Experience of implementation of this "A harmonized, report-friendly SDTM and ADaM Data Flow"

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Pre-requisites

- Internal document ADS-SDS on :
  - SDTM 3.1.1
  - Adam General Consideration 2.0
- Work with our standard group so that all teams work in same direction and exchange on these topics
- Basis : CT4 data (OC just coming)
- “Strategically” CDISC thought at BS&P level mainly (things changing slowly…)

What was done

- Programmation of “plenty” of ADS-SDS
- Mainly phase II / III studies (and oncology phase I)
- Used to run analyses

What was NOT done

- Extraction of “pure” SDS from our ADS-SDS
- RELREC, SUPQUAL, Trial designs

Main issues encountered…

Interpretation of the recommendations

1. **“Forced” controlled terminology**
2. **Study/project/therapeutic area specificities**
3. **Content of variables versus reporting**
4. **Far from a “one-proc-away” principle**

Main issues encountered…

1. “Forced” controlled terminology

- CDISC not thought from beginning…
- Should we “map” and lose the original meaning?
- 2 examples

Main issues encountered…

1. “Forced” controlled terminology

OUTCOM Label in CT4 (or OC)	CDISC Submission Value
FATAL	FATAL
NOT RECOVERED	NOT RECOVERED/NOT RESOLVED
RECOVERED	RECOVERED/RESOLVED
RECOVERED WITH SEQUELAE	RECOVERED/RESOLVED WITH SEQUELAE
RECOVERING	RECOVERING/RESOLVING
UNKNOWN	UNKNOWN

Main issues encountered…

1. “Forced” controlled terminology (cont’d)

ACTION Label in CT4 or OC	CDISC Submission Value
NONE	DOSE NOT CHANGED
PERMANENTLY DISCONTINUED	DRUG WITHDRAWN
DOSE REDUCED	DOSE REDUCED
INTERRUPTED	DRUG INTERRUPTED
	NOT APPLICABLE
	UNKNOWN
	DOSE INCREASED
DELAYED AND REDUCED ? ?	
DELAYED ? ?	

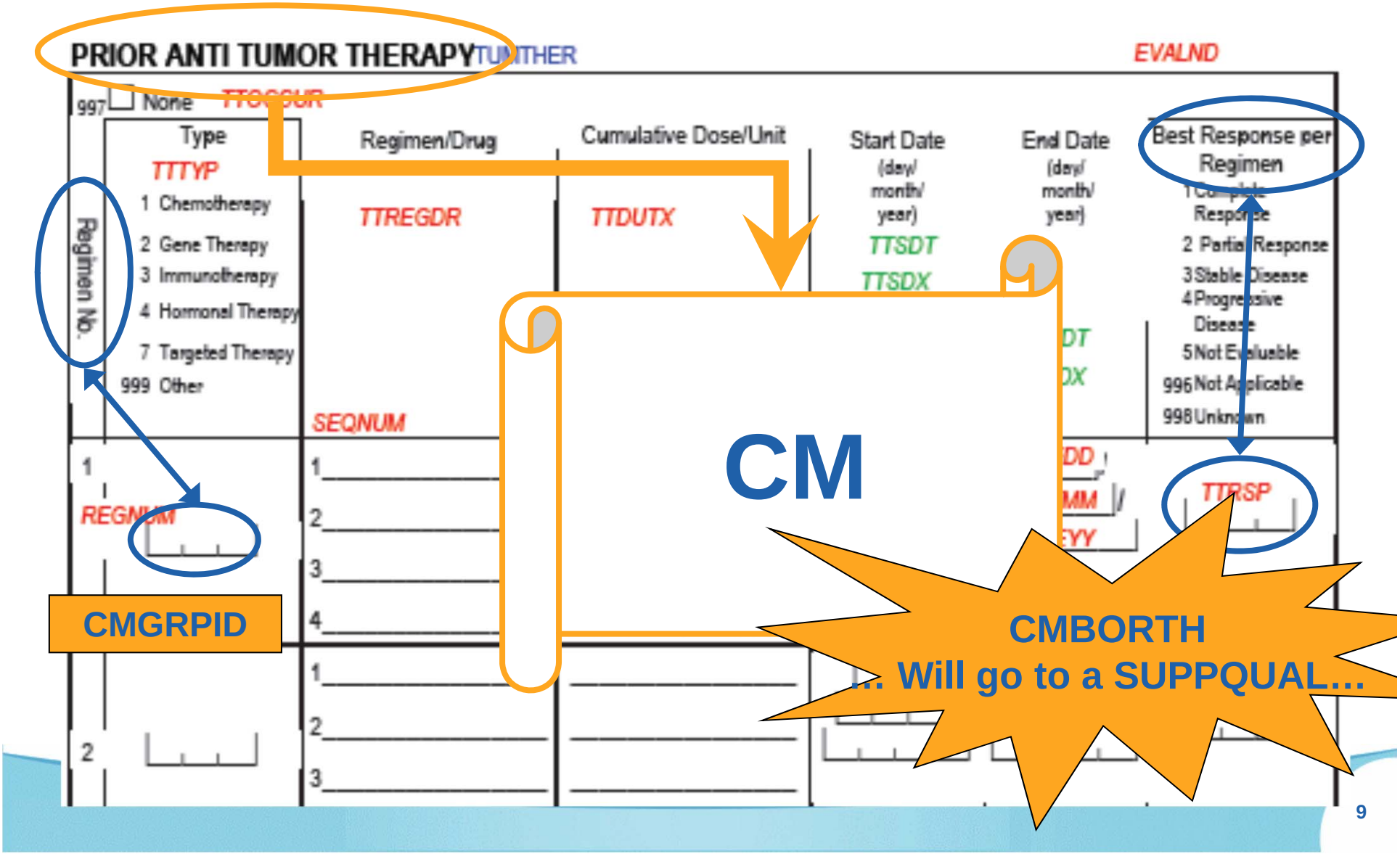
Main issues encountered…

2. Study/project/therapeutic area specificities

- Attach the data to an existing domain or create a new one?
- What in case of two candidate structures?
- Should we limit SUPPQUAL data?

Main issues encountered…

2. Study/project/therapeutic area specificities



Main issues encountered…

2. Study/project/therapeutic area specificities (cont'd)

HISTORY OF DIABETES	
Diabetes mellitus	Type 1 ☐ Type 2 ☐
Date of Diabetes diagnosis	__/___/____ | Day month year
Is the subject taking an Oral Antidiabetic Drug ?	Yes ☐ No ☐
If Yes, Start of first treatment with OAD	
Is the subject taking Insulin ?	No ☐
If Yes, Start of first treatment with Insul	
Immediate family history of diab	
History of gestational diabetes?	
Was a "drug 1" ever taken by the ject?	

MH

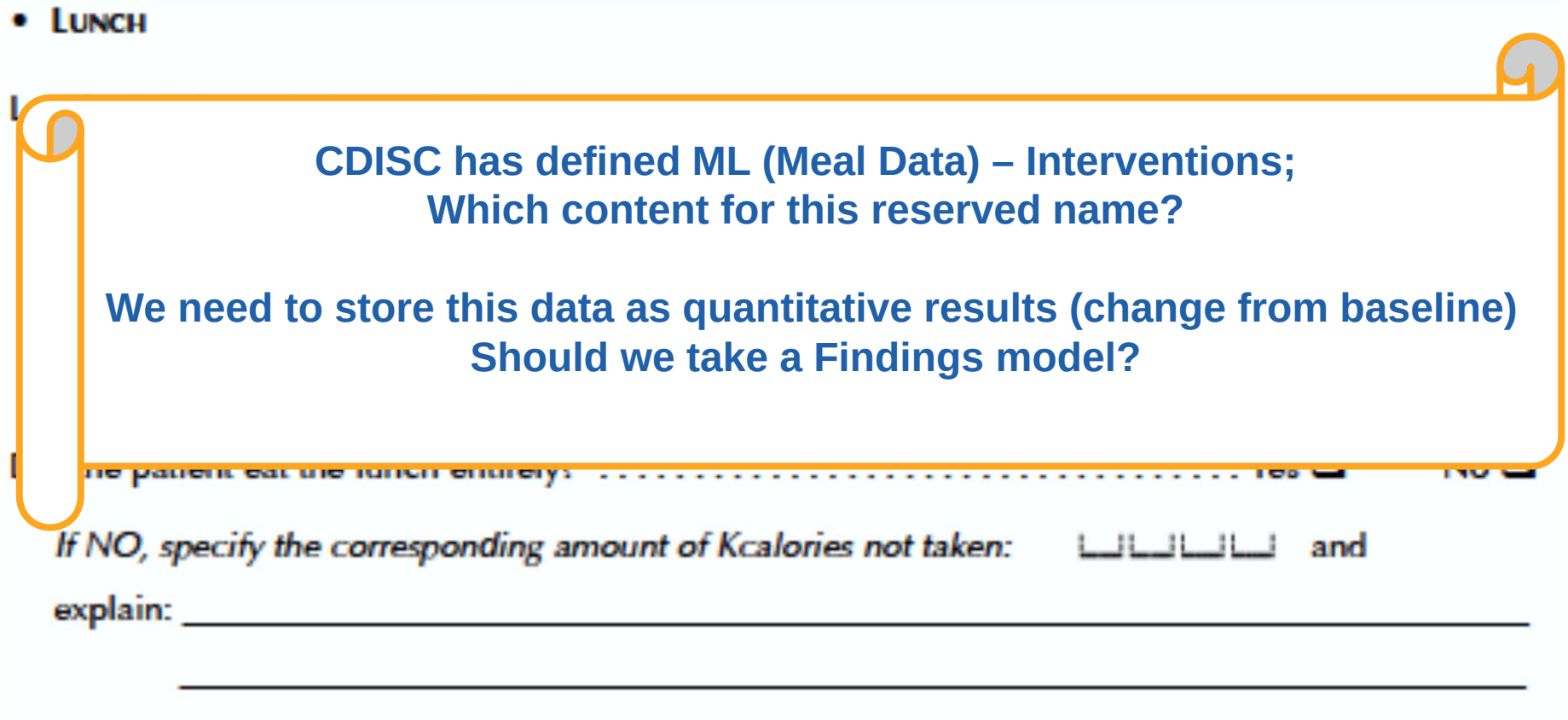
(Use of MHCAT)

Convention for dates

Main issues encountered…

2. Study/project/therapeutic area specificities (cont'd)

Food intake assessment



- LUNCH

CDISC has defined ML (Meal Data) – Interventions;
Which content for this reserved name?

We need to store this data as quantitative results (change from baseline)
Should we take a Findings model?

If NO, specify the corresponding amount of Kcalories not taken: ⌊_⌊_⌊_⌊_⌊_ and

explain: _____

_____

Main issues encountered…

3. Content of variables versus reporting

Variable Name	Variable Label	Type	Length	Controlled Terms or Format
SEX	Sex	Text	1	M, F
RACE	Race	Text	16	CAUCASIAN/WHITE, BLACK, ASIAN / ORIENTAL , OTHER

		SARxxxxxx			
	Placebo (N=151)	30 mg (N=149)	100 mg (N=149)	300 mg (N=141)	All (N=590)
Sex [n (%)]					
Number	151	149	149	141	590
Male	50 (33.1%)	45 (30.2%)	47 (31.5%)	43 (30.5%)	185 (31.4%)
Female	101 (66.9%)	104 (69.8%)	102 (68.5%)	98 (69.5%)	405 (68.6%)
Race [n (%)]					
Number	151	149	149	141	590
Caucasian	150 (99.3%)	149 (100%)	148 (99.3%)	138 (97.9%)	585 (99.2%)
Other	1 (0.7%)	0	1 (0.7%)	3 (2.1%)	5 (0.8%)

Main issues encountered…

4. Far from a “one-proc-away” principle

Visit	Value	Bas.	EOT
1	23		
2	22	Y	
3	23		
4	25		
5	24		Y

Visit (2)	Value
Baseline	22
3	23
4	25
5	24
EOT	24

		Placebo	SARXXX
Baseline	Value		
	N	xx	xx
	Median (Q1,Q3)	xx(xx.xx)	xx(xx.xx)
	Mean(SD)	xx.xx(xx.xx)	xx.xx(xx.xx)
	Min ; Max	xx ; xx	xx ; xx
Visit xx	Value		
	N	xx	xx
	Median (Q1,Q3)	xx(xx.xx)	xx(xx.xx)
	Mean(SD)		
	Min ; Max		
	Change from		
	N		
	Median (Q1,(		
	Mean(SD)		
	Min ; Max		
EOT	Value		
	N		
	Median (Q1,(		
	Mean(SD)		
	Min ; Max		
	Change from eline		
	N	xx	xx
	Median (Q1,Q3)	xx(xx.xx)	xx(xx.xx)
	Mean(SD)	xx.xx(xx.xx)	xx.xx(xx.xx)
	Min ; Max	xx ; xx	xx ; xx

One row needed per timepoint + EOT is one of the Visits xx !

PGM= SARxxxxx/YYYxxxx/CSR/PGM RPT/axxxx.sas OUT= OUTPUT/xxxxx.xxx (date - time)

Conclusion…

MERCI!