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FASTER RESULTS, BETTER OUTCOMES:

How person-centered trial design improves clinical research

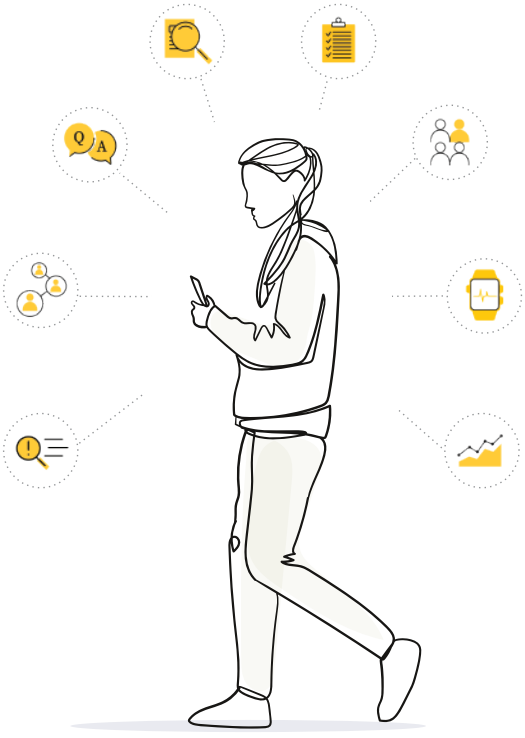
Executive summary

Some of the **most frequently reported reasons** for recruitment failures in clinical research include eligibility criteria that are too narrow and a high level of participant burden. These shortcomings, as well as others we discuss in our report, "Faster results, better outcomes: How person-centered trial design improves clinical research," characterize study designs that lack person-centricity, leading to:

- **Missing large segments of the population**, such as women, people of color, individuals with a lower socioeconomic status, and people in rural areas
- **Failing to reach a representative sample** of the specific population being studied
- **Inadequately capturing the everyday experiences** that affect individuals' health outcomes
- **Medical products and interventions that are not successful commercially** because they do not provide the benefits important to people or address people's unmet needs
- **Ultimately, operational, regulatory, and commercial challenges** due to longer study timelines, an inability to show the product has value, and a lack of acceptance by end users

As the foundation for decisions around health care, **clinical research is perfectly positioned to lead the person-centricity movement** spreading across the healthcare industry. Using the participant voice to inform study design can help **ensure the final product delivers value to the end users** and bridges the gap between the outcomes important to clinicians and researchers and those that truly matter to the individuals who will be using the product in real life.

Despite **evidence** that participant input has a direct impact on the entire research lifecycle, from study design to commercialization, the inability to efficiently collect that information often serves as a barrier for companies to actualize the full benefits. Supported by real-life case studies and example questions to ask of individuals and their families, the five strategies presented in the report can serve as a starting point for research teams to design studies that truly view participants as people.



Five strategies to design studies that work for, not against, people

STRATEGY	CONTEXT	BENEFITS
1. Identify the inclusion and exclusion criteria that more closely reflect the characteristics of the intended population	Characterizing the intended study population through diverse characteristics and preferences is key to establishing realistic, representative, and efficient inclusion and exclusion criteria.	• Faster recruitment and enrollment • More accurate benefit-risk profile • More efficient endpoint analysis • Segmented analyses
2. Prioritize person-centric outcomes in clinical trials	Combining what participants want with the specific research goals can achieve the study's aims while addressing unmet needs, resulting in better participant outcomes and greater satisfaction with treatments.	• Improved retention • Relevant outcomes • Better reimbursement potential • Increased adoption
3. Design low-burden assessments for better adherence	Making it easier to meet the study requirements makes it more likely that individuals will agree to participate and be able to complete all the required assessments.	• Faster recruitment and enrollment • Improved retention and compliance • Higher-quality data
4. Incorporate intuitive study materials and tailored support for enhanced engagement	Communicating in ways that participants understand shows respect, ensures they understand what is expected, and increases engagement with study materials.	Participants clearly understand: • What is being asked of them • What they can expect in return • How their information is being used
5. Recruit people where they are, both geographically and regarding their readiness to participate	Early participant feedback and involving organizations and community leaders they trust can ease recruitment, improve communication, and overcome negative perceptions about research.	• Faster recruitment and enrollment • Greater number of positive screens for timely enrollment • An inclusive, representative study population

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