



File Format Specification and Data Description

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1. BACKGROUND

This document describes all variables in the Cogstate dataset. This document can be used by customers programming databases to receive Cogstate data and by statisticians to understand and analyse Cogstate data.

Cogstate cognitive testing batteries are customized for each specific clinical study. Therefore, the data extract you receive will only contain data from the tests in your study battery.

Each row of a Cogstate Standard Data Extract represents one test that has at least been partially completed by the subject, and each column represents a variable code that may reflect study summary information, subject demographic information, session summary information, or Cogstate battery results.

Note that not all Cogstate tests produce the same outcome variables; therefore some columns for some tests will remain blank, indicating that the variable is not present for that test.

The following sections contain information on Cogstate tests relevant to your study, followed by a detailed description of outcome variables generated from each test and how these should be interpreted.

2. COGSTATE TESTS

Each row in the data extract represents one test in the Cogstate battery for a single subject at a single session. Tests are identified in the data extract by a test code (column name: TaskCode).

Table 1 summarises each of Cogstate tests. For a detailed description of the tests, please refer to the Cogstate Task Description document.

Table 1: Test Description

| Test Name | Test Code | Cognitive Function Tested | Description |
|-------------------|--------------------------|---------------------------|---|
| Detection | DetectionAdultReal | Psychomotor function | Has the card turned over? |
| Identification | IdentificationAdultReal | Attention | Is the card red? |
| One Card Learning | OnecardlearningAdultReal | Learning | Have you seen this card before? |
| One Back | OnebackAdultReal | Working memory – Simple | Is this card the same as the previous card? |

2.1 Primary Outcome Variables for each Test

Although each of these cognitive tests yields multiple outcome measures, Cogstate's own research has identified a set of measures that are optimal for the detection of cognitive change in clinical trials at both the group and individual level [1-3].

For each cognitive test, a single primary outcome measure was selected to minimize experiment-wise error rates. Each primary outcome measure was selected because it has been shown to be optimal for the detection of change because:

- a. it is drawn from a data distribution that contains only a small probability of floor or ceiling effects and no restriction in the range of possible performance values.
- b. it is drawn from a distribution that is distributed normally or which can be corrected to normal through the use of appropriate mathematical transformation (e.g., logarithmic base 10 or arcsine transformation).

Table 2 summarizes the primary outcome measures for all Cogstate tests. It is these variables that are recommended for use in statistical analyses.

Table 2: Primary Outcome Measures per Test.

| Test | Primary Outcome Variable Code | Unit of Measurement | Description and Interpretation of Scores |
|-------------------|-------------------------------|--|---|
| Detection | ReactionTime | Log10 milliseconds | Speed of performance; mean of the log10 transformed reaction times for correct responses. Lower score = better performance |
| Identification | ReactionTime | Log10 milliseconds | Speed of performance; mean of the log10 transformed reaction times for correct responses. Lower score = better performance |
| One Card Learning | Accuracy | Arcsine square root proportion correct | Accuracy of performance; arcsine transformation of the square root of the proportion of correct responses. Higher score = better performance |
| One Back | ReactionTime | Log10 milliseconds | Speed of performance; mean of the log10 transformed reaction times for correct responses. Lower score = better performance |

3. FULL DESCRIPTION OF DATA FILE

A full description of each column heading in the Standard Data Extract is presented in Table 3.

Please note, that demographic data are common to all rows (i.e., reported for all tests at all time points).

Table 3: Description of Variables Populated in the Standard Data Extract

| Serial No. | Variable Code | Unit of Measurement | Description | Range and Details of Possible Values |
|------------|---------------------|---|--|--------------------------------------|
| 1 | ProtocolID | Text/numbers | Protocol identification number. | N/A |
| 2 | SubjectID | Text/numbers | Subject identification number. | N/A |
| 3 | TestDate | N/A | Date at the start of the test session. | N/A |
| 4 | TestTime | N/A | Time at the start of the test session. | N/A |
| 5 | Session | Text/numbers (<i>max characters 21</i>) | Label for the session/visit. | N/A |
| 6 | SessionAttempt | Number | The number of attempts of the current session to-date (<i>including the current assessment</i>). | 0 to 999 |
| 7 | SessionDuration | Seconds (<i>number up to 7 digits</i>) | The total duration of the current session. | 0 to 9999999 |
| 8 | SessionCompletion | Number | Session completion criteria (<i>0 = all tests in session met completion criteria; 1 = at least one test in the session did not meet completion criteria</i>). | 0/1 |
| 9 | TaskCode | Text and numbers | Full code for the individual test. | N/A |
| 10 | TaskAttempt | Number | The number of attempts of the test in the current session. | 1 to 9 |
| 11 | TaskCompletionScore | Number | The completion score for the test. | 0 to 999 |
| 12 | TaskIntegrityScore | Number | The performance score for the test. | 0 to 100 |
| 13 | PrimaryOutcome | Number | The score on the primary outcome measure for this test (<i>e.g., ReactionTime for Detection, Identification and One Back; Accuracy for One Card Learning</i>). | 0 to 999 |
| 14 | ReactionTime | Number (<i>log10 milliseconds</i>) | Reaction time; mean of the log10 transformed reaction times for correct responses. | 2.001 to 6 |
| 15 | RTVariability | Number (<i>log10 milliseconds</i>) | Consistency of performance; standard deviation of the log10 transformed reaction | 0 to 2.2 |

| Serial No. | Variable Code | Unit of Measurement | Description | Range and Details of Possible Values |
|------------|----------------|--|--|--------------------------------------|
| 16 | Accuracy | Number (<i>arcsine square root proportion correct</i>) | Accuracy of performance. | 0 to 1.57080 |
| 17 | TotalCorrect | Count (<i>number up to 3 digits</i>) | Number of correct responses. | 0 to 999 |
| 18 | TotalErrors | Count (<i>number up to 3 digits</i>) | Number of errors. | 0 to 999 |
| 19 | TotalResponses | Count (<i>number up to 3 digits</i>) | Number of responses (<i>TotalCorrect + TotalErrors</i>). | 0 to 999 |
| 20 | TotalTrials | Count | Number of trials. | 0 to 999 |

4. ADDITIONAL TEST INFORMATION IMPORTANT FOR STATISTICAL ANALYSES

When Cogstate is not responsible for analyzing Cogstate data, additional information can be provided to the study team or statistician with relation to missing data, test completion and performance checks. These are detailed below.

4.1 Missing Data

There are two instances when test information will not be provided in the data extract: a) when the subject misses a study visit, and b) when the subject does not perform one or more of the tests at a particular session.

4.2 Test Completion

Test completion refers to whether a test that has been started can be considered complete.

At the request of the study team or statistician, the data extract can include an additional column that indicates the completion score for each test. This information is crucial in the analysis of data when scores are based on only a small number of trials, as these scores are not as reliable as those based on a large number of trials and are less likely to reflect accurately the subject's performance level.

The definition of completion for each test is as follows:

- Card based tests: These tests are complete if at least 75% of trials were completed (see Table 4).

Table 4: Number of Trials per Test

| Test | Number of Trials | Minimum Number of Responses Required to Meet 75% Completion Criteria |
|-------------------|------------------|--|
| Detection | 35 | 27 |
| Identification | 30 | 23 |
| One Card Learning | 80 | 60 |
| One Back | 31 | 24 |

5. REFERENCES

1. Falletti MG, Maruff P, Collie A, & Darby DG. (2006). Practice effects associated with the repeated session of cognitive function using the Cogstate battery at 10-minute, one week and one-month test retest intervals. **Journal of Clinical and Experimental Neuropsychology**, **28**, 1095-1012.
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3. Maruff P, Thomas E, Cysique L, Brew B, Collie A, Snyder P, Pietrzak RH (2009). Validity of the Cogstate brief battery: Relationship to standardized tests and sensitivity to cognitive impairment in mild traumatic brain injury, schizophrenia, and AIDS dementia complex. **Archives of Clinical Neuropsychology**, **24**, 165-178.