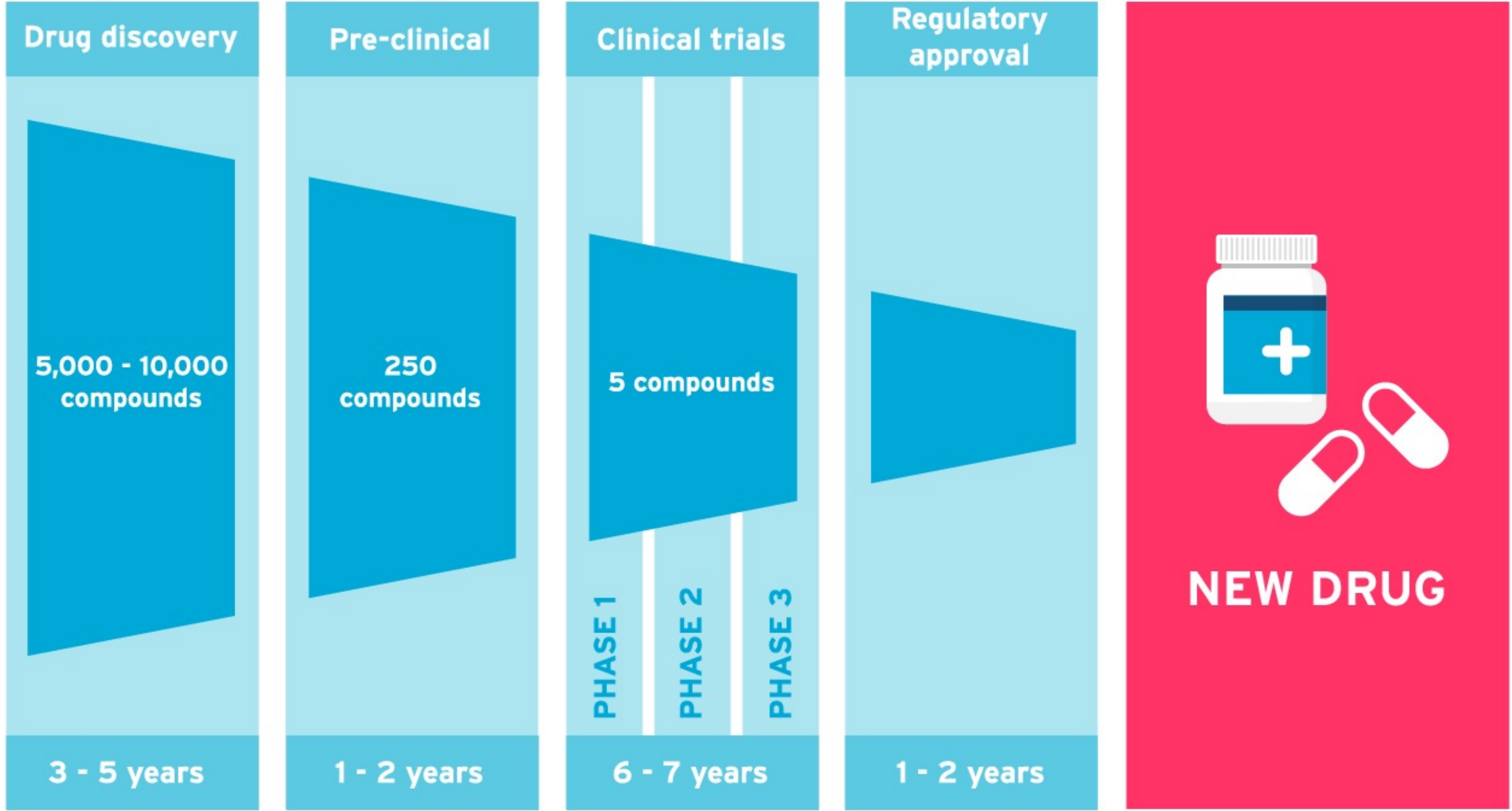


HOW RAPID SDTM DATA CONVERSION ENABLED EARLY INSIGHTS OF VACCINE SAFETY AND EFFICACY IN COVID-19 TRIALS

Gilbert Hunter | Customer Success Manager





WHY DOES IT TAKE SO LONG?





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.html

.pdf

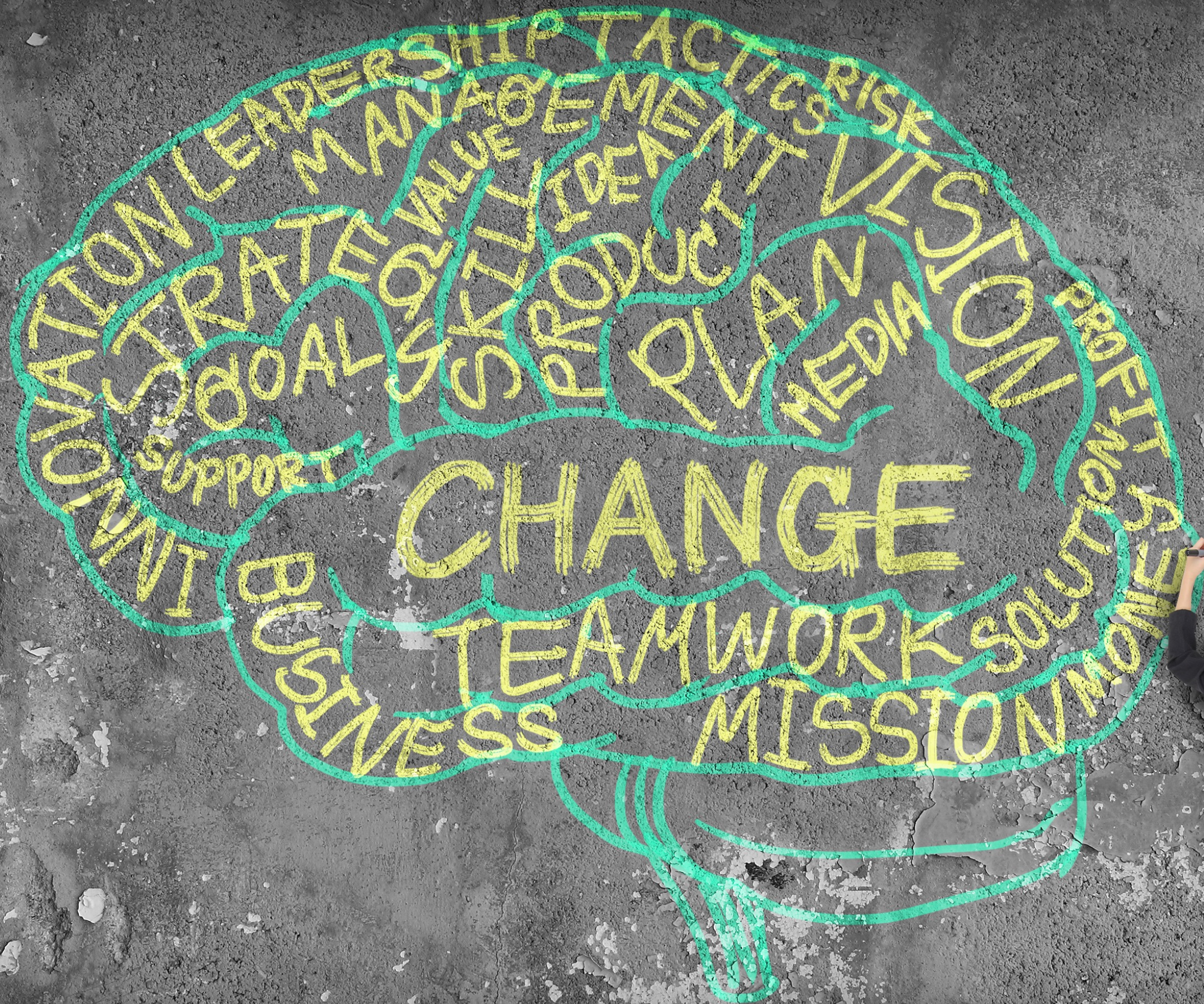
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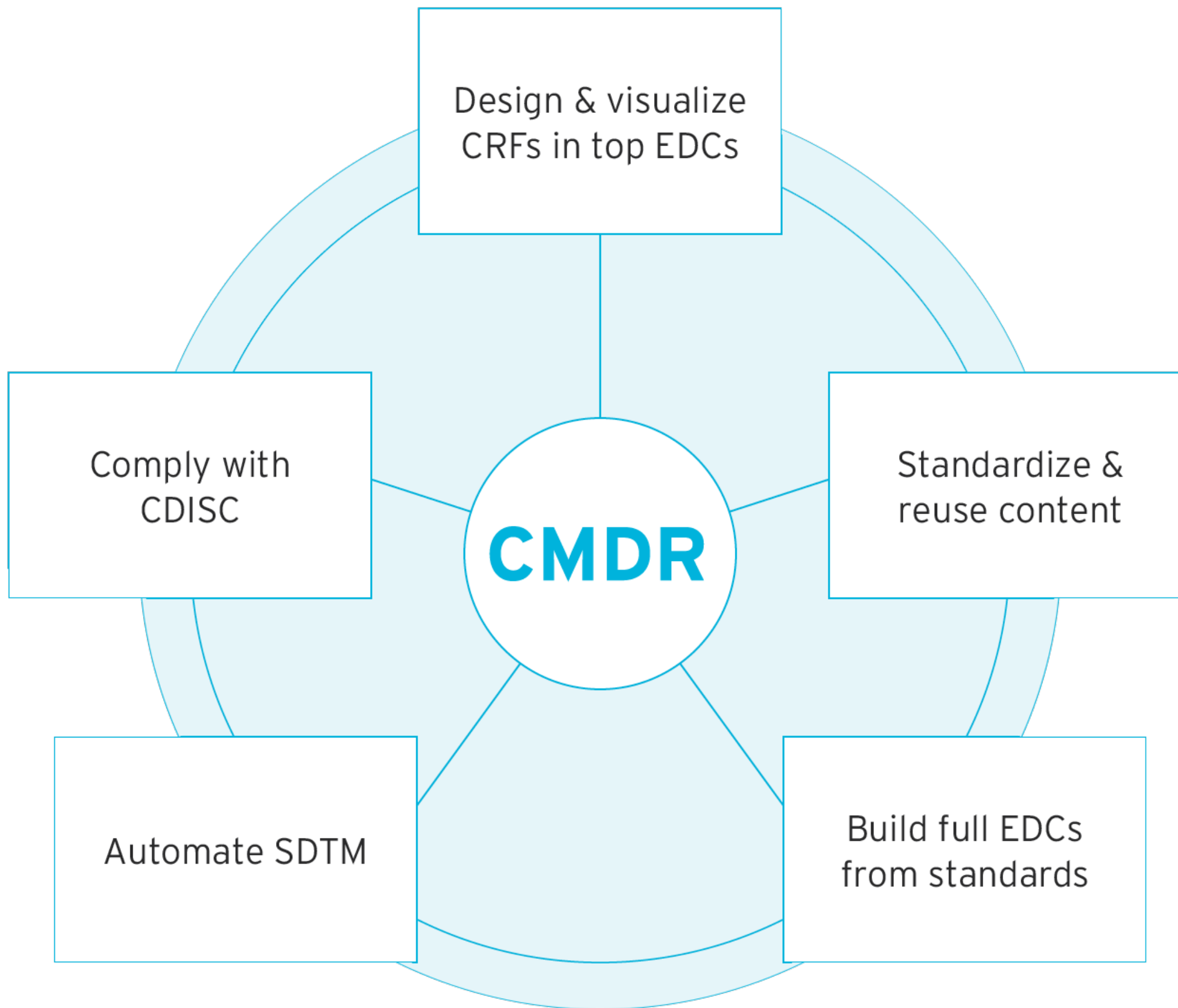
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GETTING CAUGHT IN THE TRAP



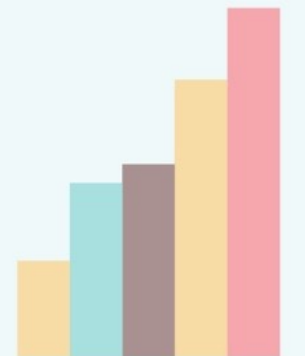
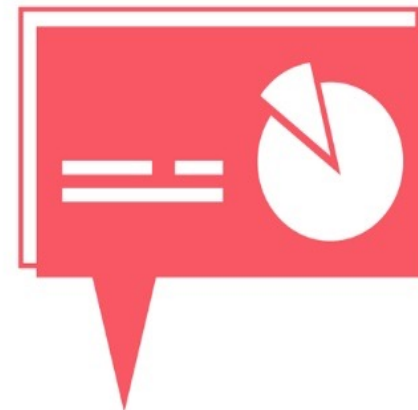




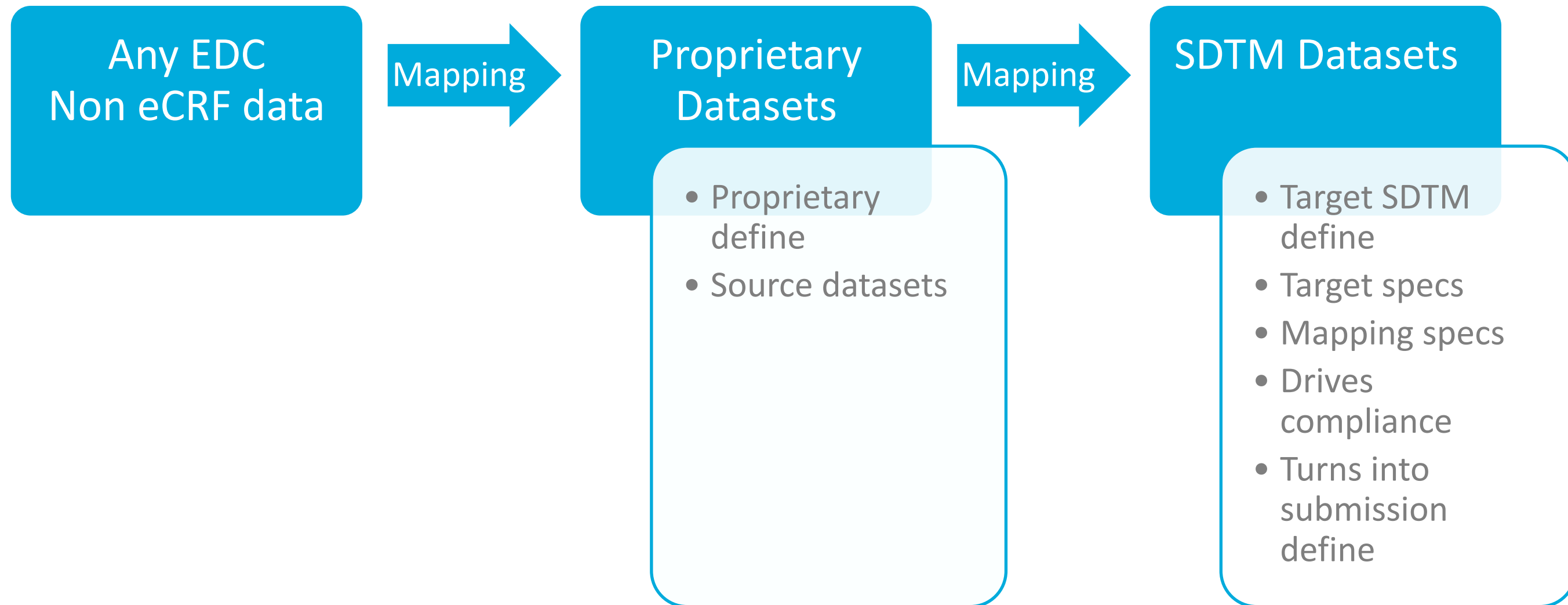
DESIGN WITH THE END IN MIND!



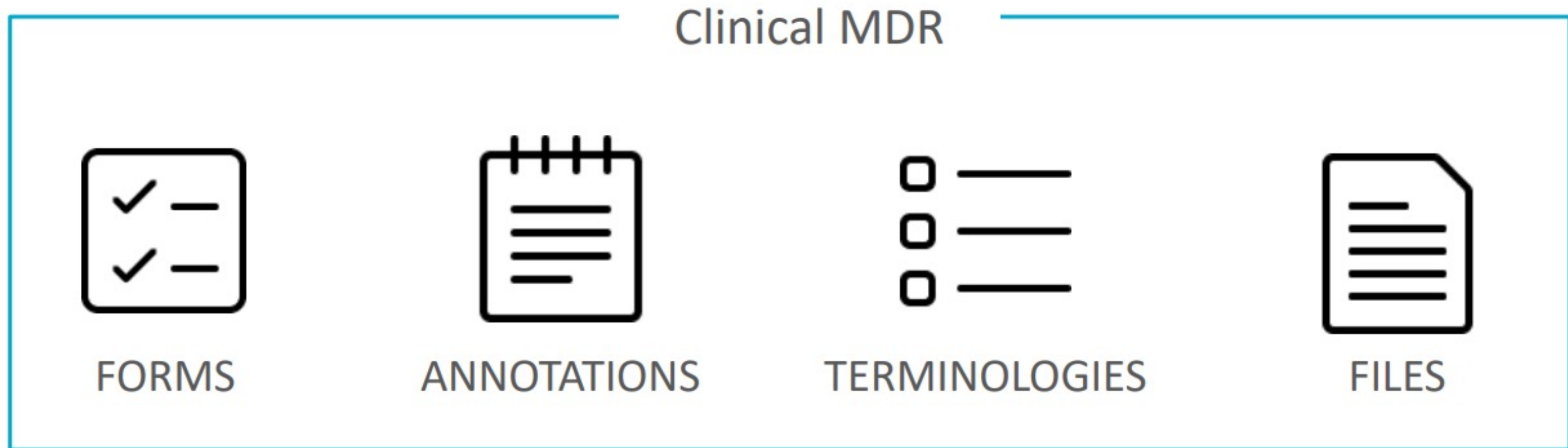
DESIGN DATASETS UPFRONT



METADATA DRIVEN DATA TRANSFORMATIONS



STANDARDIZATION IN TRIALS



AUTOMATED SDTM DATASET GENERATION

AE (Adverse Events) - EVENTS						
Location: ae.xpt 						
Related Supplemental Qualifiers Dataset: SUPPAE (Supplemental Qualifiers for AE)						
Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	200		Protocol
DOMAIN	Domain Abbreviation	text	Identifier	2	Domain Abbreviation - AE â€¢ "AE" = "Adverse Events"	Assigned
USUBJID	Unique Subject Identifier	text	Identifier	200		Derived Identifier formed by concatenating STUDYID-SITEID-SUBJID
AESEQ	Sequence Number	float	Identifier	200		Derived Sequential number identifying records within each USUBJID in the domain
AESPID	Sponsor-Defined Identifier	text	Identifier	200		CRF Annotated Case Report Form [100] 
AETERM	Reported Term for the Adverse Event	text	Topic	200		CRF Annotated Case Report Form [100] 
AELLT	Lowest Level Term	text	Variable Qualifier	200	Medical Dictionary for Regulatory Activities MedDRA 23.1	Assigned
AELLTCD	Lowest Level Term Code	integer	Variable Qualifier	8	Medical Dictionary for Regulatory Activities - Code MedDRA 23.1	Assigned

AND THE BENEFITS OF AUTOMATION?



COVID VACCINES APPROVED TODAY!



UNIVERSITY OF
OXFORD

moderna

NOVAVAX

AstraZeneca

Johnson & Johnson

BIONTECH

Pfizer


sinovac®


SINOPHARM


BHARAT
BIOTECH

ANY QUESTIONS?

...Or come and chat later

Gilbert Hunter | Formedix

Booth 21

