

Vaccine Trials: The basics you need to know

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Agenda

- What makes Vaccine trials unique?
- What are Reactogenicity events?
- How can the Reactogenicity events be collected and mapped per CDISC?
- What are the outputs to expect from a vaccine trial?





Vaccine Trials are Unique

Vaccine contains substances from live organisms like bacteria or virus

Most of the vaccines do have a second shot and followed by the booster shot

It can involve Pediatric population as well, sometimes kids are given the first shot and booster is given as they grow into adult

It could take years for a study to be completed or it could be a quick turn around

FDA Toxicity Grading Scale in Preventative Vaccine Clinical Trials

Clinical Abnormalities in the Locally Injected Area

Local Reaction to Injectable Product	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
Pain	Does not interfere with activity	Repeated use of non-narcotic pain reliever > 24 hours or interferes with activity	Any use of narcotic pain reliever or prevents daily activity	Emergency room (ER) visit or hospitalization
Tenderness	Mild discomfort to touch	Discomfort with movement	Significant discomfort at rest	ER visit or hospitalization
Erythema/Redness (Diameter)	2.5 - 5 cm	5.1 - 10 cm	> 10 cm	Necrosis or exfoliative dermatitis
Induration/Swelling (Diameter)	2.5 - 5 cm and does not interfere with activity	5.1 - 10 cm or interferes with activity	> 10 cm or prevents daily activity	Necrosis

Data extracted from The U.S. Food and Drug Administration's *Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials* (2007)

Local Reactions

Systemic Reactions

Common side effects

On the arm where you got the shot:



- Pain
- Swelling

Throughout the rest of your body



- Fever
- Chills
- Tiredness
- Headache

Collecting data

The main source of Reactogenicity data is collected using the E-Diary data

The other source is from the CRF

SDTM Datasets

From the E-Diary data, the data is mapped to Findings About (FA) domain.

The data from the CRF is collected in Clinical Events (CE) domain

Any data past the number of days in the E-Diary data are collected in the Adverse Events (AE) CRF page

ADaM Datasets

From the FA domain it goes to the ADFA dataset,
ADCE from CE domain and ADAE from AE domain

Vaccine Outputs

- + Common Outputs that are requested for Vaccine trials include
- + Systemic Reactions by severity
- + Local Reactions by severity
- + Duration of the reactions (Local or Systemic)
- + Graphs related to the same

Thank you

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References

- + [Pfizer-BioNTech COVID-19 Vaccine Reactions & Adverse Events | CDC](#)
- + [Cutaneous reactions reported after Moderna and Pfizer COVID-19 vaccination: A registry-based study of 414 cases - PMC \(nih.gov\)](#)