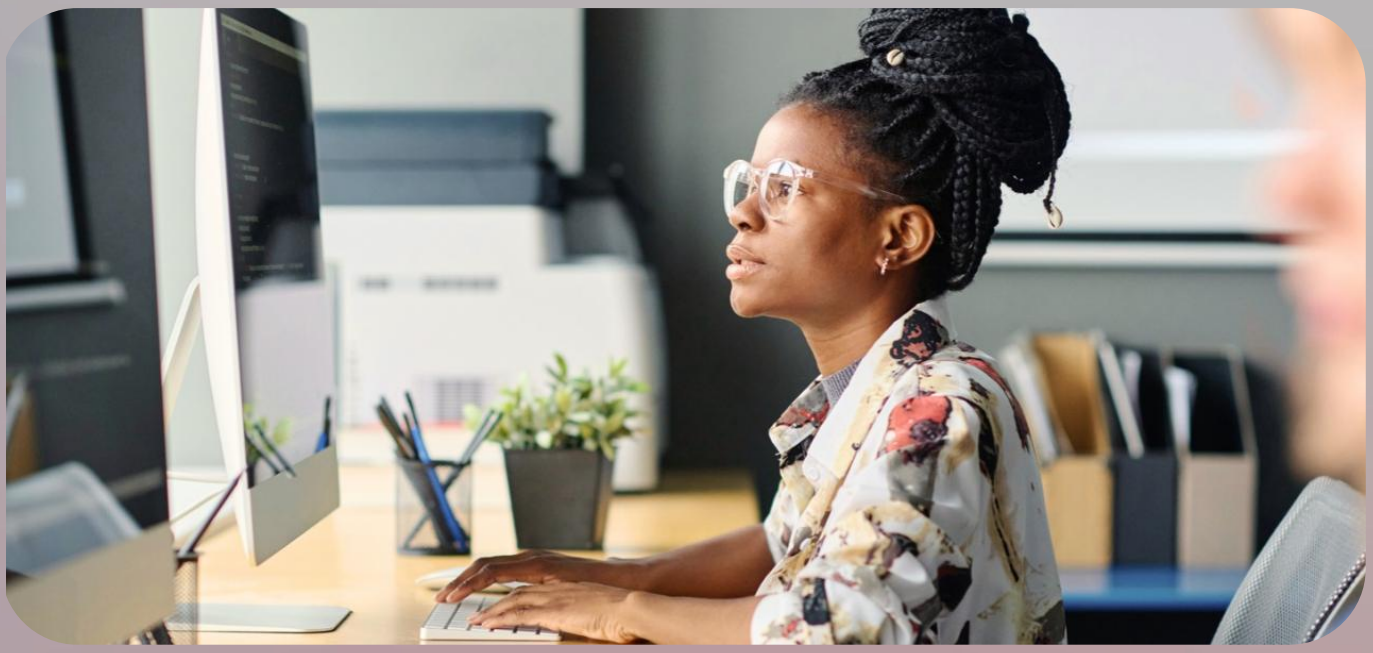
TFS HealthScience



The science behind every safety signal

How medical coding protects your safety signals, your timeline and your submission

The short version

While coding discrepancies are often easy to address early, they become significantly more challenging as studies progress. Our three-stage review process helps identify and resolve issues long before database lock.

The proof, from our projects

200

complex terms coded in 4 hours in a single study

Regular coding, internal medicine and neurology

50,000+

terms moved to a new dictionary version in 8 hours, 99.99% clean migration

Up-versioning, ophthalmology, three studies

800

coded terms reviewed in one day by one specialist, inside a 48-hour turnaround

Quality check, dermatology trial

Find your stage

How to read this paper: four steps follow your trial from the problem to database lock. Each takes one page. Find your stage and start there.

Step 01 · page 04

Understand why coded terms matter

Every adverse event and medication enters your database as free text from a site.

Go to page 04 →

Step 02 · page 08

Set your coding rules before first patient in

Your coding quality gets decided before the first verbatim arrives.

Go to page 08 →

Step 03 · page 10

Keep your data clean during enrollment

Coding runs daily. Quality checks run on a schedule. Dictionary updates run on a plan.

Go to page 10 →

Step 04 · page 12

Clear late errors before lock

Four to eight weeks before lock, coding turns into a rescue.

Go to page 12 →

01

Understand why coded terms decide what regulators see

Every adverse event and medication enters your database as free text from a site. We turn that text into the standard language regulators read. When the translation slips, you meet the damage late, in the final weeks before lock.

Your lock slips

Uncoded terms, inconsistent entries and open site queries pile up just before critical milestones.

Your safety signals hide

Five sites describe the same event five ways. Without one MedDRA Preferred Term, nobody sees the pattern.

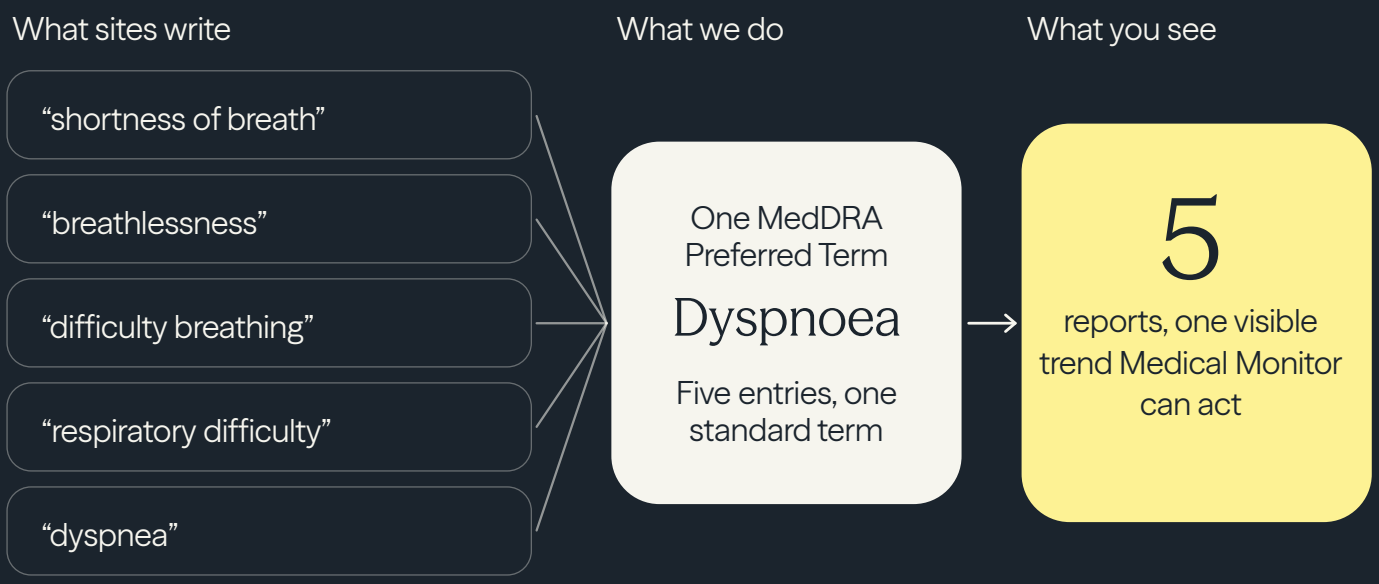
Your inspection exposure grows

Symptoms coded instead of diagnoses and wrong WHODrug ATC codes create findings in FDA and EMA inspections.

Your resources are stretched

Medical Directors, Medical Monitors and Data Managers spend hours fixing raw text instead of driving their own deliverables.

One event, five wordings

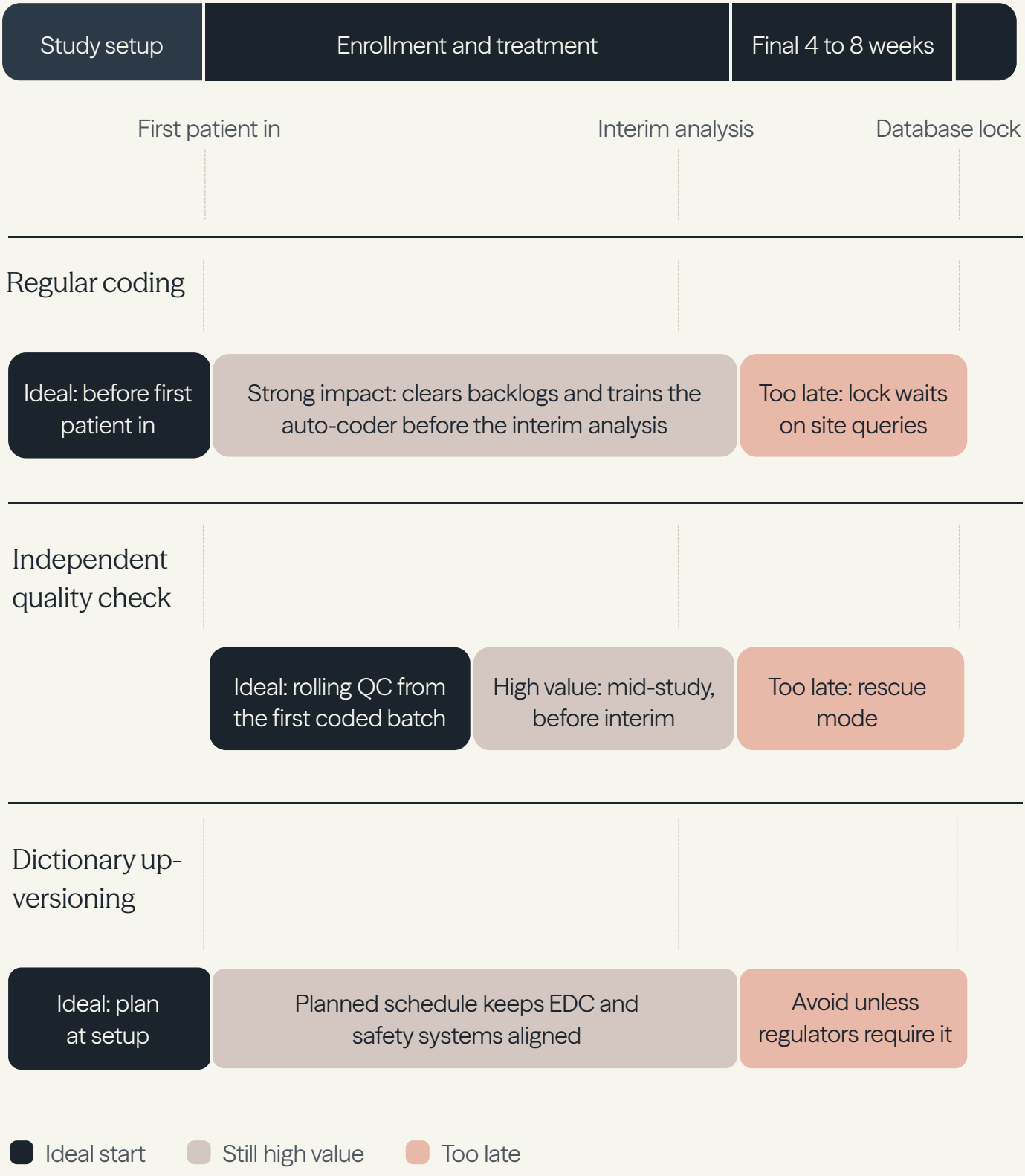


Illustrative example, not study data. All five wordings are recognized synonyms of the MedDRA term Dyspnoea.

“The FDA and EMA won’t read site coordinators’ notes. They will read the coded terms. If five sites write down the same serious adverse event five different ways and nobody standardizes them, the drug safety signal is not small. It could be invisible.”

Bartłomiej Fadrowski, Clinical Data Coder, TFS HealthScience

Our three-stage review process. The earlier you start, the less it costs.



TFS

Seven questions to ask your team this week

Every no marks a risk worth a conversation.

1	Setup	Do your coding conventions state your up-versioning frequency, yearly or per release?	☐
2	Enrollment	Does your team code new terms within 24 to 48 hours of site entry?	☐
3	Enrollment	Do your EDC, safety and statistics systems run the same MedDRA and WHODrug versions?	☐
4	Enrollment	Does your team review synonym lists for bad matches, such as multi-ingredient medications mapped to one ingredient?	☐
5	Enrollment	Do your coding and safety teams reconcile SAEs regularly, not only before milestones?	☐
6	Interim	Does someone outside your coding team review coded data on a fixed schedule?	☐
7	Any stage	Do your Medical Directors, Medical Monitors and Data Managers stay out of coding work?	☐

Study setup · you are here | Enrollment | Final weeks

02

Before first patient in: we set your coding rules

Your coding quality gets decided before the first verbatim arrives. We write the rules, load the synonym lists and fix your up-version strategy, so every coder applies the same logic from day one.

Without a dedicated coder	With our coders
Each coder applies their own logic and coding drifts across sites	We write study-specific coding conventions. Every coder applies the same logic across every site and region
Verbatims queue up from the first patient	We load auto-coding rules and synonym lists into your coding tool before data entry, so terms flow from day one
Your up-version plan stays undefined until the first release lands	We fix your up-version strategy, annual or per release, in your coding conventions before the first release

TIMING
2 to 4 weeks

our standard start, from yes to a coder working in your system

In practice

The start covers system access, protocol training and your study-specific coding guidelines. Sign early enough to go live before first patient in.

Starting later still pays off. During enrollment, we clear legacy backlogs and train your auto-coder before the interim analysis.

Watch for

— “The dictionary decides for us.” A medicine may carry many ATC options or only one or two. A cancer may list many locations or few. Decide before data entry whether your study needs the location or the tumor type, for example breast cancer or adenocarcinoma.

— “A coder can infer what the site meant.” We code what sites report and query when it is unclear. A site that writes “head” has not written “headache”. We document any deviation from dictionary rules with a medical rationale.

Study setup | Enrollment · you are here | Final weeks

03

During enrollment: we keep your data clean

Coding runs daily. Quality checks run on a schedule. Dictionary updates run on a plan. Your Medical Monitors see safety trends as they emerge and your lock stays on schedule.

Without a dedicated coder	With our coders
Regular coding. Unmapped verbatims pile up and sites drown in queries about minor typos	We code new terms within 24 to 48 hours of site entry and query sites only when a clinical answer is needed
Quality check. Misclassified terms and one event described five ways hide your safety signals	We review coded data from the first batch, then monthly, every two months or per milestone. Our two-step review enforces your conventions
Up-versioning. Your EDC, safety and statistics systems drift onto different dictionary versions	We migrate your systems in lockstep on a planned schedule, with an impact analysis before we touch production data

200

complex terms coded in 4 hours

One internal medicine and neurology study. An autocoder clears simple strings. We clear the hard, ambiguous exceptions that need clinical and pharmacology knowledge.

50,000+

terms migrated in 8 hours, clean migration 99.99%

An ophthalmology sponsor, three legacy databases, two dictionaries. About 12,000 MedDRA and 15,000 WHODrug terms sat in the synonym lists alone. We finished with minimal disruption.

Watch for

— “Synonym lists maintain themselves.” One bad match, such as a multi-ingredient medication assigned to a single ingredient, repeats in every future entry until someone checks the list.

— “Coding and safety databases line up on their own.” Late SAE reconciliation drives recoding and last-minute queries. Frequent contact between our coders and your safety team prevents it.

— “Up-versioning can wait.” A database more than two years behind takes more effort to up-version than one six to twelve months behind.

Study setup | Enrollment | Final weeks · you are here

04

Late errors stall your lock. We review 800 coded terms in one day.

Four to eight weeks before lock, coding turns into a rescue. We still clear it. Your lock now waits on site answers about visits more than a year old.

CODING

Coding still gets done. Your lock waits on site answers about old visits.

QUALITY CHECK

Findings reopen closed queries and raise new ones with your sites.

UP-VERSIONING

A high-risk change on live data. Avoid it, unless a regulator requires it.

800 coded terms reviewed in one day by one specialist, 48-hour turnaround

A dermatology sponsor needed quality control of its concomitant medication data within 48 hours. Multi-ingredient terms misclassify easily and ATC errors distort later drug interaction analysis.

We reviewed all 800 coded terms in one day and corrected the mapping to standard guidelines. The sponsor kept its timeline with no further delay to the study.

What waiting costs

— A delayed launch. Fixing legacy errors at lock freezes your timeline. Tufts CSDD estimates that a single day of delay can represent approximately USD 500,000 in unrealized sales, while clinical trials themselves cost sponsors around USD 40,000 per day to conduct.

— A masked safety signal. Identical side effects worded differently do not map to one MedDRA term. Regulators who spot it can issue audit findings and require recoding.

— Rework at five times the effort. Fixing data right before lock takes about five times longer than rolling QC.

— A mismatch at filing. Clinical data on one MedDRA version and safety data on another make side effects harder to cross-reference and can put your submission timeline at risk.

Our answer: start at step 02.

Set your coding rules before first patient in, page 08

Four ways to embed a coder in your trial

Buy coding as a standalone service or inside a broader engagement. Choose the model that matches your stage.

Step 02

Embedded coder or team

Use it from step 02 for continuous coding without hiring. Our coders work inside your EDC and coding platform, for example Medidata Rave or Anju, and follow your SOPs and coding guidelines. They work independently of whoever runs the rest of your trial data.

Step 04

Rescue project

Use it at step 04 when a backlog or critical errors threaten your interim analysis or database lock. We clear the errors and code the uncoded backlog.

Step 03

Independent quality check

Use it from step 03 when you run an internal coding team and want an objective second review of the data it coded.

Long studies

Up-version on demand

Use it for long studies. We run the impact analysis, mapping and documentation for each MedDRA or WHODrug update.

How fast we start

2 to 4 weeks	Standard start: system access, protocol training and study-specific coding guidelines
1 to 2 weeks	Rescue start: systems in place and a clear target, such as clearing the uncoded backlog
10 to 15 days	Typical business days before we process your first terms

Evaluate your coding. Secure your timeline.

Contact us · tfscro.com/contact

About us

We are TFS HealthScience, a global full-service CRO headquartered in Sweden. We take co-ownership of your clinical trials and protect your milestones as our own. Our flat organisation means fast decisions: therapeutic leads hold direct authority, with no escalation chains. And our teams stay. 88% remain for the whole study, 8 points above the industry average. Across 40+ countries, we bring over 30 years of experience straight into your operations, so promising science reaches the patients who need it.

Securing the path from science to life

TFS HealthScience