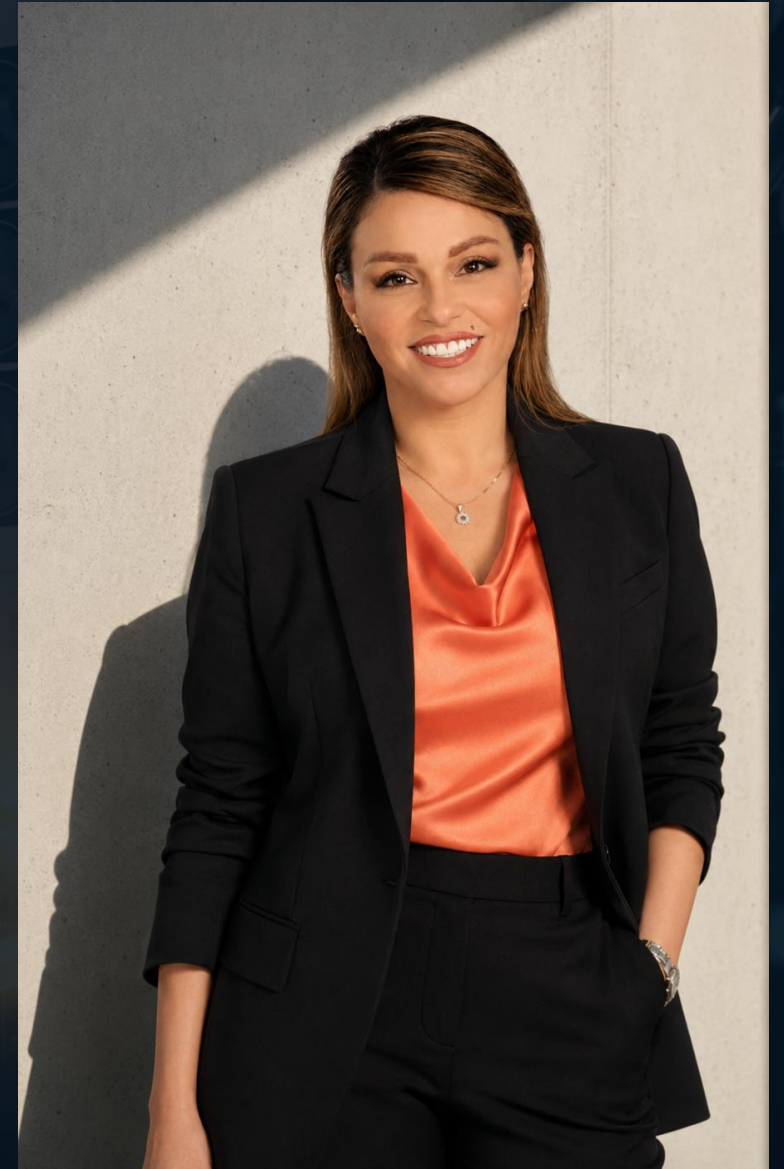




CLINICAL INTELLIGENCE FOR INTEGRITY & QUALITY

Catch the exception before it becomes a deviation.

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A trial exception begins small.

A symptom. A missing source. A delayed handoff. A question no one can answer fast enough.

1 A patient reports a serious symptom.

The team responds with urgency.

2 The record fragments.

Notes, outside records, EHR fields, sponsor systems, emails.

3 The question comes later.

What happened? Which source controlled the action? Who escalated?

What happens when a promising clinical trial loses usable data, not because the therapy failed, but because the workflow failed?



This is not just paperwork.

Trial exceptions can become delays, deviations, audit findings, and lost confidence in the data.



What cannot be traced becomes harder to trust.

Customer discovery:

Clinical research professionals described fragmented AE/SAE information, missing source documentation, and difficult event reconstruction across multiple systems and roles.

EARLY VALIDATION

Working research-stage prototype • 6 structured customer/advisor conversations • GCC REACH Stage 2 | <https://www.gccreach.org/reach-projects-6>

Selected sources: FDA diversity guidance (2025); ASCO/ACCC cancer trial diversity statement; AACR clinical trial diversity reporting; CLINIQ customer discovery appendix; GCC REACH ERB reviewer feedback summary.

Reliable trials need reliable execution.

Better treatments start by learning from every patient.

As clinical trials become more representative, enrollment cannot be the finish line.

- Symptoms must be heard.
- Adverse events must be captured.
- Escalation must be traceable.
- Patient experience must become reliable evidence.

CLINI*Q* helps the trial act from the right source and remember.

A source-governed exception-assurance layer for complex clinical trials.

1 Find the approved source

Protocol, amendment, SOP, study manual, or controlled instruction.

2 Identify what is missing

The output can be: evidence insufficient — escalate.

3 Escalate uncertainty

Route to PI, QA, pharmacy, sponsor, monitor, or other accountable human.

4 Preserve the record

Capture source, question, response, refusal, escalation, and disposition.



Boundary:

CLINI*Q* does not diagnose, grade toxicity, determine reportability, or replace PI/QA/sponsor judgment.

Start narrow. Prove value. Then expand.

CLINIQ begins where the stakes are high and the evidence burden is visible.

1

Complex oncology

AE/SAE documentation, protocol timing, source ambiguity

2

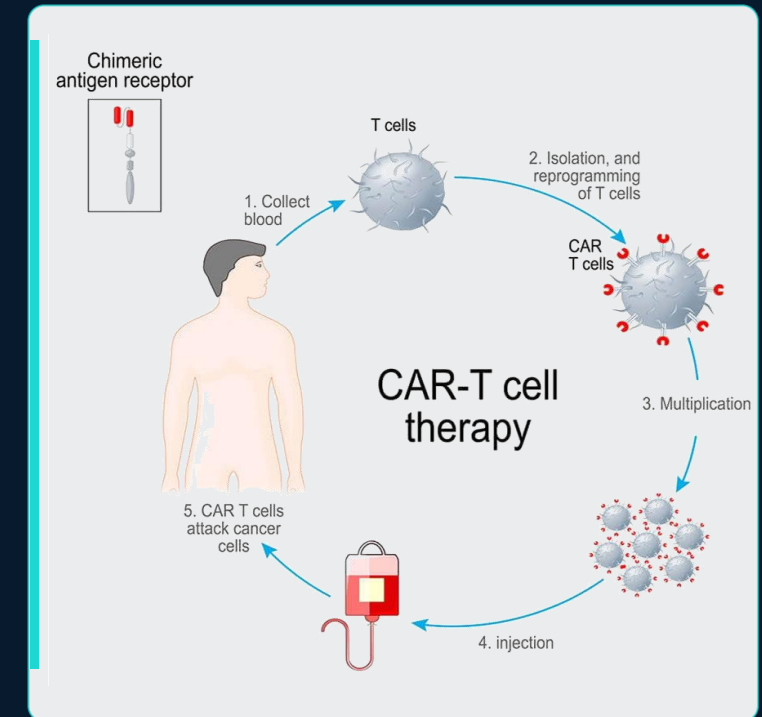
Cell therapy + high-risk trials

handoffs, toxicity checks, specialized manuals, escalation

3

Broader complex clinical research

repeatable exception-assurance layer across trial types



Phase I proof target: 50-100 controlled, non-PHI exception scenarios.

What we prove next.

Not more features - measurable evidence.

Faster evidence location

time to find controlling source

Better documentation

completeness of exception record

Safer escalation

correct reviewer when evidence is missing

Lower unsupported output

refusal when no source supports action

**The goal is not
more software.**

**The goal is proof that CLINIQ
measurably improves exception
resolution.**

Outputs: benchmark scenarios,
usability results, advisor-backed
validation design, SBIR-ready
evidence package.

\$20K can turn CLINIQ from promise into evidence.

The use of funds is milestone-driven, not feature-driven.

35%

Prototype refinement

Fit exception flow to real trial work

25%

Validation scenarios

Build non-PHI benchmark set

20%

User testing

Measure time, completeness, escalation

10%

Security roadmap

PHI boundaries and integration assumptions

10%

Pilot/SBIR readiness

Letters, aims, partner map

Why I am positioned to build this.

CLINIQ comes directly from the operational pain point, not from a generic software idea.



HBCU-led. Equity-informed. Built for the broader clinical-trials market.

Live Prototype

Already functioning. Advisor demo available upon request.



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Access is restricted to approved personnel and affiliates.

Username

Password

Login



⚠️ Disclaimer: This is a demo/training tool for SOP navigation and trial operations support. It is NOT clinical decision support and does not provide patient-specific medical advice. Do not enter PHI/PII. Always confirm with your protocol, site SOPs, and PI/QA.

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Current proof

Working interface + password protection + SOP-anchored logic.

Demo scope

Research-stage operational workflow tool; de-identified and advisor-facing.

Next validation

Test safety, citation quality, and escalation correctness before live workflow use.

<https://cliniq-trial.streamlit.app/>

Better treatments depend on reliable trials.

CLINIQ helps make sure critical trial events do not disappear between the patient and the evidence.



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Thank you.
cliniqtrial.com

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