NIH Inclusion Data by Research, Condition, and Disease Category Report Frequently Asked Questions

1. Why is median proportion displayed?

The proportion of participants is highly sensitive to outliers and skewed distributions. Therefore, the median proportion is displayed to show the percent of individuals included in a typical project associated with the research, condition or disease category. You can view the total participants and other information by clicking on the “Detail” button in the upper right-hand corner of the report.

2. Are RCDC categories mutually exclusive?

No. RCDC categories are by their nature overlapping (for example, Brain Disorders, Neurosciences, and Mental Health). See the RCDC Frequently Asked Questions webpage.

3. Can participants be counted in more than one category?

Yes. All participants enrolled in a project’s studies are included in each research, condition, or disease category applicable to the project. Research projects are often applicable to more than one RCDC category. For example, participants in a project examining the incidence of several different cancer diagnoses may be included within the Cancer category, but may also be included under Breast Cancer, Prostate Cancer, Lung Cancer, etc.

4. Are all Research Condition and Disease Categorization (RCDC) categories included?

Categories that do not follow the standard RCDC categorization process are not included.

5. Why are some categories labeled <11, <12, or <1%?

Due to privacy reasons, data are suppressed or summarized when small numbers of participants would be displayed in the resulting categories. When any group within a category has a null value or less than 12 participants (or less than11 in FY 2018), the data is displayed as <12 (or <11). Percentages less than 1% (including null values) are shown as <1%, and all other percentages are rounded to the nearest full digit.

6. Can I compare the RCDC budget data with the data in the RCDC Inclusion Statistics Report?

Inclusion data do not map directly to RCDC budget data. The data are processed differently. For example, inclusion data are divided according to the administering institute or center; in contrast, RCDC budget data are divided according to the funding institute or center. Therefore, accurate conclusions cannot be drawn by comparing the RCDC budget data with the data in the RCDC Inclusion Statistics Report.

7. **How were the age groups in the NIH Inclusion Data report determined?**

    The age groups were determined by NIH with consideration of the needs of the scientific community and the general public to understand and monitor the clinical research participation across the lifespan. Scientific, legal, policy, and developmental factors were considered in this process that involved input from various stakeholders.

    As part of the Inclusion Across the Lifespan policy development, NIH held a workshop to gather information from researchers, advocacy groups, and other stakeholders about issues related to inclusion of individuals by age, especially children and older adults, in clinical research. A summary of the discussions can be found in the June 2017 Inclusion Across the Lifespan Workshop summary. NIH also issued a Request for Information (NOT-OD-17-059) for stakeholder input on appropriate age groupings for participants in clinical research.

8. **How is older adult defined?**

    For the purpose of the NIH Inclusion Across the Lifespan policy, an older adult is an individual 65 years of age or older.

    Note: RCDC categories utilizing older populations do not contain defined age ranges, therefore aging-related RCDC categories can be comprised of research on individuals under 65.

9. **How is child defined?**

    For the purpose of the NIH Inclusion Across the Lifespan policy, a child is an individual under the age of 18.

    Note: NIH recognizes that development continues well beyond 18; however, there is particular concern about ensuring the appropriate inclusion of individuals under 18 while also safeguarding this vulnerable group.

    RCDC categories utilizing pediatric populations extend to individuals under 21. For certain RCDC categories, there may be discrepancies in how the data are represented for Inclusion purposes vs. RCDC reporting. For instance, awards reported in the Pediatric, Adolescent Sexual Activity, or Underage Drinking RCDC categories can include participants aged 18-20, which would be considered adults for Inclusion purposes.

10. **How many years of data are included in the RCDC x Inclusion age data report?**

    The RCDC x Inclusion age data report includes one year of interim enrollment data for those studies that fall under the Inclusion Across the Lifespan policy. The Inclusion Across the Lifespan policy and requirement to provide data on participant age at enrollment applies to competing applications submitted January 25, 2019 or later, and contract solicitations and intramural studies initiated after this date.

11. **Where can I find more information about RCDC categorization?**

RCDC categories are defined after consensus is reached among subject matter experts for each of the categories. For more information, visit the Research, Condition, and Disease Categorization process website or browse the RCDC Frequently Asked Questions webpage.

12. Who can I contact for inquiries about this report?

You may contact inclusion@od.nih.gov.