REPRESENTING DEVICE DATA IN CDISC STANDARDS

Jon Neville, Critical Path Institute

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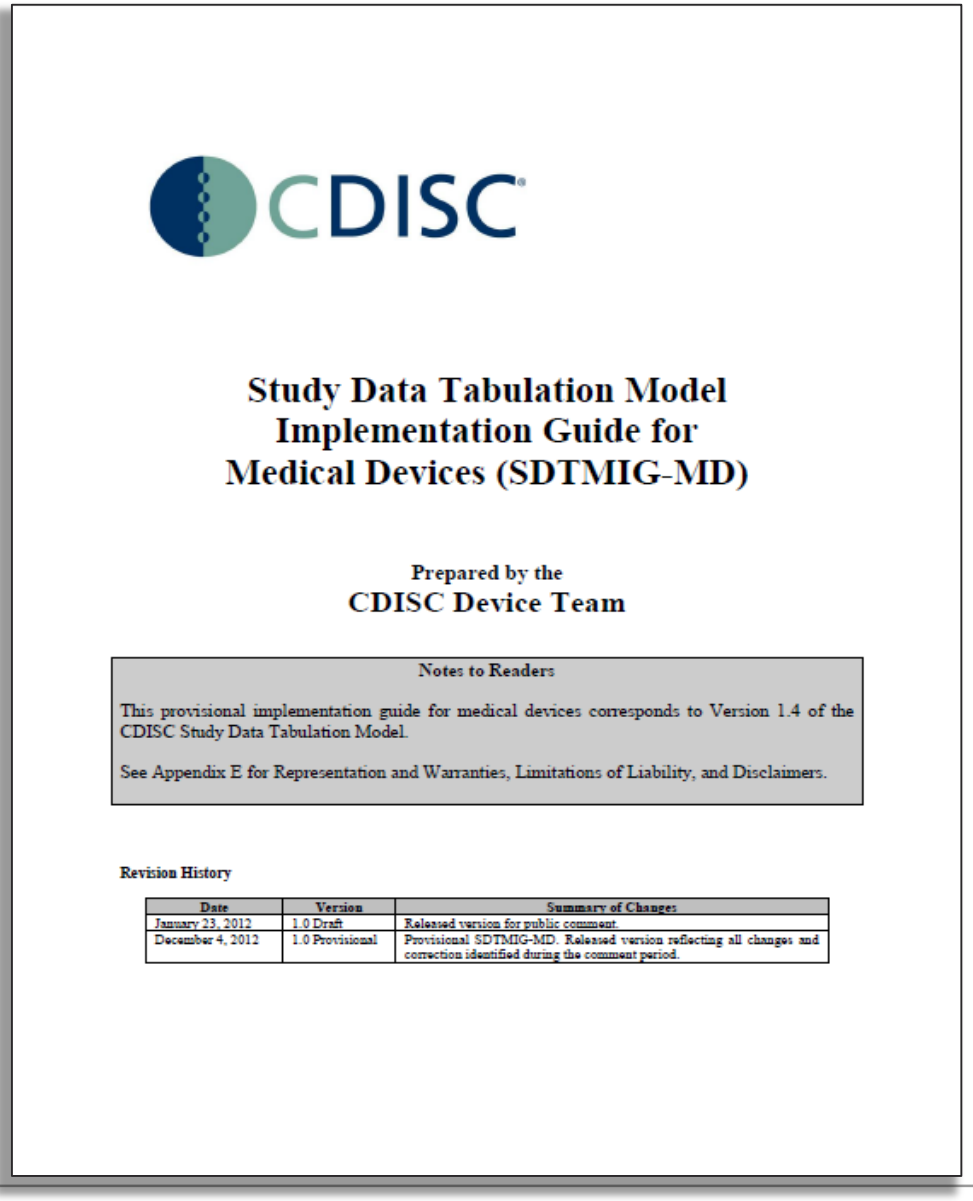
10 YEARS

CDISC SDTM implementation guide for medical devices



CDISC

Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD)

Prepared by the
CDISC Device Team

Notes to Readers

This provisional implementation guide for medical devices corresponds to Version 1.4 of the CDISC Study Data Tabulation Model.

See Appendix E for Representation and Warranties, Limitations of Liability, and Disclaimers.

Revision History

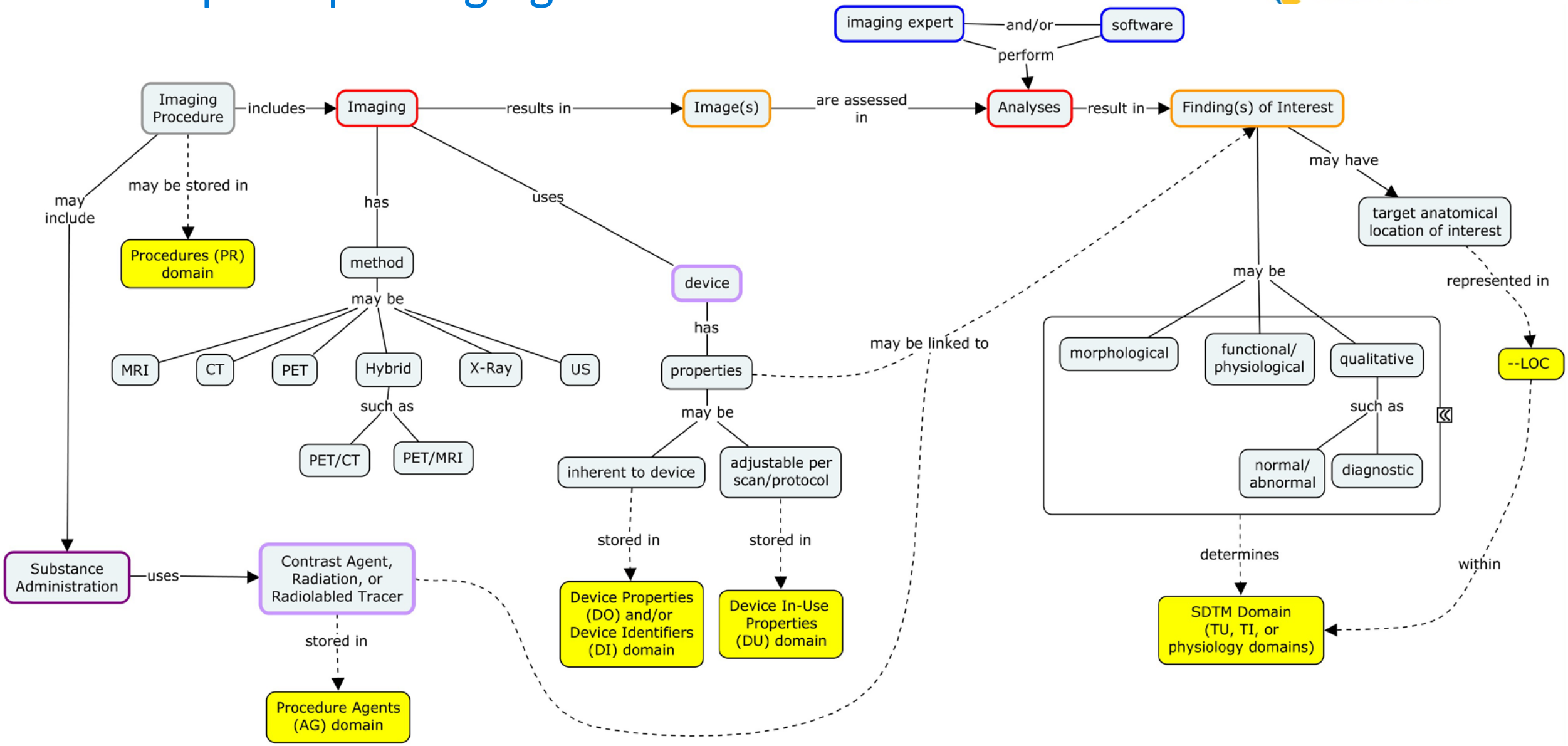
Date	Version	Summary of Changes
January 23, 2012	1.0 Draft	Released version for public comment.
December 4, 2012	1.0 Provisional	Provisional SDTMIG-MD. Released version reflecting all changes and correction identified during the comment period.

Originally developed for devices under study

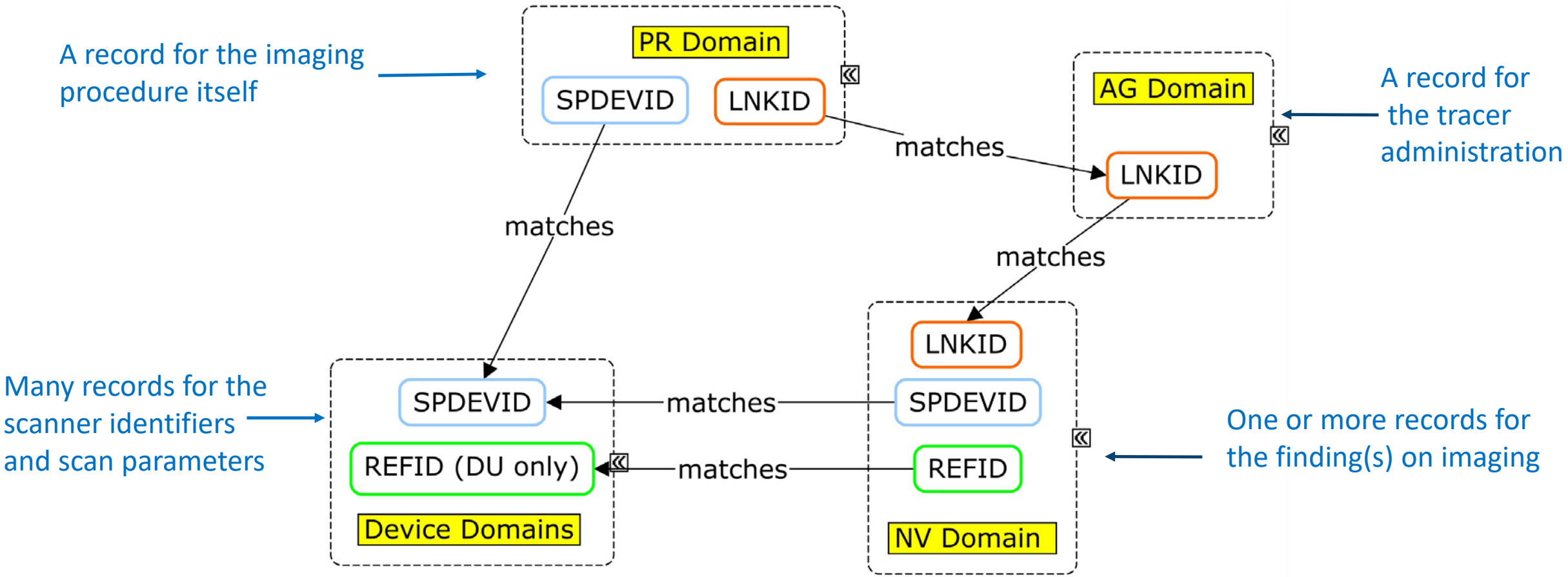
Also works well for other device use cases

Existing CDISC standards for neurodegeneration

Concept map: Imaging



Relating device/subject records in CDISC SDTM



SPDEVID= Device ID
LNKID: Link ID
REFID: Reference ID

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nv.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	NVSEQ	NVREFID	NVLNKID	NVTESTCD	NVTEST	NVORRES	NVORRESU
2	ABC123	NV	AD01-101	22	2	1236	03	SUVR	Standard Uptake Value Ratio	1.17	RATIO
3	ABC123	NV	AD01-102	22	1	1237	04	SUVR	Standard Uptake Value Ratio	1.21	RATIO
4	ABC123	NV	AD01-102	22	2	1237	04	SUVR	Standard Uptake Value Ratio	1.78	RATIO
5	ABC123	NV	AD01-103	44	1	1238	05	SUVR	Standard Uptake Value Ratio	1.52	RATIO
6	ABC123	NV	AD01-103	44	2	1238	05	SUVR	Standard Uptake Value Ratio	1.63	RATIO

ag.xpt

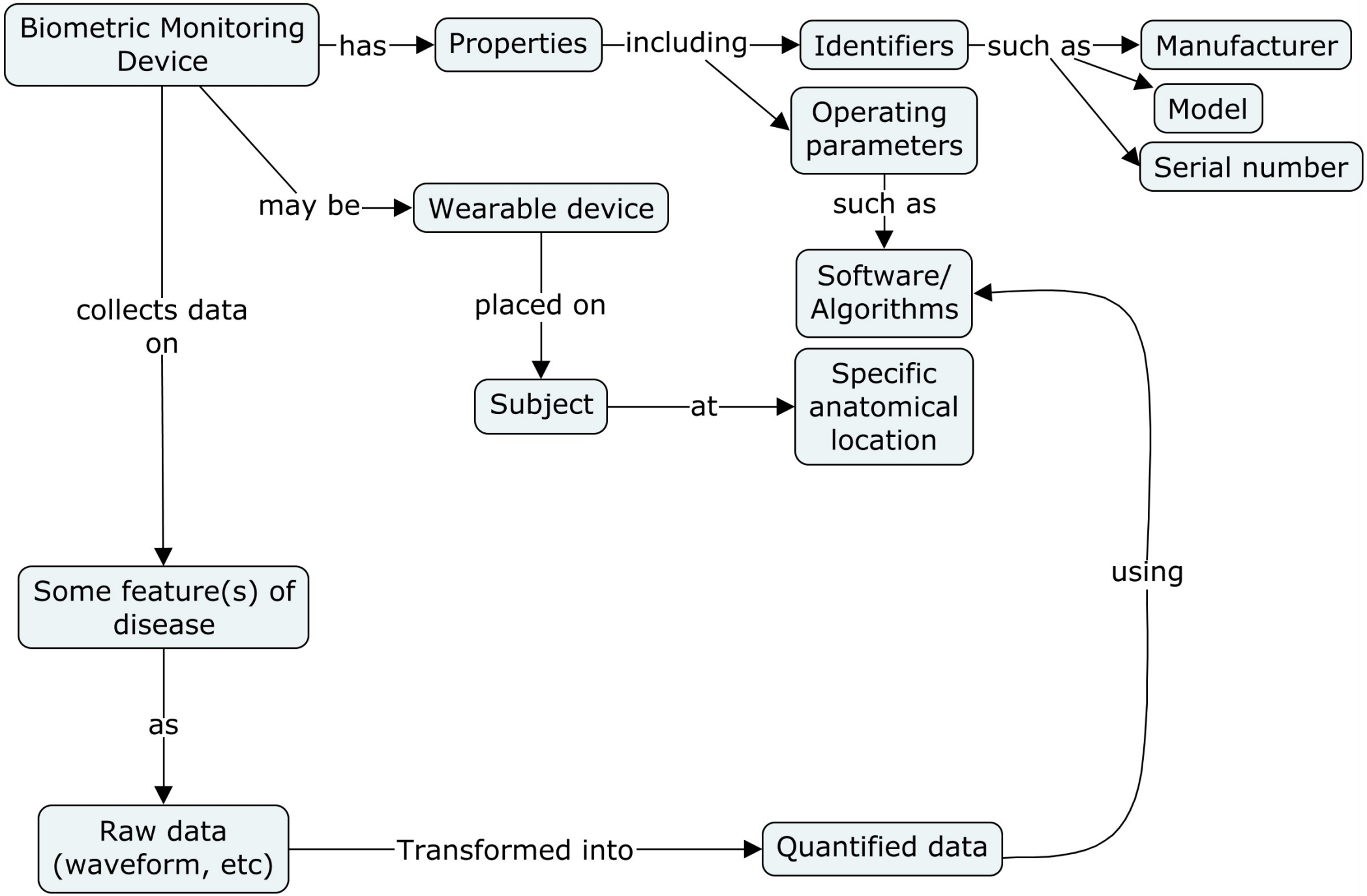
Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGLNKID	AGTRT	AGCAT	AGDOSE	AGDOSEU	AGSTDTC
1	ABC123	AG	AD01-101	1	03	18F-Florbetapir	AMYLOID TRACER	370	MBq	2012-05-22T08:40:00
2	ABC123	AG	AD01-102	1	04	11C-PiB	AMYLOID TRACER	370	MBq	2012-05-22T07:20:00
3	ABC123	AG	AD01-103	1	05	FDG	GLUCOSE TRACER	400	MBq	2012-05-22T08:30:00

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABC123	DI	22	1	DEVTYPE	Device Type	PET/CT
2	ABC123	DI	22	2	MANUF	Manufacturer	Siemens
3	ABC123	DI	22	3	MODEL	Model	TRIO
4	ABC123	DI	44	1	DEVTYPE	Device Type	PET
5	ABC123	DI	44	2	MANUF	Manufacturer	Siemens
6	ABC123	DI	44	3	MODEL	Model	INVEON

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUREFID	DUTESTCD	DUTEST	DUORRES	DUORRESU	...	VISITNUM	DUDTC
1	ABC123	DU	AD01-101	22	1	1236	ANTPLANE	Anatomical Plane	SAGITTAL		...	1	2012-05-22T09:30:00
2	ABC123	DU	AD01-101	22	2	1236	INTSPACE	Interslice Spacing	1	mm	...	1	2012-05-22T09:30:00
3	ABC123	DU	AD01-101	22	3	1236	SFTWRVER	Software Version	5.1		...	1	2012-05-22T09:30:00
4	ABC123	DU	AD01-101	22	4	1236	STHICK	Slice Thickness	5	mm	...	1	2012-05-22T09:30:00
5	ABC123	DU	AD01-101	22	5	1236	PIXSPCX	Pixel Spacing X	2	mm	...	1	2012-05-22T09:30:00
6	ABC123	DU	AD01-101	22	6	1236	PIXSPCY	Pixel Spacing Y	2	mm	...	1	2012-05-22T09:30:00
7	ABC123	DU	AD01-101	22	7	1236	AQMTRXSZ	Image Acquisition Matrix Size	256X256		...	1	2012-05-22T09:30:00
8	ABC123	DU	AD01-101	22	8	1236	FLDVIEW	Field of View	280X280	mm	...	1	2012-05-22T09:30:00
9	ABC123	DU	AD01-101	22	9	1236	NUMSLICE	Number of Slices	125		...	1	2012-05-22T09:30:00


Biometric Monitoring Device
has
Properties
including
Identifiers
such as
Manufacturer
Model
Serial number
Operating parameters
such as
Software/ Algorithms
may be
Wearable device
placed on
collects data on
Subject
at
Specific anatomical location
using
Some feature(s) of disease
as
Raw data (waveform, etc)
Transformed into
Quantified data

Summary Questions

- What is the beginning-to-end life cycle of these data?
- What happens to the raw data beyond interpretation by software?
- What's important to capture?
- How do we begin filling out the details on the previous slide?