CDISC AI INNOVATION CHALLENGE 2026 · USE CASE 1 · RUNNER-UP

Closing the loop

Testing a study build with synthetic data, from USDM to ADaM

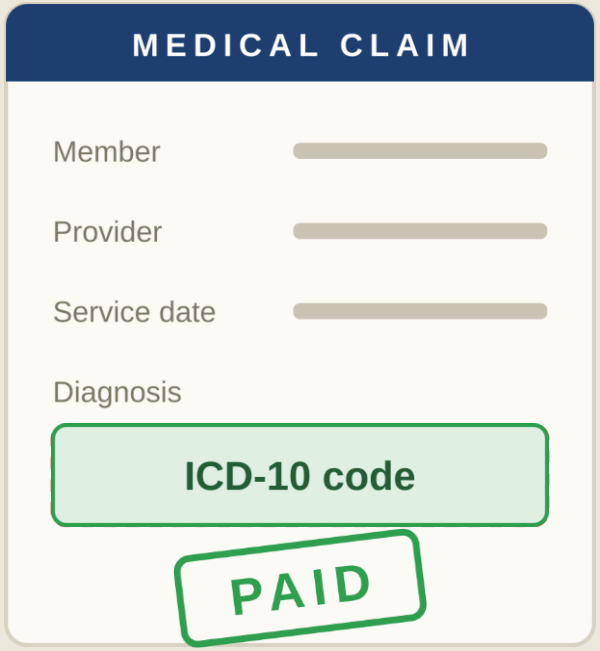
Shirley Collie, CEO · Rob Kieser, Head of Product · BioInformatiCo



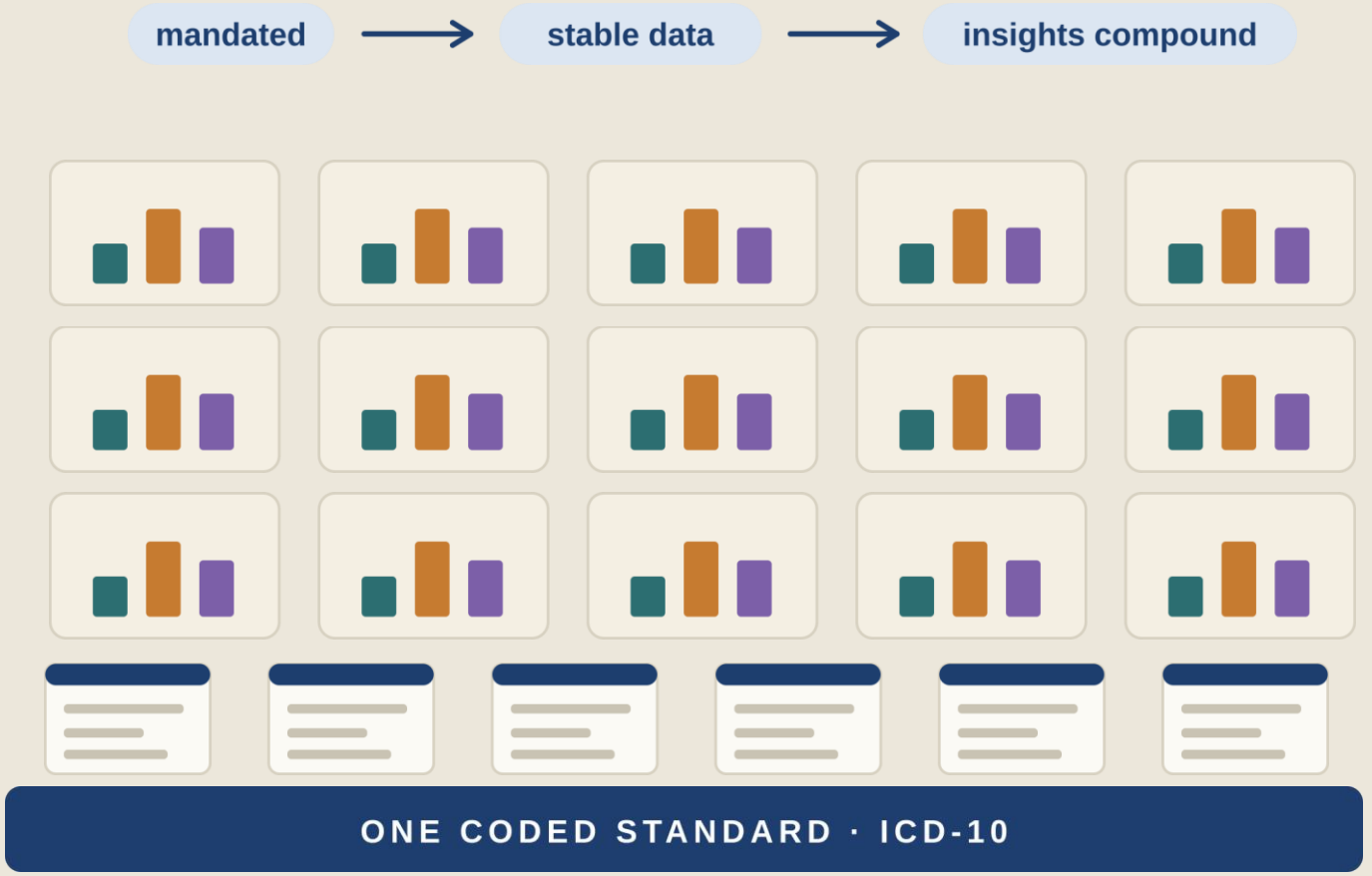
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WHERE I STARTED

Seventeen years of medical claims data



no code, no payment

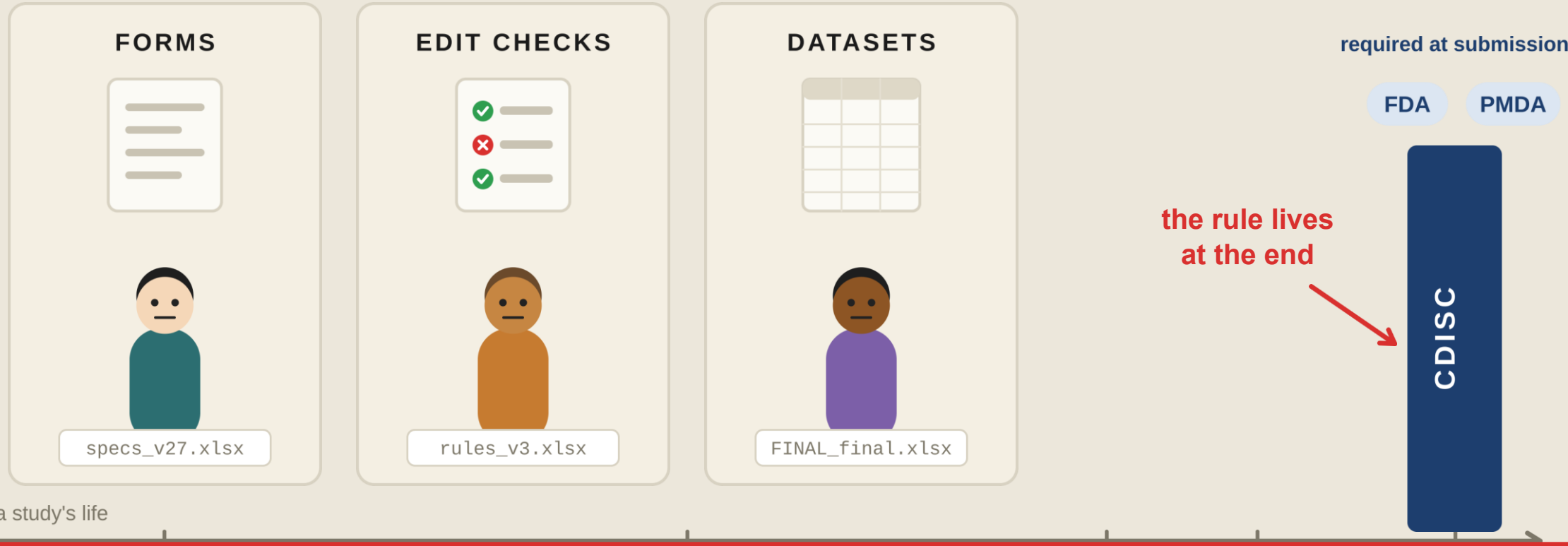


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THEN I CAME TO CLINICAL TRIALS

Something familiar, and something strange

built separately · different people · different copies of the truth



FOUND MONTHS LATER, IN A LIVE STUDY

— where every fix is change control —

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THE QUESTION WE STARTED WITH

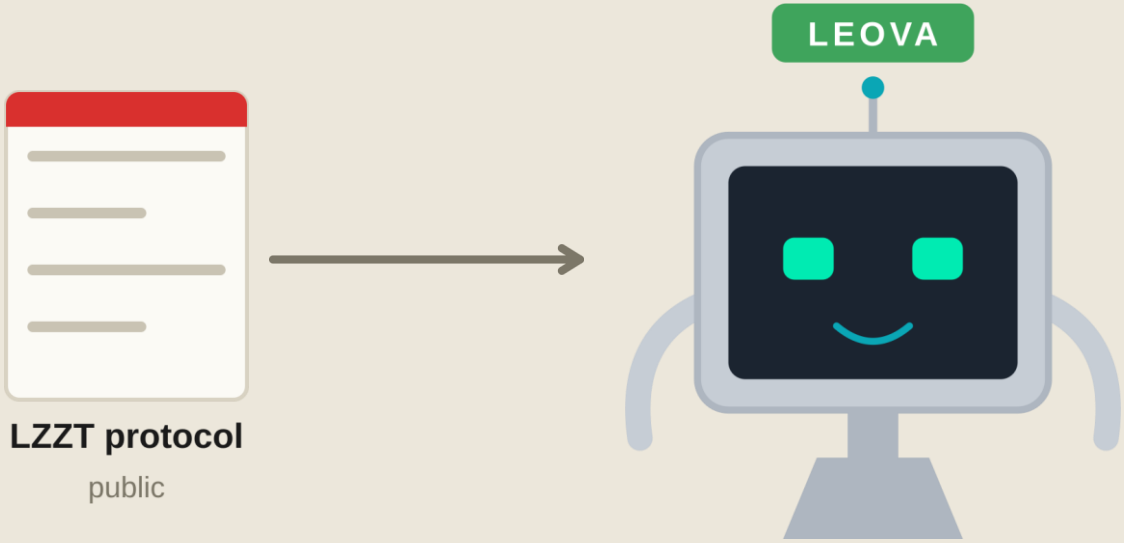
If the standard exists, why isn't the study built on it from day one?



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WHAT WE BUILT

Leova, the platform we're developing



END TO END

▶ VIDEO · 3:29



Quality Control

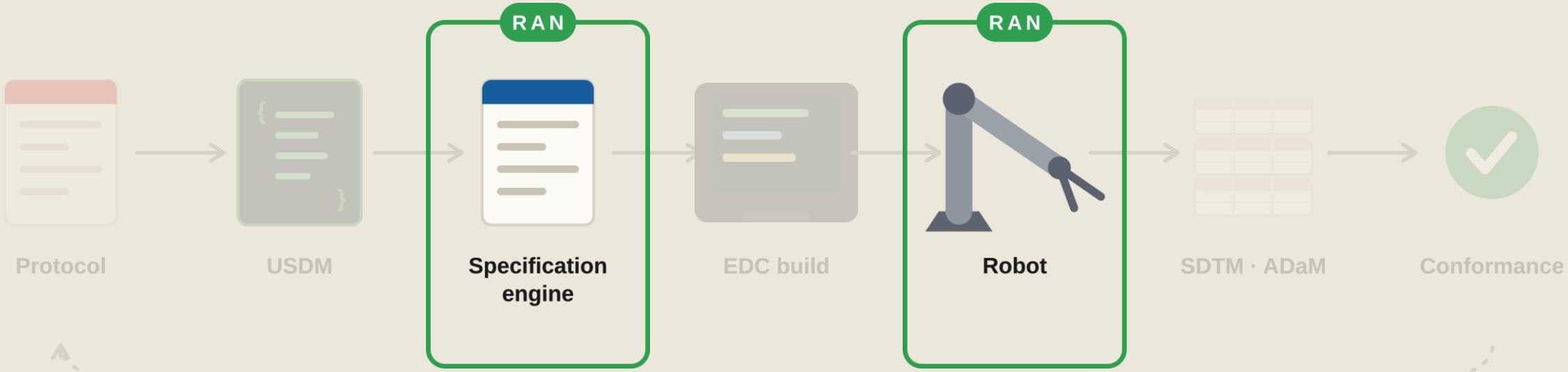
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AFTER OUR ENTRY

The same ideas, on a live study

We're a data management CRO: building studies is what we do every day.

PHASE 2a · HIV VACCINE TRIAL · 2 ARMS · 4 GROUPS

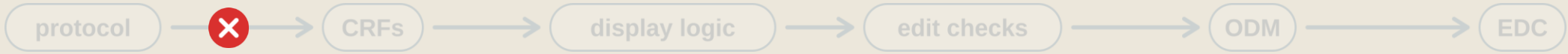


What ran: the specification engine and the robot

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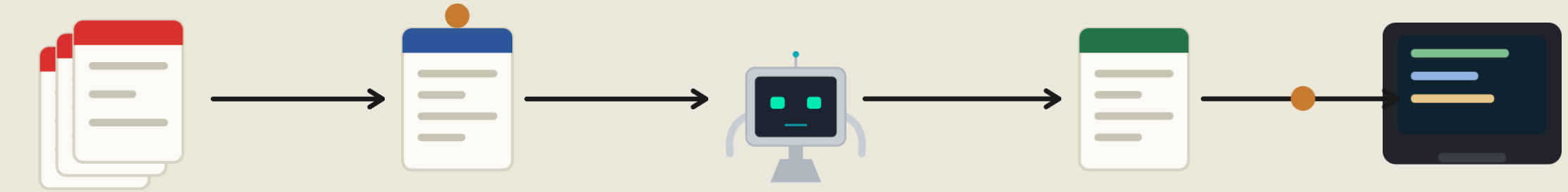
THE PATH THE STUDY TOOK

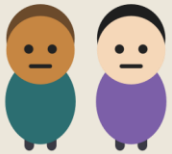
Designed for a straight line



not built for that path

…so we changed the sequence to fit the study





2 clinical specialists, both doctors



SME review before the EDC

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HOW WE WORK

Every correction becomes a rule



subject matter expert



specification



DETERMINISTIC RULES

- rule from review 01
- rule from review 02
- rule from review 03
- rule from review 04
- rule from review 05

NEXT STUDY

starts here

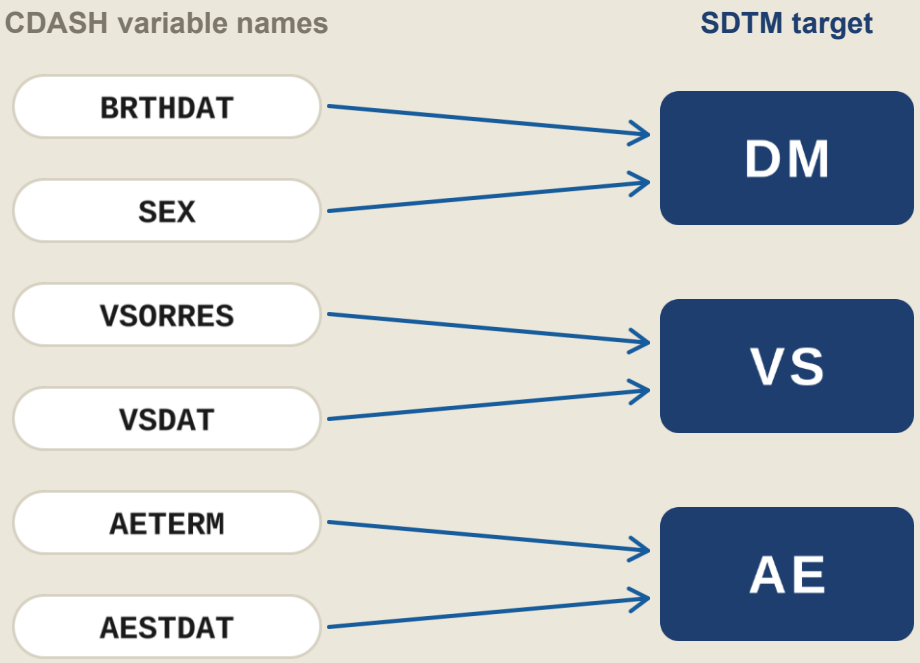


embedded in our DNA

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CDASH, BUILT IN

Not bolted on later



the SDTM target comes with them

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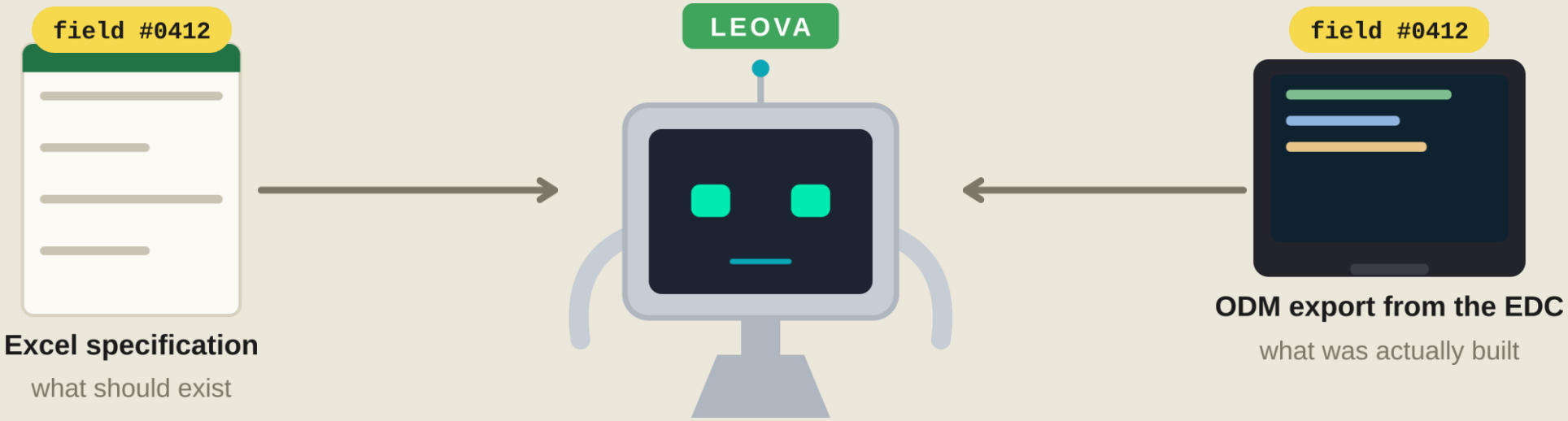
variables, CDASH-derived from the start

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THE ROBOT

Leova sees both sides

Every field carries its own number: every test, finding and screenshot traces back to it



The build proves itself against the specification
not the other way round

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EDIT CHECK TESTS

Every check, tested both ways

1,626

tests

across 170 edit checks

POSITIVE ASSERTION

The query fires when it should

the form appears when it should

NEGATIVE ASSERTION

It stays silent when it shouldn’t

the form stays hidden when it should

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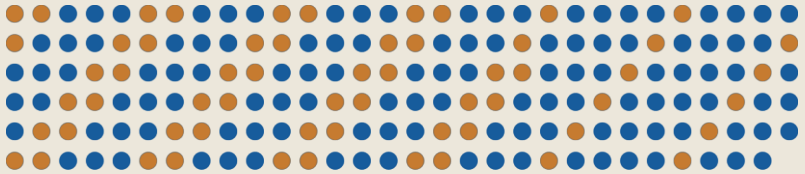
HUMAN IN THE LOOP

The first set of tests overgenerated

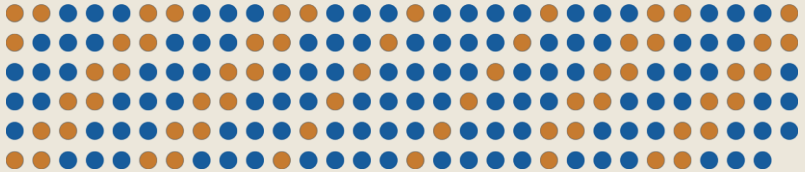


the expert

Arm A



Arm B



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raw tests

no arm lost a rule

each rule runs once, on one arm or the other

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THEN THE ROBOT

Does what a database programmer does

create participant · enrol · walk the visit schedule · enter the value · record what the EDC did



enrolled



SYN-001

visit schedule

Visit 1 · Visit 2 · Visit 3 · Visit 4 · Visit 5

FORM

field under test

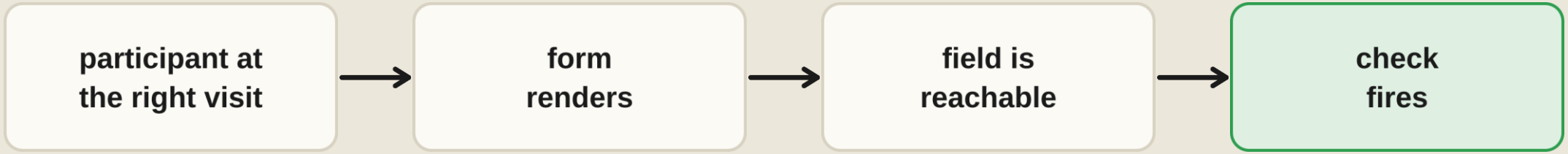
per test case

recorded: what the EDC did, against what the test expected

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WHAT WE LEARNT

You can’t test a check on its own



for the check to fire, everything before it has to be true

Realistic synthetic data shows its real value once it runs through the EDC itself

where variables and rules interact the way they will in the live study

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FINDINGS

What Leova found

ON PAPER

before the robot touched the EDC

- wrong checkbox codes
- a rule citing a codelist value that doesn't exist
- the schedule in the XML ≠ the schedule in the workbook

13

IN THE BUILD

after the robot entered data

- checks that didn't fire the way the workbook said
- display rules showing the wrong thing

34

47 problems, found before a single participant was enrolled

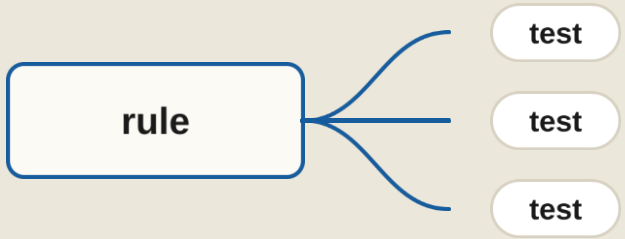
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EVIDENCE

Every run writes its own evidence

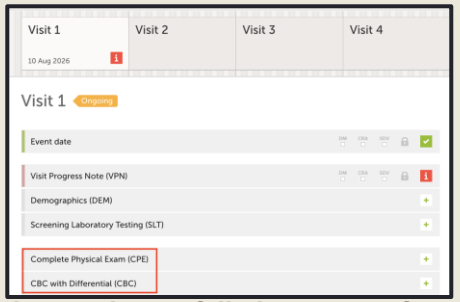
UAT LOG

INPUT	EXPECTED	WHAT THE EDC DID	TIMESTAMP	SCREENSHOT
value out of range	query fires	✓ query fired	hh:mm:ss	
value in range	no query	✓ no query	hh:mm:ss	
visit skipped	form hidden	✗ form shown	hh:mm:ss	



untested: named, with a reason





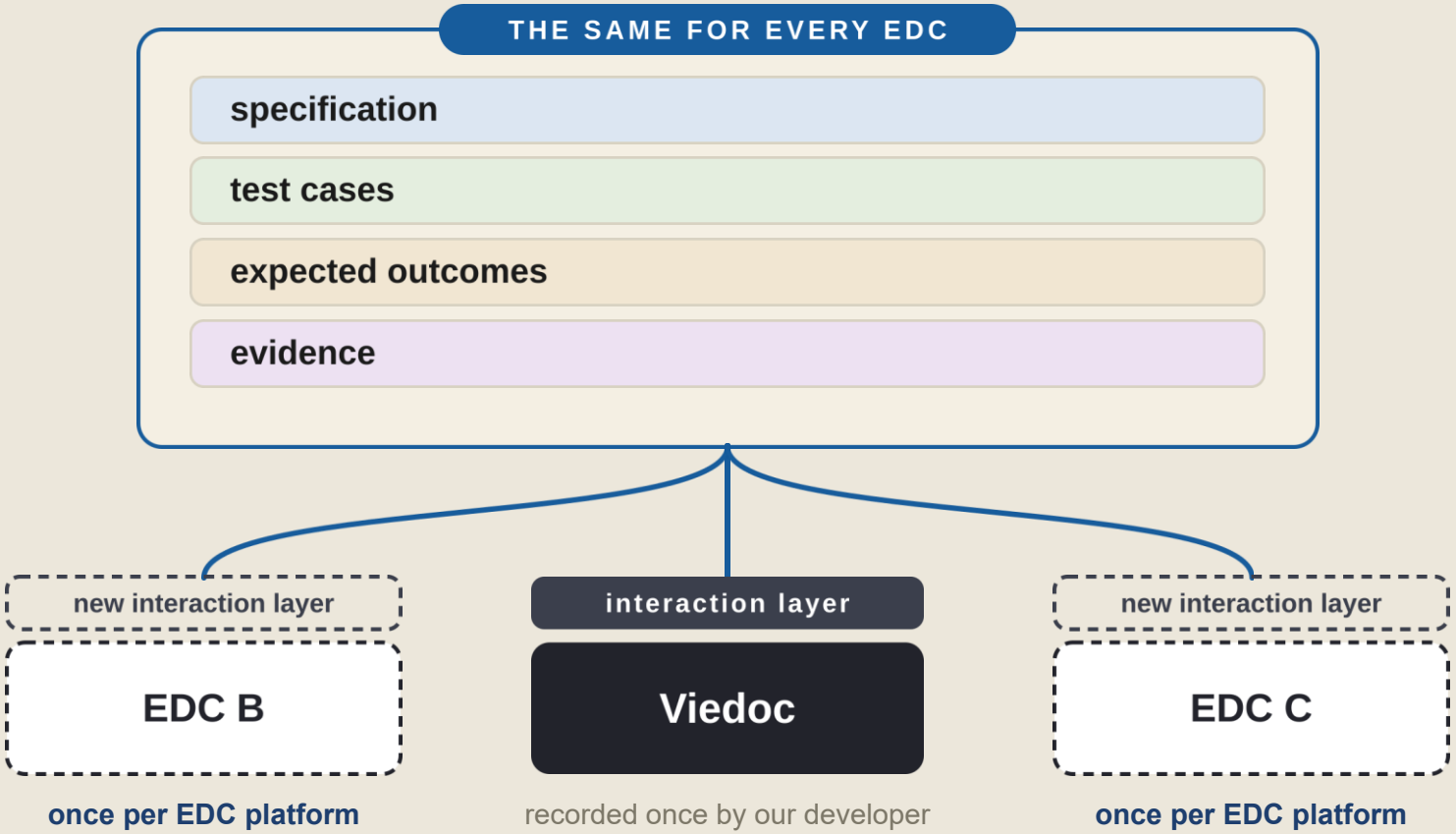
see at a glance where a failed test came from

About a month by hand on comparable studies. This study: one week.

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PORTABILITY

Once per EDC, not once per study



Keep everything that carries meaning above the EDC. Keep the EDC part thin.

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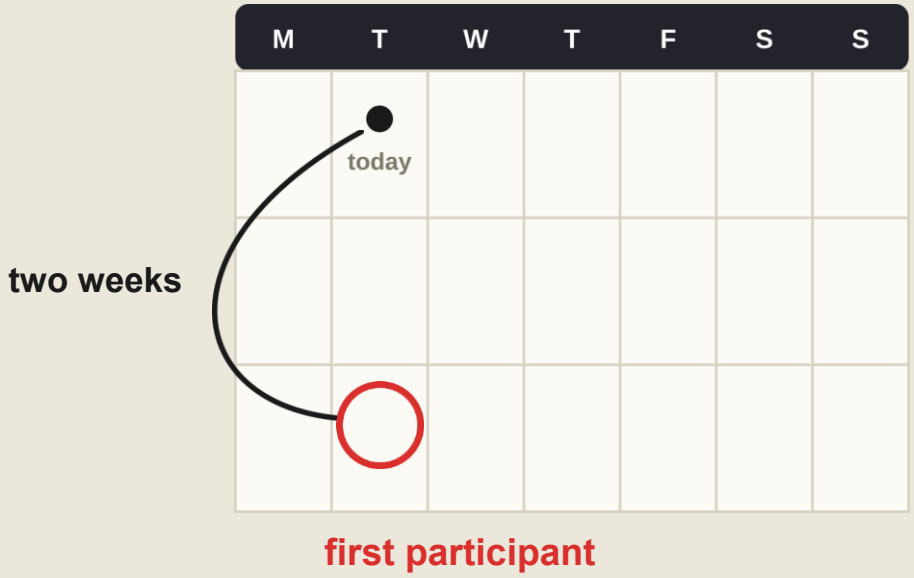
A REAL STUDY BUILD

Our challenge entry, at work

HIV vaccine study

study build

- protocol ✓
- forms ✓
- edit checks ✓



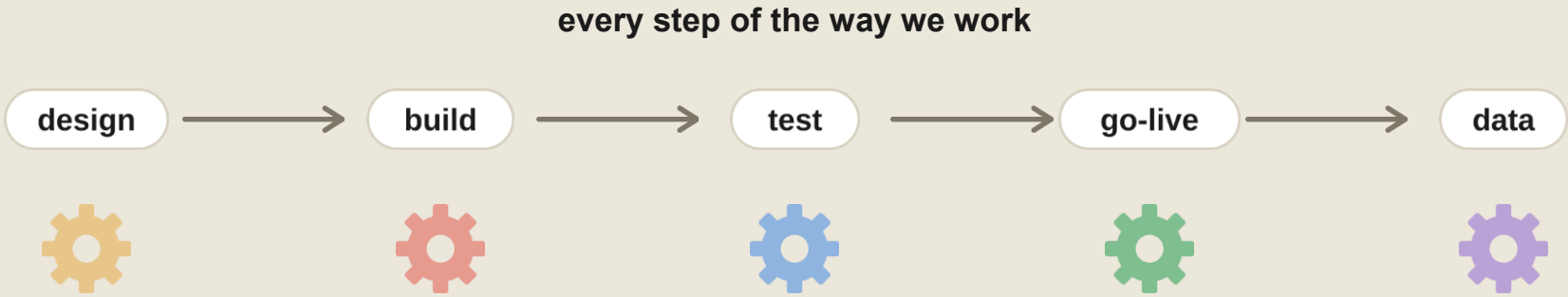
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WHO WE BUILD FOR

Grant-funded, investigator-led research



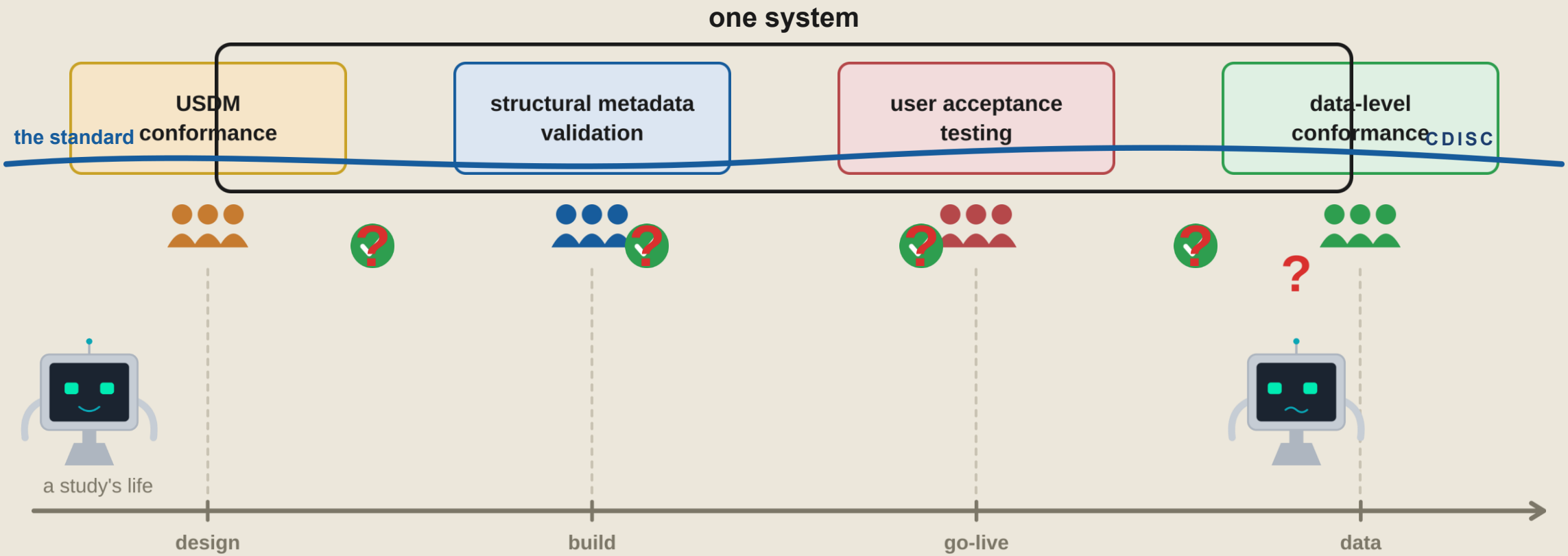




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WHAT WE BELIEVE

Four activities, four groups, four points in time?



Without CDISC, the robot has nothing to check against.

Thank you

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