



Life

MAKING RDC EVEN MORE USER-FRIENDLY

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Agenda

- ☞ What should you do or avoid doing to make a study user friendly for the sites and data managers
- ☞ Tips regarding layouts, edit checks and other options that can affect how easy or confusing RDC is to the end users

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Making RDC Even More User-Friendly

- ✓ Tips regarding Layouts
 - Hide Questions
 - Visual Appearance
 - Multi-Line fields
 - Spacing
 - Conditional Branches
 - CDISC Standards

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Layouts – Hide Questions

CDISC	Screening
Study CDISC01	Assessment Date: ___/___/___
PSYCHIATRIC HISTORY	
1. Date of onset of probable Alzheimer's Disease?	□□ □□ □□□□
2. Date of onset of depression of Alzheimer's Disease?	□□ □□ □□□□

These labels should be turned into a non enterable Question having default values

However:

- The default values should be "Alzheimer's Disease" and "Depression of Alzheimer's Disease" rather than the label shown
- In RDC we want to display the label as shown here

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Layouts – Hide Questions

➤ Solution 1:

- ✓ Set the Question as not enterable and not displayed, and define Default Repeat Values
- ✓ For the label, enter free text on the Graphic Layout

➤ This is not possible:

Note that it would work fine if using the Default Response field at the DCM Question level, but this cannot be done here



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Layouts – Hide Questions

➤ Solution 2:

- ✓ Use a derived variable and set the “default” value via a Derivation Procedure
- ✓ This works, but seems a heavy solution to resolve a display issue...

➤ Solution 3:

- ✓ Set the Question as not enterable and displayed, and define Default Repeat Values
- ✓ But hide the Question field on the screen

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Layouts – Hide Questions

- Set the Visual Appearance of the Question field to None



- Set the display size to 0 (menu Edit → Properties) May have to use Arrange → Ungroup first

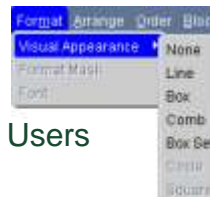


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Layouts – Visual Appearance

- The Visual Appearance assigned to Question fields may be used to facilitate the entry of data for Site Users
- Visual Appearance = None
 - ✓ Useful for not enterable fields used as labels on the screen

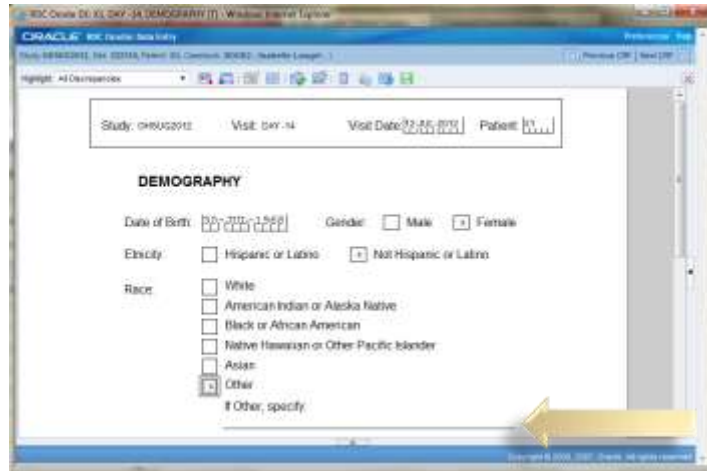


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Layouts – Visual Appearance

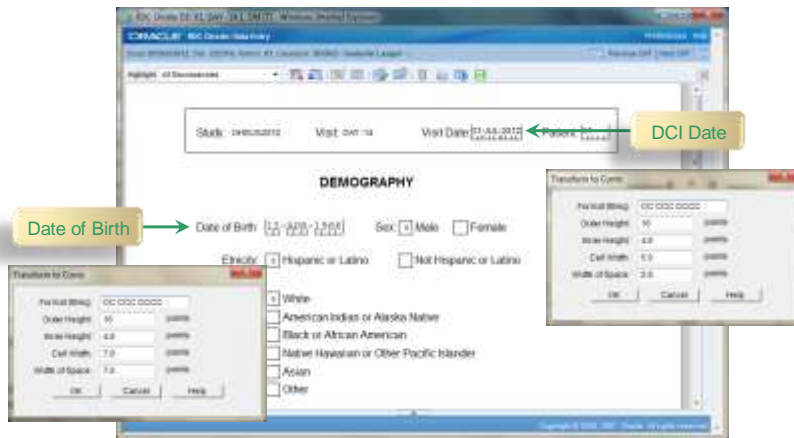
- Visual Appearance = Line



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Layouts – Visual Appearance

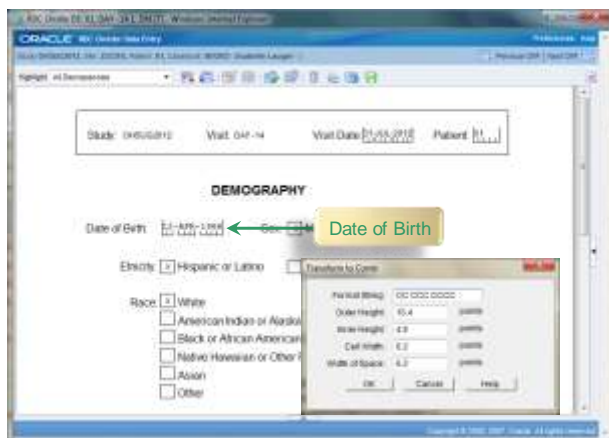
- Comb for Dates or Numeric fields
- ✓ If Font = Courier New and Font Size = 12



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Layouts – Visual Appearance

- Comb for Dates or Numeric fields
 - ✓ If Font = Courier New and Font Size = 10



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Layouts – Multi-line

- Some Questions may have long responses
- In repeating Groups you do not always want to adjust the display length to the shorter, longest or average length
- Solution: use the Multi-line feature in the Graphic Layout

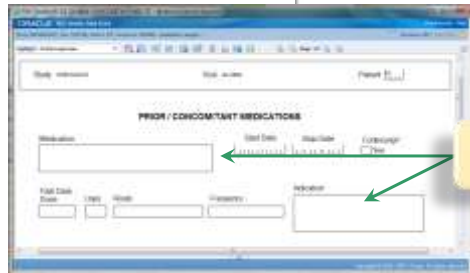


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Layouts – Multi-line

➤ Examples

- All prompts do not have the same length
- The longest responses can be displayed on two lines



Some Questions may have very long responses

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Layouts – Spacing

- Questions having a DVG setup as an LOV or Date Questions are assigned a pop-up that would display to the right of that field



- To avoid hiding questions with these pop-ups, move other fields further to the right

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Layouts – Conditional Branches

- Conditional Blocks can be setup for Conditional Branches and Indicator Questions
- However all conditions are not always easy to define
- Example 1:

PSYCHOTROPIC DRUG TREATMENT HISTORY

List all the Psychotropic drugs the patient received during the past 5 years

Brand/Drug Name (Enter the trade name for combination drugs)	Response Code	Date

Response Code
 1. As Change
 2. Poor
 3. Good

Reason for Discontinuation
 0 Ongoing
 1 Adverse Event
 2 Insufficient Response
 3 Satisfactory Response
 99 Other

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Layouts – Conditional Branches

- Define the “None” Question in a non repeating Question Group

DCM Question Group Name	Question Group Name	Question Group Element	Start	End	Date	Repeating	Map From
CR76	CR76	CR76					
CR76	CR76	CR76					

- Define the following Conditional Branch

Value	Target Question Group Name	Target Question Name	Yes	No

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Layouts – Conditional Branches

The screenshot shows the Oracle Clinical interface with a 'Conditional Block' menu open. The menu options are: 'Eliminate Source and Target Questions', 'Clear Highlighting', 'Delete Conditional Blocks', and 'Show Conditional Blocks'. The main window displays a 'PSYCHOTROPIC DRUG TREATMENT' layout with two identical sections. Each section includes a 'Generate Drug Name' field, 'Response Code' (with 'No Change', 'None', and 'None' options), 'Full Daily Dose', and 'Response to Distribution' (with 'Staying', 'Worsening', 'Improvement', and 'Subsiding/Response' options). Callouts include: 'Create the corresponding Conditional Block' pointing to the menu, and 'Note that the Conditional Block applies across several pages' pointing to the layout sections.

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Layouts – Conditional Branches

The first screenshot shows the 'PSYCHOTROPIC DRUG TREATMENT HISTORY' layout with the 'Check if NONE' checkbox unchecked. A callout states: 'The repeating QG displays if the NONE box is unchecked'. The second screenshot shows the same layout with the 'Check if NONE' checkbox checked. A callout states: 'If NONE is checked the repeating QG is not displayed'.

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Layouts – Conditional Branches

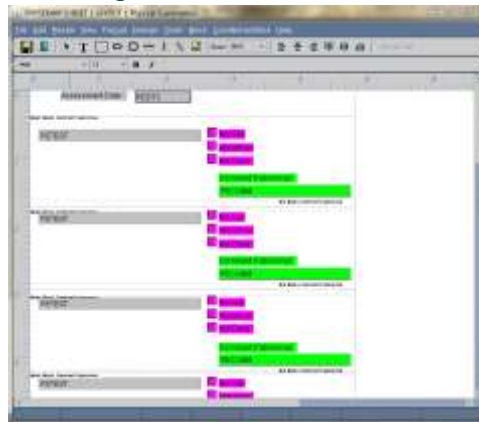
➤ Example 2:

CDISC Study CDISC01		Visit _		
		Assessment Date: _ / _ / _		
PHYSICAL EXAM				
PHYSICAL EXAM	Normal	Abnormal	Not Done	Comment only if abnormal
1. Appearance/Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Head/Neck (Including Thyroid)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Eyes-Ears-Nose-Throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Pulmonary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Repeats with Conditional Branches

Layouts – Conditional Branches

➤ Trying to setup Conditional Branches with Repeating Question Groups may end up in the following error messages



Layouts – Conditional Branches

- And if you manage to fix the errors, the DCI Form may not look as expected

These Questions are missing:

- QUESTION 1
- QUESTION 2
- QUESTION 3
- QUESTION 4
- QUESTION 5

By checking the DCM Layout, there are now new errors displayed

CONDITIONAL BRANCHING

A conditional branch group is a group of questions that are displayed or hidden based on the answer to a question. This is useful to create a form that is tailored to the user's needs.

When a question is answered, the system will automatically display or hide the questions in the conditional branch group.

When a question is answered, the system will automatically display or hide the questions in the conditional branch group.

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Layouts – Conditional Branches

- Another alternative is to create multiple DCM Subsets (one per row)

DCM Question Group Name	Library Question Group Name	Question Group Domain	Doc#	Code#	Doc#	Missing Group#	Max Prep
PE	PE	CHBLG2012	PE	1	1	1	1
PE	PE	CHBLG2011	PE	1	1	1	1

The Question Group is NOT repeating

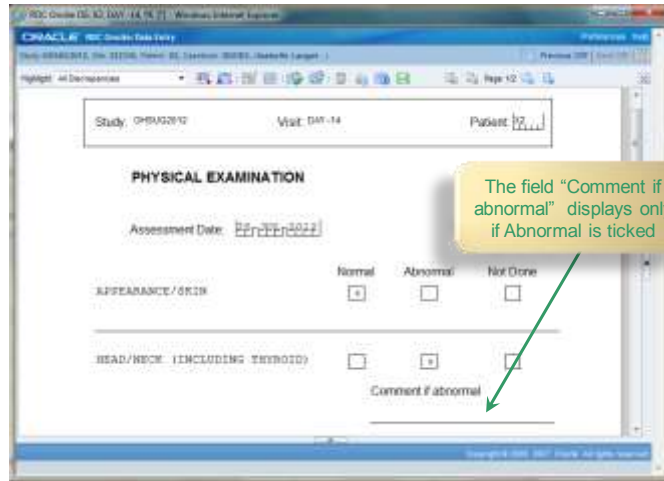
- And use a Qualifying Question
- The Conditional Branch can be created normally

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Layouts – Conditional Branches

- This produces the following result:

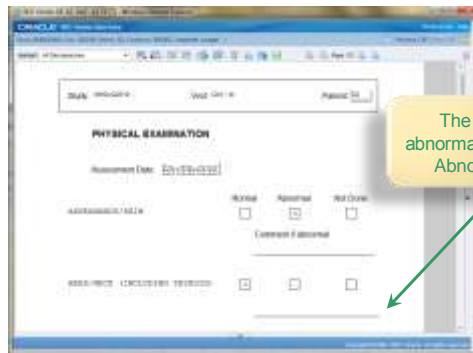


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Layouts – Conditional Branches

- ... at least as long as you do not update the DCI Layout
- For example if you remove the separators between DCM Subsets:

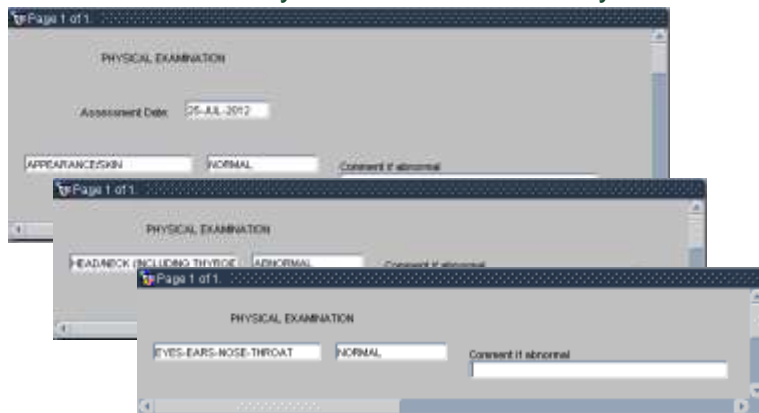


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Layouts – Conditional Branches

- However for an hybrid study this may not always look like a good alternative as the usage of multiple DCM Subsets may slow down Data Entry in OC

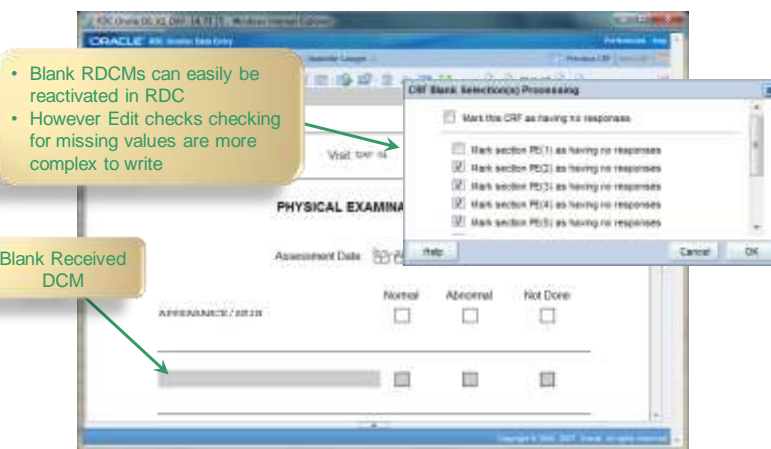


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Layouts – Conditional Branches

- The inconvenient in RDC is that any row without data entered is a Received DCM marked as Blank

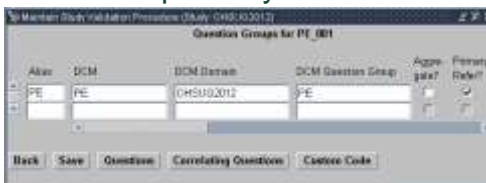


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Layouts – Conditional Branches

- Example of Procedure checking for Blank Received DCMs
 - ✓ Include the DCM and pick any enterable Question



- ✓ Create two User Variables

Used to ensure only one Discrepancy is created per RDCI

Used to Count the RDCMs within a RDCI

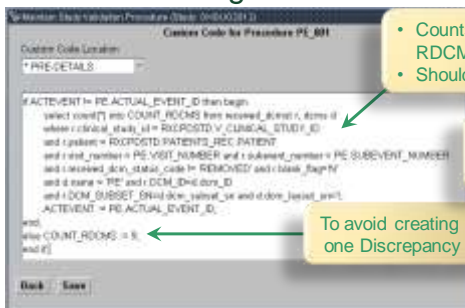


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Layouts – Conditional Branches

- Use the following Custom Code



- Counts the number of non Blank RDCMs within the RDCI
- Should be 9 if all data is present

For simplification reason this code only contains the SQL statements for Test Mode

To avoid creating more than one Discrepancy per RDCI

- Detail Expression:



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Layouts – CDISC

- Collect data using the CDISC Standards seems sometimes difficult for pages like Vitals

	STUDYID	DOMAIN	SEQID	VSSEQ	VTESTCD	VTEST	VSEQ	VSCORE	VORRESU
1	CDISC01	VS	001001	1	SYSBP	Systolic Blood Pressure	SETTING	120	mmHg
2	CDISC01	VS	001001	2	FFMSSZ	Body Frame Size		LARGE	
3	CDISC01	VS	001001	3	DIABP	Diastolic Blood Pressure	SETTING	74	mmHg
4	CDISC01	VS	001001	4	PULSE	Pulse Rate		74	BEATS/MIN
5	CDISC01	VS	001001	5	HEIGHT	Height		164	LB
6	CDISC01	VS	001001	6	HEIGHT	Height		66	IN
7	CDISC01	VS	001001	7	SYSBP	Systolic Blood Pressure	SETTING	120	mmHg
8	CDISC01	VS	001001	8	DIABP	Diastolic Blood Pressure	SETTING	80	mmHg
9	CDISC01	VS	001001	9	PULSE	Pulse Rate		84	BEATS/MIN
10	CDISC01	VS	001001	10	HEIGHT	Height		160	LB
11	CDISC01	VS	001001	11	SYSBP	Systolic Blood Pressure	SETTING	140	mmHg
12	CDISC01	VS	001001	12	DIABP	Diastolic Blood Pressure	SETTING	70	mmHg
13	CDISC01	VS	001001	13	PULSE	Pulse Rate		70	BEATS/MIN
14	CDISC01	VS	001001	14	HEIGHT	Height		160	LB
15	CDISC01	VS	001001	15	SYSBP	Systolic Blood Pressure	SETTING	140	mmHg
16	CDISC01	VS	001001	16	DIABP	Diastolic Blood Pressure	SETTING	90	mmHg
17	CDISC01	VS	001001	17	PULSE	Pulse Rate		80	BEATS/MIN
18	CDISC01	VS	001001	18	HEIGHT	Height		163	LB
19	CDISC01	VS	001001	19	SYSBP	Systolic Blood Pressure	SETTING	110	mmHg

Need to create a repeating Question group

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Layouts – CDISC

- In OC the Data Entry habits must be changed to setup certain CRFs
- But in RDC the Graphic Layout features allow the creation of CRFs like this:

Each Vital Signs corresponds to one DCM Subset

Each DCM subset uses a different DVG Subset for Units

For Blood Pressure, there are two repeats displayed on one row

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Layouts – CDISC

- In each DCM Subset you can adjust the value to what is needed
- E.g. Blood Pressure



The Position and the Unit are collected as non enterable Questions with Default Value



Layouts – CDISC

VSORRES: enterable - The responses of the two repeats are displayed on the same row



VSPOS (set to SITTING) is displayed but hidden

VSTEST (SYSBP & DIABP) is displayed but hidden

VSORRESU: Visual Appearance set to NONE so that it looks like a simple label

Making RDC Even More User-Friendly

- ✓ Tips regarding Procedures
 - Exec Context field
 - Detail Variables
 - Procedures with multiple DCMs
 - Use Derived Questions to define DCI Rules and Interval Rules
 - Assign a DCI Book to Patients

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Procedures – Exec Context

The Execution Context defines when the procedure is executed:

- ON-LINE/DCM – Discrepancies are created when the page is saved in RDC
- ON-LINE – Discrepancies are created when the Patient is validated in RDC
- OFF-LINE – Discrepancies are created when Batch Validation is run in OC (or procedure executed individually in OC)

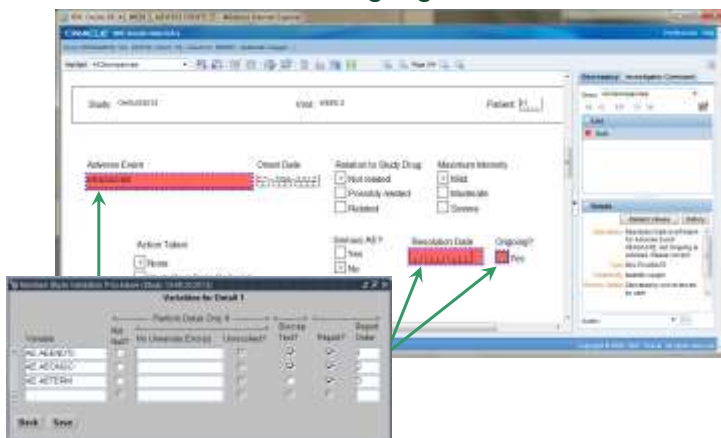
Procedure Name	Domain	Version	Status	Exec Context	Description
CM_001	OHSUG2012	0	P	ON-LINE/DCM	Medication
DM_001	OHSUG2012	0	P	ON-LINE/DCM	Date of birth
IC_001	OHSUG2012	0	P	ON-LINE/DCM	Informed Consent
IE_001					
MH_001					
MH_002					

ON-LINE/DCM procedures execute upon saving only when the Primary Reference is saved

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Procedures – Detail Variables

- When a Multivariate Discrepancy is created, all Detail Variables are highlighted in RDC



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Procedures – Detail Variables

- To facilitate the Resolution of Discrepancies, the number of Responses highlighted should be limited
- Responses that are needed in the Expression or the Message can be replaced with Procedure User Variables if they should not be highlighted



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Procedures – Detail Variables

- The same discrepancies are created

The screenshot shows the Oracle Clinical RDC interface. A discrepancy message is visible on the right side, with a callout box stating "The Discrepancy Message is still the same". In the center, the "Substitution Date" and "Ongoing?" fields are highlighted in red, with a callout box stating "Only the Questions that are Detail Variables are highlighted".

Procedures – Detail Variables

- User Variables are displayed in RDC on the DCI Form

The screenshot shows the Oracle Clinical RDC interface with a table of related values. The table has columns for QW Name, Value, Question/Variable, and Value. The following table represents the data shown in the screenshot:

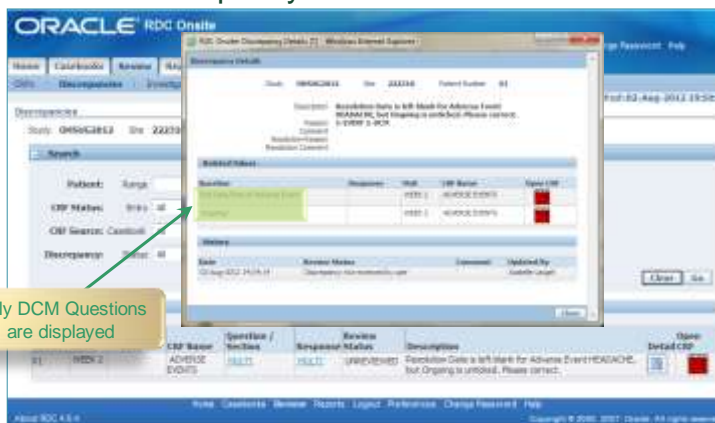
QW Name	Value	Question/Variable	Value
AD	ADEN.2	End Date Time of Adverse Event (Date)	
AD	ADEN.2	Original (over 2)	
AD	AD	Substitution Date	ADEN.2

A callout box points to the "Substitution Date" row with the following text:

- The Variable Name is converted to mixed case
- Underscores are replaced with blanks
- Max Length for Variable Name = 30

Procedures – Detail Variables

- However User Variables are not visible from the Review Discrepancy screen



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Procedures – Multiple DCMs

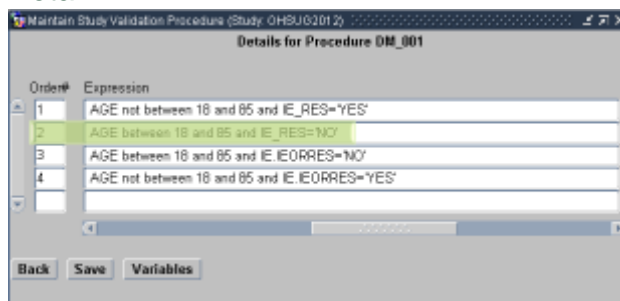
- For Discrepancies produced by Procedures including multiple DCIs:
 - ✓ The CRF containing the Primary Reference is displayed in Red or Yellow
 - ✦ CRFs containing the other Procedure DCMs are white
 - ✓ The Discrepancy is displayed only on CRFs containing Questions included as Detail Variables

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Procedures – Multiple DCMs

- Example:
 - ✓ The following procedure checks the consistency between the Date of Birth and the Response to the Inclusion Criteria “IS AGE 18-85”
 - ✓ Detail 2:

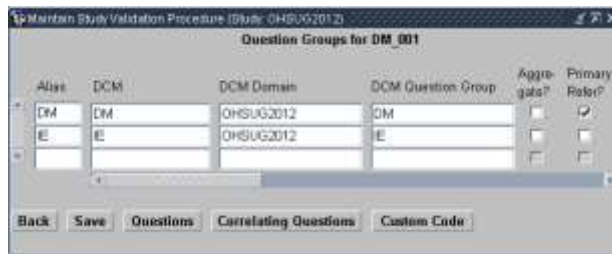


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Procedures – Multiple DCMs

- DM is the Primary Reference



- If a Discrepancy is created
 - ✓ The Demography CRF will turn to red
 - ✓ The Eligibility CRF will stay white



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Procedures – Multiple DCMs

- BRTHDTC is the only DCM Question declared as Detail Variable (the others are User Variables)



- This means that the Discrepancy will only be visible on the Demography CRF, not on Eligibility



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Procedures – Multiple DCMs

- However, with the following Detail Variables



- The DCM Questions defined as Detail Variables are in IE
- The Discrepancy will be visible only on the CRF Eligibility but not Demography



- Which may be confusing for the Site User

The white CRF contains a Discrepancy



The red one does not...

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Procedures – Multiple DCMs

- In both cases the Discrepancy is always visible on the Review Discrepancies Tab

The screenshot displays the Oracle RDC Oracle interface. The main window shows a 'Discrepancies' tab with a table of discrepancies. A callout box points to a specific discrepancy, showing a detailed view of the 'Eligibility CRF (matching to Detail Variables)'. Another callout box points to a 'Demography CRF (Primary Reference)'.

Discrepancy	Field	Value	Expected Value	Reason	Resolution
01	001-04	MEDICAL	00.00	00.00	00.00
02	001-04	MEDICAL	00.00	00.00	00.00
03	001-04	MEDICAL	00.00	00.00	00.00
04	001-04	MEDICAL	00.00	00.00	00.00
05	001-04	MEDICAL	00.00	00.00	00.00
06	001-04	MEDICAL	00.00	00.00	00.00

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Procedures – Flexible Studies

- In flexible studies, Visits and CRFs are displayed dynamically in RDC depending on data previously entered
- The Enhanced DCI Book screen allows DCI Rules and Interval Rules to be defined:
 - ✓ DCI rules allow to enable individual DCIs
 - ✦ DCI rules either apply to the current visit only, or across CPEs
 - ✓ Interval Rules allow to enable one or more intervals
 - ✦ Intervals may consist of Phases, Periods or Sub-Periods and contain one or more CPE

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Procedures – Flexible Studies

Interval Rules are created to:

- Either enable one or more intervals
- Or skip one or more intervals

Any DCI may be selected as a trigger DCI

The Interval Rule can be based

- Either on presence of any data on that DCI
- Or the response to a non repeated question having a DVG attached

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Procedures – Flexible Studies

- DCI Rules are created to enable one or more DCIs
 - ✓ Either within a Visit
 - ✓ Or across Visits
- Definition of DCI Rules is similar to definition of Interval Rules

For DCI Rules, only DCIs containing non repeated questions with DVGs may be selected as Trigger DCI

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Procedures – Flexible Studies

- All possible Interval Rules and DCI Rules cannot be defined using enterable questions:
 - ✓ Rules for which the Trigger Question is a numeric value or a Date
 - ✓ Rules based on multiple conditions, e.g.
 - ✦ Enable DCI when Question A=Yes and Question B=No
 - ✦ Enable Next Interval if all mandatory CRFs have been completed
 - ✓ Rules based on DVGs in repeating Question Groups
- In such situations, Derived Questions may be used

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Procedures – Flexible Studies

- Example of a Derived Variable used in a DCI Rule:
 - ✓ When data for a new Patient is entered:
 - ✦ Initially only the Eligibility and randomization CRFs are displayed:



- ✦ If all Inclusion Criteria are answered Yes and all Exclusion Criteria are answered No, then all CRFs in the Screening Visit are enabled

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Procedures – Flexible Studies

- Include a Derived Question (with a DVG) in the non-repeating Question Group of the Eligibility DCM



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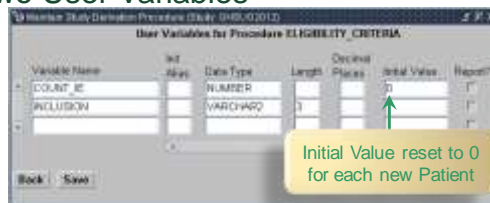
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Procedures – Flexible Studies

- Create a Derivation Procedure checking whether all Eligibility Criteria are answered as expected



- Include the two Question Groups in the procedure
- Create two User Variables



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Procedures – Flexible Studies

- In the Custom Code, count the number of “correct” responses in the repeated Eligibility Criteria

```

IFE QUALIFYING_VALUE=INCLUSION and IE (CORRECT=YES)
then COUNT_I = COUNT_I + 1;
WHILE QUALIFYING_VALUE=EXCLUSION and IE (CORRECT=NO)
then COUNT_E = COUNT_E + 1;
end if;
IF COUNT_I = 3 then INCLUSION = 'YES', else INCLUSION = 'NO', end if;
    
```

There are 3 Inclusion Criteria and 3 Exclusion Criteria in this Study

- At the Detail level, assign the value of the User Variable to the Derived Question

Question	Description	Derived Question	Response
<input checked="" type="checkbox"/>	Check if all Eligibility criteria are met	INCLUSION	INCLUSION

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Procedures – Flexible Studies

- Define the DCI Rule in the DCI Book

This DCI Rule only impacts the first Visit of the Study

Trigger				Enable DCI	Target
DCI	DCI Value	Question	Value(s)	When Active	DCI(s) at which Target DCI(s) are Collected
ELIGIBILITY CRT	INCLUSION	INCLUSION	YES	☑	DEMOGRAPHY HDR

Derived Question

Select all DCIs to be collected at Visit Day -14

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Procedures – Flexible Studies

- All CRFs for the Screening Visit are displayed in case the Eligibility Criteria are entered as expected



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Procedures – Flexible Studies

- Otherwise only Randomization CRF is available



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Procedures – DCI Book

- The DCI Rules and Interval Rules applied depend on the DCI Book assigned to the Patient
- In case the Rules to be defined are complex it may be interesting to setup multiple DCI Books and assign the right Book to each Patient
- It is possible to assign a DCI Book to a Patient using a Validation Procedure

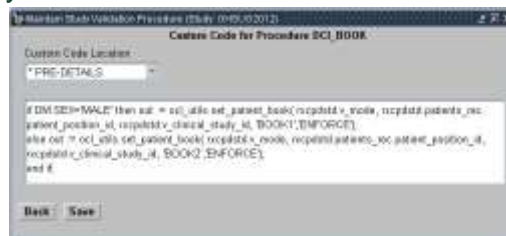


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Procedures – DCI Book

- In the Custom Code use the procedure `set_patient_book` provided by Oracle and apply any needed condition




- Create a User Variable



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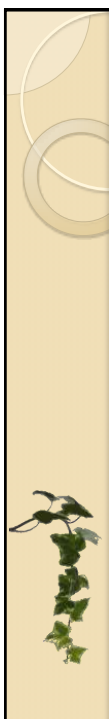
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Making RDC Even More User-Friendly

- ✓ Other Tips

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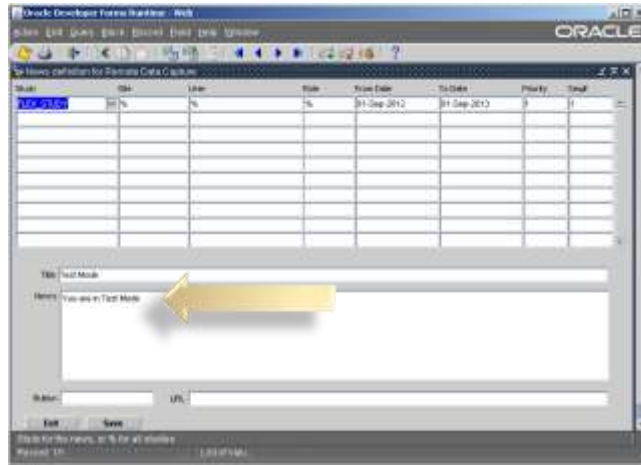
RDC in Test Mode

- The only differences in RDC Onsite between Test Mode and Production Mode are:
 - ✓ The Study Site Codes
 - ✓ The Patient IDs
- If these elements are equal in Production and Test, a Site User may enter data in Test rather than Production without noticing it
- Solution:
 - ✓ Create a News in RDC Admin for Test Mode
 - + E.g. "You are working in the test environment"

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RDC in Test Mode

- Set-up the news in RDC Admin (Test Mode):

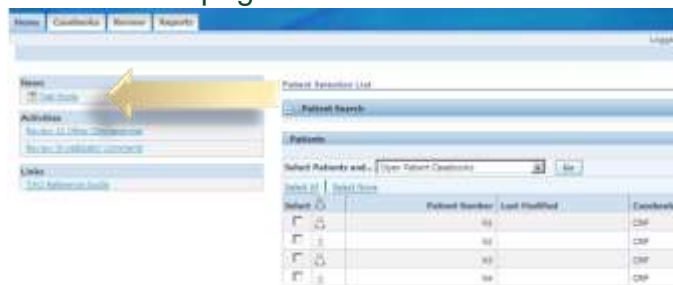


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RDC in Test Mode

- When you login to RDC Test, the News is displayed on the Home page

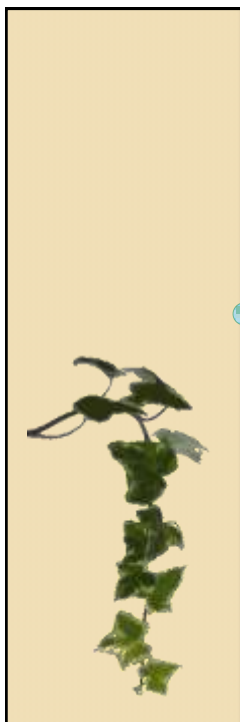


- More details may be displayed to the User who clicks on the hyperlink




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Questions?



Isabelle.Laugel@LifeSciencesExpertise.com



Biography

- Isabelle Laugel has a background of mathematician and software developer specialized in security of computer systems and optimization
- She is working in the pharmaceutical industry since 13 years and provides training, validation, consulting and support services for Life Sciences applications and business processes to pharmaceutical companies, medical devices companies and CROs of any size worldwide
- She founded Life Sciences Expertise in 2011 in order to share her experience in Data Management and Drug Safety

Life Sciences Expertise

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