

PAPER SI11

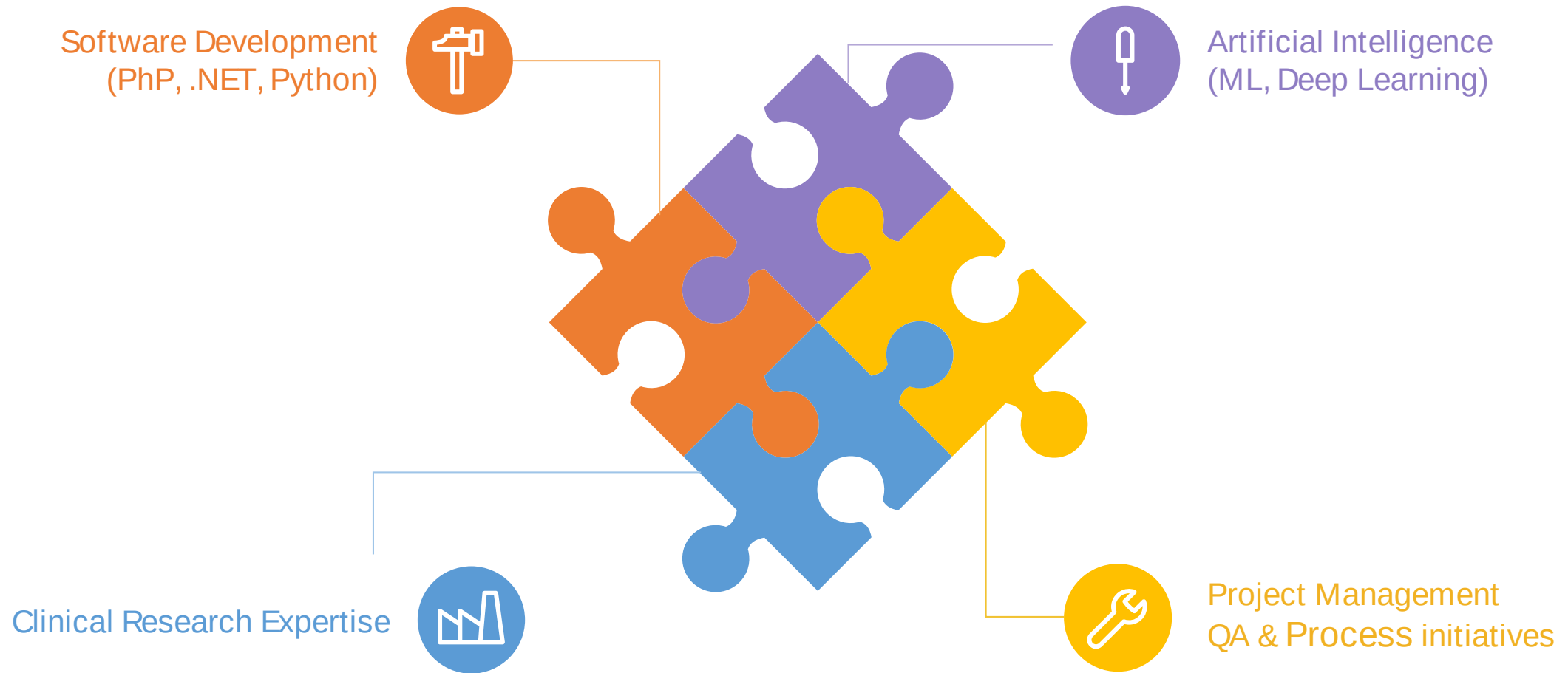
CDISC SDTM

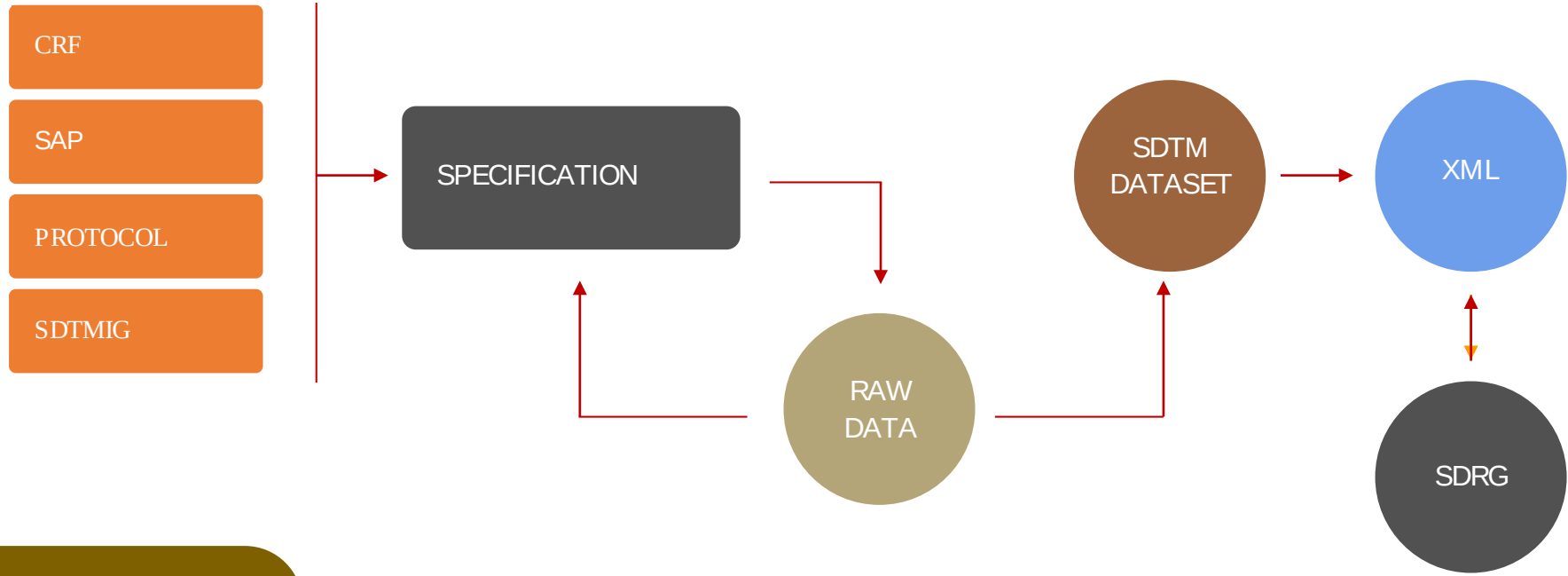
An Automated Approach



Binitha Sathyabhama
Project Manager

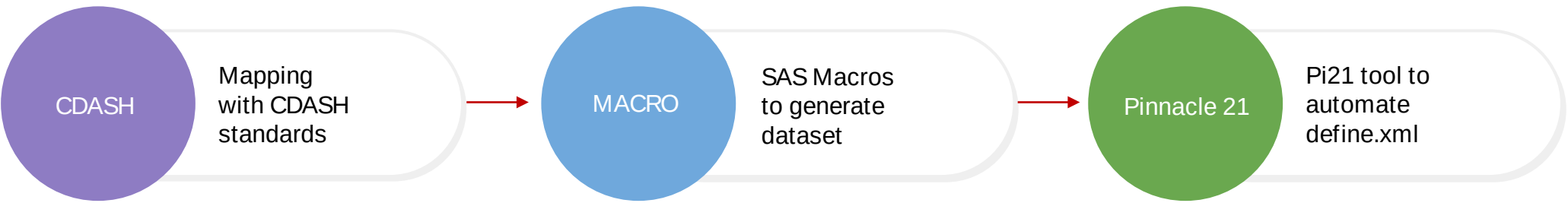
Sreedevi Menon
Vice President





Migrating legacy data to SDTM standards

Current Scenario



Process improvement & Automation

Existing Approaches



Proposed Approach

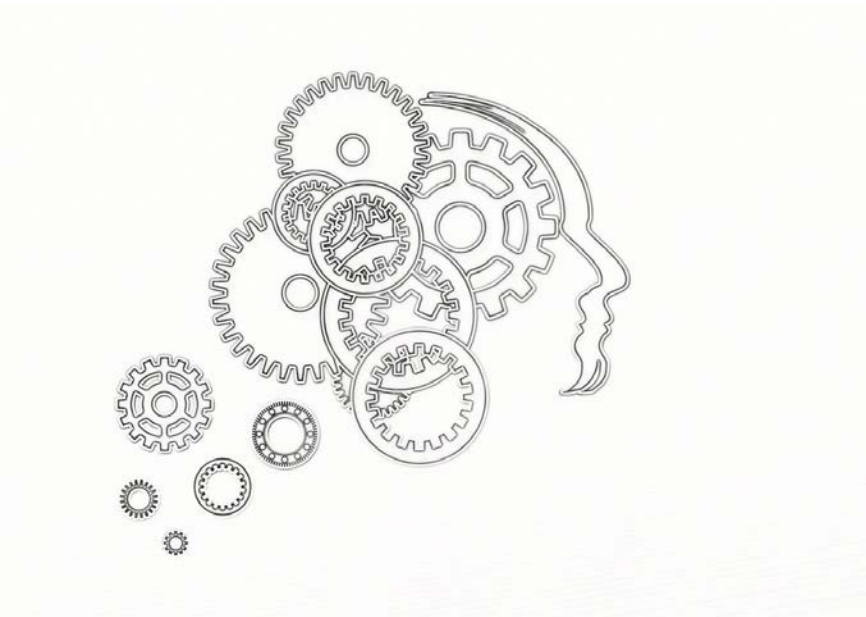
Complete Automation

- ✓ Diversity in raw data across studies / sponsors
- ✓ System performance when dealing with complex datasets
- ✓ Functional requirements considering standards set in the Clinical Domain



Key Challenges

Regulatory Compliance

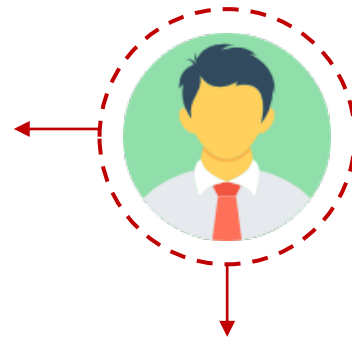


- 1 Role based Access and Security 
- 2 Specification Document Generation 
- 3 CRF Annotation 
- 4 Dataset and Define.xml Generation 
- 5 Audit Readiness 

Designated admin can add users and study details

Various user roles are incorporated to maintain quality and process

Assign users with
different privileges



Assign user to study

Add study details



Upload RAW files



SDTM	VARIABLE NAME	DATA TYPE	SDTM FIELD	FUNCTION	LOOKUP	SOURCE	COMMENTS
CD	CD	DATE	DATE	CONCAT	DATE	CD	ADD DATE FROM PROTOCOL
EX	EX	DATE	DATE	CONCAT	DATE	EX	ADD DATE FROM PROTOCOL
CR	CR	DATE	DATE	CONCAT	DATE	CR	ADD DATE FROM PROTOCOL
DT	DT	DATE	DATE	CONCAT	DATE	DT	ADD DATE FROM PROTOCOL
LS	LS	DATE	DATE	CONCAT	DATE	LS	ADD DATE FROM PROTOCOL
MR	MR	DATE	DATE	CONCAT	DATE	MR	ADD DATE FROM PROTOCOL
PC	PC	DATE	DATE	CONCAT	DATE	PC	ADD DATE FROM PROTOCOL

50-80% of automated mapping

Human interaction for editing and re-assigning variables.



In built quality control module

Communication between developer and QC through a chat bot

SDTM	VARIABLE NAME	DATA TYPE	SDTM FIELD	FUNCTION	LOOKUP	SOURCE	COMMENTS
CD	CD	DATE	DATE	CONCAT	DATE	CD	ADD DATE FROM PROTOCOL
EX	EX	DATE	DATE	CONCAT	DATE	EX	ADD DATE FROM PROTOCOL
CR	CR	DATE	DATE	CONCAT	DATE	CR	ADD DATE FROM PROTOCOL
DT	DT	DATE	DATE	CONCAT	DATE	DT	ADD DATE FROM PROTOCOL
LS	LS	DATE	DATE	CONCAT	DATE	LS	ADD DATE FROM PROTOCOL
MR	MR	DATE	DATE	CONCAT	DATE	MR	ADD DATE FROM PROTOCOL
PC	PC	DATE	DATE	CONCAT	DATE	PC	ADD DATE FROM PROTOCOL
PE	PE	DATE	DATE	CONCAT	DATE	PE	ADD DATE FROM PROTOCOL

SDTM Specification

Repeat

Assign

Download Mapping

Submit for review

Role Primary User Domain Demographic

DOMAIN	VARIABLE NAME	KEY FIELD	UNIQUE FIELD	FUNCTION	LOGIC	SOURCE	COMMENTS	
CO	DOMAIN	CO.PT	CO.PT	CONCAT	VSDT.CPEV...	-CO~	ASSIGNED FROM PROTOCOL "NALOXONE-PH1A-002"	 
DM	STUDYID	MEDSDTLS.PT	CO.PT	CONCAT	VSDT.CPEV...	TE.ELEMENT	ASSIGNED FROM PROTOCOL "NALOXONE-PH1A-002"	 
CM	RDOMAIN	PROTDEV.PT	MEDSDTLS.PT	SEQUENCE_GENERATION	VSDT.VISDATE.&&VSDT.VISDATE,	-CO~	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata.	 
DV	COVAL	SCH.PT	CO.PT	CONCAT	VSDT.CPEV...	-CO~	ASSIGNED FROM PROTOCOL "NALOXONE-PH1A-002"	 
LB	IDVAR	ECGASMT.PT	CO.PT	CONCAT	VSDT.CPEV...	-CO~	ASSIGNED FROM PROTOCOL "NALOXONE-PH1A-002"	 
MH	IDVARVAL	IAGADOSE.PT	CO.PT	CONCAT	SE.ETCD =TE.ETCD	-CO~	ASSIGNED FROM PROTOCOL "NALOXONE-PH1A-002"	 
PC	COREF	PROTDEV.PT	CO.PT	CONCAT	VSDT.CPEV...	SE.EPOCH	Please note that there should not be any gap between the end date of the previous element and immediate start date of the successive element.	 

SDTM Specification

Repeat

Assign

Download Mapping

Submit for review

DOMAIN	VARIABLE NAME	KEY FIELD	UNIQUE FIELD	FUNCTION	LOGIC	SOURCE	COMMENTS
CO	DOMAIN	CO.PT	CO.PT	CONCAT	VSDT.CPEV...	-CO-	ASSIGNED FROM PROTOCOL "NALOXONE-PH1A-002"
EX	STUDYID	MEDSDTLS.PT	CO.PT	CONCAT	VSDT.CPEV...		
CM	RDOMAIN	PROTDEV.PT	MEDSDTLS.PT	SEQUENCE_GENERATION	VSDT.VISDATE.&&VSDT.VISDATE,		
DV	COVAL	SCH.PT	CO.PT	CONCAT	VSDT.CPEV...		
LB	IDVAR	ECGASMT.PT	CO.PT	CONCAT	VSDT.CPEV...		
MH	IDVARVAL	IAGADOSE.PT	CO.PT	CONCAT	SE.ETCD =TE.ETCD		
PC	COREF	PROTDEV.PT	CO.PT	CONCAT	VSDT.CPEV...		
PE	COSEQ	CO.PT	PROTDEV.PT	CONCAT	VSDT.CPEV...		

Comments

Specification QA 08/05/2018, 12:45 pm
 Temporibus autem quibusdam et aut officiis debitis aut rerum necessitatibus saepe eveniet ut et voluptates repudiandae sint et molestiae non recusandae.

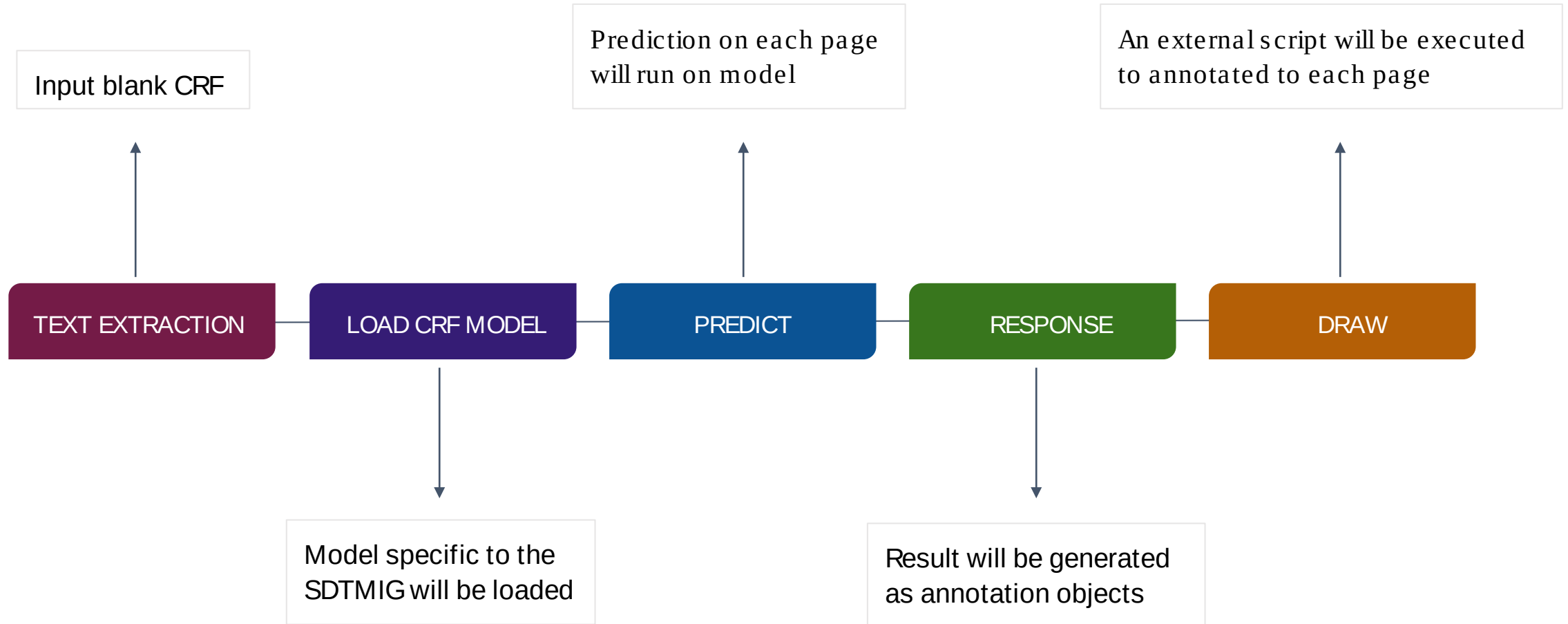
Primary User 08/05/2018, 12:50 pm
[Escalated to PM for clarification](#)
 Numquam eius modi tempora incidunt ut labore et dolore magnam aliquam quaerat voluptatem.

Project Manager 08/05/2018, 02:00 pm
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Escalate

Numquam eius modi tempora incidunt ut labore et dolore magnam aliquam quaerat voluptatem.

POST



VIEW



DOMAIN	STUDYID	DOMAIN	USUBJID	SUBJID	RPSTDT	RPENDTC	RPXSTDT	RPXENDTC	RFXDTC	RFXENDTC	DTHDTC	DTHPL	SITEID
CO	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00009	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00010	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
EX	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00021	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00022	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
CM	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00023	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00024	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
DV	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00025	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00026	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
LB	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00027	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00028	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
MH	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00029	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00030	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
PC	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00031	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00032	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
PE	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00033	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00034	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00035	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR
	RD14FHS PQQC-002	DM	RD14FHS PQQC-002 VACR-00036	2019	2019-12-02	2019-12-31	2019-12-02T00:00:00	2019-12-31T00:00:00	2019-12-02T00:00:00	2019-12-31T00:00:00			VACR

XPT

XML



- Generation of datasets at a click
- Guidelines, Specification document, controlled terminologies and raw data

- xpt file generated
- Is the input to define.xml generation

Study View Dataset

Download

DOMAIN	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC	DTHDTC	DTHFL	SITEID
CO	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02019	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02020	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
EX	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02021	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02022	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02023	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
CM	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02024	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02025	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
DV	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02026	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02027	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
LB	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02028	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02029	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
MH	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02030	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02031	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02032	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
PC	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02033	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02034	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR
PE	RO14 IFRS PIQC-002	DM	RO14 IFRS PIQC-002-VACR-02035	2019	2014-12-02	2014-12-19	2014-12-02T08:00:00	2014-12-18T08:00:00	2014-11-17T08:28:00	2014-12-22			VACR





Adherence technical controls as per 21 CFR Part 11 compliance mandates



Process oriented



Audit ready outputs and documents





- ✓ Integrating technology into standardization process
- ✓ Handling timeline challenges
- ✓ Optimal utilization of resources
- ✓ Effective adherence to standards and regulations



