Tracking of Source Data Verification in iDataFax 4.3

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The US Dept. of Veterans Affairs (VA) has a system of over 100 hospitals/clinics nationwide, and conducts dozens of multi-site clinical trials a year, with the goal of discovering new and improved treatments for the nation’s veterans.

The VA Cooperatives Studies Program (VA CSP), where we work, is the program in the VA that coordinates the conduct of these multi-site clinical trials.
Introduction

- **Existing Process:**
  
  Clinical trial monitors were doing CRF source data verification (SDV) externally to iDataFax and logging their findings in Files and Reports external to the iDataFax EDC system.
Existing Process:
• Monitor CRF SDV Findings (in Files and Reports reports at monitor offices) were separate from the actual CRF data (in iDataFax at data-management offices) that they were related to.

Breaking through the wall and integrating the 2 worlds could benefit both sides
Introduction

- **Process Improvement Objectives & Challenges:**

- Give monitors the ability to log their CRF SDV findings directly right inside of the iDataFax EDC system.

- Give monitors the ability (right inside of iDataFax) to:
  - Generate and view summary reports of their SDV findings using the iDataFax Reports View.
  - Export data related to their CRF SDV findings into an html file that could be imported into Microsoft Excel.

- Monitors made request to be able to log their CRF SDV findings at the “CRF field level” not at the form level or in unrelated “hidden/internal fields” nested in the database.
Introduction

- **Process Improvement Solution:**
  - Leveraged monitor’s iDataFax accounts.
  - Leveraged existing functions (eg DF_Tasks, RecordLevels, DF_editchecks)
  - Leveraged concept of monitor CRF-SDV work being done as last step in RecordReview
  - Leveraged existing “field-level” metadata objects (eg ReasonNotes, QCNotes)
  - Leveraged the ability to use DF_editchecks to insert pre-defined string tags like “**MonitorVerified**” or “**MonitorNotVerified**” into ReasonNotes & QCNotes so that later, when these ReasonNotes and QCNotes were exported from the database, those string tags could be searched for
  - Leveraged existing reporting tools (eg Unix ShellScripting, DF_ReportsView, HTML)
  - To allow CRF SDV activity by monitors to be logged, reviewed, and summarized, all within the iDataFax EDC environment.
  - To allow trial monitor work and trial data management work to live together, rather than exist in 2 separate silos.
Site monitor opens for review of “clean” level 4 data records using a pre-set DataFax task:
All fields on the forms will be read-only, so the monitor will NOT have the ability to change data:
When the monitor enters a field that requires source data verification, a message pops up asking if the data was verified:
If the monitor clicks “Yes,” the text “SMART Verified” is automatically added to the field’s “Reason for Data Value” box.
If the monitor clicks “No,” he/she is asked if he or she would like to query the site:
The monitor can then choose “Yes” to have a QC added automatically. He/she can choose to change the message sent to the site, or use the default.
If the monitor chooses not to query the site, “No” would simply allow a reason to be entered by the monitor. That reason would then be added to the “Reason for Data Value” box.
Final Considerations for This Workflow Process

- Once the monitor has verified all the necessary fields on a form, he/she can choose to save it as *final*, which will take it to *level 6* and make it *read-only* to the sites.

- If any QCs were added, the form can only be saved as *incomplete* and will stay at the current level for the site to review.
Now That We Have Data, What Next?

- One of the design requirements was to determine how to provide QC and Reason data to the study monitors after their visit.
- Their current practice is to document their monitoring visits in an Excel workbook within individual subject worksheets.
- Creating HTML reports would present the information in an easy to read format plus it is portable and can be imported into Excel.
Considerations for Data Retrieval

- Methods for identifying and exporting SDV related data records
  - Keyword tagging:
    - Has to be unique and part of the data record
    - Easily identifiable, but can be deleted
    - Tag built in the user name? eg. `<username>_sdv`
  - User name:
    - Not specific to SDV of critical data values
  - User role:
    - Selection of data records is more generalized
    - Requires well-controlled role-based permissions
Considerations for Report Generation

- Must be an easily executable Study Report in the iDataFax Reports View

- Format of report
  - Eg. Listing, data

- Portability of reports
  - Save-as from iDataFax Reports View
    - Access to the monitor’s native work environment limited during on-site monitoring
  - eMail generated report directly to the monitor
    - Report is more conveniently accessible within their native working environment
Basic HTML Tagging of Data

$\langle$TABLE$\rangle$$\langle$TR$\rangle$$\langle$TD$\rangle$

- Sample HTML tags for table structure:
  - Table definition
    - $\langle$TABLE$\rangle$$\langle$/TABLE$\rangle$
  - Row definition (table row)
    - $\langle$TR$\rangle$$\langle$/TR$\rangle$
  - Cell definition (table data)
    - $\langle$TD$\rangle$$\langle$/TD$\rangle$
      - ROWSPAN
      - COLSPAN

Simple 2-Column Table

```html
<HTML>
  <TABLE Border="2" Cellpadding="5" bgcolor=white width = "100">
    <TR>
      <TD COLSPAN=2><P align="center"><font size="5" face="Arial" color=black>2 Column Table</font></P></TD>
    </TR>
    <TR>
      <TD><font size="5" face="Arial" color=black>Column 1</font></TD>
      <TD><font size="5" face="Arial" color=black>Column 2</font></TD>
    </TR>
    <TR>
      <TD><font color=black>Data 1</font></TD>
      <TD><font color=black>Data 2</font></TD>
    </TR>
    <TR>
      <TD><font color=black>Data 3</font></TD>
      <TD><font color=black>Data 4</font></TD>
    </TR>
  </TABLE>
</HTML>
```
Simple 3-Row Table

```
<HTML>
  <TABLE Border="2" Cellpadding="5" bgcolor=white width="500">
    <TR>
      <TD ROWSPAN=3><P align="center"><font size="5" face="Arial" color=black>3 Row Table</font></P></TD>
      <TD><font size="5" face="Arial" color=black>Row 1</font></TD>
      <TD><font color=black>Data 1</font></TD>
      <TD><font color=black>Data 4</font></TD>
    </TR>
    <TR>
      <TD><font size="5" face="Arial" color=black>Row 2</font></TD>
      <TD><font color=black>Data 2</font></TD>
      <TD><font color=black>Data 5</font></TD>
    </TR>
    <TR>
      <TD><font size="5" face="Arial" color=black>Row 3</font></TD>
      <TD><font color=black>Data 3</font></TD>
      <TD><font color=black>Data 6</font></TD>
    </TR>
  </TABLE>
</HTML>
```
### Source Data Verification Report

**View of list report in a browser**

#### SMART Source Data Verification Report

**CSP #591: Comparative Effectiveness Research in Veterans with cox I (CERV-I)**

**As of 09-09-2015**

<table>
<thead>
<tr>
<th>Participant No.</th>
<th>Form No.</th>
<th>Data Point</th>
<th>QC / Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>10689001</td>
<td>Form 1, Phase 1 Screen, p1</td>
<td>Participant ID</td>
<td>[text] SMART Verified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>visit date</td>
<td>[text] SMART: The SMART monitor could not verify this data point</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Staff initials</td>
<td>[text] SMART: The SMART monitor could not verify this data point</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. sign consent hipaa</td>
<td>[text] SMART: Verified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. agree not to receive psycho</td>
<td>[text] SMART: Verified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.2 agree to digital recordings</td>
<td>[text] SMART: Verified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.3 regular access to phone</td>
<td>[text] SMART: Verified</td>
</tr>
<tr>
<td>10689002</td>
<td>Form 1, Phase 1 Screen, p1</td>
<td>1.2 Eyes, prior Part ID</td>
<td>[text] SMART: Verified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>referral source</td>
<td>[text] SMART: The SMART monitor could not verify this data point. Please contact your monitor in case of questions. SMART</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other, Specify</td>
<td>[text] SMART: The SMART monitor could not verify this data point</td>
</tr>
<tr>
<td>12399001</td>
<td>Form No.</td>
<td>Data Point</td>
<td>QC / Reason</td>
</tr>
</tbody>
</table>

**Grouped by:**
- Participant ID
- Form
- Variable
- Sequence
- Query
- Reason

**Hyperlink to Study SharePoint Site**

**QC / Reason query and notes placed by monitor.**
Source Data Verification Report

View of *data* report in a browser

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**SMART Source Data Verification Report**

**CSP #564: Comparative Effectiveness Research in Veterans with xxx (CER-V-xxxx)**

As of 09-09-2015

<table>
<thead>
<tr>
<th>Participant No</th>
<th>1080001</th>
</tr>
</thead>
<tbody>
<tr>
<td>pid</td>
<td>qnm</td>
</tr>
<tr>
<td>1080001</td>
<td>12</td>
</tr>
<tr>
<td>1080001</td>
<td>12</td>
</tr>
<tr>
<td>1080001</td>
<td>12</td>
</tr>
<tr>
<td>1080001</td>
<td>21</td>
</tr>
<tr>
<td>1080001</td>
<td>21</td>
</tr>
<tr>
<td>1080001</td>
<td>21</td>
</tr>
<tr>
<td>1080001</td>
<td>21</td>
</tr>
<tr>
<td>1080001</td>
<td>21</td>
</tr>
</tbody>
</table>

**Data Fields:**

- Participant ID
- Plate no.
- Plate description
- Sequence no.
- Variable no.
- Variable description
- QC / Reason: query, note
- User ID
- Modify date
- Modify time
Source Data Verification Report

View of data report in Excel

**Data Filters in Excel:**
- Participant ID
- Plate no.
- Plate description
- Sequence no.
- Variable no.
- Variable description
- QC / Reason: query, note
- User ID
- Modify date
- Modify time

```
eMail: $DATAFAX_DIR/bin/mpack -s "Source Data Verification Report As of: $mmddyyyy" "$REPORT_DIR/$REPORT_NAME.htm" $DFUSER_EMAIL
```
HTML files in iDataFax Reports View

- For consistency use **color=black** and **bgcolor=white**
**Conclusion**

- **Process Problem:** [Allow monitors to log CRF SDV Findings at the ‘field level’ right inside iDataFax & enable CRF SDV Findings to be summarized via reports right inside iDataFax]

- **Process Improvement Solution:**
  - Gave monitors iDataFax accounts
  - Leveraged existing functions (eg DF_Tasks, RecordLevels, DF_editchecks)
  - Leveraged concept of monitor CRF-SDV work being done as last step in RecordReview
  - Leveraged existing “field-level” metadata objects (eg ReasonNotes, QCNotes)

  Leveraged the ability to use DF_editchecks to insert pre-defined string tags like “**MonitorVerified**” or “**MonitorNotVerified**” into ReasonNotes & QCNotes so that later, when these ReasonNotes and QCNotes were exported from the database, those string tags could be searched for

- Leveraged existing reporting tools (eg Unix ShellScripting, DF_ReportsView, HTML)

- To allow CRF SDV activity by monitors to be logged, reviewed, and summarized, all within the iDataFax EDC environment

- To allow trial monitor work and trial data management work to live together, rather than exist in 2 separate silos
Conclusion (TakeAways & Generalizability)

- **Process Improvement Solution (Generalizability):**

  This solution (though used specifically here to Integrate data management work and trial monitoring work) can potentially be used to Integrate any supporting trial work that centers around CRF data-review (e.g.):
  - DataManagementWork & EndpointAdjudicationCommitteeWork
  - DataManagementWork & CORELABCommitteeWork

- If monitors have 24/7 remote access to electronic source documents or electronic patient medical charts and 24/7 remote access to the clinical CRF database (e.g. iDataFax), CRF SDV can be done 24/7 remotely

- With CRF SDV findings being logged right directly inside the EDC system (iDataFax), other processes and reporting functions like risk-based monitoring and key performance indicator dashboards can be streamlined
Q & A

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