



2022 eSource Symposium
Where is Your Healthcare Data?
**The Silos of Healthcare, Clinical Research and Public
Health Data**

15 November 2022

Rebecca D. Kush, PhD

Moderator

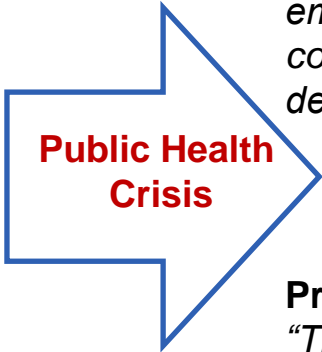
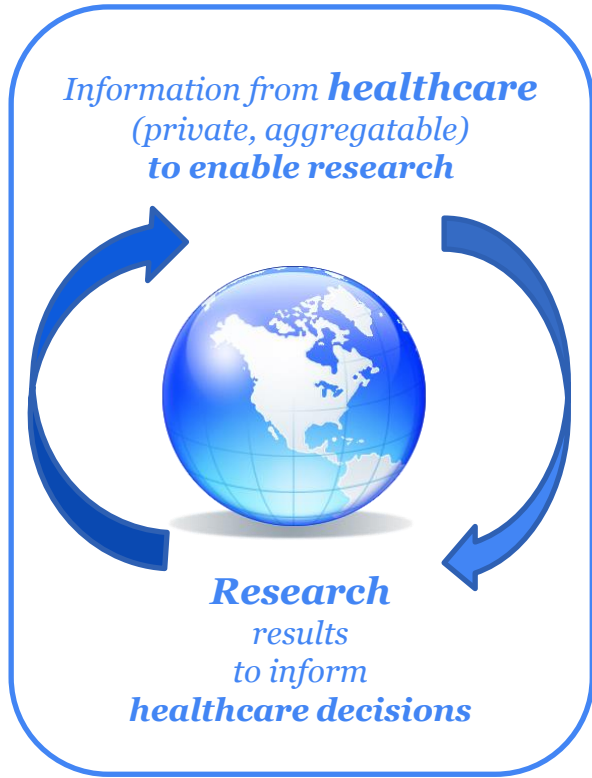


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Dr. Kush is the Founder and President Emeritus for CDISC, President of Catalysis and Chief Scientific Officer, Elligo Health Research. She is a founding director on the Board of the Learning Health Community and Chair of the Vulcan Advisory Council.

Dr. Kush has ~40 years of experience in the area of clinical research and related technology and standards, including positions with the U.S. National Institutes of Health, academia, a global CRO and biopharmaceutical companies in the U.S. and Japan. She led CDISC for 20 years and has served on boards for HITSP, DIA, CDISC, NCI and HL7 and was appointed to the U.S. HIT Standards Committee for 5 years.



New York Times (13 July 2020)

*“Before public health officials can manage the pandemic, they must deal with a broken data system that sends incomplete results in formats they can’t easily use.....**Health departments track the virus’s spread with a distinctly American patchwork:** a reporting system in which some test results arrive via smooth data feeds but others come by phone, email, physical mail or fax... These reports often come in duplicate, go to the wrong health department, or are missing crucial information...”*

Protocol (7 July 2020)

*“The COVID-19 crisis laid bare all the ways that EHRs have fallen short—and what needs to be done....as with any systemic problem, there are endless root causes. One of them it the **lack of uniform standards for how data is entered into EHRs to begin with.**”*

Sharing (Your) Data Across Silos



Consensus document on providing access to individual participant data (IPD) from clinical trials

Received: 13 July 2020 | Revised: 2 November 2020 | Accepted: 17 November 2020

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TECHNICAL REPORT

Learning Health System

Addressing the Covid-19 pandemic and future public health challenges through global collaboration and a data-driven systems approach

Francisco Ros¹ | Rebecca Kush² | Charles Friedman³ | Esther Gil Zorzo⁴ | Pablo Rivero Corte⁵ | Joshua C. Rubin³ | Borja Sanchez⁶ | Paolo Stocco⁷ | Douglas Van Houweling³





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Joshua C. Rubin, JD, MBA, MPH, MPP **President and CEO, Learning Health** **Community**



Josh Rubin is the Program Officer for Learning Health System Initiatives at the University of Michigan Medical School Department of Learning Health Sciences. He also serves as Executive Director of the Joseph H. Kanter Family Foundation, the only philanthropic foundation founded by a patient whose overarching mission is to realize a patient empowering Learning Health System vision.

Previously, Rubin served as Senior Policy Fellow at eHealth Initiative and as Senior Consultant at IBM Global Business Services. He serves as the founding President and CEO of the Learning Health Community, a multi-stakeholder grassroots movement dedicated to realizing the Learning Health System vision on a national (and ultimately global) scale.



LEARNING HEALTH COMMUNITY

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Core Values of the Learning Health System

 1) Person Focused	 2) Privacy
3) Inclusiveness 	4) Transparency 
 5) Accessibility	 6) Adaptability
7) Governance 	<small>Cooperative & Participatory</small> 8) Leadership 
 9) Scientific Integrity	 10) Value

<https://lillypad.lilly.com/entry.php?e=8284>



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Rhonda Facile, VP, Partnerships and Development, CDISC



Rhonda Facile has over 25 years of clinical operations and standards development experience. She has worked in a global CRO, pharmaceutical and biotech companies in the United States and abroad. She has experience in clinical trial monitoring, project management, regulatory affairs, and standards development.

During her career at CDISC Rhonda has led numerous standards development projects and initiatives, including CDASH, devices and therapeutic area guides. Most recently, she led the CDISC RWD Connect project and spearheads CDISC's RWD activities. She has raised signification funds for CDISC development projects.

Vaccine Administration v1.0 – Mapping Curation

Rationale & Goals

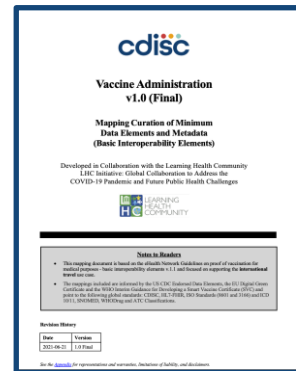
- Use case – International Travel
- Urgent need - global COVID-19 pandemic
- Support emerging applications with an international data standard for interoperability of core data elements and underlying metadata related to vaccine administration
- Harmonize a set of core vaccine administration data elements
- Deliver a short readily implementation standard that leverages and maps to **available** and widely used data standards and terminologies
- No new standards
- Follow endorsed governance process.

Activities

- Harmonize a set of 20 core elements
 - Based on European eHealth Network – Guidelines for proof of vaccination for medical purposes - basic interoperability elements*
- Align with:
 - US CDC Endorsed Data Elements
 - Digital Green Certificate
 - WHO Interim Guidance for Developing a Smart Vaccine Certificate (SVC)
- Map/point to:
 - CDISC
 - HL7-FHIR
 - ISO Standards
 - ISO 8601
 - ISO 3166
 - IDMP
 - ICD 10/11
 - SNOMED CT
 - WHODrug
 - ATC Classification
- Develop a CDISC Vaccine Administration v1.0 Guide and mapping spreadsheet

Core Data Elements*

- **Vaccination Information**
 - Disease or agent targeted
 - Vaccine/Prophylaxis
 - Vaccine medicinal product
 - Marketing Authorization Holder
 - Manufacturer
 - Number in a series of vaccinations/doses
 - Batch/lot number
 - Date of Vaccination
 - Administering center
 - Health Professional identification
 - Country of vaccination
 - Next vaccination date
- **Patient Identification Information**
 - Person Name: First and last
 - Person Identifier
 - Sex/Gender
 - Date of Birth
- **Certificate Metadata**
 - Certificate issuer
 - Certificate Identifier
 - Certificate Valid from
 - Certificate Valid until





Vaccine Administration v1.0

Mapping Curation of Minimum Data Elements and Metadata



Vaccine Administration V1.0 is a powerful data mapping solution created to connect diverse travelers, security officials, and application solutions providers with global vaccine entry requirements.

As countries around the world reopen, the increase in international travel is creating confusion and delays due to inconsistent vaccine regulation and status. Differing regulations for each country create confusion for travelers who must sort through different sets of vaccine status entry rules. Once they arrive at the airport, these travelers are increasingly met with delays due to long lines as airline personnel work to process additional vaccine-related paperwork. The difficulties continue as new variants of the COVID-19 virus emerge globally.

Version 1.0 of the Vaccine Administration: Mapping Curation of Minimum Data Elements maps existing international standards to facilitate interoperability of data and metadata related to vaccine administration.

The goal is to achieve a multinational agreement around one global core data standard that will enable the success of various vaccine credentialing and vaccine 'passport' applications to foster rapid and comprehensible sharing of essential information for uses such as safe international travel. Security, validation, and privacy remain the responsibility and expertise of the technology developers and implementers.

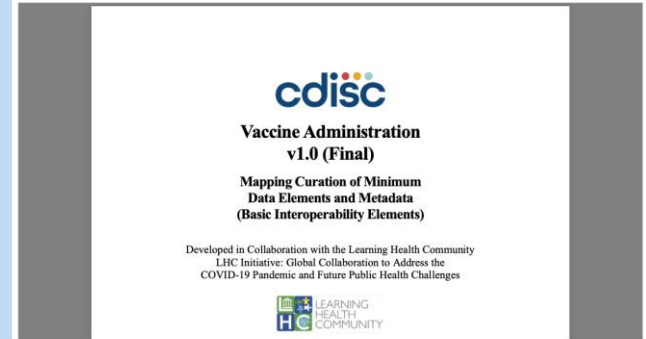
Clear data.
Clear impact.



Files

Vaccine Administration v1.0 provides direction on how to define and organize data elements by delivering metadata that enables machine readability, data sharing, and semantic interoperability, with the added benefit of facilitating the flow of data for submission to global regulatory authorities.

The standard and metadata are free to download and implement. Security, validation, and privacy remain the responsibility and expertise of the technology developers and implementers.



[Vaccine_Administration_v1.0_Final](#) [Download](#)

[Vaccine_Administration_Metadata](#) [Download](#)

CDISC posts [Public Review](#) comments and resolutions to ensure transparency and show implementers how comments were addressed in the standard development process.

[Vaccine_Administration_v1.0](#) information available on the CDISC Website.

<https://www.vaccineadministration.org>



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Sagar Anisingaraju, Strategic Advisor to Saama Technologies.



As Chief Strategy Officer for Saama Technologies, Sagar architected and built its transformational journey, helping the company raise funding from global PE firms and Pharma. Saama's unique growth story was studied and published as a Case Study by Kellogg Business School.

Sagar is passionate to help biopharma create intelligent analytical solutions to operationalize insights and solve drug development challenges.

Sagar has received the following awards and honors:

- 2020 Pharma Voice 100: Recognized as one of the "100 Most Influential People in the Healthcare Industry."
- 2019 PM360 ELITE: Recognized in Strategist category of ELITE (Exceptional Leaders Innovators Transformers Entrepreneurs) award.
- 2013 Innovation Enterprise: Recognized with Chief Strategy Officer of the Year Award.

Sharing of Data & Insights -- Relevance of Technology

1. Data Sharing

Clinical research data across therapeutic areas and industry today stays in multiple silos. We have to address this problem both within a company and across the industry.

- **Within a company:** Companies should implement data platforms to enable seamless access to clinical research data across multiple functional team silos. Robust, secured technology already exists today to implement enterprise wide Clinical Data Hubs. Internal data governance rules and centralized security controls should allow for data flows across functional usage from pre clinical to development to commercial.
- **Across the industry:** Sharing of clinical data across the industry for broader good is a bigger challenge. While CT.Gov and other open publications are a good start, the quality and fidelity of the data is not adequate for meaningful usage. Technology can provide some innovative models here to accelerate higher quality data sharing. By providing clear incentive models for pharma to share their proprietary data sets across the industry. One example is a **Clinical Innovation Coin** which improves its value as more companies utilize the shared data. A blockchain enabled reference architecture can be the backbone for this sharing.

2. Insights Sharing

- **Lack of Standards:** Sharing of valuable insights that pharma learns from each study with their peers and competitors is still in infancy. There are neither adequate standards for sharing insights other than publications nor any incentive for pharma to share. Repetitive mistakes and errors across other studies by the industry are the natural consequences of these proprietary ownership of clinical insights.
- **Clinical Research In a Chip:** We will see more and more companies adopting AI models for various aspects of clinical data management. Example, Saama's SDQ. The high quality insights that companies learn from each study using these AI Systems is often a blackbox to other studies. There is a need to standardize these model definitions, governance and sharing of model parameters across TAs and industry for federated learning. Today's modern computers are not built from scratch. Why should every clinical study be unique and built from scratch? Building blocks of prior clinical research in a chip to take hardware metaphor is the need of the hour for accelerated drug development. Regulators, academic institutions and pharma should fund initiatives to build such clinical research building blocks.

Sharing of Experiences

Concept of Total Experience (Tx) for Healthcare

- **What is Total Experience or Tx?**
 - Tx is a summation of customer experience, employee experience, user experience & multi-experience (a seamless digital experience across every platform and channel)
- **What is Total Experience for Healthcare?**
 - Tx for Healthcare is a strategy that gives seamless user experience, and uses the experience insights from patients, employees and machines across touchpoints and timelines to design & provide superior healthcare. For example, the clinical data managers in a pharma can share their experiences with Principal Investigators of a study to prevent data errors at inception. Tx allows for those connections in a digital metaverse.
- **Benefits of Tx for Healthcare:**
 - Think of this as an intelligent Yelp for healthcare. Patients share their experiences, be it in a clinic for treatment or for participating in a clinical research. Similarly employees or care providers share their side of the encounter experiences. AI enabled technology connects the relevant pieces of these shared experiences and builds cause and effect summaries. Superior systems will be designed from these shared experiences summaries to prevent repetition of unwanted episodes.



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Matthew Cowperthwaite, PhD
VP, Data Sciences
Elligo Health Research



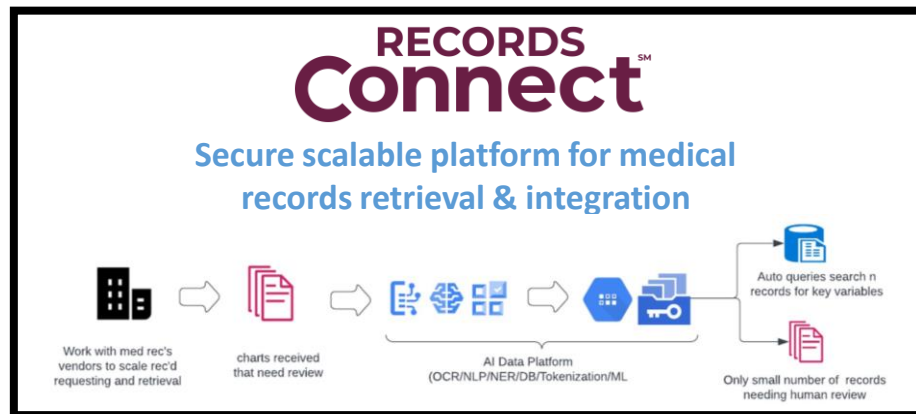
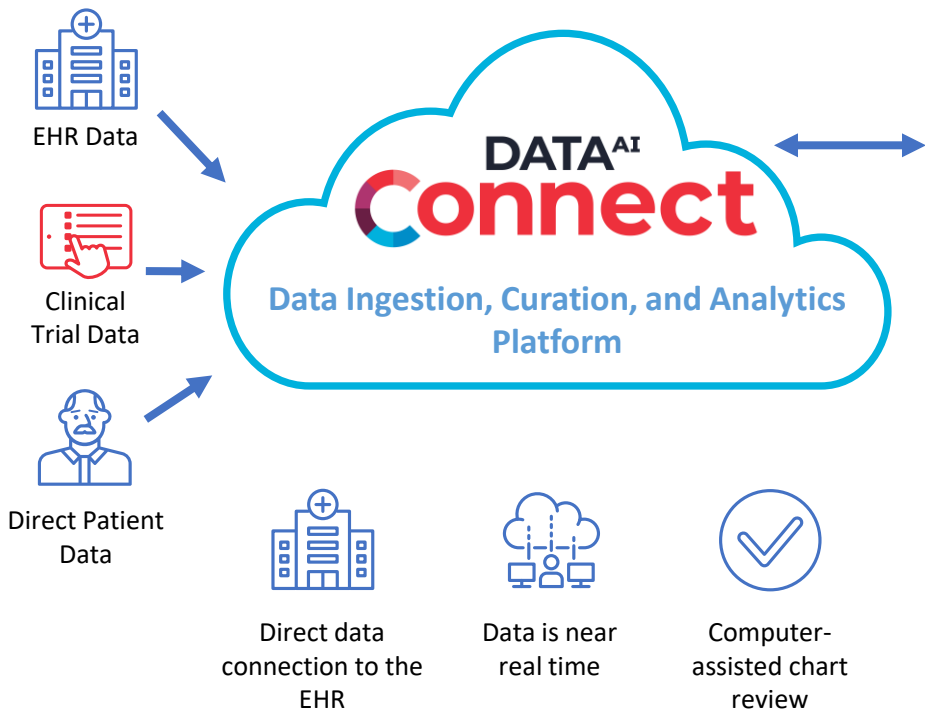
In this role at Elligo, Dr. Cowperthwaite leads key areas of Elligo's data science operations including building ML/AI platforms, advanced analytics, engineering data architectures, and creating data partnerships. Prior to his current role, Dr. Cowperthwaite was the Director of Research at St. David's HealthCare (an HCA health system) for 13 years where he led roles of increasing responsibility in the development of a neuroscience research institute and an umbrella human research protection program.

Dr. Cowperthwaite's PhD is from the University of Texas at Austin in Cellular and Molecular Biology. Under the supervision of Dr. Lauren Ancel Meyers, his dissertation research focused on mathematical modeling, computer simulations, and bioinformatic studies of naturally and artificially evolved model systems.

Bridging Research and Healthcare Data



Elligo is reducing the friction of acquiring and using RWD data from healthcare institutions for clinical trials.



Applications

- Protocol Feasibility Assessment
- Population Health
- Rapid Patient Identification
- Advanced Analytics
- Algorithmic Monitoring
- Reconstruct Patient Journey

Kaci Sykora

MS in Health Care Informatics

COO, Learning Health Community



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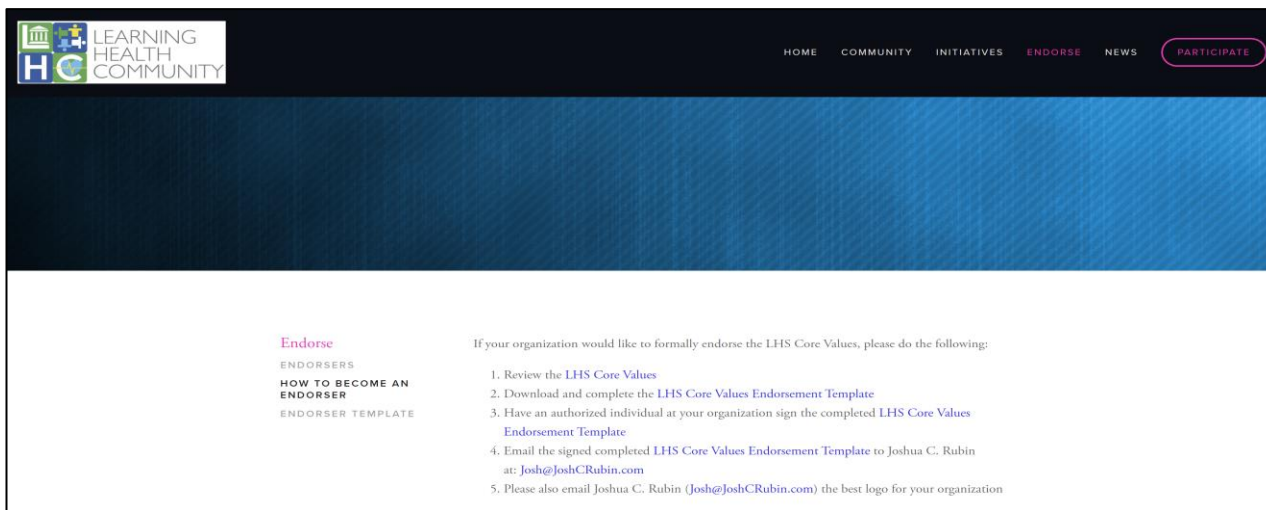


Thank you, Kaci!

Please see www.learninghealth.org.

Slides will be posted here after the Symposium. You can also endorse the LHC Core Values.

<http://www.learninghealth.org/how-to-become-an-endorser>



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**HOW TO BECOME AN
ENDORSER**
ENDORSER TEMPLATE

If your organization would like to formally endorse the LHS Core Values, please do the following:

1. Review the [LHS Core Values](#)
2. Download and complete the [LHS Core Values Endorsement Template](#)
3. Have an authorized individual at your organization sign the completed [LHS Core Values Endorsement Template](#)
4. Email the signed completed [LHS Core Values Endorsement Template](#) to Joshua C. Rubin at: Josh@JoshCRubin.com
5. Please also email Joshua C. Rubin (Josh@JoshCRubin.com) the best logo for your organization