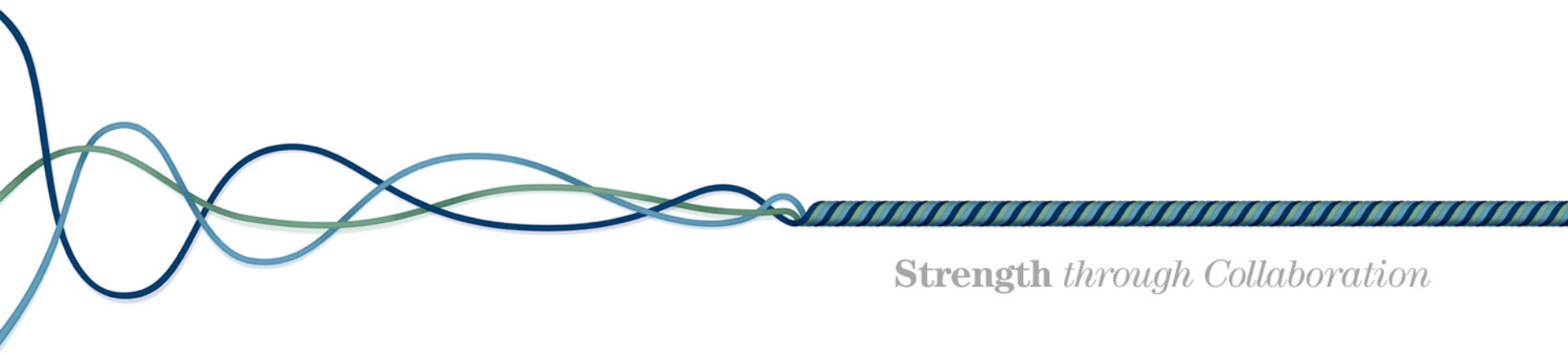
CDISC Public Webinar – Standards Updates and Additions

8 Jan 2015



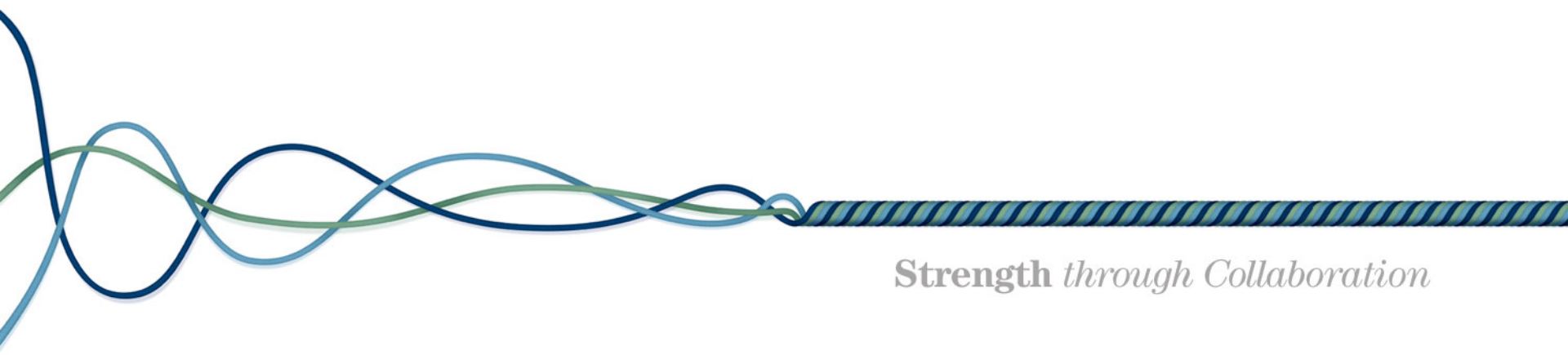
Agenda

- CHCV v1.0 Public Review (Hepatitis C)
  - John Owen, Janssen Pharmaceuticals Research and Development
- CDISC Education and Events Updates*
  - Saad Yousef, CDISC

**After Q&A session & time permitting*

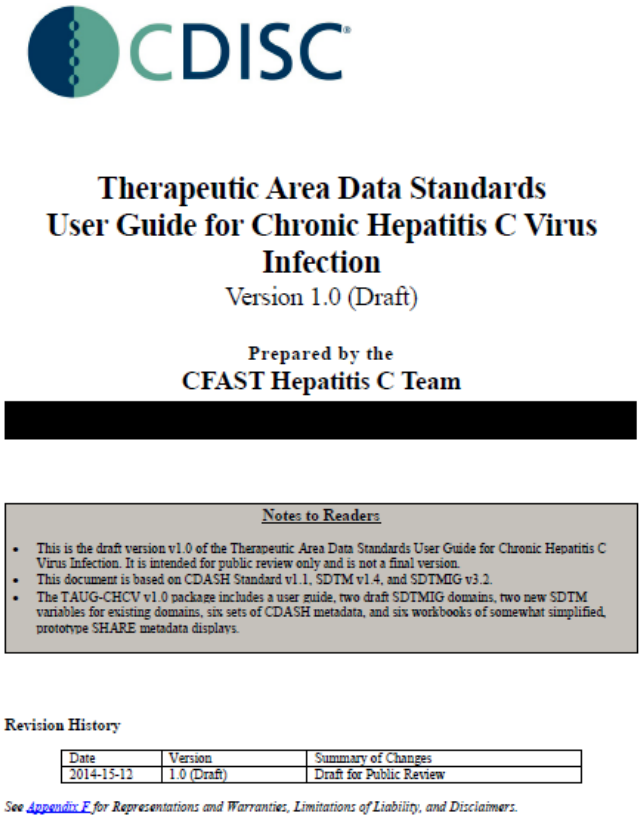
Therapeutic Area User Guide – CHCV V1.0
Public Review Webinar
January 8, 2015

John Owen, Janssen Pharmaceuticals Research and Development
CFAST HEP C Project Manager



Chronic Hepatitis C

- CFAST Program
- Development Principles
- CHCV Background
- CHCV TAUG
- Public Review
  - Areas to focus
  - How to submit comments
- Q & A



CDISC

Therapeutic Area Data Standards User Guide for Chronic Hepatitis C Virus Infection

Version 1.0 (Draft)

Prepared by the CFAST Hepatitis C Team

[redacted]

Notes to Readers

- This is the draft version v1.0 of the Therapeutic Area Data Standards User Guide for Chronic Hepatitis C Virus Infection. It is intended for public review only and is not a final version.
- This document is based on CDASH Standard v1.1, SDTM v1.4, and SDTMIG v3.2.
- The TAUG-CHCV v1.0 package includes a user guide, two draft SDTMIG domains, two new SDTM variables for existing domains, six sets of CDASH metadata, and six workbooks of somewhat simplified, prototype SHARE metadata displays.

Revision History

Date	Version	Summary of Changes
2014-15-12	1.0 (Draft)	Draft for Public Review

See Appendix F for Representations and Warranties, Limitations of Liability, and Disclaimers.

- The Coalition for Accelerating Standards and Therapies (CFAST)
- CFAST sponsors the development of standards for key therapy areas
- A joint initiative of CDISC and the Critical Path Institute (C-Path)
- Launched to accelerate clinical research and medical product development by facilitating the establishment and maintenance of data standards, tools and methods for conducting research in therapeutic areas important to public health.
- CFAST partners include TransCelerate BioPharma Inc. (TCB), the U.S. Food and Drug Administration (FDA), and the National Cancer Institute – Enterprise Vocabulary Service (NCI-EVS), with participation and input from many other organizations
- See http://www.cdisc.org/therapeutic for more information

Program Overview – December 2014

Approved Therapeutic Area Standards Projects

Therapeutic Area	Coordinating Organizations/ Project Manager	Proposal Approval Date	Stage 0 Scoping & Planning	Stage 1 Concept Modeling	Stage 2 Standards Development	Stage 3a Internal Review	*Stage 3b Public Review	*Stage 3c **Projected Publication
QT Studies v1	TCB John Owen	Aug 13	Oct	Feb	Mar	Jul	Sept	*Q414*
Traumatic Brain Injury v1	CDISC Rhonda Facile	Oct 13	Nov	Dec	Jan			*Q215*
Chronic Hepatitis C Virus v1	TCB John Owen	Nov 13	Feb	Apr	Jul	Nov	Jan	*Q115*
Schizophrenia v1	CDISC/DCRI Amy Palmer	Nov 13	May	Jul	Aug	Dec	Feb	*Q215*
Breast Cancer v1	TCB Pam Harvey	Nov 13	Aug	Dec	Jan	Feb		*Q215*
Dyslipidemia v1	TCB John Glover	Dec 13	May	Sept	Dec	Feb		*Q215*
COPD v1	TCB John Glover	Nov 13	Aug	Dec	Feb	Apr		*Q315*
Diabetic Kidney Disease	TCB/CDISC Rachael Zirkle	May 14	Jan	Mar				*Q116*

Key: Stage completed | Stage ongoing | All Months reflect when stage is, or is projected to be, completed.

*The Stage3b concludes at the end of the 30-day review period and Stage 3c concludes when all tasks have been completed and the standard is publically available.
** Specific Projected publication dates to be added to the notes section at the conclusion of Stage 3b.

Development Principles

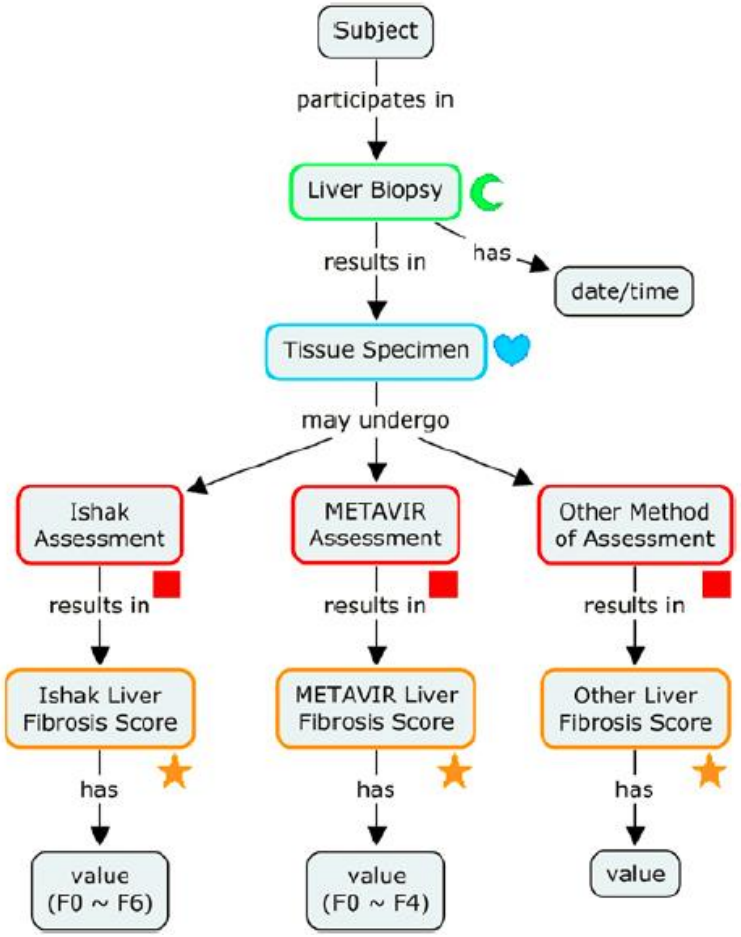
- Scope
  - core, clinically meaningful concepts
  - manage content to meet defined timelines (10-12 months)
- Re-use existing standards (SDTM, CDASH, ADaM)
  - include examples only for situations not covered by existing implementation guide(s)
- Propose new variables for existing domains or new domains
  - only where needed
- Propose new controlled terminology
  - only where needed

What is Different from Previous CDISC TA Standards?

- Disease background & context
- Concept maps
  - To diagram the relationships between concepts and among attributes of a concept
- CDASH CRFs
  - Traceability from CDASH to SDTM
- Regulatory and medical references
  - To help ensure regulatory compliance and medical appropriateness
- SHARE model based metadata development
  - Not just SDTM; but also CDASH and ADaM in later iterations

Concept Maps

- Illustrates relationships among concepts and attributes
- Facilitates understanding (semantic interoperability) among functions involved in standards development



Concept Map 4: Liver Biopsy for the Assessment of Fibrosis

Concept Maps – cont.

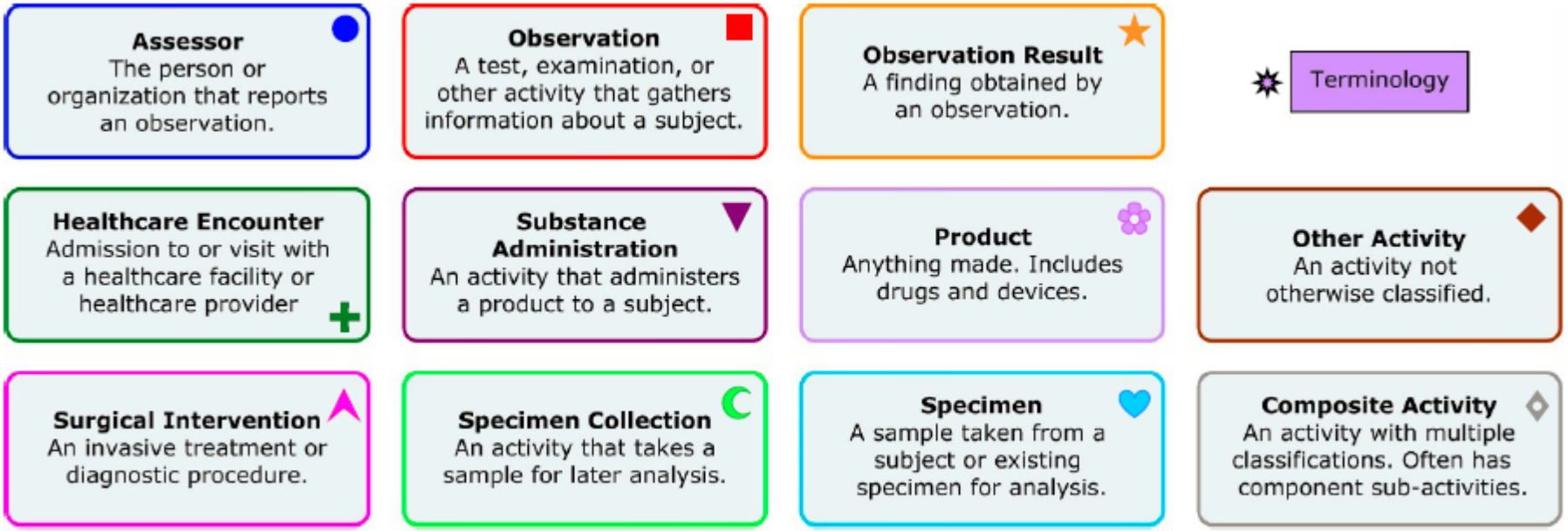


Figure 2: Concept Classification Key for Concept Maps

- Coding for classification of concepts.
- Based on classes in the Biomedical Research Integrated Domain Group (BRIDG) model.

CDASH – CRFs

- Development of TA specific CRFs
- Used together with already existing safety CRFs
- Traceability from CDASH to SDTM standard

Example CRF 4: Liver Biopsy

Was Liver Biopsy performed? PROCCUR PRBIOPYN*	☐ Yes ☐ No
Pre-specified: *Hidden/Pre-specified* PRPRESP^ = Y	YES
Reported Name of Procedure: *Hidden/Pre-specified* PRTRT^ = BIOPSY	BIOPSY
Location of Procedure: *Hidden/Pre-specified* MILOC^ = LIVER and PRLOC^ = LIVER	LIVER
If Yes, provide Liver Biopsy information below:	
Date of Procedure: MIDTC and PRSTDTC and PRENDTC (DD-MMM-YYYY) MIDAT*	__/___/____
Fibrosis Scoring System: (Not Specified) MISCRTYP*	☐ Metavir ☐ Ishak ☐ Knodell ☐ Batts-Ludwig ☐ Scheuer
Microscopic Examination Short Name: *Hidden/Pre-specified* MITESTCD^	Derived based on Fibrosis Scoring System selected. Refer to SDTM table.
Microscopic Examination Name: *Hidden/Pre-specified* MITEST^	Derived based on Fibrosis Scoring System selected. Refer to SDTM table.
Specimen Material Type: *Hidden/Pre-specified* MISPEC^ = TISSUE	TISSUE
Note: The scoring system results below are dependent on the selected Fibrosis Scoring System above.	
Metavir Scoring Result: MIORRES^	☐ F0 – No scarring ☐ F1 – Minimal scarring ☐ F2 – Scarring has occurred and extends outside the areas in the liver that contains blood vessels ☐ F3 – Bridging fibrosis is spreading and connecting to other areas that contain ☐ F4 – Cirrhosis or advanced scarring of the liver

Regulatory and Medical References

- Regulatory and key medical literature is being reviewed and referenced during the early stages of CFAST projects.

- Bibliography and footnotes included

Appendix E: References

1. FDA. Guidance for Industry: Chronic Hepatitis C Virus Infection: Developing Direct Acting Antiviral Drugs for Treatment (draft). *U.S. Food and Drug Administration*. October 2013. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM225333.pdf. Accessed August 6, 2014.
2. Hepburn MJ, Hepburn LM, Cantu NS, Lapeer MG, Lawitz EJ. Differences in treatment outcome for Hepatitis C among ethnic groups. *Am J Med*. 2004;117(3):163-8.
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6. Sulkowski MS. Viral Hepatitis and HIV Co-infection. *J Hepatol*. 2008;48(2):353-367.
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9. Mascolini M. Sofosbuvir with ribavirin in G1/2/3 HCV/HIV Co-infected Patients. Conference on Retroviruses and Opportunistic Infections. Mar 3-6 2014.. *NATAP*. 2014. Available at: http://www.natap.org/2014/CROI/croi_24.htm. Accessed August 6, 2014.
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13. Roche B, Samual D. Hepatitis C virus treatment pre-and post-liver transplantation. *Liver Int*. 2012;32(Suppl

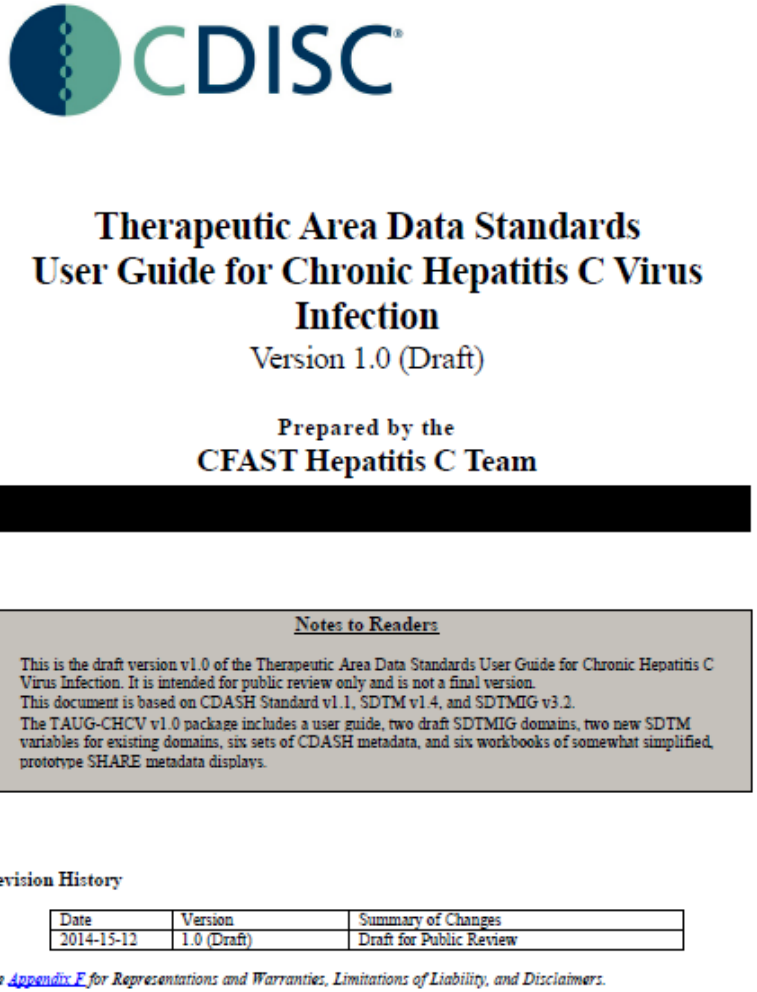
SHARE Model-Based Metadata Package

- Develop all CDISC SHARE metadata:
  - BRIDG
  - SDTM
  - CDASH
  - ADaM
  - Controlled Terminology
  - Data types
  - Definitions
  - Trial Summary Parameters/Protocol

CDISC SHARE

- Global electronic repository for developing, integrating and accessing CDISC metadata standards in electronic format.
- SHARE is envisioned to help users find, understand and use rich metadata and controlled terminologies relevant to clinical studies more efficiently and consistently, and to improve integration and traceability of clinical data from protocol through analysis.

CHCV TAUG



CDISC

Therapeutic Area Data Standards User Guide for Chronic Hepatitis C Virus Infection

Version 1.0 (Draft)

Prepared by the

CFAST Hepatitis C Team

[redacted]

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- The TAUG-CHCV v1.0 package includes a user guide, two draft SDTMIG domains, two new SDTM variables for existing domains, six sets of CDASH metadata, and six workbooks of somewhat simplified, prototype SHARE metadata displays.

Revision History

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See Appendix F for Representations and Warranties, Limitations of Liability, and Disclaimers.

CHCV

- This draft version 1.0 (v1.0) of the TAUG-CHCV
  - Phase 1-3 clinical trials
  - Drugs to treat adults with chronic hepatitis C (CHCV) infection,
  - 6 Major Genotypes
  - Out-patient setting

CHCV

- Chronic hepatitis C (CHC) is an infectious disease affecting primarily the liver (40-76% of patients develop extrahepatic manifestations)
- 150-200 million people infected worldwide
- Clinical trials typically conducted internationally
- Rapidly advancing treatments becoming available (DAAs)

CHCV

- Entry criteria important to determine Chronic nature of the infection/stratification within the study
  - Positive HCV antibody test
  - HCV RNA test
  - HCV Genotype
    - 6 major Genotypes/67 subtypes
  - Liver Biopsy/non-invasive liver test (Transient Elastography)
  - Prior treatment history
  - Co-morbidities (HIV, HEP B, TB, Renal Impairment, Cirrhosis, Liver Transplantion)

- Efficacy endpoints
  - HVC Viral load – SVR (Sustained Virologic Response)

CHCV Review Package

- ReadMe for TAUG-CHCV v1.0draft
- TAUG-CHCV v1.0draft
- CHCV CDASH Metadata
- CHCV Prototype SHARE Metadata

CHCV TAUG

- ***Section 1, Introduction***
  - Provides an overall introduction to the purpose and goals of the Chronic Hepatitis C Virus Infection project
- ***Section 2, Subject and Disease Characteristics***
  - Special Populations
  - Medical and Treatment History
  - Liver Assessments
  - Subject Pharmacogenomics
  - Viral Genotyping and Subtyping
- ***Section 3, Disease Assessments***
  - Viral Load
  - Laboratory tests, Biomarkers and Microscopic Tests
  - Viral drug resistance

CHCV TAUG

- ***Section 4, Routine Data***
  - Adverse Events of Special Interest to CHC
  - Healthcare Resource Utilization
  - Medications and Medication Categories of Special Interest to CHC
  - Substance Use
  - Questionnaires
- ***Section 5, Data Analysis***
  - Subject Level Analysis Dataset
  - Efficacy Analysis Datasets
- ***Appendices***
  - Provide additional background material and describe other supplemental material relevant to CHC.

CHCV TAUG – cont.

- ***Supplemental Material***
  - New SDTM Variables
    - --RSDISC
    - MHEVTYP (MH Only)
  - Clinical Classifications (CC)
  - Pharmacogenomics/Genetics Findings (PF)

CHCV TAUG

- SDTM Domains referenced

Domains from SDTMIG		Section
MH	Medical History	2.3 2.4.2
CM	Concomitant and Prior Medications	2.3.1.1
PR	Procedures	2.3.1.2, 2.4.1
MI	Microscopic Findings	2.4.1
MO	Morphology	2.4.2
FA	Findings About Events or Interventions	2.4.2
CC*	Clinical Classification	2.4.4, 2.4.4.2
LB	Laboratory Test Results	2.4.4.2
CE	Clinical Events	2.4.4.2
Domains from SDTMIG-PGx		**Section**
PF*	Pharmacogenomics/Genetics Findings	2.5, 2.6

** Domain is not final. This model is for informational purposes only, and the published CDISC CC and PF domains on the CDISC portal should be referenced when modeling this data.*

CHCV TAUG - MHEVTYP

6 Domain Models Based on the General Observation Classes

6.2 Events

Medical History (MH)

MH - Specification for Medical History Domain Model

Additional variable approved for use in the MH domain by the SDTM Governance Committee.

mh.xpt, Medical History — Events, Version 3.x. One record per medical history event per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MHEVTYP	Medical History Event Type	Char		Record Qualifier	Specifies the aspect of the medical condition or event by which its start date is defined. Examples: DIAGNOSIS, SYMPTOMS, RELAPSE, INFECTION	Perm

Variable order should be as follows:

MHEVTYP	After MHTERM

CHCV TAUG - MHEVTYP

Example CRF 1: History of Hepatitis C

Category for Medical History: *Hidden/Pre-specified*	MHCAT = HEPATITIS C	**HEPATITIS C**
Subcategory for Medical History: *Hidden/Pre-specified*	MHSCAT = GENERAL	**GENERAL**
Reported Term for the Medical History: *Pre-specified*	MHTERM = HEPATITIS C	**HEPATITIS C**
Medical History Event Pre-specified: *Hidden/Pre-specified*	MHPRESP^ = Y	**YES**
Medical History Occurrence: *Hidden/Pre-specified*	MHOCCUR = Y	**YES**
Date of Infection: (DD-MMM-YYYY)	MHSTDTC and MHEVTYP* = INFECTION MHINFDAT*	__/___/____
Date of Diagnosis: (DD-MMM-YYYY)	MHSTDTC and MHEVTYP* = DIAGNOSIS MHSTDAT	__/___/____
What is the subject's mode of HCV infection? (If applicable) QVAL when QNAM = MODINF and QLABEL = Mode of Infection MHMODINF*		☐ Contaminated needle or IV drug use (current/past) ☐ Blood product transfusion ☐ Vertical transmission (Mother to Child) ☐ Contact with infected individual (other than vertical transmission) ☐ Surgery/operation ☐ Occupational exposure ☐ Unknown

CHCV TAUG - MHEVTYP

In this example, the representation of disease history uses the standard medical history domain and the new SDTM variable MHEVTYP to differentiate MHSTDTC for date of infection and date of diagnosis. This examples also uses the SUPPMH domain in order to represent the mode of infection.

Note that the variable MHEVTYP is a domain-specific variable and is only approved for use in the MH domain.

Row 1: The subject's date of infection was 13 July 2004.
Row 2: The subject was diagnosed on 18 September 2004.

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHTERM	MHEVTYP	MHSEQ	MHCAT	MHSCAT	MHPRESP
1	XYZ	MH	XYZ789-002	HEPATITIS C	INFECTION	1	HEPATITIS C	GENERAL	Y
2	XYZ	MH	XYZ789-002	HEPATITIS C	DIAGNOSIS	2	HEPATITIS C	GENERAL	Y

Row	MHOCCUR	MHSTDTC
1 (cont)	Y	2004-07-13
2 (cont)	Y	2004-09-18

CHCV TAUG

- SDTM Domains referenced

Domains from SDTMIG		Section
MH	Medical History	2.3 2.4.2
CM	Concomitant and Prior Medications	2.3.1.1
PR	Procedures	2.3.1.2, 2.4.1
MI	Microscopic Findings	2.4.1
MO	Morphology	2.4.2
FA	Findings About Events or Interventions	2.4.2
CC*	Clinical Classification	2.4.4, 2.4.4.2
LB	Laboratory Test Results	2.4.4.2
CE	Clinical Events	2.4.4.2
Domains from SDTMIG-PGx		**Section**
PF*	Pharmacogenomics/Genetics Findings	2.5, 2.6

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CHCV TAUG --RSDISC

2 Model Fundamentals

2.2 The General Observation Classes

2.2.1 The Interventions Observations Class

Additional variable approved for use in the Intervention domains by the SDTM Governance Committee.

Table 2.2.1: Interventions — Topic and Qualifier Variables, One Record per Constant-Dosing Interval or Intervention Episode

Variable Name	Variable Label	Type	Role	Description
Qualifier Variables				
--RSDISC	Reason for Discontinuation	Char	Record Qualifier	Describes reason or explanation for why a treatment was ended. Examples: ADVERSE EVENT, LACK OF EFFICACY

Variable order should be as follows:

--DSDISC	After --ADJ

CHCV TAUG --RSDISC

Example CRF 2: HCV Treatment History

Has the subject been previously treated for HCV infection? Not Specified CMINDYN*	☐ Yes ☐ No
Category for Medication: *Hidden/Pre-specified* CMCAT^ = HCV TREATMENT	HCV TREATMENT
Treatment Regimen ID: CMGRPID^	_____
Treatment: CMTRT	_____
Start Date: (DD-MMM-YYYY) CMSTDTC CMSTDAT	__/___/____
End Date: (DD-MMM-YYYY) CMENDTC CMENDAT	__/___/____
For Unknown Start or End Dates, specify duration of treatment: CMDUR CMCDUR*	_____
Duration Unit: CMDUR CMCDURU*	☐ Days ☐ Weeks ☐ Months ☐ Years
Outcome of Treatment: QVAL when QNAM = CMOUTTRT and QLABEL = Outcome of Treatment CMOUTTRT*	☐ Non-Responder ☐ Relapse ☐ Sustained Virologic Response ☐ Unknown
For Non-Responders, further classify outcome of treatment: QVAL when QNAM = CMNONRSP and [illegible] CMNONRSP*	☐ Null Responder ☐ Partial Responder
Primary Reason Treatment was Discontinued: CMRSDISC^*	☐ Completed full course of treatment ☐ Toxicity/Intolerance ☐ HCV Virologic Failure ☐ Pregnancy ☐ Breastfeeding ☐ Receipt of prohibited medication ☐ Withdrawal of consent ☐ Non-compliance with study drug ☐ Investigator decision, not otherwise listed ☐ Other, specify
If Reason is "Other", please specify: CMRSDISC* CMRSDIOT*	_____

CHCV TAUG --RSDISC

Rows 1-2: Show two medications and why the treatment was discontinued.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMGRPID	CMTRT	CMCAT	CMSTDTC	CMENDTC
1	ABC123	CM	ABC123-789	1	Regimen 1	Telaprevir	HCV TREATMENT	2013-08-15	2013-12-17
2	ABC123	CM	ABC123-789	2	Regimen 1	Ribavirin	HCV TREATMENT	2013-08-15	2013-12-17

Row	CMRSDISC
1 (cont)	Completed course of treatment
2 (cont)	Completed course of treatment

CHCV TAUG - CC

- SDTM Domains referenced

Domains from SDTMIG		Section
MH	Medical History	2.3 2.4.2
CM	Concomitant and Prior Medications	2.3.1.1
PR	Procedures	2.3.1.2, 2.4.1
MI	Microscopic Findings	2.4.1
MO	Morphology	2.4.2
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LB	Laboratory Test Results	2.4.4.2
CE	Clinical Events	2.4.4.2
Domains from SDTMIG-PGx		**Section**
PF*	Pharmacogenomics/Genetics Findings	2.5, 2.6

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- Child-Pugh
- MELD and UNOS MELD

CHCV TAUG - PF

- SDTM Domains referenced

Domains from SDTMIG		Section
MH	Medical History	2.3 2.4.2
CM	Concomitant and Prior Medications	2.3.1.1
PR	Procedures	2.3.1.2, 2.4.1
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PF*	Pharmacogenomics/Genetics Findings	2.5, 2.6

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- Subject Pharmacogenomics
- Viral Genotype and Subtype

CHCV – Public Review

- 30-day public review upcoming
  - Published in the CDISC website Friday 19th December 2014
  - Closing date for comments ***Wednesday 28th January 2015***
- Download the document using Adobe Reader (http://get.adobe.com/reader/)
- Submit comments using the CDISC public commenting tool located on the CDISC website located here:
- http://portal.cdisc.org/CT/default.aspx
- Instructions on using the comment tracker tool
- http://portal.cdisc.org/CT/Documents/How%20to%20Use%20the%20CDISC%20Public%20Comment%20Tracker.docx

Future CHCV Training

- Future CHCV implementation training will include:
  - Implementation examples
  - Exercises
  - Tests to check knowledge level
  - And additional detail
- Training will be delivered online soon after publication of the standard
  - so you can train at your convenience

CFAST CHCV Core Team

John Owen	JnJ
Stephanie Caruso	FSTRF
Deb Copeland	GSK
Chris Corbett	JnJ
Karen Dhami	Gilead
Delanya Dubinson	Merck
Nikki Flores	Gilead
Miho Hashimo	GSK
Gloria Jones	JnJ
Sara Pauwels	JnJ
Mithun Kumar Ranga	Boehringer Ingelheim
Ceal Scarinzi	Novartis
Rodica Van Solingen-Ristea	JnJ
Sherry Wunder	JnJ

CFAST CHCV Consultant Team

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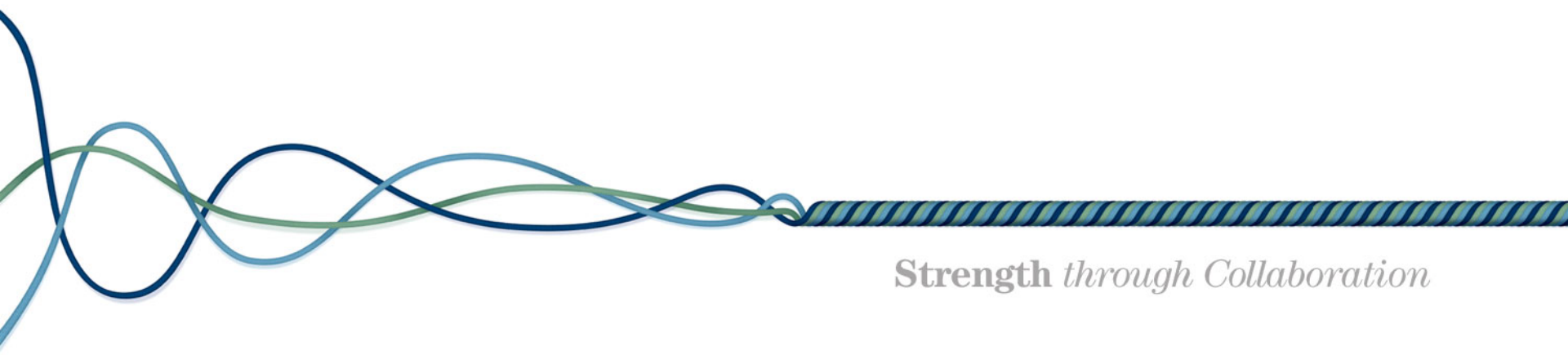
Diane Wold	GSK
Fred Wood	Accenture
Erin Muhlbradt	NCI-EVS
Darcy Wold	CDISC Consultant
Pam Harvey	CDISC
Rene DahlHeimer	CDISC
Nate Freimark	Theorem Clinical
Julie Evans	CDISC
Bernice Yost	CDISC
Susan Kenny	CDISC
Trisha Simpson	UCB

Questions?

CDISC Education & Events Announcements

Saad Yousef, CDISC, Manager of Education and Membership Services



Standards currently out for review

- Terminology Package, Batch 21
  - Comments due 23 Jan
  - Visit http://cdisc.org/terminology for more information.

- CDISC in RDF Reference
  - Comments due 20 Feb
  - Visit http://www.cdisc.org/standards/dataexchange for more information.

- Hepatitis C TAUG
  - Comments due 28 Jan
  - Visit http://www.cdisc.org/therapeutic for more information.

Click here to submit your comments.

Other News

- Europe Interchange abstracts deadline extended to Friday, 9 Jan. Submit yours now!

- FDA Final Binding Guidance

Upcoming USA Public Course Events

Location	Dates	Courses Offered	Registration Deadline	Discounts?	Host
Carlsbad, CA	27-30 Jan 2015	SDTM, CDASH, ADaM	**Only offline registrations accepted now.**	*Expired*	SynteractHCR
Reading, Berkshire, UK	27-30 Jan 2015	SDTM, ADaM, Define-XML, Dataset-XML	**Only offline registrations accepted now.**	*Expired*	QUINTILES
Morrisville, NC	10-13 Feb 2015	SDTM, CDASH, ADaM	10 Jan 2015	*Expired*	SynteractHCR
Chicago, IL	24-27 Mar 2015	SDTM, CDASH, ADaM	24 Feb 2015	*Expired*	astellas Leading Light for Life
Palo Alto, CA	14-17 Apr 2015	SEND, ODM, Dataset-XML, Define-XML	14 Mar 2015	*Expired*	Jazz Pharmaceuticals

Registration deadline indicates online deadline. Offline registration deadlines for each event can be found here. Additional 2015 public training events can be found @ http://cdisc.org/public-courses.

CDISC In-House Education

- Below courses readily available for ‘in-house’ training:
  - ADaM
  - BRIDG Deep Dive
  - CDASH
  - SDTM
  - SDTM for Medical Devices
  - SEND
  - *Others pending availability*

- For more information visit our website or submit request here.

Online Training

- SDTM, CDASH, BRIDG, ADaM, and Therapeutic Area modules available on CDISC Training Campus (http://CDISC.trainingcampus.net)
- Bundle packages available for SDTM, CDASH, and BRIDG modules
- *All members should contact training@cdisc.org to retrieve company-specific discount code.*

Next Public Webinar

- **Agenda:**
  - TBD
- **Date**: 26 Feb 2015, 11:00-12:30 PM EST
- **Speaker:**
  - TBD
- Register here.

Webinar details also at www.cdisc.org/webinars

Next Members Only Webinar

- **Topic**: Overview on Define-XML and Dataset-XML
- **Date/Time**: 15 Jan 2015, 11:00-12:30 PM EST
- **Speaker**: Sally Cassells, Next Step Clinical Systems
- Register here.

Webinar details also at www.cdisc.org/webinars

Any more questions?

Thank you for attending this webinar.

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