



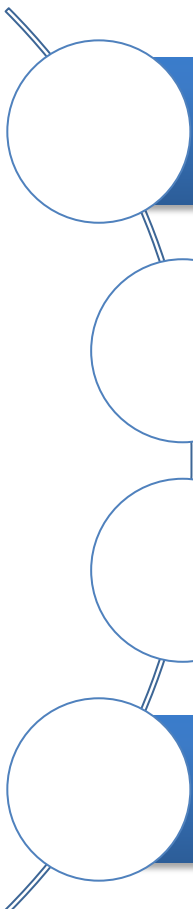
Business & Decision Life Sciences

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

Nick De Donder 13 OCT 2014



Agenda

A vertical timeline diagram on the left side of the slide. It consists of four white circles connected by a thin grey line. The top circle has a short line extending from its top-left, and the bottom circle has a short line extending from its bottom-left. Each circle is positioned to the left of a blue horizontal bar containing text.

Introduction to Asthma

Evolution of CDISC TAUG

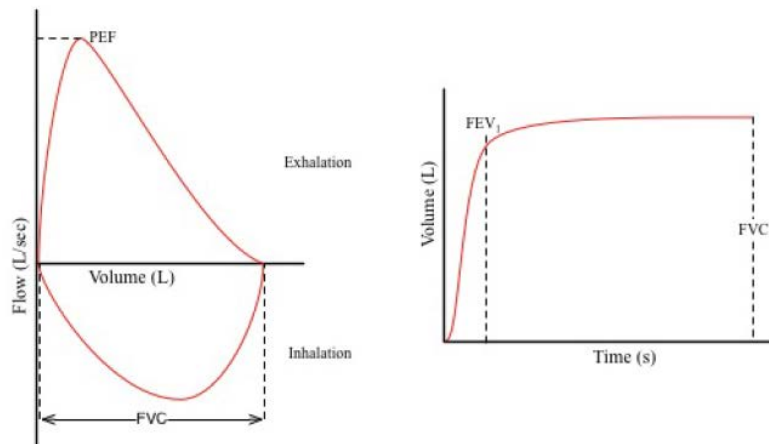
Impact on ongoing projects

Conclusion

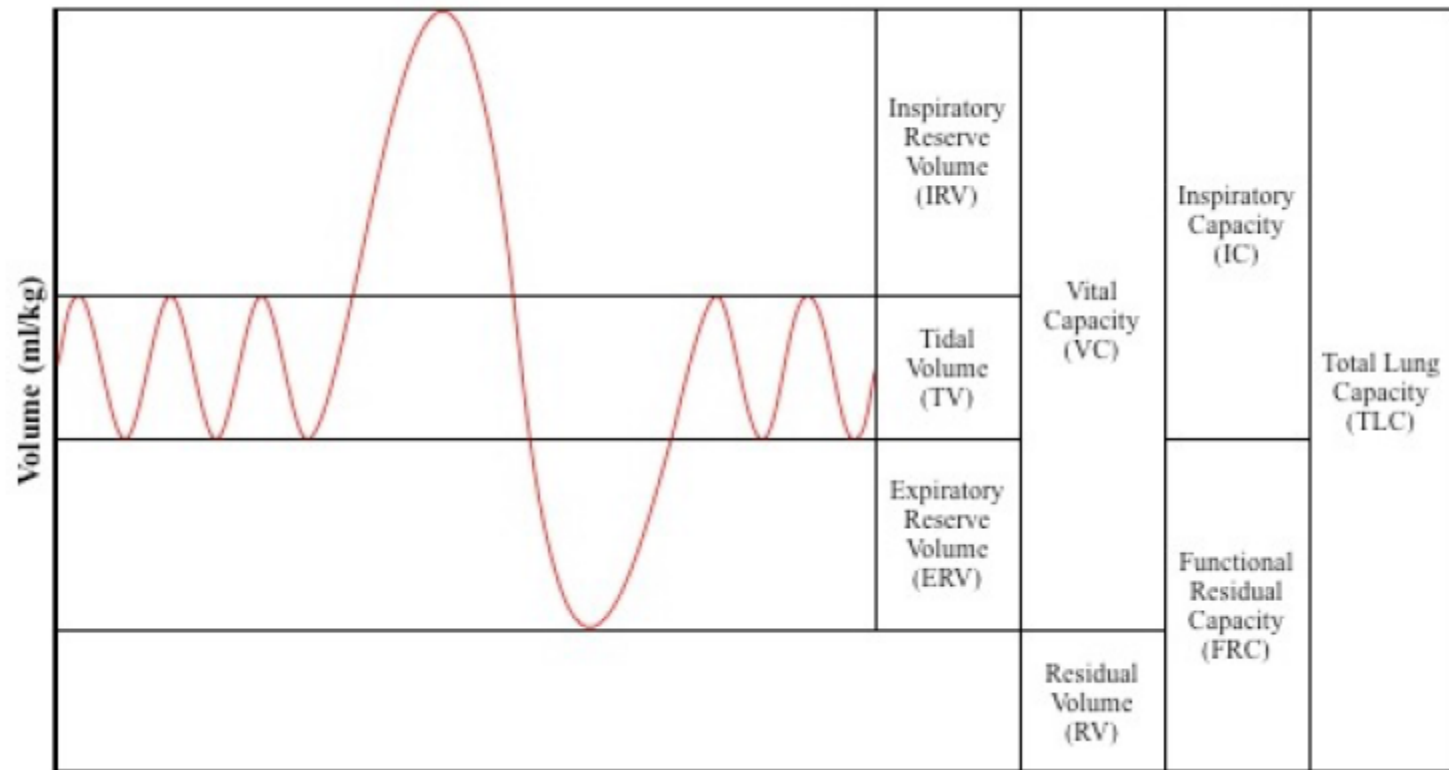
Asthma Theory



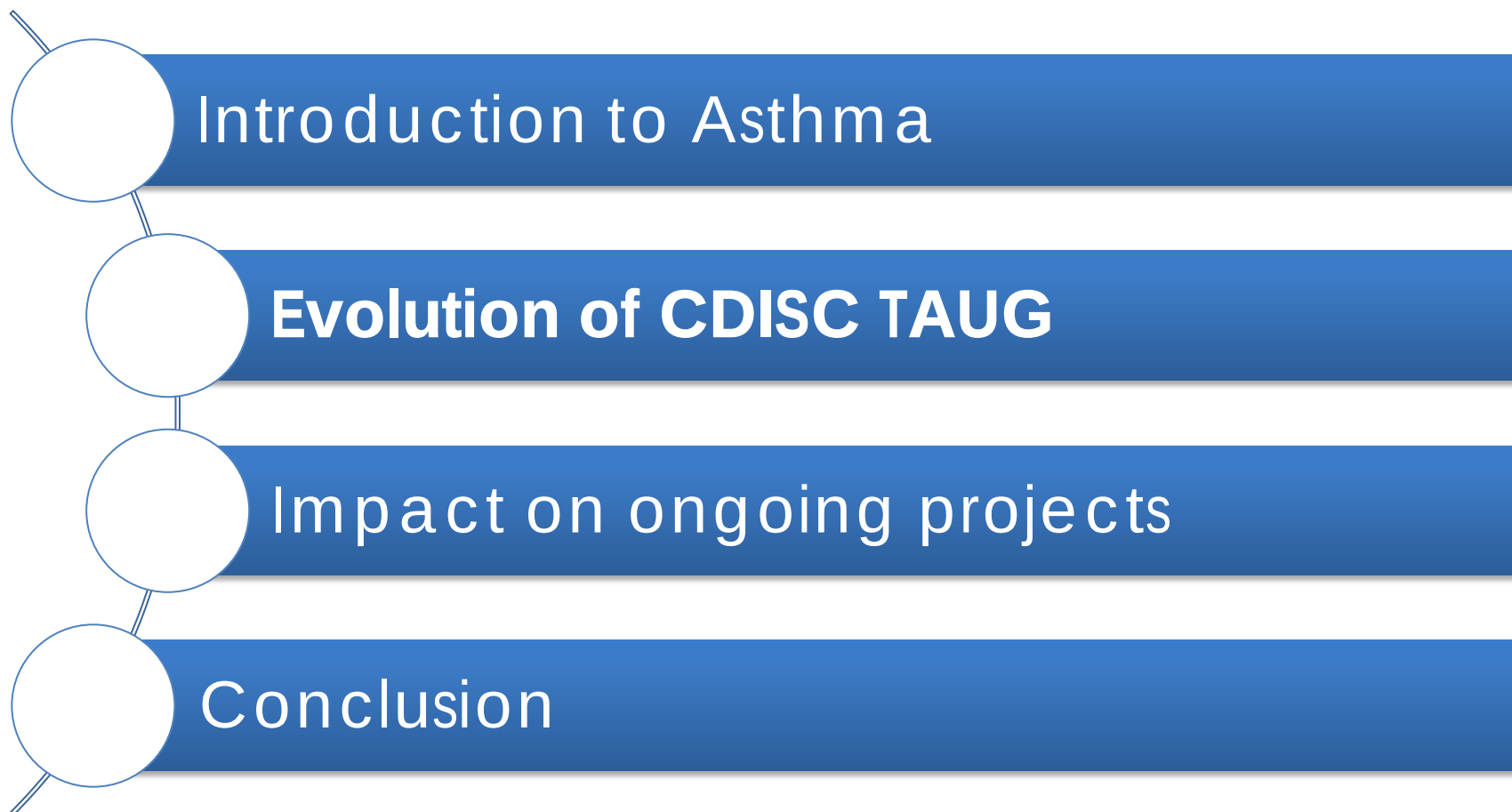
- From the Greek ásthma = panting
- Chronic inflammatory disease of the airways
- Diagnosis classified according to:
 - Frequency of symptoms
 - Forced expiratory volume in one second (FEV1)
 - Peak expiratory flow rate



Spirometry

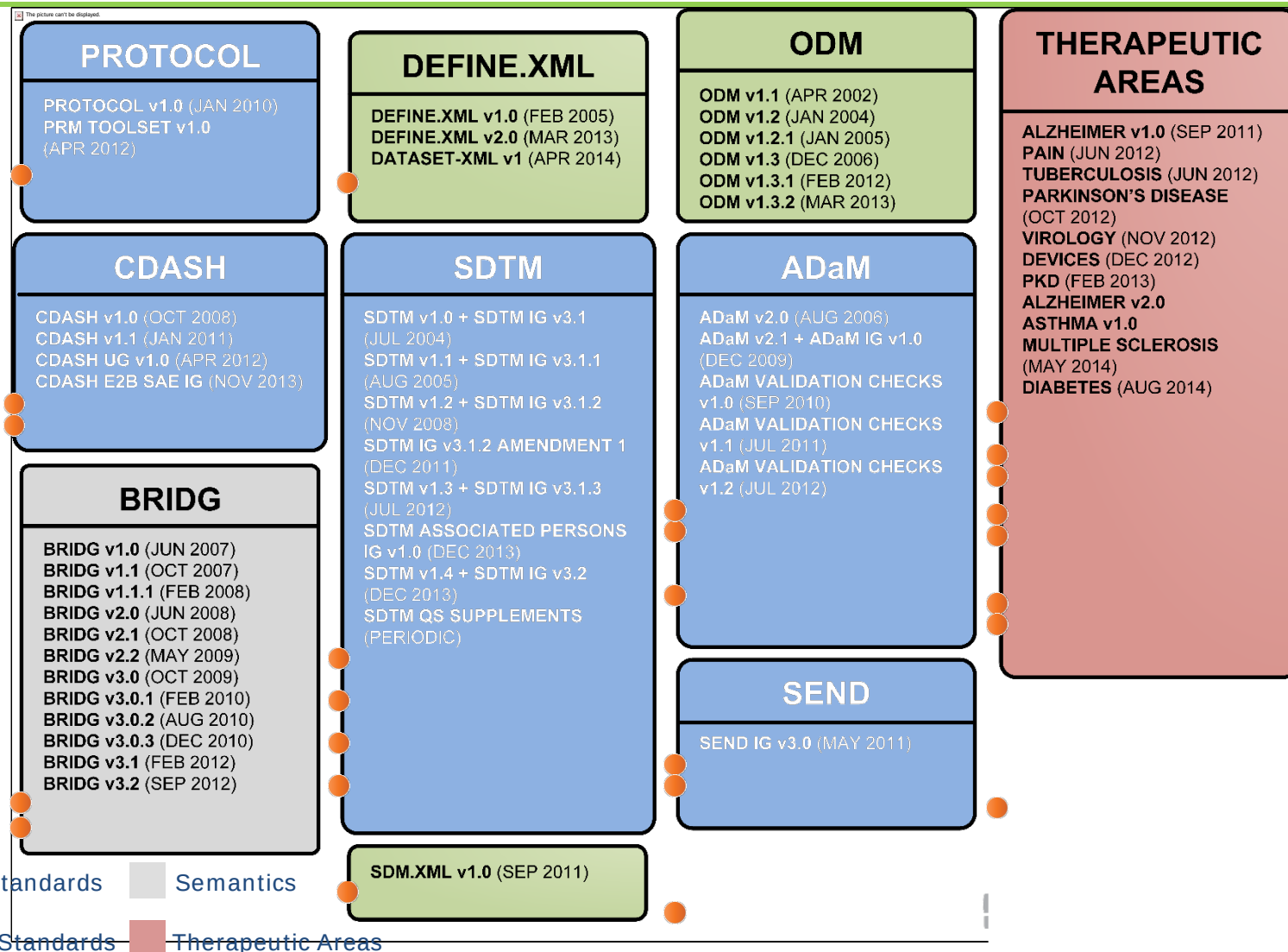


Agenda



Overview of CDISC Models

(SEP 2014)



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

CONTENTS

1	INTRODUCTION	5
1.1	PURPOSE	5
1.2	ASTHMA REGULATORY AND CLINICAL GUIDELINES	6
1.3	ORGANIZATION OF THIS DOCUMENT	7
1.4	CONCEPT MAPS	8
1.5	CONTROLLED TERMINOLOGY	8
1.6	RELATIONSHIPS TO OTHER STANDARDS	9
2	SUBJECT AND DISEASE CHARACTERISTICS	10
2.1	ASTHMA HISTORY	10
2.1.1	Examples for Asthma History	11
2.2	MEDICAL HISTORY OF SPECIAL INTEREST	12
2.2.1	Examples for Medical History of Special Interest	14
2.3	ALLERGEN SKIN TESTS	16
2.3.1	Examples for Allergen Skin Tests	19
3	DISEASE ASSESSMENTS	20
3.1	PULMONARY PHYSIOLOGY	20
3.1.1	Peak Flow Measurements	20
3.1.1.1	Sample Peak Flow Meter Report	23
3.1.2	Spirometry	24
3.1.2.1	Spirometry Test Results	28
3.1.2.2	Sample Spirometry Reports	31
3.1.2.3	Interpretation of Spirometry Results	33
3.1.3	Other Pulmonary Physiology Measures	33
3.1.4	Reversibility (Bronchodilator Response)	33
3.1.5	Airway Responsiveness	36
3.1.6	Examples for Pulmonary Physiology	38
3.2	EXACERBATIONS OF ASTHMA	43
3.3	BIOMARKERS	45
3.3.1	Specimen Collection	45
3.3.2	Measures of Inflammation	46
3.3.2.1	Laboratory Tests	46
3.3.2.2	Exhaled Breath	49
3.3.3	Examples for Biomarkers	50
3.4	SYMPTOM ASSESSMENT	51
3.4.1	Examples for Asthma Symptom Assessments	52
3.5	QUESTIONNAIRES AND DIARIES	53
3.5.1	Quality of Life Measures	54
3.5.2	Asthma Severity and Control	54
4	ROUTINE DATA	55
4.1	ADVERSE EVENTS OF SPECIAL INTEREST	55
4.1.1	Examples for Adverse Events of Special Interest	56
4.2	CONCOMITANT MEDICATIONS OF SPECIAL INTEREST	57
4.2.1	Additional Assumptions for Concomitant Medications	59
4.2.2	Examples for Concomitant Medications of Special Interest	60
4.3	HEALTHCARE ENCOUNTERS OF SPECIAL INTEREST	64
4.3.1	Examples for Healthcare Encounters of Special Interest	65
APPENDICES		67
APPENDIX A: PROTECT PROPOSAL		67

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

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

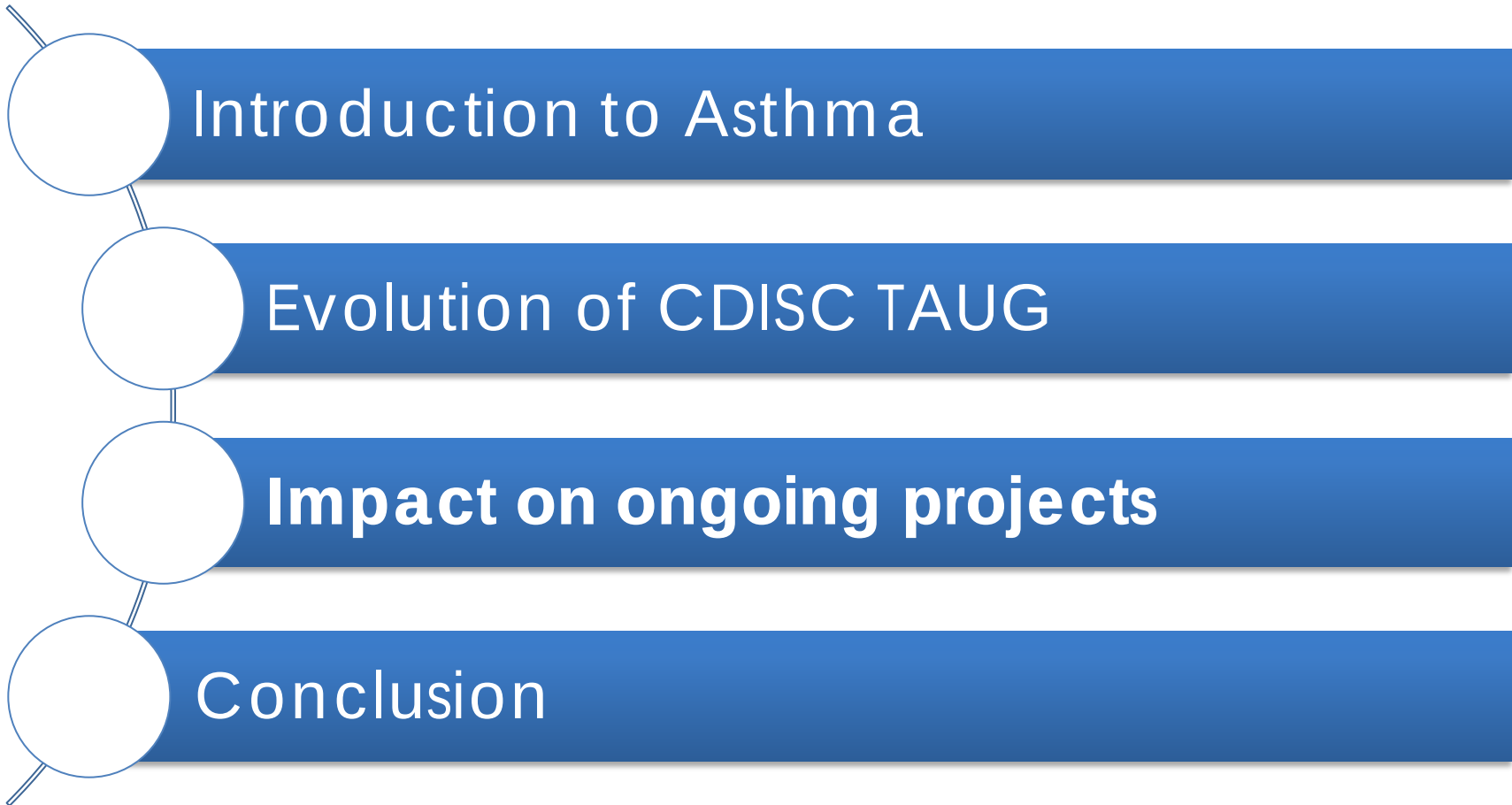
TAUG Asthma 7/7



- 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.

Agenda



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



Amendment 1 to the Study Data Tabulation Model (SDTM) v1.2 and the SDTM Implementation Guide: Human Clinical Trials V3.1.2

Prepared by the
CDISC Submission Data Standards Team

Principal Contributors: Fred Wood, Dana Wild, Wayne Schick, Bruce J...

Notes to Readers

This is the first Amendment to Version 1.2 of the Study Data Tabulation Model (SDTM) v1.2 of the SDTM Implementation Guide: Human Clinical Trials. This document includes related to human clinical trials, subject to the report of FDA, CDISC, and is being posted for the next formal release of the SDTM and SDTMIG.

Revision History

Date	Version	Initial release for comment	Summary of Changes
2011-04-01	Version 1.2 Draft	First release for comment	
2011-04-14	Version 1.2 Draft	First release for comment	

Note: Please see [Appendix A](#) for Representations and Warnings, Limitations of Liability, and...

Procedure
present in the
SDTM IG 3.1.2 A1



Therapeutic Area Data Standards User Guide for Asthma Version 1.0 Draft

Prepared by the
CFAST Asthma Team

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

SUPP-- Domain

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

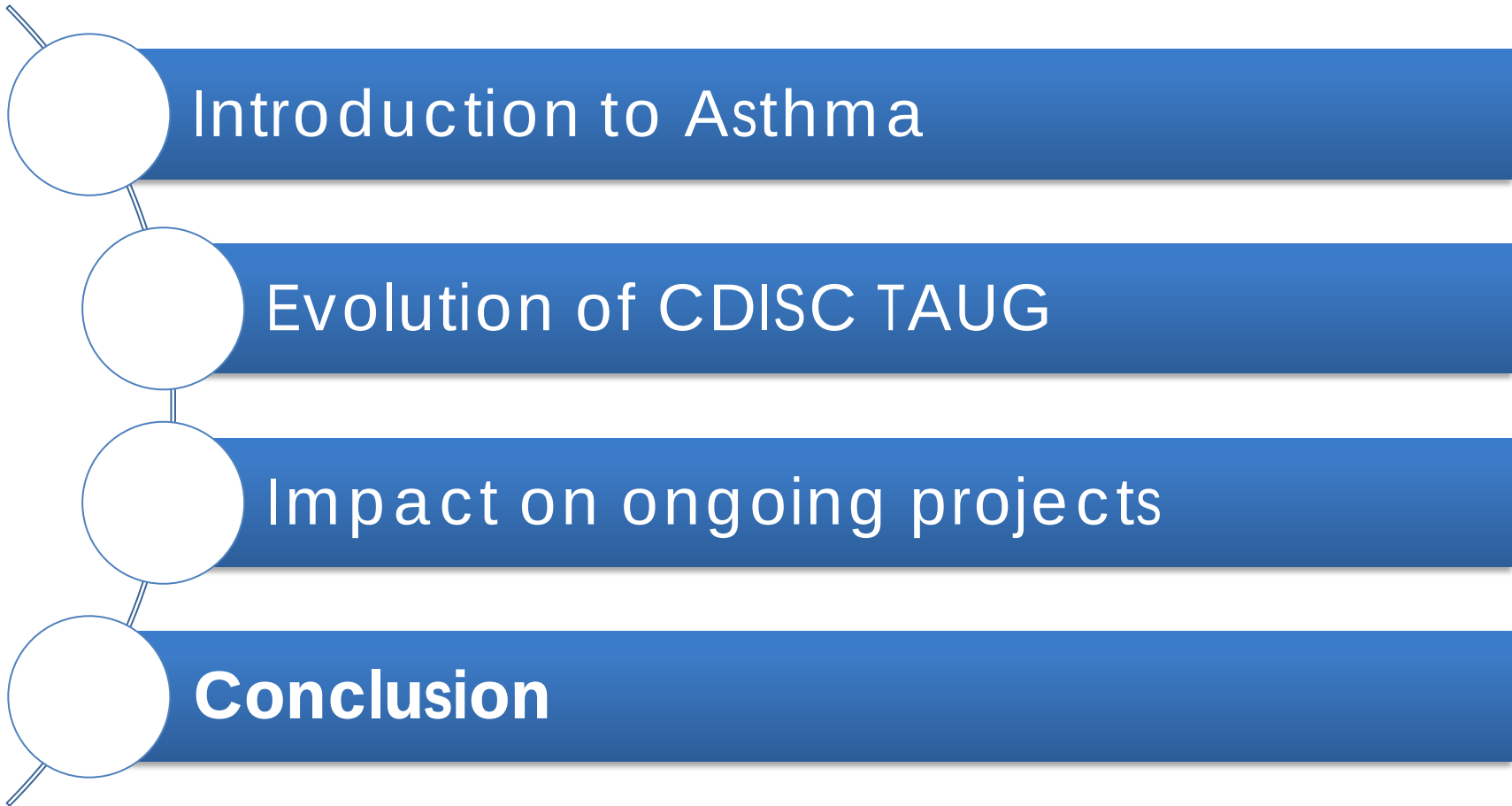


How to manage dates ?

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.

Join us for a coffee at our stand.

London, United Kingdom, 14 OCT 2014





Nick De Donder | Project Manager | +32 (0)476 82 20 27 | nick.dedonder@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/>