

What's New in the SDTMIG v3.3 and what am I missing?

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A poster which has complete information in one slide on what is new in SDTM IG v 3.3 and what needs to be considered while creating SDTM data using this SDTM version.

INTRODUCTION

- Are you tired of thinking to read through the new version of SDTM IG documents page by page? No worries. Here you go!
- This poster will take you through a tour of what has been added in SDTM IG 3.3 and will give you some ideas on what really needs your attention.
- Domains + 11, New Flag variables which help us in speeding up our data to be presented in more complaint to the standard and easy to analyze.

TM - TRIAL DISEASE MILESTONES

which are observations or activities anticipated to occur in the course of the disease under study.

FT-Functional Tests (FT)

the functional-test data is under the QRS umbrella.

SM - SUBJECT DISEASE MILESTONES

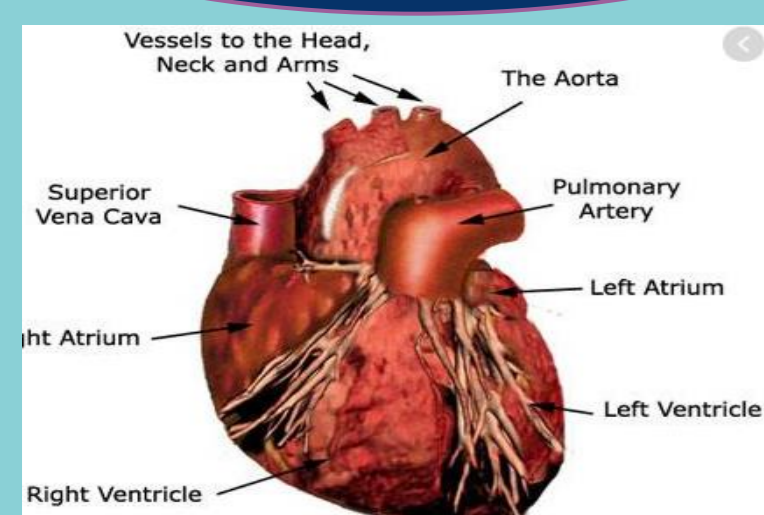
- to record the timing, for each subject, of Disease Milestones

OI-Non-host Organism Identifiers (OI)

created to provides further taxonomic classification data

CV

findings related to the cardiovascular system



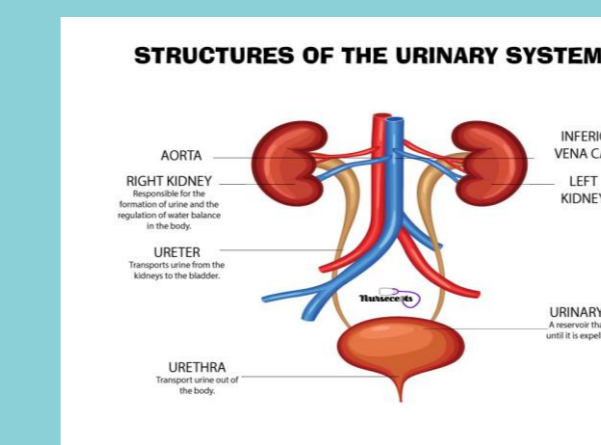
MK

findings related to the system of muscles



UR

related to the urinary tract, including the organs involved in the creation and excretion of urine



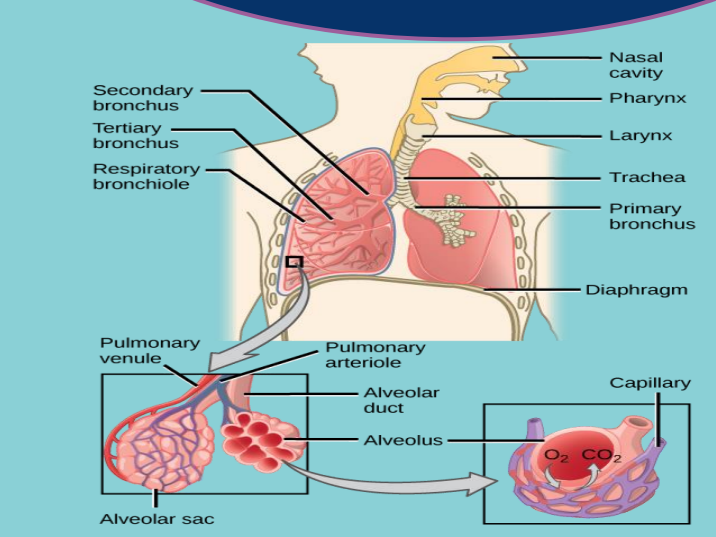
ML - MEAL DATA

describing a subject's food product consumption.



RE

related to the respiratory system, including the organs that are involved in breathing



SI.No	Domain	Description
1	AG	Procedure Agents
2	CV	Cardiovascular System Findings
3	FT	FT-Functional Tests (FT)
4	MK	Musculoskeletal Findings
5	ML	Meal Data
6	NV	Nervous System Findings
7	OE	Ophthalmic Examinations
8	OI	OI-Non-host Organism Identifiers (OI)
9	RE	Respiratory System Findings
10	SM	Subject Disease Milestones
11	TM	Trial Disease Milestones
12	UR	Urinary System Findings

AG - PROCEDURE AGENTS

- for the agents administered to the subject as part of a procedure or assessment

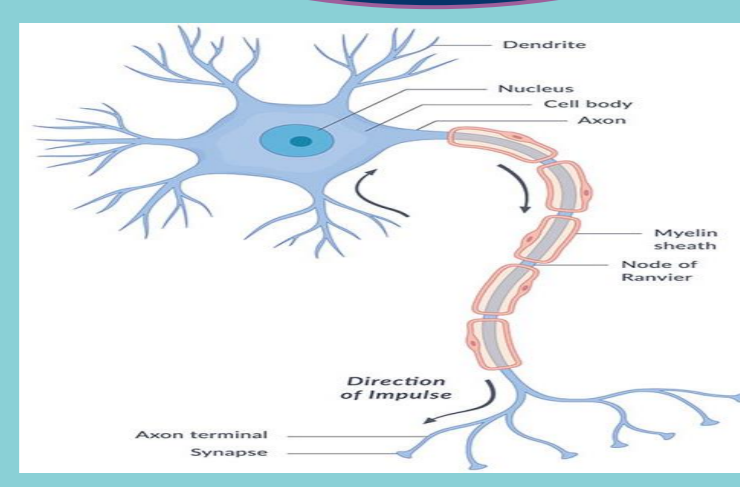
OE

related to tests that measure a person's ocular health and visual status



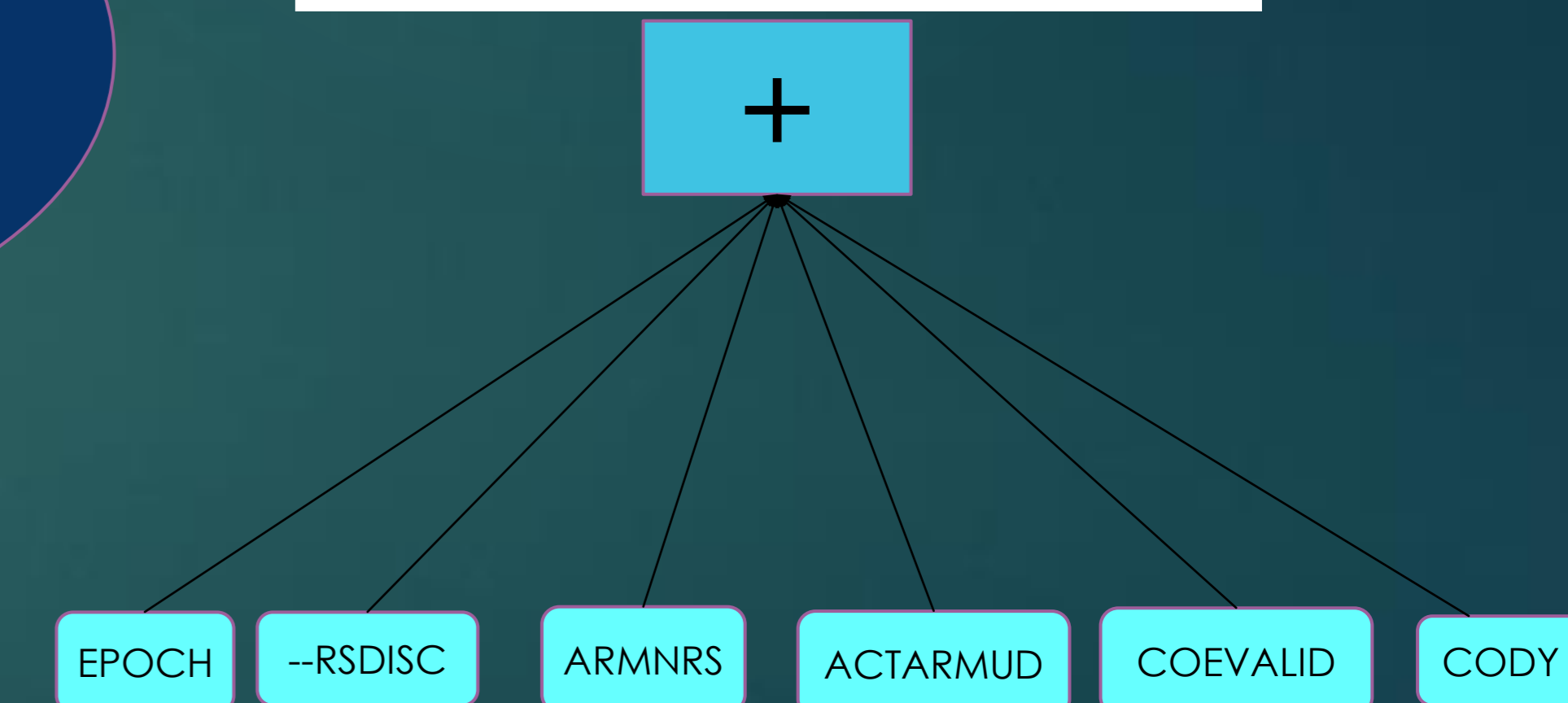
NV

related to the nervous system based on neurological examinations or procedures



QS domain split into three domains

NEW SDTM VARIABLES



SDTMIG V3.2

QS

SDTMIG V3.3

QS

RS

FT

Benefits :

- Revised Disposition (DS) assumptions to facilitate greater clarity
- Many new examples, revisions, and corrections across domains
- Associations to supplemental implementation guides
- Additional new supporting domains (e.g., ML, TM, SM)
- Greater guidance on managing text strings that are more than 200 characters

Conclusion:

With rapid release of SDTM versions, it is important for a statistical programmer to upgrade his knowledge on that. This poster gives an overview of all the changes in SDTM V3.3 in one show. New domains, new rules to make things smoother towards the submission of data. more

REFERENCES:

<https://www.lexjansen.com/phuse/2018/ds/DS08.pdf>