



INSTRUCTIONS FOR MISSED DATA COLLECTION FORM (MDCX)

I. General Instructions

The Missed Data Collection (MDCX) form will be used to document any missed 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, *even if the visit or forms are missed due to a recommendation to skip a visit based on target windows or competing demands requiring prioritizing other ACHIEVE participants.*

For the Ancillary studies we will only enter data for visits that occur after the intervention visit. This form should be completed when it is clear that the missed visit or missed forms will not be collected.

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 MDCX 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 MDCX 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).

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.

Follow-up Visit 6 Month

1. 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, or the visit was missed due to scheduling demands, including target window recommendations or competing site resource demands for prioritizing other ACHIEVE participant visits). 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).

2. If item 1=Missed, select the reason the participant missed the 6-month follow-up visit. If the visit was missed due to scheduling demands, please choose E for "Other" reason.

2a. If selecting "Other" for item 2, specify the reason here. If the visit was missed due to scheduling demands, specify "Scheduling demands."

3a-3o. If item 1= 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

4. 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, or the visit was missed due to scheduling demands, including target window recommendations or competing site resource demands for prioritizing other ACHIEVE participant visits). 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).

5. If item 4=Missed, select the reason the participant missed the Year 1 follow-up visit. If the visit was missed due to scheduling demands, please choose E for "Other" reason.

5a. If selecting "Other" for item 5, specify the reason here. If the visit was missed due to scheduling demands, specify "Scheduling demands."

6a-6x. If item 4= 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

7. 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, or the visit was missed due to scheduling demands, including target window recommendations or competing site resource demands for prioritizing other ACHIEVE participant visits). 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).

8. If item 7=Missed, select the reason the participant missed the 18-month follow-up visit. If the visit was missed due to scheduling demands, please choose E for "Other" reason.

8a. If selecting "Other" for item 8, specify the reason here. If the visit was missed due to scheduling demands, specify "Scheduling demands."

9a-9h. If item 7= 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

10. 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).

11. If item 10=Missed, select the reason the participant missed the Year 2 follow-up visit.

11a. If selecting "Other" for item 11, specify the reason here.

12a-12x. If item 10= 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

13. 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, or the visit was missed due to scheduling demands, including target window recommendations or competing site resource demands for prioritizing other ACHIEVE participant visits). 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).

14. If item 13=Missed, select the reason the participant missed the 30-month follow-up visit. If the visit was missed due to scheduling demands, please choose E for "Other" reason.

14a. If selecting "Other" for item 14 specify the reason here. If the visit was missed due to scheduling demands, specify "Scheduling demands."

15a-15h. If item 13= 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

16. Indicate the status of the Year 3 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).

17. If item 16=Missed, select the reason the participant missed the Year 3 follow-up visit.

17a. If selecting "Other" for item 17, specify the reason here.

18a-18x. If item 16= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing.

Follow-up Visit 42 Month

19. Indicate the status of the 42-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, or the visit was missed due to scheduling demands, including target window recommendations or competing site resource demands for prioritizing other ACHIEVE participant visits). 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).

20. If item 19=Missed, select the reason the participant missed the 42-month follow-up visit. If the visit was missed due to scheduling demands, please choose E for "Other" reason.

20a. If selecting "Other" for item 20, specify the reason here. If the visit was missed due to scheduling demands, specify "Scheduling demands."

21a – 21h. If item 19= 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 4

22. Indicate the status of the Year 4 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).

23. If item 22=Missed, select the reason the participant missed the Year 4 follow-up visit.

23a. If selecting "Other" for item 23, specify the reason here.

24a – 24x1. If item 22= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing.

Follow-up Visit 54 Month

25. Indicate the status of the 54-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, or the visit was missed due to scheduling demands, including target window recommendations, or competing site resource demands for prioritizing other ACHIEVE participant visits). 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).

26. If item 25=Missed, select the reason the participant missed the 54-month follow-up visit. If the visit was missed due to scheduling demands, please choose E for "Other" reason.

26a. If selecting "Other" for item 26, specify the reason here.

27a – 27h1. If item 25= Partial, check off the forms that the site wishes to document the reason for missingness, then enter the reason for missing.