EDC Design and DFsetup Considerations

Lisa Ondrejcek
Enhancing the EDC Experience

With DataFax/DFdiscover, studies can be:

- Paper
- Hybrid paper/EDC
- EDC only
Paper only

iDataFax/DFexplore Background
Paper only

Hybrid Paper/EDC

iDataFax/DFexplore Background
### iDataFax/DFexplore Background

#### Paper only

- **Visit Date:**
- **Eligibility:**
- **Randomization:**
- **Consent:**
- **Assent:**
- **Blood Draw:**
- **Phlebotomy:**
- **Drug Administration:**
- **Adverse Events:**
- **Comments:**

#### Hybrid Paper/EDC

- **Visit Date:**
- **Eligibility:**
- **Randomization:**
- **Consent:**
- **Assent:**
- **Blood Draw:**
- **Phlebotomy:**
- **Drug Administration:**
- **Adverse Events:**
- **Comments:**

#### EDC only

- **Visit Date:**
- **Eligibility:**
- **Randomization:**
- **Consent:**
- **Assent:**
- **Blood Draw:**
- **Phlebotomy:**
- **Drug Administration:**
- **Adverse Events:**
- **Comments:**

---

**Tabula Rasa**
### Participant Study Drug Adherence

**Visit Date:** 02/10/2024

**Visit Code:** 01.0

**Participant ID:**

**Partner Study Drug Adherence:** There are several external questions and should be used with caution.

#### Partner Study Drug Adherence

1. **When was the last time you took study pills?**
   - **Date:** 27/03/09
   - **Reason:** Yes, 07-200

2. **During the past month, did you take both tablets every day?**
   - **Yes:** Yes
   - **No:** No
   - **Reason:** Yes, if you go to item 4.

3. **What is the number of days that you did not take one of the study tablets?**
   - **Number of Days:**
     - Number of days: 0

4. **During the past month, what helps you to remember to take your tablets?**
   - **Methods:**
     - 1. As scheduled
     - 2. 2. As scheduled
     - 3. 3. As scheduled
     - 4. 4. As scheduled
     - 5. 5. As scheduled
     - 6. 6. As scheduled
     - 7. 7. As scheduled

5. **What causes you to not take your tablets?**
   - **Reasons:**
     - 1. 1. As scheduled
     - 2. 2. As scheduled
     - 3. 3. As scheduled
     - 4. 4. As scheduled

6. **For a variety of reasons, other persons may want to see your study records. Do you think that someone other than you has seen any of your study tablets?**
   - **Reason:**
     - Yes: Yes
     - No: No
     - Other: Other

7. **Estimate how many light blue tablets were used by someone other than you?**
   - **Estimated Number:**
     - Number of light blue tablets: 0

8. **Estimate how many blue tablets were used by someone other than you?**
   - **Estimated Number:**
     - Number of blue tablets: 0

9. **Do you think it is possible that someone other than you took some of your study tablets?**
   - **Reason:**
     - Yes: Yes
     - No: No
     - Other: Other

10. **How many tablets were used by someone other than you?**
    - **Number of Tablets:**
      - Number of light blue tablets: 0
      - Number of blue tablets: 0
What’s wrong with the old school?

• Works just fine for me!
• Looks just fine, too.
“It’s the 80’s calling. They want their screens back.”

• “Kiss of death” for demonstrations
• “Don’t EVER show the black background again.”
• Difficult to get buy-in from younger employees
• Less appealing for your sites

Let’s improve their experience.
Change it up

- The EDC background doesn’t have to look like a paper CRF
- It doesn’t have to look like a web screen
- It can be portrait or landscape
- 8 ½ x 11, 8 ½ x 14, 11 x 17
- Colored backgrounds
- Take advantage of the rich canvas!
### CDAS Templates

**Site / Subject ID:** 001001  
**AE Number:** 010  

#### Adverse Event

**Any AEs?**  
- [ ] Yes  
- [ ] No  

> If no, do not complete this form.

1. **Adverse Event**

2. **Serious**  
   - [ ] Yes  
   - [ ] No  

   - [ ] Yes  
   - [ ] No  
   - [ ] Congenital anomaly or birth defect
   - [ ] Yes  
   - [ ] No  
   - [ ] Significant disability
   - [ ] Yes  
   - [ ] No  
   - [ ] Death
   - [ ] Yes  
   - [ ] No  
   - [ ] Hospitalization
   - [ ] Yes  
   - [ ] No  
   - [ ] Life-threatening
   - [ ] Yes  
   - [ ] No  
   - [ ] Other medically-important event

3. **Start Date**  
   - [ ] 08/jul/2017

4. **Ongoing**  
   - [ ] Yes  
   - [ ] No  

   - [ ] If no, provide end date.

5. **Severity**  
   - [ ] Mild  
   - [ ] Moderate  
   - [ ] Severe

6. **Relationship to Study Treatment**  
   - [ ] Yes  
   - [ ] No

7. **Action Taken with Study Treatment**  
   - [ ] Dose increased  
   - [ ] Dose not changed

---

**Please contact the medical monitor immediately at +1.123.555.12.12**

---

*Switch to List View*
### Example 1

**Collection Date:** 12-JAN-16  
**Collection Time:** 13:15 (24-hour clock)

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Result</th>
<th>Units</th>
<th>Low Normal</th>
<th>High Normal</th>
<th>Clinically Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>13.5</td>
<td>g/dl</td>
<td>12.0</td>
<td>18.0</td>
<td></td>
</tr>
<tr>
<td>White blood cell count</td>
<td>05.9</td>
<td>x 10⁹/L</td>
<td>04.8</td>
<td>12.8</td>
<td></td>
</tr>
<tr>
<td>Platelets</td>
<td>012</td>
<td>x 10⁹/L</td>
<td>13.0</td>
<td>40.0</td>
<td></td>
</tr>
</tbody>
</table>

### Example 2

**RELEVANT LAB RESULTS**

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Collection Date</th>
<th>Result</th>
<th>Units</th>
<th>Low Normal</th>
<th>High Normal</th>
<th>Clinically Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol</td>
<td>12-JAN-16</td>
<td>00184</td>
<td>mg/dL</td>
<td>00100</td>
<td>00199</td>
<td></td>
</tr>
<tr>
<td>Triglyceride</td>
<td>12-JAN-16</td>
<td>00116</td>
<td>mg/dL</td>
<td>00000</td>
<td>00149</td>
<td></td>
</tr>
<tr>
<td>HDL Cholesterol</td>
<td>12-JAN-16</td>
<td>00061</td>
<td>mg/dL</td>
<td>00039</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient ID</td>
<td>Visit Date (DD/MMM/YY)</td>
<td>Log #</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------</td>
<td>-------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>000001001</td>
<td>19/JUL/17</td>
<td>010</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DF/Net 99 (AE) 460

### Adverse Event Log

1. **Adverse Event:** Record diagnosis if available. Include anatomical location, if applicable.

2. **Onset Date:** 19/JUL/17

3. **Visit AE first reported:** [ ]

4. **Severity**
   - Grade 1—mild
   - Grade 2—moderate
   - Grade 3—severe
   - Grade 4—potentially life-threatening
   - Grade 5—death

5. **Relationship to study product**
   - Related
   - Not related

   **Record pertinent details for relationship assessment in Comments.**

6. **Study product administration**
   - No change
   - Held
   - Permanently discontinued
   - N/A

   **Mark N/A if vaccinations completed or previously discontinued.**

7. **Status or Outcome of AE**
   - Continuing
   - Resolved
   - Death
   - Severity/frequency increased
   - Report as new AE
   - Continuing at end of study

8. **Status**

9. **Treatments**
   - None
   - Procedure/surgery
   - New/prolonged hospitalization
   - Medication(s)
   - Other — specify

   **CM page #: [ ]**

10. **Is this an SAE according to protocol guidelines?**
    - Yes
    - No

11. **Has or will this AE be reported as an EAE?**
    - Yes
    - No

12. **Is this AE an STI?**
    - Yes
    - No

13. **Is this event an AE of special interest (AES)?**
    - Yes
    - No

14. **Is this a new chronic condition requiring medical intervention for > 30 days?**
    - Yes
    - No

15. **Is this AE related to mucosal sampling?**
    - Yes
    - No

| New AE page #: | 02 |
| EAE #:         |    |
| Code #:        | 05 |
**LOCAL LABORATORY RESULT—FOLLOW-UP**

**DIFFERENTIAL**

**Alternate Collection Date:** 01/JUL/17

<table>
<thead>
<tr>
<th>Cell Type</th>
<th>Not reported</th>
<th>Value</th>
<th>Severity Grade</th>
<th>AE Log page</th>
<th>Not reportable as an AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutrophils</td>
<td>✓</td>
<td>01234</td>
<td>2</td>
<td>01</td>
<td>OR ✓</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td>✓</td>
<td>9999</td>
<td></td>
<td></td>
<td>OR ✓</td>
</tr>
<tr>
<td>Monocytes</td>
<td>❌</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eosinophils</td>
<td>❌</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basophils</td>
<td>✓</td>
<td>8888</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Cardiac Catheterization and PCI Report**

**DF/Net Study 252 (CC) 060**

**Procedure Date**: 07/SEP/2016  
**Start Time**: 10:05  
**End Time**: 13:10

**Procedure Description**

**Clinical Indications and Occlusion Percentages**

<table>
<thead>
<tr>
<th>Vessel</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAD</td>
<td>010</td>
</tr>
<tr>
<td>AIV</td>
<td>000</td>
</tr>
<tr>
<td>CFX</td>
<td>000</td>
</tr>
<tr>
<td>RCA</td>
<td>010</td>
</tr>
<tr>
<td>GCV</td>
<td>010</td>
</tr>
<tr>
<td>PDA</td>
<td>000</td>
</tr>
<tr>
<td>CS</td>
<td>000</td>
</tr>
<tr>
<td>MCV</td>
<td>000</td>
</tr>
<tr>
<td>SCV</td>
<td>000</td>
</tr>
</tbody>
</table>

*A and posterior (B) views of epicardial coronary circulation.*

LAD indicates left anterior descending coronary artery; AIV, anterior interventricular vein; CFX, circumflex coronary artery; RCA, right coronary artery; GCV, great cardiac vein; PDA, posterior descending artery; CS, coronary sinus; MCV, middle coronary vein; and SCV, small coronary vein.
Bling Warning

- So much choice, so much freedom
- How to choose? How to not go overboard?
- Choose landscape or portrait
  - Don’t mix and match in a single study
Start with one look

Color
- For our new demo study, we started with a simple palate:
  - Satin yellow, light green, and white
  - All white can be a little hard on the eyes

Tables
- Create CRFs using tables
- Shade the rows
<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Visit Date (DD/MMM/YYYY)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DF/Net Study 252 (SE) 101  
Subject Encounter

- Missed scheduled visit → End of form.

1. Type of visit:
   - Scheduled → Go to item 2.
   - Unscheduled

1a. Besides this form, which CRFs were completed for this unscheduled visit? *Mark all that apply or “None”*

- None
- Lab Results
- AE
- Reactogenicity
- CM
- Adherence
- Vital Signs
- Acceptability Assessment
- Physical Exam
- Other, specify:
Header rows
Body rows
Shading
<table>
<thead>
<tr>
<th>Type of visit:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Scheduled: Go to item 2.</td>
<td></td>
</tr>
<tr>
<td>[ ] Unscheduled</td>
<td></td>
</tr>
</tbody>
</table>

**1a.** Besides this form, which CRFs were completed for this unscheduled visit? *(Mark all that apply or “None”)*

<table>
<thead>
<tr>
<th>CRF</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] None</td>
<td>[ ] Lab Results</td>
</tr>
<tr>
<td>[ ] AE</td>
<td>[ ] Reactogenicity</td>
</tr>
<tr>
<td>[ ] CM</td>
<td>[ ] Adherence</td>
</tr>
<tr>
<td>[ ] Vital Signs</td>
<td>[ ] Acceptability Assessment</td>
</tr>
<tr>
<td>[ ] Physical Exam</td>
<td>[ ] Other, specify:</td>
</tr>
</tbody>
</table>
½ inch top and left border not necessary
DFsetup filters top $\frac{1}{2}$ inch for barcoded CRFs
DFsetup: No adjustment for “skinny” margins
### DFexplore

**DFexplore**

**DF/Net Study 252 (SE) 101**

<table>
<thead>
<tr>
<th>Site</th>
<th>Description</th>
<th>Subject</th>
<th>Visit</th>
<th>Plate</th>
<th>Field</th>
<th>Window</th>
<th>Header</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>350001 - Error Monitor (Error Monitor)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>250</td>
<td>Site 250 - Clinic 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>350</td>
<td>Site 350 - Clinic 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35001</td>
<td>350001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0 : Screening</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 : Enrollment</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>
### DFexplore

**File**  | **Edit**  | **View**  | **Select**  | **Show**  | **Subject**  | **Visit**  | **Plate**  | **Field**  | **Window**  | **Help**
---|---|---|---|---|---|---|---|---|---|---

350001 - 79 of 80

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<td></td>
</tr>
</tbody>
</table>

**Subject ID**  

350001

**DF/Net Study 252 (AE) 400**

1. Adverse Event *(Record diagnosis and anatomical)*
Text fields: Instead of a single straight line:
Graphics in FrameMaker / Word / InDesign

Text fields: Instead of a single straight line:

☐ Other, specify: ____________________

Use a white rectangle:

☐ Other, specify: ____________________
“Skinny up” date fields

Instead of ¼-inch boxes (DD/MMM/YYYY = 2.5 inches)
“Skinny up” date fields

Instead of ¼-inch boxes (DD/MMM/YYYY = 2.5 inches)

Use 1.0 inch rectangle
Faster setup with rectangles

• Just click on the rectangle
• No need to drag out text field
• No need to click-click-click-click-click....to set up date fields.
• For longer comment fields, draw fatter rectangles—in ¼-inch increments (.25, .5, .75, or 1.0)
Wider text field display in DFexplore

<table>
<thead>
<tr>
<th>Procedure Date</th>
<th>Start Time</th>
<th>End Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/SEP/2016</td>
<td>10:05</td>
<td>13:10</td>
</tr>
</tbody>
</table>

(DD/MMM/YYYY) (24-Hour Clock – HH:MM) (24-Hour Clock – HH:MM)

Procedure Description
DFsetup: Global Settings - Guides

**Left Panel:**
- Enable Snap
- Display CRF
- Display Fields
- Maximum Box Height: 25

**Right Panel:**
- Enable Snap
- Display CRF
- Display Fields
- Maximum Box Height: 100
Building eCRF backgrounds instead of paper CRFs
Changes in DFexplore

Checkboxes are actually checkboxes

Date picker

Visit Date

09/JAN/2017

Placeholder text

Visit Date

DD/MMM/YYYY
Auto text alignment (numbers, dates, time)

Tab into the field: Data Entry mode. Tab off the field: Display mode.
Characters are auto aligned across the field.

1. Date subject signed enrollment consent
   09/JAN/2017

3. Date study drug dispensed
   09/JAN/2017

1. Diastolic: 080 mmHg

2. Diastolic: 075 mmHg
DFexplore Preferences

Data Window:
- expand all visits when a subject binder is open
- display first page when a visit is open
- advance to next field after current field is completed
- open first task record when task set is built
- warn before opening next subject when traversing task records
- retain scroll position when traversing task records
- show date picker for current date field
- auto text alignment for number, date, and time fields
### DFexplore: Proportional width font

<table>
<thead>
<tr>
<th>Condition/Event</th>
<th>Condition/Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatitis</td>
<td>Pancreatitis</td>
</tr>
<tr>
<td>DFexplore</td>
<td>iDataFax 2016.0.2</td>
</tr>
<tr>
<td>Proportional width font</td>
<td>Proportional width font</td>
</tr>
</tbody>
</table>
**DFexplore: Proportional width font**

<table>
<thead>
<tr>
<th>Condition/Event</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatitis</td>
<td></td>
</tr>
<tr>
<td><strong>DFexplore</strong></td>
<td></td>
</tr>
<tr>
<td>Proportional width font</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Condition/Event</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatitis</td>
<td></td>
</tr>
<tr>
<td><strong>DFexplore</strong></td>
<td></td>
</tr>
<tr>
<td>iDataFax 2016.0.2</td>
<td></td>
</tr>
<tr>
<td><strong>NOT</strong></td>
<td></td>
</tr>
<tr>
<td>Proportional width font</td>
<td></td>
</tr>
</tbody>
</table>
Proportional v. fixed width font

<table>
<thead>
<tr>
<th>Condition/Event</th>
<th>Condition/Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatitis</td>
<td>Pancreatitis</td>
</tr>
<tr>
<td>DFexplore</td>
<td>iDataFax 2016.0.2</td>
</tr>
<tr>
<td>Proportional width font</td>
<td>fixed width font</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vital Signs</th>
<th>Weight</th>
<th>Height</th>
<th>Pulse</th>
</tr>
</thead>
<tbody>
<tr>
<td>DF/Net Study 252 (VS) 030</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td>189.9 kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td></td>
<td></td>
<td>070 beats/min</td>
</tr>
</tbody>
</table>

**BMI**

| BMI | 30.0 |

**Blood Pressure — Left Arm**

<table>
<thead>
<tr>
<th>Systolic</th>
<th>Diastolic</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 mmHg</td>
<td>070 mmHg</td>
<td>Sitting</td>
</tr>
</tbody>
</table>

**Blood Pressure — Right Arm**

<table>
<thead>
<tr>
<th>Systolic</th>
<th>Diastolic</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>102 mmHg</td>
<td>070 mmHg</td>
<td>Sitting</td>
</tr>
</tbody>
</table>
## Vital Signs

<table>
<thead>
<tr>
<th>Weight</th>
<th>Height</th>
<th>Pulse</th>
</tr>
</thead>
<tbody>
<tr>
<td>189.9 kg</td>
<td>nnn cm</td>
<td>070 beats/min</td>
</tr>
</tbody>
</table>

**BMI**

30.0

**Blood Pressure — Left Arm**

1. **Systolic:** 120 mmHg  
2. **Systolic:** nnn mmHg

1. **Diastolic:** 070 mmHg  
2. **Diastolic:** nnn mmHg

**Position:**  
- Standing  
- Sitting

**Blood Pressure — Right Arm**

1. **Systolic:** 102 mmHg  
2. **Diastolic:** nnn mmHg

1. **Diastolic:** 070 mmHg  
2. **Diastolic:** nnn mmHg

**Position:**  
- Standing  
- Sitting

**DFexplore**
White “cushion” with colored background

Enter RGB value for that color into new “Erase Color” property in setup.
Add HTML to edit checks
Summary

- Background screens won’t be necessary in DFcollect and DFweb
- They’ll still be needed in DFexplore
- Getting pushback for your organization about outdated look?
- DFexplore has new features
- YOU can make the changes to the backgrounds. YOU have the power.
What’s stopping you?

- Time?
- Indecision?
- Company standards?
- It’s analogous to the CDASH dilemma.

JUST JUMP IN AND DO IT.
Thanks to our teams in Dundas and Seattle
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