CTSA Program PI Webinar

Wednesday, September 26, 2018
2:00 – 3:00 ET

Agenda

Time	Topic	Presenter
2:00 - 2:05	Welcome NCATS and CTSA Program Updates	Michael Kurilla
2:05 - 2:10	CLIC Announcements	Martin Zand (CLIC)
2:10 - 2:45	Relationship between HL7 International and the CTSA Program	Ed Hammond (Duke) Chuck Jaffe [CEO Health Level Seven International (HL7)]
2:45 - 3:00	Dissemination & Implementation Activities Across the CTSA Program: The PI survey results	Rowena Dolor (Duke)

NCATS and CTSA Program Updates

Michael Kurilla

NCATS Director's Update – FY 2019 Budget

House and Senate "Conferenced" on 9/13/18 to create Minibus containing:

- Defense
- Labor/HHS/Education
- Continuing Resolution through December 7, 2018, for remaining appropriation bills

Status of Minibus:

- Senate – passed 9/18/18
- House – vote scheduled for 9/??/18
- President – needs to sign by 9/30/18 to prevent partial shutdown
  - Energy-Water, Military Construction-VA, and Legislative Branch already became law on 9/21/18

Minibus – Details:

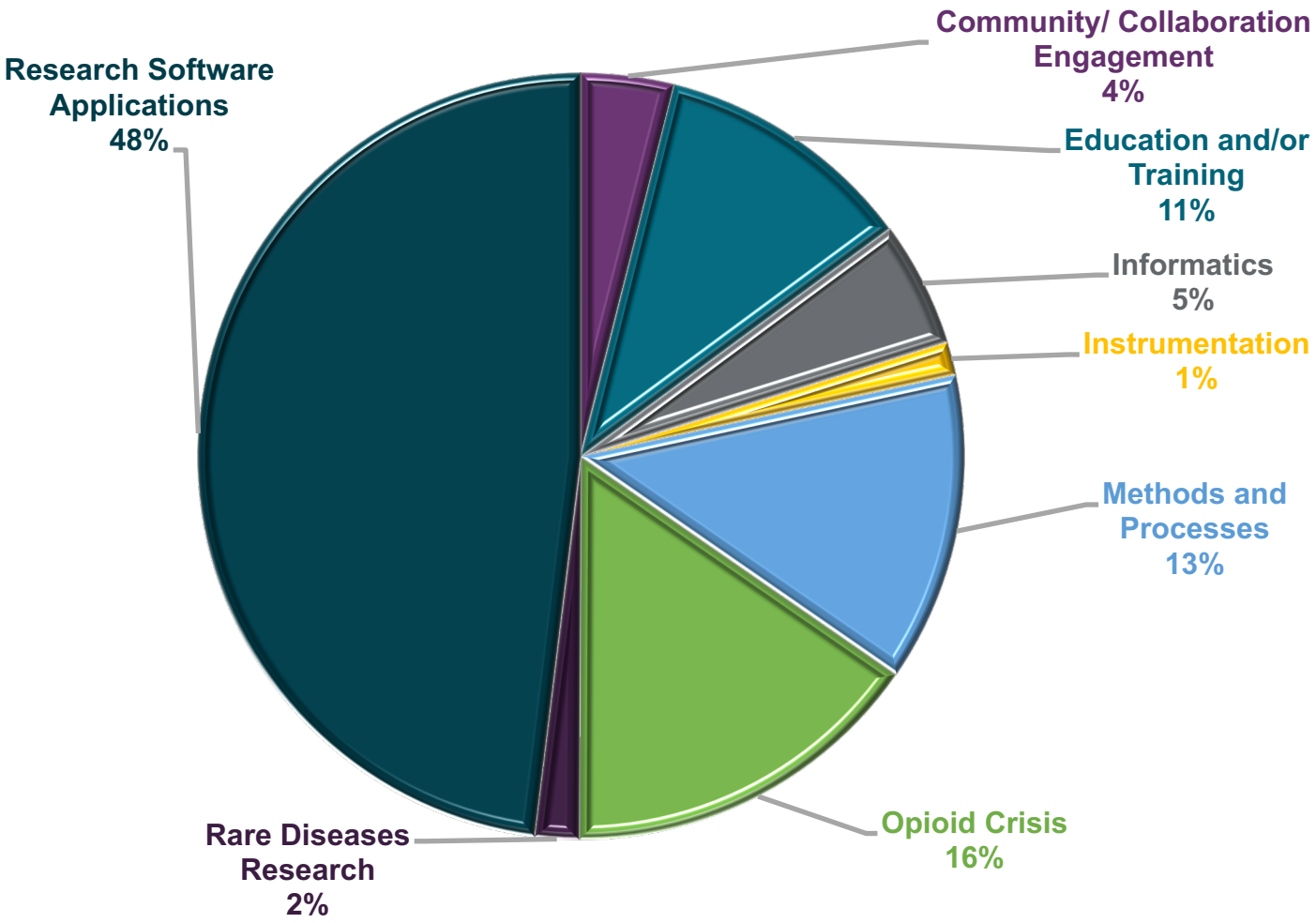
- NIH: $39.084 billion ($2 billion increase, or 5.4%, above FY 2018)
- NCATS:

	FY 2017 ($M)	FY 2018 ($M)	FY 2019 ($M)
CTSA	516.1	542.8	559.8
CAN	25.8	25.8	"up to 80.0"
NCATS	**705.9**	**742.4**	**806.4**

National Center for Advancing Translational Sciences

Supplements Awarded to CTSA Program UL1s and Collaborative Innovation Awards by Priority Research Areas as a Percent of Total Awarded Supplements

- Notice for Availability of Administrative Supplements (NOT-TR-18-022)
- Total estimated cost: $14 M
- Awards to:
  - 24 CTSA Program hub Institutions
  - 2 CTSA Program Collaborative Innovation Awards



National Center for Advancing Translational Sciences

Priority Research Area: Research Software Applications

- **Supplements to support the implementation of clinical trial management systems to:**
  - Medical University of South Carolina
  - University of Colorado Denver
  - University of Kentucky
  - Icahn School of Medicine at Mount Sinai

- **Deliverables:** Enhanced efficiency for tracking clinical trial information and assessment of accrual goals. Enhanced ability to conduct multi-site clinical trials to better adhere to the NIH's single Institutional Review Board (sIRB) policy.

National Center for Advancing Translational Sciences

Priority Research Area: Opioid Crisis

- **Addressing Diseases of Despair (Deaths from Suicide, Chronic Substance Abuse, and Overdoses) in a Rural Community**
  - Pennsylvania State Univ Hershey Med Ctr
  - **Deliverable: D**emonstration project of an approach to community engagement
- **Patient Registry for Analyzing Opioid Usage in Burn and Trauma Patients: Building Capacity to Support Multi-Institutional Clinical Trials**
  - University of Texas Med Br Galveston
  - **Deliverable:** identification of a best practice for prescribing pain relief
- **Deep Learning solutions for classifying patients on Opioid Use**
  - Mayo Clinic Rochester
  - **Deliverable:** Identification of a best practice for prescribing pain relief
- **Collaboration to enhance Naloxone Dispensing in Rural and Underserved Areas (CONsiDER)**
  - University of New Mexico Health Scis Ctr
  - **Deliverable:** Pharmacy-based intervention: develop, and subsequently disseminate a sustainable model to increase the dispensing of naloxone by community pharmacists to patients at risk of opioid OD and their caregivers.

National Center for Advancing Translational Sciences

Priority Research Area: Education / Training

- **Expanding Kaizen-Education: Gamification for CTSA Translational Training**
- Collaboration between UAB and OSU
- UAB has developed a gamification platform which is an innovative approach to learning that engages the learner
- **Deliverable:** innovative approach to education
  - Game manager portal and question bank
  - 2 games will be disseminated to the consortium to enhance Translational Science workforce development:
    - Rigor, Reproducibility, and Transparency
    - Good Clinical Practice

National Center for Advancing Translational Sciences

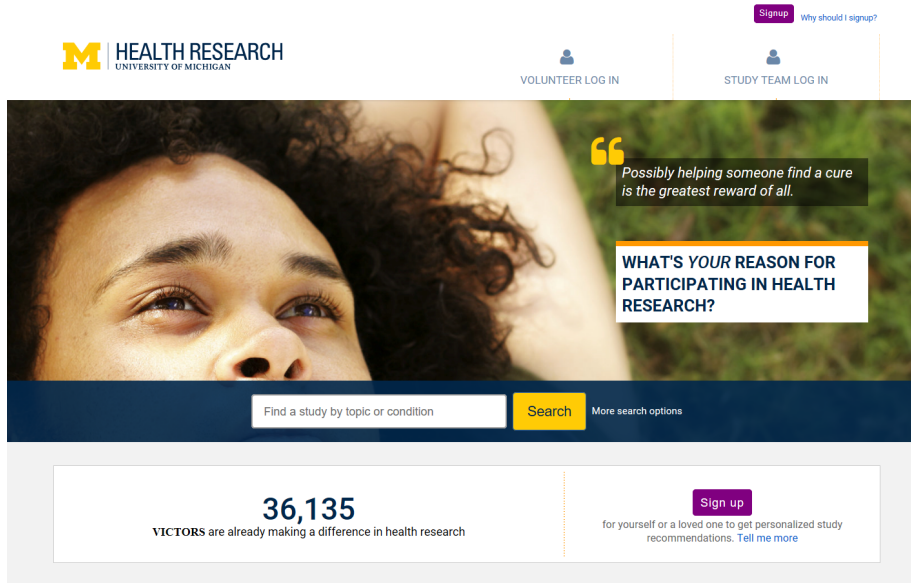
Priority Research Area: Methods & Processes

- **Using Matched Controls to Measure the Impact of CTSA Program Pilot Grant Funding**
- Harvard
- Proposing to assess the impact of CTSA Program pilot funding by developing an innovative outcome to measure the value of the CTSA Program pilot awards program through its effect on investigator teams
- **Deliverable:** Dissemination of a process to assess team science impact of the pilot project funding across the CTSAs

National Center for Advancing Translational Sciences

Priority Research Area: Community Engagement

- **Engaging the Community to Participate in Health Research**
- Collaboration between University of Chicago, University of Illinois Chicago, and Northwestern
- Adopt the Michigan CTSA UMHealthResearch.org recruitment website (platform)
- Replicating an online tool to connect research study teams to interested study participants will better establish bidirectional community-based participation, far reaching across the entire city of Chicago
- DELIVERABLE: approach to enhance recruitment of participants into clinical trials



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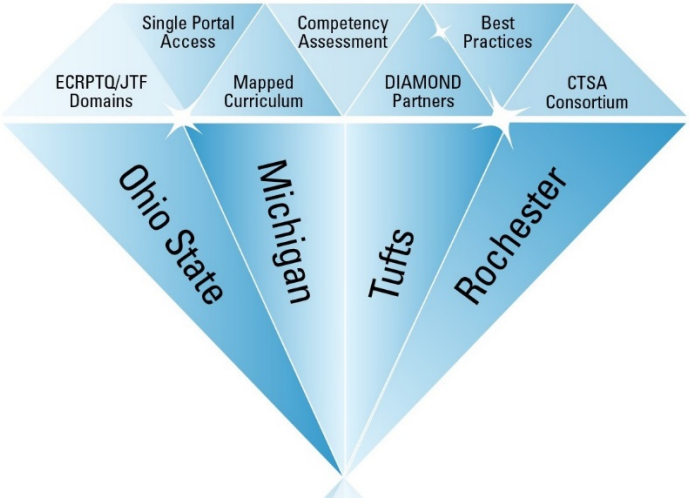
Development, Implementation, and AssessMent Of Novel Training in Domain-based Competencies (DIAMOND)



Deliver a sustainable, collaborative **discovery learning space** for clinical research professionals (CRPs) working in CTSA institutions & partners including:

- Shared competency-based clinical research training offerings
- Assessments
- A unique ePortfolio system to encourage workforce development and connection

National Center for Advancing Translational Sciences

https://clic-ctsa.org/diamond contactdiamond@umich.edu U01TR002013

Thank you!

Next Call: Wednesday November 28, 2018

2:00 – 3:00 ET

Suggestions for meeting topics to the CLIC Suggestion Box:

https://clic-ctsa.org/contact/suggestion-box

Upcoming Meetings

Date (2018)	Institution/Organization	Event Name
September 27	NCATS	NCATS Advisory Council Meeting
September 27	HL7	HL7 FHIR Applications Roundtable
September 27	U Rochester & PhRMA	Regulatory Science to Advance Precision Medicine Forum
September 28	NCATS	NCATS Day 2018
September 28	Georgia CTSA	Clinical Trial Challenges: Lessons Learned from the NIH Collaboratory Biostatistics & Design Core
October 1	Harvard Catalyst	Symposium: Advancing Uptake of Evidence-based Practices & Policies for Healthy Child Weight
October 4	Multiple CTSAs	Human Subject Protection: Roll With It
October 5-6	Colorado CTSA	Zoobiquity Colorado: Connecting Human and Animal Health through Regenerative Medicine
October 22	CTSA Program	Face-to-Face CTSA Program Steering Committee Meeting
October 22	CTSA Program	Face-to-Face CTSA Program Administrator's Meeting
October 23	CTSA Program	2018 CTSA Program Fall Meeting
October 24	NYU CTSI	NYU CTSI Sponsored Fourth Annual Health Disparities Symposium

And many more!! Add your events on the CLIC website here: https://clic-ctsa.org/event-list (login required)

Connect With the NCATS CTSA Program:

Websites:

Consortium: ctsa.ncats.nih.gov/
CLIC: clic-ctsa.org/
CD2H: ctsa.ncats.nih.gov/cd2h/
TIN: trialinnovationnetwork.org/
ACT: actnetwork.us/National
SMARTIRB: smartirb.org/

Twitter:

NCATS: twitter.com/ncats_nih_gov
CLIC: twitter.com/CLIC_CTSA
CD2H: twitter.com/data2health
Hashtag: #CTSAProgram

Newsletters:

NCATS: https://ncats.nih.gov/enews

CTSA Program Newsletter:

https://clic-ctsa.org/news/newsletter-subscribe

Submit WOW!s:

Login to submit WOW!s: https://clic-ctsa.org/news

National Center for Advancing Translational Sciences

CLIC Announcements

Martin Zand

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

UNIVERSITY of ROCHESTER MEDICAL CENTER

CLIC Announcements: Synergy Paper and Un-Meeting RFAs

CTSA Program PI Webinar
26 September 2018

Martin Zand MD PhD
Deborah J Ossip PhD

The University of Rochester Center for Leading Innovation and Collaboration (CLIC) is the coordinating center for the Clinical and Translational Science Awards (CTSA) Program, funded by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), Grant U24TR002260.

CTSA
Clinical & Translational Science Awards Program

CLIC
Center for Leading Innovation & Collaboration

RFAs Available

Un-Meetings

- Apply to host an attendee-driven event without traditional rules and structure
- One hub will receive funds, planning guidance and materials, and high-level coordination from CLIC

Application deadline: **October 15, 2018**

- Learn more: https://clic-ctsa.org/funding/un-meeting-request-applications
- Contact: unmeetings@clic-ctsa.org

Synergy Papers

- Apply to collaborate on a cross-hub, cross-stage manuscript to address a translational science challenge
- Writing team will receive publication funds and administrative support from CLIC

Application deadline: **November 5, 2018**

- Learn more: https://clic-ctsa.org/funding/synergy-paper-request-applications
- Contact: synergy_papers@clic-ctsa.org

Relationship between HL7 International and the CTSA Program

Ed Hammond (Duke)
Chuck Jaffe (CEO HL7 International)

HL7 FHIR

Emerging Role in Translational Science

W. Edward Hammond, PhD
Director, Duke Center for Health Informatics,
Duke Clinical &Translational Science Institute

Charles Jaffe, MD, PhD
CEO, Health Level 7

NCATS CTSA Program
26 September 2018

HL7 FHIR

Guiding Principle

"How much easier it is to be critical than to be correct."

- Benjamin Disraeli

HL7® FHIR®

Our Message

Clinicians & Researchers

deserve a much better solution

for exchanging data…and

data that can then be repurposed.

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Fast Healthcare Interoperability Resources

A little compromise:
FHIR for non-Engineers
in 3 minutes

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The principles underlying
FHIR development
are meant to address the
challenges learned in
30 years of
standards development.

HL7 INTERNATIONAL

Fresh Look asked,
"What would interoperability look like
if only we could start over?"

And not throw out the good stuff
we learned along the way.

My coach said
that I kick
like a girl.

I told him that if
he tried harder,
he could too.

Mia Hamm

FHIR enables an
evolutionary
development path
with
other HL7 standards*

* Many are embedded in Federal regulation

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FHIR focuses on implementation*

* and implementers

HL7® FHIR®

FHIR development is global*

FHIR development workshops in UK, Canada, Australia, Netherlands, Argentina, and Japan…as of Monday.

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FHIR is Free

FHIR is licensed through Creative Commons without fees or royalties

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What makes FHIR fast?

Faster to learn
Faster to develop
Faster to implement

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The FHIR Development Process has created a *Maturity Model* that describes global implementation and validates reliability

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Resource Maturity

- FMM1 – Validated
- FMM2 – Tested at approved Connectathon
- FMM3 – Successfully balloted
- FMM4 – Prototype implementation published
- FMM5 – 5 distinct production implementations, in 2 or more countries

“Perfection is achieved,
not when there is nothing
more to add,
but when there is nothing left
to take away.”

Antoine de Saint-Exupery

Business Case for HL7 FHIR

- Faster to learn, to develop, to implement
- Based upon modern internet technology
- Supports REST & Service Oriented Architecture
- *Human readable*
- Supported by large implementation libraries
- Developed and implemented around the world
- Readily integrates with existing standards
- FHIR is FREE!

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FHIR in a nutshell

FHIR is both the
technology and
the agreement on
the meaning of the data.

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REST: The Essence of FHIR

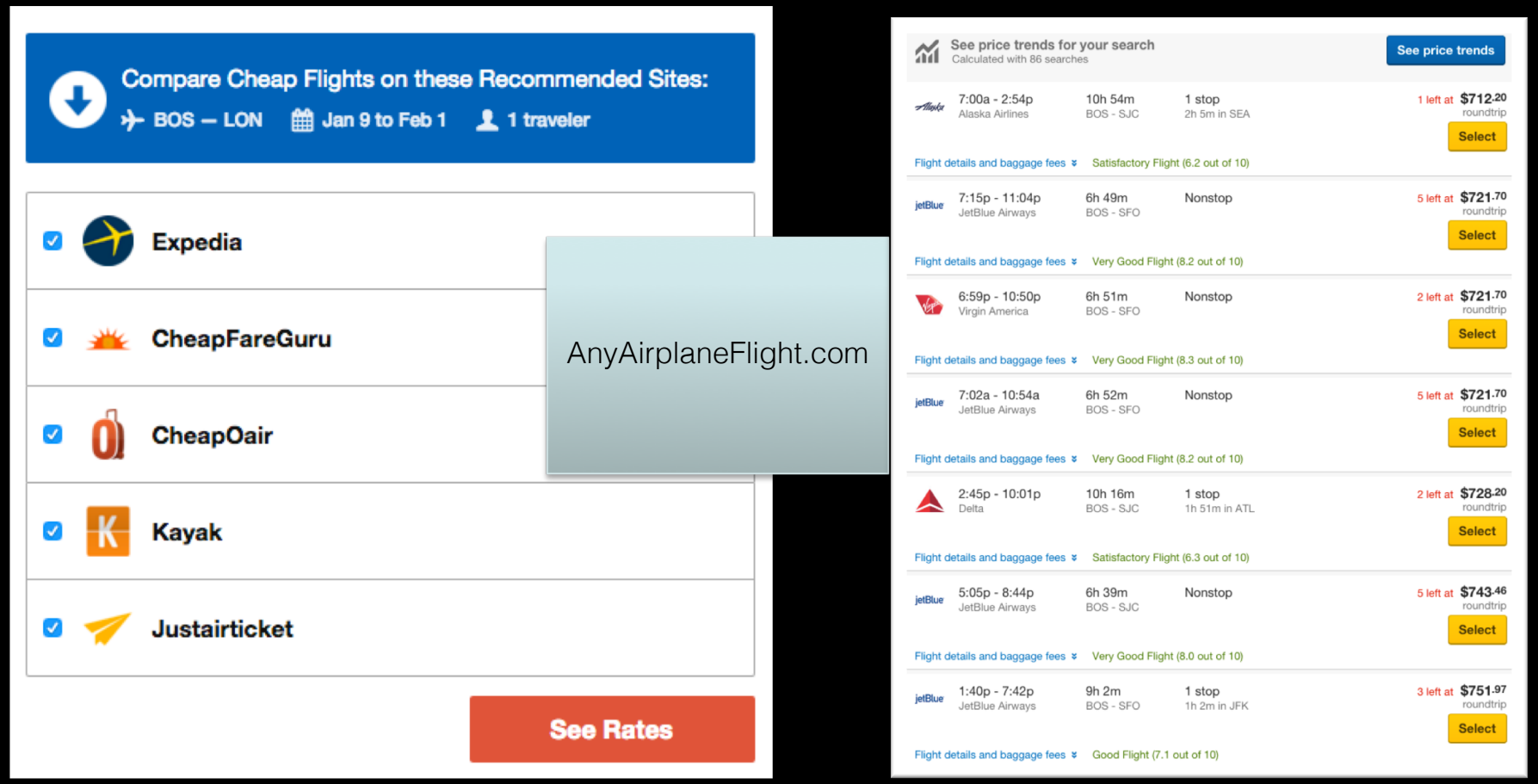
REpresentational STate

Google, Twitter, Facebook

Your favorite travel site

HL7 FHIR

APIs Explained
Your favorite travel site



Courtesy: Russ Leftwich, MD

HL7 FHIR

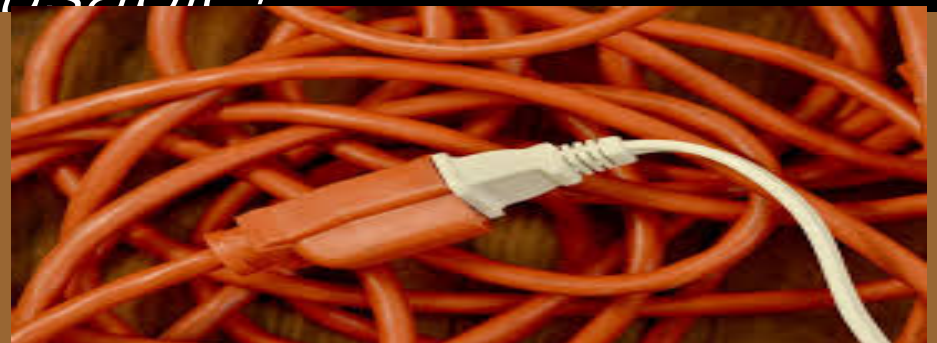
FHIR Profiles

Profiles describe adaptations based on use & content

- Resources used
- API features required
- Terminologies employed
- Mappings to local requirements

FHIR Extensions

- Satisfy exceptions to *80/20 Rule*
- Follow ISO definitions
- Do not break interoperability
- Support local requirements
- *Reusable!*



HL7 FHIR

FHIR Implementation Guide*

- Scope of usage
- Implementation requirements
- Relevant FHIR artifacts (profiles)
- Usage
- Con

** Computable!*

HL7 FHIR

FHIR Foundation
Profiles & Implementation Guides

HL7 FHIR Profile Registry
https://registry.fhir.org

HL7 FHIR Implementation Guides
http://www.fhir.org/guides/registry

HL7 FHIR

HL7 FHIR is more than technology.

HL7 FHIR is about Community.

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The HL7 FHIR Community of Implementers

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Argonaut Project

A private-sector initiative established in 2014 to accelerate FHIR implementation.

Now serves as the bridge for Carequality & Commonwell

Argonaut implementation guides are utilized around the world for localization & international data exchange

Apple iOS 11.3 & beyond supports EHR data

based upon the Argonaut Project Implementation Guide

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Bulk Data on FHIR

- The technology & policy for exchanging records from an unlimited number of patients or study subjects
- Developed cooperatively with Boston Children's Hospital / Harvard
- Supports data analytics for population health, value-based care, clinical trial design and pharmaco-vigilance.

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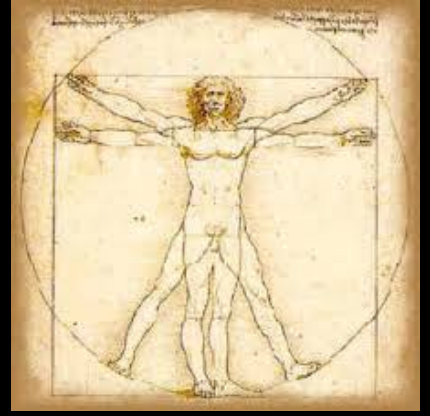
HL7 FHIRcast

- Application Context Synchronization
- Extends the SMART on FHIR Launch protocol
- Web-based approach to legacy HL7 CCOW*

* Clinical Context Object Workgroup
http://fhircast.org/
http://wiki.hl7.org/index.php?title=201805_FHIRcast



Da Vinci Project

Advancing “Value-Based Care”
by leveraging FHIR for the capture of
granular clinical data from patient records
to improve quality, to reduce costs,
and to enhance care management

http://www.hl7.org/about/davinci/index.cfm?ref=common

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The Dirty Dozen & CMS

CMS announced its participation and funding to support the Coverage use cases and to expose authorization rules.

CMS participation provides a unique opportunity to capture required documentation for requests within the clinical workflow.

ONC P2 FHIR Task Force Project

A group of payers, standards developers, and healthcare organizations collaborating on the development of a FHIR API to reduce variability in industry implementation

The Office of the National Coordinator for Health Information Technology

HL7 FHIR

The fundamental character of
HL7 FHIR Community of Implementers
is Collaboration

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International BioPharma is leveraging HL7 FHIR for real-world evidence for clinical trials, post-marketing bio-surveillance, and genomics integration.

TransCelerate
BIOPHARMA INC.

Sync4Science,
Sync4Genes,
& DIGITizE
use FHIR to enable
Genomic Data for
Precision Medicine,
Translational Science,
& Clinical Decision Support

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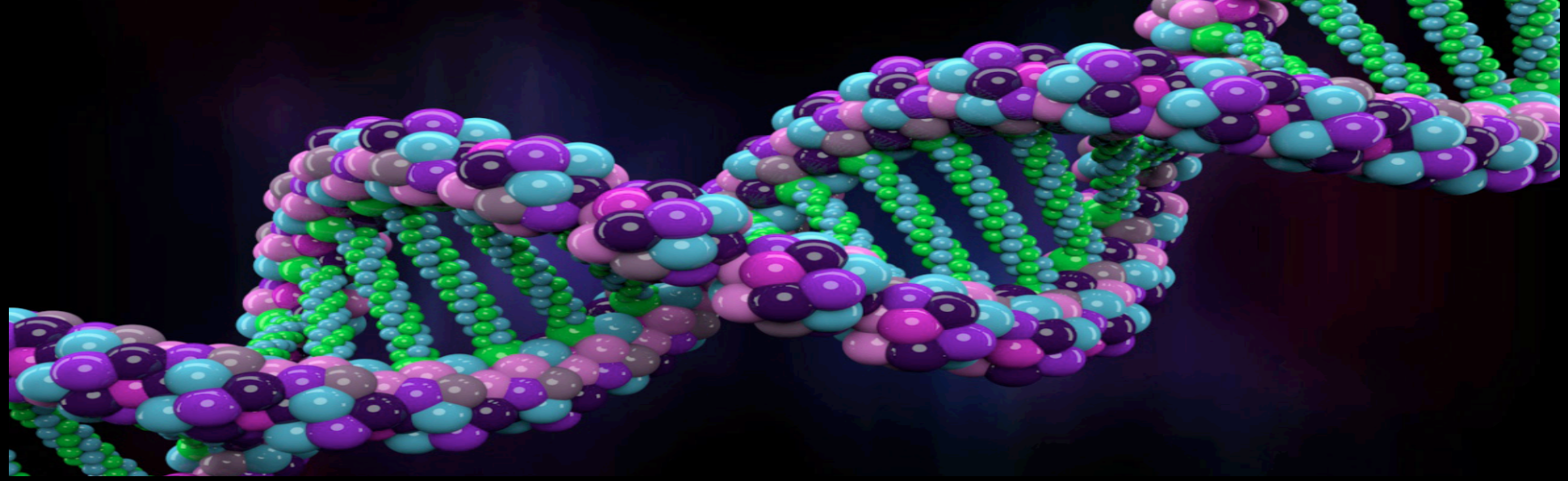

Agile Genomics Consortium

partnership with
Global Alliance for Genomics &
Health

Global Alliance
for Genomics & Health
Collaborate. Innovate. Accelerate.

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Health Agency Collaboration

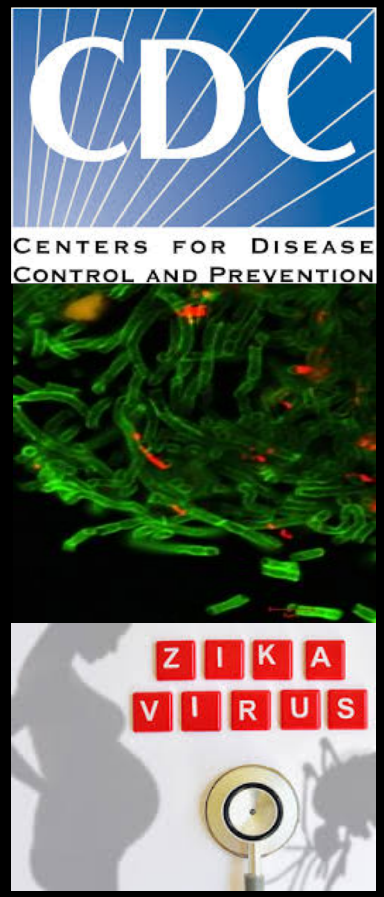
US Federal agencies,
including FDA, CDC, NIH,
DoD, VAH, and others
actively collaborate on
FHIR integration programs

VA API Developer Project

API gateway platform enabling developers to build mobile and web Apps for both providers and patients

HL7 FHIR

CDC is developing initiatives to leverage FHIR for reporting & analytics



The FDA is evaluating solutions to collect data from the EHR in order to leverage *Real-World Data* for drug safety and effectiveness.

Corrigan-Curry, C., et al, JAMA, 320, p.867-8, 4Sep18

Translational Science: CTSA

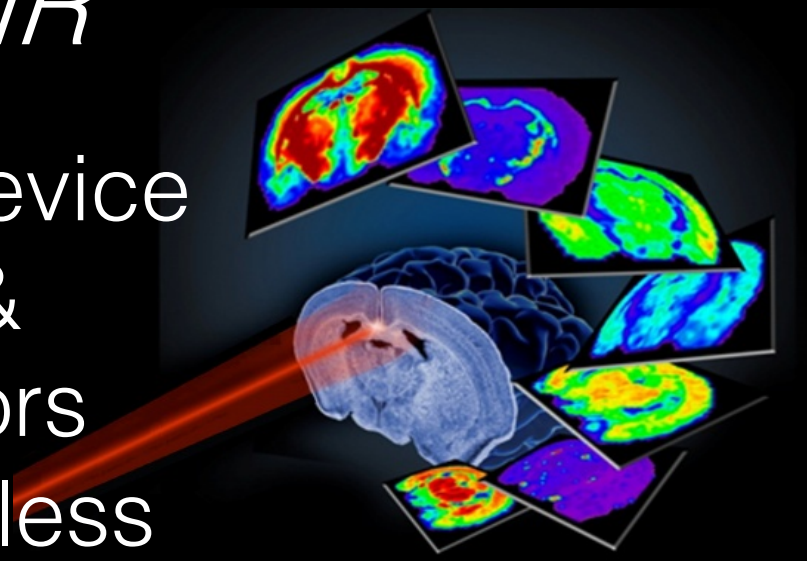
Collaboration with this community will help establish the FHIR platform as a viable solution for optimizing data exchange between pre-clinical science and patient care

NIH National Center for Advancing Translational Sciences

HL7 FHIR

Devices on FHIR

A collaboration of device manufacturers & technology vendors committed to seamless exchange of data between clinical devices and health information systems



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Tech Giants Announce Collaboration on FHIR API for Healthcare Cloud Interoperability

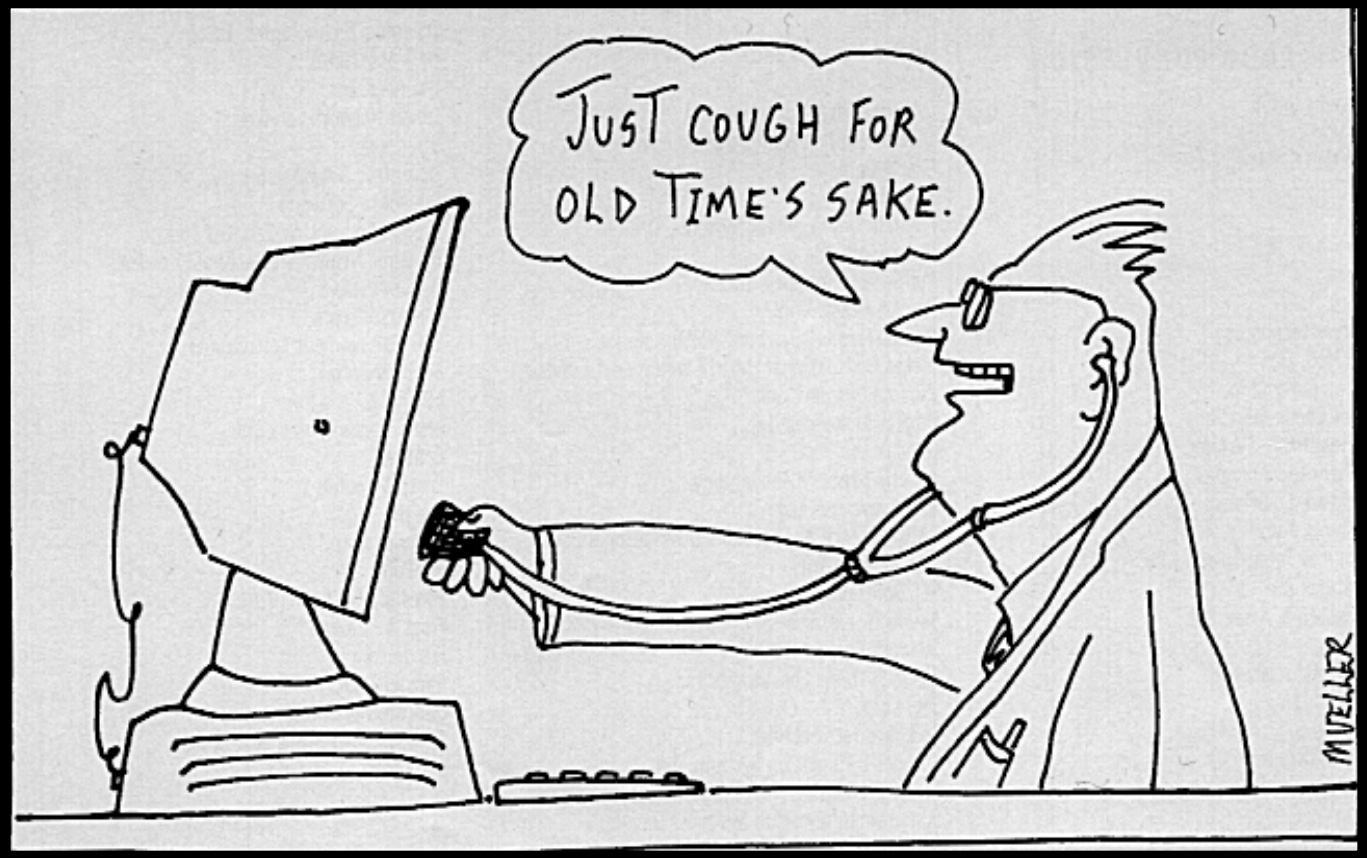
August 13, Washington

What's Next for HL7 FHIR?

- CDS Hooks Implementation Guide
- FHIR Certification
- Inter-version Support
- Bulk data Support
- New content (New Resources)
- FHIR Foundation services
- R4 Normative Release

HL7 FHIR

Thanks



william.hammond@duke.edu
cjaffe@hl7.org

Dissemination & Implementation Activities Across the CTSA Program: The PI survey results

Rowena Dolor (Duke)

D&I Science Activities Across CTSA Consortium: The PI survey results

September 2018

Rowena Dolor, MD, MHS, Duke University
Laura-Mae Baldwin, MD, MPH, University of Washington
Paul Meissner, MSPH, Albert Einstein College of Medicine

D&I Workgroup: Purpose

- Increase awareness of the critical importance of D&I science to the translational science process
- Promote coordination of D&I efforts across CTSA hubs
- Enhance availability of D&I methods and approaches across CTSA settings

- WG started September 2016
- 56 members, 29 CTSAs represented

D&I Environmental Scan

- Leads: Laura-Mae Baldwin (UW) and Rowena Dolor (Duke)

- Gathering information on D&I resources and services, training, and scientific projects directly funded or supported by CTSA programs

Step 1: Brief PI/CTSA administrator survey (today's presentation)

Step 2: In depth survey of D&I activities (analysis phase)

Methods

- Survey created by D&I Workgroup
- Reviewed & Revised by CE DTF, PI Steering Committee and approved by NCATS
- Programmed into REDCap and e-mailed to CTSA PI's or administrators
- Two reminder e-mails and CTSA Newsletter posting
- Collected responses between June 6 – August 18, 2017
- Exported into MS Excel for analysis
- Frequency statistics for quantitative data
- Qualitative questions reviewed by LMB and RD, coded, and verified

Response

- 37 of the 64 CTSAs responded (57.8% response rate)
- No significant differences in characteristics in table below between two groups

	Respondents N=37	Nonrespondents N=27
Average direct costs, FY 2017 (Standard deviation) Median direct costs, FY 2017	$5,046,681 ($4,204,250) $3,639,047	$4,554,762 ($2,104,093) $3,829,500
Census Regions		
West	21.6%	18.5%
Midwest	29.7%	14.8%
South	24.3%	37.0%
Northeast	24.3%	29.6%
Average number of years as a CTSA (Standard deviation)	9 (2)	9 (3)

Support for D&I research activities

- About half report directly funding each of the 3 types of D&I research activities; Indirect support is higher
- Five CTSAs reported no direct or indirect D&I activities

	D&I Research Program/Resource * N (%)	D&I Research Training/Workforce Development N (%)	D&I Scientific Research Projects** N (%)
Direct CTSA funding (n=37)	19 (51.4%)	30 (54.1%)	33 (59.5%)
Indirect CTSA support (n=37)	26 (70.3%)	24 (64.9%)	21 (56.8%)

	Supporting 3 D&I research activities N (%)	Supporting 2 D&I research activities N (%)	Supporting 1 D&I research activities N (%)	Supporting 0 D&I research activities N (%)
Direct CTSA funding (n=37)	14 (37.8%)	8 (21.6%)	4 (10.8%)	11 (29.7%)
Indirect CTSA support (n=37)	17 (45.9%)	7 (18.9%)	7 (18.9%)	6 (16.2%)

What are some of the challenges or barriers you've encountered in developing and supporting D&I science activities within your CTSA?

- Results shown in Table 4 of report
- Funding was the top barrier cited by 39.4% of respondents. Reported funding barriers included lack of funding to protect faculty time for working on D&I programs, limited funds for pilot studies, and fewer external grant opportunities for D&I research.
- Several CTSAs (30.3%) mentioned the limited number of faculty adequately trained to lead D&I programs and training, and to mentor young investigators interested in D&I science.
- Some CTSAs (27.3%) commented that faculty have a lack of understanding of D&I science and the resources available, as well as noted a perception that D&I science is not a well-defined area and thus more difficult to fit into CTSA programs.

How to help CTSAs support researchers to include dissemination and implementation research activities across all phases of research (excluding funding)

- Results shown in Table 5 of report
- A majority of respondents (63.4%) noted the importance of D&I training activities, especially in D&I methods and best practices, as well as in how D&I science can contribute to research across the translational spectrum.
- Growing the D&I workforce (30.3%), in particular mentors, was another important strategy for helping CTSAs support researchers to include D&I research activities within all phases of translational research.
- National coordination across CTSA D&I programs (24.2%), tools and resources to support use of best practice D&I science methods (21.2%), and consultation services (12.1%) were related strategies for supporting researchers to include D&I science in their research.

CTSA Consortium services and resources that can be used strategically to support D&I research

- Results shown in Table 5 of report
- One-third of respondents expressed that the CTSA program could more strategically coordinate D&I activities across CTSAs hubs and support collaboration among hubs.
- Several cited the need to create a compendium of educational materials and to provide trainings (27.3%) as well as to have D&I resources and tools (24.3%) for CTSAs to share widely at their institutions.

Implications

- Top resources needed to overcome challenges and barriers include a robust D&I-experienced workforce supported by training materials and tools, as well as well-coordinated D&I activities across the CTSA Consortium.
- There is a reported lack of understanding of D&I science across the CTSA Consortium, suggesting that D&I scientists have work to do in communicating the value of D&I science to the translational science community.
- The CTSA National Program is recognized as having an important role to play in supporting collaborative D&I activities.

D&I Environmental Scan

Step 2: In depth survey of D&I activities

- Survey of the 37 CTSAs that responded to the PI survey and 6 additional CTSAs with Workgroup members
- Asked to provide detail on their D&I resources and services, training, and scientific projects.
  - 34 of the 43 have responded
  - Survey closed on March 31
  - Plan: Analyze data, share information in usable format

Other D&I workgroup projects

- Pilot test of D&I metrics → revision to simpler metrics
- D&I webinar June XX, 2018
- D&I consultation form review from several institutions → CTSA administrative supplement to develop common D&I consultation form (recently awarded)
- Publication of PI survey results and the in-depth D&I environmental scan
- JCTS supplement on D&I science (in development)

Questions?