Greetings,

We are the Young Professionals Network (YPN) of iCAN, a U.S.-based nonprofit that amplifies the pediatric voice in clinical research. As young adults with firsthand experience navigating chronic conditions and the pediatric healthcare system, we champion for early and continuous engagement of young patients in trial design—especially during feasibility assessments.

Pediatric patients face significant barriers when it comes to participating in clinical trials, which may include substantial travel burdens, considerable financial costs for families, and concerns surrounding medical procedures. Failing to understand and address these barriers can lead to low recruitment, poor retention, and ultimately, less reliable data.

A key barrier to pediatric research is poor communication between patients, patient engagement groups, and pharmaceutical companies. When patient and family concerns about clinical trials are not addressed, trust is diminished, reducing the patient's willingness to participate. Trial materials may fail to reflect the information patients and families need to make informed decisions, further distancing them from research. These patients are already navigating complex medical diagnoses, and if they don't feel heard, mistrust in medical care and research deepens—ultimately hindering progress in therapeutic advancement.

Therefore, it is imperative that feasibility studies incorporate robust engagement with pediatric patient advocacy groups, like iCAN, from the very beginning and throughout the research process. These groups serve as invaluable channels to the patient community, offering insights into the real-world challenges that patients and families face. For instance, by partnering with pharmaceutical companies such as Pfizer and Eli Lilly to host direct engagements with pediatric patients and caregivers, iCAN provides a platform for these companies to directly hear from young people and to truly understand the challenges they face. This direct insight allows companies to design clinical trials that are genuinely patient-centric. By fostering open communication and demonstrating a genuine commitment to addressing patient needs, we can significantly improve enrollment and retention rates, ultimately making the research process more efficient and cost-effective.

Organizations like iCAN serve to work as a link between patients and pharmaceutical companies. Without this link, we risk creating clinical trials that are not representative of the patients' needs. We respectfully recommend that the FDA include a formal requirement or incentive for incorporating pediatric patient groups during feasibility assessments in all pediatric trials. This approach is ultimately necessary for ensuring the successful advancement and delivery of therapies for our most vulnerable patients.

Sincerely,

iCAN Young Professionals Network Members