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Automated CRF Annotation – A Shift from Manual

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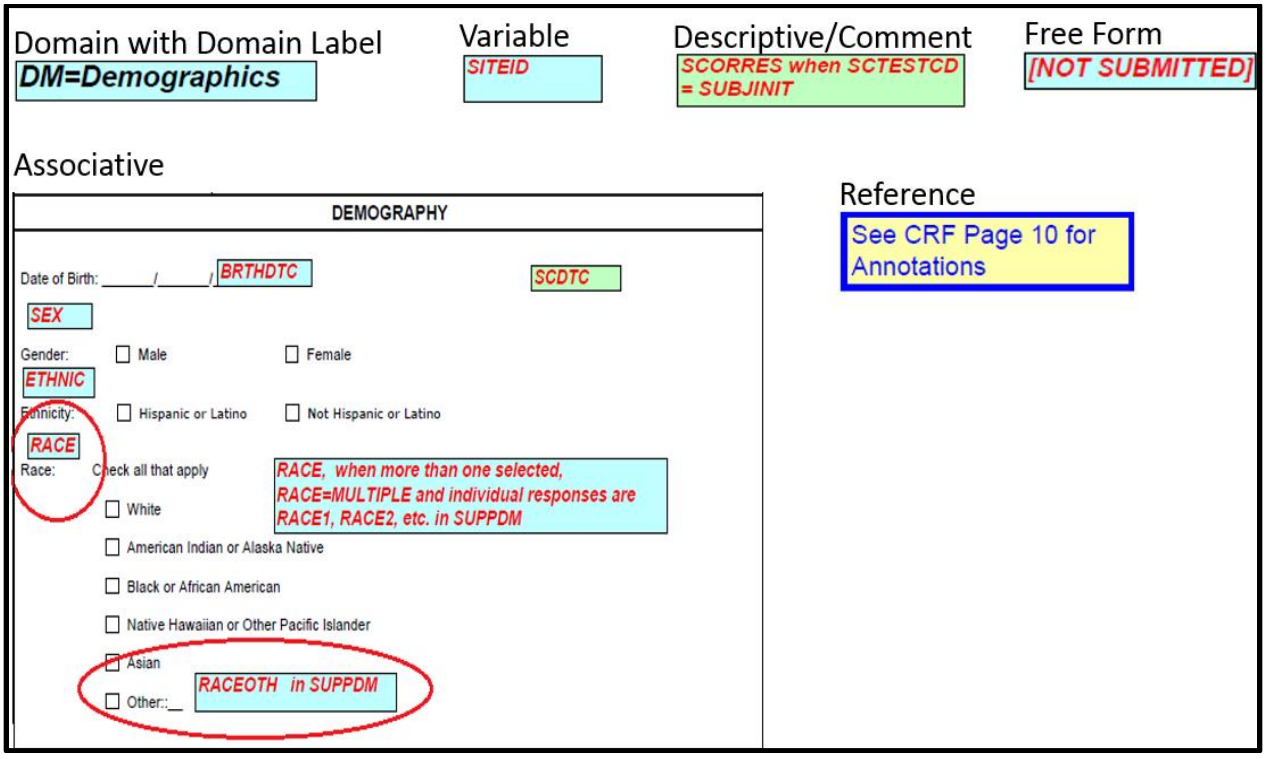
ABSTRACT

CRF Annotation is a manual and time-consuming process presently. Also, the time and effort spent in the Annotation does not transfer onto subsequent efforts or studies. With application of SMART technology and continuous learning, this process can be made completely **automatic** and repeatable over-time, significantly reducing the amount of time and effort expended. This paper discusses the mechanics of the automation, the application of the relevant standards, and the benefits thereof.

INTRODUCTION

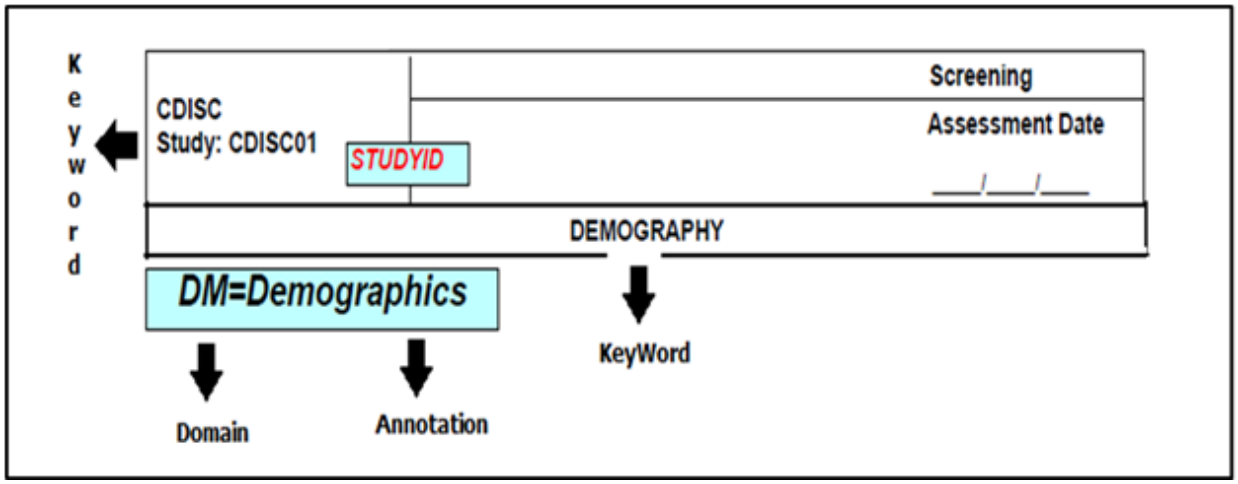
Ratilan Technologies has developed – SMART aCRF – a Tool to Automate CRF Annotation. This has been done with the application of SMART technology, the determination of a structure for each Annotation that facilitates the automated discovery of keywords (Questions) in the blankCRF, the association of those with the appropriate annotations, writing the Annotations out electronically, thereby rendering this process automatic. The heart of this tool is a Keyword-Annotation Repository Engine that learns, assists, remembers and reproduces the annotations along with its **positional** and physical attributes on a blank CRF document.

Types of Annotations



Anatomy of an Annotation

The content in each page of the blankCRF refers specifically to some Form, Domain or Variable (CDISC) within those for which specific Annotations are manually drawn. Essentially Annotations have their source in a keyword and identify a Domain or a Variable.



Annotations in a CRF identify the location of data using the appropriate dataset name and variable name contained within that dataset with certain physical and locational (on the page) attributes.

Keyword-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

- User uploads a blank CRF document.
- The application analyzes the blank CRF for any or all matches of Keywords and automatically applies the associated Annotations to the Keywords found in the blank CRF.
- User can highlight CRF text to create a new Keywords and assign the Annotation with attributes. This 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.
- Generate the blankCRF as a PDF with Annotations.

The Learnings

- Existing keywords will function as wild card for possible match ups for pairing with Annotations to accommodate variations between documents. Example – Variations in SUBJECT # like SUBJECT ID/ SUBJECT No/SUBJECT NUMBER will be associated with a SUBJECTID under the Domain.
- An existing annotated blankCRF will be reverse engineered to learn and record the physical placement of the Annotation and reuse in the annotation of a blank CRF.
- Increasing Keywords-Annotation pairings in the repository will lead to greater percentages of automation and shorter & shorter effort.
- Seeding of the Annotation Repository using file-based inputs for Keyword-Annotation combinations and physical locations in the document.
- Keywords for Custom Domains and variable that can be created into the Repository for repeat use.

Reports

- Matched Keywords-Annotation Report
- Repeating Pages Summary
- Unidentified Pages Summary
- Form, Domain and Variable Metrics

CONCLUSION

The SMART aCRF Tool converts a profoundly manual process into a significantly automated one reducing the time and effort, learning and remembering all the edits and additions, making the process repeatable.

CONTACT INFORMATION

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

Please feel free to contact us –

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