DEFINITION

An annotated case report form (CRF) is a blank CRF with annotations that identify the location of the data using the appropriate dataset name and variable name contained within that dataset.

SPECIFICATIONS

• The annotated CRF is a blank CRF.
• The annotated CRF should include all pages/forms from the database.
• Each field on the CRF is mapped to the corresponding variable in the database.
• Each annotation should include the dataset name, variable name and variable value (where applicable).
WHAT ARE THE CHALLENGES

- CRF annotation is manual and time consuming.
- Time and effort spent in annotating is not transferable to subsequent annotation efforts (i.e. standard forms across studies, studies in same therapeutic area, etc.).
- Annotation effort is not customizable nor repeatable.

WHY CHOOSE SMART aCRF

- The SMART aCRF application significantly reduces the manual effort in CRF annotation via the Annotation Repository.
- The Annotation Repository will be a growing body of Keyword–Annotation pairs.
- Annotations and their attributes can be created/modified easily and saved into the Annotation Repository for repeat usage.
- Smart learning – ML/NLP/AI - within the application enhances the repository with each use.
- The application utilizes Reverse Engineering of existing annotated CRFs to store keywords and annotations for future usage.
- Storage of annotated CRFs facilitates future full re-use and comparison.
- The application is preloaded with CDISC Metadata and the recommended default Text and Annotation attributes.
- Flexibility allows Sponsor defined Metadata to be integrated into the application.
## TYPES OF ANNOTATIONS

<table>
<thead>
<tr>
<th>Domain with Domain Label</th>
<th>Variable</th>
<th>Descriptive/Comment</th>
<th>Associative</th>
<th>Free Form</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DM=Demographics</strong></td>
<td>SITEID</td>
<td><strong>SCORRES when SCTESTCOD = SUBJINIT</strong></td>
<td><strong>DEMOGRAPHY</strong></td>
<td><strong>[NOT SUBMITTED]</strong></td>
<td><strong>See CRF Page 10 for Annotations</strong></td>
</tr>
<tr>
<td><strong>Date of Birth:</strong></td>
<td><strong>BRTHDTC</strong></td>
<td></td>
<td><strong>SEX</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gender:</strong></td>
<td></td>
<td><strong>SCDTC</strong></td>
<td><strong>ETHNIC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Race:</strong></td>
<td></td>
<td><strong>RACE</strong></td>
<td><strong>RACE</strong></td>
<td><strong>[NOT SUBMITTED]</strong></td>
<td><strong>See CRF Page 10 for Annotations</strong></td>
</tr>
<tr>
<td><strong>Other:</strong></td>
<td></td>
<td><strong>RACEOTH</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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ANATOMY OF AN ANNOTATION

![Diagram showing the anatomy of an annotation with keywords, CDISC, Study: CDISC01, Screening, Assessment Date, Demographics, Domain, Annotation, KeyWord, and STUDYID.]
ANATOMY OF AN ANNOTATION

CDISC  
Sponsor

KeyWord  
Domain  
Variable  
Annotation

Annotation

Annotation Attributes

Location Attributes

DB

Annotation Repository

CDISC  
Sponsor

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What is the Annotation Repository

- It is a combination of a Keyword with its associated Annotation and its Physical and Locational attributes.

**Example**

- **Keyword** - DEMOGRAPHY
- **DOMAIN** - DM
- **Annotation** - DM = Demographics
  - **Physical Attributes** - Font color: Dark Blue, Fill-in color: Light Blue, Font Type: Arial Bold Italic, Font size: 12-point, Border: Yes
  - **Location Attributes** - 0,0 (Top of Page).

- **The full inventory of Keywords with Annotations of a/any blank CRF represents the Annotation Repository**

How does it Work

- A user uploads a blank CRF document.
- The application analyzes the blank CRF for any or all matches of Keywords.
- The application automatically applies the associated Annotations to Keywords found in the blank CRF.
- The user can highlight CRF text to create a new Keyword and assign the Annotation with attributes. This Keyword-Annotation pair is saved into the Annotation Repository for repeat usage.
- The user can also ‘Drag and Drop’ variables from the preloaded CDISC Metadata and create an Annotation as needed.
- The Annotated CRF is saved and stored for repeat future use.
How do we match

<table>
<thead>
<tr>
<th>Common Term</th>
<th>DOMAIN</th>
<th>VARIABLE</th>
<th>VERSION</th>
<th>KEYWORD</th>
<th>TYPE</th>
<th>ANNOTATION TEXT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Event</td>
<td>AE</td>
<td>3.2</td>
<td>AE</td>
<td>AE registration form</td>
<td>DOMAIN</td>
<td>Adverse Event</td>
</tr>
<tr>
<td>AE</td>
<td>AE</td>
<td>3.2</td>
<td>Adverse Event</td>
<td></td>
<td>DOMAIN</td>
<td></td>
</tr>
<tr>
<td>Action Taken</td>
<td>AE</td>
<td>AEACN</td>
<td>3.2</td>
<td>Action taken to treat AE</td>
<td>Variable</td>
<td>AEACN</td>
</tr>
<tr>
<td>AE</td>
<td>AEACN</td>
<td>3.2</td>
<td>Action Taken</td>
<td></td>
<td>VARIABLE</td>
<td></td>
</tr>
<tr>
<td>AE</td>
<td>AEACN</td>
<td>3.2</td>
<td>[Study drug action taken]</td>
<td>Variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AE</td>
<td>AEACNO TH</td>
<td>3.2</td>
<td>[Other action taken]</td>
<td>Variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Level Group Term</td>
<td>AE</td>
<td>AEHLGT</td>
<td>3.2</td>
<td>[High Level Group Term - Term]</td>
<td>Variable</td>
<td>AEHLGT AEHLGTCD AEHLT AEHLTCD AEHLT AEHLTCD</td>
</tr>
<tr>
<td>Low Level Group Term</td>
<td>AE</td>
<td>AEHLGTCD</td>
<td>3.2</td>
<td>[High Level Group Term - Code]</td>
<td>Variable</td>
<td></td>
</tr>
<tr>
<td>Level Term</td>
<td>AE</td>
<td>AEHLT</td>
<td>3.2</td>
<td>[High Level Term - Term]</td>
<td>Variable</td>
<td>AEHLT AEHLTCD AEHLT AEHLTCD AEHLT AEHLTCD</td>
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<tr>
<td>Group Term</td>
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<td>AEHLTCD</td>
<td>3.2</td>
<td>[High Level Term - Code]</td>
<td>Variable</td>
<td></td>
</tr>
<tr>
<td>AE</td>
<td>AELLT</td>
<td>3.2</td>
<td>[Low Level Term - Term]</td>
<td>Variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AE</td>
<td>AELLTCD</td>
<td>3.2</td>
<td>[Low Level Term - Code]</td>
<td>Variable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Direct Keyword matches
- Process each page for possible keyword matches, map it to possible Domain/Variable, display listing to the User who can confirm all the correct mappings and add them into the Annotation Repository
- Wild card/Pattern Matching - like Subject * where * could be ID/Num/Number/#/No all mapping to SUBJID
- Find common terms like – Level Group Term – append words to the left and right like – High/Low – and map appropriately to Variables
- Incorporate principles of Natural Language Processing to understand the contents of the page/CRF.
SMART aCRF TOOL

Matched

- Domains Identified: 12
- Variables Identified: 83
- Forms Identified: 18

Pages

- Repeating Pages: 3
- Unidentified Pages: 0

Document Properties

- File Name: Sample crf_Removed Annotation.pdf
- Pages: 20
- Title: Annotated Study CRF
- Author: Symbiance
- Prefix domain name: No

Study Level Annotation Preferences

<table>
<thead>
<tr>
<th>Style Name</th>
<th>Text Color</th>
<th>Background Color</th>
<th>Border Color</th>
<th>Font</th>
<th>Font Size</th>
<th>Font Style</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>Red</td>
<td>LightBlue</td>
<td>Black</td>
<td>Arial</td>
<td>10</td>
<td>Normal</td>
</tr>
<tr>
<td>Primary</td>
<td></td>
<td></td>
<td></td>
<td>Arial</td>
<td>10</td>
<td>Normal</td>
</tr>
<tr>
<td>Not Submitted</td>
<td>Red</td>
<td></td>
<td>Black</td>
<td>Arial</td>
<td>10</td>
<td>Normal</td>
</tr>
<tr>
<td>Free Text</td>
<td>Red</td>
<td></td>
<td>Black</td>
<td>Arial</td>
<td>10</td>
<td>Normal</td>
</tr>
<tr>
<td>Reference</td>
<td>Green</td>
<td></td>
<td></td>
<td>Arial</td>
<td>10</td>
<td>Normal</td>
</tr>
</tbody>
</table>
SMART aCRF TOOL
## REPORTS
- Matched Keyword-Annotation Report
- Repeating Pages Summary
- Unidentified Pages Summary
- Form, Domain and Variable Metrics

## WHAT ARE THE KEY ASPECTS OF SMART aCRF
- Annotation Repository – A continuously growing body of Keywords and Annotations (including annotation attributes).
- Custom/Sponsor Metadata can be easily integrated into the application.
- Ability to Reverse Engineer existing Annotated CRFs to Machine Learn both Keywords and Annotations.
- Annotation Repository can be built using File Based input.
- Comes preloaded with the CDISC Metadata and default Annotations.
- Eliminates manual task significantly and progressively.
We are Booth 11. Please stop by.
CONTACT INFORMATION

Your comments, questions and concerns are very useful inputs to us.

Please feel free to contact us –

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