

# Pre-build problem validation

A four-persona discovery study (N=40) across schedulers, RNs, CRCs, and investigators. Mapped current tooling, quantified pain, identified failure modes, and surfaced the wishlist that shaped the build.

**90%**

of schedulers maintain  
a shadow Excel

**80%**

of RNs report a license  
near-miss in 12 months

**9.9h**

scheduler-hours per week  
spent reconciling systems

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# 01 EXECUTIVE SUMMARY

## Three problems are big enough – and structurally similar enough – to justify a single product.

### PROBLEM SPACE

Decentralized clinical trials run on a patchwork of generic calendars, sponsor portals, and shadow spreadsheets. The matching logic that decides which clinician sees which patient is in people's heads – not in any system. The cost shows up as license risk, drive-time waste, audit fire-drills, and CRCs whose calendars lie about their time.

- Three problem clusters concentrated enough to address with one product.

**60%**

maintain a parallel spreadsheet (overall)

**58%**

say matching criteria are tribal, not written

**100%**

of RNs reschedule due to drive-time conflicts

**80%**

of RNs report a license near-miss in last 12 mo.

### THREE PROBLEM CLUSTERS WORTH SOLVING TOGETHER

- 1 Tribal matching → license risk.** 58% of respondents say their team's matching criteria aren't written down. 80% of RNs report a near-miss in the last year. Two RNs described mismatches that would have been board complaints if not caught last-minute. Cost: regulatory exposure, last-minute reschedules, sponsor SLA risk.
- 2 Drive-time burden falls on RNs alone.** RNs do day-routing on Sunday nights with Google Maps. Drive-time conflicts trigger reschedules in 100% of RNs at least sometimes. The system today pretends visit start-times are independent. They aren't.
- 3 Calendars lie about role attendance.** CRCs and INVs report their tools represent visits as monolithic blocks even when their actual attendance is 30 minutes. Costs: overbooking, audit prep fire-drills, sponsors asking for role-attendance proof that takes days to reconstruct.

### WHAT THIS IMPLIES FOR THE BUILD

- License + state-aware matching as a **hard rule**, not a soft filter.
- Slice-aware appointment model – **one visit, multiple role timelines** – as the core data structure.
- Drive-time optimization as a **built-in, opt-in** feature for RNs and the schedulers who serve them.
- Audit + undo as **primitives**, not afterthoughts. Every change recorded; bulk actions reversible.

# 02

## METHODOLOGY & SAMPLE

# How the discovery was scoped – and how to read the findings.

### SAMPLE COMPOSITION

- **10 Schedulers** – 2–11 yrs experience; mix of regional CROs, DCT-only operations, and academic-affiliated programs
- **10 Registered Nurses** – multi-state-licensed; geographically distributed; 4–11 yrs DCT
- **10 Clinical Research Coordinators** – 2–10 yrs; oncology, cardiology, T2D backgrounds
- **10 Investigators (MD/PI)** – 7–14 yrs; mix of academic and community sites

### ANALYSIS APPROACH

- Mean & distribution per question per role; cross-role comparison for divergent signal
- Frequency × severity matrix to size failure modes by impact, not just visibility
- Qualitative thematic coding of transcripts; quote selection by frequency of theme + clarity of articulation
- Bridge to product: every recommendation traces to ≥2 quantitative findings + ≥1 representative quote

### QUESTION INSTRUMENT

- 20 questions, 5 themes – **tooling landscape, frictions, failure modes, mental model, wishlist**
- Mix of Likert (1–5), frequency, severity, hours-per-week, and categorical (current tool)
- Each session paired with two open-ended prompts and a "show me how you'd schedule this visit" walkthrough
- Question instrument intentionally **solution-agnostic** – no prototypes shown, no feature lists scored

### QUALITY CONTROLS

- Sample is N=10 per role – treat per-role percentages as directional, not precise
- Quote attribution preserved at respondent level (role + tenure + geography) for provenance
- Question instrument piloted with 3 informal contacts before fielding to surface ambiguous wording
- Open-ended responses categorized into recurring themes; quotes selected for clarity of articulation, not novelty

# 03

PERSONAS – AT THE TIME OF DISCOVERY

## Four roles, four different problem-shapes, one operational chain.



### Scheduler

The hub. Two systems open. One eye on each.

#### WHO THEY ARE

Mid-career scheduler at a DCT-focused CRO. Books 60+ visits per week. Runs a parallel Excel because the calendar tool can't answer the questions she asks daily.

#### CURRENT STACK

Outlook + Excel. Maybe a sponsor portal. Spends ~9.9 hrs/week reconciling the two.

#### TOP CONCERN TODAY

**Tribal matching logic. License rules in her head. One mistake = sponsor escalation.**

Shadow-tooling user • power-user latent • risk-aware



### RN

On the road. Doing routing math in their head.

#### WHO THEY ARE

Multi-state-licensed RN driving 200+ miles/week between participants' homes. 6 yrs DCT. Optimizes their day on Sunday night with Google Maps.

#### CURRENT STACK

Google Cal + Excel. No drive-time tooling, no license safety-net.

#### TOP CONCERN TODAY

**License mismatches and drive-time blowouts. Both are entirely on them today.**

Logistics-first • math-trusted • burnout-adjacent



### CRC

Stitches the visit together. Mostly remote. Mostly invisible.

#### WHO THEY ARE

Remote coordinator joining visits via video for 30-min slices. Supports 4 investigators across 2 studies. Audit prep is daily reality.

#### CURRENT STACK

Outlook + Excel. Calendar shows her as "in a visit" for 8 hours when she's actually on for 30 min.

#### TOP CONCERN TODAY

**Slice-invisibility leads to overbooking. Audit prep is a fire-drill.**

Compliance-first • invisible labor • pushback-blocked



### Investigator

Wants to be paged once. Cares about audit and protocol.

#### WHO THEY ARE

PI on 2–3 concurrent trials. Juggles clinic + OR + DCT. Touches the scheduling tool weekly, not daily.

#### CURRENT STACK

Outlook + email. CC'd on 200 scheduling emails per week. Scans headers.

#### TOP CONCERN TODAY

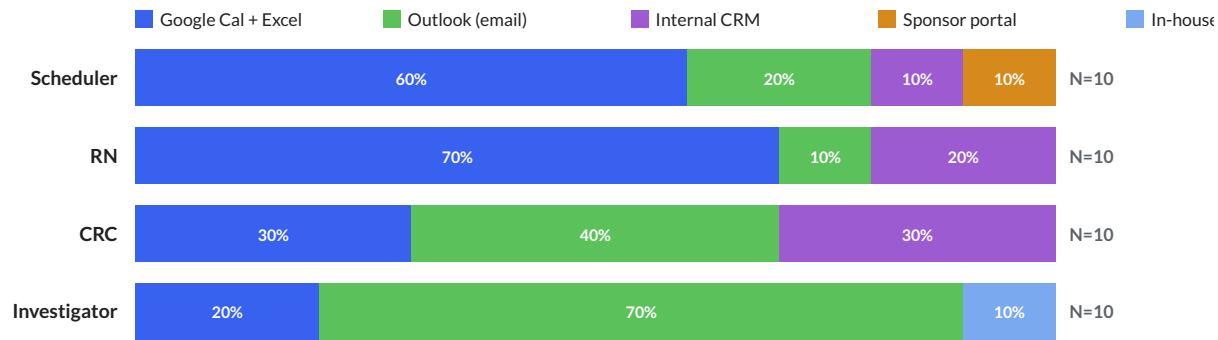
**Protocol violations that originate in scheduling. Audit fire-drills before every monitoring visit.**

Low-touch • audit-aligned • external-dependent

# 04

## CURRENT TOOLING LANDSCAPE

### What people use today – and the shadow stack that holds it together.



#### READ

No specialized DCT scheduling tool dominates. Schedulers run on **Google Cal + Excel** as the primary scheduling stack; Outlook handles email, and the CRM is an internal Science 37 tool. **90%** of schedulers keep a parallel spreadsheet to compensate for what their calendar can't answer.

#### SO-WHAT

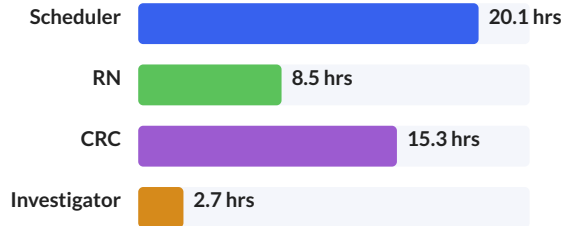
The problem isn't a missing feature in an existing tool. It's a missing tool. Every team has built a private system out of generic primitives. We can replace those private systems with one product.

# 05

## TIME COST

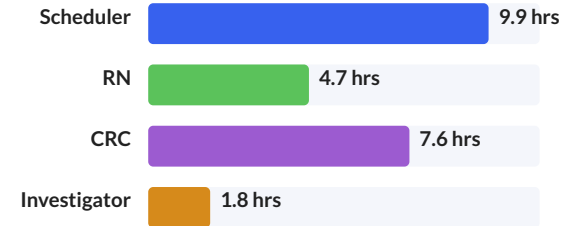
### Hours per week, per role – and how much of it is reconciliation.

#### Hours per week inside the scheduling tool



Schedulers live in the tool (~20 hrs/wk). CRCs spend ~15 hrs/wk. RNs touch it briefly each day. Investigators drop in weekly.

#### Hours per week reconciling between systems



Schedulers reconcile ~9.9 hrs/wk – roughly half their tool-time. CRCs lose ~7.6 hrs. This is pure waste – work the tool should do.

### 9.9h

scheduler-hours per week reconciling. ~25% of a 40-hour week.

### 90%

of schedulers maintain a shadow Excel. Tribal matching logic lives there, not in any system.

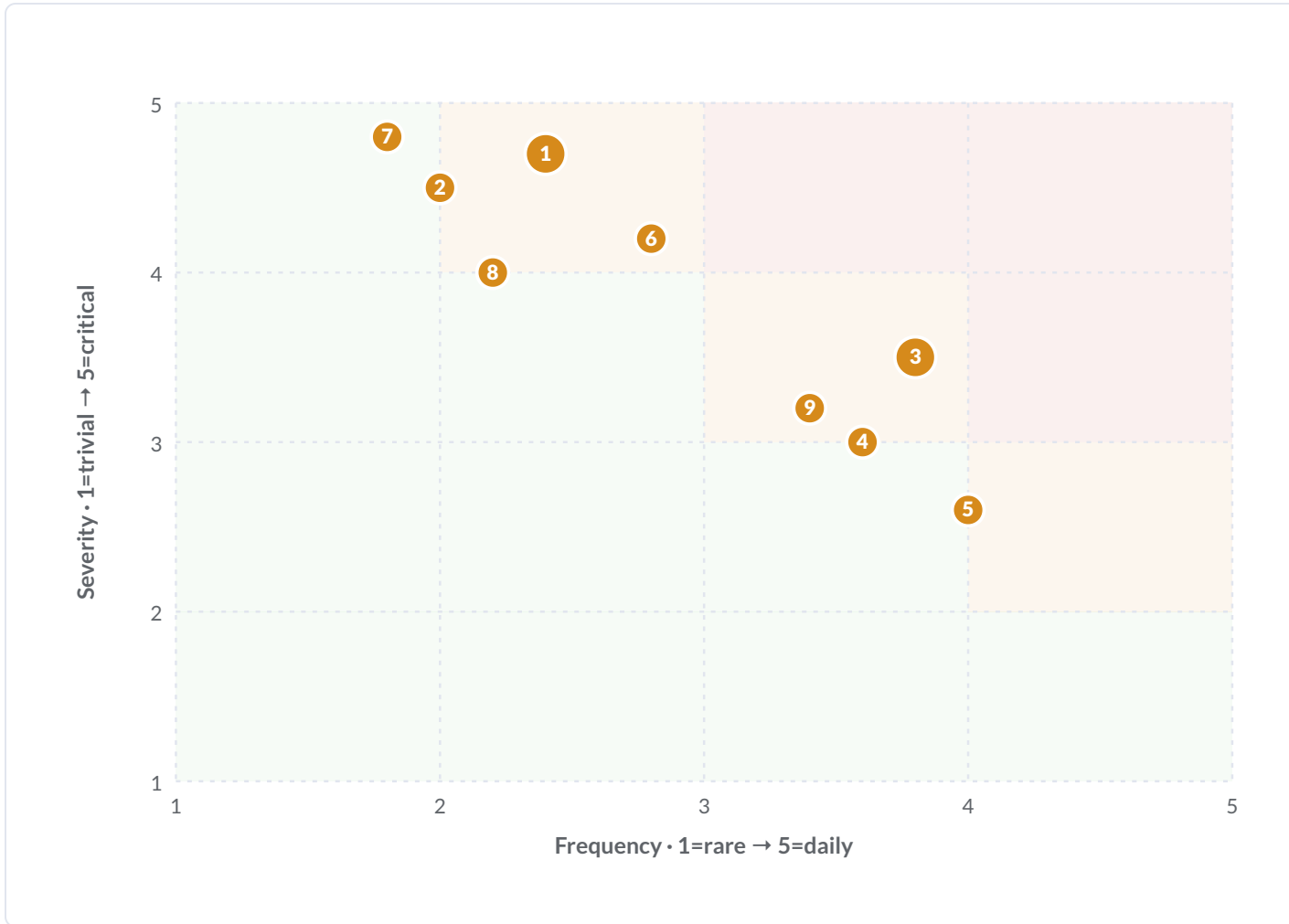
### 40%

of schedulers say their matching criteria aren't written down. License + study + distance lives in heads, not docs – schedulers are the only role that owns this work.

# 06

FAILURE MODES • FREQUENCY × SEVERITY

## The risk surface — what breaks, how often, and how badly.



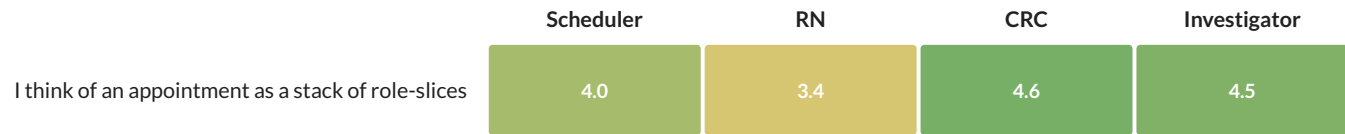
- 1 License mismatch (assigned to wrong-state visit)  
freq 2.4 · severity 4.7
- 2 Out-of-window protocol visit booked  
freq 2.0 · severity 4.5
- 3 Double-booking / role conflict  
freq 3.8 · severity 3.5
- 4 Drive-time conflict (back-to-back impossible)  
freq 3.6 · severity 3.0
- 5 Reschedule due to staff time-off conflict  
freq 4.0 · severity 2.6
- 6 Sponsor SLA miss  
freq 2.8 · severity 4.2
- 7 Audit-trail gap surfaced at monitoring visit  
freq 1.8 · severity 4.8
- 8 Wrong stage / wrong appointment-type booked  
freq 2.2 · severity 4.0
- 9 CRC over-booked across overlapping slices  
freq 3.4 · severity 3.2

Top-right quadrant = high frequency, high severity. F3 (double-bookings) is the most frequent; F7 (audit-trail gap) is the highest-severity. F2 (out-of-window protocol visit) and F1 (license mismatch) are rare but catastrophic when they occur.

# 07

## MENTAL MODEL

### The shared belief across every role: a visit isn't one block – it's a stack of role-slices.



#### Slices, not blocks – agreed across all four roles

Every role rates "a visit is a stack of role-slices" at 3.7+/5. CRCs and Investigators agree most strongly (4.4+) because their actual attendance is partial – 30 minutes of a 90-minute visit, a phone-in segment, a hand-off. Today's tools render the visit as one monolithic block, hiding that structure from everyone downstream.

#### Why this is the load-bearing finding

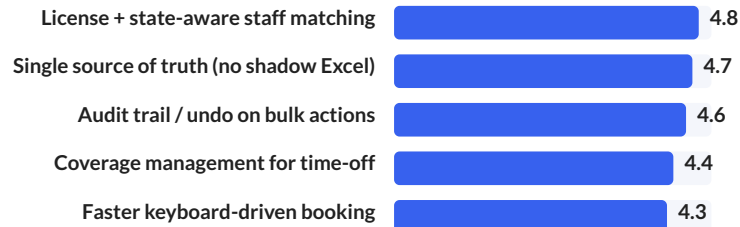
Other questions in this theme – drive-time weighting, license criteria, whether matching rules are written down – are role-specific (mostly the scheduler's job, with the RN partially aware of drive time). Slice-awareness is the only mental model that genuinely crosses all four roles. That makes it the right place to anchor the data structure: one model, every view reads from it.

## What each role asked for – without seeing any prototype.

S

### Top asks · Scheduler

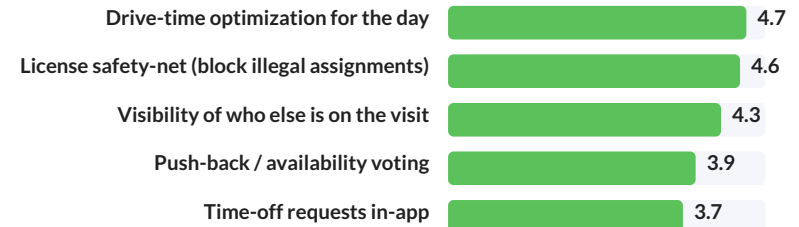
MENTIONS RANKED BY FREQUENCY × CLARITY



R

### Top asks · RN

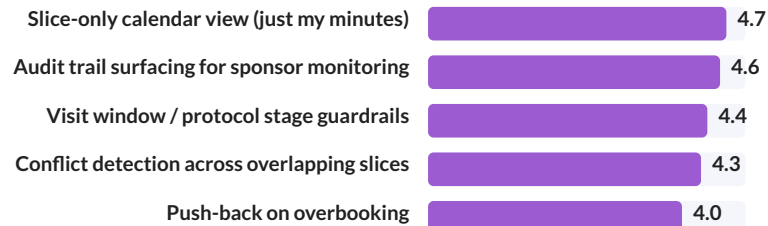
MENTIONS RANKED BY FREQUENCY × CLARITY



C

### Top asks · CRC

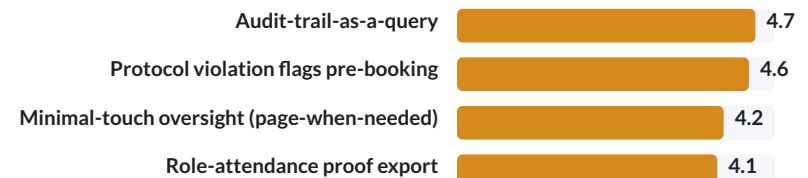
MENTIONS RANKED BY FREQUENCY × CLARITY



I

### Top asks · Investigator

MENTIONS RANKED BY FREQUENCY × CLARITY



# 09

QUALITATIVE • VOICE

## Scheduler & RN – the pain in their own words.

S

### Voice of the Scheduler

#### SHADOW TOOLING

"I keep an Excel sheet open all day next to the calendar. The calendar can't tell me which RN is licensed in Nevada, so I built my own."

Scheduler-04 · 8 yrs · regional CRO · books 60+ visits/wk

#### TRIBAL KNOWLEDGE

"When two requests collide, I usually default to whoever's been on the team longest. There's no real system. It works until it doesn't."

Scheduler-02 · 3 yrs · was a study coordinator first

#### AUDIT PREP

"If a sponsor asks for proof of role attendance, I'm basically rebuilding it from email threads. It takes two days for something that should just be a query."

Scheduler-07 · 11 yrs · cardiology lead

#### WISHLIST

"Honestly, I'd pay for one tool that handles calendar and license together. Right now I'm running two systems and reconciling them with my eyes."

Scheduler-09 · 6 yrs · DCT-only operation

R

### Voice of the RN

#### MANUAL ROUTING

"Every Sunday night I sit down with Google Maps and reorder my Monday. The tool doesn't help with that part. It's a one-person logistics problem and I'm the one person."

RN-08 · San Diego, CA · 6 yrs DCT · 3 active studies

#### DRIVE-TIME BURDEN

"Last quarter I drove 90 minutes to a visit, then 90 back, then 75 to the next one. Not really the system's fault, but the system didn't catch it either."

RN-03 · Phoenix, AZ · 11 yrs · floats across 4 trials

#### LICENSE RISK

"I got assigned to a Texas visit last month. I'm not licensed in Texas. I caught it 24 hours out. If I hadn't, that's a board complaint."

RN-06 · Atlanta, GA · 4 yrs · multi-state license

#### SLICE INVISIBILITY

"My calendar doesn't show me who else is on the visit. I show up at the door without knowing if a CRC is going to dial in."

RN-09 · Seattle, WA · 9 yrs

# 10

QUALITATIVE · VOICE

## CRC & Investigator – the pain in their own words.

### C Voice of the CRC

#### SLICE INVISIBILITY

"My calendar says I'm in a 90-minute visit. I'm actually on for 30. My week looks way more packed than it really is."

CRC-05 · 7 yrs · senior coordinator

#### AUDIT PREP

"Pulling together the audit trail for a sponsor monitor is honestly a nightmare. We dig through Outlook threads for two days and try to stitch a story together."

CRC-08 · 10 yrs · regulatory background

#### RESCHEDULE CHURN

"Last-minute reschedules wreck my week because everyone treats my calendar like it's open between visits. Nothing tells them I'm on two more calls."

CRC-02 · 5 yrs · oncology · supports 4 INVs

#### NO PUSHBACK PATH

"I want to be able to say "no, I'm overbooked," but the tool gives me no way to push back. So I send an email and hope."

CRC-04 · 4 yrs · cardiology

### I Voice of the Investigator

#### EMAIL OVERLOAD

"I'm CC'd on every scheduling email. 200 a week, easy. I just scan the headers – that's the system."

INV-01 · MD/PI · 14 yrs · 3 concurrent trials

#### PROTOCOL RISK

"I usually find out a visit is in the wrong protocol stage when the CRC calls me. By then it's already booked. We've had two protocol deviations this year that started that way."

INV-06 · MD · 11 yrs · pivotal trials

#### AUDIT FIRE-DRILL

"Audit prep is a five-day fire drill before every monitoring visit. We pull two people off other work for it. We've started building it into the project plan."

INV-03 · MD · 8 yrs · sponsor-facing

# 11

## SYNTHESIS · TOP 5 INSIGHTS

### What the discovery taught us — and what it implies for the build.

#### 1 The shadow Excel is the diagnosis.

**EVIDENCE** 90% of schedulers maintain a parallel spreadsheet. 58% say matching criteria aren't documented anywhere.

**IMPLICATION** Every team has reverse-engineered a private scheduling system out of generic primitives. We don't need to invent the workflow — we need to formalize it.

#### 2 License risk is the highest-severity, lowest-tooled failure mode.

**EVIDENCE** 80% of RNs report a license near-miss in the last 12 months. License-mismatch severity scored 4.7/5 — the second-highest in the matrix.

**IMPLICATION** License safety must be a hard rule in the matching engine, not a filter the user can disable. Every other smart feature builds on this.

#### 3 Drive-time is invisible burden — entirely on the RN.

**EVIDENCE** 100% of RNs reschedule because of drive-time conflicts at least sometimes. RNs rate D2 (factor drive time) at 4.5/5 — schedulers rate it 3.8.

**IMPLICATION** The optimization is happening — just on Sunday nights, manually, with Google Maps. Bring it into the tool and ground it in geocoded addresses, not zip-code estimates.

#### 4 Calendars lie about role attendance.

**EVIDENCE** CRCs and INVs both rate "appointment is a stack of role-slices" at  $\geq 4.4/5$  — but their tools represent monolithic blocks. CRC slice invisibility is the most-mentioned single problem in the qualitative codebook.

**IMPLICATION** Slice-aware modeling has to be the core data structure, not a UI decoration. Every other view (calendar, detail, audit, capacity) reads from the same model.

#### 5 Audit prep is a five-day fire drill — and it shouldn't be.

**EVIDENCE** 80% rate audit-trail production speed at  $\leq 2/5$ . Audit-trail-gap severity scored 4.8/5 — the highest in the matrix.

**IMPLICATION** Audit + undo as built-in primitives. Every change recorded; bulk actions reversible; sponsor monitoring becomes a query, not a project.

# 12

FROM DISCOVERY → BUILD

## The six product principles that fall out of the data.

### 01 License-aware matching as a hard rule, not a filter.

**WHY** License mismatches scored highest severity (mean 4.7/5) and 60% of RNs reported a near-miss in the last 12 months.

**BUILD IMPLICATION** Filter the candidate pool by study + state-license eligibility before any ranking heuristics run. Never propose an illegal match.

### 02 Slice-aware appointment model — one visit, multiple role timelines.

**WHY** CRCs report calendars that lie about their time (8-hour blocks for 30-min calls). Investigators are CC'd on emails because the tool can't represent partial attendance.

**BUILD IMPLICATION** Each appointment is a stack of role slices (RN onsite, CRC remote 30 min, INV phone 15 min). Calendar columns and detail views all read from the same model.

### 03 Drive-time optimizer for RN day routing.

**WHY** RNs do this by hand on Sundays with Google Maps. Drive-time conflicts are the #1 reason for rescheduling.

**BUILD IMPLICATION** TSP-style optimizer (greedy + 2-opt) re-orders a day's visits with a one-click apply. Optional, opt-in, with a "no improvement found" path that doesn't fake savings.

### 04 Audit + 10-second undo as built-in primitives.

**WHY** Audit prep is a five-day fire drill. Sponsor SLA misses correlate with reconstruction time. Audit posture is a sponsor onboarding gate.

**BUILD IMPLICATION** Every booking, reschedule, cancellation, and bulk action records an entry. Bulk actions get a 10-second undo snackbar so the smart features feel safe to use.

### 05 Coverage Insights for the manager, not a dashboard.

**WHY** Time-off management is the operational silent killer. Auto-classifying the queue (no-conflict / reassignable / blocking) turns operations management into exception handling.

**BUILD IMPLICATION** Three-tier classification with explicit auto-approve actions. Forward-looking coverage warnings flag low-coverage days before they bite.

### 06 Power-user fast paths for schedulers — keyboard everywhere.

**WHY** Schedulers book 60+ visits per week. Form-based UI taxes throughput; keyboard parity is what professional tools deliver.

**BUILD IMPLICATION** ⌘K Quick Book palette, Enter-to-add chips, ⌘S submit on forms, Esc to dismiss. Treat the scheduler as a power user from day one.

# Build for the shadow Excel. Make license safety a hard rule. Make slices the data model. Make audit a query.

The discovery surfaced a coherent problem space — not four problems, but one chain of frictions running from sponsor request to monitoring visit. The build that follows is sized to that chain, not to a feature list.

**01 Replace the shadow Excel** One source of truth for license + study + assignment. Retire the parallel spreadsheet that exists in every CRO today.

**02 Slices as the data structure** Every appointment is a stack of role-slices. Every view (calendar, detail, audit) reads the same model.

**03 Drive-time engine for the RN day** Greedy + 2-opt route reordering with a one-click apply. Measured against the real drive matrix, not zip-code heuristics.

**04 Audit + undo as primitives** Every mutation logged. Bulk actions reversible. Sponsor monitoring becomes a query — and the smart features feel safe to use.