CDMS User Community Meeting

How to Implement and Use 21R3 Features

January 2022

Veeva

Customer Success Managers (CSM),

CDMS Customer Success

Kathy Tibaldi
Presenter

Pratik Patel
Presenter
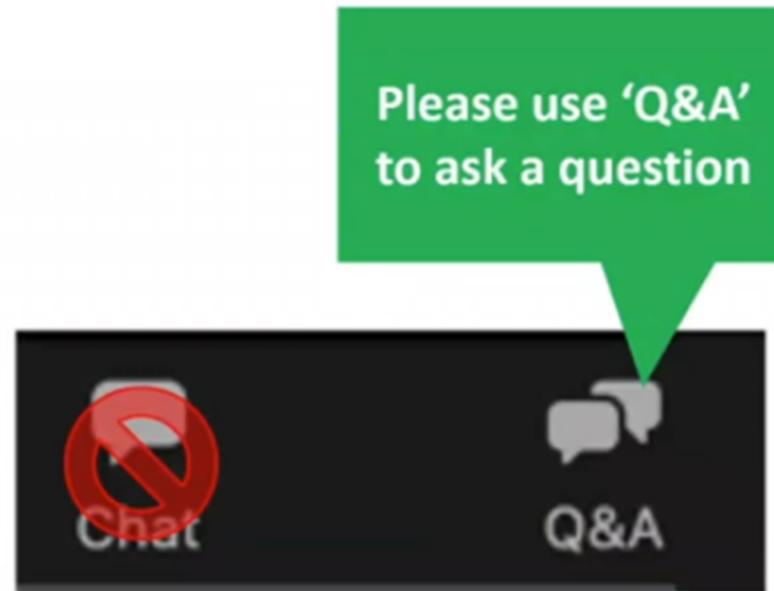
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veeva

Interact With Us!

Please use 'Q&A' to ask a question

Chat

Q&A

Questions?
cdmscustomersuccess@veeva.com

Vault CDMS

Agenda

- Rules

- EDC Tools

    - SDE Enhancements

    - New Data Listings

    - Audit Trail Options

- Safety

- References & Upcoming Dates

Rules

New Functions

The following were added in 21R3:

- Previous / Next comparators
- IsAnyBlank (must compare the same data types)
- AllEqual
- Count
- CountIf
- GetAllMatches
- Text no longer requires format
- Email rules:
  - previous_Submit_Value__v
  - has_value_changed__v
  - submit_counter__v

Check Previous Value in an Item Group

Expression [Check Syntax] [Format] Formula Language Reference   View Rule Bindings

```
1  #define EGDTC @Form.ig_ECG6.EGDTC
2  #define EGDTC_PREV @Form.ig_ECG6[-1].EGDTC
3
4  Not(IsAnyBlank(EGDTC, EGDTC_PREV)) &&
5  EGDTC_PREV > EGDTC
```

#define to create Variables,

Actions

Perform the following action(s) when the Expression evaluates to true.

Query ▼   Item ▼   *this event >* **ECG6 > ig_ECG6 > EGDTC** ✏️   This ECG is BEFORE the previous ECG. Please correct so that ECGs are in order, with the earliest ECG first.

Check Next Value in an Item Group

Expression [Check Syntax] [Format] Formula Language Reference   View Rule Bindings

```
1  #define EGDTC @Form.ig_ECG6_2.EGDTC
2  #define EGDTC_Next @Form.ig_ECG6_2[+1].EGDTC
3
4  Not(IsAnyBlank(EGDTC, EGDTC_Next)) &&
5  EGDTC > EGDTC_Next
```

#define to create Variables, Ctrl + Space

Actions

Perform the following action(s) when the Expression evaluates to true.

Query ▼   Item ▼   *this event* > **ECG6_2** > **ig_ECG6_2** > **EGDTC** ✏

This ECG is AFTER the next ECG. Please correct so that ECGs are in order, with the earliest ECG first.

Check Previous Value in an Event Group

Expression [Check Syntax] [Format]   Formula Language Reference   View Rule Bindings

```
1  #define Weight @EventGroup.Visit-1.Vital-Signs.Vital-Sign-Measurement.Weight
2  #define PrevWeight @EventGroup[-1].Visit-1.Vital-Signs.Vital-Sign-Measurement.Weight
3
4  Not(IsAnyBlank(Weight, PrevWeight)) &&
5  (Abs(Weight - PrevWeight)/PrevWeight) >= .1
```

#define to create Variables, Ctrl + Space

Actions

Perform the following action(s) when the Expression evaluates to true.

Query ▼   Item ▼   *this event* > **Vital-Signs** > **Vital-Sign-Measurement** > **Weight** ✎   Weight has changed by more than 10%

Count that AE Term > 0

Expression [Check Syntax] [Format] Formula Language Reference   View Rule Bindings

```
1  #define COMPLTYN @Form.DSES.COMPLTYN
2  #define AEYN $common_forms.common.Adverse-Event-YN.AE-General-information.AEYN
3  #define AETERM $common_forms.common.Adverse-Event[*].ig_AE.AETERM
4
5  Not(IsBlank(COMPLTYN)) &&
6  AEYN = "Y" &&
7  Count(AETERM) = 0
```

#define to create Variables, Ctrl + Space

Actions

Perform the following action(s) when the Expression evaluates to true.

Query ▼   Item ▼   *this event* > **DSES** > **DSES** > **COMPLTYN** ✏ | End of Study completion is entered, and AE is reported as Yes, but no AE names are found in the casebook.

Multiple AE Marked as Fatal Using CountIf()

Expression [Check Syntax] [Format] Formula Language Reference   View Rule Bindings

```
1  #define DSDECOD_EOS @Form.DSES.DSDECOD_EOS
2  #define Outcome $common_forms.common.Adverse-Event[*].ig_AE.Outcome
3
4  DSDECOD_EOS = "DEATH" &&
5  CountIf("FATAL", Outcome) > 1
```

#define to create Variables, Ctrl + Space

Actions

Perform the following action(s) when the Expression evaluates to true.

Query ▾   Item ▾   *this event* > **DSES** > **DSES** > **DSDECOD_EOS** ✏   Only 1 AE should be marked as Fatal

Confirm AllEqual() for Dates

Expression | Check Syntax | Format | Formula Language Reference   View Rule Bindings

```
1 #define AEEndDate @Form.ig_AE.AE-End-Date
2 #define DTHDAT $eg_EOS.End-of-Study.DD.DD.DTHDAT
3 #define Outcome @Form.ig_AE.Outcome
4
5 Not(IsAnyBlank(AEEndDate, DTHDAT)) &&
6 Outcome = "FATAL" &&
7 Not(AllEqual(AEEndDate, DTHDAT))
```

#define to create Variables, Ctrl + Space

Actions

Perform the following action(s) when the Expression evaluates to true.

Query ▼   Item ▼   *this event* > **Adverse-Event** > **ig_AE** > **AE-End-Date** ✏   End date must match Date of Death when Outcome is Fatal.

Tumor Growth Across Weeks Using GetAllMatches()

Expression [Check Syntax] [Format] Formula Language Reference View Rule Bindings

```
1 #define TRORRES_MEASURMENT @Form.TUTG2[*].TRORRES_MEASURMENT
2 #define week_assessed @Form.TUTG2[*].week_assessed
3
4 Not(IsAnyBlank(TRORRES_MEASURMENT)) &&
5 Max(GetAllMatches("WK1", week_assessed, TRORRES_MEASURMENT)) < Max(GetAllMatches("WK3", week_assessed, TRORRES_MEASURMENT))
```

#define to create Variables, Ctrl + Space

Actions

Perform the following action(s) when the Expression evaluates to true.

Query ▼   Item ▼   *this event* > **TU_TRG** > **TUTG2 [3]** > **TRORRES_MEASURMENT** ✏️   Lesion size has not reduced since week 1.

Confirm Two Digits After the Decimal with Text()

Expression [Check Syntax] [Format] Formula Language Reference   View Rule Bindings

```
1  #define Weight_Kg @Form.Dosing-Info-IG.Weight-kilograms
2
3  Not(IsBlank(Weight_Kg)) &&
4  Left(Right(Text(Weight_Kg), 3), 1) != "."
```

#define to create Variables, Ctrl + Space

Actions

Perform the following action(s) when the Expression evaluates to true.

Query ▾   Item ▾   *this event* > **Dosing-Information** > **Dosing-Info-IG** > **Weight-kilograms** ✏   Please enter 2 digits after the decimal.

Email Rule to Send Only on First Submission

Expression | Check Syntax | | Format | Formula Language Reference   View Rule Bindings

```
1  #define Serious @Form.ig_AE.Serious
2  #define AE @Form.submit_counter__v
3
4  Serious = "Y" &&
5  AE = 1
```

#define to create Variables, Ctrl + Space

Actions

Perform the following action(s) when the Expression evaluates to true.

Send Email ▾   To: SAE_Notification ⊗   ▾   Search for token

Email Rule for SAE Downgrade

Expression [Check Syntax] [Format] Formula Language Reference   View Rule Bindings

```
1  #define Serious @Form.ig_AE.Serious.previous_submit_value__v
2  #define Serious_Changed @Form.ig_AE.Serious.has_value_changed__v
3
4  Serious = "Y" &&
5  Serious_Changed
```

#define to create Variables, Ctrl + Space

Actions

Perform the following action(s) when the Expression evaluates to true.

Send Email ▾   To: SAE_Notification ⊗   ▾   Search for token

Study Data Extracts (SDE) New Data Listings

Study Data Extracts

- Increased consistency with coding columns to remove spaces

- Included information in the Job History about which options were selected for the job run

- Increased naming consistency between key clinical data columns and system dataset columns

- Added columns for arms and cohorts to the SYS_SUB dataset

- Added the Last Signature Date column to the SYS_FORM dataset

- Added the Item Definition and Lab Analyte Name columns to the SYS_ILB dataset

SYS Dataset
contents are outlined
in CDMS Help

Study Data Extracts

- Additional columns are available to align with Utilities version 5 to the following System Datasets:

  - ## SYS_EVT

    - Event Group, Event External ID, Last Modified Date/Time of the Event Date, Scheduled Window Status, Dates Outside Window, Expected number of forms, When one or more forms not yet complete - number of days past due

  - ## SYS_FORM

    - Event Group, Event External ID, SDV Required, Date/Time of last SDV Modification, DMR Required, Last Signature Date

  - ## SYS_ILB

    - Event Group, Event External ID, Event Group Sequence, Form External ID, Item Definition, Analyte Name

  - ## SYS_Q

    - Event Group, Event External ID, Event Group Sequence, Form External ID, Whether the data changed after query creation

SYS Dataset
contents are outlined
in CDMS Help

Generating the SDE

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

Study Listings

- With this release, we added four (4) new study listings:
  - Subject Progress
  - Event Progress
  - Form Progress
  - Query Details

Audit Trail Exports

- ## 21R3 Introduced Audit Trail Export by Site

  - Up to ten Sites can be selected for a single job. Like the Audit Trail by Study and Audit Trail by Site jobs, the output of this job will contain a .CSV file for each Subject in the selected site(s)

- ## Filtering

  - Audit Trail Exports generated from EDC Tools now allow for optional filtering to limit the information included in the exported audit .CSV files.

Safety

CDMS Safety Link

Automated

Sites simply submit SAE forms and the system sends Cases to the Safety System. CDMS receives ACKs that are received and parsed

First-Send & Follow Up

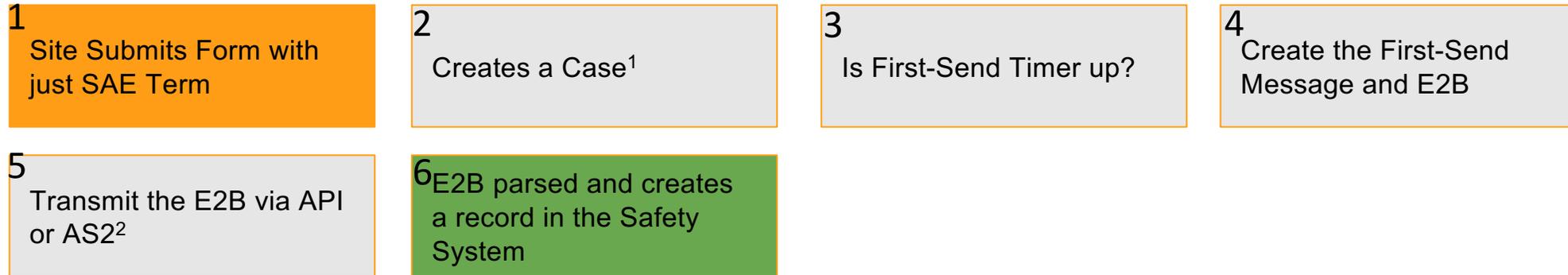Messages included newly captured or changed items in the Submitted state.

SAE & Related Forms

All SAE Form data that can map to E2B is included in transmitted Messages. It can also include data from several related forms via Form Linking.
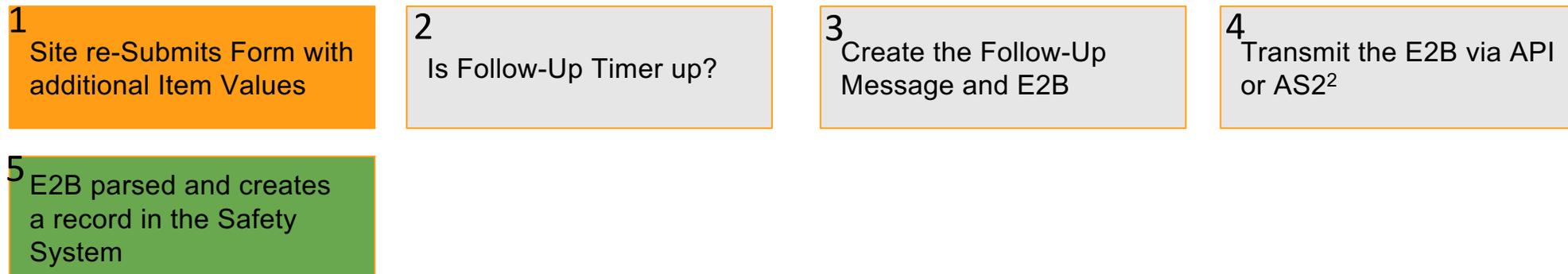
Flow in a Live Study

Site Submits SAE Form Instance for the first time. This creates a Case and the first Message (First-Send).

1 Site Submits Form with just SAE Term	2 Creates a Case[1]	3 Is First-Send Timer up?	4 Create the First-Send Message and E2B

5 Transmit the E2B via API or AS2[2]	6 E2B parsed and creates a record in the Safety System

Site re-Submits SAE Form Instance with additional or updated data or updated form linking. This creates a second Message to an existing Case (Follow-Up).

1 Site re-Submits Form with additional Item Values	2 Is Follow-Up Timer up?	3 Create the Follow-Up Message and E2B	4 Transmit the E2B via API or AS2[2]

5 E2B parsed and creates a record in the Safety System

[1] Also use and Send Email Rule to notify an email group on new SAEs. Include relevant Study and Form data in the email

[2] Data is transmitted via APIs if integrating with a Safety Vault and via AS2 if integrating with Argus or other Third Party Safety System

CDMS Safety Link Timeline

21R1

- Initial Release
- Vault Safety
- AS2 Gateway

Apr. 2021

21R3

- Long Narratives
- Coding values in E2B
- Support for External Labs
- Treatment Form in E2B

Dec. 2021

Aug. 2021

21R2

- Multiple SAEs per Safety Case
- Additional Integration Support (Indicate Investigational Product is blinded)
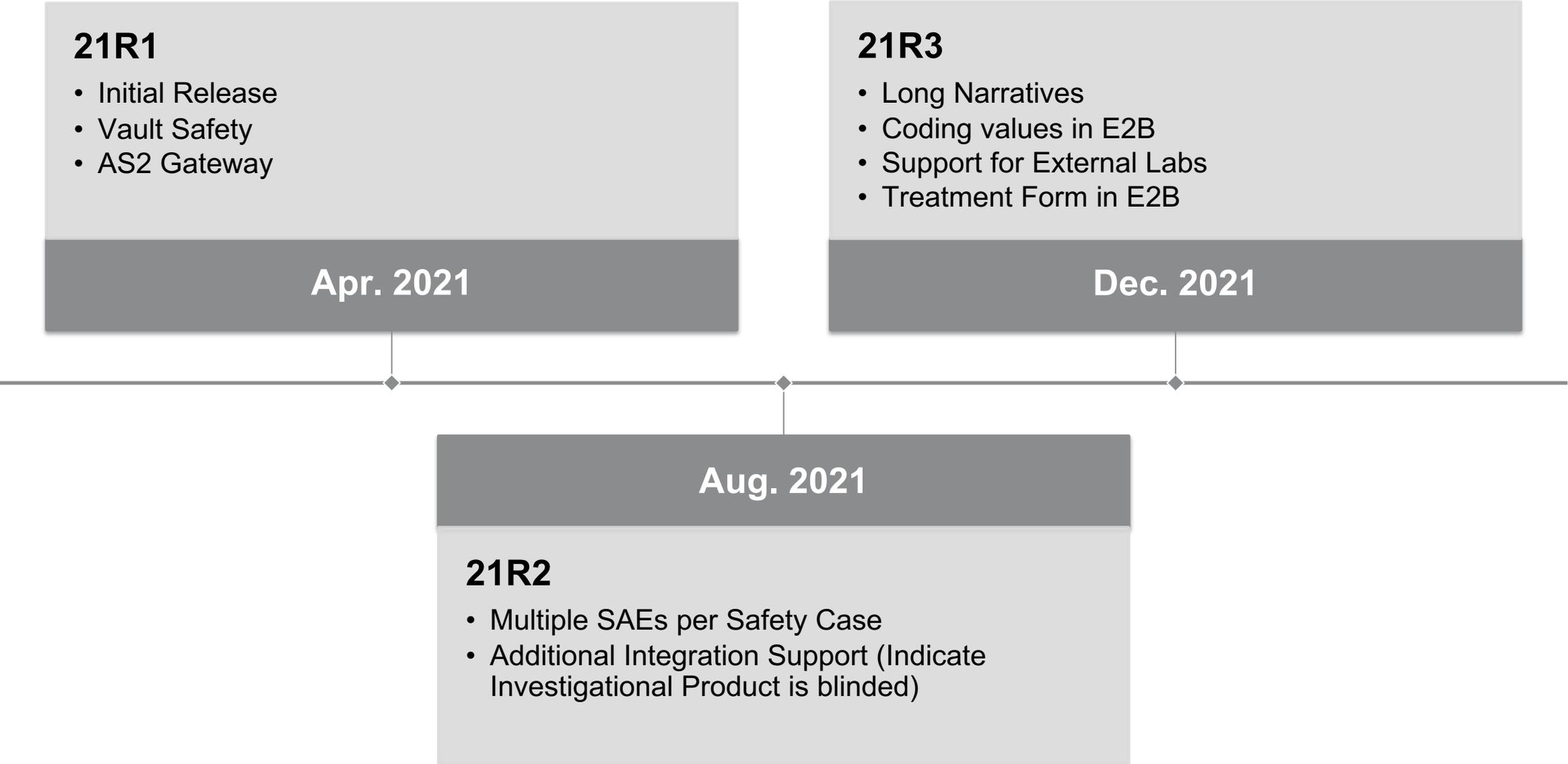
21R3 Updates in Depth

Long Narratives included in XML file Transfer

Up to 100,000 characters for Case Narrative field (repeating item group)

Up to 20,000 characters for Reporter's Comments field on SAE form

Coding Values in E2B XML

Coding values assigned to SAE in Vault Coder automatically included in E2B

Changes to coding values generate follow up message

21R3 Updates in Depth

External Unscheduled Lab Forms

- Safety Admin can map an external unscheduled lab form definition
- If linked to SAE, Safety link will generate follow up message
- E2B will include item values such as lab name, result, unit, lab date, normal range, and more

Treatment Form(s)

- More than one treatment form can be mapped
- First Send or Follow up will include the one Treatment form instance administered most recently prior to Start Date
- Follow up generated if newly submitted Treatment form meets criteria

▼ External Labs

Include External Labs ◉ Yes

External Labs Form*

External Labs Fields

E2B ID ▲	E2B Element	Data Ty
F.r.1	Test Date	Datetim
F.r.2.1	Test Name (free text)	Text (25
F.r.3.1	Test Result (code)	Number
F.r.3.2	Test Result (value / qualifier)	Text (50
F.r.3.3	Test Result (unit)	Text (50
F.r.3.4	Result Unstructured Data (free text)	Text (20

		Text (50
G.k.9.i.2.r.3	Result of Assessmer	
G.k.9.i.3.1a	Time Interval betwee Reaction / Event (nu	
G.k.9.i.3.1b	Time Interval betwee Reaction / Event (un	
G.k.9.i.3.2a	Time Interval betwee (number)	
G.k.9.i.4	Did Reaction Recur	

➕ Add Treatment

Configuration Components of Safety Link

Connection to Safety System

- Connections are Vault Level

- Connection can either be to Vault Safety over Spark or any Safety System with an AS2 Gateway

- Vault CDMS can support multiple connections to different Safety Systems

- Connections are not part of deployment and are not listed in the SDS

CDMS Help Page References
Configuring the Safety Link

Study Specific Mappings

- Each study has its own mapping of E2B elements

- Each study is configured with one (and only one) connection to a Safety System

- Mappings and which connection is setup in EDC Tools

- Mapping details are not part of deployments nor are included in the SDS

- You can import and export a mapping file
  - Used to move from UAT to Prod
  - Can also be used from study to study

Considerations During Study Build

- What form data will be included?
  - How will differences in Standards vs E2B values be handled?
    - CDASH/Sponsor Standard codelists vs expected E2B Values (eg. Numeric vs. Text)
    - EDC Multiple Selections (eg. Action Taken) vs. E2B (single value)
  - Allow Multiple SAEs per Case? (requires repeating item groups)
  - Enable necessary form links for related case information
  - Use repeating item groups for long narratives (Item 1000 characters x 100 max repeat Item Group)

- General Settings
  - Reporter
  - Blinded IP?
  - First Send and Follow up schedule
  - Minimum requirements to send
  - Handling of null values for coding

E2B Mapping
Serious Adverse Events
Adverse Events
Concomitant Medications
Medical History
Patient Characteristics
In Case of Death
External Labs
Treatment

External Connection

External Connections

LMS | **Safety**

Name	Type	Status ▲
Bryce_Pharma_AS2_Gateway	AS2 Gateway	Active
Bryce_Pharma_Safety_Vault	Vault Safety	Active

Vault Safety

- For integrating with a Safety Vault
- Vault Connections establishes connection between Vault CDMS and Vault Safety
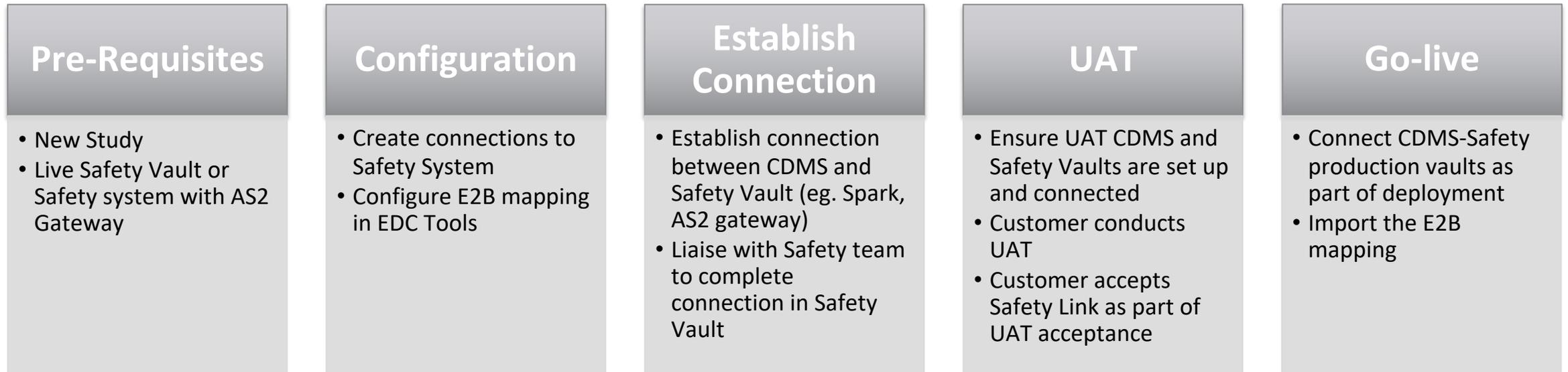- Vault Safety APIs used to post E2B and receive ACKs

AS2 Gateway

- For integrating with a Third Party Safety Systems (Argus, ArisG, etc.)
- Safety Link provides the CDMS AS2 Gateway
- Requires the Safety System to have an AS2 Gateway (purchased separately)

Fully activating the External Connection of any type requires steps from a a member of the CDMS Services Team (costs involved).

Process Flow

Minimum 8 weeks

Pre-Requisites
- New Study
- Live Safety Vault or Safety system with AS2 Gateway

Configuration
- Create connections to Safety System
- Configure E2B mapping in EDC Tools

Establish Connection
- Establish connection between CDMS and Safety Vault (eg. Spark, AS2 gateway)
- Liaise with Safety team to complete connection in Safety Vault

UAT
- Ensure UAT CDMS and Safety Vaults are set up and connected
- Customer conducts UAT
- Customer accepts Safety Link as part of UAT acceptance

Go-live
- Connect CDMS-Safety production vaults as part of deployment
- Import the E2B mapping

Community Resources

Reference Pages

CDMS Help

- What's New in 21R3

  https://cdmshelp.veeva.com/gr/rn/general-releases/21r3/whats-new/

- CDMS Study Designer - Creating Rules (v2)

  https://cdmshelp.veeva.com/gr/study-designers/rules/

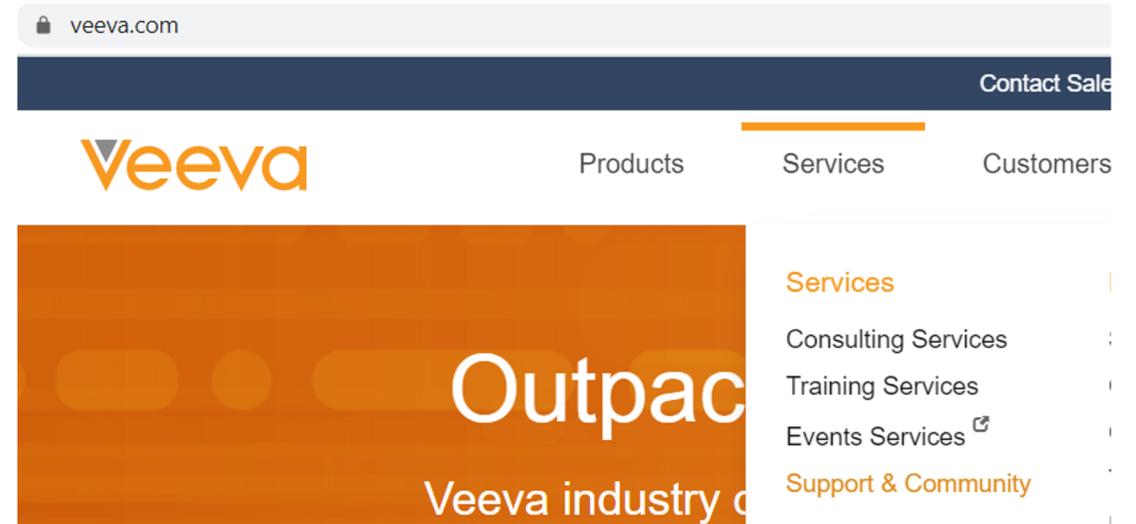**Vault Formula Reference (v2)**

  http://cdmshelp.veeva.com/gr/resources/formula-reference-v2/#casebook-1

Vault Community

- To access Vault Community
  - Navigate for veeva.com
  - Select **Services > Support & Community**
- The Vault Community Portal opens
  - To Register, select **Sign up**

Vault Community

- Enabled users
    - *Role select **System/Business Administrator**
    - *Product select **Veeva Vault**

*First Name

*Last Name

*Job Title

*Phone

*Email

*Company Name

*Region

System/Business Administrator

Veeva Vault

*Manager Email (for approval)

CRM Org ID, Vault ID, or Network Instance

Submit >

Upcoming Dates

Dates for 22R1

➢ March 21 Release Notes
➢ March 24 Customer Preview Webinar
➢ March 28 PreRelease Availability
➢ April 22 General Release

Veeva Trust Site

https://trust.veeva.com/

> ⓘ Veeva 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:
>
> VV1-22 , VV1-1090 , VV2-2092 , VV1-1127 , VV3-3121,VV1-1139,VV1-17,VV1-37
>
> 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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Thank you

Questions?

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