



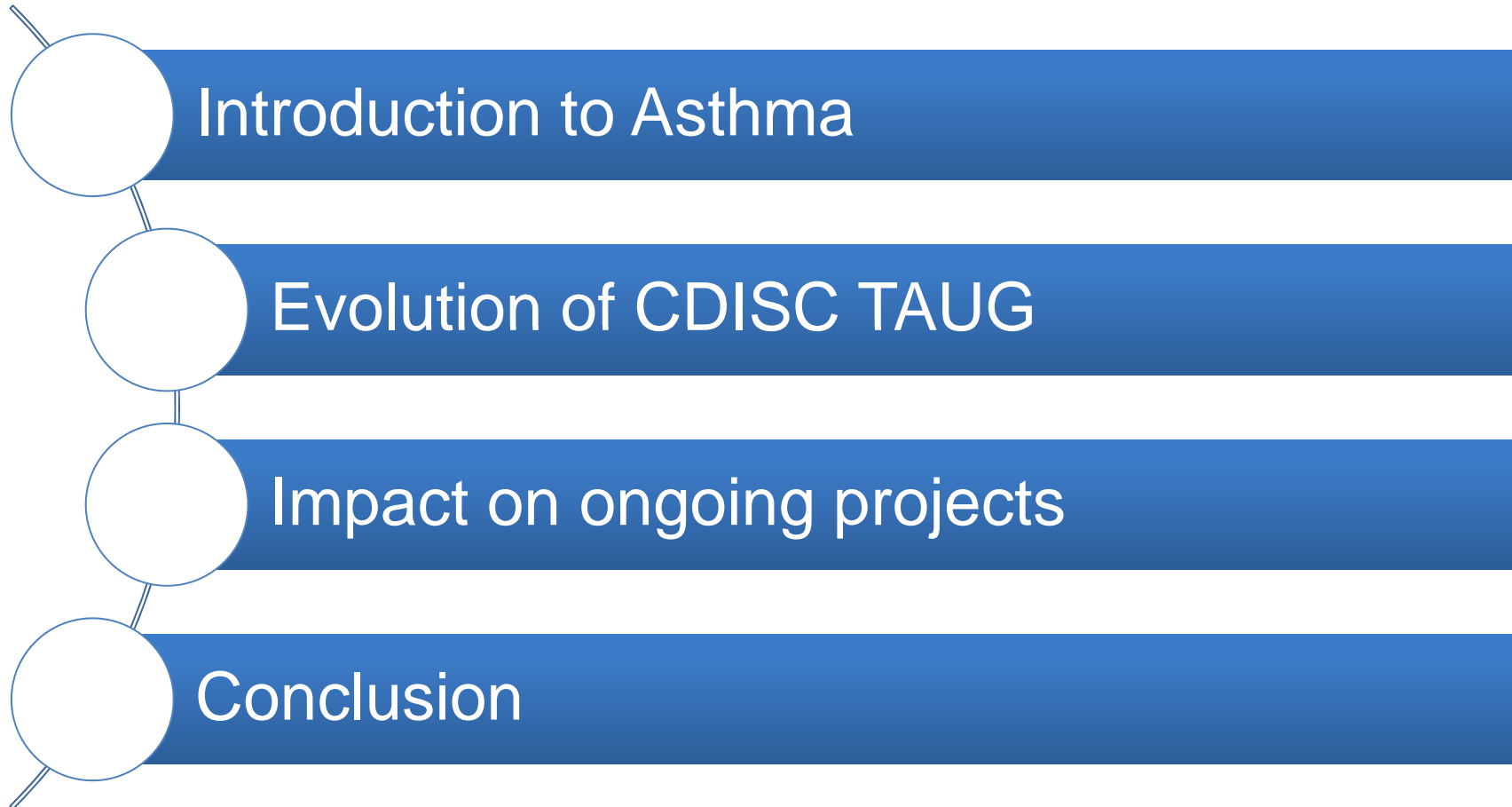
Business & Decision Life Sciences

- *How the release of the Therapeutic Area Asthma User Guide affects an ongoing submission*

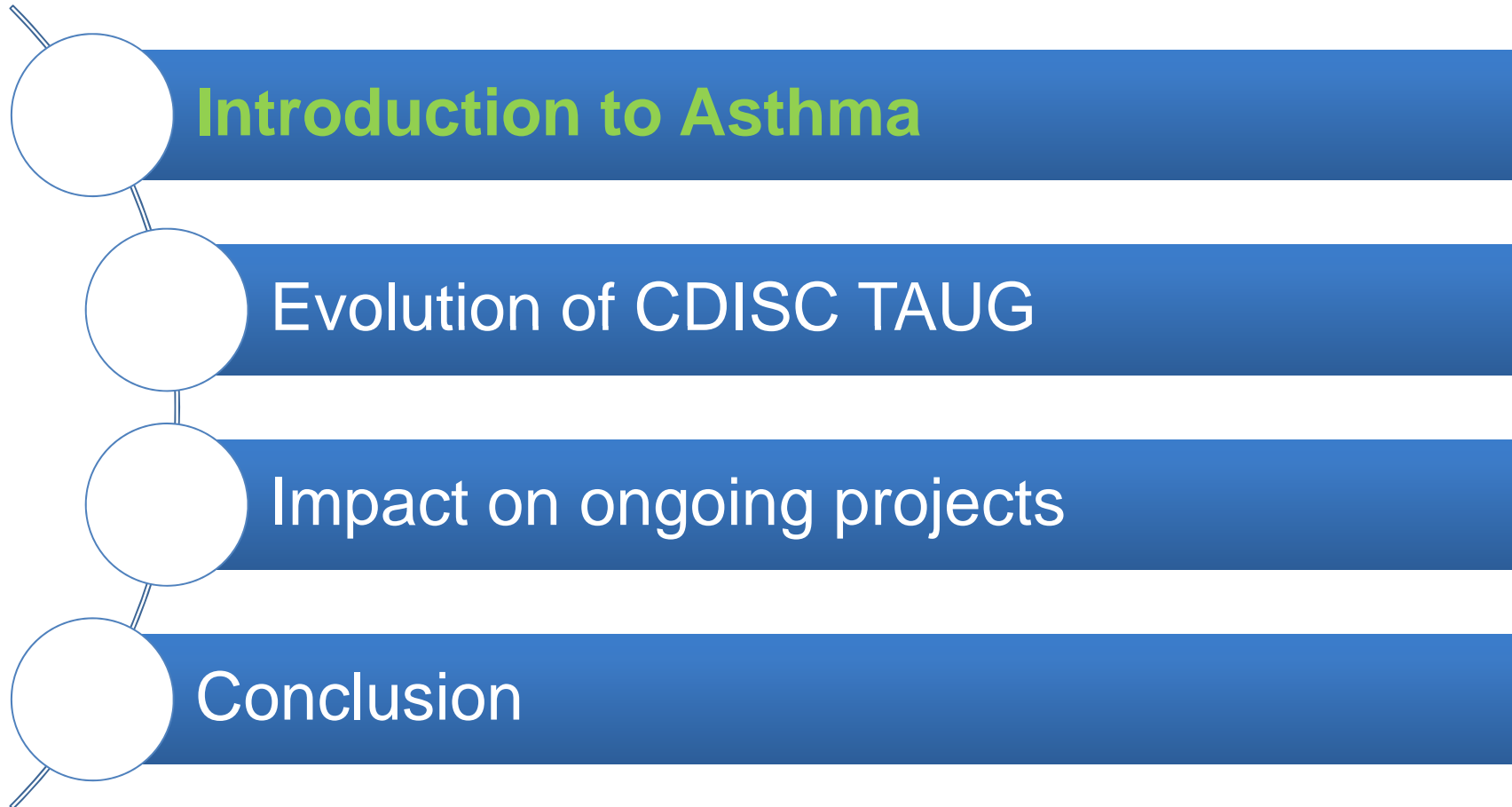
Nick De Donder 02 FEB 2016



Agenda

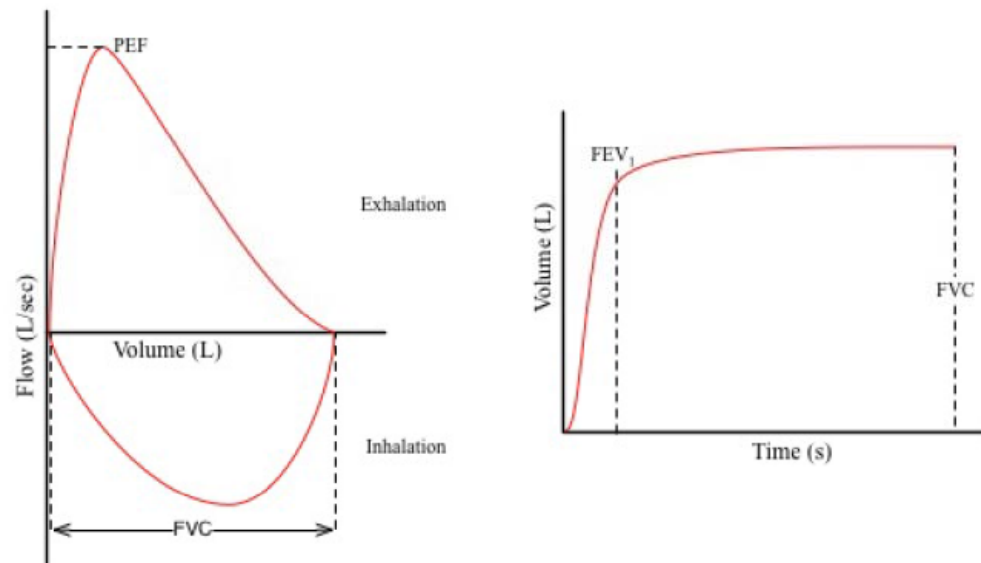


Agenda

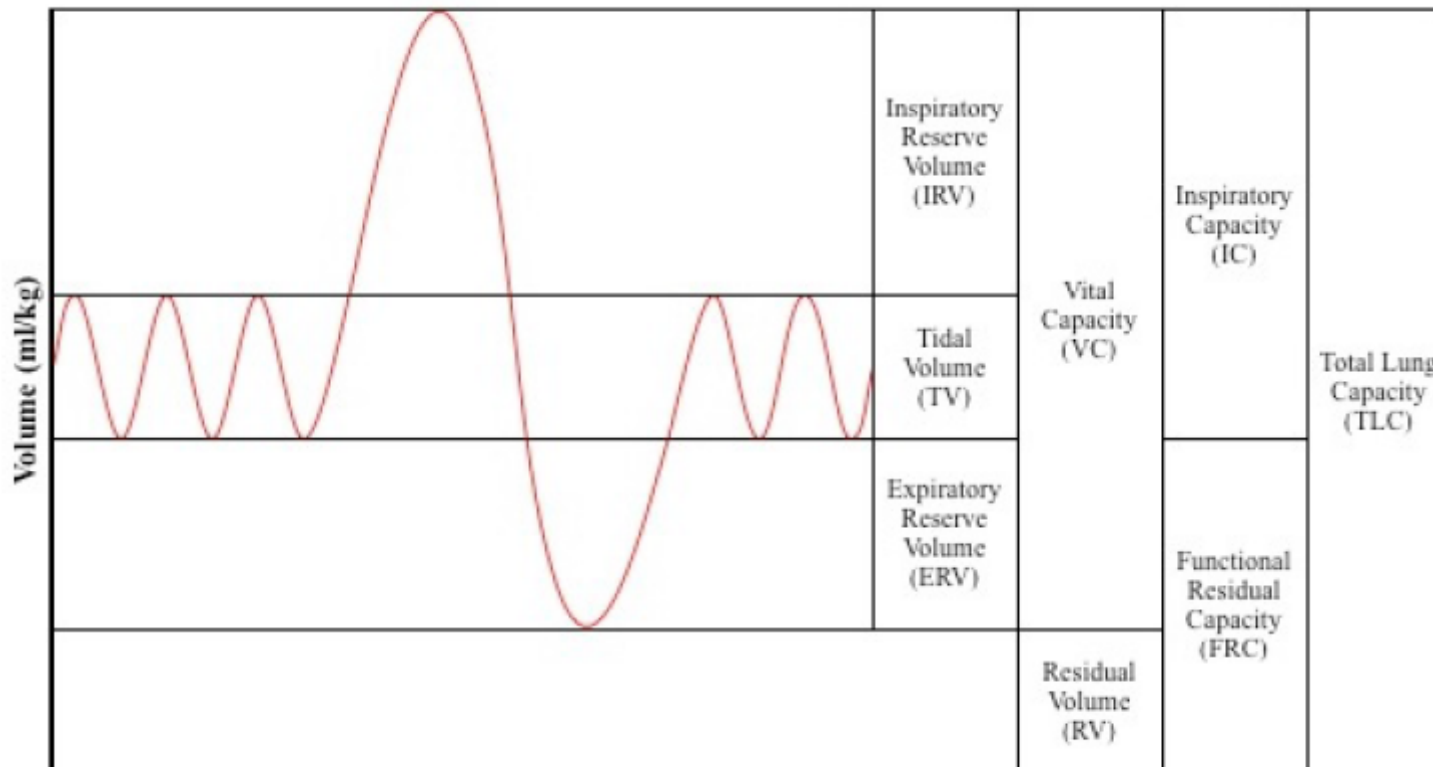


Asthma Theory

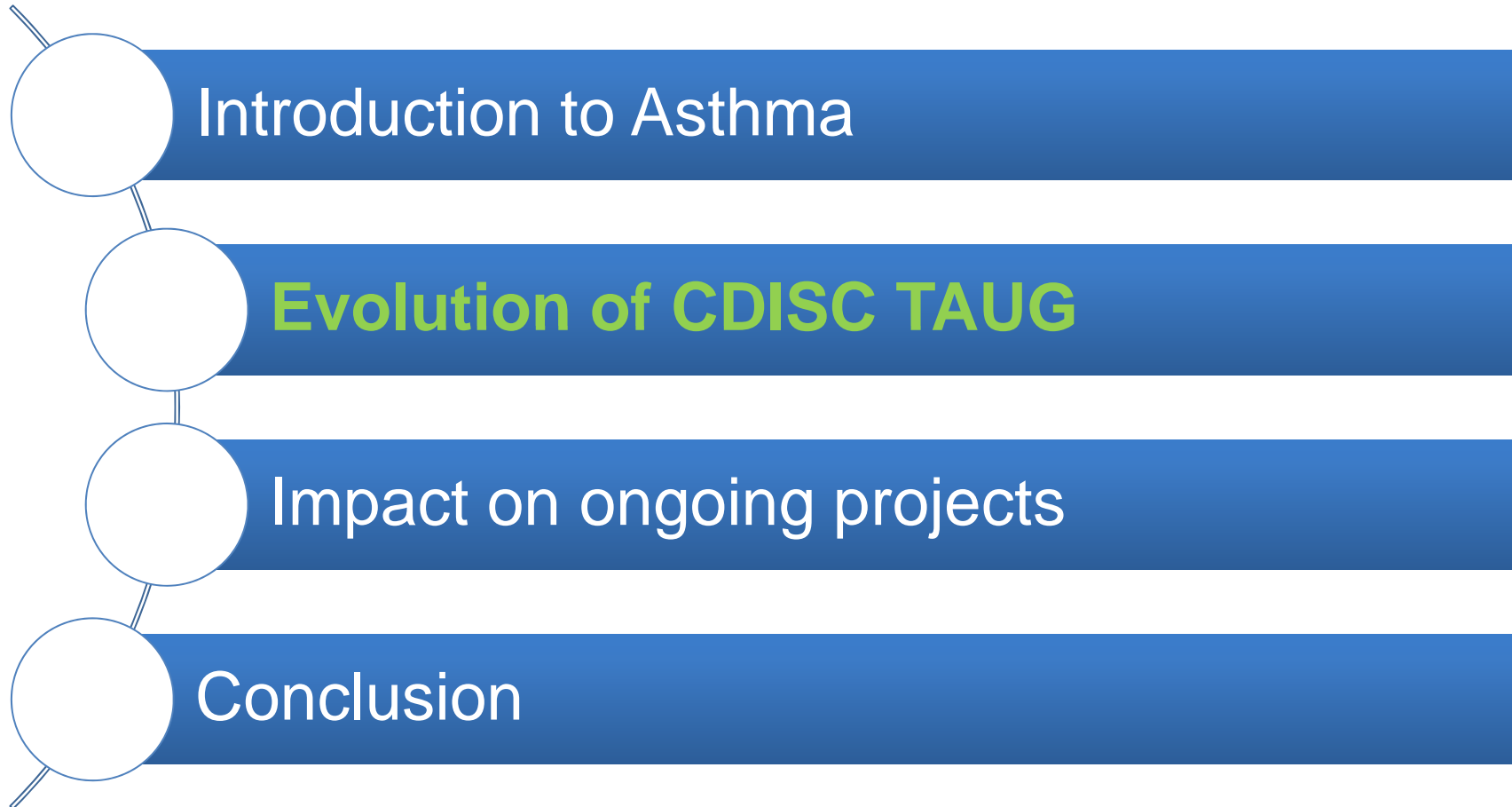
- From the Greek *ásthma* = panting
- Chronic inflammatory disease of the airways
- Diagnosis classified according to:
 - Frequency of symptoms
 - Forced expiratory volume in one second (FEV₁)
 - Peak expiratory flow rate



Spirometry



Agenda



Overview of CDISC Models

(DEC 2015)



- Upcoming
- Content Standards
- Technical Standards
- Semantics
- Therapeutic Areas

PROTOCOL

- PROTOCOL v1.0 (JAN 2010)
- PRM TOOLSET v1.0 (APR 2012)
- PROTOCOL CONCEPTS GUIDE (AUG 2014)

CDASH

- CDASH v1.0 (OCT 2008)
- CDASH v1.1 (JAN2011)
- CDASH UG v1.0 (APR 2012)
- CDASH E2B SAE IG (NOV 2013)
- CDASH v1.2 (AUG 2014)
- CDASH v2.0 (DEC 2014)

BRIDG

- BRIDG v1.0 (JUN 2007)
- BRIDG v1.1 (OCT 2007)
- BRIDG v1.1.1 (FEB 2008)
- BRIDG v2.0 (JUN 2008)
- BRIDG v2.1 (OCT 2008)
- BRIDG v2.2 (MAY 2009)
- BRIDG v3.0 (OCT 2009)
- BRIDG v3.0.1 (FEB 2010)
- BRIDG v3.0.2 (AUG 2010)
- BRIDG v3.0.3 (DEC 2010)
- BRIDG v3.1 (FEB 2012)
- BRIDG v3.2 (SEP 2012)
- BRIDG v4.0 (NOV 2014)
- BRIDG UG v2.0 (MAR 2015)

DEFINE.XML

- DEFINE.XML v1.0 (FEB 2005)
- DEFINE.XML v2.0 (MAR 2013)
- DATASET-XML v1 (APR 2014)
- DEFINE.XML IG VALIDATION (NOV 2014)
- CTR-XML v1.0 (2016)
- DEFINE.XML v2.1 (2016)

SDTM

- SDTM v1.0 + SDTM IG v3.1 (JUL 2004)
- SDTM v1.1 + SDTM IG v3.1.1 (DEC2014)
- SDTM v1.2 + SDTM IG v3.1.2 (NOV 2008)
- SDTM IG v3.1.2 + AMENDMENT 1 (DEC 2011)
- SDTM MEDICAL DEVICES v1.0 (DEC 2012)
- SDTM ASSOCIATED PERSONS IG v1.0 (DEC 2013)
- SDTM v1.4 + SDTM IG v3.2 (DEC 2013)
- SDTM QRS SUPPLEMENTS (PERIODIC)
- SDTM PHARMACOGENOMICS IG v1.0 (MAY 2015)
- SDTM v1.5 + SDTM IG v3.3 (MAY 2014 – DEC 2015)
- SDTM DEVICE IG v2.0 (FEB 2015)
- SDTM IG v3.4 Batch 1 (Q1 2016)

XML TECH

- SDM.XML v1.0 (SEP 2011)
- RDF RG v1.0 (JUN 2015)
- RDF UG v1.0 (JUL 2015)
- PROTOCOL.XML (Q3 2016)

ODM

- ODM v1.1 (APR 2002)
- ODM v1.2 (JAN 2004)
- ODM v1.2.1 (JAN 2005)
- ODM v1.3 (DEC 2006)
- ODM v1.3.1 (FEB 2012)
- ODM v1.3.2 (MAR 2013)

ADaM

- ADaM v2.0 (AUG 2006)
- ADaM v2.21 + ADaM IG (DEC 2009)
- ADaM VALIDATION CHECKS v1.0 (SEP 2010)
- ADaM VALIDATION CHECKS v1.1 (JUL 2011)
- ADaM VALIDATION CHECKS v1.2 (JUL 2012)
- Analysis Results Metadata v1.0 (JAN 2015)
- ADaM OCCDS v1.0 (JUL 2015)
- ADaM VALIDATION CHECKS v1.3 (MAR 2015)
- ADaM IG v1.1 (JUL 2014)
- ADaM IG v1.2 (Q1 2016)
- ADaM IG v2.0 (Q4 2016)

SEND

- SEND IG v3.0 (MAY 2011)
- SEND IG v3.1 (Q1 2016)
- SEND DART v1.0 (Q1 2016)

SHARE

- CDISC SHARE
- SHARE API PILOT (Q2 2016)

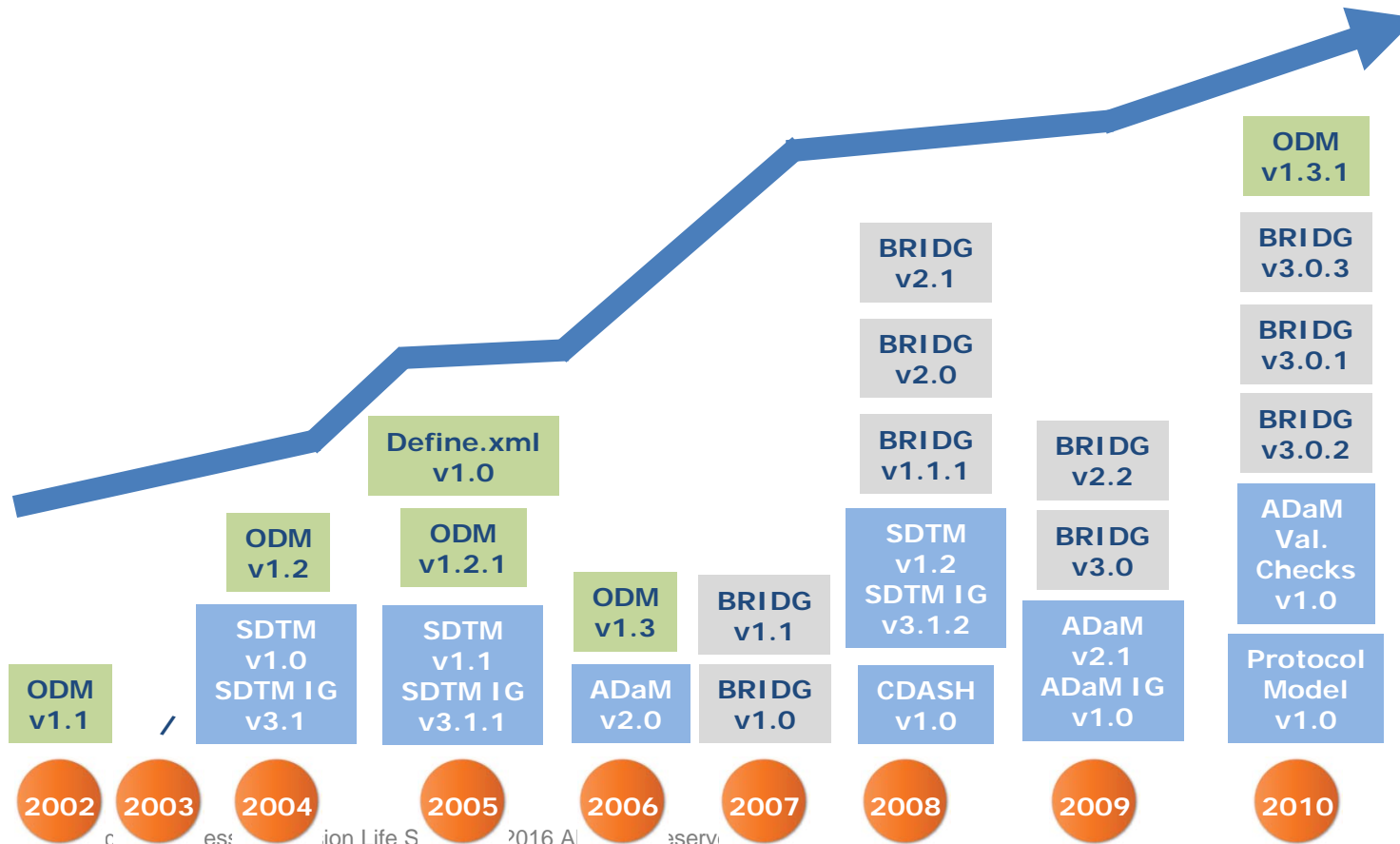
THERAPEUTIC AREAS

- ALZHEIMER v1.0 (SEP 2011)
- PAIN (JUN 2012)
- TUBERCULOSIS (JUN 2012)
- PARKINSON'S DISEASE (OCT 2012)
- VIROLOGY v1.0 (NOV 2012)
- DEVICES (DEC 2012)
- PKD (FEB 2013)
- ALZHEIMER v2.0
- ASTHMA v1.0
- MULTIPLE SCLEROSIS (MAY 2014)
- DIABETES (AUG 2014)
- CARDIOVASCULAR v1.0 (OCT 2014)
- INFLUENZA v1.0 (NOV 2014)
- QT STUDIES v1.0 (DEC 2014)
- HEPATITIS C v1.0 (MAY 2015)
- DISLIPIDEMIA v1.0 (JUN 2015)
- SCHIZOPHRENIA v1.0 (JUN 2015)
- VIROLOGY v2.0 (SEP 2015)
- BREAST CANCER v1.0 (Q1 2016)
- TRAUMATIC BRAIN INJURY v1.0 (Q4 2015)
- COPD v1.0 (Q4 2015)
- ADaM SUPPLEMENT TO DIABETES (Q4 2015)
- DIABETIC KIDNEY DISEASE v1.0 (Q1 2016)
- TUBERCULOSIS v2.0 (Q1 2016)
- RHEUMATOID ARTHRITIS (Q2 2016)
- CV IMAGING v1.0 (Q2 2016)
- PROSTATE CANCER v1.0 (Q3 2016)
- MAJOR DEPRESSIVE DISORDER (Q3 2016)
- GENERAL ANXIETY DISORDER v1.0(Q3 2016)
- BI-POLAR DISORDER v1.0 (Q3 2016)
- SOLID ORGAN (KIDNEY) TRANSPLANT (Q3 2016)

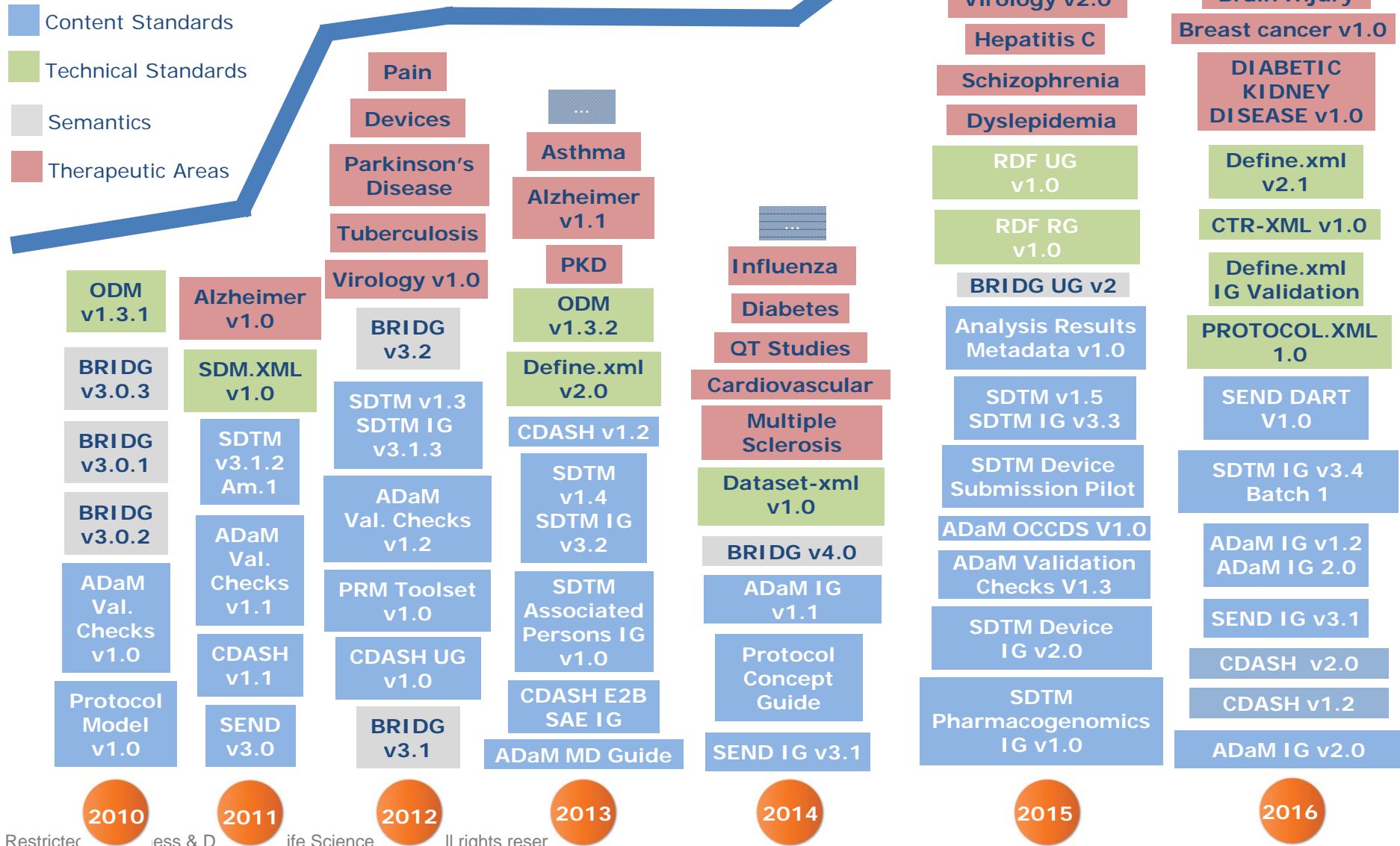
HEALTHCARE LINK

Updates over time (DEC 2015)

- Content Standards
- Technical Standards
- Semantics
- Therapeutic Areas



Updates over time (DEC 2015)



Therapeutic Area Handling



Therapeutic Areas

Alzheimer's Disease
Asthma
Multiple Sclerosis
Oncology
Pain
Parkinson's Disease
Polycystic Kidney Disease
Tuberculosis
Virology

Questionnaires

Alzheimer's disease Assessment Scale – Cognitive (ADAS-Cog)
Mini Mental Scale (MMSE)
Audio Verbal Learning Test Version A (AVLTvA)
Pain Intensity
Brief Pain Inventory (BPI)
EuroQol (EQ-5D)
Karnofsky Performance Status Scale
SF-36 Health Survey
Hamilton Depression Scale
Faces Pain Scale
Modified Medical research Council Dyspnea (MMRC)
...

SDTMIG 3.1.3

TU – Tumor Identification
TR – Tumor Results
RS – Disease Response
RELREC – Related Records

SDTMIG 3.2

EC - Exposure as Collected
IS - Immunogenicity Assessments
SR - Skin Response
RD - Reproductive Details
MO - Morphology
MI - Microscopic Findings
CV - Cardiovascular Physiology
PR - Procedures
TD - Trial Disease Assessments
DD - Death Details
SS - Subject Status
SDTM 1.4
SDTMIG for Associated Persons
HO - Healthcare Resource Utilization

TAUG Asthma 1/7



❏ The Asthma v1.0 User Guide – Provisional version was published on 26 NOV 2013



Therapeutic Area Data Standards User Guide for Asthma Version 1.0

Prepared by the
CFAST Asthma Team

Notes to Readers

- This is the provisional version 1.0 of the Therapeutic Area Data Standards User Guide for Asthma.
- This document corresponds to the SDTM v1.3 and SDTMIG v3.1.3, but incorporates new domains developed after v3.1.3 was released.
- This document also corresponds to the CDASH Standard v1.1.
- The TAUG-Asthma v1.0 package includes a user guide (this document), two draft domains, and seven workbooks of somewhat simplified, prototype metadata as they may be represented in the CDISC SHARE repository.

Revision History

Date	Version	Summary of Changes
2013-11-26	1.0	Provisional
2013-09-13	1.0 Draft	Draft for Public Review

See [Appendix H](#) for Representations and Warranties, Limitations of Liability, and Disclaimers

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TAUG Asthma 2/7



■ The Asthma v1.0 User Guide contains:

- Existing SDTM standard domains that can be used in Asthma studies without additional development or customization:
 - DM (Demography)
 - PE (Physical Examination)
 - EG (ECG)
 - SU (Substance Use)

TAUG Asthma 3/7



■ The Asthma v1.0 User Guide contains:

- **Assumptions for existing SDTM standard domains at time of publication of the TAUG:**

- CM (Concomitant Medications)
- AE (Adverse Events)
- MH (Medical History)
- LB (Laboratory Test Results)
- FA (Findings About)
 - For MH, AE, HO

→ All assumptions present in the SDTMIG are applicable

→ Additional assumptions added for TA Specific implementations



The Asthma v1.0 User Guide contains:

■ Domains that are new in the next version of the SDTMIG

- HO (Health Care Encounters)
- SR (Skin Response)

- All assumptions present in the new published SDTMIG are applicable
- Domains and assumptions are subject to change or deletion without formal notice

TAUG Asthma 5/7



The Asthma v1.0 User Guide contains:

- **Domains that are not yet published in any SDTMIG at time of publication of the TAUG**

- AG (Procedure Agents)
- RE (Respiratory System Findings)

→ **The suggested approach present in the TAUG are applicable**

→ **Domains and assumptions are subject to change or deletion without formal notice once the domains have been published in an SDTMIG**



TAUG Asthma 6/7



The Asthma v1.0 User Guide contains:

■ Assumptions and examples for SDTMIG – Medical Devices domains:

- DI (Device Identifiers)
- DU (Device in Use)

- All assumptions present in the SDTMIG- MD are applicable
- Additional assumptions added for TA Specific implementations

TAUG Asthma 7/7



■ Specific Questionnaires created for the Asthma TA

Full Name and Abbreviation	Status of Permission to develop controlled terminology	Status of controlled terminology
Asthma Control Questionnaire ACQ	Permission denied	Terminology will not be developed.
Asthma Control Test ACT	Under discussion	
Asthma Quality of Life Questionnaire AQLQ	Permission denied	Terminology will not be developed.
Airway Questionnaire 20 AQ20	Permission received	Terminology will be developed.
Baseline and Transition Dyspnea Indexes BDI / TDI	Permission received	Terminology in Package 14 (release date 28Jun2013)
Borg Scale of Peak Dyspnea Borg CR-10 Scale Questionnaire BORG-CR-10	Permission requested	
Modified Medical Research Council Dyspnea Questionnaire MMRC	Public Domain	Terminology in Package 14 (release date 28Jun2013)
Short Form -36 SF-36	Under discussion	
St. George's Respiratory Questionnaire SGRQ	Permission received	Terminology will be developed.
Work productivity and activity impairment - Asthma version WPAI - Asthma	Public Domain	Terminology will be developed.

CDISC Questionnaire Supplements



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



Questionnaire Naming Rules



QSCAT Codelist Rules	Notes	Comments
<p>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></p> <p><i>text only.</i></p>		<p>All questionnaires should have a version number even if there is only one version.</p>
<p>public domain instruments) or copyright details (for copyrighted instruments) in parentheses. <i>Sentence case text format.</i></p>		
Rules for Questionnaires	Notes	Comments
<p>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></p> <p>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></p>		<p>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</p>



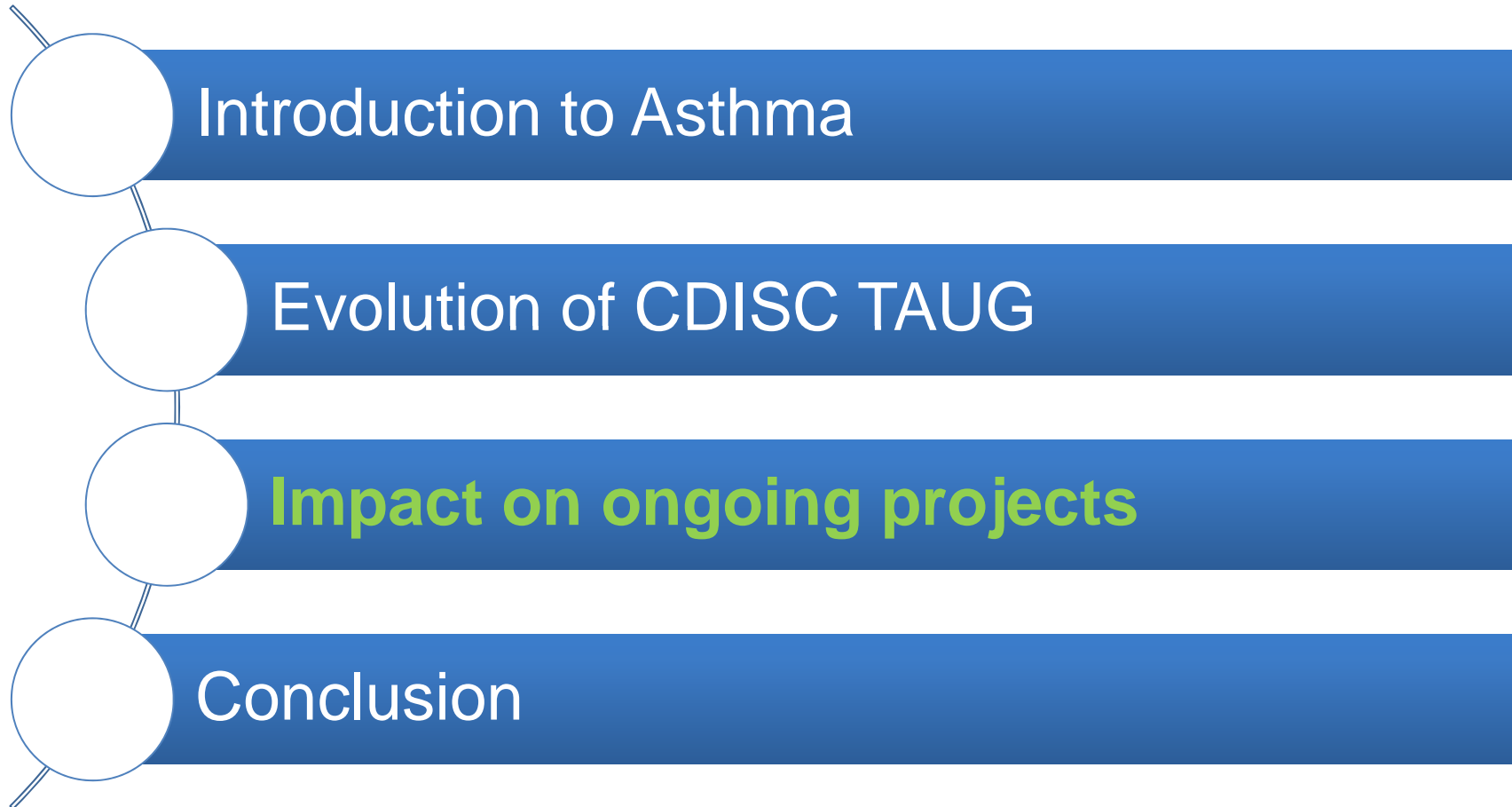
Controlled Terminology



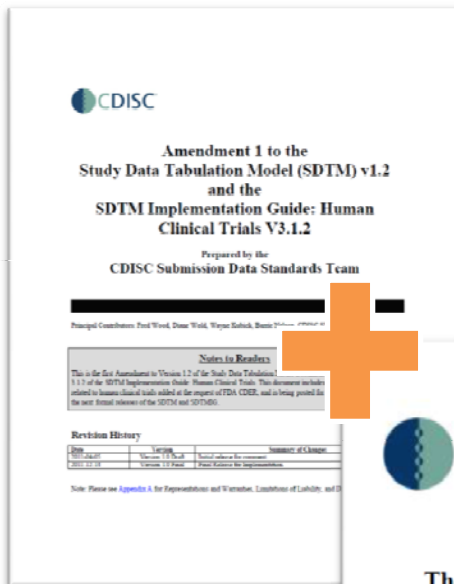
Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C103519	C100129		Category of Questionnaire	GAD-7	GAD01	Generalized Anxiety Disorder - 7 (GAD-7) (Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing 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



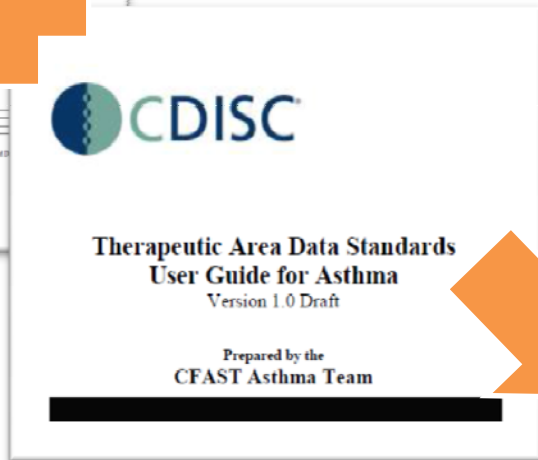
Agenda



Process of data integration before the release of TA Asthma User Guide



Procedure present in the SDTM IG 3.1.2 A1



Information present in the draft version of the TA Asthma User Guide



SDTM Conversion of Asthma Trials



What's new in the TA Asthma user guide?



SDTM IG v3.1.2 A1	TA Asthma User Guide v1.0
CM: Concomitant Medication	AG: Procedure Agents
HU: Healthcare Resource Utilization	HO: Healthcare Encounters

[Redacted]

SUPP-- Domain

[Redacted]

QS Domain

- Questionnaires and diaries in **QS**
- Symptom assessment in **FACE** (Finding About Clinical Event).



Case examples 1/4



SDTMIG V3.1.2 A1

STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	...
XXXX-0001	CM	XXXX-0001-00001	1	ALBUTEROL	

TAUG-Asthma

STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	...
XXXX-0001	AG	XXXX-0001-00001	1	ALBUTEROL	

Case examples 2/4



SDTMIG V3.1.2 A1

STUDYID	DOMAIN	USUBJID	HUSEQ	HUTERM	...
XXXX-0001	HU	XXXX-0001-00001	1	HOSPITALIZATION	

TAUG-Asthma

STUDYID	DOMAIN	USUBJID	HOSEQ	HOTERM	...
XXXX-0001	HO	XXXX-0001-00001	1	HOSPITALIZATION	



Case examples 3/4



SDTMIG V3.1.2 A1

STUDYID	RDOMAIN	USUBJID	QNAM	QVAL	...
XXXX-0001	HU	XXXX-0001-00001	HOREAS	ASTHMA	

TAUG-Asthma

STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FAOBJ
XXXX-0001	FA	XXXX-0001-00001	1	OCCUR	HOSPITALIZATION

Case examples 4/4



STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD
XXXX-0001	RE	XXXX-0001-00001	ABC001	1	FEV1
XXXX-0001	RE	XXXX-0001-00001	ABC001	2	FVC
XXXX-0001	RE	XXXX-0001-00001	ABC001	3	FEV1PP
XXXX-0001	RE	XXXX-0001-00001	ABC001	4	FVCP
XXXX-0001	RE	XXXX-0001-00001	DEF003	5	PEF

RETEST	REORRES	REORRESU	REORREF	RESTRESC	...
Forced Expiratory Volume in 1 Second	2.73	L	3.37	2.73	
Forced Vital Capacity	3.91	L	3.86	3.91	
Percent Predicted FEV1	81	%		81	
Percent Predicted FVC	101.3	%		101.3	
Peak Expiratory Flow	6.11	L/s	7.33	6.11	

Different interpretation of the data

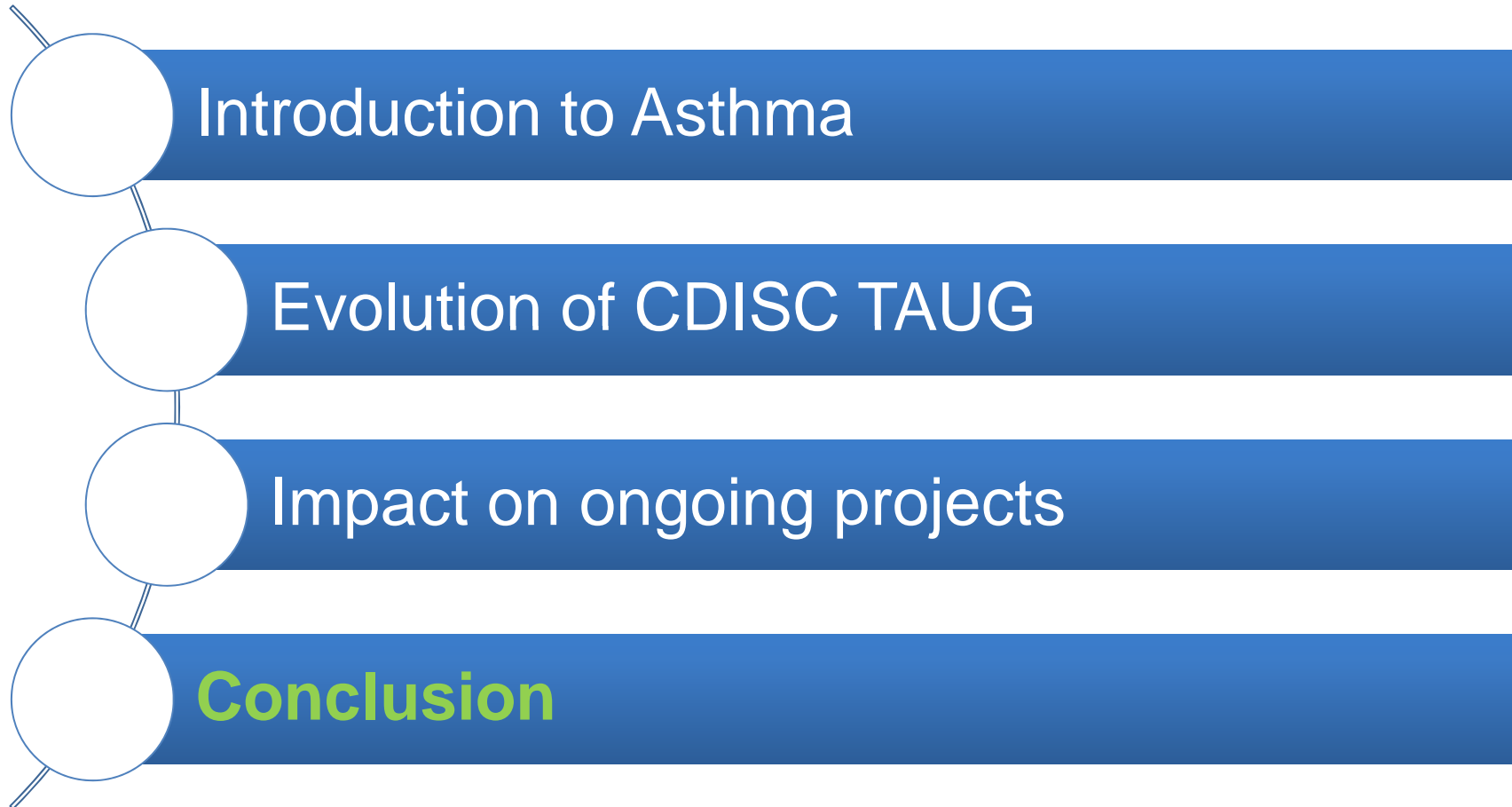


How to manage dates ?

Date of diagnostic
vs
Date of collection



Agenda



Important



- ❑ **TAUG-Asthma is a guiding document**
- ❑ **SDTMIG x.x is still the basis**
- ❑ **Nothing in the TAUG-Asthma supercedes the SDTMIG**
- ❑ **Domains published in TAUG-Asthma are draft**
- ❑ **New variables present are not part of a published model... Yet**

Conclusion



When working on a specific TA for which the CDISC user guide is not yet released:



Use of the latest SDTM IG is a good basis to follow

The impact could be considered minor



Thank you for your attention.

Paris, France, 02 FEB 2016





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