

CDMS User Community Meeting

Item to Form Linking - 22R1 Feature Highlight

May 2022



Customer Success Managers (CSM), CDMS Customer Success



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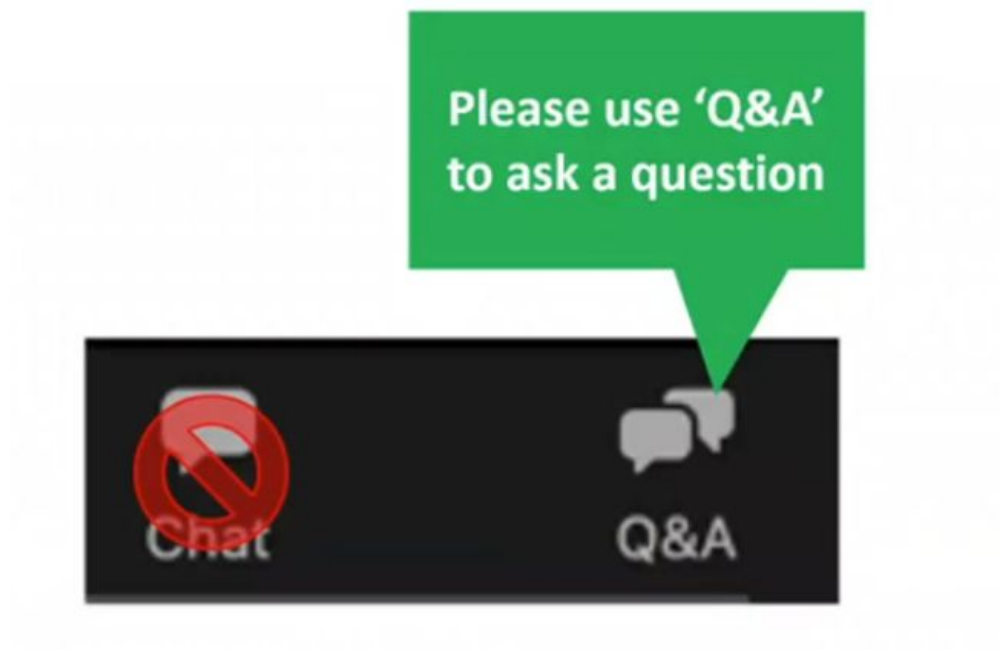


Megan Ferris
CSM, Presenter



Melanie Migliore
CSM, Presenter

Interact With Us!



Questions?

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 **Vault** CDMS



Agenda

- Feature Review
- Role specific perspectives
 - CRC
 - Data Reviews
 - Extracts and Listings
 - Studio Design
- Safety Updates
- References & Upcoming Dates



Item to Form Linking

- Why this feature was added?
 - More specificity and seeing the specific items directly on the form
 - Reduce toggling from form to linked form
 - People forgetting to link forms
 - Refined per needed query rules, so sites don't miss linking the related data - progressive display & making it required
- Where can this be found?
 - Data Entry and Review tabs UI
 - In the Data Extracts and also Coder we'll take you through these in more detail as part of this community webinar





CRC

Item to Form Linking

Common Forms: **Adverse Events**: Reference #3 of 3 < > Complete #1 of 2 < > Edit Form

Severity Mild
 Moderate
 Severe

Serious? Yes No

Relationship to Study Treatment Not Related Related

Action Taken with Study Treatment

Other Action(s) Taken Not Related

Another Medication Given

Procedure

Select Procedure

Infusion Exposure

Other Action Not Related to Study Treatment

Outcome

Did the Adverse Event Cause the Subject to Be Discontinued From the Study? Yes No

System 1/20/2022 2:13 PM EST
Data Management
There are two AE forms with the same term.
Edit Value Comment

No ⚠

Diagnostic and Medical Procedures

Reference #	Name of Procedure
<input type="radio"/> 1	Additional medication given

Cancel Save



Item to Form Linking

Common Forms: **Adverse Events**: Reference #2 of 3 < > Edit Form ...

Other Action(s) Taken Not Related to Study Treatment (select all that apply):

Another Medication Given

Select all related Medications at the bottom of the form

Procedure Δ

Select Procedure

Form [Diagnostic and Medical Procedures](#)
Reference # 1
Name of Procedure Additional medication given Δ

Other Action Not Related to Study Treatment

Outcome Recovered/Resolved Δ

Did the Adverse Event Cause the Subject to Be Discontinued From the Study?

Related Medication(s) (1 of 1)

Select Related Medication(s)

Form [Concomitant Medications](#)
Reference # 2
What was the term for the medication / therapy taken? Tylenol
Start Date 21-Apr-2022
Dose 2
Dose Unit Tablet
Dose Frequency Once



Item to Form Linking

Common Forms: **Adverse Events**: Reference #1 of 3 < > Edit Form ...

Procedure

Other Action Not Related to Study Treatment

Outcome Recovered/Resolved

Did the Adverse Event Cause the Subject to Be Discontinued From the Study? No

Related Medication(s) (1 of 2)

Select Related Medication(s)

Form [Concomitant Medications](#)

Reference # 1

What was the term for the medication / therapy taken? Advil ...

Start Date 19-Apr-2022

Dose 1

Dose Unit Tablet

Dose Frequency Once

Related Medication(s) (2 of 2)

Select Related Medication(s)

Form [Concomitant Medications](#)

Reference # 2

What was the term for the medication / therapy taken? Tylenol Δ

Start Date 21-Apr-2022

Dose 2

Dose Unit Tablet

Dose Frequency Once







Data Review

Overall Benefits for Data Review

- Facilitate and speed for SDV and DMR
 - On screen, no need to jump from one screen to another
 - On extract, linkage information available in datasets/listings
- Increased data quality
 - Item can be required, allowing for a query to be raised if the item link is blank
 - Manual Queries can be applied to item links
 - Can be frozen and locked like other items on the CRF



Review UI View

- As with any other item, a reviewer with permission can:
 - Query
 - Mark as Reviewed
 - Freeze
 - Lock
 - Create a Protocol Deviation
 - View the Audit Trail

The screenshot displays a software interface for reviewing medication data. At the top, a header reads "Related Medication(s) (1 of 1)". Below this is a section titled "Select Related Medication(s)".

The main content area is divided into two parts. The upper part shows medication details: "Form Concomitant Medications", "Reference # 1", and a query: "What was the term for the medication / therapy taken?". Below the query, the following details are listed: "Start Date 03-May-2022", "Dose 250", "Dose Unit mg", and "Dose Frequency Every Four Hours".

The lower part of the main content area contains a query box with a red question mark icon. The text of the query is: "Bill+CRA Nazzaro 5/17/2022 4:33 PM EDT. ConMed Start Date is prior to AE Start Date. Please review and correct." Below the query text is a blue link labeled "Close Query".

On the right side of the interface, there is a vertical sidebar with a green circle icon. A context menu is open over this sidebar, triggered by a blue question mark icon. The menu is divided into two sections: "ACTIONS" and "VIEW". Under "ACTIONS", there are two items: "Freeze Item" (with a star icon) and "Create Protocol Deviation". Under "VIEW", there is one item: "Item Audit Trail" (with a document icon).





Data Extracts

Extraction of item to form linking data

- Data regarding item to form linking information can be found in different extracts
 - **Study Data Extracts System Datasets**
 - **SYS_LINKS**: no changes. Show the link between forms using the sequence number

EGROUP	EVENT	EVENTEID	ESEQ	FORM	FORMEID	FSEQ
Common Forms	Common Forms	evLOGS	1	Adverse Events	AE	1
Common Forms	Common Forms	evLOGS	1	Concomitant Medications	CM	1

- **Study Data Extracts Clinical Datasets / Core Listings**
New variables available on datasets where link was created
 - (Form Link ItemDef Name)_DEF : Ex AE_CM_DEF
 - (Form Link ItemDef Name)_LINKEDFORMID
 - LINKEDITEM
 - ITEMLINKEDTO

SYS Dataset contents are outlined in [CDMS Help](#)



Generating the SDE

- EDC Tools > Select Study > Jobs > New Job > Study Data Extract
- Complete Job Options

New Job

Type
Study Data Extract

SDE Version ⓘ
Version 22R1

Restricted Data Options
 Include Restricted Data

Clinical Data Options

Use Item External ID instead of Item Name for column headers
 Include separate Date and Time columns for Datetime items
 Include forms intentionally left blank
 Exclude blank forms

Data to Export
 Export all System Datasets Export all Clinical Datasets Include Custom Objects

Export Options
Zip File Name ⓘ
[Text Field] .zip

Export File Type
[Dropdown]

Cancel Run Now

Clinical Data Options

- Use Item External ID instead of Item Name for column headers
- Include separate Date and Time columns for Datetime items
- Include forms intentionally left blank
- Exclude blank forms

Export Options

Zip File Name ⓘ

[Text Field] .zip

Generating the SDE

- Complete Data Export

New Job

Type: Study Data Extract

SDE Version: Version 22R1

Frequency: Run Now

Restricted Data Options

Include Restricted Data

Clinical Data Options

Use Item External ID instead of Item Name for column headers

Include separate Date and Time columns for Datetime items

Include forms intentionally left blank

Exclude blank forms

Data to Export

Export all System Datasets Export all Clinical Datasets Include Custom Objects

Export Options

Zip File Name: .zip

Export File Type:

Cancel Run Now

Data to Export

Export all System Datasets Export all Clinical Datasets Include Custom Objects

System Datasets (0) Clinical Datasets (0)

Search

Available System Datasets

- Event System Dataset (SYS_EVT)
- Form System Dataset (SYS_FORM)
- Intentionally Left Blank System Dataset (SYS_ILB)
- Links System Dataset (SYS_LINKS)
- Protocol Deviations System Dataset

Selected System Datasets

System Datasets (0) Clinical Datasets (1)

Search Restore defaults

Available Clinical Datasets

- PR
- safety_follow_up
- ENRL
- IE
- MH
- Randomization

Selected Clinical Datasets 1 selected

- AE



Core Listings

- EDC Tools > Select Study > Jobs > New Job > Core Listings
- Review > Select Study > Listings & Exports > New > Core Listings

New [Close]

Type
Core Listing

Frequency
Run Now

Forms (3) Sites (1)

Search [Magnifying Glass] [Restore defaults](#)

Available Forms	Selected Forms
safety_follow_up	AE
ENRL	MH
IE	CM
Randomization	
DM	
LB	
zDA	
VS9	
ECG	
EX	

Cancel **Run Now**



Clinical datasets variables

Variable Name Variable Example	Description
(Form Link ItemDef Name)_DEF Ex: AE_CM_DEF variable or AE_PR_DEF variable	External ID of the item used to create the form linking If multiple items to form linking in the CRF page, multiple variables will be shown in extract (1 per item link)
(Form Link ItemDef Name)_LINKEDFORMID Ex: AE_CM_LINKEDFORMID	Form OID of the linked form (system code automatically generated)
ITEMLINKEDTO	Display the number of forms and forms names that are linked to a particular record as well as the display items (up to 5) chosen during the build
LINKEDITEM	Display the number of forms and the item label used to link information



Clinical datasets variables

STUDYID	COUNTRY	SITENUM	SUBJID	EVENT	ESEQ	FORM	FORMEID	AETERM	AE_CM_DEF	AE_CM_LINKEDFORMID	ITEMLINKEDTO	LINKEDITEM
Labrinone-8_DEV1	United States	102	SCR-0005	Common Forms	1	Adverse Events AE		HEADACHE	Concomitant Medications [CM] (#2)	OPT000000053045	2 Form(s): Select Procedure: Diagnostic and Medical Procedures [PR] (#1) -- Name of Procedure = MRI Select Related Medication(s): Concomitant Medications [CM] (#2) -- What was the term for the medication / therapy taken? = ADVIL, Start Date = 01-May-2022, Dose = 500, Dose Unit = mg, Dose Frequency = QD	2 Item(s): Adverse Events [AE] (#1) -- Select Related Medication(s) Adverse Events [AE] (#1) -- Select Procedure

AE “Headache” is linked to Concomitant Medication Form record #1 (which has a FormOID) .

The AE form is linked to 2 forms (Procedure and Concomitant therapy) . Following items were used to make the link.

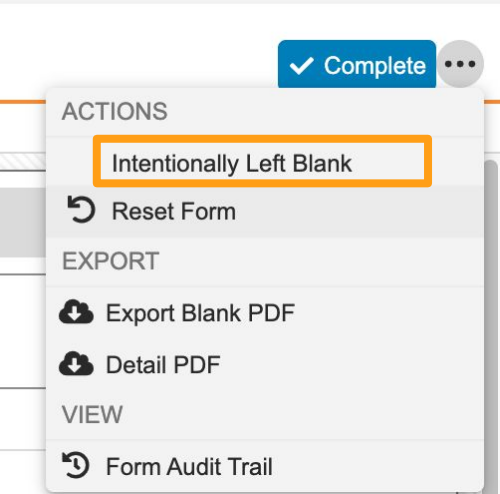
Delimiter if multiple links is the “pipe” char.

Not shown due to space issue but on same row you’ll find description to the Procedure form link

AU	AV
AE_PR_DEF	AE_PR_LINKEDFORM
Diagnostic and Medical Procedures [PR] (#1)	OPT00000004T003



Output when ILB



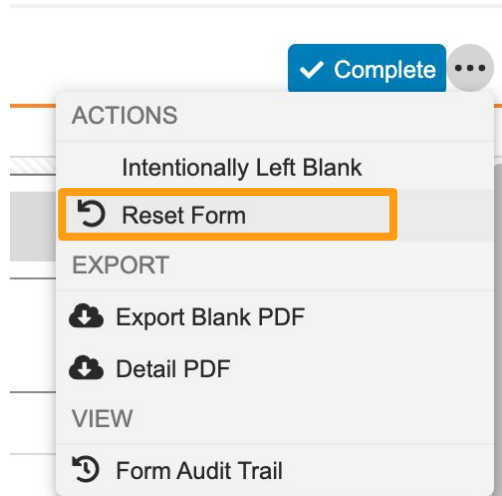
If a record previously linked to another record is Set Intentionally Left Blank

- The link is kept and visible in the output
- Linked items are showing as “null”

AE_CM_DEF	AE_CM_LINKEDFORMID	ITEMLINKEDTO	LINKEDITEM
Concomitant Medications [CM] (#1)	OPT00000004U001	2 Form(s): Select Procedure: Diagnostic and Medical Procedures [PR] (#1) -- Name of Procedure = MRI Select Related Medication(s): Concomitant Medications [CM] (#1) -- What was the term for the medication / therapy taken? = null, Start Date = null, Dose = null, Dose Unit = null, Dose Frequency = null	2 item(s): Adverse Events [AE] (#1) -- Select Related Medication(s) Adverse Events [AE] (#1) -- Select Procedure



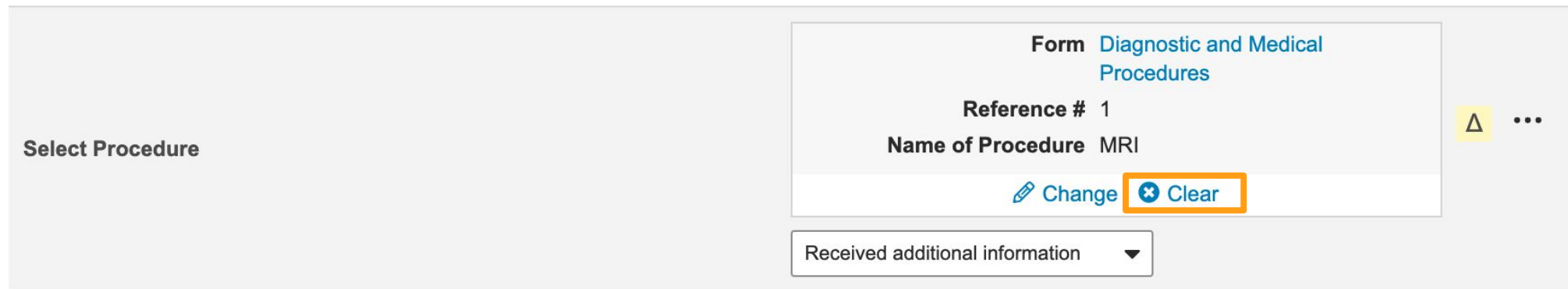
Output when Reset Form



When resetting a form:

1. Remove the link first choosing the “Clear” option
2. Reset the form

Output will not show the link as it has been cleared







Coder

Seeing Item to Form Linking in Coder (1)

Coding Status: All ▾ Query Status: All ▾ Site: All ▾ Subject:

Verbatim	Search Verb...	Indication
<input checked="" type="checkbox"/>	ADVIL	 
<input type="checkbox"/>	INSULIN	

Concomitant Medications: Reference #2 of 2

Start Date	03-May-2022
Is the medication / therapy still ongoing?	Yes
End Date	
Dose	500
Dose Unit	mg
Dose Frequency	Twice Daily
Route	Oral
Reason for Medication	Adverse Event
If Other, Specify	
Select Medical History	

Related Adverse Event(s) (1 of 1)

Selected Related AE(s)														
<table border="1"><tr><td>Form</td><td>Adverse Events</td></tr><tr><td>Reference #</td><td>1</td></tr><tr><td>Adverse Event</td><td>HEADACHE</td></tr><tr><td>Other Action Taken</td><td></td></tr><tr><td>Start Date</td><td>03-May-2022</td></tr><tr><td>End Date</td><td></td></tr><tr><td>Ongoing?</td><td>Yes</td></tr></table>	Form	Adverse Events	Reference #	1	Adverse Event	HEADACHE	Other Action Taken		Start Date	03-May-2022	End Date		Ongoing?	Yes
Form	Adverse Events													
Reference #	1													
Adverse Event	HEADACHE													
Other Action Taken														
Start Date	03-May-2022													
End Date														
Ongoing?	Yes													

Close





Studio Designers

Considerations During Study Build

- Which form(s) will I use item link(s)?
- What wording will I use for the item link?
 - The reason for relating the form(s) to the item
 - Other medication given? [for the AE] vs. Did this Medication cause an AE?
- What questions from the linked form should be included?
- Will my item link need to be able to select more than one?
- Rule Considerations
 - Progressive Display and Required checks for item links (reduces user defined rules)
 - User defined rules for evaluating data in the linked form



Considerations During Study Build

- Library Collection revisions

Copy From Study

How should duplicate definitions be handled?

Create a copy Use existing Update with Changes

Include Rules

Vault CDMS CDASH li... From Library Study VEEVA_CDASH... Environment VEEVA_CDASH_DM2_DEV1

Filter By Classifications

Search

<input type="checkbox"/>	Name ▲	Label	Repeating	External ID
<input checked="" type="checkbox"/>	AE	Adverse Events	Yes	AE
<input checked="" type="checkbox"/>	CM	Prior and Concomitant Medications	Yes	CM

Vault CDMS Search Subjects CDMS S

Data Entry Library Review Assessments Studio Coder

My Studies > Labrinone > Labrinone_DEV1

STUDY DESIGN

Schedule

Settings

Assessments (1)




Email Groups (1)

Form Links (3)

Protocol Deviations

Form Links

+ New Form Link Search

Name	Description
AE to CM	  Edit
AE to EOS	 Delete
CM to MH	



Item Links - Single

AE - related Procedure

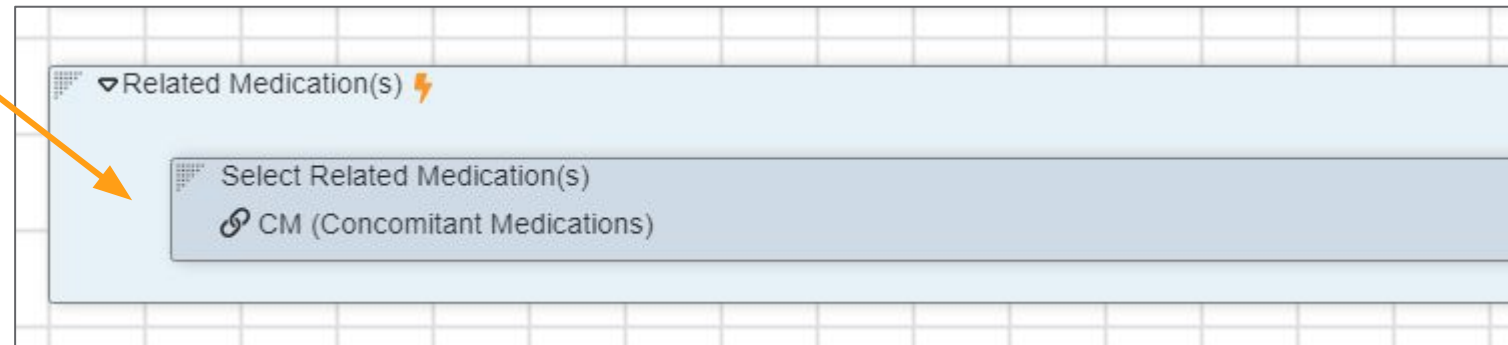
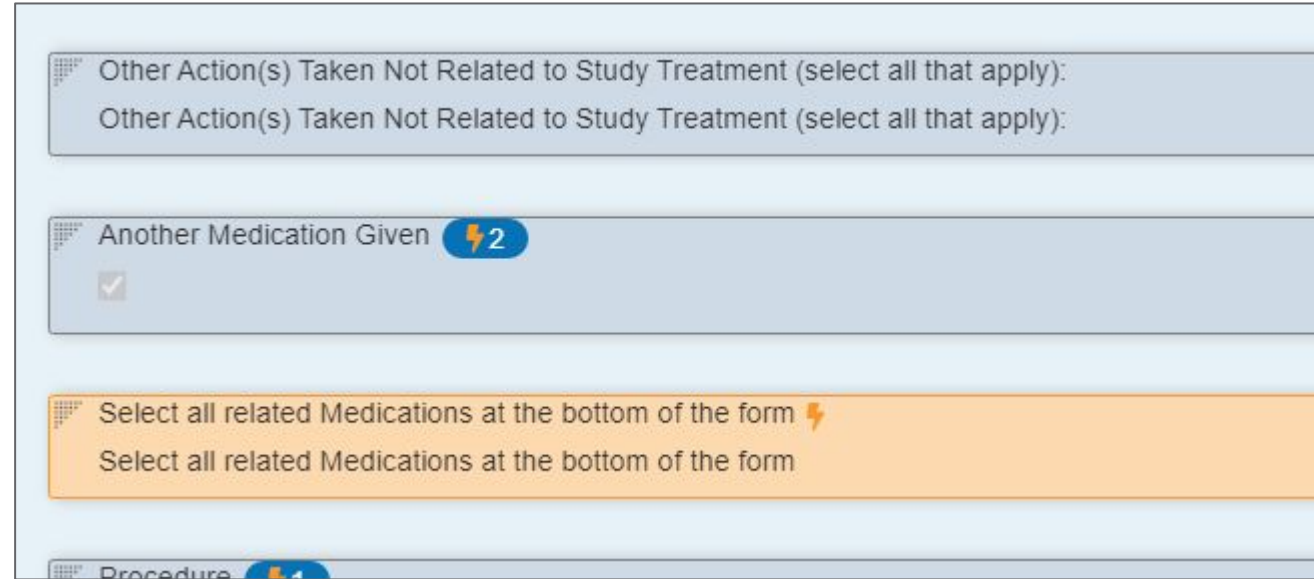
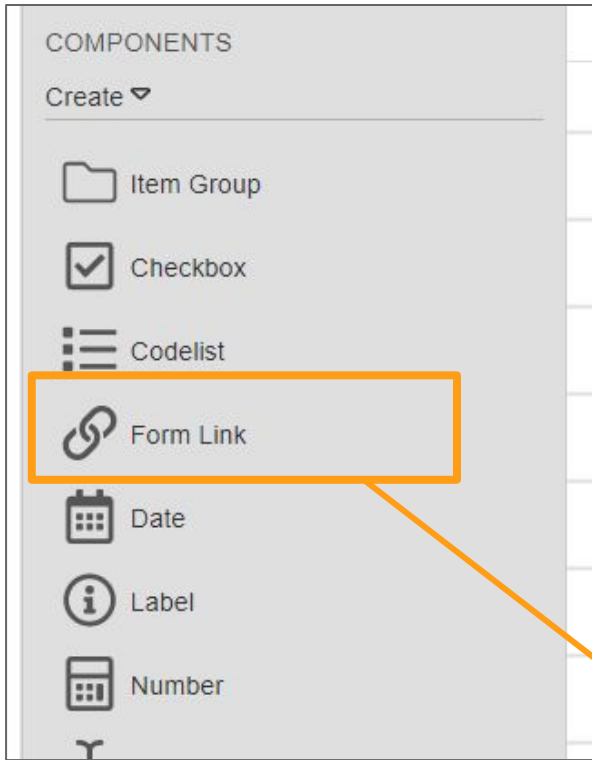
The screenshot shows a form section with two rows. The first row is labeled 'Procedure' and has a lightning bolt icon with the number '1' next to it. Below the label is a checked checkbox. The second row is labeled 'Select Procedure' and has a lightning bolt icon. Below the label is a link icon followed by the text 'PR (Diagnostic and Medical Procedures)'.

EOT/EOS -
Discontinued due to AE

The screenshot shows a form section titled 'End of Study'. It contains three rows. The first row is labeled 'Completion or Discontinuation Date' and has an empty text input field. The second row is labeled 'Status' and has a lightning bolt icon with the number '2' next to it. Below the label is a dropdown menu with the text 'Select an option'. The third row is labeled 'Select AE' and has a lightning bolt icon. Below the label is a link icon followed by the text 'AE (Adverse Events)'.



Item Links - Multiple




Repeating item group
with the Form Link

Rule Expression Examples - Repeat IG

Related Medication(s) (2 of 2)

Select Related Medication(s)

Form	Concomitant Medications
Reference #	1
What was the term for the medication / therapy taken?	Tylenol
Start Date	09-May-2022
Dose	600
Dose Unit	mg
Dose Frequency	Every Six Hours

 System 5/17/2022 5:10 PM EDT ⓘ

The linked ConMeds are duplicated.

The same link is selected more than once


```
1 #define CM_TERM_AGG @Form.igAE_CM[*].AE_CM
2 #define CM_TERM @Form.igAE_CM.AE_CM
3
4 CountIf(CM_TERM, CM_TERM_AGG) > 1
```



Rule Expression Examples - Repeat IG

...

Another Medication Given

 System 5/18/2022 3:17 PM EDT ⓘ

Another Medication Given is Yes, but there is no ConMed linked.

Procedure

Other Action Not Related to Study Treatment

Outcome

Did the Adverse Event Cause the Subject to Be Discontinued From the Study?

Related Medication(s)

No records to display

No Link has been added to the repeating IG.

```
1 #define AE_CM @Form.igAE_CM[1].AE_CM
2 #define AECONTRT @Form.igAE.AECONTRT
3
4 IsBlank(AE_CM) && AECONTRT
```

Rule Expression Examples - Checking Values

End of Study	
Completion or Discontinuation Date	17-May-2022
Status	Adverse Event
Select AE	<div><p>Form Adverse Events</p><p>Reference # 1</p><p>Adverse Event Headache</p><p>Start Date 09-May-2022</p><p>End Date 18-May-2022</p><p>Serious? No</p><p>Did the Adverse Event Cause the Subject to Be Discontinued From the Study?</p></div> <div><p>? System 5/17/2022 5:58 PM EDT ⓘ</p><p>The Linked AE form end date cannot be greater than the End of Study date</p><p>Edit Value Comment</p></div> <div><p>? System 5/17/2022 5:58 PM EDT ⓘ</p><p>The Linked AE form must record that it is the cause of the subject's withdrawal.</p><p>Edit Value Comment</p></div>

AE Stop Date is > Date of Discontinuation:

```
1 #define DSDAT @Form.igEOS.DSDAT
2 #define AELink @Form.igEOS.DSREASAE/igAE.AEENDAT
3
4 Not(IsBlank(DSDAT)) &&
5 Not(IsBlank(AELink)) &&
6 AELink > DSDAT
```

Did the AE cause the Subject to Be Discontinued From the Study? Is not Yes for the linked AE

```
1 #define AELink @Form.igEOS.DSREASAE/igAE.AEDIS
2
3 AELink != "Y"
```

Rule and Validation Best Practices

- Use validated features to reduce Rule programming and UAT efforts
 - Use Progressive Display
 - Use Required Checks
 - Review and remove any previous User Defined Rules
- Create User Defined Rules to evaluate data values in linked forms
 - Confirm start/end dates for linked items
 - Confirm the same link is not chosen (where more than one is selected)
 - Confirm the linked AE data is appropriate for subject disposition - DSET/DSES forms
- Take advantage of Library reports to confirm reuse and reduce UAT





Safety Link Configuration

Safety Link

- Using Item to Form linking, customers using our Safety Link integration can include ‘Characterization of Drug Role’ in a case
 - Requires a code list item included within the link item Item Group
 - Configuration is done on the CM section of the E2B

Edit Codelist

Name: External ID:

Description:

	Code	Label	Description
⊖	1	Suspect	<input type="text"/>
⊖	2	Concomitant	<input type="text"/>

▼ Concomitant Medications

Include Concomitant Medications Yes No

Concomitant Medications Form*

Concomitant Medications Fields

E2B ID ▲	E2B Element	E2B Data Type	Mapped Item
G.k.1 ⓘ	Characterization of Drug Role	Number (1)	drug_role (Drug Role)





Closing

Item to Form Linking

- Why this feature was added?
 - More specificity and seeing the specific items directly on the form
 - Reduce toggling from form to linked form
 - Users forgetting to link forms
 - Refined per needed query rules, so sites don't miss linking the related data - progressive display & making it required



References

- [About the 22R1 Release](#)
- [What's New in 22R1](#)
- [Release Impact Assessment \(xls\)](#)
- [Compliance Docs Registration](#)
- [Community](#)



Upcoming Webinars & Releases

Important Dates

- Look for upcoming Webinars this summer
- Next Release
 - 22R2 - Aug 5th

Veeva Trust Site

<https://trust.veeva.com/>

Veve Vault CDMS Maintenance 21R3.0.19- No expected downtime

01/12/2022 7:00 pm PST

There is a 21R3.0.19 maintenance release scheduled for the Veeva Vault CDMS service on Wednesday, Jan 12th at 7:00 PM PT for CDMS PODs: W1-22 , W1-1090 , W2-2092 , W1-1127 , VV3-3121,VV1-1139,W1-17,W1-37

Approximate duration is 30 minutes with no expected downtime.

For more details, please visit our [21R3 Release Notes](#)

Email for feedback and Suggestions for upcoming Webinar topics

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Questions?

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The Veeva logo consists of a white downward-pointing triangle followed by the word "veeva" in a lowercase, sans-serif font.



Thank you