

Single Day Event

Leveraging Machine-Readable Specifications
for Automating SDTM Creation

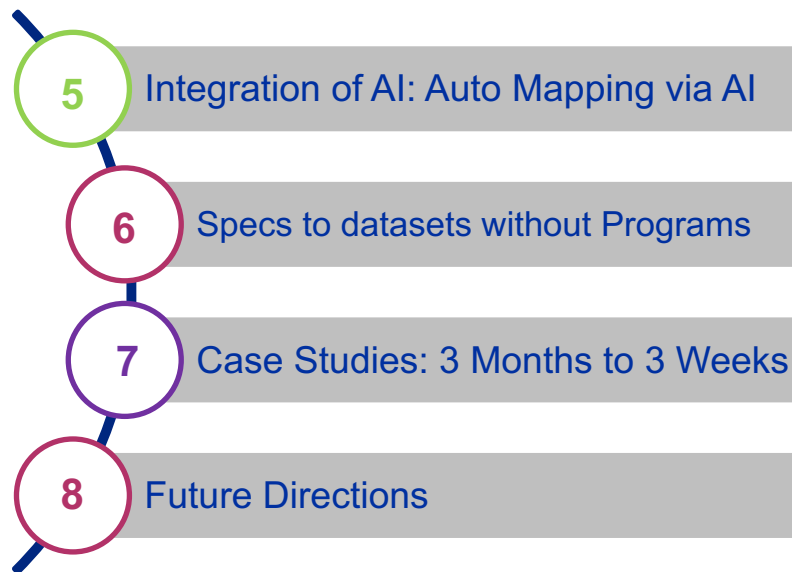
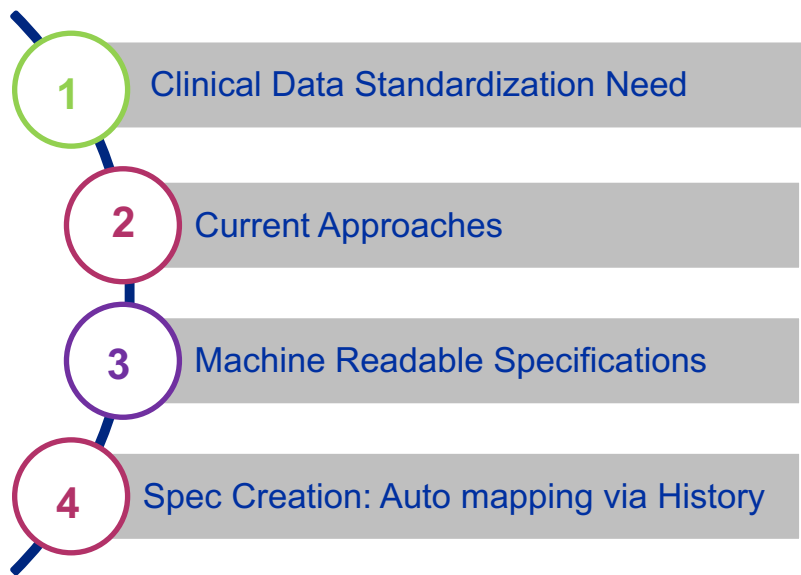
Presented by:
Vineet Jain
Founder & CEO
Nimble Clinical Research, USA
Ranvir Singh
AD, Statistical Programming
Nimble Clinical Research, India



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Clinical Data Standardization Needs



Clear Structure
Contents of Data
Optimize Collection
Enhanced Consistency



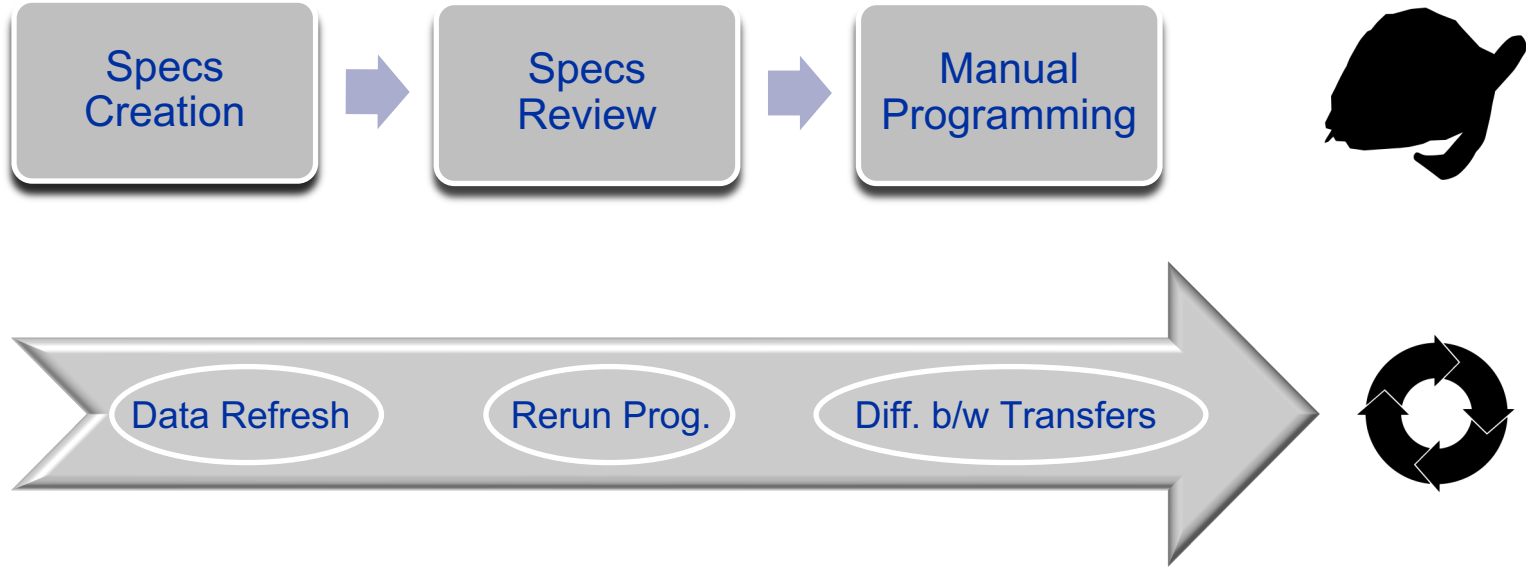
Supports Visualization
Reusable Templates
Data Sharing
Pooling Analysis



Accelerated Timelines
Increased Efficiency
Reduced Errors
Quick Review



Faster Approval



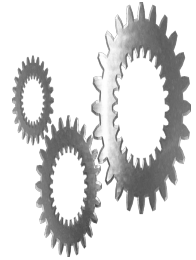


Semi-Automated Tools

- Initial Mapping
- Draft Templates
- More Manual Intervention

Limitations

- Need Domain Expertise
- Scalability Issues
- Poor Integrations





Machine Readable Specifications Example



Study Level Metadata

PARAMETER CATEGORY	PARAMETER CODE	PARAMETER	VALUE
CDISC	CDISCOVER	CDISC IG Version	SDTM 3.3
CDISC	CTVER	Controlled Terminology Version	2022-09-30
DEFINE	CRFNAME	File name for blank CRF (default acrf.pdf if not specified)	acrf.pdf
DERIVATION	RELDAY	DM reference variable for relative day calculation	SDTM.DM.RFSTDTC
INITIALIZE	LIBIDSRC	Library ID of Source Data	L001
CDISC	ENGVER	Pinnacle21 Checks Engine	FDA 2010.1

Source Data Metadata

DATA SOURCE	DATA TYPE	DESCRIPTION	TIME STAMP	CATEGORY	SDTM DOMAINS	REASON SKIPPED	PREPROCESS	COMMENT	CHECKS
AE	EDC	Adverse Events	28-09-2023 19:08		AE				
CM	EDC	Concomitant Medications	28-09-2023 19:08		CM				
CM2	EXTERNAL		28-09-2023 19:09		PR				
CODINGDECISIONREPORT_MEDDRA			21-09-2023 11:38		_NA_	Not needed			Description is missing Description is missing; Data type is missing
CODINGDECISIONSREPORT_MEDDRA	EXTERNAL	Meddra			_NA_	Not needed			Dataset not present in source

Dataset/Variable level Metadata

DATASET (IN)	DATASET (OUT)	VARIABLE (IN)	VARIABLE (OUT)	CORE	ACTION	ID VARIABLE	DERIVATION	LABEL (IN)	LABEL (OUT)	FORMAT (IN)	FORMAT (CDISC)	TYPE (IN)	TYPE (OUT)	LENGTH	ORIGIN
							SAS: %conv2dtc(mm= __AESTDTX_mm, dd= __AESTDTX_dd, yyyy= __AESTDTX_yyyy); if ~missing(__AESTTM) then AESTDTC = strip(AESTDTC) 'T' strip(__AESTTM);								
AE	AE	AESTDTX	AESTDTC	EXP				Onset Date	Start Date/Time of Adverse Event		ISO 8601	N	C		CRF 81
AE	AE	AESTDTX_RAW			Drop			Onset Date (Character)				C			



Historical Data Utilization:

- Spec. is Automatically created by leveraging Historical studies data
- System Learns from Past Mappings
- Apply Mapping Automatically for similar data in new studies
- Function: Baseline Flag
- Params: Any derivation

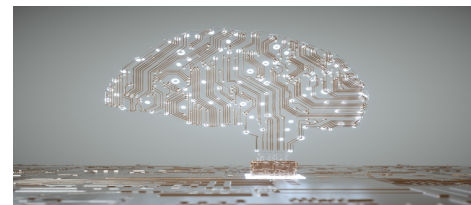


Dataset	Source	Target	Destination	ID Variable	Function	Params	Map Name	Label	Type	Origin	Define Comment
IN	ACTEVENT		NA	✓		✓				✓	
IN	CPEVENT		NA	✓		✓				✓	
IN	CPEVENT1	VISIT		✓		✓	VISITNUM	Visit Name	C	✓ CRF	
IN		VISITNUM		✓	map	{ "var": "VISIT", "map": "VISITNUM", "mapto": "decode", "mapfrom": "data_target" }		Visit Number	N	✓ ASSIGNED	
IN	TESTCD	VSTESTCD		✓	default	✓	_NA_	Vital Signs Test Short Name	C	✓ ASSIGNED	
IN		VSTEST		✓	default	✓	VSTESTCD	Vital Signs Test Name	C	✓ CRF	

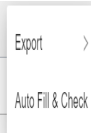


AI Integration:

- For Complex or unseen data structures
- AI Algorithm analyse data patterns, suggest mappings
- Predict classification, streamlines the process for future



Dataset	Source	Test Code	Test	Derivation List	CT	CT Code	Origin	Define Comment	Other Notes
DF1	GOT	AST	Aspartate Aminotransferase	list("LBCAT"="CHEMISTRY","LBSCAT"="LIVER")	LBTESTCD	C64467			
DF1	SBASA	BASO	Basophils	list("LBCAT"="HEMATOLOGY")	LBTESTCD	C64470			
DF1	SBAS	BASOLE	Basophils/Leukocytes	list("LBCAT"="HEMATOLOGY")	LBTESTCD	C64471			
DF1	DBILR	BILDIR	Direct Bilirubin	list("LBCAT"="CHEMISTRY","LBSCAT"="LIVER")	LBTESTCD	C64481			
DF1	LBIDS1	BILI	Bilirubin	list("LBCAT"="CHEMISTRY","LBSCAT"="LIVER")	LBTESTCD	C38037			





SDTM Dataset Creation:

Machine Readable
Spec & Raw Datasets



No Manual SAS/R
Programming



SDTM Datasets

* Domain

AE

* Keys

STUDYID,USUBJID,AEDECOD,AESTDTC

► Variables

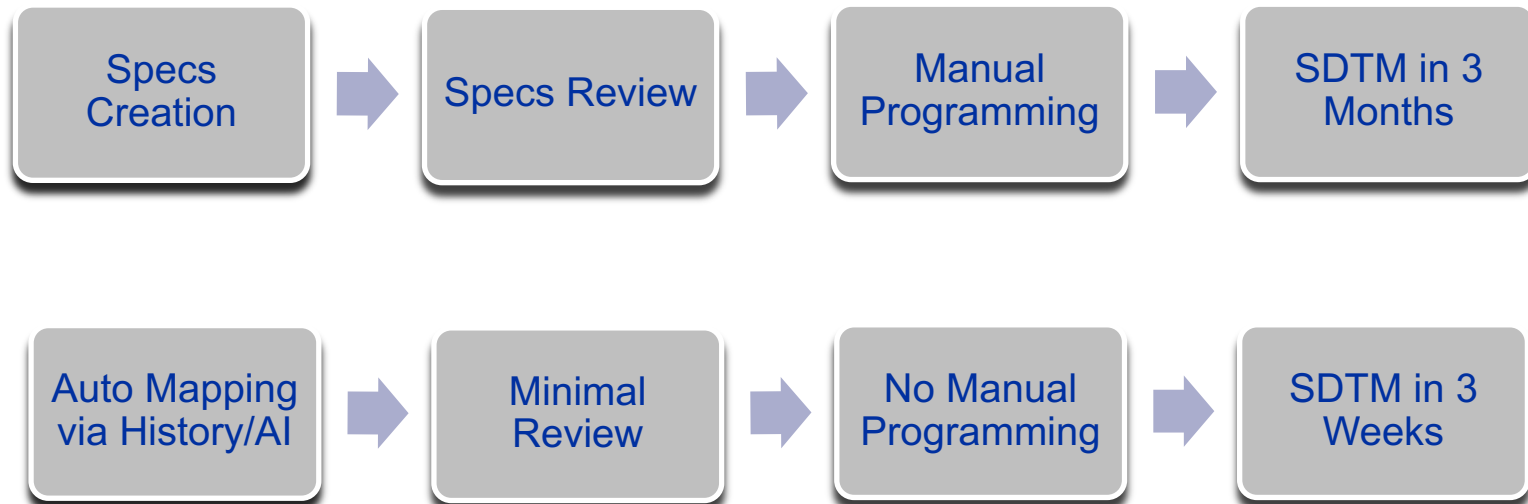
► Tests

▼ Values

	Map N...	CT	Map/CT Label	Source	Target	Decode	CT It...	
1 :	AESEV	AESEV	Severity/Intensity Scale f...	5	FATAL			
2 :	AESEV	AESEV	Severity/Intensity Scale f...	4	LIFE-THREATENING			
3 :	AESEV	AESEV	Severity/Intensity Scale f...	1	MILD	Mild Adverse Event	C41338	
4 :	AESEV	AESEV	Severity/Intensity Scale f...	2	MODERATE	Moderate Adverse Event	C41339	
5 :	AESEV	AESEV	Severity/Intensity Scale f...	3	SEVERE	Severe Adverse Event	C41340	

Export

Auto Fill & Check





Next Level Automation:

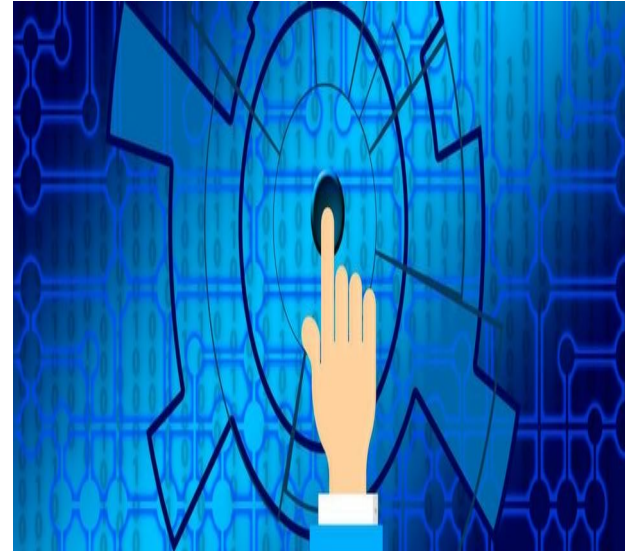
- Automation of Domains via CRF, external DTS

Enhancing Compliance:

- Real time checks integration

Automatic Reviewers Guide:

- Streamlining the Documentation



Thank you !!
We are happy to answer your questions !!



**The Global Healthcare
Data Science Community**

Contact Channels

📞 UK +44 1843 609600
✉ office@phuse.global
🌐 phuse.global

Social Media

🐦 [@phusetwitta](https://twitter.com/phusetwitta)
📘 [/phusebook](https://facebook.com/phusebook)
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Please contact us @
Vineet.jain@nimble-cr.com
Ranvir.singh@nimble-cr.com