

Strategies to Collaboratively Manage Protocol Deviations in Multi-site Clinical Trials-Overview – **Leveraging the system**

Ashley Case

Manager Data Management, Emmes Company

Using the electronic data capture system (EDC)

- Looking at data that is collected
- Looking at data that is expected but is not collected

Using the electronic data capture system (EDC)

- Looking at data that is collected
 - Consent Error Report
 - Out of Window Assessments
- Looking at data that is expected but is not collected

Using the electronic data capture system (EDC)

- Looking at data that is collected
 - Consent Error Report
 - Out of Window Assessments
- Looking at data that is expected but is not collected
 - Missed Visits and Assessments*

Consent Error Report

- Site staff upload informed consent to the EDC using a secure upload feature
- ICF is remotely reviewed

This form is to be completed by the document upload reviewer.

Throughout the form, "document" refers to the applicable consent/assent document being reviewed.

Date file(s) uploaded:

Did the participant ID in the file name match the participant ID assigned by eClinical? ☐ No ☐ Yes

	Document 1
1 The participant was consented/assented on the current IRB-approved version of the document:	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A
If "No", specify:	<input type="text"/>
If "Yes", IRB document approval date:	<input type="text" value="MM/DD/YYYY"/>
2 Informed consent/assent quiz completed correctly:	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A
If "No", specify:	<input type="text"/>
3 All pages of the document are present:	<input type="checkbox"/> No <input type="checkbox"/> Yes

Consent Error Report Cont.

CTN-
Informed Consent Errors identified in Secure Document Upload (ZC3)
16-Dec-2020

SITE=

Participant ID	Document Type	Sequence Number	Date of CCC Review	Consented/assented on Current IRB approved version	Quiz completed correctly	Each page of the document is initialed by participant/guardian	Participant/LAG signature/date/ time correct	Required staff signature/date correct	Impartial witness signature/date correct	Opt-out/additional clauses correct	Internal Reviewer Comments	External Comments	Is this Consent approved
006	Multiple documents	01	04/09/2018	Yes	No	N/A	Yes	Yes	N/A	Yes	Follow-up in 2 weeks if update not re-submitted	On the ICF, both "yes" and "no" responses to Question 4 are circled and crossed out. It is unclear whether or not the participant understood the correct answer. Next time the participant comes to clinic, please have participant write in the correct answer, initial and date (current date), and write "late entry for 4/6/2018."	No but Approved at Other Date
032	Informed Consent	01	12/17/2018	Yes	No	N/A	Yes	No	N/A	No		Participant did not correctly answer Question 4 on the consent quiz. Please review with the participant and ask the participant to make a GCP correction to this the next time they are in clinic.	No but Approved at Other Date
044	Informed Consent	01	01/20/2019	Yes	No	N/A	Yes	Yes	N/A	Yes		Research staff did not sign/date the Informed Consent Quiz. Please have Sandra Munoz sign/date the ICF quiz with the current date and write "late entry for 1/20/2019."	No but Approved at Other Date
078	Informed Consent	01	01/29/2019	Yes	Yes	N/A	Yes	Yes	N/A	No	Double check GCP followed with correction	Participant incorrectly crossed out initials next to "yes" for Genetic testing. Please ask participant to write in their initials to the left of initial line, write the current date, and write "late entry for 1/29/2019."	No but Approved at Other Date

Assessments Completed Out of Window Report

- Visit windows are defined within our EDC

Month 2
10/01/2019
10/01/2019 - 10/21/2019

- Date of assessment

Date of assessment:



08/13/2019

- Audit history

Field	Old Value	New Value	Reason	User	Date	Time
Chronic health ppt	--	No			08/13/2019	18:30:
Plans to move ppt	--	No			08/13/2019	18:30:

Assessments Completed Out of Window Report Cont.

CTN- [REDACTED]
Listing of Assessments Completed Out of Window

Sunday, January 10, 2021 11:02 PM ET

						Date Range for Completing Assessment					
Participant ID	Enrollment Date	Segment	Visit	Form	Date Form is Triggered	Date Visit Window Opened	Target Date for Completing Assessment	Date Visit Window Closed	Date of Assessment	Number of Days Out of Window	Tier Categorization
[REDACTED] 03	10/15/2020	B	W01	XYZ	10/15/2020	01/07/2021	01/07/2021	01/13/2021	01/06/2021	1	2b - Critical: Primary Outcome
[REDACTED] 03	10/15/2020	B	W01	ABC	10/15/2020	01/07/2021	01/07/2021	01/13/2021	01/06/2021	1	4 - Other

Assessments Completed Out of Window Report Cont.

Admin Fields

CTN- [REDACTED]
Listing of Assessments Completed Out of Window

[REDACTED]
Sunday, January 10, 2021 11:02 PM ET

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Assessments Completed Out of Window Report Cont.

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Date form available

Assessments Completed Out of Window Report Cont.

Admin Fields

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Date form available

Visit expectations

Assessments Completed Out of Window Report Cont.

Admin Fields

Details on actual visit

CTN-[REDACTED]

Listing of Assessments Completed Out of Window

[REDACTED]

Sunday, January 10, 2021 11:02 PM ET

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Date form available

Visit expectations

Assessments Completed Out of Window Report Cont.

Admin Fields

CTN- [REDACTED]

Listing of Assessments Completed Out of Window

[REDACTED]

Sunday, January 10, 2021 11:02 PM ET

Details on actual visit

					Date Range for Completing Assessment					Tier Categorization	
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Date form available

Visit expectations

Categorization

Missed Assessments Report

- Upon registration -> forms become required

Target Date	11/09/2017
Date Range	11/09/2017 - 11/10/2017
Form	
Urine Drug Screen	★
Vital Signs	★
DSM-5 Checklist	★

- Missing and will never be obtained

Missing Form Exception Reason

Select Exception Reason

Participant refused procedure or assessment

Comment

Save

Close

1 Was a urine drug screen performed?

✓

☒

 No ☐ Yes

a If "No", reason:

✓

Participant refused to provide sample

Missed Assessments Report Cont.

CTN- [REDACTED]
Listing of Assessments Required and Not Completed
[REDACTED]
Sunday, January 10, 2021 11:29 PM ET

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Participant ID	Enrollment Date	Segment	Visit	Form	Date Form is Triggered	Date Visit Window Opened	Target Date for Completing Assessment	Date Visit Window Closed	Missing Form Exception Request Status	Exception Request Reason	Tier Categorization
[REDACTED] 021	11/01/2020	A	W01	ABC	11/01/2020	11/01/2020	11/01/2020	11/08/2020	Exception requested		2a - Critical: Eligibility
[REDACTED] 032	12/15/2020	A	W03	XYZ	12/15/2020	12/15/2020	12/15/2020	12/22/2020			2b - Critical: Primary Outcome
[REDACTED] 038	01/07/2021	A	W01	AA1	01/07/2021	01/07/2021	01/07/2021	01/14/2021	Granted exception	Participant refused to provide sample or assessment	4 - Other

Missed Assessments Report Cont.

CTN- [REDACTED]
Listing of Assessments Required and Not Completed

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[REDACTED] 038	01/07/2021	A	W01	AA1	01/07/2021	01/07/2021	01/07/2021	01/14/2021	Granted exception	Participant refused to provide sample or assessment	4 - Other

Missed Assessments Report Cont.

CTN- [REDACTED]
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Thank you!