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Motivations, Challenges, and Benefits of Building and Deploying the NCI CTEP CDISC CDEs

Advancing the Use and Development of Common Data Elements in Research Workshop

Session III-C: Approaches to Improve Interoperability

March 6-7, 2024 @ the National Institutes of Health (NIH)

Speaker Overview

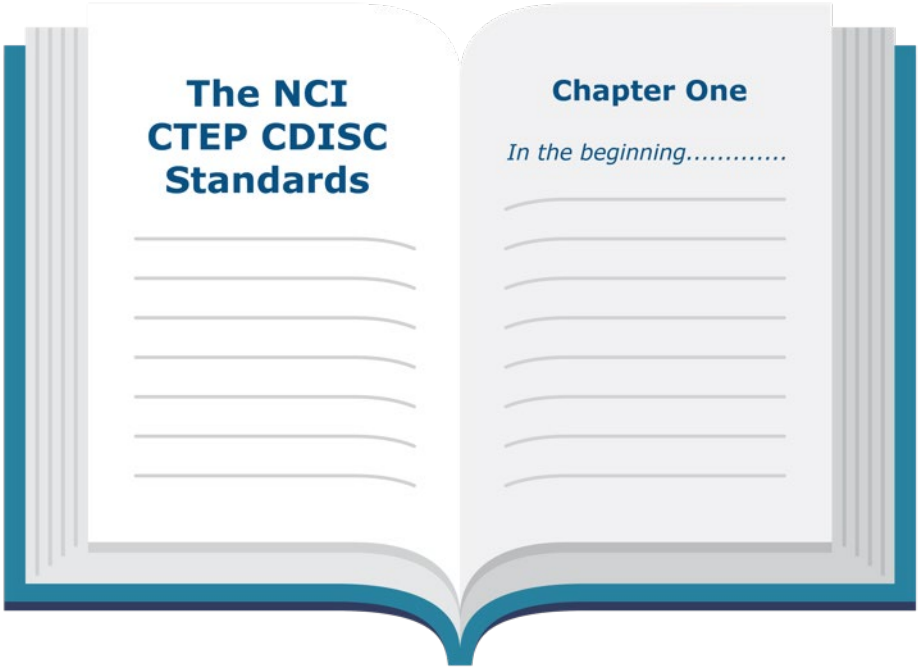
Ginger Riley, Senior Clinical Data Manager – Data Solutions Sector, Westat

- 20 years supporting the National Cancer Institute (NCI) in data management and standards areas
- CDMS Task/Standards Lead for the Cancer Trials Support Unit (CTSU)
- Provides subject matter expertise on content management and standardization in support of Cancer Therapy Evaluation Program (CTEP) initiatives and other NCI entities that collaborate with CTEP (e.g., the Precision Medicine Initiative)

Our Story

Starting from limited standardization to become a fully Clinical Data Interchange Standards Consortium (CDISC)-compliant organization utilizing standard Common Data Elements (CDEs) and electronic Case Report Forms (eCRFs) in a Clinical Data Management System (CDMS).

It’s all about stakeholder engagement, lessons learned, and governance.



Motivations for NCI CTEP Standard CDEs

2005

- Outcomes of the "Restructuring the National Cancer Clinical Trials Enterprise" report (Clinical Trials Working Group, June 2005)

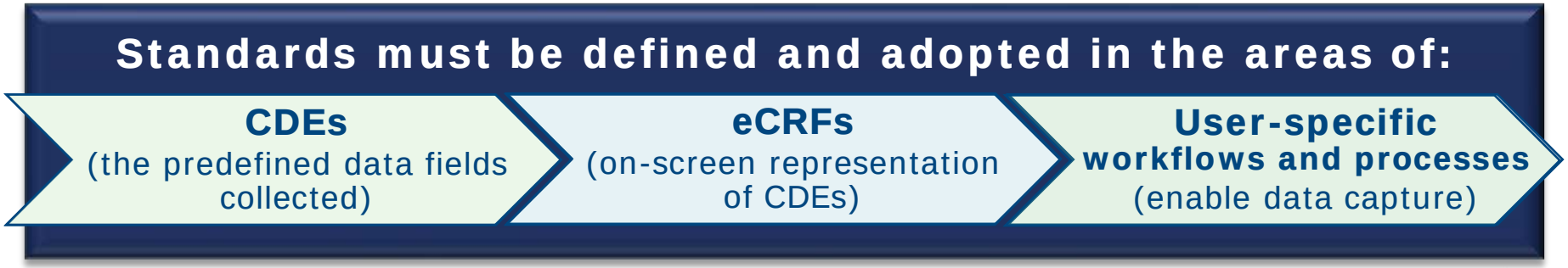
2011

- National Clinical Trials Network/Experimental Therapeutics Clinical Trials Network (NCTN/ETCTN) Stakeholder Collaboration

2017

- The U.S. Food and Drug Administration (FDA) CDISC Study Data Tabulation Model (SDTM) reporting mandate

Consideration and Challenges



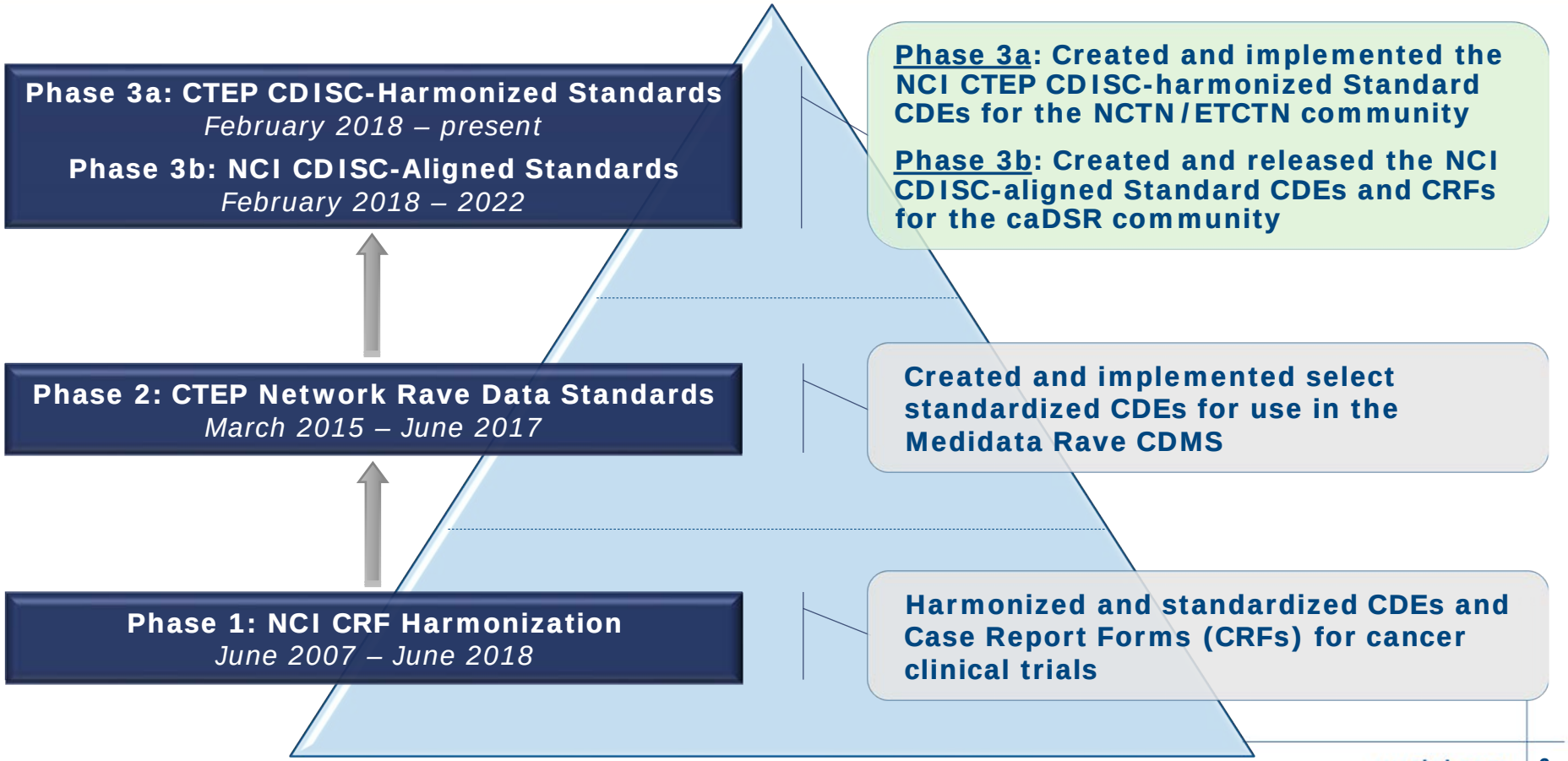
Considerations

- A common methodology for capturing data is critical
- A common approach to data capture must be adopted
- Success is conditional to stakeholder engagement

Challenges

- Organization-specific data collection systems
- Lack of existing harmonization and data standards
- Reliance on legacy systems and manual reconciliation

Evolution of the NCI CTEP Standard CDEs

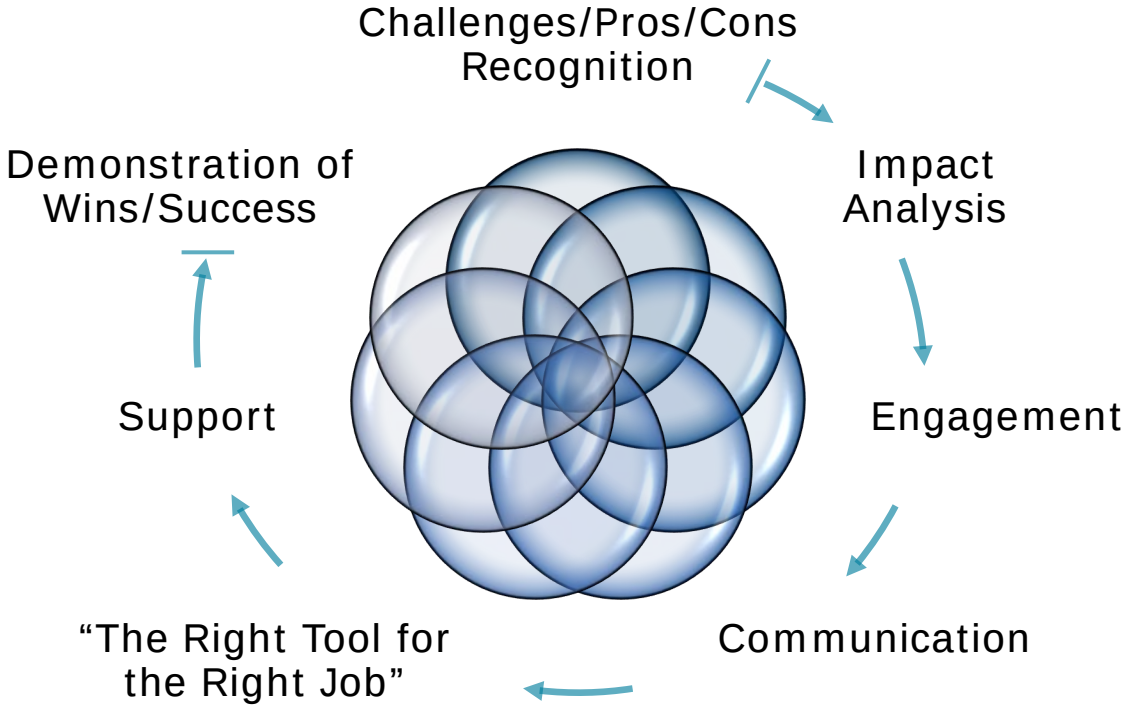


Benefits and Wins of the NCI CTEP Standardization

- 43 NCI CTEP CDISC Domain-based CRFs with >1000 CTEP CDISC-Harmonized Standard CDEs (NCI CTEP CDISC Global Library (GLIB))
- 15 CDISC CTSU Standard Forms with >180 CTEP CDISC-Harmonized Standard CDEs (integration-related forms)
- 48 NCI CTEP CDISC-Harmonized CRFs v1.0 with >550 CTEP CDISC-Harmonized Standard CDEs
- Within 18 months, 75 percent of activated NCI CTEP Investigational Drug Branch (IND) studies were CDISC-compliant
- Addressed 90 percent of identified challenges for the NCI CTEP community regarding use of standardized CRFs and CDEs
- Increased scientific collaborations and cross-study analysis
- Standardized end user experience
- Innovative partnership with the CDISC organization
- Proven, reusable methodology

NCI CTEP Methodology

Data Science Stakeholder Engagement Model (DSSEM)



A proven methodology for stakeholder engagement has been critical to the successful development, adoption, and implementation of the NCI CTEP CDISC-harmonized Standards.

Thank you

For additional information on the NCI CTEP CDISC Implementation and Harmonization activities or the Data Science Stakeholder Model (DSSEM), please contact:

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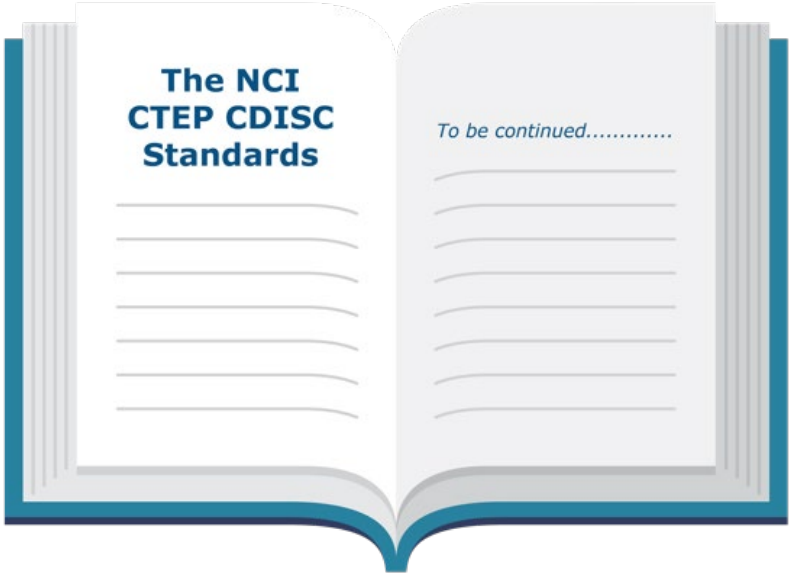

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Reference Materials

- Phase 3ba: NCI CTEP CDISC-Harmonized Standards
- NCI CTEP CDISC-Harmonized Standard Forms v1.0
- NCI CTEP CDISC Harmonization Road Map
- NCI CTEP Methodology – DSSEM Key Area Considerations
- NCI CTEP Wins Set 1 and Set 2
- Acronym Glossary

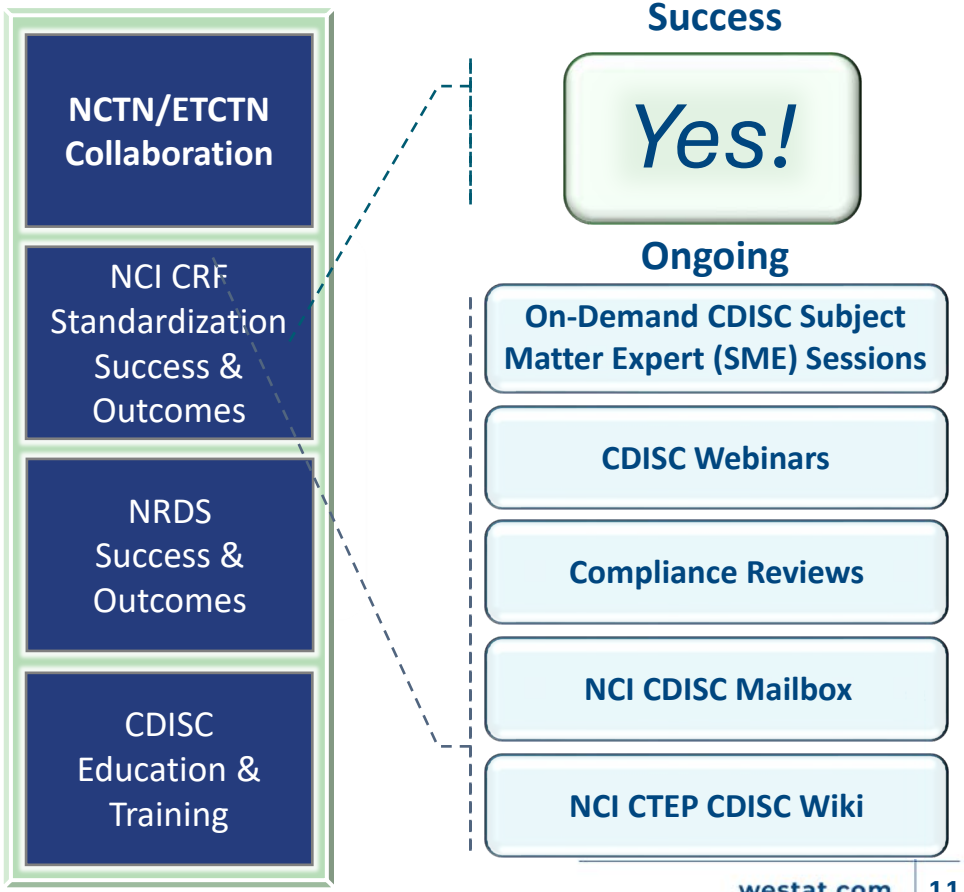
Phase 3a: NCI CTEP CDISC-Harmonized Standards (ongoing)

NCI CTEP Resources

- CDMS GLIB Release Notes v1.0
- CDMS GLIB ALS v1.0
- CTSU Standard Forms Release Notes v7.0+
- CTSU Standard Forms ALS v7.0+

Project Deliverables

- Data Standards Implementation Processes
- NSVs and Supplemental Questions Harmonization
- Policy and Governance
- Supplemental Question Management
- Study Waiver Request Process

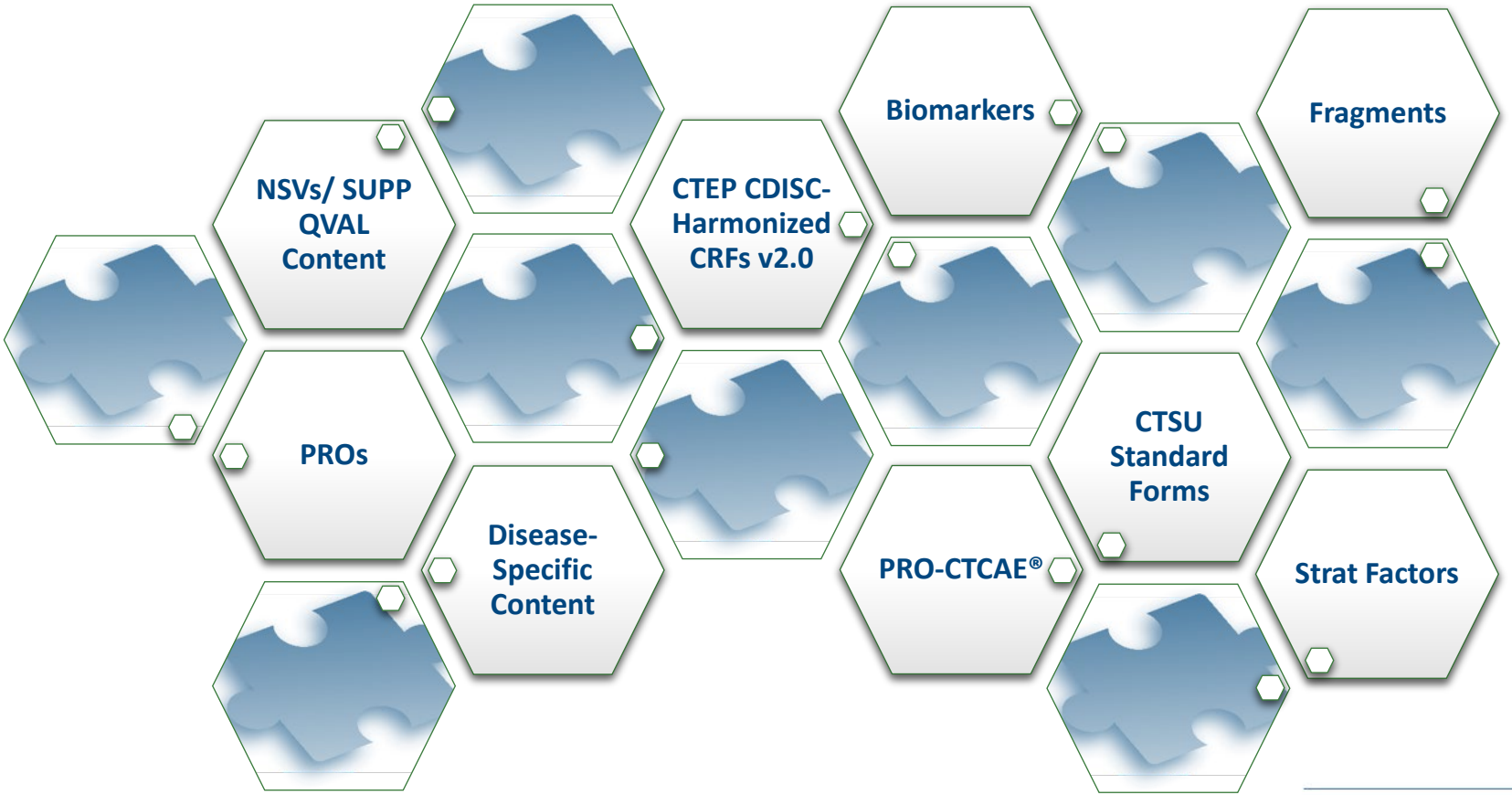


NCI CTEP CDISC-Harmonized Standard Forms v1.0

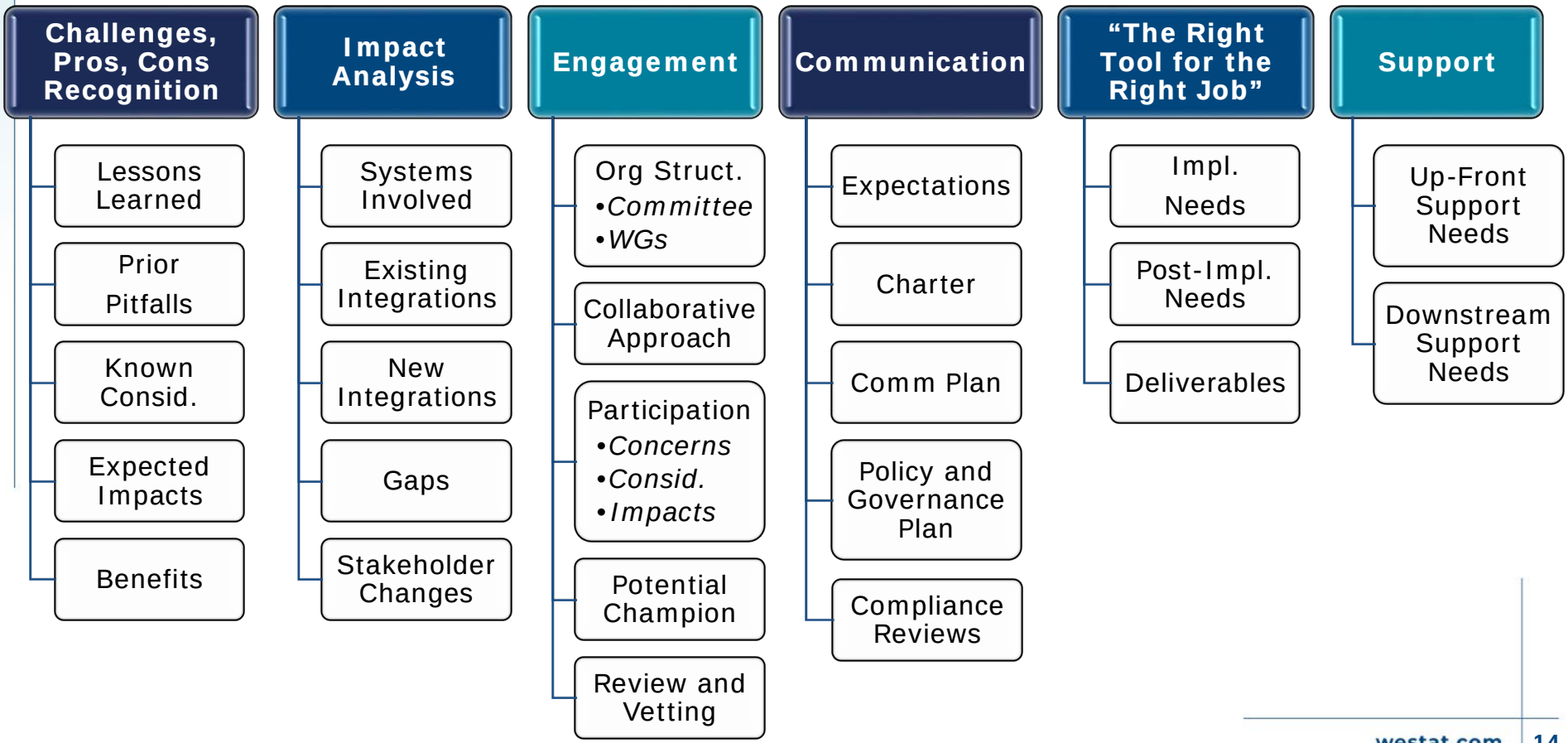
R1 Oct 20, 2020	R3 Oct 30, 2020	R4 Jan 27, 2021		R5 March 29, 2021	R6a June 15, 2022	R6b March, 2024	R7 tbd	R8 June 7, 2021	R9 March, 2024
RECISTv1.1	Physical Examination	Adverse Event/ Serious Adverse Event CTCAE v4.0	Diagnosis Administrative	~~Diagnosis Intervention~~	Diagnosis	Response	Staging AJCC Edition 8, Breast	Brief Pain Inventory-BPI	FACT-P (ver. 4)
Screening	Follow-Up/ Survival	Adverse Event/ Serious Adverse Event CTCAE v5.0	Diagnosis Gross Pathology	Equipment	PET Scan	iRECIST	Staging AJCC Edition 8, Prostate	EPIC-26 Short Form	EORTC QLQ-C30 (ver. 3)
Off Treatment	Lost to Follow-Up		Enrollment	Image Administration	Radiation Therapy	irRECIST	Staging AJCC Edition 8, Colorectal	EQ-5D-3L (ver. 1)	EORTC QLQ-H&N35 (ver. 1)
Off Study	Eligibility	Consent	Laboratory Test/Results	Metastasis	Study TX Administration	irRC	*Staging AJCC Edition 8 Lung*	EQ-5D-5L (ver. 1)	PROMIS - Fatigue - Short Form 7a (ver. 1)
	Demography	Consent Withdrawal	Prior Therapies	PET Imaging Agent	CT Imaging Agent	*RECISTv1.1*			MDADI (ver. 1)
R2 ***No Active Use Case***	Medical History	Consent Withdrawal Specimen	Registration	PET Patient Prep	Diagnosis Microscopic Pathology				LASA-6
TRIAD	Surgery	Consent Withdrawal Quality of Life Study	Staging AJCC Edition 8 Lung	Progression	*N/A, administrative forms, not used in SDTM:*				DLQI (ver. 3/4/2019)
	Vital Signs			Protocol Deviations	*CT Image Acquisition*				*TBD PROs*
	Concomitant Medication			PET Equipment QC Assessment	*Image Quality*				
	Diagnosis Intervention			Participant Identification					

Completed
In Progress
Pending
Revisiting

NCI CTEP CDISC Harmonization Road Map



NCI CTEP Methodology – DSSEM Key Area Considerations



NCI CTEP Wins

Set 1

- **S** NCI CTEP has become an innovative partner with the CDISC organization, proposing novel standards and updates to external standards (e.g., AJCC, RECIST+, PRO CTCAE, PROs) for the Oncology Domain
- **U** Within 18 months, 75 percent of activated NCI CTEP Investigational Drug Branch (IND) studies were CDISC-compliant
- **C** Addressed 90 percent of identified challenges for the NCI CTEP community regarding use of standardized CRFs and CDEs
- **C** Developed and implemented 50+ CDISC-harmonized standard forms for use in the Rave CDMS
- **E** Improved data quality by increasing standardization and decreasing data manipulation and transformation
- **S** Reduced study build activities, minimized cost, and decreased time spent on data submission activities
- **S** NCI CTEP's CDISC harmonization model utilized to create 10+ CDISC-harmonized standard forms for the NCI Precision Medicine Initiative (PMI), NCI-MATCH

NCI CTEP Wins

Set 2

- **S** Increased potential for investigators to share data for scientific collaborations and perform cross-study analysis
- **U** Promoting compliance with the CDMS End User License Agreement and NCI CDMS Usage Guidelines
- **C** Reducing data management burden on participating sites and Lead Protocol Organizations
- **C** Reducing need for content curation and form-build activities in the NCI Cancer Data Standards Registry and Repository (caDSR) II
- **E** Simplifying system integration efforts (CDUS, SAE, CTRP)
- **S** Standardizing the form and field experience for participating sites for studies within and across Lead Protocol Organizations
- **S** Streamlining overall clinical trial operations by linking the CDMS to the SAE reporting process, NCI and FDA results reporting (CDUS & CTRP), and Group Network Applications (biorepository federation)

Acronym Glossary

Term	Description	Add'l Information/ Link
ALS	**Architect Loader Specification.** A file created in an Excel-based format to export and import study build details.	*Example ALS File: CTSU_StandardForms_ALS_v7.0_20190731.xml*
CDE	**Common Data Element**. A standardized, precisely defined question, paired with a set of allowable responses, used systematically across different sites, studies, or clinical trials to ensure consistent data collection.	*https://cde.nlm.nih.gov/home*
CDISC	**Clinical Data Interchange Standards Consortium**. A global, open, multidisciplinary, nonprofit organization that has established standards to support the acquisition, exchange, submission, and archive of clinical research data and metadata. CDISC defines models to support global, platform-independent data standards that are aligned with the needs of clinical trial data exchange as it relates to clinical research workflow.	*https://www.cdisc.org/about*
CDUS	**Clinical Data Update System.** The system by which NCI CTEP collects summary data on clinical studies; for consistency, the NCI's Clinical Trial Monitoring Services (CTMS) adopted the CDUS Code Lists for equivalent terms.	*https://www.theradex.com/downloads/DTSM_312.pdf*
Lead Protocol Groups	The NCI Lead Protocol Groups are large networks of researchers, doctors, and healthcare professionals at public and private institutions that conduct multicenter, large-scale, phase II and phase III cancer clinical trials across the country.	*https://www.cancer.net/navigating-cancer-care/cancer-basics/cancer-care-team/find-nci-designated-cancer-center*

Acronym Glossary (continued)

Term	Description	Add'l Information/ Link
CTEP	**Cancer Therapy Evaluation Program.** A division of NCI that funds an extensive national program of cancer research and sponsoring clinical trials to evaluate new anticancer agents, with a particular emphasis on translational research to elucidate molecular targets and mechanisms of drug effects.	https://ctep.cancer.gov/about/default.htm
CTROC	**Clinical and Translational Research Operations Committee.** An internal oversight committee designed to coordinate clinical trials and translational programs across the institute and to make recommendations to improve cost-effectiveness and reduce duplication and overlap among NCI components.	https://www.cancer.gov/about-nci/organization/ccct/ctrp
CTSU	**The Cancer Trials Support Unit.** A service of the National Cancer Institute (NCI) designed to facilitate access to NCI-funded clinical trials for qualified clinical sites and to support the management and conduct of those clinical trials. The CTSU collaborates with the NCI and its funded organizations to develop and support operational processes and informatics solutions leading to cost-effective solutions that reduce administrative burden on the clinical sites.	https://www.ctsu.org/Public/
ETCTN	**NCI's Experimental Therapeutics Clinical Trials Network.** A network of clinicians created to evaluate innovative cancer therapies using a coordinated, collaborative, and inclusive team-based approach to early-phase experimental therapeutic clinical trials.	https://ctep.cancer.gov/initiativesprograms/etctn.htm#objectives

Acronym Glossary (continued)

Term	Description	Add'l Information/ Link
GLIB	**Global Library.** The central repository of definitions used for clinical studies; the definitions provide structure, organization, and control over the clinical study database.	Example GLIB File: CTEP_CDISC_GLIB_ALS_v1.0_20190731.xml
NCI	**National Cancer Institute.** The Federal Government's principal agency for cancer research and training.	https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-cancer-institute-nci
NCI-MATCH	**NCI Molecular Analysis for Therapy Choice.** A precision medicine cancer treatment clinical trial. In this trial, people with cancer are assigned to receive treatment based on the genetic changes found in their tumors through genomic sequencing and other tests.	https://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/nci-match
NCTN	**NCI's National Clinical Trials Network.** A collection of organizations and clinicians that coordinates and supports cancer clinical trials at more than 2,200 sites across the United States, Canada, and internationally. NCTN provides the infrastructure for NCI-funded treatment and primary advanced imaging trials to improve the lives of people with cancer.	https://www.cancer.gov/research/infrastructure/clinical-trials/nctn
NRDS	**Network Rave Data Standards.** An NCI CTEP initiative to facilitate the standardization and implementation of selected CDEs in Medidata Rave.	https://wiki.nci.nih.gov/display/NNRDSC/NCI+Network+Rave+Data+Standards+Committee+Wiki

Acronym Glossary (continued)

Term	Description	Add'l Information/ Link
NSVs	**Non-Standard Variables.** Variables not defined by CDASH and are stored into a different dataset in SDTM.	https://www.cdisc.org/kb/articles/sdtm-and-cdash-why-you-need-both
OPEN	**Oncology Patient Enrollment Network.** The web-based registration system for patient enrollments in NCI-sponsored Network Group clinical trials. The system is integrated with the CTSU Enterprise System for regulatory and roster data, and with each of the Network Groups' registration/randomization systems for patient registration/randomization.	https://open.ctsu.org/open/logonForm.open
PRO-CTCAE®	**NCI's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events.** This Measurement System was developed to evaluate symptomatic toxicities by self-report in adults, adolescents, and children participating in cancer clinical trials. It was designed to be used as a companion to the Common Terminology Criteria for Adverse Events (CTCAE), the standard lexicon for adverse event reporting in cancer trials.	https://healthcaredelivery.cancer.gov/pro-ctcae/measurement.html https://healthcaredelivery.cancer.gov/pro-ctcae/