Considerations of Study Design for Graphical Mode vs. Classic Mode Data Entry in RDC 4.5.

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Goals and Agenda

- Discuss some considerations in Graphical PDF Mode Study design in RDC which do not necessarily apply to Classic Mode design.

- Suggest some overall decision points and methodology for approaching PDF Study Design.

- Draw some conclusions about PDF Study design utilisation and increasing efficiency.

Graphical Mode RDC 4.5 as a CRF Master Design Tool

- One strategy for the use of OC 4.5 and RDC 4.5 is to use the PDF Graphic Layout tools as a master CRF design platform for studies, and then to generate paper copies of these CRFs using the CRF Workbook reports in RDC 4.5

- Some advantages of this approach would be to have one central Oracle-based repository which stores both the meta-data and data for a CRF page. This would supply the advantages of a robust RDBMS to both the clinical data and the design of the clinical data.

- Additionally, storing CRF Design and Data in OPA would provide additional integration benefits in an OPA-specific context

RDC 4.5 as a CRF Master Design Tool (2)

- Along with this concept of an Oracle-based repository for both CRF design and data, other advantages of using an Oracle database also are extended to the CRF itself, such a increased granularity of controlled access, possibilities of automatically auditing changes and access to the CRF objects, strong backup and recovery techniques with Disaster Recovery, and transaction level integrity and commit points.

- Most of these advantages do not exist for the CRF in the file-system based realm (such as designing CRFs in MS-Word and saving to a network share).

- Usually, to achieve this functionality outside of an Oracle RDBMS, another separate document management solution would be required (such as Documentum).

Expectations of a Graphical CRF Design in RDC 4.5

- Since the majority of clinical sites and users of CRFs are used to paper-based CRF forms, creating a data-entry interface which is exactly like a paper CRF is expected to be nearly seamless to a user, being understood almost immediately and intuitively once the general principals of using a GUI are known.

- Therefore, the most natural reaction to approaching a CRF design in Graphical (PDF) mode is to attempt to make an exact copy of the actual paper form.

- These expectations are not made on Classic Mode layouts, since they are expected **not** to be similar to paper CRFs, and therefore, more functionality of Classic Mode design can be used with less consideration to remaining true to the users' familiar Physical CRF which may be more efficient in many situations.

Expectations of a Graphical CRF Design in RDC 4.5 (2)

- However, the Graphical Layout Mode of RDC 4.5 is not intended to have all of the same functionality as a document design tool, such as MS Word or Quark Express

- Therefore, finding a reasonable balance between creating forms which **look similar** but are not **exact** copies of the existing paper CRFs can achieve goals of
  - Designing an data-entry GUI which is intuitive to the user
  - Efficiently using RDC 4.5 to create and store CRFs

Current Limitations on RDC 4.5 Graphic Layout Design

- Some limitations on Graphic RDC 4.5 CRF design include:
  - Inability to create multi-line labels without placing individual labels on top of each other
  - Inability to generate a sequence of number labels in a range and equally spaced on a layout
  - Inability to completely hide the Data Entry Ink field
  - Inability to automatically create table or grid objects without building the table one line at a time
  - Inability to view Default Responses at PDF Design time
  - Inability to cut/paste objects between different layouts, including label objects
  - Inability to customise Graphic Layout Header and Footer fields
- Most of these limitations are mitigated by the impending RDC 4.5.1 release

Workarounds for Some Current Graphic Design Mode Limitations

- Use a Sequence number question to assist with generation of enumerated items instead of actually creating sets of labels. Even though this adds additional redundant data in the Responses table (vs. Repeat Sequence Numbers), this is a small trade-off in space over time saved in the PDF Layout.

- Do not try to create actual grids to contain data values. Instead, layout the Data Entry Ink Fields with visualization set to line to give the same relative positioning as the original forms

- Use Default Repeating values where possible. Even though the Repeating Value is not as visible as an actual label, it can provide the same information for the users.

CRF section compared from Paper to Graphical Mode Layout

Typical section from a Paper CRF for Medical History:

Any relevant family history?							Yes ☐	No ☐
If yes, please describe: (Please refer to the Check-list for Family History as given below)								
	Checklist for Family History	**Yes**	**No**		**Checklist for Family History**		**Yes**	**No**
1.	Bleeding Disorder	☐	☐	8.	Hemolytic Anemia		☐	☐
2.	Bronchial Asthma	☐	☐	9.	Hyperlipoproteinemia		☐	☐
3.	Cancers	☐	☐	10.	Hypertension		☐	☐
4.	Coronary Artery Disease	☐	☐	11.	Muscular Dystrophies		☐	☐
5.	Diabetes Mellitus	☐	☐	12.	Psychiatric Disorders		☐	☐
6.	Epilepsy	☐	☐	13.	Tuberculosis		☐	☐
7.	Stroke	☐	☐	14.	Other (specify)		☐	☐
COMMENTS IF ANY (Please specify the category and describe):								

Similar CRF in Graphical Mode Layout View

- Question SL_NO is used for the enumeration of items instead of actual labels.

- The surrounding grid is not actually modeled, but the relative position is the same

- Comments are actually a repeating QG

Print Preview mode from the Graphical Layout editor

- Default Repeating values and numbers are not visible, forcing a view from RDC test mode during modeling

- Comments are multiple lines, not a single box

View of Similar CRF Page from RDC Test Mode

Family Medical History

Please refer to the Checklist for Family Medical History given below. Please mark the response in the 'Yes/No' column of checklist if any of the answers is 'Yes', please tick "Yes" here:

Any relevant family medical history? ☐ Yes ☐ No

	Medical condition	Yes	No		Medical condition	Yes	No
1	BLEEDING DISORDER	☐	☐	8	HEMOLYTIC ANEMIA	☐	☐
2	BRONCHIAL ASTHMA	☐	☐	9	HYPERLIPOPROTEINEMIA	☐	☐
3	CANCERS	☐	☐	10	HYPERTENSION	☐	☐
4	CORONARY ARTERY DISEASE	☐	☐	11	MUSCULAR DYSTROPHIES	☐	☐
5	DIABETES MELLITUS	☐	☐	12	PSYCHIATRIC DISORDERS	☐	☐
6	EPILEPSY	☐	☐	13	TUBERCULOSIS	☐	☐
7	STROKE	☐	☐	14	Other (specify)	☐	☐

Other Medical condition:

_____

_____

If any of the answers in the above checklist if 'Yes' please tick at the appropriate category & specify below:

Comments (if any):

_____

Any relevant family history?   Yes ☐   No ☐
If yes, please describe: (Please refer to the Check-list for Family History as given below)

	Checklist for Family History	Yes	No			Checklist for Family History	Yes	No
1.	Bleeding Disorder	☐	☐	8.	Hemolytic Anemia	☐	☐
2.	Bronchial Asthma	☐	☐	9.	Hyperlipoproteinemia	☐	☐
3.	Cancers	☐	☐	10.	Hypertension	☐	☐
4.	Coronary Artery Disease	☐	☐	11.	Muscular Dystrophies	☐	☐
5.	Diabetes Mellitus	☐	☐	12.	Psychiatric Disorders	☐	☐
6.	Epilepsy	☐	☐	13.	Tuberculosis	☐	☐
7.	Stroke	☐	☐	14.	Other (specify)	☐	☐

COMMENTS IF ANY (Please specify the category and describe):

Any relevant family medical history? ☐ Yes ☐ No

	Medical condition	Yes	No		Medical condition	Yes	No
1	BLEEDING DISORDER	☐	☐	8	HEMOLYTIC ANEMIA	☐	☐
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3	CANCERS	☐	☐	10	HYPERTENSION	☐	☐
4	CORONARY ARTERY DISEASE	☐	☐	11	MUSCULAR DYSTROPHIES	☐	☐
5	DIABETES MELLITUS	☐	☐	12	PSYCHIATRIC DISORDERS	☐	☐
6	EPILEPSY	☐	☐	13	TUBERCULOSIS	☐	☐
7	STROKE	☐	☐	14	Other (specify)	☐	☐

Other Medical condition:

_____

_____

If any of the answers in the above checklist if 'Yes' please tick at the appropriate category & specify below:

Comments (if any):

Comparing the Graphic Layout and Paper CRF section

- By using a few simple workarounds, much of the time for creating this layout was reduced.

- Even though the appearance is not **exactly** the same and the sizes are different of the original vs. the Graphic Layout section, it is still in the same relative position and relative content. This achieves an ease-of-use functionality for the end-user.

- In empirically comparing the design time of this form vs. a classic mode layout, it is only marginally higher (about 25%) and compared to a PDF form where actual labels were added for the default responses and numbers with manual spacing, and a grid was constructed from individual lines, this PDF form can be constructed in less than half of the time.

- We are very hopeful that even more time savings can be realized when RDC 4.5.1 is available.

Considerations of Signatures When Designing Similar PDF Forms

- Many existing CRFs might have a number of signatures that are not directly analogous to an Approval electronic signature in RDC.

- These signature points are relied upon heavily in some paper-based environments as they were previously the only way of verifying that a specific user entered or changed or review a specific data value or set of values

- Even though an audit-trail is viewable from within RDC, this might not necessarily create a level of comfort for the user and viewing some of these signature fields might help considerably with the acceptance of RDC use at a site.

Considerations of Signatures When Designing Similar PDF Forms (2)

- In the CRF footer below, there is a signature required for Completion By: and Checked By:

COMPLETED BY AND DATE: CHECKED BY AND DATE:

- One possible way to make something conceptually similar, but not exact in the Graphical Mode layout would be use Verified and Approved checkboxes in the Graphical Mode Layout footer:
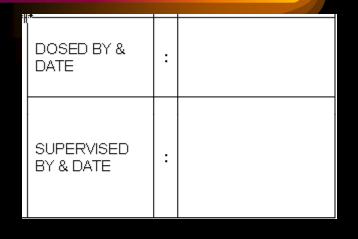
COMPLETED? ☐   CHECKED? ☐

- Note the default Layout labels have been changed from "Verified:" and "Approved:" to "Completed?" and "Checked?" respectively. This provides an analogous object to the user, which is enabled through an RDC system process, providing them something familiar but yet imparting the notion that a physical signature is not necessary to verify data in RDC.

Considerations of Signatures When Designing Similar PDF Forms (3)

- In many cases, it is useful to capture the actual user's name and response entry timestamp and display it in the place where the data-specific signoffs once existed with the use of an ON-LINE/DCM Derivation Procedure.

- This can help to reinforce the idea that a signature next to a data value is not necessary when the audit trail can be displayed as part of the CRF at Save Complete time.

DOSED BY & DATE	:	
SUPERVISED BY & DATE	:	

Enforcing Legacy Workflows in Either RDC Classic or PDF Mode

- An interesting property of a Physical CRF page is that only one person can control it at one time, and that person can make a choice of where and whom to send this Physical CRF page based on the data written on the page (barring copying of the pages).

- This means that Physical CRFs have their own de-facto workflow built into them (and the existing processes), which can be rigorously enforced (or violated) by human controls.

Enforcing Legacy Workflows
RDC Classic/PDF Mode (2)

- RDC is a very open system. Both the Activity List and the Search Window allow viewing and entry all of a Patient's data once privilege has been granted for this action at the study and/or site level. By presenting information in a tabular grid, by default, RDC allows or even arguably encourages the simultaneous entry of pages by multiple users, which may not be consistent with the intended workflows built into a Physical CRF page based process.

- Automatic switch of the DCI book is extremely useful in this situation, and even though additional Validation Procedure programming is required, it can programmatically enforce these same workflows in a more consistent manner.

- This method was graciously presented in the RDC Early Adopter's group teleconference of 27-Jul-2004 by the OPA development group.

Page-turn time/Real-Time data entry Paper vs. PDF Mode RDC

- Physical Paper CRF pages can generally be turned over or flipped through extremely rapidly. Also, Physical CRF case books can be left open for some specific pages if that page is being used for many patients at the same time. This means the same page can be accessed for different patients almost instantaneously.

- Suppose some type of samples are being collected from 10 patients at a particular time. The CRF case books can be opened for all 10 patients to the page where the information regarding this sample collection is going to occur, before the patients are called in the order they are called. This makes the time to change to the same page for patient to patient almost instantaneous.

Page-turn time/Real-Time data entry Paper/PDF Mode RDC (2)

- Given that RDC 4.5, even with automatic progression, the user must save data to the instance, close a PDF form, retrieve XML, and open a PDF to "turn" a page, this time may be much longer across patients. In a situation where sample data collection is time sensitive, this could become a consideration for certain types of studies.

- Some additional capability of performing near simultaneous data entry by having multiple PDF pages open through different IE -> RDC login sessions might also be useful in these situations, where even additional speed over the ability to switch between Browse mode of multiple open pages is required.

Conclusions

- It will become more feasible to create master CRF Designs in Graphical Mode PDF version once:
    - RDC 4.5.1 enhancements are available
    - An expectation is established that a primary objective of creating usable and intuitive forms for data entry users can be achieved without exact replicas of existing CRFs
    - Not spending time on features which may be more time-consuming to model will improve the efficient use of Graphical Mode PDF design in RDC 4.5
- Many other study considerations should be made which arise from having a very paper-like interface, but not all of the dynamic written or physical properties of paper pages.

Additional Questions ?

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