Educational Informatics on the Assent Processes of Oncology Research to Children and Adolescents with Cancer

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A Comprehensive Cancer Center Designated by the National Cancer Institute

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Background

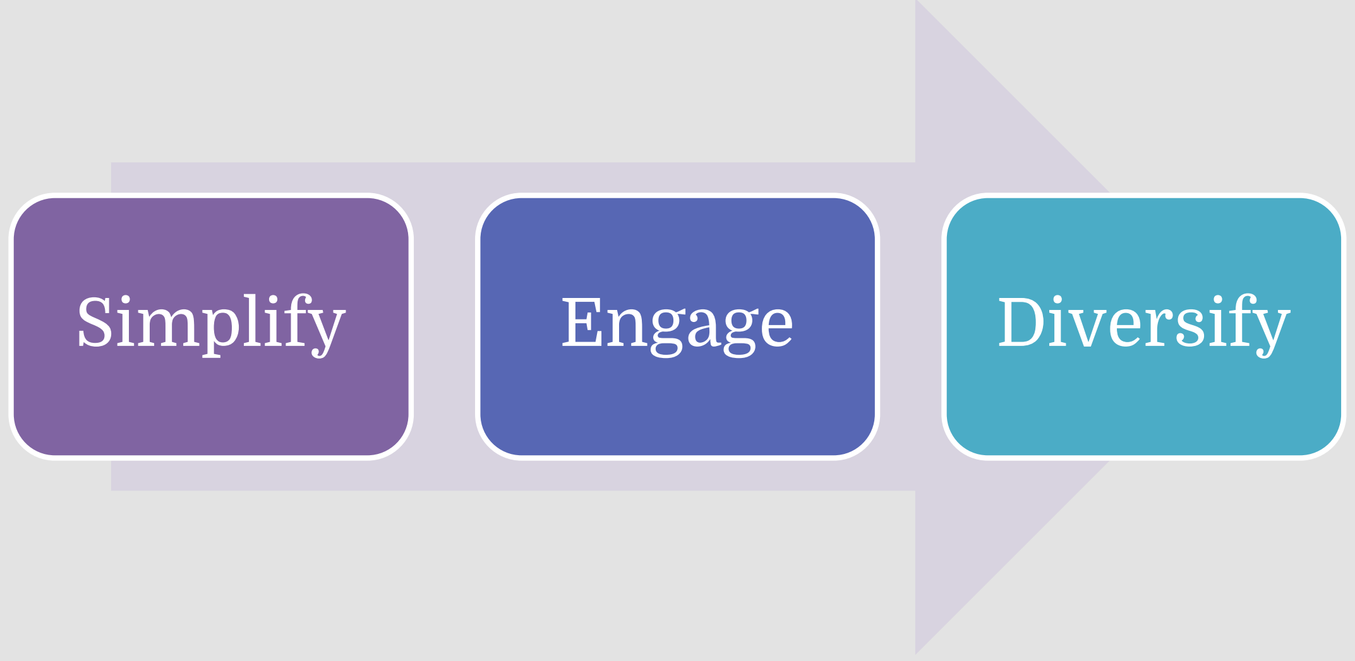
Clinical trials play a vital role in the development of new cancer treatments by assessing their safety and efficacy across various age groups. These trials are especially critical for children, who differ physiologically from adults, necessitating not only parental consent but also the child's assent—an affirmative agreement to participate.

Existing approaches to securing assent often fail to directly engage pediatric participants. This neglect results in a substantial gap in these children's comprehension of their role in clinical trials, emphasizing the need for enhanced communication and education strategies designed specifically for young patients.

Goals

- ✓ **Development of Interactive Resource:** Simplification of clinical trials for young cancer patients aged 6-12, to demystify complex medical terminology involved in consent and assent processes.
- ✓ **Inclusive Representation:** Incorporate diversity within an educational material to enhance inclusivity and foster familiarity for pediatric patients from various cultural and socioeconomic backgrounds, aiming to bridge healthcare participation gaps.
- ✓ **Educational Outreach:** Raise awareness and understanding of clinical trials among pediatric patients and their families, promoting it as a key tool for education and engagement in healthcare settings.
- ✓ **Enhanced Accessibility:** Adaptation of the interactive educational material into multiple languages and accessible formats for children with disabilities, broadening access and effectiveness to encompass a diverse range of pediatric patients, thereby reducing barriers to information and participation in clinical trials.

Solutions



Simplify

Engage

Diversify

Methodology

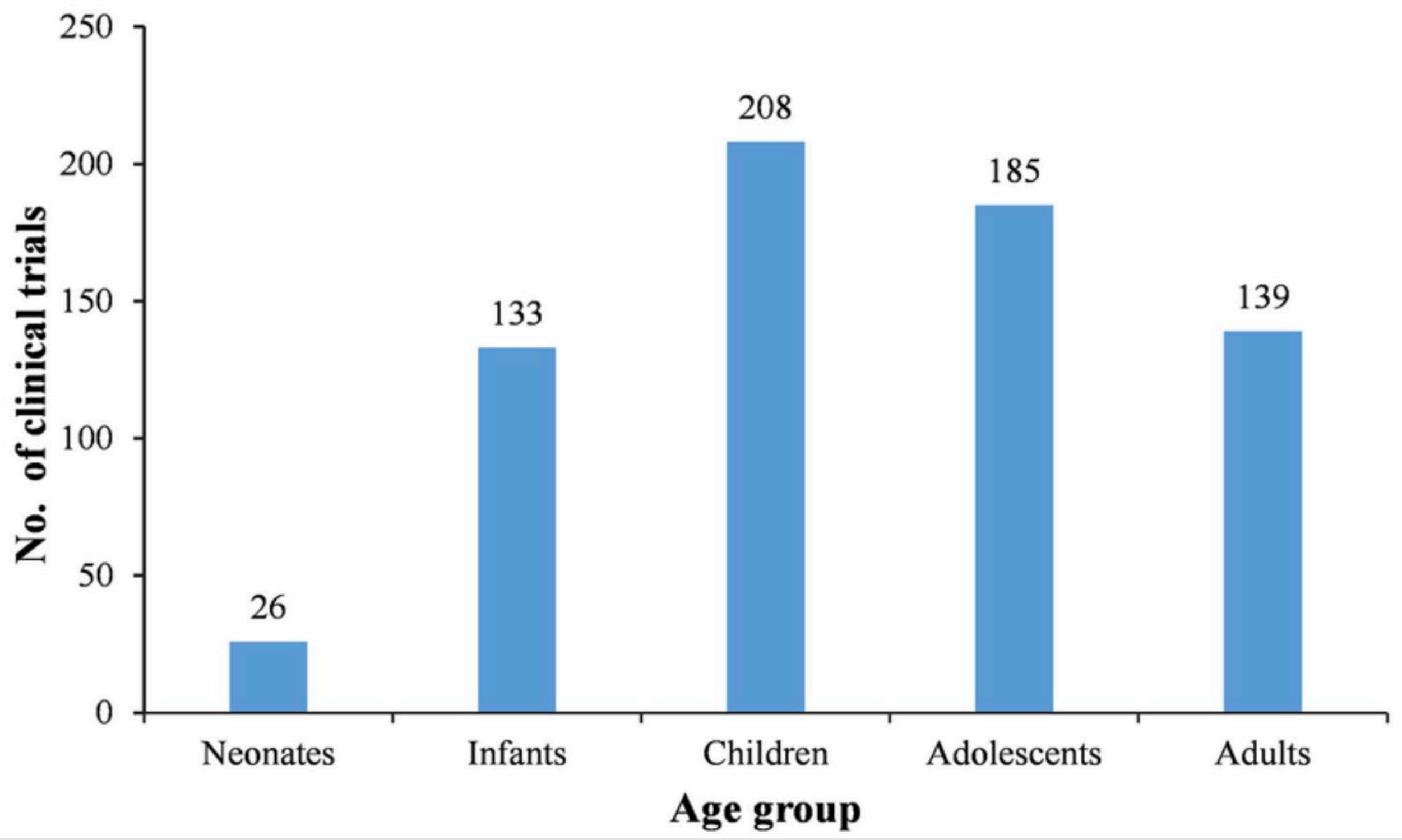


Figure 1: Distribution of pediatric clinical trials by age group;
[Wu et al. (2021). Pediatric Clinical Trials in Mainland China Over the Past Decade (From 2009 to 2020). *Frontiers in Medicine, 8*.]

- ➢ Assessment of Existing Assent Forms: throughout the YCCI internship, the group analyzed several assent forms, revealing significant comprehension challenges stemming from the use of complex medical terminology and poor connectivity.
- ➢ Development of Educational Tool: Created an interactive comic book specifically designed for pediatric oncology patients.
- ➢ Visual Glossary Implementation: Integrated a visual glossary to clearly define intricate clinical trial terms and symptoms relative to different skin tones, making them accessible to young readers.

Anticipated Outcomes

Aspect	Current State	Objectives	Methodology	Projected Outcomes
Understanding Clinical Trials	Low due to complex terminology	Simplify medical terminology for children	Interactive comic book with visual glossary	Pediatric patients will have a better understanding of clinical trials and treatment options
Inclusivity	Limited by lack of diverse representation	Ensure diverse representation in materials	Diverse characters and culturally inclusive storylines	Higher representation of children from differing backgrounds, ensuring more comfortability with clinical trials
Engagement	Low engagement with existing material/ lack of materials provided due to inability to comprehend	Increase engagement through interactive content	Interactive features in comic book	Interactive content will maintain children's interest, improving engagement
Participation	Hesitancy to participate due to lack of understanding	Promote trial participation by increasing understanding	Educational outreach and collaborative dissemination	Enhanced understanding and representation, increasing overall participation

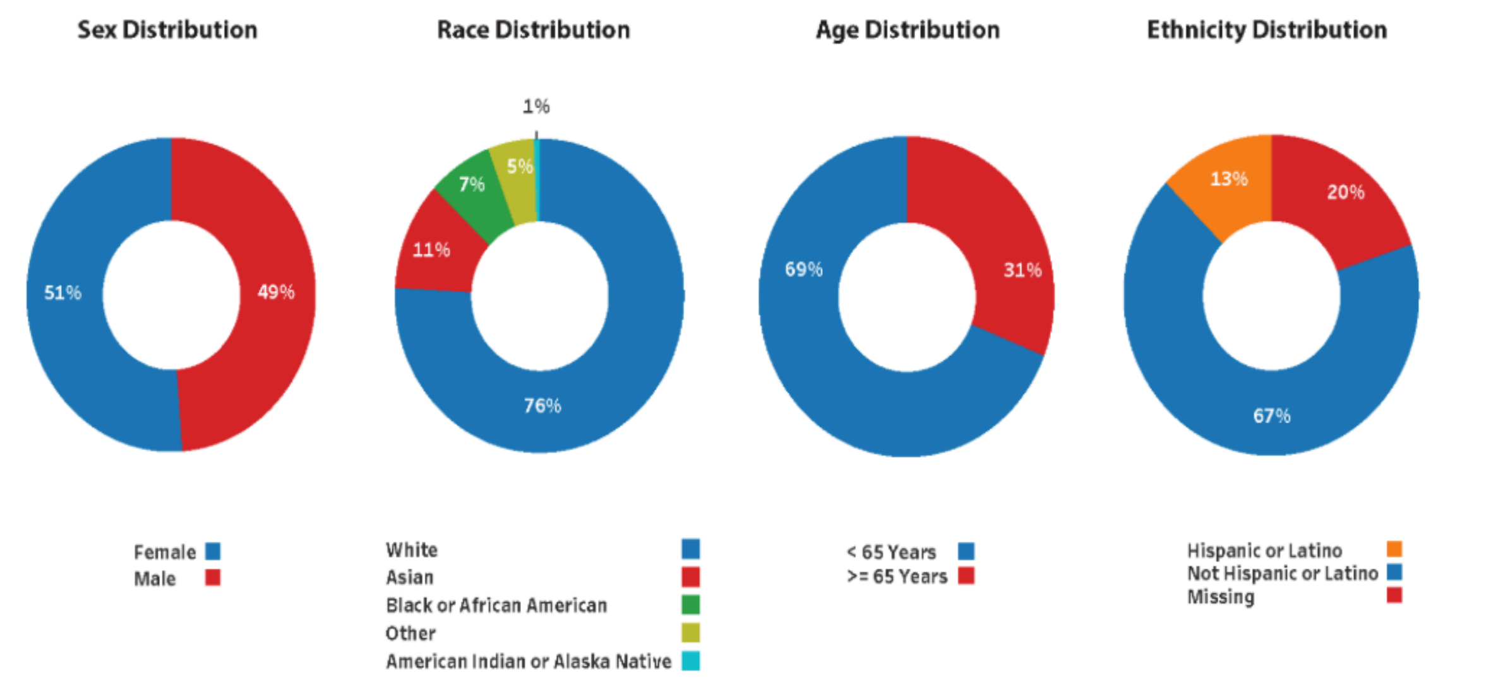


Figure 2: Demographic of Trial Participation (2021)
[Why Representation Matters in Clinical Trials, *U.S Food and Drug Administration, Drug Trials Snapshot Summary Report, www.fda.gov]*

Diversity, Equity, & Inclusion

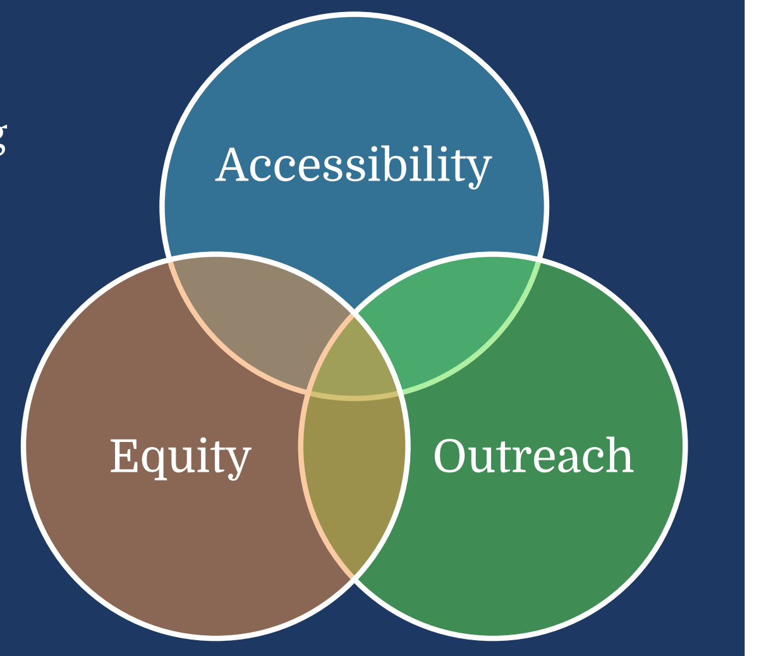
Community Outreach and Engagement are essential to the project because:

1. They ensure that clinical trial information reaches diverse audiences, increasing understanding and participation by making details accessible and relevant.

2. Effective engagement builds trust, fostering a collaborative environment through open communication and active community involvement.

3. By featuring diverse characters and scenarios, the project addresses healthcare disparities, ensuring equitable access and participation in medical research.

4. Incorporating a wide range of demographics reflects global diversity, enhancing the research's applicability and generalizability across various populations.



Future Directions

- ✓ **Feedback Collection:** Obtain additional feedback from Yale Cancer Center Community Advisory Board and Cultural Ambassadors for future iterations.
- ✓ **Educational Outreach:** Gather insights directly from children to align content with their interests and needs. Foster education among pediatric patients and their families through the targeted content.
- ✓ **Dissemination Strategy:** Plan for widespread distribution in collaboration with healthcare professionals, researchers, and community stakeholders.
- ✓ **Impact Goals:** Enhance information accessibility and encourage participation in clinical trials, contributing to the advancement of pediatric oncology research both locally and globally.

Acknowledgements

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