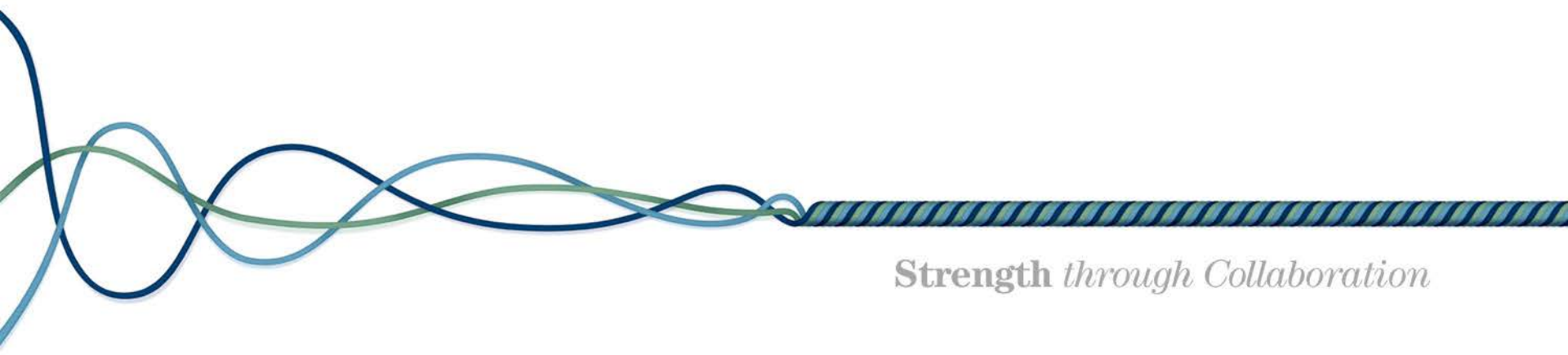
# CDISC Public Webinar – Standards Updates and Additions

9 Mar 2015



# Agenda

- Dyslipidemia
  - John Glover, TransCelerate BioPharma Inc
  - Martin Benson, ICON
  - Kristin Kelly, Accenture
  - Vladimir Kryzhanovski, Eli Lilly
  - Erin Muhlbradt, EVS
  - Jerry Salyers, Accenture
  - John Vincent, Pfizer
  - Fred Wood, Accenture

- CDISC Education and Events Updates*
  - John Ezzell, CDISC

**After Q&A session & time permitting*

# Question & Answer

- ‘Presenter’: Question

Examples:

John: What are the symptoms of Dyslipidemia?

CDISC®

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

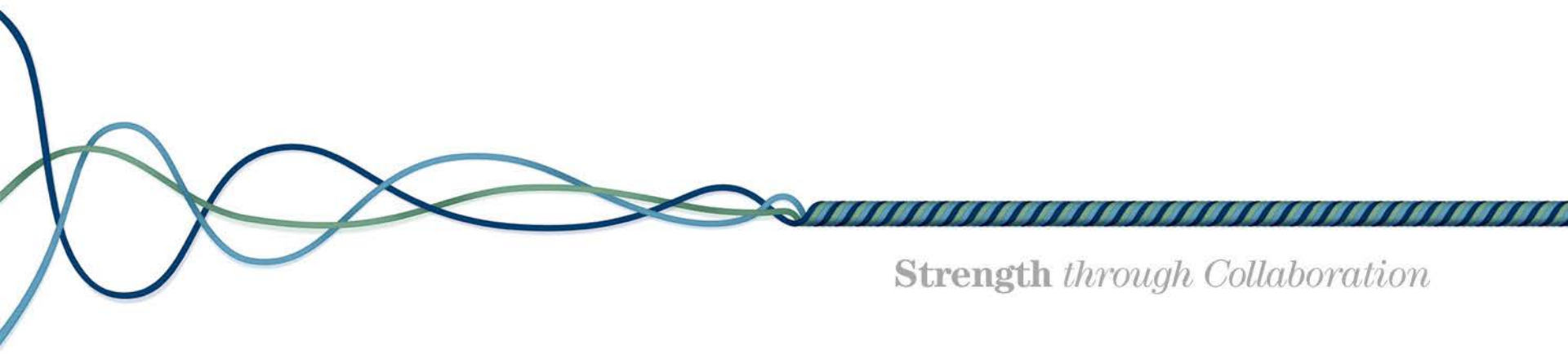
*The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research*

**Strength** *through Collaboration*

# Therapeutic Area User Guide – Dyslipidemia V1.0 Public Review Webinar March 9, 2015

John Glover, TransCelerate BioPharma Inc.

CFAST Dyslipidemia Project Manager



# Dyslipidemia Studies

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


- 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 – March 2015

## Approved Therapeutic Area Standards Projects

| Therapeutic Area | Coordinating Organization(s) / Project Manager | Proposal Approval Date | Stage 0 Scoping | Stage 1 Modeling | Stage 2 Standards Development | Stage 3a Internal Review | Stage 3b Public Review | Stage 3c Publication |
|---|---|---|---|---|---|---|---|---|
| Traumatic Brain Injury v1 | CDISC- Rhonda | Oct 13 | Dec | Jan | Feb | Mar | | Q315 |
| Chronic Hepatitis C Virus v1 | TCB- John Owen | Nov 13 | Feb | Apr | Jul | Nov | Jan | Q115 |
| Schizophrenia v1 | CDISC/DCRI- Amy | Nov 13 | May | Jul | Aug | Jan | Mar | Q215 |
| Breast Cancer v1 | TCB- John Owen | Nov 13 | Aug | Dec | Jan | Mar | | Q215 |
| Dyslipidemia v1 | TCB- John Glover | Dec 13 | May | Sept | Dec | Mar | Apr | Q215 |
| COPD v1 | TCB- John Glover | Nov 13 | Aug | Dec | Feb | Mar | | Q315 |
| Diabetes (ADaM) v1 Supplemental | TCB/CDISC- Rachael | NA | NA | NA | Feb | Apr | | Q215 |
| Diabetic Kidney Disease | TCB/CDISC- Rachael | May 14 | Feb | Apr | | | | Q116 |
| Tuberculosis v2 | C-Path - Laura | Dec 14 | Feb | Apr | | | | Q116 |
| Rheumatoid Arthritis | UCB- Trisha | Jul 13 | Feb | | | | | Q116 |
| CV Imaging | CDISC/DCRI- Amy | Dec 13 | Feb | | | | | Q116 |
| Virology v2 | C-Path - Laura | pending | Feb | Apr | | | | Q315 |

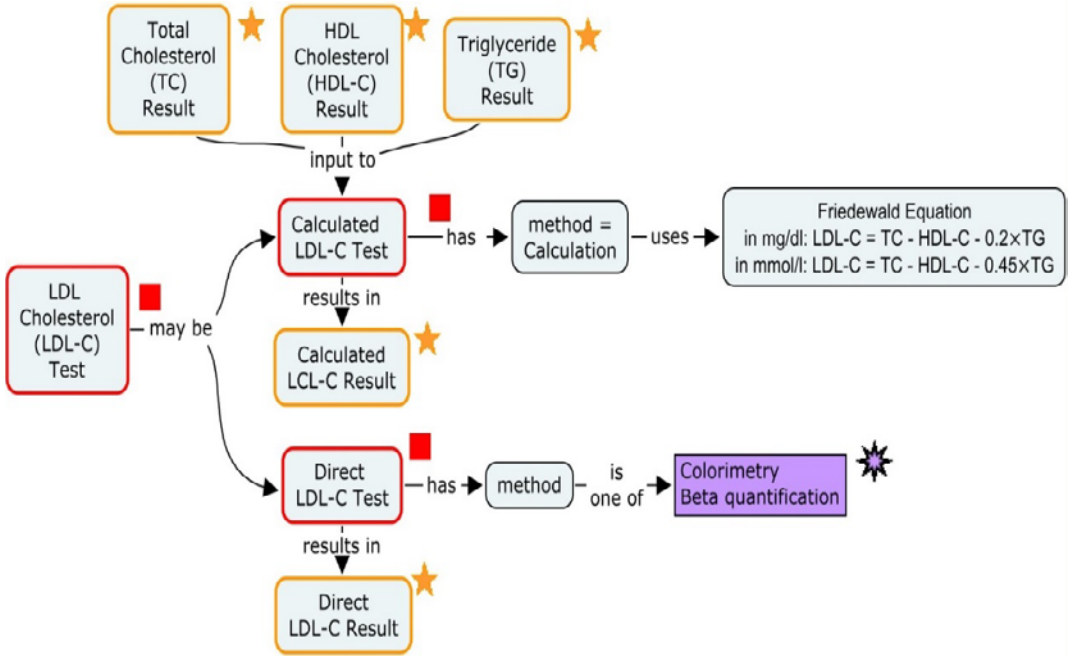
Pink = Stage Completed | Blue = Stage Ongoing| Months reflect stage **completed**

# What is Different from Previous CDISC TA Standards?

- Disease background & context
- Concept maps
  - To illustrate 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

# Concept Maps

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




**Concept Map 1: LDL-Cholesterol**

# Concept Maps – cont.

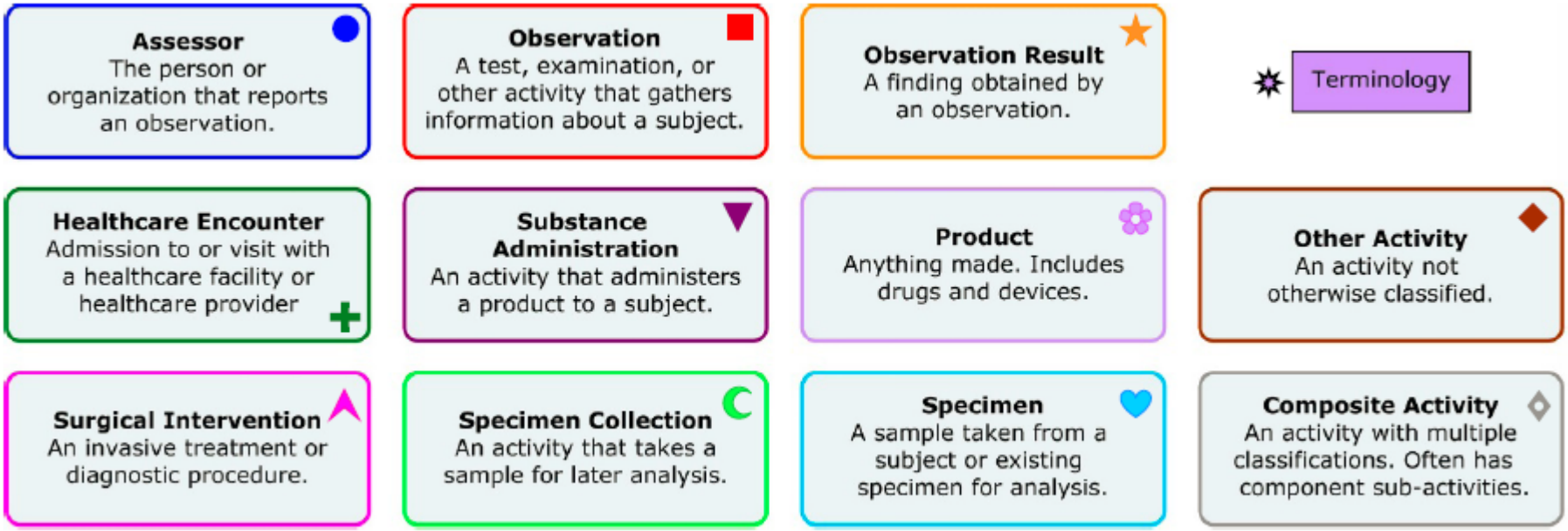



**Figure 2: Concept Classification Key for Concept Maps**

- 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 1: Dyslipidemia Treatment History**

| | |
|---|---|
| Has the subject been previously treated for Dyslipidemia?<br>CMIN1YN^<br>Not Specified | ☐ Yes<br>☐ No |
| If subject is Treatment Experienced, please provide the treatment history. | |
| CMCAT = DYSLIPIDEMIA TREATMENT<br>Category for Medication: *Hidden/Pre-specified* | DYSLIPIDEMIA TREATMENT |
| CMINDC = HYPERCHOLESTEROLEMIA<br>Indication: | HYPERCHOLESTEROLEMIA |
| Dyslipidemia Treatment:<br>CMTRT | _____ |
| Dose:<br>CMSDTXT<br>CMDOSE | _____ |
| Dose Unit:<br>CMDOSU | _____ |
| Dose Form:<br>CMDOSFRM | _____ |
| Frequency:<br>CMDOSFRQ | _____ |
| Route:<br>CMROUTE | _____ |
| CMSTDTC<br>CMSTDAT<br>Start Date: (DD-MMM-YYYY) | __/___/____ |
| CMENDTC<br>CMENDAT<br>End Date: (DD-MMM-YYYY) | __/___/____ |
| CMDUR<br>For Unknown Start or End Dates, specify duration of treatment: | _____ |
| CMDURU<br>Duration Unit:<br>CMDUR | ☐ Days ☐ Weeks<br>☐ onths ☐ Years |
| CMRSDISC*<br>CMRSDISC*<br>Primary Reason Treatment was Discontinued: | ☐ Toxicity/Intolerance<br>☐ Lack of efficacy<br>☐ Other specify below |
| If Reason is "Other", please specify:<br>CMTRTDOT<br>CMRSDISC* | _____ |

CRF Annotated to show mapping. SDTM variables are in Red. If CDASH variable differs from SDTM, the CDASH variable is in Blue.
* New variable request submitted
^ New variable under consideration

# 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

### Appendix E1: Works Cited


1. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic. *Circulation*. 2013:1-85.
2. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: part 1 - executive summary. *J Clin Lipidol*. 2014;8(5):473-88.
3. Reiner Z, Catapano AL, De backer G, et al. ESC/EAS Guidelines for the management of dyslipidemias. *Rev Esp Cardiol (Eng Ed)*. 2011;64(12):1168.
4. Fifth Joint Task Force for the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice. European Guidelines on Cardiovascular Disease Prevention in Clinical Practice (Version 2012). *Eu H J*. 2012;33:555-76.
5. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. *Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Full Report*. Bethesda, Maryland 2012. NIH Publication No. 12-7486.
6. Expert Dyslipidemia Panel of the International Atherosclerosis Society. An International Atherosclerosis Society Position Paper: Global recommendations for the management of dyslipidemia. *J Clin Lipidol*. 2014;8:29-30.
7. Kavey RE, Daniels SR, Lauer RM, Atkins DL, Hayman LL, Taubert K. American Heart Association Guidelines for Primary Prevention of Atherosclerotic Cardiovascular Disease Beginning in Childhood. *Circulation*. 2003;107:1562-6.
8. Williams CL, Hayman LL, Daniels SR, et al. Cardiovascular Health in Childhood: A statement for health professionals from the Committee on Atherosclerosis, Hypertension, and Obesity in the Young (AHOY) of the Council on Cardiovascular Disease in the Young, American Heart Association. 2002;106:143-60.
9. United States National Heart, Lung and Blood Institute. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report. *NHLBI, NIH*. 2002. Available at: http://www.nhlbi.nih.gov/health-pro/guidelines/current/cholesterol-guidelines. Accessed December 22, 2014.
10. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous Familial Hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the consensus panel on familial hypercholesterolaemia of the European Atherosclerosis Society. *Eur Heart J*. 2014;35(32):2146-57.
11. Nordestgaard BG, Chapman MJ, Humphries SE, et al. Familial hypercholesterolaemia is underdiagnosed and undertreated in the general population: guidance for clinicians to prevent coronary heart disease: Consensus Statement of the European Atherosclerosis Society. *Eur Heart J*. 2013;34(45):3478-90a.
12. Sjouke B, Kusters DM, Kindt I, et al. Homozygous autosomal dominant hypercholesterolemia in the Netherlands: prevalence, genotype-phenotype relationship and clinical outcome. *Eur Heart J*. 2014;[Epub ahead of print]. doi: 10.1093/eurheartj/ehu058.
13. Shah RV, Goldfine AB. Statins and Risk of New-Onset Diabetes Mellitus. *Circulation*. 2012;126:e282-e284.
14. Graham D, Staffa JA, Shatin D, et al. Incidence of hospitalized rhabdomyolysis in patients treated with lipid-lowering drugs. *JAMA*. 2004;292:2585-90.
15. McKinney JM, Davidson MH, Jacobson TA, Guyton JR. Final Conclusions and Recommendations of the National Lipid Association Statin Safety Assessment Task Force. *Am J Cardiol*. 2006;97(8A):89C-94C.
16. Savel J, Lafitte M, Pradeau V, Tabarin A, Couffinhal T. Very low levels of HDL cholesterol and atherosclerosis, a variable relationship - a review of LCAT deficiency. *Vasc Health Risk Manag*. 2012;8:357-61.
17. Oram J. Tangier disease and ABCA1. *Biochimica et Biophysica Acta Mol Cell Biol Lipids*. 2000;1529(1-3):321-30.

# 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.

# Dyslipidemia TAUG

## Therapeutic Area Data Standards User Guide for Dyslipidemia

Version 1.0

**Prepared by**

**The CFAST Dyslipidemia Team**

[redacted]

**Notes to Readers**

- This is a draft version of the Therapeutic Area Data Standards User Guide for Dyslipidemia. It is intended for public review only and is not a final version.
- This document is based on CDASH Standard v1.1, ADaM v2.1 and ADaMIG v1, and SDTM v1.4 and SDTMIG v3.2.
- This TAUG-Dyslipidemia v1.0 package contains a user guide, two sets of CDASH metadata, and one simplified prototype SHARE metadata display.

**Revision History**

| Date | Version | Summary of Changes |
|---|---|---|
| 2015-03-09 | 1.0 | Draft for Public Review |

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

# Dyslipidemia

- This draft version 1.0 (v1.0) of the TAUG
  - Phase 1-4 adult & pediatric clinical trials of diet, drugs, and devices
  - Focus on labs
  - Other development around concomitant medications and adverse events
  - This document does not address major adverse cardiac events (MACE) endpoints, e.g., stroke, myocardial infarction, death, etc. since they are addressed in other TAUGs.
  - Dietary data and physical activity may be considered for v2 of the TAUG

# Dyslipidemia

- Defined as an abnormal blood plasma or serum lipid status
- Lipids are transported in the blood in lipoprotein particles. Lipoproteins can be separated into different types based on density, electrical charge, and particle size
- Common lipid abnormalities include elevated total cholesterol, low-density lipoprotein (LDL) cholesterol (“bad” cholesterol), and triglycerides (TG) and reduced high-density lipoprotein (HDL) cholesterol (“good” cholesterol)
- Risk factor for coronary heart disease and other forms of cardiovascular disease (CVD) (e.g. stroke)
- An estimated 31 million adults in the USA have total serum cholesterol levels ≥240 mg/dL (considered high level)

# Dyslipidemia

- Primary Dyslipidemia
  - Genetic Causes:  single- or multi-gene mutations that result in either overproduction or defective clearance of TG and LDL cholesterol, or an underproduction or excessive clearance of HDL

  Example - Familial Hypercholesterolemia: Very high levels of bad cholesterol present from early childhood, potentially causing subclinical atherosclerosis or sometimes even coronary events within the first decade of life
- Secondary Dyslipidemia
  - Smoking
  - Sedentary lifestyle
  - Excessive dietary intake of saturated fats or trans-saturated fats, carbohydrates, or alcohol
  - Certain medical conditions can cause secondary dyslipidemias

# Dyslipidemia Review Package

**TAUG-Dyslipidemia v1.0draft.zip**

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

# Dyslipidemia TAUG

- ***Section 1, Introduction***
  - Provides an overall introduction to the purpose and goals of the Dyslipidemia project
- ***Section 2, Subject and Disease Characteristics***
  - Primary Dyslipidemia
  - Secondary Dyslipidemia
  - Treatment History
  - Family Medical History
- ***Section 3, Dyslipidemia Assessments***
  - Dyslipidemia-Specific Laboratory Tests
  - Clinical Outcomes Assessments and Other Instruments
  - Adjudicated Cardiovascular Events

# Dyslipidemia TAUG – cont.

- ***Section 4, Routine Data***
  - Physical Examinations
  - Concomitant Medications of Special Interest
  - Adverse Events of Special Interest
- ***Section 5, Data Analysis***
  - Statistical Endpoints
  - Subject Level Analysis Dataset
  - Efficacy Analysis Datasets
- ***Appendices***
  - Provide additional background material and describe other supplemental material relevant to Dyslipidemia.

# Dyslipidemia TAUG – cont.

- ***Supplemental Material***
  - New SDTM Variables
    - --RSDISC
  - Clinical Classifications (CC)

| Instrument Name | SDTM Domain | Copyright Status |
|---|---|---|
| ACC/AHA Atherosclerotic Cardiovascular Disease 10-Year Risk Score (Contained within the ACC/AHA Guidelines) | CC* | Public Domain |
| ASSIGN Cardiovascular Disease 10-Year Risk Score | CC* | Public Domain |
| Framingham Cardiovascular Disease 10-Year Risk Score | CC* | Public Domain |
| PROCAM Cardiovascular Disease 10-Year Risk Score | CC* | Copyrighted |
| Reynolds Score | CC* | Public Domain |
| QRISK Cardiovascular Disease 10-Year Risk Score | CC* | Copyrighted |
| SCORE Cardiovascular Disease 10-Year Risk Score | CC* | Copyrighted |
| Tanner Scale | CC* | Public Domain |

  - Questionnaires (QS)

| Instrument Name | SDTM Domain | Copyright Status |
|---|---|---|
| European Quality of Life Five-Dimensional Scale (EQ-5D) | QS | Copyrighted |
| Short Form 36, version 2 (SF-36v2) | QS | Copyrighted |

# Dyslipidemia 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 |

# Dyslipidemia TAUG --RSDISC

**Example CRF 1: Dyslipidemia Treatment History**

| | |
|---|---|
| Has the subject been previously treated for Dyslipidemia?<br>Not Specified CMIN1YN^ | ☐ Yes<br>☐ No |
| If subject is Treatment Experienced, please provide the treatment history. | |
| Category for Medication:<br>*Hidden/Pre-specified* CMCAT = DYSLIPIDEMIA | DYSLIPIDEMIA TREATMENT |
| Indication: CMINDC = HYPERCHOLESTEROLEMIA | HYPERCHOLESTEROLEMIA |
| Dyslipidemia Treatment:<br>CMTRT | _____ |
| Dose:<br>CMDOSE CMSDTXT | _____ |
| Dose Unit:<br>CMDOSU | _____ |
| Dose Form:<br>CMDOSFRM | _____ |
| Frequency:<br>CMDOSFRQ | _____ |
| Route:<br>CMROUTE | _____ |
| Start Date:<br>(DD-MMM-YYYY) CMSTDTC CMSTDAT | __/___/____ |
| End Date:<br>(DD-MMM-YYYY) CMENDTC CMENDAT | __/___/____ |
| For Unknown Start or End Dates, specify duration of treatment:<br>CMDUR | _____ |
| Duration Unit:<br>CMDUR CMDURU | ☐ Days ☐ Weeks<br>☐ Months ☐ Years |
| Primary Reason Treatment was Discontinued:<br>CMRSDISC* CMRSDISC* | ☐ Toxicity/Intolerance<br>☐ Lack of efficacy<br>☐ Other specify below |

# Dyslipidemia TAUG --RSDISC

In this example, the subject reported taking two medications for hypercholesterolemia.

**Row 1:** Subject started and stopped taking suprastatin.
**Row 2:** Subject began taking varastatin, and was still taking it as of the Screening visit.

*cm.xpt*

| Row | STUDYID | DOMAIN | USUBJID | CMSEQ | CMTRT | CMCAT | CMINDC | CMRSDISC |
|---|---|---|---|---|---|---|---|---|
| 1 | ABC-123 | CM | ABC-123-1001 | 1 | Suprastatin | Dyslipidemia Medications | Hypercholesterolemia | Lack of Efficacy |
| 2 | ABC-123 | CM | ABC-123-1001 | 2 | Varastatin | Dyslipidemia Medications | Hypercholesterolemia | |

| Row | CMSTDTC | CMENDTC | CMENRTPT | CMENTPT |
|---|---|---|---|---|
| 1 (cont) | 2011-08-15 | 2012-02-13 | | |
| 2 (cont) | 2012-02-20 | | ONGOING | SCREENING |

# Dyslipidemia TAUG – cont.

- Lipid Lab Tests

| Common Test Abbreviation | Test Name | Description | Specimen(s) |
|---|---|---|---|
| LDL* | Low-Density Lipoprotein | LDL is usually the main transporter of cholesterol in the blood, and is often referred to as "bad cholesterol". The concentration of LDL-cholesterol is often calculated using the Friedewald equation (calculated LDL-cholesterol). It can also be measured directly (direct LDL-cholesterol) after separation from other lipoproteins. (See concept map below.) | Serum, Plasma (generally collected while patient is fasting) |
| TC | Total Cholesterol | Total cholesterol consists of free cholesterol and cholesterol esters. Cholesterol is ingested in foods and synthesized in the body. One of the primary sites of cholesterol synthesis is the liver. Due to its hydrophobic nature, cholesterol cannot travel in the blood on its own, but needs to be transported within lipoproteins. The major lipoproteins that carry cholesterol and contribute to its total blood level are low-density, (LDL), high-density (HDL), and very-low-density (VLDL) lipoproteins. A high total cholesterol level may indicate a problem with cholesterol, but it is more important to measure the content in the individual lipoproteins. | Serum, Plasma (generally collected while patient is fasting) |
| TG | Triglycerides | Triglycerides are present in food, absorbed as free fatty acids and monoglycerides in the small intestine and then converted back into triglycerides and carried by lipoproteins in the blood plasma. They may ultimately be stored in fat cells in adipose tissue if not used as an energy source immediately. Later, hormones release fatty | Serum, Plasma (should be collected while patient is fasting) |

# Dyslipidemia TAUG – cont.

- Biomarker Lab Tests

| Common Test Abbreviation | Test Name | Description | Specimen(s) |
|---|---|---|---|
| | Adiponectin | Adiponectin is adipocytokin with anti-inflammatory and anti-atherogenic properties. Low concentrations of adiponectin are associated with dyslipidemia and coronary heart disease. | Serum, Plasma |
| CETP | Cholesteryl ester transfer protein | CETP facilitates the exchange of cholesteryl esters and triglycerides between lipoproteins. Inhibition of CETP in humans increases the concentration of cholesterol in the potentially protective HDL fraction, while decreasing it in potentially proatherogenic non-HDL fractions. | Serum, Plasma |
| | Fibrinogen | Fibrinogen plays a role in blood clotting. Higher concentrations of fibrinogen have been shown to be associated with dyslipidemia and may be a predictor of cardiovascular disease. | Serum, Plasma |
| hs CRP | High-Sensitivity C-reactive Protein | hs C-reactive protein is a measure of inflammation. Elevated basal concentrations of high-sensitivity C-reactive protein are associated with risk of stroke and cardiovascular disease. | Serum, plasma |
| IL-6 | Interleukin 6 | Increased concentrations of IL-6 are associated with a higher risk of dyslipidemia, and may be a predictor of cardiovascular disease. | Serum, Plasma |
| MMP-9 | Matrix metalloproteinase 9 | Higher concentrations of matrix metalloproteinase 9 have been found to be associated with progression of idiopathic atrial fibrillation. It also appears to play a role in the development of aortic aneurysms. | Serum, Plasma |
| MCP-1 | Monocyte chemotactic Protein 1 | Elevated concentrations of monocyte chemoattractant protein 1 are associated with increased cardiovascular disease. | Serum, Plasma |
| MPO | Myeloperoxidase | Myeloperoxidase plays a role in oxidation of lipoproteins. Elevated myeloperoxidase concentrations are associated with acute coronary syndrome and coronary artery disease. | Serum, Plasma |

# Dyslipidemia – Public Review

- 30-day public review upcoming
  - Published in the CDISC website est. Friday 13th March 2015
  - Closing date for comments est. **Friday *10th April 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 Dyslipidemia Training

- Future Dyslipidemia 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 Dyslipidemia Team

| Name | Organization |
|---|---|
| Lauren Beacham | Eli Lilly and Company |
| Martin Benson | ICON Clinical Research |
| Diane Corey | Critical Path Institute |
| Rene Dahlheimer | CDISC |
| Rhonda Facile | CDISC |
| John Glover | TCB |
| Ron Fitzmartin | FDA Liaison |
| Nate Freimark | Theorem Clinical |
| LiFeng Good | AstraZeneca |
| Pamela Harvey | Transcelerate BioPharma Inc. |
| Jordan Li | National Institutes of Health |
| Jennie G. Jacobson | Eli Lilly and Company |
| Grace Kao | Westat |
| Kristen Kelly | Accenture |
| Susan Kenny | Independent Contractor |
| Naveed Khaja | Independent Contractor |
| Vladimir Kryzhanovski | Eli Lilly and Company |
| Bess LeRoy | Critical Path Institute |
| Mary McGowan | Genzyme, a Sanofi Company<br>Dartmouth Hitchcock Medical Center Heart and Vascular Center |

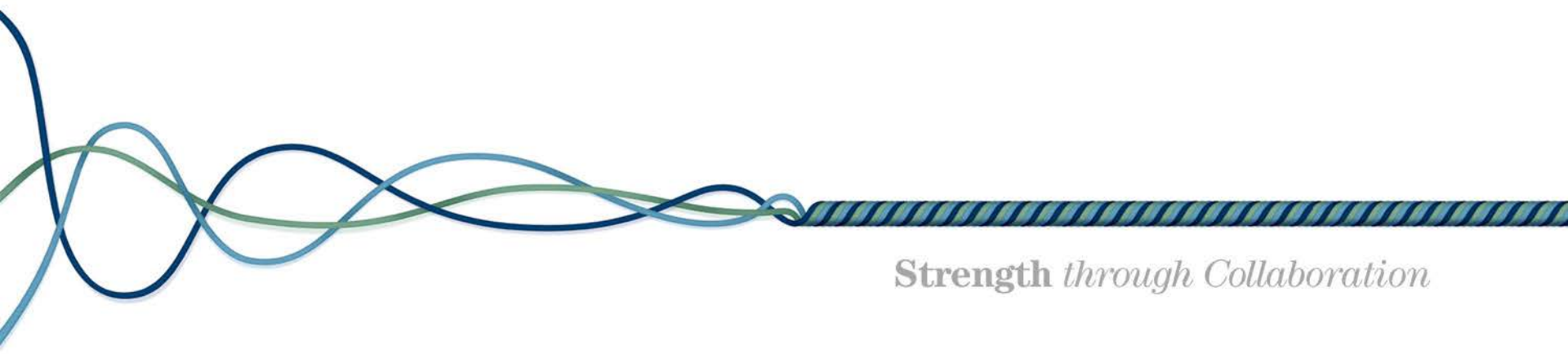
# CFAST Dyslipidemia Team – cont.

| Name | Organization |
|---|---|
| Elizabeth Mendel | Novartis |
| Erin Muhlbradt | National Institutes of Health |
| Seva Panfilov | AstraZeneca |
| Pamela Rinaldi | Boehringer Ingelheim |
| Jerry Salyers | Accenture |
| Pamela Schwartz | Pfizer |
| Trisha Simpson | UCB |
| Alana St. Clair | CDISC |
| James Underberg | New York University Medical Center |
| John Vincent | Pfizer |
| Darcy Wold | CDISC |
| Diane Wold | Glaxo SmithKlein |
| Fred Wood | Accenture |
| Guowei Wu | Merck |

# Dyslipidemia – Public Review Webinar

# CDISC Education & Events Announcements

John Ezzell, CDISC, Manager of Education Products



# Standards currently out for review

- TA CFAST TAUG for Schizophrenia
  - Visit http://www.cdisc.org/standards/dataexchange for more information.
  - Deadline for Comments: 27 Mar 2015

Click here to submit your comments.

# Upcoming USA Public Course Events

| Location | Dates | Courses Offered | Registration Deadline | Discounts? | Host |
|---|---|---|---|---|---|
| Chicago, IL | 24-27 Mar 2015 | SDTM, CDASH, ADaM | *Expired* | *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 |
| Audubon, PA | 18-22 May 2015 | SDTM, CDASH, ADaM | 18 Apr 2015 | *Expired* | BIOCLINICA Global clinical trial solutions. Real-world results. |
| Minneapolis, MN | 23-26 June 2015 | SDTM for Med. Devices, CDASH, CT | 23 May 2015 | *Expired* | MedNet Solutions |

*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.*

# Upcoming Europe Public Course Events

| Location | Dates | Courses Offered | Registration Deadline | Discounts? | Host |
|---|---|---|---|---|---|
| Europe Interchange in Basel, Switzerland | 4-8 May 2015 | FDA Review, CDASH, ODM, CT, Healthcare Link, Dataset-XML, Define-XML, SDTM, SDTM for Med. Devices, SEND, ADaM | 20 April 2015 | Early Bird Discount Available until 23 Feb 2015 | CDISC |
| Eschborn (Frankfurt), Germany | 14-17 Jul 2015 | SDTM, CDASH, ADaM | 14 June 2015 | 28 Feb 2015 | ACCOVION |

*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.*

# Upcoming Asia Public Course Events

| Location | Dates | Courses Offered | Registration Deadline | Discounts? | Host |
|---|---|---|---|---|---|
| Beijing, China | 12-15 May 2015 | SDTM, CDASH, ODM, Dataset-XML, Define-XML, ADaM | 24 Apr 2015 | 13 Mar 2015 | PPD |
| Shanghai, China | 18-21 May 2015 | SDTM, CDASH, ODM, Dataset-XML, Define-XML, ADaM | 24 Apr 2015 | 13 Mar 2015 | PPD |

*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

- **Topics**: Controlled Terminology, Batch 21 & 22 (Public Review), Quarterly Technical Update, and CDISC Medical Devices Standards

- **Date/Time**: 26 Mar 2015, 110:00-11:30 AM CST

- **Speakers**:
  - Bernice Yost, CDISC
  - Wayne Kubick, CDISC
  - Kit Howard, CDSIC

- Register here.



*Webinar details also at www.cdisc.org/webinars*

# Next Member's-Only Mini Training

- **Agenda:**
  - Associated Persons Domain
- **Date**: 23 April 2015, 10 AM -11:30 AM CST
- **Speakers:**
  - Alyssa Wittle, Theorem Clinical
- Register here.

*Webinar details also at www.cdisc.org/webinars*

# CDISC Members Drive Global Standards

# Thank you for your support!

*Any more questions?*

*Thank you for attending this webinar.*

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