



# Navigating Clinical Trial Finance:

## Accruals, Automation & AI



# With you today



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# What we've heard this week

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01

Everyone knows they need AI.  
Many don't know where to  
start, or how to scale

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02

How do we teach the next  
generation the "how" and the  
"why" in the age of AI?

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03

Can you share practical,  
hands-on examples of how to  
use AI in clinical finance?



## Poll: Which resonate with you? (choose all that apply)

1. Everyone knows they need AI. Many don't know where to start, or how to scale
2. How do we teach the next generation the “how” and the “why” in the age of AI?
3. Can you share practical, hands-on examples of how to use AI in clinical finance?



AI is reshaping industries at unprecedented speed... *and evolving faster than enterprises can adapt*

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CLOUD

12–14 years  
for rollout

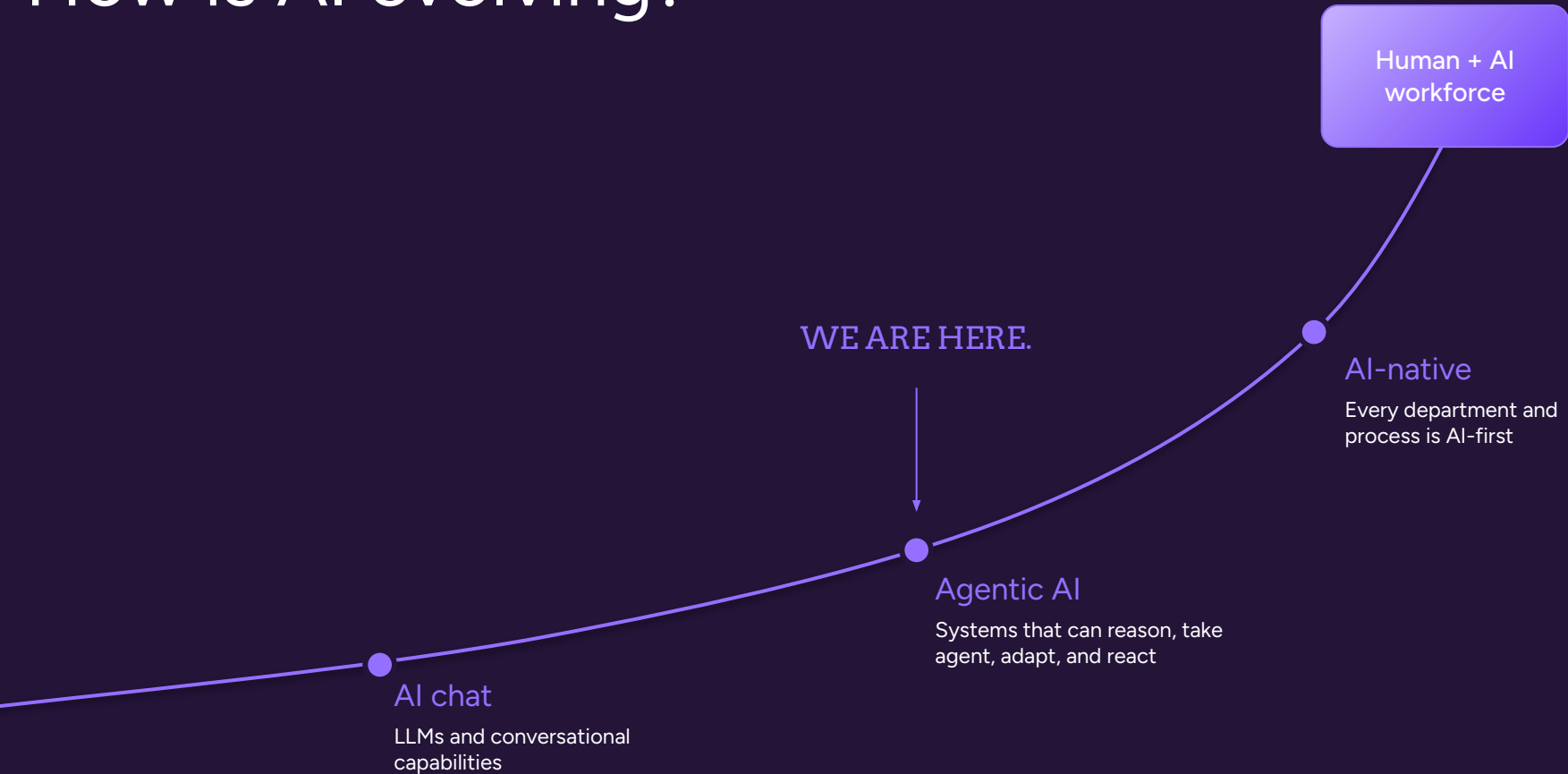
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AI

90 day  
cycles



# How is AI evolving?

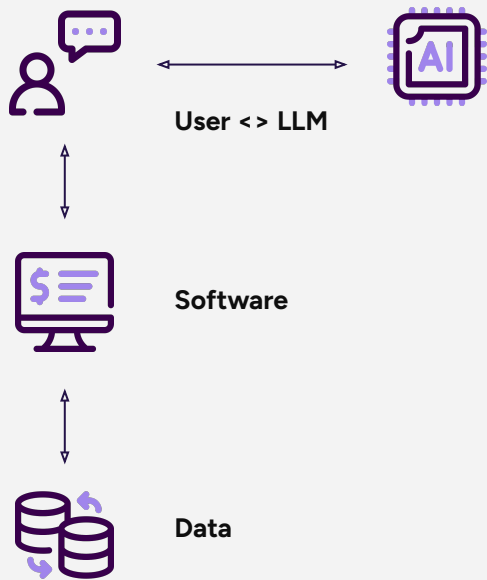




# The three levels of AI use case maturity

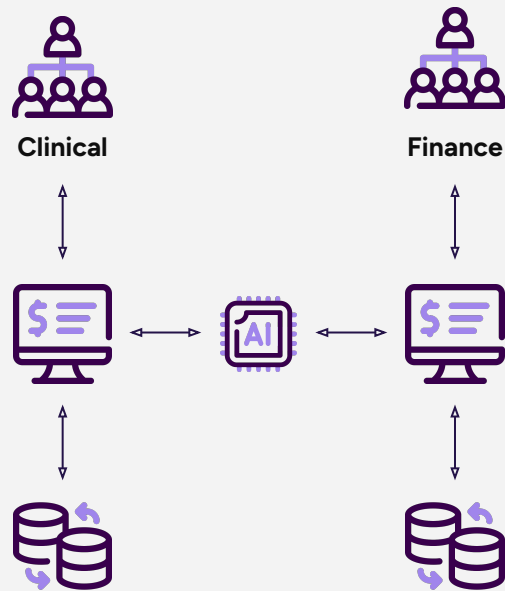
1

Ad hoc LLM + tools



2

Pockets of AI use cases



3

Shared context  
across the  
value chain



## Poll: What level of maturity is your team at? (choose 1)

1. Ad hoc LLM + tools
2. Pockets of AI use cases
3. Shared context across the value chain



# Reimagining two use cases with AI

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01

CRO change order  
management

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02

Investigator grants

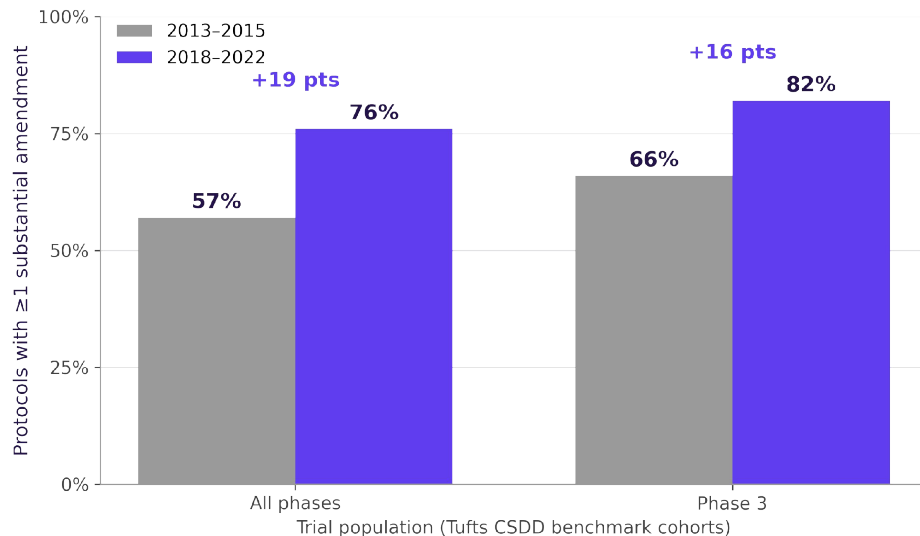
# 01

## The Change Order Problem

Why CRO change orders are uniquely painful for biotech and life sciences finance teams

# Amendments Went From Common to Near-Universal

Share of protocols with at least one substantial amendment, the primary trigger of CRO change orders



## 4 in 5

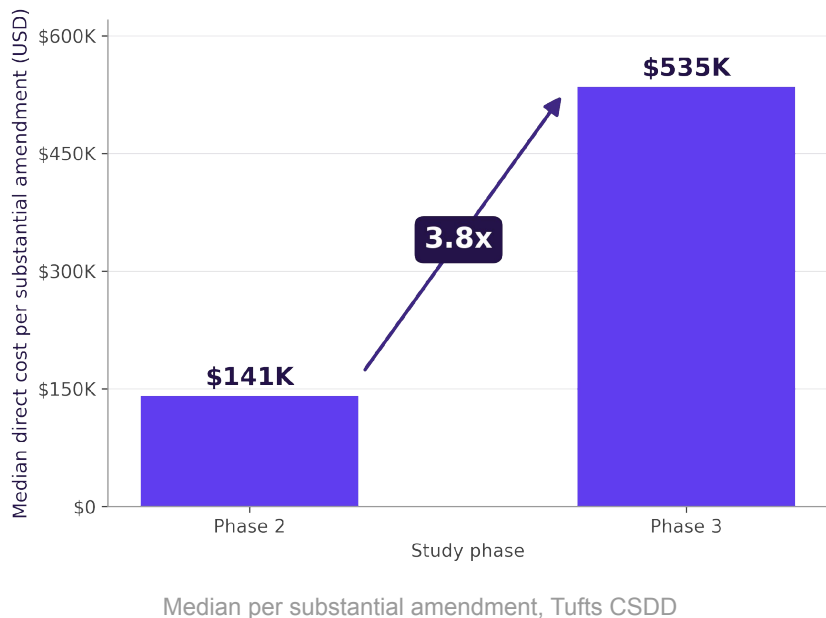
Phase 3 protocols now get amended. If you run late-stage trials, this is your baseline, not your bad luck.

## 3.3 per protocol

Mean substantial amendments, up 60% from 2.1 in 2015. Each one cascades into vendor change orders.

# The Later the Phase, the Bigger the Bill

Median direct cost to implement one substantial amendment: site fees plus CRO and vendor change orders



## And it compounds

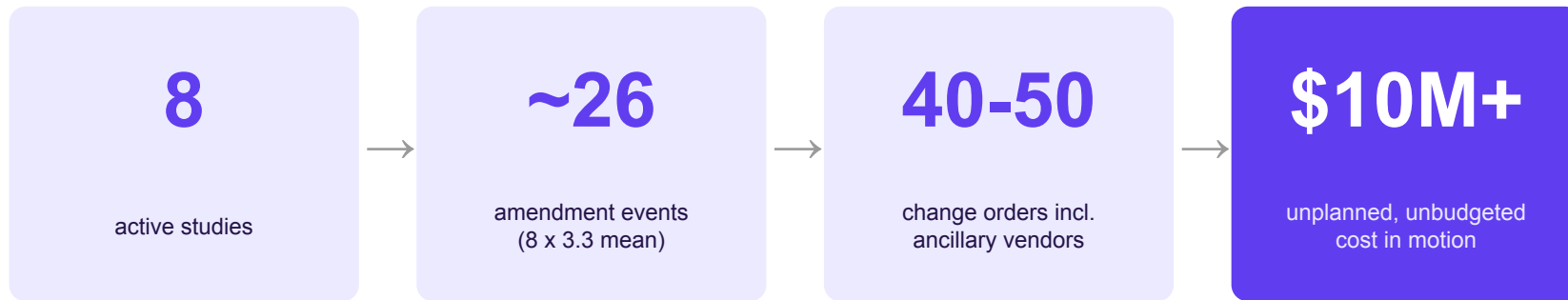
**+3 months** of unplanned time per amendment, on average

**30-60%** total contract growth via COs on fixed-fee CRO deals without strong CO controls

**Underbid, then change-order.** Vendors win on low bids and recover margin through COs. Refunds when scope shrinks are rare.

# Now Scale It: A Typical Biotech Portfolio

*Illustrative math for 8 active studies, mid-Phase 2 / Phase 3 mix, using Tufts CSDD inputs*



**A change order is in flight at all times, often 3-5 in parallel.**

Each is a multi-tab workbook landing on a finance team of 2-4 people who also own the close, forecasts, audit support, LRP and board reporting. These documents aren't built for review. They're built for signature, with the costs buried where a skim won't find them.

Derived estimates based on Tufts CSDD amendment benchmarks; CO-per-amendment multiplier reflects ancillary vendor cascade (central lab, IRT, imaging).

# Why the Burden Lands on Clinical / Finance

1

## Hidden costs

Unit price increases arrive bundled with legitimate scope changes. Re-baselined pass-throughs and management fees applied to inflated bases hide in 40-tab workbooks.

2

## Negotiation asymmetry

The CRO built the budget and knows every assumption. Your team gets days to respond, with no tooling, while the trial clock keeps running and leverage sits with the vendor.

3

## Retrospective recognition

Change orders often formalize work performed 6-12 months earlier. The accrual impact lands all at once, mid-close, and auditors want to know why you didn't see it coming.

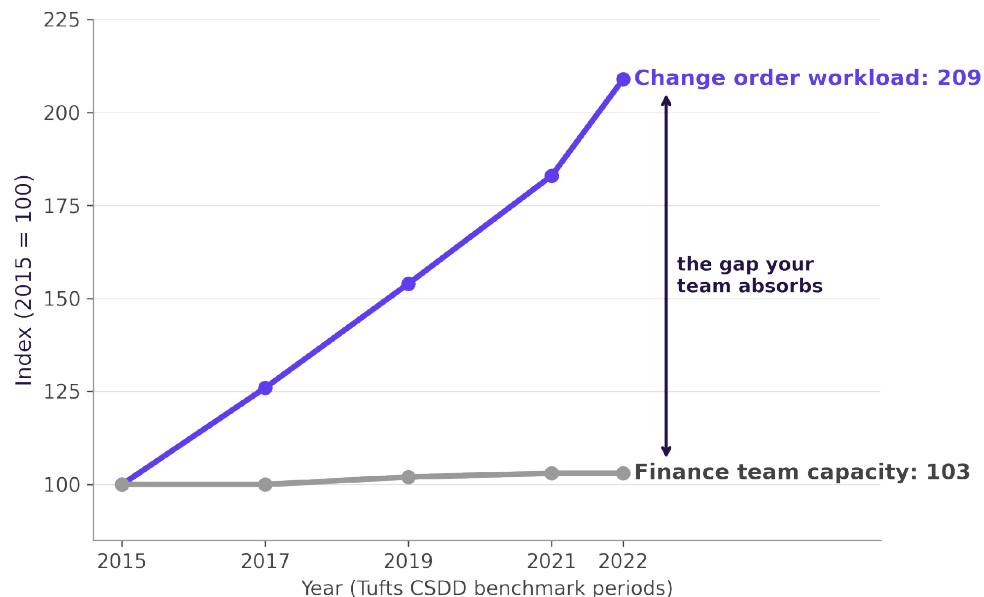
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## No system of record

Outdated trackers, inconsistent unit pricing, and version control chaos turn a simple scope adjustment into weeks of delay. Most teams cannot even report their CO cycle time.

# Workload Doubled. Headcount Didn't.

Change order workload vs. finance team capacity at a typical clinical-stage biotech, indexed to 2015 = 100



2x

the change order workload in  
under a decade, on roughly the  
same finance headcount.

**The gap gets closed with  
tooling or with weekends.**

Purple line: Tufts CSDD amendment prevalence x mean amendments per protocol, indexed (2015 = 100). Gray line illustrative: finance headcount at clinical-stage biotechs has stayed roughly flat.

# Live Demo: Microsoft Copilot

A quick and easy change order analysis with the tools you already have

# What Generic AI Gets You

*Honest scorecard from the demo you just watched*

## Genuinely useful

- Fast, readable summary of total cost change
- Decent category breakdown of what moved
- Solid starter questions for the CRO
- CFO-ready memo formatting in seconds
- Zero procurement: it's already on your desktop

## Where it stops

- Can't tie units back to the original contract
- No knowledge of your protocol or history
- Can't spot unlabeled retroactive work
- No benchmark for what 'normal' looks like
- Different answer every run: no audit trail

**It gets you from zero to informed. It does not get you to defensible.**

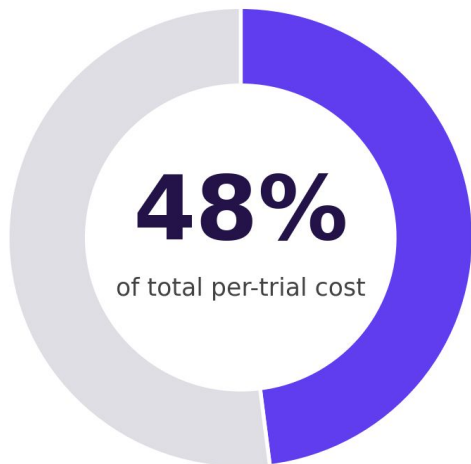
# 02

## The Investigator Grant Problem

Why investigator grants are painful for biotech and life sciences finance teams

# Nearly Half the Trial Budget Flows Through Investigator Grants

Investigator payments as a share of total per-trial cost



■ Investigator payments    ■ All other trial costs

## \$6,900

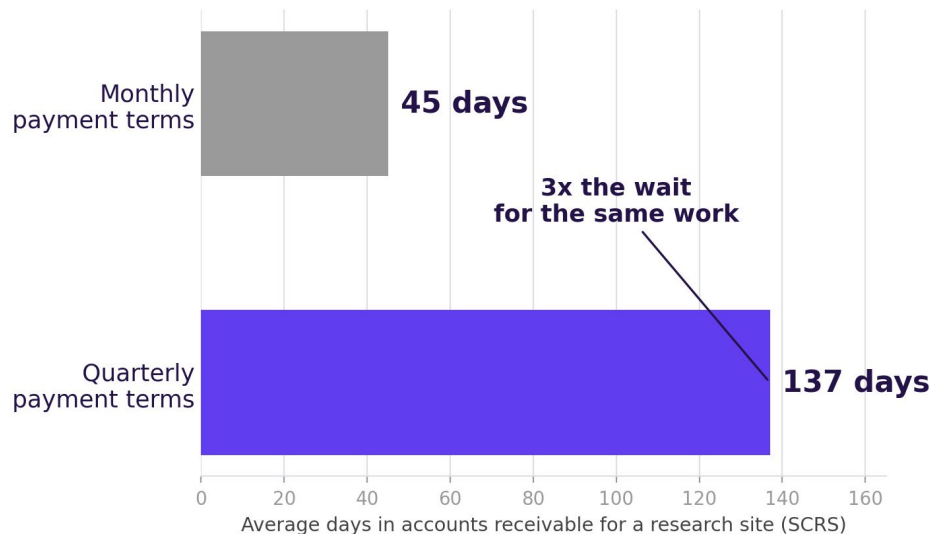
average investigator grant per patient across therapeutic areas.  
Oncology runs closer to \$18,700 per completed patient.

## Tens of thousands

of payment lines in a mid-sized trial when budgets are drafted at the procedure level. This stopped being a spreadsheet-scale problem years ago.

# The People You're Paying Can't Afford Your Payment Terms

How long a research site waits to be paid for work already performed



43%

of sites report three months or less of operating capital in the bank

40%

of sites drop out of studies over payment delays, per CTTI estimates

23%

of sites report payment delays of 90 days or longer

***Payment accuracy is not back-office hygiene. It is site relationship and enrollment risk.***

# Why Grants Are the Hardest Line to Get Right

## 1 Activity and money live in different systems

The EDC knows which visits actually happened. Finance sees invoices and payment files. At most sponsors, nobody reconciles the two line by line.

## 2 Every site contract is a snowflake

Per-visit rates, invoiceable procedures, screen failures, unscheduled visits, holdbacks, overhead percentages, currencies. The terms that define a correct payment are buried in PDFs.

## 3 Amendments re-price the study mid-stream

Protocols now average 3.3 substantial amendments, and each one changes visit schedules and budgets. Payment logic set at startup quietly goes stale.

## 4 Invoiceables accrue in the dark

Procedures, screen failures, and unscheduled visits get billed as they occur. If nobody tracks them against actuals, they surface all at once as a true-up at closeout.

# The Outsourcing Tradeoff: Convenience vs. Accuracy

Most sponsors hand grants management to their CRO or a payments vendor. That is often the right call. It is never a complete one.

## What outsourcing buys you

- Site relationships and budget negotiation handled by people who do it all day
- Global payment rails: currencies, VAT, tax forms, Sunshine Act reporting
- Headcount you don't have to hire for a function you don't want to build
- One vendor to manage instead of hundreds of site relationships

## What it quietly costs you

- Line of sight: your accruals are built on vendor-reported summaries, not study activity
- Incentives: payments are a low-margin afterthought inside a much larger CRO contract
- Quality control: the vendor approves, calculates, and reports on its own work
- Accountability: your auditors and your board ask you about the number, not your CRO

**You can outsource the work. You cannot outsource the accountability.**

# When Convenience Wins: Two Stories From the Field

## THE AUTO-PAY TRAP

A top-five global CRO replaced its investigator payments team with an automated pay platform. Every payment request was approved. Sites were paid for patient visits before the patients had enrolled, and the confusion took months to unwind.

## THE CLOSEOUT SURPRISE

A mid-cap oncology sponsor closed out a trial and received a five-million-dollar true-up. The CRO had not tracked or accrued invoiceable activity along the way. The money had been spent for years. The sponsor was simply the last to know.

***Automation without reconciliation just makes the wrong payment happen faster.***

# Live Demo: Microsoft Copilot

A quick and easy investor grant analysis with the tools you already have

# What General-Purpose AI Gets You

Honest scorecard from the demo you just watched

## Genuinely useful

- Fast, readable summary of the payment register
- Clean per-site totals and top-spender rankings
- Catches the obvious: duplicates, round numbers, outliers
- Solid starter questions for your CRO
- CFO-ready memo formatting in seconds, zero procurement

## Where it stops

- Can't see the EDC, so it can't tie a payment to a visit that actually happened
- Doesn't know your contracts: rates, caps, holdbacks, and overhead are invisible to it
- Accrual estimate is an extrapolation of past payments, not a measure of activity
- Can't tell an early payment from an unearned one
- Different answer every run, and no evidence trail behind any of them

**It reads the payment file. It cannot read the trial.**



# Questions