Enhancing Clinical Trial Participation, Relevance, and Impact Through Meaningful Patient and Community Engagement

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Agenda

1. Identifying and Addressing Patient and Community Needs
2. Strategies for Earning Trust and Fostering Sustained Engagement
3. Key Collaborations Driving Meaningful Change
4. Approaches to Developing Patient-Centered Endpoints and Outcomes
5. Methods for Effectively Communicating and Disseminating Trial Results

Identifying and addressing patient and community needs

Patient and Community Engagement

- Meaningful and ongoing outreach
- Patient and community advisory panels
- Collaboration with community-based and advocacy organizations to develop programs to promote clinical trial awareness and education
- Addressing logistical (e.g., transportation, time) constraints

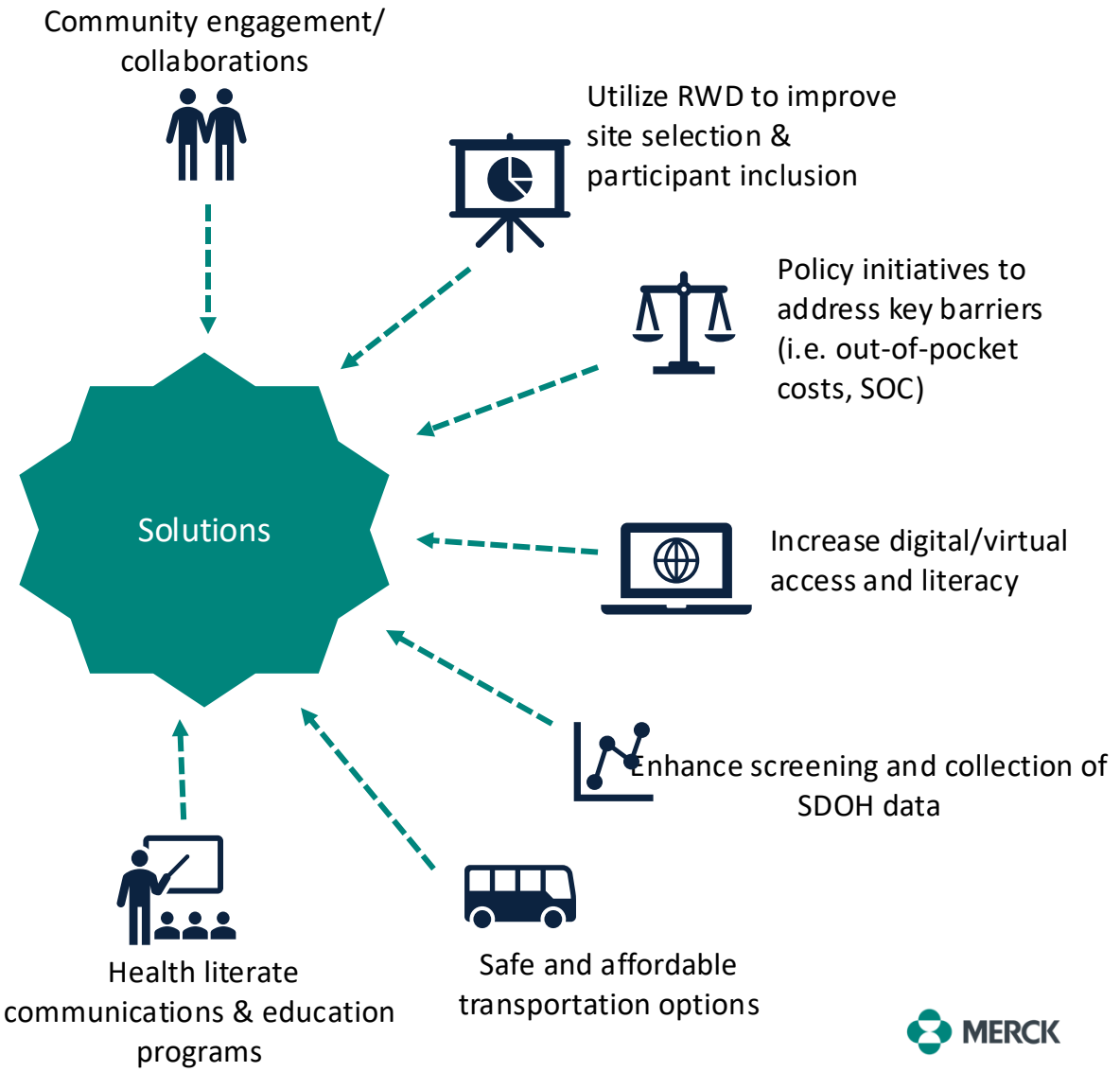
Recognizing and Addressing Social Determinants of Health

- Data driven strategies

Bridging the Gap Between Research and Clinical Practice

- Integration of research into real-world clinical practice
- Ensuring relevance and applicability of research findings
- Balancing health care needs and research participation

Strategies for earning trust and fostering sustained engagement



Key collaborations driving meaningful change

OneTen

The OneTen initiative is a collaborative program launched by Ken Frazier, former CEO of Merck, and other leaders, driving a skills-first movement to unlock career opportunities for talent without four-year degrees.

OneTen has a dedicated coalition of leading companies and executives across industries committed to upskilling, hiring and unlocking career opportunities for talent across the U.S.

To stay connected with Merck, join our Skills First Talent Community for job alerts.

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Approaches to developing patient-centered endpoints and outcomes

Endpoints

- Measures designed to test the efficacy and safety of study medications (e.g., mortality, disease progression, other clinical events, measures of function)

Patient-Centered Endpoints

- Outcomes or measures relevant and meaningful to patients, aligned with patient preferences, needs and priorities (e.g., quality of life, knowledge and satisfaction, caregiver burden)

"The Patient Matters in the End(point)"*

Patient engagement early in trial design, including identification of endpoints that matter to them, can help overcome critical barriers, leading to more patient-centered trials, better participant recruitment, retention and outcomes

Clark et al. Curr Probl Cardiol 2019; 44:148-172.

*Griffiths P, Rofail D, Lehner R, Mastey V. The Patient Matters in the End(point). Adv Ther. 2022;39(11):4847-4852.

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Enhancing clinical trial relevance, value and equity

Study Relevance and Value

- Results relevant to and understood by participants and communities
- Consistency of treatment benefits and/or risk differences
- Participant experience and feedback to improve design of future trials

“Underrepresented groups acutely feel the disconnect between trial efficacy and real-world effectiveness both because they do not see themselves in trials and because underrepresentation can affect trial results.*”

Study Attrition: Indicator of Social Vulnerability

- Representative clinical trials includes recruitment, enrollment and equity in trial completion
- Differential attrition of participants can lead to bias and limit generalizability of results
- Participant attrition may be associated with financial resource strain and/or other vulnerability indicators, independent of race or gender
  - Understanding differential attrition may help advance patient care, outcomes and equity

“… enrolling a diverse population provides the best opportunity for an informed analysis of important subgroups, illuminating potential signals of disproportionate benefit or risk …”**

*Shah SJ, Essien UR. Equitable Representation in Clinical Trials: Looking Beyond Table 1. Circ Cardiovasc Qual Outcomes. 2022 May;15(5).

**Bierer B.E., White S.A., Meloney L.G., Ahmed H.R., Strauss D.H., Clark L.T., (2021). Achieving Diversity, Inclusion, and Equity in Clinical Research Guidance Document and Supplementary Toolkit Version 1.2. Cambridge and Boston, MA: Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard (MRCT Center). Available at: https://mrctcenter.org/diversity-in-clinical-trials/.

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Relationship Between Social Vulnerability Indicators and Trial Participant Attrition: Findings From the HYVALUE Trial
Kamal H. Henderson, MD, MSc, Laura J. Helmkamp, MS, John F. Steiner, MD, MPH, Edward P. Havranek, MD, Suma X. Vupputuri, PhD, Rebecca Hanratty, MD, Irene V. Blair, PhD, Julie A. Maertens, PhD, Miriam Dickinson, PhD, Stacie L. Daugherty, MD, MSPH

National Academies of Sciences, Engineering, and Medicine. 2022. Envisioning a Transformed Clinical Trials Enterprise for 2030: Proceedings of a Workshop. Washington, DC: The National Academies Press. https://doi.org/10.17226/26349.

Methods for effectively communicating and disseminating clinical trial results

Engaging Patients

- Planning
- Conduct (study execution)

Dissemination of Results

- Plain language summaries
- Post publication meetings with key patient advocates and organizations
- Journal initiated patient summaries

Improved Outcomes

- Demonstration of results relevance to and understood by participants and communities
- Ensuring transparency, fostering trust and enhancing understanding of research findings

Summary and Conclusion

Engagement

- Meaningful patient and community engagement enhances clinical trial participation, outcomes and relevance

Trust

- Effective and open communication helps build trust and foster sustained engagement

Patient-Centered Research

- Incorporating patient perspectives in the development of study endpoints leads to more relevant and impactful research findings

Transparency

- Clear, plain language during communication of study results informs participants and strengthens research community relationships, fostering trust and encouraging future participation

Thank you