Society for Clinical Data Management
DATA DRIVEN

eSource Implementation Consortium

Progress Update

Mike Buckley (MSKCC) & Rakesh Maniar (Novartis)
Chair(s)

November 7, 2017

11 AM - 12:30 PM

FDA Building 21, RM 1537

FDA Center for Drug Evaluation and Research (CDER) Health Information Technology (IT) Board

Disclaimer

"Not all the views expressed in this presentation may be those of the individual companies or entities for which presenters/attendees are employed or affiliated. "

Attendees

Michael Buckley

Rakesh Maniar
Rajesh Modi
Vikas Adlakha (TC)
Patricia McGovern (TC)

Elsie Matthews (TC)
Mari Clovis (TC)

Wayne Kubick (TC)

Ravi Thadhani (TC)

Tesheia Johnson
Allen Hsiao

Linda King
Donald Jennings
Hugh Dai

Brett Wilson
Timothy Joy (TC)

Linda King

Yi Zhang (TC)

Denise Snyder (TC)

Agenda

1. Progress since Oct.-Nov. 2016 meeting

   Founding eSource Consortium

   First working group project milestone: Local lab data, core data set package - presented by Hugh Dai (Eli Lilly)

2. Proof of concept results: Eli Lilly local lab data transfers with MSK and Yale - presented by **Donald Jennings & Hugh Dai (Eli Lilly) and Tesheia Johnson (Yale School of Medicine**)

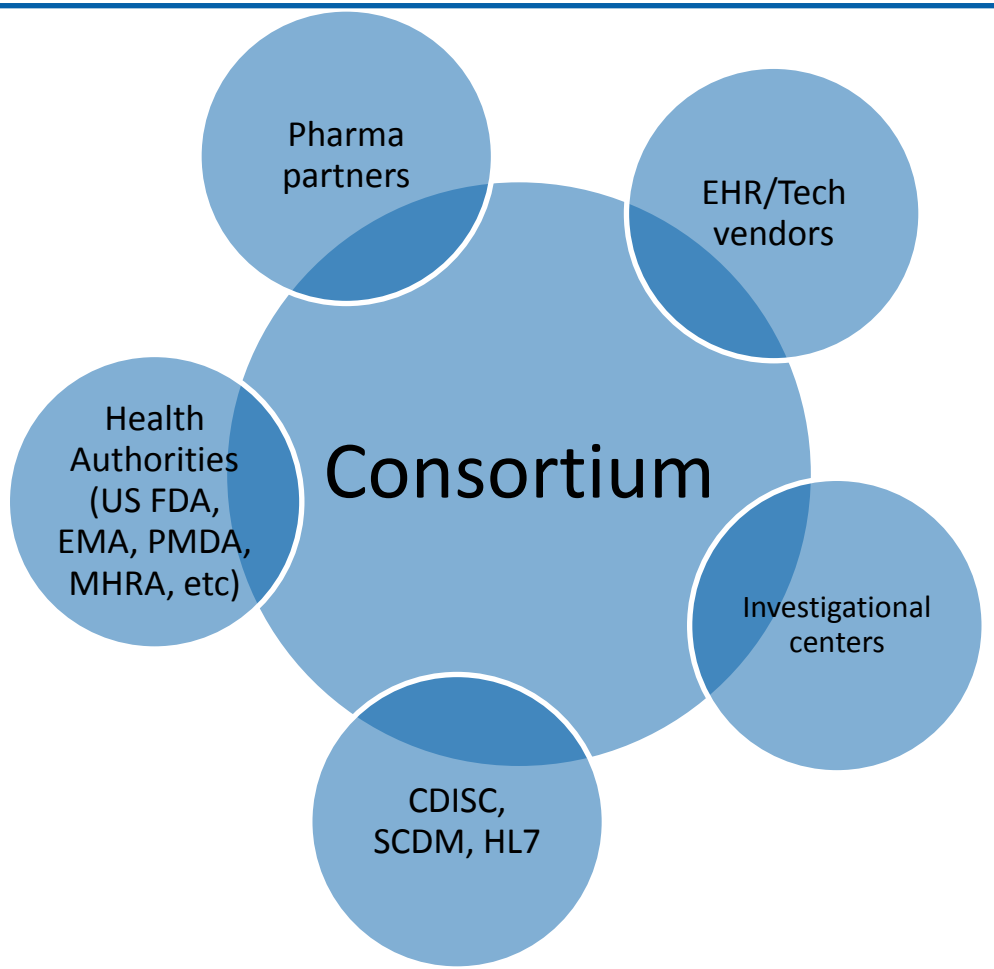
3. Next steps

Why the Consortium?

- Academic medical centers have been working with sponsors on eSource point to point solutions
- Different approaches/technologies depleted limited resources for both sites and sponsors
- Novartis/MSKCC presented to the US FDA in Oct 2016 for eSource initiatives
- Lilly/MSKCC presented to the US FDA in Nov 2016 for eSource initiatives
- MSKCC and BMS were engaged with similar objective
- Common-goal: to enable more efficient digital exchange of clinical research source data from academic medical sites to industry sponsors, through Electronic Data Capture (EDC) and /Clinical Data Management Systems (CDMS)
- Creation of Consortium involving academia, Industry, EHR /technology vendors proposed under auspices of independent body (e.g. SCDM, HL7, CDISC, etc.)
- Received positive feedback from the US FDA-CDER IT Health Board

eSource Implementation Consortium

Collaboration between Industry, academia, EMR vendors (Epic, Cerner, Fujitsu, Allscripts, etc.), Regulators (e.g. US FDA) , including other industry partners to form a Consortium under sponsorship of independent organization like SCDM, CDISC, HL7, etc.



Value Proposition

- Bring together academia and biopharmaceutical companies along with EHR vendors, academic EDC, and technology providers.
- The Consortium will establish agreed upon methods of clinical trial data transfer, define best practices that can be scaled up across the clinical research enterprise, and consistently share progress with the FDA Center for Drug Evaluation and Research (CDER) Health Information Technology (IT) Board, and other regulatory authorities.

Purpose

- Enable faster digital exchange of clinical research source data from sites to sponsors for quicker decision making - including the potential value-add to enhance patient-safety reporting processes and study oversight by allowing more near real-time access to source data, adverse events, and dosing information
- Standardize common clinical research data sets including working with EHR vendors to develop CDISC/CFAST based standard efficacy EHR templates (sponsor/academia agnostic)
- Leverage existing industrial standards for clinical research data exchange (e.g. FHIR API, SMART on FHIR)
- Share Consortium collaboration outcomes with other entities and regulatory agencies

Vision

- The eSource Consortium is comprised of the country's leading biopharmaceutical companies, academic medical centers, and industry healthcare technology providers with the vision of enabling a faster digital exchange of clinical research source data from academic medical sites to industry sponsors Electronic Data Capture (EDC)/Clinical Data Management Systems (CDMS) for faster decision making to augment Patient Safety.
- The Consortium seeks to streamline existing data transfer processes to free up site staff to focus on higher value patient touchpoints and bring efficiencies to sponsors.

Mission

- Agree upon standardization of the clinical research data set to enable faster adoption of direct data transfers by academic sites and sponsors. We action this mission by leveraging existing clinical research such exchange standards such as HL7 Fast Healthcare Interoperability Resources (FHIR) standards.

Our Progress: (1 of 3)

- MSKCC, Novartis, and Eli Lilly shared their work in this space with the US FDA CDER Health IT Board meetings in 2016. Positive feedback from the FDA CDER Health IT Board
- Recommendation to work with EHR partner to develop a detail value proposition.
- Expand membership to include organization like Google, Apple
- MSKCC was in a similar engagement with BMS. Created on opportunity for collaboration.

- eSource Consortium launched under the auspices of SCDM. Kickoff meeting was on July 26, 2017

Our Progress: (2 of 3)

eSource Consortium Members (Working Group):

eSource Consortium Members (In discussion/ to be contacted)):

Our Progress: (3 of 3)

- Charter & governance structure, Steering Committee & general membership guidelines being drafted
- Bi-monthly meetings
- Chairs will be jointly between academia and industry on rotating terms for 1 year
- Membership will be open to all academic, industry sponsor participation, Federal & other research sponsors (e.g. NIH) , technology vendors, and CRO
- The Consortium's first key working group deliverable is local lab data exchange specifications
- The group has defined: a common core data set using Logical Observation Identifiers Names and Codes (LOINC) standards, and operationalizing data transfer of local labs using FHIR APIs and JavaScript Object Notation (JSON).

Consortium Governance Structure

- Society for Clinical Data Management (SCDM): administrator of collaboration
- Steering Committee:
  - 5 academic medical centers:
  - 5 biopharmaceutical firms:
- Chairs: Co-chair structure, rotating terms of 1 year
- General membership

eSource Consortium Working Group
Local Lab Core Data Set Package

- First Consortium milestone
- High volumes
- Panel-generated data = best traceability
- Improve site user experience
- Reduce transcription errors and subsequent queries
- All 3 sponsors and academic sites started in the same area
- Agreed upon collaborations during previous conference calls

Collaborations Among Consortium Members

- Harmonizing with TransCelerate and other key outside stakeholders (e.g. CDISC, eClinical Forum, etc) in this space
- Leverage established standards and best practices where available
- Stronger alignment & communication to avoid any duplication

First Working Group Project:

Local Lab Data
Core Data Set Package

Background: Why Local Lab?

- All local lab data is generated by hospital's automatic lab panels (Lab Info System)

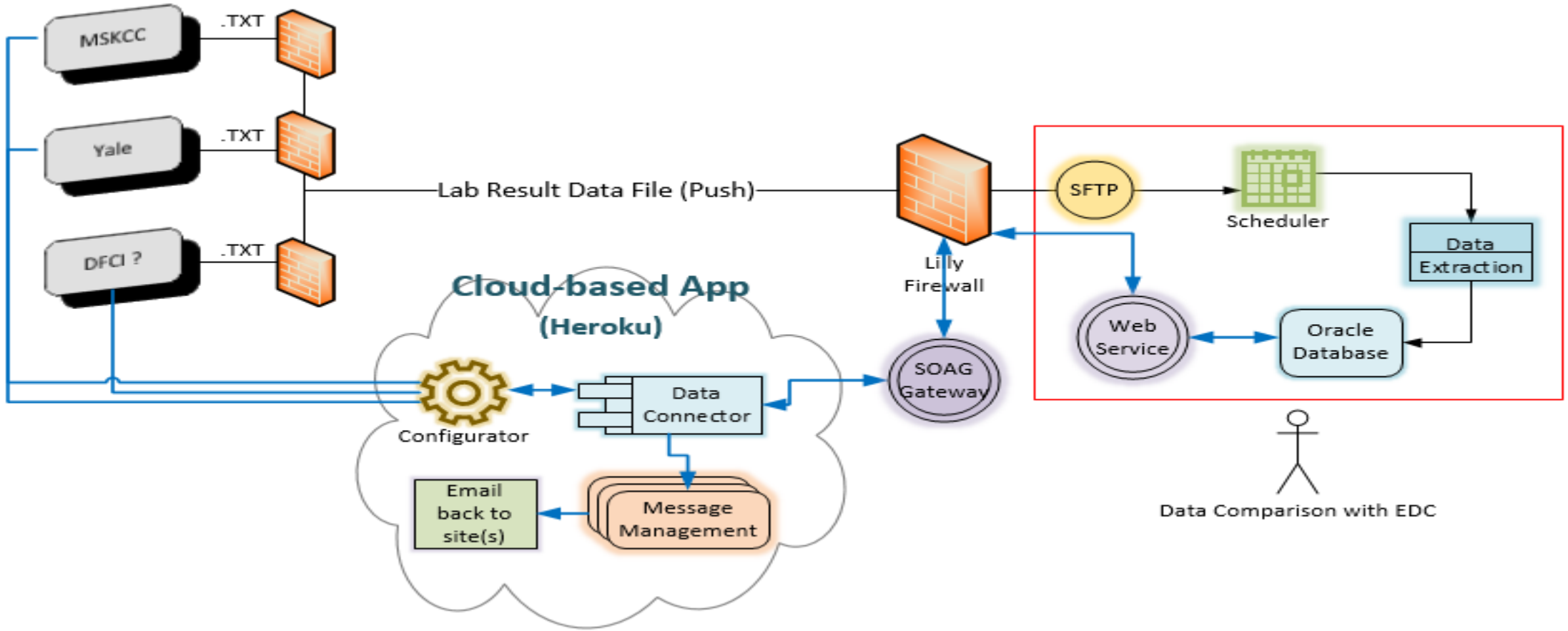
- eCRF requires manual data transcription from one computer system into another **->** dual-monitors

- High volume: 20-30% of eCRF effort in early phase oncology -> top dissatisfaction factor from sites
- Slow process: ~25 days post-visit -> no lab data
- Transcription error: ~8% -> reduction in queries…
- eLab has the best data traceability

Current Initiatives/Collaborations

- Sponsors: Lilly, Novartis, BMS, Merck, Pfizer
- Academics: MSKCC, Yale, Partners Health, Duke Health, Wash U, NCCE (Japan with NVS only)
- Approaches:
  - EHR/EDC integration
  - Direct file transfer from site to sponsor
  - FHIR API

Lilly PoC Project



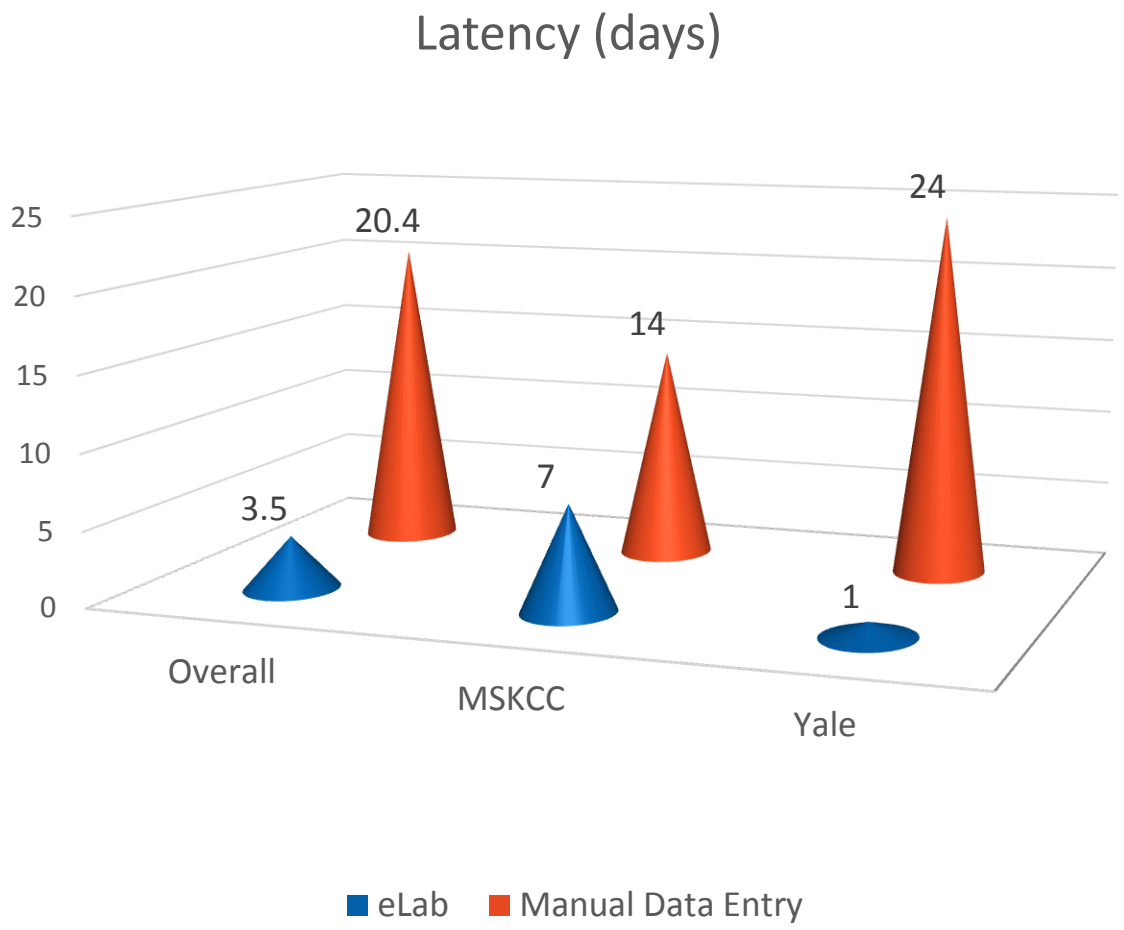
- POC: connect to study sites and consume local lab data directly
- Reduce data availability from 25-days to within 7-days after visit
- Reduce transcription error from 8% to ~0%

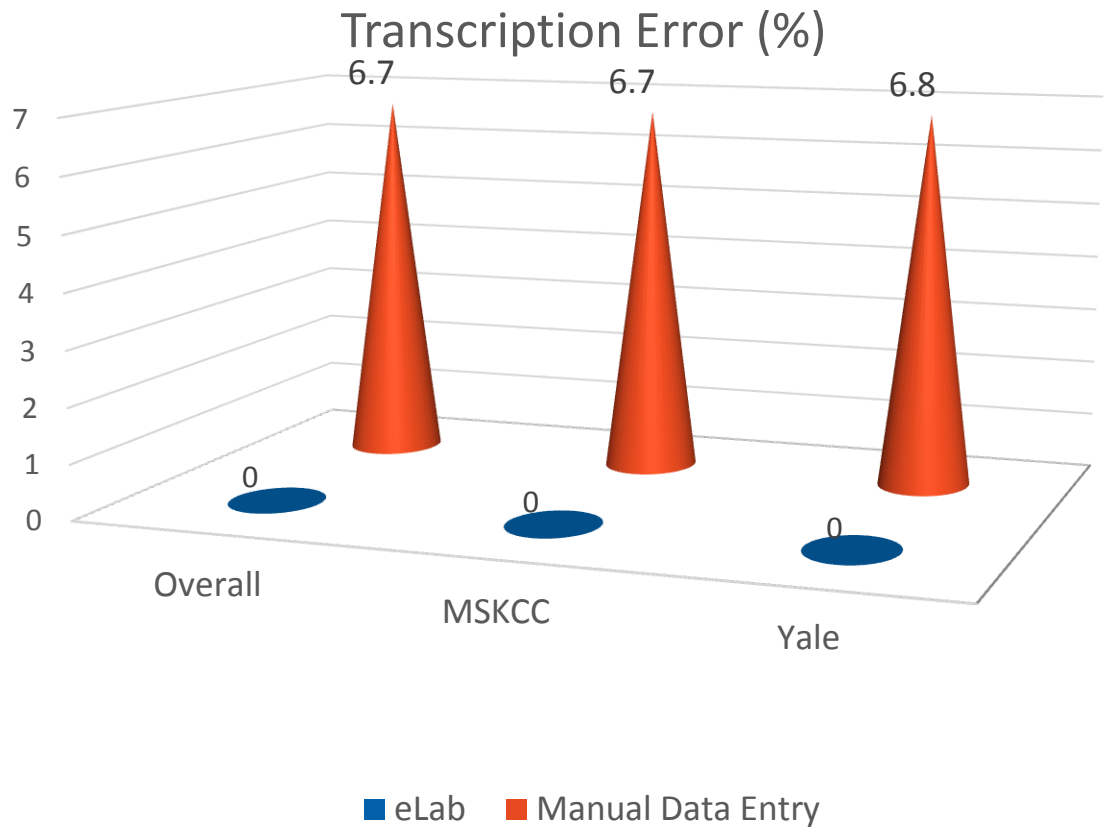
Lilly PoC Methodology

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%

Lilly PoC Outcomes





Lilly PoC Outcomes (cont.)

Other estimated savings for local lab:

1. Reduced site effort: 8 hours/patient/study
2. Reduced queries: 2 queries/patient/study
3. Reduced monitoring activity: 2 hours/patient/study

Current Efforts

- Sponsor-site data exchange specifications
  - How sponsor and site data systems interact
- Pilot implementation
  - Advance PoC to production
  - Limited sites, limited studies
  - Learn how sponsor and site processes change
  - Understand regulatory, data privacy challenges
  - Evaluate approach for eventual scale-up
- HL7-FHIR lab data representation

Local lab data transfer specifications

- Provides common specifications
- Promote industry standards (FHIR, LOINC)
- Options for both pushing and pulling data
- Patient privacy
- Data validation
- Data lineage
- Transaction logging

MSKCC – Value proposition with Novartis Experience

Decreasing the cost of clinical research by exploiting technology advances and reducing sponsor, CRO, and data management staff time and effort by leveraging existing systems to streamline current work flows

eMonitoring

- Since 2011, MSK provides secure and offsite access to the EHR for approved NVS monitors to source verify data.
- eMonitoring reduces historical face time with study coordinators from 4 hours per monitor visit to 1 hour (fixed appointment) per visit, and allows MSK to reclaim 3 hours of time and effort from each visit

Direct Data Capture of MSK Local Labs

- Since 2015, MSK has been sending local labs to NVS using the direct data transfer process
- As a result of this initiative, approximately 20% of manually entered data related to local labs can be removed using the direct data capture process with NVS & there was reduction in query rate by approximately 50%

Leverage MSKCC EKG machines to collect & transit data to 3rd party EKG vendor

- Improved patient safety and more accurate & reliable data transmissions to sponsors and/or CROs
- All EKG machines used for protocol reads are part of the existing MSK EKG quality assurance and control plan

Questions to FDA?

- Role of the US FDA in this Consortium?
  - Advisory
  - Steering Committee
  - Membership
- Status of EHR Guidelines
- CDER IT roadmap around eSource


thank you
danke
謝謝
ngiyabonga
teşekkür ederim
gracias
merci
go raibh maith agat
obrigado
dziękuję
bedankt
спасибо
рахмат
Баярлалаа
faafetai lava
kiitos
dankie
dhanyavad
nanni
nandri
bayarlalaa
gràcie
hvala
mauruuru
enkosi
vinaka
спасибі
blagodaram
dank je
misaotra
matondo
paldies
grazzi
mahalo
tapadh leat
хвала
asante
manana
obrigada
tenki
murakoze
chokrane
mamnun
djiere dieuf
tau
mochchakkeram
дякую
sulpáy
gràcies
gratias ago
chnorakaloutioun
akun
dankon
aciú
kia ora
barka
welalin
tack
spas
mersi
kop khun krap
sukriya
sagolun
taiku
arigatô
takk
dakujem
trugarez
grazie
ありがとう
tanemirt
rahmet
dhanyavadagalu
shukriya
merce
мерси
diolch
ευχαριστώ
terima kasih
najis tuke
didi madloba
kam sah hamnida
rahmat
তোমাকে ধন্যবাদ
감사합니다
xièxie
sobodi
dėkuji
mèsi