Pediatric Trials in Antibacterial Drug Development: Findings from the Clinical Trials Transformation Project

**Background**

The Clinical Trials Transformation Initiative (CTTI) is a public-private partnership between the Food and Drug Administration (FDA), National Institutes of Health (NIH), and industry stakeholders to improve the efficiency and effectiveness of clinical trials. The initiative aims to address the challenges faced by investigators in conducting pediatric trials and to enhance the recruitment and enrollment of pediatric participants.

**Purpose**

To identify potential barriers to conducting antibiotic (AB) drug trials among pediatric populations.

**Methods**

- **Surveys with Investigators of Pediatric Antibacterial (AB) Drug Trials and Community Providers**
  - Community providers and pediatricians were surveyed to identify perceived barriers to conducting pediatric AB trials.
  - Pediatricians were asked to identify potential barriers to conducting AB trials among pediatric populations.

- **Qualitative Interviews**
  - In-depth interviews were conducted with 12 industry representatives who have experience with pediatric antibacterial drug development.

- **Observational Studies**
  - Observational studies registered in ClinicalTrials.gov between 2007 and 2015 (n=12,703) were examined to assess the prevalence of AB drugs in pediatric populations.

**Main Findings**

- **Barriers Identified**
  - Potential barriers include study implementation, ethics and regulatory, parental concerns, and child-related logistics.
  - Key barriers include: insufficient budget to cover trial costs, shortage of qualified investigators, and difficulty in obtaining parental consent.

- **Recommendations**
  - Suggestions for simplifying antibacterial drug trials are to:
    - Use extrapolation
    - Reduce burden among trial investigators by altering eligibility criteria to make trials easier to recruit
    - Combine trials

**Conclusion**

The findings suggest that further engagement with parents is needed to address some of the barriers identified. Additional research is needed to better understand the impact of these barriers on the conduct of pediatric AB trials.