



REPRESENTING DEVICE DATA IN CDISC STANDARDS

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10 YEARS



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

Alzheimer's/ MCI



Therapeutic Area Data Standards
User Guide for Alzheimer's Disease
and Mild Cognitive Impairment
Version 2.0

Prepared by the
CFAST Alzheimer's Development Team

Parkinson's



Therapeutic Area Data Standards
User Guide for Parkinson's Disease

Prepared by
CDISC, National Institute
of Mental Health (NIMH), National Institute
of Neurological Disorders and Strokes (NINDS), and
National Institute on Aging (NIA) Against Major Disease

MS



Therapeutic Area Data Standards
User Guide for Multiple Sclerosis
Version 1.0

Prepared by the
Multiple Sclerosis Outcome Assessments Consortium
the CFAST Multiple Sclerosis Development Team

Notes to Readers

- This document corresponds to the SDTM v1.4 and SDTMIG v3.2.
- The TAUG-MS v1.0 package includes a user guide (this document) and all available draft documents.
- This work was funded by the National Multiple Sclerosis Society (Grant #RG 4869-A-1 to the CDISC Institute) as part of the MSOAC initiative.

Revision History

Date	Version	Summary of Changes
2014-05-02	1.0	Multiple Sclerosis User Guide v1.0 release
2014-02-28	1.0 Draft	Draft release for public review
2014-01-17	1.0 Draft	Draft released for internal review

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

TBI



Therapeutic Area Data Standards
User Guide for Traumatic Brain Injury
Version 1.0 (Provisional)

Prepared by the
CFAST Traumatic Brain Injury Standards Team

Notes to Readers

- This is version 1.0 of the Therapeutic Area Data Standards User Guide for Traumatic Brain Injury.
- This document is based on SDTM v1.4 and SDTMIG v3.2, and on CDASH v1.1 and CDASHUG v1.0.

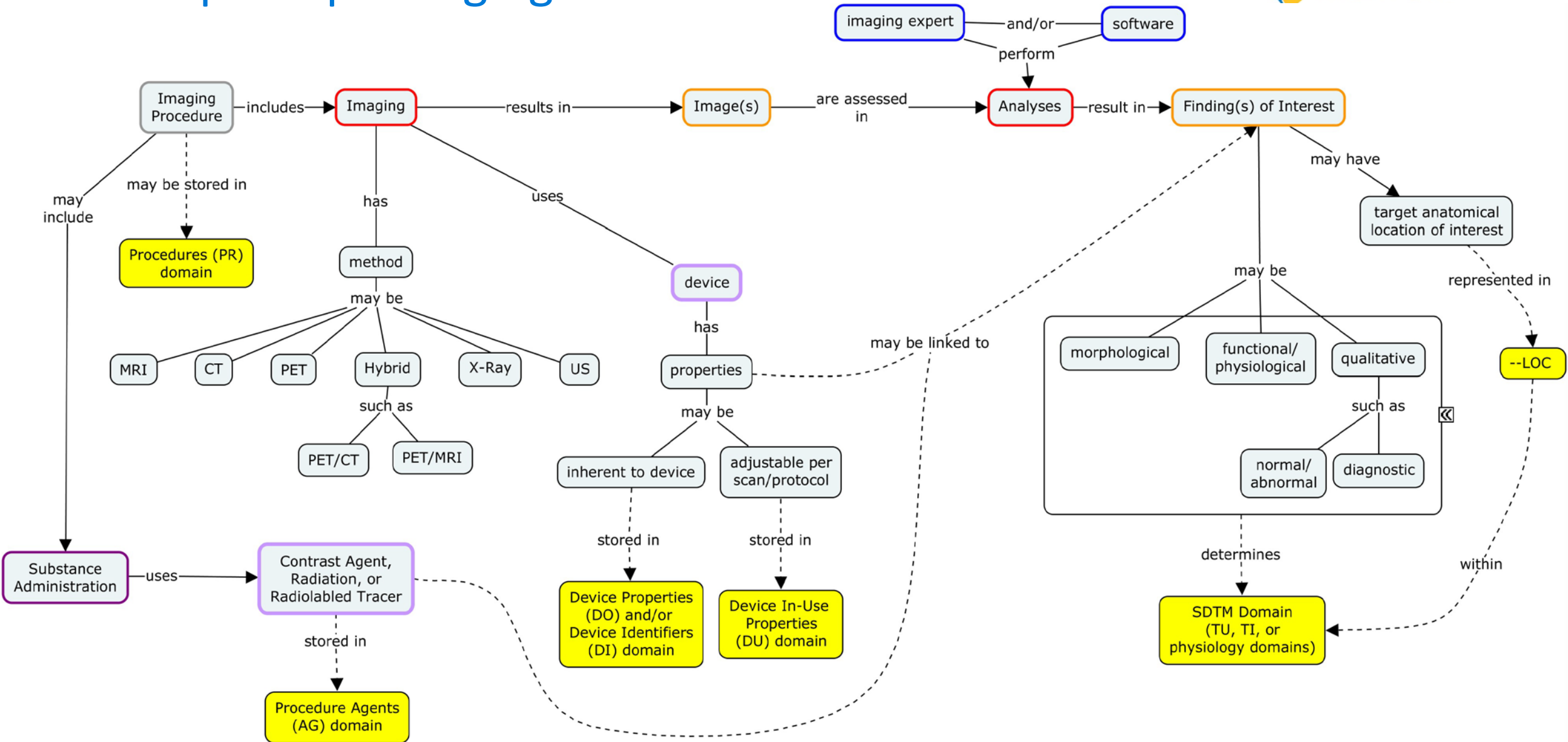
Revision History

Date	Version	Summary of Changes
2015-12-02	1.0 Provisional	First release for provisional use
2015-07-13	1.0 Draft	Draft for public review

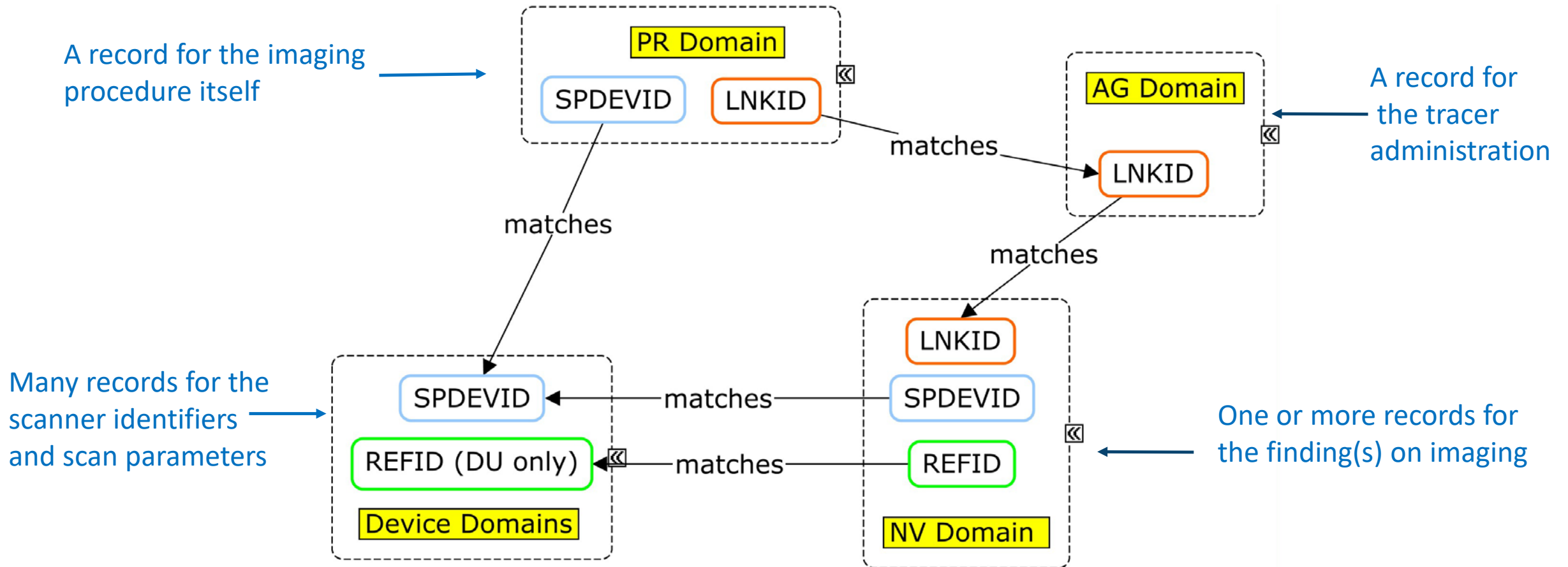
See [Appendix E](#) for Representations and Warranties, Limitations of Liability, and Disclaimers.

Huntington's Disease
currently in development

Concept map: Imaging



Relating device/subject records in CDISC SDTM



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

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

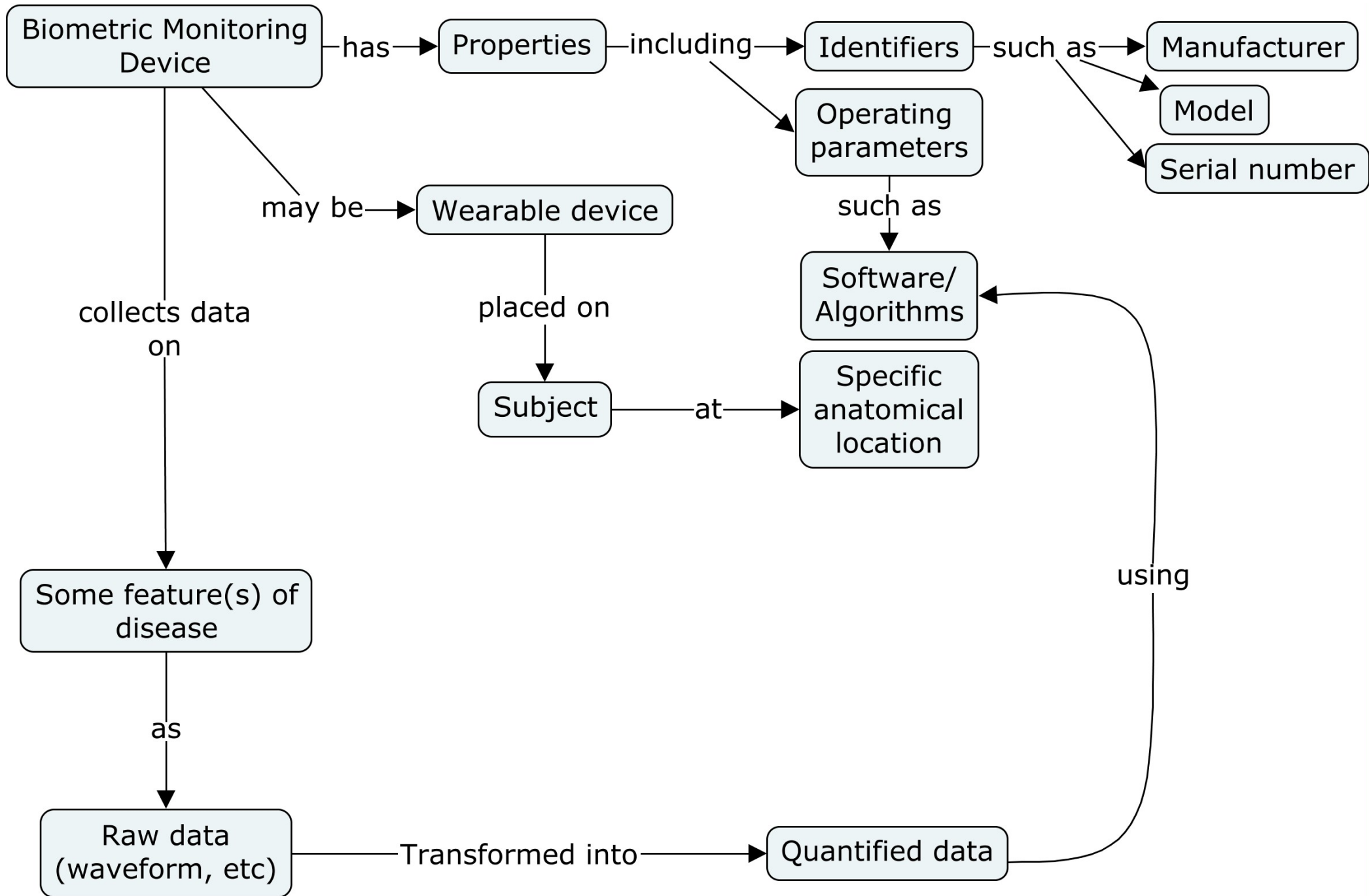
Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGLNKID	AGTRT	AGCAT	AGDOSE	AGDOSEU	AGSTDTC
1	ABC123	AG	AD01-101	1	03	18F-Florbetapir	AMYLOID TRACER	370	MBq	2012-05-22T08:40:00
2	ABC123	AG	AD01-102	1	04	11C-PiB	AMYLOID TRACER	370	MBq	2012-05-22T07:20:00
3	ABC123	AG	AD01-103	1	05	FDG	GLUCOSE TRACER	400	MBq	2012-05-22T08:30:00

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



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?
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