Evaluating Inclusive Representation across Clinical Trial Participation

**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 and their families, promoting it as a key tool for education and engagement in healthcare settings.
- **Educational Outreach:** Raise awareness and understanding of clinical trials among pediatric patients and their families, encouraging active participation by making details accessible and relevant.
- **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**

- **Understanding Clinical Trials:** Low due to complex terminology. Simplify medical terminology for children. Interactive comic book with visual glossary.
- **Inclusivity:** Limited by lack of diverse representation. Ensure diverse representation in materials. Interactive features in comic book.
- **Engagement:** Low due to lack of engagement. Increase engagement through interactive content. Interactive comic book with visual glossary.
- **Participation:** Heinously due to lack of understanding. Promote trial participation by increasing understanding. Interactive comic book.

**Anticipated Outcomes**

- **Enhanced Accessibility:** Pediatric patients will have a better understanding of clinical trials and treatment options.
- **Inclusivity:** Higher representation of children from differing backgrounds, ensuring more comfortability with clinical trials.
- **Engagement:** Interactive comic book with visual glossary.
- **Participation:** Interactive content will maintain children’s interest, improving engagement.

**Participation Hesitancy to Engagement Low**

- **Trials**
- **Demographic of Trial Participation (2021)**

**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.

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

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

**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/)

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**Table 1:** Anticipated Outcomes

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<thead>
<tr>
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