# PAIR

## AI TFL Automated Generation

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CDISC AI Innovation Challenge 2026 · Use Case 3 · Winning submission

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# The CDISC Challenge: AI-Driven TFL Generation

## PROBLEM

- TFLs are generated manually
- Requires repeated effort
- Tedious tasks
- Limits traceability from objective to result



## CHALLENGE

- AI-assisted TFL generation
- End-to-end traceability
- Reduced manual effort
- Transparent outputs

Judging weights:

**Innovation & Relevance 30%** · **Technical Quality & Feasibility 30%** · **Standards Integration, Traceability & Impact 40%**

The challenge is not generating tables.

The challenge is maintaining consistency, traceability and trust.

# PAIR
# Pipeline for AI-assisted Reporting

Clinical reporting AI that understands the study, applies company standards, and keeps every decision transparent and reviewable.

For stages, review built in




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# How PAIR works

**01**

**Study Documents**

- Statistical Analysis Plan (SAP)
- ADaM specifications
- TFL Shells

**02**

**Study Context**

- Objectives
- Endpoints
- Analysis populations

**03**

**Executable Specification**

- Analysis
- Display rules
- Audit trail
- CDISC ARS v1.0 aligned

**04**

**Reviewable Outputs**

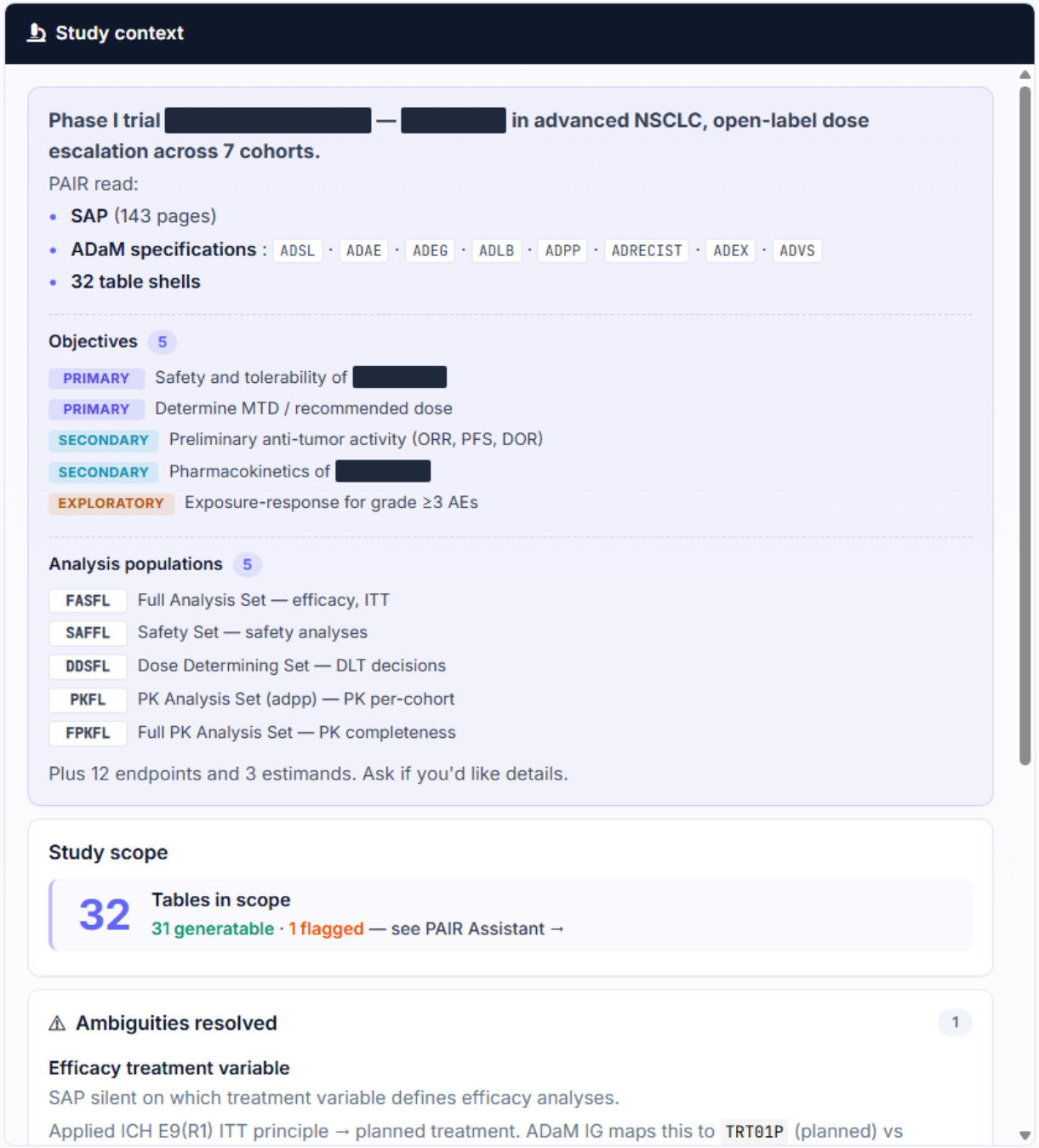
- Draft tables
- Traceability
- Change impact analysis

# Always keeping the human in the loop

**PAIR provides a study context**, to help understanding:

- Objectives & Endpoints
- Analysis population
- Treatment strategies
- Dataset dependencies

"Before any generation occurs, PAIR builds a structured study model that users can review and modify at any stage. Once the model is approved, code generation begins, creating a transparent and trusted workflow."




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# From Study Understanding to Executable Specification

## ANALYSIS

```
method_ref: METH-AESOC                    → AnalysisMethod
sub_variant: AE-SOC-PT-SEV
operations:
- id: OP-AESOC-01
name: count_subjects_by_soc_pt
result_pattern: n (%)                     → Operation
- id: OP-AESOC-02
name: compute_big_n
result_pattern: 'N'                       → Operation
analysis_set_ref: AS-SAFETY               → AnalysisSet
grouping_ref: GF-TRT-ACTUAL               → GroupingFactor
data_subset_ref: DS-TEAE                  → DataSubset
treatment_var: TRT01A
primary_dataset: adae
```

## DISPLAY

```
severity_columns:
- All grades
- Grade >= 3 (filter: AETOXGRN>=3)        → from shell
sorting:
soc: alphabetical                         → from method index
pt: descending_frequency
sort_col: All Patients, All grades
total_column:
include: true                             → from shell
precision:
percentage: 1                             → from formatting_config
```

## AUDIT TRAIL

```
decisions:
- type: ASSUMPTION
  text: Safety set for summaries,
  TRT01A per as-treated
  convention.
  source: SAP §2.7
- type: ASSUMPTION
  text: Missing CTCAE grades
  counted in "All grades",
  not in "Grade >= 3".
  source: SAP §2.7.1
programming_notes:
- Sources METH-AESOC_helpers.R
- Sorting: SOC alpha, PT desc freq
confidence:
● HIGH (2 assumptions)
```

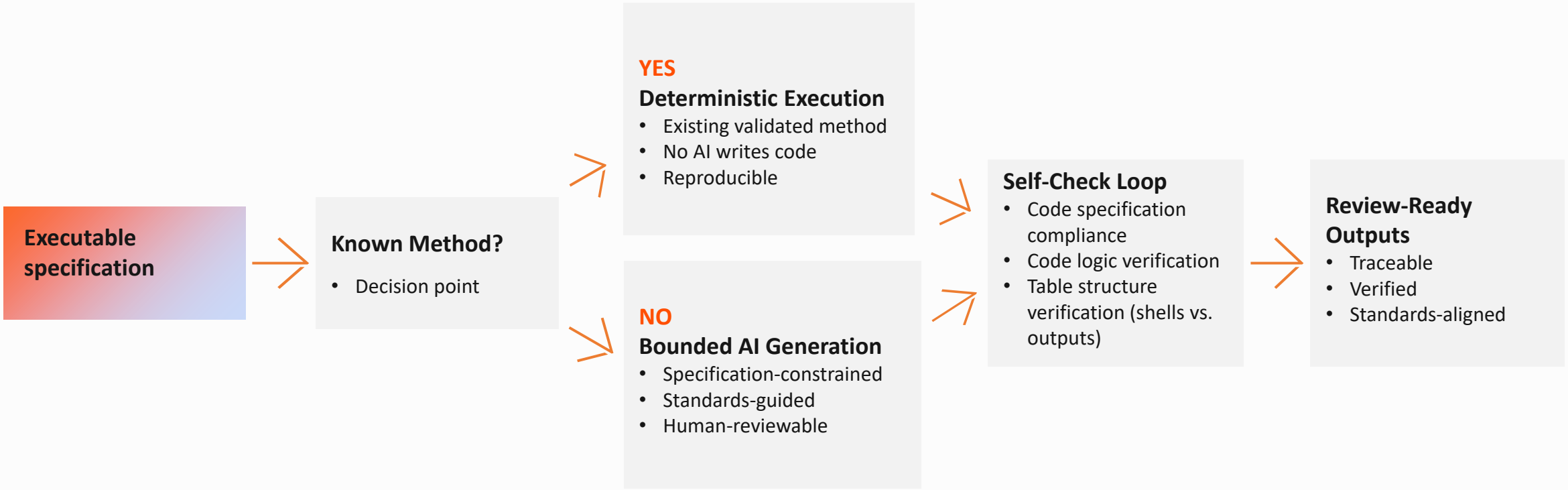
**CDISC ARS-aligned entities**

AnalysisSet | DataSubset | GroupingFactor | AnalysisMethod

**Defined once and reused across the study**

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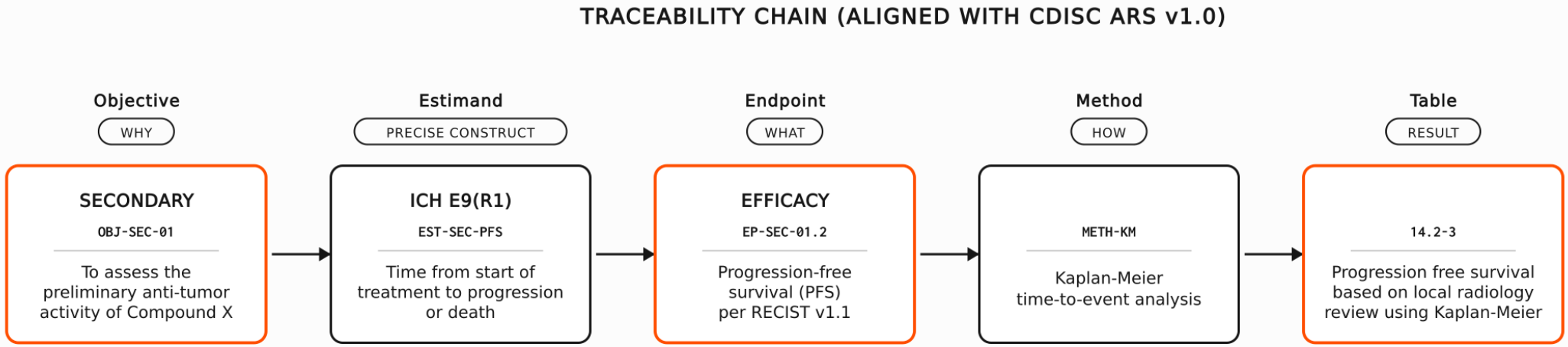
# AI is the glue, not the foundation




**AI is invited, not put in charge.**

It guides decisions and assembles proven components rather than replacing them.

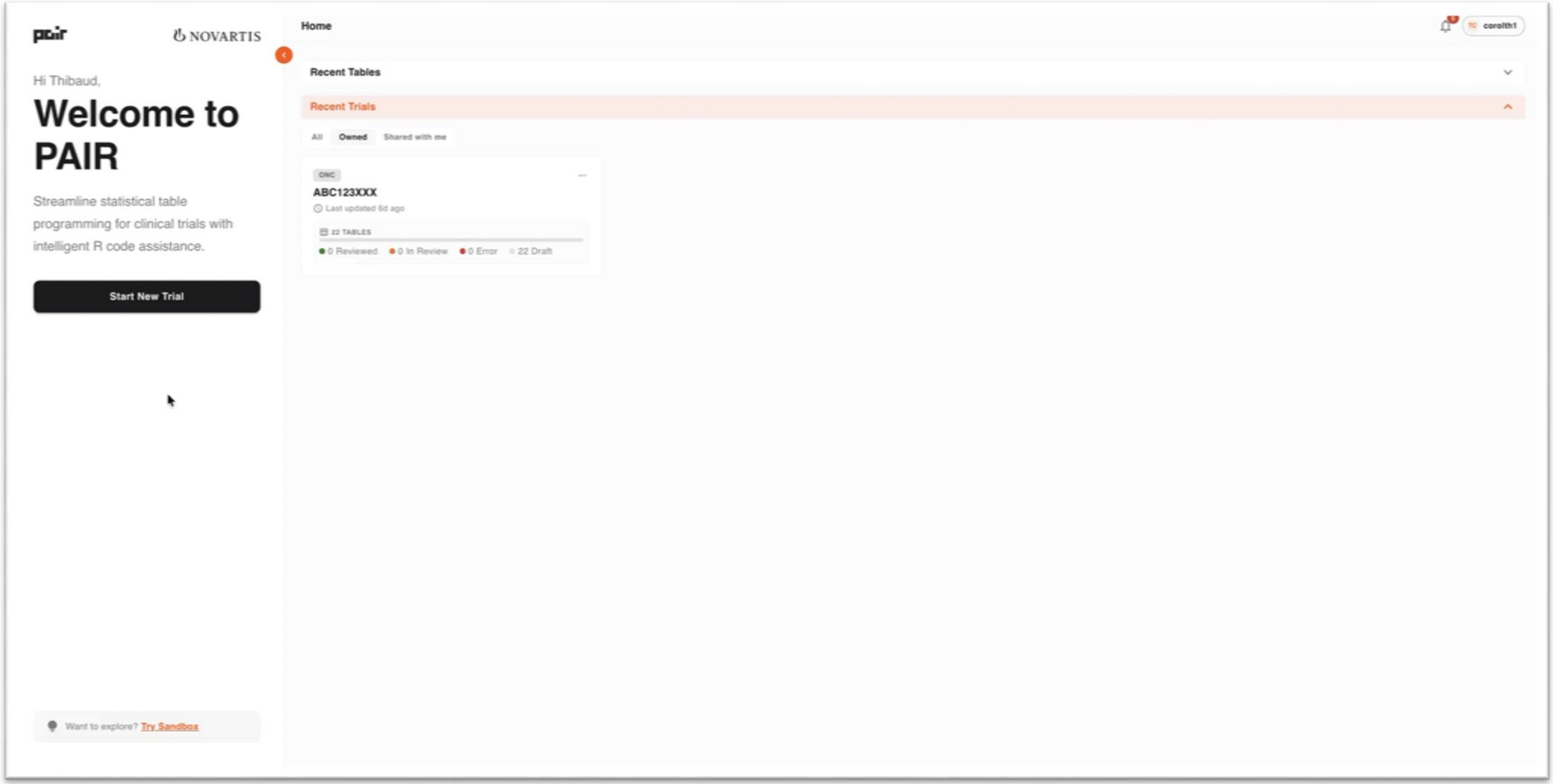
# End-to-end Traceability



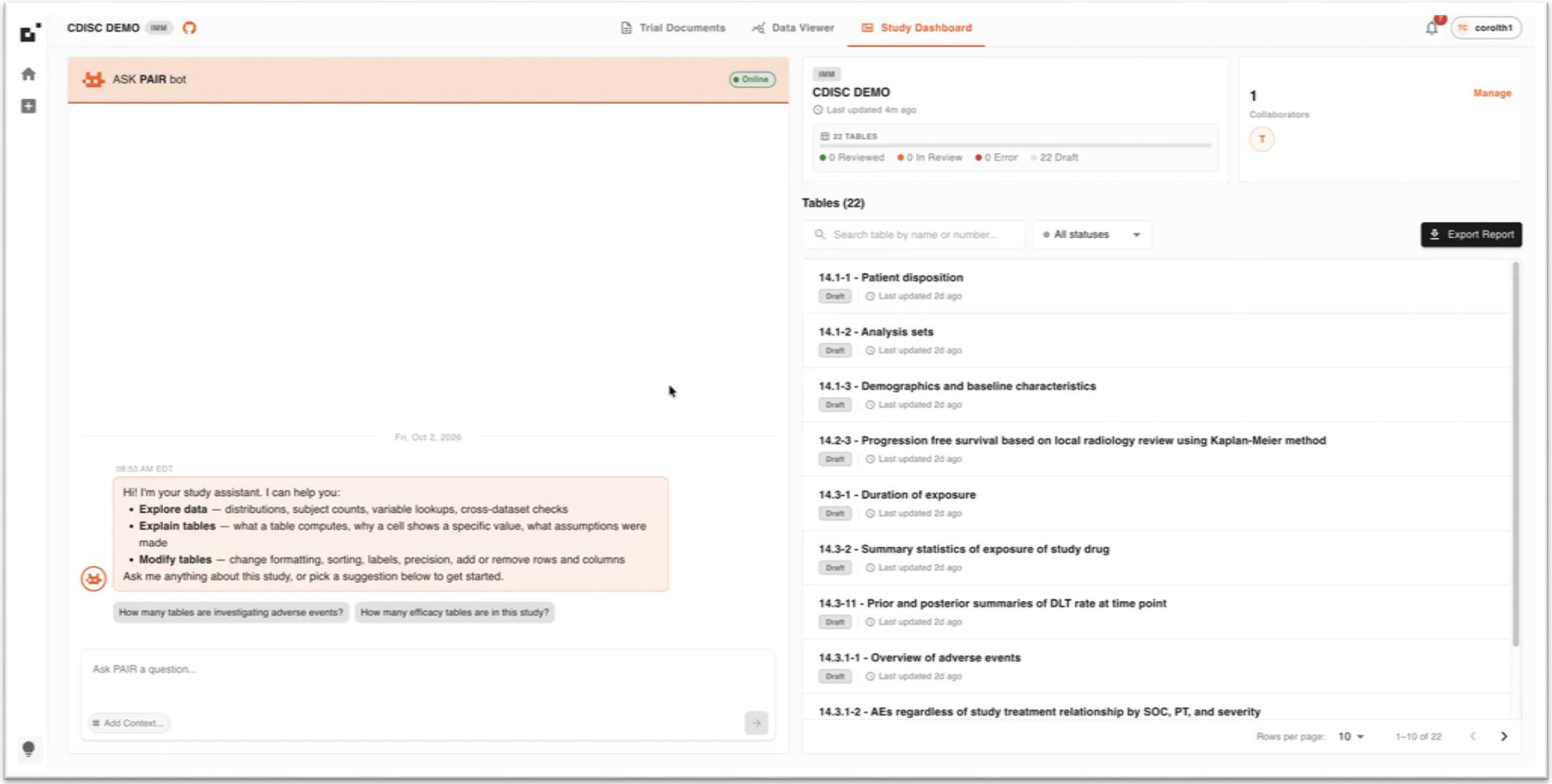
# Demo

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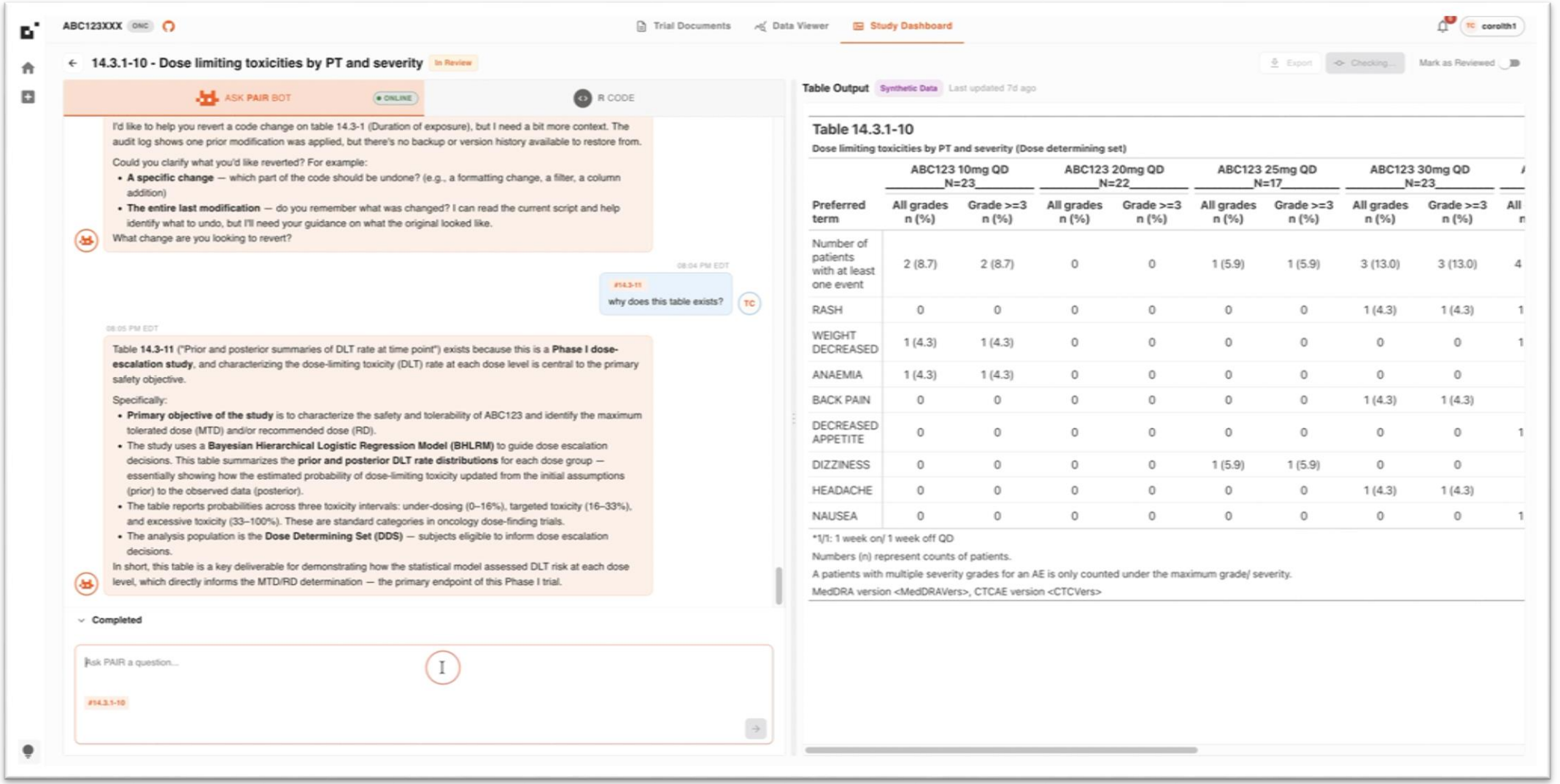
# How to create a trial under 30s with PAIR



# The trial page overview, from documents to R scripts



# Review Scientific Intent, Not Code

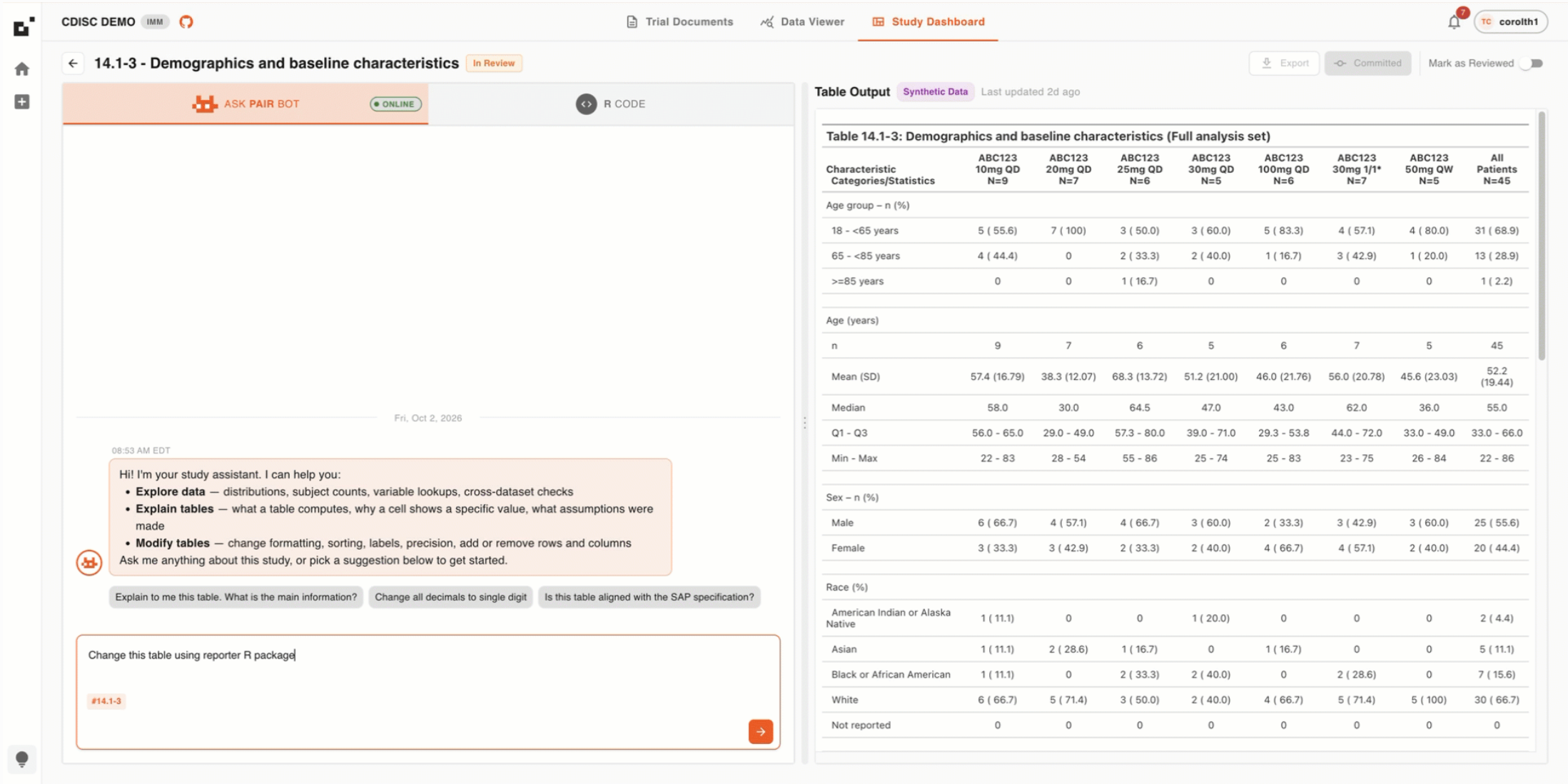



PAIR makes those relationships directly visible.

Every objective, endpoint, method, variable, and SAP reference remains linked and traceable.

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# The chatbot makes all changes. Simply ask, review and approve



# The pilot: a Phase 1 study, built for R from day one

## EARLY PHASE 1 PILOT

Sentinel dosing • slow-moving by design

### Luxury of time to experiment

The pilot's deliberate pace created space to test, learn and iterate.

### Built for R from day one

The trial was intended to use an end-to-end R-based workflow.

### A demanding test environment

Complex gene-therapy administration and dummy data that were difficult to make representative of real life.

**Real complexity, controlled pace**

## EARLY PAIR

A lot of work. Limited value.

**Built from standard TLF shells**

### Many errors

Frequent failures slowed iteration

### Outputs did not match

Results required manual reconciliation

### Replicated human code

Little value beyond conventional programming

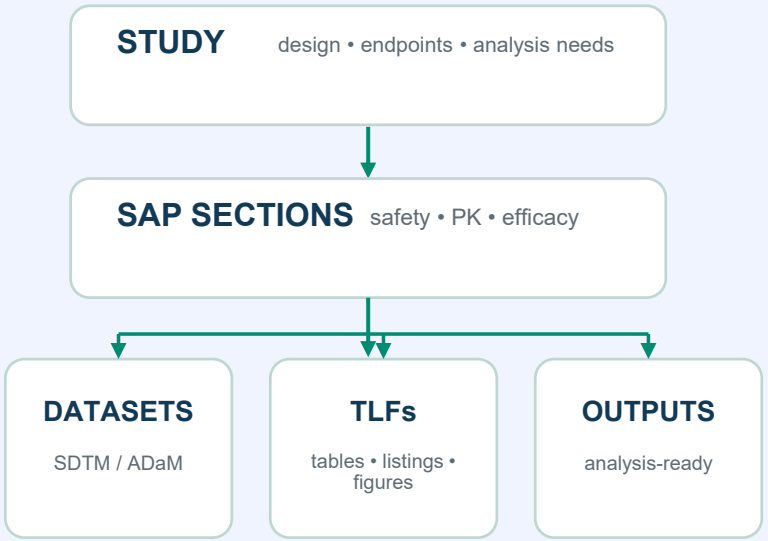
**~1 YEAR LATER**

## PAIR EVOLVED

From code generation to intelligent mapping

**PAIR now understands the study structure**

It connects study intent to the SAP and the datasets required for analysis.




**From isolated code to connected study intelligence**

# Lessons learned

01

## Keep the human in the loop

Expert review remains essential for judgment, interpretation and final accountability.

02

## Precision starts with the SAP

The biggest lesson: the SAP must be specific, complete and accurate.

03

## Ambiguity creates discrepancies

Many apparent programming mistakes traced back to SAP language that was ambiguous or not fully specified.

04

## PAIR added an independent quality check

The QC programmer identified issues caused by ambiguity, but the QC code also contained an error that PAIR did not make.

# PAIR

**Traceable.**
Every output connects to its clinical objective.

**Scalable.**
The same architecture extends to listings and figures.

**Standards-driven.**
Aligned with CDISC ARS v1.0.

**Trusted.**
Transparent decisions, human oversight and reviewable outputs.

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# Many thanks to the team behind



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