

Society for Clinical Data Management (SCDM) eSource Implementation Consortium

2019 Face to Face
Meeting

14 October 2019
Peapack, NJ



Society for Clinical Data Management
DATA DRIVEN

SCDM © 2019

Agenda

8:00 AM-8:10 AM: **Welcome/Goal of the Meeting: Linda King**, Astellas Pharma, SCDM Chair

8:10-8:20 **Kick-Off: Demetris Zambas**, Pfizer Inc., Global Head Data Monitoring and Management

8:20-8:30 **Introductions, Roles, Expectations: Mike Buckley**, MSKCC, [SCDM eSource Implementation Co-Chair](#)

8:30-9:00 **Read out of HL7 9/15 eSource Thought Leader Meeting, Rakesh Maniar**, Novartis, Inc., [TransCelerate BioPharma, Inc. \(TCB\)](#), [eSource Initiative Co-Lead](#), SCDM eSource Implementation Co-Chair

9:00-9:30 **Where Do We Fit? Review of Current and Planned Deliverables** for TCB, [Biomedical Research and Regulation Working Group](#) (BR&R), [Health Level Seven International](#) (HL7), and SCDM
TCB Perspective: Rakesh Maniar
SCDM eSource Perspective: Mike Buckley
BR&R Perspective: Amy Nordo, Pfizer Inc, [HL7 Clinical Interoperability Council](#) (CIC) Co-Chair

9:30-10:00 **Break and Group Picture**

10:00-11:00 **2019 Three Tracks Review: Linda King**

State 1A: eLabs White paper, Hugh Dai, Eli Lilly, Inc.

State 1B: Tech workstream: FHIR + MSKCC + Pfizer Amy Nordo, Pfizer, Inc., HL7 CIC Co-Chair

State 2: Future State Leveraging HL-7 BR&R Implementation Guide: All

11:00-12:00 **2020 Road Map, Wrap Up and Action Items, Rakesh Maniar**

12:00- 1:00 **Lunch**

Current Steering Committee Membership Roster



Welcome!!!

Sponsors

Novartis
Merck
Eli Lilly
Bristol Myers Squibb
Pfizer

Technology Vendors

Advarra Forte

Sites

MSKCC
Yale School of Medicine
Duke University School of Medicine
Washington University- St. Louis,
School of Medicine

***University of Manchester, UK
(under discussion)***

Standards Development

Organizations

HL7
CDISC (under discussion)

Welcome and Goal of Our Meeting

Linda King, SCDM Chair, Board Liaison to Consortium (Astellas Pharma)



Consortium Vision

- Leading biopharmaceutical companies, academic medical centers, and healthcare technology providers have partnered to create an eSource Implementation Consortium (Consortium) with the **vision** of enabling a faster and more efficient digital exchange of clinical research source data from academic medical sites to industry sponsors, through Electronic Health Records (EHR) to Electronic Data Capture (EDC) and Clinical Data Management Systems (CDMS). The Consortium seeks to streamline existing data transfer processes to free up site staff to focus on patient touchpoints.



Welcome and Goal of Our Meeting

Linda King, SCDM Chair, Board Liaison to Consortium (Astellas Pharma)

Consortium Mission

- The **mission** of this academic-industry eSource Implementation Consortium is to agree upon standardization of clinical research data sets that will enable faster adoption of direct data transfers by academic sites and industry sponsors. We will implement this mission by leveraging existing clinical research HL7 Fast Healthcare Interoperability Resources (FHIR) standards where available.

Welcome and Goal of Our Meeting

Linda King, SCDM Chair, Board Liaison to Consortium (Astellas Pharma)



Scope of SCDM

- **New vision and mission for the Society**
- **Expanded SCDM scope from clinical data management to clinical data science**
- **Key objectives of SCDM: Education, Thought leadership and Advocacy**
- **Increased engagement with other Societies and associations; A Connector**
- **eSource Implementation Consortium fits well with our expanded scope, vision and mission**

Our Vision: "Leading innovative clinical data science to advance global health research and development"

Our Mission: "Connect and inspire professionals managing global health data with global education, certification and advocacy"

Today's Goals

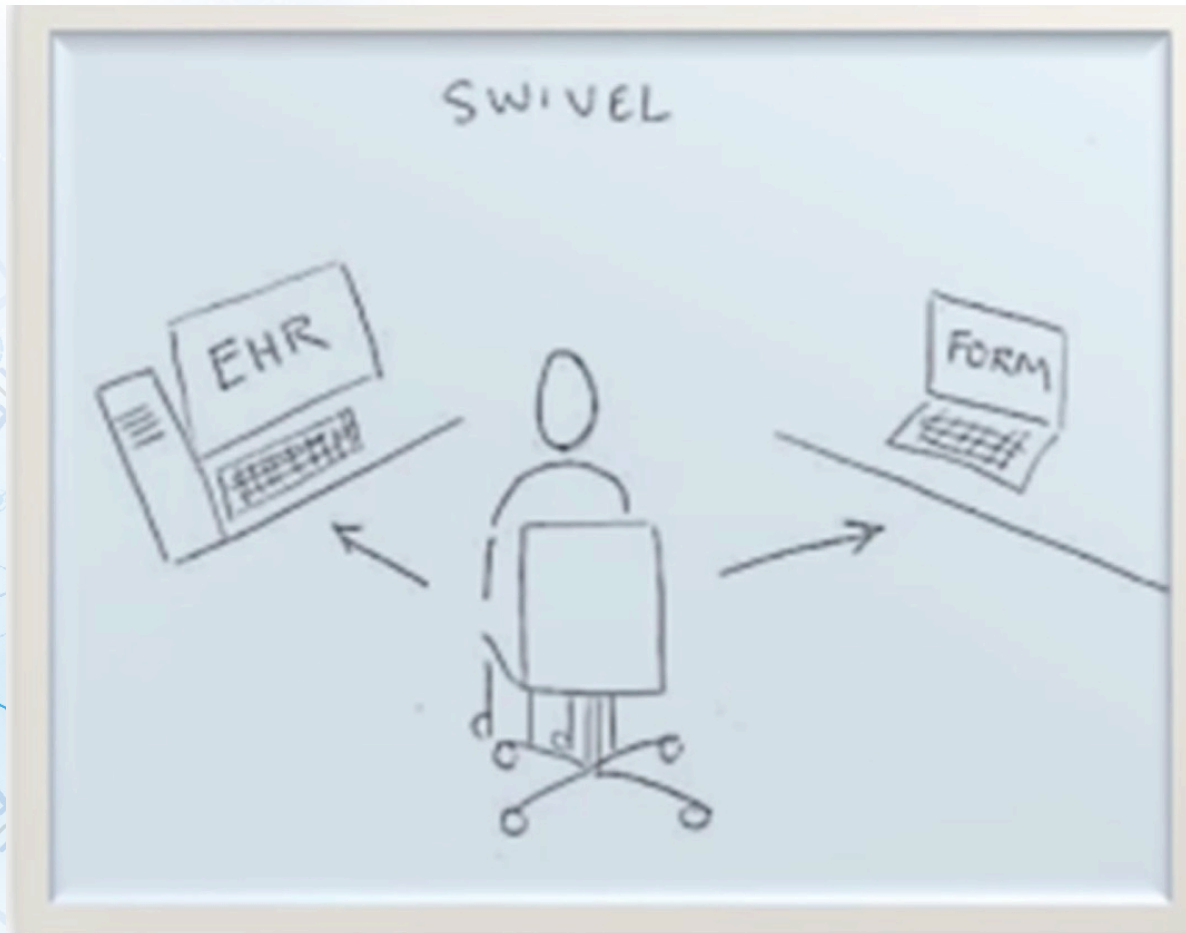


- Review current landscape and align on Consortium's opportunity
- Energize and continue to execute on leveraging our 2019 roadmap tracks using HL7 FHIR[®] for acquisition, exchange, and use of data for clinical research
- Plan our 2020 roadmap (what/who/how)

Kick-Off

Demetris Zambas

Pfizer Inc., Global Head Data Monitoring and Mgmt.



Introductions, Roles, Expectations



Mike Buckley

MSKCC, SCDM eSource Implementation Co-Chair

- Steering Committee: decision makers for our roadmap and deliverables
(*appoint deputy decision makers*)
- Harmonize across Sites, Industry and Technology Vendors
- Recruitment champions → membership
- 2019 Deliverables update
- 2020 Planning and Succession (Vice Chairs)

eSource Implementation Consortium 2019 Workstreams

WORKSTREAM	LOCAL LABS State IA Flat File Xfers.	LOCAL LABS State IB FHIR Exchange	LOCAL LABS State II Future State HL7-BR&R
TEAM LEAD & DUE DATE	Team Lead: H. Dai • Q1: use in dev. • Q2: use in production • Paper: Q2	Team Lead: M. Koch/Amy Nordo • Q2-Q3: POC • Q3-Q4: use in prod. • Guide: Q3-Q4	• Q2: Analysis phase • Q3: use in dev. • Q4: use in production
DELIVERABLE	• Implementation Guide or Best Practices paper • Use in production	• Implementation Guide, Best Practices paper	
RESOURCE MEMBERS	• Lilly: H. Dai • MSK: M. Buckley • NVS: R. Maniar	• MSK: M. Koch • NVS: A. Vattikola + DM and IT staff • Pfizer: A. Nordo, M. Cherry • Lilly: Hugh Dai	
KNOWLEDGE REQUIREMENTS	• Use of flat file xfers. • Desire and resources to implement	• FHIR experience • Standards creation • Know how a restful API works • Desire and resources to implement	

Read out of HL7 9/15 eSource Thought Leader Meeting



Rakesh Maniar,

Novartis, Inc., TransCelerate BioPharma, Inc. (TCB), eSource Initiative Co-Lead,
SCDM eSource Implementation Co-Chair

Amy Nordo, MMCI, BSN CPHQ, HL7 CIC Co-Chair

Pfizer, Inc.



HL7FHIRADVANC
RESEARCH_ATLAN

Reflections from attendees

Shannon Roznoski

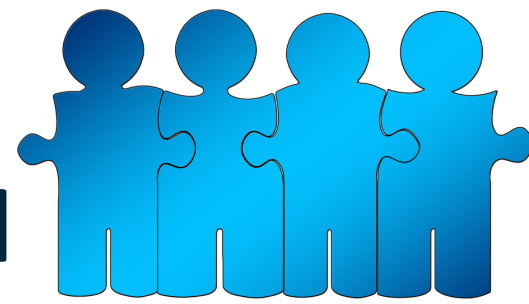
Aruna Vattikola

Mike Buckley



Where Do We Fit?

Review of Current and Planned Deliverables



TransCelerate Biopharma (TCB): Rakesh Maniar

SCDM eSource Implementation Consortium: Mike Buckley

Biomedical Research and Regulation (BR&R) Working Group: Amy Nordo

TCB Perspective

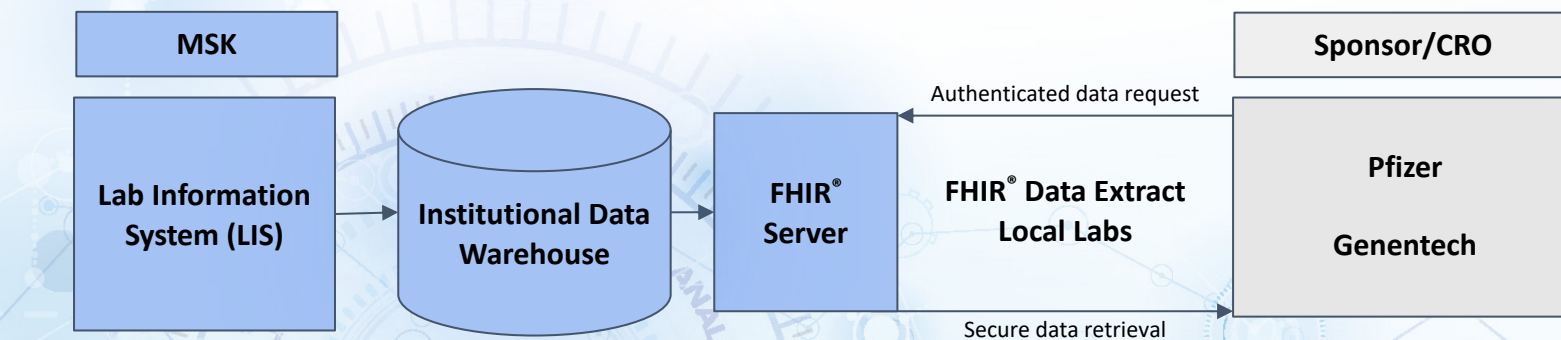
Rakesh Maniar, Novartis, Inc., TCB eSource Initiative Co-Lead, SCDM eSource Implementation Co-Chair



Adobe Acrobat
Document

Current Work Streams with HL7 FHIR®

WORKSTREAM 1



WORKSTREAM 2

Vendor discussions for two sponsored protocols

BR&R Perspective



Amy Nordo

Pfizer Inc.

HL7 Clinical Interoperability Council (CIC) Co-Chair

- **Lab Implementation Guide**
- **Adverse Event Reporting**
- **FHIR to BRIDG**



Break and Group Picture



2019 Three Tracks Review

Linda King, SCDM Chair, Board Liaison, Astellas Pharma

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State 1A: eLabs White paper

Hugh Dai, Eli Lilly, Inc.



eLab Whitepaper

Local Lab Solution

October 14, 2019

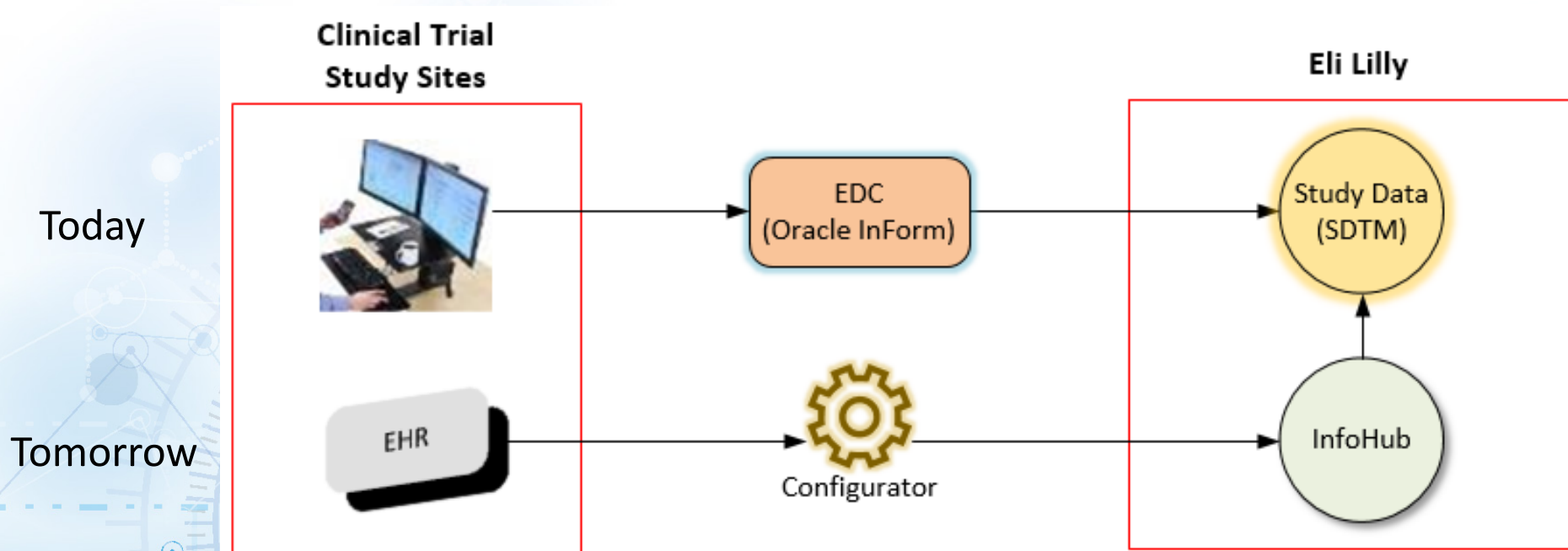


Lilly


Objectives

- “Think Big, Start Small, Learn Fast”
- Share experiences and outcomes
- Privacy and security considerations
- Flat file transfer – Pro/Con
- Sample technology and template

Transformation



eCRF local lab collection example

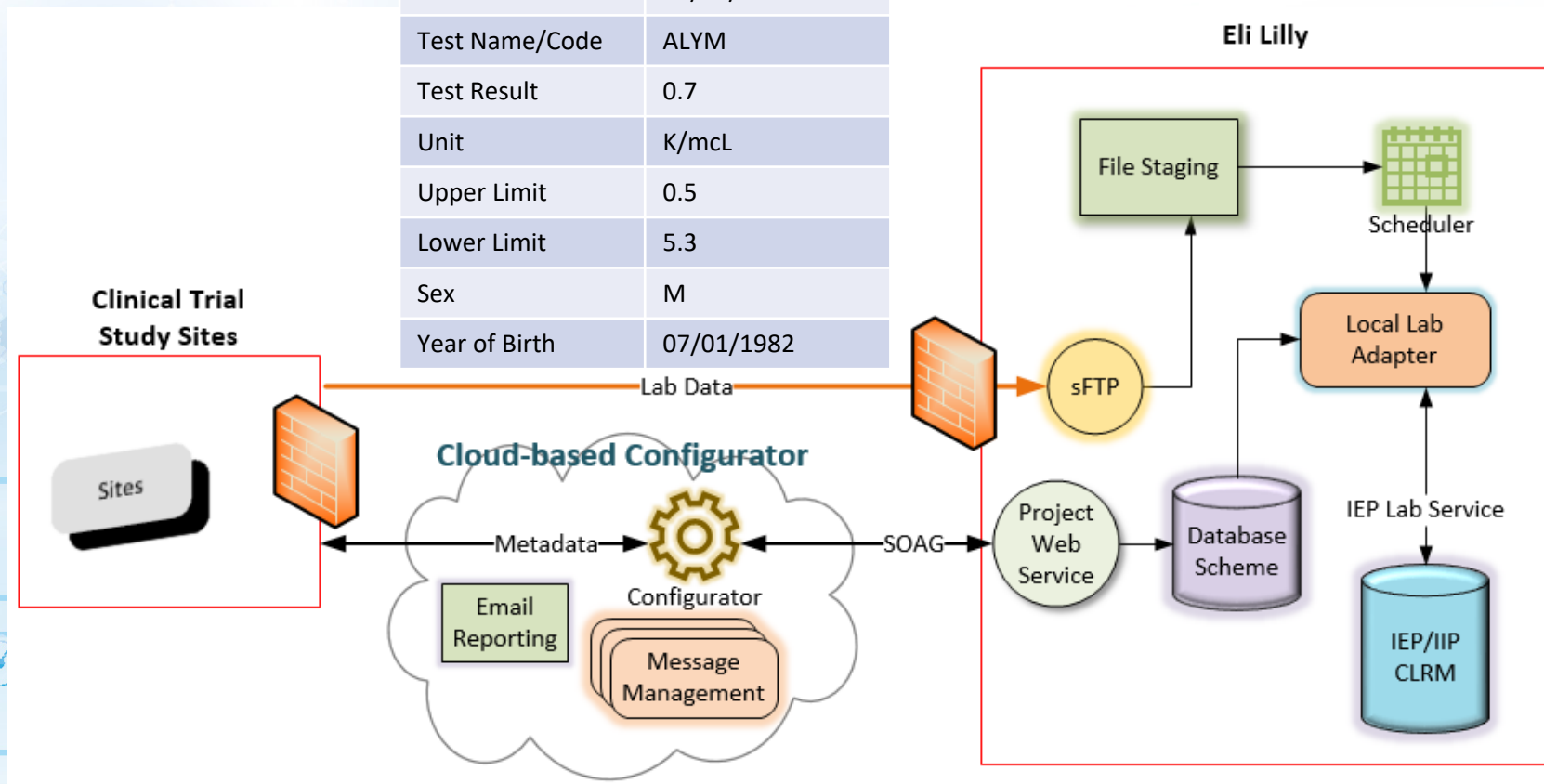
Hepatic Monitoring Tests		
1.	Lab Sequence Identifier	
2.*	Was the lab performed?	<input type="radio"/> No <input type="radio"/> Yes
3.	What was the lab specimen collectic	<input type="text"/> / <input type="text"/> / <input type="text"/> 
4.	Bilirubin Results	<input type="radio"/> Not Done <input checked="" type="radio"/> What was the result of the test? <input type="text"/> What were the units for the result? <input checked="" type="radio"/> Microgram per Milliliter <input type="radio"/> Milligram per Deciliter <input type="radio"/> Micromole per Liter What was the lower limit of the reference range for this test? <input type="text"/> What was the high limit of the reference range for this test? <input type="text"/>
5.	Direct Bilirubin Results	<input type="radio"/> Not Done <input type="radio"/> What was the result of the test? <input type="text"/> What were the units for the result? <input type="radio"/> Microgram per Milliliter <input type="radio"/> Milligram per Deciliter <input type="radio"/> Micromole per Liter What was the lower limit of the reference range for this test? <input type="text"/> What was the high limit of the reference range for this test? <input type="text"/>

Available: Well-formatted data source

SiteID	SubjectID	SiteName	ResultDate	ResultTime	TestCode	TestName	Result	Unit	LowerLimit	UpperLimit
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303671	UBLD Blood	NEGATIVE			
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303671	UGLUC Glucose	NEGATIVE	mg/dl		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303671	UKET Ketone	NEGATIVE	mg/dl		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303671	LEU Leukocyte Esterase	SMALL			
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303671	UALB Protein	NEGATIVE	mg/dl		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303671	USPG Specific Gravity	1.016	1.003 1.03		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303671	UPH pH	5.5	4.6 7		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	ABAS Absolute Basophil	0.1	K/mcL 0 0.2		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	AEOS Absolute Eosinophil	0.2	K/mcL 0 0.8		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	ALYM Absolute Lymphocyte	0.7	K/mcL 0.5 5.3		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	AMON Absolute Monocyte	0.4	K/mcL 0 1.3		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	ANEUT Absolute Neutrophil	4.7	K/mcL 1.5 8.8		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	HCT Hematocrit	34.5	% 34 46		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	HGB Hemoglobin	10.5	g/dL 11.5 16		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	MCV Mean CORPUSCULAR Volume	82	fL 82 98		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	MCH Mean Corpuscular Hemoglobin	24.8	pg 27 33		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	MCHC Mean Corpuscular Hemoglobin Concentration	30.4	g/dL 31 36.5		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	UNVPLT Platelets	186	K/mcL 160 400		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	RBC Red Blood Cell	4.23	M/mcL 4 5.2		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	RCDW Red Cell Distribution Width	16.5	% 11.5 14.5		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303662	WBC WBC	6	K/mcL 4 11		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303663	PALT Alanine Aminotransferase (ALT), Plasma	7	U/L 5 37		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303663	PALB Albumin, Plasma	3.9	g/dL 4 5.2		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303663	PALK Alkaline Phosphatase (ALK), Plasma	77	U/L 45 129		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303663	PGOT Aspartate Aminotransferase (AST), Plasma	32	U/L 10 37		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303663	PBUN Blood Urea Nitrogen, Plasma	10	mg/dL 6 20		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303663	PLCA Calcium, Plasma	10	mg/dL 8.5 10.5		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303663	PLCL Chloride, Plasma	98	mEq/L 98 109		
001	1002	(---) Memorial Sloan Kettering Cancer Center	3-Jun-15	9:17	15060303663	PLCO2 CO2, Plasma	31	mEq/L 24 30		

Data Flow

Variable	Sample Value
Site ID	002
Study ID	724
Subject ID	1005
Test Date	02/15/2015
Test Name/Code	ALYM
Test Result	0.7
Unit	K/mcL
Upper Limit	0.5
Lower Limit	5.3
Sex	M
Year of Birth	07/01/1982



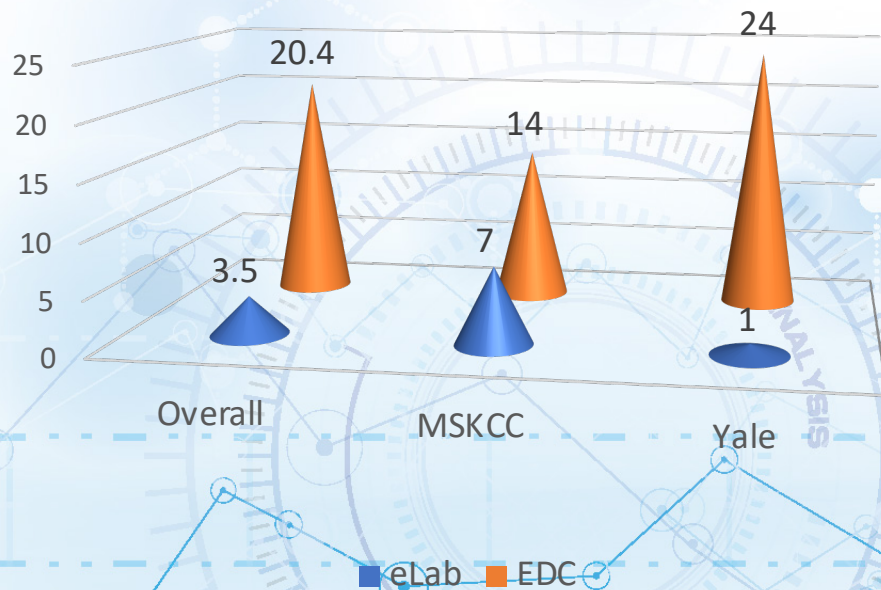
PoC Methodology

1. Two sites, seven perspective oncology studies
2. **Parallel** data collections (EDC and eLab)
3. Data collection: 6/20/17-8/18/17
4. 2,546 lab results from 6 studies / 26 patients

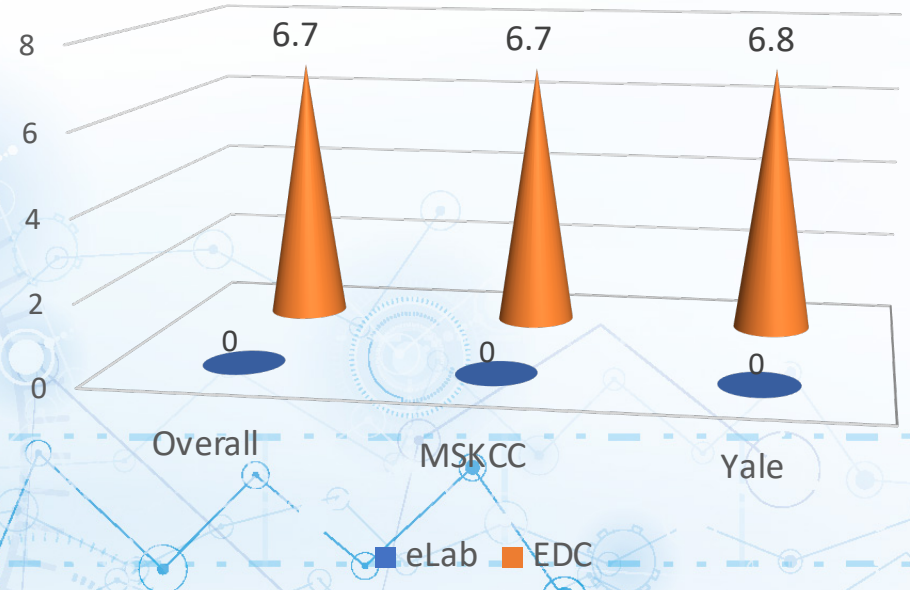
Objectives	Baseline	Goal
Connect site clinical data directly	None exist	Enable
Data availability post-visit	~25 day	< 7 days
Accuracy (data entry error)	~8%	Near 0%

PoC Outcomes

Latency (days)



Transcription Error (%)



eLab Whitepaper (Draft)

SCDM eSource Implementation Consortium.

Direct Data Extraction and Exchange of Local Labs for Clinical Research Protocols: A Partnership with Academic Medical Centers, Biopharmaceutical Companies, and Clinical Research Organizations

Introduction

Traditional industry-sponsored clinical trial data entry into Electronic Data Capture (EDC) systems, and on-site sponsor source data verification from the Electronic Health Record (EHR) is inefficient, consumes valuable site and sponsor time and effort (T/E), and can introduce errors into the dataset from manual transcription processes. To address these shortcomings, both the sponsors and trial sites have been looking for alternative venues to leverage the rich EHR data. For example Memorial Sloan Kettering Cancer Center (MSKCC) launched its eTrials Program in 2014. In coordination with major biopharmaceutical sponsors, the primary goals of the program were to avoid redundancies, reduce errors, and decrease T/E for all parties involved.

The direct data extraction (DDE) and transfer process was developed to comply with the electronic source data regulatory framework of the US Food and Drug Administration (FDA),¹ the Medicines and Healthcare Products Regulatory Agency (MHRA) GXP data integrity guide,² HIPAA, and other applicable local and state laws.

This document summarizes the collective experience of the members of the Society for Clinical Data Management eSource Implementation Consortium (SCDMeSIC), whose goal is to develop Data Exchange Specifications for core safety domains and various therapeutic areas efficacy

Discussion

State 1B: Tech workstream:

FHIR + MSKCC + Pfizer

Amy Nordo, Pfizer, Inc., HL7 CIC Co-Chair

State 2: Future State Leveraging HL-7 BR&R Implementation Guide: All



2020 Road Map

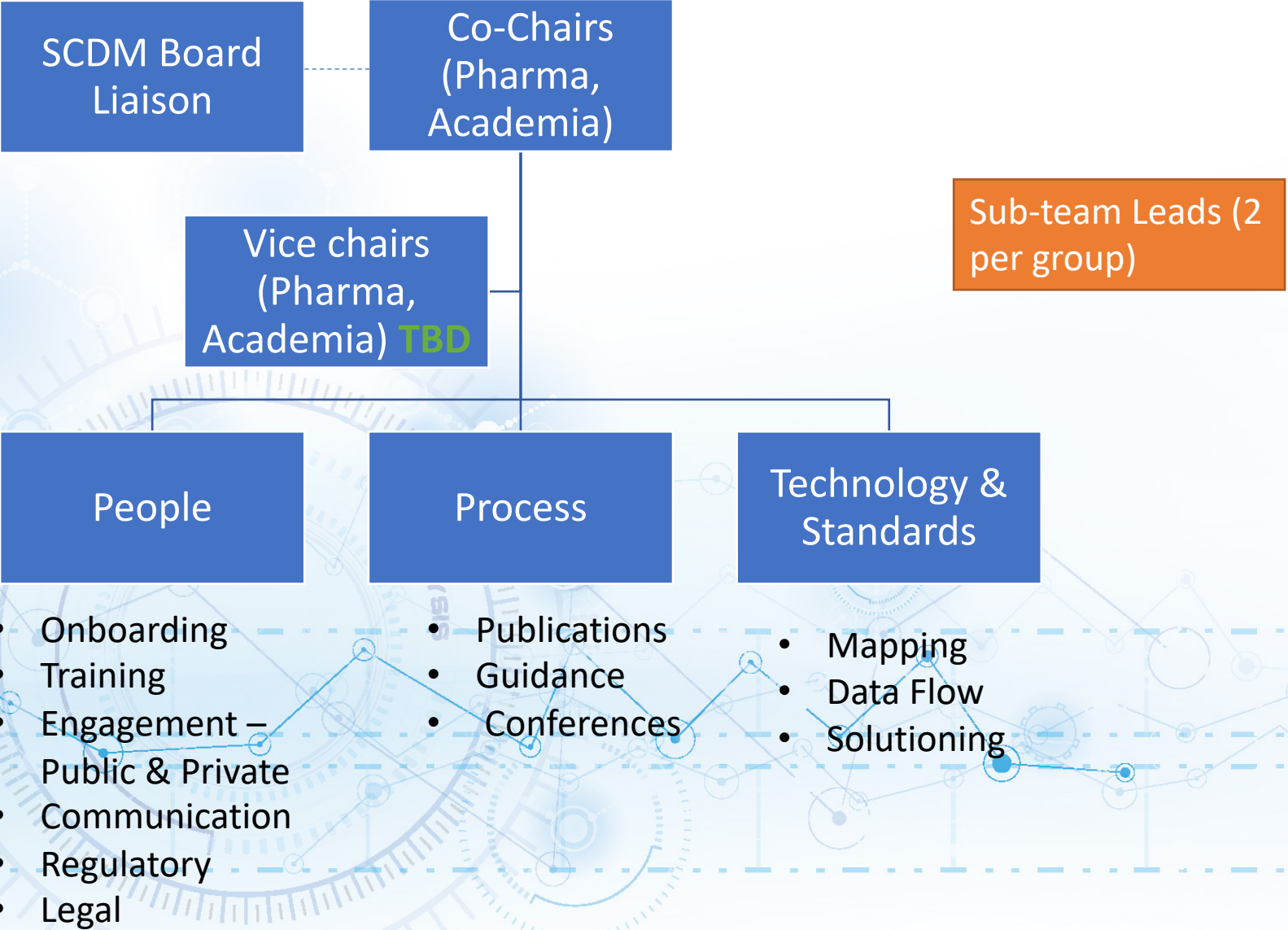
Wrap Up

Action Items



Rakesh Maniar, Novartis, Inc., TCB eSource Initiative Co-Lead, SCDM eSource Implementation Co-Chair

Team Structure (Proposed)



2020 Planning

- Identification of Consortium Vice-Chairs (Succession Planning for Mike B and Rakesh M)
- Enrollment Drive (Academia, Pharma, Regulators, CRO, Technology Vendors)
- Identification of Team Leads
- Identification of member resources to support various tracks
- Identification of conferences to present /represent
- Memorandum of Understanding - HL7 Accelerator, TransCelerate, CDISC, IMI, other
- HL7 Accelerator – Board Member AND/or SC?
- Priority Domains – Mapping & POC in consultation with HL7 Accelerator
- Deliverables – Publication – Track 1A - timing??
- Budget – SCDM ?

Lunch

