



Zoom Meeting Interface and Basic Logistics



*image above is a publicly available tutorial image obtained from Zoom website

- **VIDEO:**
 - **Panelists/Presenters/Facilitators** - Please enable your video using **bottom left video button with camera icon.**
 - **Attendees** - If you did not receive an invitation to be a panelist, you are in attendee only mode and **will not have access to enable video**
- **AUDIO:**
 - **Panelists/Presenters/Facilitators** - Adjust your audio settings as needed (choose computer audio, call in, mute, etc.) using **audio button bottom left, microphone icon. Please remain muted unless speaking.**
 - **Attendees** - If you did not receive an invitation to be a panelist, you are in attendee only mode and **will not be able to enable audio**
- **CHAT:** The chat function is open to **ALL** participants (bottom, middle right, highlighted in orange in this image). Those in Attendee only mode are encouraged to provide feedback and questions via chat throughout the discussion. Chat will be monitored by the *FAST* team and key themes will be pulled into the discussion.
- **TECHNICAL DIFFICULTIES:** Having trouble hearing the presenters or seeing the shared screen? Put your issue in chat and the Meeting Host will help you.



Regulations / Policy
ONC *FAST* Workshop
September 14, 2020



Session Facilitator



ROBERT DIETERLE

CEO

EnableCare

FAST Coordinating Committee Member, and
the Directory, Versions & Scale Tiger Team
Co-Lead





FAST Taskforce Antitrust Notice

- The ONC FHIR At Scale Taskforce (*FAST*) (Hereinafter “Taskforce”) is committed to full compliance with existing federal and state antitrust laws.
- All members involved in the Taskforce effort, including its advisory groups, will comply with all applicable antitrust laws during the course of their activities. During Taskforce meetings and other associated activities, including all informal or social discussions, each member shall refrain from discussing or exchanging competitively sensitive information with any other member. Such information includes, but may not be limited to:
 - Price, premiums, or reimbursement charged or paid for products or services
 - Allocation of customers, enrollees, sales territories, sales of any products or contracts with providers
 - Any other competitively sensitive information that is proprietary to a member company
- If you have any specific questions or concerns, seek guidance from your own legal counsel.
- Members should not bring confidential information or intellectual property (hereinafter “Intellectual Property”) owned by their respective member companies into Taskforce meetings. To the extent such Intellectual Property is shared with the Taskforce that shall not be construed as a waiver of member company’s rights to, or ownership in, the Intellectual Property.



Agenda

- **Welcome & Introductions**
- **Session Goals**
- **Overview**
- **Discussion Topics**
 - Interactive Panel
 - Participant Q&A
- **Wrap Up/ Key Takeaways**





FAST Panelists

FAST Panelists	
<i>Carmen Smiley</i>	HHS ONC, <i>FAST Identity Tiger Team Member</i>
<i>Rose Marie Nsahlai</i>	HHS ONC, <i>FAST Security Tiger Team Lead</i>
<i>Durwin Day</i>	HCSC, <i>FAST Exchange Tiger Team Lead and FAST Testing & Certification Tiger Team Member</i>





Roles & Logistics: Panelist vs. Attendee Modes

FAST Key Panelists

- Invited to join, actively engage and support the conversation
- Encouraged to communicate verbally (mics on) and to turn on video
- Monitor the attendee chat box for feedback, address questions via chat or promote questions that are significant to the discussion topic or warrant a verbal debate /reaction with the panel group

Industry Expert Reaction Panelist (in panelist mode)

- Invited to join the live interactive discussion with the *FAST* team
- Encouraged to communicate verbally (mics on) and to turn on video
- Provide their industry expertise and feedback
- Discuss or debate the topic with the facilitator and the panelist group
- Raise questions or concerns
- Feedback will inform *FAST* next steps

General Audience and *FAST* Technical Learning Community Members (in attendee mode)

- Encouraged to engage and contribute feedback and questions via the chat box
- Do not have the ability to contribute verbally to the conversation (mics off)
- No ability to be on video



Session Description

Along with the technical barriers to FHIR based solution scalability, the *FAST* Initiative identified a series of regulatory requirements that may present challenges or have implications for FHIR adoption.

We will discuss opportunities to mitigate challenges under existing regulations that may impact the utilization of FHIR standards. The participants in this track will review the implications of recent regulations that have mandated the adoption of FHIR. Finally, we will focus on the opportunity to explore policy concepts and considerations that could facilitate the use of the FHIR based solutions at scale.

Join us for a session where *FAST* members and an expert reaction panel will discuss the policy and regulatory aspects that could support the *FAST* ecosystem infrastructure to scale and accelerate the FHIR standard adoption.



Regulations / Policy

Session Goals

1. Consider the current regulatory landscape and how it presents opportunities or challenges related to each of the proposed solutions
2. Explore policy concepts and considerations that would allow for transparent and predictable update cycles in response to industry need.
3. Discuss ways to mitigate impact of understanding and implementing regulatory requirements on for smaller organizations.

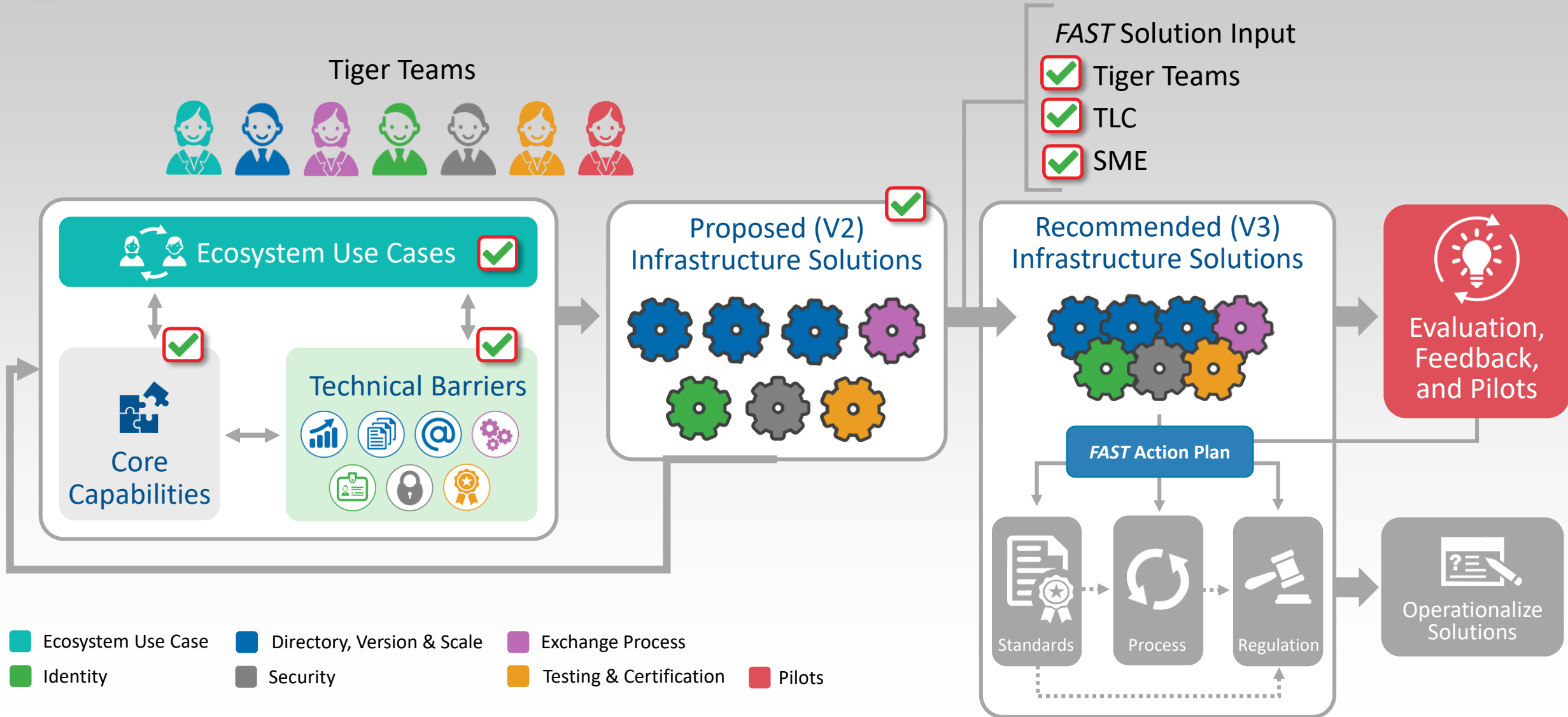
Overview





FAST Solution Process and Where Are We Now

Tiger Teams



FAST Solution Input

- ✓ Tiger Teams
- ✓ TLC
- ✓ SME

Ecosystem Use Cases ✓

Proposed (V2) Infrastructure Solutions ✓

Recommended (V3) Infrastructure Solutions

Evaluation, Feedback, and Pilots

FAST Action Plan

Standards

Process

Regulation

Operationalize Solutions

- Ecosystem Use Case
- Identity
- Directory, Version & Scale
- Security
- Exchange Process
- Testing & Certification
- Pilots



FAST Proposed Solutions

■ Directory, Version & Scale (3) ■ Identity (4) ■ Exchange Process (1) ■ Testing & Certification (1) ■ Security (4)

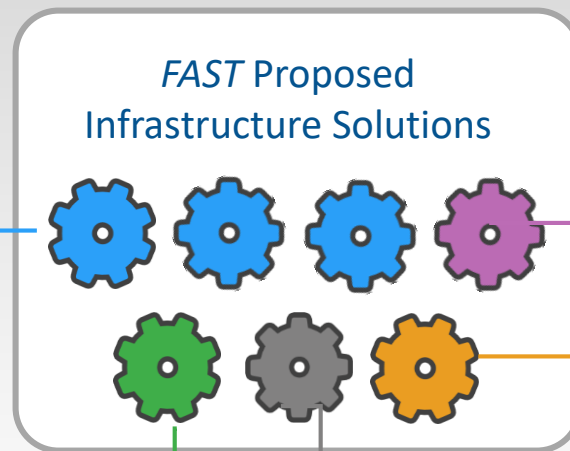
⚙️ **A US Wide Solution for FHIR Endpoint Discovery (Version 2)**

⚙️ **A US Wide Methodology for Supporting Multiple Production Versions of FHIR (Version 2)**

⚙️ **US Wide Scaling Requirements for FHIR RESTful Exchange Intermediaries (Version 2)**

⚙️ **Standards Based Approaches for Individual Identity Management (Version 2)**

- Mediated Patient Matching
- Collaborative Patient Matching
- Networked Identity Management
- Distributed Identity Management



⚙️ **An HL7 FHIR Standard Based Solution for Intermediary-to-Intermediary Exchange and Reliable Routing with Metadata (Version 3 Draft)**

- Reliable Routing with Metadata Across Intermediaries

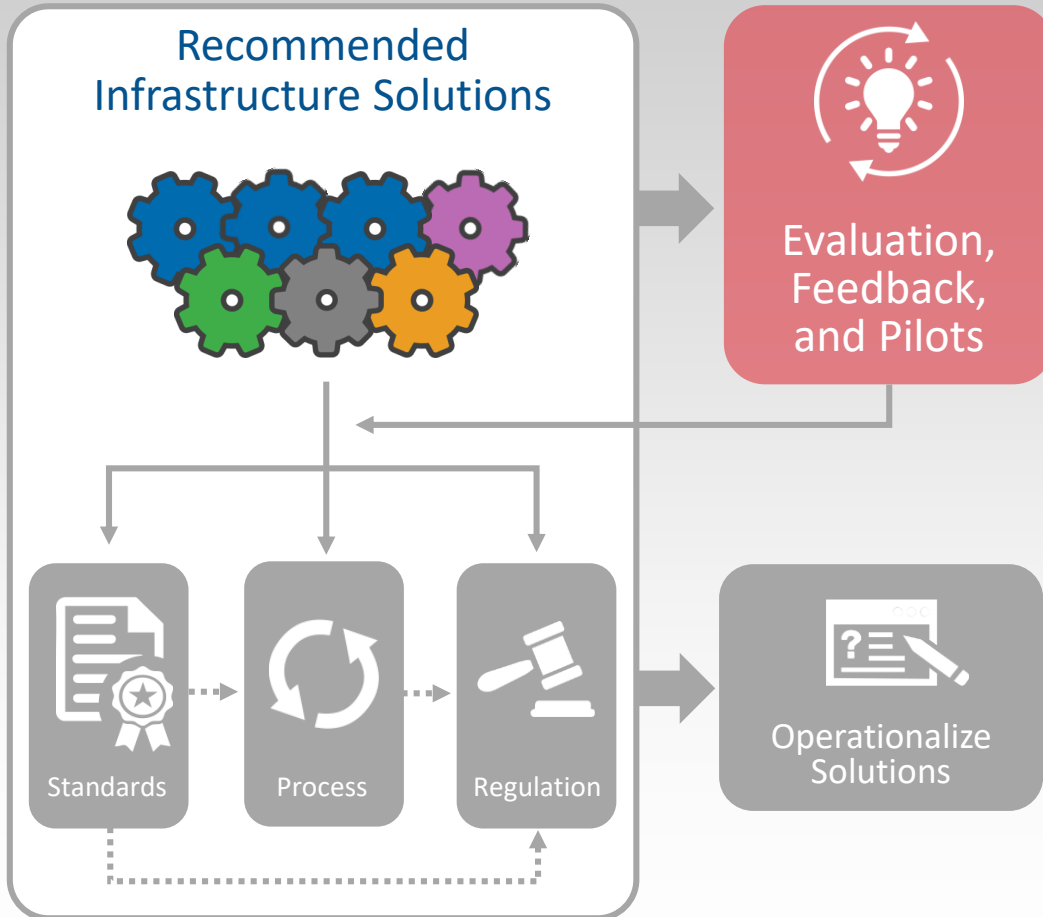
⚙️ **A Scalable FHIR Testing & Certification Platform (Version 2)**

⚙️ **US Wide Model(s) for Scalable Security Solutions (Version 3 Draft)**

- UDAP Trusted Dynamic Client Registration
- UDAP Tiered OAuth for User Authentication
- UDAP JWT-Based Client Authentication
- UDAP JWT-Based Authorization Assertions



Assessment Process

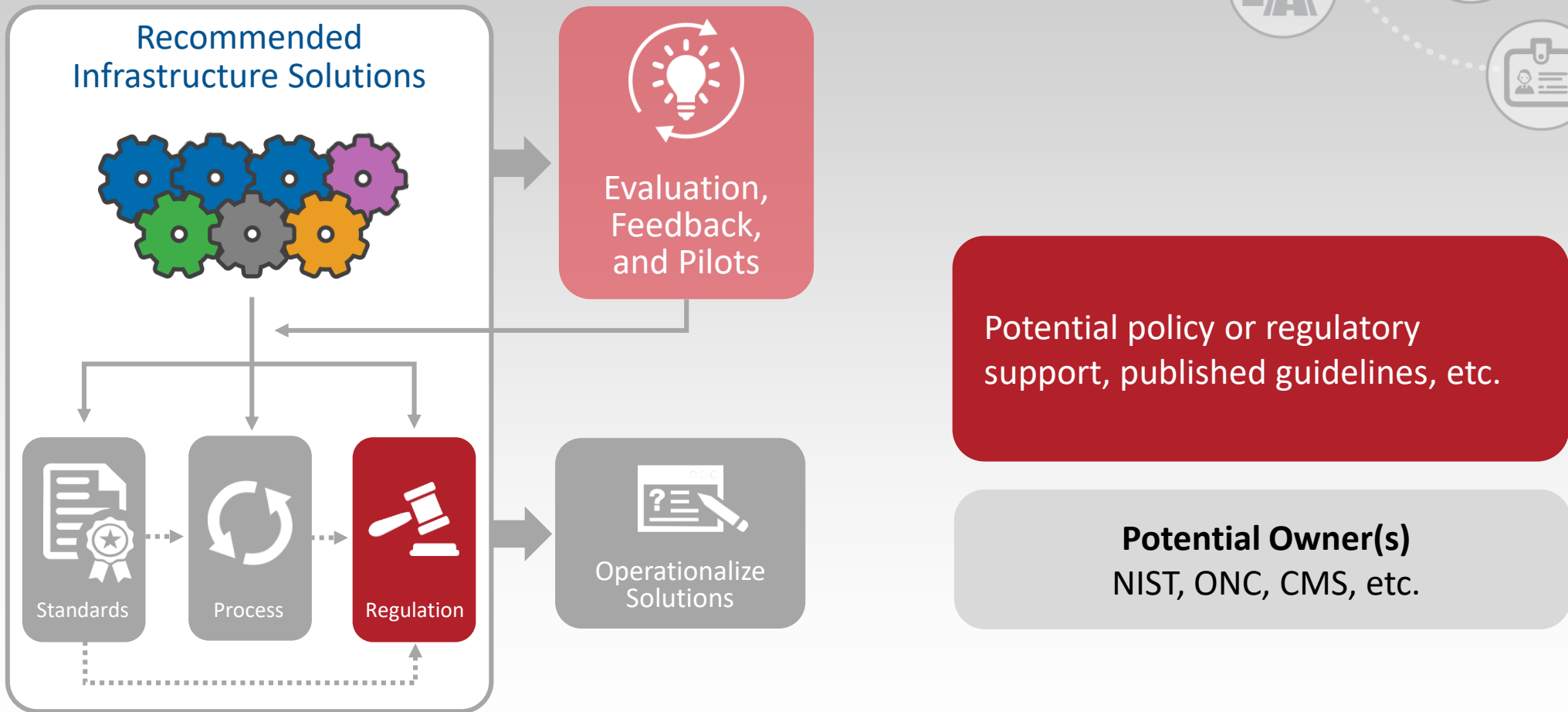


How do we make the results of *FAST* persistent?

- Creating standards (examples)
 - Updating FHIR core specification
 - Creating FHIR Implementation Guide(s)
 - Updating specific artifacts and tools (e.g. FHIR version management/conversion)
- Supporting testing and piloting (e.g. making certain the solutions are implementable)
- Supporting regulatory process
- Establish persistent process
 - Testing & Certification
 - Endpoint Directory(ies)
 - Trust Frameworks



Assessment Process





Potential Regulatory Barriers – Initial List

HIPAA Minimum Necessary

Regulatory Mandate for a Single Named Standard

HIPAA Transactions Requiring X12

Use of NPPES as the Repository for Endpoints

Patient Identifier

Data Blocking



FEDERAL/STATE REGULATORY BODIES



REGULATORY BARRIERS



Requestor IT Vendor



Restricted Data Flow



IT Vendor Responder

TODAY



FEDERAL/STATE REGULATORY BODIES



REMOVAL OF REGULATORY BARRIERS



Requestor IT Vendor



More Efficient Data Flow



IT Vendor Responder

FUTURE



FAST Solution Areas	Regulation	Standard(s)	Ongoing Process
Directory	<ul style="list-style-type: none"> • CMS authority to operate • Incentives for participation 	<ul style="list-style-type: none"> • HL7: Update VhDir IG for US Realm • HL7: Endpoint query IG • HL7: IG for attestation and validation 	<ul style="list-style-type: none"> • Provide Directory services
Version	None planned	<ul style="list-style-type: none"> • HL7: Standards for version control • HL7: Conversion process/tool 	<ul style="list-style-type: none"> • Provide tools with each version release
Scaling Architecture	<ul style="list-style-type: none"> • Consider alignment with TEFCAs and HIPAA (as they start to cover FHIR exchanges) 	<ul style="list-style-type: none"> • HL7: Intermediary / Endpoint performance criteria • TBD: SLA for RESTful FHIR exchanges • Incorporate declaration of compliance into directory metadata 	<ul style="list-style-type: none"> • Testing and certification of compliance with guidance and SLAs
Security	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 	<ul style="list-style-type: none"> • HL7: Publish standard for security as part of FHIR core specification • NIST: Add to their security standards • TBD : Trust framework (standard) 	<ul style="list-style-type: none"> • Testing and certification of compliance with guidance and SLAs
Identity	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 	<ul style="list-style-type: none"> • HL7: Publish standard for identification as part FHIR specification for patient matching operation 	<ul style="list-style-type: none"> • Testing and certification of compliance with guidance and SLAs
Exchange	<ul style="list-style-type: none"> • Non planned but may need to be aligned with future versions(s) of HIPAA 	<ul style="list-style-type: none"> • HL7: Publish as brief FHIR IG for FHIR R4 	<ul style="list-style-type: none"> • Testing and certification of compliance with guidance and SLAs
Testing and Certification	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 	<ul style="list-style-type: none"> • HL7: Endpoint test standards 	<ul style="list-style-type: none"> • ONC and CMS required certification process

Discussion





Potential Regulatory Barriers – Initial List

?

Are these all still relevant in light of recent **ONC and CMS** final rules?

HIPAA Minimum Necessary

Regulatory Mandate for a Single Named Standard

HIPAA Transactions Requiring X12

Use of NPPES as the Repository for Endpoints

Patient Identifier

Data Blocking

?

How do we deal with existing regulations that negatively impact scaling FHIR adoption?



FEDERAL/STATE REGULATORY BODIES



REGULATORY BARRIERS



Requestor IT Vendor



Restricted Data Flow



IT Vendor Responder

TODAY



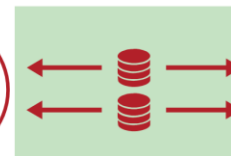
FEDERAL/STATE REGULATORY BODIES



REMOVAL OF REGULATORY BARRIERS



Requestor IT Vendor





More Efficient Data Flow





IT Vendor Responder

FUTURE

FAST Solution Areas	Regulation	Session Goal: Consider the current regulatory landscape and how it presents opportunities or challenges related to each of the proposed solutions	
Directory	<ul style="list-style-type: none"> • CMS authority to operate • Incentives for participation 	<div style="text-align: center; margin-bottom: 10px;">  </div> <ol style="list-style-type: none"> 1) Discuss the value of regulatory support for each of the <i>FAST</i> solutions. 2) What are the issues related to establishing these regulations? 3) What is the process and timing to advance the proposed regulatory solutions? 	
Version	None planned		
Scaling Architecture	<ul style="list-style-type: none"> • Consider alignment with TEFCA and HIPAA (as they start to cover FHIR exchanges) 		
Security	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 		
Identity	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 		
Exchange	<ul style="list-style-type: none"> • Non planned but may need to be aligned with future versions(s) of HIPAA 	<ul style="list-style-type: none"> • HL7: Publish as brief FHIR IG for FHIR R4 	<ul style="list-style-type: none"> • Testing and certification of compliance with guidance and SLAs
Testing and Certification	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 	<ul style="list-style-type: none"> • HL7: Endpoint test standards 	<ul style="list-style-type: none"> • ONC and CMS required certification process

FAST Solution Areas	Regulation	Session Goal: Consider the current regulatory landscape and how it presents opportunities or challenges related to each of the proposed solutions			
Directory	<ul style="list-style-type: none"> • CMS authority to operate • Incentives for participation 	<div style="text-align: center;">  <p>Which specific agencies (HHS, CMS, ONC, NIST, ...) should be advancing each or all of the potential regulatory support for FAST solutions?</p> </div>			
Version	None planned				
Scaling Architecture	<ul style="list-style-type: none"> • Consider alignment with TEFCA and HIPAA (as they start to cover FHIR exchanges) 				
Security	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 				
Identity	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 			<ul style="list-style-type: none"> • TBD : Trust framework (standard) • HL7: Publish standard for identification as part FHIR specification for patient matching operation 	<ul style="list-style-type: none"> • Testing and certification of compliance with guidance and SLAs
Exchange	<ul style="list-style-type: none"> • Non planned but may need to be aligned with future versions(s) of HIPAA 			<ul style="list-style-type: none"> • HL7: Publish as brief FHIR IG for FHIR R4 	<ul style="list-style-type: none"> • Testing and certification of compliance with guidance and SLAs
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FAST Solution Areas	Regulation	Session Goal: Explore policy concepts and considerations that would allow for transparent and predictable update cycles in response to industry need.
Directory	<ul style="list-style-type: none"> • CMS authority to operate • Incentives for participation 	<div data-bbox="1821 239 1974 392" style="text-align: center;">  </div> <p data-bbox="1363 406 2433 692" style="text-align: center;">How do we establish regulations related to <i>FAST</i> as minimal requirements (e.g. floor only and not floor and ceiling)?</p> <ul data-bbox="1375 785 2458 1213" style="list-style-type: none"> • How do we allow for trading partner adoption of enhancements without creating inappropriate pressure? • How do we progressively raise the minimum requirements over time (where appropriate)?
Version	None planned	
Scaling Architecture	<ul style="list-style-type: none"> • Consider alignment with TEFCA and HIPAA (as they start to cover FHIR exchanges) 	
Security	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 	
Identity	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 	
Exchange	<ul style="list-style-type: none"> • Non planned but may need to be aligned with future versions(s) of HIPAA 	
Testing and Certification	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 	

FAST Solution Areas	Regulation	Session Goal: Discuss ways to mitigate impact of understanding and implementing regulatory requirements for smaller organizations.			
Directory	<ul style="list-style-type: none"> • CMS authority to operate • Incentives for participation 	<div style="text-align: center; margin-bottom: 20px;">  </div> <ol style="list-style-type: none"> 1) Which of the potential regulations will have a significant impact on smaller organizations? <ul style="list-style-type: none"> • How? / Why? 2) How can we mitigate the impact of these regulations on smaller organizations? 			
Version	None planned				
Scaling Architecture	<ul style="list-style-type: none"> • Consider alignment with TEFCA and HIPAA (as they start to cover FHIR exchanges) 				
Security	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 				
Identity	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 			<ul style="list-style-type: none"> • HL7: Publish standard for identification as part of FHIR specification for patient matching operation 	<ul style="list-style-type: none"> • Testing and certification of compliance with guidance and SLAs
Exchange	<ul style="list-style-type: none"> • Non planned but may need to be aligned with future versions(s) of HIPAA 			<ul style="list-style-type: none"> • HL7: Publish as brief FHIR IG for FHIR R4 	<ul style="list-style-type: none"> • Testing and certification of compliance with guidance and SLAs
Testing and Certification	<ul style="list-style-type: none"> • Pursue as ONC/CMS certification requirements? 			<ul style="list-style-type: none"> • HL7: Endpoint test standards 	<ul style="list-style-type: none"> • ONC and CMS required certification process

Wrap Up





Breakout Sessions Schedule

2:30pm – 3:00pm: Afternoon Break

3:00pm – 4:00pm: **Afternoon Breakouts Part 2 - FAST Pathways to Implementation** (limited attendance, concurrent)

Room #1:

Timing Considerations / Interim Steps & Solutions

Session Goals:

1. Capture feedback on interim plans for endpoint directories.
2. Explore options for interim security solutions above and beyond what already exists – what do we need for 2021?
3. Capture any concerns regarding recommended metadata approach.
4. Discuss implementation planning and timelines to prepare for Testing & Certification (above and beyond HL7 tooling, and what's available in the industry to use voluntarily).

Room #2:

Pilots

Session Goals:

1. Explain and reiterate what we are seeking to pilot from a *FAST* perspective (test *FAST* core capabilities with Da Vinci use cases initially provided as the workflow).
2. Discuss if the model of using Da Vinci use cases makes sense.
3. Explore interest for potential future pilots' partners.

Room #3:

Intermediaries

Session Goals:

1. Identify intermediary requirements for RESTful FHIR exchanges.
2. Identify intermediary- intermediary exchange requirements.
3. Define service level required for intermediaries to meet (1) and (2).



FAST Workshop – Full Day Agenda and Resources

- View the [FAST Workshop Summary and Detailed Agenda](#)
 - Morning and Closing Plenary
 - Breakout Room Sessions Schedule
 - Handouts and Resources
- Explore these *FAST* resources
 - New to *FAST*? Breakout sessions target interactive discussion and references the *FAST* work to date. Please consider exploring any of the following *FAST* artifacts before attending these breakout sessions:
 - [The FAST 2020 Mid-Year Report](#)
 - [The FAST 2019 End of Year Report](#)
 - [SME Panel Session Pages](#)

CONTINUE THE CONVERSATION!

Join the Technical Learning Community to stay up to date – receive updates about FAST presentations & events, provide additional input and follow our progress.

[JOIN THE LINKEDIN GROUP](#)

&

[SIGN UP FOR THE TLC](#)

All content is available on the [FAST Project Page](#) or <https://tinyurl.com/ONC-FAST>



Thank You

Connect with *FAST* on [LinkedIn](#) to stay informed

For more information on the *FAST* Initiative,
visit the *FAST* [Project Page](#) or <https://tinyurl.com/ONC-FAST>

Have any further questions/suggestions?

Please contact Stephen Konya at Stephen.Konya@hhs.gov
& Diana Ciricean at Diana.Ciricean@hhs.gov

