

**Clinical study
oversight:
different
approaches to
using data
standards**



AGENDA



Innovion



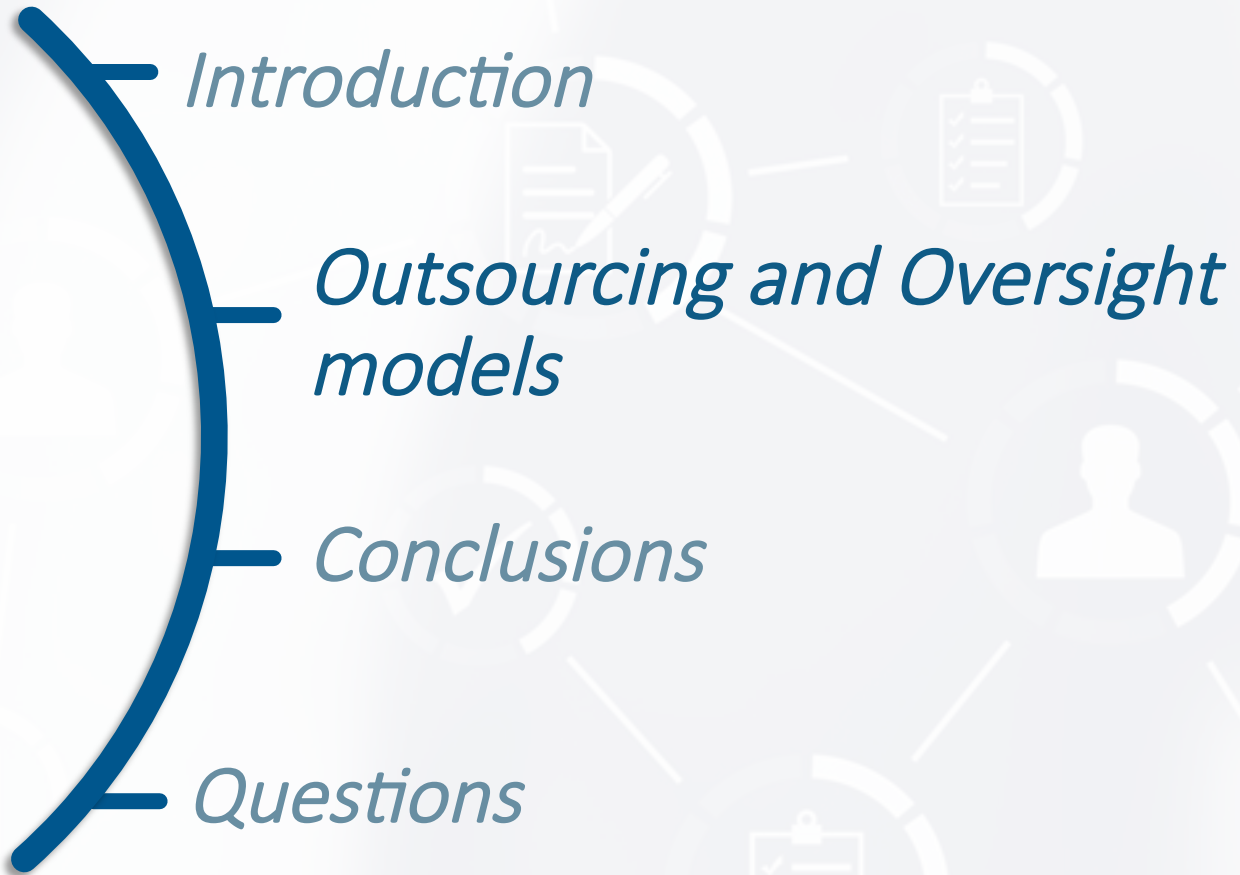
Common concerns when outsourcing

- ? Is my CRO collecting the right data?
- ? Will my data be fit for a regulatory submission?
- ? My CRO delivers “CDISC”, so I guess that’s good enough?
- ? Will I be able to compare data between different trials?
- ? Am I giving the right information to the CRO?
- ? How do I check the CRO deliverables?
- ? I am keeping my study data on my server, I guess that’s ok?

➔ *You may need Standards*



AGENDA



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OUTSOURCING AND OVERSIGHT MODELS



I Feel Lucky

Using a Standards Library

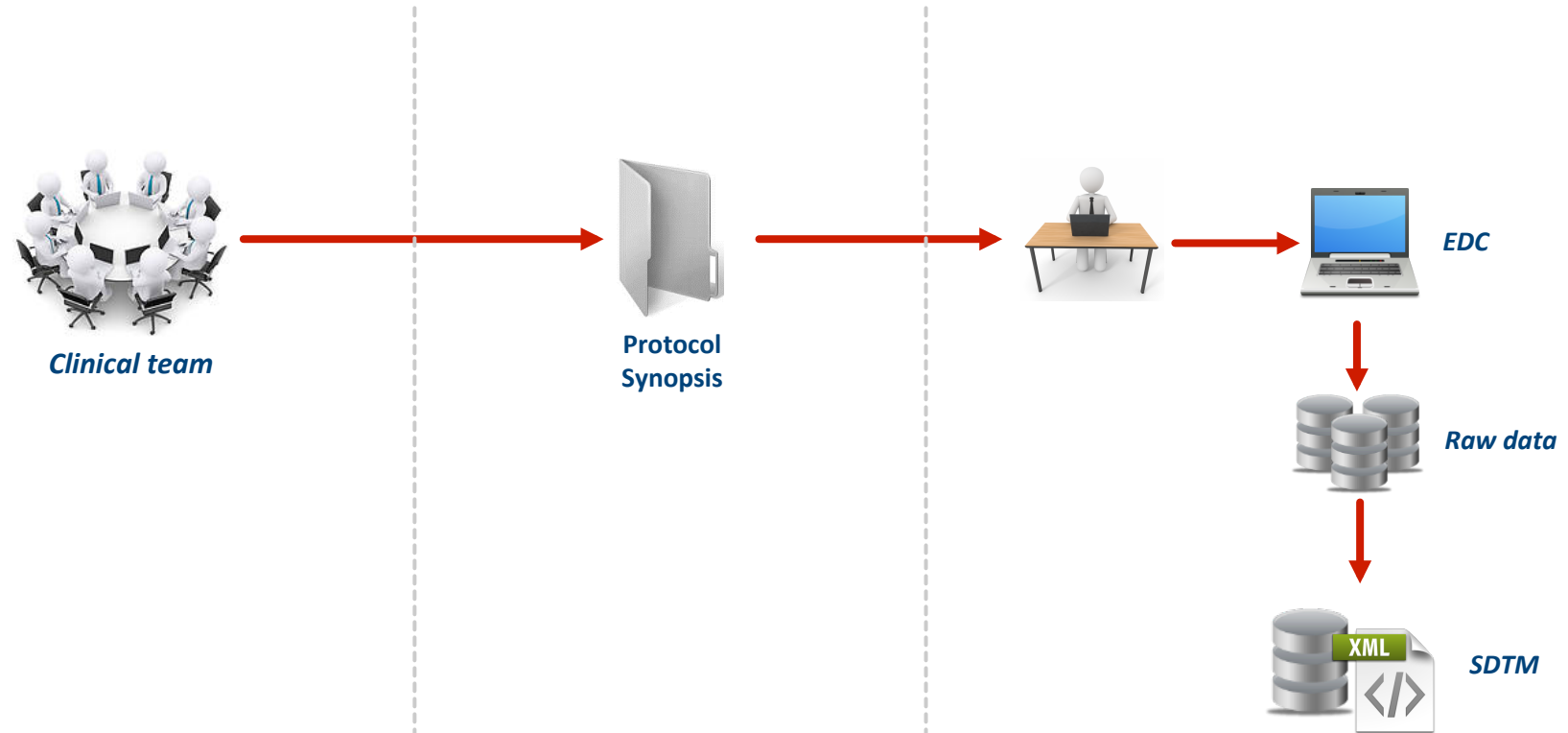
Using an Integrated Standards Library



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Outsourcing Model I: Let the CRO decide

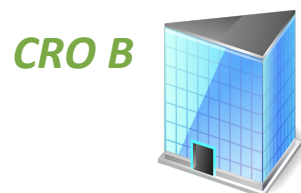


What will you get back?



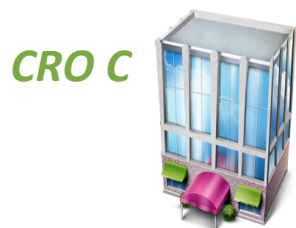
STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	...	SITEID
ABC	DM	ABC-CANI-001	001	2017-04-09		CANI

RFSTDTC = date of informed consent



STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	...	SITEID
DEF	DM	DEFCANI001	001	2017-04-12		CANI

RFSTDTC = date of first visit



STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	...	SITEID
GHI	DM	GHI-CANI-01001	01001	2017-04-15		CANI

RFSTDTC = date of first dosing

When it gets more complex

CUMULATIVE PAGES

Death Report

Date of Death:
DD MM YYYY

Primary Cause of Death: _____

Was Death Related to Study Treatment? ☐ Yes ☐ No ☐ Unknown
If yes specify AE number

Was Death Witnessed ? ☐ Yes ☐ No

Where Did The Patient Die ? Mark One ☐ Home
☐ Hospital
☐ Other (specify _____)

Was Autopsy Performed ? ☐ Yes ☐ No ☐ Unknown

Date Of Autopsy:
DD MM YYYY

When it gets more complex

[DS]

[SUPPDS]

CUMULATIVE PAGES

Death Report **DSCAT = "DISPOSITION EVENT"**

Date of Death: **DSSTDTC**

Primary Cause of Death: **DSDECOD = "DEATH"**

DTHRELST in SUPPDS

Was Death Related to Study Treatment? ☐ Yes ☐ No ☐ Unknown

If yes specify AE number **Linked via RELREC**

Was Death Witnessed? ☐ Yes ☐ No **DTHWIT in SUPPDS**

Where Did The Patient Die? Mark One ☐ Home ☐ Hospital ☐ Other (specify _____) **LOCDTH in SUPPDS**

Was Autopsy Performed? ☐ Yes ☐ No ☐ Unknown **AUTOPSY in SUPPDS**

Date Of Autopsy: **AUTOPDTC in SUPPDS**

[DS]

[FU]

CUMULATIVE PAGES

Death Report **DSCAT = "DISPOSITION EVENT"**

Date of Death: **DSSTDTC**

Primary Cause of Death: **DSDECOD = "DEATH"**

Was Death Related to Study Treatment? ☐ Yes ☐ No ☐ Unknown

DTHRELST If yes specify AE number **Linked via RELREC**

Was Death Witnessed? ☐ Yes ☐ No **DTHWIT**

Where Did The Patient Die? Mark One ☐ Home ☐ Hospital ☐ Other (specify _____) **LOCDTH**

Was Autopsy Performed? ☐ Yes ☐ No ☐ Unknown **AUTOPSY**

Date Of Autopsy: **FUDTC**

FUORRES where FUTESTCD =

[DD]

[PR]

CUMULATIVE PAGES

Death Report

Date of Death: **DDDTC**

Primary Cause of Death: **"PRCDTH"**

Was Death Related to Study Treatment? ☐ Yes ☐ No ☐ Unknown

If yes specify AE number **Linked via RELREC**

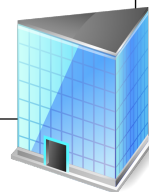
Was Death Witnessed? ☐ Yes ☐ No **"DTHWIT"**

Where Did The Patient Die? Mark One ☐ Home ☐ Hospital ☐ Other (specify _____) **"LOCDTH"**

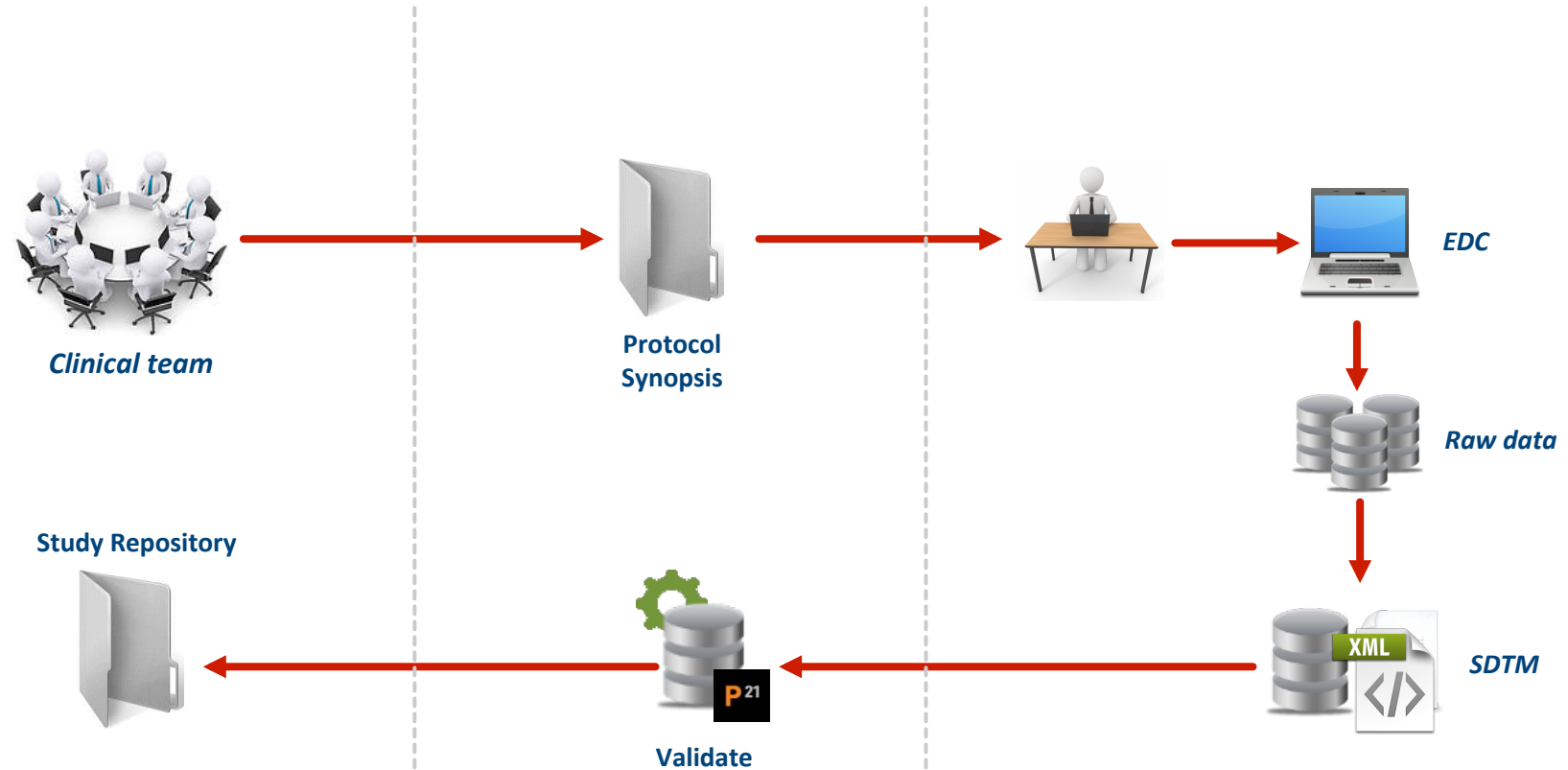
Was Autopsy Performed? ☐ Yes ☐ No ☐ Unknown **PRTRT = "AUTOPSY"** **[Not Submitted]**

Date Of Autopsy: **PRSTDTC**

DDORRES where DDTESTCD =



Oversight and Quality Control



Outsourcing Model I: Let the CRO decide



ADVANTAGES of this model

- Minimal investment from sponsor company
- Quick initiation of study set-up activities after final protocol



DISADVANTAGES of this model

- Minimal control by sponsor
- Quality Control is re-active
- Across trial variation unavoidable → *Data will be difficult to pool or re-use*
- No consistency of submission package → *Costly conversion required*



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When does this model work?

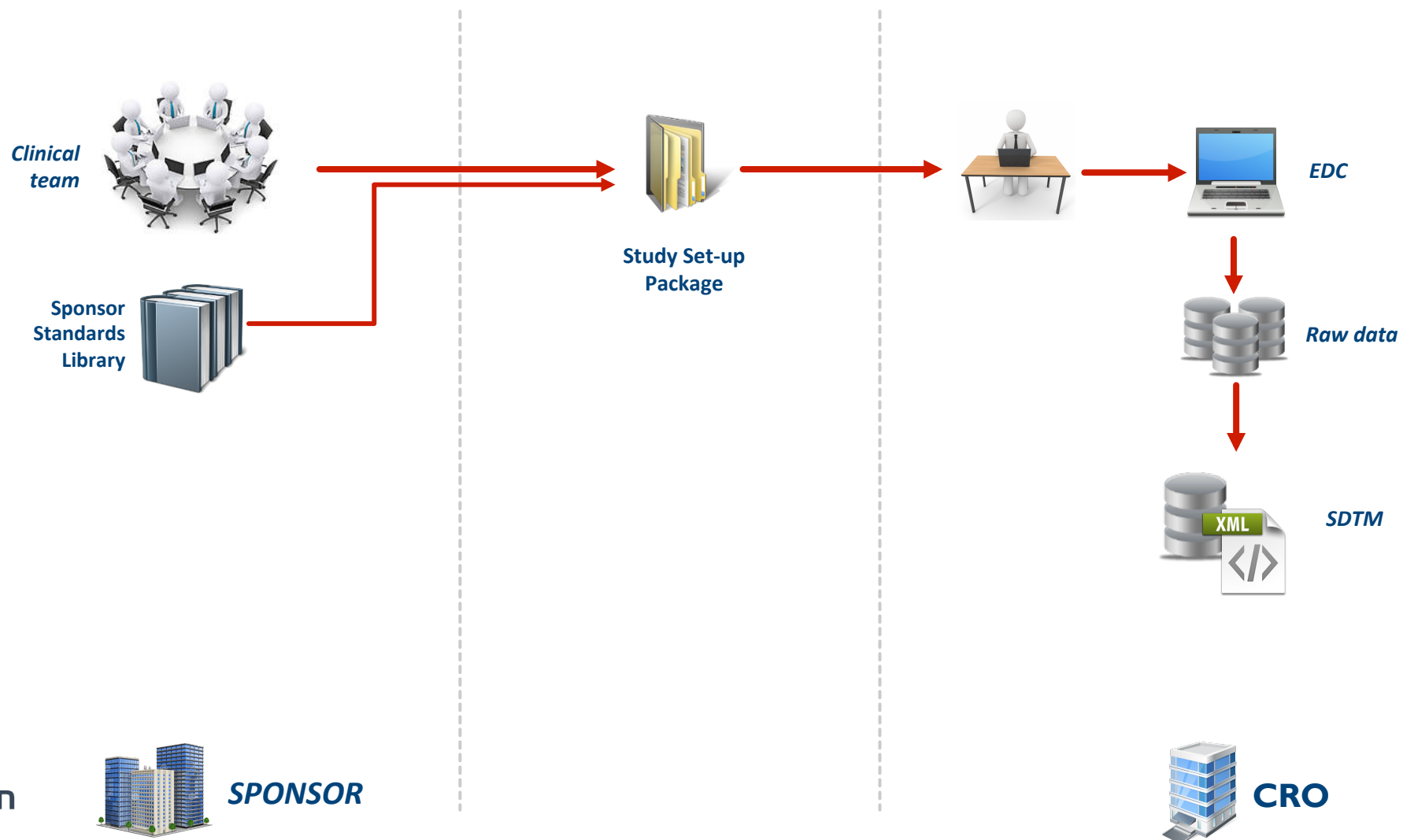


- ✓ Select 1 CRO and remain with this CRO throughout development program
- ✓ Define some conventions, such as formats of USUBJID, reference dates,...
- ✓ Sell your assets before planning a submission



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Outsourcing Model II: With Standards Library



Example Standards Library

AE		ADVERSE EVENTS		DCM ID: AE_GL_001	
STUDYID	STUDYID	Study		[Free text]	[Preprinted]
SITEID	SITEID	Site		[Free text]	[Preprinted]
SUBJID	SUBJID	Subject		[Free text]	[Preprinted]
Adverse Events					
[Not Submitted]	AEYN	Were any adverse events experienced?		[Radiobutton {Yes; No}]	NY
AESPID	AESPID	AE number		[Numeric field]	[Preprinted]
AETERM	AETERM	What is the adverse event term?		[Free text]	
AESTDTC	AESTDAT	Start Date		[Date {DD-MMM-YYYY}]	
	AESTTIM	Start Time		[24 hr clock]	
	AEENDAT	End Date		[Date {DD-MMM-YYYY}]	
AEENDTC	AEENTIM	End Time		[24 hr clock]	
If Yes, AEENRPT = ONGOING	AEONGO	Is the adverse event still ongoing?		[Radiobutton {Yes; No}]	NY
AESEV	AESEV	Severity		[Radiobutton {Mild; Moderate; Severe}]	AESEV
AESER	AESER	Is the adverse event serious?		[Radiobutton {Yes; No}]	NY
		If Yes:			
AEREFID	AEREFID	SAE Number		[Free text]	
AESCONG	AESCONG	Congenital Anomaly		[Radiobutton {Yes; No}]	NY
AESDISAB	AESDISAB	Significant Disability		[Radiobutton {Yes; No}]	NY
AESDTH	AESDTH	Death		[Radiobutton {Yes; No}]	NY
AESHOSP	AESHOSP	Hospitalization		[Radiobutton {Yes; No}]	NY
AESLIFE	AESLIFE	Life Threatening		[Radiobutton {Yes; No}]	NY
AESMIE	AESMIE	Other Medically Important Event		[Radiobutton {Yes; No}]	NY
				[Radiobutton {Not related; Unlikely Related; Possibly Related; Probably Related}]	REL
AEREL	AEREL	Relationship to Study Treatment			
				[Radiobutton {Dose Not Changed; Drug Withdrawn; Dose Reduced}]	ACN
AEACN	AEACN	Action taken with Study Treatment			

Provide Expectations

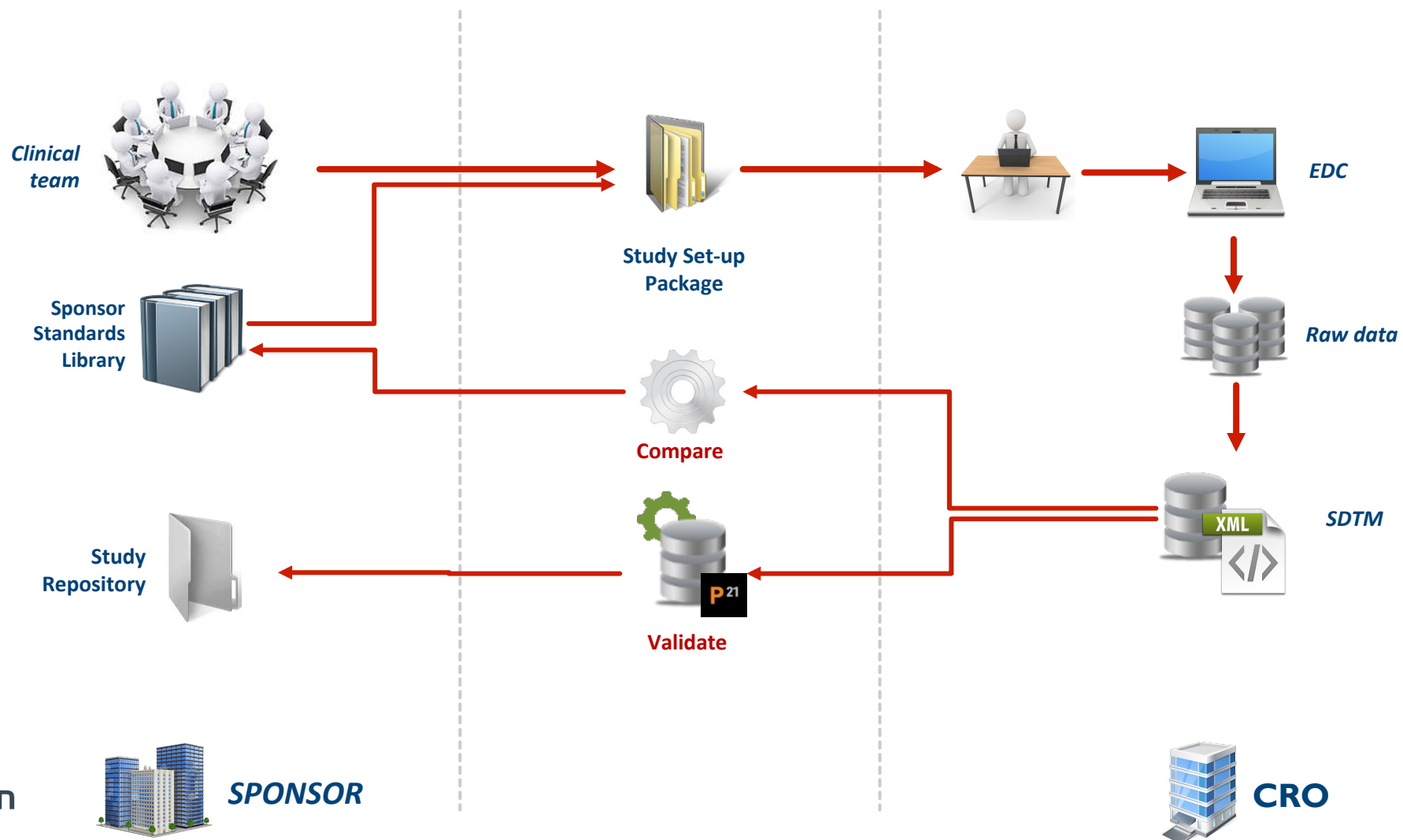
■ *Set-up package*

- Protocol
- CRO guides for using Standards Library & standards governance
- Sponsor Standards Library
 - Standard Data Collection Modules
 - CDISC SDTM Library
 - Data Standards Conventions



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Oversight and Quality Control



Enables Additional Quality

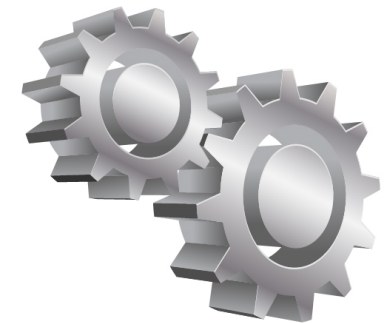
■ *Review of Annotated CRF*

- Compare against sponsor Data Collection library
- Enhances consistent data collection across CROs and Trials
- Review SDTM mapping



■ *Electronic Comparison of datasets and define.xml*

- Check if data standards conventions were followed
- Check consistency with Data Standards Library



Outsourcing Model II: With Standards Library



ADVANTAGES of this model

- Moderate investment by sponsor company
- Can work with multiple CROs and get same results
- Consistent data collection and representation in CDISC SDTM



DISADVANTAGES of this model

- Quality Control is still re-active
- Review steps are needed to verify CRO's use of the library
- Increased communication with the CRO
- Need to maintain the library by an expert



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When does this model work?

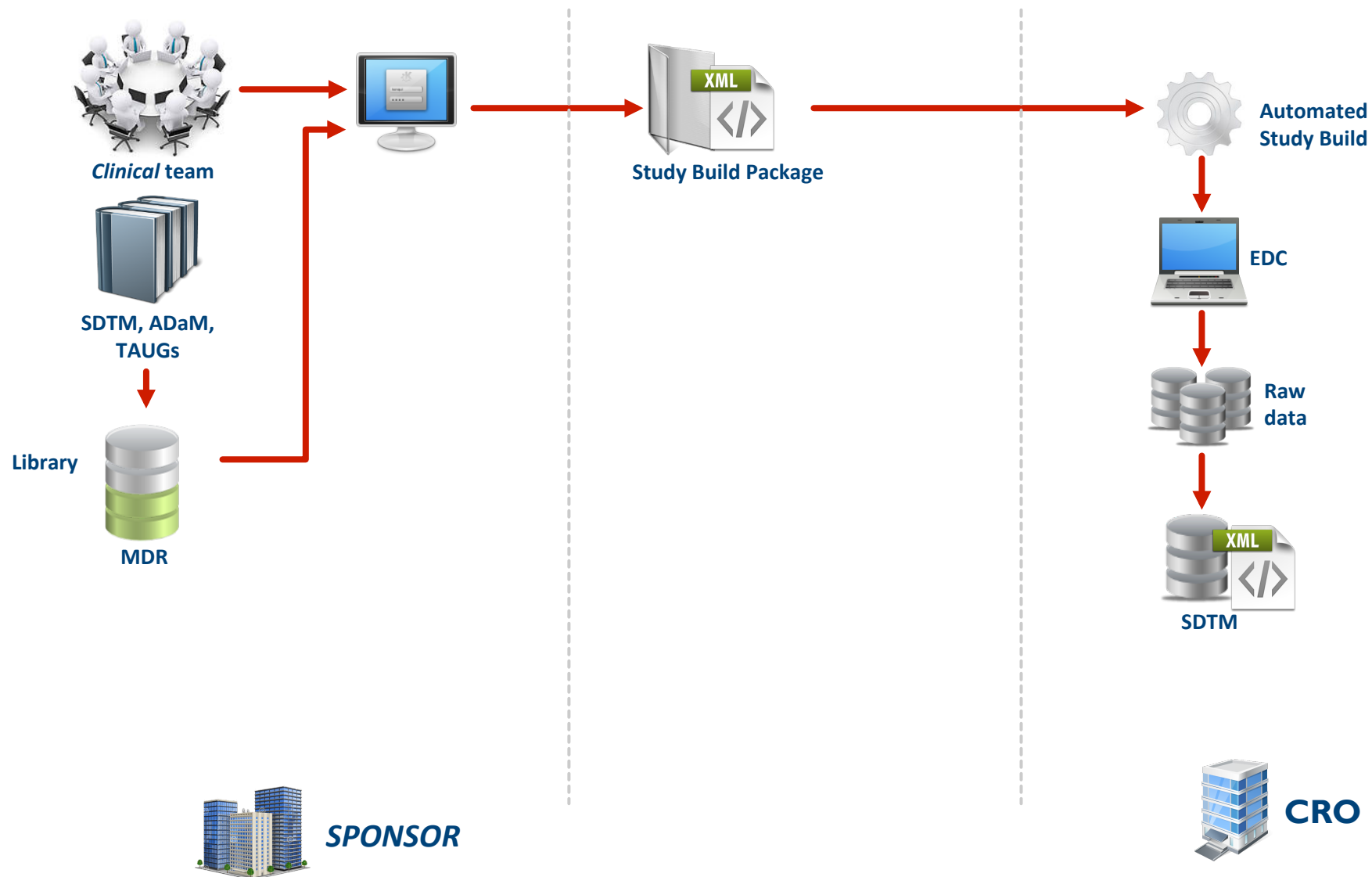


- ✓ Working with One or Multiple CROs
- ✓ Small to midsize companies with a growing portfolio, but limited budget
- ✓ Access to standards SME



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Outsourcing Model III: Extended Standards Functionality



Example Extended Standards Library

AE		ADVERSE EVENTS		DCM ID: AE_GL_001												
STUDYID	STUDYID	Study	[Free text]		[Preprinted]											
SITEID	SITEID	Site	[Free text]		[Preprinted]											
SUBJID	SUBJID	Subject	[Free text]		[Preprinted]											
Adverse Events	Dataset	Description	Class	Structure	Purpose	Key Variables	Repeating	Reference Data								
[Not Submitted]	AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation	STUDYID,USUBJID,AECAT,AEDECOD,AESTDTC	Yes	No								
[Not Submitted] AE were any adverse events experienced? [radio button (yes, no)]																
AESI	Dataset	Variable	Label	Data Type	Length	Significant Digits	Format	Mandatory	Codelist	Origin	Pages	Method	Predecessor	Role	Comment	Core
AETI	AE	STUDYID	Study Identifier	text	12			Yes		Protocol				Identifier		Req
	AE	DOMAIN	Domain Abbreviation	text	2			Yes	AE.DOMAIN	Assigned				Identifier		Req
AES	AE	USUBJID	Unique Subject Identifier	text	18			Yes		Derived		USUBJID		Identifier		Req
	AE	AESEQ	Sequence Number	integer	8			Yes		Derived		SEQ		Identifier		Req
	AE	AEGRPID	Group ID	text	20			No		Derived		AEGRPID		Identifier		Perm
AEEI	AE	AEREFID	Reference ID	text	20			No		CRF				Identifier		Perm
	AE	AESPID	Sponsor-Defined Identifier	text	20			No		CRF				Identifier		Perm
If Yes	AE	AETERM	Reported Term for the Adverse Event	text	200			Yes		CRF				Topic		Req
C	AE	AEMODIFY	Modified Reported Term	text	200			No		Assigned				Synonym Qualifier		Perm
AESI	AE	AELLT	Lowest Level Term	text	200			No	MedDRA	Assigned				Variable Qualifier		Exp
ID	Name		NCI Codelist Code	Data Type	Order	Term		NCI Term Code		Decoded Value		Extensible				
ACN	Action Taken with Study Treatment		C66767	text		DOSE INCREASED		C49503		Dose Increased		N		Exp		
ACN	Action Taken with Study Treatment		C66767	text		DOSE NOT CHANGED		C49504		Dose Not Changed		N		Exp		
ACN	Action Taken with Study Treatment		C66767	text		DOSE REDUCED		C49505		Dose Reduced		N		Exp		
ACN	Action Taken with Study Treatment		C66767	text		DRUG INTERRUPTED		C49501		Drug Interrupted		N		Exp		
ACN	Action Taken with Study Treatment		C66767	text		DRUG WITHDRAWN		C49502		Drug Withdrawn		N		Perm		
ACN	Action Taken with Study Treatment		C66767	text		NOT APPLICABLE		C48660		Not Applicable		N		Perm		
ACN	Action Taken with Study Treatment		C66767	text		UNKNOWN		C17998		Unknown		N		Exp		
	AE	AEBDSYCD	Body System or Organ Class Code	integer	8			No	MedDRA	Assigned				Variable Qualifier		Exp
	AE	AESOC	Primary System Organ Class	text	200			No	MedDRA	Assigned				Variable Qualifier		Exp
AERI	AE	AESOCCD	Primary System Organ Class Code	integer	8			No	MedDRA	Assigned				Variable Qualifier		Exp
	AE	AELOC	Location of Event	text	200			No	LOC	CRF				Record Qualifier		Perm
	AE	AESEV	Severity/Intensity	text	20			No	AESEV	CRF				Record Qualifier		Perm
AEA	AE	AESER	Serious Event	text	1			No	NY_YN	CRF				Record Qualifier		Exp
	AE	AEACN	Action Taken with Study Treatment	text	40			No	ACN	CRF				Record Qualifier		Exp
	AE	AEACNOTH	Other Action Taken	text	200			No		CRF				Record Qualifier		Perm
	AE	AEREL	Causality	text	20			No	REL	CRF				Record Qualifier		Exp
	AE	AERELNST	Relationship to Non-Study Treatment	text	40			No		CRF				Record Qualifier		Perm



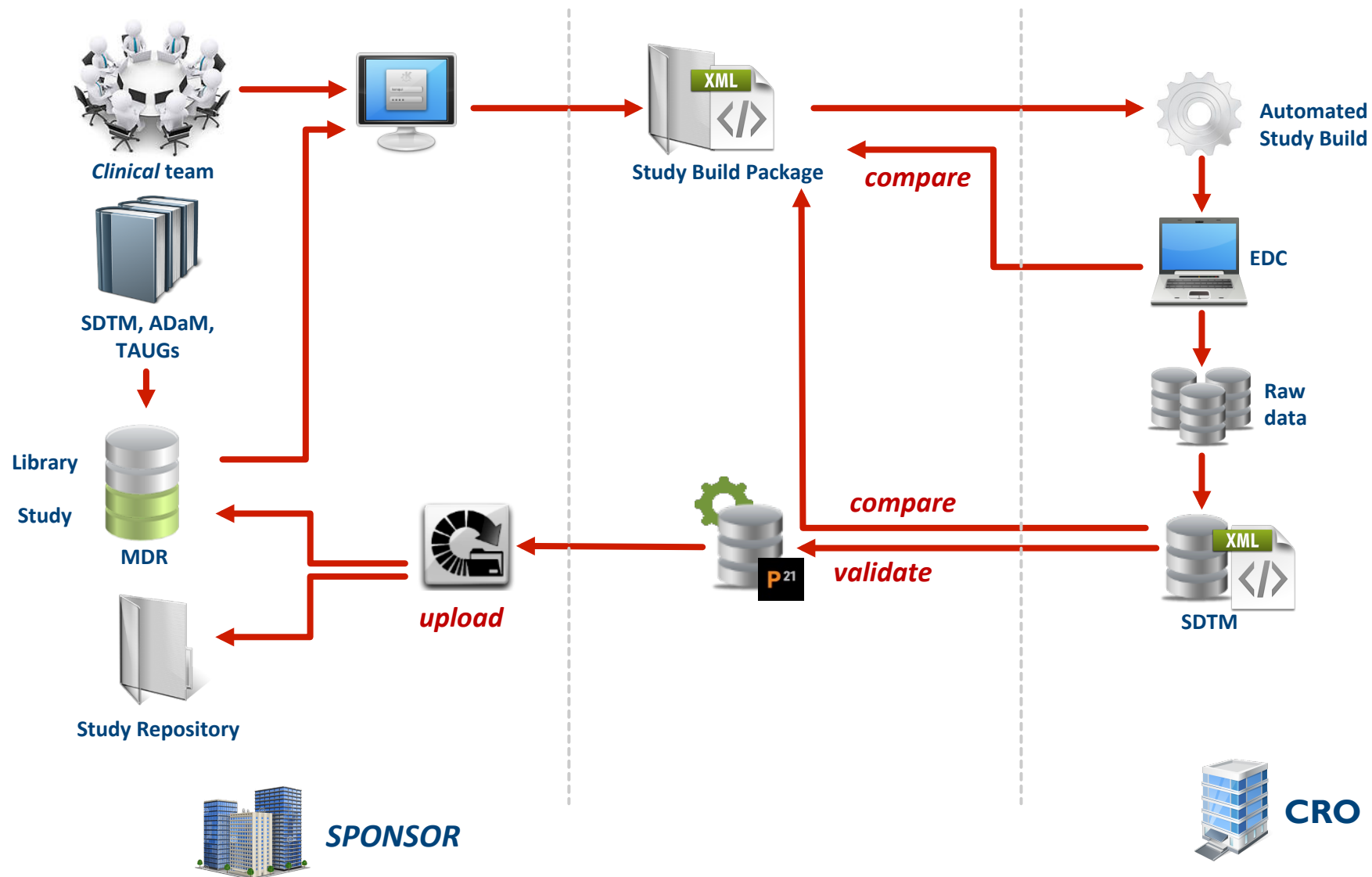
Provide Specifications

■ *Study Build Package*

- Protocol
- Electronic Study Specification
 - Define.xml
 - EDC Build File
 - SDTM annotated CRF



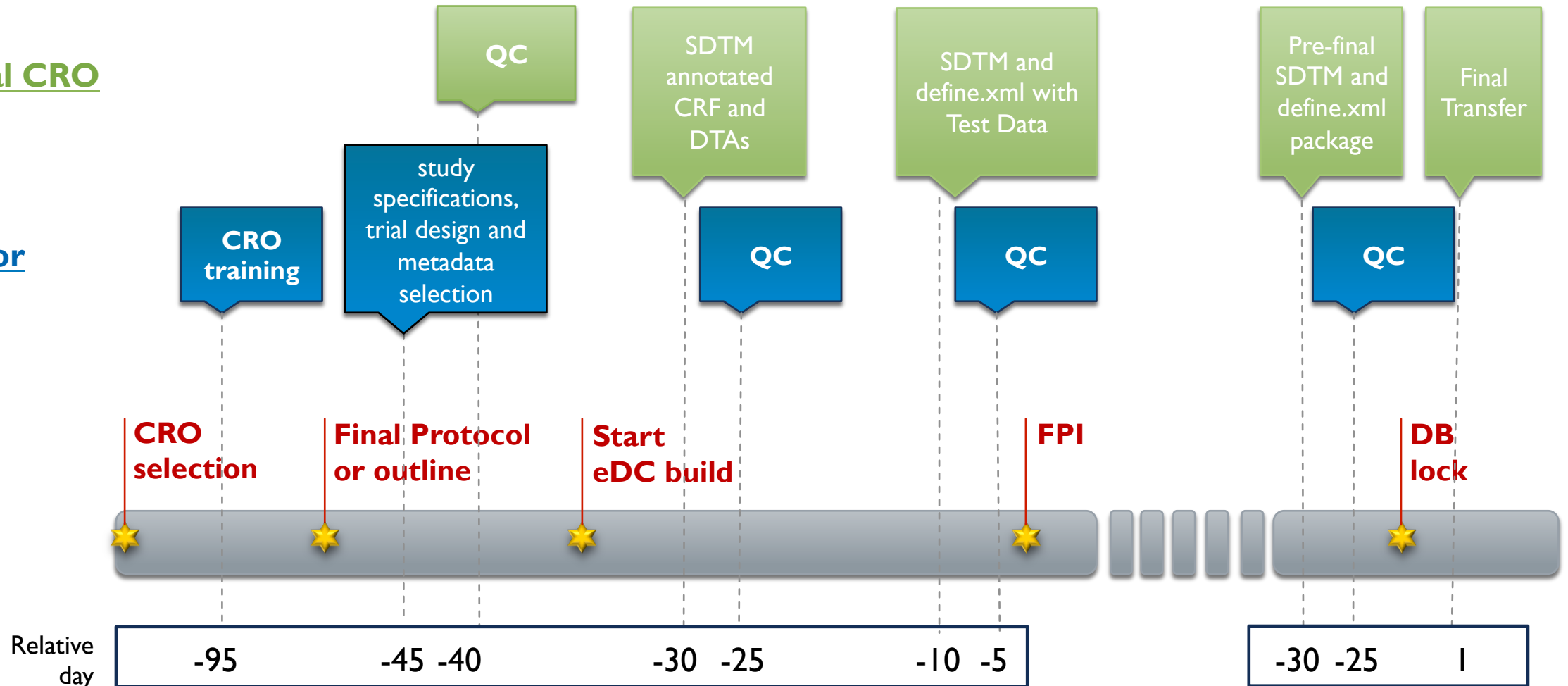
Oversight and Quality Control



Quality Control Activities and Timelines

Clinical CRO

Sponsor



Enables Highest Level Of Control & Quality

- *EDC system is automatically generated*
 - Ensures consistent data collection
- *Provides electronic SDTM specifications for the CRO*
 - Enables electronic check between specifications and CRO datasets
 - Ensures consistency with Data Standards Library
- *Ensures consistency*
 - Between Trials
 - Between CROs
 - Fit for use in analysis poolings and re-usability of trial data



Standards Integration

Analysis Results

Table 1 Demographic Data - Per-Protocol		
	Treatment 1	Treatment 2
Baseline body mass index (BMI) [kg/m**2]		
N	167	167
Mean	29.08	29.04
SD	4.84	4.80
Min	20.3	16.0
Median	28.69	28.47
Max	40.1	41.2
Baseline BMI (categorical) [N (%)]		
<25 kg/m**2	41 (24.6%)	71 (21.1%)
25-<30 kg/m**2	60 (35.9%)	130 (38.7%)
>=30 kg/m**2	66 (39.5%)	135 (40.2%)

CRF

VITAL SIGNS					
PROTOCOL	ABC-DIA-0012				
SUBJECT	20001				
VISIT	WEEK 4				
WERE VITAL SIGNS COLLECTED? ☐ YES ☐ NO					
DATE	__/__/____ [dd/mm/yyyy]				
PLANNED TIMEPOINT	ACTUAL TIME	TEST	RESULT	UNIT	CLINICALLY SIGNIFICANT
1. PRE DOSE	--:--	Height	---	cm	
		Weight	---	kg	
		Systolic Blood Pressure	---	mmHg	
		Diastolic Blood Pressure	---	mmHg	
		Pulse Rate	---	beats/min	
		Temperature	---	°C ☐ °F ☐	
		Respiratory Rate Interpretation	☐ NORMAL ☐ ABNORMAL	breaths/min	☐ YES ☐ NO
2. 30 MINUTES	--:--	Systolic Blood Pressure	---	mmHg	
		Diastolic Blood Pressure	---	mmHg	
		Pulse Rate	---	beats/min	
		Temperature	---	°C ☐ °F ☐	
		Respiratory Rate	---	breaths/min	
		Respiratory Rate Interpretation	☐ NORMAL ☐ ABNORMAL	breaths/min	☐ YES ☐ NO
		Interpretation	☐ NORMAL ☐ ABNORMAL		☐ YES ☐ NO

ADaM Data

	STUDYID	USUBJID	SUBJID	BMI	BMIGR1	BMIGR1N	BMIGR2	BMIGR2N
2	9999-0001	9999-0001-000001	000001	27.77777778 <30 kg/m**2		1	25-<30 kg/m**2	2
3	9999-0001	9999-0001-000002	000002	25.503615702 <30 kg/m**2		1	25-<30 kg/m**2	2
4	9999-0001	9999-0001-000003	000003	26.175194521 <30 kg/m**2		1	25-<30 kg/m**2	2
5	9999-0001	9999-0001-000004	000004	35.15625 >=30 kg/m**2		2	>=30 kg/m**2	3
6	9999-0001	9999-0001-000005	000005	30.968858131 >=30 kg/m**2		2	>=30 kg/m**2	3
7	9999-0001	9999-0001-000006	000006	39.697163916 >=30 kg/m**2		2	>=30 kg/m**2	3
8	9999-0001	9999-0001-000007	000007	25.826446281 <30 kg/m**2		1	25-<30 kg/m**2	2
9	9999-0001	9999-0001-000008	000008	30.103806228 >=30 kg/m**2		2	>=30 kg/m**2	3
10	9999-0001	9999-0001-000009	000009	32.280962683 >=30 kg/m**2		2	>=30 kg/m**2	3
11	9999-0001	9999-0001-000010	000010	28.876133787 <30 kg/m**2		1	25-<30 kg/m**2	2
12	9999-0001	9999-0001-000011	000011	29.372397383 <30 kg/m**2		1	25-<30 kg/m**2	2
13	9999-0001	9999-0001-000012	000012	26.714952608 <30 kg/m**2		1	25-<30 kg/m**2	2
14	9999-0001	9999-0001-000013	000013	32.718619869 >=30 kg/m**2		2	>=30 kg/m**2	3
15	9999-0001	9999-0001-000014	000014	28.719723183 <30 kg/m**2		1	25-<30 kg/m**2	2
16	9999-0001	9999-0001-000015	000015	32.270420377 >=30 kg/m**2		2	>=30 kg/m**2	3



CDISC Data Models

CDASH EDC Extract

	STUDYID	SUBJID	VISIT	VSPERF	VSDAT	VSTIM	VSSPID	VSTPT	HEIGHT	HEIGHTU	WEIGHT	WEIGHTU
1	9999-0001	000011	BASE LINE	YES	14/06/2017	855	1	PRE_DOSE	184	cm	100	kg
2	9999-0001	000011	BASE LINE	YES	14/06/2017	931	2	30 MINUTES				
	SYSP	YSBP	DIAB	DIABU	PULSE	PULSEU	TEMP	TEMPU	RESP	RESPU	INT	VSCLSIG
1	130	mmHg	80	mmHg	62	BEATS/MIN	36	C	12	BREATHS/MIN	NORMAL	kg
2	150	mmHg	100	mmHg	95	BEATS/MIN	36	C	30	BREATHS/MIN	ABNORMAL	NO

SDTM Data

	STUDYID	DOMAIN	USUBJID	VSSEQ	VSPID	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSTRESNC	VSTRESN	VSRLU	VSNRFL	VSTNRH	VST	VSTDT	VSTDC	VSTPT
1	9999-0001	VS	9999-0001-000011	1	1	HEIGHT	HEIGHT	184	CM	184	184	Y		2	BASELINE	18	2017-06-14T08:55	PRE-DOSE
2	9999-0001	VS	9999-0001-000011	2	1	HEIGHT	HEIGHT	100	KG	100	100	Y		2	BASELINE	18	2017-06-14T08:55	PRE-DOSE
3	9999-0001	VS	9999-0001-000011	3		BP	BODY BP INDEX	29.54	CGH			Y	Y	2	BASELINE	18	2017-06-14T08:55	PRE-DOSE
4	9999-0001	VS	9999-0001-000011	4	1	SBP	SBP	130	mmHG	130	130	Y		2	BASELINE	18	2017-06-14T08:55	PRE-DOSE
5	9999-0001	VS	9999-0001-000011	5	1	DBP	DBP	80	mmHG	80	80	Y		2	BASELINE	18	2017-06-14T08:55	PRE-DOSE
6	9999-0001	VS	9999-0001-000011	6	1	PULSE	PULSE RATE	42	BEAT/MIN	42	42	Y		2	BASELINE	18	2017-06-14T08:55	PRE-DOSE
7	9999-0001	VS	9999-0001-000011	7	1	TEMP	TEMPERATURE	36	C	36	36	Y		2	BASELINE	18	2017-06-14T08:55	PRE-DOSE
8	9999-0001	VS	9999-0001-000011	8	1	RSP	RESPIRATORY RATE	12	BREATH/MIN	12	12	Y		2	BASELINE	18	2017-06-14T08:55	PRE-DOSE
9	9999-0001	VS	9999-0001-000011	9	1	INTPT	INTERPRETATION		NORMAL		NORMAL			2	BASELINE	18	2017-06-14T08:55	30 MINUTES
10	9999-0001	VS	9999-0001-000011	10	2	SBP	SBP	150	mmHG	150	150			2	BASELINE	18	2017-06-14T09:31	30 MINUTES
11	9999-0001	VS	9999-0001-000011	11	2	DBP	DBP	100	mmHG	100	100			2	BASELINE	18	2017-06-14T09:31	30 MINUTES
12	9999-0001	VS	9999-0001-000011	12	2	PULSE	PULSE RATE	95	BEAT/MIN	95	95			2	BASELINE	18	2017-06-14T09:31	30 MINUTES
13	9999-0001	VS	9999-0001-000011	13	2	TEMP	TEMPERATURE	36	C	36	36			2	BASELINE	18	2017-06-14T09:31	30 MINUTES
14	9999-0001	VS	9999-0001-000011	14	2	RSP	RESPIRATORY RATE	30	BREATH/MIN	30	30			2	BASELINE	18	2017-06-14T09:31	30 MINUTES
15	9999-0001	VS	9999-0001-000011	15	2	INTPT	INTERPRETATION		ABNORMAL		ABNORMAL			2	BASELINE	18	2017-06-14T09:31	30 MINUTES

	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEQVAL
1	9999-0001	VS	9999-0001-000011	VSSEQ	15	VSCLSIG	CLINICALLY SIGNIFICANT	NO	CRF	

Built-in Traceability

Analysis Results

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CRF

VITAL SIGNS						
PROTOCOL	ABC-DIA-0012					
SUBJECT	20001					
WEEK	WEEK 4					
WERE VITAL SIGNS COLLECTED?	☐ YES ☐ NO					
DATE	--/--/----					
PLANNED TIMEPOINT	ACTUAL TIME	TEST	RESULT	UNIT	CLINICALLY SIGNIFICANT	
1. PRE-DOSE	--/--/----	Weight	---	cm		
		Systolic Blood Pressure	---	mmHg		
		Diastolic Blood Pressure	---	mmHg		
		Pulse Rate	---	beats/min		
		Temperature	---	°C		
		Respiratory Rate	---	breaths/min		
		Interpretation	☐ NORMAL ☐ ABNORMAL ☐ YES ☐ NO			
2. 30 MINUTES	--/--/----	Systolic Blood Pressure	---	mmHg		
		Diastolic Blood Pressure	---	mmHg		
		Pulse Rate	---	beats/min		
		Temperature	---	°C		
		Respiratory Rate	---	breaths/min		
		Interpretation	☐ NORMAL ☐ ABNORMAL ☐ YES ☐ NO			



CDISC Metadata

Trial Arms (TA) [Location: ta.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	7		Protocol	
DOMAIN	Domain Abbreviation		text	2	["TA" = "Trial Arms"] <Domain Abbreviation (TA)>	Assigned	
ARMCD	Planned Arm Code	2	text	8	["PLACEBO" = "Placebo", "SCREENFAIL" = "Screen Failure", "WONDER10" = "Miracle Drug 10 mg", "WONDER20" = "Miracle Drug 20 mg"] <Planned Arm Code>	Assigned	
ARM	Description of Planned Arm		text	20	["Miracle Drug 10 mg", "Miracle Drug 20 mg", "Placebo", "Screen Failure"] <Description of Planned Arm>	Protocol	
TAETORD	Order of Element within Arm	3	integer	1		Assigned	
ETCD	Element Code		text	8		Assigned	
ELEMENT	Description of Element		text	40		Protocol	
TABRANCH	Branch		text	35		Protocol	
TATRANS	Transition Rule		text	1		Protocol	
EPOCH	Epoch		text	30		Protocol	

SDTM Metadata

ADaM data

	STUDYID	USUBJID	SUBJID	BMI	BMIGR1	BMIGRN	BMIGR2	BMIGRN
2	9999-0001	9999-0001-000001	000001	27.77777778	<30 kg/m**2		1 25-<30 kg/m**2	2
3	9999-0001	9999-0001-000002	000002	25.50361502	<30 kg/m**2		1 25-<30 kg/m**2	2
4	9999-0001	9999-0001-000003	000003	26.179194521	<30 kg/m**2		1 25-<30 kg/m**2	2
5	9999-0001	9999-0001-000004	000004	35.15625	>=30 kg/m**2		2 >=30 kg/m**2	3
6	9999-0001	9999-0001-000005	000005	30.86858111	>=30 kg/m**2		2 >=30 kg/m**2	3
7	9999-0001	9999-0001-000006	000006	39.69163916	>=30 kg/m**2		2 >=30 kg/m**2	3
8	9999-0001	9999-0001-000007	000007	25.82444201	<30 kg/m**2		1 25-<30 kg/m**2	2
9	9999-0001	9999-0001-000008	000008	30.10386228	>=30 kg/m**2		2 >=30 kg/m**2	3
10	9999-0001	9999-0001-000009	000009	32.20962583	>=30 kg/m**2		2 >=30 kg/m**2	3
11	9999-0001	9999-0001-000010	000010	28.876133787	<30 kg/m**2		1 25-<30 kg/m**2	2
12	9999-0001	9999-0001-000011	000011	33.72287383	<30 kg/m**2		1 25-<30 kg/m**2	2
13	9999-0001	9999-0001-000012	000012	26.714852688	<30 kg/m**2		1 25-<30 kg/m**2	2
14	9999-0001	9999-0001-000013	000013	32.718618688	>=30 kg/m**2		2 >=30 kg/m**2	3
15	9999-0001	9999-0001-000014	000014	28.719723183	<30 kg/m**2		1 25-<30 kg/m**2	2
16	9999-0001	9999-0001-000015	000015	32.270420377	>=30 kg/m**2		2 >=30 kg/m**2	3

Analysis Datasets for Study CDISC-Sample (ADaM-IG 1.0)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADSL	Subject-Level Analysis	SUBJECT LEVEL ANALYSIS DATASET	one record per subject	Analysis	STUDYID, USUBJID	adsl.xpt	Screen Failures are excluded since they are not needed for this study analysis. See Analysis Data Reviewer's Guide, page 6. Analysis Data Reviewer's Guide
ADQSADAS	ADaM-Cos Analysis	BASIC DATA STRUCTURE	One record per subject per parameter per analysis visit per analysis date	Analysis	STUDYID, USUBJID, PARAMCD, AVISIT, ADT	adqsadas.xpt	See referenced dataset creation program and Analysis Data Reviewer's Guide, Section 2.1 adqsadas.xpt Analysis Data Reviewer's Guide
ADAE	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE	one record per subject per adverse event	Analysis	STUDYID, USUBJID, AETERM, ASTDT, ASEQ	adae.xpt	See SAS program adae.sas

ADaM Metadata

Outsourcing Model III: Extended Standards Functionality



ADVANTAGES of this model

- Full control
- Pro-active Quality Control
- High level of automation possible
- Many automatic quality checks
- Submission ready deliverables



DISADVANTAGES of this model

- Higher investment by sponsor company
- Continuous maintenance and governance of standards mandatory



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When does this model work?



- ✓ Midsize to large companies
- ✓ Training is provided
- ✓ Intuitive Interfaces for end-users



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Conclusion

- *Higher level of standardization will lead to better quality*
 - Choose the approach that fits your company
 - **Expectations**
 - **Budget**
 - **Staff**
 - **Partners**





Questions....



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Thank you for your attention