EHIGNITE CHALLENGE · PHASE 1 CONCEPT BRIEF

Clarity

Your health, fully visible.

A unified portal where patients connect every provider once, see their full health story through AI-assisted summaries, and send records on their own terms.

SUBMISSION	ONC EHIgnite Challenge — Phase 1: Concept and Design
HEADLINE SCENARIO	**Scenario 3** — Integration Across Settings
SECONDARY CAPABILITIES	Scenario 1 (Interactive Patient Tools) + Scenario 4 (Streamlined Payer Use Cases)
STANDARDS ANCHOR	FHIR R4 · US Core IG v6 · SMART App Launch 2.0 · CMS Patient Access API
SUBMITTED	May 2026

Executive Summary

Electronic Health Information (EHI) exports are mandated by the ONC Certification Program, but uptake has been minimal. The reason is simple: today's exports are technically compliant data dumps — XML, CSV, FHIR bundles, or PDFs that arrive without context, narrative, or a path to use them. Patients receive their records and have no idea what to do next.

Clarity is a unified, patient-owned health portal that turns those exports into something patients can actually live with. With one onboarding flow, a patient connects every provider, lab, pharmacy, and payer they use. Clarity continuously syncs records via SMART on FHIR, presents them through an AI-assisted dashboard written in plain language, and lets the patient send a clean, current bundle to any new provider in under a minute.

Clarity leads with **Scenario 3 (Integration Across Settings)** because the foundational problem patients face is fragmentation: their records live in five EHRs that don't talk to one another. We solve that first. From that aggregated foundation, we deliver **Scenario 1** (an Interactive AI Assistant grounded in the patient's own records) and **Scenario 4** (payer integration via the CMS Patient Access API), without spreading effort thin across the entire challenge surface.

Our Phase 2 prototype will demonstrate end-to-end functionality with at least three EHR sandboxes (Epic, Cerner/Oracle Health, athenahealth) and one payer sandbox (CMS Blue Button 2.0). We are competing for the grand prize and for the Most Innovative Use of AI award.

SECTION 01

The Problem

EHI exports work on paper. They fail in practice.

The ONC Certification Program requires every certified EHR to support Single Patient and Patient Population EHI Exports. Patients can request, and developers must deliver, a complete electronic copy of the designated record set. The mandate has been in effect since the Cures Act final rule took effect, and certified products comply. Adoption among patients, however, remains marginal.

The failure is not regulatory. It is experiential. A patient who requests their EHI export typically receives one of three things:

- **A ZIP file** containing dozens or hundreds of CCDA XML files, organized by encounter, parseable only by other software.
- **A multi-hundred-page PDF** that mixes clinical notes, lab results, and billing codes with no consistent structure.
- **A FHIR R4 bundle** as JSON, which only developers can read.

None of these is usable by the person who owns the data. Worse, the export only contains records from one provider — and the average American sees **five different providers across their lifetime of care**, per AHRQ data. A patient with diabetes, hypertension, and a recent injury might have records at a primary care office, an endocrinologist, an imaging center, an urgent care, and two pharmacies. Five separate exports. Five separate formats. Zero integration.

What we heard from patients (informal interviews, March–April 2026)

> *"I asked for my records before switching doctors and they gave me a USB drive with 400 PDFs. I never opened it. I just retold my whole medical history to the new doctor from memory."*
>
> — Patient interview, age 54, suburban Chicago

> *"My mom has six specialists. I'm her health proxy. I have six logins, six apps, and a folder of paper. When she had her stroke, the ER didn't have her medication list."*
>
> — Caregiver interview, age 47, Brooklyn

Why a Challenge fits this problem

ONC's framing is correct: this is a "thousand flowers" problem, not a "one specification" problem. Different patients need different surfaces — a parent managing a chronically ill child needs something different from a snowbird splitting time between two states' health systems. A prize challenge invites multiple legitimate solutions; Clarity is ours.

SECTION 02

The Solution

Clarity, end to end

Clarity is a web and mobile application (Phase 2 will deliver web; mobile follows). It does four things, in this order of importance:

1. **Aggregates** EHI from every provider, lab, pharmacy, and payer the patient uses, via SMART on FHIR patient-facing app launch. One provider connection takes ~45 seconds; subsequent syncs are automatic.
2. **Translates** the aggregated record into plain-language summaries, with every claim traceable to a source document. This is where the patient experience changes most dramatically.
3. **Routes** records outbound on the patient's command: to a new provider, a specialist, a family member, or a download for personal use. All bundles are FHIR R4 and US Core IG v6 conformant.
4. **Surfaces** payer data alongside clinical data, so a patient can see what their endocrinology visit cost, what their insurance covered, and what they owe — without leaving the app.

How Clarity maps to the Challenge

Challenge Scenario	Clarity capability	How we deliver
3. Integration Across Settings	Multi-provider aggregation + outbound sharing	SMART on FHIR for inbound; Direct Secure Messaging and FHIR bundles for outbound; canonical patient-owned data store.
1. Interactive Patient Tools	Plain-language summaries and grounded chat	LLM-driven summarization over the patient's FHIR resources, with citations to source documents and explicit refusal of clinical advice.
4. Streamlined Payer Use Cases	Insurance + bills next to clinical records	CMS Patient Access API integration; matching of claims to encounters; deductible and out-of-pocket tracking.
2. Customization for Clinical Domains	Future — Phase 2 stretch	Domain-specific views (cardiac, oncology, prenatal) are a natural extension of our data layer, but are not in the Phase 2 MVP scope.

Differentiation from existing solutions

Apple Health	Strong aggregation, but iOS-only, no AI-assisted summarization, no outbound sharing to non-Apple providers, no payer integration.
b.well, Particle Health, Health Gorilla	B2B2C or pure B2B plays. The patient is not the customer. Clarity is patient-first by design.
Provider patient portals (MyChart, FollowMyHealth)	Single-provider views. Don't solve the fragmentation problem; in many cases they cause it.
CommonHealth (Android)	Closest comparison. Open-source aggregator. Clarity differs by adding AI-assisted summarization, payer integration, and outbound sharing — and by being platform-agnostic.

SECTION 03

Technical Architecture

System overview

Clarity has four logical layers. Each can be developed and tested independently, which matters for Phase 2 timelines.

Layer	Components & technical choices
1. Connectors	**SMART on FHIR App Launch 2.0** against provider FHIR R4 endpoints. We register Clarity as a confidential patient-facing app in each EHR network (Epic Open.Epic, Cerner Code Console, etc.). On a per-provider basis the patient is redirected to their portal, authenticates, and authorizes the requested scopes. Clarity receives an OAuth 2.0 access + refresh token, stored encrypted at rest.
2. Sync engine	A background worker fetches the US Core IG v6 resource set (Patient, Encounter, Condition, Observation, MedicationRequest, AllergyIntolerance, Immunization, Procedure, DiagnosticReport, DocumentReference, etc.) on a tunable cadence — typically nightly with on-demand syncs after a visit. Resources are de-duplicated across providers using OIDs, identifiers, and clinical matching heuristics, and stored in a normalized FHIR-shaped Postgres schema.
3. Intelligence layer	Retrieval-Augmented Generation over the patient's own FHIR resources. A document index is built per-patient and queried by an LLM for both proactive summaries (dashboard) and reactive Q&A (Ask Clarity). Every generated statement carries a citation to one or more source resources. Section 05 covers this in detail.
4. Outbound	Two delivery modes: **(a) Direct Secure Messaging** via DirectTrust-accredited HISP for transmission to provider Direct addresses, and **(b) time-limited, encrypted download links** for cases where the recipient lacks a Direct address. All outbound bundles are FHIR R4 + US Core v6 conformant, with optional CCDA C-CDA R2.1 generation for legacy receivers.

A note on "connect once"

We want to be precise here, because vague claims fail technical scrutiny. Clarity does not provide a single sign-on across providers — that does not exist and would be a security failure if it did. What Clarity provides is **one onboarding session** during which the patient connects each of their providers in sequence. After that, the patient does not log in to any provider again. Clarity's refresh tokens keep data flowing in the background, the patient logs in only to Clarity, and re-authentication to a provider happens only if a refresh token expires (per that EHR's policy).

Standards conformance

- **FHIR R4** as the canonical resource format, inbound and outbound.
- **US Core IG v6** for resource profiles, terminology bindings, and Must Support fields. This aligns with the ONC Certification Program's adopted standards.
- **SMART App Launch Framework 2.0** for OAuth 2.0 authorization, including the standalone patient launch profile and granular scopes.
- **CMS Blue Button 2.0 + Patient Access API** for payer-side data ingestion.
- **Direct Project + XDM/XDR** for outbound transmission via an accredited HISP partner.
- **USCDI v4** as the floor for what data we expect to receive and what we surface in summaries.

SECTION 04

Key User Flows

Four flows define the product. Each is depicted in the accompanying wireframes file; the descriptions below trace the user's path and the system's response.

Flow 1 — First-time provider connection (Screens 01–02)

Maria signs up with email + passkey. She is prompted to add her first provider. She searches for "Mount Sinai," sees the match, taps Connect. Clarity redirects her into Epic MyChart in a secure WebView. She enters her MyChart credentials (Clarity never sees them), reviews the scopes Clarity is requesting (read-only access to her clinical records), and approves. She is returned to Clarity. Within 90 seconds, her dashboard renders with a plain-language summary of her last six months of care. She repeats for her other four providers — a process that takes roughly 5 minutes total.

Flow 2 — Daily check-in (Screen 02)

On any morning, Maria opens Clarity. The dashboard shows an updated AI summary that incorporates anything new since her last visit (e.g., a lab result that posted overnight). Her active medications, upcoming appointments, and a vitals strip with sparkline trends sit below. She taps a refill alert on Metformin and is taken to her CVS prescription history, where she can request a refill.

Flow 3 — Asking a question (Screen 04)

Maria switched primary care providers last year. She wants to know if her new doctor said anything about her cholesterol. She types into Ask Clarity: "What did my doctor say about my cholesterol last week?" Clarity retrieves the relevant after-visit summary and lab result, generates a plain-language answer, and presents it with citations to both source documents. A disclaimer reminds her that Clarity does not provide medical advice and offers a one-tap path to message Dr. Patel through her connected portal.

Flow 4 — Sending records to a new provider (Screen 06)

Maria is referred to a cardiologist, Dr. Chen. In Clarity, she taps Send Records, searches for Dr. Chen's practice (Clarity looks up Direct addresses from the DirectTrust directory), and selects what to share: visits, medications, allergies, and labs from the last 12 months. The preview pane on the right shows exactly what Dr. Chen will receive. She sets the access window to 30 days and confirms. Within seconds, a FHIR R4 bundle is delivered via Direct Secure Messaging to Dr. Chen's intake. Maria sees the delivery confirmed in her access log; Dr. Chen sees a structured record arrive in his EHR.

SECTION 05

AI Approach

TARGETING THE $20,000 MOST INNOVATIVE USE OF AI PRIZE

The innovation is not that Clarity uses an LLM — many will. The innovation is **how Clarity constrains the LLM** so its output is trustworthy enough to put in front of a patient making decisions about their own care.

Three architectural choices

1. **Structured extraction before generation.** The LLM never sees a raw CCDA blob or a PDF. Every incoming document is parsed into FHIR resources first, validated against US Core profiles, and stored as structured data. When the LLM generates a summary, it works from a curated, schema-checked slice of the patient's record — not unstructured text. This eliminates a large class of hallucinations.
2. **Citation-mandatory generation.** The LLM is prompted to produce output in a structured format where every clinical claim must reference the FHIR resource ID it came from. The UI renders these citations as inline footnote markers. If a claim has no citation, the UI strips it and logs the event as a model failure for our evaluation suite.
3. **Hard refusal boundaries.** A separate guardrail model (or rule set) classifies user queries before the main LLM sees them. Anything that asks for diagnosis, treatment recommendation, dose change, or symptom interpretation is intercepted and routed to a templated response that points the patient to their connected provider's secure message function. We trade some perceived helpfulness for a sharp scope of liability.

What this produces

A patient reading a Clarity summary sees a plain-language paragraph that says, in effect: "Your LDL was 142 [↗ source: Lab Report 2026-04-25]. Last year it was 128 [↗ source: Lab Report 2025-04-12]. Your doctor's visit note from 2026-04-23 [↗ source] mentions this and starts you on atorvastatin." Every fact is traceable. Every recommendation is the doctor's, not Clarity's.

Evaluation

In Phase 2 we will build an evaluation harness with synthetic patient records (using Synthea) and a curated set of ~500 patient-style questions. We will score the model on four dimensions:

- **Factual accuracy** (does every claim trace to a real resource in the synthetic record?)
- **Citation completeness** (does every clinical claim carry a citation?)
- **Boundary adherence** (does the model refuse clinical advice when prompted, including in adversarial framing?)
- **Reading level** (target: Flesch-Kincaid grade 7 or lower).

SECTION 06

Privacy, Security & Regulatory

Our regulatory posture

Clarity's regulatory status warrants precise framing. When a patient uses Clarity to access their own records through a SMART on FHIR patient-facing app, Clarity is *not* a HIPAA Covered Entity, and in most architectures is not a Business Associate either. We act as a personal health record (PHR) vendor receiving data at the patient's direction. The applicable federal regime is the **FTC Health Breach Notification Rule**, along with state-level health privacy laws (notably California's CMIA, Washington's My Health My Data Act, and similar regimes coming online in other states). We will comply with each.

Where Clarity is acting on behalf of a provider — for example, if a provider organization licenses Clarity to offer it to their patients — Clarity would enter into a Business Associate Agreement (BAA) with that organization and operate within the HIPAA framework accordingly. Our architecture supports both modes.

Technical controls (Phase 2 commitments)

- **Encryption at rest** with AES-256; encryption in transit with TLS 1.3 minimum.
- **Encrypted token vault** for OAuth refresh tokens, separated from the application database.
- **Per-patient access logs** visible to the patient, including every internal access, every sync, and every outbound share.
- **SOC 2 Type II readiness** as a Phase 2 milestone, with HITRUST CSF as a follow-on.
- **Passkey-first authentication** with optional TOTP fallback; no SMS-based 2FA.

- **No third-party analytics or trackers** on authenticated pages. Patient records do not leave Clarity's environment except via patient-directed shares.

Patient controls

- **Granular per-provider revoke.** Disconnecting a provider revokes Clarity's OAuth tokens and either deletes or archives that provider's records, at the patient's option.
- **Per-share expiration.** Every outbound share has a default 30-day access window, configurable by the patient.
- **Account export and deletion.** Patients can export their complete data in FHIR + CCDA at any time, and can delete their account with a 30-day grace period.

AI-specific safeguards

We will publish a clear AI use policy: what the assistant will and won't do, how citations work, how to report a bad response, and how Clarity logs and remediates failures. Every AI response includes a one-tap "This is wrong" feedback channel that flags the conversation for review.

SECTION 07

Wireframes, Roadmap & Team

Wireframes

Six high-fidelity screens are included in the accompanying file **Clarity_Wireframes.html**. Together they show the complete first-session and ongoing user experience:

Screen	Title	What it demonstrates
01	**Connect Your Providers**	First-run flow showing the SMART on FHIR provider-by-provider connection model, with one provider already connected and the user mid-search for another.
02	**Health Dashboard**	Home view with the AI-generated plain-language summary, active medications, upcoming events, and recent vitals — all aggregated across five providers.
03	**Records Library**	Unified, filterable timeline of every record across providers. Source provenance is preserved ("Mount Sinai", "Quest"). Each record can be viewed, downloaded as FHIR, or shared.
04	**Ask Clarity**	Bounded AI chat with inline citations, a clinical-advice disclaimer, and an explicit "What Clarity won't do" boundary card visible at all times.

05	**Insurance & Bills**	CMS Patient Access API integration. Deductible progress, out-of-pocket max, outstanding bills, and a claim-by-claim table tied to clinical encounters.
06	**Send to a Provider**	Patient-directed outbound share. Granular record selection, real-time preview of what the recipient will see, expiration controls, and Direct Secure Messaging delivery.

Phase 2 roadmap

Jun–Aug 2026	Connector layer & sync engine against Epic, Cerner/Oracle Health, and athenahealth sandboxes. Postgres FHIR store. Authentication.
Sep–Nov 2026	Intelligence layer: RAG pipeline, summarization, Ask Clarity MVP, evaluation harness with Synthea data.
Dec 2026–Jan 2027	CMS Blue Button 2.0 integration. Outbound: Direct Secure Messaging via HISP partner. Wireframes → production UI.
Feb 2027	Closed beta with 25–50 patient testers. Security review. Iterate on summarization quality.
Mar 2027	Phase 2 submission: working prototype, evaluation results, demo video, technical documentation.

Team

Clarity is being developed by a two-person founding team: a product lead responsible for design, user research, regulatory analysis, and standards work, and a backend engineer responsible for the connector layer, sync engine, and FHIR data model. Phase 2 funding will support a part-time clinical advisor (board-certified internist) and a security consultant for the SOC 2 prep. We have informal commitments from both.

SECTION 08

Impact, Metrics, Eligibility

Who benefits

- **Patients with multiple providers** — the chronically ill, the elderly, snowbirds, anyone who has moved cities or switched insurance. The fragmentation tax falls hardest on them.
- **Caregivers** — a single Clarity account can be jointly managed with appropriate proxy controls (Phase 2 stretch).
- **Providers receiving referrals** — instead of a faxed packet or a verbal history, they receive structured FHIR data they can ingest into their EHR.

- **The broader interoperability ecosystem** — Clarity demonstrates that EHI exports, properly surfaced, can become a daily-use tool rather than a niche compliance artifact.

Success metrics

Metric	Phase 2 target	How measured
Median providers connected per user	≥ 3	Beta cohort analytics
Time to first useful summary	< 5 minutes from signup	Instrumentation
Weekly active rate	≥ 40% of beta cohort	Product analytics
Summary factual accuracy	≥ 98% (Synthea eval)	Evaluation harness
Reading level of summaries	Flesch-Kincaid grade ≤ 7	Automated scoring
Outbound shares per user (90-day)	≥ 1.5	Beta cohort analytics

Eligibility & commitments

The submitting team meets the EHIgnite Challenge eligibility requirements: U.S.-based, not employed by ONC or its contractors, no federal employees on the team. By accepting a Phase 1 prize we commit to participate in Phase 2.

Closing

ONC's Challenge framing was right: EHI exports are not a single-format problem, and the absence of patient-facing tooling has held back what the rule was meant to enable. Patients should not have to be data engineers to use their own records. Clarity is a focused, defensible answer for the person who has too many providers, too many logins, and not enough understanding of what their own health story actually says.

If selected for Phase 1, our team will use the prize and the feedback to refine our connector targets, our AI evaluation harness, and the scope of our closed beta. Our Phase 2 prototype will be live, working software running against real EHR sandboxes — not a slide deck. We are ready to build it.

What's included with this submission

- **This document** — Clarity_Phase1_Brief.docx (10 pages)
- **Wireframes file** — Clarity_Wireframes.html (six high-fidelity screens, web-rendered)

Submitted to the ONC Office of the National Coordinator for Health Information Technology — EHIgnite Challenge, Phase 1: Concept and Design. May 2026.