

Quick Poll – Show of Hands



Experience with integration studies?



What would you prefer?

Option A – Integrated Studies from SDTM datasets

Option B - Integrated Studies from Raw CRF data



What would you prefer?

Option A – Integrated Studies from SDTM datasets

Option B - Integrated Studies from Raw CRF data



What would you prefer?

Option A – Integrated Studies from SDTM datasets

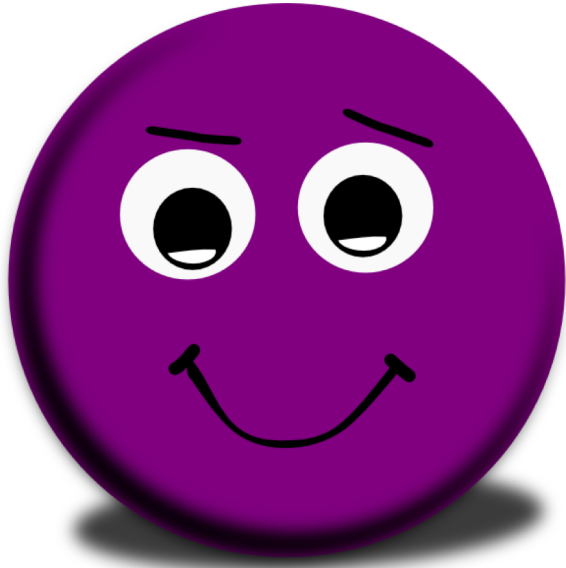
Option B - Integrated Studies from Raw CRF data



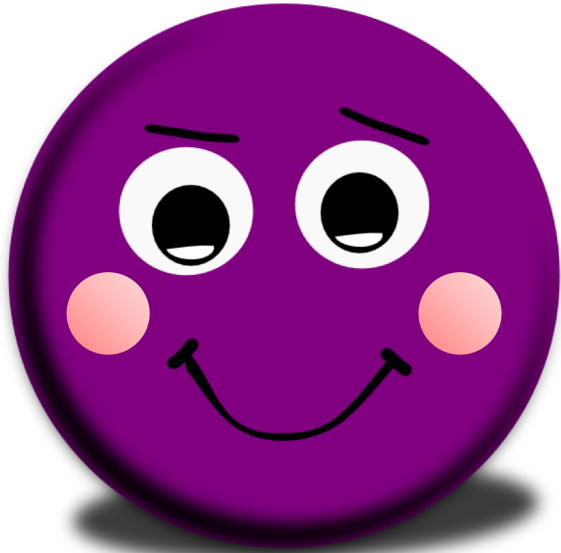
Simplifying the Integration Riddle

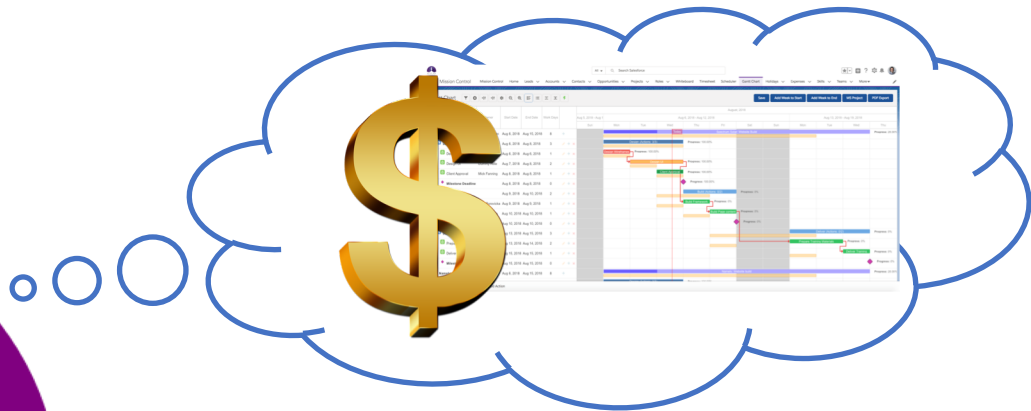
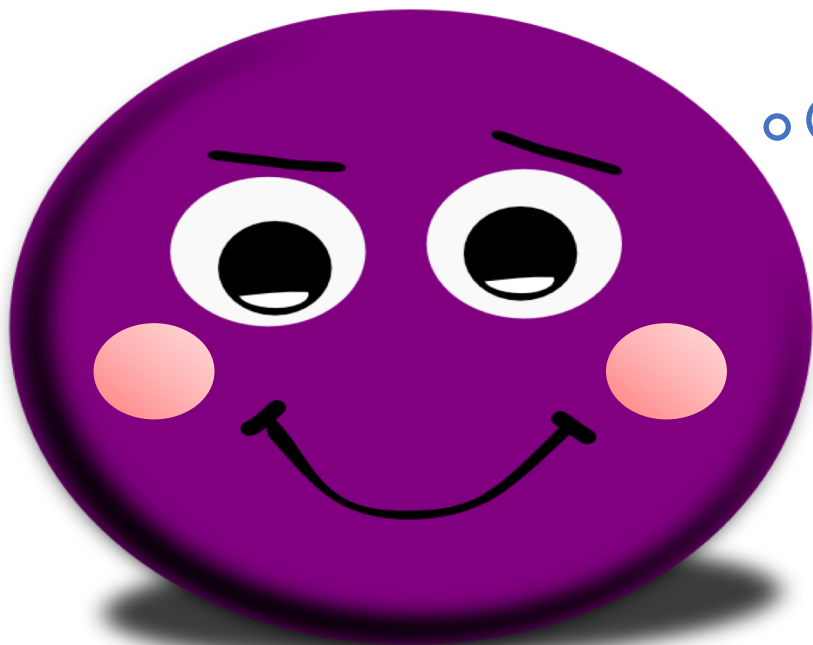


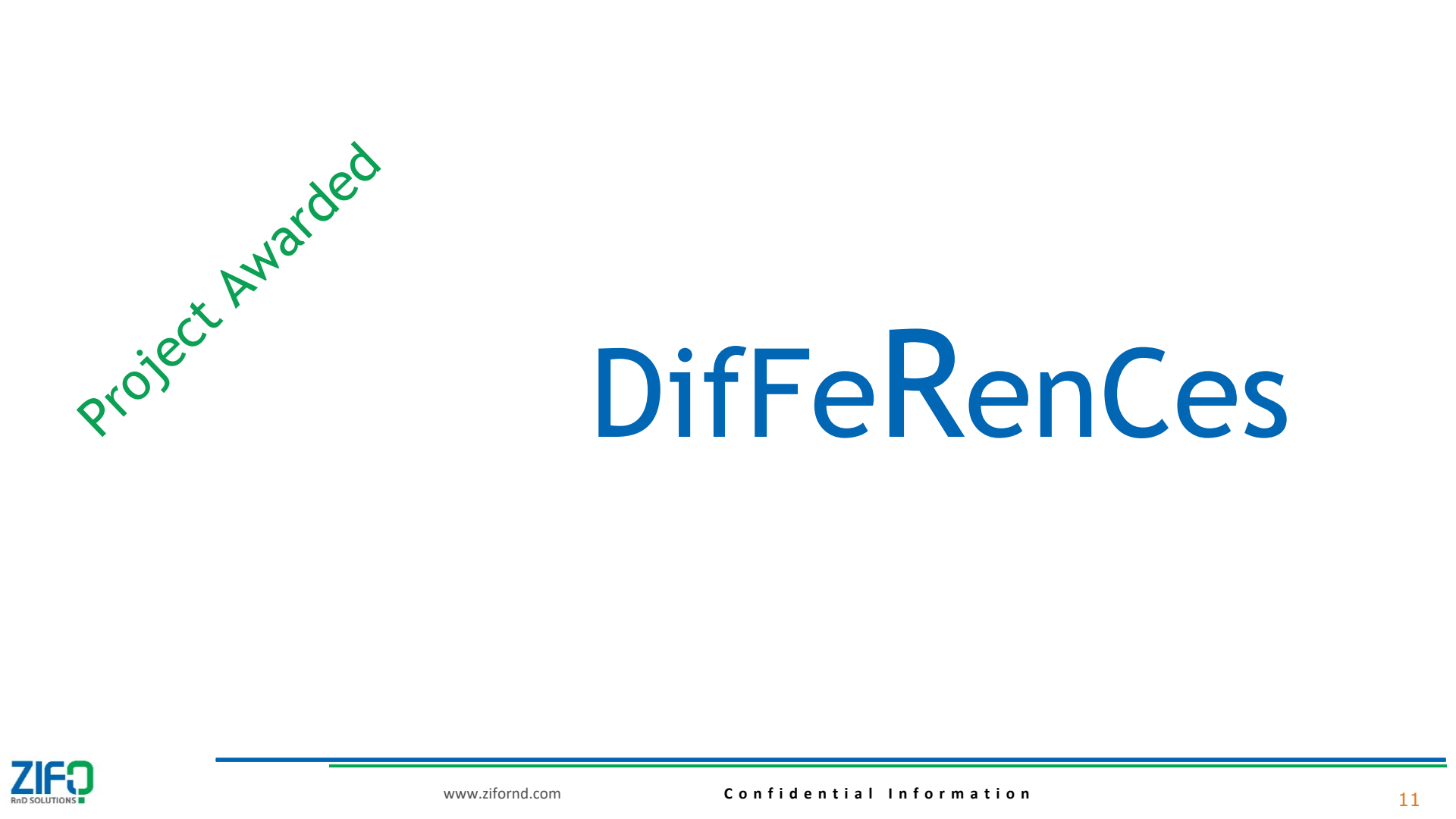
New Integration Project



New Integration Project from SDTM datasets



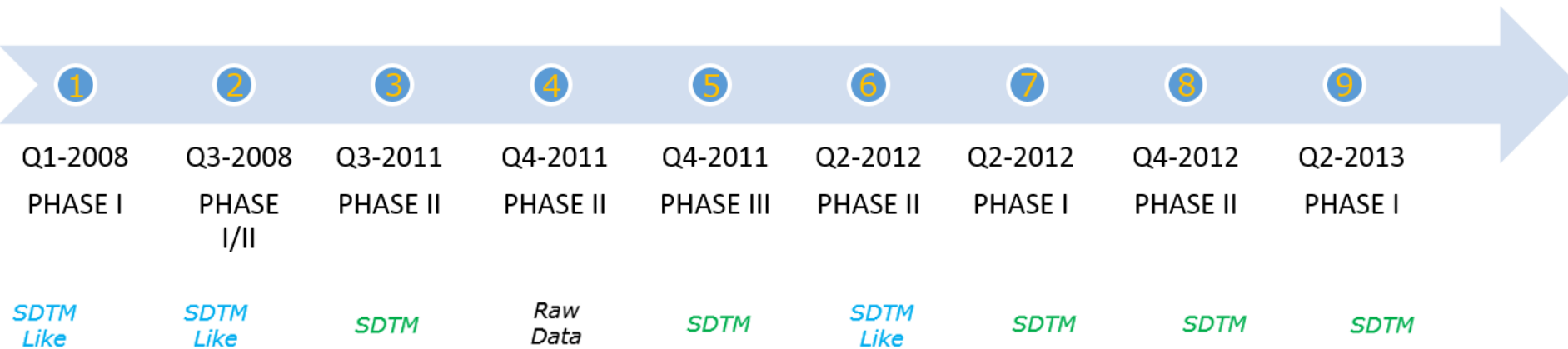




Project Awarded

DifFeRenCes

Different
Indications
End Points
EDC
CROs
Data Managers
Statistical Programmers



Source Data

SDTM “Like”

Studies are **not** created with
**foresight of Integrated
studies**

SDTM Datasets

5 of 9 Studies

Knowledge Drain

adding to timelines

SD0012	FDAC106	EXSTDY is after EXENDY	Limit	Error
SD0012	FDAC106	EXSTDY is after EXENDY	Limit	Error
SD0013	FDAC107	EXSTDTC is after EXENDTC	Limit	Error
SD0013	FDAC107	EXSTDTC is after EXENDTC	Limit	Error

SD0040	FDAC085	Inconsistent value for LBTEST within LBTESTCD	Consistency	Error
SD0040	FDAC085	Inconsistent value for LBTEST within LBTESTCD	Consistency	Error
SD1043	FDAC086	Inconsistent value for LBTESTCD within LBTEST	Consistency	Error
SD1043	FDAC086	Inconsistent value for LBTESTCD within LBTEST	Consistency	Error

QSTESTCD in source SDTMs	Corresponding QSTEST in Source SDTM	Actual QSTESTCD as per CT
FILLING	Filling Up Quickly When You Eat	EARLYSAT
PAINRIBS	Pain Under Ribs On Left Side	RIBSPAIN
ECOG	ECOG Performance Status	ECOG101
BNEPAIN	Bone Or Muscle Pain	BONEPAIN
LEFTPAIN	Pain Under Ribs On Left Side	RIBSPAIN

Looks Standardized Right?

FILLING
PAINRIBS
ECOG
BNEPAIN
LEFTPAIN
EARLYSAT
RIBSPAIN
ECOG101
BONEPAIN
RIBSPAIN



Macros to match with CT



FILLING
PAINRIBS
ECOG
BNEPAIN
LEFTPAIN

EARLYSAT
RIBSPAIN
ECOG101
BONEPAIN
RIBSPAIN

Example: AE relationship to study drug

<u>Study 1</u>	<u>Study 2</u>	<u>Study 3</u>	<u>Integrated</u>
No	Unlikely	None	None
Yes	Possible	Possible	Possible
	Probable	Definite	Probable
			Definite

Differences in data
collected across studies

Clarity in Analysis Plan



Different
CROs
Interpretation
Mapping

No documentation

Attribute Differences

Datatype Length

NAME	LENGTH	NAME	LENGTH
domain	2	domain	2
studyid	10	studyid	10
svendtc	10	svendtc	17
svendy	8	svendy	8
svstdtc	10	svstdtc	113
svstdy	8	svstdy	8
usubjid	18	usubjid	18
visit	17	visit	17
visitnum	8	visitnum	8

NAME	TYPE	NAME	TYPE
domain	2	domain	2
studyid	2	studyid	2
svendtc	2	svendtc	1
svendy	1	svendy	1
svstdtc	2	svstdtc	1
svstdy	1	svstdy	1
usubjid	2	usubjid	2
visit	2	visit	2
visitnum	1	visitnum	2

Huge Datasets

Good Coding Practices

Proc SQL or Merge or Hash objects

Divide and Conquer

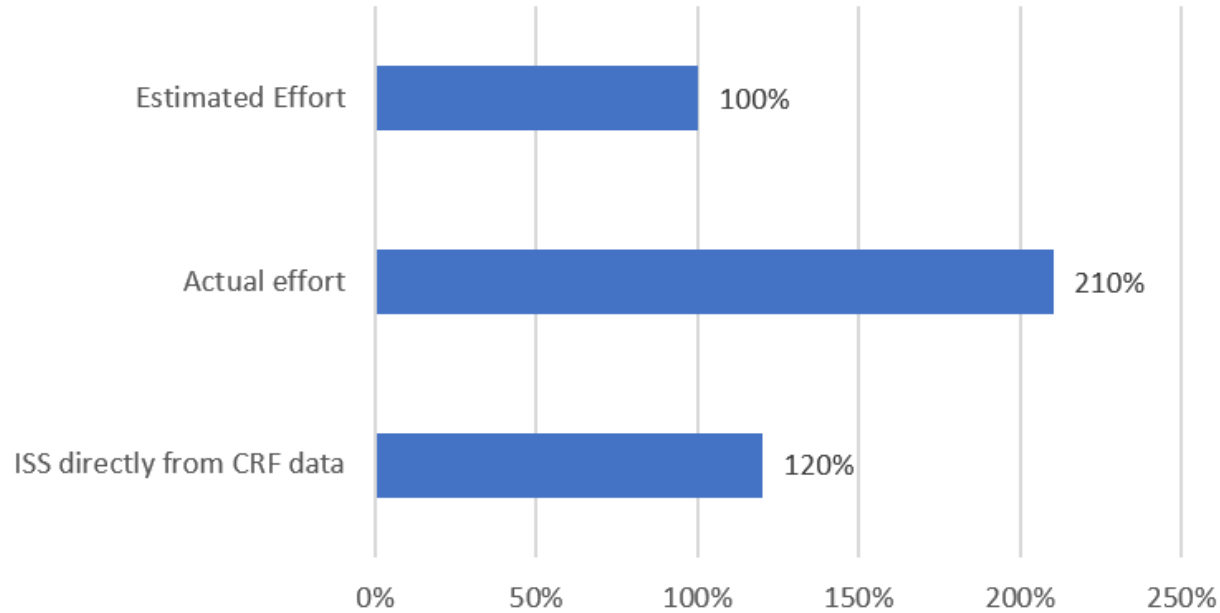
What would you prefer?

Option A - Creating ISS from SDTM datasets

Option B - Creating ISS from Raw CRF data



Comparison of effort







Thank You

Accelerating Research and Development