<table>
<thead>
<tr>
<th>Order of Elements</th>
<th>Data Element</th>
<th>Definition</th>
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<tbody>
<tr>
<td></td>
<td><strong>IDENTIFIERS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Study Name/Identifier</td>
<td>Name or identifier of the study for which data is provided.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>CROMS Assigned Site Identifier</td>
<td>The CROMS assigned identifier of the site where the participant is enrolled.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Participant ID</td>
<td>A unique identifier assigned to each participant in a study.</td>
<td></td>
</tr>
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</table>
| 4                | Participant Type                                 | Indicates the role of the person involved in the study. For example, primary participant, co-participant/study partner (e.g., caregiver, informant), care provider. | - Primary Participant  
- Study Partner/Co-Participant  
- Care Provider  
- Other |
| 5                | ID of the Primary Participant associated to the Co-Participant | APPLICABLE ONLY FOR CO-PARTICIPANT RECORDS IN SPECIAL STUDIES (e.g., DYAD studies)  
The identifier of the primary participant (e.g., PWD) to which a study participant/co-participant (e.g., caregiver) is associated. |                                                                              |
|                  | **PARTICIPANT STATUS**                            |                                                                             |                                                                              |
| 6                | Study Enrollment Date                             | Date on which the participant enrolled in the study.                       |                                                                              |
| 7                | Participant Intervention Start Date               | The date when the participant started on intervention for the first time.   |                                                                              |
| 8                | Participant Permanently Off Intervention Date     | The date when the participant permanently stopped all study interventions.  |                                                                              |
| 9                | Participant Permanently Off Intervention Reason   | The reason for the participant being permanently off all study interventions. | - Adverse events  
- Completed treatment as defined by the protocol  
- Death  
- Does not want to take number and/or volume of medication and/or mode of administration has problems with the timing of the intervention or does not like the intervention (e.g., taste of medication)  
- Lack of efficacy  
- Lost to follow up  
- No longer believes treatment is helping  
- Participant declined continuation in the study  
- Physician decision  
- Physician/clinician/investigator request, not in best interest of the participant to continue  
- Pregnancy  
- Protocol violation  
- Specify other reason(s) why participant is off study intervention  
- Study partner/guardian/caregiver declined continuation in the study  
- Unexpected closure of entire study or any of its components; completed study requirements up to the time of unexpected closure  
- Willing but unable to tolerate intervention when administered |
<p>| 10               | Participant Permanently Off Study Date            | Indicates the date the participant permanently went off study and is no longer participating in the study. |                                                                              |</p>
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| 11                | Participant Permanently Off Study Reason | The reason why the participant went off study permanently. | - Adverse Events  
- Completed the study as defined by the study protocol  
- Death  
- Eligibility  
- Inadvertent enrollment  
- Investigator decision  
- Lost to follow up  
- No longer believes treatment is helping  
- Participant withdraws consent and all further study contact prior to completion of the protocol-defined study evaluations  
- Participant/guardian/caregiver is not willing to maintain adherence with the study requirements  
- Participant/guardian/caregiver not able to get to clinic  
- Physician/clinician/investigator request, not in best interest of the participant to continue  
- Protocol violation  
- Severe debilitation or has confounding medical conditions, participant is unable to continue on study  
- Site is closing  
- Specify other reason(s) why participant is off study  
- Study partner/guardian/caregiver withdraws consent and all further study contact prior to completion of the protocol-defined study evaluations  
- Unexpected closure of entire study or any of its components; completed study requirements up to the time of unexpected closure |
| 12                | Participant Permanently Off Study Reason- Other Text | An additional description when "Other" was selected for "Participant Permanently Off Study Reason". |
| 13                | Study Design (Group/Cohort Identifier) | THIS FIELD IS OPTIONAL  
A label or descriptive text used to identify a cohort or group to which a participant is assigned.  
This is not the blinded arm to which the participant is assigned and should not be used if providing this information could unblind the study. |

**DEMOGRAPHICS**

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<tr>
<td>14</td>
<td>Age at time of Enrollment</td>
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</table>
| 15                | Sex At Birth | A person’s classification as male or female based on biological distinctions. | - Female  
- Male  
- Intersex  
- None of these describe me  
- Prefer Not to answer  
- Not Reported  
- Unknown |
| 16                | Gender Choice 1 | One’s concept of self as male, female, both, or neither. It describes how individuals perceive themselves and what they call themselves. One’s gender identity can be the same or different from the sex assigned at birth. | - Man  
- Woman  
- Non-binary  
- Transgender  
- None of these describe me  
- Prefer Not to answer  
- Not Reported  
- Unknown |
| 17                | Gender Choice 2 | USE ONLY IF A SECOND GENDER IS COLLECTED FOR A PARTICIPANT  
One’s concept of self as male, female, both, or neither. It describes how individuals perceive themselves and what they call themselves. One’s gender identity can be the same or different from the sex assigned at birth. | - Man  
- Woman  
- Non-binary  
- Transgender  
- None of these describe me  
- Prefer Not to answer  
- Not Reported  
- Unknown |
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| 18               | Sexual Orientation | An emotional, romantic, or sexual attraction to other people. To obtain a self-report of a person’s romantic attraction to other people, be it gay, lesbian, straight, bisexual, or something else. | - Gay  
- Lesbian  
- Straight; that is, not gay or lesbian, etc.  
- Bisexual  
- None of these describe me  
- Prefer Not to answer  
- Not Reported  
- Unknown |
| 19               | Race             | Participant self-identification of race(s) as defined by OMB.               | - White  
- Black or African American  
- American Indian or Alaska Native  
- Asian  
- Native Hawaiian or Other Pacific Islander  
- More than one race  
- Other  
- Not Reported  
- Unknown |
| 20               | Ethnicity        | Participant self-identification of ethnicity as defined by OMB.            | - Hispanic or Latino  
- Not Hispanic or Latino  
- Unknown  
- Not Reported |

**CHARACTERISTICS**

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| 21               | Cognitive Status | Indicates the participant's cognitive status at the start of the study.     | - Normal Cognition  
- Normal Cognition at Risk  
- Normal Cognition with subjective cognitive decline  
- MCI  
- AD/ADRD  
- Undetermined  
- Unknown  
- Not Reported |
| 22               | Education Level  | Highest level of education attained.                                       | - No formal education  
- Primary level education  
- Secondary level education / GED / Equivalent  
- Some College  
- Associate's Degree  
- Trade / Vocational Training  
- Bachelor's Degree or Higher  
- Refused  
- Unknown  
- Not Reported |
| 23               | Household Income Level | Household income level.                                                     |                                                                  |
| 24               | Occupation Category | Highest occupational attainment.                                             |                                                                  |
| 25               | Current Marital Status | Indicates the participant’s marital status at the start of the study.     | - Married  
- Divorced  
- Widowed  
- Separated  
- Never Married  
- A member of an unmarried couple  
- Prefer Not to answer  
- Not Reported  
- Unknown |
| 26               | Living Situation  | Indicates the care setting / living situation of the participant.          |                                                                  |
| 27               | Primary Language Spoken | The primary language spoken by the participant.                         |                                                                  |
| 28               | Insurance status  | Indicates if the participant has insurance.                                 | - Yes  
- No  
- Unknown  
- Not Reported |
| 29               | Zip Code          | Participant’s zip code.                                                    |                                                                  |