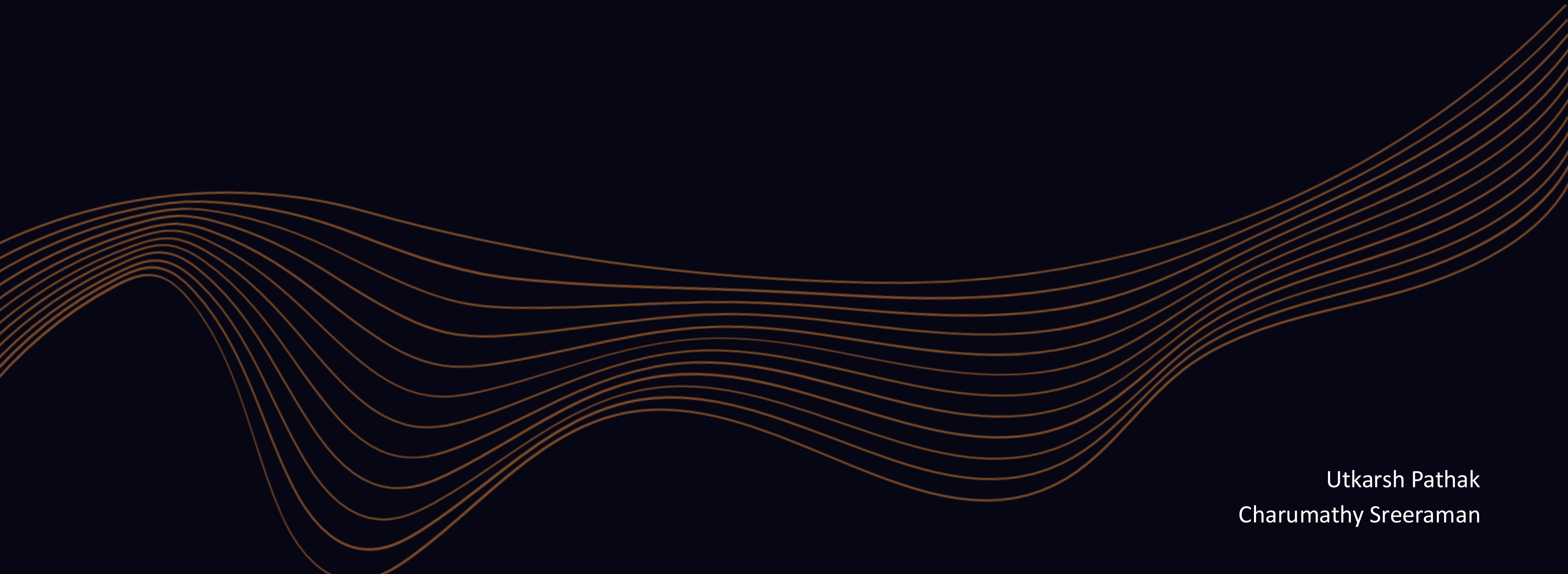


SDTM Up – Versioning – Do's & Don't's

01

A series of approximately 15 thin, parallel, wavy lines in a light brown or gold color, flowing from the left side of the slide towards the right, creating a sense of movement and depth.

Utkarsh Pathak
Charumathy Sreeraman

02

Agenda

- Introduction
- Need for Up - Versioning
- Production Conversion Process
- QC Conversion Process
- Do's & Don't's



INTRODUCTION

SDTM Up – Versioning:
Process of refreshing the
version of the CDISC Study
Data Tabulation Model (SDTM)

Recent Studies - Advisable to
utilize the most current
version of the SDTM

Long Term Studies -
Transitioning to the most
recent version of the SDTM
may be prudent

Identify modifications

Determine which versions to
refresh

Consider alignment

04

CDISC and It's Evolution

Emerged as a crucial part of the clinical research process since they provide a framework for standardizing and organizing data across different clinical studies

Regulatory agencies demand that data be submitted in a consistent format that conforms to CDISC standards

The increasing complexity of clinical research and technological improvements are driving the ongoing growth of CDISC standards

To handle new opportunities and difficulties in the area, CDISC is always trying to improve current standards and create new ones

Need For Up - Versioning

05

SDTM up-versioning is necessary to maintain consistency and make the data standard applicable to evolving clinical trial practices.

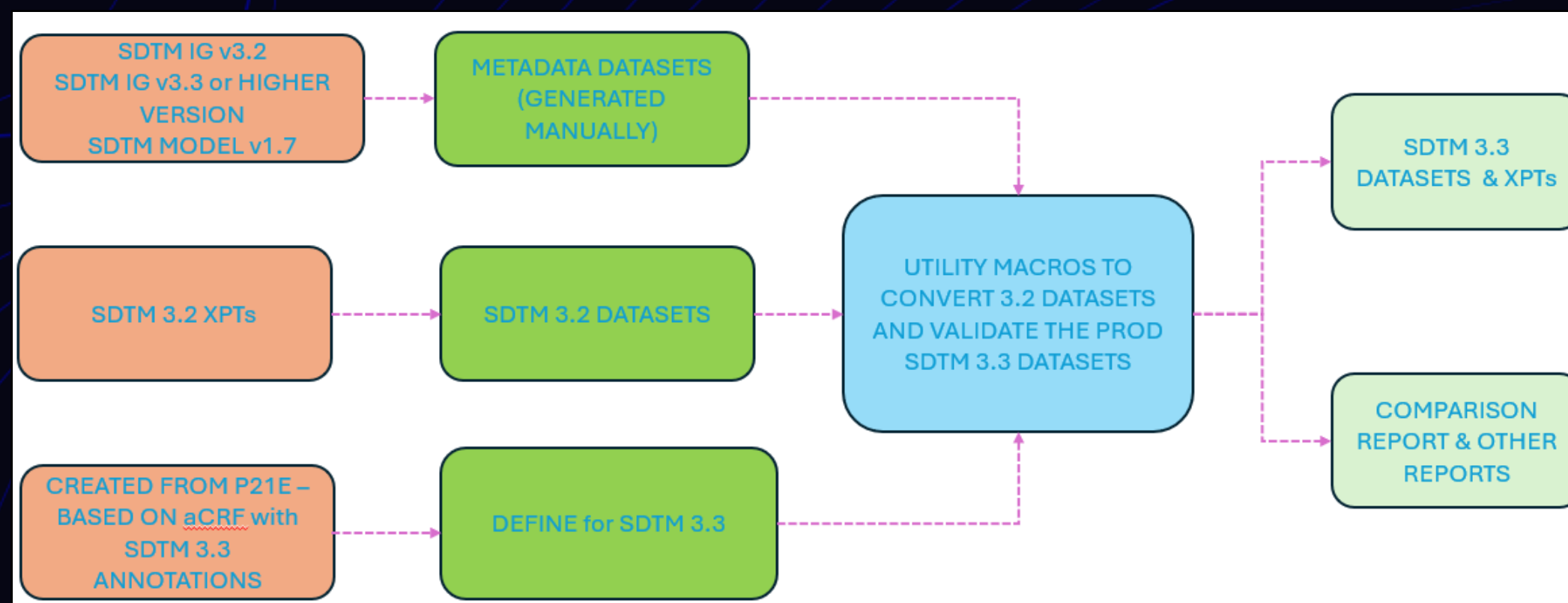
New data types, improved analysis methods, and enhanced data capture capabilities can all be added as a result.

Regulatory agencies like the FDA mandate that studies be submitted using the most recent version of the SDTM standard in order to preserve consistency across submissions and expedite review processes.

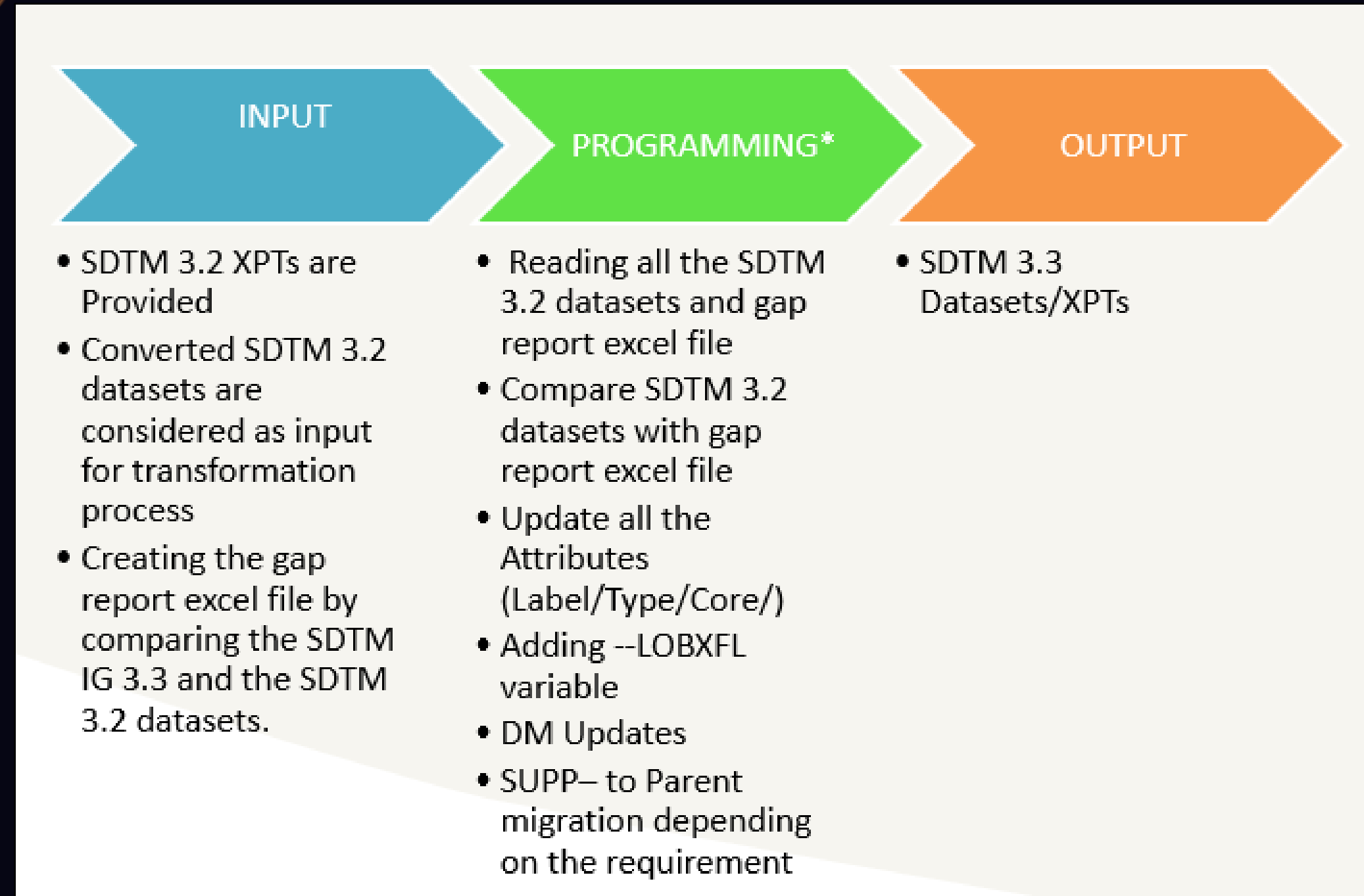
06



**PROCESS
FLOW**



PROD CONVERSION PROCESS



Metadata Updates

- ❖ Variable Labels, Type & Core
- ❖ Dataset Names

General Updates

- ❖ Addition of LOBXFL
- ❖ Addition of DM variables
- ❖ TS Updates
- ❖ Conversion from SUPPxx to Parent Domain

Study-Level Updates

- ❖ Conversion of custom domains to CDISC compliant domains
- ❖ Retaining Sponsor Mapping Practices (wherever required)
- ❖ Creation of new domains (e.g., if CC or MO domains were used, these will need to be remapped)

QC CONVERSION PROCESS - MANUAL

Apart from the above double programming comparison explained above manual QC is done on the reverse approach method.

By reading the gap analysis report and all the SDTM 3.3 datasets and making sure that whether the SDTM IG 3.3 updates are incorporated and no gaps in the transformation and reported in granular level report in excel file

10

CONFORMANCE CHECKS

P21E report will be analyzed for any metadata issues and annotating the P21E report with explanations for the errors/warnings.

When performing validation of SDTM v3.3 datasets using, it is advised you use the SDTM and SDTMIG Conformance Rules v2.0 Rules for.

SDTM Up – Versioning – DO's

11

- Keeping up with the CDISC evolution
- Determine the key updates and changes in SDTM IG 3.2 to the higher versions of SDTM IG.
- Bear in mind the processes in place for requesting new domains or changes to the standard
- Should always verify the most recent model, IG, and non-standard variable registry
- Should check with the appropriate foundational teams to determine impact.
- Preparing your team for a smooth transformation process and implementation
- Gather necessary study data and documentation as pre-requisite
- Maintain high standards for data quality and compliance.
- Perform quality assurance checks post-transformation

12

SDTM Up – Versioning – DON'T's

Correcting inaccuracies in SDTMIG 3.2 mapping that are not associated with updates to the SDTM version.

Address the data issues in the SDTM 3.2 datasets

Refrain from creating or updating sponsor-specific domains that do not adhere to CDISC standards.

Thank You

Utkarsh Pathak
Charumathy Sreeraman