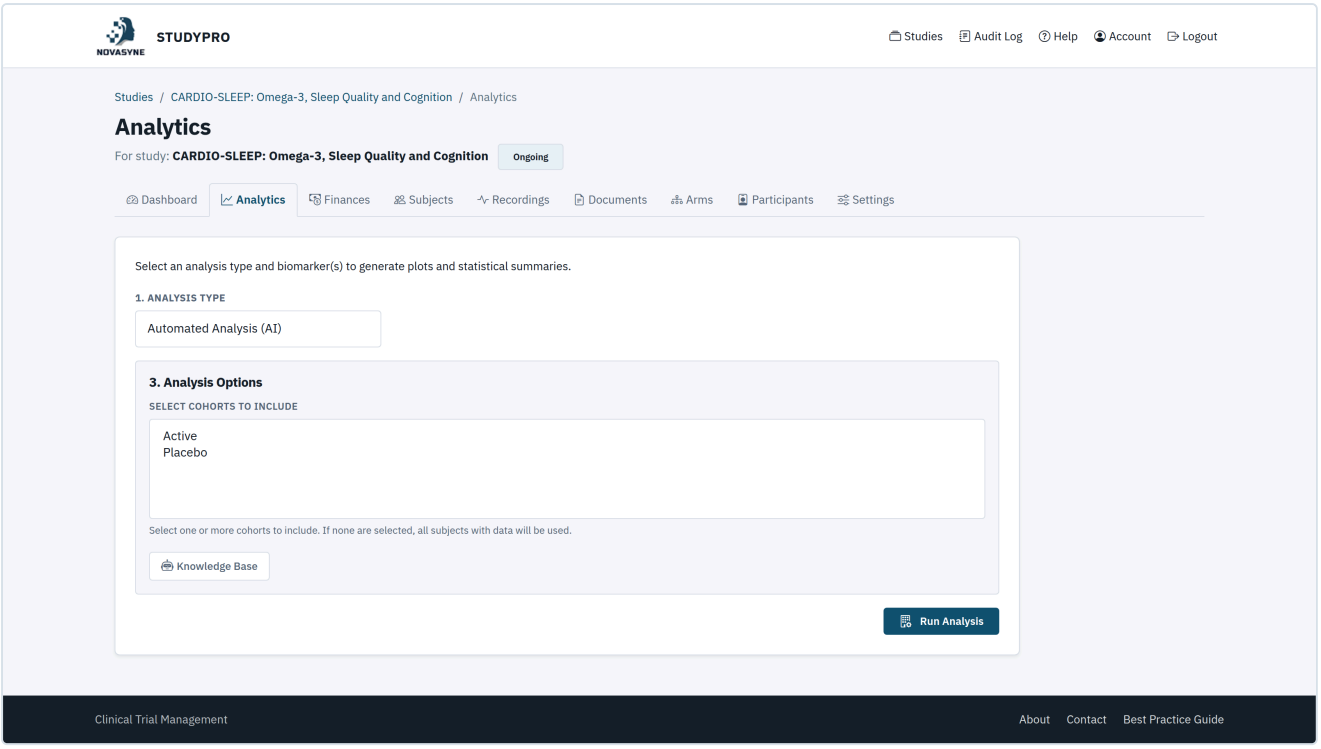


Figure 40 — What the AI analysis offers to do.

Automated Analysis reads the study's own data and the library you give it, and writes an interpretation.

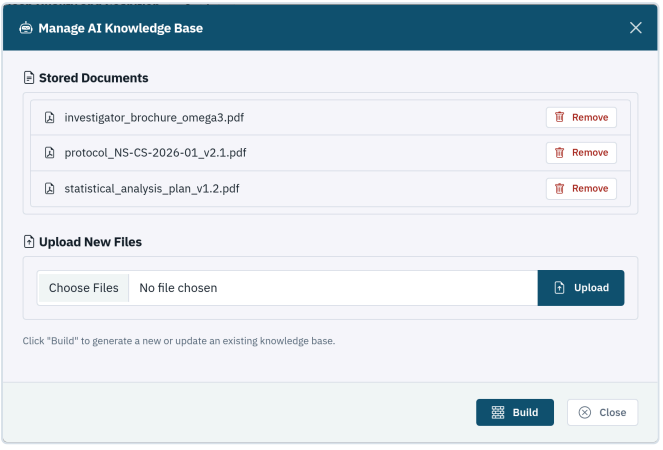


Figure 41 — The study library the assistant reads.

The **Knowledge Base** is that library: protocol, analysis plan, prior publications. Uploading files needs no key. **Building vectors** — the step that makes them searchable — and the analysis itself both call the provider.

WHAT THE AI FEATURES NEED, AND WHAT THEY SEND

An OpenAI key on the study, with credit. The study's summary data and the text of the knowledge files are what get sent. If your governance does not permit that, leave the key unset: the option disappears and every other analysis in this guide still works.

Money

Budget and spend

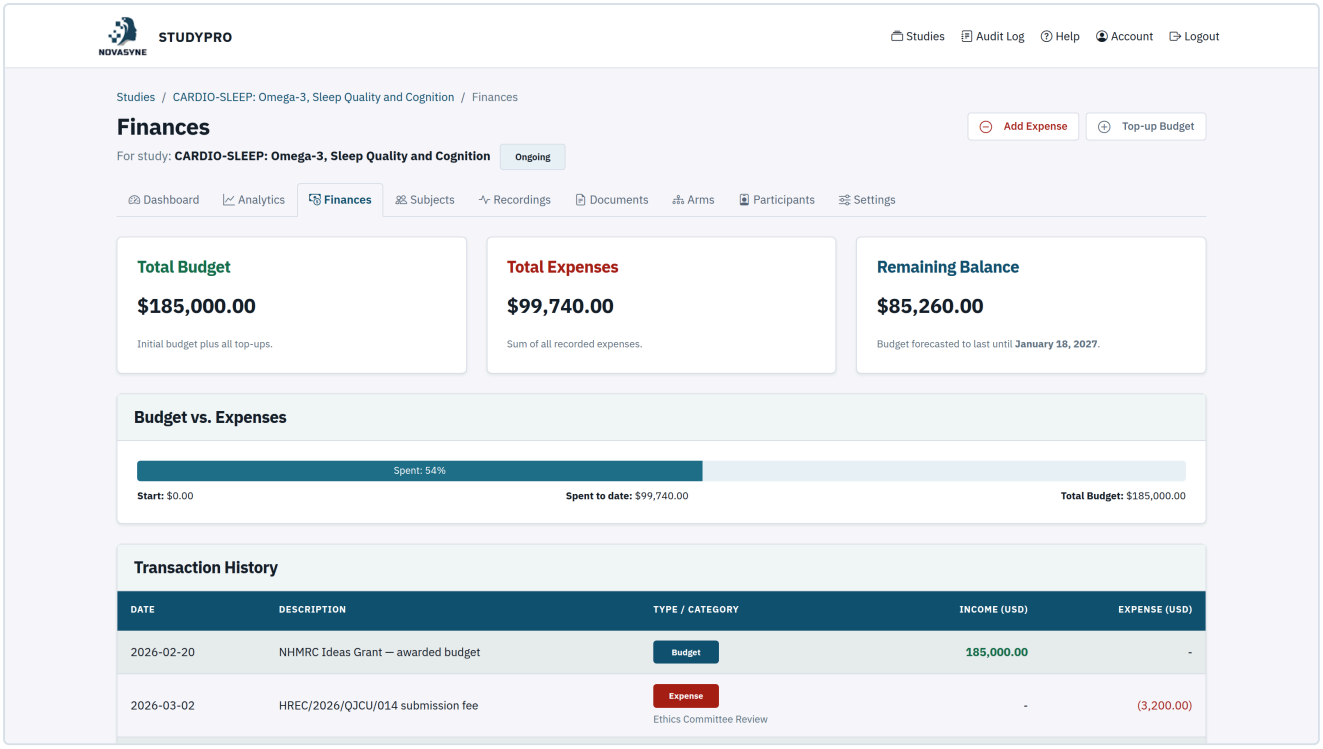


Figure 42 — Budget, spend and what is left.

Three figures at the top — total budget including every top-up, total spend, and the balance, with a forecast of how long it lasts at the current rate.

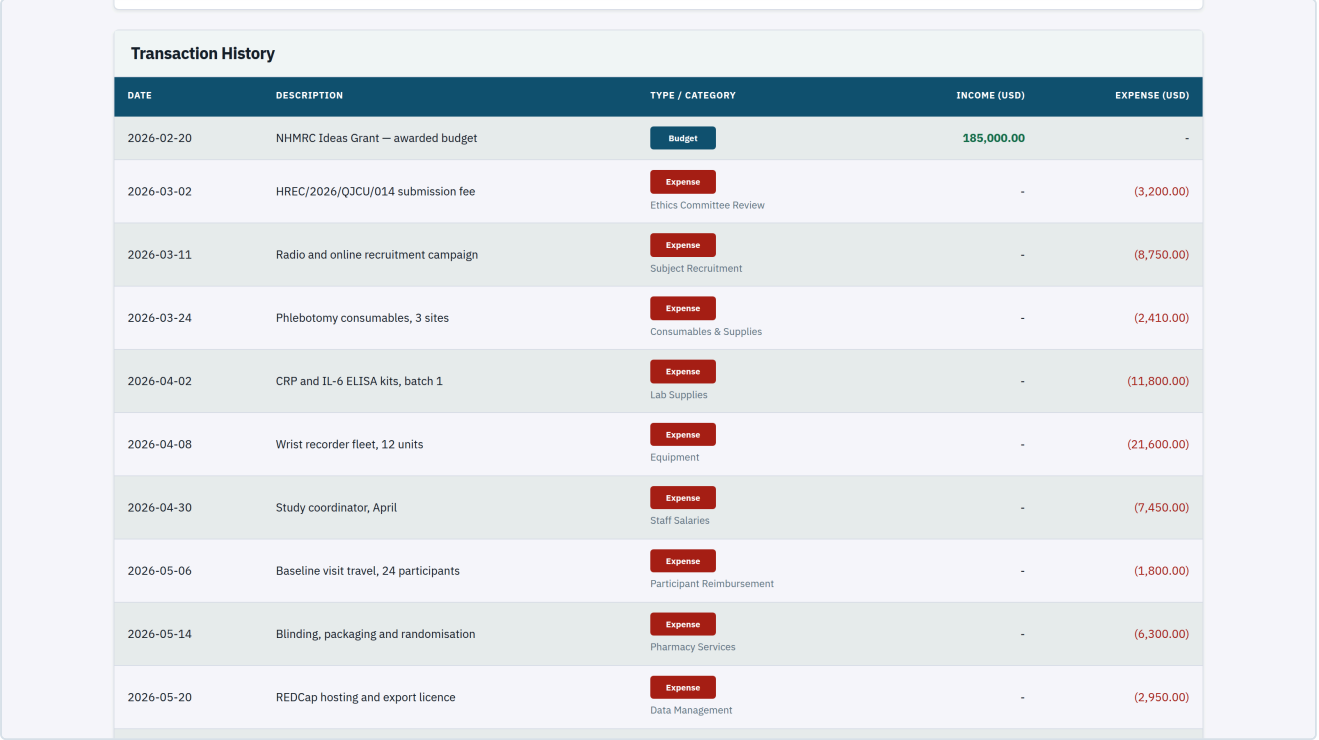


Figure 43 — Every transaction, categorised.

Below them the ledger: income and expense, one row each, with the category the expense was booked to.

Recording an expense

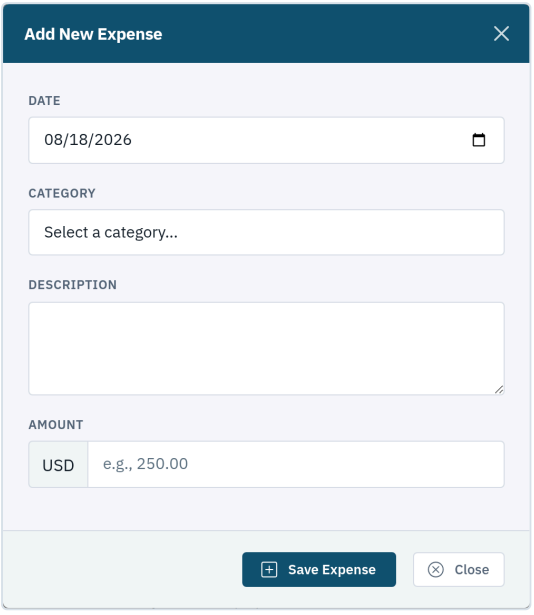


Figure 44 — Recording an expense.

Date, description, category and amount. Categories are shared across studies so that the same kind of cost is comparable between them.

Topping up

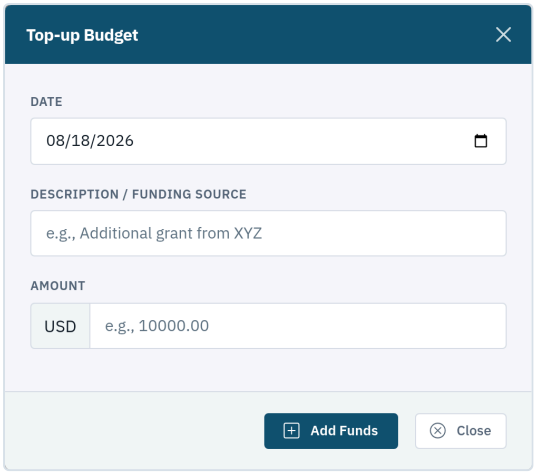


Figure 45 — Adding money to the budget.

A top-up is income, not an edit to the original number: the budget figure on the dashboard is the initial budget plus every top-up, and the history shows where each came from.

The study binder

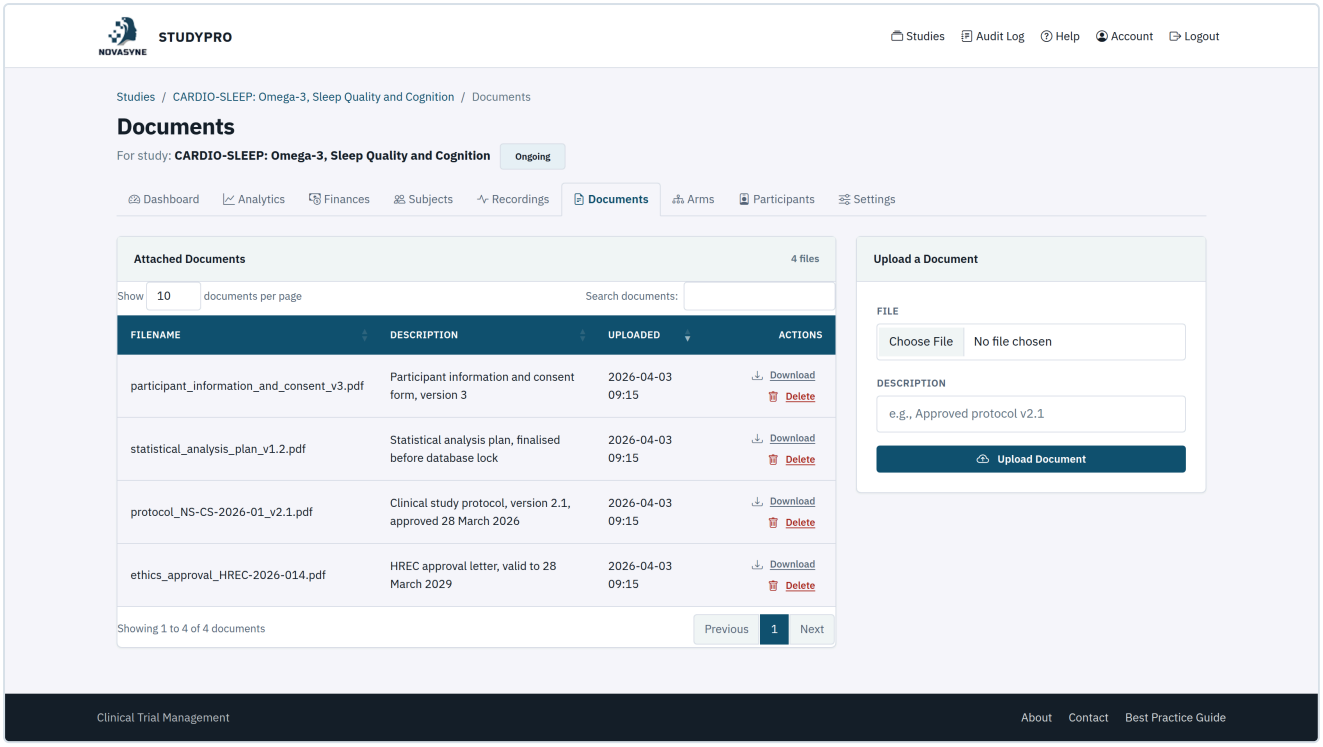


Figure 46 — The study binder.

Protocol, consent form, statistical analysis plan, ethics approval. Each upload carries a description, and the pack can be downloaded whole from Settings.

Arms and participants

Arms

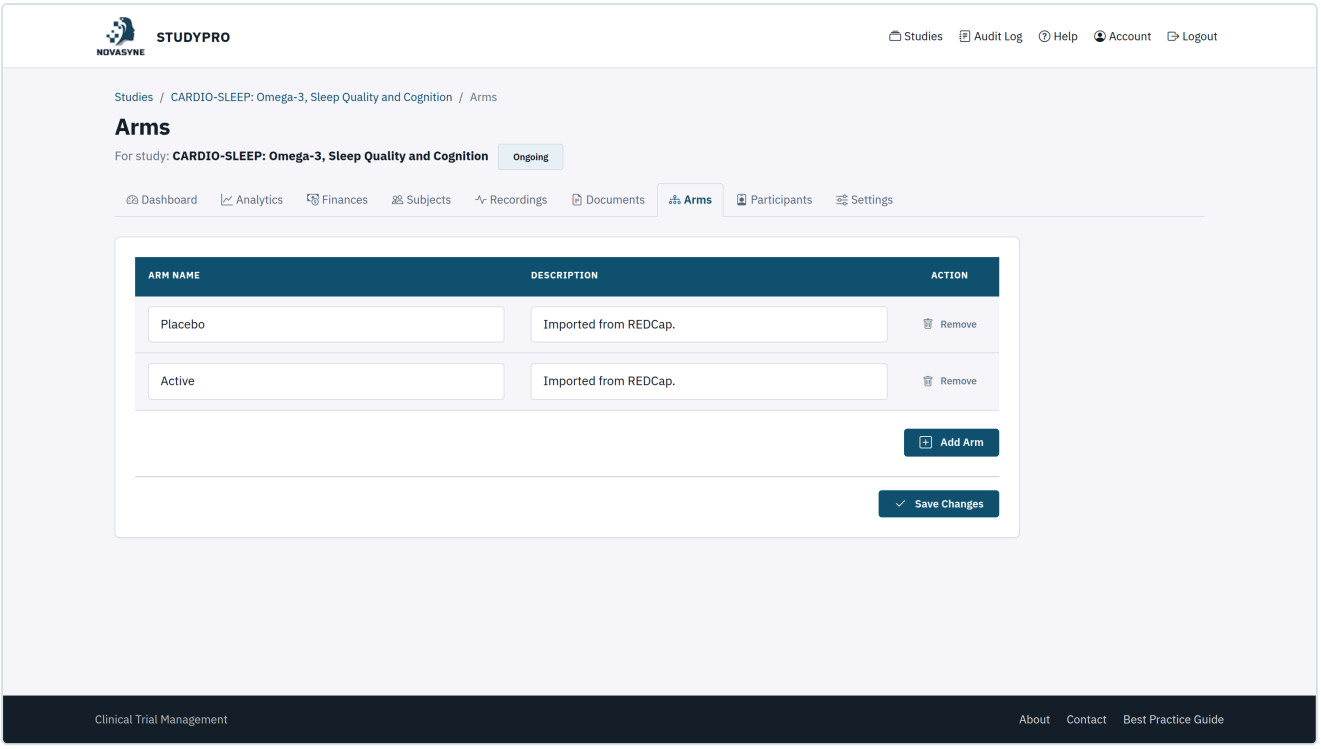


Figure 47 — The arms subjects are allocated to.

An arm is a cohort — Active and Placebo here. Every subject belongs to one, and every cohort comparison in the Analytics tab is a comparison between them.

Who can see the study

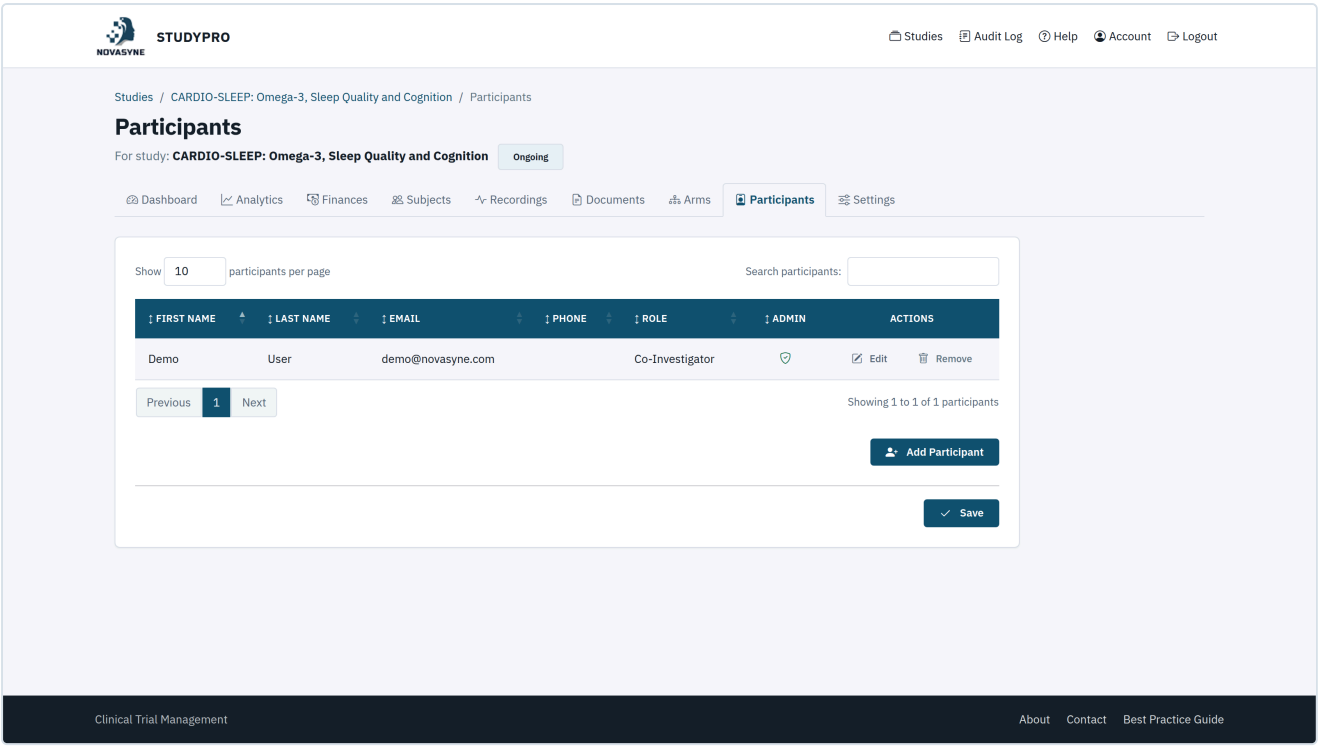


Figure 48 — Who works on the study.

Participants are the people, with the role each plays. This is the list that grants access: a person is on the study because their email address is here.

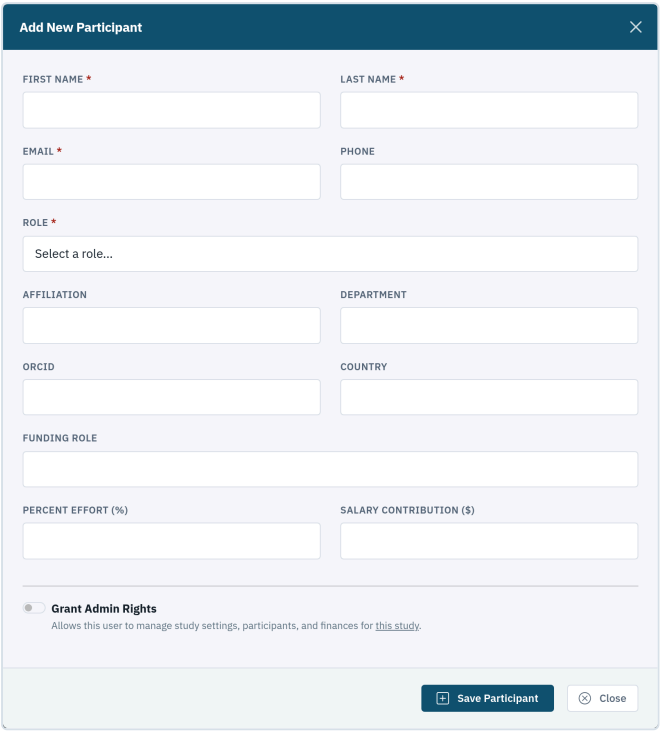


Figure 49 — Adding a colleague.

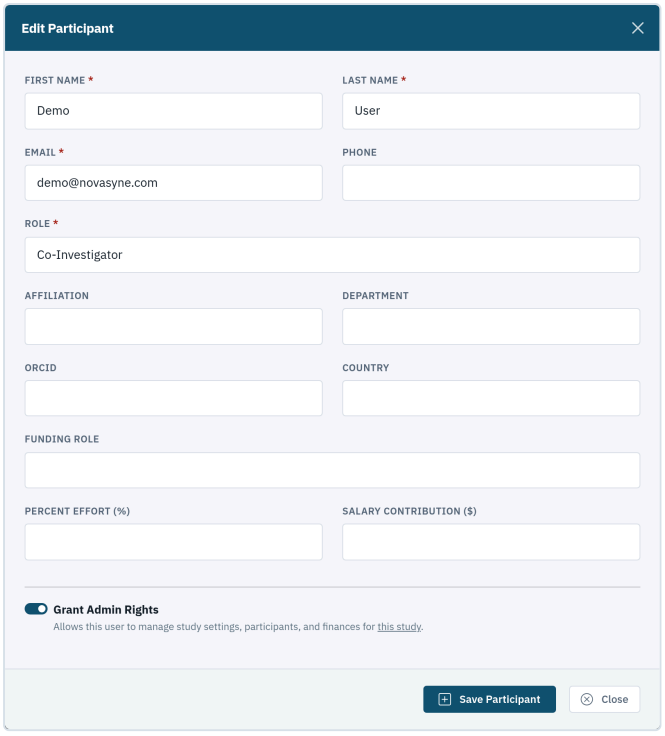


Figure 50 — The same form, filled.

The record carries more than a name — affiliation, department, ORCID, funding role, percent effort and salary contribution — because a grant report needs all of it and a spreadsheet kept beside the study will drift.

> **GRANT ADMIN RIGHTS IS THE WHOLE PERMISSION MODEL**
>
> With it, a participant can change study settings, participants and finances. Without it they can work in the study but not reshape it. There is no finer grain than that, and it is per study rather than global.

Settings

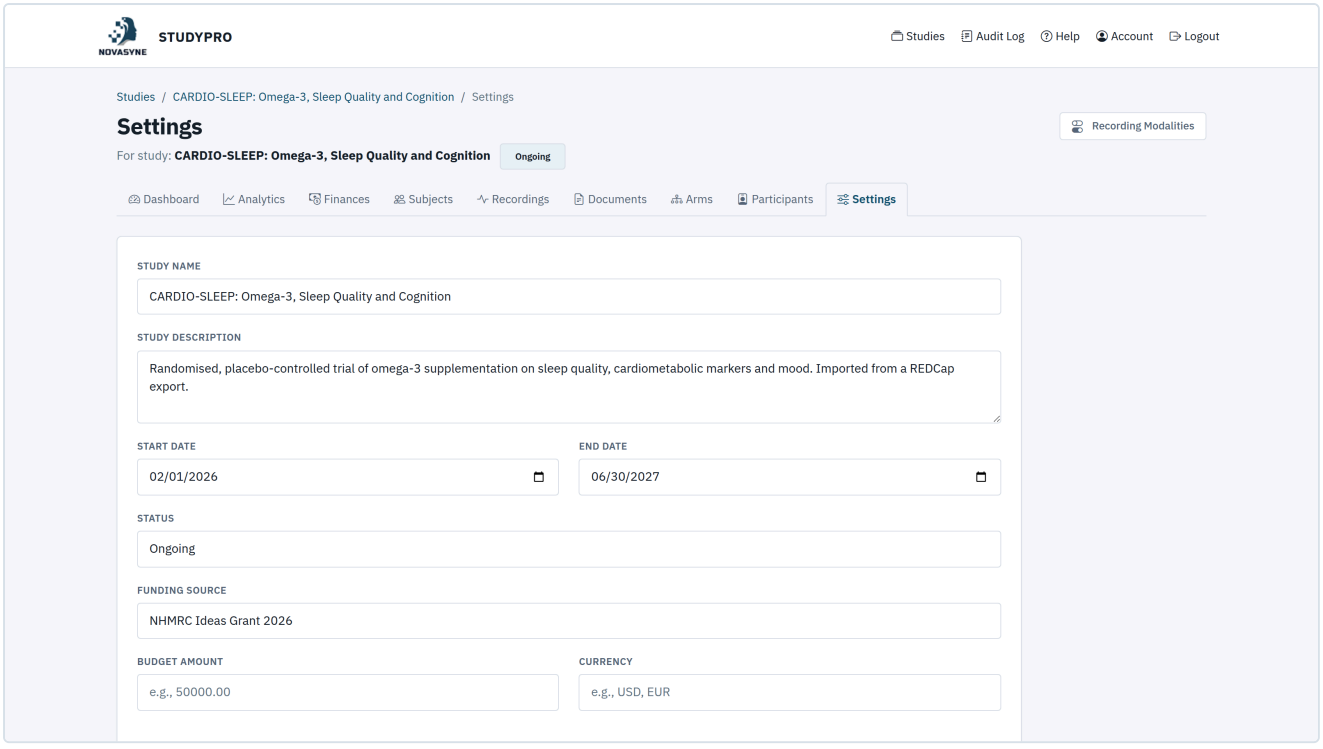


Figure 51 — The study record itself.

Name, description, dates, status, funding source, budget and currency.

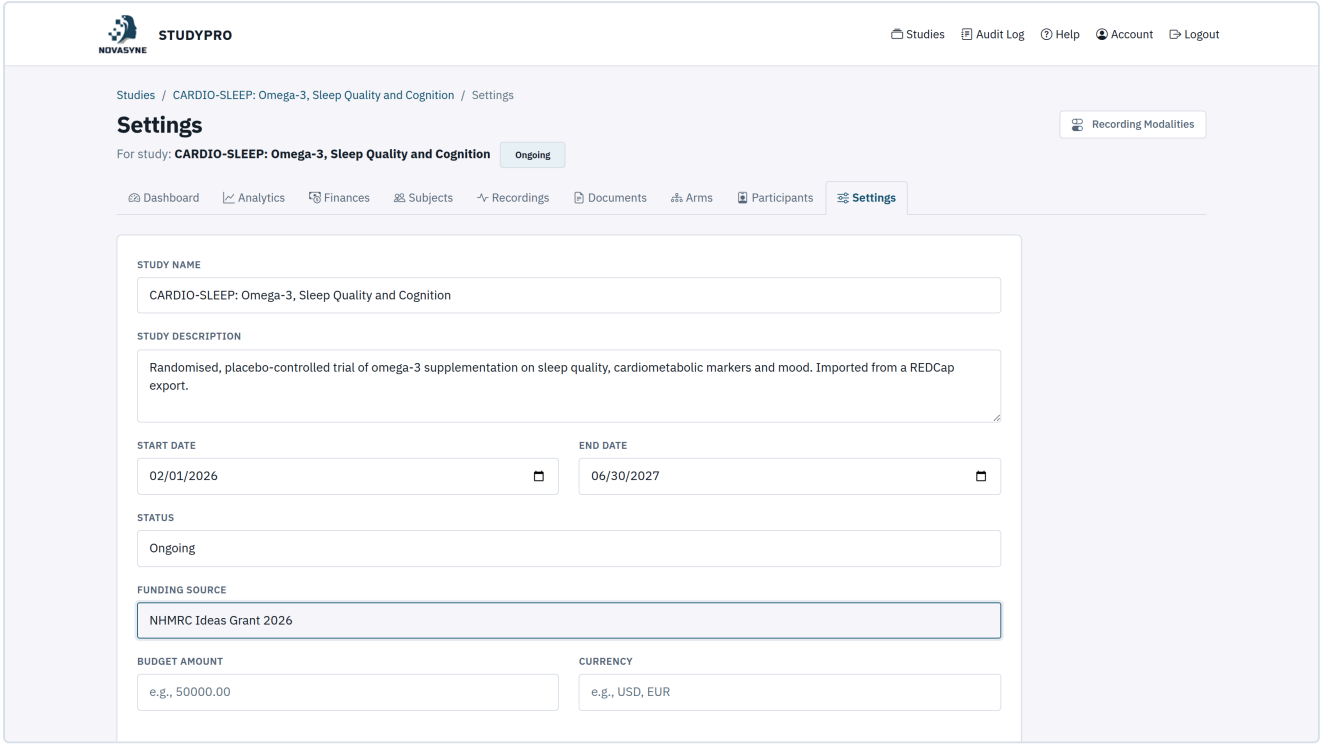


Figure 52 — Dates and funding, filled in.

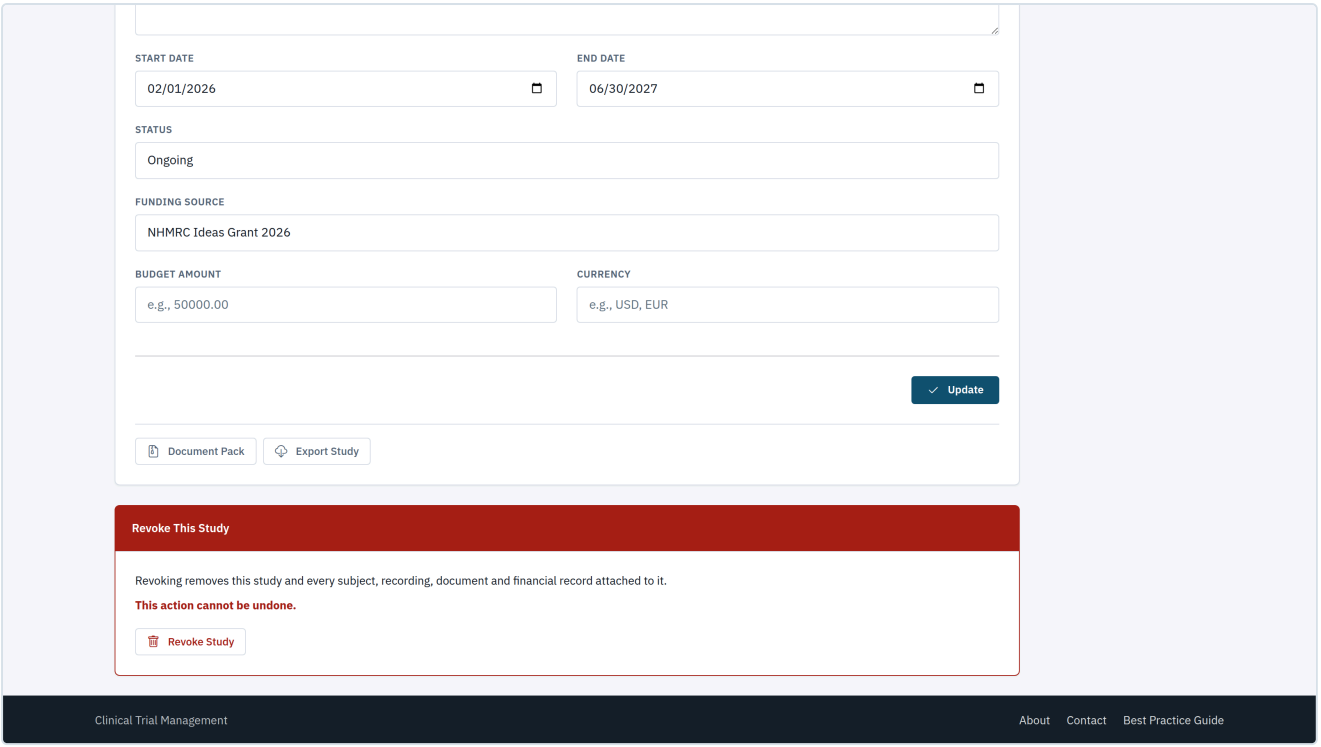


Figure 53 — Document pack, export, and the danger zone.

Document Pack downloads every study document as one archive. **Export Study** writes the study itself — subjects, recordings and all — for archiving or for moving it elsewhere.

Revoke This Study is at the bottom, in its own red card, and it is what the wording says: the study and every subject, recording, document and financial record attached to it. It cannot be undone.

The audit log

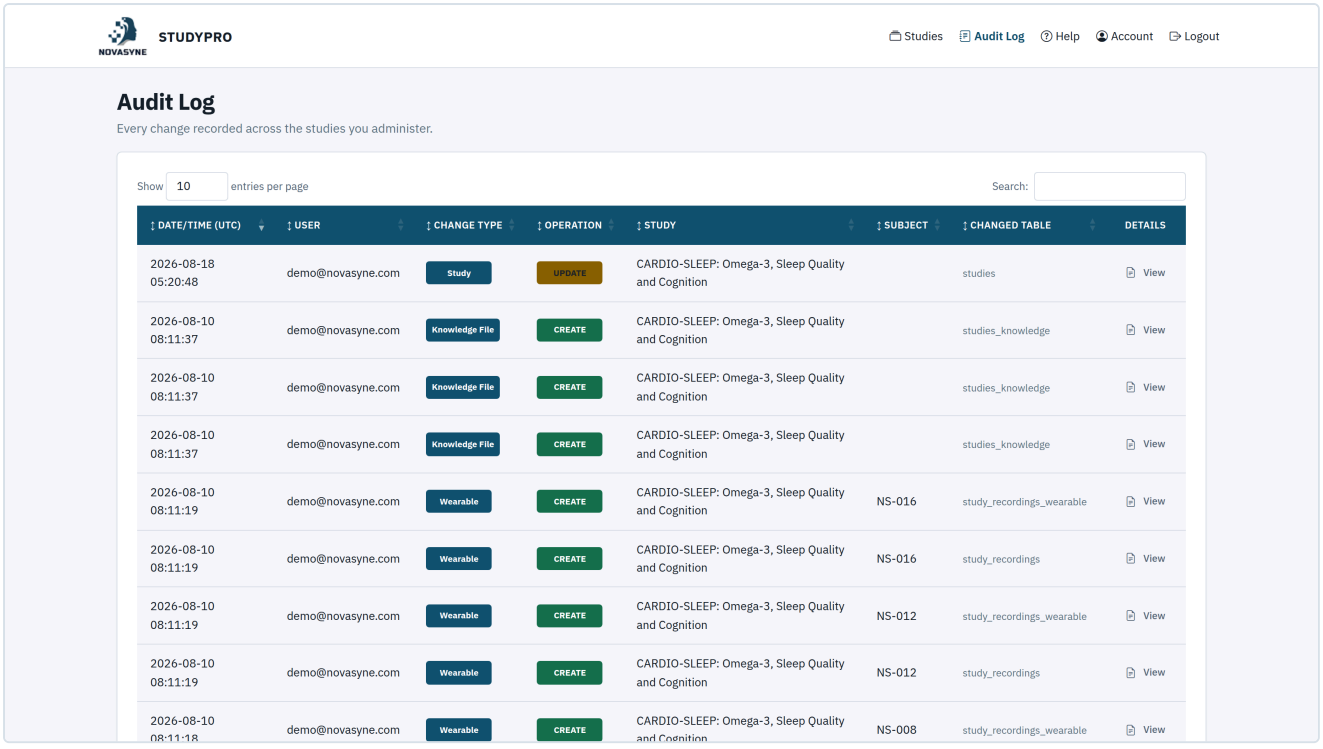


Figure 54 — Every change, across every study you administer.

Who, when, what kind of thing, which study, which subject, and which table. It is filterable and searchable, and it covers every study you administer rather than one at a time.

Figure 55 — One entry, field by field.

Opening an entry shows the fields that changed, with the old value beside the new one. Where the value was a file, the content reads `[redacted]` — the log records that a file was written and what it was called, not the file itself.

> **THIS IS THE RECORD THAT MAKES THE REST DEFENSIBLE**
>
> Every write in this guide — enrolling a subject, editing consent, adding a recording, changing the budget — appears here. Releasing a subject appears here too, along with a count of the historical values that were scrubbed to honour it.

Your account

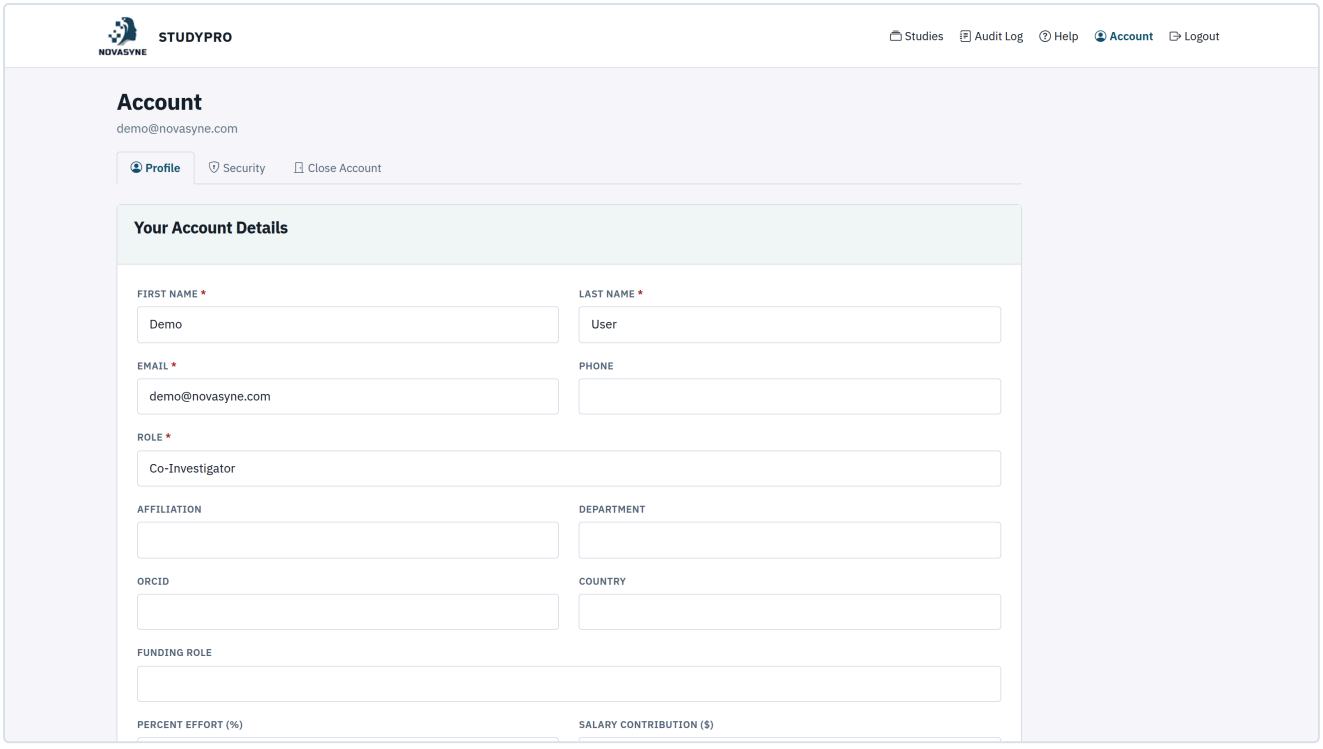


Figure 56 — The account.

Your own details and password, and the studies you belong to.

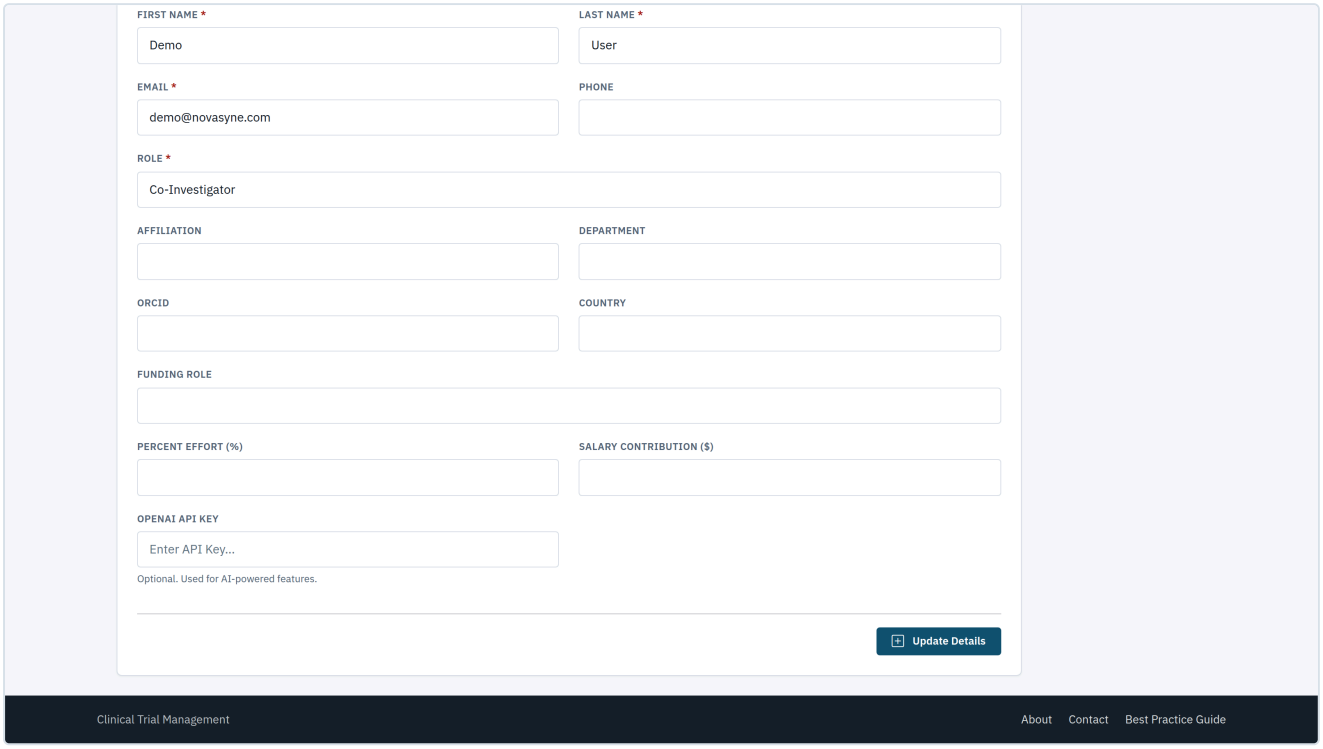


Figure 57 — Who may see what, per study.

Closing the account is here as well. It removes you; it does not remove the studies you worked on, and any study you are the only administrator of has to be handed over first.

Starting a new study

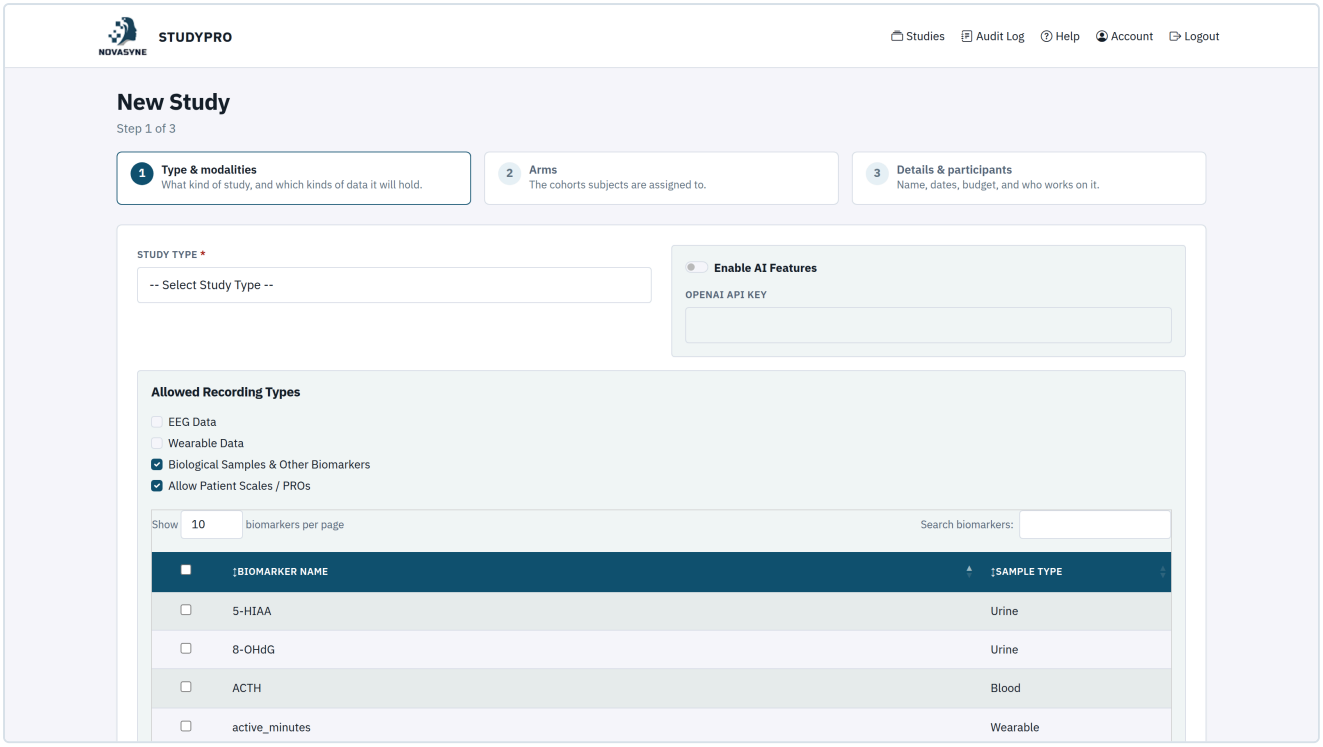


Figure 58 — Step one: what kind of study, and what it may hold.

Three steps. The first is the one that matters most.

Study type is the design — randomised controlled trial, crossover, observational cohort, diagnostic accuracy, and so on.

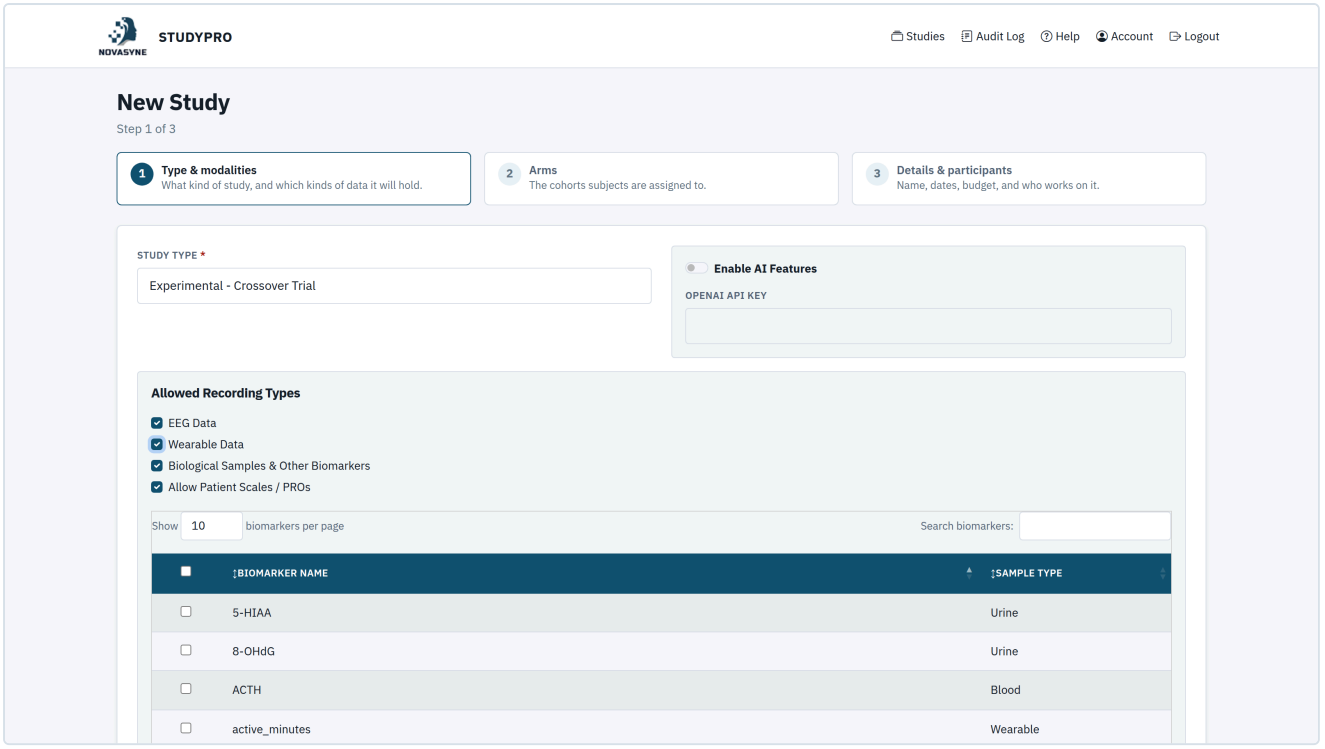


Figure 59 — Modalities decide what the rest of the platform offers.

Allowed recording types decide what this study can hold: EEG, wearable data, biological samples and other biomarkers, patient scales. Ticking a modality here is what makes it appear in the recordings tab, the import template and the analysis bench.

The biomarker table below is the study's own list. Only what you tick here can be recorded against a subject, which keeps a study from accumulating fields nobody agreed to collect.

Step two is the arms. Step three is the study's name, dates, budget and the people on it — the same fields the Settings and Participants tabs edit later, gathered once at the start.

> **MODALITIES CAN BE CHANGED AFTERWARDS**
>
> Settings has a **Recording Modalities** button for exactly that. It is easier to add one later than to explain a study that holds a kind of data its protocol never mentioned.

Importing from REDCap

A study that already exists in REDCap does not need to be typed in again.

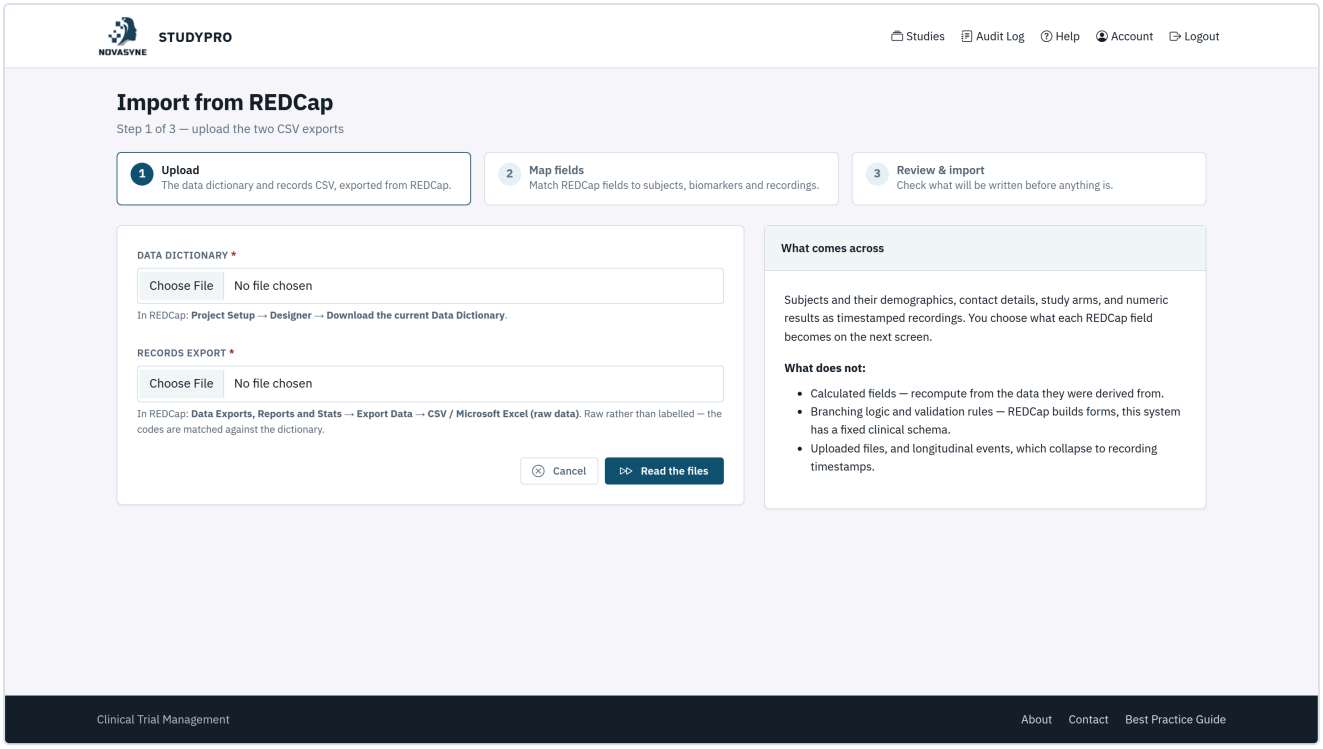


Figure 60 — The two exports REDCap gives you.

STUDYPRO reads two files, both of which REDCap exports directly:

The data dictionary — Project Setup → Designer → Download the current Data Dictionary. It is what tells STUDYPRO what each field means.

The records export — Data Exports, Reports and Stats → Export Data → CSV / Microsoft Excel (raw data). Raw rather than labelled: the codes are matched against the dictionary.

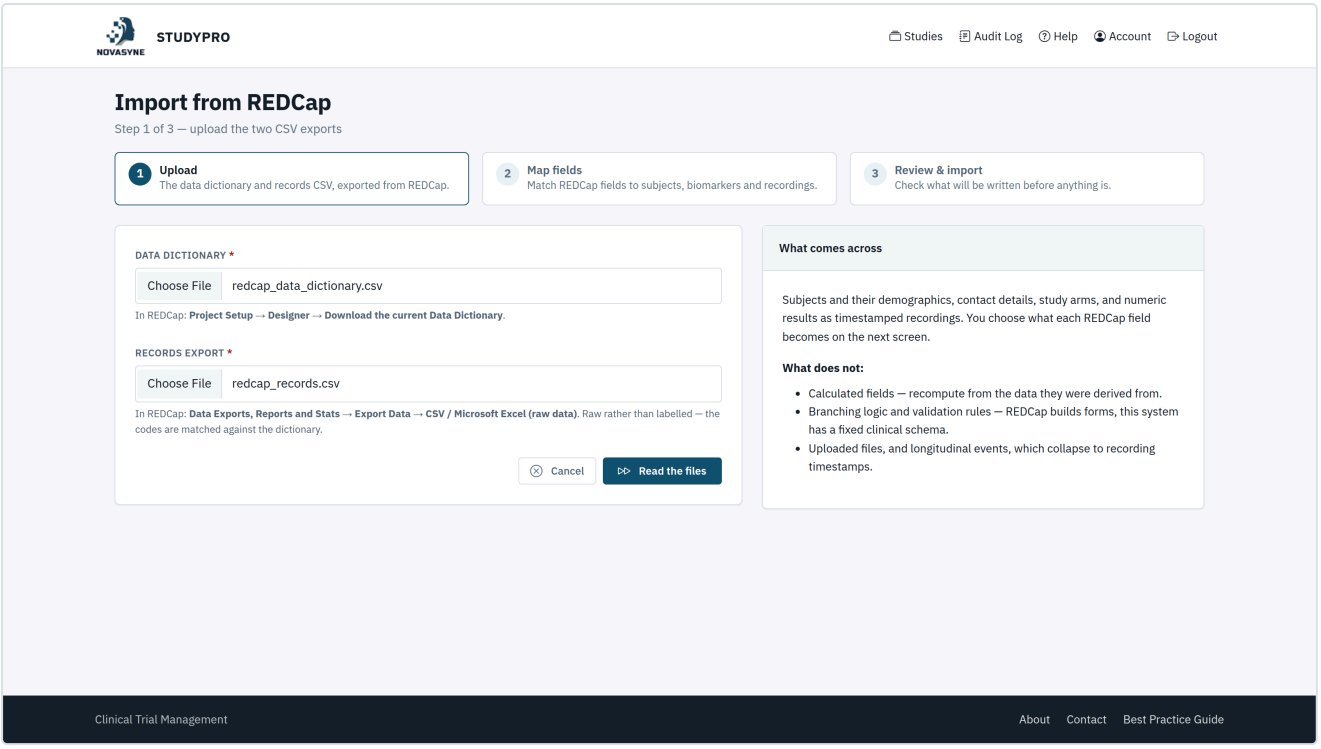


Figure 61 — Both files chosen.

Mapping

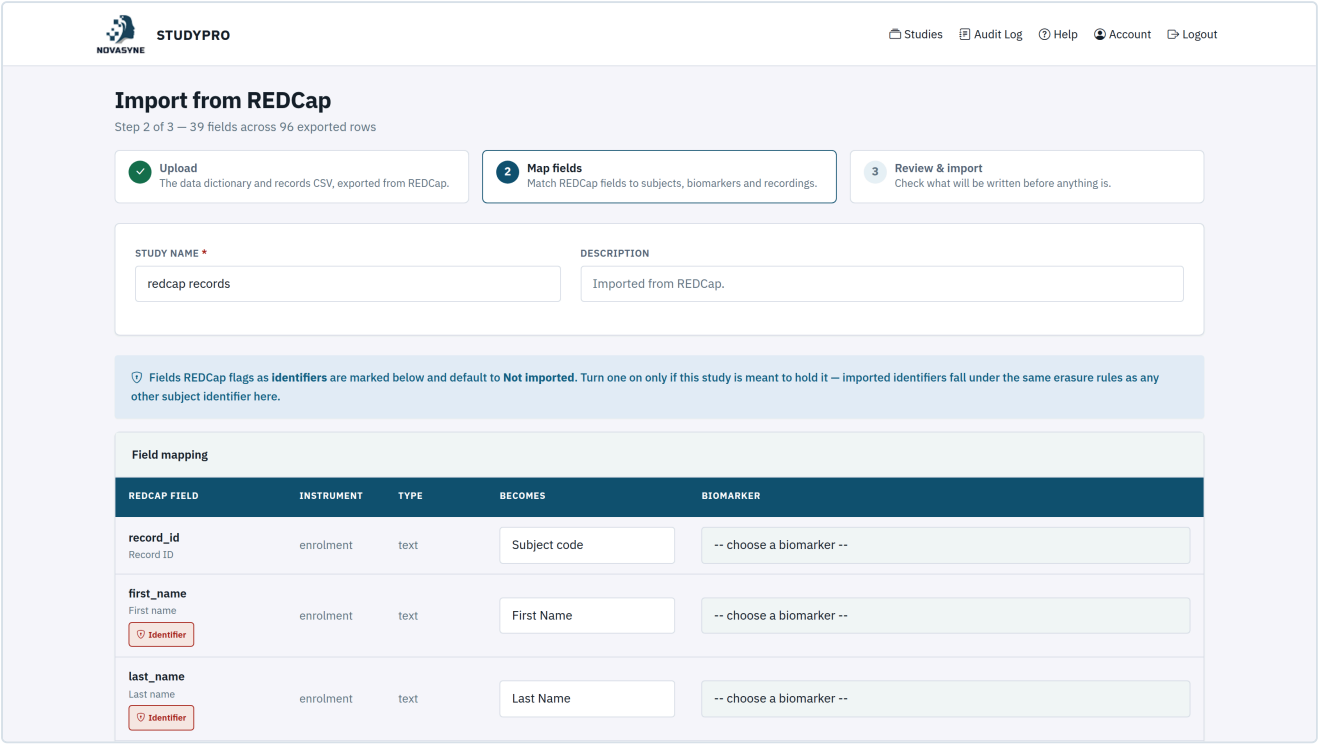


Figure 62 — Every REDCap field, and what it becomes here.

The mapping screen is the heart of the import. Every field in the dictionary is listed with the instrument it came from and its type, and you say what it becomes: a subject attribute, a biomarker observation, an arm, or nothing.

Fields REDCap flags as identifiers are marked, and default to **not imported**.

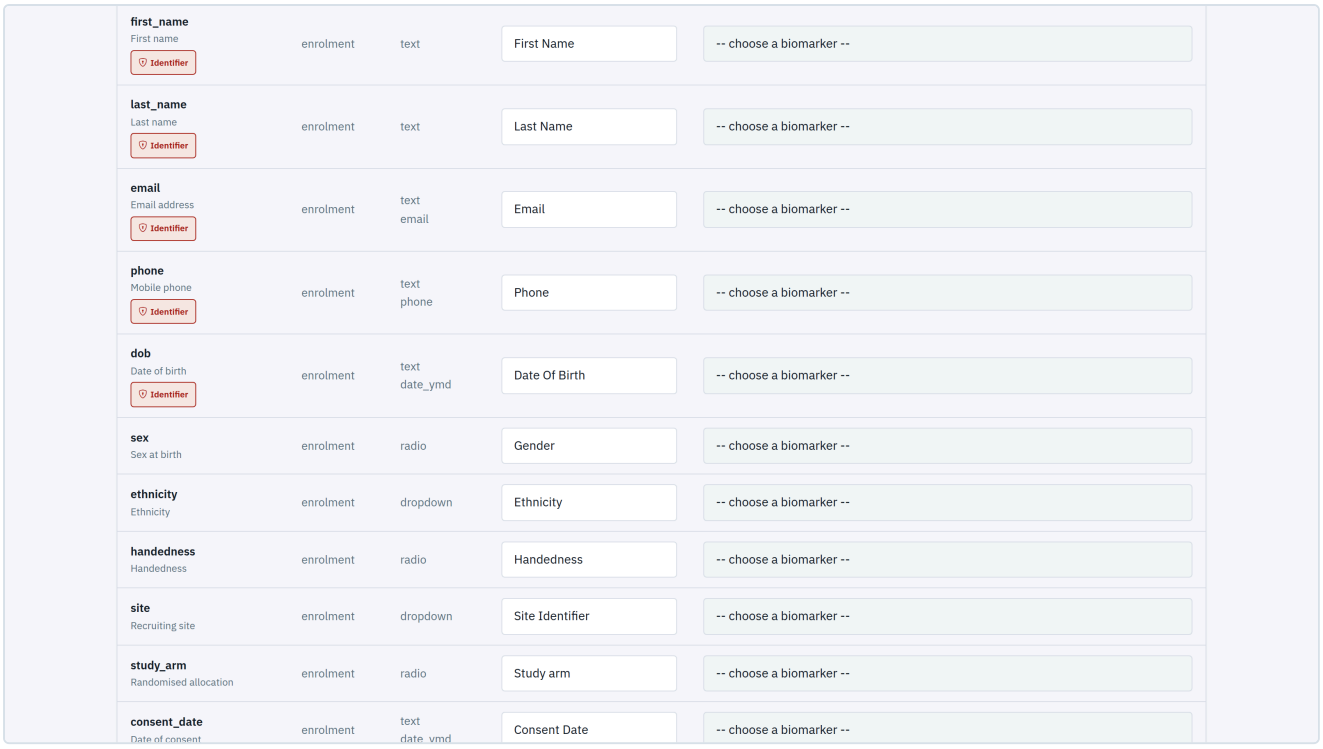


Figure 63 — An observation needs a biomarker, or it is skipped.

> **AN OBSERVATION WITHOUT A BIOMARKER IS SKIPPED, AND THE REPORT SAYS SO**
>
> Mapping a field to *observation* is only half the decision — it also needs the biomarker its values are. Leave that unset and the field imports nothing. This is the single most common reason a first import brings in subjects and arms but no results.

What does not come across

Four things, and they are stated on the upload screen before you begin:

Calculated fields. Recompute them from the data they were derived from.

Branching logic and validation rules. REDCap builds forms; this system has a fixed clinical schema.

Uploaded files. Add them as study or subject documents.

Longitudinal events. They collapse into recording timestamps.

> **THE IMPORT IS READ-ONLY, ON PURPOSE**
>
> Nothing is written back to REDCap. The project of record stays the project of record, and re-importing after a change in REDCap updates what is here rather than diverging from it.

Appendix A — Control reference

Everywhere

Control	Effect
Studies	The list of studies you can reach
Audit Log	Every change across every study you administer
Help	Context help for the page you are on
Account	Your details, your studies, closing the account
Logout	Ends the session

Inside a study

Tab	Holds
Dashboard	Status, recruitment, spend, completeness
Analytics	Nine analyses plus the AI ones
Finances	Budget, expenses, top-ups, ledger
Subjects	Roster, enrolment, history, consent, documents, release
Recordings	Every observation, the calendar, the viewers, import and export
Documents	The study binder
Arms	Cohorts
Participants	People and admin rights
Settings	The study record, document pack, export, revoke

Recordings tab

Control	Effect
Type tabs	Filter to Biomarkers, Scales, EEG, Wearables, Symptoms, Adverse Events or Medication
CSV / Excel	Export what the table is showing
Calendar View	The same recordings by date
New Recording	Add one by hand
Export Template	A spreadsheet shaped for this study
Import Template	Read that spreadsheet back
Export Analysis Packet	Tables plus raw signal files, for analysis elsewhere

Appendix B — The analyses

Analysis	Needs	Produces
Cohort Comparison	One biomarker, two or more cohorts	Box plot, or t-test, ANOVA, Mann-Whitney U, Kruskal-Wallis
Subject Analysis Over Time	One biomarker, one subject	The series for that person
Data Distribution	One biomarker	Histogram, density or violin
Correlation Analysis	Two or more biomarkers	Correlation matrix
Comprehensive Correlation	Selected cohorts	Every pair across all data types
Demographics Summary	One demographic field	Counts by arm
Event/Symptom Frequency	Adverse events or symptoms	Counts by MedDRA term
Concomitant Medication Frequency	—	Counts by medication
Cohort Distribution Report	—	Every cohort at once
Automated Analysis (AI)	An OpenAI key with credit	A written interpretation

Appendix C — What STUDYPRO refuses to do

Run an analysis whose inputs do not fit it. The Run button stays disabled and the line under the biomarker list says what is missing — exactly one biomarker for a cohort comparison, two or more for a correlation.

Read a raw wearable export. The viewer needs a flat CSV with a `time` column in seconds, and says so rather than rendering something wrong.

Import a REDCap observation with no biomarker chosen. The field is skipped and the reason is in the import report.

Import REDCap identifiers by default. They are flagged and off until you turn each one on.

Show you a study you have not been added to. Access is by email address on the participant list; there is no URL that works around it.

Delete a released subject's clinical record. Release removes identity, not data. The two are deliberately different operations.

Appendix D — The study used in this guide

Study	CARDIO-SLEEP: Omega-3, Sleep Quality and Cognition
Design	Randomised, placebo-controlled
Subjects	24, in two arms — Active and Placebo
Recordings	About 1,100, across biomarkers, scales, EEG, wearables, symptoms and adverse events
Documents	Protocol, consent form, statistical analysis plan, ethics approval
Budget	$185,000, against which about $99,700 had been spent
Provenance	Imported from the REDCap export in `demo/novasyne-assets/`, then extended with signal recordings

It is synthetic. No person in it exists, and the clinician, diagnosis and medication in the Subjects chapter were entered while this guide was being captured, to give those tables something to show.