A Novel Approach: Leveraging The "Affective Trust Framework" To Develop A Sponsor-Specific Clinical Trial Diversity Playbook

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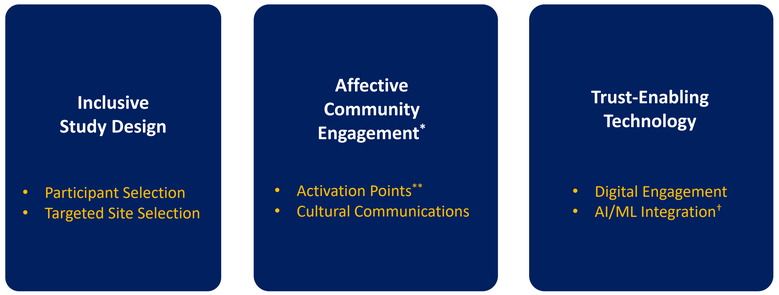
BACKGROUND

- New laws (i.e., Food and Drug Omnibus Reform Act – FDORA, sections 3601-3604) and recent regulatory guidance (i.e., FDA Draft Guidance to Industry on Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials) require submission of diversity action plans to the FDA prior to the start of pivotal clinical trials. [1-3]
- Research sponsors have had to reassess their current approaches for including historically excluded patient populations, particularly from communities of color, in their studies.
- Here, we offer novel guidance to research sponsors on how to use "affective" (i.e., emotion-based) trust, regulatory guidance, organizational assessment, and therapeutic area (TA) considerations to develop a sponsor-specific approach for addressing clinical trial diversity.
- The **"Affective Trust Framework" for Clinical Trial Diversity,** which has 3 key pillars focused on elements of inclusive trial design, sustained community engagement with historically excluded populations, and trust-enabling technology, serves as the foundation for the clinical trial diversity playbook.[4]



**This should be a comprehensive strategy that starts before study kick-off, lasts the duration, and continues after study ends*
***Activation Points = Persons or organizations within the community who can serve as trusted messengers regarding disease state awareness and clinical research information*
†AI/ML = Artificial Intelligence/Machine Learning

METHODS

Begin with the "Affective Trust Framework" as the foundation

Review industry best practices
- Review regulatory guidance and laws (i.e., FDA Draft Guidance, FDORA)
- Review trade organization recommendations
- Assess "state of clinical trial diversity" within the TA using various TA-specific sources (i.e., guidance/policies from national and professional societies, additional frameworks etc).

Conduct an organizational gap analysis (Company/TA-specific considerations)
- Assess company's corporate internal/external mindset on clinical trial diversity and current approaches through a review of processes, policies, communications
- Gather insights through interviews with cross-functional team members (e.g., Clinical Operations, Clinical Development, Patient Engagement, Medical Affairs, Patient Advocacy, Marketing, etc)

Develop the sponsor/TA-specific clinical trial diversity playbook
- Compile and synthesize all researched information
- Identify critical gaps
- Make recommendations for improvement, aligned with elements of the Affective Trust Framework

USE-CASE: ONCOLOGY

- Beginning with the "Affective Trust Framework" and using the Oncology TA as a use-case, an assessment of FDA guidance documents, FDORA, trade organization "industry best practices," and clinical trial diversity recommendations from the American Association for Cancer Research (AACR), American Society for Clinical Oncology (ASCO), Association for Community Cancer Centers (ACCC) and American Society for Hematology (ASH) then yields recommendations specific to improving diversity in oncology clinical trials that can be layered on top of the initial framework.[1-8]

USE-CASE: ONCOLOGY (cont.)

- Recommendations may include suggestions on which key components to consider for diversity action plan submission to the FDA, as well as advice for improving culturally-tailored health literacy, leveraging digital means and community partnerships (i.e., activation points) to extend reach, and upskilling community oncology practices as research sites.
- Lastly, an organizational gap analysis of the sponsor's current approach to trial diversity, including a review of the sponsor's internal/external prioritization of it and feedback from employee interviews, results in sponsor-specific recommendations for achieving diversity in the sponsor's oncology clinical trials.
- Outputs from the organizational gap-analysis may include revisions to the sponsor's clinical development planning templates, addition of race/ethnic demographic questions to study-specific site feasibility questionnaires, consideration of "up-and-coming" oncology researchers with diverse backgrounds for protocol steering committees/investigator opportunities, and new cross-functional team collaborations to facilitate broader understanding of the sponsor's clinical trial diversity goals within the organization.

CONCLUSION

- By leveraging the "Affective Trust Framework," and then layering insights gleaned from the FDA, recommendations from TA-specific resources, and a critical review of organizational gaps on top of the framework, sponsors are able to create step-by-step playbooks specific to their organizations for improving clinical trial diversity.
- While the use-case provided here is for oncology, a similar approach may be applied across different TAs and sponsors, with the expectation of generalizable yet nuanced outcomes that aid in playbook development.

DISCLOSURES & REFERENCES

- All presentation authors are employees of Acclinate, Inc. Special acknowledgment to the BeiGene Clinical Trials Optimization Coalition for the use-case.
- Please scan QR code or contact corresponding author to download poster and references.