



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

*The CDISC vision is to inform patient care & safety
through higher quality medical research.*

A decorative graphic consisting of several overlapping, wavy lines in dark blue and teal, extending horizontally across the lower portion of the slide. The lines start on the left and end on the right, where they transition into a solid horizontal band with a diagonal hatched pattern in dark blue and teal.

Strength *through Collaboration*

Agenda

- Putting the CDISC Protocol Representation Standards to Work
- Using the Protocol Study Design in the EHR Workflow
- Detailed walk through of EHR Workflow
- Next steps for the Protocol Representation Standard
- How to Get Involved with CDISC projects
- Q&A

Putting the Protocol Representation Standard to Work

Presented by David Gemzik, PRG Team Lead, Medidata Solutions Inc.



Strength *through Collaboration*

Protocol Team Objective

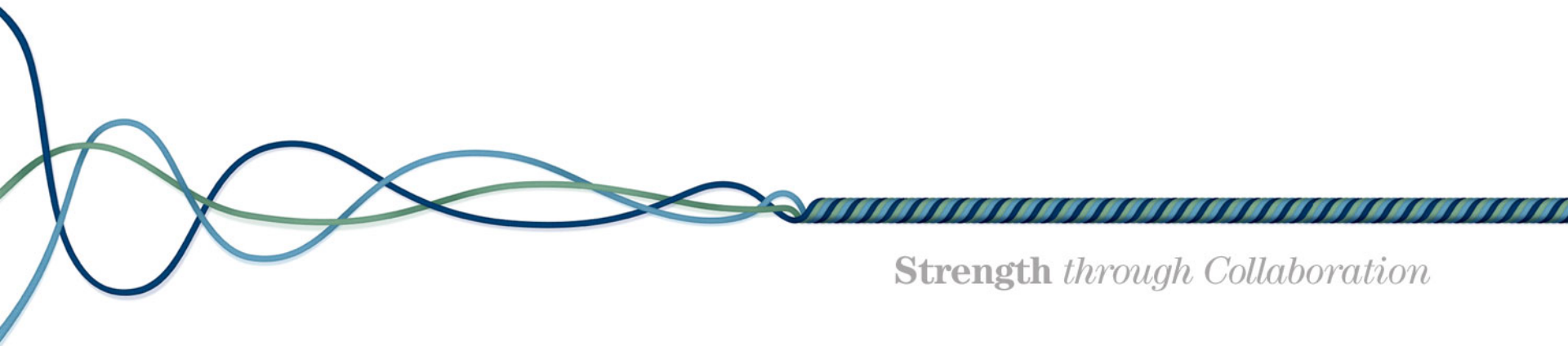
- Publication of a standard, structured, representation of protocol concepts that will enable interchange of protocol data and metadata among systems and stakeholders throughout the lifecycle of the study.
- Project charter is posted to the CDISC public website here: <http://www.cdisc.org/team-charters>

Available Protocol Standards

Web Site Link: <http://www.cdisc.org/protocol>

- Study Outline
 - Standard Concepts mapped to BRIDG, SPIRIT, and SDTM
 - Standard Document template and controlled terminology picklists
- Study Outline Web Wizard
 - Online tool available through CDISC
 - Through web interface, outputs SDTM TS domains and Study Outline PDF document
- Protocol PRM V1.0
 - UML Model of Protocol Domain in BRIDG

Study Outline Standard



Strength *through Collaboration*

Standard Study Outline Concepts

Web Site Link: <http://www.cdisc.org/protocol>

prn_tool_set_study_outline_concepts (1).pdf - Adobe Reader

File Edit View Window Help

1 / 3 65% Tools Sign Comment

SOC ID	STUDY OUTLINE CONCEPT NAME	MASTER CONCEPT NAME	PRO CONCEPT & MASTER LINE NUM	SPRIT	SDTM T3 Domain	CONCEPT NAME EXPLANATION	NOTES
1	Protocol Title	Protocol Title		N	TITLE	Full text of the protocol study title	Include Drug Name, and note the length may be restricted in various target systems such as CT.gov (300 characters max)
3	Phase	Clinical Trial Phase	12	N	TPHASE	Phase (0 through 5, or combination) of trial	Use CDISC Controlled Terminology in Template

SOC ID	STUDY OUTLINE CONCEPT NAME	MASTER CONCEPT NAME	PRO CONCEPT & MASTER LINE NUM	SPRIT	SDTM T3 Domain	CONCEPT NAME EXPLANATION	NOTES
8	Primary Objective	Primary Objective	68	Y	OBJPRIM	The primary objective(s) is the main question to be answered and drives any statistical planning for the trial (e.g. calculation of the sample size to provide the appropriate power for statistical testing).	More than one allowed
9	Other Objectives	Secondary Objectives	69	Y	OBJSEC	Secondary objectives are goals of a trial that will provide further information to support the primary objective.	Note within the textual description the objective type when other than Primary
10	Primary Endpoint	Primary endpoint	72	Y	OUTMEPRI	The outcome variable(s) of interest in the trial. Differences between groups in the outcome variable(s) are believed to be the result of the differing interventions.	

Octagon Research Solutions Confidential 5/3/2012 Page 1

Study Outline Document Template

Web Site Link: <http://www.cdisc.org/protocol>

Document1 - Microsoft Word

Home Insert Page Layout References Mailings Review View Developer Add-Ins Medidata Solutions Laserfiche

Clipboard Font Paragraph Styles Editing

Prototol Title

Phase	Multicenter
1	Multicenter
1-2	Indication
2	Target Study Population
2-3	Trial Purpose Summary
2A	Primary Objective
2B	Other Objectives
3	Primary Endpoint
3A	
3B	
4	
5	

Page: 1 of 2 Words: 214

Click here to enter text

Study Outline Web Wizard

Web Site Link: <https://cdiscprm-sandbox.imedidata.net/>



Welcome

The purpose of this site is to provide users open access to utilize the provided features and functionality in order to produce a Study Outline PDF document and/or related SDTM domains as defined in the CDISC PRM Study Outline standard provided by the [CDISC PRM Toolset Version 1.0](#).

The site does not require a user login and does not save any data entered beyond the timeframe of a single web browser session. Once the session is terminated (e.g. the web page is closed), all data entered will be lost. Be sure to save the Study Outline PDF document and/or related SDTM domains before closing your browser session.

The site provides the user a set of fields based on the CDISC PRM Standard. The fields are mapped to both BRIDG (3.0.3) classes and attributes as well as SDTM (3.1.3) elements where applicable. The mapping can be referenced [here](#). Where applicable, drop down selection fields are provided, which use the current [CDISC Controlled Terminology](#).

The current version of the site produces both a PDF output of the Study Outline and applicable attributes in the SDTM export (both the TS and TI Domains). Not all SDTM attributes are included. Both outputs should be saved to a local directory on the user client computer. Exported files are then solely under the control of the end user.

This site is provided by CDISC free of charge as an example implementation of the CDISC PRM standards. Users can create a Study Outline PDF and/or SDTM export based on the CDISC PRM Study Outline standard.

This site is not a validated application. CDISC does not collect any user information, nor does it store any data entered into the site web pages. Because data entered during a session is not saved, it is lost once a session is terminated (when web page is closed).

CDISC and its Suppliers shall not be liable for any claims, expenses, damages (including direct, indirect, special or consequential damages), loss of profits, opportunities or information arising from the use of this site, including:

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- Any inaccuracy or omission in such information or failure to keep the information current
- Any Internet software used in connection with this website or computer viruses or other destructive programs encountered as a result of using this website
- Any other matter connected with this website; even if CDISC and its Suppliers are made aware of the possibility of such claims, expenses, damages or losses

Enter your Protocol Title

▼ General Information

Protocol Identification Number

Sponsor

Phase

Choose an Item



Multicenter

☐ Yes ☐ No

Planned Countries

Choose an Item



Add Planned Country

Enter your Protocol Title

▶ General Information

▶ Trial Objective and Purpose

▶ Trial Design

▶ Selection of Subjects

▶ Statistics

Save as PDF

Save as SDTM

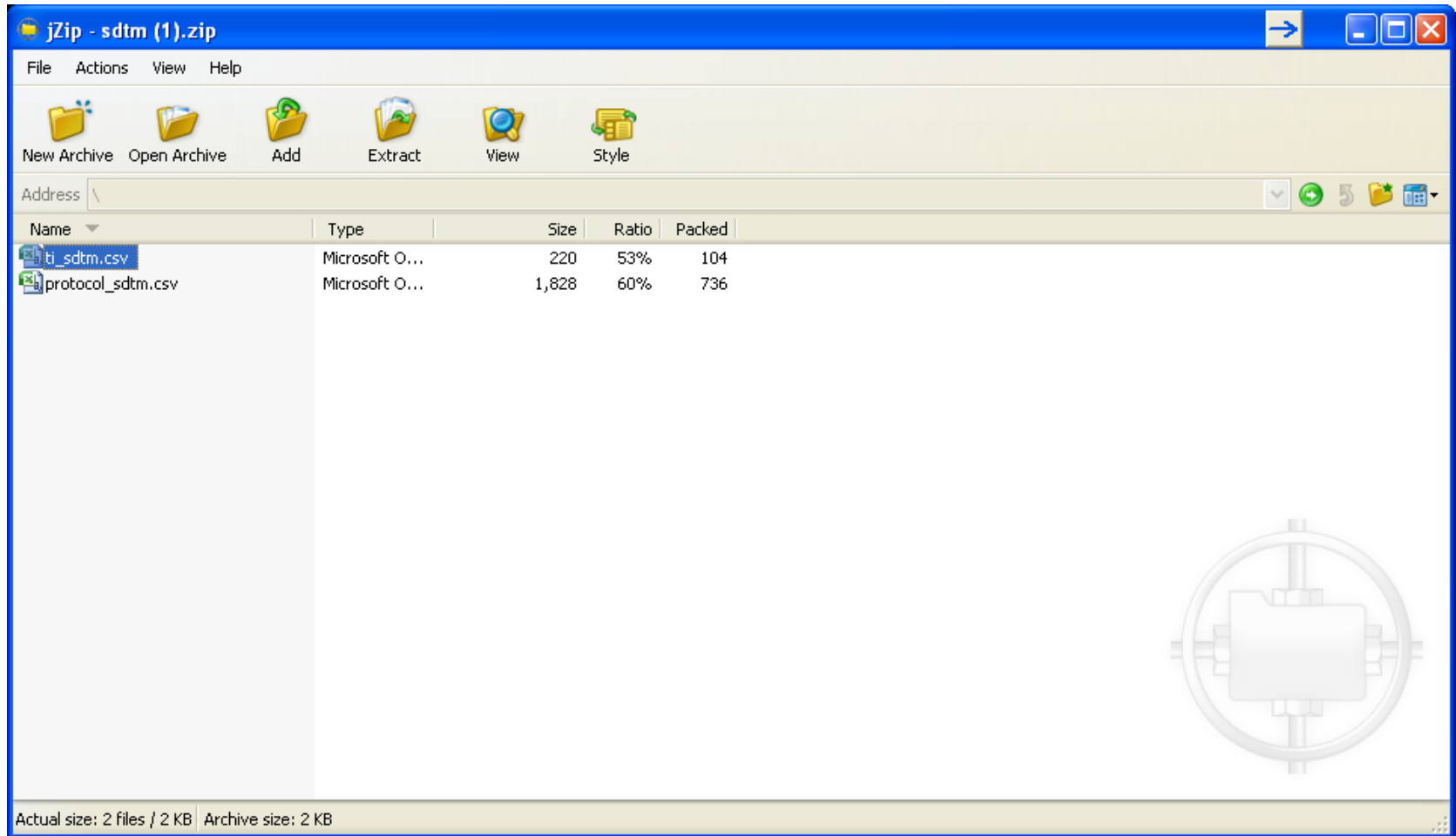
Clear

Exit

Study Outline PDF Export

General Information	
Protocol Identification Number	
Sponsor	
Phase	
Multicenter	
Planned Country	
Trial Objective and Purpose	
Trial Purpose Summary	
Primary Objective	
Other Objective	
Trial Design	
Description of Study Design	
Description of Interventions	
Randomized Study?	
Blinding	

SDTM TS & TI Domains Export (CSV)



SDTM TS Domain

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
							Syndrome (Disorder)				
12	XYZ	TS	1		TINDTP	Trial Indication Type	TREATMENT		C49656	CDISC	2011-06-10
13	XYZ	TS	1		TITLE	Trial Title	A 24 Week Study of Oral Gabapentin vs. Placebo as add-on Treatment to Phenytoin in Subjects with Epilepsy due to				

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
14	XYZ	TS	1		TPHASE	Trial Phase Classification	Phase II Trial		C15601	CDISC	2011-06-10

17	XYZ	TS	1		CURTRT	Current Therapy or Treatment	Phenytoin		6158TKW0C5	UNII	
18	XYZ	TS	1		OBJPRIM	Trial Primary Objective	Reduction in the 3-month seizure frequency from baseline				
19	XYZ	TS	1		OBJSEC	Trial Secondary Objective	Percent reduction in the 3-month seizure frequency from baseline				
20	XYZ	TS	2		OBJSEC	Trial Secondary Objective	Reduction in the 3-month tonic-clonic seizure frequency from baseline				
21	XYZ	TS	1		SPONSOR	Clinical Study Sponsor	Pharmaco		1234567	DUNS	
22	XYZ	TS	1		INDIC	Trial Indication	Tonic-Clonic Epilepsy (Disorder)		352818000	SNOMED	
23	XYZ	TS	1		TRT	Investigational Therapy or Treatment	Gabapentin		6CW7F3G59X	UNII	
24	XYZ	TS	1		RANDQT	Randomization Quotient	0.67				
25	XYZ	TS	1		STRATFCT	Stratification Factor	SEX				
26	XYZ	TS	1		REGID	Registry Identifier	NCT123456789		NCT123456789	CT.GOV	
27	XYZ	TS	2		REGID	Registry Identifier	XXYYZZ456		XXYYZZ456	EUDRAC	
28	XYZ	TS	1		OUTMSPRI	Primary Outcome	SEIZURE				

PRM V1.0 BRIDG Object Classes

Study Attributes: phaseCode

Name:

Constraints

Stereotype:

Alias:

Scope: ☐ Static ☐ Const ☐ Is Literal

Containment: ☐ Property

Notes:

A coded value specifying the designation of approval phase for a study.

Name	Type	Initial Value
accrualReportingMethodCode	CD	
acronym	ST	
aeCodingSystem	II	
designConfigurationCode	CD	
diseaseCode	DSET<CD>	
multiInstitutionIndicator	BL	
participatingCountryCode	DSET<CD>	
participatingOrganizationTypeCode	CD	
periodicTargetAccrualNumber	RTO<INT,PQ>	
phaseCode	CD	

Putting It To Work

Study Concept Design

- Web Wizard
- Enter standard concepts

Study Outline Document

- Generate standard Document
- Review standard Study Design

Protocol & Downstream Standards

- Author Protocol on approved Outline
- Generate SDTM TS and TI Domains
- Exchange standard terminology and concepts

Key Value to the Organization

Standards

- Standard Terminology & Structure
- Promotes Reuse & Usability
- Simplified Data Exchange

Process Rigor

- Study Outline development and review
- Focus & consensus on key concepts early
- Facilitative Study Review and Design Challenge

Interoperability

- Harmonized with CDISC domain through BRIDG
- CDASH, SDTM
- Cross Study Analysis (Apples to Apples)

Detailed walk through of EHR work flow

Presented by Landen Bain, CDISC



Strength through Collaboration

The Protocol Defines Process; EHRs Execute Processes

- The protocol, especially the study design sections, defines processes that the healthcare site executes.
- Why not leverage the Electronic Health Record to help automate these processes?
- The EHR is an **application** that automates healthcare process.
- The data generated by the process automation is a by-product of an EHR, not its main task.

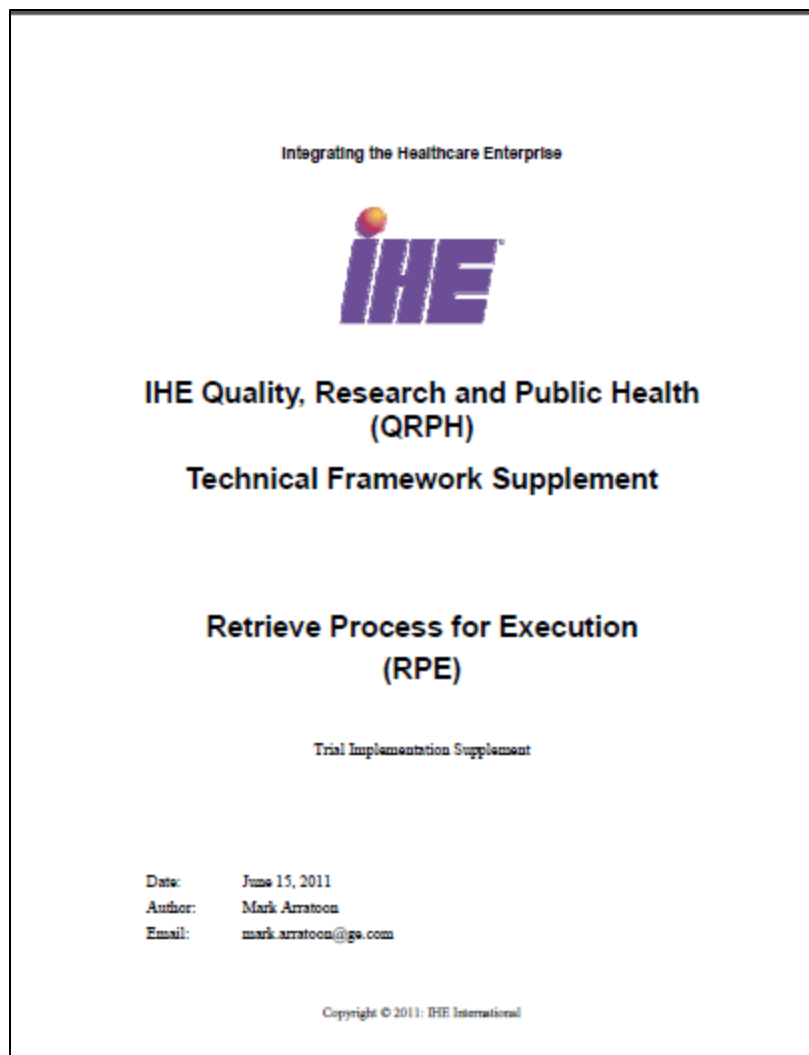
What can the EHR do for Regulated Research?

- Identify qualified patients based on inclusion criteria
- Enroll patients and manage the patient/subject identity at the site
- Schedule visits – human mediated process
- Auto-populate and surface eCRFs
- End the subject's participation.

IHE Profiles that Coordinate Workflow

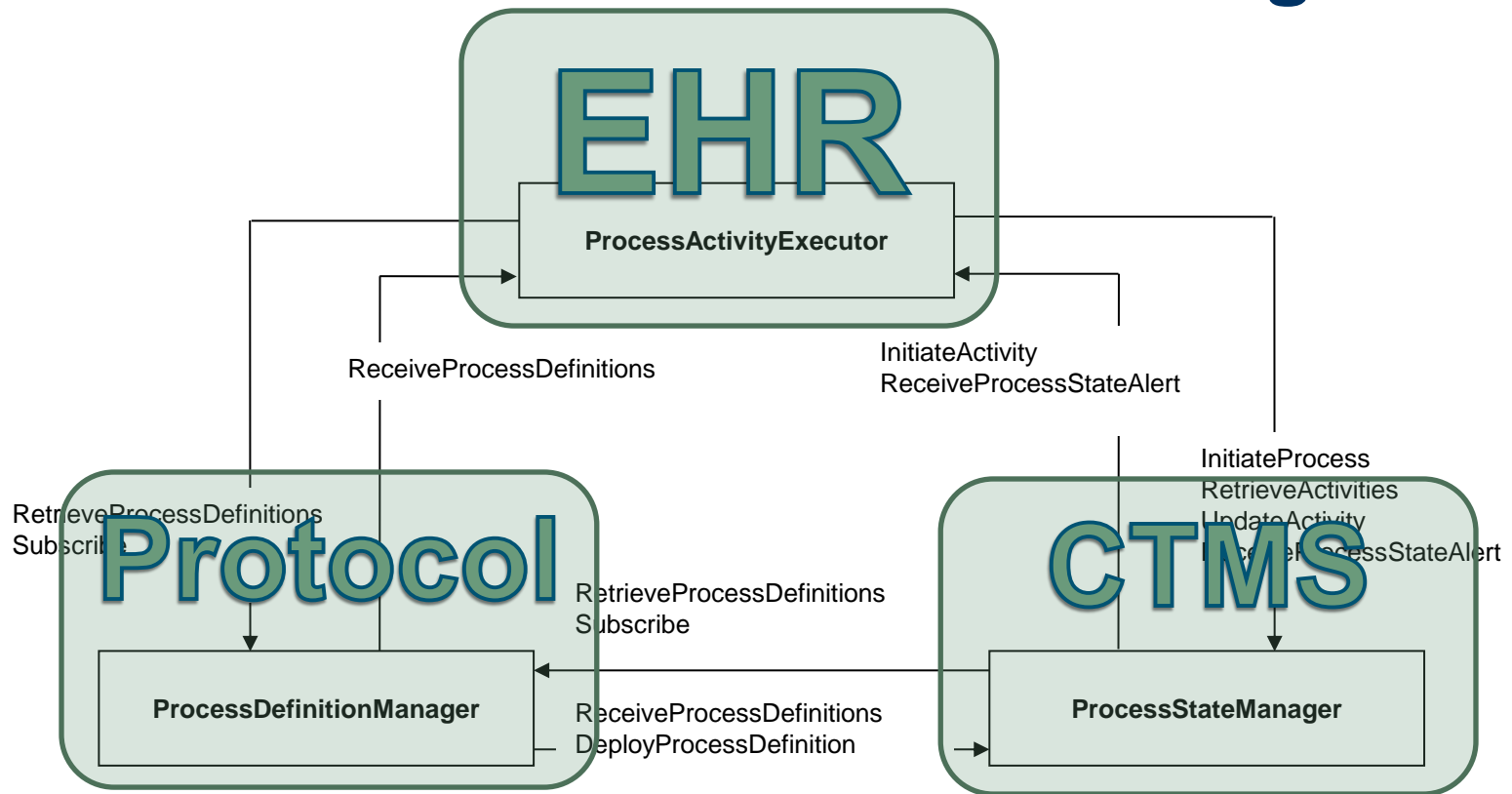
- Retrieve Process for Execution (RPE) – the framework for workflow coordination
- Clinical Research Process Content (CRPC) – defines transactions for study execution.
- Research Matching – defines workflow for pre-study processes

Retrieve Process for Execution



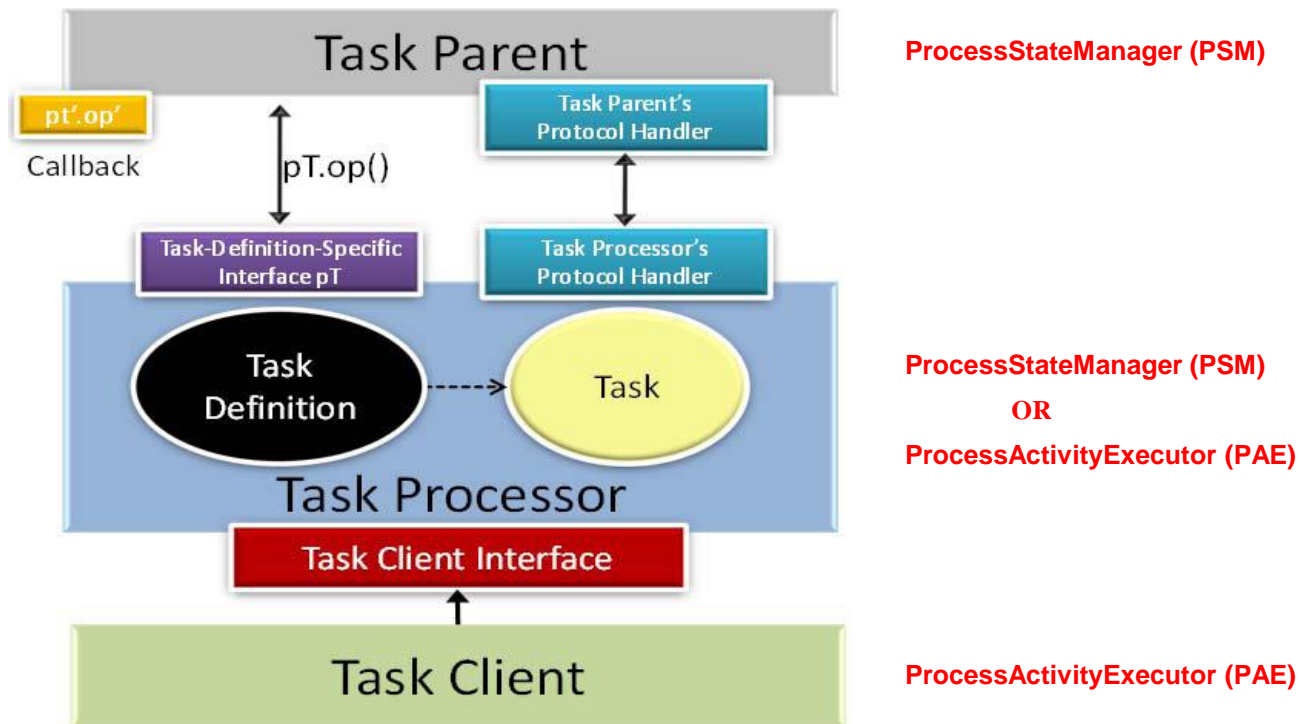
http://www.cdisc.org/stuff/content_mgr/files/0/f5a0121d251a348a87466028e156d3c3/misc/cdisc_healthcare_link_profiles.pdf

Collaborative Process Management



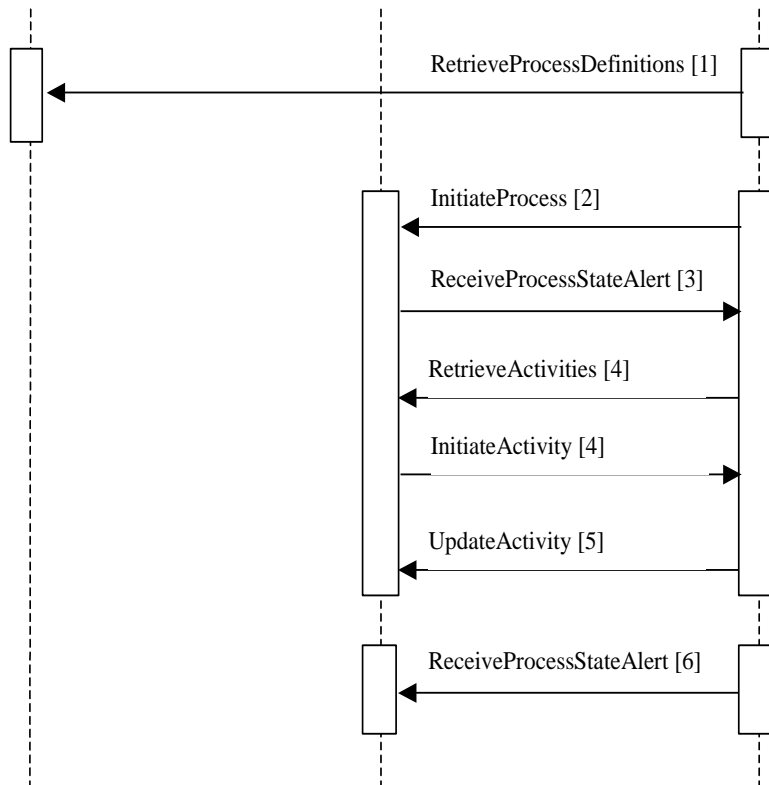
Consistent with BPM Design

Mapping of RPE 2.0 Actors:



RPE Use Case Walkthrough

ProcessDefinitionManager ProcessStateManager ProcessActivityExecutor



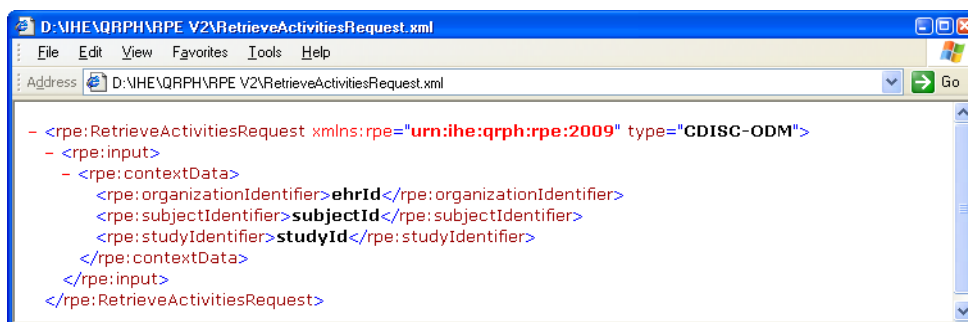
1. The ProcessActivityExecutor retrieves process definitions of potential interest from the ProcessDefinitionManager.
2. The ProcessActivityExecutor request's process initiation by the ProcessStateManager forwarding a given process definition identifier as well as other required data, e.g., a patient identifier, demographics or eligibility criteria.
3. The ProcessStateManager notifies the ProcessActivityExecutor that the process is proceeding or otherwise.
4. The ProcessActivityExecutor either:
 - Retrieves the current activities it has to perform when activity creation is managed by the ProcessStateManager OR
 - Creates activities itself but as initiated and defined by the ProcessStateManager
5. After performance of an activity, the ProcessActivityExecutor sends the ProcessStateManager the updated activity state and data.
6. The ProcessActivityExecutor can always notify the ProcessStateManager of unscheduled events that may effect the process state, e.g., a patient withdrawal from a clinical trial.

RetrieveActivities – CDISC

4. The ProcessActivityExecutor either:

- Retrieves the current activities it has to perform when activity creation is managed by the ProcessStateManager OR
- ...

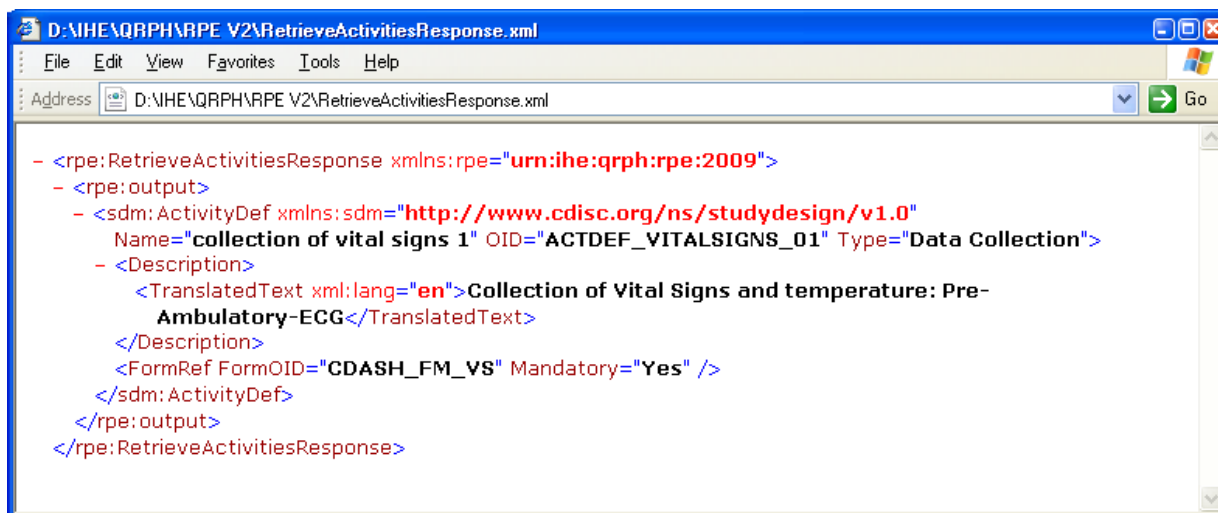
Request:



The screenshot shows a web browser window with the address bar pointing to 'D:\VHE\QRP\H\RPE V2\RetrieveActivitiesRequest.xml'. The main content area displays an XML document with the following structure:

```
<?xml version="1.0" encoding="UTF-8"?>
<rpe:RetrieveActivitiesRequest xmlns:rpe="urn:ihe:qrph:rpe:2009" type="CDISC-ODM">
  <rpe:input>
    <rpe:contextData>
      <rpe:organizationIdentifier>ehrId</rpe:organizationIdentifier>
      <rpe:subjectIdentifier>subjectId</rpe:subjectIdentifier>
      <rpe:studyIdentifier>studyId</rpe:studyIdentifier>
    </rpe:contextData>
  </rpe:input>
</rpe:RetrieveActivitiesRequest>
```

Response:



The screenshot shows a web browser window with the address bar pointing to 'D:\VHE\QRP\H\RPE V2\RetrieveActivitiesResponse.xml'. The main content area displays an XML document with the following structure:

```
<?xml version="1.0" encoding="UTF-8"?>
<rpe:RetrieveActivitiesResponse xmlns:rpe="urn:ihe:qrph:rpe:2009">
  <rpe:output>
    <sdm:ActivityDef xmlns:sdm="http://www.cdisc.org/ns/studydesign/v1.0"
      Name="collection of vital signs 1" OID="ACTDEF_VITALSIGNS_01" Type="Data Collection">
      <Description>
        <TranslatedText xml:lang="en">Collection of Vital Signs and temperature: Pre-
        Ambulatory-ECG</TranslatedText>
      </Description>
      <FormRef FormOID="CDASH_FM_VS" Mandatory="Yes" />
    </sdm:ActivityDef>
  </rpe:output>
</rpe:RetrieveActivitiesResponse>
```

Clinical Research Process Content

Integrating the Healthcare Enterprise



**IHE QRPH
Technical Framework Supplement**

**Clinical Research Process Content
(CRPC)**

Draft for Public Comment

Date: December 27, 2011
Author: Vassil Peytchev, Landen Bain
Email: lbain@cdisc.org

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http://www.cdisc.org/stuff/content_mgr/files/0/f5a0121d251a348a87466028e156d3c3/misc/cdisc_healthcare_link_profiles.pdf

Research Matching

Integrating the Healthcare Enterprise



**IHE QRPH
Technical Framework Supplement**

Research Matching (RM)

Draft in preparation for Public Comment

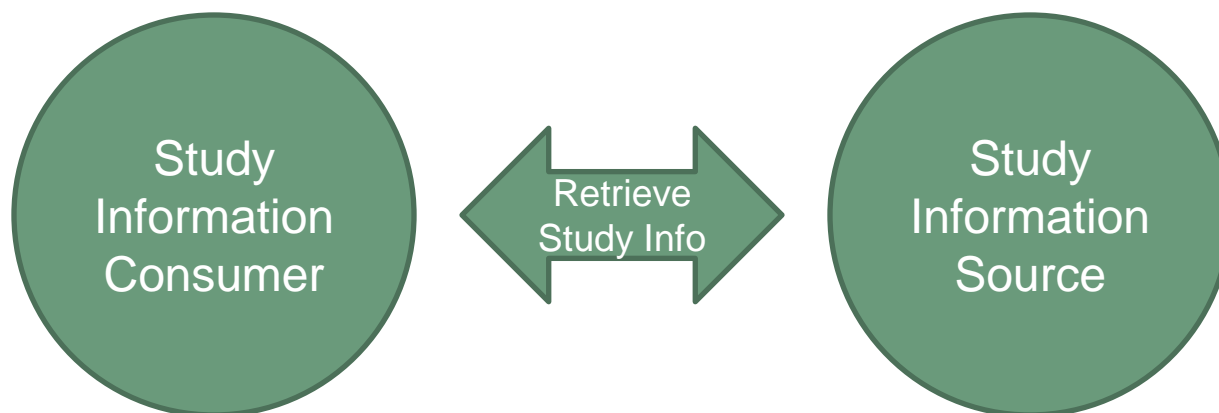
Date: February 25, 2013
Author: Landen Bain
Email: lbain@cdisc.org

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ftp://ftp.ihe.net/Quality/2013_2014_YR_7/QRPH_Technical/ResearchMatching/

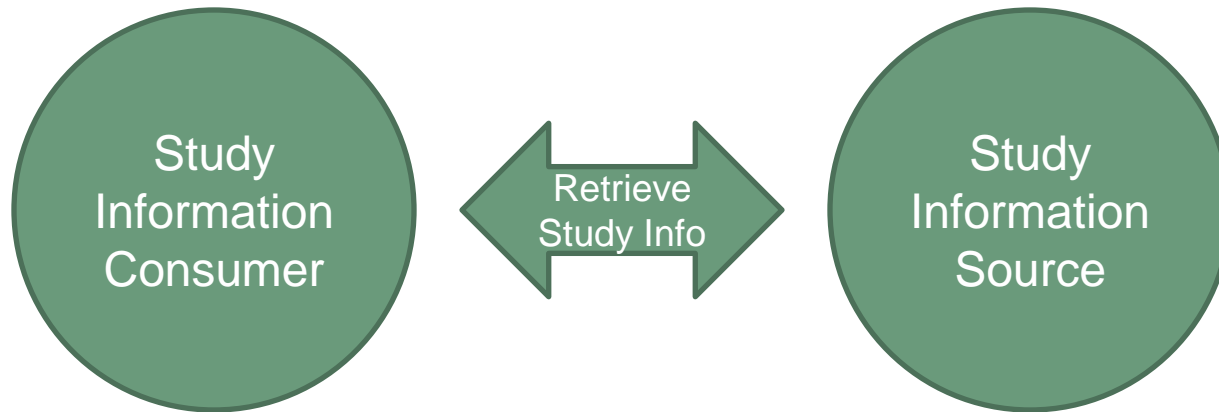
Find studies for interested patients

“Match.com”



The Study Information Consumer retrieves relevant study descriptions and links from a Study Information Source, something like clinicaltrials.gov. HL7 Info Button

Find Eligible Patients “The App”



The Study Information Consumer retrieves eligibility criteria as executable code from the Study Information Source, a sponsor-hosted protocol representation.

Work to be done

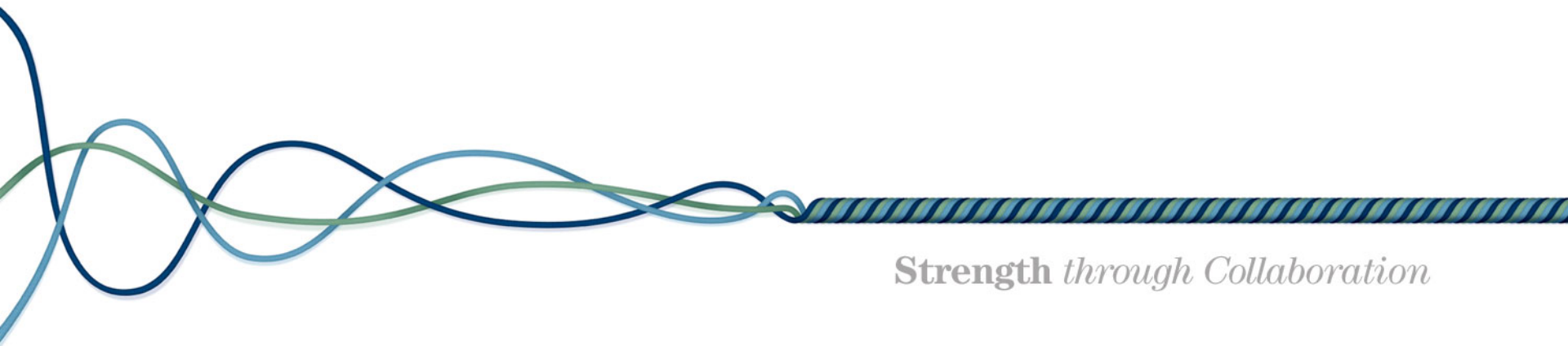
- Develop the protocol as a rigorous process definition
- Use the IHE profiles as the gateway to handing off process definition to EHRs

IHE's role

- Develop QRPH profiles, leveraging CDISC standards and HL7, as appropriate
- Review and comment profiles
- Test profiles at Connectathons
- Demonstrate interoperability at Showcases
- Implement

- Contact information: lbain@cdisc.org

PRG Current Project & Next Steps



Strength *through Collaboration*

Next Steps for the CDISC PRG

- 2013 – Protocol Concepts
 - Publish Protocol Concepts Standard
 - Including mapping to BRIDG
 - Comprehensive list of standard Protocol Concepts
- 2014 H1 – Protocol XML
 - An ODM extension to SDM ODM to include representation of the Protocol (and Study Outline) Concepts
- 2014 H2 – Standard Protocol Template
 - ICH E6 Document Sections
 - Incorporate standard Protocol Concepts within Document Template

Industry Collaboration

- CDISC PRG focus is on standardization and interchange of content
- Work closely with the following industry initiatives and stakeholders
 - HL7 – Protocol-related messages harmonized with CDISC BRIDG
 - DIA SIAC – Process related activities leverage CDISC standard concepts and available standards
 - SPIRIT – Harmonize standard concepts and tool implementations
 - FDA – Internal process and tool development to leverage CDISC standards and terminology

How to Get Involved with CDISC Projects

Presented by Katie Carothers, CDISC Technical Project Manager



Strength *through Collaboration*

How to get involved

How can you contribute to the CDISC mission?

❖ Participate in the review process

- Review draft standards posted to CDISC.org
- Record comments for documents via public comment tracker

❖ Join a CDISC project team

- Submit new volunteer registration form indicating which project teams/sub-teams you have interest in joining

❖ Future opportunities

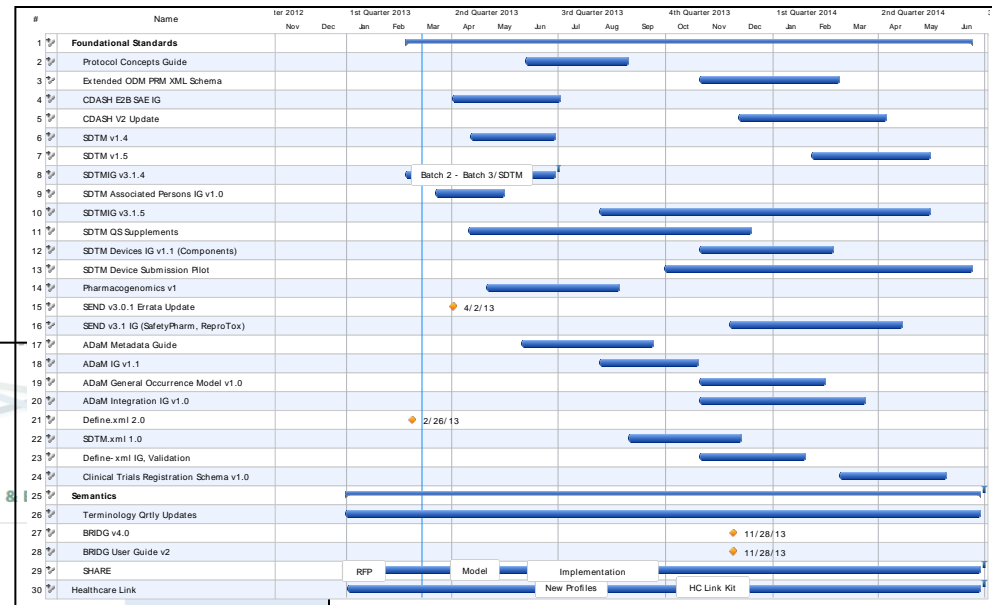
- Opt in for news announcements and reviews through mail lists
- Develop and contribute to a wiki for use cases and examples – share your experiences with the CDISC Community
- Attend the CDISC Intra-change!

Where to find the CDISC Technical Plan

Pathway: www.CDISC.org > Standards & Innovations > Technical Plan Project Schedule



Technical Plan Project Schedule (GANTT Chart)



The screenshot shows the CDISC website header with the logo and tagline 'Strength Through Collaboration'. Below the header are navigation tabs: 'ABOUT CDISC', 'STANDARDS & INNOVATIONS', 'RESOURCES', 'NEWS', and 'EDUCATION & TRAINING'. Under 'STANDARDS & INNOVATIONS', there are sub-links: 'Foundational Standards', 'Implementations', 'Innovations', and 'Technical Plan Project Schedule'. A large green arrow points to the 'Technical Plan Project Schedule' link.

Technical Plan Project Schedule
Updated 12 March 2014

The CDISC Technical Plan Project Schedule provides a one-page Gantt Chart overview of significant upcoming CDISC planned project deliverables for the current calendar year. Projects represented as milestones are not expected to require a public comment review period (either because the contents have previously completed public review or because posting is not required, as with BRIDG updates). For projects presented as task bars, the beginning of the bar typically represents the planned beginning of the comment period and the end of the bar represents the expected posting date for the completed provisional or final standard. In some cases, smaller specific deliverables may be overlaid as notes on the task bar as well.

Because projects in progress and schedules are likely to change over time (often due to limited availability of our volunteers), the chart will be generally be reviewed and updated every 2-3 months.

Click the following link to view the **Technical Plan Project Schedule**.

<http://www.cdisc.org/technical-plan->

Where to find recently posted documents

- “What’s New” on homepage
- CDISC Standards Latest Updates
- Individual Project team pages or the Newsroom

CDISC is the Common Language for Clinical Research



What's New

Upcoming CDISC Webinar: Volunteering for CDISC
How to get involved?
 6 June 2013
 11:00-12:30 PM ET

Just Added: CDISC Public Training in Copenhagen, Denmark (25-26 June 2013)
 Click here to register!

C-PATH AND CDISC LAUNCH VERSION 1.0 OF THE POLYCYSTIC KIDNEY DISEASE THERAPEUTIC USER GUIDE

CDASH-SAE Draft Standards is now Available for Public Review and Comment – Comments due June 5, 2013

CDISC Healthcare Link Profiles Information Available Here.

CDISC Advisory Council Call for Nominations - Deadline is 16 July 2013
 The CDISC Advisory Council (formerly known as the CDISC Advisory Board) is now requesting nominations for Chair-elect of this Council. Contact Sheila Leaman for details.

May Newsletter Available Now!
 CDISC International Interchange 2013 Call for Abstracts; Release of the 2012 CDISC Annual Report; CDISC Success Story Featuring Cytel; Blogs and updates from the CDISC European Interchange 2013; CDISC Foundational Standards in Chinese and more!
[Click here to view the newsletter.](#)

CDISC International Interchange in Bethesda, MD on 4-8 November 2013 - Call for Abstracts!
 We are now accepting abstracts on case studies that include metrics on utilizing the CDISC standards.
[Click here to submit your abstract.](#) The deadline for abstract submission is Tuesday, 16 July 2013.

[Click here for details on the CDISC International Interchange 2013.](#)

CDISC Standards Latest Updates
 Standards open for review and comment as well as new standards available for use.

Sponsorship Opportunities for Upcoming CDISC Interchanges

Become a CDISC Member
 Read about the benefits of membership and how to join more...

CDISC 2012 Annual Report
 Click here to download the Annual Report!
 Click the image below to download more...

Join Our E-mail List
 more...

Volunteer for CDISC
 Follow the link.

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CDISC *Strength Through Collaboration*

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[RESOURCES](#)
[NEWS](#)
[EDUCATION & EVENTS](#)

Foundational Standards >

- Implementations >
- Innovations >
- Technical Plan Project Schedule

Protocol

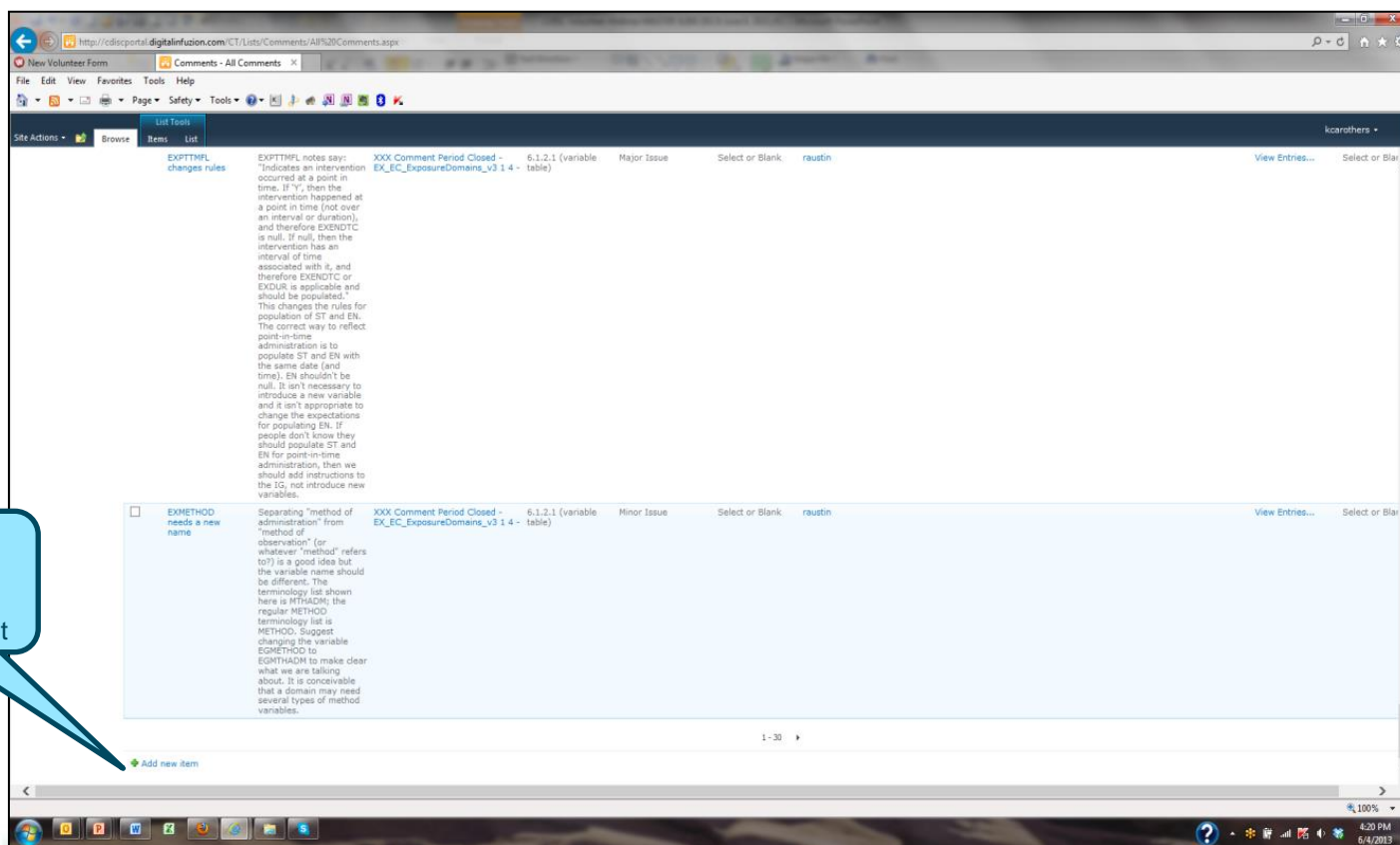
- Study/Trial Design Model
- CDASH
- LAB
- Study Data Tabulation Model
- SEND
- ADaM
- Operational Data Model
- Define-XML
- Glossary
- Terminology
- BRIDG Model

<http://www.cdisc.org>

How to get involved: public reviews

Provide feedback for drafts in CDISC public comment tracker:

1. Note – you need a portal account (set up through link on website)
2. Microsoft Internet Explorer is preferred browser
3. Read guidance document for how to use the tracker posted at <http://cdiscportal.digitalinfuzion.com/CT/Pages/CCTT-Help.aspx>
4. Record your comments in the tracker:



How to get involved: sign up for a team

Joining a CDISC project team....it all starts here!

The screenshot shows the CDISC website with the following content:

- Header:** CDISC logo with tagline "Strength Through Collaboration". Navigation links: ABOUT CDISC, STANDARDS & INNOVATIONS, RESOURCES, NEWS, EDUCATION & EVENTS, MEMBERSHIP, MEMBERS ONLY.
- Main Banner:** "Strength through Collaboration" featuring a woman in a lab coat. Text: "The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare."
- What's New:**
 - C-PATH AND CDISC LAUNCH VERSION 1.0 OF THE POLYCYSTIC KIDNEY DISEASE THERAPEUTIC USER GUIDE
 - CDISC LHS-ESTEL Webinar Slides Available
 - Job Position Opening - Terminology Specialist
 - CDISC Healthcare Link Profiles Information Available Here
 - CDISC Europe Interchange 2013-Sponsorship and Exhibitor Opportunities are Available too
 - Define-XML 2.0 now available for use
 - SDTM v1.3 and SOTMIG v3.1.3 Metadata Spreadsheet Now Available in the Member's Only Area
 - Updated Version of SDTM/ADaM Pilot Submission Package Now Available on the CDISC Member's Only Site
 - Board of Directors Call for Nominations - Deadline for Nominations is 30 June 2013
- April Newsletter Available Now!**

CDISC Europe Interchange 2013-Offline Registration is Open this Week; Launch of PKD User Guide V1.0; Success Story on Sharing Clinical Research Data; CDISC Standards Latest Updates; CDISC Members and User Network Updates and More! Click here to view the newsletter.
- CDISC Announces Speakers from IMI, FDA and EMA for 10th Europe Interchange in Germany**
- CDISC Europe Interchange 2013**

Join CDISC in Germany & attend our Europe Interchange in April 2013! Sponsorship and Exhibitor opportunities are available too. Only Offline Registration is open now, click here.
- CDISC Standards Latest Updates**

Standards open for review and comment as well as new standards available for use.
- Sponsorship Opportunities for Upcoming CDISC Interchanges**
- Why Should I Attend the 2013 CDISC European Interchange?**
- Become a CDISC Member**

Read about the benefits of membership and how to join here
- CDISC 2011 Annual Report**

Download your copy of the 2011 CDISC Annual Report Today! Click the image below to download:
- Join Our E-mail List**
- Volunteer for CDISC!**

Follow the link.
- Follow CDISC Today!** (Social media icons for Facebook, LinkedIn, Twitter, YouTube)

A blue speech bubble points to the "Volunteer for CDISC!" section with the text: "New volunteers enroll on CDISC website".

How to get involved: sign up for a team

❖ Step 1: Enroll as new volunteer via online registration page:

The screenshot shows a web browser window displaying the "New Volunteer Form" on the CDISC website. The browser's address bar shows the URL: <http://cdisc.wufoo.com/forms/m7p6i7/#public>. The form has two tabs: "1 CDISC Project Teams and Sub-teams" (active) and "2 Contact Information".

Callouts point to the following sections of the form:

- Team member responsibilities:** Points to the introductory text about CDISC's reliance on volunteers and the list of activities.
- Posted draft documents:** Points to the link "Draft standards documents are posted [here](#)."
- Information about TA standards:** Points to the link "Click [here](#) to see the latest CDISC Technical Plan which shows major project deliverables for the year. For more information on Therapeutic Area standards, click [here](#)."
- CDISC Technical Plan:** Points to the link "Click [here](#) to see the latest CDISC Technical Plan..."
- Select your project team(s)!** Points to the "Please list where you would like to contribute to the CDISC mission (at least one selection is required):" section, which includes checkboxes for ADAM, BRIDG, CDASH, and Define.XML.

The form content includes the CDISC logo, the title "New Volunteer Form", and the following text:

CDISC depends on volunteers like you to develop, use and maintain our open standards. The goal is to create a responsive community that can efficiently review and comment on draft standards documents as they become available as well as to build up membership on teams that develop new standards. Participating in the public review process is a necessary first step to becoming involved in CDISC team activities. Draft standards documents are posted [here](#).

What additional activities can you expect to be involved in as a CDISC volunteer? In addition to reviewing draft standards, you may be asked or decide to participate in any of the following:

- Actively participate during scheduled team teleconferences and take action items
- Evaluate and help resolve internal and external review comments on draft standards documents
- Participate in the development of new and updated standards documentation
- Help identify new versions of standards or new domains and align development with other standards teams
- Provide subject matter expertise and consultation
- Contribute to the development of team training materials

Click [here](#) to see the latest CDISC Technical Plan which shows major project deliverables for the year. For more information on Therapeutic Area standards, click [here](#).

If you think you're interested in contributing 8 or more hours a month to help, please fill out the form below and someone will follow up with you.

Thank you for considering volunteering for CDISC!

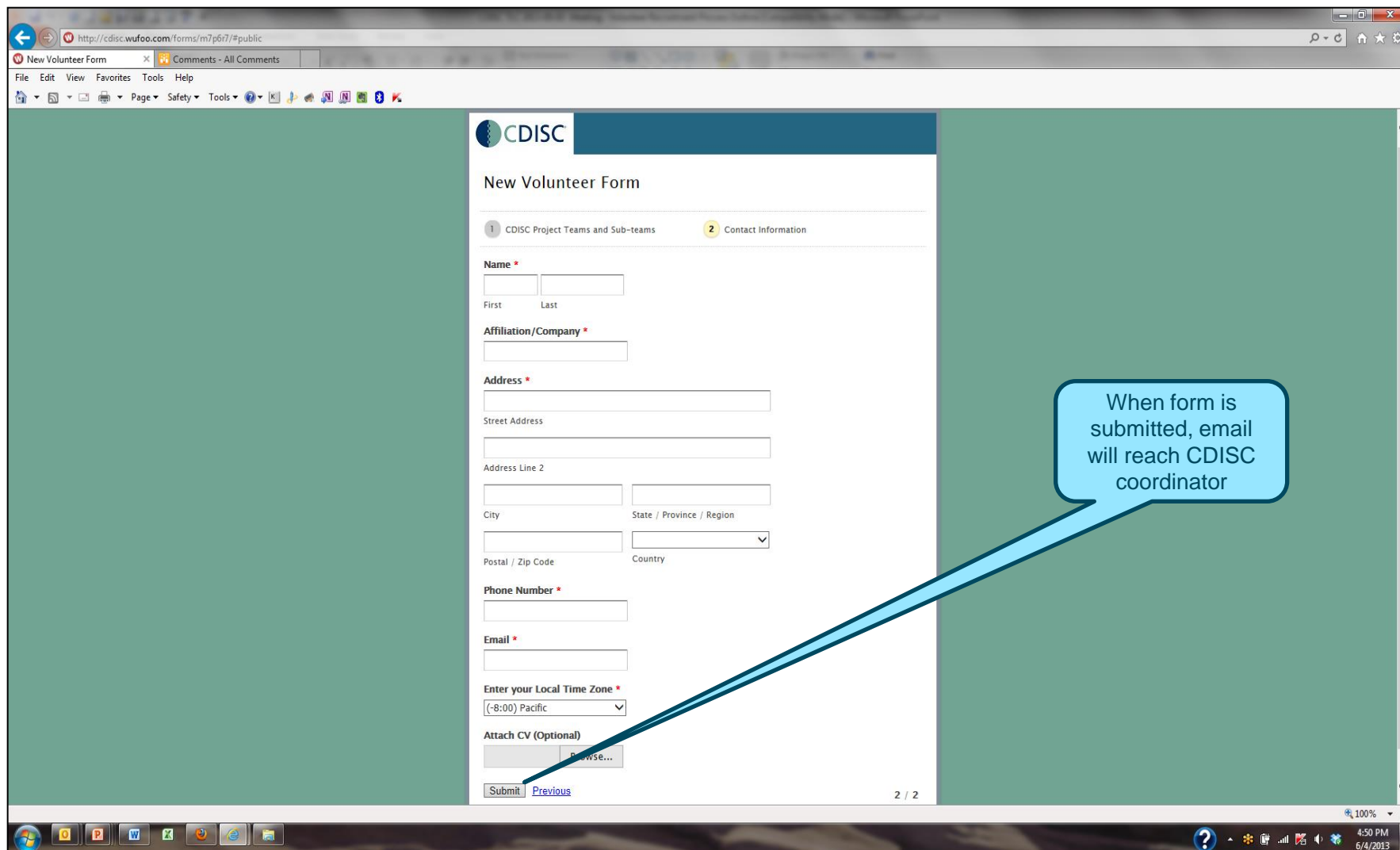
Italics indicate team is not currently recruiting new volunteers.

Please list where you would like to contribute to the CDISC mission (at least one selection is required):

- ☐ ADAM (Analysis Domain Model)
- ☐ BRIDG (Biomedical Research Integrated Domain Group)
- ☐ CDASH (Clinical Data Acquisition Standards Harmonization)
- ☐ Define.XML (Define Specifications)

How to get involved: sign up for team

❖ Step 2: Submit volunteer form to CDISC



The screenshot shows a web browser window displaying the "New Volunteer Form" on the CDISC website. The browser's address bar shows the URL "http://cdisc.wufoo.com/forms/m7p6r7/#public". The form is titled "New Volunteer Form" and is divided into two sections: "1 CDISC Project Teams and Sub-teams" and "2 Contact Information". The "Contact Information" section is active and contains the following fields:

- Name ***: Two input fields for "First" and "Last".
- Affiliation/Company ***: One input field.
- Address ***: Three input fields for "Street Address", "Address Line 2", and "City".
- State / Province / Region**: A dropdown menu.
- Postal / Zip Code**: An input field.
- Country**: A dropdown menu.
- Phone Number ***: An input field.
- Email ***: An input field.
- Enter your Local Time Zone ***: A dropdown menu with "(-8:00) Pacific" selected.
- Attach CV (Optional)**: A "Browse..." button.

At the bottom of the form, there are "Submit" and "Previous" buttons. A blue callout bubble points to the "Submit" button with the text: "When form is submitted, email will reach CDISC coordinator". The browser's taskbar at the bottom shows various application icons and the system clock indicating 4:50 PM on 6/4/2013.

How to get involved: volunteer for CDISC

Things to remember....

❖ Registration form

- Not all active CDISC project teams are currently recruiting new volunteers
- We have indicated which projects are in need of additional resources
- Some project teams (Devices, Terminology, etc.) include a list of sub-teams
- If you select a project team with sub-teams on the form, if possible please indicate which sub-team(s) interest you

❖ Once your registration is submitted you will be contacted by a CDISC representative to discuss next steps

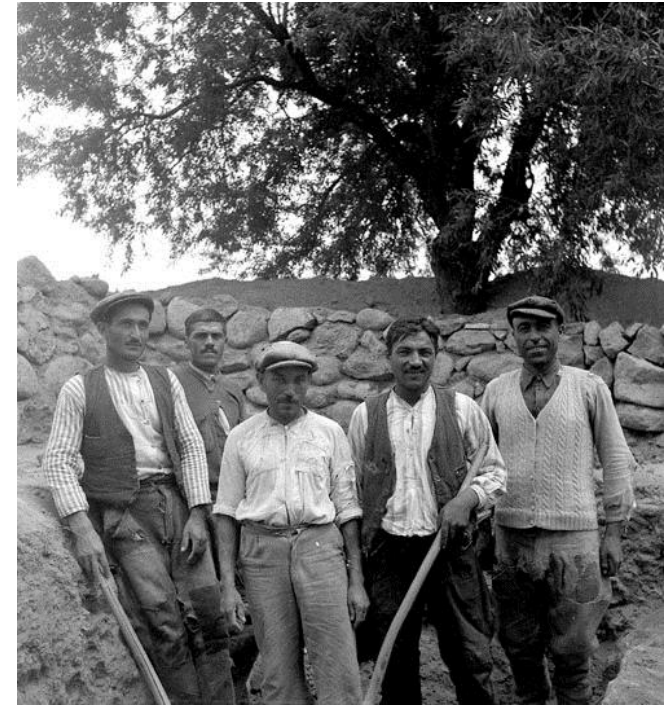
❖ Project needs vary based upon their deliverable schedule

- Just because the team is not recruiting today does not mean they will not need help in six months! Check the CDISC website often.

❖ ***Regardless of project status, there is always a need for document reviewers***

CDISC INTRA-change: July 30-Aug 1, 2013

- Bringing together active CDISC volunteers for internal discussions and to make progress on cross-team topics
- No conference frills; few plenary talks
- Plenty of hard work
- Deadline to register = 19JUL2013



Question & Answer Session

All



Strength *through Collaboration*

CDISC Education and Communications Updates

Presented by: Saad Yousef, CDISC, Manager of Education and Membership Services



Strength *through Collaboration*

CDISC Education Public Course Opportunities

- Cambridge, MA on 17 July 2013



- Canton, MI (Detroit Area) from 6-9 August 2013



- Brussels, Belgium from 9-12 Sep 2013



- Seattle, WA from 16-19 Sep 2013



- **Full schedule** and **registration** at www.cdisc.org/public-courses

CDISC In-House Education

- Schedule **in-house authorized CDISC education** for your company - designed to meet your CDISC education needs.
- For more information:
 - Visit our website **www.cdisc.org/private-training**
 - or fill out private education request form found [here](#) (form can also be found at above webpage).

Upcoming CDISC Webinars

- Watch for more CDISC Team Updates and other topics in our Webinar Series in the coming months
- CDISC Webinar schedule published at:
www.cdisc.org/webinars
- **Next CDISC Webinar scheduled for: TBD.**

Get Involved!

- Become a CDISC Member
- Participate in Public Reviews
- Attend the Interchanges and authorized training
- Be a key collaborator
- Adopt the standards—ask partners to do so
- Spread the word
- Volunteer

For more information about CDISC
please visit our website:

www.cdisc.org

Any more questions?

Thank you for attending this webinar.

**CDISC's vision is to:
Inform Patient Care & Safety Through Higher Quality Medical Research**



Strength *through collaboration.*