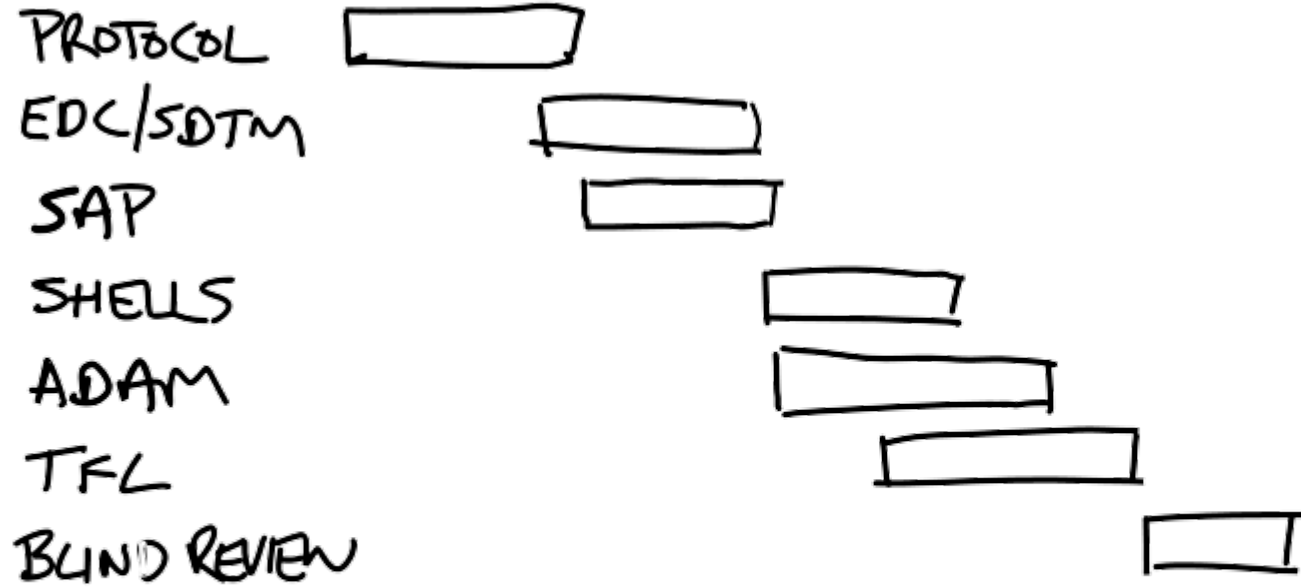


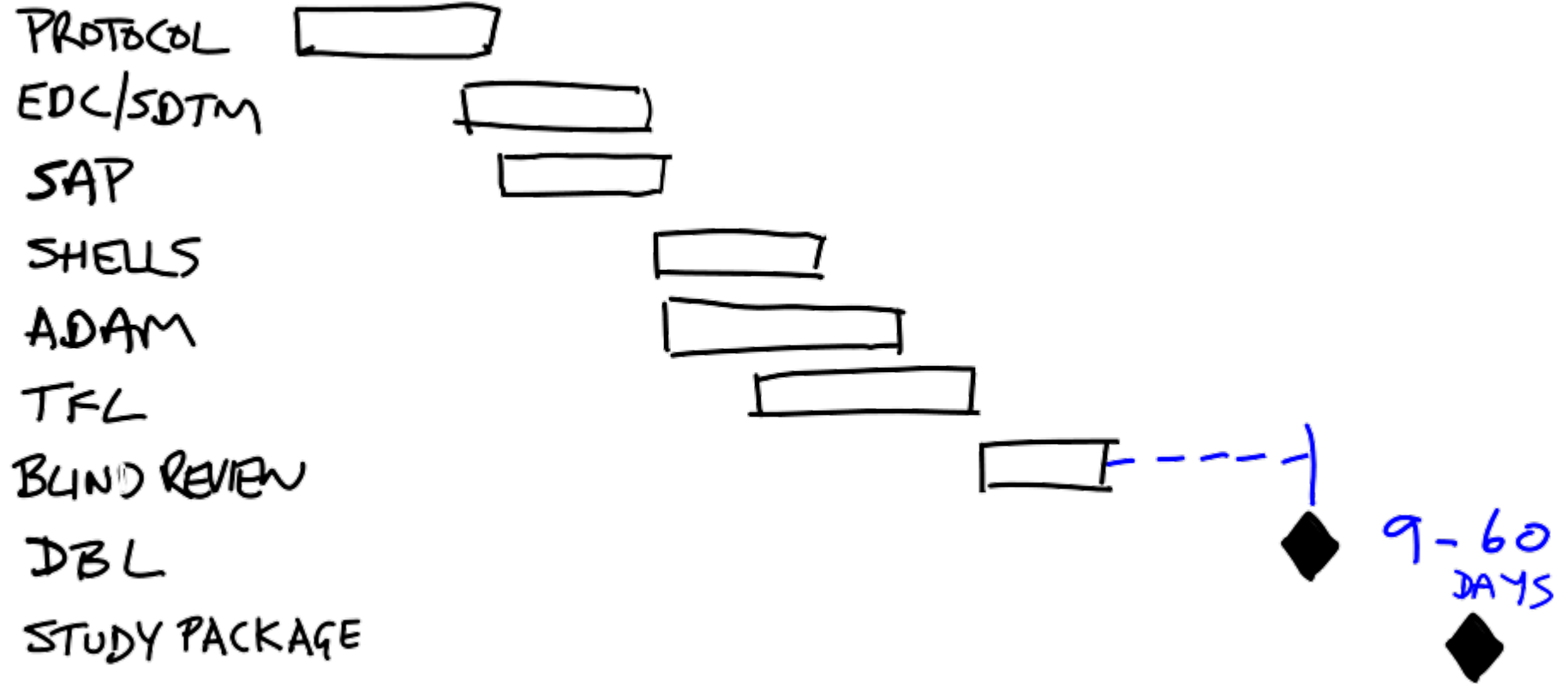
Automation of CDISC ADaM using Statistical Data and Metadata eXchange (SDMX)

Stuart Malcolm
PHUSE US Connect 2021
SI08

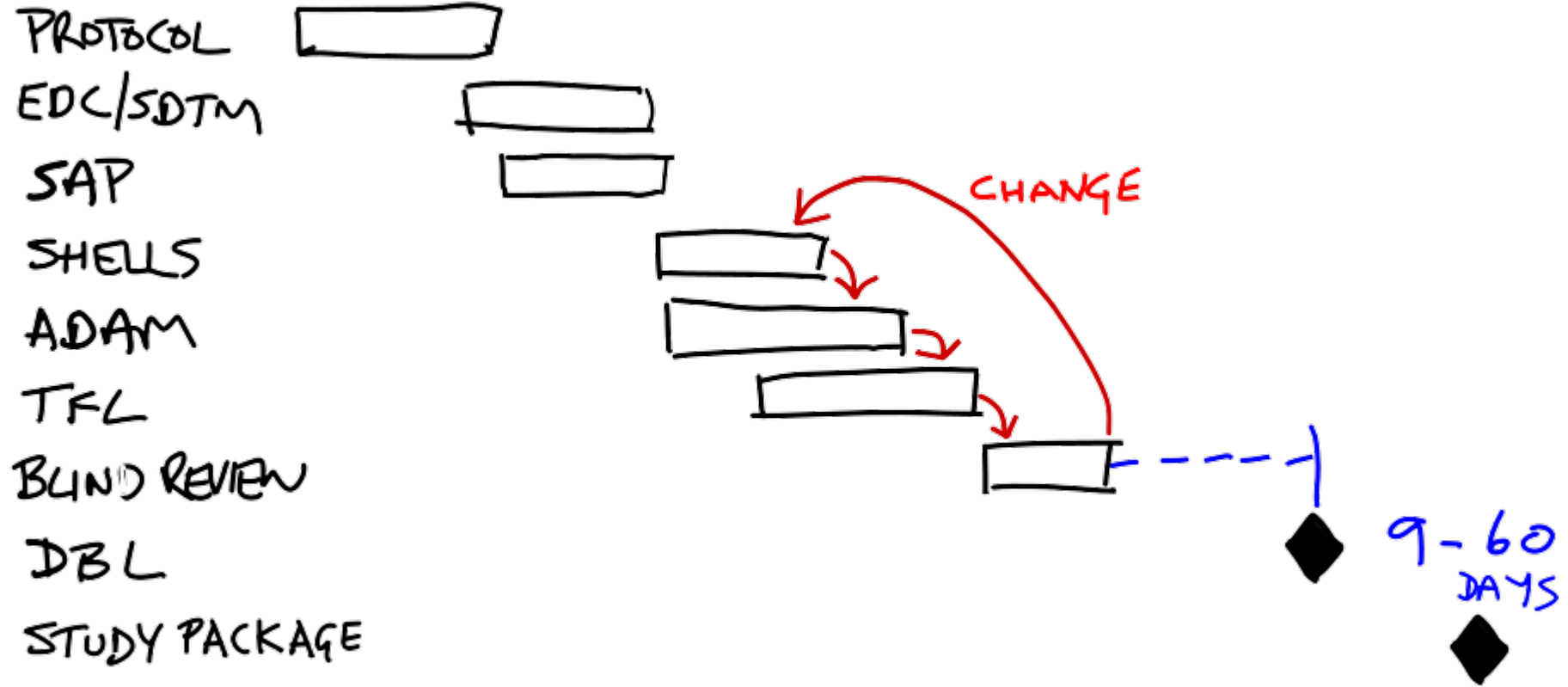
What's the problem?



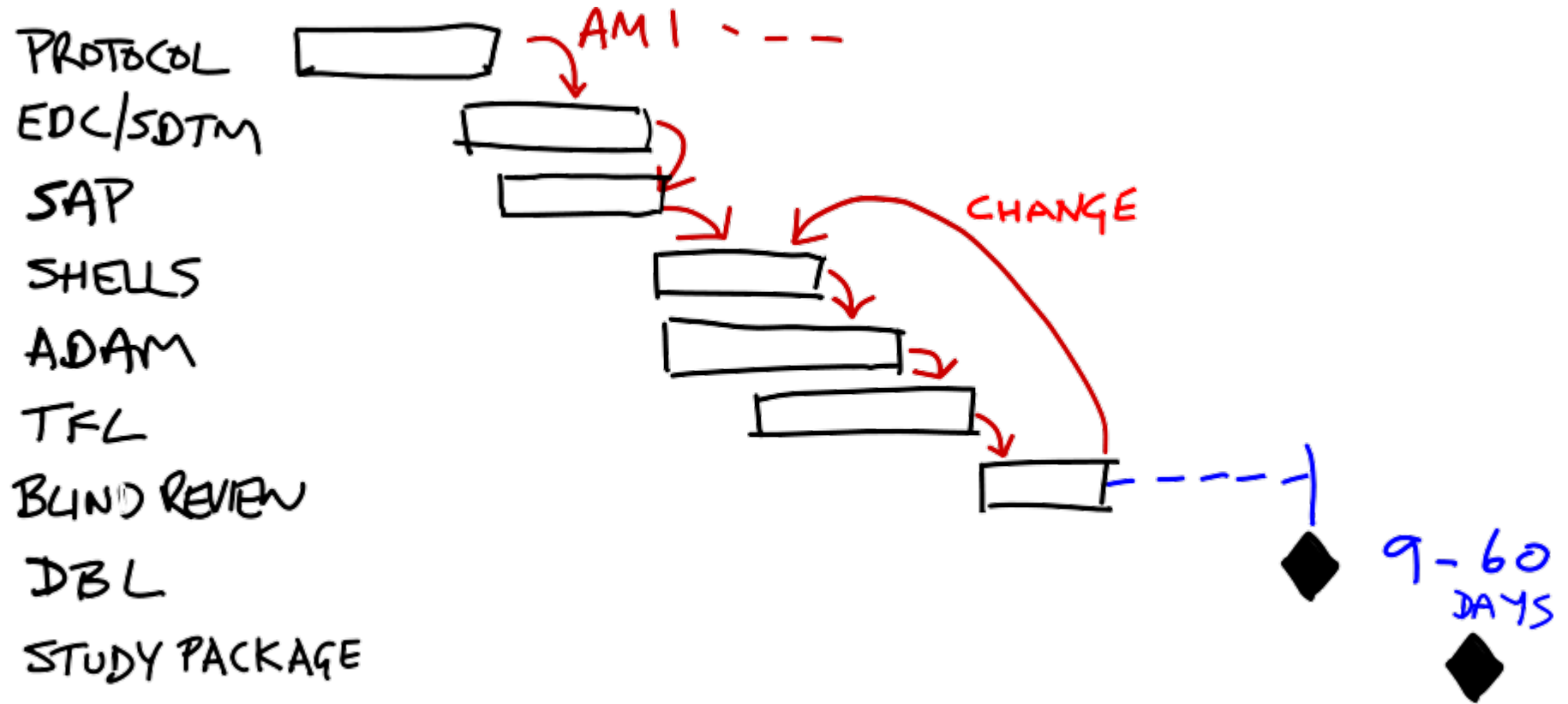
What's the problem?



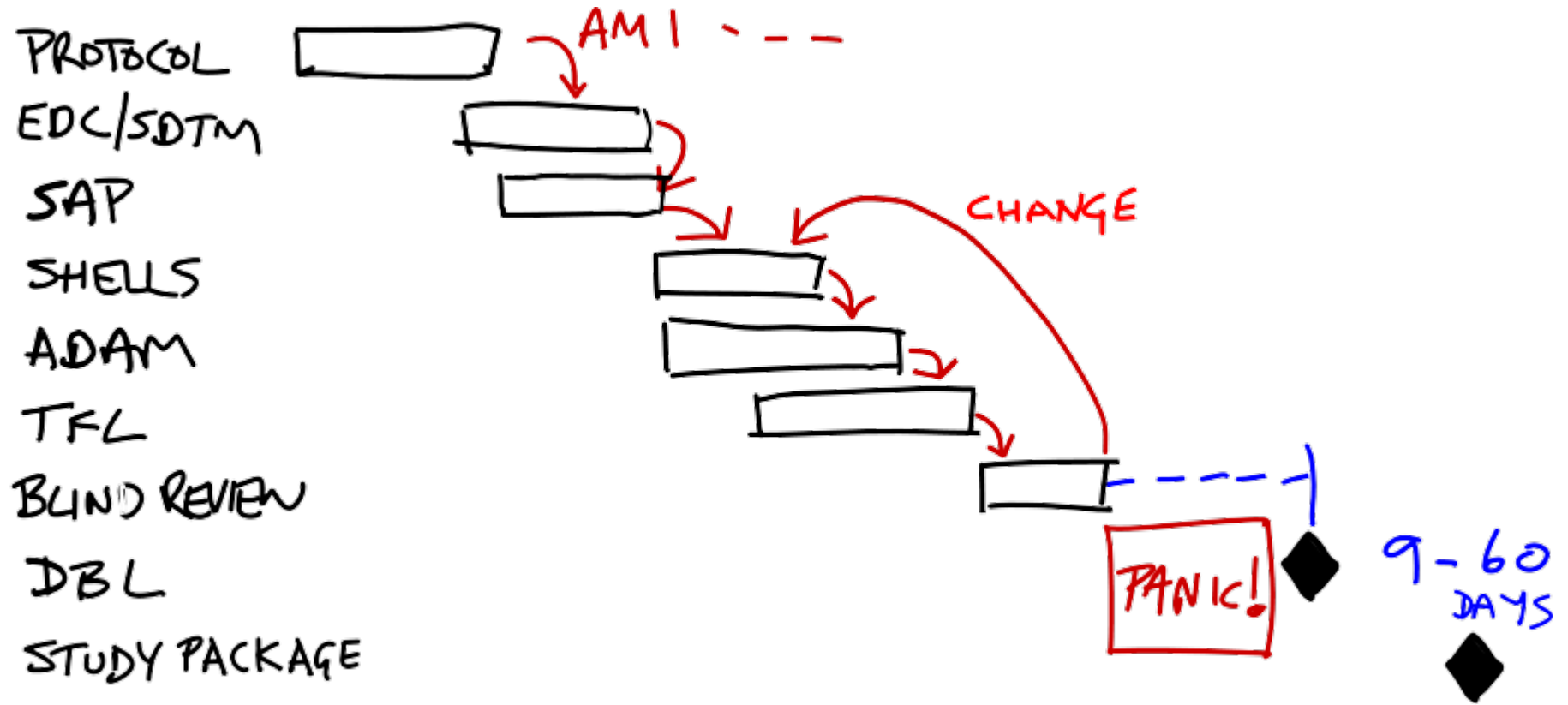
What's the problem?



What's the problem?



What's the problem?



New workflow

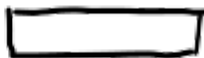
PROTOCOL



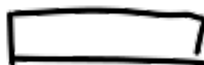
EDC/SDTM



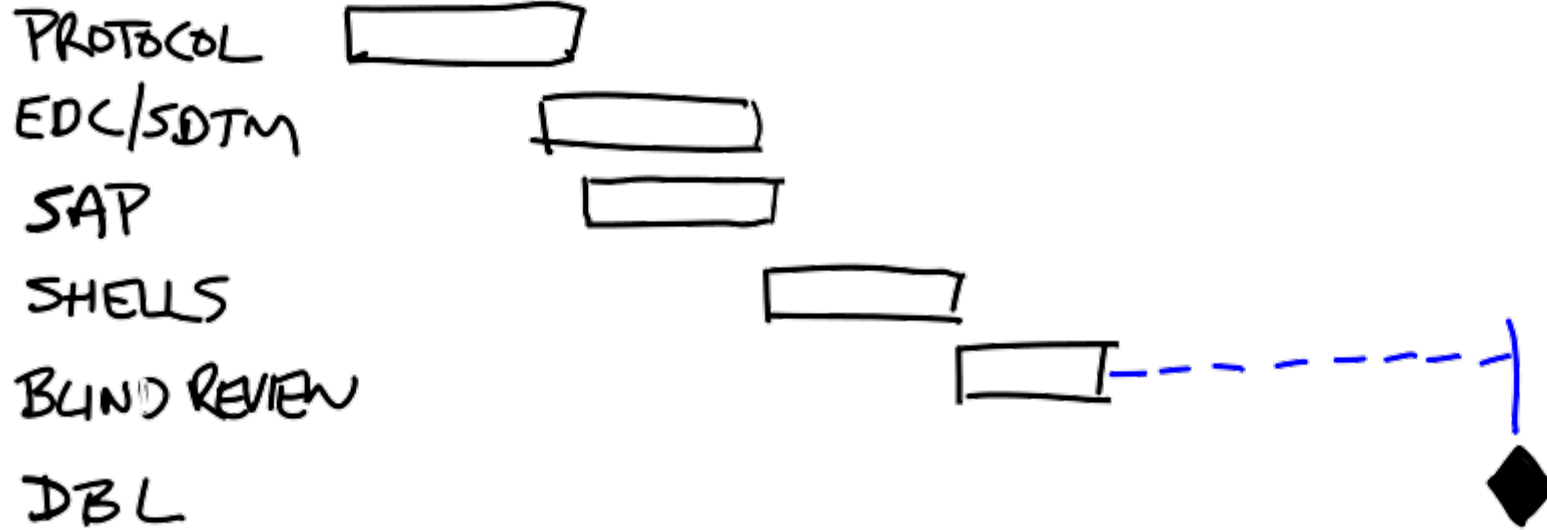
SAP



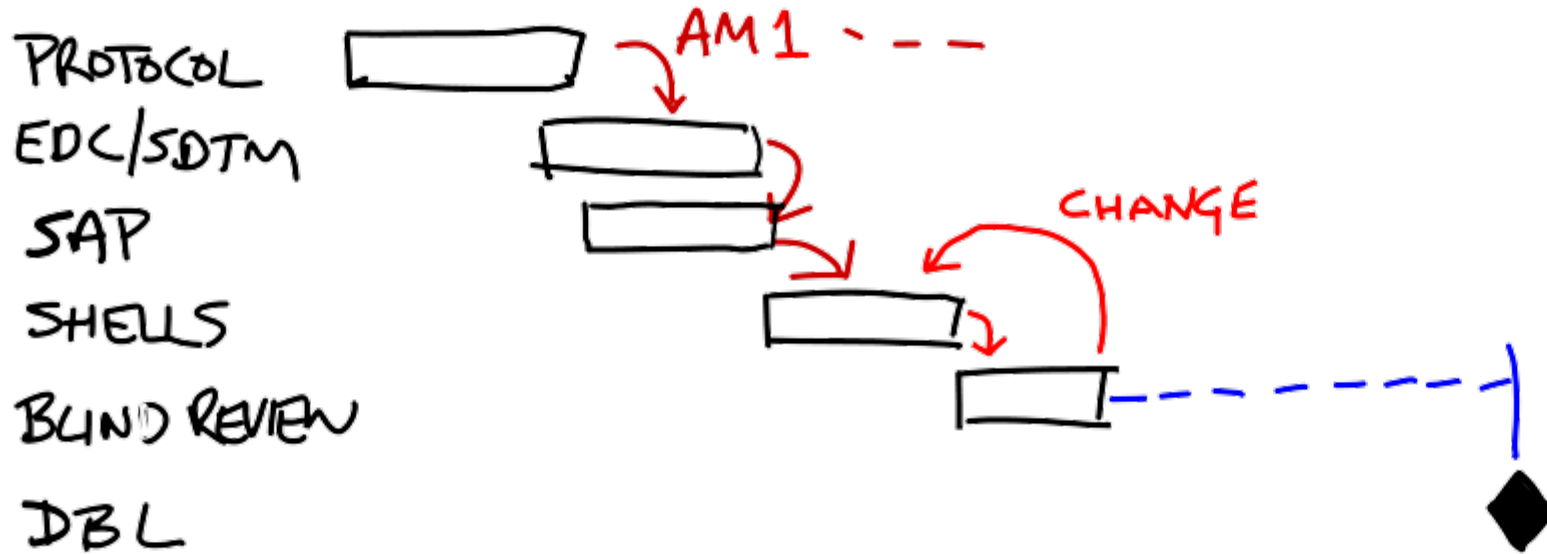
SHELLS



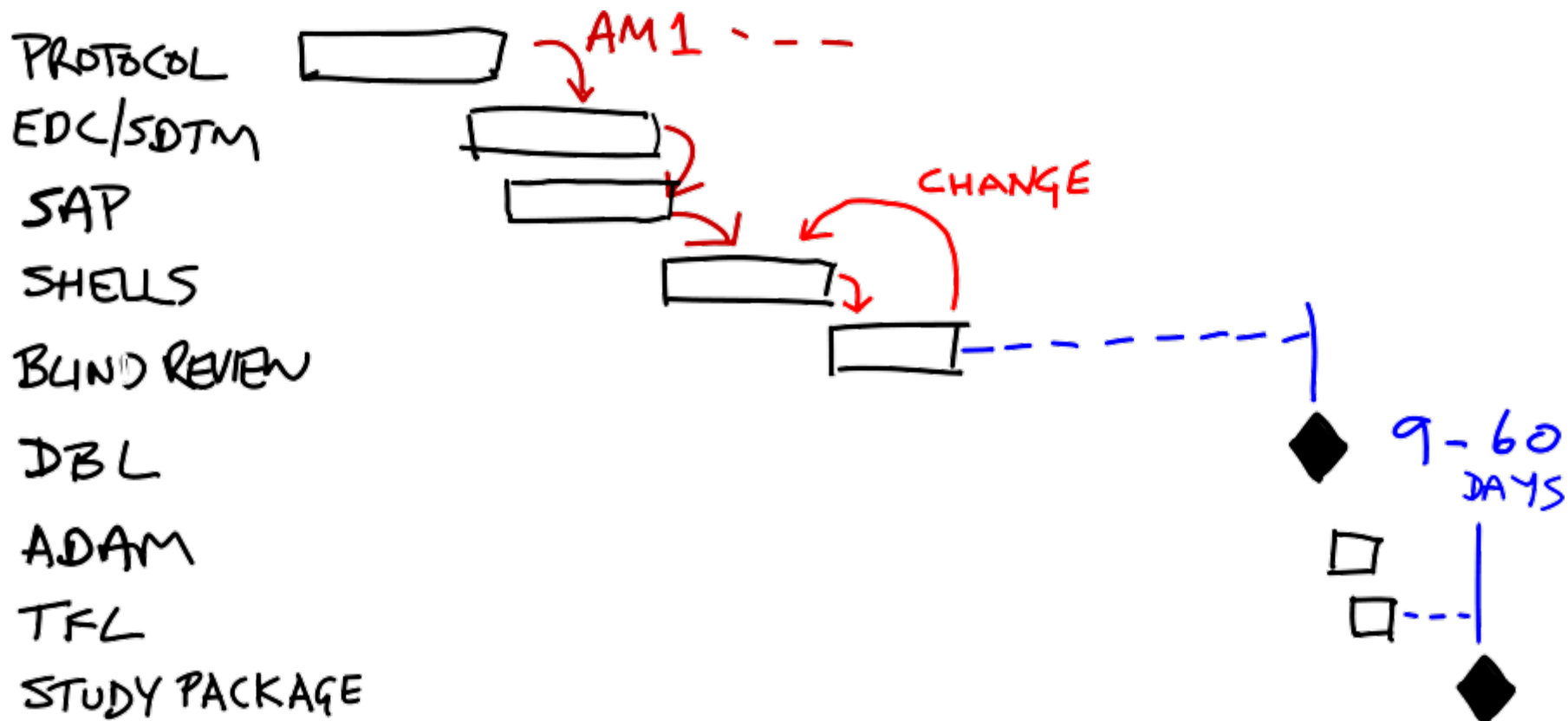
New workflow



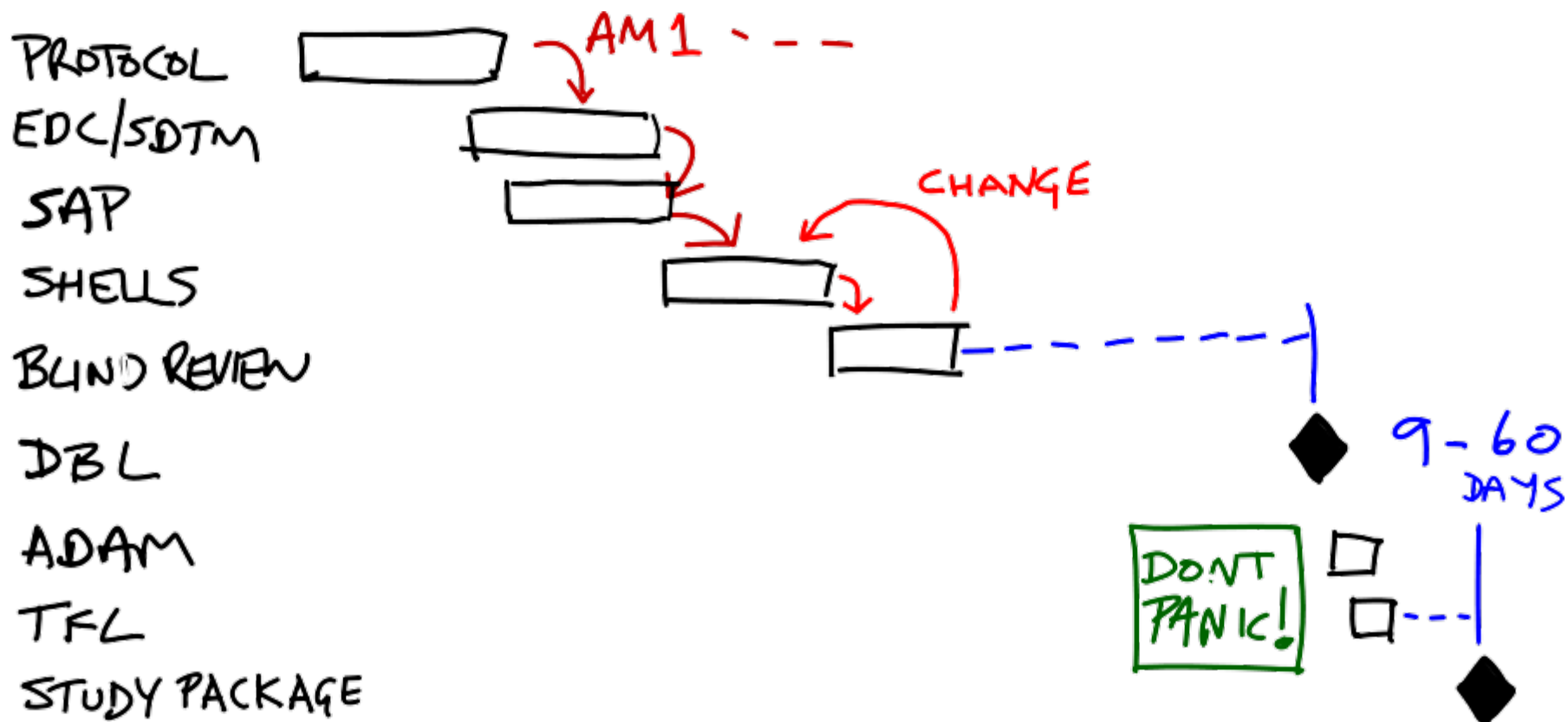
New workflow



New workflow

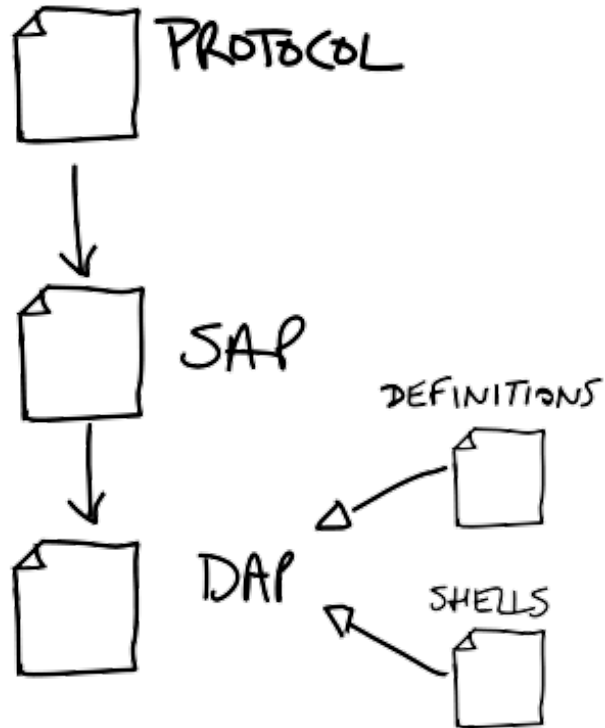


New workflow



New dataflow

DOCUMENTS

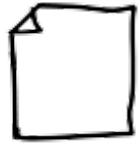


New dataflow

TOOLS

DOCUMENTS

WORD



PROTOCOL



WORD



SAP



WORD



DAP

DEFINITIONS



SHELLS



New dataflow

TOOLS

DOCUMENTS

METADATA

WORD



PROTOCOL

WORD



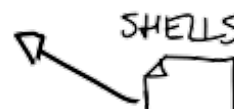
SAP

~~WORD~~



DAP

DEFINITIONS



SHELLS

TRIAL
METADATA



STANDARDS
METADATA



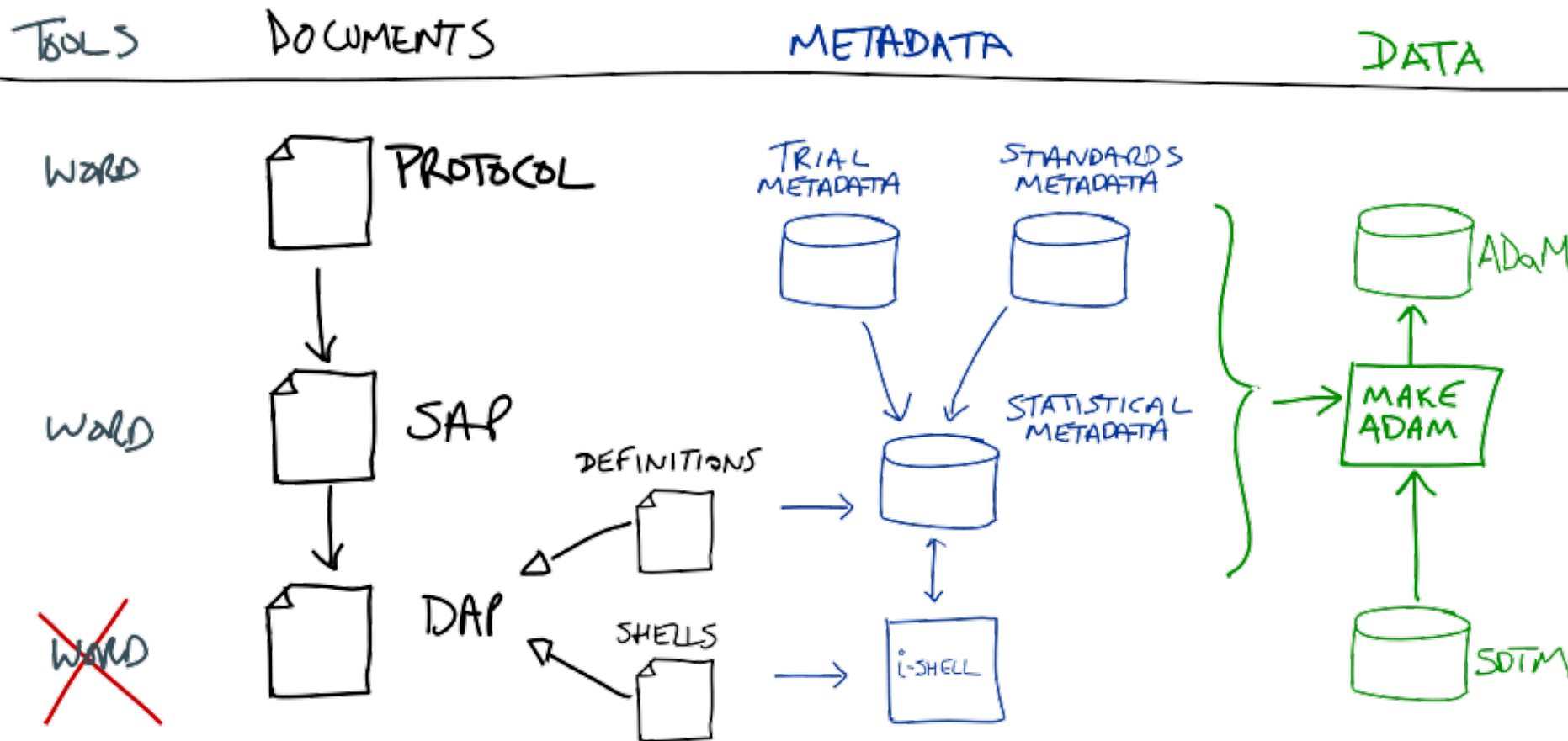
STATISTICAL
METADATA



L-SHELL

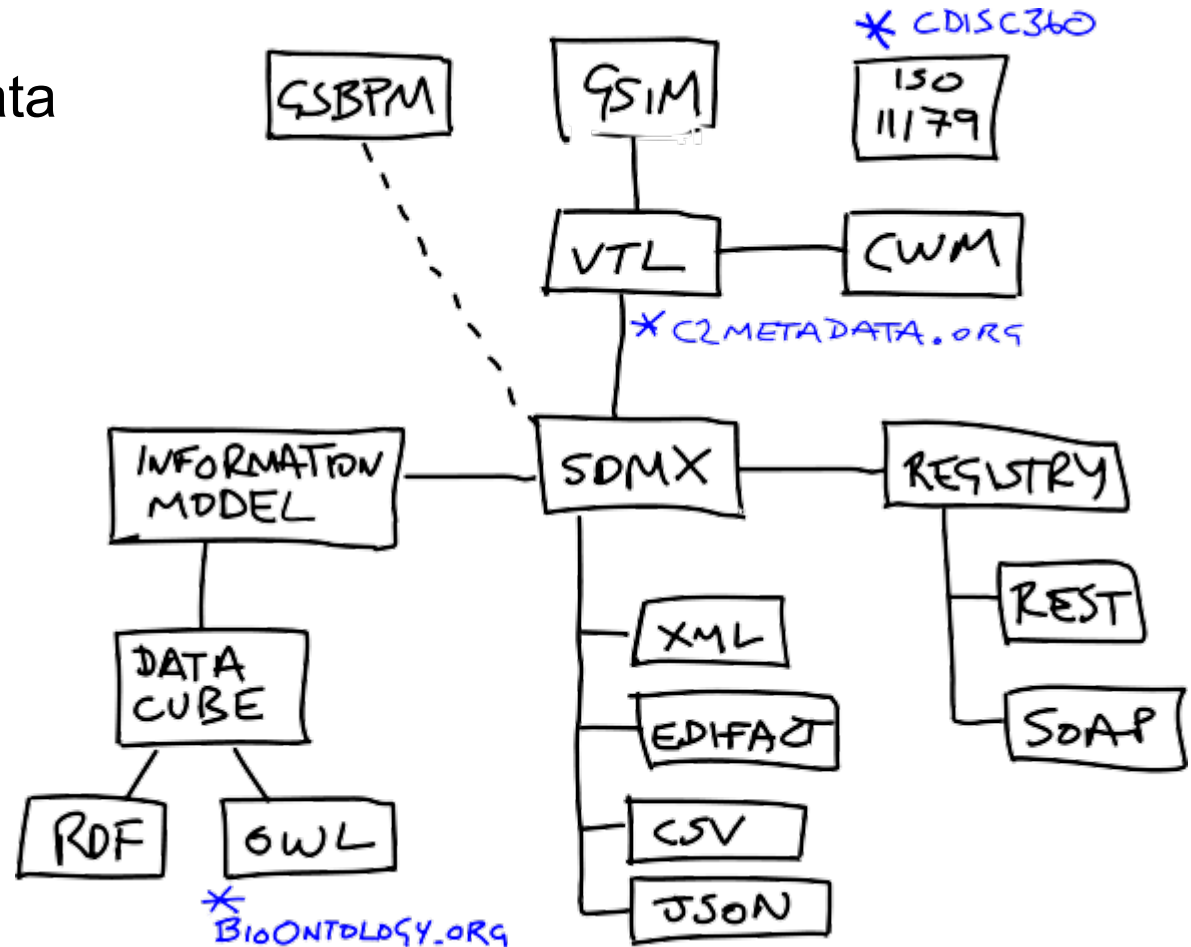


New dataflow



What is SDMX?

- Statistical Data & Metadata Exchange
- Established 2002
- UN, IMF, OECD, etc.
- ISO 17369
- Domain neutral
- Comprehensive



What is a data cube?

INFORMATION
MODEL



CODELIST



DATA FORMAT



What is a data cube?

INFORMATION
MODEL

STRUCTURE
DEFINITION



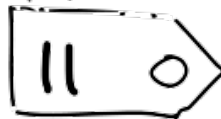
CODELIST



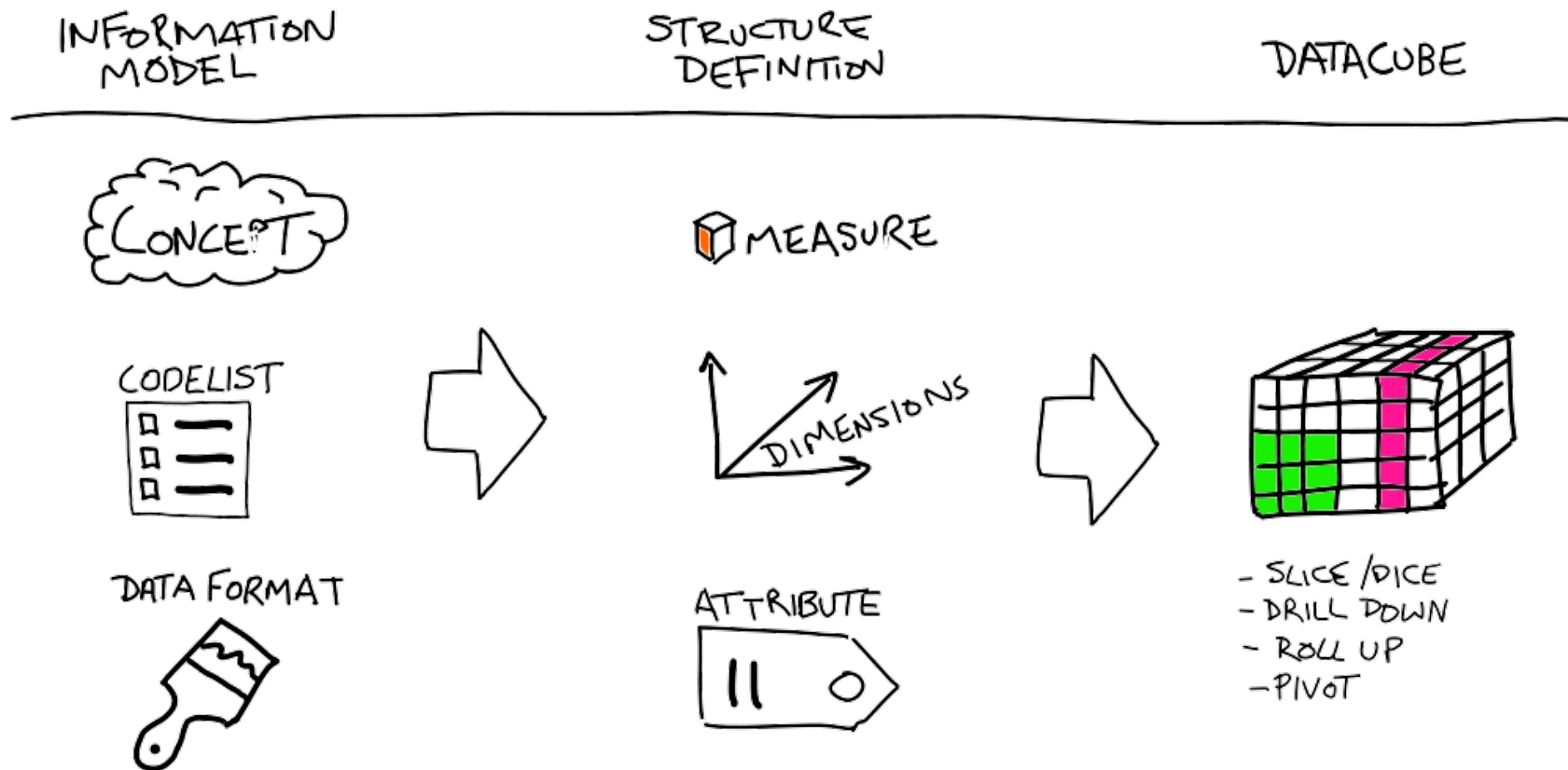
DATA FORMAT



ATTRIBUTE



What is a data cube?



Profile of Mood (POMS) Form

Subscale + Total Scores

5-point
Likert scale [0,4]

Total Mood disturbance
[-32,200]
= (Tension+Depression+
+Anger+Fatigue
+Confusion) - Vigor

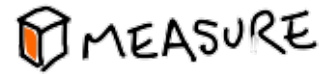
6 subscales:
Tension [0-36]
Depression [0-60]
Anger [0-48]
Vigor [0-32]
Fatigue [0-28]
Confusion [0-28]

The diagram illustrates the structure of the ADAMOOD dataset and the calculation of the Total Mood Disturbance score. It shows a central box labeled 'ADMOOD' which is linked to a 'Profile of Mood (POMS) Form' and 'Subscale + Total Scores'. The 'Profile of Mood (POMS) Form' is linked to a '5-point Likert scale [0,4]'. The 'Subscale + Total Scores' box lists six subscales: Tension [0-36], Depression [0-60], Anger [0-48], Vigor [0-32], Fatigue [0-28], and Confusion [0-28]. The '5-point Likert scale [0,4]' is linked to the 'Total Mood disturbance [-32,200]' box, which contains the formula:
$$\text{Total Mood disturbance} [-32,200] = (\text{Tension} + \text{Depression} + \text{Anger} + \text{Fatigue} + \text{Confusion}) - \text{Vigor}$$

QBMOOD

INFORMATION
MODEL

STRUCTURE
DEFINITION



CODELIST



DATA FORMAT



ATTRIBUTE



QBMOOD

INFORMATION
MODEL

STRUCTURE
DEFINITION



- MULTIVARIATE VARIANCE
- PROFILE OF MOOD (POMS)
- SUBSCALE SCORES
- TOTAL SCORE

CODELIST



- LIKERT SCALE [0,4]
- VISIT [BASELINE, WEEK 6]
- STATO [MANOVA]
- SNOWMED-CT [POMS]
- DISC-CT [LIKERT]

DATA FORMAT



- INTEGER
- RANGE [-32,200]

 MEASURE



ATTRIBUTE



QBMOOD

INFORMATION MODEL



- MULTIVARIATE VARIANCE
- PROFILE OF MOOD (POMS)
- SUBSCALE SCORES
- TOTAL SCORE

CODELIST



- LIKERT SCALE [0,4]
- VISIT [BASELINE, WEEK 6]
- STATO [MANOVA]
- SNOWMED-CT [POMS]
- DISC-CT [LIKERT]

DATA FORMAT



- INTEGER
- RANGE [-32,200]

STRUCTURE DEFINITION



MEASURE

- SCORE
- CHANGE FROM BL



- SUBJECT
- SCALE
- VISIT
- MEASURE

ATTRIBUTE

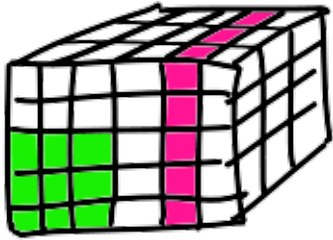


- TREATMENT
- POPULATION

QBMOOD -> ADMOOD

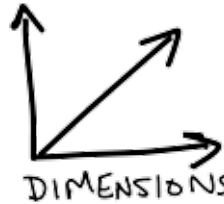
QBMOOD

DATA CUBE
STRUCTURE



MEASURE

- SCORE
- CHANGE FROM BL



DIMENSIONS

- SUBJECT
- SCALE
- VISIT
- MEASURE

ATTRIBUTE



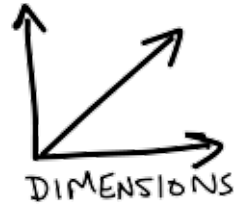
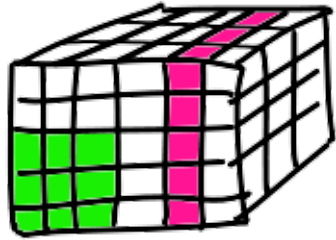
- TREATMENT
- POPULATION

QBMOOD -> ADMOOD

QBMOOD

DATA CUBE
STRUCTURE

ADaM



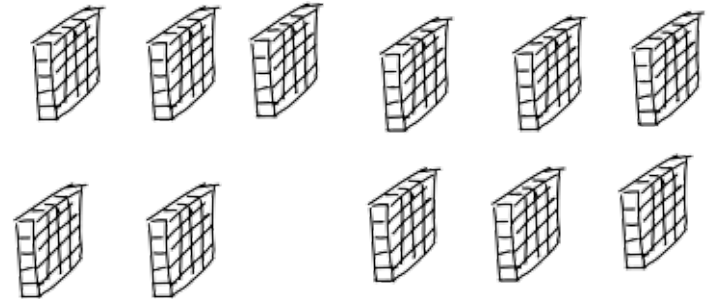
ATTRIBUTE



- SCORE
- CHANGE FROM BL

- SUBJECT
- SCALE
- VISIT
- MEASURE

- TREATMENT
- POPULATION

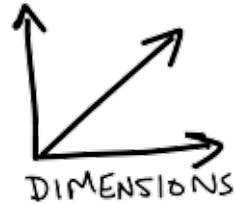
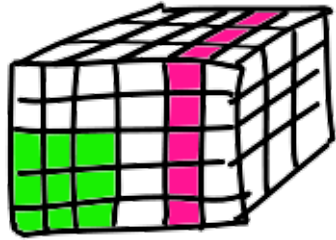


QBMOOD -> ADMOOD

QBMOOD

DATA CUBE
STRUCTURE

ADaM



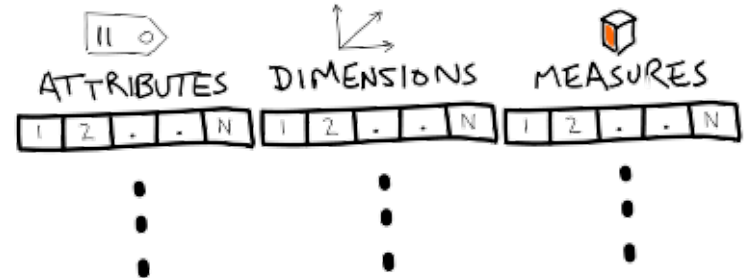
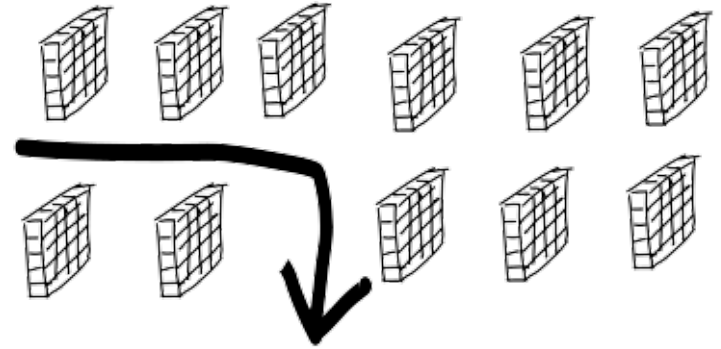
ATTRIBUTE



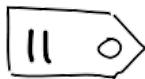
- SCORE
- CHANGE FROM BL

- SUBJECT
- SCALE
- VISIT
- MEASURE

- TREATMENT
- POPULATION



ADaM.ADMOOD



ATTRIBUTES



DIMENSIONS



MEASURES

Row	STUDYID	USUBJID	TRTP	TRTPN	ITTFL	PARAM	PARAMCD	AVISIT	AVISITN	ABLFL	AVAL	BASE	CHG
1	MXX123	101-001	Drug ZZZ	1	Y	Tension/Anxiety Total Score	ANXIETY	Baseline	2	Y	8	8	
2	MXX123	101-001	Drug ZZZ	1	Y	Depression/Rejection Total Score	DPRESS	Baseline	2	Y	3	3	
3	MXX123	101-001	Drug ZZZ	1	Y	Anger/Hostility Total Score	ANGER	Baseline	2	Y	4	4	
4	MXX123	101-001	Drug ZZZ	1	Y	Vigor/Activity Total Score	VIGOR	Baseline	2	Y	8	8	
5	MXX123	101-001	Drug ZZZ	1	Y	Fatigue/Inertia Total Score	FATIGUE	Baseline	2	Y	10	10	
6	MXX123	101-001	Drug ZZZ	1	Y	Confusion/Bewilderment Total Score	CONFUS	Baseline	2	Y	4	4	
7	MXX123	101-001	Drug ZZZ	1	Y	Total Score	TOTAL	Baseline	2	Y	37	37	
8	MXX123	101-001	Drug ZZZ	1	Y	Tension/Anxiety Total Score	ANXIETY	Week 6	4		7	8	-1
9	MXX123	101-001	Drug ZZZ	1	Y	Depression/Rejection Total Score	DPRESS	Week 6	4		5	3	2
10	MXX123	101-001	Drug ZZZ	1	Y	Anger/Hostility Total Score	ANGER	Week 6	4		16	4	12
11	MXX123	101-001	Drug ZZZ	1	Y	Vigor/Activity Total Score	VIGOR	Week 6	4		15	8	7
12	MXX123	101-001	Drug ZZZ	1	Y	Fatigue/Inertia Total Score	FATIGUE	Week 6	4		9	10	-1
13	MXX123	101-001	Drug ZZZ	1	Y	Confusion/Bewilderment Total Score	CONFUS	Week 6	4		3	4	-1
14	MXX123	101-001	Drug ZZZ	1	Y	Total Score	TOTAL	Week 6	4		55	37	18

Summary

- SDMX
 - Mature, comprehensive, ISO and W3C standards
- Domain neutral
 - Generic operations: Slice/Dice/Roll/Drill/Pivot
 - Generic programs: Vizualisation, Automation
- Challenges
 - New workflow, new dataflow, new toolchain

<Thank you/>

- Contact me
 - <https://www.linkedin.com/in/stuart-malcolm/>
- Repository
 - <https://github.com/metadata-driven/CDISC-SDMX>
- Documentation
 - <http://www.metadata-driven.com/?s=SDMX>