CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

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

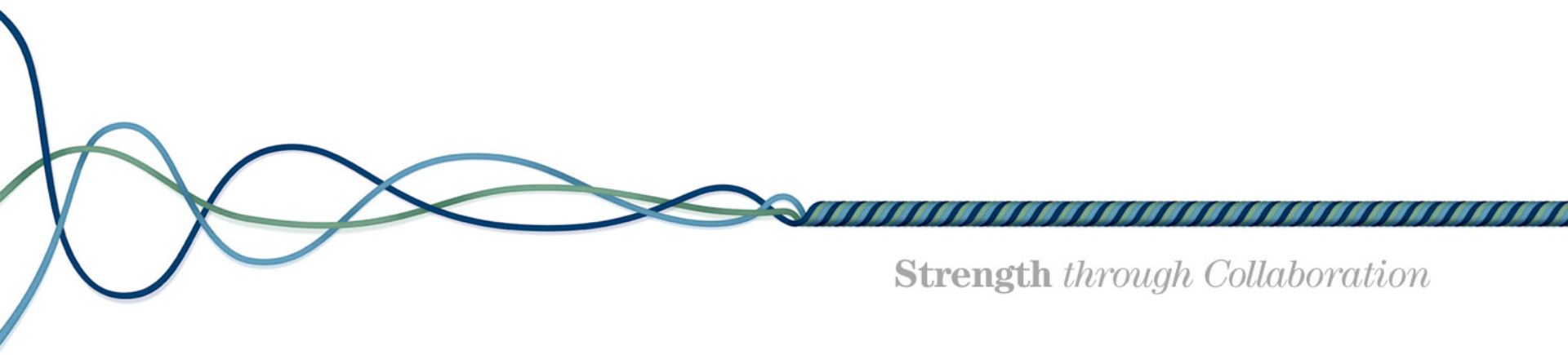
Strength *through Collaboration*

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.



Protocol Team Objective

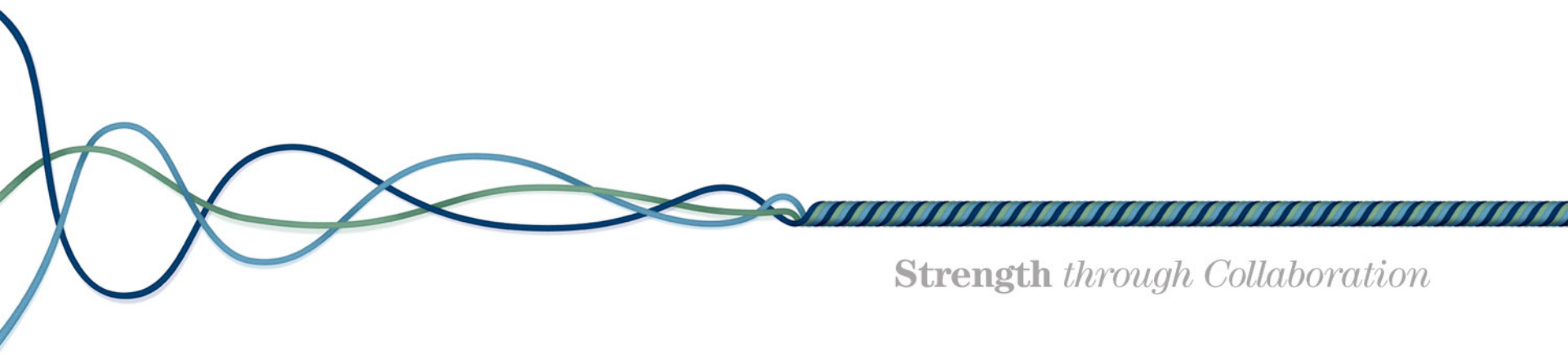
- Publication of a standard, structured, representation of protocol concepts that will enable interchange of protocol data and metadata among systems and stakeholders throughout the lifecycle of the study.
- Project charter is posted to the CDISC public website here: http://www.cdisc.org/team-charters

Available Protocol Standards

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

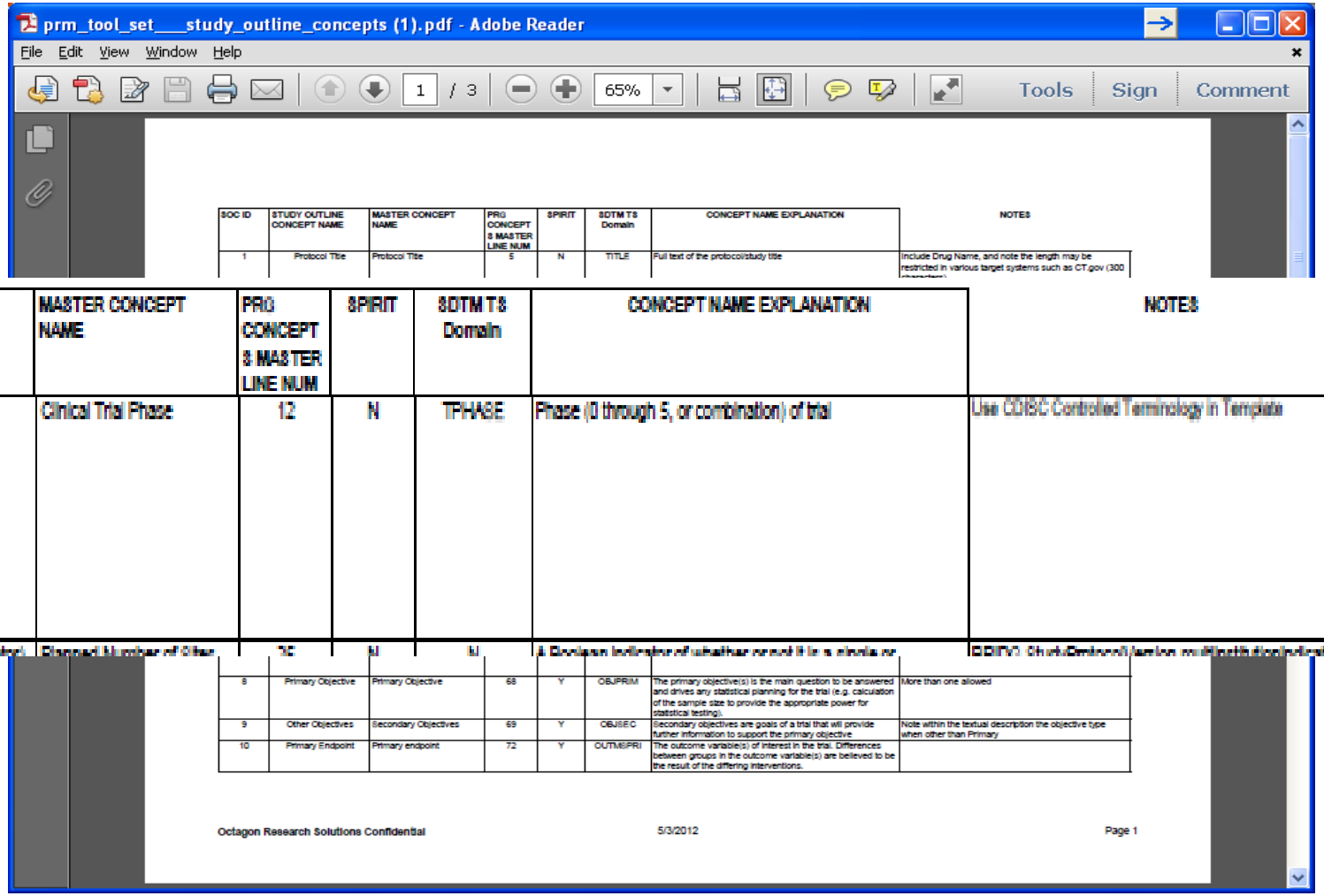
- Study Outline
  - Standard Concepts mapped to BRIDG, SPIRIT, and SDTM
  - Standard Document template and controlled terminology picklists
- Study Outline Web Wizard
  - Online tool available through CDISC
  - Through web interface, outputs SDTM TS domains and Study Outline PDF document
- Protocol PRM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

Study Outline Standard



Standard Study Outline Concepts

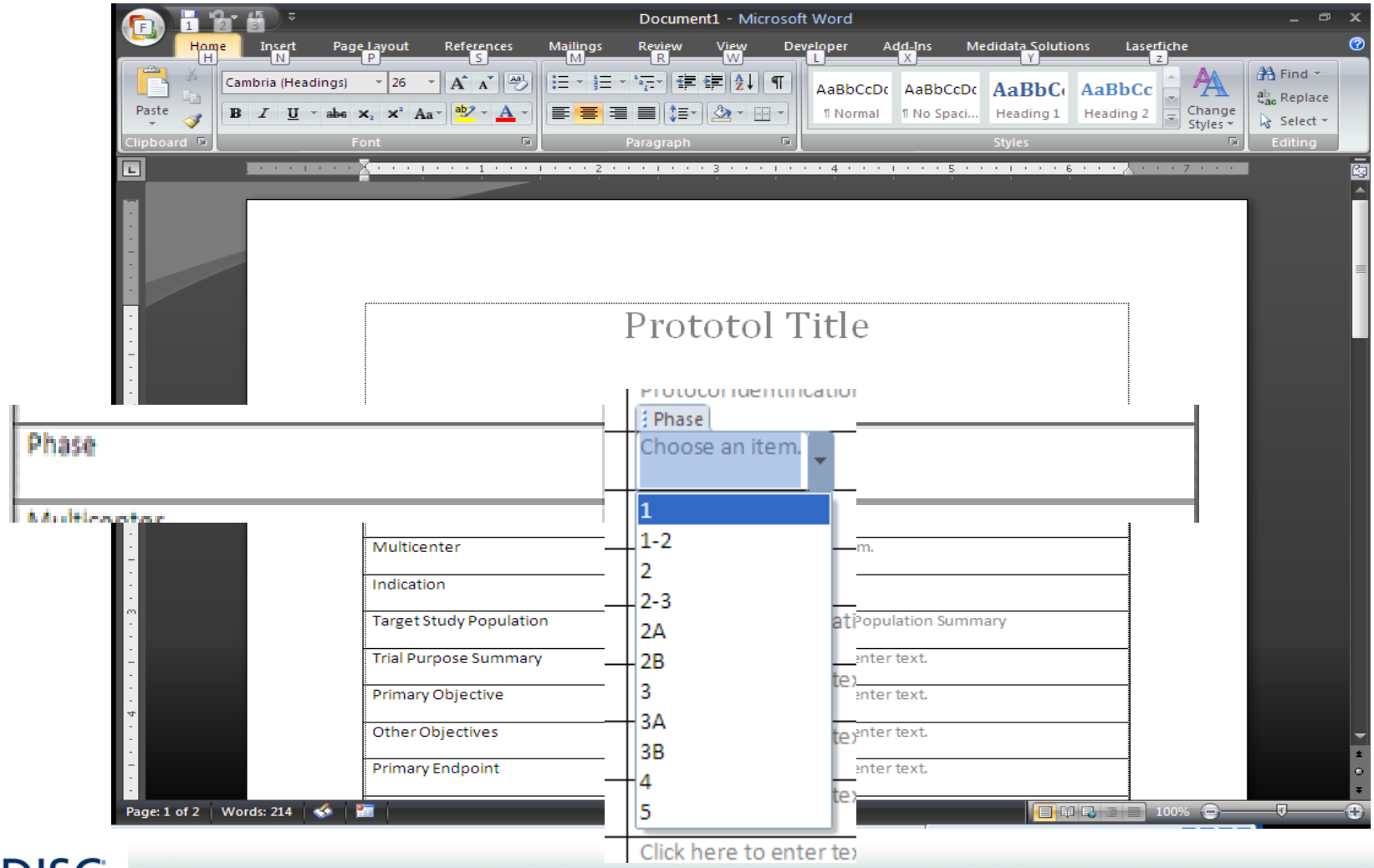
Web Site Link: http://www.cdisc.org/protocol



SOC ID	STUDY OUTLINE CONCEPT NAME	MASTER CONCEPT NAME	PRO CONCEPT & MASTER LINE NUM	SPIRIT	SDTM TS Domain	CONCEPT NAME EXPLANATION	NOTES
3	Phase	Clinical Trial Phase	12	N	TPHASE	Phase (0 through 5, or combination) of trial	Use CDISC Controlled Terminology in Template

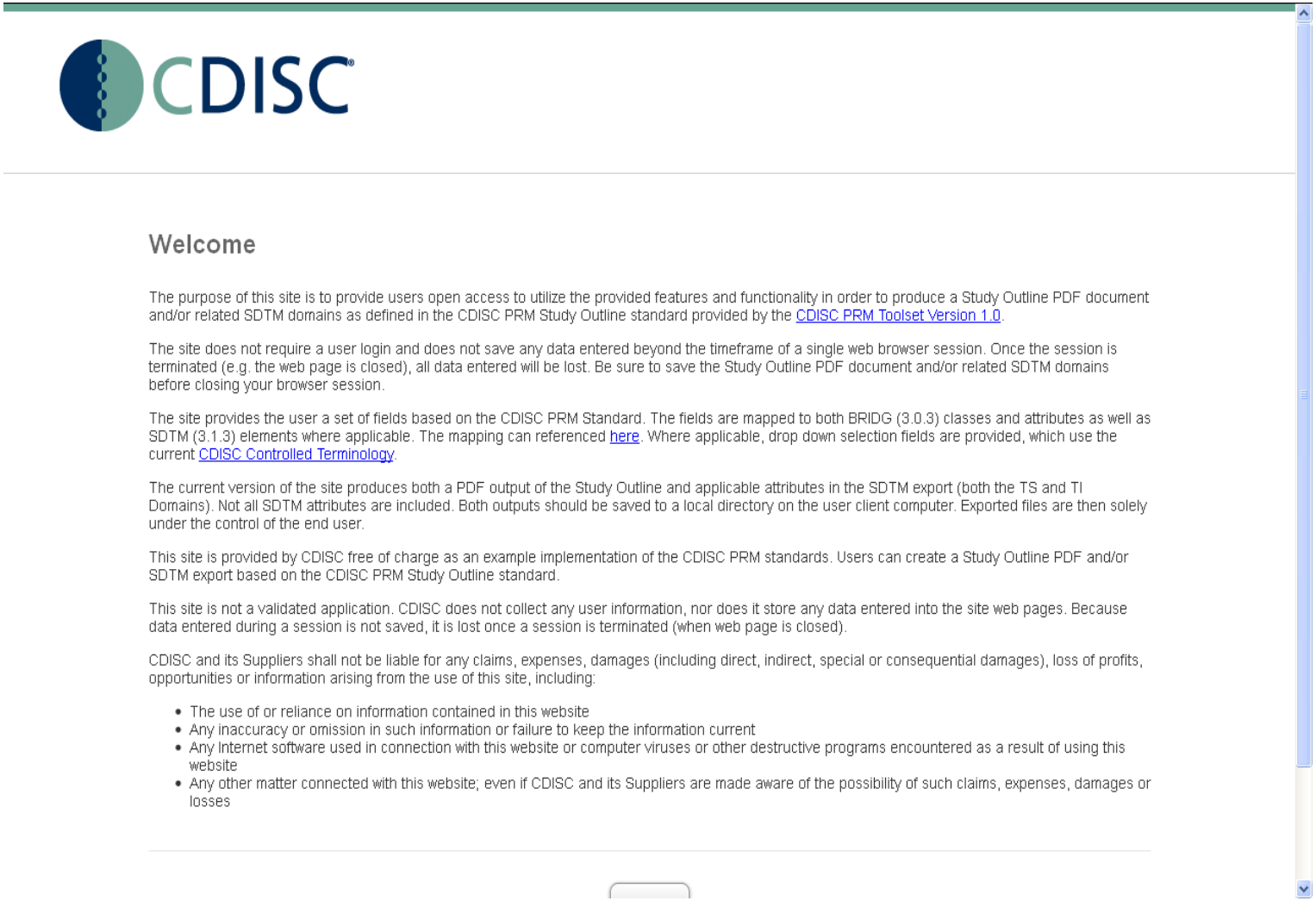
Study Outline Document Template

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



Study Outline Web Wizard

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



CDISC

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 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:

- The use of or reliance on information contained in this website
- 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
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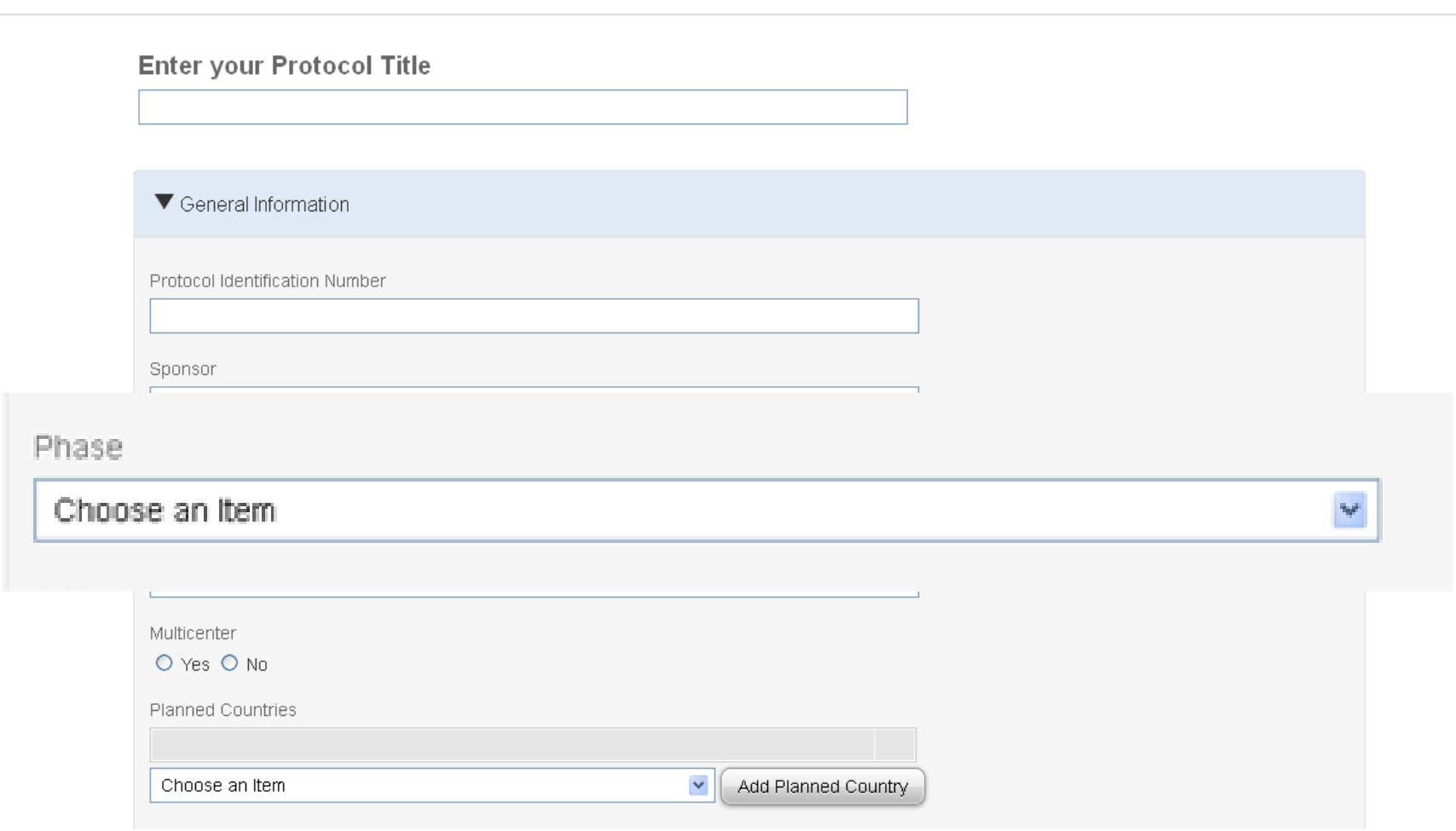

Enter your Protocol Title
General Information
Protocol Identification Number
Sponsor
Phase
Choose an Item
Multicenter
Yes
No
Planned Countries
Choose an Item
Add Planned Country

Enter your Protocol Title

▶ General Information

▶ Trial Objective and Purpose

▶ Trial Design

▶ Selection of Subjects

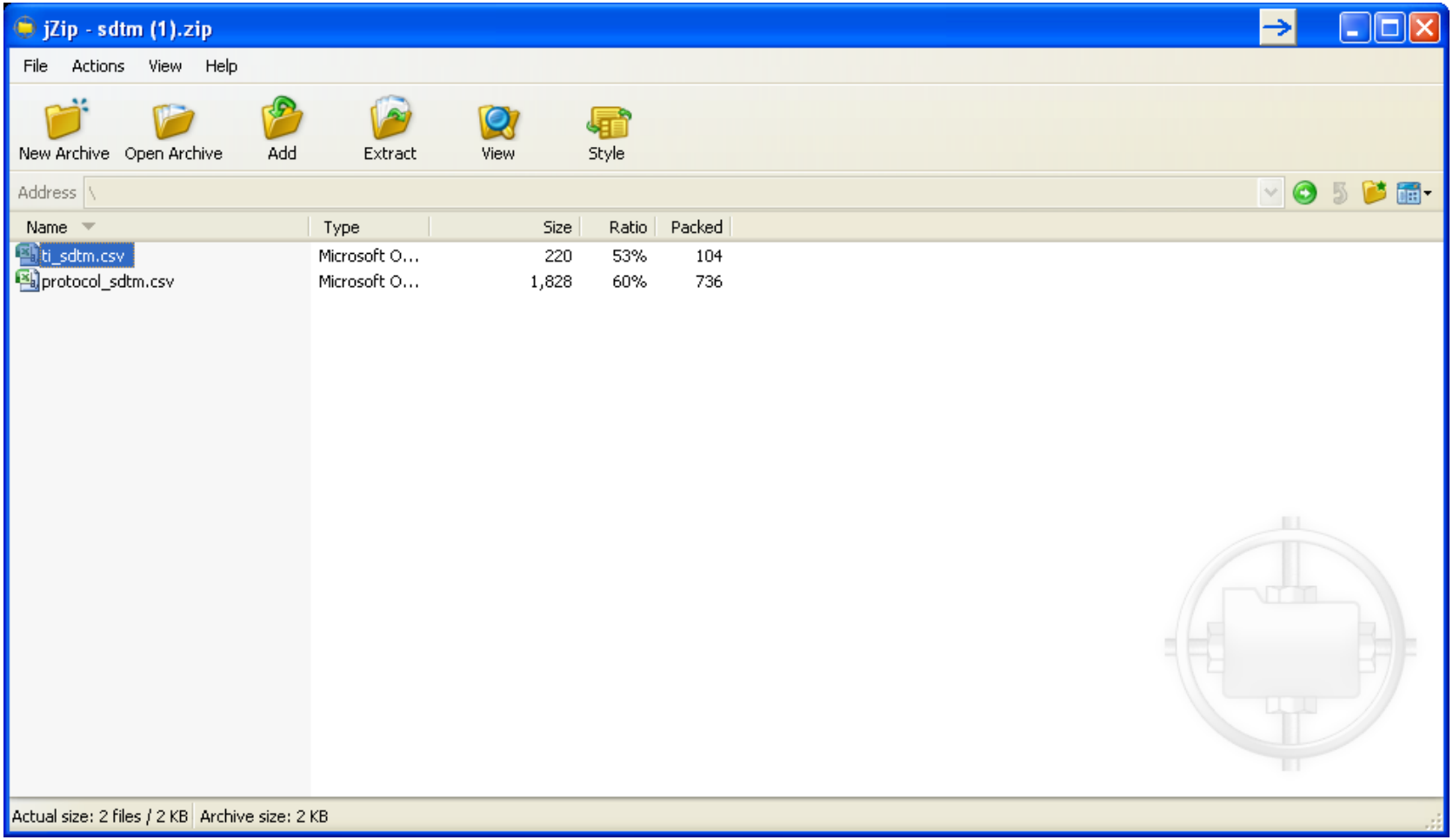
▶ Statistics

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	

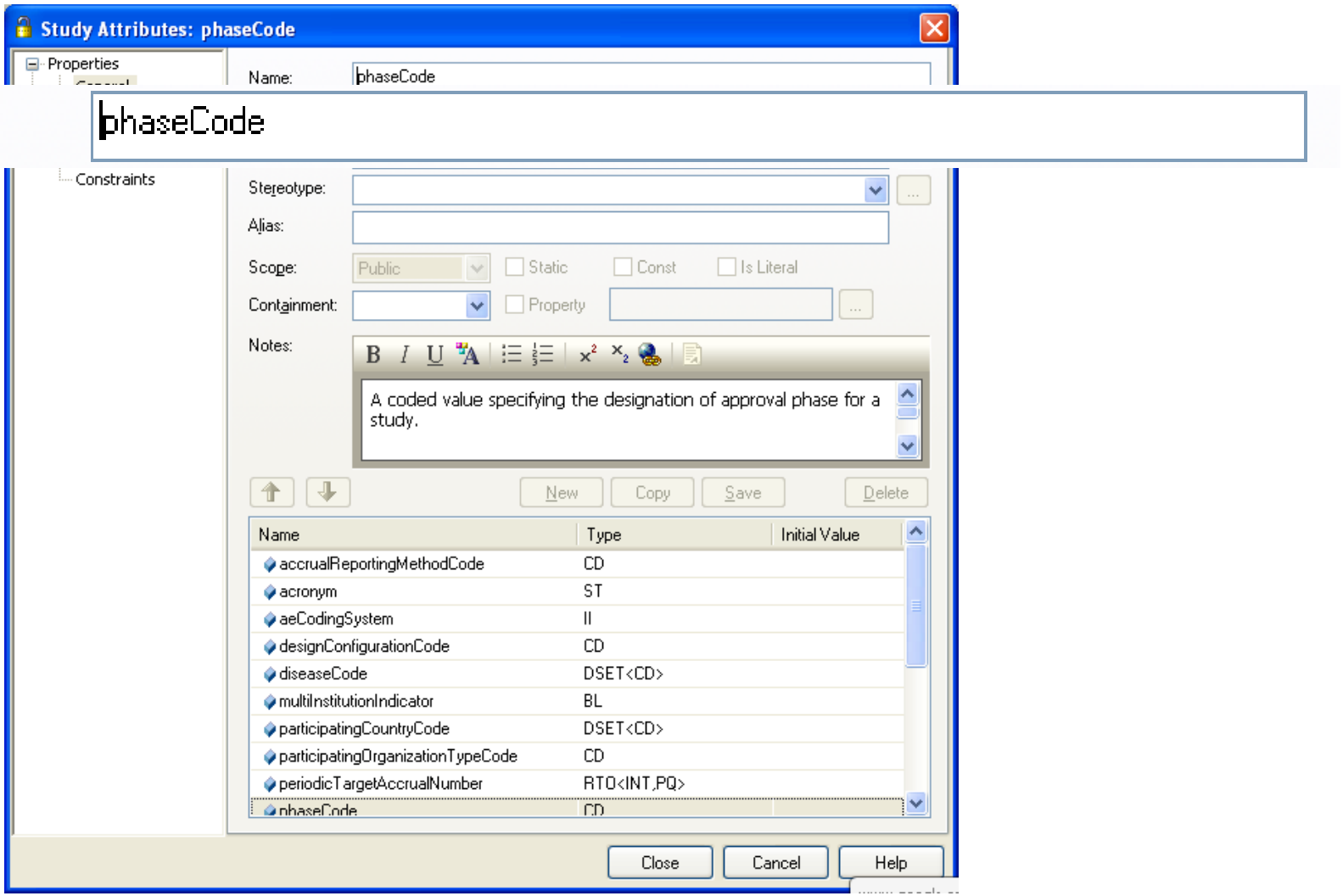
SDTM TS & TI Domains Export (CSV)



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				
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



Name: phaseCode

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

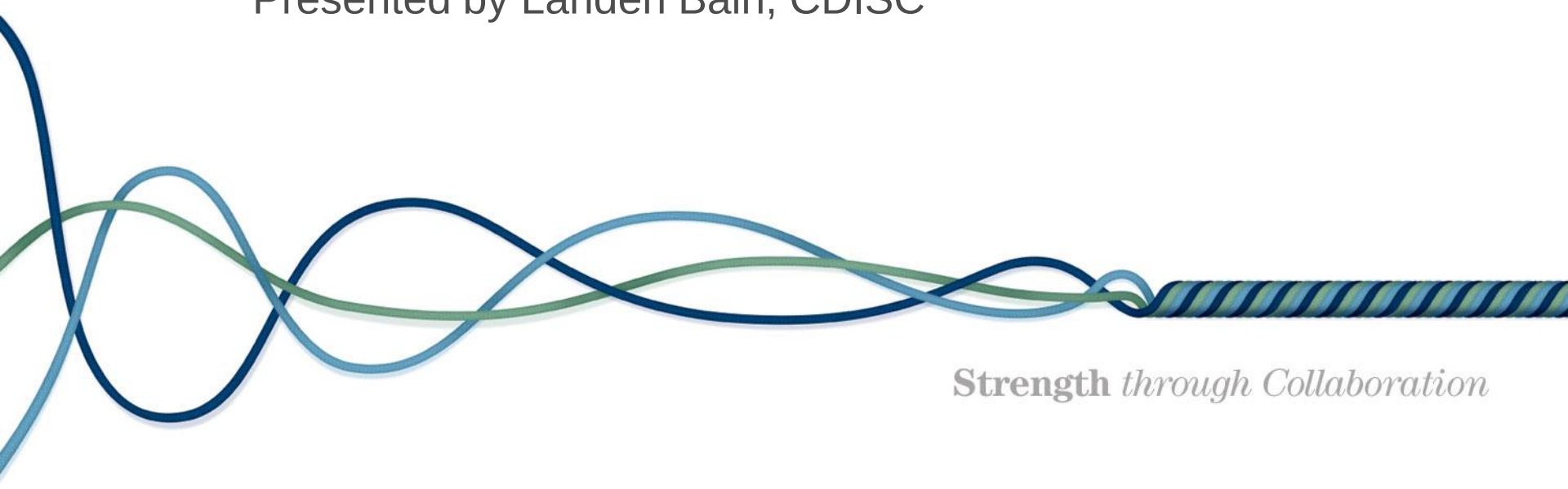
- Author Protocol on approved Outline
- Generate SDTM TS and TI Domains
- Exchnage standard terminology and concepts

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



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.

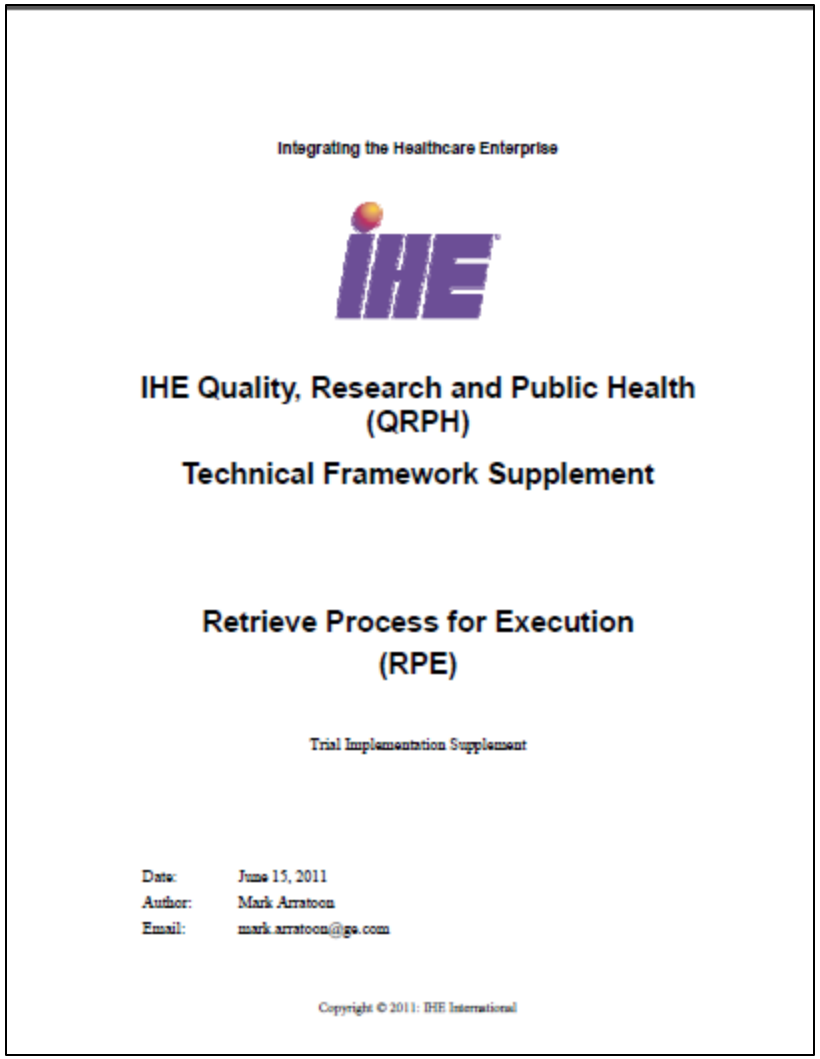
What can the EHR do for Regulated Research?

- 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



Integrating the Healthcare Enterprise

IHE Quality, Research and Public Health (QRPH)

Technical Framework Supplement

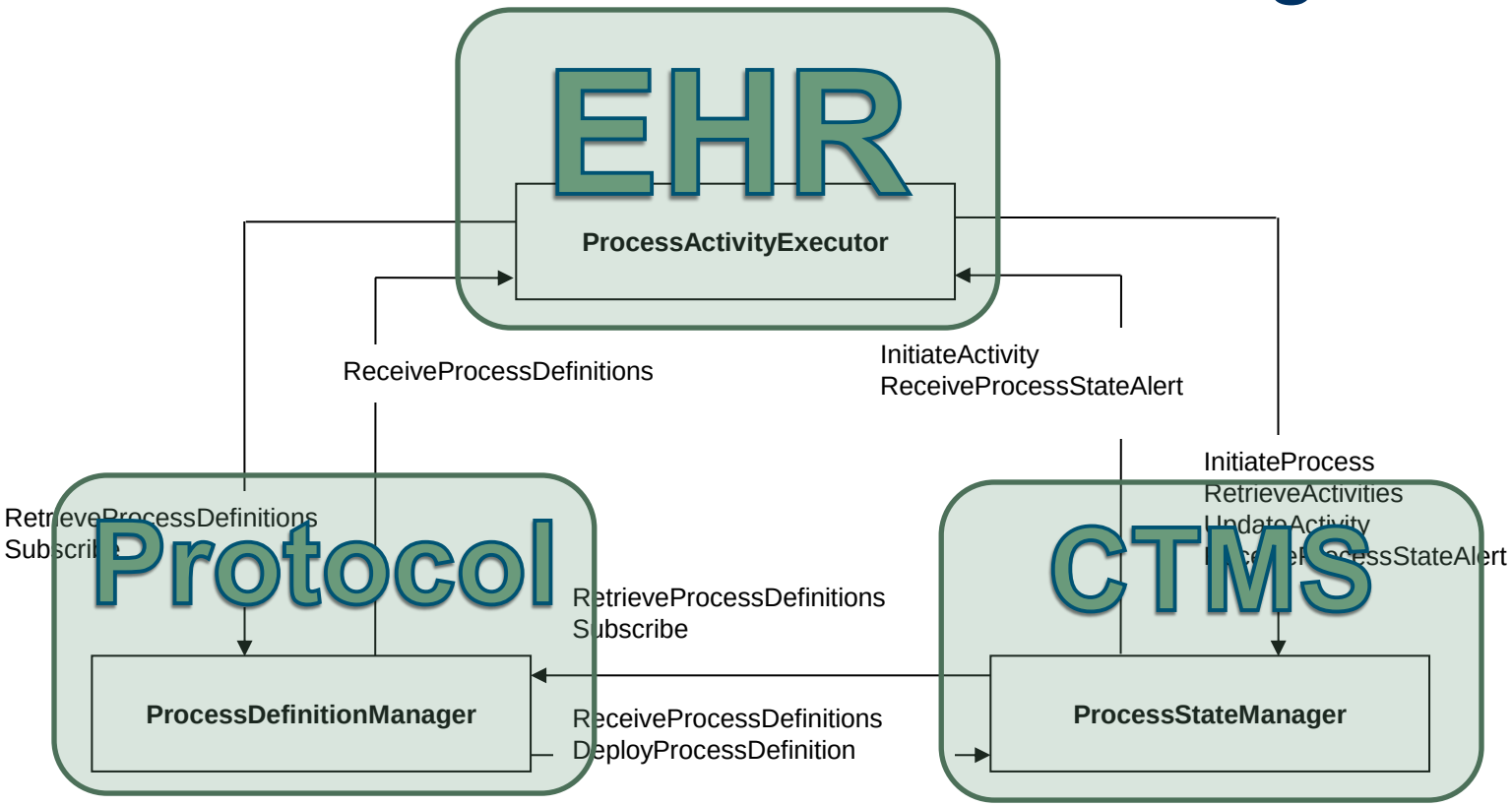
Retrieve Process for Execution (RPE)

Trial Implementation Supplement

Date: June 15, 2011
Author: Mark Arratoon
Email: mark.arratoon@ge.com

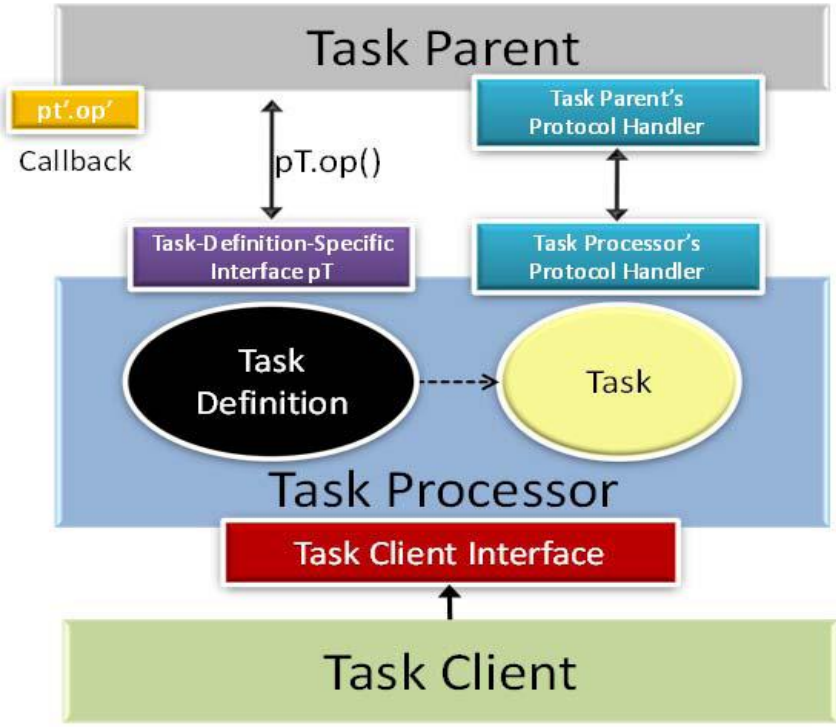
http://www.cdisc.org/stuff/contentmgr/files/0/f5a0121d251a348a87466028e156d3c3/misc/cdisc_healthcare_link_profiles.pdf

Collaborative Process Management



Consistent with BPM Design

Mapping of RPE 2.0 Actors:



ProcessStateManager (PSM)

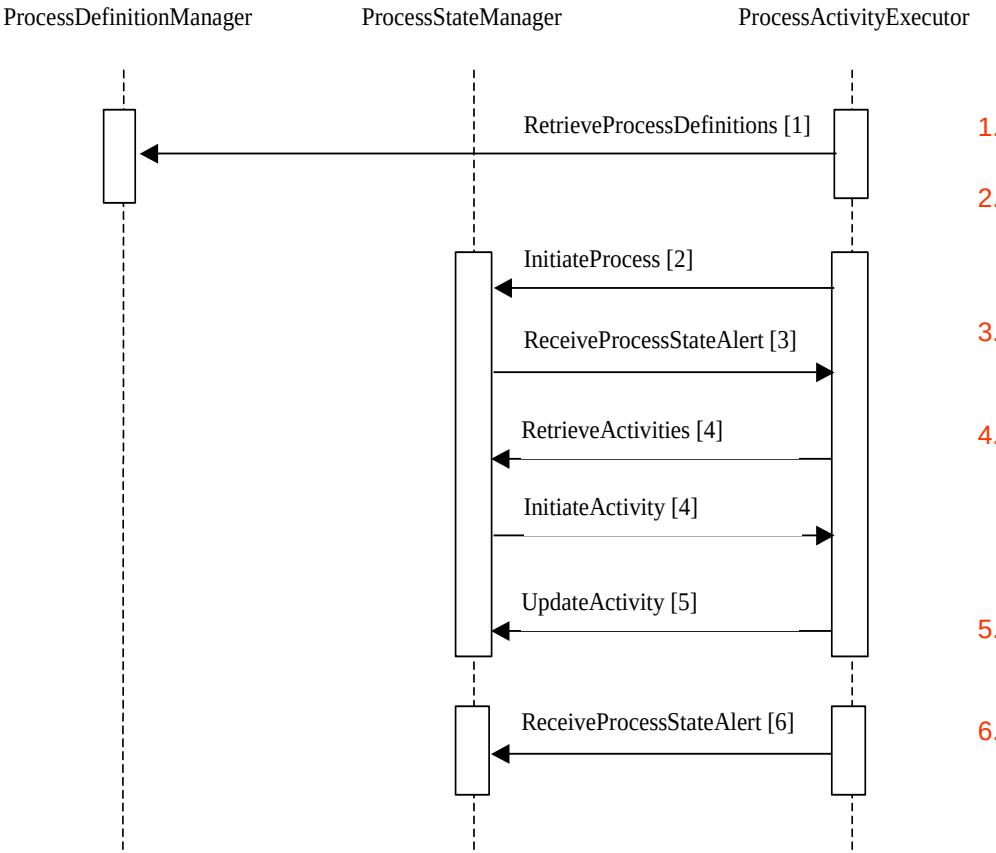
ProcessStateManager (PSM)

OR

ProcessActivityExecutor (PAE)

ProcessActivityExecutor (PAE)

RPE Use Case Walkthrough

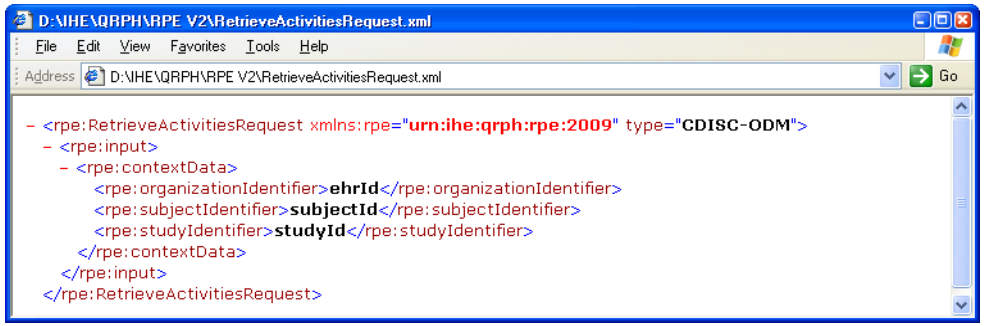


1. The ProcessActivityExecutor retrieves process definitions of potential interest from the ProcessDefinitionManager.
2. The ProcessActivityExecutor request's process initiation by the ProcessStateManager forwarding a given process definition identifier as well as other required data, e.g., a patient 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.

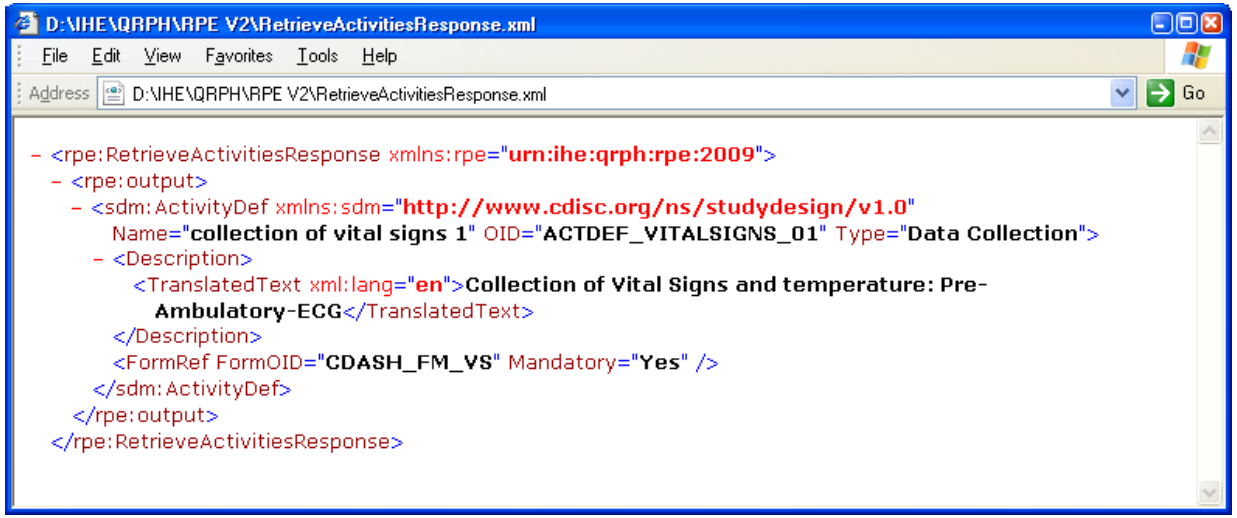
RetrieveActivities – CDISC

4. The ProcessActivityExecutor either:
   - Retrieves the current activities it has to perform when activity creation is managed by the ProcessStateManager OR
   - …

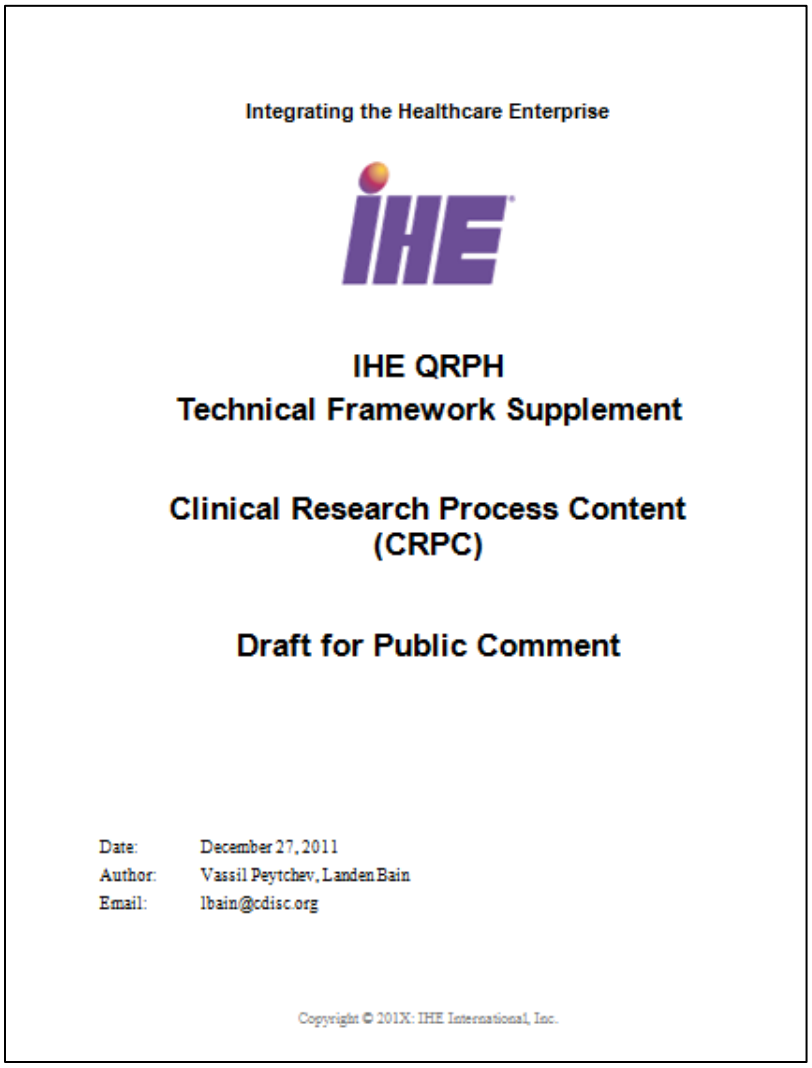
Request:



Response:



Clinical Research Process Content



Integrating the Healthcare Enterprise

IHE QRPH
Technical Framework Supplement

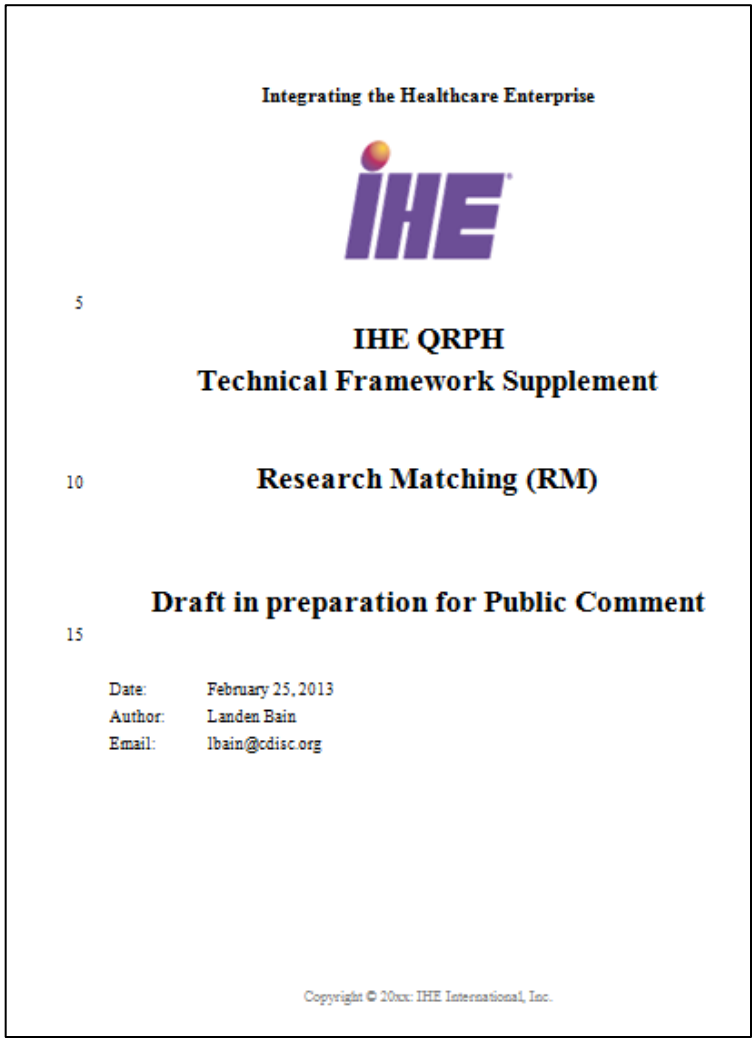
Clinical Research Process Content
(CRPC)

Draft for Public Comment

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

http://www.cdisc.org/stuff/contentmgr/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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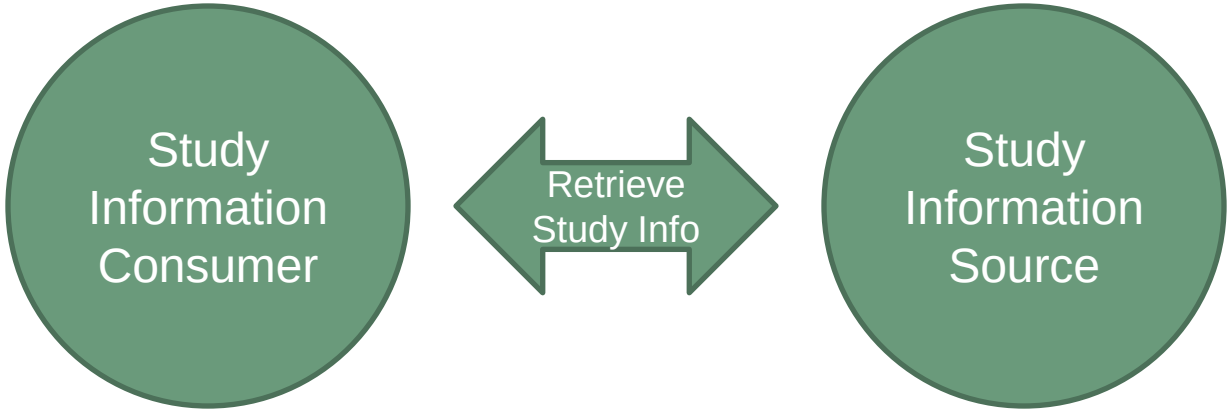
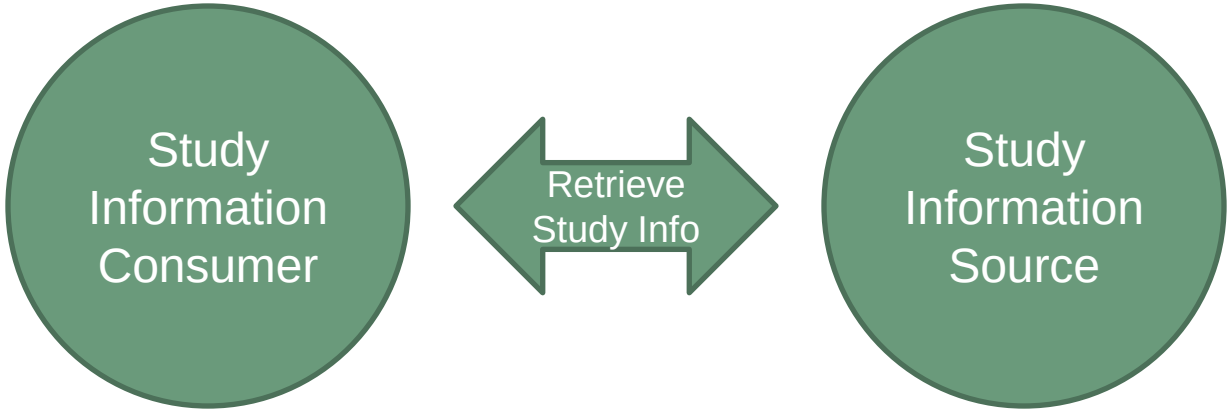
ftp://ftp.ihe.net/Quality/2013_2014_YR_7/QRPH_Technical/ResearchMatching/

Find studies for interested patients "Match.com"



The Study Information Consumer retrieves relevant study descriptions and links from a Study Information Source, something like clintrials.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

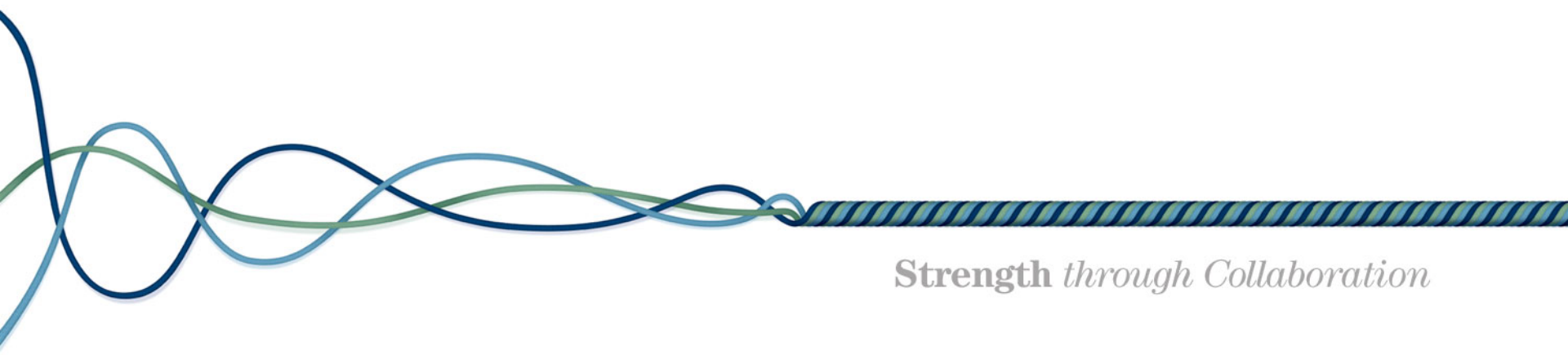
- Develop the protocol as a rigorous process definition
- Use the IHE profiles as the gateway to handing off process definition to EHRs

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



Next Steps for the CDISC PRG

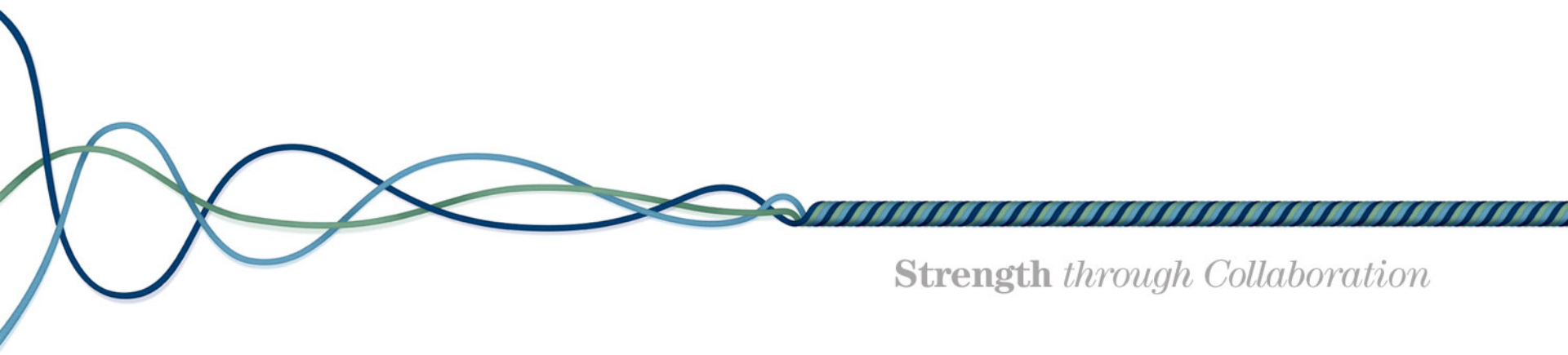
- 2013 – Protocol Concepts
  - Publish Protocol Concepts Standard
  - Including mapping to BRIDG
  - Comprehensive list of standard Protocol Concepts
- 2014 H1 – Protocol XML
  - An ODM extension to SDM ODM to include representation of the Protocol (and Study Outline) Concepts
- 2014 H2 – Standard Protocol 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 stanards
  - 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



How to get involved

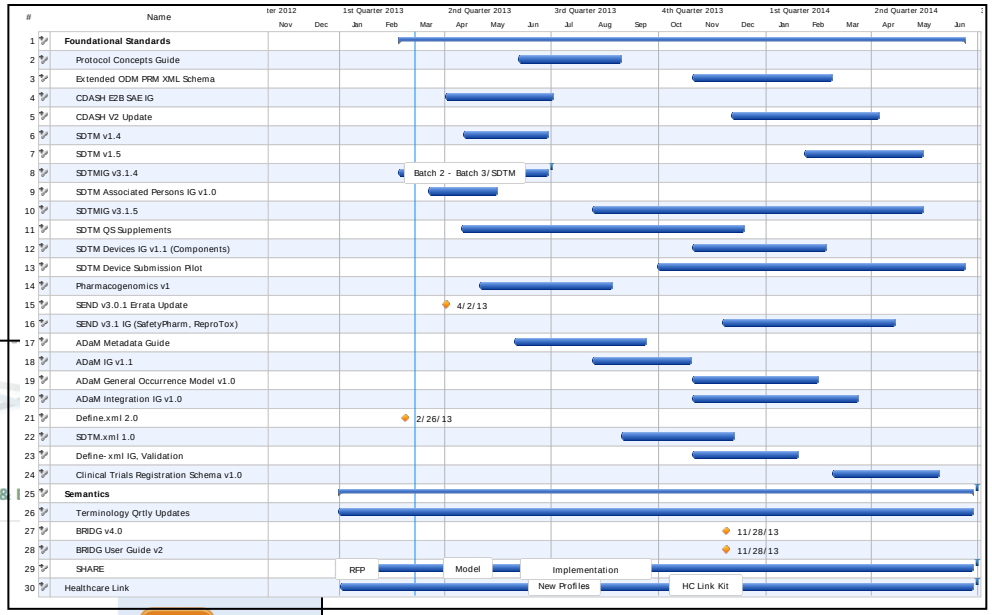
How can you contribute to the CDISC mission?

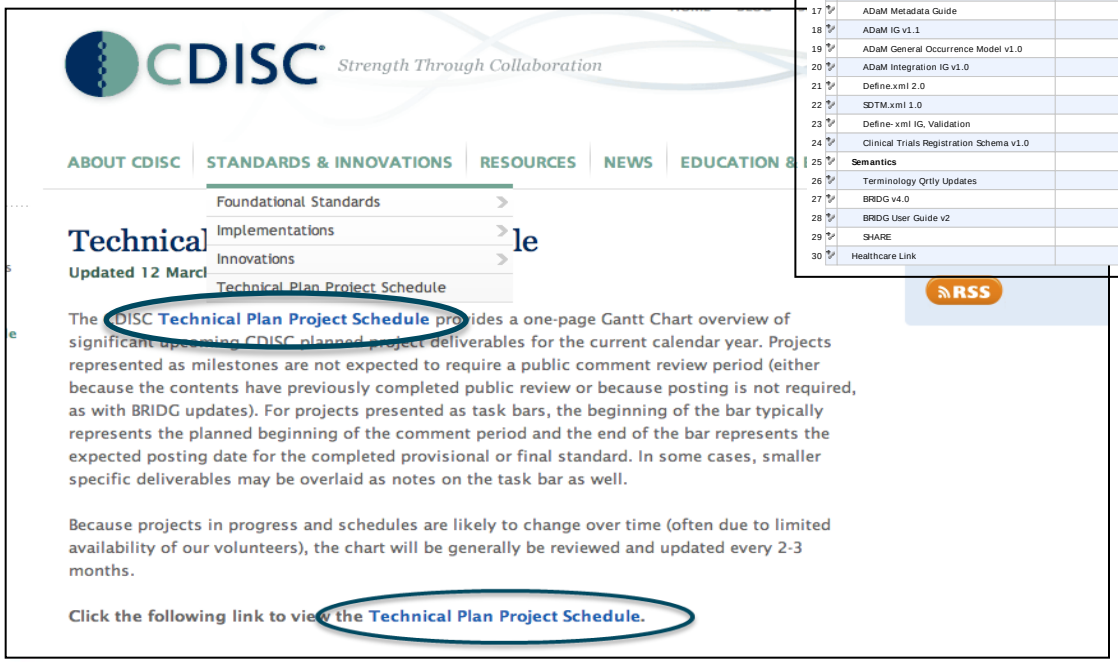
- **Participate in the review process**
  - Review draft standards posted to CDISC.org
  - Record comments for documents via public comment tracker
- **Join a CDISC project team**
  - Submit new volunteer registration form indicating which project teams/sub-teams you have interest in joining
- **Future 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)





http://www.cdisc.org/techical-plan-

Where to find recently posted documents

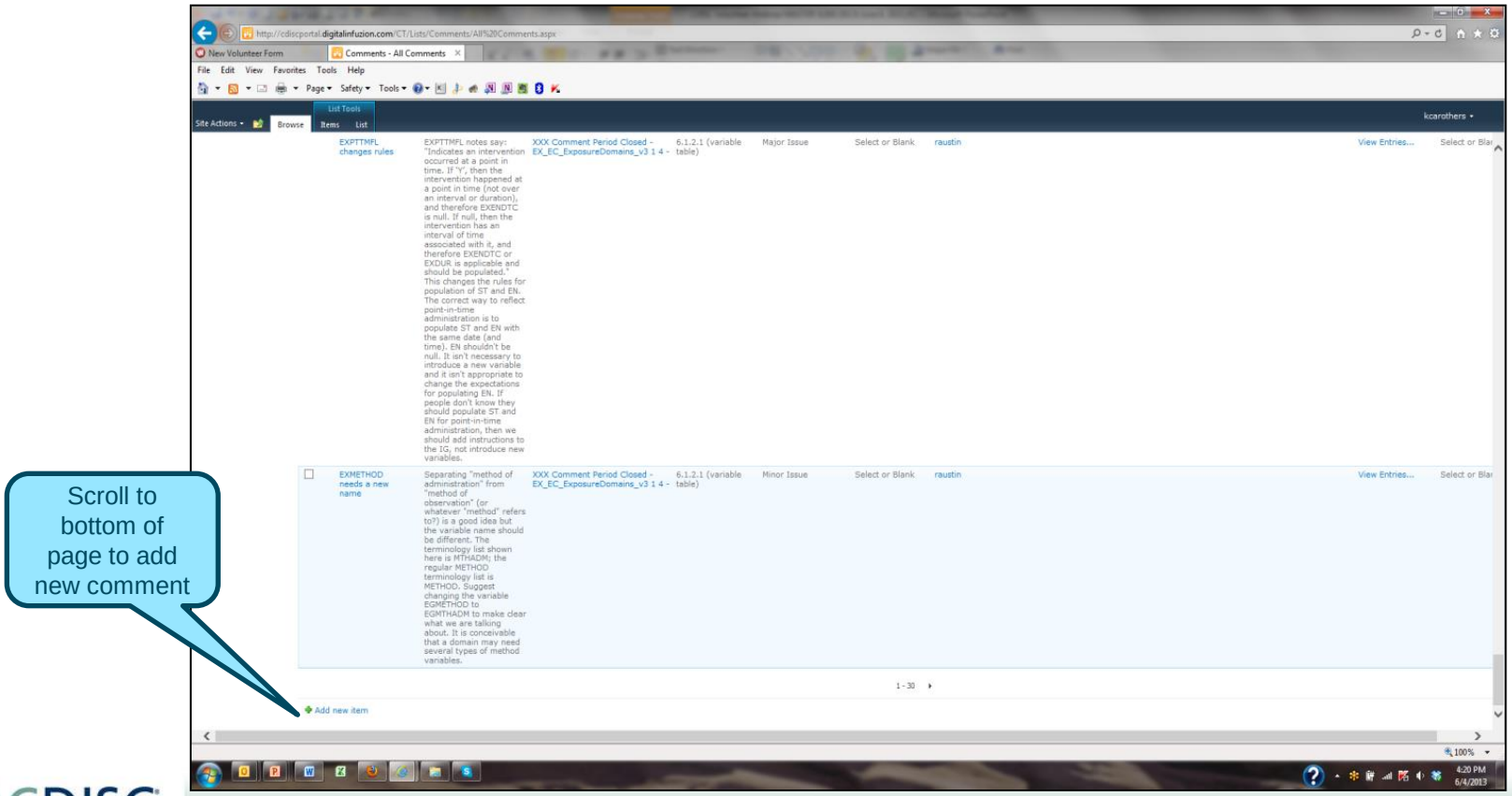
- "What's New" on homepage
- CDISC Standards Latest Updates
- Individual Project team pages or the Newsroom

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:

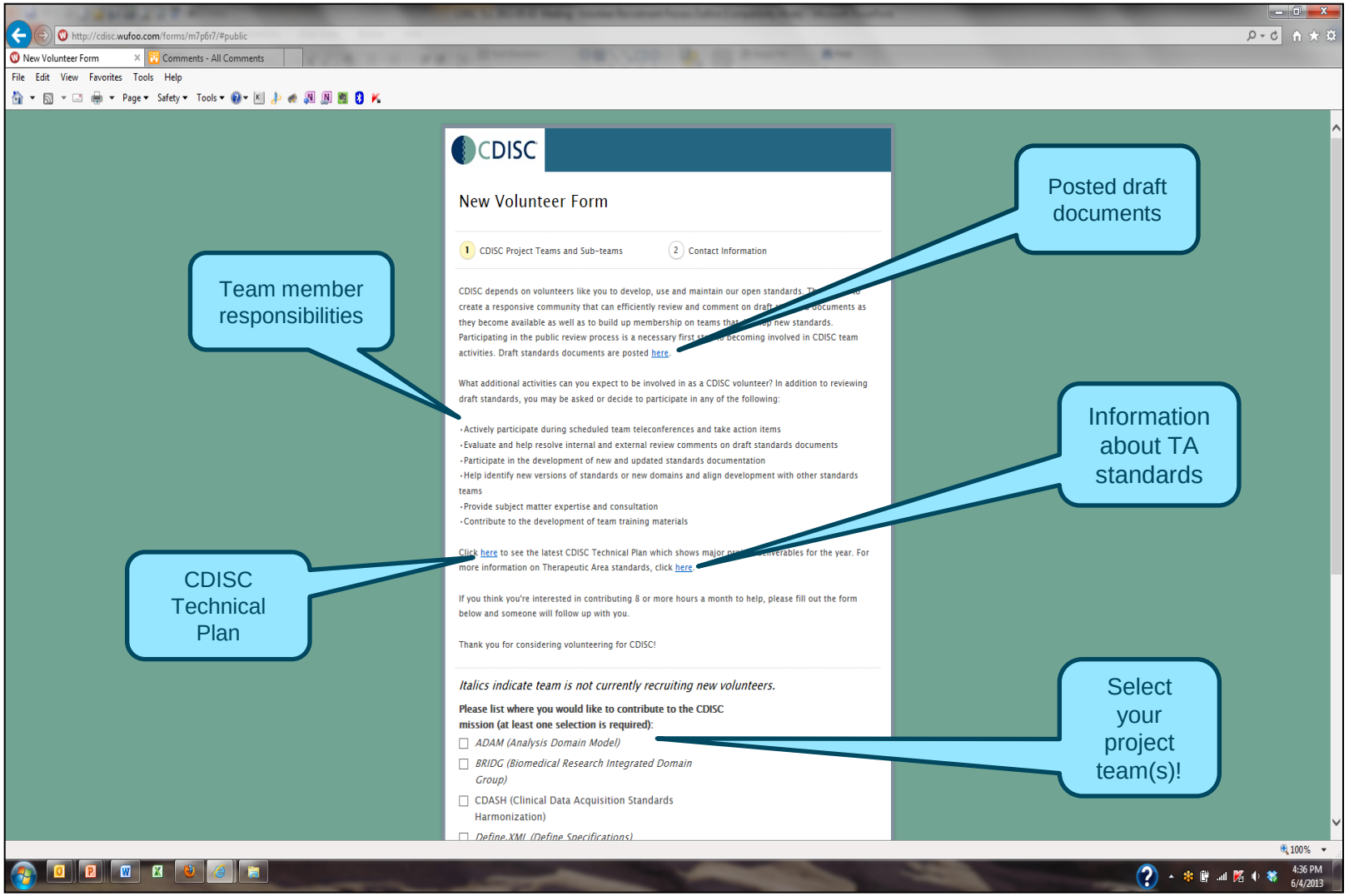


How to get involved: sign up for a team

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

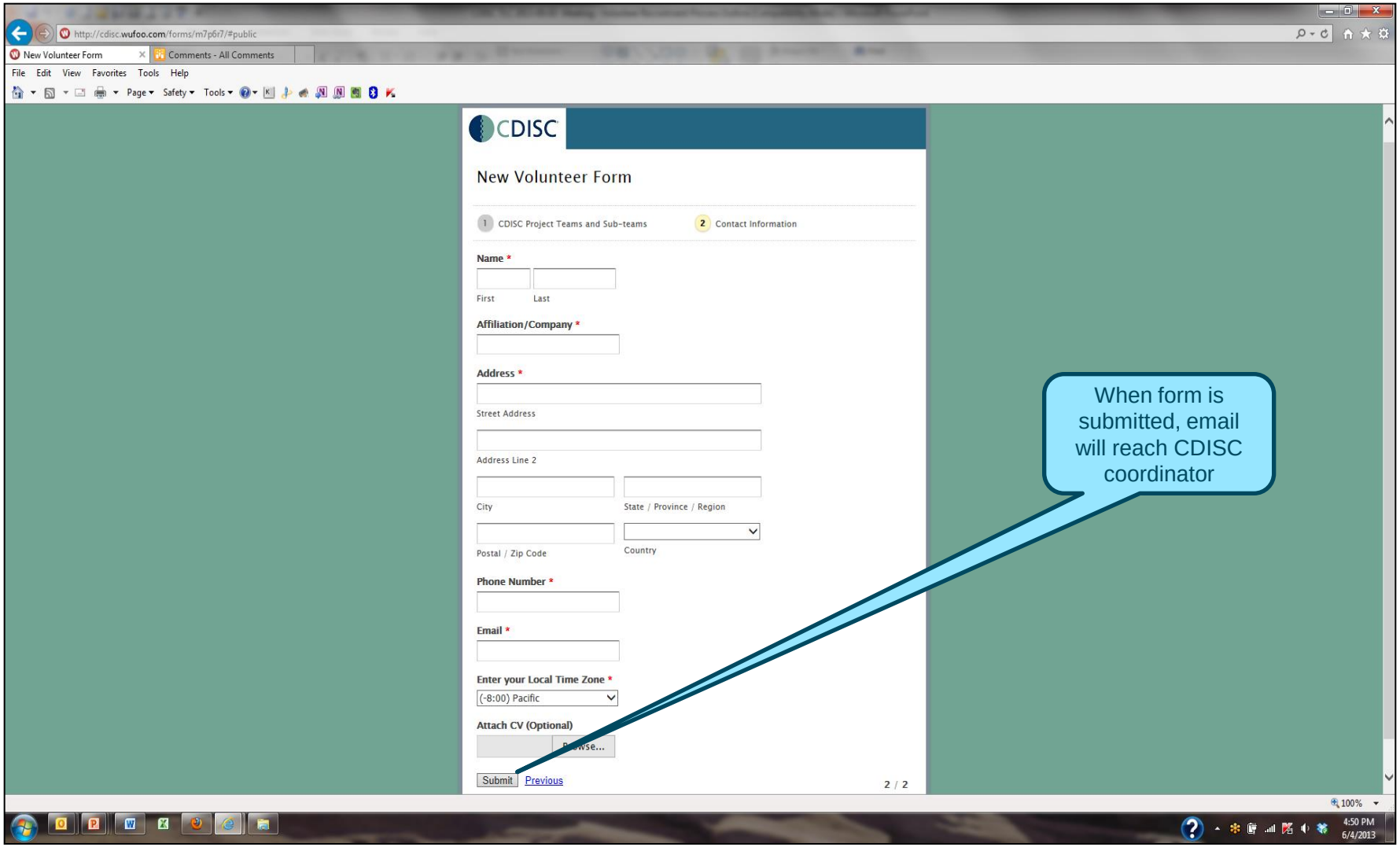
How to get involved: sign up for a team

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



How to get involved: sign up for team

- Step 2: Submit volunteer form to CDISC



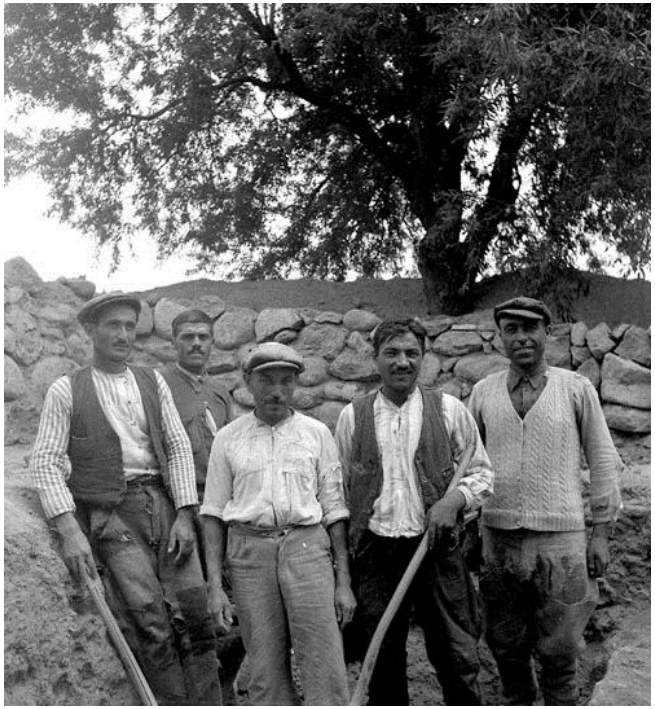
How to get involved: volunteer for CDISC

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

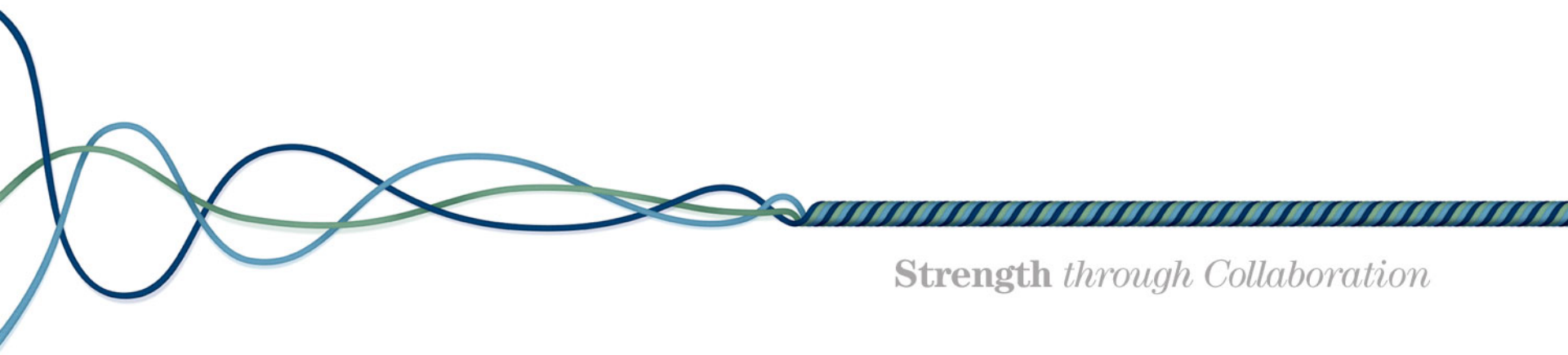


Question & Answer Session

All

CDISC Education and Communications Updates

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



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