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DISTANCE AS AN OBSTACLE TO CLINICAL TRIAL ACCESS:

Who Is Affected and Why It Matters

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The Milken Institute is a nonprofit, nonpartisan think tank focused on accelerating measurable progress on the path to a meaningful life. With a focus on financial, physical, mental, and environmental health, we bring together the best ideas and innovative resourcing to develop blueprints for tackling some of our most critical global issues through the lens of what's pressing now and what's coming next.

EXECUTIVE SUMMARY

Access to clinical trials is valuable for patients as it provides the possibility to obtain novel treatments that are not yet commercially available. There are many barriers to access for patients wishing to join clinical trials, including travel distance. This report maps counties that are more than 60 miles from a county containing a Phase 2 or 3 clinical trial for a given disease in the past five years.

Though a small proportion of the US population lives more than 60 miles from any type of trial, the part of the population more than 60 miles away is larger when specific diseases are considered, with rarer diseases having larger populations living far away. There are also noticeable differences in the demographics of counties that are over 60 miles away relative to counties closer to a clinical trial, and these differences vary based on the geographic dispersal of the trials.

There are "high-prevalence remote counties," which are locations that have much higher disease prevalence than the national average and are more than 60 miles from the nearest relevant clinical trial. These locations represent a unique opportunity for expanding access: Strategies aimed at expanding access, such as decentralized clinical trials, would have larger-than-average returns (such as new enrollment).

This report highlights the following points:

- Clinical trials predominate in major metropolitan areas and their outlying suburbs. Coastal counties are more likely to host a trial than those in the country's interior, a pattern that matches with population density.
- Counties more than 60 miles from a clinical trial tend to have lower incomes and education levels, less access to the internet, and a higher rate of disability than closer counties.
- Specific types of places tend to be far from clinical trials regardless of the disease being studied. Affluent suburbs, college towns, and urban cores are rarely over 60 miles from a trial, whereas agricultural counties (particularly in the Great Plains region) and American Indian Reservations are disproportionately likely to be over 60 miles from a trial.
- Clinical trials are not always close to high-prevalence populations. There are "high-prevalence remote counties" that contain populations in the top quarter of disease prevalence and are over 60 miles from the nearest trial county. These locations are high-priority places for expansion of clinical trials.

BACKGROUND

In addition to advancing science and the development of new medicines, clinical trials for pharmaceuticals are valuable for patients as trials provide access to novel treatments that are not yet commercially available. Because most trials require a physical location where treatment is administered, how close patients live to a relevant trial site matters. Patients who live farther away bear a larger cost in time spent traveling and the opportunity cost of that time to participate.

Empirically, distance to a trial has been shown to be relevant for trial recruitment and retention. Greater distance (or travel time) to a clinical trial decreases the likelihood of enrolling and increases the likelihood of participant attrition.[1] Survey responses disclosed that increasing travel time decreased the likelihood that potential trial participants would self-report their willingness to participate.[2]

Economic resources and demographic characteristics are also unevenly distributed across the United States. There is tremendous variability from place to place in income, education, economic mobility, and longevity.[3] This means that not only does the distribution of clinical trials across space create disparities in who has easier access to new treatments, but also that these disparities interact with existing locational differences in demographic makeup and socioeconomic status.

This report documents locational variation in sites for Phase 2 and Phase 3 clinical trials (this does not include Phase 0, 1, or 4 drug trials, or other types of nondrug trials such as comparative effectiveness trials, trials of surgeries, or behavioral trials) conducted in the United States and compares the traits of places near to and far from those sites. This exercise allows us to identify counties over 60 miles from the nearest clinical trial for a given disease, which we refer to as a "remote" county for that type of trial. We explore where remote counties are, who lives in them, and how they vary according to the disease being researched.

This last variation is crucial: Different diseases have different sets of study sites, meaning that for any given set of studies, the set of counties that are remote will be different. The final part of this report explores these differences in depth and reveals which locations tend to be systematically underserved, as well as which locations have both a high prevalence of a given disease and long travel distances for study participation. These "high-prevalence remote counties" are locations where expanding clinical trial access would increase the inclusion of underserved patient populations. These locations are high-value targets for strategies that can broaden access, such as decentralized clinical trials.

DATA

Information on clinical trial location comes from the Clinical Trials Transformation Initiative's Aggregate Analysis of ClinicalTrials.gov (AACT) database. The AACT database is an accurate snapshot of all information contained on ClinicalTrials.gov, which is the central online database for clinical studies.

We collect information on all Phase 2 and Phase 3 trials started and registered to ClinicalTrials.gov between January 1, 2017, and September 30, 2023, which captures 14,567 studies and their location sites. We then restrict to only US study sites. This yields 256,566 US study site/trial combinations, as single trials may (and frequently do) use multiple US sites. The 256,566 site/trial combinations include many repeated sites, as a single hospital may host many studies and, thus, a single address may be simultaneously listed as the site for multiple studies. Each site is then matched to the county where it was conducted, yielding 1,189 counties with at least one clinical trial site. We repeat this process for several different diseases, matching diseases to studies (and subsequently studies to sites and sites to counties) via a text filter.

To document Phase 2 and 3 clinical trials, the AACT data can be considered a complete record of all registered clinical trials. This is because, as part of the 2017 Final Rule for the Food and Drug Administration (FDA) Modernization Act, any clinical study that is considered for eventual FDA approval must be registered on ClinicalTrials.gov. So, if a Phase 2 or 3 trial is part of the drug development process, intended to go to the US market eventually as an approved drug, then it will be registered.

Then, we calculate the distance to the nearest trial for each county. A county is assigned a distance of zero if a Phase 2 or 3 clinical trial is present anywhere within the county. This means that we are unable to measure within-county travel distances. County-to-county distances are calculated as the distance between the centermost internal points in each county.[4] Again, this process is repeated for several different diseases.

We acquire county-level prevalence data for selected diseases. For cancer, chronic obstructive pulmonary disease, and diabetes, we draw from the Centers for Disease Control and Prevention's PLACES data, which has county-level prevalence for all states other than Florida for the US population.[5] For Alzheimer's disease and related dementias, we draw from the Centers for Medicare and Medicaid Services' prevalence data, which covers all states but is limited to the Medicare-eligible population.[6] Given the age profile for Alzheimer's disease and related dementias, we consider this to be a reasonable tradeoff.

County Population Characteristics

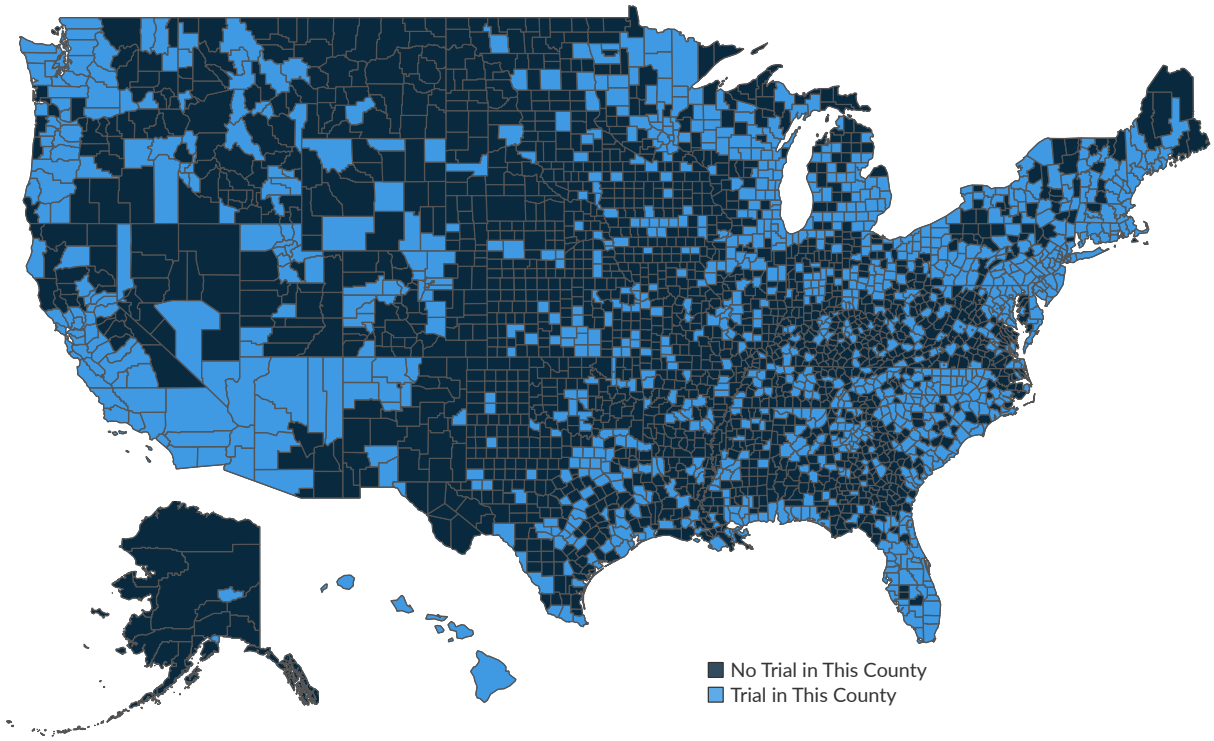
Each county's population characteristics are drawn from the US Census Bureau's American Community Survey (ACS) five-year data. The ACS is an annual survey that covers a broad range of the social, economic, and demographic characteristics of the US population. The five-year estimates are available for all geographies down to the Census block group level. In the present report, we employ the 2015–2019 ACS data for 3,142 US counties and match it to the AACT data from 2017 to 2023.[7] The slight mismatch in the years is to avoid using economic data from the COVID-19 pandemic, as we are trying to capture a general demographic snapshot and not a measure of economic susceptibility to the pandemic.

Two types of information are drawn from the 2015–2019 ACS data: basic demographic information (which includes data such as the racial composition of each county) and additional information on household-level data (such as educational attainment, disability status, and computer access, among others). The variables used are listed in their entirety in the Appendix. For aggregate statistical analyses, we weighted the county-level data by total population (also obtained from the ACS) to approximate data representative at the aggregate (e.g., national) level. All demographic, social, and economic information from the ACS is representative of the population at the county level, except for the educational attainment information, which is representative of the population aged 25 years and older.

LOCATIONS OF REMOTE COUNTIES

Figure 1 is a map of the 1,189 counties that contain at least one of the 14,567 Phase 2 or 3 clinical trials' 256,566 facilities. Counties containing a trial are light blue, and counties without a clinical trial are dark blue. Clinical trials predominate in major metropolitan areas and their outlying suburbs. Coastal counties are more likely to host a trial than those in the country's interior, a pattern that coincides with population density.

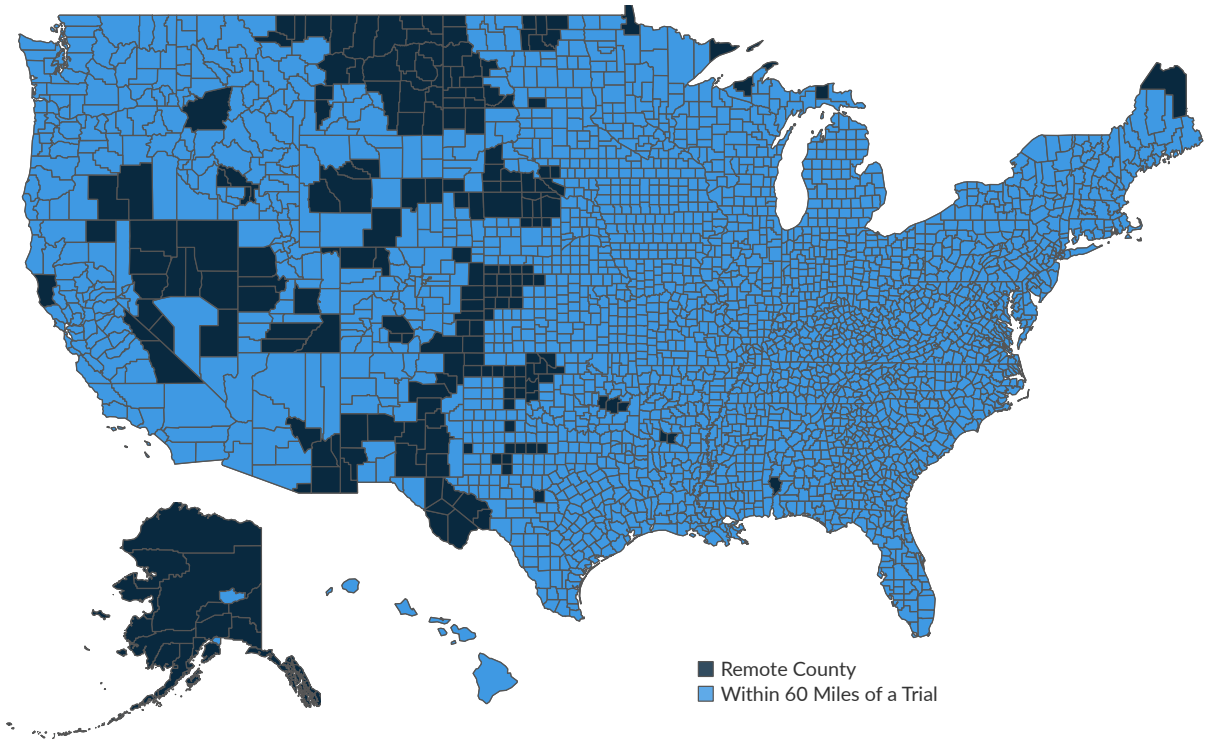
Figure 1: The Counties Containing Phase 2 or 3 Clinical Trials



Source: AACT Database (2023), Milken Institute (2024)

Figure 2 shows which counties are within 60 miles of a Phase 2 or 3 clinical trial (highlighted in light blue) and which counties are not (dark blue), thereby meeting our definition of a remote county. Remote counties are most common in the western US and Alaska, although there are scattered remote counties elsewhere in the country, such as parts of south-central US and northern Maine.

Figure 2: Remote Counties

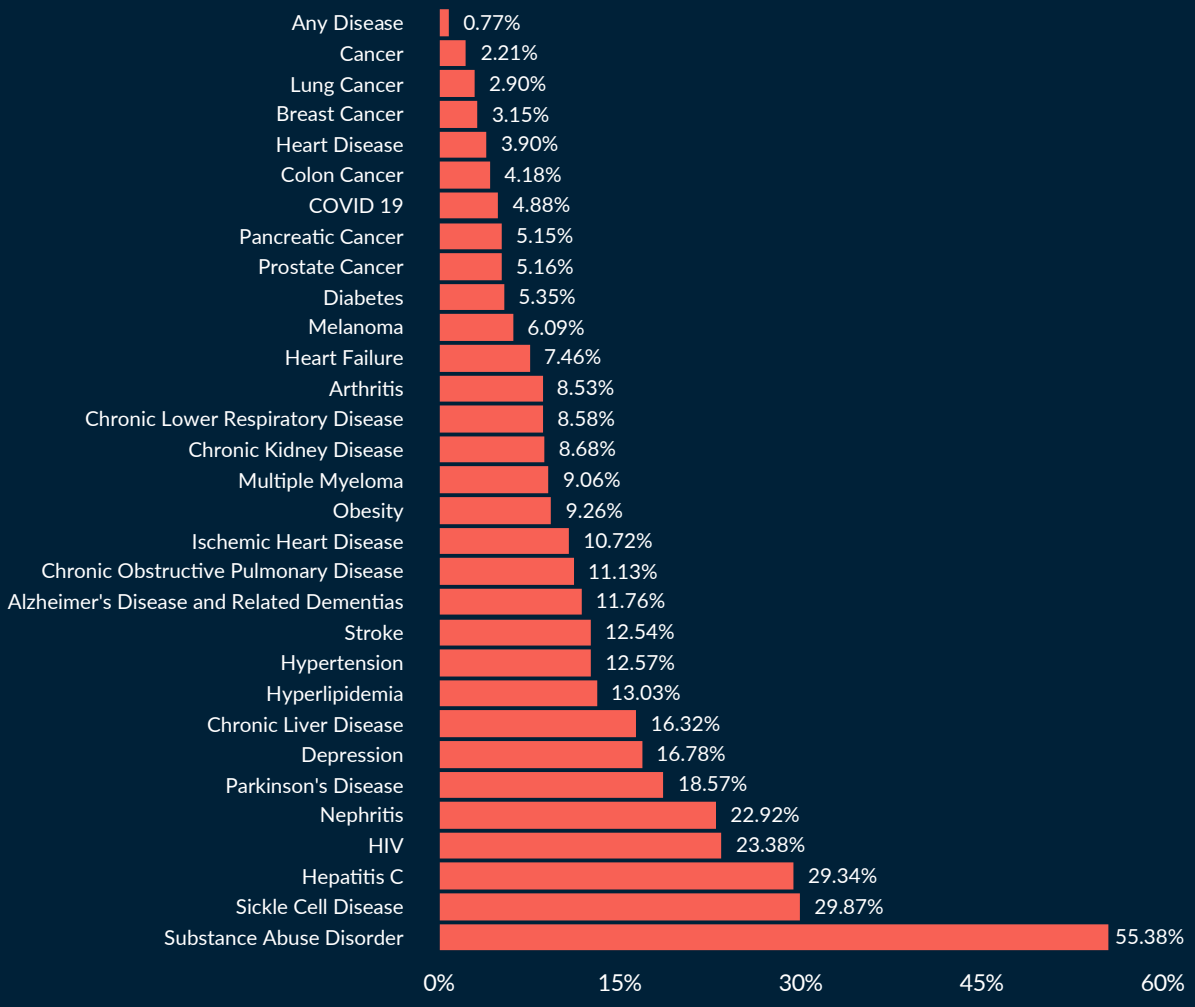


Source: AACT Database (2023), Milken Institute (2024)

Just 7.26 percent of counties are more than 60 miles from a clinical trial, and these counties are generally sparsely populated. Counties that are remote relative to any Phase 2 or 3 clinical trial account for only 0.77 percent of the total US population.

Living within 60 miles of a Phase 2 or 3 clinical trial does not mean that the clinical trial a person lives near is relevant to their health issues. Being close to cutting-edge research for cancer treatment does not help someone who would benefit from being close to cutting-edge research for the treatment of Alzheimer's disease. Figure 3 reports the share of the US population that resides in a county that is 60 miles or more from a Phase 2 or 3 clinical trial targeting the listed disease. The proportion of the population that lives in a remote county ranges considerably based on the type of illness.

Figure 3: Percent of Population Living over 60 miles from a Phase 2 or 3 Clinical Trial

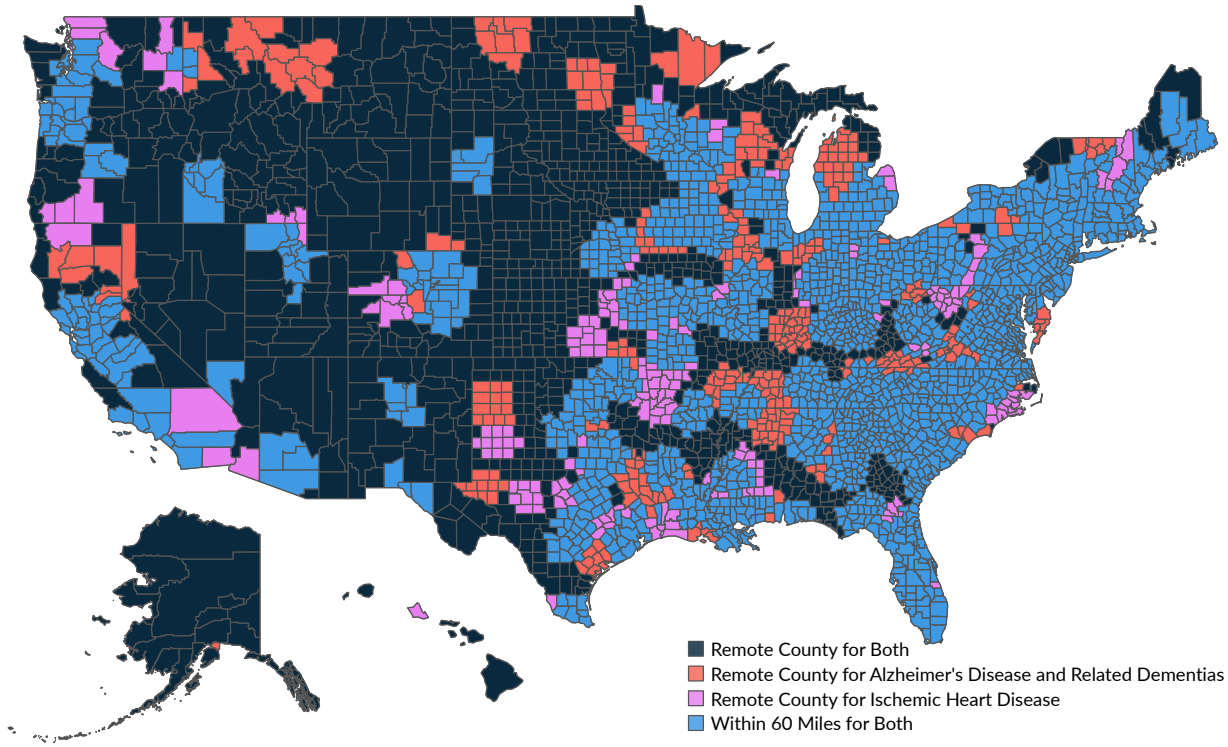


Source: AACT Database (2023), American Community Survey (2021), Milken Institute (2024)

Remote counties have the smallest footprint (in the size of the population living in a remote county) for cancers, diabetes, and heart failure. The diseases that have remote counties covering the largest portion of the population are hepatitis C, sickle cell disease, and substance abuse disorder. Substance abuse disorder has the largest population living in remote counties of all the diseases examined: Over 55 percent of the US population lives more than 60 miles away from a county that hosted a Phase 2 or 3 drug trial treating substance abuse disorder.

Because a clinical trial's location differs depending on the disease it studies, a single county may be remote for one disease but not for another, even if the remote counties for the two diseases cover similar-sized populations. For example, the remote counties for ischemic heart disease and for Alzheimer's disease and related dementias contain a similar share of the population (10.72 percent and 11.76 percent, respectively) but have different geographic footprints, as shown in Figure 4.

Figure 4: Remote Counties for Two Different Diseases



Source: AACT Database (2023), Milken Institute (2024)

Though there is considerable overlap in remote counties based on clinical trials for each of these diseases (shown in dark blue), there are notable differences in each disease's remote county footprint. Counties that are remote for Alzheimer's disease and related dementias but are not remote for ischemic heart disease are shown in red. These places include many counties across the north-central US. Similarly, many counties are remote for ischemic heart disease but are not remote for Alzheimer's disease and related dementias (shown in pink). These places are common in the south-central US, particularly in Texas and Louisiana. The accompanying data visualization tool (which can be found here) maps remote counties for all diseases listed in Figure 3. The tool allows users to explore the differences in the location of remote counties as well as their demographics.

WHO LIVES IN REMOTE COUNTIES?

Remote counties tend to be rural, and their residents tend to experience worse health outcomes than their urban and suburban counterparts.[8] Only 16.2 percent of the counties classified as remote are in an area with at least one urban cluster, with the remaining 83.8 percent located in fully rural areas. In contrast, only 39.3 percent of non-remote counties are rural. The rurality of remote counties is also reflected in population density: The average county within 60 miles of a Phase 2 or 3 clinical trial has 112,279 people per square mile, whereas the average county outside the 60-mile radius has just 11,164 people per square mile.

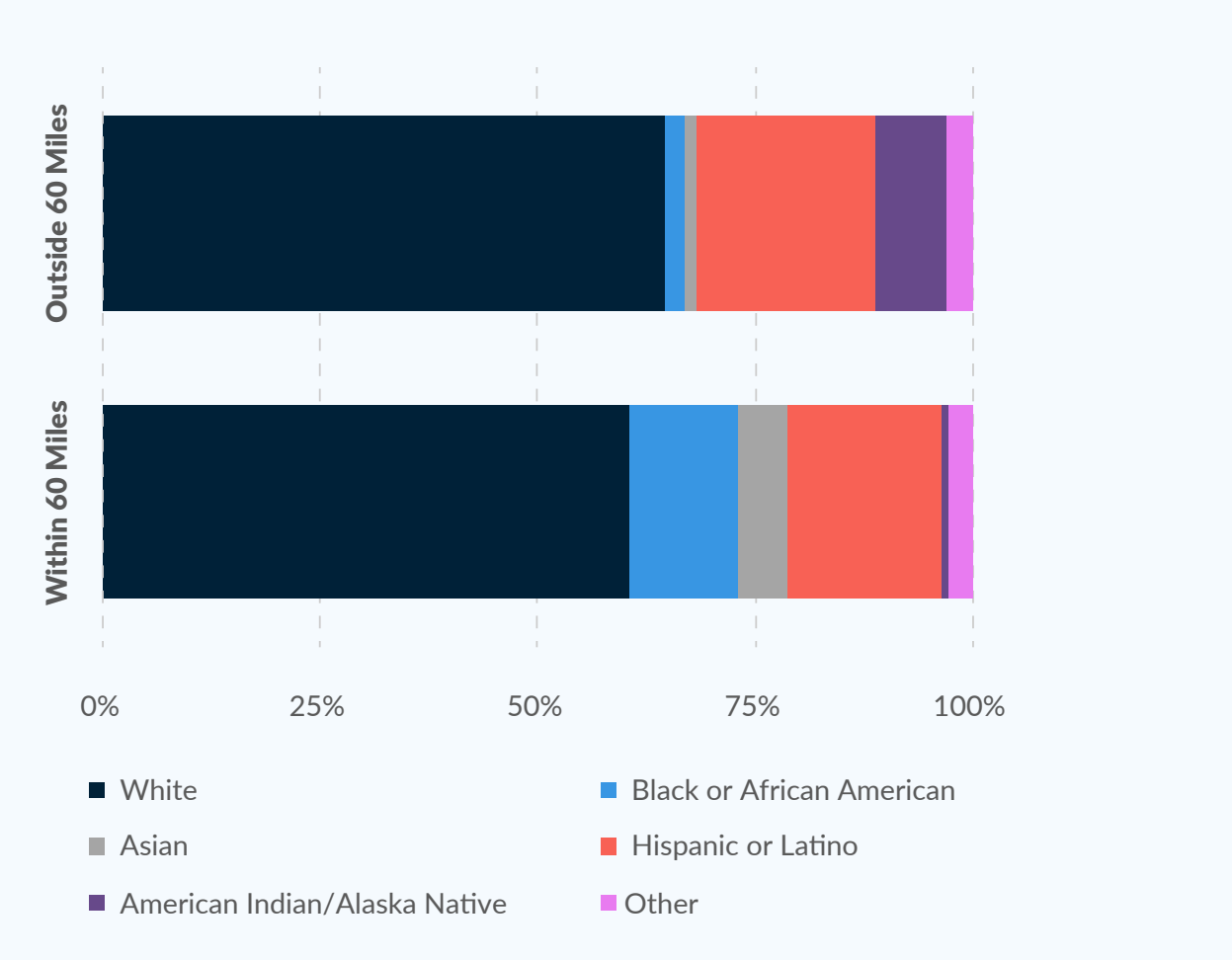
Given their distinctive geography, it is not surprising that remote counties are home to a population with demographic characteristics that differ from the rest of the US population. Remote counties tend to be low-income areas, with an average median household income of $55,185, compared to $65,973 in counties within 60 miles of a clinical trial. This difference is largely due to a smaller proportion of the population earning $150,000 or more (8.4 percent compared to 14.7 percent in non-remote counties), though the proportion of people below the poverty level is also higher in remote counties (15.6 versus 13.4 percent in non-remote counties; see Figure 5b).

In addition to having lower income on average, people living in remote counties have other demographics that are correlated with economic vulnerability. Compared to counties within 60 miles of a clinical trial, remote counties have, on average, a higher proportion of residents with a disability (15.5 percent versus 12.6 percent) and a higher proportion of those uninsured (11.9 percent versus 8.8 percent). Remote county residents are less likely to have a bachelor's or higher educational degree and include a higher proportion of civilian veterans (9.7 percent versus 7.3 percent; see Figure 5b).

In racial composition, remote counties have, on average, a lower proportion of Black or African American[9] (2.2 percent versus 12.4 percent) and Asian populations (1.3 percent versus 5.5 percent) than non-remote counties. This means that remoteness is unlikely to be the barrier that underlies documented disparities in study enrollment based on these demographics.[10] In contrast, remote counties, on average, have a higher proportion (8.1 percent) of American Indian residents than counties within 60 miles of a trial (which have only 0.6 percent of the American Indian population). Last, the proportions of White and Hispanic or Latino populations are similar in both types of counties, with 64.7 and 60.7 percent of White and 20.7 and 18.0 percent of Hispanic populations in remote and non-remote counties, respectively (Figure 5a).

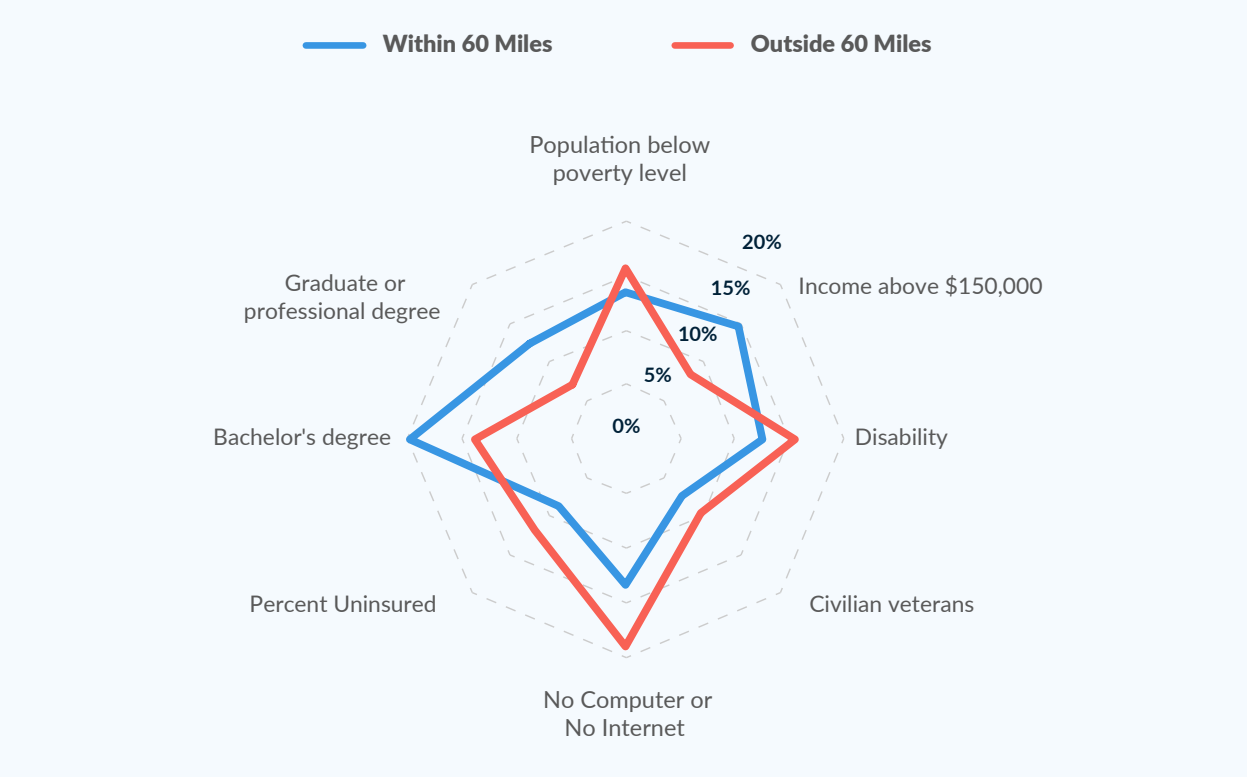
Figure 5: Selected Demographic Characteristics of Remote versus Non-remote Counties

Figure 5a: Racial Composition



Source: AACT Database (2023), Milken Institute (2024), American Community Survey (2019)

Figure 5b: Other Selected Demographics

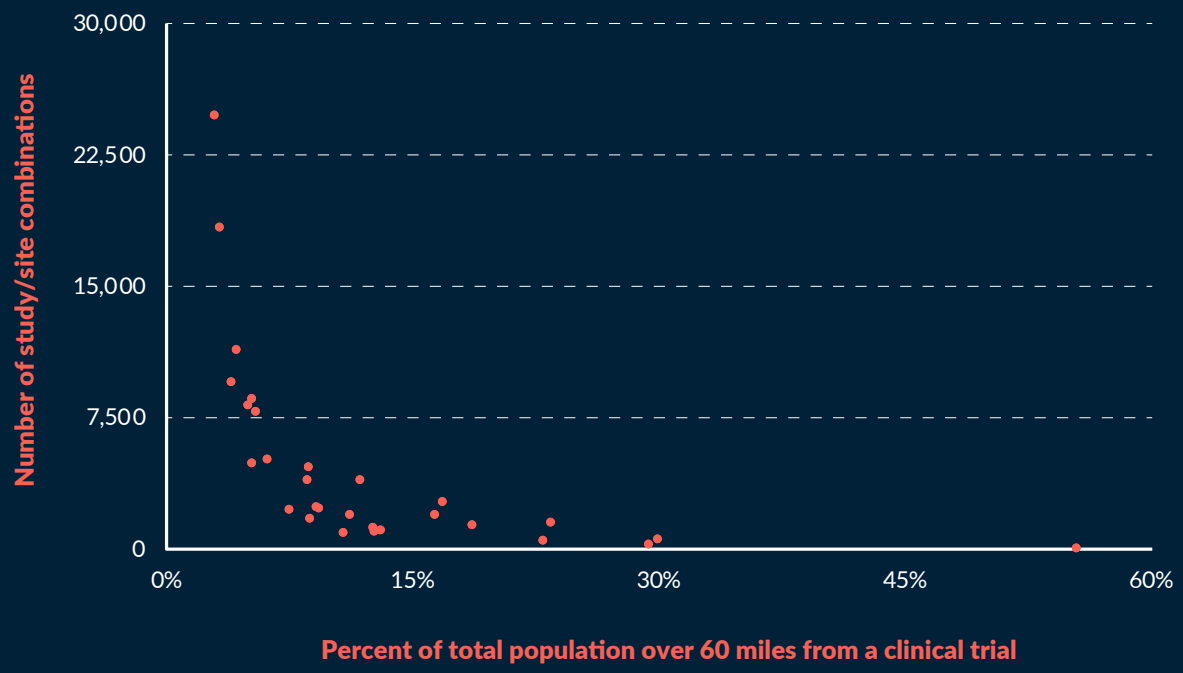


Source: AACT Database (2023), Milken Institute (2024), American Community Survey (2019)

Differences Based on Disease Studied

There is considerable variation in the land area and total population contained in remote counties based on the disease being studied. Depending on the disease, remote areas can be large and capture a sizable portion of the population. In general, as a disease is studied more frequently, a larger portion of the population falls within 60 miles of a study. This is shown in Figure 6, which plots one point for each disease. The percentage of the population that lives in a remote county for that disease is plotted on the horizontal axis and the number of study/site combinations for a given disease is on the vertical axis.

Figure 6: Intensity of Study for a Disease and Population Living in Remote Counties

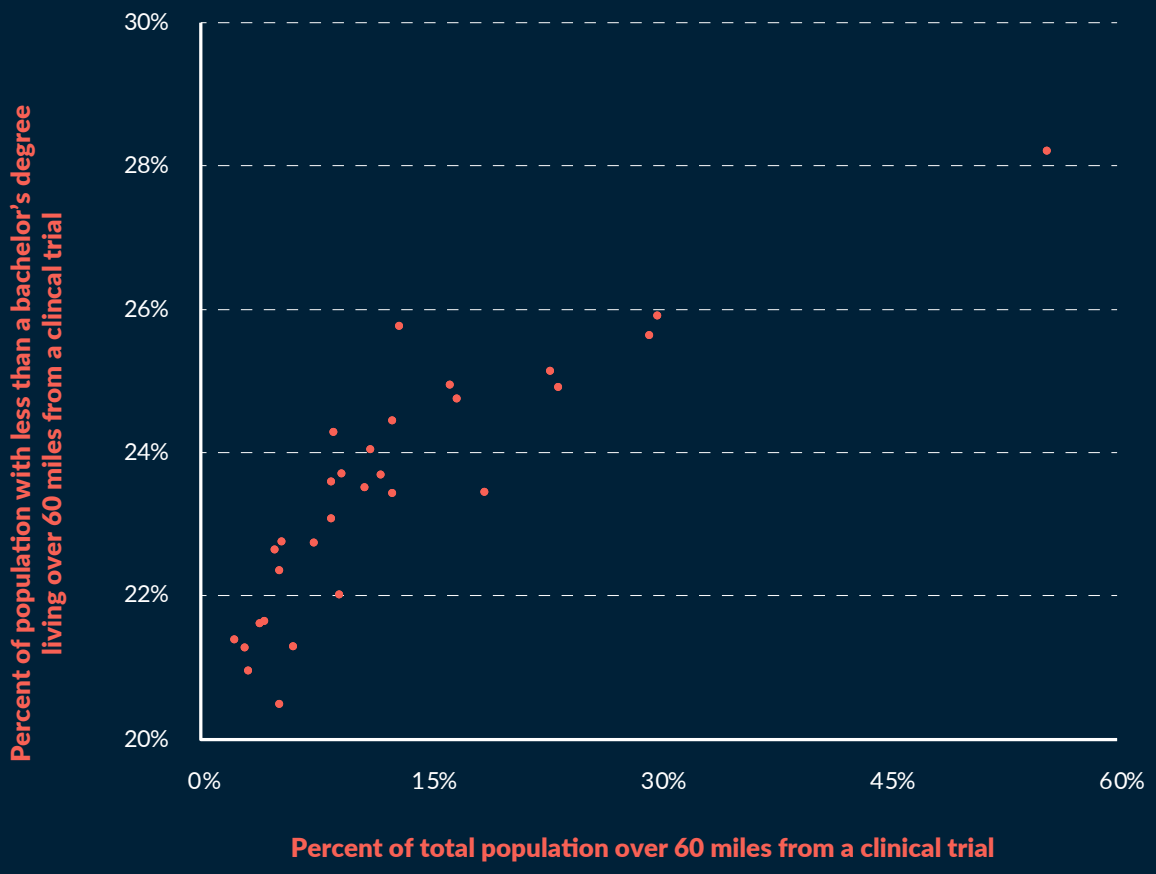


Source: AACT Database (2023), Milken Institute (2024)

Generally, as a given disease is studied more intensively (has more study/site combinations), the percentage of the population living in a remote county decreases. Or, to put it differently, the less frequently a disease is studied, the bigger the population living in remote counties. This relationship is approximately log-linear.

Clinical trials for diseases that cover a larger share of the population also tend to include a larger share of the population with low educational attainment in a remote county. This means that as clinical trials for a disease become more widespread, the counties that remain outside 60 miles from a clinical trial have a higher share of the population with a relatively low education. This is evidenced by Figure 7, which plots the US population that lives in a remote county and the remote counties' average education for clinical trials for different diseases. Each dot represents "remoteness" based on clinical trials for a specific disease. There is a positive association between how much of a population is over 60 miles from a trial for that disease and the average education of that population. In other words, as clinical trials for different diseases each cover smaller and smaller geographies (leaving larger and larger geographies as remote), the areas that are remote start to include locations that are more densely populated and populations that are more highly educated on average.

Figure 7: Population Living in a Remote County and Educational Level of That Population



Source: AACT Database (2023), Milken Institute (2024), American Community Survey (2019)

A similar pattern can be seen with the percentage of a population with a disability. As we move from diseases with clinical trials that cover a smaller area to diseases with clinical trials that cover a broader area, the counties that remain outside 60 miles' distance from a clinical trial have a higher share of individuals with a disability.

This is evidenced by Figure 8, which plots the US population that lives in remote counties, and the remote counties' rates of disability for clinical trials for different diseases. Each dot represents a definition of "remote" that is based on clinical trials for a specific disease. There is a negative association between the size of the population over 60 miles from a trial for that disease and the average education of that population. In other words, as clinical trials for different diseases each cover smaller and smaller geographies (leaving larger and larger geographies as remote), the remote areas start to include locations with lower rates of disability on average.

Figure 8: Population Living in a Remote County and Percent of That Population with a Disability

Source: AACT Database (2023), Milken Institute (2024), American Community Survey (2019)

While these patterns are informative, many potential demographics are interrelated, and any one demographic cannot fully describe a location. This leads to a more fundamental question: What types of places are more likely to be far away from clinical trials? The answer requires a more holistic view of how demographic characteristics move in tandem.

To accomplish this, we turn to the Community Explorer, a tool that breaks counties in the US into "community profiles" based on common demographic characteristics, using a machine learning model.[8] We then calculate the distance to a Phase 2 or 3 clinical trial for the average person living within each community profile for each disease.

Figure 9: Average Distance to a Clinical Trial by Community Profile

	Urban Core	Affluent Suburbs	College Towns	Lower-Middle Class	Middle Class	Retiree Communities	Manufacturing Midwest	Low-Wage Manufacturing	Black South	White Appalachia	Hispanic Southern Border	Isolated Seniors	Hispanic Agriculture	Great Plains	American Indian Reservations
Alzheimer's Disease and Related Dementias	0.7	15.3	22.9	23.9	36.5	46.0	48.8	49.4	49.8	53.6	27.8	78.0	94.1	171.2	169.3
Any Disease	0.0	0.6	0.9	1.8	2.6	9.8	12.4	15.5	20.1	17.3	4.5	35.6	31.2	51.8	26.3
Arthritis	0.8	9.0	12.3	19.1	21.9	36.5	46.0	39.6	53.7	42.4	26.8	70.8	67.1	102.7	106.6
Breast Cancer	0.0	1.4	5.0	7.7	7.4	16.2	17.1	27.0	37.7	29.4	18.6	53.3	48.8	58.5	96.0
Cancer	0.0	1.0	4.0	4.8	6.2	13.0	15.2	23.5	33.1	26.1	14.9	49.2	42.3	56.2	96.0
Chronic Kidney Disease	1.2	17.9	17.4	18.8	31.0	43.1	41.3	40.1	39.6	53.4	37.4	80.5	75.6	124.3	96.4
Chronic Liver Disease	2.4	24.6	25.8	33.8	45.1	59.1	57.1	53.8	55.2	71.1	89.5	90.6	92.6	146.3	160.9
Chronic Lower Respiratory Disease	0.7	15.6	14.5	18.7	29.1	38.1	41.7	37.3	43.9	45.0	36.7	70.9	85.9	132.1	116.6
Colorectal Cancer	0.0	2.9	5.3	9.7	9.4	21.2	18.1	30.3	42.2	32.9	31.7	53.1	56.7	61.5	96.0
Chronic Obstructive Pulmonary Disease	2.1	23.1	19.5	24.3	33.9	41.1	50.0	41.9	48.4	49.5	42.0	76.7	97.4	142.8	120.4
COVID-19	0.3	5.8	8.0	11.6	17.2	28.6	35.3	33.4	35.9	42.7	21.6	60.0	52.7	83.4	35.1
Depression	1.1	17.5	31.9	33.9	45.3	55.7	57.4	54.2	60.7	74.4	96.1	88.6	116.5	207.7	201.3
Diabetes	0.1	13.5	8.2	13.4	20.5	31.9	37.2	33.6	35.0	44.4	19.3	68.5	65.9	104.1	103.9
Drug Abuse	61.5	52.5	105.8	118.4	101.7	127.9	111.2	123.6	148.0	114.0	204.2	156.3	162.4	279.0	230.6
Heart Disease	0.1	4.1	6.1	9.1	11.2	25.3	30.7	29.7	33.3	36.9	21.3	62.1	53.8	86.2	112.0
Heart Failure	1.2	7.9	14.0	17.4	21.6	35.2	39.1	37.4	41.2	51.5	63.3	72.7	64.1	101.7	122.6
Hepatitis-C	10.9	36.8	60.5	67.0	64.5	78.5	70.4	75.6	80.7	92.2	201.8	134.9	150.9	241.0	267.3
HIV	1.8	30.6	45.1	47.2	58.8	65.0	71.3	69.5	69.4	89.9	111.2	107.2	127.9	222.7	211.6
Hyperlipidemia	2.1	21.5	28.6	25.5	38.8	45.4	50.7	41.4	48.1	54.8	41.9	80.7	86.7	124.9	138.2

	Urban Core	Affluent Suburbs	College Towns	Lower-Middle Class	Middle Class	Retiree Communities	Manufacturing Midwest	Low-Wage Manufacturing	Black South	White Appalachia	Hispanic Southern Border	Isolated Seniors	Hispanic Agriculture	Great Plains	American Indian Reservations
Hypertension	2.7	20.9	22.1	27.7	38.6	49.9	52.3	43.4	50.1	61.9	86.0	87.7	102.7	145.3	158.1
Ischemic Heart Disease	4.2	11.0	21.4	20.6	24.4	40.8	43.1	42.9	48.3	52.6	42.0	75.8	72.4	119.6	141.2
Lung Cancer	0.1	2.0	4.4	6.4	7.9	14.7	16.7	26.8	36.4	29.4	24.8	52.0	45.5	56.9	96.1
Melanoma	1.4	5.1	8.3	14.6	13.2	28.2	23.1	38.3	53.0	43.6	62.3	60.0	57.0	68.8	101.2
Multiple Myeloma	0.9	8.9	15.9	21.3	19.7	34.0	28.3	44.5	53.8	41.9	118.5	70.9	91.6	79.6	112.2
Nephritis	6.9	29.0	47.4	47.0	49.7	72.7	65.5	66.0	72.9	81.7	106.3	109.6	118.4	218.9	200.8
Obesity	1.2	16.6	16.8	19.8	29.7	43.3	42.6	40.6	42.5	56.9	31.4	76.2	74.5	122.4	144.4
Pancreatic Cancer	0.1	5.1	8.0	13.4	12.8	26.8	21.7	33.4	45.5	33.9	31.8	54.7	58.0	72.5	135.4
Parkinson's Disease	4.3	23.3	27.3	40.9	43.3	57.7	61.8	58.2	67.0	58.7	107.8	95.0	107.8	197.1	198.5
Prostate Cancer	0.1	2.6	6.2	11.3	9.9	19.4	20.7	34.7	44.0	36.4	102.4	56.5	62.3	71.5	101.8
Sickle Cell Disease	8.0	38.0	59.4	63.6	79.7	83.2	78.0	73.8	75.3	105.0	210.5	136.8	173.1	250.8	272.3
Stroke	4.5	20.7	21.4	27.1	34.0	55.5	44.5	45.9	61.6	49.8	44.4	88.4	84.0	116.3	148.7

Source: AACT Database (2023), Milken Institute (2024), American Community Survey (2019)

The results of this exercise are presented in Figure 9. Descriptions of each community profile can be found in the Appendix, and in-depth information on the Community Explorer and each community's demographic profile can be found by accessing the Community Explorer interactive tool. Each cell in Figure 9 reports the distance to the nearest county, with a clinical trial for the disease in each row for the average person living in the community profile in each column. Cells over 60 miles from the nearest county with a trial (meaning that the average person in that community profile lives in a remote county for that disease) are shaded, with darker colors signifying a greater distance to the nearest Phase 2 or 3 clinical trial.

A few patterns emerge. The first is based on disease. Unsurprisingly, the diseases that have the greatest number of community profiles with the average person living in a remote county are those diseases with the largest number of remote counties, as shown in Figure 3: substance abuse disorder, sickle cell disease, hepatitis C, and HIV. The remaining patterns of note are based on the community profiles. There is only one profile for which the average resident is never in a remote county: Affluent Suburbs. The Urban Core community profile also rarely has its average resident in a remote county. The average Urban Core resident is only in a remote county for trials relating to substance abuse disorder.

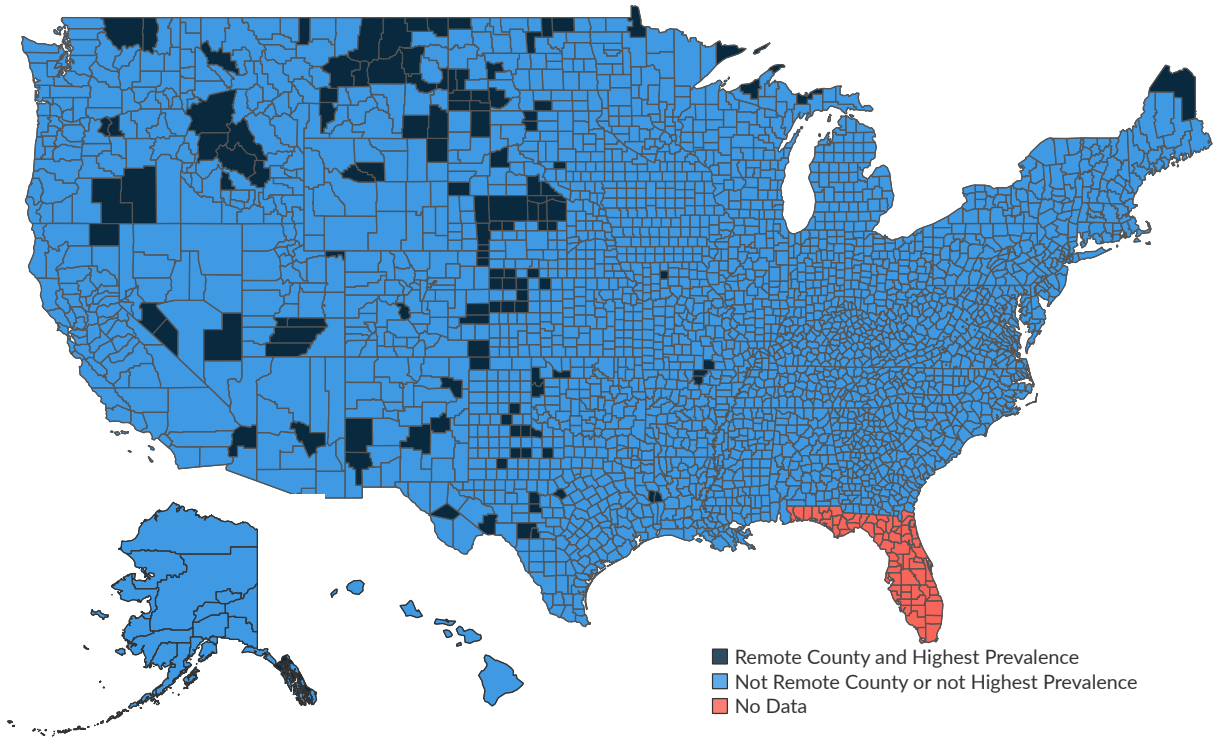
The community profiles that most commonly have their average resident living in a remote county are the Isolated Seniors, Hispanic Agriculture, Great Plains, and American Indian Reservations. The problem of being geographically isolated from places hosting Phase 2 and 3 clinical trials is especially pronounced for these final two community profiles, where the average person frequently lives more than 120 miles from the nearest relevant Phase 2 or 3 clinical trial.

Differences Based on Disease Prevalence

Counties over 60 miles from a clinical trial are particularly problematic if the population of the remote counties has a high prevalence of the disease that the trials are seeking to treat. To explore the extent to which this may be the case, we register the rate of prevalence of the disease in the population of each county. This allows us to rank counties based on disease prevalence. We then map counties that are both over 60 miles from the nearest trial for that disease and in the top quarter of all counties nationally for the prevalence of that disease. The resulting maps are shown in Figure 10a-d.

Figure 10: High-Prevalence Remote Counties for Selected Diseases

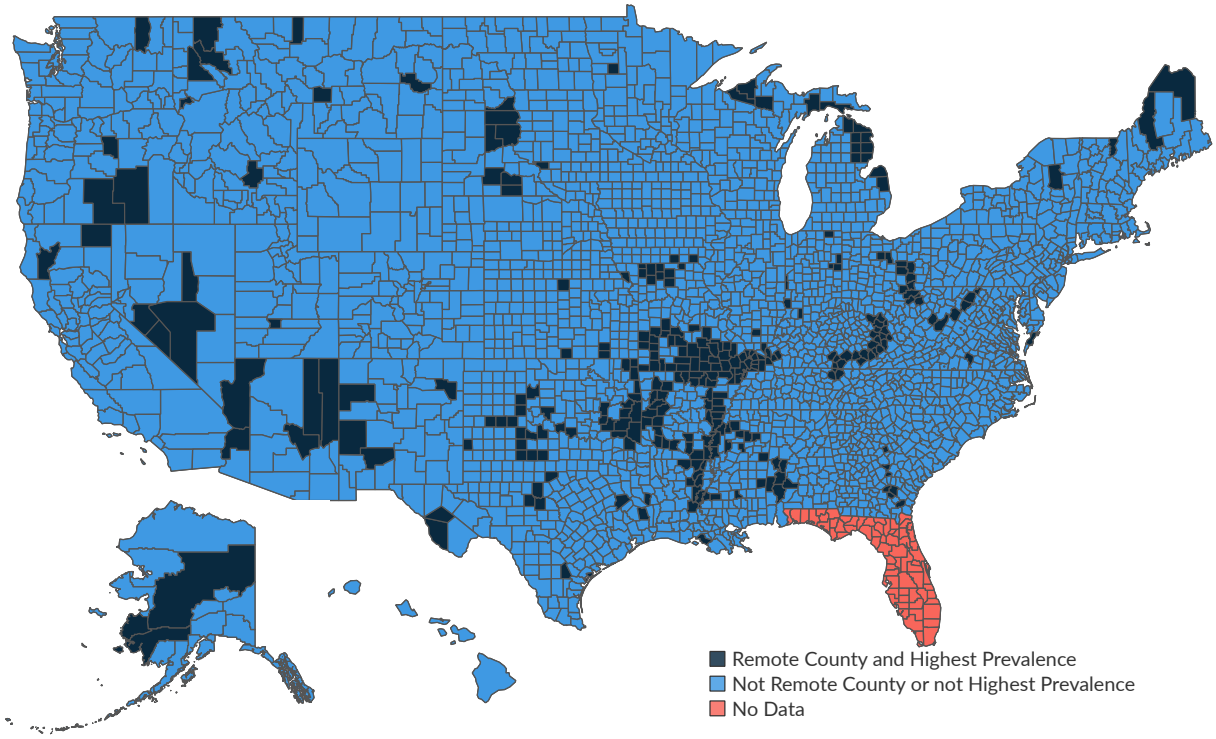
Figure 10a: High-Prevalence Remote Counties for Cancer



Source: AACT Database (2023), Centers for Disease Control and Prevention (2023), Milken Institute (2024)

There are many high-prevalence remote counties for cancer. They are predominantly located in the northern US in places such as Montana, Idaho, and the Dakotas, as well as in Plains States, such as Kansas and Nebraska. Almost the entire US east of the Mississippi River (except for a small number of counties along the Canadian border) is free from high-prevalence remote counties for cancer. There are also no high-prevalence remote counties for cancer along the entire west coast of the US.

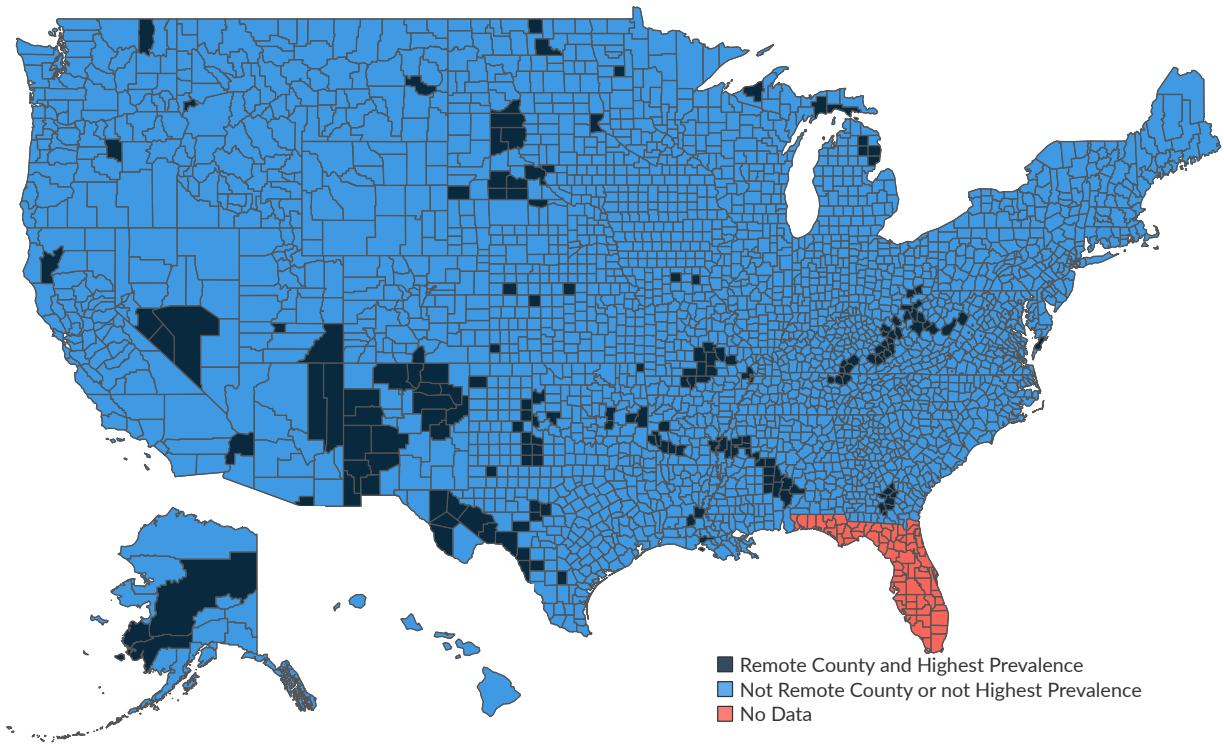
Figure 10b: High-Prevalence Remote Counties for Chronic Obstructive Pulmonary Disease



Source: AACT Database (2023), Centers for Disease Control and Prevention (2023), Milken Institute (2024)

High-prevalence remote counties for chronic obstructive pulmonary disease have a very different footprint from those for cancer. The most noticeable difference is the concentration of high-prevalence remote counties for chronic obstructive pulmonary disease clustered on the southern Mississippi River, particularly on the western side in Missouri, Arkansas, and Louisiana, as well as in parts of Mississippi and Oklahoma. There are also sizable clusters of these high-prevalence remote counties in the western US and northern Michigan.

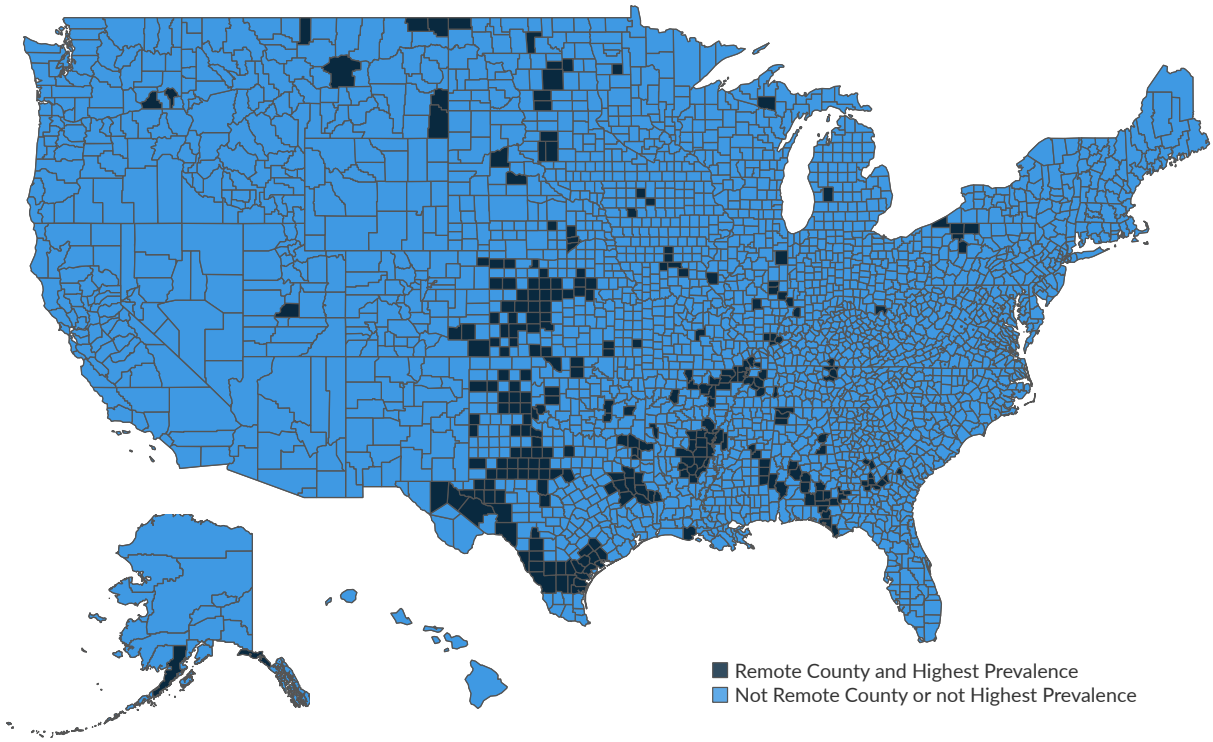
Figure 10c: High-Prevalence Remote Counties for Diabetes



Source: AACT Database (2023), Centers for Disease Control and Prevention (2023), Milken Institute (2024)

High-prevalence remote counties for diabetes cover most of the landmass in New Mexico, as well as sizable clusters in western Texas, central Mississippi (into parts of Alabama), and in the center of the Appalachian Mountains, particularly in West Virginia and Kentucky. The coastal regions of the US have very few high-prevalence remote counties for diabetes, with the entire northeastern US, including all of New England, New York, Pennsylvania, New Jersey, and Delaware, completely devoid of high-prevalence remote counties for diabetes.

Figure 10d: High-Prevalence Remote Counties for Alzheimer's Disease and Related Dementias



Source: AACT Database (2023), Centers for Medicare and Medicaid Services (2023), Milken Institute (2024)

High-prevalence remote counties for Alzheimer's disease and related dementias are predominantly located in the central and southern US, with large pockets in Texas, Oklahoma, Kansas, Louisiana, and Arkansas. Both the east and west coasts are free of these high prevalences, with Georgia, Florida, and Washington being the only states on the east or west coasts with any high-prevalence remote counties. Unlike other diseases, there are also no high-prevalence remote counties for Alzheimer's and related dementias in Arizona, New Mexico, Wyoming, or Nevada.

LIMITATIONS

This report measures the distance from each county to the nearest county hosting a Phase 2 or 3 clinical trial. This is meant to be a proxy for the time cost for study participation. While county-to-county distance is likely a decent proxy for travel time over long distances, it does not account for difficulties common across shorter distances (for example, within a city), such as traffic congestion or lack of transportation options.

The presence of a clinical trial in a county only means that the travel distance is small based on this proxy measure. It does not mean that travel is necessarily easy or low-cost for an individual living in that county. To put it differently, distance is likely to be correlated with time cost to get to a clinical trial but is not the only relevant variable. This report does not capture other dimensions of the cost of participation that may prevent someone from participating in a clinical trial, such as an inability to take off time from work, lack of insurance, or mistrust in the health-care system.

A second limitation is this report's singular focus on Phase 2 and 3 clinical trials. This limits study to drug trials and excludes other clinical trials, such as trials of diagnostic imaging, surgeries, or behavioral interventions. This was done because drug trials are subject to mandatory reporting to ClinicalTrials.gov, and other interventions are not, which would call into question the completeness of the analysis.

CONCLUSION

Remote counties are problematic as they represent locations where it is difficult to participate in Phase 2 and 3 clinical trials due to large travel distances. Though travel distance is not the only relevant barrier to participation in clinical trials, it is one of the easiest to identify and has potential remedies. Having clear documentation of where remote counties are, and for which types of diseases, allows for better targeting of advancements, such as decentralized clinical trials and the use of digital health technologies.[11]

Through that lens, this report serves not just as documentation of where there is an access problem, but as documentation of places where the expansion of clinical trials would make large improvements. For example, if one were to deploy decentralized clinical trials for diabetes treatment, then targeting such trials to remote counties with high prevalence of diabetes would be likely to yield greater benefits. Remote counties are a shortcoming but also an opportunity in the current clinical trial system. Places with access problems are also places with populations that can enrich study sampling, and with populations that have a lot to gain from improved access to emerging technologies.

APPENDIX

Table A1: Demographic Characteristics of Remote versus Non-remote counties

	Within 60 Miles	>60 Miles	Percent Difference
Income			
Median household income	65973.44	55184.92	-16.4%
Less than $25,000 (%)	19.05	22.77	19.5%
$150,000 or more (%)	14.70	8.39	-42.9%
Population below poverty level	13.39	15.60	16.5%
Racial Composition			
White alone	60.71	64.74	6.6%
Black or African American	12.38	2.18	-82.4%
Asian	5.49	1.25	-77.2%
Hispanic or Latinx	17.96	20.65	15.0%
Other	3.46	11.18	222.9%
Educational Attainment (at age 25+)			
No high school diploma	12.03	12.72	5.7%
High school graduate	26.82	31.79	18.5%
Some college, no degree	20.43	25.26	23.6%
College or graduate degree	40.72	30.24	-25.7%
Other Relevant Demographics			
Median age	38.40	39.27	2.3%
Households with people 65 years and over	29.21	32.31	10.6%
Disability	12.59	15.46	22.7%
Disability 65 years and over	73.41	84.21	14.7%
Percent uninsured	8.80	11.90	35.2%
Civilian veterans	7.29	9.70	33.1%
Unemployment rate	5.39	5.94	10.1%
No computer or no internet	13.45	19.03	41.4%

Source: AACT Database (2023), Milken Institute (2024), American Community Survey (2019)

Table A2: Community Explorer Profiles for the Contiguous US (from Most to Least Populous)

Profile Name	Description
Urban Core	Prosperous, ethnically and linguistically diverse large metro areas with substantial disparities between their highly educated and less educated residents (26 percent of the US population)
Affluent Suburbs	Affluent and more populous (but less diverse) suburban and small metro counties that jointly represent the profile with the highest median income (16 percent of the US population)
College Towns	Communities where colleges are located with a relatively young, highly educated, and highly geographically mobile population (5.4 percent of the US population)
Lower-Middle Class	Less populous suburban and small metro counties that are not as economically prosperous as the rest of Urban America (18 percent of the US population)
Middle Class	Middle-income communities with a largely White population that resides in large- to medium-sized suburban and small metro counties (14 percent of the US population)
Retiree Communities	Communities with a large retiree population with adequate household incomes and access to economic resources (4.5 percent of the US population)
Manufacturing Midwest	Counties mostly located along the US southern border with a majority of a relatively young Hispanic or Latino population living in extreme poverty (1.4 percent of the US population)
Isolated Seniors	Geographically isolated (i.e., living alone) seniors with high disability rates and relatively low incomes (0.6 percent of the US population)
Lower-Middle Class	Less populous suburban and small metro counties that are not as economically prosperous as the rest of Urban America (18 percent of the US population)
Low-Wage Manufacturing	Low-wage workers in the manufacturing and chemical industries located largely in the South and Northeast regions of the country, with an above-average proportion of the population living below the poverty line (4.9 percent of the US population)

Manufacturing Midwest	Counties primarily located in the Midwest that form the profile with the highest proportion of the White population working in the manufacturing sector (5.2 percent of the US population)
Isolated Seniors	Geographically isolated seniors with high disability rates and relatively low incomes (0.6 percent of the US population)
Hispanic Agriculture	Highly agricultural communities with a higher-than-average concentration of Hispanic or Latino population residing mostly in the West and South (1.2 percent of the population)
Great Plains	Agricultural counties located in the Great Plains with a high proportion of the White population (0.3 percent of the population)
American Indian Reservations	American Indian reservation communities living in extreme poverty with more than one-third of the population with income below the poverty line (0.1 percent of the population)

ENDNOTES

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3. Claude Lopez and Brittney Butler, *Informing Policy with County-Level Data: The Community Explorer* (Milken Institute, April 2021), https://milkeninstitute.org/reports/community-explorer-county-level; Raj Chetty et al., "Where Is the Land of Opportunity? The Geography of Intergenerational Mobility in the United States," *The Quarterly Journal of Economics* 129, no. 4 (January 2014): 1553–1623, https://academic.oup.com/qje/article/129/4/1553/1853754.; Raj Chetty et al., "The Association between Income and Life Expectancy in the United States, 2001–2014," *JAMA* 315, no. 16 (April 26, 2016): 1750–1766, https://jamanetwork.com/journals/jama/article-abstract/2513561.

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6. Prevalence State Level: All Beneficiaries by Sex and Age, 2007–2018, Centers for Medicare and Medicaid Services, updated March 27, 2024, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/cc_prev_state_all_sex_age.zip.

7. In 2019, Valdez-Cordova Census Area in Alaska was divided into two counties. We use the pre-2019 county classification in our analysis, which includes 3,142 US counties, for matching purposes to the pre-2017 AACT data.

8. Arthur G. Cosby et al., "Growth and Persistence of Place-Based Mortality in the United States: The Rural Mortality Penalty," *American Journal of Public Health* 109, no. 1 (January 2019): 155–162, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6301407/.

9. Here and throughout the report we refer to racial or ethnic descriptions as recorded by the US Census Bureau. All racial or ethnic groups include only the non-Hispanic population (except for the Hispanic or Latino group, which includes the Hispanic population of any race).

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11. "The Evolving Role of Decentralized Clinical Trials and Digital Health Technologies", US Food and Drug Administration, May 2, 2023, https://www.fda.gov/drugs/cder-conversations/evolving-role-decentralized-clinical-trials-and-digital-health-technologies.

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