
Submitting Clinical Trial Data to Evaluate the Ability to Operate a Motor Vehicle

Guidance for Industry Technical Specifications Document

For questions regarding this technical specifications document, contact
CDER at cdер-edata@fda.hhs.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

**October 2026
Technical Specifications Document**

Revision History

Date	Version	Summary of Revisions
October 2026	1.0	Initial Version

TABLE OF CONTENTS

1.0	Introduction.....	1
1.1	Purpose.....	1
1.2	Background	1
1.3	Scope.....	2
1.4	Relationship to Other Documents	3
2.0	Relevant Acronyms	4
3.0	Overview of Dataset Specifications	5
3.1	Driving Assessment Datasets	5
3.1.1	SDTM Functional Tests Dataset.....	6
3.1.1.1	General Considerations	6
3.1.1.2	Additional Considerations.....	7
3.1.1.3	Handling of Missing and Partial Driving Assessment Data in SDTM.....	7
3.1.2	ADaM Functional Tests Analysis Dataset (ADFT).....	9
3.1.2.1	General Considerations	9
3.1.2.2	Joining Driving Assessment Data to Other Data	14
3.1.2.2.1	Linking Data in SDTM via RELREC	15
3.1.2.2.2	Joining Data in ADaM.....	15
3.1.2.3	Handling of Missing and Partial Driving Assessment Data in ADaM.....	15
3.1.2.3.1	Approaches to Represent Missing Data	16
3.1.2.3.2	Approaches to Represent Partial Data	16
3.1.2.4	Handling of ‘Out of Window’ Driving Assessment Data in ADaM	17
3.2	Datasets for Measurement Tool-Level Review.....	17
3.2.1	Measurement Tool Identifiers	18
3.2.2	Measurement Tool -Subject Relationships.....	18
3.2.3	Properties and Settings Pertaining to Measurement Tools.....	18
3.2.4	Events Pertaining to Measurement Tools.....	18
3.3	Comments Dataset	19
3.4	Trial Summary Dataset	19
3.5	Questionnaires Datasets	20
3.5.1	SDTM Specifications for Questionnaires Data	20
3.5.1.1	Handling of Missing Questionnaires Data in SDTM.....	21
3.5.2	ADaM Specifications for Questionnaires Data	21
3.5.2.1	Handling of Missing Questionnaires Data in ADaM.....	21
4.0	Specifications for Tables and Figures	22
Appendix		24
Example Datasets		24
Example SDTM Functional Tests Dataset.....		25
Example ADaM Functional Tests Analysis Dataset		29
Example Tables and Figures.....		32

TABLE OF TABLES

Table 1. Specifications for a Subset of FT Variables	6
Table 2. Specifications for a Subset of SUPPFT Variables	7
Table 3. Representing Missing and Partial Driving Assessment Data in SDTM.....	8
Table 4. Specifications for a Subset of ADFT Variables	10
Table A1. Example Schedule of Assessments	24
Table A2. Example Sequence of Treatments.....	24
Table A3. Subset of Sample FT Dataset.....	26
Table A4. Subset of Sample SUPPFT Dataset.....	29
Table A5. Subset of Sample RELREC Dataset	29
Table A6. (Part 1) Subset of Sample ADFT Dataset.....	31
Table A6. (Part 2) Subset of Sample ADFT Dataset.....	31
Table A6. (Part 3) Subset of Sample ADFT Dataset.....	32
Table A7. Participant Continuation Summary by Treatment Sequence and Period.....	32
Table A8. Driving Assessment Completion Summary by Treatment Sequence, Period, and Dosing.....	33

TABLE OF FIGURES

Figure A1. Example Annotated Case Report Form	28
---	----

Submitting Clinical Trial Data to Evaluate the Ability to Operate a Motor Vehicle

Guidance for Industry Technical Specifications Document¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

1.0 INTRODUCTION

1.1 Purpose

This document provides technical specifications for submitting data from a clinical trial to evaluate the ability to operate a motor vehicle (herein referred to as a *driving study*) to support a marketing application for drug or biological product. As presented in FDA's guidance for industry *Evaluating Drug Effects on the Ability to Operate a Motor Vehicle* (November 2017),² driving studies are primarily conducted to evaluate the effects of psychoactive drugs on the ability to operate a motor vehicle, though driving studies can also be conducted to evaluate effects of certain non-psychoactive drugs. These technical specifications should be referenced when a driving assessment is conducted as part of a clinical drug development program.

1.2 Background

Driving assessments are functional tests that are used to collect objective findings of a participant's ability to operate a motor vehicle by using a measurement tool such as a computer simulator or a specially instrumented on-road vehicle. The measurement tool produces data relevant to the clinical investigation but is not under study, and example measurements collected during a driving assessment can include Standard Deviation of Lateral Position (SDLP), lane exceedance or lane drifts, response time, and number of collisions. When the drug under study has significant safety issues where the risk of assessing a participant on the road using a specially instrumented vehicle is determined to be too high, a computer simulator may be preferable.

¹ This guidance has been prepared by the Office of Biostatistics, Office of Clinical Pharmacology, and Office of New Drugs in the Center for Drug Evaluation and Research at the Food and Drug Administration. You may submit comments on this guidance at any time. Submit comments to Docket No. FDA-2018-D-1216 (available at <https://www.regulations.gov/docket?D=FDA-2018-D-1216>) (see the instructions for submitting comments in the docket).

² See the guidance for industry *Evaluating Drug Effects on the Ability to Operate a Motor Vehicle* (November 2017). For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

Contains Nonbinding Recommendations

Driving studies typically employ a crossover design to compare the effects of an investigational drug at one or multiple doses against both a positive control and a placebo. The timing of the planned driving assessment in each period can vary depending on the intended therapeutic use of the drug under study.³ For instance, to evaluate the effect that an investigational sleep drug has on the ability to operate a motor vehicle, a next-day driving assessment can be conducted nine hours postdose. Alternatively, to evaluate the effects of an investigational migraine drug the driving assessment can be performed 90 minutes postdose to assess an immediate effect on the operability. It is recommended that before initiating the trial, the sponsor consult with the FDA for specific guidance on designating the primary and secondary endpoints that align with the study objectives.

1.3 Scope

This document provides specifications for the submission of Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) datasets and specifications for tables and figures. These technical specifications aim to provide general guidelines for standardized content and structure to facilitate FDA review of the marketing application that the submitted data and analysis outputs are intended to support. The SDTM and ADaM dataset specifications outlined in [section 3.0 Overview of Dataset Specifications](#) emphasize clinical outcome assessment (COA) data, including the driving assessment data and questionnaires data used to evaluate the primary and secondary endpoints defined within the driving study. The dataset specifications are not prescriptive and do not include an exhaustive list of all datasets, variables, and controlled terminologies to be submitted for FDA review. Further, the recommended tables and figures within [section 4.0 Specifications for Tables and Figures](#) do not comprise all information critical to support FDA review of a marketing application. Sponsors should discuss with FDA which specifications are applicable for their particular clinical development program.

This document does not pertain to:

- (1) Submissions intended to support FDA review of a device to the Center for Devices and Radiological Health (CDRH) or Center for Biologics Evaluation and Research (CBER) if the measurement tool used to collect clinical trial data meets the definition of device under the Federal Food, Drug, and Cosmetic Act (FD&C Act);⁴
- (2) The proposed interpretation and use of outputs generated by a measurement tool within the context of a specific clinical trial; or

³ For the purposes of this guidance, all references to drugs include both human drugs and therapeutic biological products unless otherwise specified.

⁴ See section 201(h) of the FD&C Act for the definition of *device*. How to determine whether a measurement tool proposed for use in a clinical investigation meets the definition of device under the FD&C Act is outside the scope of this guidance. For information about how to determine if a measurement tool meets the definition of device, see <https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device>. In addition, for information about FDA digital health regulatory policies, see <https://www.fda.gov/medical-devices/digital-health-center-excellence/ask-question-about-digital-health-regulatory-policies>.

Contains Nonbinding Recommendations

(3) The verification, validation, or usability of a measurement tool.

FDA's guidance for industry *Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments* (October 2025),⁵ which is part of the FDA Patient-Focused Drug Development (PFDD) Guidance series,⁶ discusses validation for COAs. As described in the Biomarkers, EndpointS, and other Tools (BEST) Resource glossary,⁷ a COA refers to the assessment of a clinical outcome made through a report by a clinician, a patient, a non-clinician observer, or through a performance-based assessment; thus, there are four types of COAs: clinician-reported outcome (ClinRO), observer-reported outcome (ObsRO), patient-reported outcome (PRO), and performance outcome (PerfO) measures. Within this document, driving assessments are considered to be PerfO measures.

In addition, this document does not include formal definitions for driving assessment endpoints. Sponsors should provide comprehensive definitions of all endpoints within the study protocol with corresponding rationale. The measurement tool(s) used to collect driving study data and corresponding analyses should be discussed with FDA as early as possible in a clinical drug or biologic development program (e.g., the End-of-Phase 2 Meeting). Sponsors are strongly encouraged to use the resources described in [section 1.4 Relationships to Other Documents](#) and to seek Agency input for confirmation and clarification as appropriate. Sponsors should consult with the Agency to determine which requested displays defined in [section 4.0 Specifications for Tables and Figures](#) apply to the driving study data used to support their marketing application.

1.4 Relationship to Other Documents

These technical specifications have been drafted in accordance with the conformance rules and assumptions outlined in the CDISC SDTM,⁸ the SDTM Implementation Guide (SDTMIG),⁹ the SDTMIG for Medical Devices (SDTMIG-MD),¹⁰ the ADaM,¹¹ and the ADaM Implementation Guide (ADaMIG). As new versions of the models and implementation guides become available, these technical specifications can be updated to maintain alignment. In addition, the FDA Study Data Technical Conformance Guide (sdTCG)¹² provides general specifications and recommendations for submitting datasets using the SDTM and ADaM standards. Sponsors

⁵ See the guidance for industry *Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments* (October 2025).

⁶ More information is available at FDA's PFDD Guidance series web page: <https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical>.

⁷ More information is available at NCBI's web page: <https://www.ncbi.nlm.nih.gov/books/NBK338448/def-item/glossary.clinical-outcome-assessment/>.

⁸ More information is available at CDISC's SDTM web page: <https://cdisc.org/standards/foundational/sdtm>.

⁹ More information is available at CDISC's SDTMIG web page: <https://cdisc.org/standards/foundational/sdtmig>.

¹⁰ More information is available at CDISC's Medical Devices web page: <https://www.cdisc.org/standards/foundational/medical-devices>.

¹¹ More information is available at CDISC's ADaM web page: <https://cdisc.org/standards/foundational/adam>.

¹² More information is available at FDA's Study Data Standards Resources web page: <https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>.

Contains Nonbinding Recommendations

should review the FDA Data Standards Catalog¹³ to ensure data submissions follow FDA-supported standards.

In addition, sponsors should reference the following:

- Guidance for industry *Evaluating Drug Effects on the Ability to Operate a Motor Vehicle* (November 2017)¹⁴
- CDISC Controlled Terminology¹⁵
- CDISC Questionnaires, Ratings and Scales (QRS) Supplements, and CDISC QRS Resources, which include QRS Naming and Business Rules¹⁶
- FDA Patient-Focused Drug Development (PFDD) Guidance series¹⁷

2.0 RELEVANT ACRONYMS

Abbreviation	Description
ADaM	Analysis Data Model
ADaMIG	Analysis Data Model Implementation Guide
ADRG	Analysis Data Reviewer's Guide
BEST	Biomarkers, EndpointS, and other Tools
BDS	Basic Data Structure
CDISC	Clinical Data Interchange Standards Consortium
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
ClinRO	Clinician-Reported Outcome
COA	Clinical Outcome Assessment
CRF	Case Report Form
cSDRG	Clinical Study Data Reviewer's Guide
CSR	Clinical Study Report
eDT	Electronic Data Transfer
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
NCI EVS	National Cancer Institute Enterprise Vocabulary Services
ObsRO	Observer-Reported Outcome
PerfO	Performance Outcome
PFDD	Patient-Focused Drug Development
PK	Pharmacokinetic

¹³ More information is available at FDA's Study Data Standards Resources web page:

<https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>.

¹⁴ See the guidance for industry *Evaluating Drug Effects on the Ability to Operate a Motor Vehicle* (November 2017).

¹⁵ More information is available at NCI's web page: <https://datascience.cancer.gov/resources/cancer-vocabulary/cdisc-terminology>.

¹⁶ More information is available at CDISC's QRS web page: <https://cdisc.org/standards/foundational/qrs>.

¹⁷ More information is available at FDA's PFDD Guidance series web page: <https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical>.

Contains Nonbinding Recommendations

Abbreviation	Description
PRO	Patient-Reported Outcome
QRS	Questionnaires, Ratings and Scales
SAP	Statistical Analysis Plan
SDLP	Standard Deviation of Lateral Position
sdTCG	Study Data Technical Conformance Guide
SDTM	Study Data Tabulation Model
SDTMIG	Study Data Tabulation Model Implementation Guide
SDTMIG-MD	Study Data Tabulation Model Implementation Guide for Medical Devices

3.0 OVERVIEW OF DATASET SPECIFICATIONS

These dataset specifications detail the CDISC datasets that are used to support the submission of driving assessment data and questionnaires data. Sponsors should implement the CDISC SDTM standard when submitting data collected during the clinical trial and the CDISC ADaM standard when submitting analysis data. Throughout this document, the terms domain and dataset are used interchangeably and refer to the same concept. This section supplements existing guidance by providing specifications for submitting driving assessment data and questionnaires data but does not cover all data to be submitted for a clinical trial. As documented in the FDA sdTCG,¹⁸ both SDTM and ADaM datasets should be accompanied by informative metadata provided in a compliant data definition file (i.e., Define-XML) and are expected to be accompanied by a Clinical Study Data Reviewer's Guide (cSDRG) and an Analysis Data Reviewer's Guide (ADRG), respectively. Standard CDISC Controlled Terminology¹⁹ developed and maintained by CDISC and National Cancer Institute Enterprise Vocabulary Services (NCI EVS) should be used where applicable, and codelists can be extensible by adding controlled terminology that is not previously defined. Sponsor-extended codelists and use of alternative (e.g., non-CDISC or sponsor-defined) terminologies should be indicated in the study metadata (e.g., Define-XML file, cSDRG). In addition, software programs (source code) used to create the ADaM datasets and to analyze the driving study data should be submitted with the marketing application for FDA review.

3.1 Driving Assessment Datasets

This section specifies the datasets used to submit driving assessment data from a measurement tool such as a computer simulator or a specially instrumented on-road vehicle. These datasets include the SDTM Functional Tests (FT) dataset and the ADaM dataset containing analysis-ready driving assessment data (herein referred to as the Functional Tests Analysis Dataset (ADFT)).

¹⁸ More information is available at FDA's Study Data Standards Resources web page:

<https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>.

¹⁹ More information is available at NCI's web page: <https://datascience.cancer.gov/resources/cancer-vocabulary/cdisc-terminology>.

3.1.1 SDTM Functional Tests Dataset

This section focuses on submitting data collected and/or processed by a measurement tool during a driving assessment to measure an investigational drug's effect on a participant's ability to operate a motor vehicle. The driving assessment measurements (e.g., SDLP) produced using a computer simulator or a specially instrumented on-road vehicle are submitted using the SDTM FT domain specifications.

3.1.1.1 General Considerations

A single driving assessment can produce multiple measurements for an individual participant at an assessment timepoint. The subset of standard FT variables in Table 1 is included to clarify how variables should be completed for driving assessments to foster consistency and standardization across industry. An example FT dataset is provided in [Appendix 5.1.1](#).

Table 1. Specifications for a Subset of FT Variables

Variable Name	Variable Label	Type	Comment
SPDEVID	Sponsor Measurement Tool Identifier	Char	Identifier used to indicate the measurement tool used to produce measurements during a participant's driving assessment at an assessment timepoint (See section 3.2.1 Measurement Tool Identifiers).
FTTESTCD	Short Name of Test	Char	Short name for the value in FTTEST (e.g., SDLP). Controlled Terminology should be implemented if applicable. Note that within a single driving assessment similar measurements can be collected. For example, if lapses (i.e., brief periods of inattention and reduced alertness) are collected multiple types of lapses can be defined and reported. In these scenarios, it is recommended that the FTTESTCD and FTTEST values within the FT dataset clearly distinguish between each measure.
FTTEST	Name of Test	Char	Verbatim name of the driving assessment measurement (e.g., SDLP). Controlled Terminology should be implemented if applicable. If FTTEST is > 40 characters in length, sponsors should put meaningful text in FTTEST and describe the full-text in the study metadata (e.g., the cSDRG and/or the Define-XML).
FTSTAT	Completion Status	Char	This is populated as "NOT DONE" when the value for the driving assessment measurement (i.e., Result or Finding in Original Units (FTORRES)) is empty/null. Conversely, FTSTAT is empty or null when a value exists in FTORRES.
FTREASND	Reason Not Done	Char	This is used in conjunction with FTSTAT when FTSTAT = "NOT DONE" to describe why a driving assessment measurement is empty/null, when collected (See section 3.1.1.2 Handling of Missing and Partial Driving Assessment Data in SDTM).
FTDTC	Date/Time of Test	Char	Date and time of start of driving assessment.
FTENDTC	End Date/Time of Test	Char	Date and time of end of driving assessment. Note that collecting both start and end time of a driving assessment enables the identification and subsequent analysis of partial driving assessment measurements when a driving assessment begins as planned but ends prematurely.

Contains Nonbinding Recommendations

3.1.1.2 Additional Considerations

Additional driving study data collected beyond what is specified in the SDTM FT domain specifications should be submitted either as additional rows with relevant FTTEST and FTTESTCD values in the FT dataset or in a Supplemental Functional Tests (SUPPFT) dataset. For example, this can include environmental factors such as temperature of the room where the participant is administered the driving assessment using a simulator or the temperature in the car if an on-road vehicle is used for the driving assessment. If appropriate for analysis, the additional data should be provided in the ADFT dataset. Table 2 shows additional data recommended to be collected and subsequently reported in the SUPPFT dataset for each applicable participant and driving assessment timepoint.

Table 2. Specifications for a Subset of SUPPFT Variables

Qualifier Variable Name	Qualifier Variable Label	Comment
FTREASPE	Reason for Premature End	Reports the collected reason for the premature end of a driving assessment, when collected. FTREASPE is recommended to be collected when a driving assessment begins as planned but ends prematurely and thus is considered a ‘partial assessment’ (See section 3.1.1.2 Handling of Missing and Partial Driving Assessment Data in SDTM). FTREASPE can be collected on the Case Report Form (CRF). An example CRF is provided in Figure A1. Example Annotated Case Report Form .

3.1.1.3 Handling of Missing and Partial Driving Assessment Data in SDTM

Understanding the reasons for and prevalence of missing and partial driving assessment data are critical to support FDA review and regulatory decision-making. FDA is especially interested in understanding the safety and/or tolerability issues that prevented a participant from completing an assessment in full, which can affect FDA’s assessment of benefit-risk. To aid in making this determination, the study protocol and statistical analysis plan (SAP) should contain the definition and rationale for the criteria that compose a “complete” driving assessment.

When the reason for the missed assessment is collected, missing driving assessment data are represented in the FT dataset with FTSTAT = ‘NOT DONE’ and the reason for the missed assessment entered within ‘Reason Not Done’ (FTREASND), when the reason is collected in the source data (e.g., collected on the CRF). When a result is produced for a driving assessment measurement based on a partial driving assessment (i.e., a driving assessment begins as planned but ends prematurely), the partial driving assessment data are submitted in the FT dataset with FTORRES, FTDTTC, and FTENDTTC populated, and FTSTAT and FTREASND set to empty. In this scenario, Reason for Premature End (FTREASPE) of the driving assessment is encouraged to be collected and subsequently reported as a supplemental qualifier in the SUPPFT dataset as shown in Table 2. Conversely, when a result is not produced for a driving assessment measurement based on a partial driving assessment, this scenario is treated like missing data in the FT dataset with FTSTAT and FTREASND populated and FTORRES set to empty. Capturing details for missing and partial data on the CRF supplements the collected driving assessment

Contains Nonbinding Recommendations

results for each measurement (e.g., SDLP) when the data are transmitted directly via electronic data transfer (eDT) and not reported on a CRF.

For example, consider the scenario where a study protocol specifies that participants will perform a 60-minute driving assessment using a computer simulator at multiple assessment timepoints during the study. A participant performs the assessment at the first assessment timepoint, but due to severe dizziness, terminates the simulation after 30 minutes; thus, only 30 minutes out of the expected 60 minutes were completed. If driving assessment measurements such as SDLP are calculated based on the shortened 30-minute assessment, then these data are provided as a row for each resulting measurement within the parent FT dataset with FTORRES, FTDTTC, and FTENDTTC populated for each row. For the rows corresponding to the 30-minute assessment, QVAL = 'SEVERE DIZZINESS' where QNAM = 'FTREASPE' in the SUPPFT dataset as indicated on the CRF or by the measurement tool. An example CRF is provided in [Figure A1. Example Annotated Case Report Form](#).

Sponsors are encouraged to represent all protocol-specified assessment timepoints where a driving assessment is planned to be completed in the FT dataset for each participant and measurement. However, when no source data exist (e.g., data on the CRF was not collected) to indicate that a driving assessment was not done for a protocol-specified timepoint, there may be no resulting row present in the FT dataset. In this scenario, if a row is appropriate for analysis purposes, a phantom record is added within the ADFT dataset (See [section 3.1.2.3 Handling of Missing and Partial Driving Assessment Data in ADaM](#)). Table 3 describes further scenarios for representing missing and partial driving assessment data at planned (i.e., per protocol) assessment timepoints in the SDTM FT dataset. [Appendix 5.1.1](#) demonstrates scenarios for representing missing data within the FT dataset.

Table 3. Representing Missing and Partial Driving Assessment Data in SDTM

Example Scenario	Recommended Representation in FT Dataset
A participant did not perform the driving assessment at a planned assessment timepoint but participant is active in the study and did not discontinue.	A single row for the entire missing driving assessment in the FT dataset includes: • FTTESTCD = 'FTALL' • FTTEST = 'Driving Assessment Results' • FTSTAT = 'NOT DONE' • FTREASND contains the reason the participant did not perform the driving assessment if known/collected in the source data (e.g., collected on a CRF). Otherwise, FTREASND is empty/null.
A participant did not perform the driving assessment at a planned assessment timepoint due to discontinuation from the study.	If not known/collected, no rows are expected within the FT dataset. Rows are excluded from the FT dataset when details for the missed driving assessment are not known/collected in the source data (e.g., not collected on a CRF). If known/collected, a single row for the entire missing driving assessment in the FT dataset includes: • FTTESTCD = 'FTALL' • FTTEST = 'Driving Assessment Results' • FTSTAT = 'NOT DONE'

Contains Nonbinding Recommendations

Example Scenario	Recommended Representation in FT Dataset
	• FTREASND contains the reason the participant did not perform the driving assessment if known/collected in the source data (e.g., collected on a CRF).
A participant performed the driving assessment at a planned assessment timepoint but prematurely ended the driving assessment. Values for each driving assessment measurement (i.e., FTORRES) are produced based on the partial assessment and are provided in the FT dataset.	A single row for each driving assessment measurement corresponding to the partial driving assessment in the FT dataset includes: • FTORRES is populated with the result of the measurement. • FTDTC and FTENDTC are populated with the start and end date/time of the partial assessment, respectively. • FTSTAT and FTREASND are empty/null. • Reason for Premature End (FTREASPE) contains the reason the participant prematurely ended the assessment if known/collected. FTREASPE is provided in the SUPPFT dataset as shown in Table 2 Specifications for a Subset of SUPPFT Variables.
A participant performed the driving assessment at a planned assessment timepoint but prematurely ended the driving assessment. Values for each driving assessment measurement (i.e., FTORRES) are not produced based on the partial assessment and thus are not provided in the FT dataset. Instead, this assessment timepoint is treated as missing data.	A single row for the entire partial driving assessment in the FT dataset includes: • FTORRES is empty/null. • FTDTC and FTENDTC are populated with the start and end date/time of the partial assessment, respectively. • FTTESTCD = 'FTALL' • FTTEST = 'Driving Assessment Results' • FTSTAT = 'NOT DONE' • FTREASND contains the reason the participant prematurely ended the assessment if known/collected. Otherwise, FTREASND is empty/null.

3.1.2 ADaM Functional Tests Analysis Dataset (ADFT)

This section provides specifications for the ADaM dataset containing analysis-ready driving assessment data within the Functional Tests Analysis Dataset (ADFT). The ADFT dataset follows the ADaM Basic Data Structure (BDS) and is created from data in the SDTM FT dataset discussed in [section 3.1.1 SDTM Functional Tests \(FT\) Dataset](#) in conjunction with other SDTM and ADaM data.

3.1.2.1 General Considerations

Table 4 contains specifications for a subset of ADFT variables, some of which are standard variables (included to clarify how they should be completed for driving assessments to foster industry consistency, standardization, and traceability) and some of which are newly defined. Table 4 does not represent a complete list of ADFT variables to be submitted. Additional variables important for analysis (such as indicator variables and analysis flags; variables to aid in traceability; and treatment, discontinuation, demographic, covariate, and period-level variables originally provided within the ADSL dataset) should also be included within the ADFT dataset so that it is analysis-ready. For standard BDS variables prespecified in ADaM, reference the ADaMIG for additional details. An example of ADFT dataset is provided in [Appendix 5.1.2](#).

Contains Nonbinding Recommendations

Table 4. Specifications for a Subset of ADFT Variables

Variable Name	Variable Label	Type	Comments
Timing variables			
ASTDTM	Analysis Start Datetime	Num	Date and time of start of driving assessment using an appropriate display format.
AENDTM	Analysis End Datetime	Num	Date and time of end of driving assessment using an appropriate display format.
Variables used to assess residual concentration at the time of the driving assessment			
PCVAL	Pharmacokinetic Concentration Value	Num	Denotes the pharmacokinetic concentration value from the SDTM Pharmacokinetics Concentrations (PC) dataset or the ADaM ADPC dataset that is captured at each specified driving assessment timepoint. This value should be provided for the driving assessment parameters that support each primary and/or secondary driving endpoint, such as SDLP, to more effectively assess changes in SDLP and other endpoints based on residual concentrations (See section 4.0 Specifications for Tables and Figures). The SAP should specify the rules used to populate PCVAL.
PCVALU	Unit of Pharmacokinetic Concentration Value	Char	Denotes the unit for the pharmacokinetic concentration value reported in PCVAL.
PCDTM	Pharmacokinetic Concentration Analysis Datetime	Num	Date and time of the pharmacokinetic concentration value reported in PCVAL using an appropriate display format.
Variables used to assess missing or partial driving assessment data			
APREFL	Premature End of Driving Assessment Flag	Char	Indicates when a driving assessment begins as planned but ends prematurely. Derived based on start time and end time of the driving assessment. Alternatively, if a flag indicating the driving assessment ends prematurely is collected on the CRF or by the measurement tool and thus is considered to be source data, then this flag is submitted a supplemental qualifier within the SUPPFT dataset (See section 3.1.2.3.2 Approaches to Represent Partial Data).
ADURN	Analysis Duration (N)	Num	Reports the duration of the assessment. Derived based on start time and end time of the driving assessment. (See section 3.1.2.3.2 Approaches to Represent Partial Data).
ADURU	Analysis Duration Units	Char	Denotes the unit for the analysis duration reported in ADURN.
AREASND	Analysis Reason Not Done	Char	Describes the reason for the missing driving assessment data, when known/collected. When FTREASND is populated, it may not be appropriate to derive AREASND in the ADFT dataset. AREASND is only derived when appropriate; for example, AREASND may be useful to standardize the submitted values for reason using sponsor-defined terminology if not done so within the values for FTREASND. Similarly, if reason for missing driving assessment data are populated from other sources such as the SDTM DE dataset such that there are differences between FTREASND and AREASND, then AREASND is provided. The sponsor should provide details in the ADaM study metadata as to how AREASND is derived (See section 3.1.2.3.1 Approaches to Represent Missing Data).

Contains Nonbinding Recommendations

Variable Name	Variable Label	Type	Comments
Variables used to assess windowing of driving assessments			
ATPT	Analysis Timepoint	Char	Analysis timepoint description that may contain the timepoint names as observed (i.e., from SDTM Planned Time Point Name (FTTPT)) when FTTPT is submitted in the FT dataset), derived timepoint names, timepoint window names, conceptual descriptions (such as Average, Endpoint, etc.), or a combination of these. ATPT is relative to the Analysis Timepoint Reference (ATPTREF). When submitted, ATPTREF denotes the description of the fixed reference point referred to by ATPT. For example, in a study where a driving assessment is specified by the protocol to be performed 9 hours postdose, ATPT is set as ‘9 hours’ and ATPTREF is set as ‘previous dose’. In addition to ATPT, Analysis Timepoint (N) (ATPTN) is provided as the numeric representation of ATPT.
DOSEDTM	Previous Dose Analysis Datetime	Num	Denotes the previous and most recent dose date and time before start of the driving assessment using an appropriate display format. Can be populated from the SDTM Exposure (EX) or Exposure as Collected (EC) datasets, or from the ADaM ADEX or ADEC datasets.
ARELTM	Analysis Relative Time	Num	The amount of time from the anchor time within DOSEDTM to the start of the driving assessment within ASTDTM.
ARELTMU	Analysis Relative Time Unit	Char	Denotes the unit for the analysis relative time reported in ARELTM.
Variables used to assess difference from placebo			
TRTP / TRTPN	Planned Treatment / Planned Treatment (N)	Char	Record-level treatment variables that represent the planned and actual treatments attributed to a record for analysis purposes. These variables indicate how treatment varies across rows for the same participant to enable the analysis of driving studies with crossover study designs.
TRTA / TRTAN	Actual Treatment / Actual Treatment (N)	Char	
Note: The sponsor can consult with the Agency to determine whether ABLFL, BASE, BASETYPE and PLACDIFF shown in the rows below should be provided in the ADFT dataset, and if so, for which driving assessment measurements these variables should be populated (e.g., SDLP, brake time reaction). These variables are used with the record-level treatment variables to evaluate difference from placebo for multiple baselines (e.g., baseline at single dose, baseline at repeated dose). An example of these variables is provided in Appendix 5.1.2 .			
ABLFL	Baseline Record Flag	Char	Equal to ‘Y’ when TRTA denotes placebo for each subject, parameter, and baseline type.
BASE	Baseline Value	Num	Equal to AVAL when ABLFL = ‘Y’ at placebo for each baseline type. Used to calculate PLACDIFF.
BASETYPE	Baseline Type	Char	Denotes the baseline definition where TRTA denotes placebo (e.g., baseline at single dose, baseline at repeated dose) for which the current record is being assessed. Used to populate BASE and to calculate PLACDIFF.

Contains Nonbinding Recommendations

Variable Name	Variable Label	Type	Comments
PLACDIFF	Difference from Placebo	Num	Equal to AVAL – BASE. Note that PLACDIFF is used instead of the Change from Baseline (CHG) variable specified in the ADaMIG. This is because BASE is populated specifically for the driving assessment timepoints where TRTA denotes placebo, which may occur in a later period after the participant has already been exposed to the treatment and/or the positive control, given the crossover study design used for driving studies.
Additional recommended variables to support analysis			
CRITy / CRITyFL / CRITyFN	Analysis Criterion y / Criterion y Evaluation Result Flag / Criterion y Evaluation Result Flag (N)	Char / Char / Num	Identifies a pre-specified criterion and indicates whether the record satisfies the criterion on the current record. When SDLP is calculated, criteria flags are encouraged to indicate whether a participant's difference from placebo in SDLP value reported within PLACDIFF exceeds a threshold of impairment. The threshold(s) of impairment for the study should be defined and prespecified within the study protocol and SAP. An example of these variables is provided within Appendix 5.1.2 .
DTYPE	Derivation Type	Char	Analysis value derivation method. DTYPE should be populated with the algorithm or statistical method used when AVAL has been imputed or derived differently than other analysis values within a parameter. This document references the use of phantom records (i.e., where DTYPE = 'PHANTOM') to represent rows for missing driving assessments that are absent from the SDTM FT dataset (See section 3.1.2.3.1 Approaches to Represent Missing Data). Based on the study attributes, alternative DTYPE values can be used to handle missing data depending on the imputation method(s) implemented. When imputation is performed, imputation rules are included in the study's SAP. Imputation methods are not specified within this document for driving studies.
Variables in ADFT copied from the SDTM Comments (CO) Dataset			
COVAL	Comment	Char	Denotes the text of a comment collected for a given participant and driving assessment timepoint (See section 3.3 Comments Dataset). Comments data can be provided in multiple columns (i.e., COVAL1 – COVALn) within the ADFT dataset. Other variables from the CO dataset can be included in the ADFT dataset to aid in traceability between the ADFT and CO datasets.

Contains Nonbinding Recommendations

Variable Name	Variable Label	Type	Comments
Variables in ADFT copied from the ADaM ADSL Dataset			
AGEGRy	Pooled Age Group y	Char / Num	Character description of a grouping or pooling of the subject's age for analysis and reporting. Note that in addition to AGEGRy, Pooled Age Group y (N) (AGRGRyN) is submitted as a numeric representation of AGEGRy used for ordering. Pooling and grouping variables from the ADSL dataset such as AGEGRy should be copied into the ADFT dataset to support demographic subgroup analysis across the driving assessment measurements. For example, a single AGEGRy variable to categorize participants by ‘non-elderly’ vs. ‘elderly’ (e.g., where AGEGR1 is set to ‘<=65’ or ‘> 65’) can be used to assess driving assessment results when only one driving study is performed within an application. Alternatively, multiple driving studies can be conducted within an application (e.g., one study in elderly participants and one study in non-elderly participants), which can be important for certain indications such as sleep to ensure that a substantial proportion of the overall population is composed of elderly participants. The sponsor should consult with the Agency during the IND phase regarding plans for participant enrollment. Enrolling participants in driving studies from the population(s) likely to use the drug, including the elderly, is important for providing information about disease-drug interactions.
TRTSEQP / TRTSEQN	Planned Sequence of Treatments / Planned Sequence of Treatments (N)	Char	The planned and actual sequence of treatment for a participant based on the crossover study design typically employed in driving studies.
TRTSEQA / TRTSEQA	Actual Sequence of Treatments / Actual Sequence of Treatments (N)	Char	
Variables in ADFT copied from input SDTM FT Dataset			
FTSEQ	Sequence Number	Num	Sponsors should include any SDTM variables in the ADFT dataset that are critical to provide traceability to the source SDTM FT dataset.
VISIT	Visit Name	Char	
VISITNUM	Visit Number	Num	
FTSTAT	Completion Status	Char	Sponsors should include SDTM variables in the ADFT dataset that provide details of missing driving assessment data. See comments for FTSTAT and FTREASND provided in Table 1 Specifications for a Subset of FT Variables and in section 3.1.1.2 Handling of Missing and Partial Driving Assessment Data in SDTM .
FTREASND	Reason Not Done	Char	
SPDEVID	Sponsor Measurement Tool Identifier	Char	Identifier to indicate the measurement tool used to produce measurements during a participant’s driving assessment at an assessment timepoint. (See section 3.2.1 Measurement Tool Identifiers).

Contains Nonbinding Recommendations

Variable Name	Variable Label	Type	Comments
Variables in ADFT copied from input SDTM Supplemental Qualifiers for FT (SUPPFT) Dataset			
FTREASPE	Reason for Premature End	Char	Supplemental qualifier reporting the collected reason for a premature end of a driving assessment (See Table 2 Specifications for a Subset of SUPPFT Variables). The handling of missing and partial data are presented within section 3.1.2.3 Handling of Missing and Partial Driving Assessment Data in ADaM . Note that, in addition to providing SDTM variables in the ADFT dataset that support traceability and provide explanations for partial driving assessment data, any additional supplemental qualifiers within the SUPPFT dataset should be provided in the ADFT dataset when used in analysis.

3.1.2.2 Joining Driving Assessment Data to Other Data

As presented in [Table 4 Specifications for a Subset of ADFT Variables](#), joining non-driving assessment data to the driving assessment data reported within the ADFT dataset is recommended for certain data such as pharmacokinetic (PK) concentrations data, which can be joined from the SDTM Pharmacokinetics Concentrations (PC) dataset or the ADaM ADPC dataset. Providing PK data within the ADFT dataset supports exposure-response analysis, which is conducted in addition to the primary statistical analysis done for driving endpoints such as SDLP (See [section 4.0 Specifications for Tables and Figures](#)). Questionnaires data are an example of other non-driving assessment data that can be joined to the ADFT data depending on analysis needs of the study. When the protocol specifies the joining of non-driving assessment data to the driving assessment data during data collection, the Related Records (RELREC) dataset is employed in SDTM as described in [section 3.1.2.2.1 Linking Data in SDTM via RELREC](#). Alternatively, if the joining is performed retrospectively for analysis purposes and not while the driving assessment data are collected, data are linked directly in the ADFT dataset as described in [section 3.1.2.2.2 Joining Data in ADaM](#).

Joining adverse event (AE) data and driving assessment data can be beneficial when assessing whether an AE affects a participant's performance during a driving assessment. It is understood that the occurrence of an AE during a driving assessment may not result in missing or partial data. FDA is interested in knowing whether an AE occurred during the time of the driving assessment, and if so, which AE. However, joining AE data from the Analysis Data Adverse Event (ADAE) dataset to the driving assessment data in the ADFT dataset may not be feasible, given that multiple AEs can be present for a single driving assessment timepoint. Furthermore, the same AE can be ongoing and span multiple driving assessment timepoints. Thus, when applicable, submission of a standalone additional ADaM dataset that joins AE and driving assessment data and contains corresponding AE(s) for each driving assessment timepoint for a given participant is encouraged. This may result in repeated AEs when an AE spans multiple driving assessment timepoints, as well as repeated driving assessments when multiple AEs occur at a single driving assessment timepoint. Note that including a row for each individual driving assessment measurement at a given assessment timepoint is not critical within this dataset. This dataset is used to create the AE summary described in [section 4.0 Specifications for Tables and Figures](#). It is recommended that the sponsor consider how to capture the AEs experienced at the time of the driving assessment during study planning and before conducting the driving study.

Contains Nonbinding Recommendations

The sponsor should consider including AE characteristics found within the ADAE dataset in the standalone analysis dataset, such as severity, seriousness, and causality. The sponsor can consult with the Agency to discuss the structure, content, and submission of this additional analysis dataset.

3.1.2.2.1 Linking Data in SDTM via RELREC

The RELREC dataset is an SDTM special-purpose dataset used to identify relationships between records in disparate SDTM datasets. If the source data (e.g., data collected using a CRF) indicate a relationship between the driving assessment data in the FT dataset and data in another SDTM dataset at the time of data collection, this association is shown using the RELREC dataset. FDA is interested in the completeness and clarity with which RELREC variables — including Related Domain Abbreviation (RDOMAIN), Identifying Variable (IDVAR), Identifying Variable Value (IDVARVAL), and Relationship Identifier (RELID) — are populated to illustrate these relationships. An example of an annotated CRF (aCRF) is shown in [Figure A1. Example Annotated Case Report Form](#), and an example of a RELREC dataset that links driving assessment data in the SDTM FT dataset to adverse events data in the SDTM AE dataset is provided in [Table A5 Subset of Sample RELREC Dataset](#). If the measurement tool used to capture driving assessment data directly outputs an identifier to link measurement tool events, properties, settings, or other findings to the driving assessment measurements (e.g., SDLP), the RELREC dataset should be used to illustrate the linkage of the driving assessment records in the FT dataset to the records submitted within other measurement tool dataset(s) as described in [section 3.2. Datasets for Measurement Tool-Level Review](#).

3.1.2.2.2 Joining Data in ADaM

When the relationship between records across SDTM datasets is not captured in the source data and thus not represented using the RELREC dataset, the algorithm used to link driving assessment data within the ADFT dataset to the other data should be defined in the study metadata such as the ADaM Define-XML file. For example, ADaM Analysis Visit (AVISIT) or another analysis timing variable can be used to join records for a subject at each specified driving assessment timepoint. In addition, the software programs (source code) used to join data to the ADFT dataset should be provided, which can be included in the program used to create the ADFT dataset.

3.1.2.3 Handling of Missing and Partial Driving Assessment Data in ADaM

As discussed in SDTM [section 3.1.1.2 Handling of Missing and Partial Driving Assessment Data in SDTM](#), understanding the reasons for and prevalence of missing and partial driving assessment data are critical to support FDA review and regulatory decision-making. Within the ADFT dataset, it is ideal that a record be provided for every planned (per protocol) driving assessment timepoint for each participant, regardless of whether the driving assessment is complete, partial, or missing. Considerations for approaches to represent missing data within the ADFT dataset are provided in [section 3.1.2.3.1 Approaches to Represent Missing Data](#) and approaches to represent partial data within the ADFT dataset are provided in [section 3.1.2.3.2 Approaches to Represent Partial Data](#).

3.1.2.3.1 Approaches to Represent Missing Data

Approaches to represent rows for missing driving assessment data within the ADFT dataset where AVAL is empty include the following:

- Copying records from the SDTM FT dataset when collected, where FT.FTSTAT = 'NOT DONE' and FT.FTREASND is populated with the reason the driving assessment is missing
- Deriving phantom records in the ADFT dataset, where DTYPE = 'PHANTOM'

It is encouraged that rows for missing driving assessment data in the ADFT dataset be originally represented in the SDTM FT dataset with FTSTAT and FTREASND populated to support traceability, rather than derived as new phantom records in ADaM. When FT.FTREASND is populated within the SDTM FT dataset for a record, the value should be copied into the FTREASND variable within the ADFT dataset for each affected driving assessment measurement. Alternatively, phantom records can be added to the ADFT dataset if rows for the missing data do not exist in the SDTM FT dataset (e.g., records are missing due to participant discontinuation). Adding rows for phantom records is one solution to represent missing data when the missing data are not originally present in the SDTM FT dataset; however, based on analysis needs specified in the SAP, values can be imputed within AVAL instead. The sponsor should consult with the Agency to determine whether phantom records should be added within the ADaM dataset for the clinical trial.

In addition, a sponsor-defined analysis variable for Reason Not Done (e.g., ADFT.AREASND) may be useful to indicate the reason (if known and/or collected) that a driving assessment was not done when FT.FTREASND is not populated and/or not informative (see AREASND in [Table 4 Specifications for a Subset of ADFT Variables](#)). For example, AREASND can be derived from other sources when phantom records are used to represent missing driving assessment data. When populated, values for AREASND should be distributed across all measurements for a given driving assessment timepoint within the ADFT dataset.

3.1.2.3.2 Approaches to Represent Partial Data

Partial data are represented in the SDTM FT dataset and the ADFT dataset when driving assessment measurements such as SDLP are calculated, even though the driving assessment ends prematurely. Within the ADFT dataset, the resulting values are provided in AVAL for each driving assessment measurement, and supporting variables are recommended within the ADFT dataset as defined within [Table 4 Specifications for a Subset of ADFT Variables](#). In this scenario, the Premature End of Driving Assessment Flag (APREFL) is populated as 'Y', and the duration is reported within the Analysis Duration (N) (ADURN) and Analysis Duration Units (ADURU) variables. Note that if duration were originally collected in lieu of start and end datetime variables as source data, either on the CRF or by the measurement tool, the duration would be represented within the Duration of Functional Test (FTDUR) variable in International Organization for Standardization 8601 (ISO 8601) duration format within the FT dataset. [Appendix 5.1.2](#) shows an example of these supporting variables within the ADFT dataset.

3.1.2.4 Handling of ‘Out of Window’ Driving Assessment Data in ADaM

As presented in [Table 4 Specifications for a Subset of ADFT Variables](#), variables to assess whether a driving assessment was conducted outside of the planned window are useful for analysis. The windows used for analysis should be prespecified in the SAP, and the target time for a driving assessment to be conducted can be dependent on the indication for the drug under review. For example, the driving assessment for an investigational insomnia drug can be planned to occur 9 hours post-dose, whereas the driving assessment for an investigational migraine drug can be planned to occur 90 minutes post-dose.

Consider the example for an insomnia drug where a driving assessment is planned to occur 9 hours post-dose (i.e., the following morning) and the window is defined as 8 to 10 hours such that it is permissible for the participant to perform the driving assessment at any time within this window. If the driving assessment is performed either before 8 hours or after 10 hours, then the driving assessment is outside of the planned window. Note that empty values for variables such as the primary analysis timing variable used in the study (e.g., AVISIT) will aid in the determination of records that are outside of the planned window.

In addition to the variables defined in Table 4, the suite of Analysis Visit Windowing Variables for BDS Datasets as well as Analysis Flag zz (ANLzzFL) prespecified in the ADaMIG can further aid in the understanding and selection of records in the ADFT dataset that are used in analysis. These variables can be used to select the appropriate record(s) when multiple driving assessments are conducted within the same planned window. Further, they can be used to populate the appropriate value for the primary analysis timing variable used in the study (e.g., AVISIT, ATPT) based on the protocol schedule compared to what is captured in the CRF or via eDT for a given assessment timepoint.

3.2 Datasets for Measurement Tool-Level Review

Within a driving study, the measurement tool used to capture driving assessment data and generate measurement results can include a driving simulator or a specially instrumented on-road vehicle. The submission of additional data for the measurement tool(s) used in a driving study is recommended to enable measurement tool-level review and analysis. These data can include measurement tool identifier information, properties, settings, software version(s), and other participant interaction data (e.g., error codes generated by the measurement tool while it is in use by the participant). When multiple measurement tools are in use for a single driving study, this additional data can be useful in assessing which measurement tool was used by each participant at each assessment timepoint and can enhance the overall traceability of the driving assessment data. Note that the metadata reported within the additional datasets described in the subsections below can be collected in the protocol, collected on the CRF, or output by the measurement tool.

Contains Nonbinding Recommendations

3.2.1 Measurement Tool Identifiers

A dataset containing the identifiers or characteristics used to uniquely identify each measurement tool used in a driving study should be submitted. In the dataset, Sponsor Measurement Tool Identifier (SPDEVID) denotes the single identifier for each measurement tool and is used to link data. For example, the identifiers used to uniquely identify a driving simulator can include manufacturer, model, and serial number. Similarly, identifiers for a specially instrumented on-road vehicle can include the vehicle's manufacturer, model name, and model year. If this is not enough information to identify the vehicle uniquely, then additional identifiers such as Vehicle Identification Number (e.g., DIPARMCD = 'VIN'), can be included and represented by an alphanumeric string (e.g., DIVAL = 'ABC123...789XYZ'). Sponsors should supply the minimum number of identifiers appropriate to uniquely identify each measurement tool within the DI dataset. As shown in [Table 1 Specifications for a Subset of FT Variables](#) and [Table 4. Specifications for a Subset of ADFT Variables](#), FDA recommends that SPDEVID be submitted within the SDTM FT dataset and the ADFT dataset.

3.2.2 Measurement Tool -Subject Relationships

A measurement tool used in a study can be associated with multiple participants over the course of the study; conversely, multiple measurement tools can be associated with an individual participant. For example, a participant can use one driving simulator at one visit and a different driving simulator at a later visit, depending on the number of driving simulators available at the clinical trial site. To facilitate review, it is recommended that all distinct pairs of SPDEVID and USUBJID values observed in the study data be presented in a dataset.

3.2.3 Properties and Settings Pertaining to Measurement Tools

Driving assessment data depicting the properties and settings of a measurement tool such as software name and/or version are recommended to be submitted in separate findings dataset. Example properties captured for a driving simulator can include the frame rate or resolution of the simulator display, the course difficulty level, or the name and/or version of the software used to generate driving assessment measurements (e.g., SDLP). Note that representing properties and settings of each measurement tool are useful within a dataset when there are differences observed across measurement tools, participants, and/or driving assessment timepoints. Alternatively, when properties and settings are identical throughout the study, these details can instead be presented directly in the study protocol.

3.2.4 Events Pertaining to Measurement Tools

Driving assessment data depicting events that occur to a measurement tool during a driving study are recommended to be submitted, especially when the events can affect the results and interpretation of a driving assessment. Relevant events can include application program issues, electrical issues, software upgrades or downgrades, sensor issues when using a specially instrumented on-road vehicle, calibration issues, or other events that result in loss of data. When a relationship between the driving assessment and a corresponding measurement tool event is

Contains Nonbinding Recommendations

prespecified on the CRF, the data are linked in SDTM using the RELREC dataset. An example of this is provided in [Figure A1. Example Annotated Case Report Form](#).

3.3 Comments Dataset

The Comments (CO) domain is a special-purpose dataset prespecified within the SDTM that provides a solution for submitting free-text comments (e.g., voluntary free text or unsolicited observations). Within a driving study, an observer or evaluator can collect observations while the participant is performing the driving assessment at a distinct assessment timepoint, either while using a driving simulator or a specially instrumented on-road vehicle. Observations can be related to behavior (e.g., participant seemed upset or withdrawn), performance (e.g., participant drove erratically), the measurement tool (e.g., driving simulator had to be restarted before drive due to a technical issue), compliance (e.g., participant was not following clear directions), or the protocol (e.g., participant started the assessment after the target postdose time specified in the protocol), but they can also be more general in nature. FDA is interested in the consistency and accuracy with which variables — including Related Domain Abbreviation (RDOMAIN), Identifying Variable (IDVAR), Identifying Variable Value (IDVARVAL), and Comment Text (COVAL) — are populated within the CO dataset to effectively join comments data with other driving assessment data.

It is recommended that the comments data in the CO dataset related to the driving assessment are joined to the driving assessment data within the ADFT dataset as shown in [Table 4 Specifications for a Subset of ADFT Variables](#). Incorporating related comments directly within the ADFT dataset can aid in an overall understanding and interpretation of the data, including for driving assessment measurement results where outliers are present. Providing the comments data directly in the ADFT dataset also allows for the comment(s) related to each participant and driving assessment timepoint to be easily viewed. Within the ADFT dataset, the sponsor can consider creating classification flags to categorize the comments for analysis if applicable for the driving study, given the CO dataset can contain multiple categories of comments related to the driving assessment.

To improve the submission of standardized data within a driving study, the sponsor should consider how data will be collected (e.g., values captured as free text, in a structured field, or from a pre-defined list of values) during initial study planning and CRF design. For example, if environmental factors such as room temperature are to be collected for all participants before conducting the driving assessment adding a field on the CRF to capture this value in specified units helps ensure that room temperature will be collected consistently across participants and driving assessment timepoints. With the incorporation of these structured fields on the CRF, the resulting data can be represented within the SUPPFT dataset rather than as free text in the Comments dataset (see [section 3.1.1.1 General Considerations](#) for the FT dataset).

3.4 Trial Summary Dataset

Data related to the trial summary should be stored in the Trial Summary (TS) dataset. FDA is particularly interested in the frequency with which these technical specifications are used to

Contains Nonbinding Recommendations

create and submit driving study data. Per the FDA sdTCG,²⁰ sponsors can include the following parameters and associated values in the TS dataset to indicate that these technical specifications were used to support the submission of a driving study:

- TSPARAMCD = 'FDATCHSP'
- TSPARAM = 'FDA Tech Spec'
- TSVAL = 'Driving Study Technical Specifications Guidance v1.0'

3.5 Questionnaires Datasets

This section provides dataset specifications for submitting questionnaires data (i.e., other COA data separate from the driving assessment) in CDISC format and includes other considerations for questionnaires data, such as the handling of missing data. Like driving assessments, questionnaires have documented methods for administering and scoring a test using a valid instrument and can have continuous or categorical outcomes. Within a driving study, questionnaires data can be collected to support study objectives as separate study endpoint(s), i.e., to supplement the objective driving assessment endpoint(s) (e.g., SDLP), and to measure related constructs. Questionnaires data can also be used to aid in the clinical interpretation of the objective driving assessment results and the participant's performance. The sponsor should consider whether capturing questionnaire data before and/or immediately after a driving assessment is relevant to its clinical interpretation and to evaluate a participant's pre-driving and post-driving outcomes. For example, before performing a driving assessment, a PRO can be used to ask questions related to readiness to drive and participant safety (e.g., 'Do you feel safe to drive?'). Similarly, immediately after a driving assessment, a PRO can be used to ask questions related to the participant's awareness of their recent performance (e.g., 'How well did you drive during the driving assessment?', 'How motivated were you to drive to the best of your ability during the driving assessment?').

Consider a participant with a poor SDLP result who reported in a questionnaire that they felt safe to drive immediately before performing the driving assessment and rated both their driving performance and their motivation to drive well as high immediately after the driving assessment. In this scenario, impairment without awareness can be more concerning than a participant with an extremely poor SDLP result who documented in a questionnaire that they did not feel safe to drive and/or gave low ratings to their driving performance and their motivation to drive well. To better compare the questionnaires data to the driving assessment data for a given participant and assessment timepoint, the sponsor can consider joining the questionnaires data to the driving assessment data within the ADFT dataset or creating a separate summary table to compare the data. The sponsor can consult with the Agency to discuss whether this analysis is recommended for the driving study.

3.5.1 SDTM Specifications for Questionnaires Data

The SDTM dataset containing questionnaires data are referenced as the Questionnaires (QS) dataset throughout this document, and questionnaires data are tabulated using the SDTM QS

²⁰ More information is available at FDA's Study Data Standards Resources web page: <https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>.

domain specifications. For select measures, CDISC publishes QRS Supplements²¹ that provide guidance on representing named COA measures in the SDTM. CDISC also provides submission values within the controlled terminology related to named COA measures. These resources should be consulted for guidance on a COA measure, in addition to the guidance provided in the SDTM and SDTMIG. The QS dataset contains questionnaires data that were collected for individual participants at distinct assessment timepoints during the driving study. Collected questionnaires data represented within the SDTM QS dataset include individual items (i.e., questions) and can also include summary scores when summary scores are considered source data (herein referenced as a ‘source data summary score’²²). Alternatively, summary scores are derived using the ADaM.

3.5.1.1 Handling of Missing Questionnaires Data in SDTM

Similar to the evaluation of missing driving assessment data within the FT dataset as described in [section 3.1.1.2 Handling of Missing and Partial Driving Assessment Data in SDTM](#), understanding the reasons for and prevalence of missing questionnaires data are critical to support FDA review and regulatory decision-making. Sponsors should defer to the instructions provided within the instrument scoring manual to determine what constitutes a ‘complete’ measure. When such instructions are not provided within the instrument scoring manual or if a scoring manual does not exist for a given instrument, then sponsors should provide rationale for the responses appropriate to constitute a complete measure within the study protocol and SAP. When collected, missing questionnaires data should be represented within the QS dataset with Completion Status (QSSTAT) set to ‘NOT DONE’ and the reason for missingness captured under ‘Reason Not Performed’ (QSREASND).

3.5.2 ADaM Specifications for Questionnaires Data

The ADaM dataset containing analysis-ready questionnaires data (referenced in this document as the Analysis Data Quality Summary (ADQS) dataset) is derived from the questionnaires data in the SDTM QS dataset in conjunction with other SDTM and ADaM data. The ADQS dataset follows the ADaM BDS. Though parameters for total scores and/or subscale scores can be originally submitted within the SDTM QS dataset if they are considered ‘source data summary scores’, these parameters can also be derived within the ADQS dataset according to the study rules defined within the SAP. Within the ADQS dataset, it is recommended that sponsors include the SDTM variables critical to provide traceability to the source SDTM QS dataset, including the SDTM variables that support the understanding of missing questionnaires data (i.e., QSSTAT and QSREASND).

3.5.2.1 Handling of Missing Questionnaires Data in ADaM

Similar to the evaluation of missing driving assessment data within the ADFT dataset as described in [section 3.1.1.2 Handling of Missing and Partial Driving Assessment Data in ADaM](#), missing questionnaires data can be represented within the ADQS dataset by (1) copying records

²¹ More information is available at CDISC’s QRS web page: <https://cdisc.org/standards/foundational/qrs>.

²² Source data summary scores are summary scores (e.g., total scores, subscale scores) that are considered source data (e.g., data reported within a CRF) and submitted in the SDTM QS dataset.

Contains Nonbinding Recommendations

from the SDTM QS dataset when collected, where QS.QSSTAT = 'NOT DONE' and QS.QSREASND is populated with the reason the item(s) and/or source data summary score(s) are missing, or (2) deriving new phantom records in the ADQS dataset (e.g., where DTYPE = 'PHANTOM'). It is recommended that rows for missing questionnaires data within the ADQS dataset are initially represented as collected data within the QS dataset with QSSTAT and QSREASND populated, and thus traceable to the input QS dataset. Alternatively, phantom records can be added to the ADQS dataset if important for analysis when rows for the missing questionnaires data do not originally exist in the SDTM QS dataset. The sponsor can consult with the Agency to determine whether phantom records are recommended to be added within the ADQS dataset for the driving study to support the evaluation of missing questionnaires data. Deriving phantom records is one solution to represent missing data; however, based on the study attributes, values can instead be imputed according to the SAP. Note that QS.QSSTAT and QS.QSREASND are empty or null for phantom records that are provided in the ADQS dataset. If QS.QSREASND is empty or null, a sponsor-defined analysis variable for Reason Not Performed (e.g., ADQS.AREASND) may be useful to derive the reason (if known/collected from other sources) that an individual item and/or entire measure was not completed for a questionnaire, which can be applicable for records such as phantom records.

4.0 SPECIFICATIONS FOR TABLES AND FIGURES

In addition to the sponsor's prespecified tables and figures presenting analyses of study endpoint data from the driving assessment, the Agency recommends the following analyses be provided within the Clinical Study Report (CSR) to facilitate the evaluation of driving assessment data. The sponsor can consult with the Agency for further clarity on the analyses to be submitted. Variables presented in [Table 4 Specifications for a Subset of ADFT Variables](#) facilitate some of the requested analyses defined below.

- Difference from placebo in SDLP for all non-placebo treatment arms at both the single and repeated doses. The sponsor can consult with the Agency to determine if outputs should be created for driving assessment endpoints other than SDLP. Note: Both a table (e.g., mean, median, range, standard deviation, and mean [95% CI] difference from placebo) and a figure (e.g., box plot) may be useful for this analysis.
- Proportion of participants with difference from placebo in SDLP based on a categorical grouping of the prespecified threshold of impairment to indicate improved, neutral, or impaired (e.g., <-2.4 cm, -2.4 to 2.4 cm, >2.4 cm) for all non-placebo treatment arms at both the single and repeated doses. This analysis can further break out outputs by demographic subgroup (e.g., age group, sex, race, ethnicity). The sponsor can consult with the Agency to determine if outputs should be created for driving assessment endpoints other than SDLP. Note: Both a table and a figure may be useful for this analysis.
- Relationship between next-day residual concentrations and difference from placebo in SDLP for all non-placebo treatment arms at both the single and repeated doses. The sponsor can consult with the Agency to determine if outputs should be created for driving assessment endpoints other than SDLP. Both a table and a figure may be useful for this analysis.

Contains Nonbinding Recommendations

- Participant continuation summary by treatment sequence and period to represent the proportion of participants who did not drop out or discontinue from the study by period. A table may be useful for this analysis (see example in [Appendix 5.2](#).)
- Driving assessment completion summary by treatment sequence, period, and dosing to represent the proportion of missing data due at each planned driving assessment timepoint due to discontinuation and intermittent missingness. A table may be useful for this analysis (see example in [Appendix 5.2](#)).
- Partial driving assessment completion summary by treatment sequence, period, and dosing to represent the proportion of partial assessments at each planned driving assessment timepoint. A table may be useful for this analysis.
- Completion summaries by reason to summarize the primary reason(s) why a driving assessment is missing or partially completed. A table may be useful for this analysis.
- AE summary of the AEs observed during the driving assessments. Note: Both a table and a figure may be useful for this analysis.

APPENDIX

Example Datasets

Table A1 is an example of a schedule of assessments within the study protocol (not pictured) for a hypothetical study (Study A). Study A employs a crossover design with four periods where participants receive each of the following: 50 mg of the investigational drug, 100 mg of the investigational drug, a positive control, and a placebo. The primary endpoint for Study A is Standard Deviation of Lateral Position (SDLP), which is determined by a driving assessment conducted using a simulator for a planned period of 60 minutes per assessment.

Table A1. Example Schedule of Assessments

Activity	Visit		
	Screening	Double-Blind Treatment Periods 1 through 4	
		Day 2 (Single Dose)	Day 6 (Repeated Dose)
Driving Assessment	X	X	X

As shown in Table A1, an onsite driving assessment is administered initially at the screening visit and then on Day 2, after administration of the single dose, and on Day 6, after a repeated dose, for each of the four periods. According to the study protocol (not pictured), there is a one-week washout period in between each of the four treatment periods. The sequence of treatments for Study A is represented in Table A2.

Table A2. Example Sequence of Treatments

Sequence	Treatment			
1	50 mg Treatment	100 mg Treatment	Positive Control	Placebo
2	100 mg Treatment	Positive Control	Placebo	50 mg Treatment
3	Positive Control	Placebo	50 mg Treatment	100 mg Treatment
4	Placebo	50 mg Treatment	100 mg Treatment	Positive Control

Study A is referenced in the example Functional Tests (FT) dataset in [Appendix 5.1.1](#) and the example Functional Tests Analysis Dataset (ADFT) in [Appendix 5.1.2](#). The example driving assessment captures SDLP along with other driving parameters. For brevity,

Contains Nonbinding Recommendations

only SDLP is shown in the example datasets below. Note that the numeric values provided in FT.FTSTRESN within Table A3 and ADFT.AVAL within Table A6 are provided for illustrative purposes only.

Example SDTM Functional Tests Dataset

Table A3 shows an example of an FT dataset for a single participant (i.e., USUBJID = 'A_100_1') and a single driving assessment measurement (i.e., FTTESTCD = 'SDLP') across multiple visits. Table A3 shows a subset of variables to be submitted within the FT dataset and illustrates how missing driving assessment data are represented when the driving assessment is not completed as expected. Scenarios displayed in Table A3 include the following:

- The participant completed the planned driving assessments as expected based on the protocol-defined schedule of assessments at all visits except the Period 3 Day 6 visit and the Period 4 Day 2 visit.
- The participant did not perform the driving assessment at the Period 3 Day 6 visit due to an adverse event (AE).
 - Row 7 shows FTSTRESN set to empty/null, FTSTAT = 'NOT DONE', and FTREASND = 'ADVERSE EVENT'. In this example, FTSTAT and FTREASND are collected using the example annotated CRF (aCRF) shown in Figure A1.
 - Within the example aCRF shown in Figure A1, the affected record in the FT dataset (Row 7 in the FT dataset) links to the AE dataset (not pictured) via the RELREC dataset shown in Table A5.
 - FTDTC and FTENDTC are populated with the start date and time and the end date and time, respectively, when the driving assessment is performed. Because the assessment was not completed for the Period 3 Day 6 visit, FTDTC and FTENDTC are empty or null for Row 7.
- The participant commenced the driving assessment at the Period 4 Day 2 visit but did not complete the 60-minute assessment as specified in the protocol. In this specific example, the numeric driving assessment measurement for SDLP is calculated by the computer simulator, even though a partial assessment occurred.
 - Based on FTDTC and FTENDTC, the assessment duration is 29 minutes. SDLP is calculated based on the partial assessment and is provided in FTORRES (not pictured) and FTSTRESN. Assessment duration is not captured on the CRF shown in Figure A1 and is instead derived in the ADFT dataset.

Contains Nonbinding Recommendations

- A subset of the SUPPFT dataset is shown in Table A4. Within this table, QNAM.FTREASPE shows the reason for the partial assessment, which is submitted as a supplemental qualifier. Row 1 in Table A4 shows QVAL = ‘DIZZINESS’ as the reason for the affected Period 4 Day 2 record found in Row 8 of the FT dataset in Table A3.
- In this example, the reason for the partial assessment is collected within the example aCRF shown in Figure A1. Row 1 of the SUPPFT dataset shows QORIG = ‘CRF’.
- The affected record in the FT dataset (Row 8 in the FT dataset) links to the AE dataset (not pictured) via the RELREC dataset shown in Table A5.
- Whether or not the partial driving assessment results are included within the analysis is indicated within the ADFT dataset and is not handled within the SDTM FT dataset. Additional analysis variables to calculate duration are also included within the ADFT dataset as shown in [Appendix 5.1.2](#).

Table A3. Subset of Sample FT Dataset

Row	USUBJID	FTSPID	FTTEST	FTTESTCD	FTSTRESN	FTSTRESU	FTSTAT	FTREASND	VISIT	FTDTC	FTENDTC
1	A_100_1	1	Standard Deviation of Lateral Position	SDLP	22.54	cm			SCREENING	2023-08-20 T09:30:00	2023-08-20 T10:30:00
2	A_100_1	2	Standard Deviation of Lateral Position	SDLP	23.26	cm			PERIOD 1 DAY 2	2023-09-02 T09:05:00	2023-09-02 T10:05:00
3	A_100_1	3	Standard Deviation of Lateral Position	SDLP	22.91	cm			PERIOD 1 DAY 6	2023-09-06 T09:22:00	2023-09-06 T10:22:00
4	A_100_1	4	Standard Deviation of Lateral Position	SDLP	25.69	cm			PERIOD 2 DAY 2	2023-09-16 T09:08:00	2023-09-16 T10:08:00
5	A_100_1	5	Standard Deviation of Lateral Position	SDLP	26.72	cm			PERIOD 2 DAY 6	2023-09-20 T09:27:00	2023-09-20 T10:27:00
6	A_100_1	6	Standard Deviation of Lateral Position	SDLP	29.09	cm			PERIOD 3 DAY 2	2023-09-30 T09:41:00	2023-09-30 T10:41:00

Contains Nonbinding Recommendations

Row	USUBJID	FTSPID	FTTEST	FTTESTCD	FTSTRESN	FTSTRESU	FTSTAT	FTREASND	VISIT	FTDTC	FTENDTC
7	A_100_1	7	Standard Deviation of Lateral Position	SDLP			NOT DONE	ADVERSE EVENT	PERIOD 3 DAY 6		
8	A_100_1	8	Standard Deviation of Lateral Position	SDLP	21.33	cm			PERIOD 4 DAY 2	2023-10-14 T09:02:00	2023-10-14 T09:31:00
9	A_100_1	9	Standard Deviation of Lateral Position	SDLP	22.18	cm			PERIOD 4 DAY 6	2023-10-18 T09:19:00	2023-10-18 T10:19:00

Figure A1 shows an example aCRF to illustrate how scenarios within Table A3 link to the AE dataset (not pictured) via the RELREC dataset shown in Table A5.

Figure A1. Example Annotated Case Report Form

FT = Functional Tests	
<u>Driving Assessment</u>	
Unique Subject Identifier: _____	USUBJID
Assessment Identifier: _____	FTSPID
Performed? ☐ Yes ☐ No	When 'No', FTSTAT= 'NOT DONE'. Otherwise, null.
Reason Not Performed: ☐ Adverse Event	
☐ Device Event	FTREASND
☐ Other	
Start of Assessment: _____	FTDTC
End of Assessment: _____	FTENDTC
Reason Ended Prematurely: ☐ Adverse Event	
☐ Device Event	FTREASPE in SUPPFT
☐ Other	
If Reason Not Performed or Reason Ended Prematurely due to adverse event(s), provide the associated ID(s): _____	
AESPID	RELREC when AESPID = AESPID

Contains Nonbinding Recommendations

Table A4 shows an example of the Supplemental Qualifiers for Functional Tests (SUPPFT) dataset. The reason for the partial assessment is provided within the example SUPPFT dataset for the affected Period 4 Day 2 record in Row 8 of the FT dataset.

Table A4. Subset of Sample SUPPFT Dataset

Row	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	FT	A_100_1	FTSEQ	8	FTREASPE	Reason for Premature End	DIZZINESS	CRF

Table A5 shows an example of the Related Records (RELREC) dataset used to link records between the FT dataset and the AE dataset.

Table A5. Subset of Sample RELREC Dataset

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	StudyA	FT	A_100_1	FTSPID	7	ONE	1
2	StudyA	AE	A_100_1	AESPID	12	ONE	1
3	StudyA	FT	A_100_1	FTSPID	8	ONE	2
4	StudyA	AE	A_100_1	AESPID	17	ONE	2

Example ADaM Functional Tests Analysis Dataset

Table A6, shown in three parts, shows an example ADFT dataset for the same participant and scenario descriptions as those provided in [Appendix 5.1.1](#). Within Table A6, PARAM = ‘Standard Deviation of Lateral Position (cm)’ for all records. Some of the derived variables included in [Table 4. Specifications for a Subset of ADFT Variables](#) are shown in the dataset as examples. Note that this table only shows a subset of variables to be submitted within the overall ADFT dataset. The ordering of variables within Table A6 is incidental to group similar variables for illustrative purposes and is not part of the specification for the ADFT dataset. Scenarios and/or variables displayed in Table A6 include the following:

Contains Nonbinding Recommendations

- For the driving assessments that were not administered (i.e., the driving assessment at the Period 3 Day 6 visit shown in Row 7) or were partially completed (i.e., the driving assessment at the Period 4 Day 2 visit shown in Row 8), SDTM variables originally reported in the FT and SUPPFT datasets are provided within the ADFT dataset to support traceability and an understanding of missing and partial data.
 - These variables include FTSTAT, FTREASND, and FTREASPE.
- Additional analysis variables support the understanding of partial data. These variables include Analysis Duration (N) (ADURN), Analysis Duration Units (ADURU), and Premature End of Driving Assessment Flag (APREFL).
 - Within Row 8 (i.e., the driving assessment at the Period 4 Day 2 visit), APREFL = ‘Y’, which denotes the scenario where the participant performed the driving assessment at the Period 4 Day 2 visit but did not complete the full 60-minute assessment as specified in the study protocol. In this study, driving assessment measurements such as SDLP were calculated for partial assessments.
 - Within Row 8, ADURN = ‘29’ and ADURU = ‘min’ to indicate the partial assessment lasted 29 minutes based on the start and end time of the driving assessment.
- Values are populated for ABLFL, BASE, BASETYPE, and PLACDIFF to calculate the difference from placebo in non-placebo treatment arms. Reporting the difference from placebo within the ADFT dataset is recommended so that the requested analysis within [section 4.0 Specifications for Tables and Figures](#) can be performed.
 - For the screening visit (i.e., where AVISIT = ‘SCREENING’), Difference from Placebo (PLACDIFF) and corresponding variables were not calculated because this visit is not used in analysis.
 - In addition, for the records in the placebo treatment arm (i.e., where TRTA = ‘Placebo’) PLACDIFF is not calculated because placebo is used as the comparator (i.e., the subtrahend) for each of the other treatment groups for the determination of the difference.
- Criteria variables, including CRIT1 and CRIT1FL, are provided to indicate when the threshold of impairment defined and prespecified in the protocol (not pictured) was exceeded. In this case, the difference from placebo in SDLP values reported in PLACDIFF that are greater than 2.4 cm (i.e., indicates ‘impaired’) are flagged as shown in rows 4, 5, and 6.

Contains Nonbinding Recommendations

- Variables used to assess whether driving assessments occurred within the specified window, including ATPT, ATPTREF, DOSEDTM, ARELTM and ARELTMU, are provided. Per the study protocol (not pictured), participants aim to perform the driving assessment 12 hours after their last dose, where the last dose is taken the evening prior. A window of 11 to 13 hours is defined for Study A for the driving assessment results to be used in analysis. As shown in Part 3 of the table, all driving assessments were conducted within the defined window.

Table A6. (Part 1) Subset of Sample ADFT Dataset

Row	USUBJID	TRTA	ASTDTM	AENDTM	AVISIT	PARAMCD	AVAL	FTSTAT
1	A_100_1		20Aug2023 9:30 AM	20Aug2023 10:30 AM	SCREENING	SDLP	22.54	
2	A_100_1	Placebo	02Sep2023 9:05 AM	02Sep2023 10:05 AM	PERIOD 1 DAY 2	SDLP	23.26	
3	A_100_1	Placebo	06Sep2023 9:22 AM	06Sep2023 10:22 AM	PERIOD 1 DAY 6	SDLP	22.91	
4	A_100_1	Treatment 50 mg	16Sep2023 9:08 AM	16Sep2023 10:08 AM	PERIOD 2 DAY 2	SDLP	25.69	
5	A_100_1	Treatment 50 mg	20Sep2023 9:27 AM	20Sep2023 10:27 AM	PERIOD 2 DAY 6	SDLP	26.72	
6	A_100_1	Treatment 100 mg	30Sep2023 9:41 AM	30Sep2023 10:41 AM	PERIOD 3 DAY 2	SDLP	29.09	
7	A_100_1	Treatment 100 mg			PERIOD 3 DAY 6	SDLP		NOT DONE
8	A_100_1	Zopiclone 7.5mg	14Oct2023 9:02 AM	14Oct2023 9:31 AM	PERIOD 4 DAY 2	SDLP	24.65	
9	A_100_1	Zopiclone 7.5mg	18Oct2023 9:19 AM	18Oct2023 10:19 AM	PERIOD 4 DAY 6	SDLP	21.83	

Table A6. (Part 2) Subset of Sample ADFT Dataset

Row	FTREASND	FTREASPE	APREFL	ADUR	ADURU	ABLFL	BASE	BASETYPE	PLACDIFF
1				60	min				
2				60	min	Y	23.26	Placebo for Day 2	
3				60	min	Y	22.91	Placebo for Day 6	
4				60	min		23.26	Placebo for Day 2	2.43
5				60	min		22.91	Placebo for Day 6	3.81
6				60	min		23.26	Placebo for Day 2	5.83
7	ADVERSE EVENT								
8		DIZZINESS	Y	29	min		23.26	Placebo for Day 2	1.39
9				60	min		22.91	Placebo for Day 6	-1.08

Contains Nonbinding Recommendations

Table A6. (Part 3) Subset of Sample ADFT Dataset

Row	CRIT1	CRIT1FL	ATPT	ATPTREF	DOSEDTM	ARELTM	ARELTMU
1			12 Hours	Postdose	19Aug2023 9:30 PM	12.0000	Hours
2			12 Hours	Postdose	01Sep2023 9:00 PM	12.0833	Hours
3			12 Hours	Postdose	05Sep2023 9:15 PM	12.1167	Hours
4	Difference from Placebo in SDLP Exceeds 2.4cm	Y	12 Hours	Postdose	15Sep2023 9:00 PM	12.1333	Hours
5	Difference from Placebo in SDLP Exceeds 2.4cm	Y	12 Hours	Postdose	19Sep2023 9:00 PM	12.4500	Hours
6	Difference from Placebo in SDLP Exceeds 2.4cm	Y	12 Hours	Postdose	29Sep2023 9:30 PM	12.1833	Hours
7							
8			12 Hours	Postdose	13Oct2023 9:00 PM	12.0333	Hours
9			12 Hours	Postdose	17Oct2023 9:30 PM	12.8167	Hours

Example Tables and Figures

The example tables and figures provided in this section are illustrated using the same scenario for Study A outlined in section [5.1 Example Datasets](#).

Table A7. Participant Continuation Summary by Treatment Sequence and Period¹

	Treatment Sequence			
Period	Sequence 1 (50mg 100mg PC ² PBO ³) N = 20	Sequence 2 (100mg PC PBO 50mg) N = 21	Sequence 3 (PC PBO 50mg 100mg) N = 22	Sequence 4 (PBO 50mg 100mg PC) N = 23
Period 1	50mg: 20 (100%)	100mg 21 (100%)	PC: 22 (100%)	PBO: 23 (100%)
Period 2	100mg: 20 (100%)	PC: 21 (100%)	PBO: 22 (100%)	50mg: 23 (100%)
Period 3	PC: 19 (95%)	PBO: 21 (100%)	50mg: 22 (100%)	100mg: 23 (100%)
Period 4	PBO: 18 (90%)	50mg: 20 (95.23%)	100mg: 22 (100%)	PC: 22 (95.65%)

¹ Counts provided for each treatment sequence and period within Table A7 represent the population count at the start of each period.

² PC = Positive Control.

³ PBO = Placebo.

Contains Nonbinding Recommendations

Table A8. Driving Assessment Completion Summary by Treatment Sequence, Period, and Dosing⁴

Period	Single or Repeated Dose	Treatment Sequence			
		Sequence 1 (50mg 100mg PC PBO) N = 20	Sequence 2 (100mg PC PBO 50mg) N = 21	Sequence 3 (PC PBO 50mg 100mg) N = 22	Sequence 4 (PBO 50mg 100mg PC) N = 23
Period 1	Single	50mg: 20 (100%)	100mg: 21 (100%)	PC: 22 (100%)	PBO: 23 (100%)
	Repeated	50mg: 20 (100%)	100mg: 20 (95.23%)	PC: 22 (100%)	PBO: 23 (100%)
Period 2	Single	100mg: 20 (100%)	PC: 20 (95.23%)	PBO: 22 (100%)	50mg: 21 (91.30%)
	Repeated	100mg: 18 (90%)	PC: 21 (100%)	PBO: 22 (100%)	50mg: 23 (100%)
Period 3	Single	PC: 19 (95%)	PBO: 21 (100%)	50mg: 22 (100%)	100mg: 23 (100%)
	Repeated	PC: 19 (95%)	PBO: 21 (100%)	50mg: 22 (100%)	100mg: 22 (95.65%)
Period 4	Single	PBO: 18 (90%)	50mg: 20 (95.23%)	100mg: 22 (100%)	PC: 22 (95.65%)
	Repeated	PBO: 18 (90%)	50mg: 20 (95.23%)	100mg: 21 (95.45%)	PC: 22 (95.65%)

⁴ Table A8 includes missing data due to discontinuation and intermittent missing data.