FHIR at Scale Taskforce (*FAST*)

Proposed Solutions Working Document: Scaling Architecture V2

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# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Author | Description of Change |
| 0.5 | 7/9/19 | Robert Dieterle | Initial draft |
| 0.9 | 10/19/19 | Brandon Neiswender | Update prior to TLC |
| 2.0 | 3/5/2020 | Robert Dieterle | Incorporation of all new content from TLC preparation and TLC curated feedback |
| 2.1 | 3/5/2020 | Robert Dieterle | Updated based on DVS TT review |
| 2.2 | 3/11/2020 | Patrick Murta | Partial Review of Document |
| 2.3 | 3/18/2020 | Robert Dieterle | Draft Final |
| 2.3.1 | 3/10/2021 | Alix Goss / Tiger Team | Revision work to incorporate workshop feedback and Tiger Team modifications |
| 2.3.2 | 3/17/2021 | Tiger Team | Incorporated Tiger Team modifications |
| 2.3.3 | 3/24/2021 | Tiger Team | Incorporated Tiger Team modifications |

Proposed Solution Status: Working on refinements

1. Determine scope of requirements
2. Explore standards for intermediary to intermediary exchanges
3. Clarify exchange services that must be supported
4. Detail the specific availability and performance requirements
5. Determine the best method for establishing requirements

# FAST Workshop Breakout Session Takeaways/Action Items (9/14/20)

## Intermediary Discussion

**Closing Key Takeaways**

* In order for intermediaries to be transparent, a guiding principle should be that they can format or add to messages, but not subtract (i.e., they need to preserve the context from the original message for end to end auditability)
* Intermediaries should be able to handle when the receiving endpoint service is down
* The group discussed the difference between intermediaries who perform business processing vs. those who strictly provide routing and determined there may be different requirements to consider for different use cases
* Some areas where FAST solutions may need adaptations for intermediaries:
  + Security – there’s no specification to chain OAuth requests together, which will be challenging when one or more intermediaries are participating in FHIR exchange
  + Testing & Certification – interoperability testing will be more complex than testing for IG or FHIR conformance; do we need midpoint registration and certification?
  + Identity – when dealing with HIEs/broadcast queries, patient matching becomes more complex

**Specific Intermediary Requirements**

* In order for intermediaries to be transparent, a guiding principle should be that they can format or add to messages, but not subtract (i.e., they need to preserve the context from the original message for end to end auditability)
* Provenance is required from auditing perspective, but optional to send to information receiver
* Provenance should always include whether data was provider vs. patient reported
* Intermediaries should be able to handle when the receiving endpoint service is down
* May need to address OAuth challenges in scenarios with intermediaries, where there’s no specification for chaining OAuth requests together
* The group discussed the difference between intermediaries who perform business processing vs. those who strictly provide routing and determined there may be different requirements to consider for different use cases
* Need to support continuity of operations events or disaster recovery
* Market should let intermediaries compete on which value-added services the offer, but there should be core requirements that they all must support (e.g., Provenance)
* System administrators/developers need to know what intermediaries are involved in a transaction
  + There are also policy and accountability reasons where the intermediaries would need to be known
* Mixed feedback regarding whether all intermediaries should be required to connect with each other, with following concerns:
  + Potential conflicts with TEFCA model
  + Information blocking, “islands” of specialized intermediaries saying you have to go through me to get to point B
* SLA Requirements
  + Availability
  + Consider defining guidelines/best practices that parties could reference in their contracts and stipulate compliance
  + Don’t necessarily need two separate sets of rules for intermediaries and endpoints

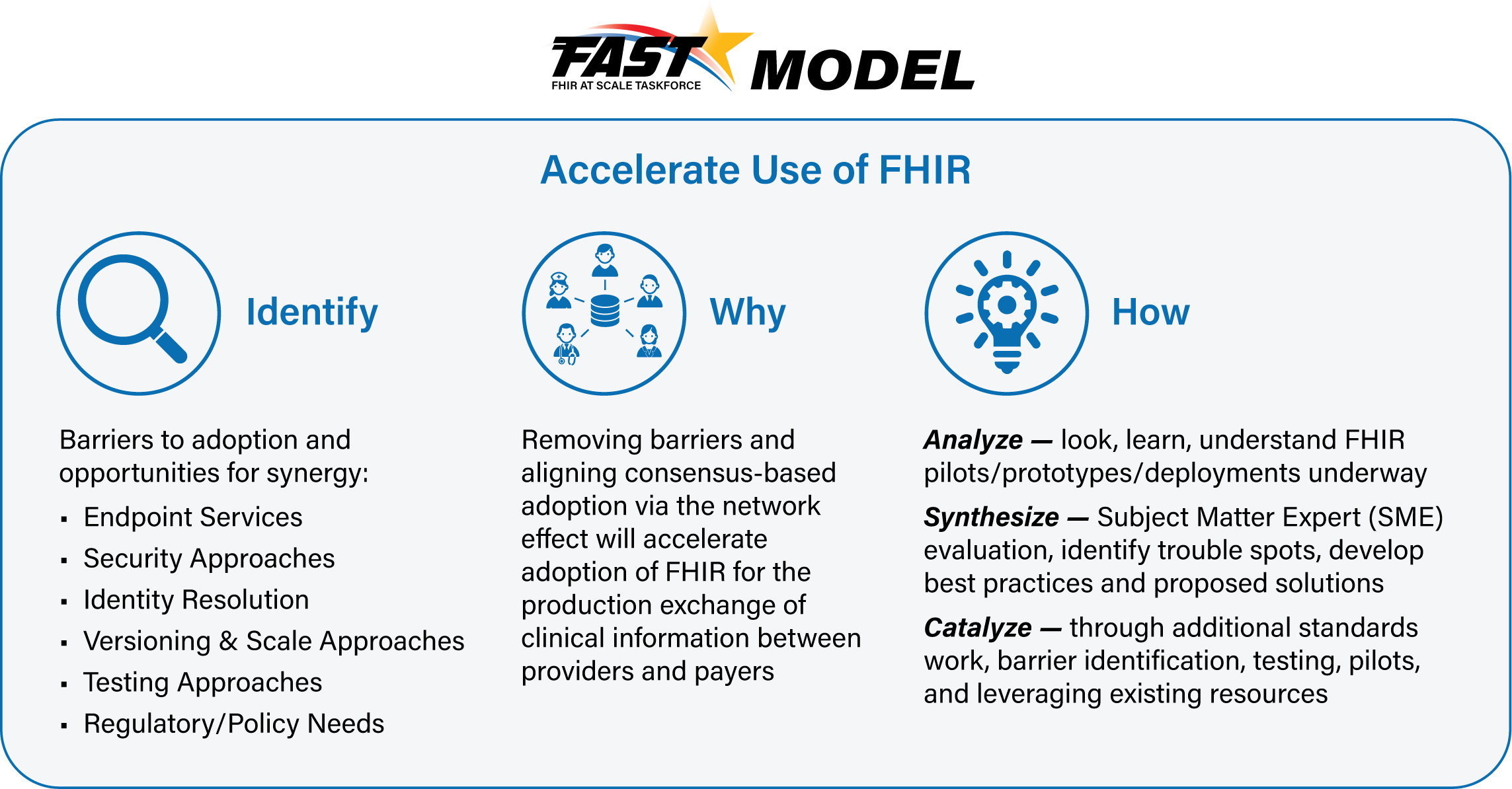
**Tiger Team Considerations**

* Security
  + There’s no specification to chain OAuth requests together, which will be challenging when one or more intermediaries are participating in FHIR exchange
* Testing & Certification
  + Interoperability testing will be more complex than testing for IG or FHIR conformance
  + Do we need midpoint registration and certification?
* Identity
  + When dealing with HIEs/broadcast queries, patient matching will become an issue
  + Do we also need to think about identity of actors?
    - With intermediaries, it becomes more difficult to track down the human actor when issues occur
    - Also a challenge for determining what has been disclosed to whom
* Exchange
  + How do you identify initial client and intermediaries, and what do you put in your metadata requirements

|  |
| --- |
| Reference Documentation |
| * *FAST*-Technical Barriers * *FAST*-Regulatory Barriers * *FAST*-UC-Endpoint\_Discovery-Core\_Capability-CC1 * *FAST*-UC-Authentication\_and\_Authorization-Core\_Capability-CC2 * *FAST*-UC-Version\_Identification-Core\_Capability-CC3 * *FAST*-UC-Patient\_and\_Provider\_Identity\_Management-Core\_Capability-CC4 * *FAST*-UC-Patient\_Information\_Request\_Plan\_to\_Provider * *FAST*-UC-Patient\_Information\_Request\_Provider\_to\_Plan * *FAST*-UC-Documentation\_Templates\_and\_Rules\_Processing * *FAST*-UC-Event\_Based\_Alerts * *FAST*-UC-Quality\_Reporting * *FAST*-UC-Push\_Patient\_Information * *FAST*-UC-Shared\_Care\_Planning * *FAST*-UC-Consults\_and\_Referrals * *FAST*-UC-Care\_Team\_Coordination * *FAST*-UC-Scheduling |

# Introduction & Background

The purpose of the FHIR at Scale Taskforce (*FAST*) is to augment and support recent HL7® Fast Healthcare Interoperability Resources (FHIR®) efforts focused on ecosystem issues that, if mitigated, can accelerate adoption. A number of regulatory and technical barriers, as well as required core capabilities, have been identified related to Directory, Versioning and Scale. This document will outline proposed solutions to address these issues and capabilities.



# Current State Overview

EXPERIENCE

1. Limited implementation of FHIR based solutions operating at scale to support anticipated healthcare needs
2. Limited practical experience in scaling FHIR transactions via intermediaries or point to point
3. Limited intermediary support for brokering FHIR interactions

REGULATORY

1. Inconsistent federal and state regulatory and policy environments related to real-time exchange of information
2. Current issues related to privacy (e.g. minimum necessary) create barriers to national adoption of FHIR at scale

EXISTING SOLUTIONS

1. Current FHIR solutions may not handle anticipated volume and predictable response time requirements
2. Multiple competing, potentially incompatible, solutions for scaling (HIEs, Clearinghouses, Trust Framework based exchanges, etc.)
3. Concern with multiple intermediaries and impact on performance, scaling, synchronous transactions

STANDARDS

1. Lack of experience using FHIR to handle synchronous exchanges and maintain connection state via intermediaries
2. Impact of proprietary interoperability models on access to data endpoints

Definitions:

Intermediary – any entity that participates in the exchange of a FHIR based transaction other than the ultimate requester and responder (e.g. a business associate, Clearinghouse, HIE)

Scalable – the ability to support national production level exchange of FHIR based RESTful transactions between all entities (e.g., patients, providers, organizations) that request, respond, or broker exchanges of clinical, administrative or research information

Performance – meeting roundtrip response expectations reasonably associated with the clinical and administrative activities they support (e.g., if a provider needs a laboratory result as part of their clinical workflow, any roundtrip delay exceeding 20 seconds would be considered not meeting response expectations)

Availability – depends on the specific transaction use case for clinical transactions with provider and/or patient waiting requirements. Any intermediary involved in real-time transactions must be available 24/7.

# Scaling Architecture (e.g. intermediaries) Considerations

1. Intermediaries [I] (along with other responder and requestor actors [R] where appropriate) must support the following FAST solutions
   1. Endpoint discovery (e.g. directory) [I]
   2. Determine endpoint services and version support [I/R]
   3. Version management [I/R]
   4. Authentication and authorization [I/R]
   5. Patient matching (is this a value-added service?)
   6. Security (e.g. same version of TLS) [I/R]
   7. Meta data for routing [I/R]
   8. Certification and Testing of compliance with FAST Standards [I/R]
2. Intermediaries must provide
   1. connectivity to other intermediaries
   2. SLAs consistent with real-time exchanges regardless of volume
   3. support for synchronous exchanges
   4. consistent error handling
   5. support for required terminologies (where appropriate) and must support elements
3. Intermediaries should
   1. Manage OAuth Scopes that may vary by endpoint
   2. Support for search parameters and optional elements that vary by endpoint
   3. Handle all commonly supported Operations (e.g. Subscription, Messaging, Operations, …)
   4. Handle consent and privacy
4. Intermediaries may provide one or more of the following services (not exhaustive)
   1. Patient matching
   2. Version translations
   3. Terminology translation

# Technical Barriers

1. **Multiple Interoperability Models:** Hybrid exchange models (e.g., spoke/hub, direct connections/point-to-point, and regionally interconnected spoke/hub) create challenges in adopting standards for scaling FHIR and implementing consistent approaches such as authentication, endpoint detection, standards for matching, and end-to-end performance.
2. **Lack of Predictability and Response Times:** Scaling real-time transactions requires infrastructure that may not be currently available through existing intermediaries. The lack of predictable end-to-end response time limits specific use cases where providers require a response prior to proceeding with diagnosis or treatment. Some intermediary models do not support end-to-end synchronous real-time applications. The industry will need to adopt synchronous FHIR front-end interfaces and migrate to near real-time backend solutions.
3. **Anticipating Increase in FHIR-Based Volume:** There are currently no models to predict the volume of FHIR-based transactions as FHIR is adopted broadly in the ecosystem. This may lead to unpredictable scaling and performance challenges. Adopting real-time (RESTful) solutions to solve real-time synchronous FHIR scalability is required by the industry. Payers and providers need to increase services (and related perception of reliability) to support significant increase in real-time transactions embedded in the clinical workflow.
4. **Data Blocking:** The industry is moving to a utilization model for access to patient data using FHIR APIs. As FHIR can make information readily available within an encounter clinical workflow and through multiple mobile, portable and wearable devices in real time, the volume of transactions will increase exponentially. If there is limited access to this information, or the cost per access/transaction is too high, it could constitute a new form of data blocking.

# Problems to be Solved

The following technical and regulatory barriers to Scaling Architectures identified by the *FAST* team were found to impede the adoption of FHIR at scale and will be the basis for *FAST*-proposed scaling architecture solutions:

1. **Multiple Current Interoperability Models:** Hybrid exchange models (e.g., spoke/hub, direct connections/point-to-point, and regionally interconnected spoke/hub) create challenges in adopting standards for scaling FHIR and implementing consistent approaches such as authentication, endpoint detection, standards for matching, and end-to-end performance.
2. **Lack of Predictability and Response Times:** Scaling real-time transactions requires infrastructure that may not be currently available through existing intermediaries. The lack of predictable end-to-end response time limits specific use cases where providers require a response prior to proceeding with diagnosis or treatment. Some intermediary models do not support end-to-end synchronous real-time applications. The industry will need to adopt synchronous FHIR front-end interfaces and migrate to near real-time backend solutions.
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4. **Data Blocking:** The industry is moving to a utilization model for access to patient data using FHIR APIs. As FHIR makes information readily available within an encounter clinical workflow and through multiple mobile, portable and wearable devices in real time, the volume of transactions will increase exponentially. If there is limited access to this information, or the cost per access/transaction is too high, this will constitute a new form of data blocking. The CMS NPRM is working to address both of these issues.

Problems that may be solved by intermediaries

1. **Record Location:** Lack of a comprehensive national patient record locator service limits the ability to discover all records for a given patient in a distributed service environment. There is no current process for universally discovering endpoints either in general or for a specific patient.
2. **Patient Matching:** Without consistent identifiers, Patient matching will rely on the quality of demographic data stored at the requestor / responder level. Often demographics are not consistent across organizations. There is a dependency on Patient Identity Tiger Team solution.
3. **Data Quality:** De-duplication and aggregation will be the responsibility of the receiver. Services that can map data elements from disparate organizations and serve them up in a single usable data set are imperative. Appropriate coding and data integrity will be the responsibility of the sender.
4. **Patient Privacy:** Consent decisions are captured at every requester / responder organization. Patients have no way to understand how their data flows through the new FHIR ecosystem.

# Recommended Future State & Intermediate Steps

**Future State**

1. Support a mixed model (point to point, gateways, and via intermediaries)
2. Established minimum availability and performance requirements for any scale architecture (including multiple intermediaries)
3. Requirement to support synchronous transactions (e.g. maintaining “state” across intermediaries)
4. Intermediaries (regardless of the number) need to support, transparently, all FHIR workflow operations (including subscription)
5. Intermediaries capable of handling volume, response time, and routing to all available end points
6. Consistent support of metadata for “routing” through multiple intermediaries

**Intermediate Goals**

1. Establish voluntary performance standards for intermediary support for FHIR exchanges
2. Define and test an appropriate intermediary – intermediary exchange solution
3. Test performance for intermediaries

**Additional Considerations from the TLC Feedback (Fall 2019/HL7 webinar)**

1. Add comments on impact of TEFCA and role as an intermediary (as an example of an intermediaries) (examples: carequality, HIE) try to craft short statement
2. Definition of Intermediary: One or more entities in the middle between the originator of the transaction and the ultimate destination. The intermediary is responsible for ensuring delivery of any request and any response. The initial intermediary always has a formal FHIR endpoint -- that may or may not be true of others in the chain. we consider HIEs to be one form of an intermediary -- other exist such as Clearinghouses and technical switches. We have no preconceived preferences for the type of intermediary. Some “intermediaries” can act as an endpoint, if they have access to the data (add back into definition)
3. Services of an Intermediary: We are assuming that the intermediary will provide services (e.g. translation, routing) and not just act as a point-point connection. The primary requirement is that there is a predictable round-trip message time to enable "real-time" transactions with a human waiting for the response. Intermediaries may provide value added services to deal with trust frameworks, on-boarding, authentication and authorization, translations, monitoring, integration with other information sources …. Consider creating a definition of intermediary in the solution document
4. Intent is to make performance standards an industry requirement, the question is the path and enforcement (add recommendations)
5. Clarify that we are not “planning a transition from one model to another, but rather setting requirements for current and future players to be part of the FHIR scaling ecosystem.
6. Do we need to add any specific comments regarding the applicability of the solution to public health?

**Deployment (placeholder for V3)**

1. Add section to this document for deployment considerations
2. Add comments on operational support, reliability, backup, rollover/failover, etc.
3. Solution must be deployable and supportable

# Proposed Scaling Architecture Solution Overview

Through use case development and barrier definition, the *FAST* team has determined that the following core capabilities related to Scaling Architecture need to be satisfied to accelerate FHIR adoption at scale:

|  |  |
| --- | --- |
| **Core Capability** | **Proposed Solution(s)** |
| 1. Scaling Architecture | * Ability to utilize intermediaries to reduce the complexity of connecting with a large number of endpoints and managing authentication and authorization with each * Intermediaries will have predictable performance required to meet real-time exchanges * Intermediaries may provide value added services to assist in patient matching, version translation, etc. |

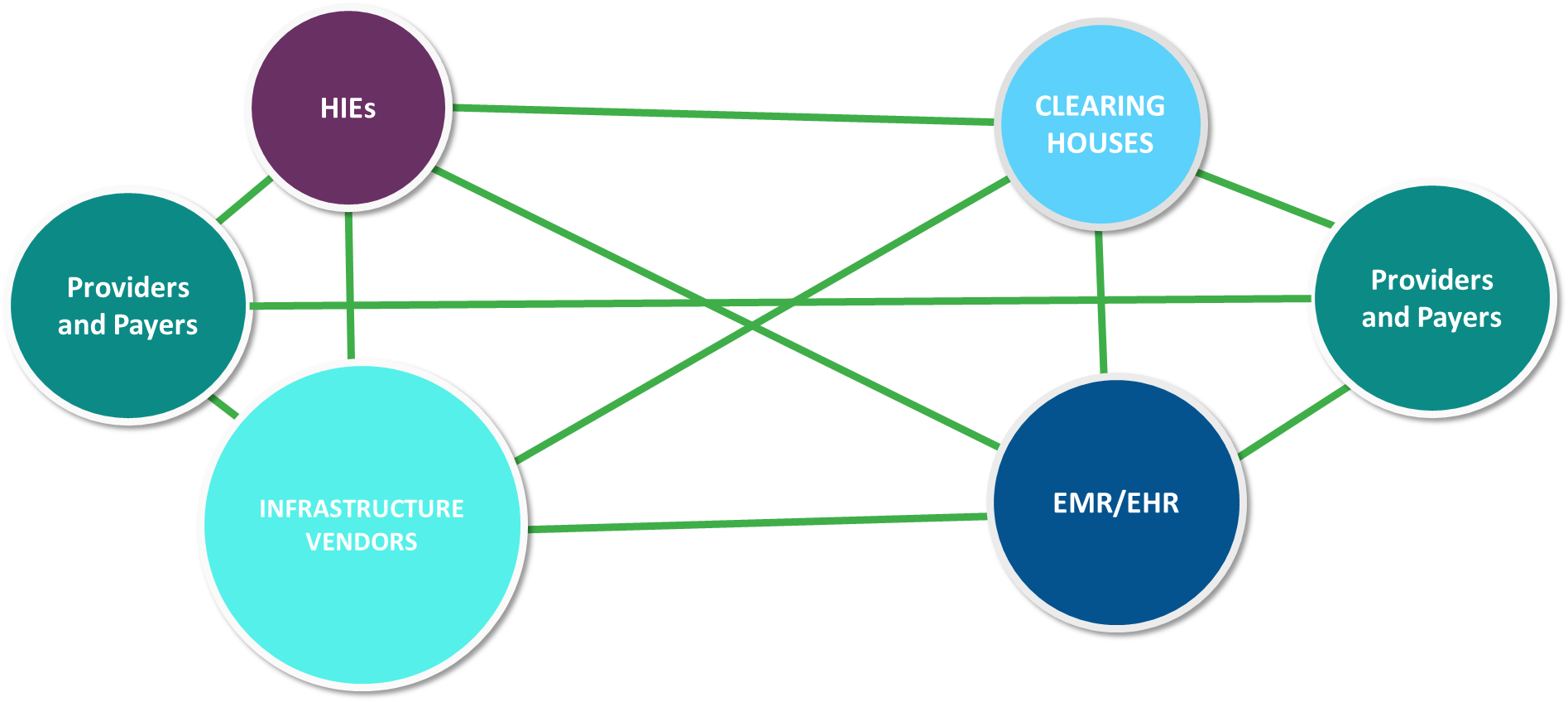
# Overview & Description

# The goal is for ubiquitous access to permitted endpoint regardless of the architecture (point-to-point), intermediary, multiple intermediaries). The performance reliability and availability characteristics should substantially the same as for point-to-point connections and in any case must be acceptable for real-time information exchange where there is a provider / patient waiting for the response before clinical workflow can continue. The intermediaries will justify there added cost by providing value-added services that minimize the overall cost associated with FHIR transactions. Such value-added services may include, endpoint resolution, patient matching, record locator, version translation, error handling. The basic services and the value-add services should allow the application user, system, and API endpoint to see the rest of the world as a consistent set of endpoints.

# Proposed Solution Overview

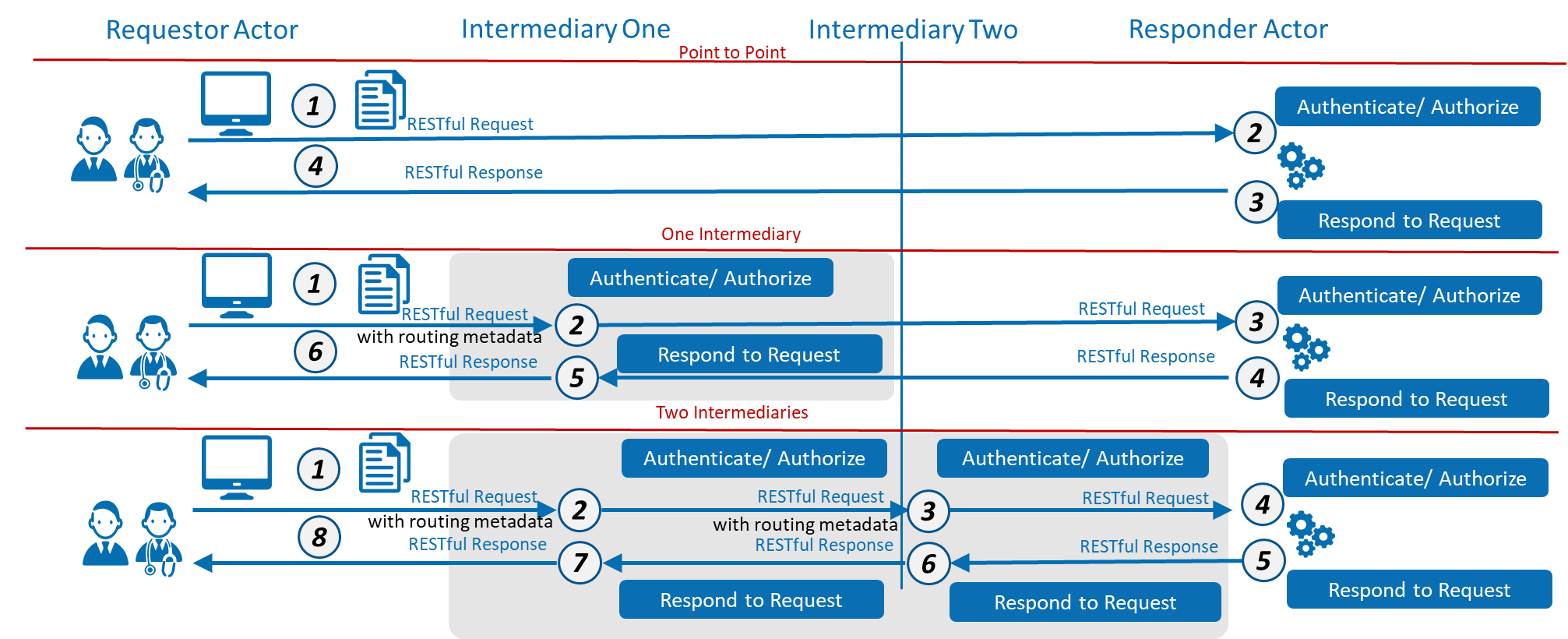
The *FAST* team has determined that the following core capabilities related to Scaling Architectures need to be satisfied as we propose a set of solutions that will accelerate FHIR adoption at scale:

**Mixed model environment with full connectivity(future state)**





Exchange model showing: 1) Point to Pont, 2) one intermediary, and 3) two intermediaries





The above diagram and interaction descriptions assume that the endpoint has already been determined.

**Point to Point**

|  |  |  |
| --- | --- | --- |
| **ID** | **Description** | **Notes** |
| 1 | Requester uses endpoint directory information to connect to the Responder endpoint and send request |  |
| 2 | Responder authenticates requestor |  |
| 3 | Responder process request and returns results |  |
| 4 | Requestor receives response from Responder |  |

**One Intermediary**

|  |  |  |
| --- | --- | --- |
| **ID** | **Description** | **Notes** |
| 1 | Requester uses endpoint directory information to connect to the Intermediary endpoint and send request including routing information |  |
| 2 | Intermediary, using routing information connects to Responder endpoint and sends request |  |
| 3 | Responder authenticates Requestor/Intermediary |  |
| 4 | Responder process request and returns results to Intermediary |  |
| 5 | Intermediary returns response to Requester |  |
| 6 | Requestor receives response from intermediary |  |

**Two Intermediaries**

|  |  |  |
| --- | --- | --- |
| **ID** | **Description** | **Notes** |
| 1 | Requester uses directory endpoint information to connect to the Intermediary endpoint and send request including routing information |  |
| 2 | Intermediary using endpoint directory information connects to the Intermediary endpoint supporting the Responder and forwards the request including routing information |  |
| 3 | Intermediary, using routing information connects to Responder endpoint and sends request Responder |  |
| 4 | Responder authenticates requestor/intermediary |  |
| 5 | Responder process request and returns results to intermediary |  |
| 6 | Responder Intermediary sends response to Requester Intermediary |  |
| 7 | Intermediary returns response to Requester |  |
| 8 | Requestor receives response from intermediary |  |

# In Scope

1. Interoperability models with, point-to- point, single and multiple intermediaries
2. Issues related to RESTful FHIR exchanges/messages and related technologies (like CDS Hooks) via intermediaries
3. Related authentication and authorization models (OAuth, OpenID, UDAP)
4. Planning for future volume increase
5. Establishing SLA and Performance requirements for intermediaries and endpoints
6. Establishing functionality of endpoints and the method of declaration

# Out of Scope

1. Identification, security, directory, versioning, metadata, certification or piloting
2. Ownership models
3. Trust frameworks
4. Legal agreements
5. Non-RESTful exchange methods (e.g. Direct)
6. Technical Architecture of the ultimate requestor, ultimate responder, and intermediary implementation

# Assumptions

1. Standards exist for intermediary – intermediary exchange
2. Standards exist for Point to Point exchange (including where the intermediary is one end)
3. RESTful FHIR exchanges include both FHIR payload and the RESTful interactions for exchange of the payload
4. Standards exist for complementary interactions such as CDS Hooks, SMART on FHIR, and bulk data exchange
5. Relevant standards for identification, security, directory, versioning, metadata, and certification are defined and supported by all participants
6. Service level agreements/statements are established and enforced

# Pre-Conditions

1. Endpoints must be available to support FHIR exchanges
2. Endpoints are compliant with established FHIR standards (and indicated conformance)
3. Endpoints (including intermediaries) have passed testing and certification

# Post Conditions

1. The FHIR transaction environment works at scale with no significant issues.
2. Use of intermediaries is transparent to the end-user

# Solution Component Analysis

The following new components or modifications to existing components are required to address current gaps and support the proposed solution:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ID** | **Component** | **New/ Existing** | **Proposed Build/Modifications** | **Owner** |
| *1* | *Standard for Intermediary to intermediary exchange* | *New* | *Defined by SDO* | *FAST with HL7* |
| **2** | Standard for intermediary performance (SLA) | New | Defined by FAST | FAST |
| **3** | Testing for conformance with exchange and SLAs | New | Defined by FAST, performed by industry testing and certification entity | FAST, Industry |
| **4** | FHIR enabled Intermediary | New/Existing | Build by interested industry parties | Industry |

# Key Impacts to Timeline & Cost

*<FAST team to identify the key components listed above that will have the most impact on timeline and cost. Include rough order of magnitude for level of effort and comment on any known blockers or dependencies.>*

|  |  |  |  |
| --- | --- | --- | --- |
| **ID** | **Component** | **Level of Effort** | **Comments** |
| 1 | *Standard for Intermediary to intermediary exchange* | *Medium* |  |
| 2 | Standard for intermediary performance (SLA) | Small |  |
| 3 | Testing for conformance with exchange and SLAs | Medium-Large |  |
| 4 | FHIR enabled Intermediary | Large-Jumbo |  |