

Shopping for your CRF: Combining sources for a simple data collection browser

Rod Bower, Roche, Welwyn Garden City, UK

ABSTRACT

Roche pRED CDM has an established library of data collection standards with associated guidance for use and SDTM mapping destinations. These are available for reference in various sources; the database library, annotated form PDFs, guidance documents and mapping specifications. Study Teams utilize the standards, as per their operational requirements, during the database design-build phase to greatly speed up development.

This paper illustrates how such multiple sources can be combined into a simple in browser tool, providing a one-stop-shop of resources.

The browser illustrates standard CRF layout, datatypes, dictionaries, build/use guidance and SDTM mapping locations. Team members can use the pooled information to select the appropriate objects for the study build, filling their 'shopping basket' to store selections made.

Of course this doesn't replace the database library or detailed guidance documents but provides a quick in-browser reference/collaboration tool. The online nature also allows for user behavior tracking that could potentially highlight areas for improvement.

INTRODUCTION

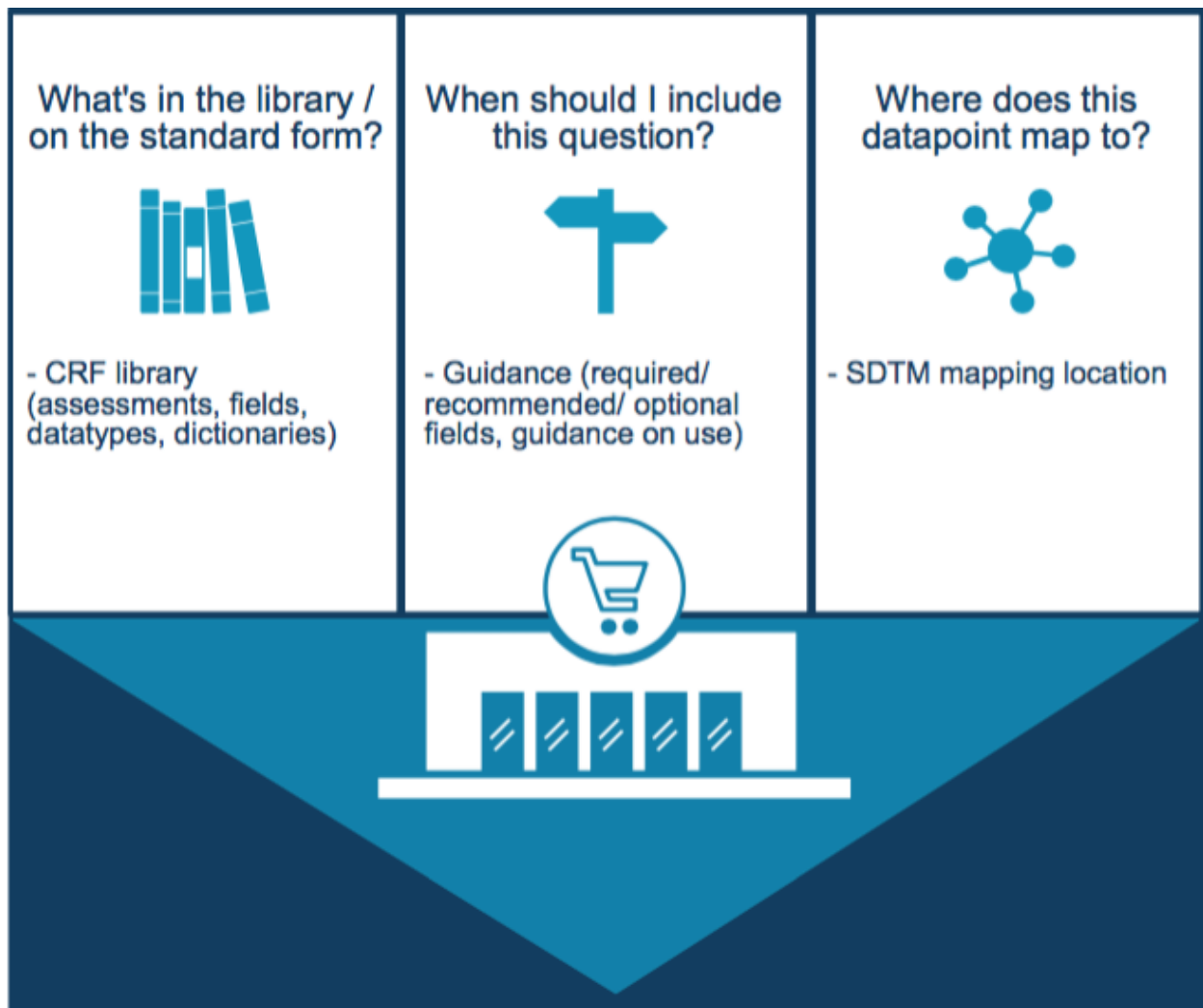
A library of data collection standards greatly speeds up study design/build with further downstream reporting gains. Selecting from established library objects leaves time to concentrate on getting the non-standard study specifics right. However, the selection from standards of what is relevant to an individual study still takes some thought. All relevant data points should be included but to optimize data value, not all library objects are desirable for all studies.

Including what is detailed in the protocol plus additional objects required for reporting requires detailed guidelines, discussion and review. Such guidelines highlight mandatory, recommended and optional objects. This can depend on the type of study or mode of data capture (CRF/data from a file). Clinical Data Acquisition Standards Harmonization (CDASH) is heavily referenced.

For the Study Management Team (SMT) to agree on the CRF design it helps to visualize the library. Annotated standard forms are often used before EDC build has begun. Once the build is underway, CRF pages can be reviewed in the EDC system or via PDF annotated forms (from the EDC system).

The benefits of a stable set of data collection standards are that it allows for standardization of SDTM reporting. SDTM mapping specifications will show the destination of the standard CRF data.

All this information is stable and available but in the various sources mentioned. Not all SMT members have access or require all levels of detail. This paper details an exercise in bringing this related information together in a useful and accessible way.



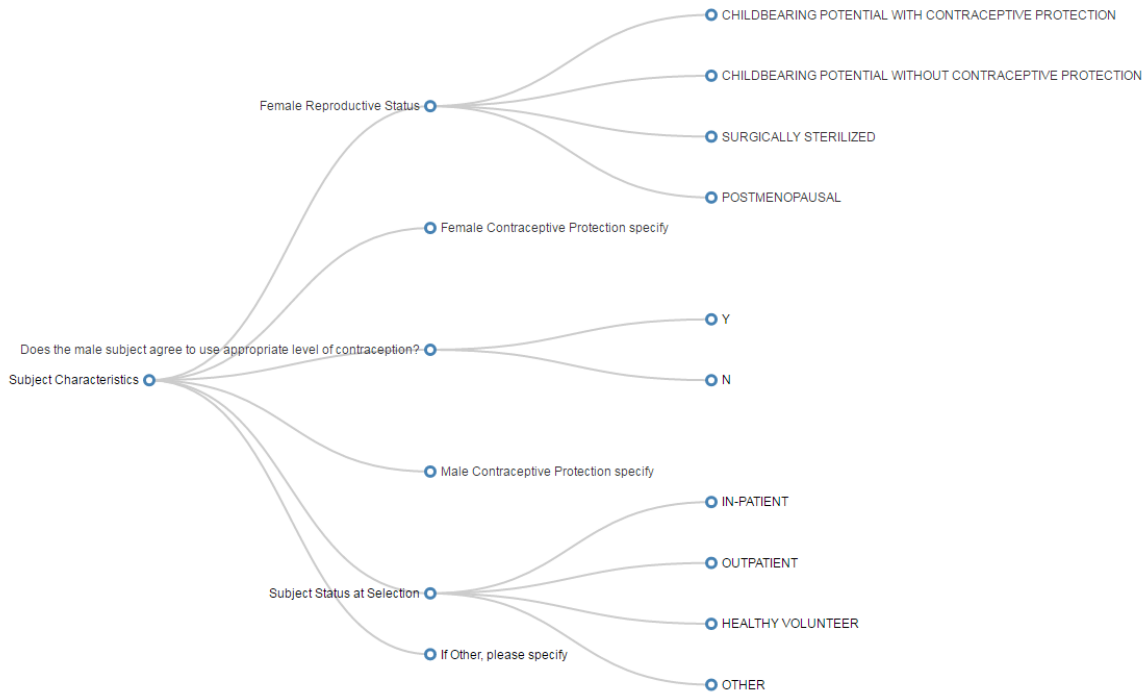
METHODOLOGY

Firstly, the basic blocks of the Standard Library were extracted from the EDC system. This included forms, fields and data dictionaries.

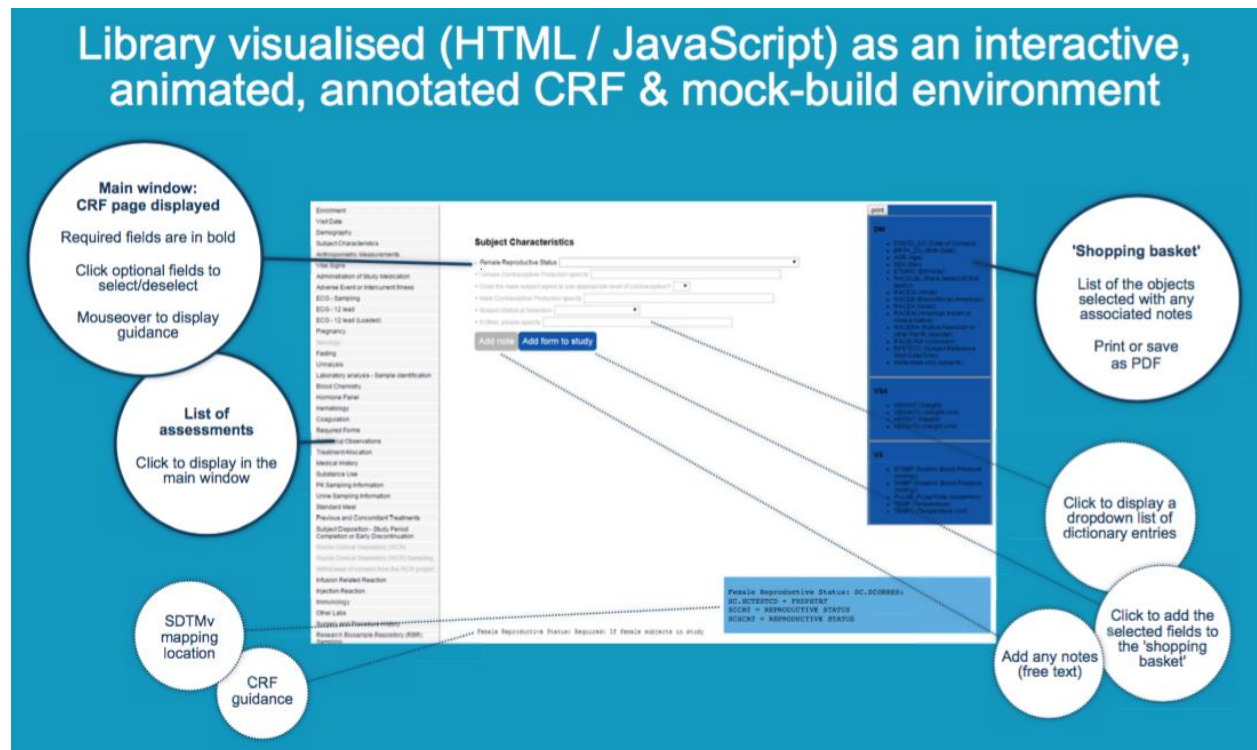
This was merged with associated use-guidance text and simple mapping information on common keys (in Roche Early Phase, these are both separate excel guidance documents).

This combined dataset was hierarchically organised allowing for effective visualization.

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With the goal of usefully representing this combined data, JavaScript/HTML was used to reconstruct the eCRF layout, displaying dictionaries, datatypes, guidance and mapping destinations. Functionality was added to illustrate optional variables and to allow the user to select/deselect. If desired, this could be printed or saved as a record of the final design.



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This resulted in an interactive animated, annotated CRF that can easily distributed company wide, accessed quickly and easily in a chrome browser.

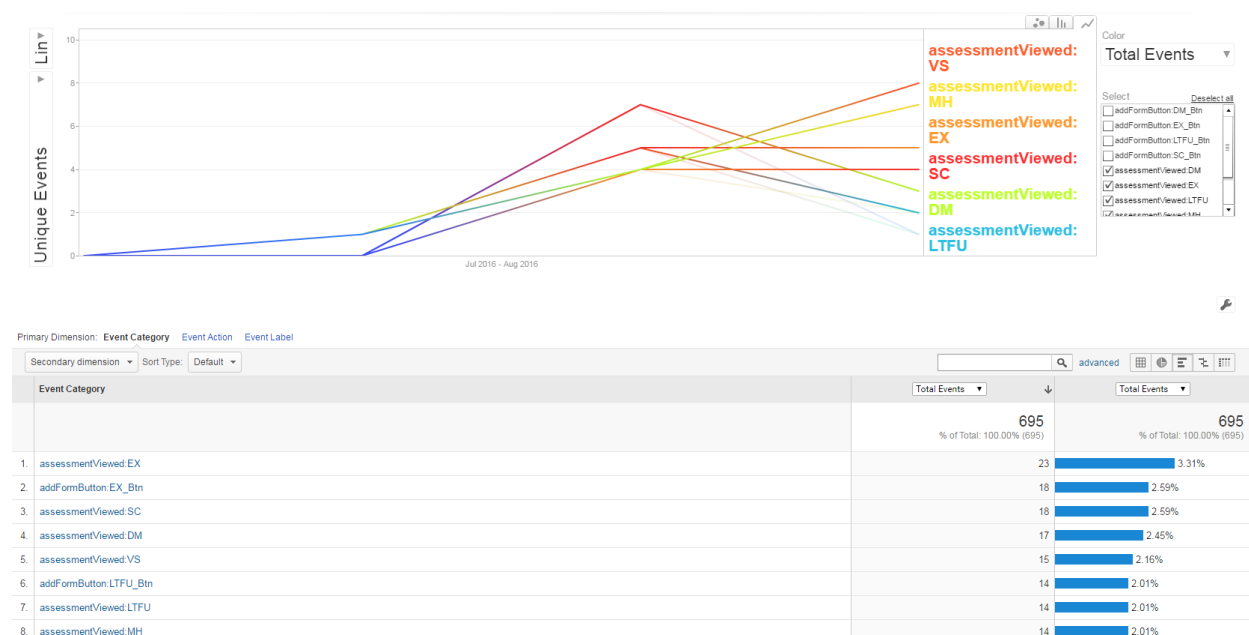
As well being a general reference source of what's in the library and where it's mapped, it can also be utilized as a mock build environment. A team member involved in setup can 'shop' for standard assessment objects. Relevant fields are selected, after consulting the displayed guidance, and finally added to the 'shopping bag' as a record of any decisions made.

FUTHER BENEFITS

Continuing the online shopping analogy, even the act of browsing can generate interesting data to the retailer. In this case the retailer equates to the Data Standards Office, those responsible for maintaining the library and associated guidance.

Utilizing web analytics, metrics showing specific use of the library browser can be tracked. Here it's possible to highlight which assessment/fields users are referencing most often. This may suggest areas of uncertainty, highlighting where guidance may benefit from further attention or improvement.

The analytics report below shows the most common user actions (events) while using the browser.



CONCLUSION

By taking the essence of the standard library out of the database and not presenting it as a static annotated PDF/spreadsheet with guidelines, it is hoped that the wider SMT can engage with it easily and embrace its effective use (including ODV).

This exercise hopefully demonstrates how using fairly simple techniques, related sources can be easily and effectively combined.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Rod Bower
Roche Products Ltd.
Shire Park
Welwyn Garden City AL7 1TW
Email: Rodrick.bower@roche.com

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