



**Let food be thy medicine and medicine be
thy food**



Fatima Kassim & Louella Schoemacher

Agenda



- Introduction
- CRF Design
- Data collection and data management
- Data standardisation
- Regulatory requirements
- Discussion and take-home messages

Introduction: who are we?



- Career starters at OCS Life Sciences 2,5 years ago
- Fatima Kassim
 - Graduated in Chemical Sciences
 - Nowadays data standardisation and creation of TLF for pharmaceutical clinical trials
- Louella Schoemacher
 - Graduated in Nutrition and Health
 - Nowadays data standardisation and creation of TLF for nutritional studies
- What can we learn from each other?





“Dear diary,

This morning I had one bowl of yoghurt. I drank one glass of grapefruit juice and one glass of water to take my medication.”

Case Laura Smith



35-year old woman

Complaints: Diarrhoea

Pharma



- Exposure:
Drug A100: Loperamide bioequivalent
- Outcome measurements:
Blood samples, physical examinations including vitals.

Nutrition



- Exposure:
Yoghurt with added probiotics
- Outcome measurements:
questionnaires about stools, physical activity and food intake

CRF Design part 1



Pharma



- (SDTM) annotated
- Options for units, e.g. “g” or “mg”
- Controlled answers

SV = Subject Visits				Screening Visit
DM = Demographics	Page: - 1 -			
DS = Disposition	Date of Visit:			
DEMOGRAPHY				
DSTERM = "INFORMED CONSENT OBTAINED"				
Date of written Inform Consent:				
DSSDTC when DSTERM = "INFORMED CONSENT OBTAINED"				
Date of Birth:	Sex:	Race:		
	☐ Male	☐ Asian		
	☐ Female	☐ Black		
		☐ Hispanic		
		☐ White		
		☐ Not listed		

Nutrition



- Conditional questions
- Diaries
- Free-text

<u>Nationality</u>	
*In what country is the mother born?	Text
*In what country is the father born?	Text
*In what country is the infant born?	Text

CRF Design part 2



Pharma



Alcohol consumption: **SUTRT = "ALCOHOL"** **SUCAT = "ALCOHOL CONSUMPTION"**
(N) ☐ No **SUOCCUR** (Y) ☐ Yes ⇒ Average daily consumption: g/day **SUDOSFRQ**
SUTRT = "XANTHINES" **SUCAT = "XANTHINES CONSUMPTION"**
Xanthines consumption:
(N) ☐ No **SUOCCUR** (Y) ☐ Yes ⇒ Average daily consumption: Cup/day **SUDOSFRQ**

Fasting status: Is the patient 10-hour fasting?
☐ No → Reschedule a visit within 2 days*
☐ Yes **LBFAST**

Date of specimen collection blood(haematology and biochemistry) and urine
LBDTC
____ - ____ - ____
d d m m m y y y y

Time of sampling: **LBDTC** ____ : ____ (24-hour clock; hr : min)

Please copy label text: **LBREFID** _____

Nutrition



3. Thinking about a usual day in the past week, how many times did milk come out of your baby's mouth?
☐ 0 times in a usual day
☐ 1 time in a usual day
☐ 2 to 3 times in a usual day
☐ 4 to 6 times in a usual day
☐ 7 or more times in a usual day
☐ Don't know or no response
[If response is 0 times in a usual day, then skip Questions 4-6;]

29. Did you take any medicines or nutritional supplements (DHA, vitamins, minerals, etc.) during the pregnancy? Yes ☐ No ☐
If yes, please provide info on the kind and brand names. _____

*Did you have a normal conception or via IVF? Text



Data collection and management

Pharma



- Exposure – Outcomes
- EDC (electronic data capture)
 - SAS, R
- Data manager and queries

Nutrition



- Exposure (environmental factors) – outcomes
- Often SPSS and Excel files
- Principal investigator and research assistants



Data standardisation

Pharma



- SDTM domains based on pharma
- Variables accommodate "pharmaceutical" data
- Many TAUGs
 - Different disease areas
- Findings

Nutrition



- SDTM domains not based on food
- Variables do not accommodate "nutritional" data
- Nutrition TAUG
 - Product – nutrient hierarchy
- Findings about

Exposure



■ *Pharma*

STUDYID	DOMAIN	USUBJID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE
CDISC	EX	CDISC-01	DRUGA100	5	mg	SUSPENSION	ORAL

■ *Nutrition*

STUDYID	DOMAIN	USUBJID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE
CDISC	EX	CDISC-01	YOGHURT WITH ADDED PROBIOTICS	150	ml	SUSPENSION	ORAL

STUDYID	DOMAIN	USUBJID	MLTRT	MLDOSE	MLDOSU	MLDOSFRM	MLROUTE
CDISC	ML	CDISC-01	SANDWICH	2	SLICE		ORAL
CDISC	ML	CDISC-01	JAM				ORAL
CDISC	ML	CDISC-01	GRAPEFRUIT JUICE	1	GLASS		ORAL
CDISC	ML	CDISC-01	WATER	1	GLASS		ORAL

Compliance



- *Pharma*

STUDYID	DOMAIN	USUBJID	DATESTCD	DATEST	DACAT	DAORRES	DAORRESU
CDISC	DA	CDISC-01	DISPAMT	Dispensed Amount	Study Product	30	CAPSULES
CDISC	DA	CDISC-01	RETAMT	Returned Amount	Study Product	10	CAPSULES

- *Nutrition*

- Product accountability domain under construction

STUDYID	DOMAIN	USUBJID	PATESTCD	PATEST	PACAT	PAORRES	PAORRESU
CDISC	PA	CDISC-01	DISPAMT	Dispensed Amount	Study Product	300	mL
CDISC	PA	CDISC-01	RETAMT	Returned Amount	Study Product	150	mL
CDISC	PA	CDISC-01	DISPAMT	Dispensed Amount	Study Product	2	CUP
CDISC	PA	CDISC-01	RETAMT	Returned Amount	Study Product	1	CUP



Regulatory requirements

Pharma



- Regulatory agencies
 - FDA, EMA, PMDA
 - International and national laws
- Study registration and submission process
 - NDA and market approval

Nutrition



- Regulatory agencies
 - FDA, EFSA
 - Less strict laws
- Not all studies are submitted for review (hospitals and universities)

Summary: What can be learned?



Pharma



- Keep environmental factors in mind
 - Consider impact of lifestyle

Nutrition



- Keep data standardisation in mind with CRF design
 - Collect data in more structured fields to ensure higher data quality
 - Data management focus more on standardisation



Discussion

- More things for nutritional studies to learn from pharma than the other way around with regards to standardisation.

However..

- Sense of urgency is lower in nutrition studies → standardisation not mandatory
- Change takes time (= money)
- More discussion on SDTM “fit” for nutrition
- Stimulate standardisation



Conclusion and take home messages

- Pharma more focussed on standardising data
- Shift in nutritional studies
- Standardisation of nutritional data could lead to:
 - More sustainable data (pooling)
 - More reproducible data

THANK YOU!



- sasquestions@ocs-consulting.com