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 women\(^1\).
  - Of new diagnosis of type 1 diabetes, those under the age of 20 and non-Hispanic whites has the highest rates\(^2\).

1. Alzheimer’s Association
2. Beyond Type 1
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 NIH\(^1\) 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.

1. NIH Grants & Funding: Inclusion Policies for Research Involving Human Subjects
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:

<table>
<thead>
<tr>
<th>Organization</th>
<th>Website Link</th>
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<tbody>
<tr>
<td>Center for Disease Control – National Center for Health Statistics</td>
<td><a href="https://www.cdc.gov/nchs/index.htm">https://www.cdc.gov/nchs/index.htm</a></td>
</tr>
<tr>
<td>HealthData.gov</td>
<td><a href="https://healthdata.gov/">https://healthdata.gov/</a></td>
</tr>
<tr>
<td>NIH Genetic and Rare Diseases – Information Center</td>
<td><a href="https://rarediseases.info.nih.gov/diseases">https://rarediseases.info.nih.gov/diseases</a></td>
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*Not an exhaustive list of websites*
Academic institutions:

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<tr>
<td>University of Michigan</td>
<td><a href="https://guides.lib.umich.edu/c.php?g=283075&amp;p=2694935">https://guides.lib.umich.edu/c.php?g=283075&amp;p=2694935</a></td>
</tr>
<tr>
<td>Johns Hopkins Medicine</td>
<td><a href="https://www.hopkinsmedicine.org/healthlibrary/conditions/adult/">https://www.hopkinsmedicine.org/healthlibrary/conditions/adult/</a></td>
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Medical and disease-specific organizations and associations:

<table>
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<tbody>
<tr>
<td>Alzheimer’s Association</td>
<td><a href="https://www.alz.org/alzheimers-dementia/facts-figures">https://www.alz.org/alzheimers-dementia/facts-figures</a></td>
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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.

*Not an exhaustive list of websites*
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 NIH, 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.

1. NIH: Human Subjects and Clinical Trials Information
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

NIH: Inclusion Across the Lifespan

NIH: Inclusion of Women and Minorities

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](mailto:octrirecruitment@ohsu.edu)