

Disease Demographics:

Ensuring your participant population is reflective of the demographics of the disease you are researching



Outline

- What are disease demographics?
- Why is knowing them important to your research
- How to determine disease demographics
- Resources for determining disease demographics
- Applying disease demographics to your study population
- Additional resources

What are disease demographics?

- Disease demographics are the identifying features of a group who has a specific disease or condition.
- Demographics of a disease can include such things as race, ethnicity, age, sex, gender, and geographic region.
- Examples of disease demographics:
 - Of Americans living with Alzheimer's, 72% are age 75 or older and two-thirds are women¹.
 - Of new diagnosis of type 1 diabetes, those under the age of 20 and non-Hispanic whites has the highest rates².

Why is knowing these demographics important to my research?

- To ensure the inclusion criteria and enrollment demographics of your study match those of the disease.
- Because you cannot fully understand a disease and its treatments if you do not include in the research everyone who has the disease.
- To be able to produce more representative, comprehensive research results applicable to the broadest population possible.
- It's just good science.
- To be aligned with Federal regulations. The NIH¹ requires grant applicants and awardees to have study populations that are representative of the disease being studied and are required to submit de-identified participant-level data on sex, gender, race, ethnicity, and age from their funded studies throughout the life of the study.

How do I determine the demographics of the disease I'm researching?



There are many online resources available to the public that provide information on specific diseases and their statistics.

Resources are often provided by:

- government and government-related agencies
- academic institutions
- medical organizations
- disease-specific associations and nonprofits

The amount and specificity of the information varies by site.

Resources for determining disease demographics

Government and government-related agencies:

Organization	Website Link
Center for Disease Control – Data & Statistics	https://www.cdc.gov/datastatistics/index.html
Center for Disease Control – National Center for Health Statistics	https://www.cdc.gov/nchs/index.htm
World Health Organization – Health Data & Statistics	http://www.who.int/healthinfo/statistics/en/
Department of Health (per state) – Data & Statistics	https://www.oregon.gov/oha/ph/DataStatistics/Pages/index.aspx
HealthData.gov	https://healthdata.gov/
US Department of Health & Human Services	https://www.hhs.gov/ash/public-health-offices/index.html
National Institute of Health	https://www.nihlibrary.nih.gov/resources/subject-guides/web-search-thinking-beyond-google/health-statistics
NIH Genetic and Rare Diseases – Information Center	https://rarediseases.info.nih.gov/diseases

Academic institutions:

Organization	Website Link
University of Michigan	https://guides.lib.umich.edu/c.php?g=283075&p=2694935
Johns Hopkins Medicine	https://www.hopkinsmedicine.org/healthlibrary/conditions/adult/
Oregon Health & Science University	https://www.ohsu.edu/oregon-office-on-disability-and-health/oregon-disability-health-data-and-statistics

Medical and disease-specific organizations and associations:

Organization	Website Link
American Cancer Society	https://www.cancer.org/research/cancer-facts-statistics.html
American Heart Association	https://www.heart.org/en/about-us/heart-and-stroke-association-statistics
Alzheimer's Association	https://www.alz.org/alzheimers-dementia/facts-figures
American Lung Association	https://www.lung.org/lung-health-and-diseases/
American Diabetes Association	https://www.diabetes.org/resources/statistics/statistics-about-diabetes

You can also start your search for disease demographics online with your favorite browser. Whether you prefer Google, Firefox, Microsoft Edge, or Safari, a simple search of your disease focus + “demographics” will produce a list of resources to get you started.

Applying disease demographics to your study population

The easiest way to develop the criteria for your study population is to take the disease demographics and apply its percentages to your enrollment goal. For example, if you were studying a disease whose demographics were 65% female and your N was 100, you would need to enroll 65 women.

$$\text{Total } N \times \text{demographic \%} = N \text{ to include in enrollment plan}$$

When developing your enrollment plan, it is also important to consider the demographics of the state and prevalence of the disease in this area and make adjustments as necessary. This real-time data can be used to determine enrollment expectations, feasibility of the study, need for oversampling, and needed changes to the total enrollment number.

Per the NIH¹, enrollment plans need to be inclusive of disease demographics and individuals or groups can only be excluded on the basis of scientific or ethical reasons. If your study population does not match your disease demographics, you will need to justify your enrollment plan and exclusions to the NIH.

You've determined your disease demographics and applied it to your study population...now what?

- Evaluate and redesign your study protocol as needed. Is the study design and activities reflective of the population you will be studying? Are modifications or accommodations needed to match your population and make the study participant friendly?
- Don't be afraid to engage experts to assist in study design. Experts can include specialists in the disease field or your institution's clinical trials office.
- Create (or update) a recruitment strategy that is tailored to the participant of the disease demographics.
 - Use multiple recruitment methods.
 - Adapt recruitment materials to meet the needs of your participant population.
 - Meet with [OCTRI Recruitment](#) for a complimentary recruitment consult.
- Start researching!

Additional Resources

Statista: The Statistics Portal

<https://www.statista.com/topics/2070/diseases/#dossierKeyfigures>

OHSU Biostatistics & Design Program (BDP)

<https://www.ohsu.edu/research-cores/biostatistics-design-program>

OCTRI Clinical Research Development Team (CRDT)

<https://www.ohsu.edu/octri/clinical-research-development-and-consultation>

NIH: Study Population Characteristics

<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2>

NIH: Inclusion Across the Lifespan

<https://grants.nih.gov/policy/inclusion/lifespan.htm>

NIH: Inclusion of Women and Minorities

<https://grants.nih.gov/policy/inclusion/women-and-minorities.htm>

NIH: Available Resources on the Recruitment and Retention of Women, Racial and Ethnic Minorities, and Individuals Across the Lifespan

https://grants.nih.gov/sites/default/files/Resources_Recruitment_and_Retention_WM%2CIAL_final508c.pdf

For more information, additional resources, and to request a complimentary recruitment consultation, please visit our [website](#) or email us at octrirecruitment@ohsu.edu



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