

# ADVERSE EVENTS IN REDCAP: BEST PRACTICES

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Accelerating Research. Improving Health.

# ADVERSE EVENTS IN REDCAP

What is an Adverse Event?

- **Adverse event (AE)** means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. (*FDA – 312.32*)
- Unpredictable
  - Frequency
  - Scope
- “Normal” (AE) versus “Serious” (SAE)
  - Duty to report
- Captured elements are study specific

# ADVERSE EVENTS IN REDCAP

Common elements of an AE

- Description
- Date/time of occurrence
  - Start date/time
  - Stop date/time
- Outcome

Three general ways of implementing AE's in REDCap:

- Within a form
- As a separate form
- As a separate project

# AE'S WITHIN A FORM

## Advantages:

- Easy to build
- Quick to build
- Automatically linked to a record

## Disadvantages:

- Takes up screen real estate
- Hard to repeat
- Practically limit on number of AE's

## Best suited for:

- Classical projects / surveys
- Low frequency / risk of AE's
- Small number of elements tracked (< 5 per AE)

# AE'S AS A SEPARATE FORM

## Advantages:

- Easy to build
- Automatically linked to a record and / or event
- User rights

## Disadvantages:

- Separate form
- Blank spaces
- Limited by number of events in a project

## Best suited for:

- Longitudinal projects
- Medium frequency / risk of AE's
- Medium number of elements tracked (5-10 per AE)

# AE'S AS A SEPARATE PROJECT

## Advantages:

- Infinite number of AE
- Simplifies monitoring
- Easy exports for audits
- Not automatically linked to a participant/event
- Dynamic SQL requires administrator help
- Dataset merge needed for analysis

## Best suited for:

- High frequency / risk of AE's
- High number of elements tracked (10+ per AE)

## Disadvantages:

# ADDITIONAL BEST PRACTICES

- Ask your user:
  - Expected frequency of AE's?
  - Number of elements tracked by AE's?
  - Who tracks the AE's?
  - If AE's are tracked over time?
  - Protocols regarding Serious Adverse Events (SAE)?
- Branching Logic
  - Hide unnecessary AE spots
  - Hide unnecessary elements in an AE
- AE project
  - Reliable way to tie AE to a participant
  - Anonymous (Survey) or identified (User entered)

Thank You

