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FHIR®-up your EHRs and Health Apps:

Leveraging FHIR® for ONCs Certification Program

October 20th, 2020

CitiusTech

Speakers

Dr. Viet Nguyen

HL7 Board Member, Technical Director of the Da Vinci Project & Founder at Stratametrics

- Dr. Viet Nguyen is an internist, pediatrician, clinical informaticist and consultant to government and commercial organizations in developing interoperable workflows and technologies. He has over 15 years of experience in Health IT focused on interoperability standards and product development
- Dr. Nguyen is a nationally recognized FHIR educator, an HL7 and FHIR Foundation Board Member, and Technical Director for the HL7 Da Vinci Project
- He was formerly the CMIO for Lockheed-Martin and Leidos Corporation
- He is a passionate health informatics evangelist connecting the layers of the Health IT Stack from clinicians to business leaders to developers

Swanand Prabhutendolkar

Sr. Vice President & Proficiency Business Lead at CitiusTech

- Leads CitiusTech's Data Management proficiency. Had also played role of Senior Architect for development of CitiusTech BI-Clinical product
- Strong experience in regulatory reporting requirements such as MU, and healthcare standards and frameworks including HL7
- 20+ years of experience in Information Technology working with companies such as Polaris and 3i Infotech
- Started career with EPIC Corporation in late 1990s on EPICare product
- Holds Masters Degree in Information Technology from IIT Mumbai

Webinar Objective

Key Takeaways

- Understand the **importance of the 21st Century Cures Act and its implementation by CMS and ONC** through their final rules
- Details of the **ONC 2015 Cures Certification, timelines and impacts** on Health IT vendors
- **Value of FHIR** beyond the ONC Certification
- **Technology enablers and accelerators** to drive interoperability / FHIR compliance

Webinar Agenda

1. **Journey Of FHIR & Growing Importance**
2. 21st Century Cures Act & Final Rules Overview
3. Major Changes For Health IT Certifications
4. Technology Enablers For Health IT
5. Discussion/ Q&A

CitiusTech PoV: FHIR Overview

Fast Healthcare Interoperability Resources (FHIR) is a standard developed by HL7 org on open-source web-based structure and protocols, for fast, granular & human-readable exchange of data.

Fast, granular access to individual clinical components	Easily extensible without breaking compatibility
Strong focus on data model and exchange protocol consistency	Off-the-shelf API approach for lighter apps, faster & easier development
Robust 3rd party frameworks i.e. SMART-on-FHIR, HAPI	**Supports REST access (API), messaging (HL7) & Document (CCDA)**

Advantages

Challenges

Pace of standard development needs to align with regulations & trends	Barriers to entry: HL7, CCDA are quite popular
Competing standards: DICOMWeb, Direct Project offer similar benefits	Data mapping from legacy standards is always challenging
Avoiding FHIR standard bifurcation (multiple profiles, versions) like HL7	Security is not baked into the standard, only guidelines

- **Officially launched as FHIR 4 (R4)**, after being in DSTU for 4 years
- **87% hospitals and 70% clinicians are using FHIR-enabled EHRs**
- **Mandatory API for 21st Century Cures regulations from ONC and CMS**
- **Big support from Azure and Google** Cloud through APIs & infrastructure
- **Several 3rd party frameworks are now based on FHIR** i.e. SMART-on-FHIR, HAPI
- **Supports all traditional use-cases** from HL7, CCDA and even DICOM
- **Recent focus on Mobile Apps, CDS, Imaging & advanced analytics**

CitiusTech PoV: Significant Developments in FHIR Adoption

Regulatory Support

- CMS and ONC announce mandatory implementation of FHIR R4 APIs with USCDI dataset
- Validates FHIR as the de-facto interop standard for the future

Google Cloud Healthcare APIs

- Google Cloud has published their set of Health APIs which include PaaS offerings for DICOMWeb and FHIR

Microsoft Azure

- Microsoft has FHIR architecture and data support integrated into the Azure cloud offerings

Alliances

- SMART Alliance, Da Vinci Project, Argonaut project working on FHIR use cases and definitions
- IHE working on 33 FHIR-based profiles

Normative Release 4 of FHIR

- Introduced several new resources including the first set of normative resources (backward compatibility)

EMR Support

- Several large EMR providers (Cerner, Epic, etc.) launched FHIR API support and "*App Stores*"

Apple Health Kit

- Apple has been an early adopter of FHIR and provided access to FHIR compatible resources

Draft Stage

- FHIR launches under draft stage with limited support in 2012
- Gains support for more use cases and resource definitions through DSTU-2 and DSTU-3 over the years

CitiusTech PoV: FHIR Use Cases For Medical Technology

Advanced Analytics

- FHIR APIs support **well defined export formats** i.e. JSON, XML **and dataset** i.e. USCDI
- **Faster** AI/ML or CDS **model development**, with **clean datasets** and **feedback loops**

IoT / Home Health

- **iOS HealthKit, Azure & GCP support FHIR** in their IoT platform and APIs
- Can be used for **real-time health tracking** and alerts

HIT Future Scalability

- FHIR R4 now has **Federal mandate** with **guaranteed adoption in** 2 years
- Designing DBs, applications & interfaces around FHIR gives future **stability & compatibility**

HL7 FHIR

Care Coordination

- **Real-time synchronization** between HIT systems, mobile apps
- Seamless integration with OAuth2 & SMART framework for **patient access**

Unlocking Innovation

- FHIR APIs enables Health IT and Providers to **securely expose deidentified data**
- 3rd party & small developers can **design innovative apps** and **publish on marketplaces**

Medical Imaging

- **FHIR has fast, granular exchange** of imaging metadata, and clinical data
- **AI Image analytics** and patient **contextual insights** from EHR can be integrated into Viewers

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Interoperability Final Rules: Overview

CMS: Interoperability & Patient Access Rule (IPA)

ONC: Interoperability Cures Act (ONC 2015 Cures Update)

These rules provide:

- **Complete access & control** for patients over their data
- **Secure, easy, timely and precise exchange of data** among the major entities – Patients, Providers, Health Plans, HIEs/HINs, etc.
- **Penalties for Information blocking** & possible exceptions
- **Product & pricing transparency** for HIT consumers
- Promote **healthy competition & global interoperability**

Expected Outcomes

Boost Innovation

By giving patients and providers safe and secure access to health information, allowing for more choice in care and treatment.

Reduce Burden and Advance Interoperability

Through the use of USCDI standard, new API requirements, and EHI export capabilities.

Promote Patient Access

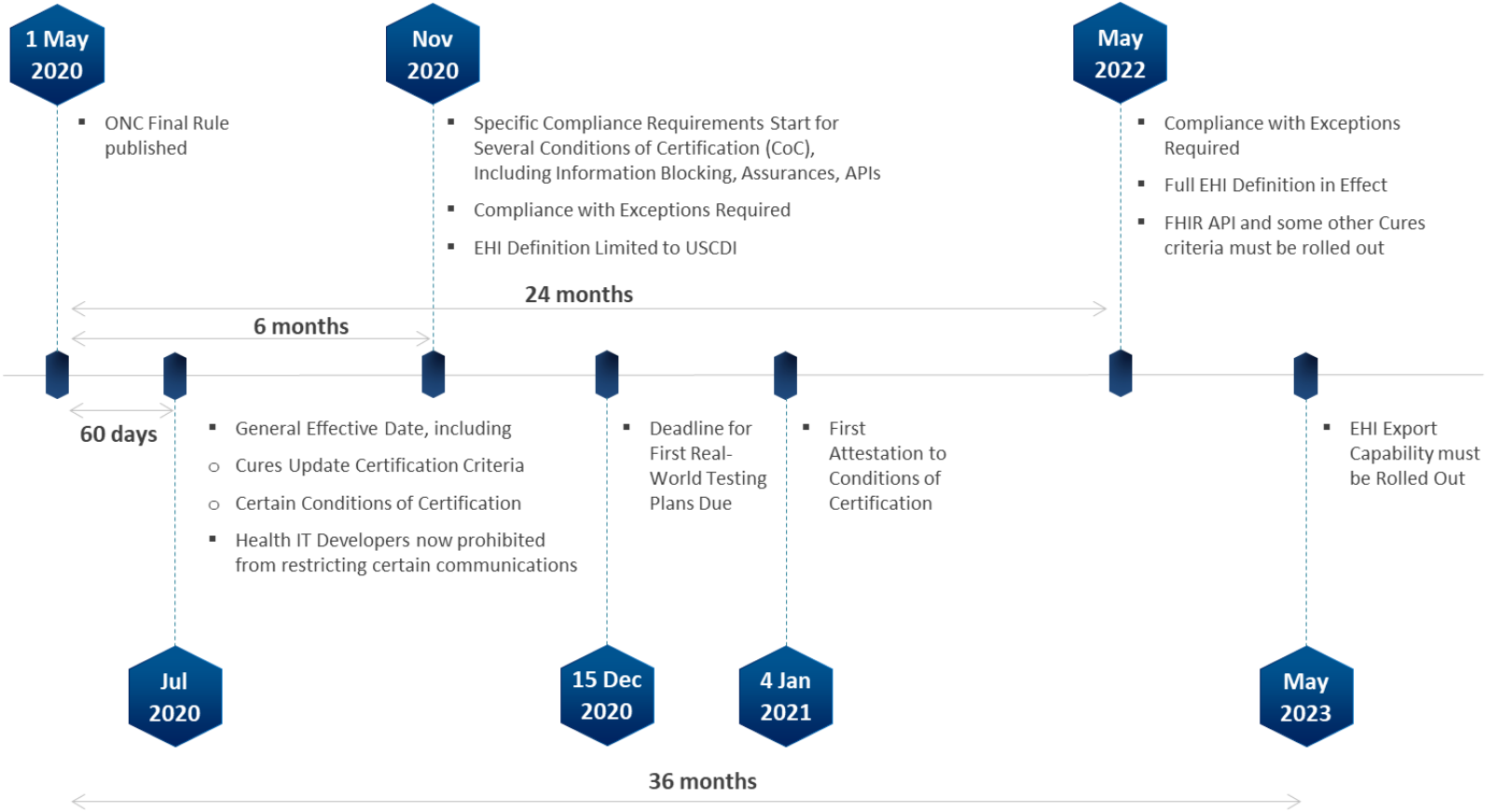
Requiring that patients can electronically access all their electronic health information, claims info, etc. at no cost.

ONC Cures Rule: Key Clauses

The Interoperability rule from the ONC released on 9th March 2020, has important clauses which Healthcare IT Companies and Providers need to comply with in-order to avoid penalties

#	ONC Rules	Impact HIT	Impact Providers	Status
1	Deregulatory Actions	✓		Finalized
2	Updating 2015 Edition Certification Criteria	✓		Finalized
3	Information blocking	✓	✓	Finalized
4	Condition of Certification and Maintenance	✓		Finalized
5	Health IT for Care Continuum (Optional)	✓		Finalized

ONC Cures Rule: Certification Timelines



CitiusTech PoV: ONC Rule Value For Medical Technology

ONC Final rule has been designed to solve some of the long-standing challenges faced by the Medical Technology companies in terms of interoperability, operations and applications

Key Challenges Today

Interoperability

Multiple methods i.e. DB Views, EAI tools, Web services, FTP etc. lead to huge integration efforts

Non-standard data sets

Multiple standards in use i.e. HL7, CDA with varying levels of clinical data and elements missing and misused

Operationalizing AI/Analytics models

AI models cannot rely on changing or unpredictable data sets due to multiple standards & exchange protocols

How FHIR Helps

Mainstream API Integration

FHIR API is well-defined by SMART and HL7 IGs & integration between FHIR systems is a matter of hours, not days

Regulatory FHIR Mandate

ONC mandates FHIR XML/JSON structure and USCDI elements removing implementation ambiguity

USCDI Minimum Guarantee

USCDI is standardized with a well-defined upgrade path, AI models can rely on availability of these elements for analysis

Key Risks That Remain

Data Quality	Real-time Availability	Legacy Data Migration	Different API Methodologies	Full Adoption Time of 2 years

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Cures Certification: Existing Modules Status

Status	Timeline	Modules	
Removed	*Within 60 days*	▪ Problem List ▪ Medication List ▪ Medication Allergies	▪ Smoking Status ▪ Common Clinical Data Set summary record – create/receive
	Within 24 months / Jan 1st 2022	▪ App Access – Data Category Request	▪ Patient-specific Education Resource
		▪ Drug Formulary & Preferred Drug List Checks	▪ Secure Messaging
	Within 36 months	▪ Data Export	
Revised	*Within 60 days*	▪ CQM Report	
	Within 24 months	▪ Transitions of Care	▪ Clinical info reconciliation & incorporation
		▪ Electronic prescribing	▪ Security tags - summary of care
		▪ Auditable events and tamper-resistance	▪ Care plan
		▪ Auditing actions on health information	▪ Audit report(s)
		▪ Transmission to public health agencies — electronic case reporting	▪ View, Download, Transmit to 3rd Party
		▪ Application Access - All Data Request	▪ Consolidated CDA creation performance

- Most of removed modules are redundant due to the new modules, use of USCDI and FHIR APIs
- Some modules are only maintained till Jan 2022 to support Medicaid programs
- Revised modules mostly only have the implementation standards updated for QRDA, CCDA, USCDI, NCPDP SCRIPT, ASTM etc.

Cures Certification: New Modules/Concepts

Concepts	Description
USCDI (United States Core Data for Interoperability)	▪ **Retire CCDS** & move to **new USCDI v1** (evolved for MU data set and CCDS) ▪ Includes additional classes i.e. **Provenance, Clinical Notes, Pediatric Vital Signs, Address, Phone Number**
Standard API for Patient and Population Services	▪ Introduced new module to **export all USCDI v1 data using FHIR 4.0.1 resources** ▪ Service available for **single patient and multiple patients** in health systems ▪ Support other FHIR capabilities like “search” with patient and user scope ▪ Utilization of **Authorization server** and **Transport Layer Security (TLS) v1.2** for security ▪ App authentication & authorization as per **SMART App Launch & OpenID Connect** ▪ Part of 2015 Base EHR certification – mandatory for all
Privacy and Security Certification	▪ **Attestation requirement** from health IT developers for ○ Encrypt Authentication Credentials ○ Multi-factor Authentication
EHI Data Export	▪ Electronically export all EHI **produced & electronically manage** in computable format ▪ Export must be available **for single patient and all patients** in health systems ▪ Provide complete support documentation for EHI and link to publicly access resource

Cures Certification: USCDI's Impact on Standardization

USCDI will standardize the minimum data set that can be expected from HIT systems leading to better care-coordination, interoperability and accurate AI/ML models

- **USCDI v1 Core Data elements**:
  - Clinical Notes of Consultation, Discharge Summary, History & Physical, etc.; must be raw text
  - Vital Signs including Pediatric Vital Signs
  - Diagnostic Reports and Lab Information
  - Patient Demographics
  - Allergies & Intolerances (Medication Allergies in CCDS): Substance (Medication), Substance (Drug Class), Reaction
- **Standards**: Supported by both HL7 C-CDA Release 2.1 and FHIR Release 4
- **API:** Requires that compliant systems must expose the USCDI data for a patient using FHIR R4 based APIs
- **Timelines:** Within 24 months from Final rule (May 2020) with an additional 3 months for compliance

Cures Certification: Condition & Maintenance of Certification

Condition of Certification (CoC)

A prerequisite to be awarded ONC's Health IT Certification initially

Condition of Maintenance (CoM)

An ongoing test to ensure Health IT is still performing as per initial Certification

Provisions	Conditions	Maintenance
Information Blocking	▪ Must not take any action that constitutes information blocking except 8 exceptions defined	▪ No specific requirement
Assurances	▪ Assure Secretary that no action be taken that forms information blocking or block EHI access	▪ EHI data export available within 36 months ▪ Retain all records for period of 10 years
Communications	▪ Should not prohibit or restrict communication regarding health IT's: Usability, Interoperability, Security, User experiences, Business practices	▪ Within 6 months inform all customers that any contract provision that violates the CoC will not be enforced by it
APIs	▪ Publish APIs for access, exchange in USCDI format and all necessary technical and business documentation	▪ Must provide API functionality within 24 months of final rule ▪ Must register & enable apps within 1 day
Real World Testing (RWT)	▪ Successfully test the real-world use of the technology for interoperability in same setting type	▪ Submit prospective annual RWT plans and retrospective annual RWT results
EHR Reporting Criteria Submission	▪ Submit reporting criteria on certified health IT in accordance with the EHR reporting program	▪ Not yet established

Attestation every 6 months to comply with these conditions starting 4 Jan' 21

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CitiusTech PoV: FHIR's Value Beyond Certification

Real-time applications	▪ Build light-weight Mobile applications using FHIR APIs ▪ Achieve use cases for care coordination, monitoring
Scalability and Compatibilty	▪ Based on APIs as which are core for next-generation solution architectures ▪ Compliance with legacy systems through HL7, CDA adapters
Healthcare Process Improvements	▪ Seamless transition of care on ongoing basis ▪ Streamline workflows between Health IT provider and payer ▪ Real-time alerts and notifications based on intelligence rules
Data Analytics & Reporting	▪ Granular, well-defined access to patient data from multiple systems ▪ API-based integrations are faster, most suited for AI/ML systems

FHIR Adoption Approach

Health IT Trends influenced by general Healthcare Trends → **Technology & Standards enablers** → **FHIR defining the Med Tech solution Roadmaps**

- Increasing need for integrating clinical information system workflows
- Patient & clinician access to relevant patient history at point of care
- Enable integration of newer devices into clinical workflows (mobiles, wearables, etc.)
- Integration of AI/ML actors into Health applications at a workflow level

- Regulatory backing formalized standard and exchange protocols
- Device and 3rd party HIT data access using FHIR improves clinical decisions, innovative apps and marketplaces
- Faster processing and light-weight endpoints due to granular access
- Faster integrations between HIT systems
- FHIR opens more advanced uses of data, including AI/ML
- FHIR APIs enable all hospital workflows to implement smart, AI driven decisions

CitiusTech PoV: Future Health IT Ecosystem

Data Ingestion

EHRs

HIEs / Trusted Exchanges

Mobile & IoT

Devices

Payors

Data Standardization & Processing

FHIR Parser

FHIR Resources

Financial Data

- Claims
- Coverage
- Document Reference

Clinical Data

- Medication Statement
- Care Plan
- Document Reference
- Diagnostic Report
- Observation
- Imaging Study
- Allergy Intolerance

Operational Data

- Practitioner
- Practitioner Role
- Organization
- Healthcare Service

+ 80 more resources covering most healthcare operations

API Exchange Gateway

Data Delivery

EHRs

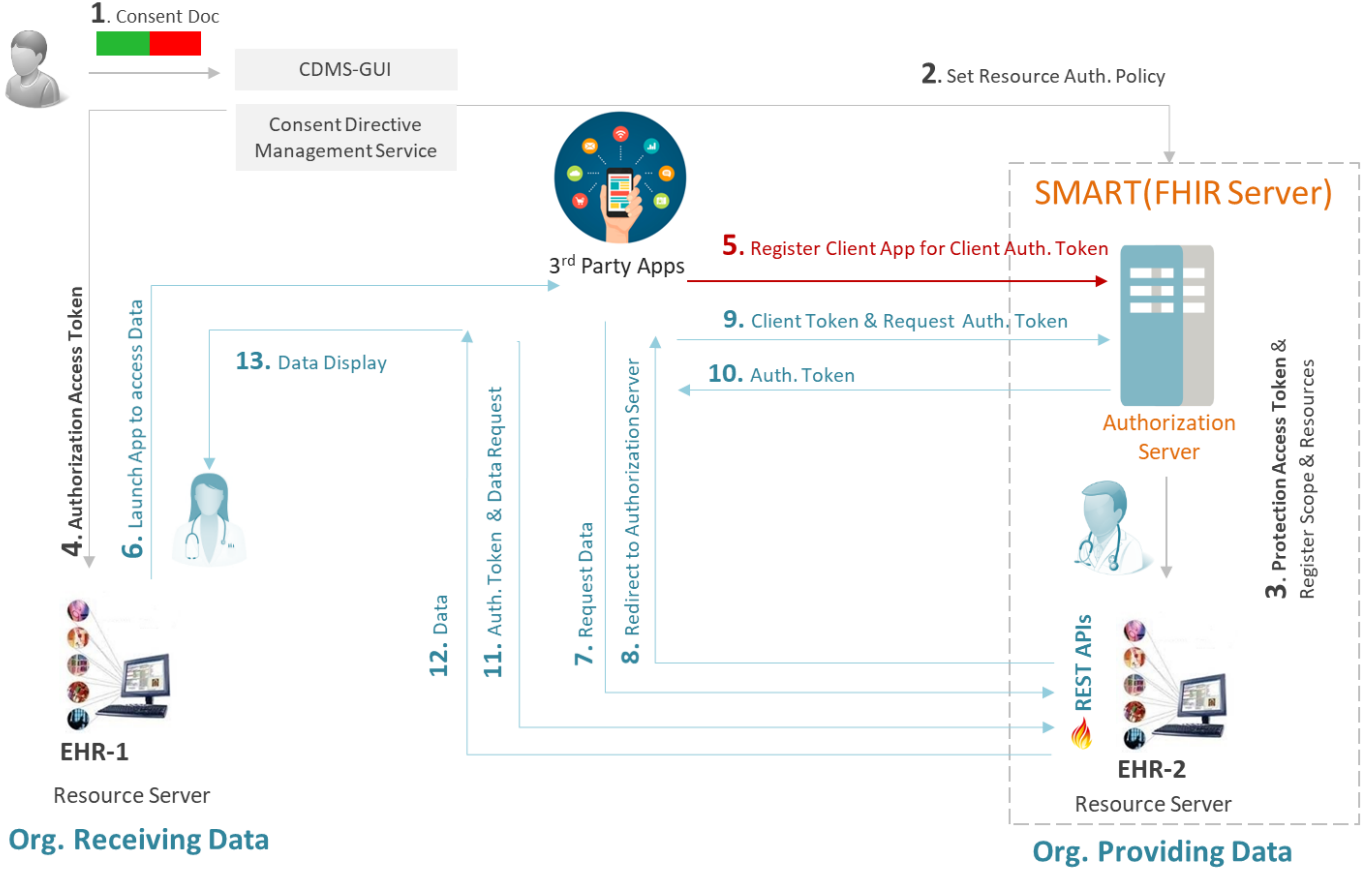
HIEs / Trusted Exchanges

Mobile & IoT

Devices

Payors

Use Case 1: Mobile App Requesting Patient Data



Use Case 2: Integration of EMR with DICOM Viewer

Before Integration

Analysis
- **Imaging Analysis**: The 2D echo shows Left ventricular hypertrophy, bilateral atrial dilatation & a thickened mitral valve

Interpretation
Suggestive of moderately severe hypertensive heart disease

Recommendation
- To be further evaluated and co-related with clinical findings

Radiologist

Integrated Viewer

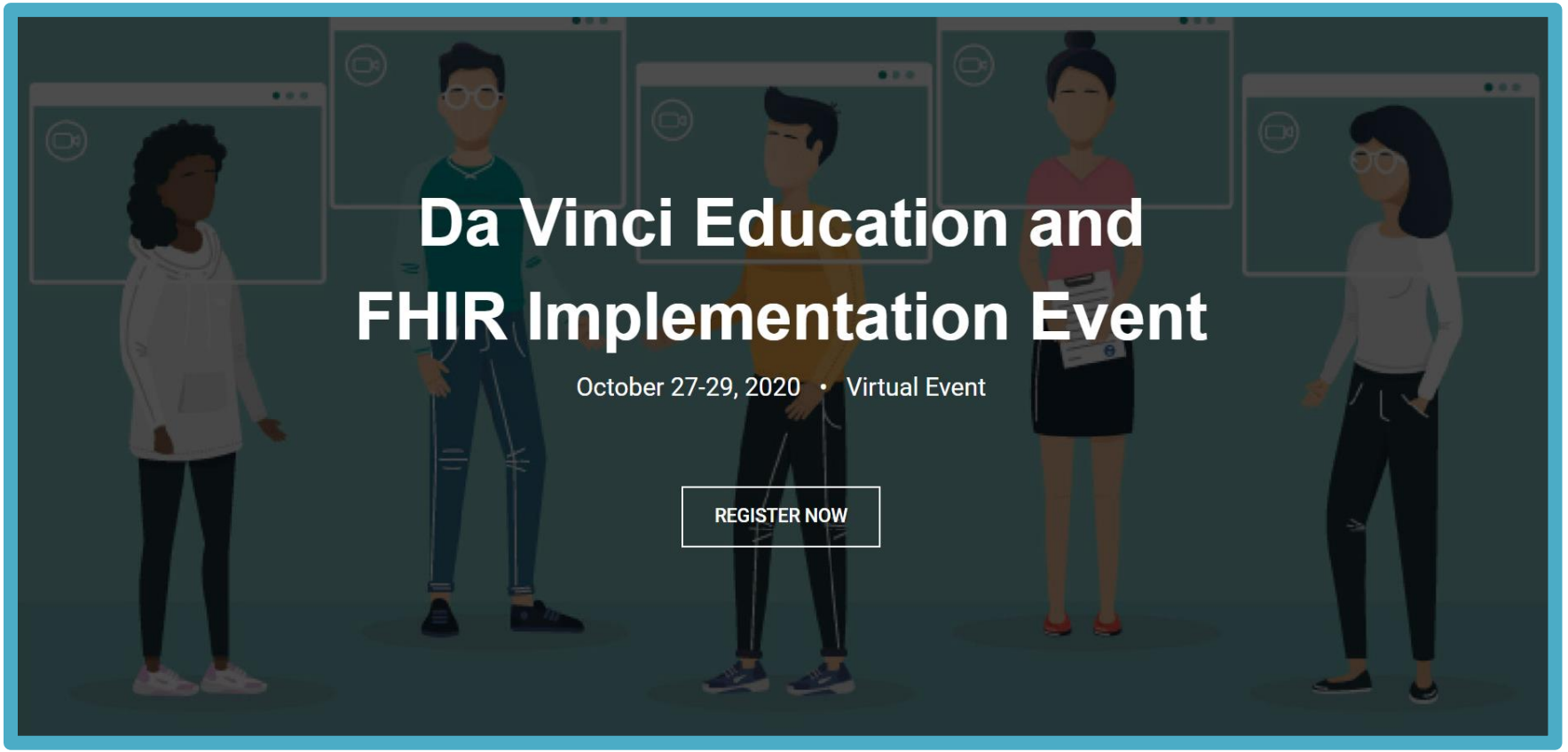
After Integration

Analysis
- **Imaging Analysis:** The 2D echo shows Left ventricular hypertrophy, bilateral atrial dilatation & a thickened mitral valve
- **Clinical Data Analysis:**
  - Obese
  - Former smoker
  - Comorbidities: Hypothyroidism, Diabetic, Hypercholesterolemia
  - Blackouts could be TIAs (transient ischemic attacks)

Interpretation
The patient has significant Atherosclerotic disease and is at high risk for an adverse event such as Myocardial Infarction (Heart Attack) or Stroke

Interpretation
- Color Doppler study
- Doppler of neck vessels & MRI of brain
- Coronary angiogram +/- stenting
- Suggests an endocrinology consult for diabetes and hypothyroidism management.

HL7 Implementers Event



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We're ready for some questions!

Key CitiusTech Highlights

4,800+
Payer / Provider Locations

4,000+
Healthcare IT Professionals

500+
HL7 & FHIR® Certified Professionals

700+
Interoperability Project Expertise Professionals

CitiusTech FHIR® Resources

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Easily test and implement FHIR® APIs

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FAST+

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FHIR® for ONC Compliance & More >

FAST+ for CMS Compliances & Beyond >

Talk to us to achieve a successful FHIR® adoption: ***FHIR@citiustech.com***

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