



# INSTRUCTIONS FOR MISSED DATA COLLECTION FORM (MDC2)

## I. General Instructions

The Missed Data Collection (MDC2) form will be used to document any missed intervention or follow-up study visits or any missed data collection forms that should have been completed during a partial visit, and the reason(s) that the visit or forms were missed. This form should be completed when it is clear that the missed visit or missed forms will not be collected. For example, do not mark the visit as missed if a participant cancels. Instead, wait until you've exhausted all efforts to reschedule the participant's visit. In the event that a visit or form previously marked as missed is later collected, update this form to remove the information.

**No visits are expected after a participant dies or withdraws from ACHIEVE. If a participant dies or withdraws, you do not need to enter data into the MDC2 for the future contacts.**

**All missed forms that will never be collected from any visit should be marked Permanently Missing on the form grid in CDART.** The MDC2 form is used by the site to document the reason for form missingness. The site is not required to document each missed form, but only those where special circumstances exist, where an explanation for missingness may inform future data collection, or for those forms of particular interest to the QC committee (see list below). For detailed instructions on how to complete the MDC2 for a phone contact, see below.

- a) Neurocognitive: CDP, CDI (for those selected to stage 2), CDS, ESU, MME6, NCS, NHX, NPI (for those selected to stage 2), WRAT
- b) Audiology: AAF (after baseline)
- c) Alerts: CES, SBP

## II. Detailed instructions for each item

0a. Enter the date the form was completed. This form is updatable throughout the study. Update the date field each time the form is updated.

0b. Enter staff ID of the person completing the form. This form is updatable throughout the study. Update the staff ID field each time the form is updated.

### Baseline Visit

1a-1x. Check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing.

### Intervention Visit A

2. Indicate the status of intervention visit A. Select "Missed" for a visit that was missed (i.e., the participant did not come in for the visit and no data collection was completed). Select "Partial" for a partial visit (i.e., the participant came in for the visit, but for some reason, some number of forms that would have been expected were not completed).

3. If item 2=Missed, select the reason the participant missed intervention visit A.

3a. If selecting "Other" for item 3, specify the reason here.

4a-4h. If item 2=Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing. Mark ICF when missed form is either ICF or SICF.

### **Intervention Visit B**

5. Indicate the status of intervention visit B. Select "Missed" for a visit that was missed (i.e., the participant did not come in for the visit and no data collection was completed). Select "Partial" for a partial visit (i.e., the participant came in for the visit, but for some reason, some number of forms that would have been expected were not completed).

6. If item 5=Missed, select the reason the participant missed intervention visit B.

6a. If selecting "Other" for item 6, specify the reason here.

7a-7h. If item 5= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing. Mark ICF when missed form is either ICF or SICF.

### **Intervention Visit C**

8. Indicate the status of intervention visit C. Select "Missed" for a visit that was missed (i.e., the participant did not come in for the visit and no data collection was completed). Select "Partial" for a partial visit (i.e., the participant came in for the visit, but for some reason, some number of forms that would have been expected were not completed).

9. If item 8=Missed, select the reason the participant missed intervention visit C.

9a. If selecting "Other" for item 9, specify the reason here.

10a-10h. If item 8= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing. Mark ICF when missed form is either ICF or SICF.

## **Intervention Visit D**

11. Indicate the status of intervention visit D. Select "Missed" for a visit that was missed (i.e., the participant did not come in for the visit and no data collection was completed). Select "Partial" for a partial visit (i.e., the participant came in for the visit, but for some reason, some number of forms that would have been expected were not completed).

12. If item 11=Missed, select the reason the participant missed intervention visit D.

12a. If selecting "Other" for item 12, specify the reason here.

13a-13h. If item 11= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing. Mark ICF when missed form is either ICF or SICF.

## **Follow-up Visit 6 Month**

14. Indicate the status of the 6 month follow-up visit. Select "Missed" for a visit that was missed (i.e., the participant did not come in for the visit and no data collection was completed). Select "Partial" for a partial visit (i.e., the participant came in for the visit, but for some reason, some number of forms that would have been expected were not completed).

15. If item 14=Missed, select the reason the participant missed the 6 month follow-up visit.

15a. If selecting "Other" for item 15, specify the reason here.

16a-16m. If item 14= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing.

## **Follow-up Visit Year 1**

17. Indicate the status of the Year 1 follow-up visit. Select "Missed" for a visit that was missed (i.e., the participant did not come in for the visit and no data collection was completed). Select "Partial" for a partial visit (i.e., the participant came in for the visit, but for some reason, some number of forms that would have been expected were not completed).

18. If item 17=Missed, select the reason the participant missed the Year 1 follow-up visit.

18a. If selecting "Other" for item 18, specify the reason here.

19a-19w. If item 17= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing.

## **Follow-up Visit 18 Month**

20. Indicate the status of the 18 month follow-up visit. Select "Missed" for a visit that was missed (i.e., the participant did not come in for the visit and no data collection was completed).

Select "Partial" for a partial visit (i.e., the participant came in for the visit, but for some reason, some number of forms that would have been expected were not completed).

21. If item 20=Missed, select the reason the participant missed the 18 month follow-up visit.

21a. If selecting "Other" for item 21, specify the reason here.

22a-22f. If item 20= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing.

### **Follow-up Visit Year 2**

23. Indicate the status of the Year 2 follow-up visit. Select "Missed" for a visit that was missed (i.e., the participant did not come in for the visit and no data collection was completed). Select "Partial" for a partial visit (i.e., the participant came in for the visit, but for some reason, some number of forms that would have been expected were not completed).

24. If item 17=Missed, select the reason the participant missed the Year 2 follow-up visit.

24a. If selecting "Other" for item 18, specify the reason here.

25a-25w. If item 17= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing.

### **Follow-up Visit 30 Month**

26. Indicate the status of the 30 month follow-up visit. Select "Missed" for a visit that was missed (i.e., the participant did not come in for the visit and no data collection was completed). Select "Partial" for a partial visit (i.e., the participant came in for the visit, but for some reason, some number of forms that would have been expected were not completed).

27. If item 26=Missed, select the reason the participant missed the 30 month follow-up visit.

27a. If selecting "Other" for item 27, specify the reason here.

28a-28f. If item 26= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing.

### **Follow-up Visit Year 3 - Telephone**

29. Indicate the status of the Year 3 follow-up telephone visit. Select "Missed" for a visit that was missed (i.e., the participant was not called and the visit and no data collection was completed). Select "Partial" for a partial visit (i.e., the participant completed some of the visit, but for some reason, some number of forms that would have been expected were not completed).

30. If item 29=Missed, select the reason the participant missed the Year 3 follow-up telephone visit.

30a. If selecting "Other" for item 30, specify the reason here.

31a-31w. If item 29= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing.

### **Follow-up Visit Year 3 – In-Clinic**

32. Indicate the status of the Year 3 follow-up in-clinic visit. Select "Missed" for a visit that was missed (i.e., the participant did not come in for the visit and no data collection was completed). Select "Partial" for a partial visit (i.e., the participant came in for the visit, but for some reason, some number of forms that would have been expected were not completed).

33. If item 32=Missed, select the reason the participant missed the Year 3 follow-up in-clinic visit.

33a. If selecting "Other" for item 33, specify the reason here.

34a-34w. If item 32=Partial, check off the forms that the site wished to document the reason for missingness, then enter the reason for missing.

## HOW TO ENTER FOR PHONE CONTACT due to COVID19

**Instructions:** If visit conducted over the phone set the completion status item to “Partial” and enter reason for forms not collected. For any form, expected at the phone visit, not collected enter the reason why, for all forms not expected at the phone visit enter “phone visit” as the reason form not collected. See below the list of expected and unexpected form by contact. If unable to reach the participant by phone set the completion status to “Missed” and enter reason for missed visit to “Other” and specify other reason as “COVID-19”

16. Check the form that was not collected and then record the reason. Mark checked forms Permanently Missing in the CDART form grid.

Missed Form	Reason Form is Missing
16a. CES	Expected for Phone Visit
16b. ESU	Expected for Phone Visit
16c. HHI	Expected for Phone Visit
16d. HOS	Expected for Phone Visit
16e. ICF	Expected for Phone Visit
16f. ICHI	Expected for Phone Visit
16g. IFF	Not Expected enter “phone visit”
16h. MME6	Not Expected enter “phone visit”
16i. SAI	Expected for Phone Visit
16j. SFH	Expected for Phone Visit
16k. SFHC	Not Expected enter “phone visit”
16l. SNI	Expected for Phone Visit
16m. ULS	Expected for Phone Visit

### Follow-up Visit Year 1

19. Check the form that was not collected and then record the reason. Mark checked forms Permanently Missing in the CDART form grid.

Missed Form	Reason Form is Missing
19a. AAF	Not Expected enter “phone visit”
19b. ACC	Not Expected enter “phone visit”
19c. ANT	Not Expected enter “phone visit”
19d. CDI	Not Expected enter “phone visit”
19e. CDP	Not Expected enter “phone visit”
19f. CDS	Not Expected enter “phone visit”
19g. CES	Expected for Phone Visit
19h. ESU	Expected for Phone Visit
19i. FAM	Expected for Phone Visit
19j. HHF	Expected for Phone Visit
19k. HHI	Expected for Phone Visit
19l. HOS	Expected for Phone Visit
19m. ICF	Expected for Phone Visit

19n. MME6	Not Expected enter "phone visit"
19o. NCS	Not Expected enter "phone visit"
19p. NHX	Not Expected enter "phone visit"
19q. NPI	Not Expected enter "phone visit"
19r. PAC	Expected for Phone Visit
19s. PFX	Not Expected enter "phone visit"
19t. SAI	Expected for Phone Visit
19u. SBP	Not Expected enter "phone visit"
19v. SFH	Expected for Phone Visit
19w. ULS	Expected for Phone Visit

### Follow-up Visit 18 Month

22. Check the form that was not collected and then record the reason. Mark checked forms Permanently Missing in the CDART form grid.

Missed Form	Reason Form is Missing
22a. ESU	Expected for Phone Visit
22b. HOS	Expected for Phone Visit
22c. ICF	Expected for Phone Visit
22d. ICHI	Expected for Phone Visit
22e. MME6	Not Expected enter "phone visit"
22f. SAI	Expected for Phone Visit

### Follow-up Visit Year 2

25. Check the form that was not collected and then record the reason. Mark checked forms Permanently Missing in the CDART form grid.

Missed Form	Reason Form is Missing
25a. AAF	Not Expected enter "phone visit"
25b. ACC	Not Expected enter "phone visit"
25c. ANT	Not Expected enter "phone visit"
25d. CDI	Not Expected enter "phone visit"
25e. CDP	Not Expected enter "phone visit"
25f. CDS	Not Expected enter "phone visit"
25g. CES	Expected for Phone Visit
25h. ESU	Expected for Phone Visit
25i. FAM	Expected for Phone Visit
25j. HHF	Expected for Phone Visit
25k. HHI	Expected for Phone Visit
25l. HOS	Expected for Phone Visit
25m. ICF	Expected for Phone Visit
25n. MME6	Not Expected enter "phone visit"
25o. NCS	Not Expected enter "phone visit"
25p. NHX	Not Expected enter "phone visit"
25q. NPI	Not Expected enter "phone visit"
25r. PAC	Expected for Phone Visit
25s. PFX	Not Expected enter "phone visit"

25t. SAI	Expected for Phone Visit
25u. SBP	Expected for Phone Visit
25v. SFH	Not Expected enter "phone visit"
25w. ULS	Expected for Phone Visit

### Follow-up Visit 30 Month

28. Check the form that was not collected and then record the reason. Mark checked forms Permanently Missing in the CDART form grid.

Missed Form	Reason Form is Missing
28a. ESU	Expected for Phone Visit
28b. HOS	Expected for Phone Visit
28c. ICF	Expected for Phone Visit
28d. ICHI	Expected for Phone Visit
28e.MME6	Not Expected enter "phone visit"
28f. SAI	Expected for Phone Visit

### Follow-up Visit Year 3

31. Check the form that was not collected and then record the reason. Mark checked forms Permanently Missing in the CDART form grid.

Missed Form	Reason Form is Missing
31a. AAF	Not Expected enter "phone visit"
31b. ACC	Not Expected enter "phone visit"
31c. ANT	Not Expected enter "phone visit"
31d. CDI	Not Expected enter "phone visit"
31e. CDP	Not Expected enter "phone visit"
31f. CDS	Not Expected enter "phone visit"
31g. CES	Expected for Phone Visit
31h. ESU	Expected for Phone Visit
31i. FAM	Expected for Phone Visit
31j. HHF	Expected for Phone Visit
31k. HHI	Expected for Phone Visit
31l. HOS	Expected for Phone Visit
31m. ICF	Expected for Phone Visit
31n. MME6	Not Expected enter "phone visit"
31o. NCS	Not Expected enter "phone visit"
31p. NHX	Not Expected enter "phone visit"
31q. NPI	Not Expected enter "phone visit"
31r. PAC	Expected for Phone Visit
31s. PFX	Not Expected enter "phone visit"
31t. SAI	Expected for Phone Visit
31u. SBP	Expected for Phone Visit
31v. SFH	Not Expected enter "phone visit"
31w. ULS	Expected for Phone Visit