

Challenges of Handling Vaccines Serology Data for Analysis and Reporting

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Overview



Introduction



Data Collection/Methods



Challenges & Mitigation



Conclusion



Q&A

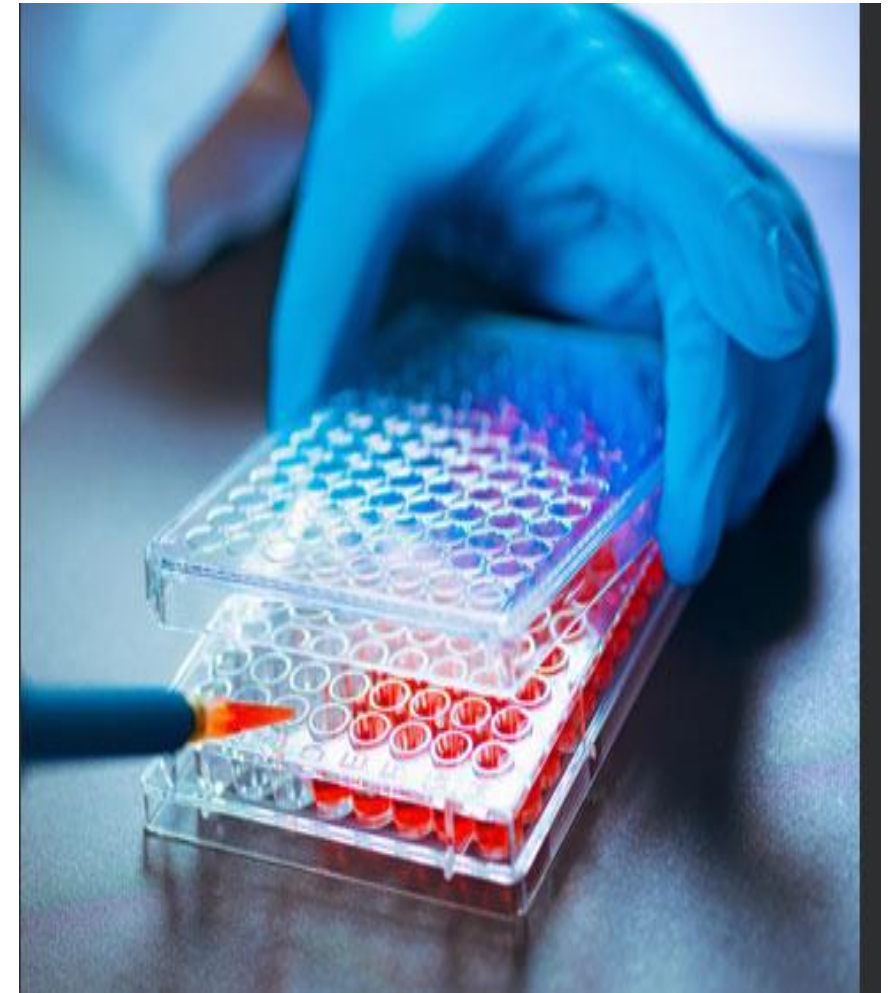
Introduction

➤ Serology

- Serology refers to the testing of blood serum to detect the presence of antibodies against a specific antigen.

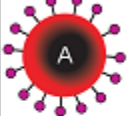
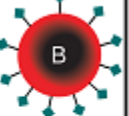
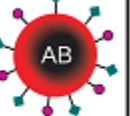
➤ Immunogenicity

- A vaccine is a biological product that can be used to safely induce an immune response that confers protection against infection and/or disease on subsequent exposure to a pathogen¹.
- Immunogenicity of vaccine refers to the ability of a vaccine to induce an immune response in a vaccinated individual².



Introduction

- Immunogenicity data help to provide a guide to the potential effectiveness of a vaccine over time.
- Large amount of serology data generated during the clinical trial pose challenges to manage, analyze, comprehend and report.
- Here we discuss about the challenges we face during the reporting of vaccine data and the steps to mitigate.

	Group A	Group B	Group AB	Group O
Red blood cell type				
Antibodies in Plasma	 Anti-B	 Anti-A	None	 Anti-A and Anti-B
Antigens in Red Blood Cell	 A antigen	 B antigen	 A and B antigens	None

□ Data Collection/Methods

➤ Serology Sample Collections

- Serology tests are performed using blood samples. Venipuncture, whereby a vein in the arm is punctured with a needle, has been the traditional method of collecting liquid blood samples in vials or tubes.

➤ Serology Assay Methods

- Serological assay methods are used for measuring antibodies in the blood to determine whether a person has been exposed to a pathogen or to assess the level of protection provided by an immune response to vaccination.





□ Data Collection/Methods

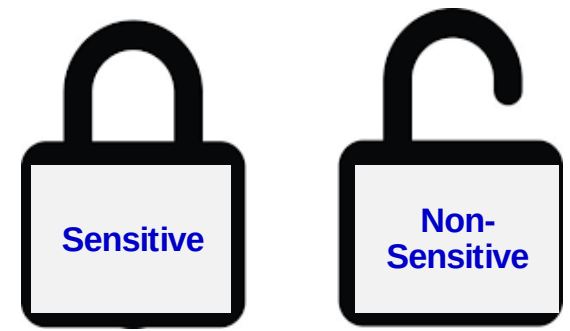
➤ Lab data transfer

- Serology data comes from central and local laboratories.

The following documents are utilized to manage the data transfers.

1. Biospecimen Analysis & Assay Plan
2. Data Transfer Specification
3. Data File Specification

□ Data Collection/Methods



➤ Sensitive v/s Non-Sensitive

- Serology data is part of sensitive data, which the sponsor considers critical and will impact the outcome of the study.
- Non-sensitive data in vaccines is mostly nasal swab results or other diagnostic assays. These results support the immunogenicity analysis but are considered non-sensitive by the sponsor.
- The difference between sensitive and non-sensitive data is that the results of sensitive data could potentially unblind subject treatment assignment. The Data Blinding Plan defines sensitive clinical data and unblinding events.

❑ Data Collection/Methods

➤ Data Preparation & Mapping

Blinded Process : Dummy Raw → Dummy IS (To create the ADaM ADVA Dataset)

Unblinded Process : Raw → SDTM (IS) → ADaM(ADVA)

- The structure of immunogenicity data is one record per Assay Name per Visit per Subject.

- Raw data

SUBJECT	VISIT_NBR	VISIT_NAME	EVENT_DATE	ANALYSIS	RESULT	UOM	TEST_COMMENT	SPECIMEN_TYPE	barcode
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- SDTM.IS data

USUBJID	ISSEQ	VISITNUM	VISIT	ISDTC	ISTESTCD	ISTEST	ISORRES	ISORRESU	ISSPEC	ISREFID	ISMETHOD	ISLLOQ
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- ADaM.ADVA data

USUBJID	SRCSEQ	AVISITN	AVISIT	ADT	PARAMCD	PARAM	AVAL	ISLLOQ
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❑ Challenges & Mitigation

Challenge	Mitigation
○ Fast Pace(Light Speed)	✓ Reinforce the requirement in advance ✓ Standardization - Data spec/plan and formats of transfer files - Assay names & lower limit of quantitation (LLOQ) - Study Data Tabulation Model (SDTM) ✓ Develop data flow

❑ Challenges & Mitigation

Challenge	Mitigation
○ Competing deliverables	✓ Prioritization - Staggered delivery/snapshot ✓ Use dummy data to plan initial set up and team reviews to expedite reporting ✓ Close communication and collaboration across each functional lines ✓ Capture and share learning with broader organization

❑ Challenges & Mitigation

Challenge	Mitigation
○ Resource constraint	✓ Proactive planning - Roles and responsibilities clearly outlined and communicated ✓ Review and assess requirements - Data reviews (formatting/modelling) in details - Monitor status and timeline closely
○ Serology Hands-off	✓ Blinded v/s unblinded

□ Challenges & Mitigation

Challenge	Mitigation
○ Immunogenicity subset selection	✓ Ensure balance on demographic/diagnostic factors impacting immune response ✓ Additional coordination across the study teams
○ Continual change to assay specifications	✓ Independent review of Biospecimen Analysis & Assay Plan

□ Challenges & Mitigation

Challenge	Mitigation
○ Assay re-testing	✓ Controlled as minimal with majority lab steps are automated ✓ Plan proactively with labs for testing schedules ✓ Might require reprioritization
○ New emerging variants	✓ Teams to accelerate to meet the external demands

❑ Challenges & Mitigation

Challenge	Mitigation
○ Potential scope change	✓ Follow up with lab to finalize/determine the transfer scope ✓ Discuss with statistician to modify/adjust analysis/population flag ✓ Team might need to update checklist and approval document to note the difference



CONCLUSION

Handling serology data can be challenging however we can keep the data quality and integrity by taking following steps :

- Standardization
- Alignment
- Proactively planning
- Communication and collaboration
- Share lesson learned

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8. Meenal Gawas – Manager, Statistical Programming

References

- 1) Pollard, A.J., Bijker, E.M. A guide to vaccinology: from basic principles to new developments. *Nat Rev Immunol* **21**, 83–100 (2021).
<https://doi.org/10.1038/s41577-020-00479-7>
- 2) <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/how-they-work.html>



Questions?

