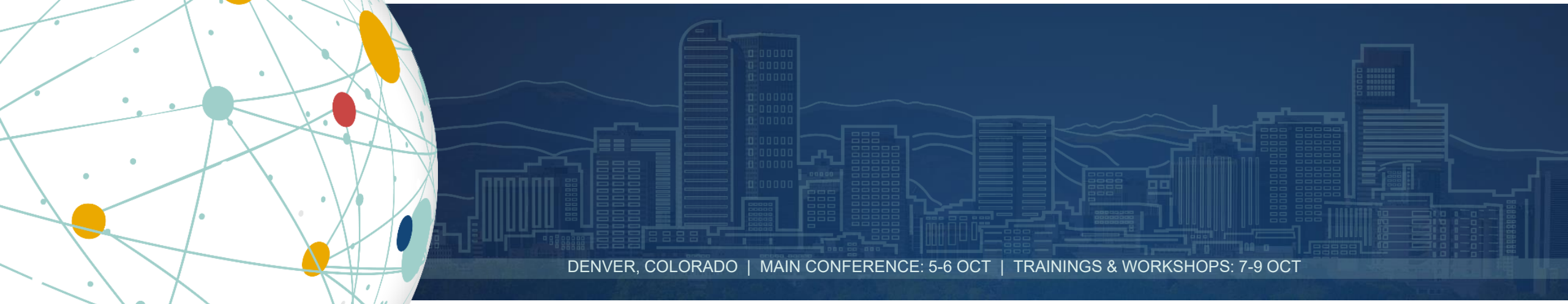


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Bridging the Gap: A Validated Pipeline for Transforming High-Frequency Sensor Data to SDTM

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Agenda

1. Introduction
2. V3 DIME Model
3. AbbVie’s Normal Dataflow
4. Why Wearable Data is Different
5. AbbVie’s Digital Analytical Data Flow
6. Conclusion

Disclaimer

Support of this presentation was provided by AbbVie. AbbVie participated in the review and approval of the content. All authors are employees of AbbVie Inc. and may own AbbVie stock

Introduction

Digital Health Technologies (DHTs): a system that uses computing platforms, connectivity, software, and/or sensors for healthcare. For example, wearables or apps used to collect clinical trail patient data

Complex physical signs and subtle movements can be captured, allowing for novel endpoints to be created to support a clinical trail

DHTs enable continuous, passive, and real-world data collection, producing a large volume of data for analysis

Raw sensor outputs require additional validation to structure the data into CDISC standards



V3 DIME Model Requires Additional Validation for DHTs



VERIFICATION

Evaluates and demonstrates the performance of a DHT

Example

Ensure a wearable smartwatch correctly measures the exact beats per minute when monitoring heart rate



ANALYTICAL VALIDATION

Evaluates the algorithm of a DHT and its ability to detect and predict physiological metrics

Example

Verify a wearable smartwatch's algorithm correctly translates raw photoplethysmography light signals to an accurate heart rate



CLINICAL VALIDATION

Evaluates whether a DHT acceptably measures or predicts meaningful clinical data

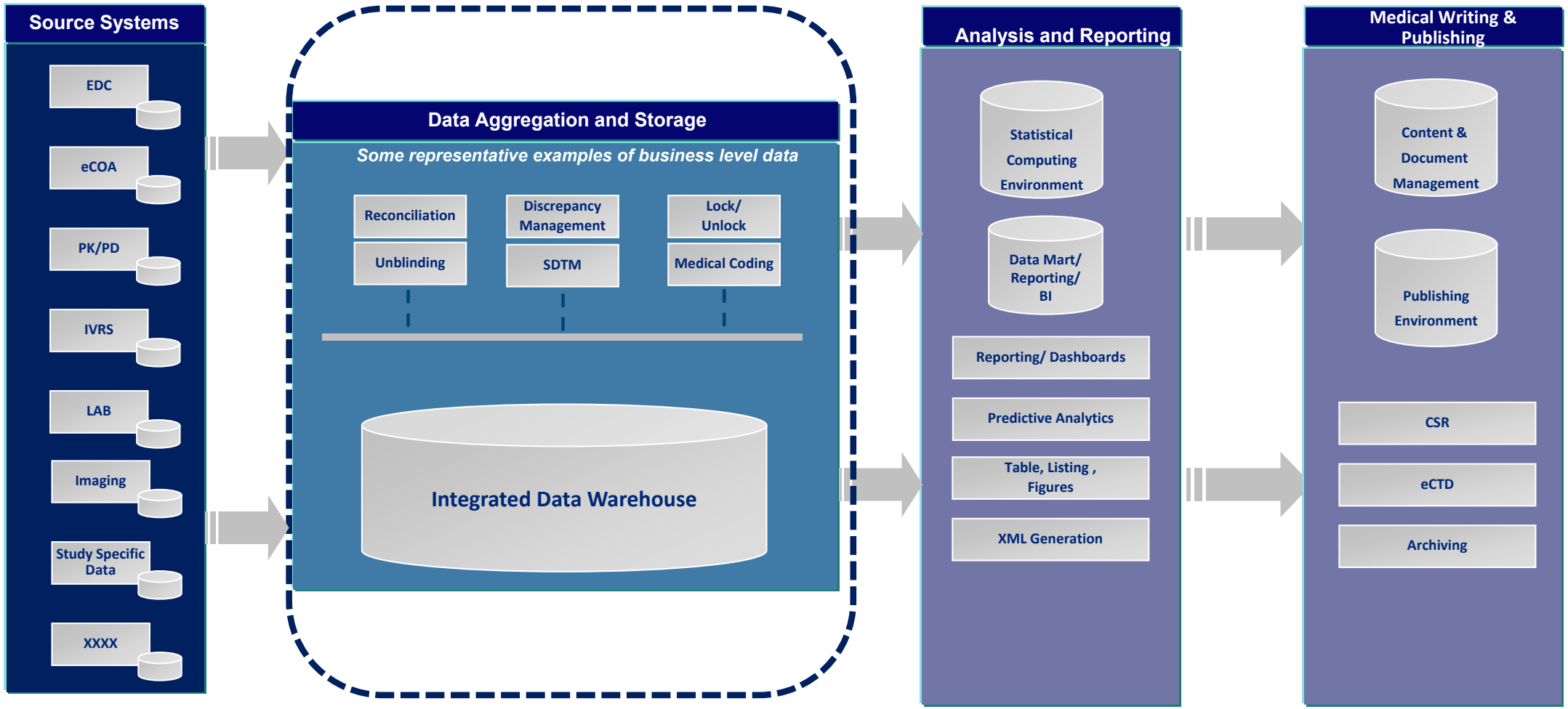
Example

Validate the heart rate measured from the wearable smartwatch accurately reflects the patient's physiological response to external stimulus

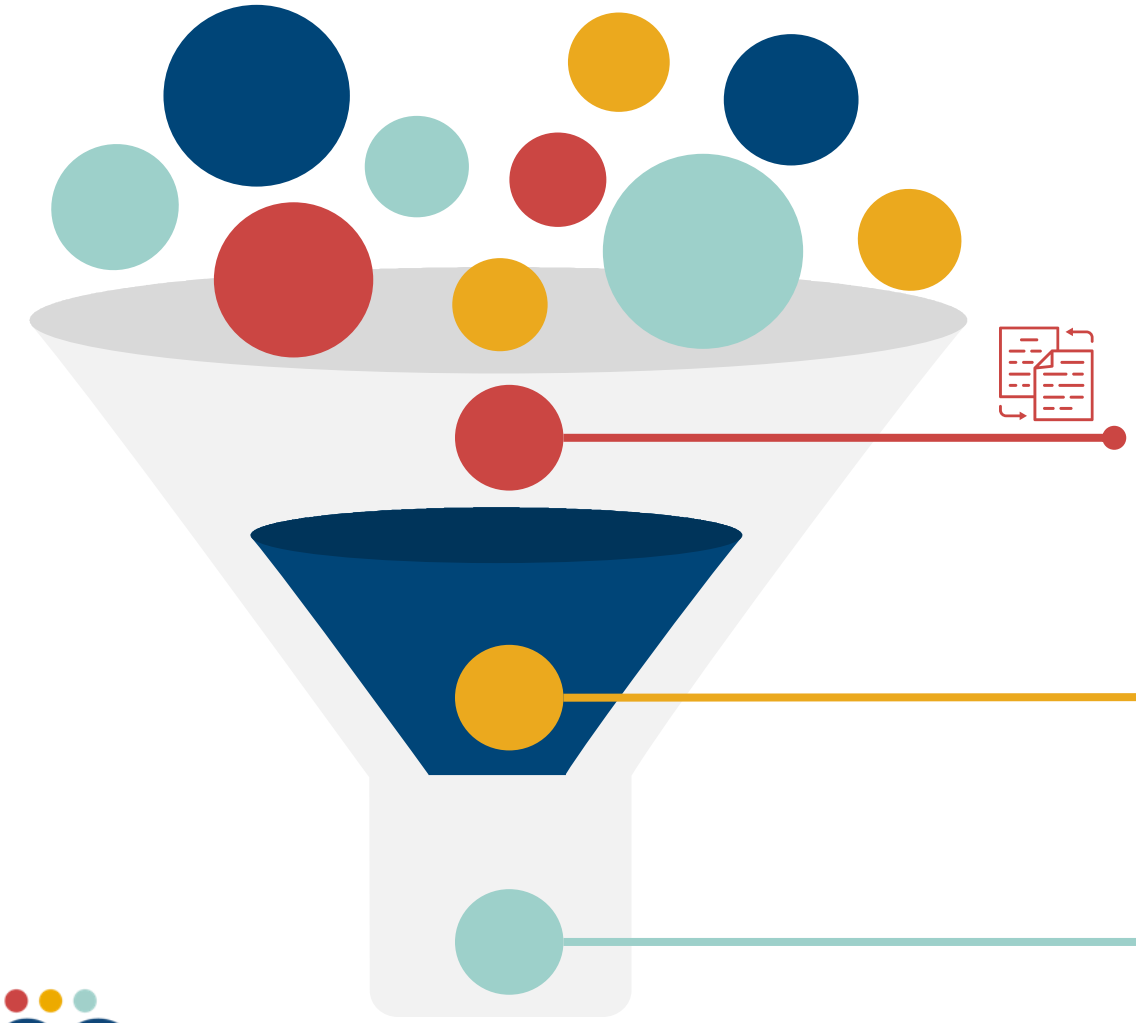
Data architecture for traditional data collection sources does not allow for required validation of DHTs. To successfully analyze DHT data, an enhanced framework is needed

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AbbVie's Legacy Dataflow (No DHT)



Why Wearable Data is Different

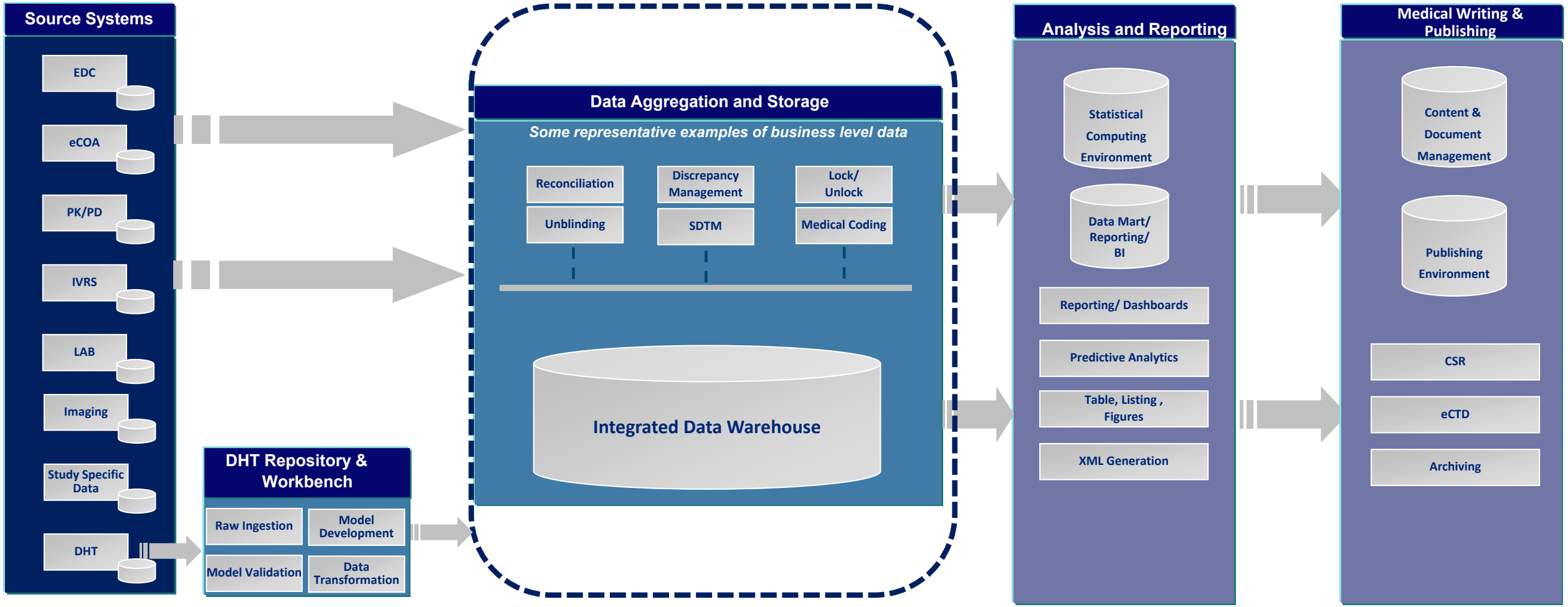


DHTs have a culmination of continuously collected, real-time data in a non-human readable format

Additional analyses are conducted in house to determine the data points that can be transformed

Determine finite data points and map to SDTM format

AbbVie's Digital Analytical Dataflow



Conclusion



As DHTs have become more common, the ability to analyze and validate data has become increasingly important



The V3 DIME Model helps provide insight for how to validate DHT data



AbbVie has created a robust validation pipeline for building a scalable bridge between raw sensor output to SDTM format

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Thank You