DATA TRANSMISSION AGREEMENT

Protocol 1418-0001

Electroretinography

Version 1.0 Date 23 MAR 2020

CONTACT:

VENDOR

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SPONSOR

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03 / 25 / 2020
OIRRC Approval&Date

BI Approval&Date

03 / 25 / 2020

DOCUMENT VERSION CONTROL:

Date	Version	Change Reference
23 MAR 2020	1.0	Initial version
		[To TDM: Please clearly track the versions and the change(s) against the previous version if the DTA is updated.]

CONTACT BACKUP:

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UPLOAD SPECIFICATIONS:

Media Type:
- BI secure EDT server (SSH Secure Shell sFTP)

Data Format:
- SAS dataset file (.sas7bdat)

All files must be in UTF8 or compatible ASCII format (i.e. unicode 0-127)

Frequency:
- After each cohort (all 3 patients of a dosing group have finished Visit 10)
- Upon BI request. The vendor can provide unscheduled exports with a lead time of *two weeks*. Immediately prior to EDC lock the lead time will be *two weeks*.
- Email notification of file transfer: Yes

Extent:

The data transfer will be done in a cumulative way.

Data will be transmitted when all tests of a device of a patient's visit have been completed. Only complete measurements with new data will be transferred for a patient (i.e. if only one response has changed, all responses and measurements for the observation of the patient need to be sent again).

The file will also include the corrected data that were already sent.

Data for screening failure subjects should be included in the transmission.
All complete data available in the vendor database will be transmitted. This must not be later than 2 weeks after the last patient out.

The metrics below are expected to be followed:
- Expected turnaround time from the first draft DTA review to approval: within *10* days.
- Expected first transfer delivered from final DTA approval: within *20* days

- Date expected for BI/vendor DTA sign off: two weeks -2020.
- Date expected for first data transfer: after first cohort (two weeks after last visit of last patient in the cohort)
- Date expected for final data transfer: 13-NOV-2020 (two weeks after last visit of last patient in the cohort).

Please note that this is an estimation according to the currently available information. If new information becomes available and the timelines must be changed, the TDM will inform the vendor contact

	person about new timelines via email. This will not necessarily lead to a DTA update. The final data transfer should be clearly communicated between the vendor and BI TDM. No further data transfer is expected from vendor after the final transfer unless BI TDM requests further data transfer for any specific reason.
Missing Responses:	Provide the complete structure for upload (all expected variables for a patient) and leave result variables empty (OEORRES, OEORRESU, OESTRESN, OESTRESC and OESTRESU) if no data are available for a test, fill OESTAT with 'NOT DONE' and provide a reason why not available in OEREASND
Retests/Unscheduled Tests (if applicable):	All unscheduled visits should be assigned to the same VISIT = UNSCHEDULED, whereas planned testing must be assigned to the visits as per protocol, see visit table 1) below.
Discontinued Patients	If a patient discontinues, data is expected only as far as tests were done for this patient. No missing information on outstanding tests is expected.
Test Upload:	Test data are to be provided at the very beginning of the trial when the first *3* patients have examinations available. This should be real data unless it causes unblinding which should be discussed within the trial team. If any error arises due to the vendor not following the DTA, the expected turnaround time to fix errors is within 5 days. • Date expected for test data transfer: first data transfer is the test transfer. • Date expected for test data approval: dependent on test data. Please note that this is an estimation according to the currently available information. If new information becomes available and the timelines must be changed, the TDM will inform the vendor contact person about new timelines via email. This will not necessarily lead to a DTA update.
Error Handling/ Data Revisions:	The vendor is expected to check the data for adherence to this DTA before each data transfer. If failures are detected in the transmitted file, BI will reject the whole file and the vendor must correct the issues and re-send the file within 3-5 days after receiving the email. All data queries between the eCRF data and vendor e-data should be resolved before the final data transfer.

The Trial Data Manager (TDM) or TDM backup is the only contact person authorized to request changes. Should any other BI employees request changes, the Trial Data Manager must be informed and agree prior to any action being taken.

Note that the usage of special characters in data files is restricted. Before sending data transfers including special characters, the vendor should contact the Trial Data Manager for confirmation.

Naming conventions

General naming conventions for transfer files uploaded to the server:

- 9 digit study number prefixed with 's',
- 8 digit date of transfer (format 'yyyymmdd'),
- 4 digit approximate time of transfer (24 hrs, format 'hhmm'),
- 3 character vendor code and
- 3 character data type code. (lower case)

Example:
*s1418_0001_201909011523_*oe_erg.sas7bdat

General naming conventions for files within .xpt files:

- The length of the file name must not exceed 8 characters
  When SDTM transformation is required after receiving the data, file name and dataset name in source_d should be confirmed and approved by SGA.

Record formats of OE domain

- Column 'Nullable' indicates whether variables may be missing in a data transfer or not.
- The variable order in the dataset(s) must follow the table below.

All variables defined below need to be provided in the data file even if no data is expected.

Variable Name	Variable Label	Type	Length (SAS)	Format	Nullable	Description
ROW_ID	Row Identifier	Char	10	$10.	No	Sequential number identifying the row. i.e. the 1st row=1, 2nd row =2.
STUDYID	Study Identifier	Char	9	$9	No	Study number 1418-0001
DOMAIN	Domain Abbreviation	Char	8	$8	No	Two-character abbreviation for the

						domain: OE
SUBJIDN	Subject Identifier for the Study	Num	8	10.	No	Subject Identifier for the study For example: 1276001002
FOCID	Focus of Study-Specific Interest	Char	2	$2.	No	Used to identify the study eye, 'OD' or 'OS'
OEGRPID	Group ID	Char	2	$2.	Yes	Used to distinguish between the ten tests of AWAVE, BWAVE and BWIMPL per subject, visit and eye Numbers from 1-10 (increasing Td s= increasing numbers)..
OETESTCD	Short Name of Ophthalmic Test or Exam	Char	8	$8	No	Ophthalmic Test Short Name - See Table for ERG
OETEST	Name of Ophthalmic Test or Exam	Char	40	$40	No	Ophthalmic Test Name- See Table for ERG
OETSTDTL	Ophthalmic Test or Exam Detail	Char	40	$40	Yes	Flash intensity in Trolands (Td s)
PUPDIAM	Pupil diameter	Char	10	$10	Yes	None CDISC compliant variable. Will be transferred into SUPPOE internally after upload.
PUPDIAMU	Pupil diameter unit	Char	10	$10	Yes	None CDISC compliant variable. Will be transferred into SUPPOE internally after upload.
OEORRES	Result or Finding in Original Units	Char	100	$100	Yes	Result of the grading or finding as originally collected and reported by vendor. All upper-case
OEORRESU	Original Units	Char	40	$40	Yes	Original units in which the data was collected. The unit for OEORRES. Note to vendor:

						OEORRESU should not be populated when OEORRES is null
OESTRESC	Character Result/Finding in Std Format	Char	100	$100	Yes	Character Result of the grading or finding as originally collected and reported by vendor All upper-case
OESTRESN	Numeric Finding in Standard Units	Num	8	11.2	Yes	Numeric Result of the grading or finding as originally collected and reported by vendor
OESTRESU	Standard Units	Char	40	$40	Yes	Original units in which the data was collected. The unit for OEORRES. Note to vendor: OEORRESU should not be populated when OEORRES is null
OESTAT	Completion Status	Char	8	$8	Yes	Used to indicate a test/grading was not done. If OEORRES is null then OESTAT='NOT DONE' and OEREASND can be populated with the reason. All upper-case
OEREASND	Reason Not Done	Char	100	$100	Yes	Describes why a measurement was not taken or graded. This is used in conjunction with OESTAT when the value of OESTAT='NOT DONE'. This column will be left blank if this information is not available to the vendor. All upper-case
OELOC	Location Used for the	Char	50	$50	No	See See Table for ERG

	Measurement					All upper-case
OELAT	Laterality	Char	15	$15	No	Populate with eye that was tested/graded. All upper-case
OEDIR	Directionality	Char	100	$100	Yes	Null
OEMETHOD	Method of Test or Examination	Char	100	$100	No	ELECTRORETINOGRAPHY All upper-case
VISIT	Visit Name	Char	40	$40	No	See Visit Table)
OEDTC	Date/Time of Collection	Char	20	$20	Yes	Start Date/Time of Assessment in ISO 8601 format e.g. 2019-09-25T07:45:59; created from date & time. Must be provided when OESTAT is not "NOT DONE"
COVAL	Comment	Char	200	$200.	Yes	If there are specific comments for measurement this can be included at record level for those OETESTCD. Comments for quality and any general comments should be concatenated All upper-case
ERGQUAL	ERG quality	Char	20	$20.	No	Used to indicate if the test is gradable or not. Possible values 'GRADABLE'/'NOT GRADABLE'

Visit table

VISIT
VISIT 01
VISIT 02
VISIT 03
VISIT 04
VISIT 05
VISIT 07
VISIT 08
VISIT 09
VISIT 10
UNSCHEDULED

Table for ERG

See below list of Tests for ERG.

OETESTCD	OETEST	OETSTDTL	OEORRESU	OELOC	OELAT
AWAVE	A-wave amplitude	*	uV	EYE	LEFT/ RIGHT
BWAVE	B-wave amplitude	*	uV	EYE	LEFT/ RIGHT
BWIMPL	B-wave implicit time	*	msec	EYE	LEFT/ RIGHT
FLBWAVE	Flicker b-wave amplitude	*	uV	EYE	LEFT/ RIGHT
FLBWIMPL	Flicker b-wave implicit time	*	msec	EYE	LEFT/ RIGHT

* in Td s

Example extract

Please note that the example is not a SAS dataset / ASCII file, but shows the information such a file should contain.
The tabular format has been chosen to obtain better readability.

For ERG:

ROW_ID	STUDYID	DOMAIN	SUBJIDN	FOCID	OETESTCD	OEGRPID	OETEST	OETSTDTL	PUPDIAM	PUPDIAMU	OEORRES	OEORRESU	OESTRESC	OESTRESN	OESTRESU	OESTAT	OEREASND	OELOC	OELAT	OEDIR	OEMETHOD	VISIT	OEDTC	COVAL	ERGQUAL
1	1418-0001	OE	1840007010	OD	AWAVE	1	A-wave amplitude	0.2 Td s	2	mm	7	uV	7	7	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		GRADABLE
2	1418-0001	OE	1840007010	OD	BWAVE	1	B-wave amplitude	0.2 Td s	2	mm	2	uV	2	2	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		NOT GRADABLE
3	1418-0001	OE	1840007010	OD	BWIMPL	1	B-wave implicit time	0.2 Td s	2	mm	5	msec	5	5	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
6	1418-0001	OE	1840007010	OD	AWAVE	2	A-wave amplitude	0.5 Td s	2	mm	7	uV	7	7	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
7	1418-0001	OE	1840007010	OD	BWAVE	2	B-wave amplitude	0.5 Td s	2	mm	2	uV	2	2	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
8	1418-0001	OE	1840007010	OD	BWIMPL	2	B-wave implicit time	0.5 Td s	2	mm	5	msec	5	5	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
11	1418-0001	OE	1840007010	OD	AWAVE	3	A-wave amplitude	1.0 Td s	2	mm	7	uV	7	7	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		

12	1418-0001	OE	1840007010	OD	BWAVE	3	B-wave amplitude	1.0 Tds	2	mm	2	uV	2	2	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
13	1418-0001	OE	1840007010	OD	BWIMPL	3	B-wave implicit time	1.0 Tds	2	mm	5	msec	5	5	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
16	1418-0001	OE	1840007010	OD	AWAVE	4	A-wave amplitude	2.0 Tds	2	mm	7	uV	7	7	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
17	1418-0001	OE	1840007010	OD	BWAVE	4	B-wave amplitude	2.0 Tds	2	mm	2	uV	5	2	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
18	1418-0001	OE	1840007010	OD	BWIMPL	4	B-wave implicit time	2.0 Tds	2	mm	5	msec	2	5	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
21	1418-0001	OE	1840007010	OD	AWAVE	5	A-wave amplitude	5.0 Tds	2	mm	7	uV	2	7	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
22	1418-0001	OE	1840007010	OD	BWAVE	5	B-wave amplitude	5.0 Tds	2	mm	2	uV	5	2	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
23	1418-0001	OE	1840007010	OD	BWIMPL	5	B-wave implicit time	5.0 Tds	2	mm	5	msec	2	5	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
26	1418-0001	OE	1840007010	OD	AWAVE	6	A-wave amplitude	7.5 Tds	2	mm	7	uV	7	7	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
27	1418-0001	OE	1840007010	OD	BWAVE	6	B-wave amplitude	7.5 Tds	2	mm	2	uV	2	2	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		

28	1418-0001	OE	1840007010	OD	BWIMPL	6	B-wave implicit time	7.5 Tds	2	mm	5	msec	5	5	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
31	1418-0001	OE	1840007010	OD	AWAVE	7	A-wave amplitude	10.0 Tds	2	mm	7	uV	7	7	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
32	1418-0001	OE	1840007010	OD	BWAVE	7	B-wave amplitude	10.0 Tds	2	mm	2	uV	2	2	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
33	1418-0001	OE	1840007010	OD	BWIMPL	7	B-wave implicit time	10.0 Tds	2	mm	5	msec	5	5	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
36	1418-0001	OE	1840007010	OD	AWAVE	8	A-wave amplitude	15.0 Cd·s/m2	2	mm	7	uV	7	7	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
37	1418-0001	OE	1840007010	OD	BWAVE	8	B-wave amplitude	15.0 Tds	2	mm	2	uV	2	2	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
38	1418-0001	OE	1840007010	OD	BWIMPL	8	B-wave implicit time	15.0 Tds	2	mm	5	msec	5	5	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
41	1418-0001	OE	1840007010	OD	AWAVE	9	A-wave amplitude	20.0 Tds	2	mm	7	uV	7	7	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
42	1418-0001	OE	1840007010	OD	BWAVE	9	B-wave amplitude	20.0 Tds	2	mm	2	uV	2	2	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
43	1418-0001	OE	1840007010	OD	BWIMPL	9	B-wave implicit time	20.0 Tds	2	mm	5	msec	5	5	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		

46	1418-0001	OE	1840007010	OD	AWAVE	10	A-wave amplitude	30.0 Td s	2	mm	7	uV	7	7	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
47	1418-0001	OE	1840007010	OD	BWAVE	10	B-wave amplitude	30.0 Td s	2	mm	2	uV	2	2	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
48	1418-0001	OE	1840007010	OD	BWIMPL	10	B-wave implicit time	30.0 Td s	2	mm	5	msec	5	5	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
51	1418-0001	OE	1840007010	OD	FLBWAVE	11	Flicker b-wave amplitude	16 Td s	2	mm		uV	1	1	uV			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		
52	1418-0001	OE	1840007010	OD	FLBWIMPL	11	Flicker b-wave implicit time	16 Td s	2	mm		msec	4	4	msec			EYE	RIGHT		ELECTRORETINOGRAPHY	VISIT 01	2019-05-30T10:30:00		