

Mapping of Gastrointestinal Tolerance Data to SDTM

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CHALLENGES

- No single modelled CDISC SDTM domain in which you can fit gastrointestinal tolerance data
- Large variety in case report forms of legacy studies
- Data collected in diaries are prone to reporting errors

CONCLUSIONS

- CDISC SDTM domains Clinical Events (CE) and Findings About (FA) are suitable for the mapping of gastrointestinal tolerance data
- Mapping of the planned time point of diaries is recommended, because diary dates are often incomplete or incorrect

Stool Characteristics

Visit 1

FATESTCD = "A_COUNT" FAORRESU = "/day"

What was the average number of stools per day last week? 3

FAOBJ = "Stool" FAEVINTX = "LAST WEEK" FAORRES

What was the average consistency of the stools last week? Watery Soft Formed Hard

FATESTCD = "A_CONSIS"

FINDINGS ABOUT (FA)

- Data or observations about an event or intervention for which no event or intervention record has been collected or created

DOMAIN	USUBJID	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FAEVINTX
FA	321-001	A_COUNT	Average Count	Stool	3	/day	LAST WEEK
FA	321-001	A_CONSIS	Average Consistency	Stool	Soft		LAST WEEK

Diary week 1 - day 1

FAEVINTX = "TODAY"

No stool today FATESTCD = "CONSIS" FATESTCD = "COLOUR"

FASPID	Stool consistency				Stool colour			
	No.	Watery	Soft	Formed	Hard	Brown	Green	Yellow
1		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2		<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FATESTCD = "COUNT" FAOBJ = "Stool"

DOMAIN	USUBJID	FASPID	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FAEVINTX
FA	321-001	1	CONSIS	Consistency	Stool	Watery		TODAY
FA	321-001	1	COLOUR	Colour	Stool	Brown		TODAY
FA	321-001	2	CONSIS	Consistency	Stool	Soft		TODAY
FA	321-001	2	COLOUR	Colour	Stool	Green		TODAY
FA	321-001		COUNT	Count	Stool	2	/day	TODAY

Gastrointestinal Symptoms

Visit 1

CEEVINTX = "LAST WEEK"

In general, did the subject suffer from the following symptoms last week:

CETERM	Absent	Mild	Moderate	Severe
Vomiting	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flatulence	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diarrhoea	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Constipation	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cramps	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

CEPRES = "Y" CEOCCUR CESEV

CLINICAL EVENTS (CE)

- To capture clinical events of interest that would not be classified as adverse events

DOMAIN	USUBJID	CETERM	CEPRES	CEOCCUR	CESEV	CEEVINTX
CE	321-001	VOMITING	Y	N		LAST WEEK
CE	321-001	FLATULENCE	Y	Y	MILD	LAST WEEK
CE	321-001	DIARRHOEA	Y	Y	MODERATE	LAST WEEK
CE	321-001	CONSTIPATION	Y	Y	MILD	LAST WEEK
CE	321-001	CRAMPS	Y	Y	SEVERE	LAST WEEK

FINDINGS ABOUT (FA)

- Data or observations about an event or intervention which have qualifiers of their own that can be represented in findings variables (e.g. units)

DOMAIN	USUBJID	CELNKID	CETERM	CEPRES	CEOCCUR	CEEVINTX
CE	321-001	CEFA1	VOMITING	Y	Y	TODAY
CE	321-001	CEFA2	REGURGITATION	Y	Y	TODAY

DOMAIN	USUBJID	FALNKID	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FAEVINTX
FA	321-001	CEFA1	COUNT	Count	Vomiting	2	/day	TODAY
FA	321-001	CEFA2	COUNT	Count	Regurgitation	1	/day	TODAY

RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
CE		CELNKID		ONE	GICOUNT
FA		FALNKID		ONE	GICOUNT

Diary week 1 - day 1

CEEVINTX/FAEVINTX = "TODAY"

Did regurgitation or vomiting occur today? CEPRESP = "Y" FATESTCD = "COUNT"

Vomiting yes How many times today? 2

Regurgitation yes How many times today? 1

CETERM/FAOBJ CEOCCUR FAORRESU = "/day" FAORRES

Timing of Diaries

Instruction to fill out the diary *daily* for 10 weeks

Diary week 1 - day 1

CEPTREF CETPT

Date (dd/mm/yyyy): 08/10/2017

Did regurgitation or vomiting occur today?

Vomiting yes How many times today?

Regurgitation yes How many times today?

--TPTREF (Time Point Reference)

- Description of the fixed reference point referred to by --ELTM, --TPTNUM and --TPT

--TPT (Planned Time Point Name):

- Text description of time when a measurement should be taken

--TPTNUM (Planned Time Point Number):

- Numeric version of planned time point (--TPT)

USUBJID	VISITNUM	VISIT	CEPTREF	CETPT	CETPTNUM	CETPTREF
321-001			2017-10-08	DAY 1	1	WEEK 1



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