



Life

PROCEDURES FOR FLEXIBLE STUDIES

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Agenda

- ☞ Define DCI Rules and Interval Rules
- ☞ Constraints on DCM structure to create Rules for flexible Studies
- ☞ Use derivation procedures to define Rules
- ☞ Use Validation Procedures to assign DCI Books to Patients

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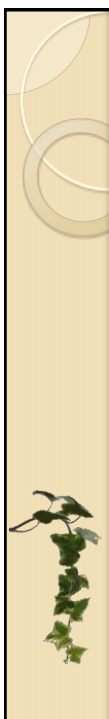
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Flexible Studies

- ✓ Define DCI Rules and Interval Rules
- ✓ Constraints on DCM structure to create Rules for flexible Studies

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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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Interval Rules

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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DCI Rules

- 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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Example of an Interval Rule

- If the Patient is Randomized, the next Visit is enabled, otherwise only the Termination Visit is available

Visit Day 1 is enabled

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Example of an Interval Rule

- If the Patient is Randomized, the next Visit is enabled, otherwise only the Termination Visit is available

Visit Day 1 is disabled

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Limitations of Rules

- 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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Flexible Studies

- ✓ Use Derivation Procedures to define DCI Rules and Interval Rules

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Derived Trigger Questions

- Derived Questions can have a DVG attached

- If such a Question is included in a non-repeating Question Group it can be used as a Trigger Question for a DCI Rule or Interval Rule

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Example 1 – 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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Example 1 – DCI Rule

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



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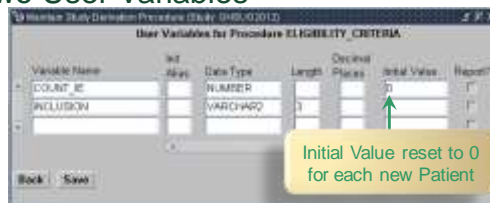
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Example 1 – DCI Rule

- 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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Example 1 – DCI Rule

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

```

IF @QUALIFYING_VALUE=@INCLUSION and @E_CORRECT=YES
then @COUNT_E = @COUNT_E + 1;
+IF @QUALIFYING_VALUE=@EXCLUSION and @E_CORRECT=NO
then @COUNT_E = @COUNT_E + 1;
end if;
IF @COUNT_E = 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

Group	Description	Derived Question	Expression
1	Check if all Eligibility criteria are met	@INCLUSION	@INCLUSION

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Example 1 – DCI Rule

- Define the DCI Rule in the DCI Book

This DCI Rule only impacts the first Visit of the Study

Trigger	DCI	DCI Value	Question	Variable	(STEP) at which Trigger DCI is	Create DCI	Value Access	Target
ELIGIBILITY CRT	@INCLUSION	@INCLUSION	YES	DAY -14		DEMOCRAPHY HDR	DAY -14	DAY -14

Derived Question

Select all DCIs to be collected at Visit Day -14

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Example 1 – DCI Rule

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



- Otherwise only Randomization CRF is available



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Example 2 – Interval Rule

- Define an Interval Rule so that Visit WEEK 2 is available only once all CRFs of Visit DAY 1 have been entered

ORACLE® RDC OnSite

Home Casebooks Review Reports

Search: 1 Patients selected from Home Page

Casebook Spreadsheet

Select Patients and... Generate Patient Data Report

Wait: Day 1

Visit WEEK 2 is not available yet as no data has been entered for the previous Visit

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Example 2 – Interval Rule

- Include a Derived Question in one of the DCMs collected at that Visit
- Create a Derivation Procedure including all DCMs collected at Visit DAY 1



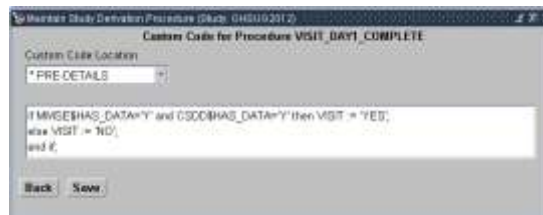
- And set the Derived Question to YES if data is collected for each of them

Example 2 – Interval Rule

- In the procedure, define a User Variable



- Calculate the value of this variable in the Custom Code:



Example 2 – Interval Rule

- As long as data for Visit DAY 1 is not completely entered, the Visit WEEK 2 is not available



- Once Data Entry is complete, the next Visit is enabled



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Example 2 – Interval Rule

- However this method has limits:
 - ✓ If the Derived Question is included in the last entered DCI for the Visit, the procedure can be set to ON-LINE/DCM and fire once the last CRF is entered
 - + Otherwise the Patient must be Validated in RDC in order to display the next Visit
 - ✓ This procedure won't work if there are DCIs marked as Blank

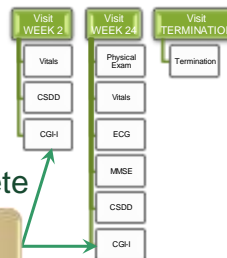


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Example 3 – Interval Rule

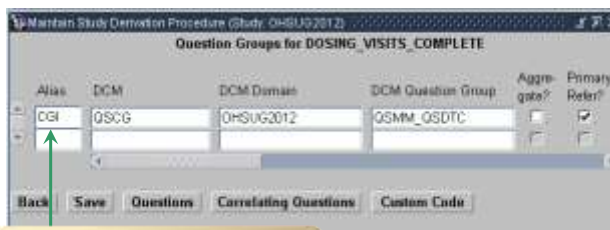
- Define an Interval Rule enabling a Visit once the previous Visit is complete
 - ✓ Similar to the previous example but the Rule will apply to multiple Visits
 - ✦ Week 24 is displayed only once Week2 is complete
 - ✦ Termination Visit is displayed only once Week 24 is complete



- The Derivation Procedure will take into account CRFs marked as blank

Example 3 – Interval Rule

- The Derived Question is included in the DCI that is the last collected at each Visit (CGI-I)
- The Derivation Procedure contains only one Question Group



- Last DCM collected in each Visit
- This DCM contains the Derived Question

Example 3 – Interval Rule

- The Custom Code checks for data collected at the current Visit

```

Custom Code for Procedure DOSING_VISITS_COMPLETE
-----
PRE-CETAL 3
-----
# CSH VISIT_NUMBER = 3 then begin
select count(*) into VISIT from received_data r, data d
where r.clinical_study_id = R0CP0010_V_CLINICAL_STUDY_ID
and r.patient = R0CP0010_PATIENTS_REC_PATIENT
and r.visit_number = CSH VISIT_NUMBER
and r.received_data_status_code != 'REMOVED'
and d.name in ('V51', 'V52', 'V53', 'V54', 'V55', 'V56', 'V57', 'V58', 'V59', 'V60', 'V61', 'V62', 'V63', 'V64', 'V65', 'V66', 'V67', 'V68', 'V69', 'V70', 'V71', 'V72', 'V73', 'V74', 'V75', 'V76', 'V77', 'V78', 'V79', 'V80', 'V81', 'V82', 'V83', 'V84', 'V85', 'V86', 'V87', 'V88', 'V89', 'V90', 'V91', 'V92', 'V93', 'V94', 'V95', 'V96', 'V97', 'V98', 'V99', 'V100')
and d.DOM_SUBJECT_SIN4 = d.data_collected_in and d.data_collected_in = 'Y';
end;

and CSH VISIT_NUMBER = 4 then begin
select count(*) into VISIT from received_data r, data d
where r.clinical_study_id = R0CP0010_V_CLINICAL_STUDY_ID
and r.patient = R0CP0010_PATIENTS_REC_PATIENT
and r.visit_number = CSH VISIT_NUMBER
and r.received_data_status_code != 'REMOVED'
and d.name in ('V51', 'V52', 'V53', 'V54', 'V55', 'V56', 'V57', 'V58', 'V59', 'V60', 'V61', 'V62', 'V63', 'V64', 'V65', 'V66', 'V67', 'V68', 'V69', 'V70', 'V71', 'V72', 'V73', 'V74', 'V75', 'V76', 'V77', 'V78', 'V79', 'V80', 'V81', 'V82', 'V83', 'V84', 'V85', 'V86', 'V87', 'V88', 'V89', 'V90', 'V91', 'V92', 'V93', 'V94', 'V95', 'V96', 'V97', 'V98', 'V99', 'V100')
and d.DOM_SUBJECT_SIN4 = d.data_collected_in and d.data_collected_in = 'Y';
end;
end if;
    
```

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

Example 3 – Interval Rule

- The following Interval Rule is created

DCI	DCI Value	Question	Value(s)	CPE(s) at which Trigger DCI is	Action	Interval(s)
C94	C9C (C,C)	VISIT_COMPLETE	YES	WEEK_2, WEEK_24	Enable	Next Interval

The Interval Rule applies to both Visits

In this Study, Phases and Periods were created so that one Interval corresponds to one Visit

- When data is entered in RDC, the next Visit displays once the last page of the previous visit is entered and saved

Example 3 – Interval Rule

Visit WEEK 24 is not available because no data was entered for Visit WEEK 2

- Visit WEEK 24 is now available as all data was entered for Visit WEEK 2
- One page was marked as blank

The same Derivation Procedure and Interval Rule works for Visit WEEK 24

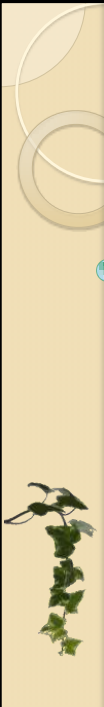
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Example 3 – Interval Rule

- This approach also has some limits:
 - ✓ The DCM containing the Derived Question needs to have data entered
 - Alternately any CRF for which data will be entered for sure could be used
 - ✓ If the DCM containing the Derived Question is not the last entered CRF within the current Visit, the Patient must be validated in RDC in order to enable the next Visit



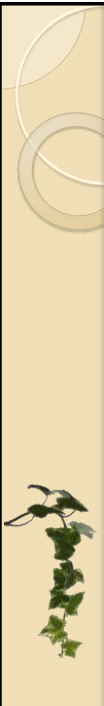
- Or run Batch Validation from OC



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- ✓ Use Validation Procedures to assign DCI Books to Patients

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Assign DCI Book to Patients

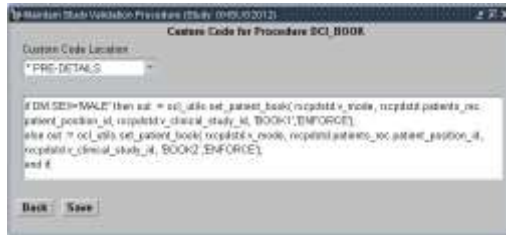
- The DCI Rules and Interval Rules applied depend on the DCI Book assigned to the Patient
- In case the Rules to be defined are complex it may be interesting to setup multiple DCI Books and assign the right Book to each Patient
- It is possible to assign a DCI Book to a Patient using a Validation Procedure



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Assign DCI Book to Patients

- 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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Questions?



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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

