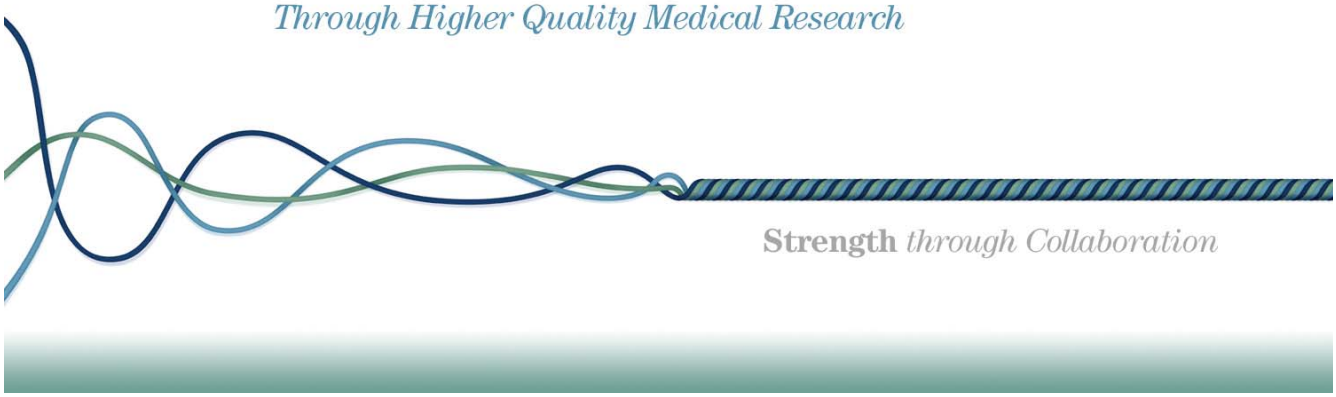
CDISC

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

CDISC Update
September 2016

The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research



2016 Milestones as of September

- Membership has grown to over **420** organizations.
- A majority of our Foundational Standards are now required for regulatory submissions to the FDA and PMDA; the FDA data standards catalog is pointing to 5 TA Standards.
- CDISC standards are being used to support research for *global public health, nutrition and observational* research.
- We completed 10 new Therapeutic Area standards to bring the total to 25, while also updating Foundational Standards.
- CDISC's metadata repository, SHARE, now delivers all CDISC standards electronically in various formats, in addition to diff files (for version control) and mappings of CDASH to SDTM, and other value-based offerings for users.

2016 Milestones

- We have increased collaborations with NIH and the Japan's AMED; AMED and NIH/NLM have joined CDISC.
- We held our first Fundraiser to bring in **unrestricted** funding.
- CDISC Education Team has developed a new course focused on implementing *beginning-to-end standards*, first delivered to academics in Japan.
- We have formed an eSource Stakeholders (grant from FDA) with 6 sub-groups addressing various aspects of implementing eSource research including EHRs.
- CFAST teams have been able to leverage SHARE to develop Therapeutic Area standards more efficiently.
- The SHARE Application Programming Interface (API) will be available as a production version in early 2017.
- New website (mobile friendly), increased attendance at Interchanges, social media and press release uptake.

Membership YTD 2016

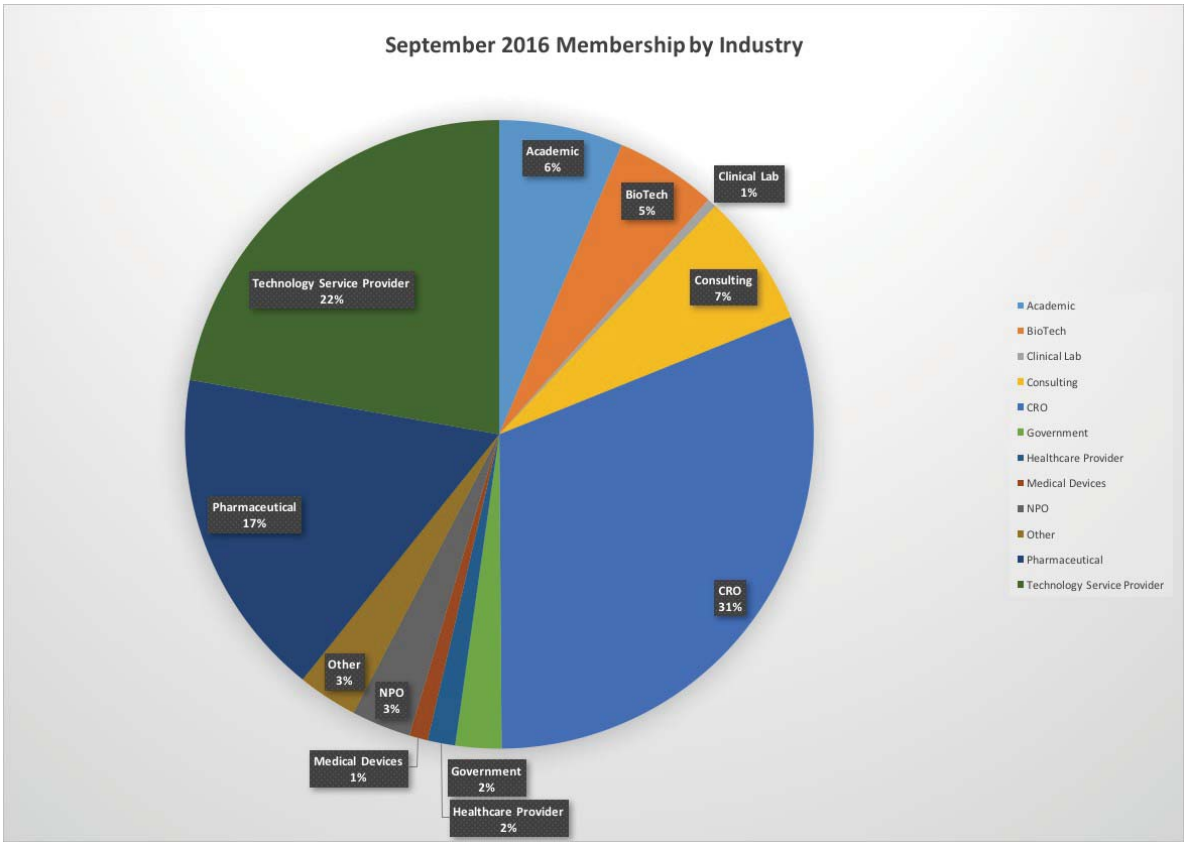
Membership By Numbers
(as of September 2016)

New Members

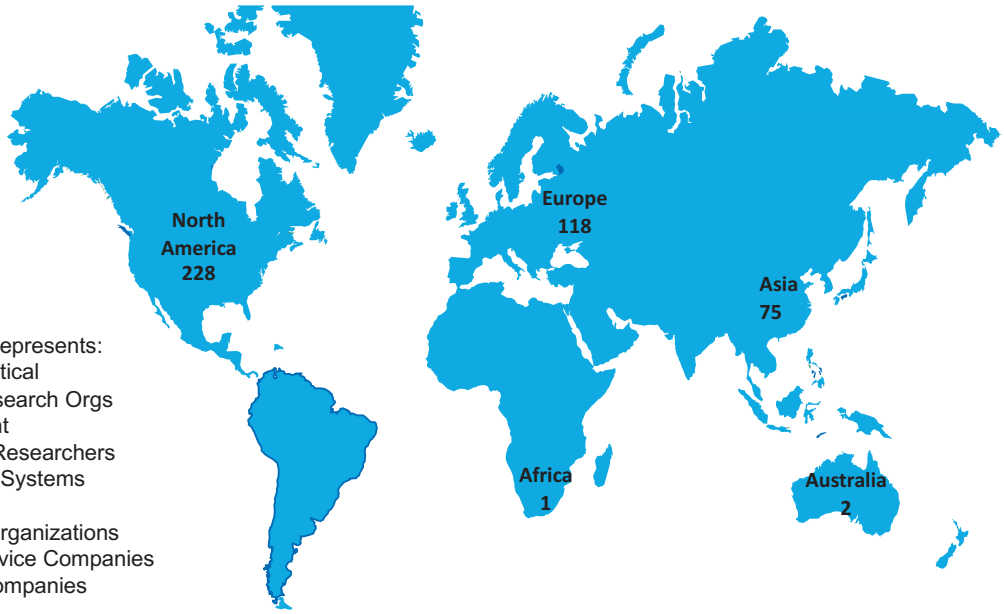
- Gold Members = 43
- Platinum Members = 7

Total New Members = <u>50</u>

TOTAL CDISC MEMBERS = <u>423</u>



CDISC Members Around the Globe



Membership Represents:

- Pharmaceutical
- Clinical Research Orgs
- Government
- Academic Researchers
- Healthcare Systems
- BioTech
- Nonprofit Organizations
- Medical Device Companies
- Nutrition Companies

MEMBERSHIP – FUN FACTS

- **Surge in Membership Growth from China over the past 12 months – 8 new Chinese members of which two joined as Platinum Members.**
- **The CFDA (Chinese Food and Drug Administration) in a July 2016 announcement has officially endorsed CDISC Standards.**
- **3 New countries added to membership – *Austria, Portugal and Russia* bringing a total of 27 countries.**
- **STAR MEMBERS – Members with long-term membership with CDISC. Out of 423 members,184 are Star Members as of 31 March. This represents about 44% of the total membership and growing.**
  - **Charter - 18**
  - **10 Years and up - 56**
  - **5 – 9 Years - 110**

Membership Growth Challenges

- **High renewal rate >90%**
- **Need Consistently Improving CDISC Value Proposition**
- **Industry consolidation**
  - Fewer major prospects
  - Loss of a CDISC member with each merger
  - Department use focused vs. total headcount
- **New prospects**
  - New Markets
  - New Regions – Australia, Latin America

2017 CDISC New, Additional Member Benefits

Platinum Members:

Gold Members:

2017 CDISC New, Additional Member Benefits

Platinum **AND** Gold Members:

- Standard Development and Adoption – Serving as volunteer or lead on standards team, attending Interchanges and Intrachanges, sponsoring events, participating in the Fellows Program, providing grants for standards development, pursuing ODM-certification for tools.
- Education and Training – Successfully completing training courses, enabling your staff to become CDISC-Authorized Instructors or Licensed Trainers, hosting public training.
- Additional CDISC Operations and Awareness – Actively participating on CDISC Advisory Council (CAC) committees, joining the CDISC Board of Directors, serving on one of the CDISC Coordinating Committees.

CDISC ENGAGEMENT TRAIL

CDISC TRAILBLAZER

TRAILBLAZER - Your organization is paving the way for using CDISC standards. Your expertise and impact are substantial.

CDISC EXPLORER

EXPLORER – Your organization has a proven track record implementing CDISC standards. Your involvement demonstrates a solid knowledge base and purpose.

CDISC PATHFINDER

PATHFINDER – Your organization is on the journey… adopting CDISC standards with an eye onward and upward.

* Categorization will be based on rolling past two years
* First categorization to take place 1 Jan 2017
* Each level stays in tact until each new year

CDISC LISTENS to OUR MEMBERS and CONTRIBUTING COMMUNITY

- Listening Tours – Published White Paper
- CDISC Advisory Council (CAC)
  - Priorities Ranking 27 September
- SHARE Survey
  - SHARE Session
- 2 August Strategy Session

CDISC Priorities based on Listening Tours

- Improve the Terminology process and transparency
- Validation rules to be aligned with FDA, PMDA and in SHARE
- Continue to increase TA standards training courses and End-to-End training (online and in-house; symposium options)
- Work to align TA standards development with Foundational Standards updates with FDA and Terminology updates.
- Leverage SHARE to help with versioning and standards harmonization and accessibility.

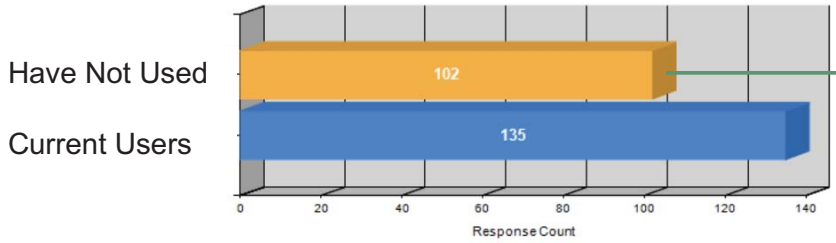
Input from the CDISC Advisory Council

- Provide implementation services
- Harmonize standards end-to-end
- Hire more staff to complement volunteer-driven teams
- Deliver more training and make it more affordable
- Identify use cases, business cases, success stories with metrics so that implementers can make case for standards to management
- Use CAC calls for problem solving

2016 SHARE Survey, 240 Respondents

Use of SHARE Exports from the CDISC Website

- 56% (*n*=135) have downloaded SHARE exports from the CDISC website with high levels of satisfaction

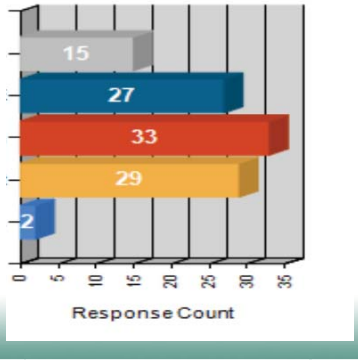


50% planning to use exports

Planned Use of SHARE API (Application Programming Interface)

- 17% (*n*=41) of respondents plan to be early adopters

- More Efficient than PDFs
- More Efficient than SHARE Exports
- Process Automation
- End-to-End Standards
- Other



To support…

- Institutional MDRs
- Diverse Other Applications & Software
- Reporting

2 August 2016 Strategy Session on the Future of Medical Research and the Role of Standards: "Forming Connections Towards Complementary Systems"

The purpose was to explore how collaboration, global CDISC standards and related enablers can catalyze more efficient and innovative medical research processes for the benefit of all.

Key Themes in Points Made By Participants

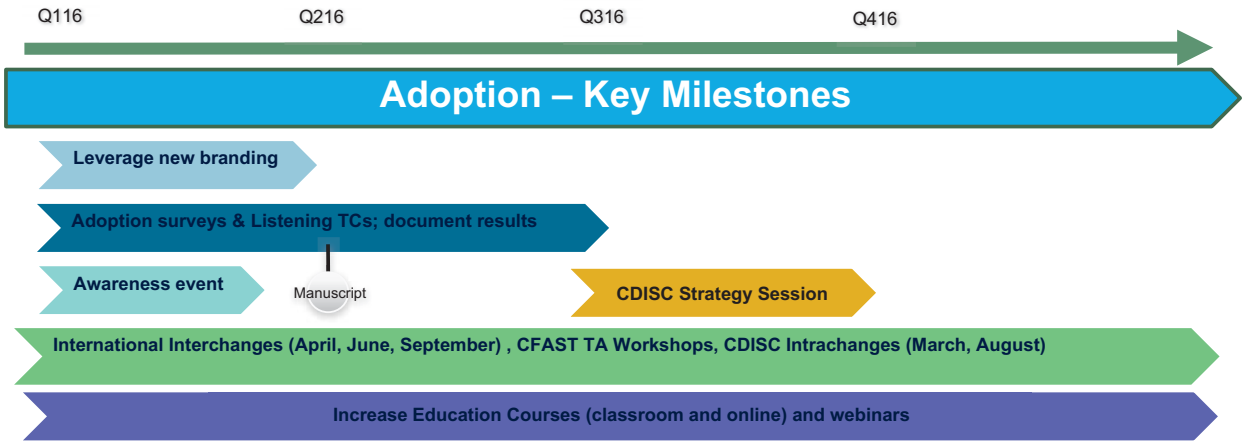
- The entire journey of each patient is important.
- There are parallel universes of patient care and research that need to be brought together.
- Bringing together parallel universes will require cooperation and collaboration among federal agencies, standards development organizations and researchers in academia, healthcare and biopharma; and, removing the uncertainty of EHR-enabled prospective research.
- Big data can be leveraged for certain use cases, but each bit of information is precious and quality matters, especially when data are scarce (e.g. outbreaks, rare diseases, clinical trials).
- Data standards have demonstrated value, but barriers to broader adoption remain to be addressed.
- Education and increased awareness around the availability and use of global standards to streamline research are necessary.
- Funding for standards development and maintenance is inadequate, but who should pay for this is unclear.

Next Steps from 2 August Strategy Session

- Common core dataset, CDASH 2.0 and harmonized clinical research models
- Common protocol template, executable tool
- Prospective EHR-enabled regulated research study
- Leveraging SHARE with a viable sustainability model
- Education and awareness building

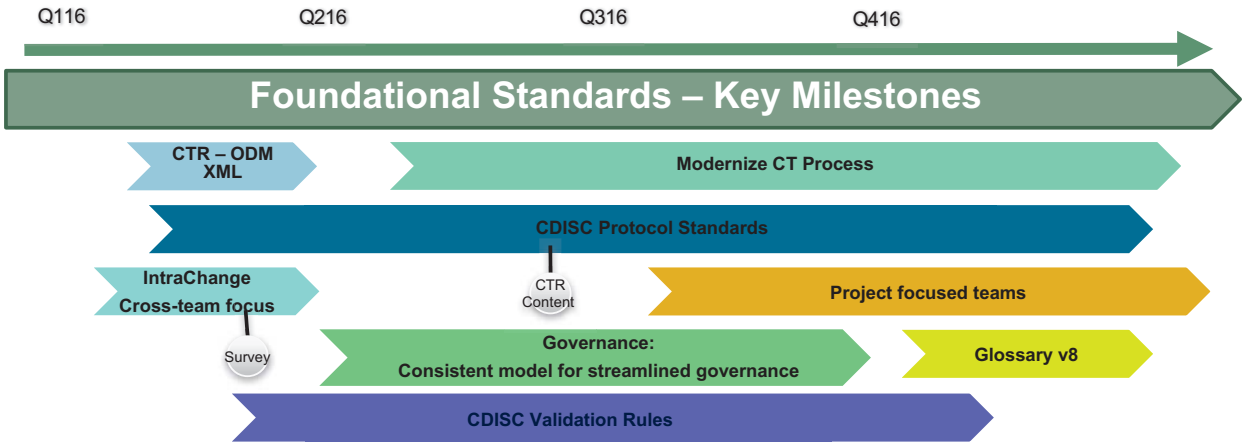
CDISC 2016 Roadmap
Q3 Status

www.cdisc.org Strength *through Collaboration*



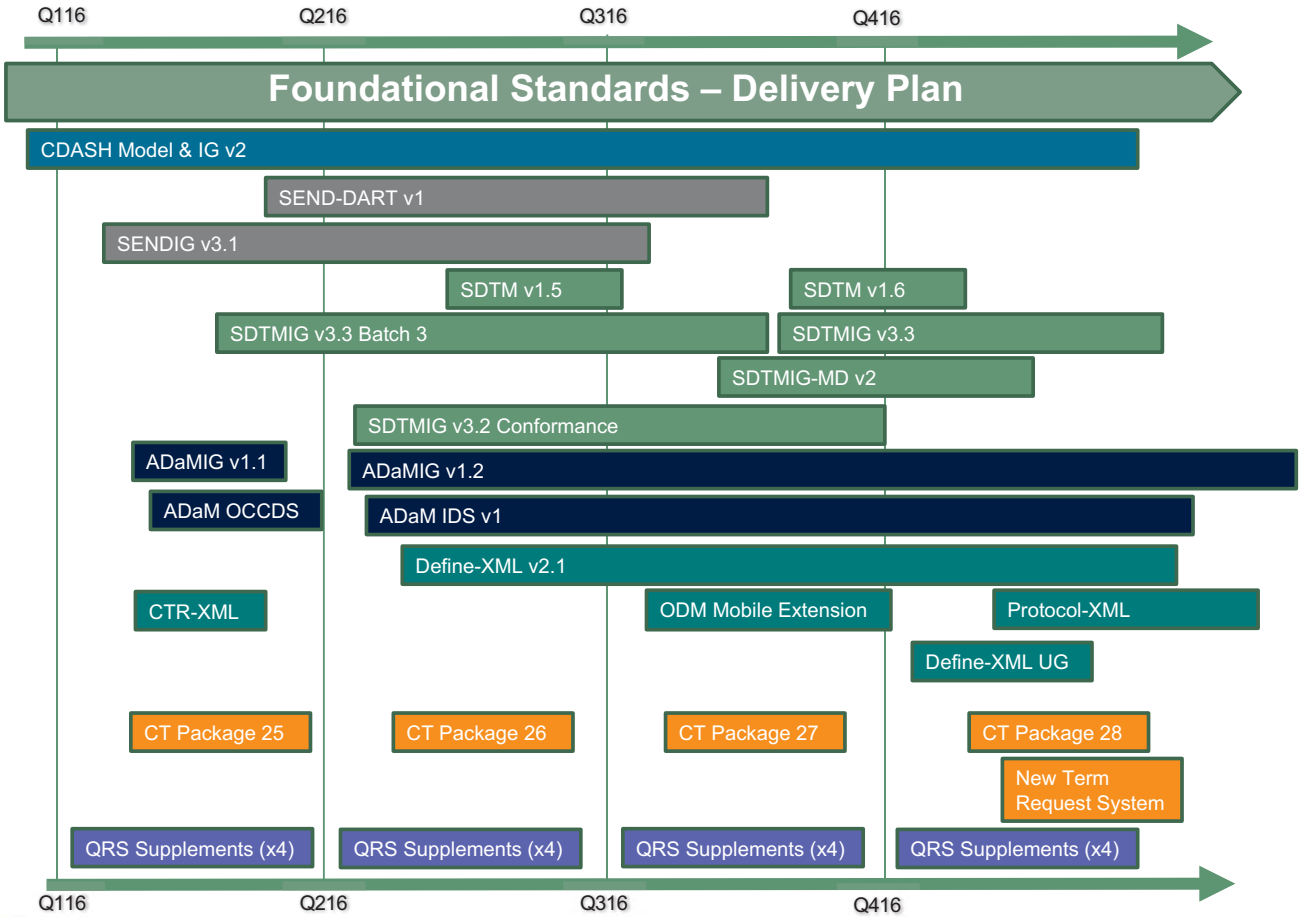
Project Description

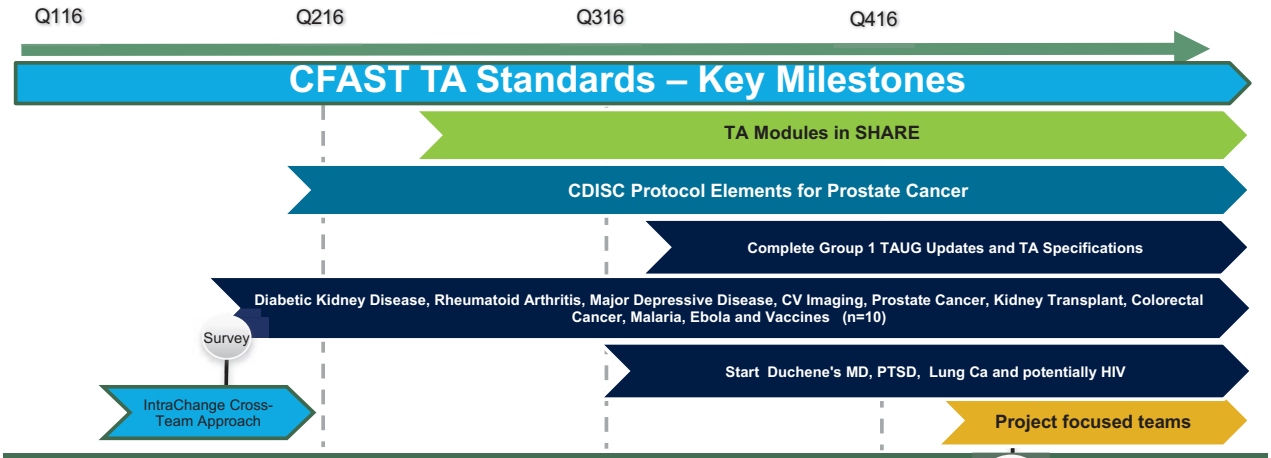
Webinars	• 3 members only and 2 public webinars completed • 9 members only and 9 public scheduled
Classroom/ online courses	• $58k ahead of budgeted income for YTD • 15 authorized classroom courses available • Private training requests up 300% over Q1 avg. • 4 Public course events completed, 12 scheduled • 62 online course modules published • 12 TA courses in development, 6 planned • 11 Foundational courses/updates in progress, 10 planned
Authorized Instructors	• 42 authorized instructors • Based in 7 countries across North America, Europe, Asia • 9 training languages
Branding	• Leverage Unlock Cures branding to reach new patient advocacy foundations, academia, clinicians through new marketing materials (brochures, updated website, videos)
Adoption Surveys & Listening Tours	• Develop a white paper and presentation with summary of listening tours with pharmaceutical companies and member survey to be utilized to understand difficulties with implementation and the landscape of end to end standards
Events	• 3 March -Cowboy Up– raising funds for PTSD • 16-18 March - Intrachange & TA Workshop • 27-28 April – European Interchange – Vienna • 1-2 June – Japan Interchange – Tokyo • 28-29 September – International Interchange - MD
CDISC Strategy Session	• 2 August – 70 invited representatives from govt, academia, nonprofit, pharma to discuss CDISC collaborations and connections, sustainability



Project Description

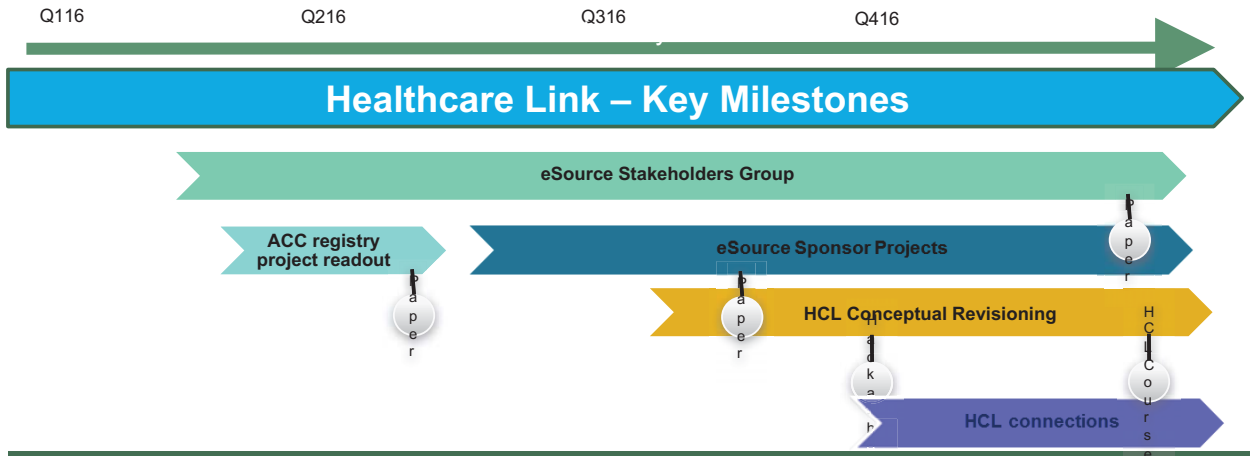
CTR-ODM XML	• Clinical Trial Repository (CTR) standard in Operational Data Model (ODM) XML format
IntraChange	• Introduce a cross-team collaboration focus to the IntraChange meeting • Gain feedback on the approach through participant survey
Governance	• Develop a standard governance model and framework to provide nimble oversight of CDISC standards, processes and systems • Update COP-001 • Evaluate formal standards update strategy
CDISC Protocol Standards	• Develop and deliver protocol concepts to support the CTR standard and the TransCelerate Biopharma Common Protocol Template (CPT) • Develop Protocol-XML standard
Modernize CT process	• Modernize the controlled terminology process to deliver efficiency improvements and embrace newer CDISC technology • Evaluate new technology and an integration with SHARE • Introduce Transparency to the new term request process
Glossary v8	• Update the CDISC glossary with new biomarker terms to support FDA/NIH Biomarker Development Initiative
Project Focused teams and processes	• Update Foundational Standards to support CDISC Healthcare Link • Cross-team collaboration on shared, consolidated goals aligned with the Roadmap
CDISC Validation Rules	• Discuss and agree on the principles of "validation". • Identify and fix known issues • Define a framework for continued development





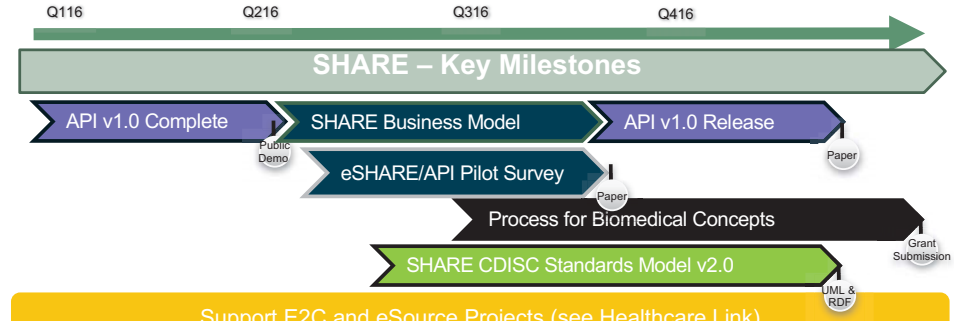
Project Description

E2E or B2E	• Begin to develop 'complete' research standards, including Foundational, Therapeutic Area (TA) augmentations and Controlled Terminology from Protocol through SDTM/ADaM.	**SHARE**	• Use SHARE tools to build TA standards from the start, re-using prior TAs; Prostate Cancer is the first use case.
IntraChange	• Introduce a cross-team collaboration focus to the IntraChange meeting • Gain feedback on the approach through participant survey	**TAUG Updates**	• Modularize and update published TA standards
Governance	• Develop a standard governance model and framework to provide nimble oversight of CDISC standards, processes and systems • Update COP-001 • Develop Escalation Policy	**FDA Specifications**	• Develop specifications for the FDA Technical Conformance Guide.
Protocol & Prostate Cancer	• Develop a limited number of protocol endpoints as part of the Prostate Cancer project	**Oncology Program**	• Initiate 1-2 Oncology Therapeutic Areas
		Project Focused teams and processes	• Cross-team collaboration on shared, consolidated goals aligned with the Roadmap



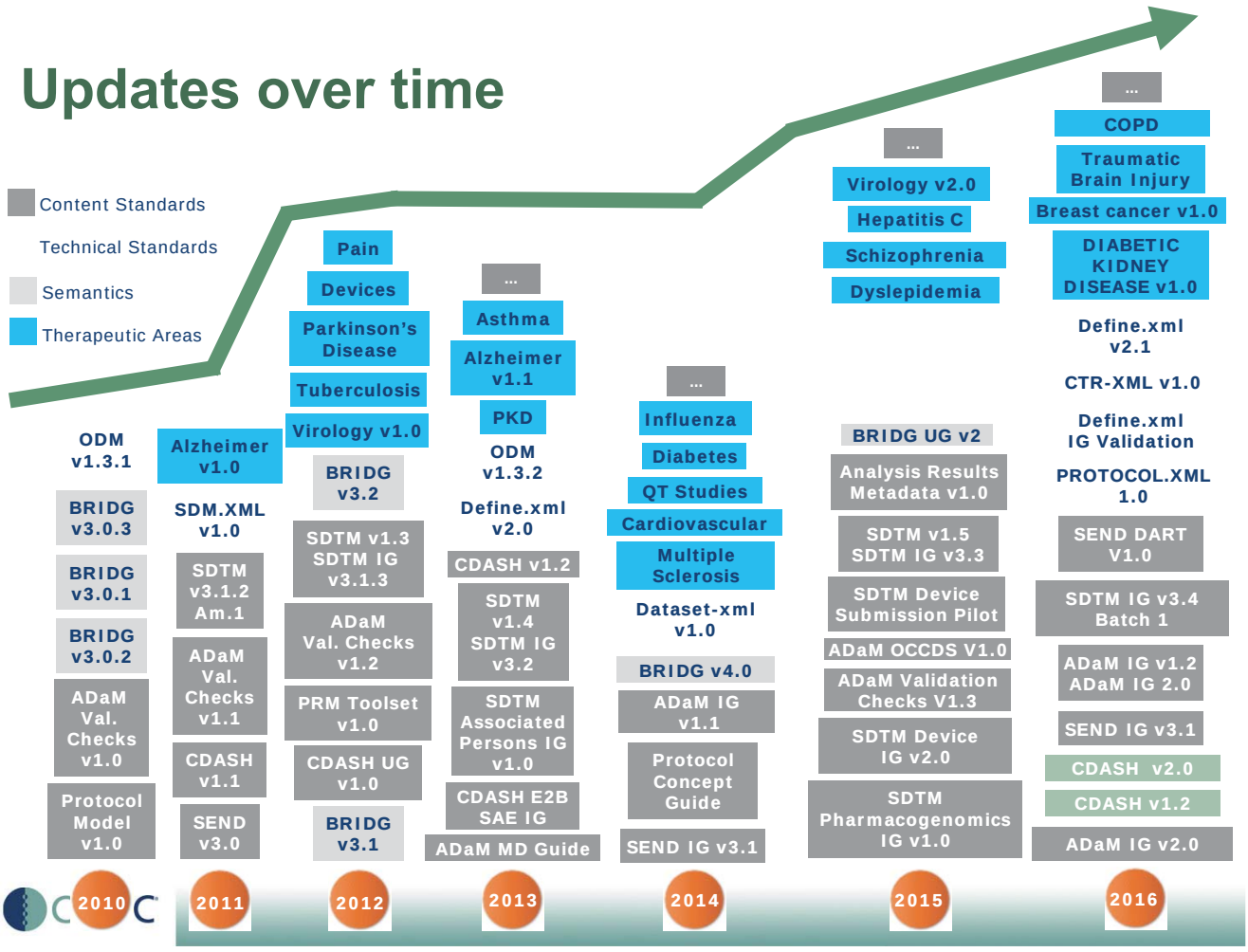
Project Description

eSource Stakeholders Group	• Multi-stakeholder group working with FDA to produce implementation guide for eSource
ACC registry project	• Single site (Duke) proof of concept study to test feasibility an usefulness of CDISC standards in registry work
eSource Sponsor Projects	• CDISC partnership with biopharma/device/med center sponsors to demonstrate benefits of using eSource for regulated research
HCL Conceptual Revisioning	• Revising Healthcare Link to update for next 5 years approach to healthcare • Review and update of HCL standards • Revise coursework • Hold conceptual 'hackathon' to inspire ideas
HCL Connections	• Develop connections to SHARE to demonstrate eCRF capabilities • Develop strategy for mobile to lay groundwork for using mobile with eSource / ODM • Explore connections to Learning Healthcare System to demonstrate use of HCL in feedback learning loop for healthcare

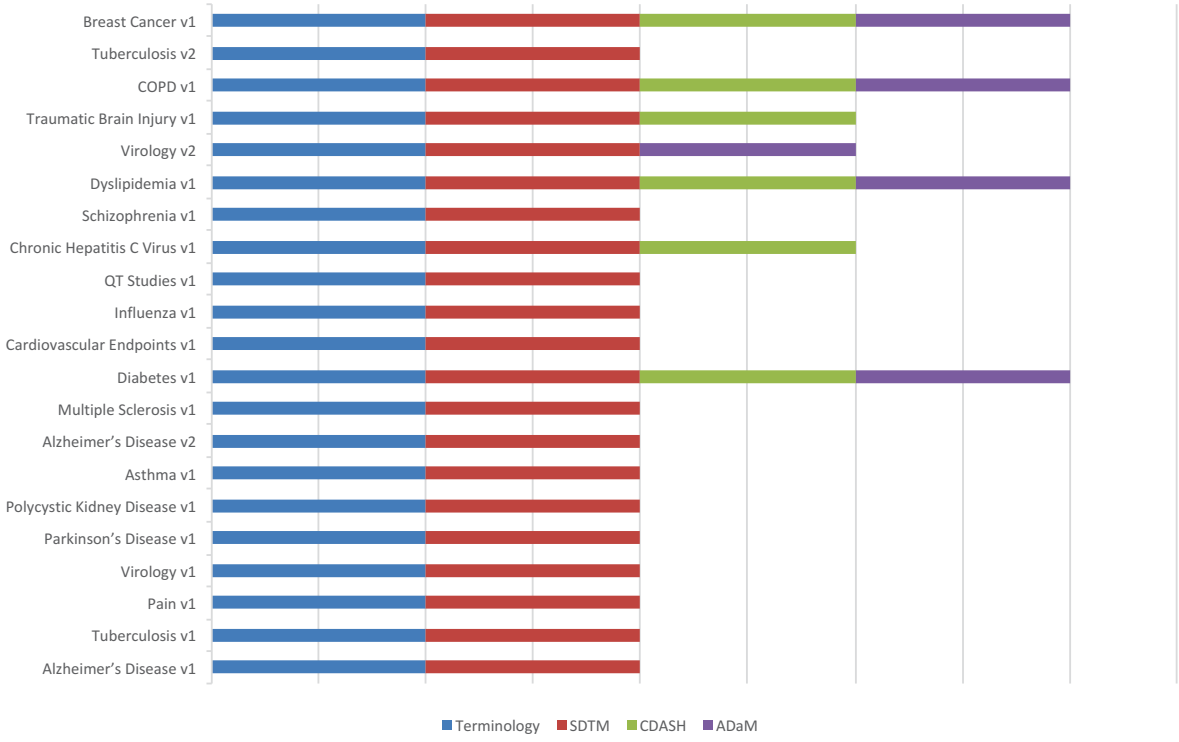


Q2 Project Updates

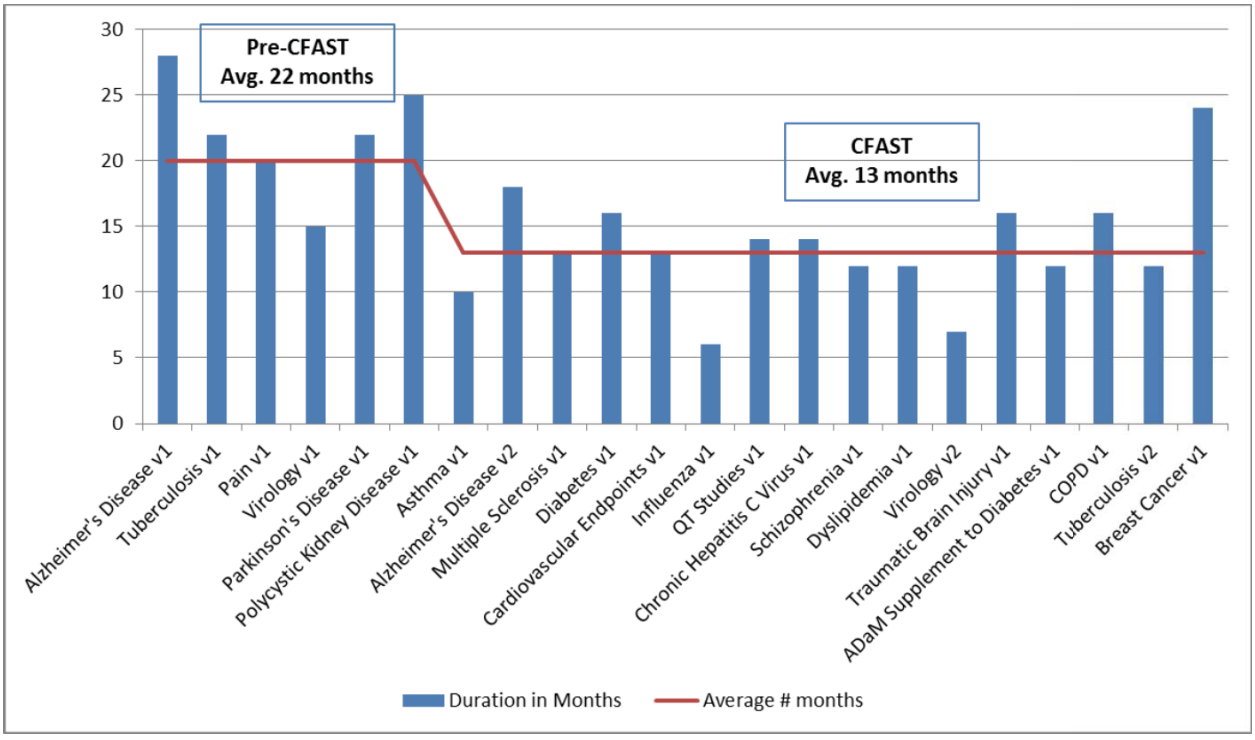
API Development & Release	• SHARE Application Programming Interface (API) Beta release: April 4 • Interchange API Showcases April 27 & September 27 • Production API release 2016
API Pilot Metrics	• Developing utility and usability. Summary data to be published. • Drafting plan to gather use cases & requirements for prioritized community-driven development
SHARE Business Model	• Draft structures for API cost models created • License cost re-negotiations ongoing with vendor on which cost recovery estimates will be based
Process for Biomedical Concepts Creation	• Roles, Processes documented • Pilot designed • Grant submitted to support work
SHARE Model 2.0	• Major enhancement over 1.0 • ISO 11179 classes, rules, biomedical concepts, codelist subsets, improved support for TAs & ADaM
Support E2C & eSource of Healthcare Link	• SHARE team participation in eSource Meeting March 18 • Early strategizing with Healthcare Links team on X-Path, DEX and FHIR
Support TA Spec and User Guides	• 90% of TA Specification derived from SHARE • Managing and reusing metadata using SHARE tools • Examples & rules repository development in progress



TA Standards Content



Project Duration



Save the Date

2017 Europe Interchange
London, England
24 - 28 April 2017

2017 Japan Interchange
Tokyo, Japan
13 - 15 June 2017

2017 International Interchange
Austin, Texas
13 - 17 November 2017

Cowboy Up! for Oncology
Austin, Texas
02 March 2017

COWBOY UP

For further details about these events, sponsorship and exhibit opportunities, visit:
www.cdisc.org/event

CDISC