



MDR and PAT Implementation at Bayer



**PHUSE US Connect
2020, Orlando, FL, USA**

Julius Kusserow, Girish Rajeev





Forward-Looking Statements

This website/release/presentation may contain forward-looking statements based on current assumptions and forecasts made by Bayer management.

Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at <http://www.bayer.com/>.

The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.



Julius Kusserow

Head Quality & Standards Management

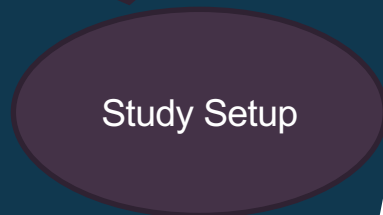
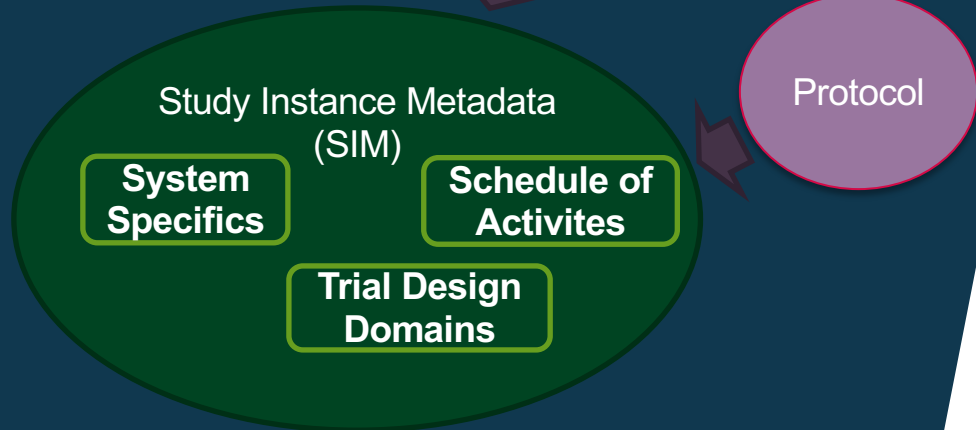
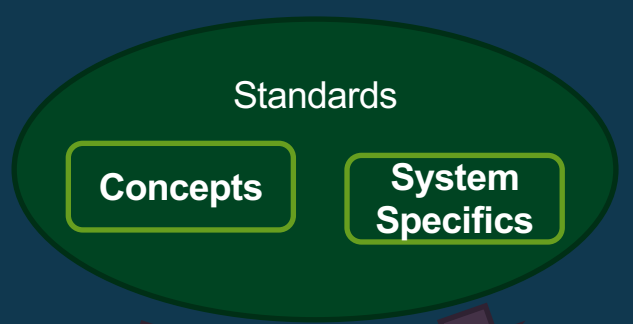
Berlin, Germany

Girish Rajeev

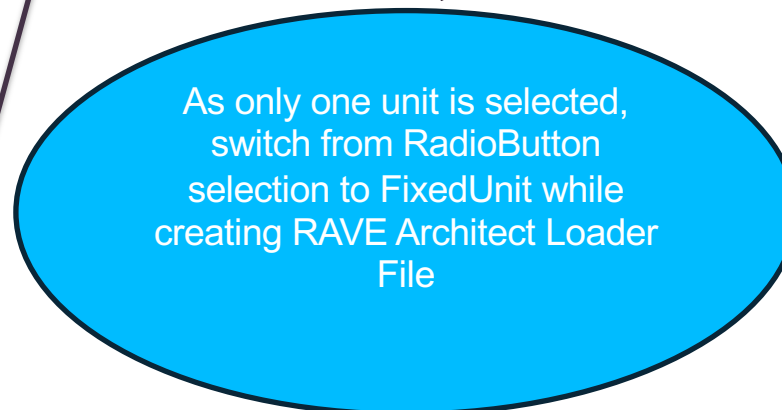
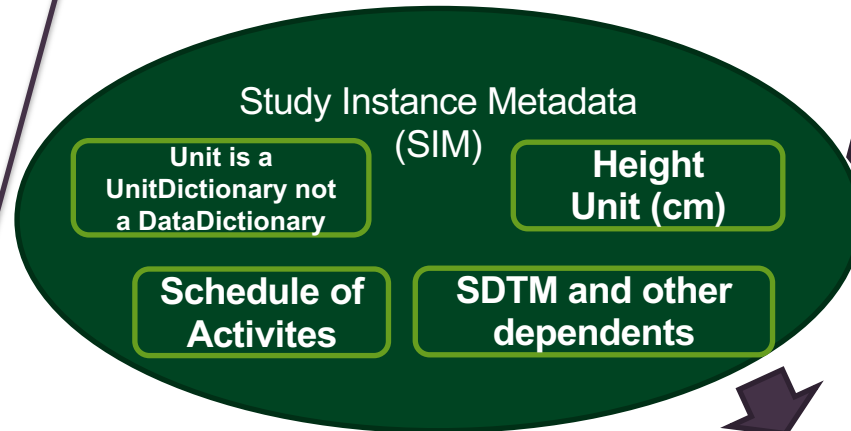
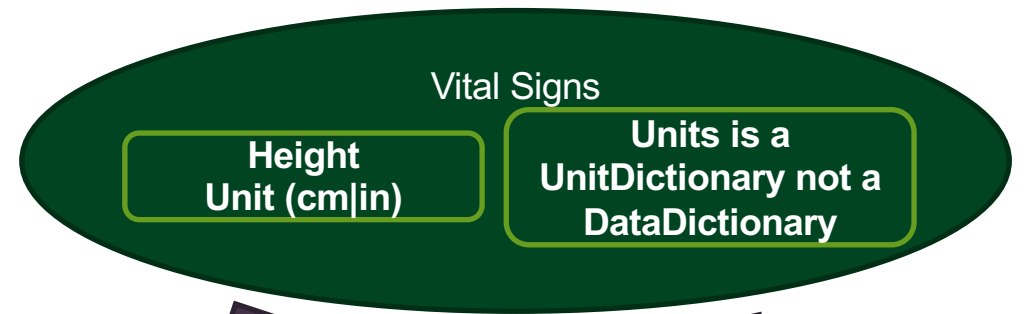
Associate Director Standards Management

New Jersey, USA

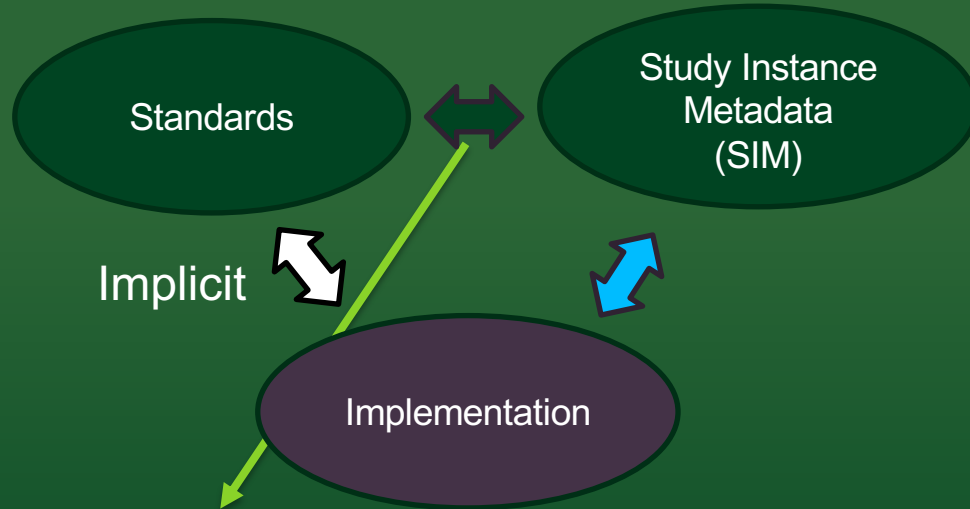




Metadata Repository
Protocol Authoring Tool
Integration Layer
Target System



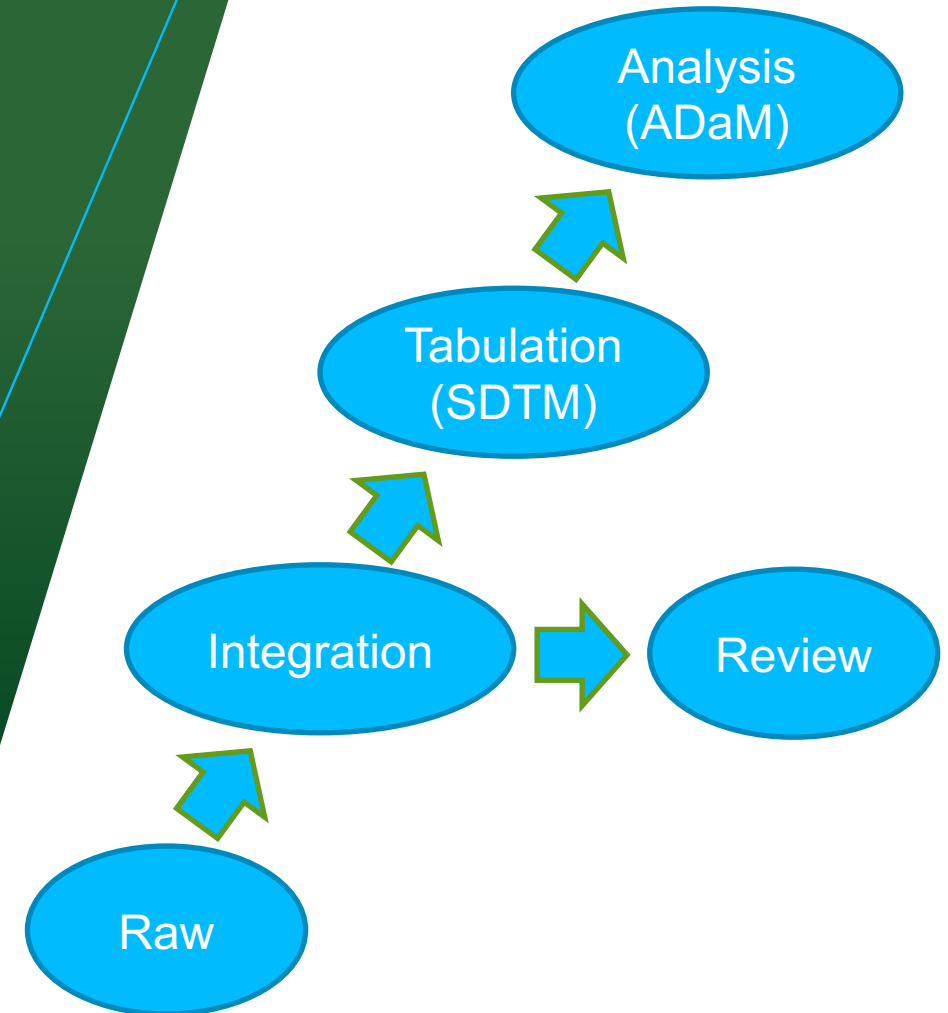
Governance



	Location for temperature	
+	Oxygen saturation	integer
-	Oxygen saturation { Pulse Oxymetry }	integer
	Unit of Oxygen	

Metadata Repository
Protocol Authoring Tool
Integration Layer
Target System

Linking Data Models





INCOMPLETERecommendRetireSupersede1UnsubscribeTab Status - Incomplete

Medical Research Concepts

ECG

Vital Signs

Other

Hip Circumference

Waist Circumference

Oxygen

Temperature

Respiration Rate

Heart Rate

Blood Pressure

bmi

Weight

Height

General

Vital Signs / Height

Medical research Concept Summary

Definition:

Notes:

Represented in Forms

Vital Signs.Standard unit for Height

Vital Signs.converted value in standard units for Height

Vital Signs.Unit for height

Vital Signs.Height

Represented in RAW

VS_H.HEIGHT_VSSTRESU

VS_H.HEIGHT_VSSTRESU

VS_H.HEIGHT_VSSTRESN

VS_H.HEIGHT_UNIT_DECO

VS_H.HEIGHT_UNIT

VS_H.HEIGHT

Represented in SDTM

VS.VSORRES.VSTESTCD

(VSTEST=HEIGHT)

Reference Value Sets

UNIT_HEIGHT

UNIT_STD

Reference Edit Checks

	1 V1 Day : -15 Trial Period : Screening a	2 V2 Day : -7 2 Trial Period : Run-in Enrollment
Activities		
Safety laboratory tests h	x	
Urine pregnancy test j	x	
HbA1c k	x	
2-hour PPG after consuming standard meal (consisting of approximately 500kcal)		
Fasting plasma glucose	x	
Renal and Liver function a c		
Fasting serum insulin		
Dispense/review subject diary		x
Dispense study intervention		
Retrieve study intervention and record accountability		
Concomitant medication	x	x
AEs		
VitalsSign	x	x
al Signs Height	x	

ary

Objectives

Endpoints

Inclusion Criteria

Exclusion Criteria

Trial Design

Summary

Governance:

Provides the framework for Governance

Standards:

Traceability of Standards

Concepts:

Ties the standards in a logical manner for re-use

End to End automation:

From Protocol to submission



Thank you!



Bye-Bye

