eHealth Exchange
ANNUAL MEETING
LOST PINES RESORT & SPA
October 27, 2026

FHIR Under the Hood

Use Cases, Services, and What's Next

Michael McCune, Product Director – Solutions Engineering

Mike Yackanich, Vice President – Technology Integration

Scott Rossignol, Partner - Farseen Consulting, Consultant to eHealth Exchange

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Agenda

- Use Cases
  - Electronic Prior Authorization
  - Patient Event Notification & Exchange (PENE)
  - NiH All of Us
  - FDA BEST Adverse Event Reporting
- eHealth Exchange FHIR services
  - FHIRProxy (including payer services)
  - Da Vinci Clinical Data Exchange (CDex) & Task Based Exchange (TBE)
  - CDA to FHIR Transformation Service

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FHIR Use Cases

Electronic Prior Authorization

- Enable network-wide ePA connectivity with a single stroke
  - Supports DaVinci Burden Reduction standards, latest release (and backwards compatible)
- Free value-added services such as:
  - Onboarding conformance testing
  - Payer endpoint discovery
  - Patient/person coverage discovery
- eHealth Exchange leads Da Vinci Project Trebuchet
  - Come and join the fun – start piloting today!

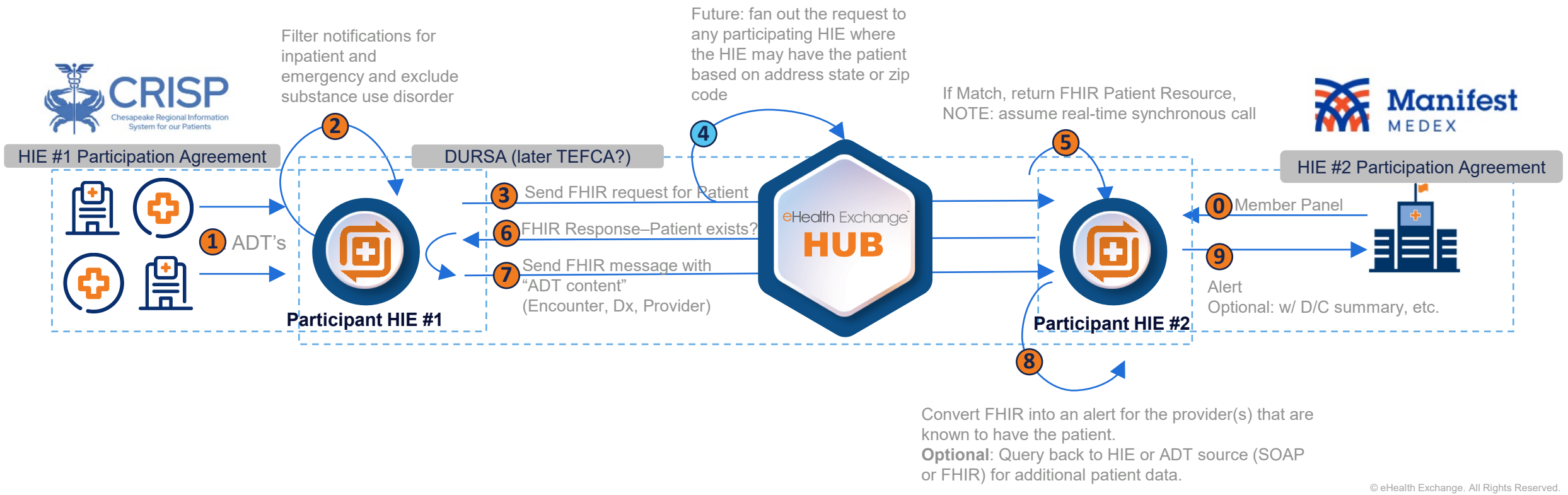
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FHIR Use Cases

Patient Event Notification & Exchange

Use Case

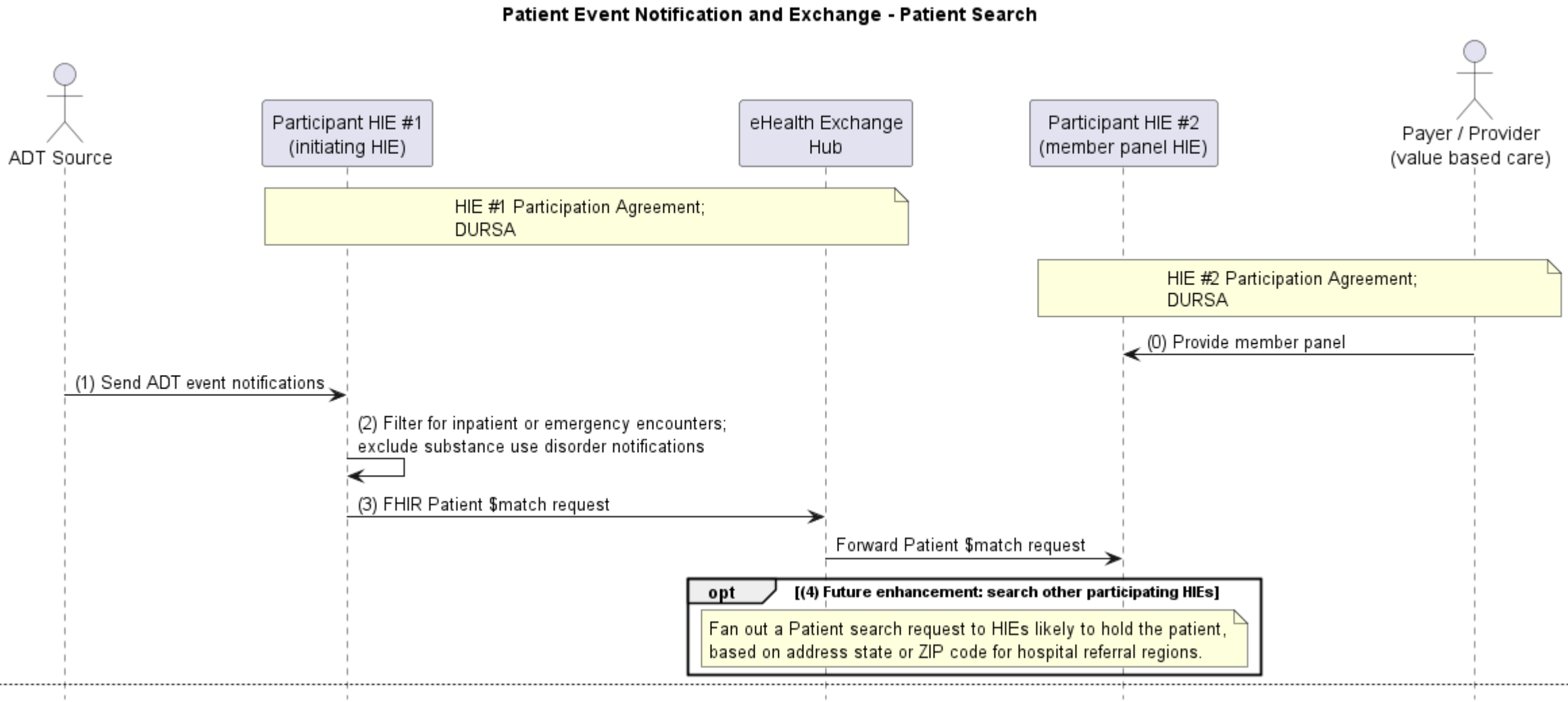
As a Payer (or a Provider w/ value-based care contracts), I want to be triggered about all member encounters (from anywhere in the USA), to then obtain episodic clinical data to update priorities for care management teams, update gaps-in-care, and update risk stratification.



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Patient Event Notification & Exchange

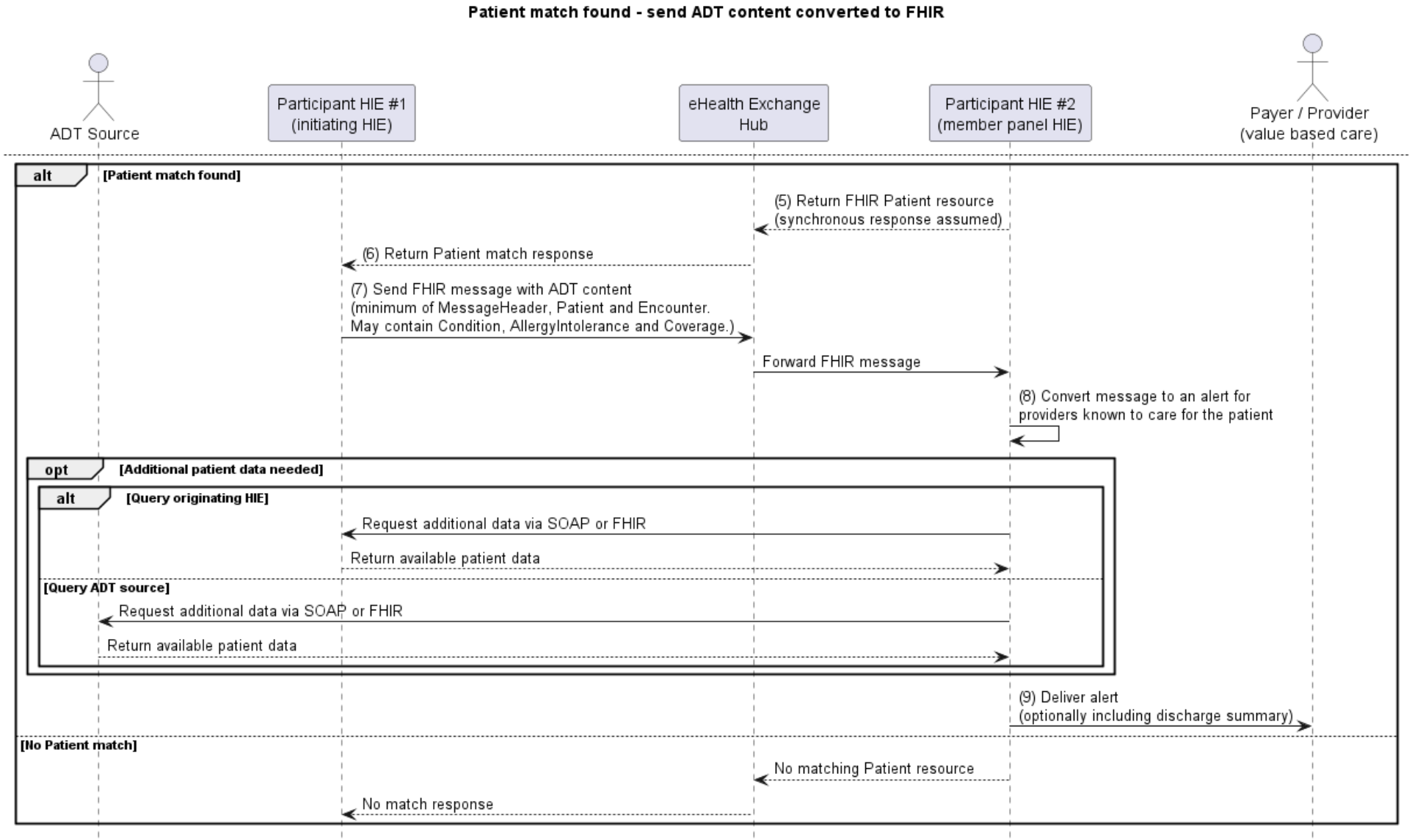
FHIR Use Cases



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Patient Event Notification & Exchange

FHIR Use Cases

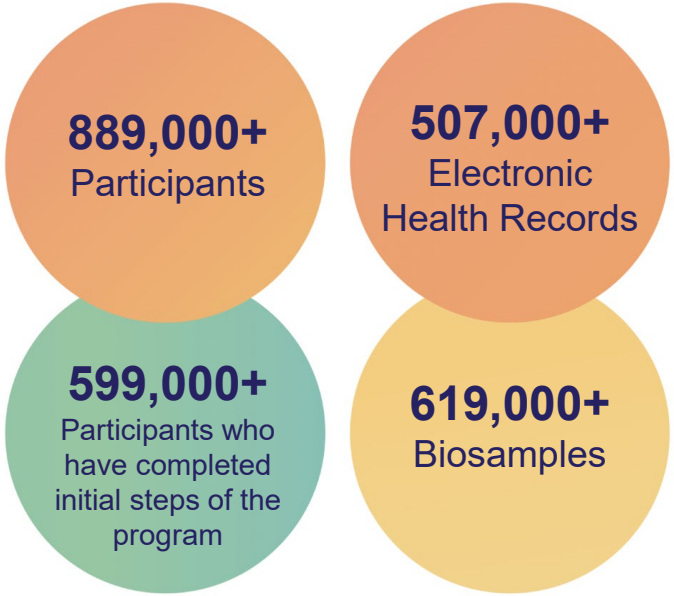


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FHIR Use Cases

NIH *All of Us*

National Institute of Health (NIH)
***All of Us* Research Program**



Accelerating health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us.

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NIH *All of Us* Research Program

FHIR Use Cases

CHALLENGES

- >90% of participants consent to share EHR, yet only ~69% have some EHR records in the current clinical data repository as of Q1 2025.
- Current methods of collecting EHR data are expensive and remain fragmented.

Center for Linkage and Acquisition of Data (CLAD),

- Led by University of North Carolina at Chapel Hill - first academic partner to use RESEARCH code at scale on eHealth Exchange network
- Acquire EHR data from HINs and HIEs that may fill gaps in records currently received for the study participants and facilitate the creation of longitudinal EHR records.
- Investigate the success rate of clinical data requests using the RESEARCH purpose of use.

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NIH *All of Us*
Trust Model and Consent Handling

FHIR Use Cases

- The exchange purpose is RESEARCH and clinical data is obtained based on the authorization/consent provided by All of Us volunteers.
- The *All of Us* program makes the volunteer's consent accessible but does not require that the healthcare organization obtain the patient's consent before clinical data is retrieved.
- Multiple trust models are supported according to the healthcare organization's requirements. For example, any of the following are possible:
  - HCO does not request/receive each authorization but may request if needed in the future.
  - HCO requests/receives each authorization but internally does not associate the document to the patient's record.
  - HCO requests/receives each authorization and associated with each patient's record (e.g., stored in patient's chart).

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FHIR Use Cases

NIH *All of Us*

Two Technical Options

<u>Preferred</u> - Retrieve clinical data as FHIR resources

- Retrieve clinical data from NIH *All of Us* project volunteers using HL7 FHIR R4.
- Data retrieval will use a task-based approach, based on DaVinci CDex.
- May leverage traditional web services (IHE SOAP) or Direct Secure Messaging to transfer the volunteer's consent document and associate it with the patient's records as many EHR APIs for FHIR do not support a workflow to accept or obtain patient consent.

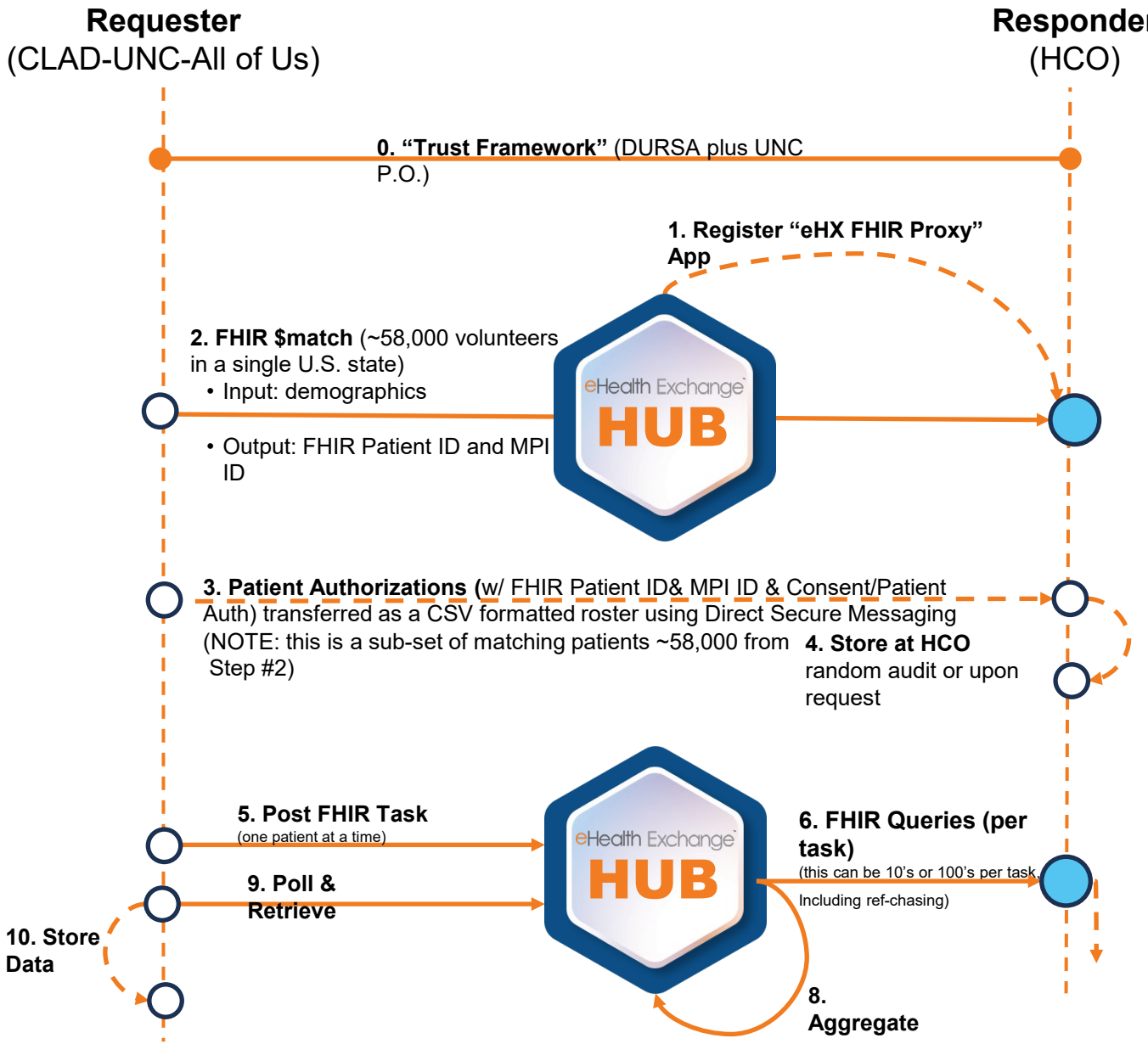
Retrieve C-CDA documents to obtain clinical data via traditional web services

- Retrieve C-CDA document clinical data from NIH *All of Us* project volunteers using traditional IHE SOAP web services

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NIH *All of Us*

Typical workflow for a FHIR-centric approach



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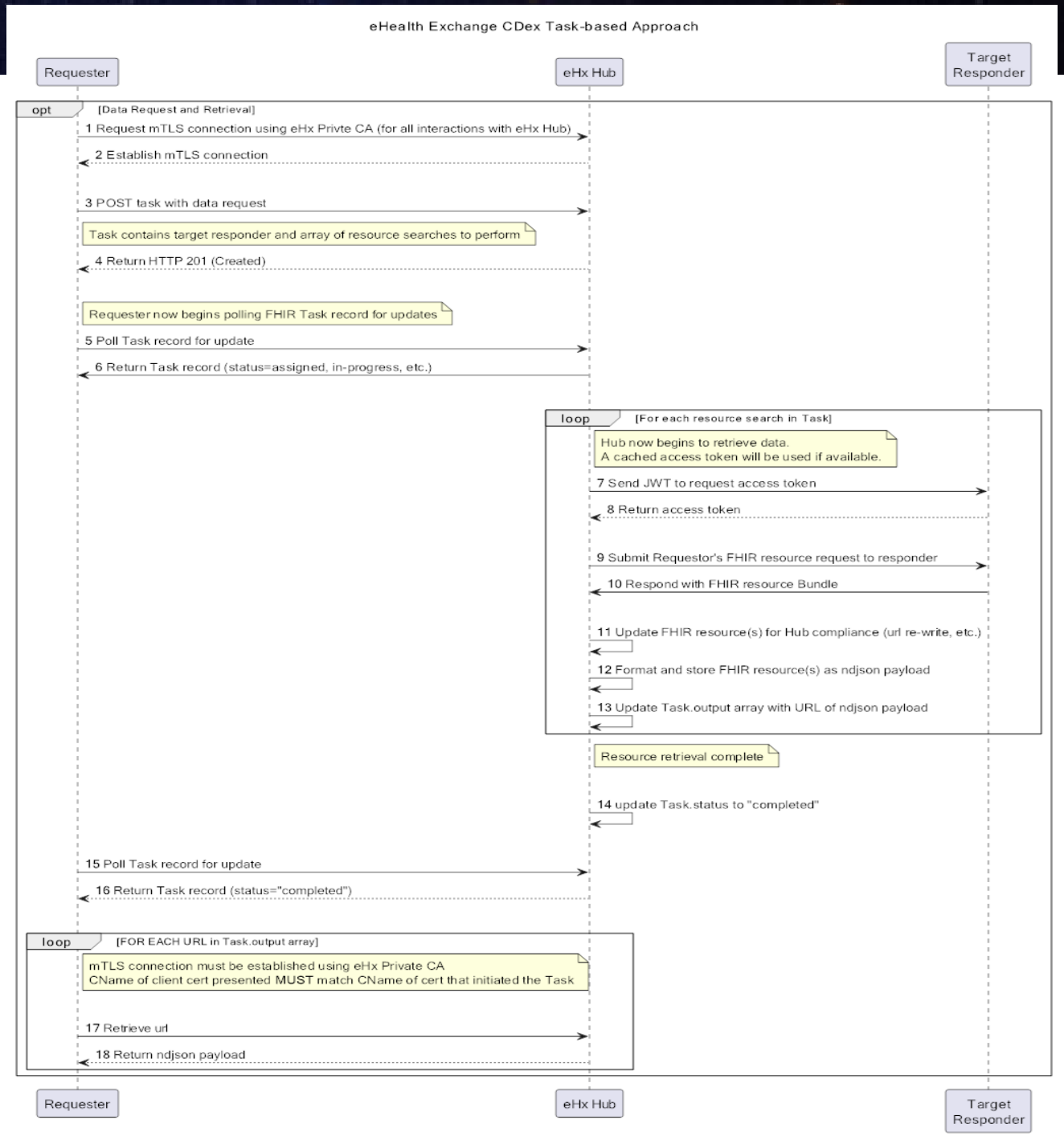
NIH *All of Us*
Task-based Approach

- The requestor (UNC Chapel Hill on behalf of *All of Us*) submits a Task to the eHealth Exchange that specifies details of the data requirements
  - Identifies a responding provider
  - Identifies the FHIR resources to retrieve

- eHealth Exchange FHIR Hub retrieves all resources requested within the Task

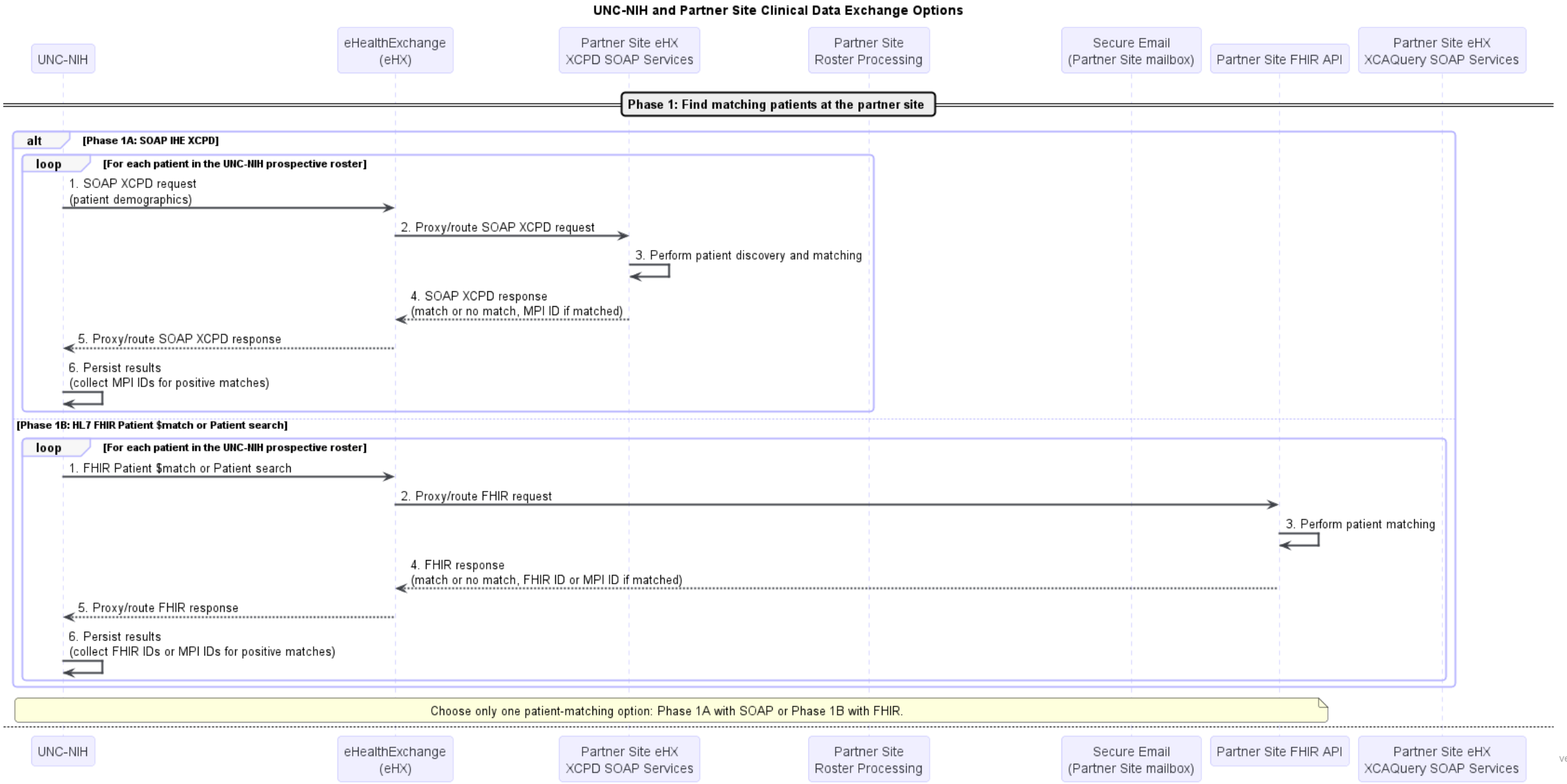
- When Task status = “completed” requestor begins to retrieve related ndjson payload

- eHealth Exchange retains the ndjson FHIR resource data for 2 hours from the completion of the Task processing.
  - Polling interval for data retrieval is expected to be 1 hour or less.



NIH *All of Us* – FHIR-SOAP hybrid options

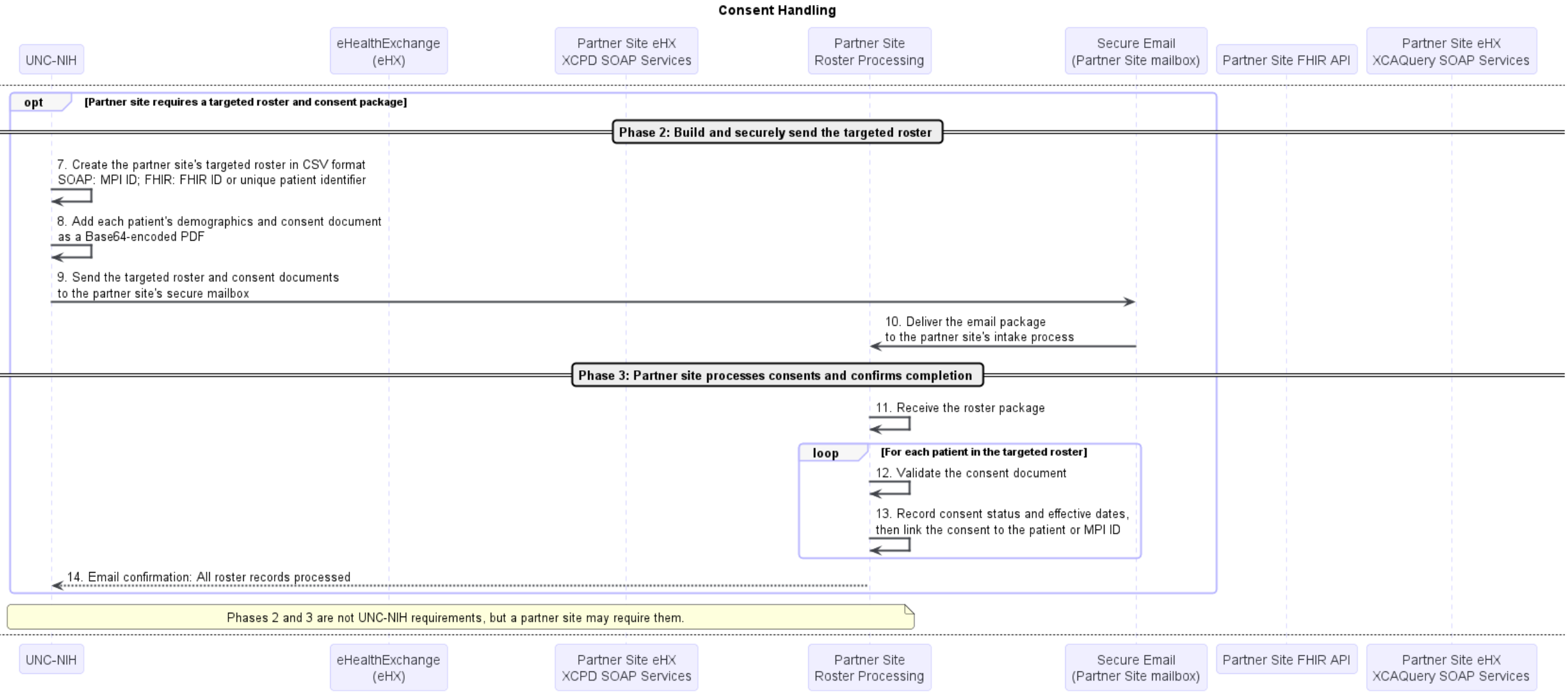
FHIR Use Cases



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NIH *All of Us* – FHIR-SOAP hybrid options

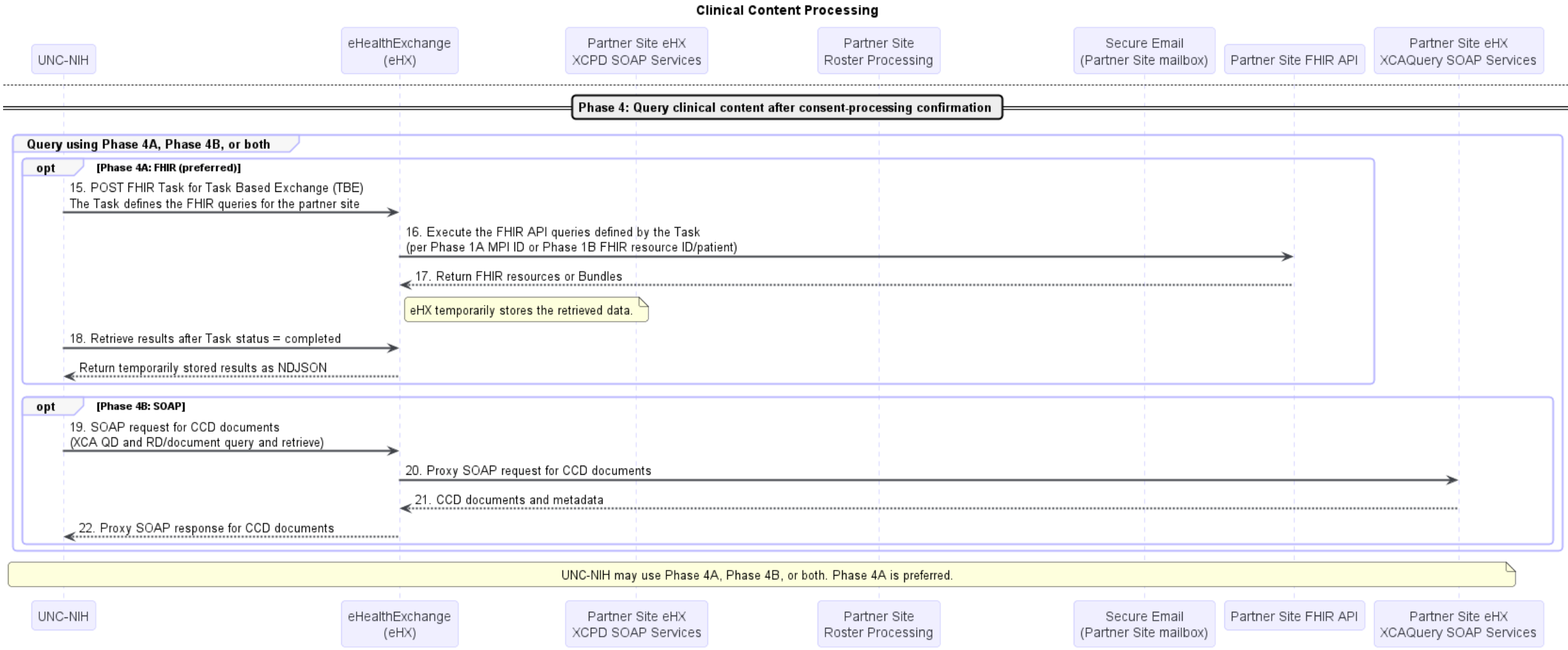
FHIR Use Cases



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NIH *All of Us* – FHIR-SOAP hybrid options

FHIR Use Cases



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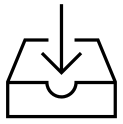
FHIR Use Cases

FDA BEST Adverse Event Reporting

Solution Redesign: The FDA has migrated the solution to their HIVE environment[1]



New security requirement !!!
All connections between FDA and the eHealth Exchange must be initiated by the FDA



The recently deployed CDex Task-based Approach solution, along with enhancements developed as part of Task Based Exchange service, aligns well with this new requirement



Three additional use cases now live

1. Expanded list of biologics being reported in addition to COVID-19, via unsolicited submission
2. Reporting of medication-based adverse events reported by patients via the MedWatch[2] system
   (FHIR Bundle contains Patient, Observation, Medication, MedicationAdministration, MedicationStatement, Practitioner, AdverseEvent)
3. Targeted "Pull" whereby FDA submits a request targeting a specific organization, versus the original geospatial fan-out

[1] High-performance Integrated Virtual Environment (HIVE)
[2] https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

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FHIR Services

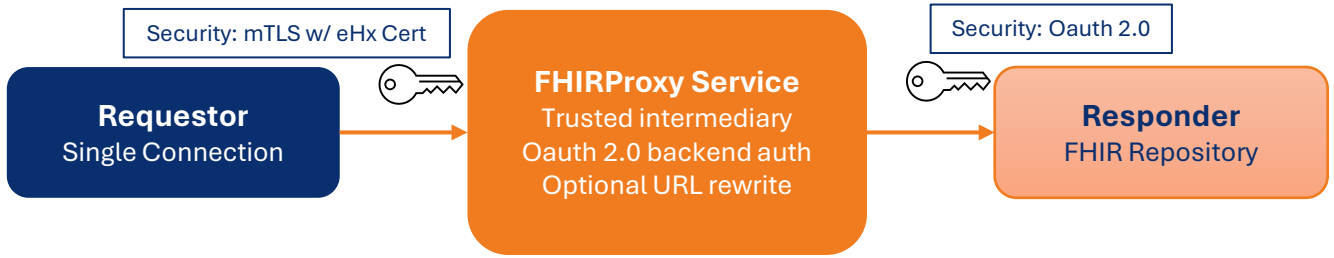
FHIRProxy

How it Works

- Foundational FHIR service
- Hub as Trusted Third Party/Intermediary
- One connection to many repos

Requirements and Security

- Routing & POU MUST be provided on request
- Hub handles backend security with target responder (typically OAuth 2.0)
- Optional URL rewriting is available



Future Enhancements

- Support for OAuth as an option to mTLS
- Support for UDAP hl7-b2b extension
- AppPath-based routing

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Task-Based Exchange

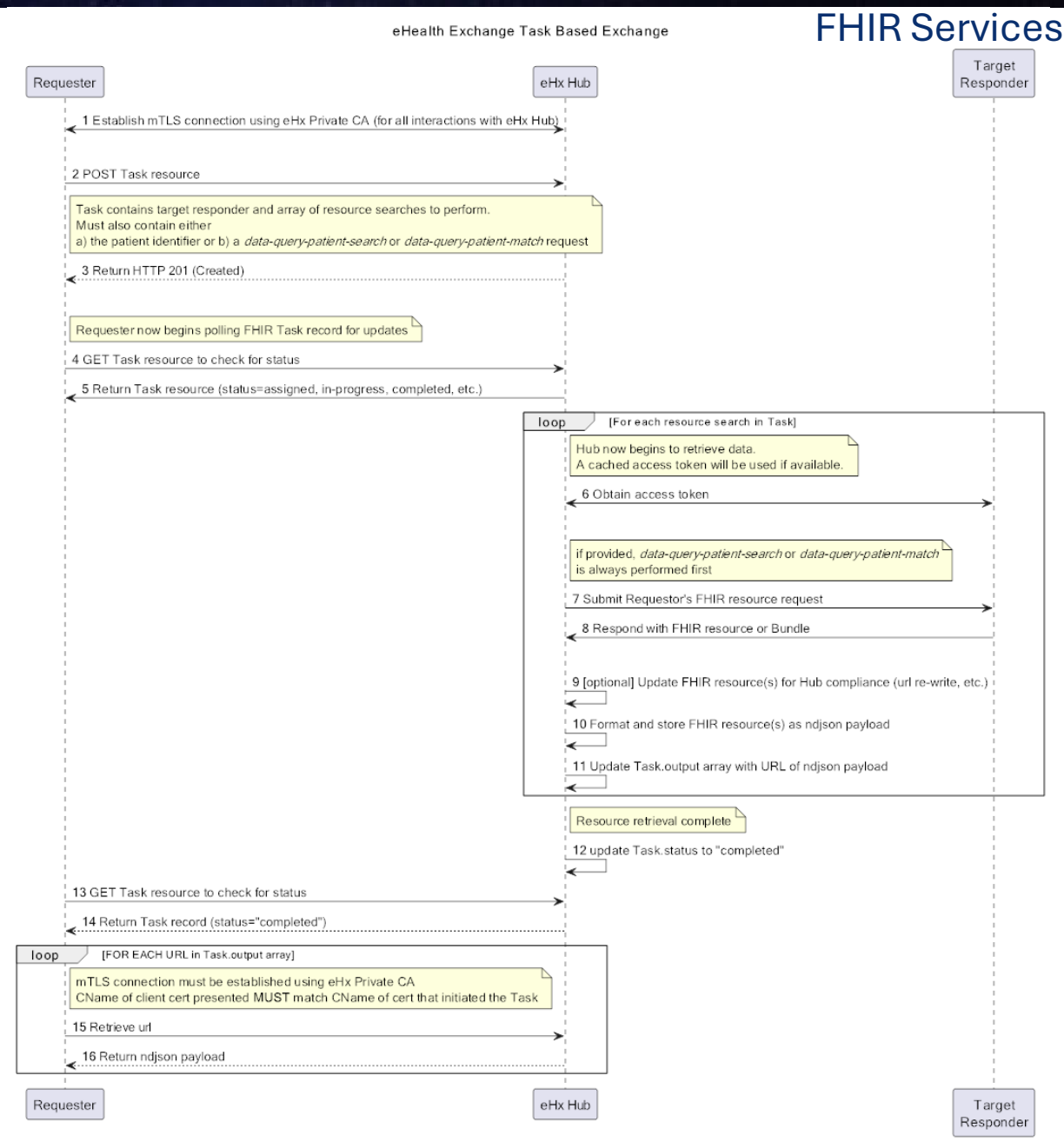
A Task-based service that enables retrieval of many FHIR query responses in a single async workflow

Process:

1. The requestor submits a FHIR Task resource to the CDex service that specifies details of the request
   - Identifies a responding organization
   - Identifies the FHIR resources to retrieve

2. The CDex service responds immediately (synchronously), and begins to process the request and retrieve data in an asynchronous manner

3. Requester can poll the Task, and when Task status is “completed” they can begin to retrieve related ndjson payload



FHIR Services

Task Based Exchange Features

Pagination

Dynamic Patient $match or Patient search

Patient search fan-out

(FHIR and HRR)

Bundle Profiles

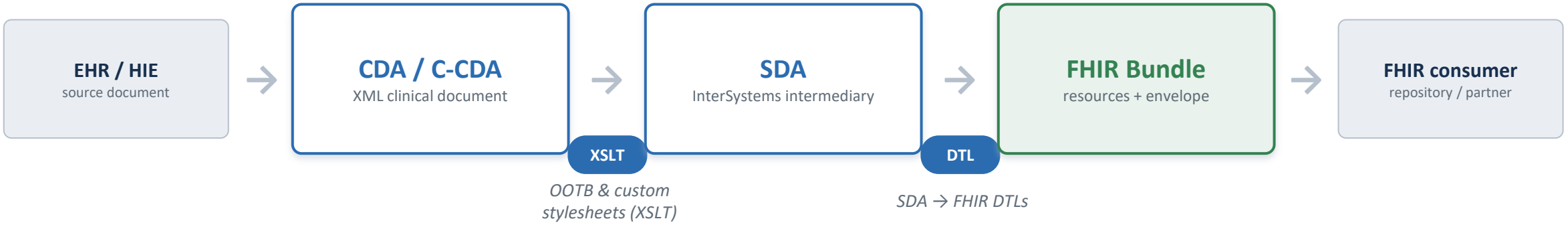
Dynamic Querystring Modifiers

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CDA → SDA → FHIR Transformation Service

FHIR Services

How the transformation service normalizes a clinical document into a FHIR Bundle within a real-world exchange workflow



What the resulting FHIR Bundle carries

1 Clinical Resources

Patient · Encounter · Composition

Condition, Observation, Medication, Procedure, Allergy — derived from the document's coded entries.

2 Source document

DocumentReference

The original CDA is preserved as a base64 attachment — audit, replay and narrative not captured discretely.

3 Diagnostics

OperationOutcome

Mapping errors and warnings travel inside the Bundle as issues — not lost in application logs.

4 Lineage

Provenance

Records the transformation activity, the service identity, and the source → target relationship.

Resources are linked by reference (e.g., Composition → Patient, Observation → Patient) — the Bundle is a connected graph, not just a list of objects.

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Transformation Assessment: Approach

FHIR Services

Objective

Transform CDA clinical documents into a FHIR Bundle of properly-linked, clinically accurate Resources — with little to no data loss.

Data Collection

Sampled synthetic data CDAs, non-prod document samples from the network, plus the standard TEFCA/QHIN certification test set (Synthea-based).

Documentation

Built fact-by-fact CDA→SDA→FHIR traceability matrices for every clinical element. Cross-referenced the transform engine's own error logs, CDA conformance validation, and the US Core spec. Every finding attributed to its responsible party.

Initial Effectiveness Rating

PARTIALLY EFFECTIVE

Clinical values were largely preserved across all documents tested, but 13 confirmed defects affecting data structure, linkage, or usability were found in every document type — remediation is needed before full production reliance.

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Findings & Recommended Actions

FHIR Services

OBJECTIVE
Little to no data loss during CDA → FHIR transformation

ACTUAL RESULT
Clinical values largely retained, but 14 structural/metadata defects confirmed across every document type

Gaps & Root Causes

HIGH	All Resolved — 4	Valid meds/immunizations marked "entered-in-error"• Allergy reactions & severity dropped • Patient references don't resolve • Lab panels not grouped into a DiagnosticReport
MEDIUM	4 Resolved / 2 In-Progress — 6	Allergies missing clinical status • Problems missing status & category •Same-day entries collide (only first survives) • Lab order time/status not pushed to results (in progress) •Timestamps forced to UTC, real offset lost (in progress) • Lab values missing UCUM units
LOW	3 Resolved / 1 In-Progress — 4	Care-plan items (goals/orders/instructions) dropped• Non-standard med codes (no data lost) •Minor CDA conformance gaps (Gazelle)• Social history answers lose their value (in progress)

Recommended Follow-Up Actions

- Total of 14 issues identified. 11 have been remediated, and 3 are in-progress (as of 10/22)
- Escalate the 4 High-priority items to eHealth Exchange/InterSystems — one is already vendor-acknowledged via a published advisory
- Remediate in priority order (High → Medium → Low); re-test after each round of fixes
- Continue to expand sampling before certifying production readiness

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FHIR Services

Demo

https://lab.ehealthexchange.org/developer/CDAlchemy

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