



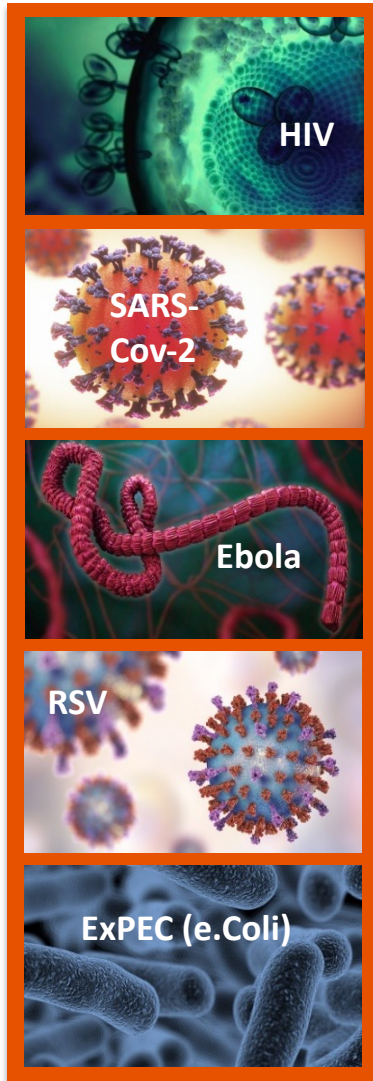
Incorporating Immunogenicity data from Various Analyzing Labs

PHUSE Presentation 04 May 2022

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Melinda, Tree of Life
Melinda's artwork reflects
her journey living with HIV.

Presentation topics



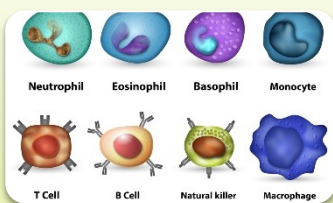
- Introduction
- Immunogenicity Data Provider
- Immunogenicity Data Flow
- Delivery of the immunogenicity data
- Summary

Introduction



Accurate representation of vaccine induced immune response is one of the main objectives in vaccine development and clinical studies

Image used for illustrative purpose only



Vaccine Immunogenicity data provides proof of the type, magnitude and duration of specific immune responses being induced by the study vaccine

Image used for illustrative purpose only



Immunogenicity assays conducted by various specialty immunogenicity labs → multiple data transfers within one clinical study

Image used for illustrative purpose only



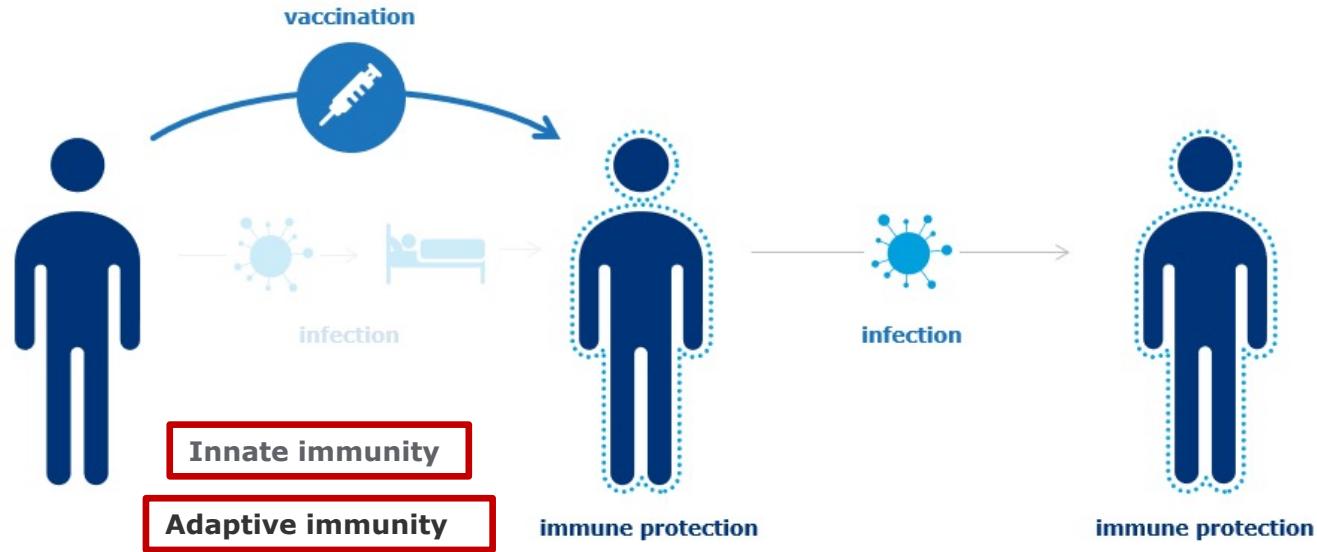
Data Management:

- document agreements with specialty immunogenicity labs
- translate the scientific immune response data to SDTM
- quick delivery of the data for analysis/submission

Image credit: www.abbreviationfinder.org

Introduction

Vaccine induced immune response



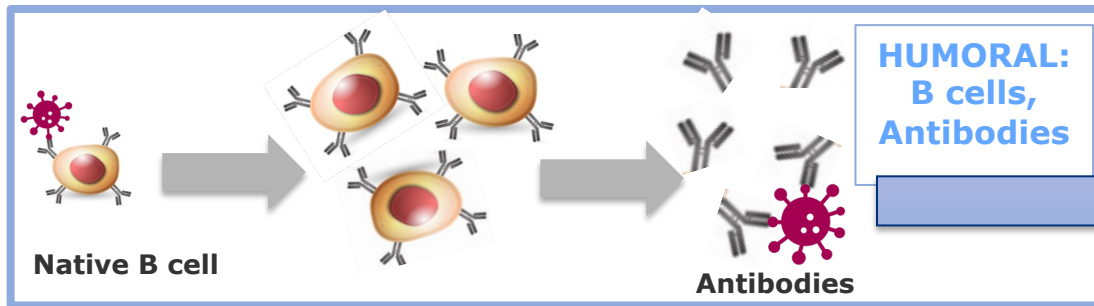
Vaccine

- biological product
- contains antigens that are either derived from the pathogen or produced synthetically to represent components of the pathogen
- safely induces an immune response
- provides protection against infection and/or disease on subsequent exposure to a pathogen *1

***1: A guide to vaccinology: from basic principles to new developments**
<https://www.nature.com/articles/s41577-020-00479-7#publish-with-us>

Immunogenicity tests – examples

Adaptive Immunity



→ **Antibody concentrations** in e.g. serum, swabbed material

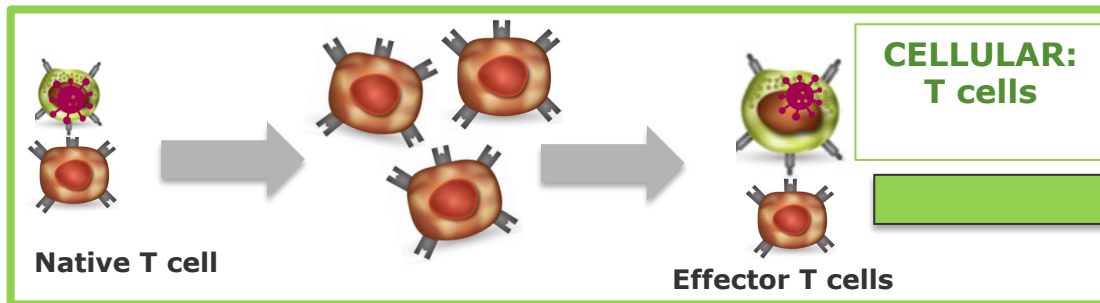
→ **ELISA**

→ **Antibody neutralization capacity** to inhibit pathogen growth in vitro

→ **VNA**

→ **Antibody functionality capacity** to inhibit pathogen growth in vitro

→ **ADCP, ADNP, ADNKA, etc.**



→ **Cytokine secretion** of e.g. PBMC

→ **ELISPOT**

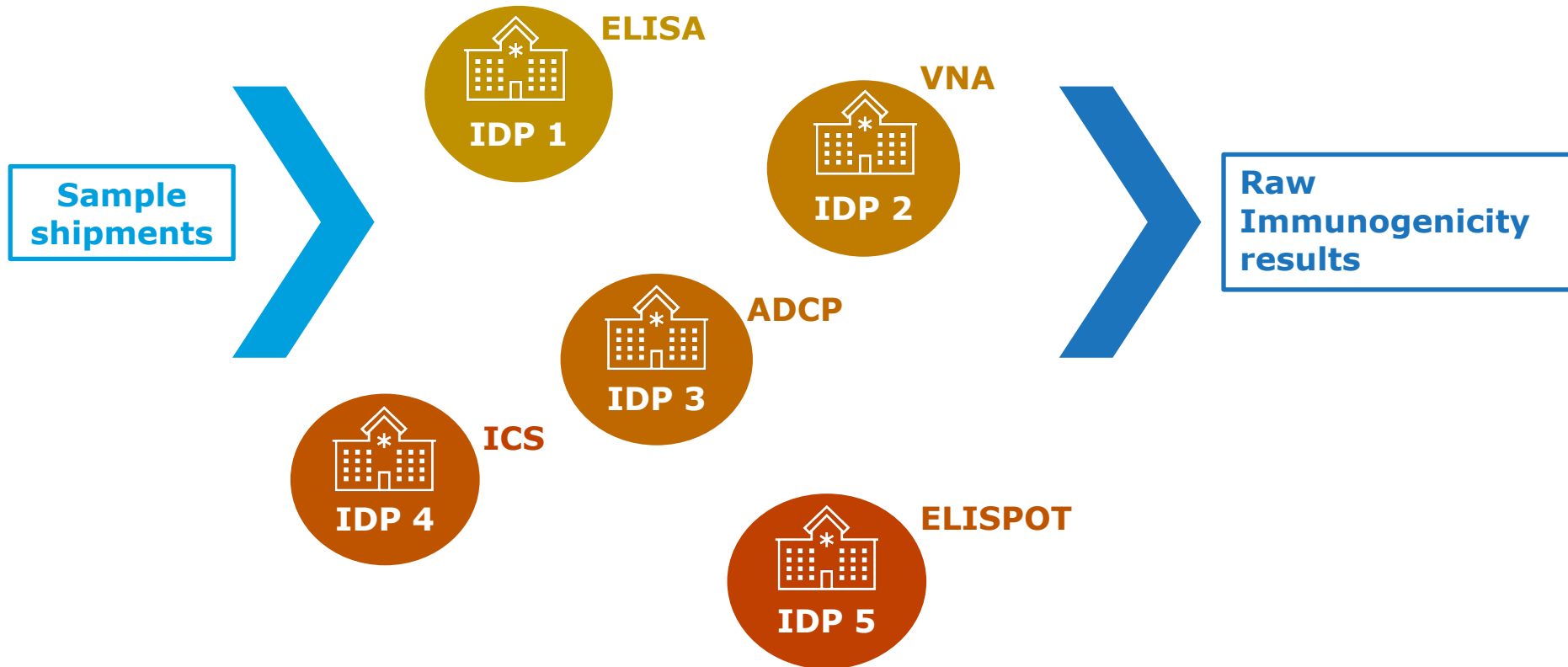
→ **Cellular markers on/in** e.g. PBMC

→ **ICS**

Immunogenicity Data Provider (IDP)

Immunogenicity Data Providers/Analyzing labs

- Immunogenicity assays are conducted by multiple specialized analyzing labs
→ Immunogenicity Data Providers (IDP)



Immunogenicity Data Providers/Analyzing labs

Are scientifically oriented and often linked to a scientific institution (partnership)

Are often specialty labs i.e. only a few labs in the world that are able to perform that specific assay

Not familiar with Pharma SDTM standards
No Data Management facilities

At Janssen, we accept the transfer capabilities of the lab

➤ Documented in the Data Transfer Agreement

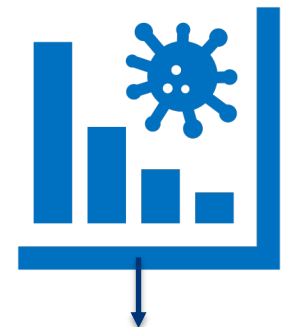
Immunogenicity Data Providers (IDPs)



Can deliver data aligned with CDISC/SDTM Standards



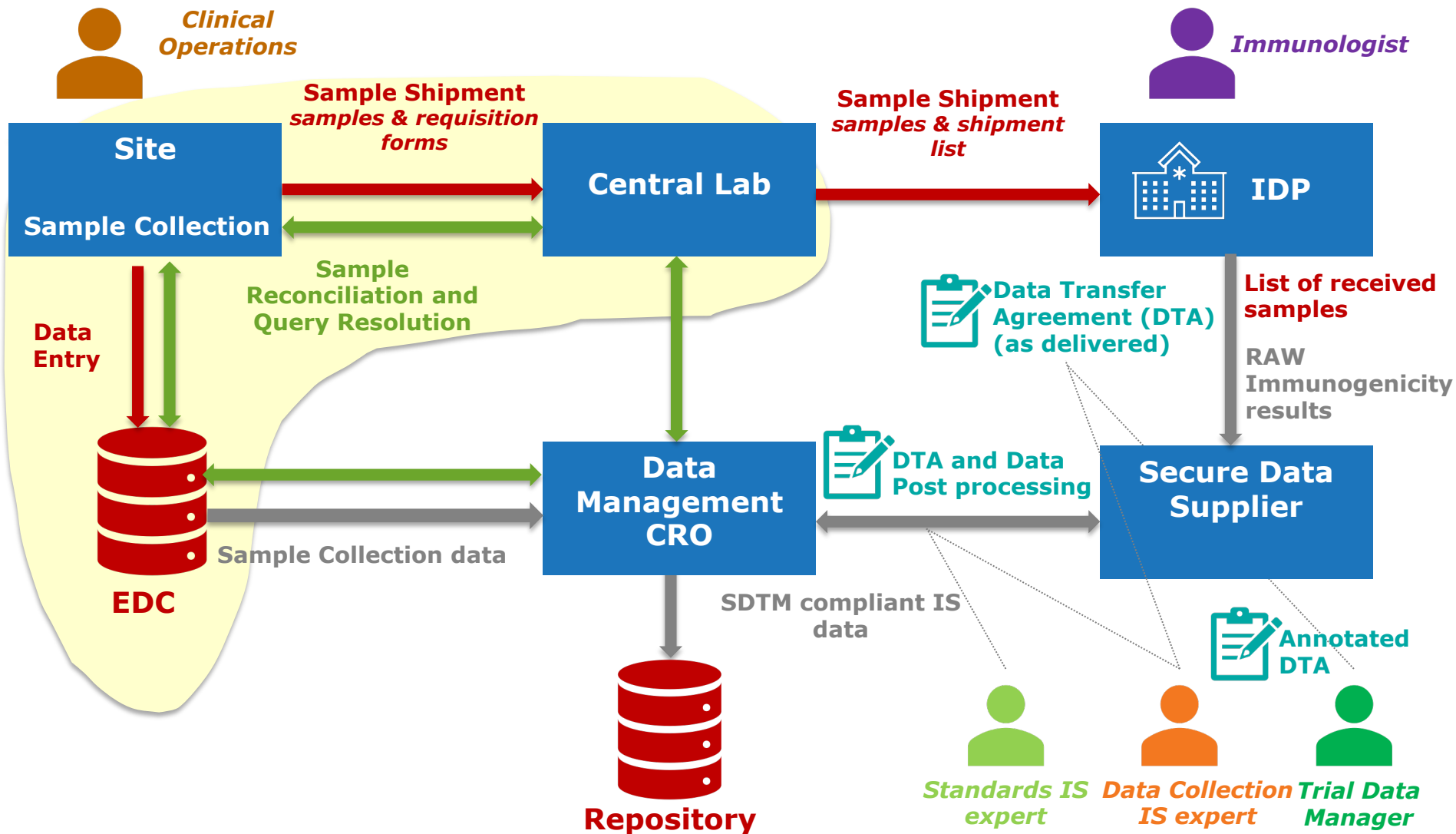
Can NOT deliver data aligned with CDISC/SDTM Standards



Postprocessing of data

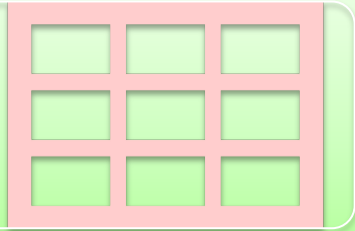
Immunogenicity Data Flow

Immunogenicity Data Flow



Delivery of the immunogenicity data

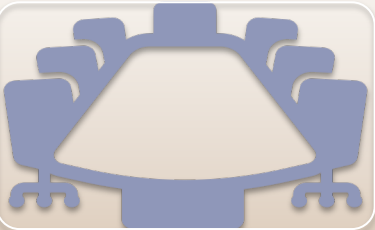
Janssen's Immunogenicity Concept Dictionary



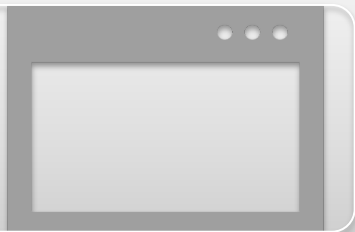
Biomedical concept dictionary – values ITEST/CD and related concept variables



Consistent within and across compounds

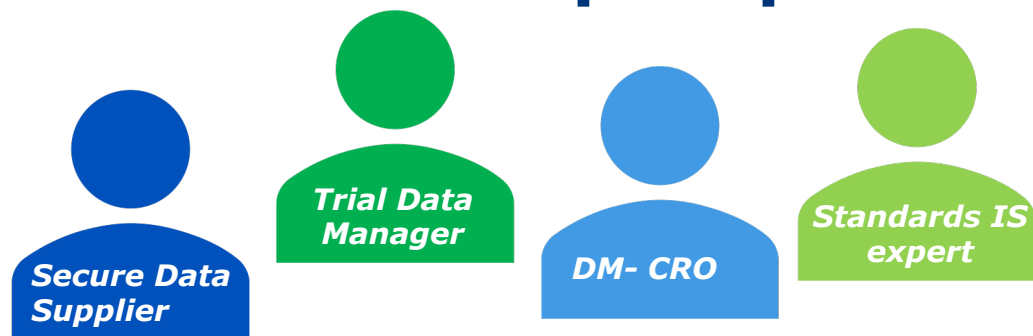


Modeled and maintained by Janssen Immunogenicity SME team



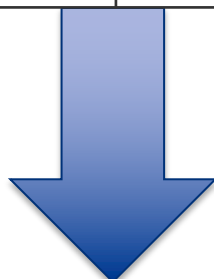
Aligned with Health authority guidance – Janssen model facing the future

Raw to SDTM post processing (annotated DTA)



Subject ID	Visit	Accession	GP IgG (ELISA U/mL)
100001	D1	1234567891	0.001
100001	D29	1234567892	80.7
100002	D1	1234512345	0.0002
100002	D29	1234512342	50.1

RAW to SDTM
mapping and
post processing



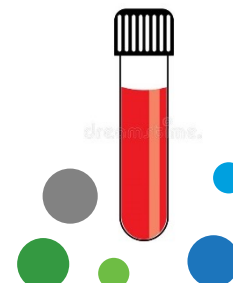
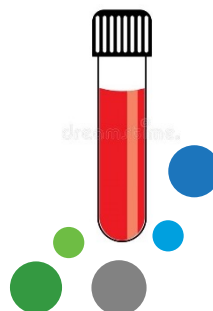
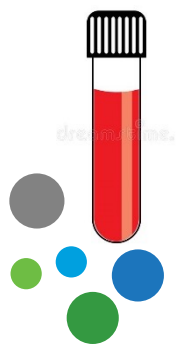
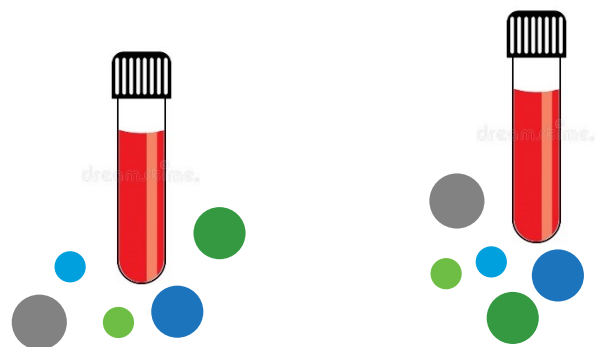
USUBJID	VISIT	ISREFID	ISORRES	ISORRESU	ISTEST	ISTESTCD
STUDY-100001	D1	1234567891	0.001	ELISA unit/mL	Binding Vaccine-induced Antibody	AVA_BAB
STUDY-100001	D29	1234567892	80.7	ELISA unit/mL	Binding Vaccine-induced Antibody	AVA_BAB
STUDY-100002	D1	1234512345	0.0002	ELISA unit/mL	Binding Vaccine-induced Antibody	AVA_BAB
STUDY-100002	D29	1234512342	50.1	ELISA unit/mL	Binding Vaccine-induced Antibody	AVA_BAB

Raw datafile provided by IDP
in **own format with own terminology**

Raw IDP's Test immunogenicity data

- converted into SDTM per specs in DTAs
- aligned with Immunogenicity Test Concepts Terminology from Concept Dictionary

Delivery process



4 Samples,
each sample 5
test results



Build Backbone from
samples and mapping in
DTAs - 20 records without
result data

QC on structure



Merge
both files

Final File – Immunogenicity
data SDTM compliant

QC on structure and content

Summary

Summary

- on scientific level discussion/communication with IDP(s)

- delivery of compliant and consistent vaccine immunogenicity data
 - obtain approval

- accepting data delivery capabilities from the Immunogenicity Lab

- data delivery expectations documented in the DTA

- proper documentation of Raw to SDTM mapping and post processing

- Immunogenicity Concept Dictionary allowing compliant and consistent mapping



- quick delivery building IS backbone file and performing QC on the structure ahead of delivery time



Thank you

Contact information

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Melinda, Tree of Life
Melinda's artwork reflects
her journey living with HIV.



PHARMACEUTICAL COMPANIES OF *Johnson & Johnson*



Thank you

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Avila Theresa

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