Navigating the road to submission: Unveiling the Impact of SDTM

Presented by Bremer Louw, VP Operations, BionData\Bioforum

Meet the Speaker

Bremer Louw

Title: VP Operations

Organization: BionData (a Bioforum company)

Bremer has been in the Clinical Research industry for 18 years, serving as SAS programmer in Data Management and Statistical Programming departments. He has been leading teams in Data Management and Statistical programing for more than a decade. Currently he is the Vice President of Operations at BionData, the technology department of Bioforum.

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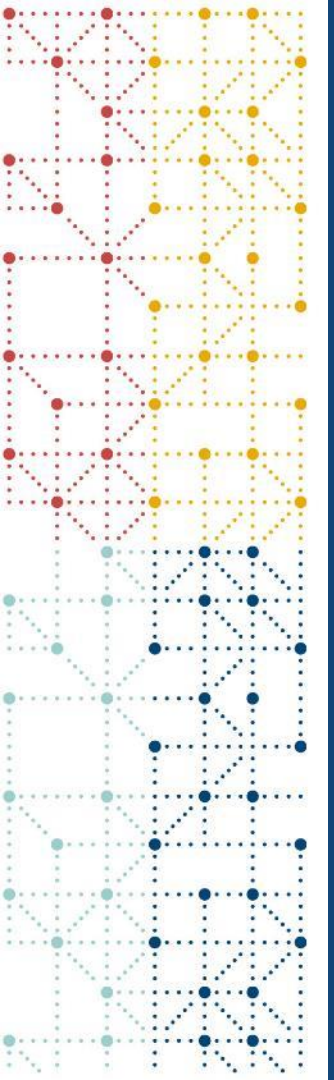
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. Introduction
2. Track study level data quality
3. Ensure cross study consistency
4. Planning for ISS\E with pooled data
5. Conclusion



Introduction

Introduction

SDTM

Study Data Tabulation Model

Organizing data collected in human clinical trials.

Introduction

FDA U.S. FOOD & DRUG ADMINISTRATION

pmda
独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Introduction

Why do regulators require SDTM?

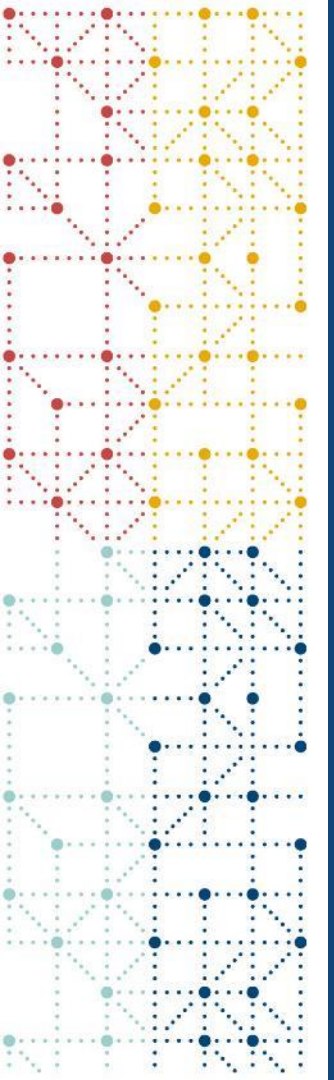
Rigid and predictable data format

Much more time-consuming reviewing #1, compared to #3.

Leverage **standardized tools** like visualizations and conformance rules

Introduction

Why not leverage **SDTM** for these same **benefits** during your road to **submission**?



Track compliance to data quality expectations on a study level

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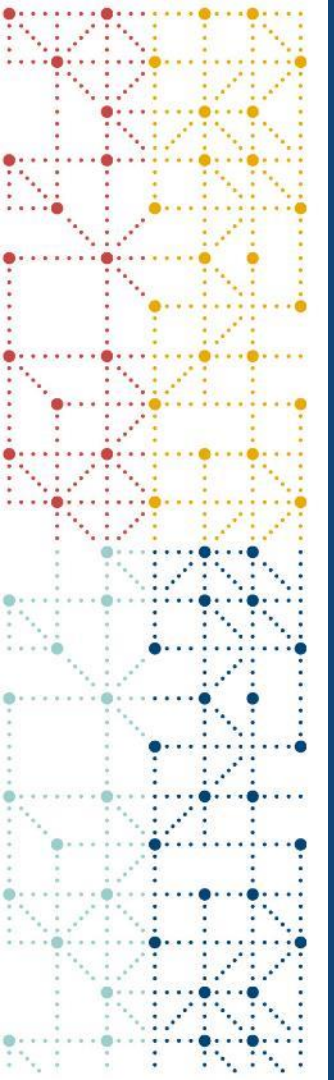
Data Quality

Conformance and Quality Checks

Submission Delays



Ensure cross study consistency to avoid downstream conflicts

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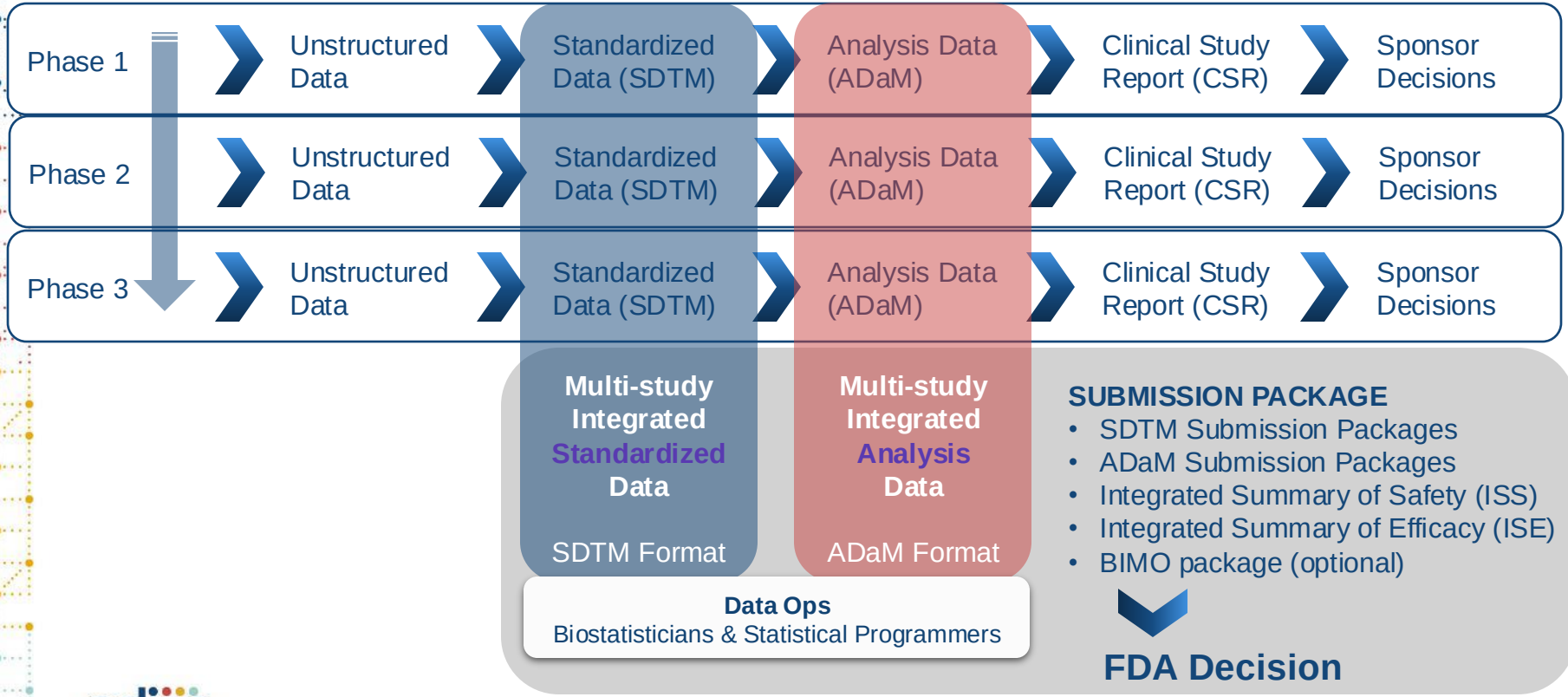

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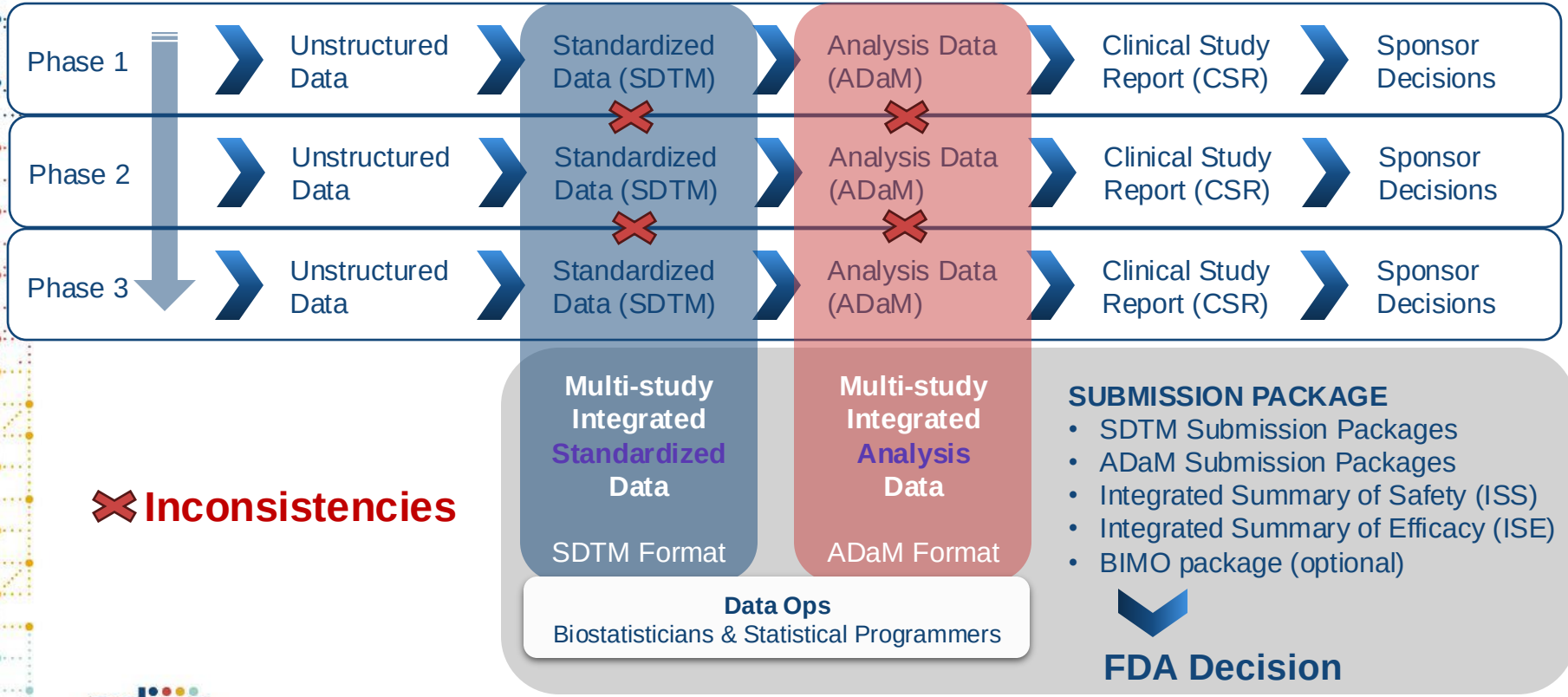

Ensure cross study consistency to avoid downstream conflicts

Identify inconsistencies early

- Convert submission studies to SDTM early
- Do consistency review between all studies in a submission

Planning your Integrated Summery of Safety & Efficacy with pooled data

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- Insights into how to effectively analyze the data
- Identify differences between individual trails
- Monitor safety and efficacy trends – Timely decisions

Conclusion

Conclusion

- SDTM is integral to your submission
- Earlier you have it in place - the more value you gain
- Mitigate data quality risks early

- Downstream quality surprises
- Costly rework
- Delays to market

Thank You!