

Introduction to SWOG's upcoming CDASH changes

Why?

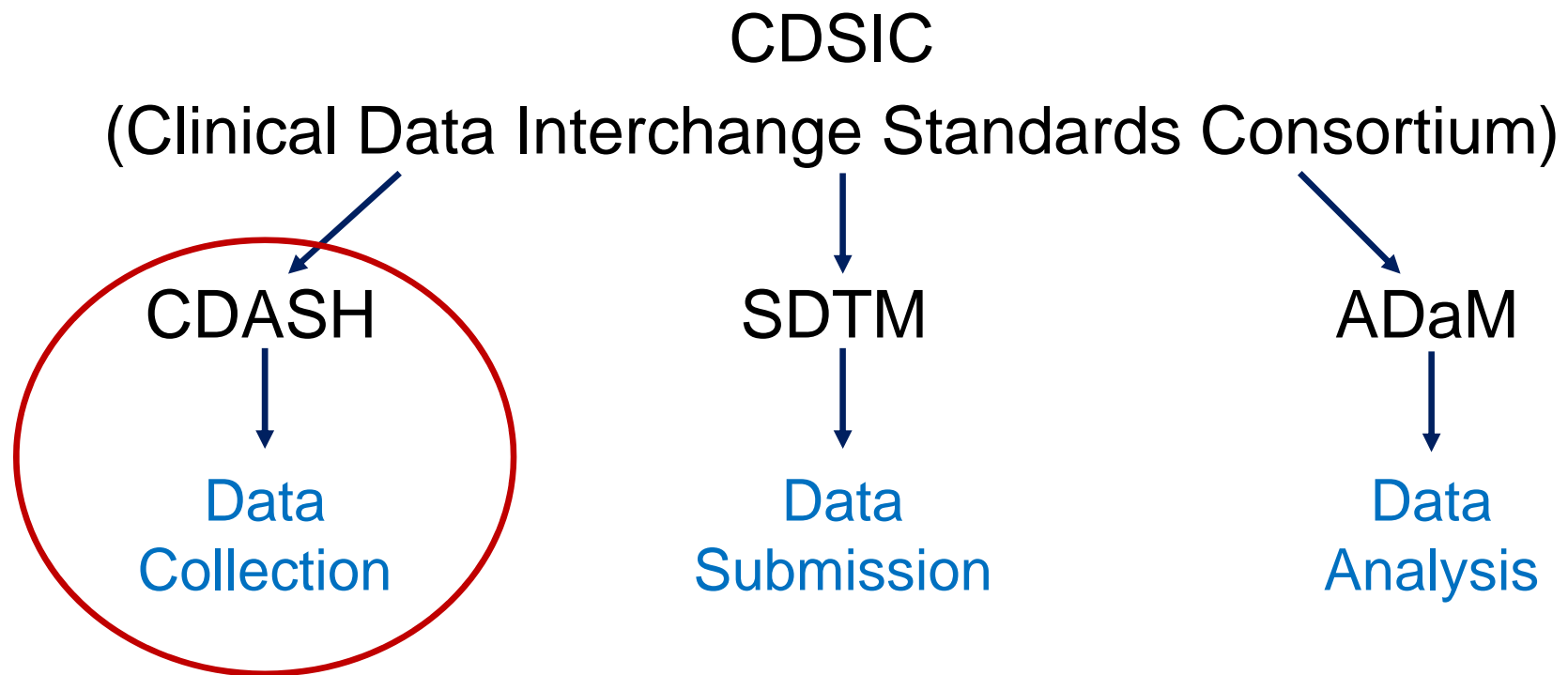
FDA Submission Requirements (2014) & NCI Data Collection Requirements (2020)

What is CDASH?

CDSIC: Clinical Data Interchange Standards Consortium

- **CDASH: Clinical Data Acquisition Standards Harmonization**
- **SDTM: Study Data Tabulation Model**
- **ADaM: Analysis Data Model**

What is CDASH?



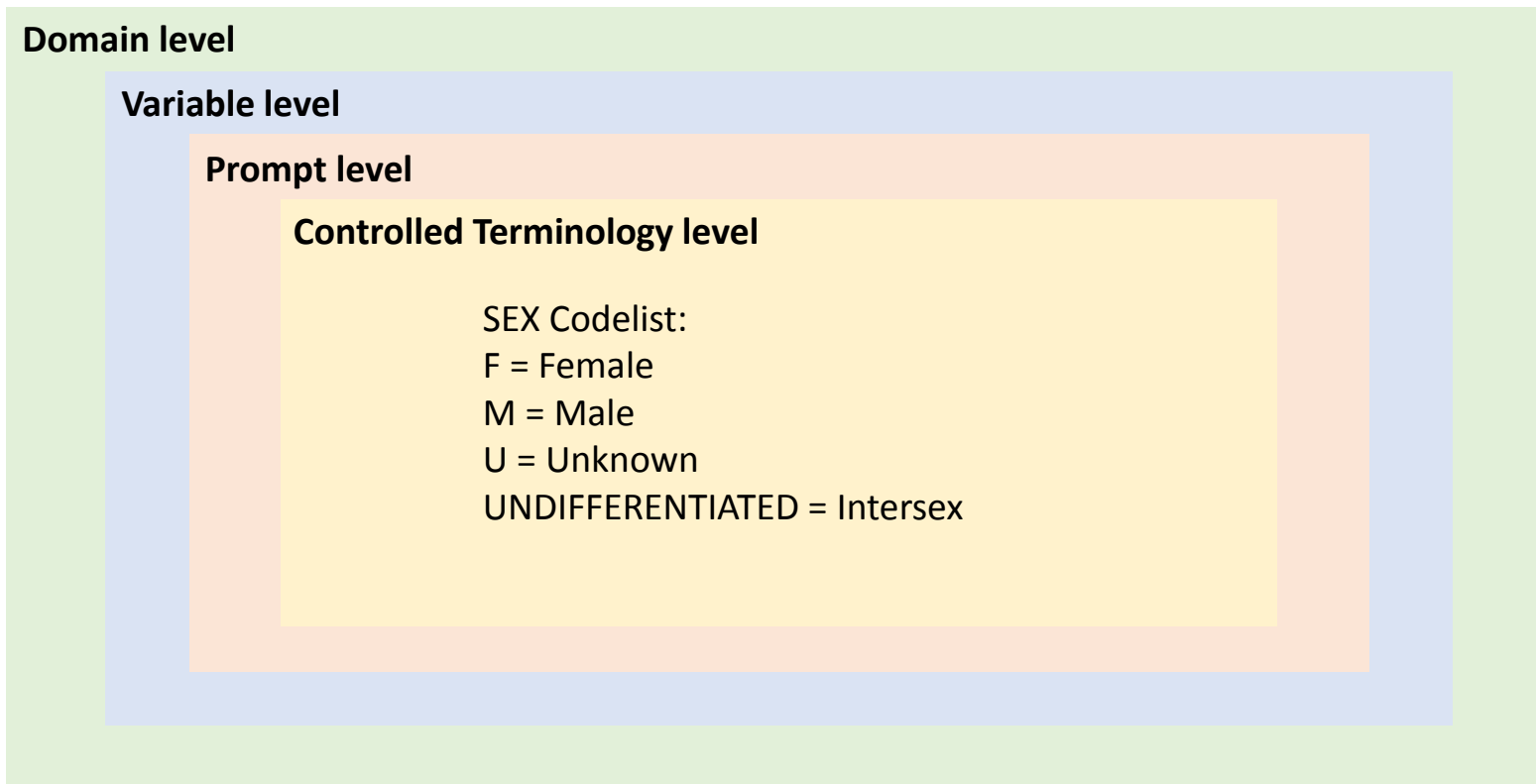
What does this mean for SWOG?

- Improvements in...
 - **Consistency**
 - Worldwide standard already in use for the past 5 years
 - **Clarity**
 - Add specificity to minimize confusion
 - **Efficiency**
 - CDASH motto: If you don't need it, don't ask for it!

What does apply to?

- To start CTEP-IND studies only.
 - **But eventually, all SWOG trials**

What does the CDASH standard look like?



Prompts

Previous SWOG Terminology



Patient

Current CDASH Terminology

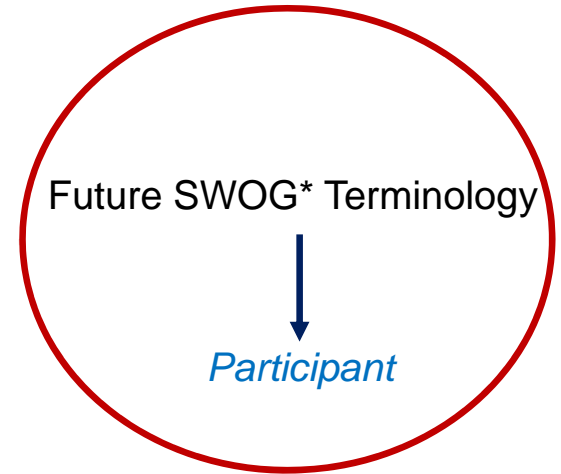


Subject

Future SWOG* Terminology



Participant



*Possible future CDASH Terminology as well.

CDASH Best Practices

- No “Check all that apply”, yes/no responses only
- Include “Not Done” or “Unknown” as needed
- Use data cleaning prompts
- Don’t collect the same data more than once
- Include an “Ongoing” field when applicable
- Allow for unknown dates
- Limit the use of free text responses

Examples: No “Check all the apply”

Past

Surgery *(select all that apply)*

Resection of primary tumor

Date ...

Resection of regional metastases (regional nodes, satellite/in-transit metastases)

Date ...

Resection of distant metastases

Date ...

Resection of recurrent disease

Date ...

Future

Surgery

Did the participant have resection of the primary tumor? Yes No

If yes, what was the date? ...

Did the participant have resection of the regional metastases (regional nodes, satellite/in-transit metastases)? Yes No

If yes, what was the date? ...

Did the participant have resection of distant metastases? Yes No

If yes, what was the date? ...

Did the participant have resection of recurrent disease? Yes No

If yes, what was the date? ...

Examples: Include “Unknown” Option

Past

Location	Treatment Intent	Total Cumulative Dose (Gy)	Total Fractions Count
	<input type="radio"/> Palliative <input type="radio"/> Curative <input type="radio"/> Preventative	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>

Future

Location	Treatment Intent	Total Cumulative Dose (Gy)	Total Cumulative Dose Unknown	Total Fractions Count	Total Fractions Count Unknown
	<input type="radio"/> Palliative <input type="radio"/> Curative <input type="radio"/> Preventative <input type="radio"/> Unknown	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>

Examples: Include “Not Done” Option

Past

Lab test	Lab test units	Lab value	LLN	ULN	Sample collection date
Absolute Neutrophil Count (ANC), Blood	/uL	<input type="text"/> , <input type="text"/>	<input type="text"/> , <input type="text"/>	<input type="text"/> , <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Platelets, Blood	/uL	<input type="text"/> , <input type="text"/>	<input type="text"/> , <input type="text"/>	<input type="text"/> , <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Hemoglobin, Blood	g/dL	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Future

Lab Performed	Lab Test Name	Result	Unit	Normal Range Lower Limit	Normal Range Upper Limit	Collection Date
<input type="radio"/> Yes <input type="radio"/> No	Absolute Neutrophil Count	<input type="text"/> , <input type="text"/>	/uL	<input type="text"/> , <input type="text"/>	<input type="text"/> , <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<input type="radio"/> Yes <input type="radio"/> No	Platelet Count	<input type="text"/> , <input type="text"/>	/uL	<input type="text"/> , <input type="text"/>	<input type="text"/> , <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<input type="radio"/> Yes <input type="radio"/> No	Hemoglobin Measurement	<input type="text"/> . <input type="text"/>	g/dL	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Examples: Use Data Cleaning Prompts

Past

Instructions: Please complete if patient receives any non-protocol therapy. If patient received a glucocorticoid to treat immune-related adverse events, record the dose and start and stop dates. List each medication on a separate line, even if given concurrently. If patient stops a medication and then restarts at a later date, list each occurrence on a separate line.

Concomitant Agent Name [?]	Start Date [?]	Stop Date [?]	Ongoing?	Dose [?]	Units of Measure [?]
<input type="text"/>	<input type="text"/> ... ▼ <input type="text"/>	<input type="text"/> ... ▼ <input type="text"/>	<input type="checkbox"/>	<input type="text"/>	... ▼ <input type="text"/>

Add a new Log line

Future

Did patient start any new concomitant medications not previously reported or is patient continuing to receive concomitant medications that have been previously reported?

Yes No

Concomitant Agent Name [?]	Start Date [?]	Stop Date [?]	Ongoing? [?]	Dose [?]	Units of Measure [?]
<input type="text"/>	<input type="text"/> ... ▼ <input type="text"/>	<input type="text"/> ... ▼ <input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/> ▼ <input type="text"/>

Examples: Don't Repeat Data

Past

Treatment

Vital status

Date of last contact

Off Treatment

Vital status

Date of last contact

Follow-up

Vital status

Date of last contact

Future

Vital Status Form

Vital Status

Alive Dead

Vital Status Date

... ▼

Examples: Include “Ongoing”

Past

Has the patient received prophylactic cranial irradiation (PCI)?

Yes No

If Yes, PCI start date:

--	--	--	--	--	--	--	--	--	--

Future

Has the participant received prophylactic cranial irradiation (PCI)?

Yes No

If yes, what was the PCI start date?

--	--	--	--	--	--	--	--	--	--

If yes, was the PCI ongoing?

Yes No

If no, what was the PCI end date?

--	--	--	--	--	--	--	--	--	--

Examples: Allow Unknown Dates

Past

- Had to input a Day, Month, and Year

Future

- “UN” for unknown Day
- “UNK” for unknown Month
- “UNKN” for unknown Year

Examples: Limit Free Text

- Tumor Assessments
 - Controlled terminology for Location

Codelist Name	CDISC Submission Value	NCI Preferred Term
Anatomical Location	LOC	CDISC SDTM Anatomical Location Terminology
Anatomical Location	LINGULA OF THE LUNG	Lingula of the Lung
Anatomical Location	LUNG	Lung
Anatomical Location	LUNG, HILUM	Hilar Area of the Lung
Anatomical Location	LUNG, LEFT	Left Lung
Anatomical Location	LUNG, LEFT LOWER LOBE	Lower Lobe of the Left Lung
Anatomical Location	LUNG, LEFT UPPER LOBE	Upper Lobe of the Left Lung
Anatomical Location	LUNG, LEFT, INFERIOR LOBE, ANTERIOR BASAL SEGMENT	Left Lung, Inferior Lobe, Anterior Basal Segment
Anatomical Location	LUNG, LEFT, INFERIOR LOBE, LATERAL BASAL SEGMENT	Left Lung, Inferior Lobe, Lateral Basal Segment
Anatomical Location	LUNG, LEFT, INFERIOR LOBE, MEDIAL BASAL SEGMENT	Left Lung, Inferior Lobe, Medial Basal Segment
Anatomical Location	LUNG, LEFT, INFERIOR LOBE, POSTERIOR BASAL SEGMENT	Left Lung, Inferior Lobe, Posterior Basal Segment
Anatomical Location	LUNG, LEFT, INFERIOR LOBE, SUPERIOR SEGMENT	Left Lung, Inferior Lobe, Superior Segment
Anatomical Location	LUNG, LEFT, SUPERIOR LOBE, ANTERIOR SEGMENT	Left Lung, Superior Lobe, Anterior Segment
Anatomical Location	LUNG, LEFT, SUPERIOR LOBE, APICOPOSTERIOR SEGMENT	Left Lung, Superior Lobe, Apicoposterior Segment
Anatomical Location	LUNG, LEFT, SUPERIOR LOBE, INFERIOR LINGULAR SEGMENT	Left Lung, Superior Lobe, Inferior Lingular Segment
Anatomical Location	LUNG, LEFT, SUPERIOR LOBE, SUPERIOR LINGULAR SEGMENT	Left Lung, Superior Lobe, Superior Lingular Segment
Anatomical Location	LUNG, RIGHT	Right Lung
Anatomical Location	LUNG, RIGHT LOWER LOBE	Lower Lobe of the Right Lung
Anatomical Location	LUNG, RIGHT MIDDLE LOBE	Middle Lobe of the Right Lung
Anatomical Location	LUNG, RIGHT UPPER LOBE	Upper Lobe of the Right Lung
Anatomical Location	LUNG, RIGHT, INFERIOR LOBE, ANTERIOR BASAL SEGMENT	Right Lung, Inferior Lobe, Anterior Basal Segment
Anatomical Location	LUNG, RIGHT, INFERIOR LOBE, LATERAL BASAL SEGMENT	Right Lung, Inferior Lobe, Lateral Basal Segment
Anatomical Location	LUNG, RIGHT, INFERIOR LOBE, MEDIAL BASAL SEGMENT	Right Lung, Inferior Lobe, Medial Basal Segment
Anatomical Location	LUNG, RIGHT, INFERIOR LOBE, POSTERIOR BASAL SEGMENT	Right Lung, Inferior Lobe, Posterior Basal Segment
Anatomical Location	LUNG, RIGHT, INFERIOR LOBE, SUPERIOR SEGMENT	Right Lung, Inferior Lobe, Superior Segment
Anatomical Location	LUNG, RIGHT, MIDDLE LOBE, LATERAL SEGMENT	Right Lung, Middle Lobe, Lateral Segment
Anatomical Location	LUNG, RIGHT, MIDDLE LOBE, MEDIAL SEGMENT	Right Lung, Middle Lobe, Medial Segment
Anatomical Location	LUNG, RIGHT, SUPERIOR LOBE, ANTERIOR SEGMENT	Right Lung, Superior Lobe, Anterior Segment
Anatomical Location	LUNG, RIGHT, SUPERIOR LOBE, APICAL SEGMENT	Right Lung, Superior Lobe, Apical Segment
Anatomical Location	LUNG, RIGHT, SUPERIOR LOBE, POSTERIOR SEGMENT	Right Lung, Superior Lobe, Posterior Segment

Examples: Limit Free Text

- Limit use of Comment fields
 - If it's important, there should be a question just for that purpose

Was disease status evaluated during this reporting period?	<input type="radio"/> Yes <input type="radio"/> No
If no, what was the reason the evaluation was not done?	<input type="text"/>
If no, what was the planned date of the evaluation?	<input type="text"/> <input type="text"/> <input type="text"/>
If yes, what was the date of the evaluation? <i>(Date 1st scan was done this reporting period.)</i>	<input type="text"/> <input type="text"/> <input type="text"/>

Existing Reports and Tools

THE
SAME!

Mostly...

Up next...

**Difficulties/Challenges/Experience of Dealing with
Re-Engaging in Clinical Trials & Questions**

Dana Little & Ofilio Vigil