



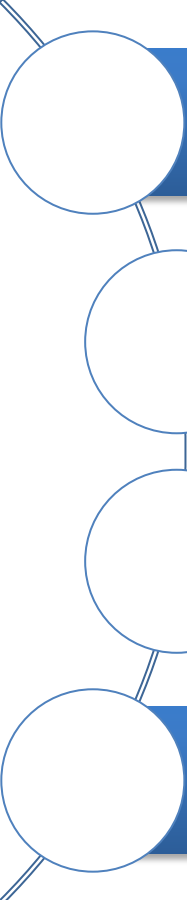
Business & Decision Life Sciences

Handling non-standardized questionnaires

Anne-Sophie Bekx

13 October 2014



A vertical navigation bar on the left side of the slide, consisting of four white circles connected by a thin line. The top circle is slightly larger than the others.

Introduction

CDISC Questionnaire Supplements

SF36: An example

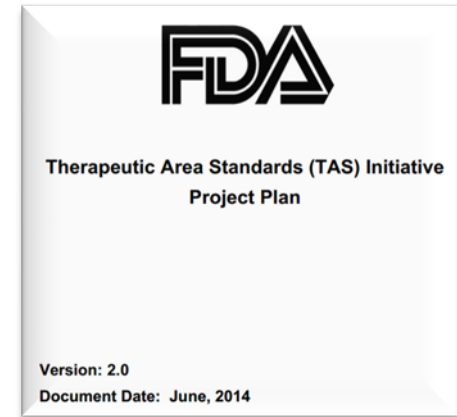
Conclusion

FDA TA Initiative Project Plan



- **Scope**

- Include the development and implementation of TA standards to support the regulatory review process for drugs and biologics



- **Objectives**

- Establish and implement FDA's requirements
- Use an open and transparent process
- Express TA requirements in sustainable standards
- Implement in guidance



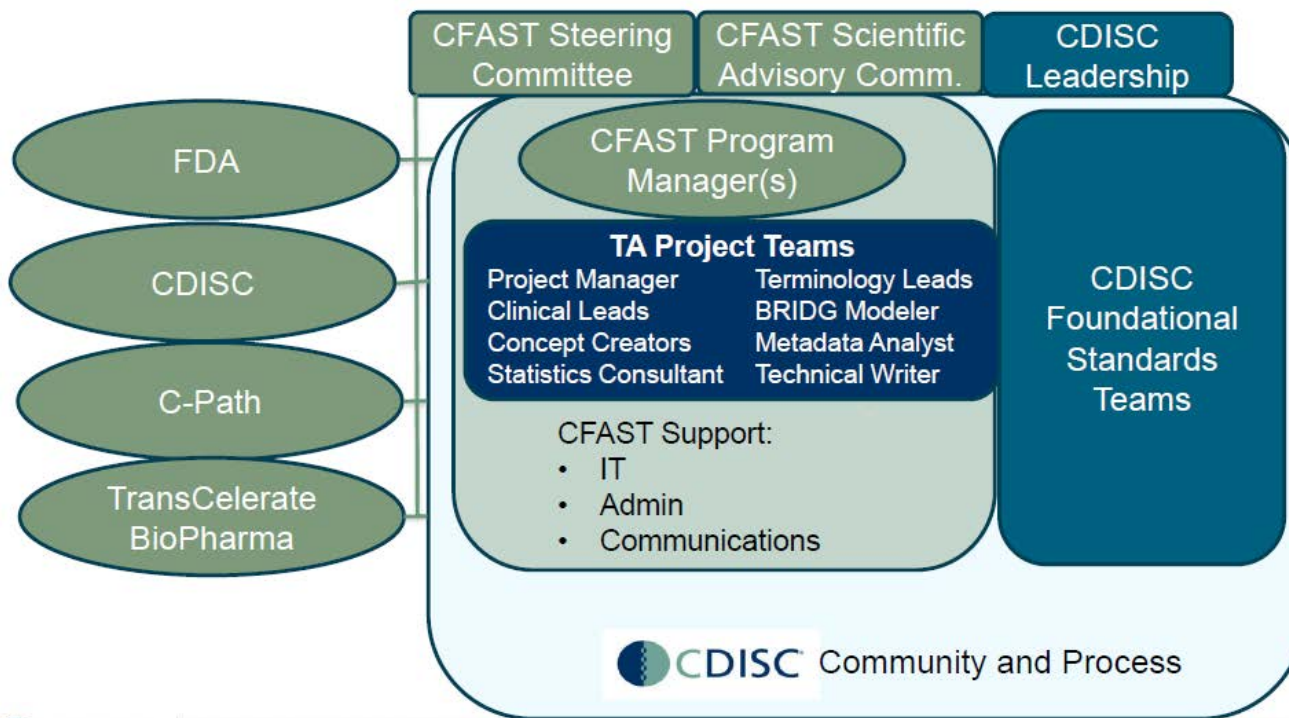
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm>



CFAST Therapeutic Area Standards



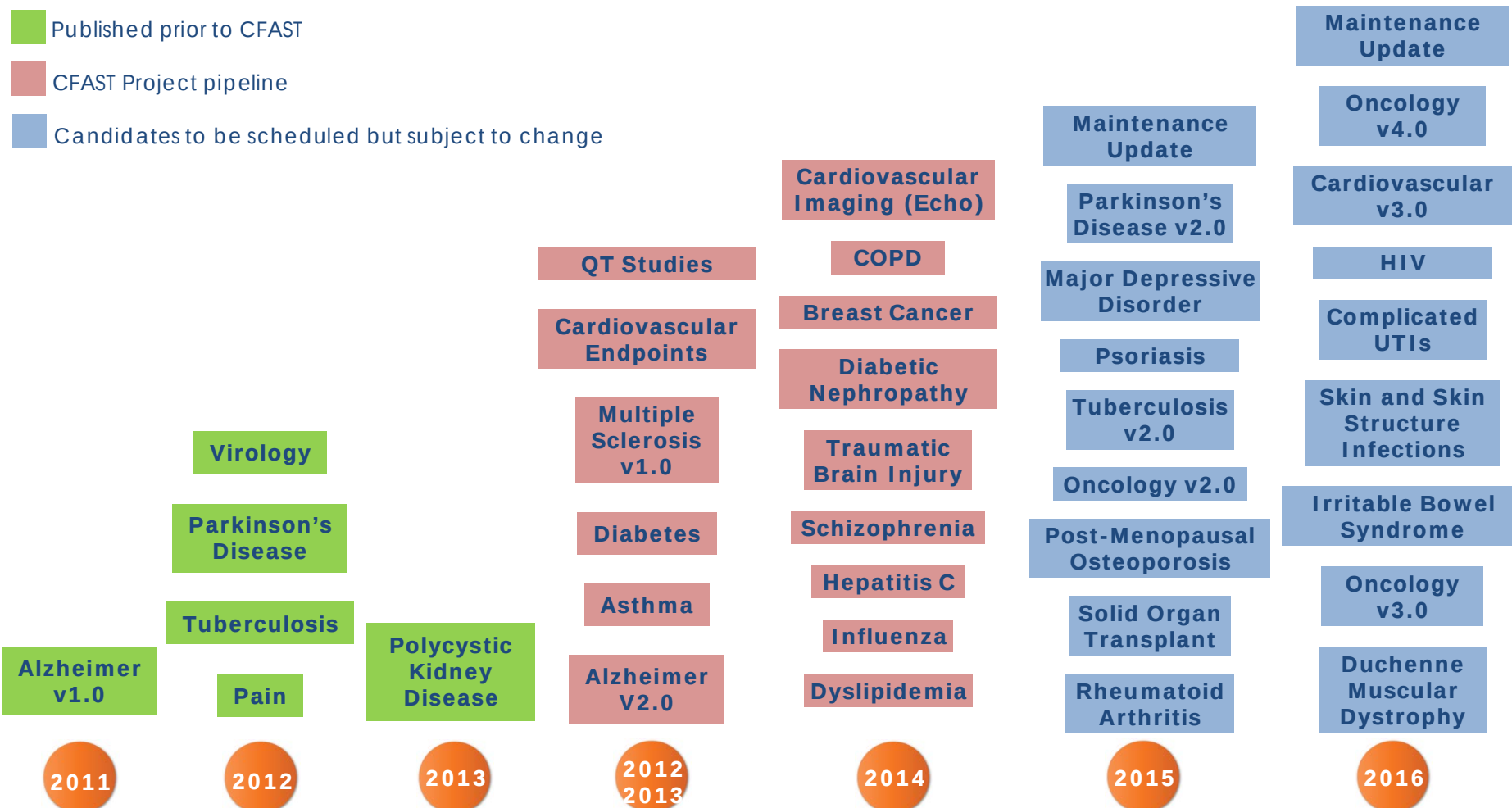
Therapeutic Area Standards Governance



© CDISC 2014

5

CFAST Working Plan – May 2014



CFAST Program overview – July 2014

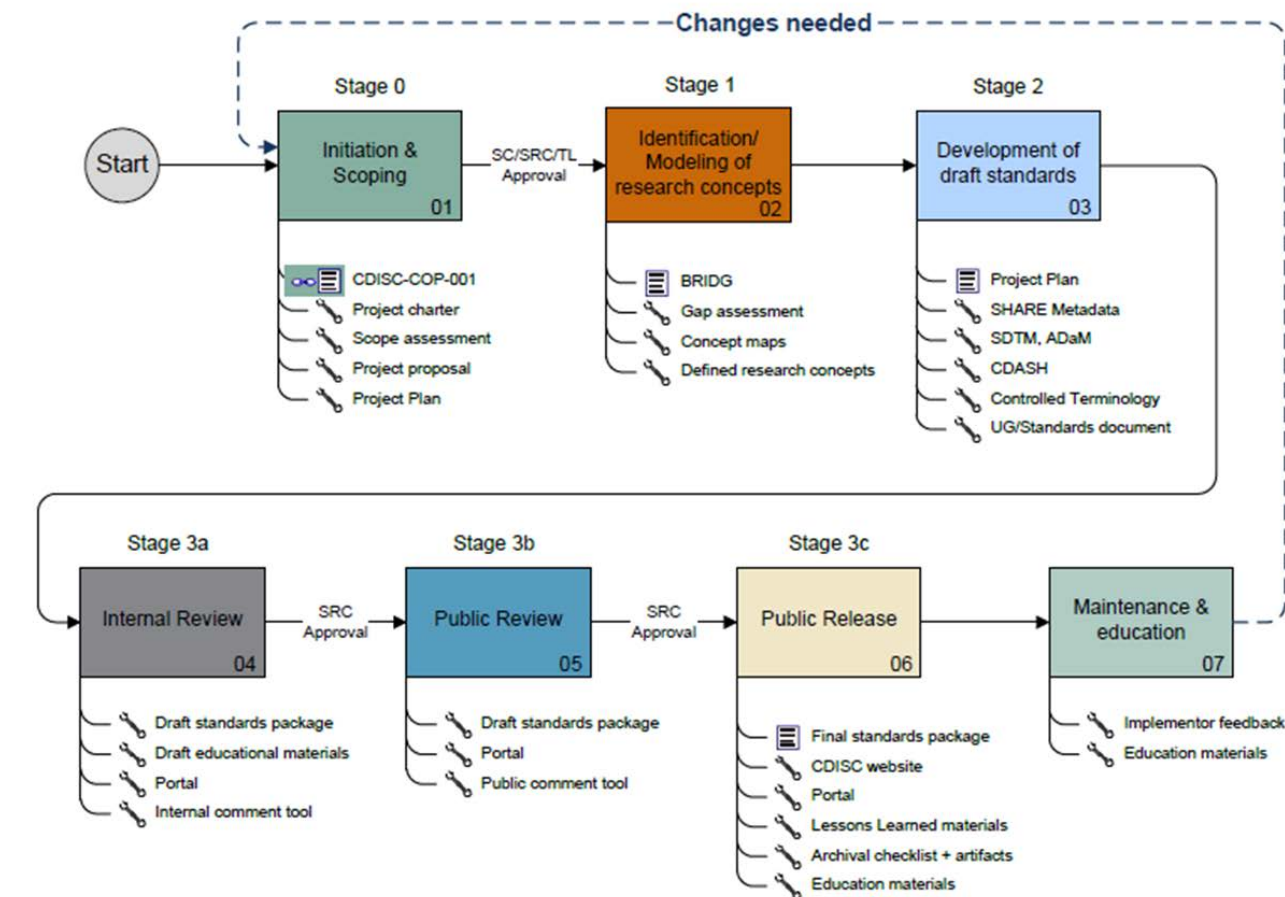


Therapeutic Area	Coordinating Organization(s)	Proposal Approval Date	Stage 0	Stage 1	Stage 2	Stage 3a	*Stage 3b	*Stage 3c
	Project Manager		Scoping & Planning	Concept Modeling	Standards Development	Internal Review	Public Review	**Projected Publication
CV Endpoints v1	CDISC/DCRI Amy Palmer	Jun 13	July	Sep	Nov	Feb	May	Q314
Diabetes v1	TCB Rachael Zirkle	Apr 13	May	Aug	Dec	Apr	May	Q314
QT Studies v1	TCB John Owen	Aug 13	Oct	Feb	Mar	Jul	Sep	Q314
Traumatic Brain Injury v1	CDISC Rhonda Facile	Oct 13	Aug	Sep				Q215
Hepatitis C v1	TCB John Owen	Nov 13	Feb	Apr	Jul	Aug	Sep	Q414
Schizophrenia v1	CDISC/DCRI Amy Palmer	Nov 13	May	Jul	Aug			Q414/Q115
Breast Cancer v1	TCB Pam Harvey	Nov 13	Aug	Sep				2015
Influenza v1	C-PATH Laura Butte	Feb 14	May	Jul	Aug	Sep		Q115
Dyslipidemia v1	TCB John Glover	Dec 13	May	Aug	Oct			Q115
COPD v1	TCB John Glover	Nov 13	Aug	Oct				Q315

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

<http://www.cdisc.org/therapeutic>

Enhanced Standards Development Process



What is CDISC SHARE?



- Shared **H**ealth **a**nd **R**esearch **E**lectronic Library
- **SHARE** is a global electronic repository for developing, integrating and accessing CDISC standards metadata in electronic format
- **Share exists of 4 releases:**
 - R1: Machine-Readable Standards (Q1 2014)
 - R2: SHARE Concept Model (Q4 2014)
 - R3: End-to-End Standards Model (Q4 2015)
 - R4: Multiple Concept Systems (Q4 2016)



<http://www.cdisc.org/cdisc-share>

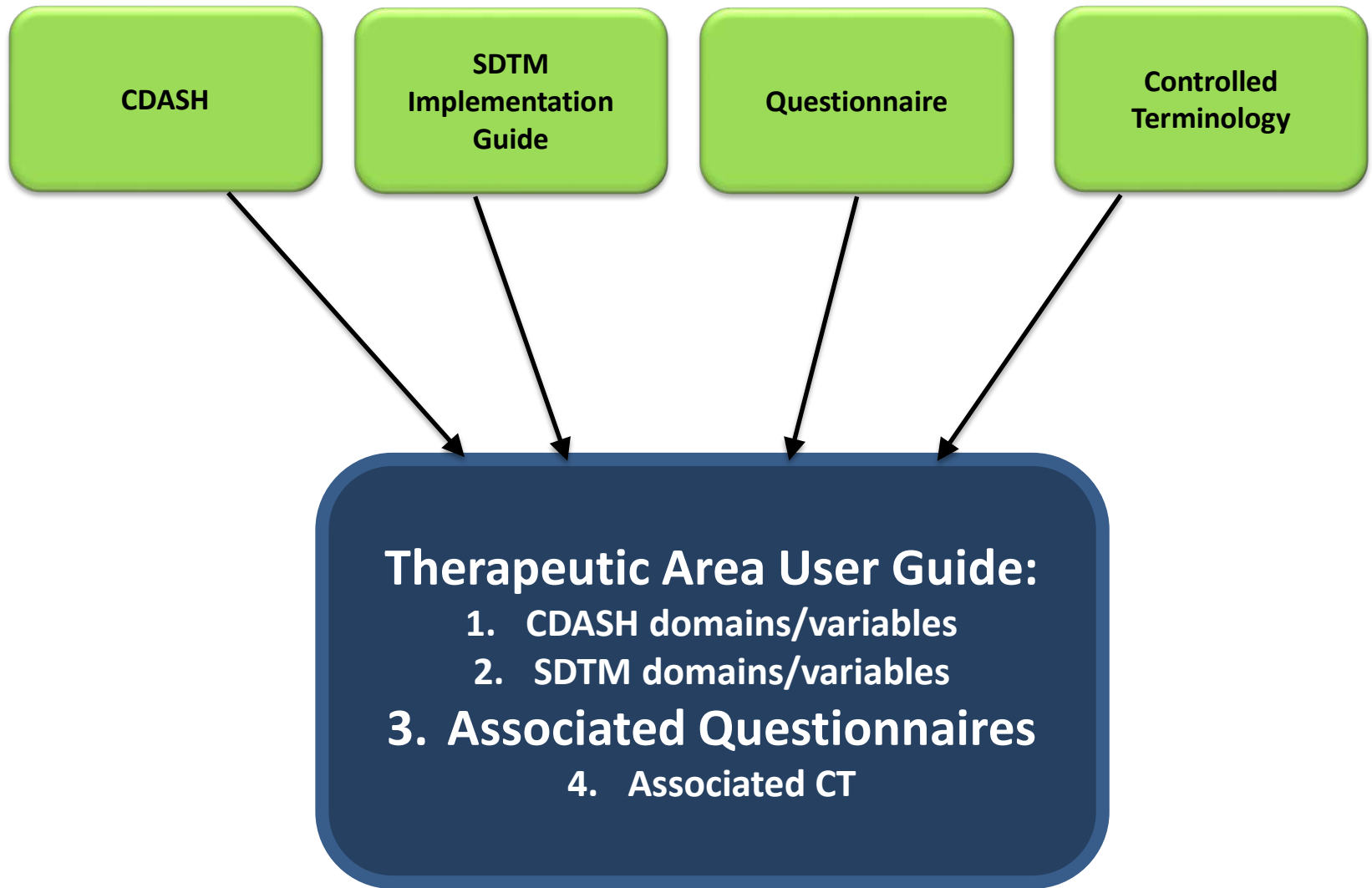


Introduction

CDISC Questionnaire Supplements

SF36: An example

Conclusion



BDLS involvement



- BDLS has 3 members involved in the creation of Questionnaire Supplements to SDTM
- 4 questionnaires have been developed and submitted to the CDISC QS sub-team:
 - **Generalized Anxiety Disorder (GAD-7)**
 - **Fibromyalgia Impact Questionnaire (FIQR)**
 - **Hospital Anxiety and Depression Scale (HADS)**
 - **Neuropathic Pain Scale (NPS)**

CDISC Questionnaire Supplements



Questionnaire	Version	Short Name (QSCAT)	Permission	Release Date
<u>General Clinical Global Impression</u>	V1.0	GENERAL CLINICAL GLOBAL IMPRESSIONS	Public Domain	August 7, 2012
<u>Geriatric Depression Scale (GDS)</u>	V1.0	GDS	Public Domain	May 22, 2013
<u>Geriatric Depression Scale Short Form (GDS SHORT FORM)</u>	V1.0	GDS SHORT FORM	Public Domain	May 22, 2013
<u>General-Pain Intensity</u>	V1.0	PAIN INTENSITY	Public Domain	August 7, 2012
<u>General-Pain Relief</u>	V1.0	PAIN RELIEF	Public Domain	August 7, 2012
<u>Hamilton Anxiety Rating Scale (HAM-A)</u>	V1.0	HAM-A	Public Domain	May 16, 2013
<u>Hamilton Depression Rating Scale 17-Item (HAMD 17)</u>	V1.1	HAMD 17	Public Domain	May 15, 2013
<u>Hamilton Depression Rating Scale 21-Item (HAMD 21)</u>	V1.0	HAMD 21	Public Domain	May 29, 2013
<u>Karnofsky Performance Scale</u>	V1.0	KPS SCALE	Public Domain	August 7, 2012
<u>McGill Pain Questionnaire (Short-Form) MPQ 2</u>	V1.0	SHORT-FORM MPQ-2	Granted	August 7, 2012
<u>Michigan Neuropathy Screening Instrument (MNSI)</u>	V1.0	MNSI	Public Domain	August 7, 2012
<u>Mini Mental Scale (MMSE)</u>	V1.0	MMSE	Not Permitted	August 7, 2012
<u>Movement Disorder Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS)</u>	V1.0	MDS-UPDRS	Granted	December 18, 2012
<u>Roland-Morris Disability Questionnaire (RDQ)</u>	V1.0	RDQ	Public Domain	August 7, 2012
<u>Screener and Opioid Assessment for Patients with Pain (SOAPP-R)</u>	V1.0	SOAPP-R	Granted	August 7, 2012
<u>Short Form 36 health survey standard, US Version 1.0 (SF36 v1.0 Standard)</u>	V1.0	SF36 v1.0 STANDARD	Not Permitted	August 7, 2012
<u>Unified Parkinson's Disease Rating Scale (UPDRS)</u>	V1.0	UPDRS	Granted	December 18, 2012
<u>Work Productivity and Activity Impairment Questionnaire - Specific Health Problem (WPAI-SH)</u>	V1.0	WPAI-SHP	Public Domain	August 7, 2012

Questionnaire Naming Rules



QSCAT Codelist Rules	Notes	Comments
Definition: The full name of the questionnaire including the version if available, followed by the questionnaire acronym in parenthesis, and the citation (for public domain instruments) or copyright details (for copyrighted instruments) in parentheses. <i>Sentence case text format.</i> <i>text only.</i>		All questionnaires should have a version number even if there is only one version.
public domain instruments) or copyright details (for copyrighted instruments) in parentheses. <i>Sentence case text format.</i>		
Rules for Questionnaires	Notes	Comments
QSTEST: A brief description of each questionnaire item's intent. Beginning with the QSCAT Synonym, followed by a hyphen, with no spaces before or after the hyphen. Item text may be shortened to maintain the 40 character limit as needed, but should faithfully retain the question intent. <i>Title case text format after the hyphen.</i> before and after the hyphen. The verbatim item text, including punctuation, follows. For clarity, text faithful to the item intent can be substituted where questionnaire formatting leaves verbatim item text ambiguous. Instructions, information in italics or a list of valid responses are not included. All definitions end with punctuation; either as it appears in the questionnaire or defaulted with a period. <i>Sentence case text format.</i>		Title Case: use lower case text for the following words: a, an, and, as, at, but, by, for, in, nor, of, on, or, per, to, the

Controlled Terminology



Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C103519	C100129		Category of Questionnaire	GAD-7	GAD01	Generalized Anxiety Disorder - 7 (GAD-7) (Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder: The GAD-7. Arch Intern Med 2006; 166:1092-1097).	Generalized Anxiety Disorder - 7 Questionnaire
C103467		No	QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	GAD-7 TESTCD	QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	Generalized Anxiety Disorder - 7 test code.	CDISC Questionnaire GAD-7 Test Code Terminology
C103565	C103467		QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	GAD0101	GAD01-Feeling Nervous Anxious or On Edge	Generalized Anxiety Disorder - 7 - Feeling nervous, anxious or on edge.	GAD-7 - Feeling Nervous Anxious or On Edge
C103566	C103467		QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	GAD0102	GAD01-Not Able to Stop/Control Worrying	Generalized Anxiety Disorder - 7 - Not being able to stop or control worrying.	GAD-7 - Not Being Able to Stop or Control Worrying
C103567	C103467		QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	GAD0103	GAD01-Worrying Too Much About Things	Generalized Anxiety Disorder - 7 - Worrying too much about different things.	GAD-7 - Worrying Too Much About Different Things
C103568	C103467		QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	GAD0104	GAD01-Trouble Relaxing	Generalized Anxiety Disorder - 7 - Trouble relaxing.	GAD-7 - Trouble Relaxing
C103569	C103467		QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	GAD0105	GAD01-Being Restless Hard to Sit Still	Generalized Anxiety Disorder - 7 - Being so restless that it is hard to sit still.	GAD-7 - Being so Restless That it is Hard to Sit Still
C103570	C103467		QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	GAD0106	GAD01-Becoming Easily Annoyed/Irritable	Generalized Anxiety Disorder - 7 - Becoming easily annoyed or irritable.	GAD-7 - Becoming Easily Annoyed or Irritable
C103571	C103467		QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	GAD0107	GAD01-Feel Afraid/Something Awful Happen	Generalized Anxiety Disorder - 7 - Feeling afraid as if something awful might happen.	GAD-7 - Feel Afraid as if Something Awful Might Happen
C103572	C103467		QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	GAD0108	GAD01-Difficult to Work/Take Care Things	Generalized Anxiety Disorder - 7 - If you checked off any problems, how difficult have these problems made it for you to do	GAD-7 - Problems Made it Difficult to Work, Take Care of Things, or Get Along with Other People
C113886	C103467		QS-Generalized Anxiety Disorder - 7 Questionnaire Test Code	GAD0109	GAD01-Total Score	Generalized Anxiety Disorder - 7 - Total score.	GAD-7 - Total Score



Introduction

CDISC Questionnaire Supplements

SF36: An example

Conclusion

SF36: An example



SF-36 v2.0 – Health Survey

1. In general, would you say your health is :
 - ☐ Excellent
 - ☐ Very good
 - ☐ Good
 - ☐ Fair
 - ☐ Poor
2. Compared to one year ago, how would you rate your health in general now?
 - ☐ Much better now than one year ago
 - ☐ Somewhat better now than one year ago
 - ☐ About the same as one year ago
 - ☐ Somewhat worse now than one year ago
 - ☐ Much worse now than one year ago

The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

3. **Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports**
 - ☐ Yes, limited a lot
 - ☐ Yes, limited a little
 - ☐ No, not limited at all
4. **Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf**
 - ☐ Yes, limited a lot
 - ☐ Yes, limited a little
 - ☐ No, not limited at all
5. **Lifting or carrying groceries**
 - ☐ Yes, limited a lot
 - ☐ Yes, limited a little
 - ☐ No, not limited at all
6. **Climbing several flights of stairs**
 - ☐ Yes, limited a lot
 - ☐ Yes, limited a little
 - ☐ No, not limited at all

SF36: An example



SF-36 v2.0 – Health Survey

...general, would

☐ Good

☐ Fair

☐ Poor

2. Compared to one year ago

☐ Much better

☐ Somewhat better

☐ About the same

☐ Somewhat worse now than one year ago

☐ Much worse now than one year ago

QSCAT

Submission value: SF-36V2 HEALTH SURVEY

Synonym: SF3602

Definition: Short Form (36) Health Survey version 2.0 (SF36)
(© The Medical Outcomes Trust (MOT), Health Assessment
Lab (HAL) and QualityMetric Incorporated)

The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

3. **Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports**
 - ☐ Yes, limited a lot
 - ☐ Yes, limited a little
 - ☐ No, not limited at all
4. **Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf**
 - ☐ Yes, limited a lot
 - ☐ Yes, limited a little
 - ☐ No, not limited at all
5. **Lifting or carrying groceries**
 - ☐ Yes, limited a lot
 - ☐ Yes, limited a little
 - ☐ No, not limited at all
6. **Climbing several flights of stairs**
 - ☐ Yes, limited a lot
 - ☐ Yes, limited a little
 - ☐ No, not limited at all

SF36: An example



SF-36 v2.0 – Health Survey

1. In general, would you say your health is :

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor

QSTESTCD: SF360201
QSTEST: SF3602-General Health

2. Compared to one year ago, how would you rate your health in general now?

- ☐ Much better now than one year ago
- ☐ Somewhat better now than one year ago
- ☐ About the same as one year ago
- ☐ Somewhat worse now than one year ago
- ☐ Much worse now than one year ago

QSTESTCD: SF360202
QSTEST: SF3602-General Health
Comp to 1Y Ago

The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports

- ☐ Yes, limited a lot
- ☐ Yes, limited a little
- ☐ No, not limited at all

QSTESTCD: SF360203
QSTEST: SF3602-Vigorous Activities

4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

- ☐ Yes, limited a lot
- ☐ Yes, limited a little
- ☐ No, not limited at all

QSTESTCD: SF360204
QSTEST: SF3602-Moderate Activities

5. Lifting or carrying groceries

- ☐ Yes, limited a lot
- ☐ Yes, limited a little
- ☐ No, not limited at all

QSTESTCD: SF360205
QSTEST: SF3602-Lifting or Carrying Groceries

6. Climbing several flights of stairs

- ☐ Yes, limited a lot
- ☐ Yes, limited a little
- ☐ No, not limited at all

QSTESTCD: SF360206
QSTEST: SF3602-Climbing Flights of Stairs

SF36: An example



STUDYID	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	VISITNUM	VISIT	QSDTC	QSDY
XXX-YYY	XXXYYY001	1	SF360201	SF3602-General Health	SF-36V2 HEALTH SURVEY	EXCELLENT	1	1	1	VISIT 1	2014-01-01	1
XXX-YYY	XXXYYY001	2	SF360202	SF3602-Gen Health Compared to 1 Year Ago	SF-36V2 HEALTH SURVEY	ABOUT THE SAME AS ONE YEAR AGO	3	3	1	VISIT 1	2014-01-01	1
XXX-YYY	XXXYYY001	3	SF360203	SF3602-Vigorous Activities	SF-36V2 HEALTH SURVEY	NO, NOT LIMITED AT ALL	3	3	1	VISIT 1	2014-01-01	1
XXX-YYY	XXXYYY001	4	SF360204	SF3602-Moderate Activities	SF-36V2 HEALTH SURVEY	NO, NOT LIMITED AT ALL	3	3	1	VISIT 1	2014-01-01	1
XXX-YYY	XXXYYY001	5	SF360205	SF3602-Lifting or Carrying Groceries	SF-36V2 HEALTH SURVEY	NO, NOT LIMITED AT ALL	3	3	1	VISIT 1	2014-01-01	1
XXX-YYY	XXXYYY001	6	SF360206	SF3602-Climbing Flights of Stairs	SF-36V2 HEALTH SURVEY	NO, NOT LIMITED AT ALL	3	3	1	VISIT 1	2014-01-01	1



Introduction

CDISC Questionnaire Supplements

SF36: An example

Conclusion

Conclusion



- The unavailability of a QS supplement to the SDTMIG **complicates standardization**
- **SDTM philosophy** to be applied
- Following the **general naming rules** published by CDISC will ensure QS data is:
 - **SDTM-compliant**
 - Of **high-quality**
 - As **consistent** as possible with future QS supplement releases

Thank you for your attention.

Join us for a coffee at our stand.

London, United Kingdom, 13 OCT 2014





Anne-Sophie Bekx | Line Manager Data Standards | T. 0032 2.774.11.00 | anne-sophie.bekx@businessdecision.com

Business & Decision Life Sciences
Sint-Lambertusstraat - 141 rue Saint-Lambert
B-1200 Brussels
T: +32 2 774 11 00
F: +32 2 774 11 99
lifesciences@businessdecision.com
<http://www.businessdecision-lifesciences.com/>