

# Adaptive Design

Design Strategies for EDC Systems

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# Disclaimer

- The views expressed in this presentation are those of the authors and do not necessarily represent the views of the Henry M. Jackson Foundation, Inc., Uniformed Services University of the Health Sciences, or the Department of Defense (DoD).

# IDCRP - Background

- Henry M. Jackson Foundation for the Advancement of Military Medicine
- My division is IDCRP – Infectious Disease Clinical Research Program.
  - Perform medical research for DOD
  - Our research focuses on infectious diseases and their effects on our military members.

# IDCRP's Healthcare Mission

- Investigate infectious diseases of concern to the US military.
- Conduct safe, effective research around the world.
- Provide clean, accurate data in a time sensitive manner.



# Data Collection

- IDCRP's data collection center. Here we design the systems that are used to collect data used for research
- Mi-Forms EDC Surveys – one of our primary data collection tools



# Mi-Forms

- A typical Mi-Forms survey may look like this:
- A user utilizes a tablet to scroll through the survey and fill out relevant information
- Information is stored for analysis

**IDCRP-037 TravMil**

Study ID: T55555-1

Follow-Up Clinic Visit Page 1 Previous Submit Next

Follow-Up Number

Visit Date (dd/mon/yyyy)  /  /

Symptoms: What is the current status of the subject's previous symptoms?

Subject did not have symptoms at previous visit.

All previous symptoms have resolved.

Subject's previous symptoms have not changed or change status is not known

Subject's previous symptoms have changed status. See list below.

Prior Symptom #	Prior Symptom	Diagnosis
1	Nausea	Resolving/Resolved
2	Fatigue	Worsening

Does the patient have any new symptoms?

No  Yes, check all that apply

General:

Fever

Chills

Anorexia

Fatigue/Lethargy/Malaise

Itching

Dizziness/Vertigo

Gastrointestinal:

Nausea/vomiting

Diarrhea

Abdominal pain

Version 9.0.0 - 01DEC2014

# Mi-Forms

**IDCRP-037 TravMil**

Study ID: T5555-1

Follow-Up Clinic Visit Page 1    Previous Submit Next

Follow-Up Number    1

Visit Date (dd/mon/yyyy)    10 / FEB / 2015 31

Symptoms: What is the current status of the subject's previous symptoms?

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Prior Symptom #	Prior Symptom	Diagnosis
1	Nausea	Resolving/Resolved
2	Fatigue	Worsening

Add Symptom    Edit Symptom    Remove Symptom

Does the patient have any new symptoms?

No     Yes, check all that apply

General:

Fever

Chills

Anorexia

Fatigue/Lethargy/Malaise

Itching

Dizziness/Vertigo

Gastrointestinal:

Nausea/vomiting

Diarrhea

Abdominal pain

Version 9.0.0 - 01DEC2014

**IDCRP-037 TravMil**

Study ID: T5555-1

Follow-Up Clinic Visit Page 2    Previous Submit Next

*New Symptoms continued*

HEENT:

Headache

Visual Disturbance

Respiratory:

Cough/sore throat

Breathing Difficulty

Skin:

Rash

Abnormal bleeding/ easy bruising

Extremities:

Myalgia

Arthralgia

Other, Specify:

Other, Specify:

Clinical Examination: What is the current status of the subject's previous abnormal exam findings?

Subject did not have abnormal exam findings at previous visit.

All abnormal exam findings have resolved.

Subject's previous abnormal exam findings have not changed or change status is not known.

Subject's previous abnormal exam findings have changed status. See list below.

Finding	Prior Abnormal Findings	Diagnosis

Add Exam Finding    Edit Finding    Remove Finding

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**IDCRP-037 TravMil**

Study ID: T5555-1

Follow-Up Clinic Visit Page 3    Previous Submit Next

Are there any new abnormal findings on physical exam today?

No     Yes, check all that apply

General

Tachycardia

Fever (Temp > 100 ° F)

Hypotension

Weight loss: (in lbs)

Other:

Eyes (check all that apply)

Conjunctival injection

Scleral icterus

Other:

Skin

Rash

Type: (check all that apply)

Petechiae/Purpura

Macular/Papular rash

Pustule/abscess

Other, specify:

Location:

Generalized

Localized: (check all that apply)

Face

Chest

Back

Abdomen

Feet

Other, specify:

Upper Arms

Lower Arms

Hands

Upper Legs

Lower Legs

Version 9.0.0 - 01DEC2014

# Subforms

- One common issue we face when collecting data is: How should you collect a dynamic set of data? (Ex. A unknown number of Flu symptoms, list of medications, etc.)
- Our most common solution - Subforms



# Subforms

**IDCRP-037 TravMil**

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Follow-Up Clinic Visit Page 1
← Previous
Submit
Next →

Follow-Up Number

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Add Symptom
Edit Symptom
Remove Symptom

Does the patient have any new symptoms?

No  Yes, check all that apply

General:

Fever

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**IDCRP-037 TravMil**

Study ID: T55555-1

Follow-Up Clinic Prior Symptoms
← Previous
Submit
Next →

Prior Symptom

N a u s e a

Diagnosis:  Resolving/Resolved  Worsening

Version 9.0.0 - 01DEC2014

# Subforms

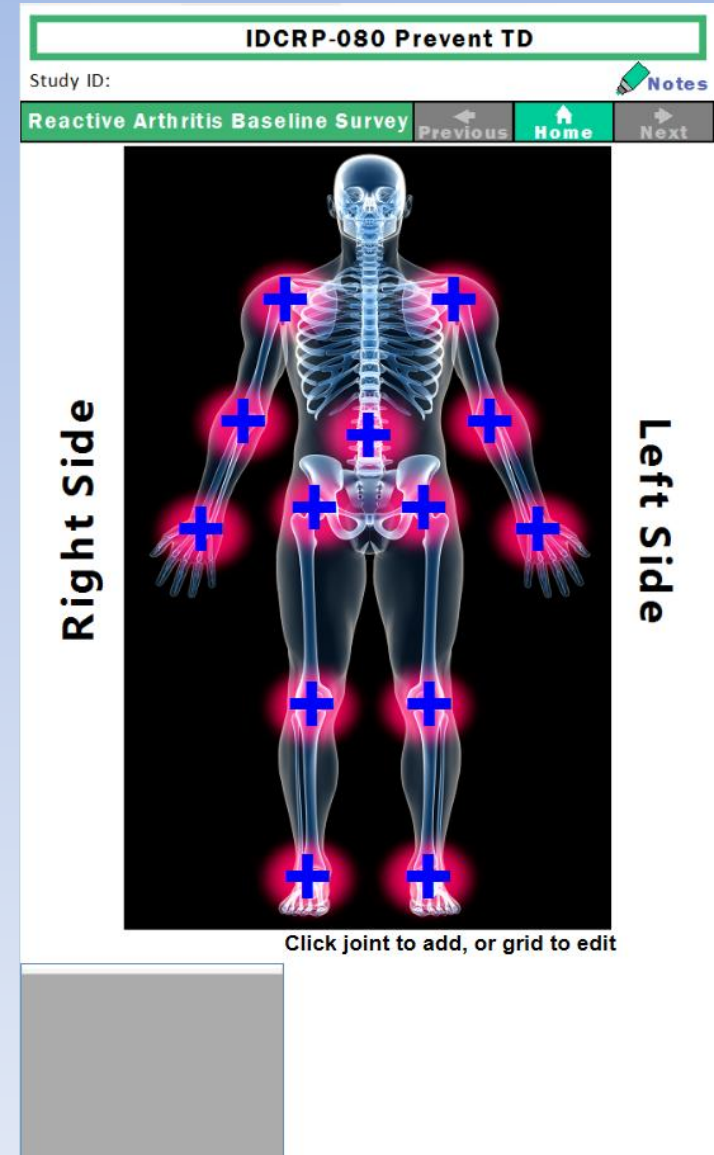
- Pros
  - Allows you to collect dynamic sets of data (ex. Unknown number of flu symptoms)
  - Organizes and displays data
  - Mostly straight-forward
- Cons
  - Temporarily removes user from the current survey context
  - When used to add many items, can become frustrating
  - When nested (subforms within subforms), can become confusing

# Try Something New

- We wanted to experiment with a new way of collecting dynamic data.
- Wanted to reduce the frustration of constantly switching between Mainform and Subform
- Wanted to keep some of Subform benefits
- Wanted to streamline the data capture process in general, using adaptive design principles

# Reactive Arthritis Survey

- Result of our experimentation
- The RA Survey is supposed to capture arthritis symptoms associated with a specific joint.
- There could theoretically be any number of symptoms (though more than 5 was not expected)



# Design

- In the RA Survey, you add an item by clicking on one of the many joints on the screen
  - Is more *natural* than choosing a name from a drop down menu
- Furthermore the contrasting color and “+” sign affords clicking
  - Implicitly tells the user to click joints
  - The changing color creates the necessary reactive feedback

File

IDCRP-080 Prevent TD

Study ID: Notes

Reactive Arthritis Baseline Survey Previous Home Next

Right Side

Left Side

Left Hand/Wrist:

Redness  Swelling

Stiffness  Pain

Start Date / / MM/YYYY

End Date / /

# Design

IDCRP-080 Prevent TD

Study ID: [Notes](#)

Reactive Arthritis Baseline Survey [Previous](#) [Home](#) [Next](#)

Right Side Left Side

Left Hand/Wrist:

Redness  Swelling  
 Stiffness  Pain

1 2 / 2 0 1 4 MM/YYYY

Start Date  
0 1 / 2 0 1 5

End Date [Submit](#) [Delete](#)

IDCRP-080 Prevent TD

Study ID: [Notes](#)

Reactive Arthritis Baseline Survey [Previous](#) [Home](#) [Next](#)

Right Side Left Side

Click joint to add, or grid to edit

Body	Start Date	ID
Left Hand	122014	1

Left Hand/Wrist:

Redness  Swelling  
 Stiffness  Pain

0 3 / 2 0 1 4 MM/YYYY

Start Date  
0 5 / 2 0 1 4

End Date [Submit](#) [Delete](#)

IDCRP-080 Prevent TD

Study ID: [Notes](#)

Reactive Arthritis Baseline Survey [Previous](#) [Home](#) [Next](#)

Right Side Left Side

Click joint to add, or grid to edit

Body	Start Date	ID
Left Hand	122014	1

Left Hand/Wrist:

Redness  Swelling  
 Stiffness  Pain

0 3 / 2 0 1 4 MM/YYYY

Start Date  
0 5 / 2 0 1 4

End Date [Submit](#) [Delete](#)

IDCRP-080 Prevent TD

Study ID: [Notes](#)

Reactive Arthritis Baseline Survey [Previous](#) [Home](#) [Next](#)

Right Side Left Side

Click joint to add, or grid to edit/remove

Body	Start Date	ID
Left Hand	122014	1
Left Hand	032014	2

Left Hand/Wrist:

Redness  Swelling  
 Stiffness  Pain

0 3 / 2 0 1 4 MM/YYYY

Start Date  
0 5 / 2 0 1 4

End Date [Submit](#) [Delete](#)

# Design

- When you add an item, the item shows up in a mini-grid
  - Keep the organizational benefit of Subform grids
- The number item associated with each joint replaces the “+”
  - Provides user with useful information (which joint they’ve added to, how many items per joint)
- In order to edit a joint item, you click the associated grid row

**IDCRP-080 Prevent TD**

Study ID: Notes

**Reactive Arthritis Baseline Survey** Previous Home Next

**Right Side** **Left Side**

Edit: Left Hand 2

Body	Start Date	ID
Left Hand	122014	1
Left Hand	032014	2
Right Shoulder	122013	3
Right Knee	092010	4

Redness  Swelling  
 Stiffness  Pain

0 3 / 2 0 1 4 MM/YYYY  
Start Date  
0 5 / 2 0 1 4  
End Date

**Submit**  
**Delete**

# Conclusion

- Using certain design principles and ideas, we can adapt common data collection strategies' to better address the needs of users
- Thanks for your time!!