**Data Extraction Form – Study design, baseline characteristics, and results**

**Purpose:**

This form is designed for the data extraction and risk of bias assessment exercise for Systematic Reviews and Meta-Analysis Workshop on developing a Cochrane systematic review

**Completed by whom:**

Student data abstractors.

**INFORMATION ABOUT THE REPORT**

1. Title of the report: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. Last name of the first author of the report: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Year of publication: \_\_ \_\_ \_\_ \_\_

**STUDY DESIGN AND METHODS**

1. Was this trial a randomized controlled trial?

( 1) Yes

( 2) No

( 3) Can’t tell/Not reported

1. Was this trial a single or multicenter trial?

*A single center trial is a trial in which study participants are recruited from a single site/hospital/clinic. A multicenter trial is a trial in which study participants are recruited from multiple sites/hospitals/clinics.*

( 1) Single center trial

( 2) Multicenter Trial

( 3) Can’t tell/Not reported

1. Was the enrollment start year reported?

( 1) Yes…Specify enrollment start year: \_\_ \_\_ \_\_ \_\_

( 2) No

( 3) Can’t tell

1. Was the end of follow-up year reported?

*If a trial reported the end year for recruitment and the length of follow-up, please add up the durations to derive the end of follow-up year.*

( 1) Yes…Specify end of follow-up year: \_\_ \_\_ \_\_ \_\_

( 2) No

( 3) Can’t tell

1. Was the maximum planned (or stated) length of follow-up of each participant after randomization reported?

*Enter the numerical value and the unit in the same way as how they were reported in the article. For example, if the article stated 4 weeks, enter 4 weeks instead of 1 month. If the ways of reporting were different in different locations of the article, use the following order of preference: Methods, Abstract, and other sections.*

( 1) Yes…Specify planned (or stated) length of follow-up: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

( 2) No

( 3) Can’t tell

1. Did the authors report a sample size calculation (or power calculation based on the available sample size)?

( 1) Yes

( 2) No

( 3) Can’t tell

1. Did the authors report conducting an "intention-to-treat" analysis for any outcome at any time point?

( 1) Yes

( 2) No

( 3) Can’t tell

1. Was a participant flow diagram available in the article?

*A flow diagram in a randomized controlled trial shows the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome for each intervention group. Examples of flow diagram can be found at http://www.consort-statement.org/consortstatement/ flow-diagram.*

( 1) Yes

( 2) No

1. Were eligibility criteria reported in the article?

*Eligibility criteria are the rules that must be satisfied in order for a person to be eligible for enrollment in a study (also known as selection criteria/entry criteria).*

( 1) Yes

( 2) No

1. What were the regions from which study participants were recruited? (select all that apply)

*If a certain country belongs to more than one region, please check all applicable regions.*

[ 1] North America

[ 2] South America

[ 3] Europe

[ 4] Asia

[ 5] Africa

[ 6] Oceania

[ 7] Can’t tell/Not reported

1. What was the total number of randomized study groups (or arms)?

*A study may include both randomized groups (or arms) and one or more observational groups (or arms). Count the number of randomized observation units on whom interventions effects were estimated.*

( 1) 2

( 2) 3

( 3) 4

( 4) 5 or more

**BASELINE CHARACTERISTICS OF PARTICIPANTS**

1. Age of participants at baseline

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| --- | --- |
| Vehicle control [ 1] Not reported [ 2] Mean:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] SD:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] Median:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] Interquartile range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  AGN-190584 [ 1] Not reported [ 2] Mean:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] SD:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] Median:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] Interquartile range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Sex of participants at baseline

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| --- | --- |
| Vehicle control [ 1] Not reported [ 2] # of male:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] % of male:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] # of female:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] % of female:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | AGN-190584 [ 1] Not reported [ 2] # of male:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] % of male:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] # of female:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] % of female:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Emmetrope status at baseline

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| --- | --- |
| Vehicle control [ 1] Not reported [ 2] # Emmetrope :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] % Emmetrope:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] # Nonemmetrope:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] % Nonemmetrope:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | AGN-190584 [ 1] Not reported [ 2] # Emmetrope:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] % Emmetrope:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] # Nonemmetrope:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] % Nonemmetrope:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Mesopic, high-contrast, binocular distance-corrected near visual acuity (DCNVA) at baseline

|  |  |
| --- | --- |
| Vehicle control [ 1] Not reported [ 2] Mean:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] SD:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] Median:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] Interquartile range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | AGN-190584 [ 1] Not reported [ 2] Mean:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] SD:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] Median:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] Interquartile range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Photopic, high-contrast, binocular corrected-distance visual acuity (CDVA) at baseline

|  |  |
| --- | --- |
| Vehicle control [ 1] Not reported [ 2] Mean:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] SD:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] Median:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] Interquartile range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | AGN-190584 [ 1] Not reported [ 2] Mean:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] SD:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] Median:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] Interquartile range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**RESULTS**

1. CONTINUOUS OUTCOME: Change from baseline in mesopic, high-contrast, binocular DCNVA at Day 30, hour 0.5
2. Extracted from Table 2

|  |  |
| --- | --- |
| Vehicle control [ 1] Not reported [ 2] Mean:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] SD:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] Median:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] Interquartile range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | AGN-190584 [ 1] Not reported [ 2] Mean:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] SD:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] Median:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] Interquartile range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Extracted from Figure 2

|  |  |
| --- | --- |
| Vehicle control [ 1] Not reported [ 2] Mean:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] SD:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] Median:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] Interquartile range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | AGN-190584 [ 1] Not reported [ 2] Mean:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] SD:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ 4] Median:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 5] Interquartile range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. DICHOTOMOUS OUTCOME: Proportion of participants gaining 3 lines or more, from baseline, in mesopic, high-contrast, binocular DCNVA at Day 30, hour 3

Extracted from Table 2

|  |  |
| --- | --- |
| Vehicle control [ 1] Not reported [ 2] n (number with outcome):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] N (total number in group):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | AGN-190584[ 1] Not reported [ 2] n (number with outcome):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [ 3] N (total number in group):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**ADMINISTRATION INFORMATION**

1. Name of the data abstractor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Date of form completion: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_

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