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Decentralized Clinical Trial (DCT) Strategies to Enhance Diversity and Inclusion of Underrepresented Patient Populations in Clinical Trials

Part of Life Science Strategy Group's Decentralized Clinical Trial (DCT) Strategies Series

Syndicated Publication

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About the Author

Life Science Strategy Group, LLC (LSSG) report authors draw upon extensive b[illegible]ulting and life science experience and backgrounds.

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Mr. Meyer is a Founder and Managing Member with the Life Science St[illegible]y Group, LLC (LSSG). Mr. Meyer leads LSSG's biopharmaceutical services consulting division which serves the leading global contract research organizations (CROs), contract drug manufacturing organizations, drug discovery and diagnostics companies globally across all phases of the biopharmaceutical discovery, development and commercialization lifecycle.

Mr. Meyer has managed consulting engagements in a variety of areas including strategic planning, opportunity assessments, pricing analyses, forecasting, brand awareness and equity assessments, competitive benchmarking, positioning and messaging strategy and clinical trial benchmarking and analysis.

Prior to LSSG, Mr. Meyer was a Director in the Life Sciences Division at Navigant Consulting, Inc. and conducted preclinical drug development in the department of inflammatory disease at Roche Bioscience. Mr. Meyer holds Masters Degrees in Biomedical Science and Business Administration.

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I. Study Background

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Study Background

Historically, women and non-white racial groups in the US have been underrepresented in clinical tr[illegible] the understanding of the safety and efficacy of new medical products. People of different backgrou[illegible]perience diseases differently, affecting the effectiveness of drugs, devices, biologics, and vaccines. T[illegible]epresentation can perpetuate health inequalities and exacerbate disparities in health outcomes. Inclusion of d[illegible]populations in clinical trials allows for a more complete understanding of safety and efficacy, improving health equity and ensuring new medical products are beneficial to all people in need. Further, advances in decentralized clinical trials (DCTs) have the potential to improve accessibility, diversity, and retention of underrepresented groups in clinical trials by simplifying trial elements and moving trial activities to participants' homes and local surroundings.

This landmark report is our second in our Decentralized Clinical Trial Strategies series, includes 467 clinical trial participants and 553 members of the general public from the United States and Europe. The report explores differences among racial groups and gender on willingness to participate in clinical trials, attitudes towards decentralized clinical trials and their impact on patient satisfaction and participation.

In the report, Life Science Strategy Group also provides commentary and interpretation of the data, which reflects more than 20 years of experience consulting to many of the leading global biopharmaceutical companies, clinical development CROs and CRO industry analysts. As such, for the purposes of this report, we are looking through the lens of our clients – specifically, what is the level of diversity and inclusion of underrepresented populations in clinical trials today and how can DCT elements potentially enhance patient participation and retention in these populations in the future.

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III. Methodology

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Report Methodology

Methodology

The primary research for this report was fielded via an internet survey in Fe[illegible] March 2023 and draws over four hundred and fifty clinical trial participants (n=467) a[illegible]dred and fifty members of the general public (n=553) from the United States and E[illegible]

Clinical trial respondents participated in one or two clinical trials for a[illegible] therapy in development in the past two years. They also had experience with a variety of clinical trial activities including both decentralized and traditional elements. Respondents from the general population had not participated in a clinical trial in the past two years. All study participants were prescreened by LSSG to ensure an accurate level of reflection upon their clinical trial (clinical trial respondents) or rationale for not participating (general population respondents). This included confirming consistency of answers for related questions, validation of companies, and knowledge-based quality control questions.

Clinical trial respondents were asked to provide information about the appeal of certain trial elements, and motivating factors for them joining their clinical trial. General population respondents were asked about their choice to have not participated in a clinical trial, and the influence of trial elements on their decision to participate in the future. To draw deeper conclusions, the data from this was segmented by race, gender, socioeconomic status, and insurance type. LSSG also included its experience and knowledge about the global biopharmaceutical and CRO industries, preferences and patient engagement practices.

All data analysis and reporting was performed by LSSG consultants.

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Terminology and Segmentation

Terminology

For the purposes of this report, the following clinical trial activities are considered[illegible]zed clinical trial strategies/approaches:

- Telemedicine/telehealth calls with a doctor
- Keeping an electronic patient diary
- Wearing a device that collects data and transmits/uploads it to the internet (e.g., Fitbit, ap[illegible]tch, continuous glucose monitor, etc.)
- Using a smartphone or tablet to record health information that is uploaded to the internet
- A nurse coming for an in-home visit during the trial
- A nurse coming for an in-home visit to administer treatment for the trial (e.g., an injection or IV infusion)
- Mailing treatment(s) for the trial mailed directly to the patient's house
- Logging into an online portal to participate in the trial
- Using online chat/support to ask questions and seek information
- Emailing a doctor

Racial categories are from the Office of Management and Budget (OMB) Standards: **White**, **Black or African American**, **Asian**, **American Indian or Alaska Native**, **Native Hawaiian or Other Pacific Islander**.

- For the purposes of this report, "Other" races includes American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, Prefer not to Answer, and Other

Segmentation

Respondents were classified into the following segments:

- ***Low-income***: respondents with a total household income of $0 - $30,000
- ***Mid-income***: respondents with a total household income of $31,000 - $60,000
- ***High-income***: respondents with a total household income of $91,000+

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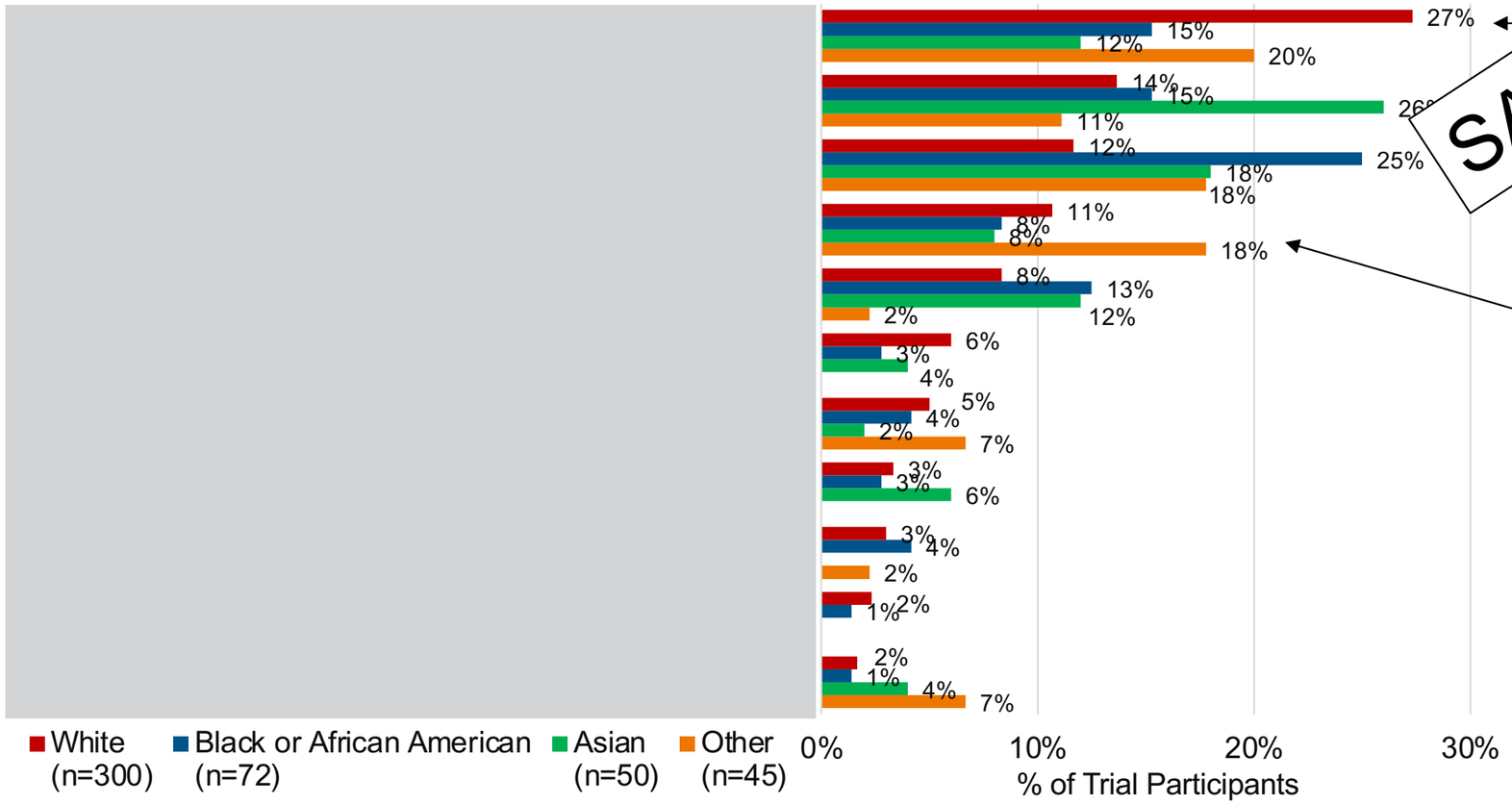
IV. Detailed Findings – Clinical Trial Participants

Where people first learn about clinical trials varies by race; most White and "Other" participants learn about trials from A, Asians find trials through B, and Black or African Americans f… ar of trials through C.

Source Where Patients First Learned About Their Clinical Trial



…learn about trials from …icans (34% vs. 18%, …vely).

Low-income participants learn about trials from Y at higher rates relative to high-income participants (26% vs. 10%, respectively).

More high-income participants learn about clinical trials from Z relative to lower income participants (36% vs. 11%, respectively).

Note: Trial participants listed other as mail/phone outreach (10x), other medical exposure (7x), or news/media (4x).

An omnichannel approach to patient-directed outreach, education, and promotional materials including A, B, and C can maximize awareness of trials across races.

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Source: Life Science Strategy Group, LLC

Clin Trial Q1. Where did you first learn about the clinical trial? Please select one.

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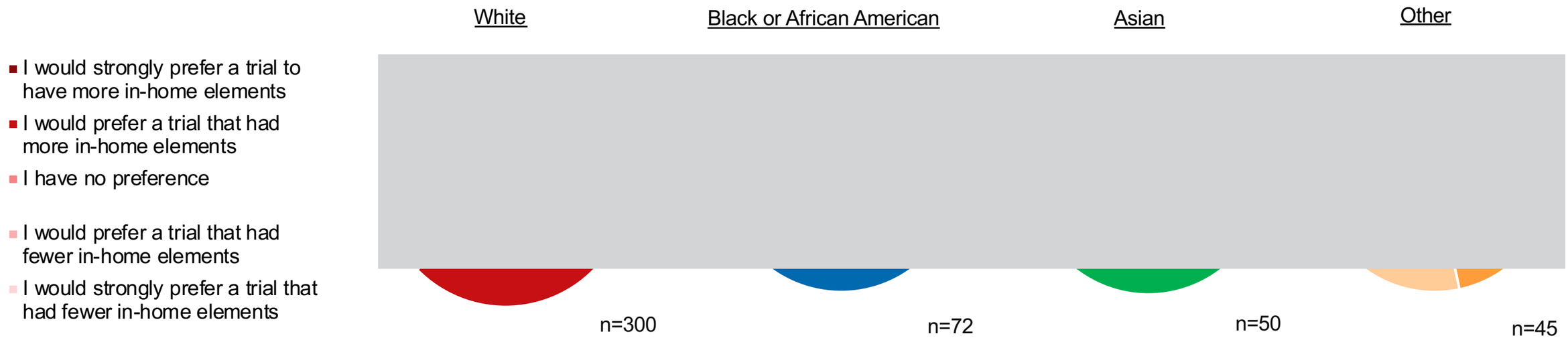
A, B, and C populations prefer/strongly prefer trials with more in-home elements compar[illegible] D (>X% of respondents vs. Y%, respectively)

- X respondents have a stronger preference for trials with in-home elements than Y (69% vs. 41%, respectively).
- A have no preference (55%), while both B and C have a stronger preference towards trials with in-home elements ([illegible]%, respectively).

Attitudes Toward Future Participation



Clinical trial outreach should emphasize X to drive greater participation.

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Q10. Which of the following statements would best describe your attitude if you were to participate in another clinical trial?

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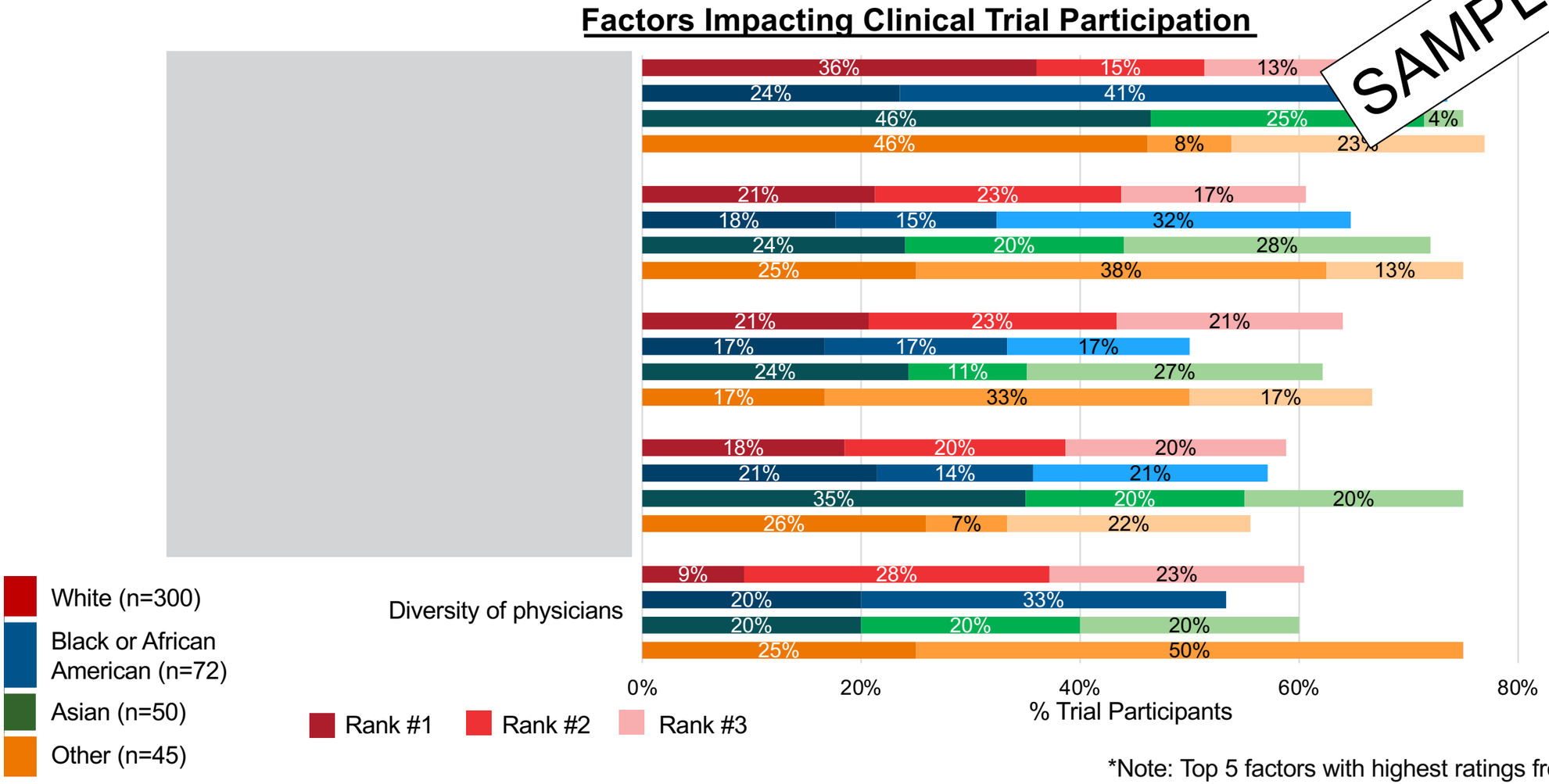
X is the most important factor impacting clinical trial participation across all races; Asian patients show preference to Y while “Other” patients desire Z when considering trial participation.

- X is ranked in the top-3 as most important for private insurance users at a higher rate than those with Medicaid (71% v… …ctively).



Note: Trial participants listed friendliness, ease of participation, convincing evidence, screening process, and lack of blood draws as “other.”

*Note: Top 5 factors with highest ratings from aggregate data displayed.

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Q11. When thinking about whether or not to join a particular clinical trial, how important are each of the following factors in your decision? Please rank order your top-5 factors based on their importance to you with rank 1=most important.

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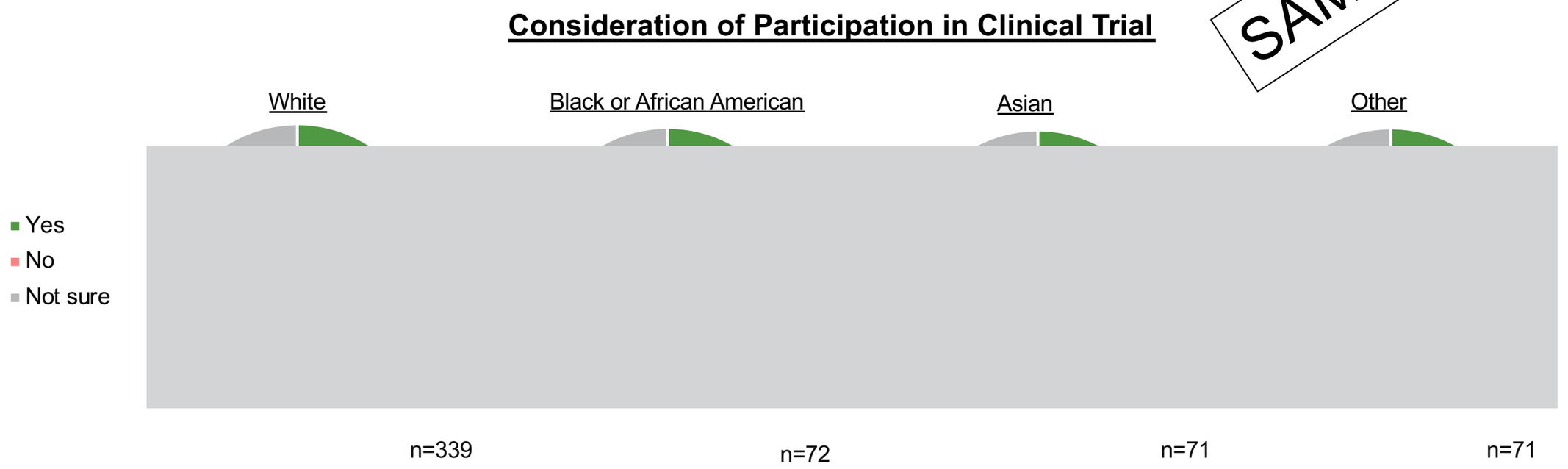
V. Detailed Findings - Clinical Trial Non-Participants

More A and B consider participating in clinical trials (X%) than C (Y%).

- A lower percentage of A consider participation in a clinical trial when compared to B and C (45% vs 59% and 59%, resp



"Other" includes American Indian or Alaska Native (18%), Native Hawaiian or Other Pacific Islander (4%), Other (66%), Prefer not to answer (11%)

Patient recruitment teams should X among the Asian and "Other" populations.

Source: Life Science Strategy Group, LLC

Q1. Have you ever considered participating in a clinical trial?

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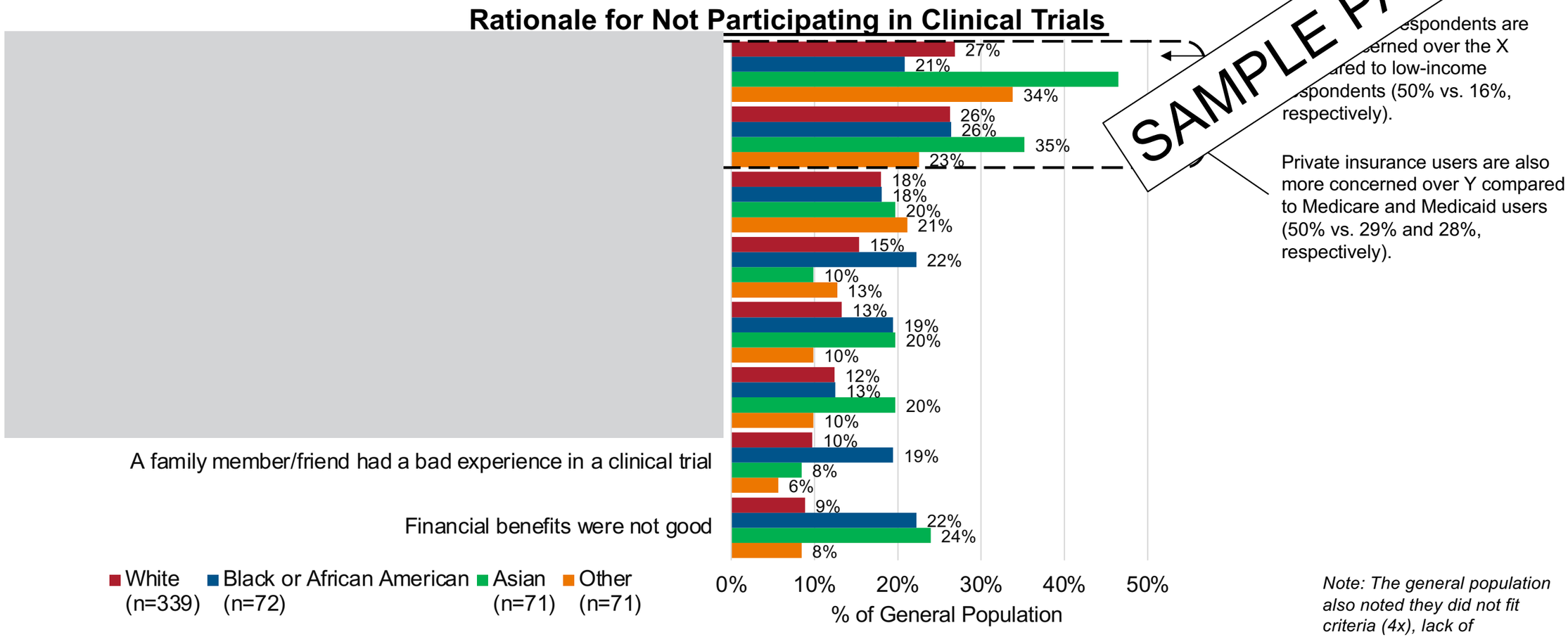
The primary reasons for non-participation in clinical trials, particularly among X, are con[illegible]s related to A and C.



Note: The general population also noted they did not fit criteria (4x), lack of availability (3x), none in area that they qualified for (2x), lack of transportation, allergic to medication, death of family member.

Providing A and B can help to assuage clinical trial safety concerns among non-participants.

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Source: Life Science Strategy Group, LLC

Q3. Why haven't you participated in a clinical trial? Please select all that apply.

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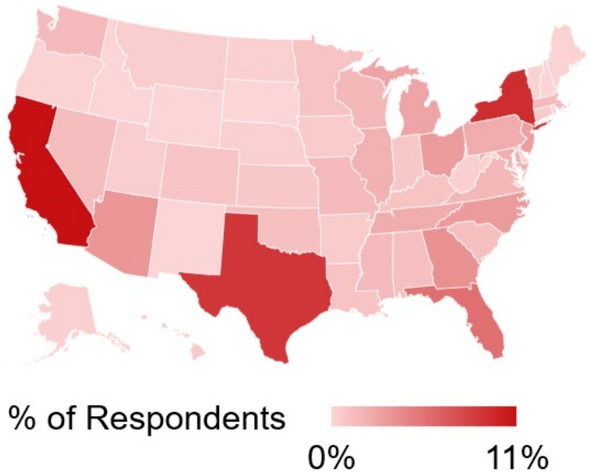
VI. Respondent Demographics

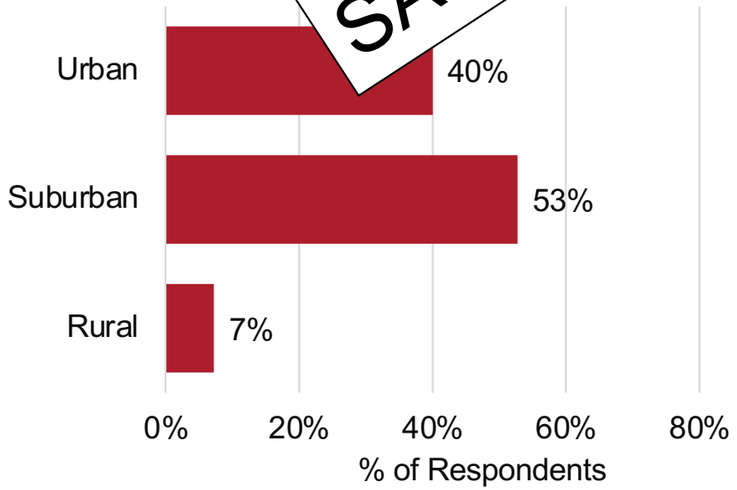
Respondent Demographics

- A total of 1020 respondents participated in LSSG's online quantitative survey.
- **63%** (n=647) of respondents were in North America and **37%** (n=373) in Europe.

State Representation

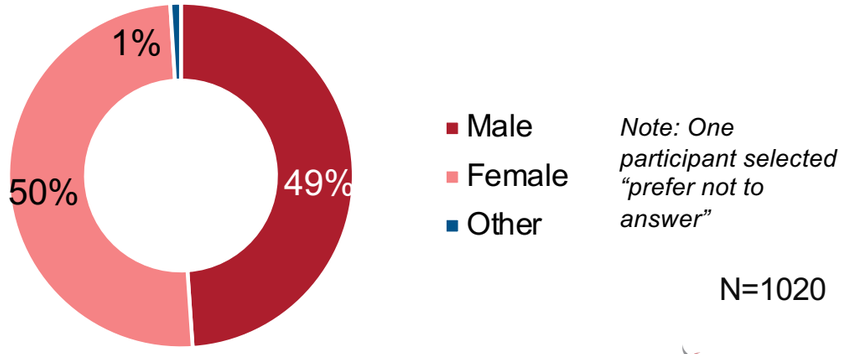


Community Type



Age Range (Years)

Gender



Note: One participant selected "prefer not to answer"

N=1020

S1. Where are you located?
S2. What state do you live in? (Note: if from Canada, put N/A)
S3. What best describes where you live?
S4. How old are you?
S5. With which gender do you identify?

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Source: Life Science Strategy Group, LLC

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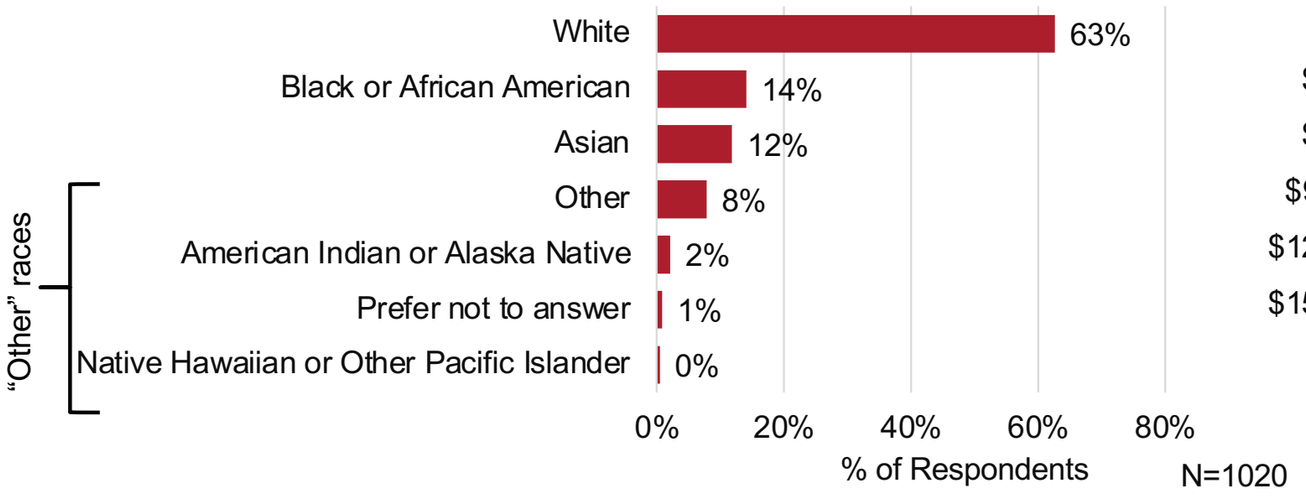
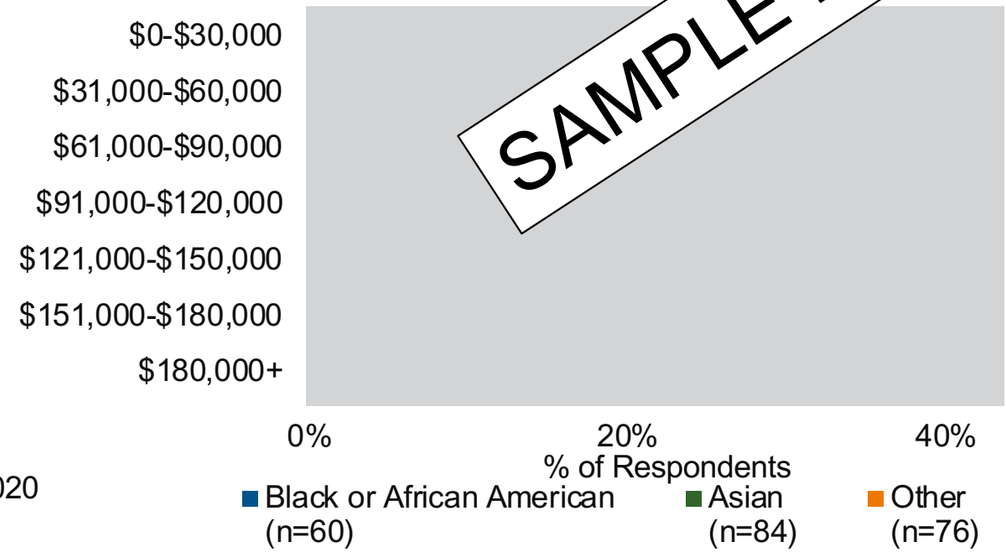
Respondent Demographics

Racial Categories

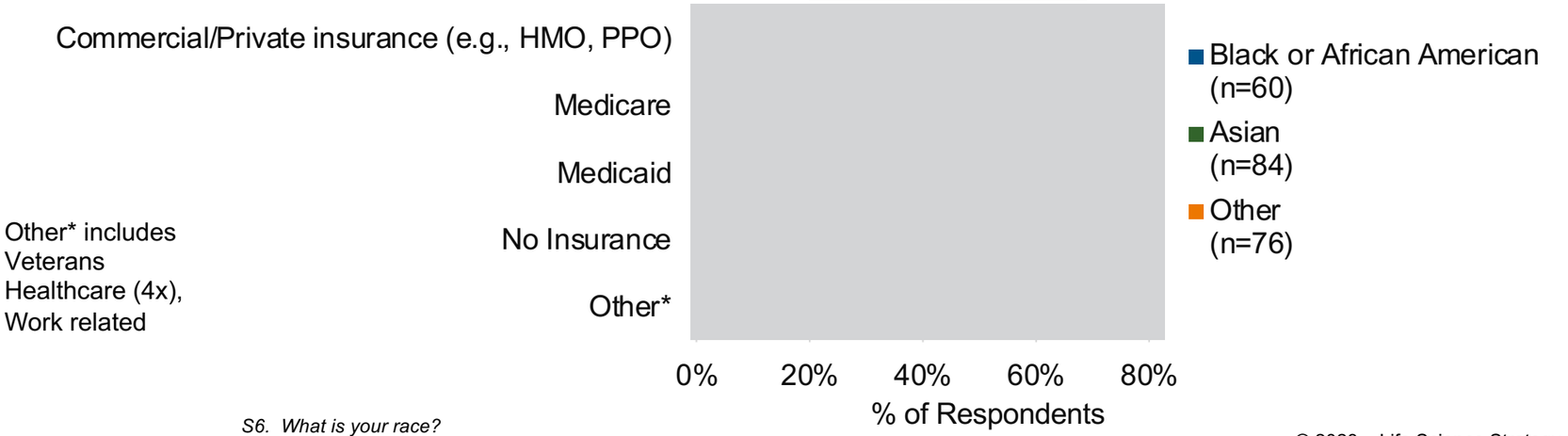


Household Incom



Respondents with income $0-$30,000 classified as "low-income", $31,000-$90,000 as "mid-income", and $91,000+ as "high-income"

Insurance Type



Other* includes Veterans Healthcare (4x), Work related

S6. What is your race?
S7. What is your total household income?
S8. Please indicate if you are covered by any of the following types of insurance? Select all that apply.

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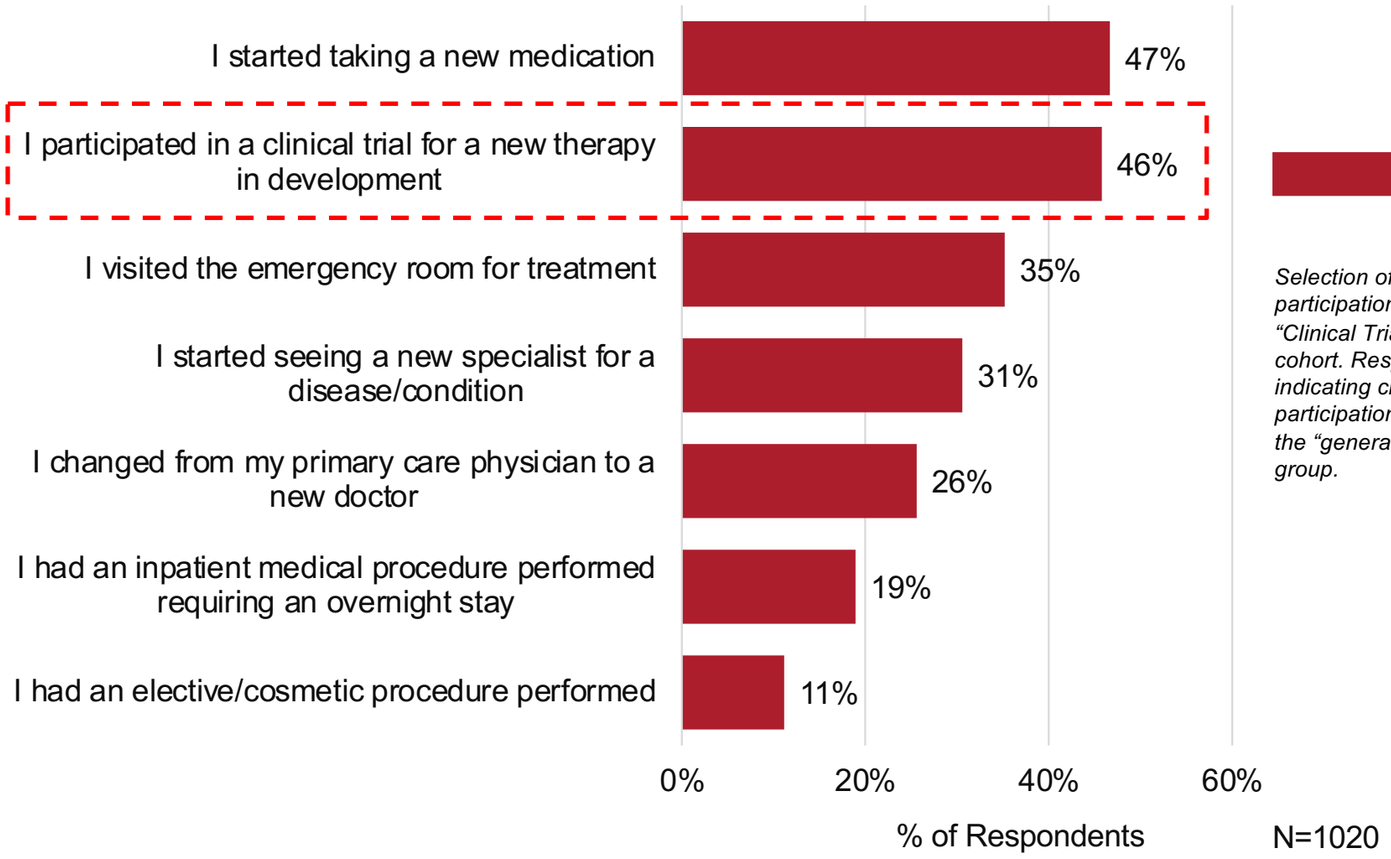
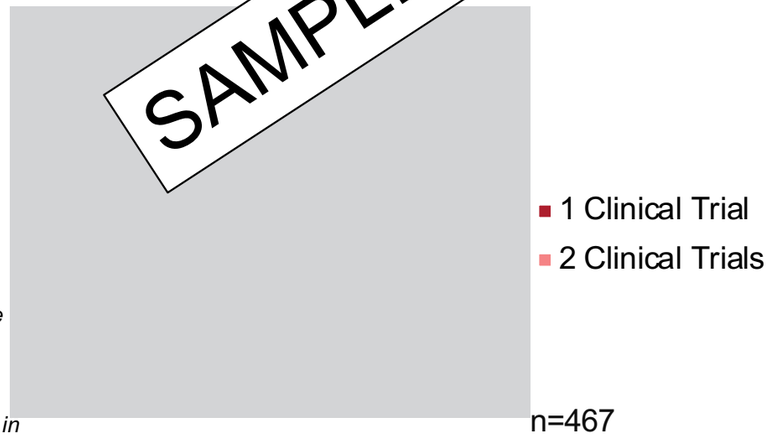
Respondent Demographics

Activities Participated In Over Past 2 Years



Selection of clinical trial participation required to be "Clinical Trial Participant" cohort. Respondents not indicating clinical trial participation are classified in the "general population" group.

Number of Clinical T… …st 2 Years



Note: Trial participants with >2 trials excluded to avoid "routine" participants.

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S9. Which of the following activities have you participated in during the past 2 years? Please select all that appl
Clin Trial S10. How many clinical trials have you participated in over the past 2 years?

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