Open Access Journal of Clinical Trials

Dovepress
Taylor & Francis Group

Open Access Full Text Article

EXPERT OPINION

Young Adults in Clinical Trials: A Roundtable Proceedings

Rose Eleanor Keller[1], Sneha Dave[1], Katherine Melton[1,2]

[1]Generation Patient, Indianapolis, IN, USA; [2]Department of Nursing Professional Practice, Rhode Island Hospital, Providence, RI, USA

Correspondence: Katherine Melton, Department of Nursing Professional Practice, Rhode Island Hospital, 593 Eddy Street, Providence, RI, 02903, USA, Email kmelton@brownhealth.org

Abstract: Clinical trial design and results often do not adequately address the needs of young adult patients (ages 18–35 years), despite the increasing prevalence of chronic conditions among young adults in the United States. A group of medical professionals, pharmaceutical industry representatives, and young adults with chronic conditions convened in a roundtable discussion hosted by Generation Patient to identify current barriers to young adult clinical trial participation and propose strategies to improve the research process for young adults. The discussion explored the added complexities of young adulthood, including developmental and situational instability and the transition from pediatric to adult care, which can make clinical trial participation more difficult and less appealing; the benefits of increased, proactive collaboration between young adult patients and researchers at every stage of the research process; and practical changes to ensure that data reporting reflects potential outcomes or dispositions unique the young adult patient population, such as arriving at a national consensus around the operational definition of "young adult" and disaggregating safety and efficacy data within finer age brackets. All stakeholders highlighted the need to make medical research more inclusive of young adults so they can be well-equipped to make informed medical decisions.

Keywords: patient perspective, roundtable, chronic illness, advocacy

Introduction

Over half of young adults in the United States manage at least one chronic medical condition, and the proportion of young adults with multiple chronic conditions is increasing.[1] Nevertheless, clinical trials frequently fail to recognize the specific needs and features of young adults, leading to evidentiary gaps in our understanding of how best to treat this population. Currently, there is no standardized definition of "young adult" in the American healthcare system; this paper considers young adulthood to include people between the ages of 18 and 35. Often, however, clinical trials group young adults into a much wider age band – lumping everyone between the ages of 18 and 64 into one group – in reporting safety and efficacy data. This is a mistake, as it creates a dearth of evidence that is needed to identify potential risks of novel therapies for young adults. Age is an important aspect of diversity in clinical trials because young adults experience and face unique challenges, particularly in healthcare settings. In addition to typical rites of passage out of childhood – first jobs, beginning college, moving away from home – young adults with chronic conditions must, at some point, transition from pediatric to adult medical care. This process introduces unique challenges, discussed below, that become barriers to young adult patient participation in research when clinical trials are not designed with them in mind, as evidenced by lower participation among young adults in clinical trials and significant loss to follow-up.[2] There is currently a significant gap in patient-centered solutions for increasing young adult representation in clinical trials, which results in a profound impact on the health of young adults with chronic and rare conditions.

Materials and Methods

To address this gap, Generation Patient, a young adult led patient advocacy organization, hosted a virtual roundtable discussion with 21 patients, researchers, healthcare providers, and members of the pharmaceutical industry to discuss

https://doi.org/10.2147/OAJCT.S616460
Received: 13 April 2026
Accepted: 1 July 2026
Published: 10 August 2026

barriers and solutions to young adult representation in clinical trials. Participants were intentionally selected based on topic area expertise to represent a wide range of perspectives. The roundtable was hosted and recorded via Zoom (Version 5.16.0) and an automated transcript was produced. Following the roundtable, the transcript was reviewed by the first and last author who each developed themes independently and then met to discuss and reach consensus on the final themes. The roundtable discussion questions provided a framework for the initial development of the themes. The final themes were then shared with the Generation Patient leadership team for final discussion and consensus. This proceedings document presents the roundtable's consensus on what should inform the design of clinical trials going forward and practical solutions to advance progress.

Results

Barriers to Young Adult Representation in Clinical Trials

As a patient population, young adults face barriers that threaten their representation in clinical trials. Historically, this period of development is associated with significant personal, professional, and emotional growth which can make attending follow-up medical appointments difficult. Researchers, wary of the developmental and situational instability experienced by young adults and risk of confounding variables to experimental integrity, have historically neglected to prioritize this demographic in trial recruitment. Similarly, overly narrow inclusion criteria often exclude young adult patients, as people between the ages of 18 and 35 do not neatly fit into either pediatric or adult populations. As one participant shared:

> When we narrow the inclusion criteria in clinical trials, we also narrow who gets to participate. That often means that young adults get eliminated from clinical trial participation.

Additionally, financial and logistical burdens may deter otherwise eligible and willing patients from participating. Insufficient compensation for trial subjects imposes a unique burden on young adults interested in participating, as the group faces greater financial instability than other populations.[3]

The nebulous status of the "young adult" age group further hinders efforts to recruit them into clinical trials. There is no consensus among researchers about what age range defines young adulthood and, as such, young adults are often grouped into the 18-to-64-year-old category in published study results. The lack of stratification does not serve a scientific purpose–18-year-olds are physiologically distinct from sexagenarians–and it creates an evidentiary gap regarding the young adult patient population. There is no established best practice that attempts to include young adults by alleviating these burdens or that acknowledges young adulthood as an age range worthy of careful consideration through stratification. This, in turn, disincentivizes young adult participation in clinical trials, as study results may not fully capture the investigational products' full effects in this population. One researcher and patient advocate hypothesized that the Food and Drug Administration should play a greater role in guiding clinical trial sponsors' practices:

> I think sponsors are often resistant to doing anything that the regulatory agency hasn't strictly endorsed or prescribed.

Further involvement of young adult patients is necessary to discover the health outcomes that are most important to them and how well currently available comparators serve the population.

Unique Challenges of Young Adulthood and Transitioning Care

The transition period from pediatric to adult care further complicates young adult patients' participation in trials. Often, patients must acclimate to new doctors, hospital systems, and care protocols as they age out of the pediatric setting; this occurs in addition to the other comprehensive life changes typical of young adulthood. A seamless transition requires that patients' data follows them to their new doctor and healthcare system, so that they have the relevant information on young adult patients not only to guide their clinical care, but to contact them about potential clinical trial opportunities. Improving data sharing mechanisms and interoperability between healthcare systems is essential to reduce fragmentation between pediatric and adult care teams, and between clinical care and research teams. Alternatively, patient-owned data platforms that collect regulatory-grade data may be one preventative measure that addresses gaps in patient records by excluding third-party entities, thereby circumventing some data-sharing issues.

Choosing to participate in a clinical trial as a young adult is made more difficult by systemic barriers and lingering ethical questions in the reconsent process. When patients turn 18, they become responsible for consenting to their own clinical care and for participation in clinical trials. Patients and healthcare providers in the roundtable reported that the reconsent process can be onerous and confusing for all involved, particularly considering that the documents are often lengthy and rife with technical language and requiring physical signatures. Reforms, such as using plain, concise language wherever appropriate, would lessen this burden. Generally, there is a demonstrated need for guidance and consistency from sponsors and regulators on the timing and process of reconsenting when trial participants turn 18.

Creating Young-Adult-Friendly Trials

The current clinical trial infrastructure is antiquated and relies heavily on outdated methods and communication channels. Trial sponsors, investigators, and regulators have an opportunity to redesign and modernize clinical trial processes to better serve and recruit young adult patients.

> When you're first looking to communicate with the population that you're interested in recruiting, you engage them in a manner that meets their expectations, their needs, and actually entices them to participate

explained one pharmaceutical industry representative. Young adults are increasingly reliant on technology and digital media to absorb information and communicate, to a greater degree than past generations.[4] Clinical trial recruitment and research protocols should, when possible, reflect this preference by communicating via online channels patients are already accustomed to, such as Email or an online patient portal.

Revising the clinical trial process to prioritize supported decision-making would better equip young adults to participate in and contribute to research efforts. Best practices currently fixate on an individualistic approach.

> We ask people to just listen to the information properly, this intense information, all by themselves. And then they're supposed to sign away all this permission.

according to one provider. As discussed above, a novel approach could include bringing other people into the room, such as parents or peers, to help the patient make decisions during the consenting process. In a study of adolescent and young adult cancer clinical trials the use of peer champions was identified a facilitator of trial participation, however, this concept is far less developed outside of the oncology space.[5] Though they bear sole responsibility for their own healthcare choices, many young adults are still developing the confidence to make these decisions independently. "You can be a great advocate for your care, but that doesn't mean you have to do it alone," noted one provider. Participants concluded that young adults should not have to make life-changing health choices in isolation.

Practical Approaches for Improvement

Reforming the clinical trial and healthcare transition processes to address these challenges is a crucial step toward adequate young adult representation in ongoing research. As discussed, young adult patients must navigate the transition from pediatric care to adult care, but guidance about at what age this transition should occur is inconsistent across United States regulatory agencies. Reaching consensus on the age of transition would provide much-needed clarity and predictability in clinical and research settings, allowing patients to anticipate and plan for significant changes to their care. While transitioning from pediatric to adult care can be empowering, it also can introduce uncertainty and stress. Some providers noted that, depending on the patient, care center, and available resources, it may make sense to delay transitioning for young adult patients enrolled in certain clinical trials. Currently, no formal guidance for this exists and further investigation by sponsors and regulatory agencies is warranted.

Trials need to be designed with the unique features of young adulthood in mind. Superficially, more research needs to name young adults as a target population, rather than a byproduct of the general 18–64 age range. To reflect this goal, trials should be designed for, and in part by, young adult patients through patient advisory groups. According to one young adult patient, patient advisory groups "starting at the first stage of clinical trial planning is so important and still underutilized." Ideally, young adults could contribute to the co-creation of clinical trials at every step. Additionally, institutional review boards that share data or create inclusion criteria that combine pediatric and adult steering

committees could be an asset in reforming clinical trials and could be "another potential solution for bridging that gap," stated a young adult patient.

Mistrust of the medical research system is also a deterrent to many from participating in clinical trials[6] and practical improvements to the consent and reconsent process are needed to enhance trust. One provider suggested shaping the informed consent process and the discussions it entails around how patients make other major life decisions, particularly by allowing the involvement of care partners (parents, peers, significant others, etc), if the young adult chooses. Additionally, one patient stressed that increasing patient-to-patient reconsent could alleviate "feeling like a guinea pig."

Clinical trials should include age-stratified analysis that reflects the unique physiological and social characteristics of young adulthood. Important and relevant data is lost when 18-year-olds are lumped into the same category as 64-year-olds. In reforming clinical trials, there is an undeniable opportunity to build a coalition of patients, advocates, pharmaceutical representatives, regulators, and investors to develop an improved understanding of the re-consent, transition, and clinical trial process. Generation Patient has begun to work toward establishing an international consensus on a globally recognized definition of young adults with non-communicable diseases and chronic conditions for adoption by healthcare organizations, governments, and regulators.[7] A cross-agency consensus meeting between patient advocacy groups, sponsors, and regulatory agencies would be an important starting point to materialize potential reforms.

Discussion/Conclusion

Young adults with chronic conditions need to be better represented in medical research and clinical trials, as they are a growing and distinct demographic. This roundtable of young adult patients, researchers, healthcare providers, and pharmaceutical industry representatives discussed many means to work toward this goal. Participants discussed the unique challenges that young adults face in clinical trial participation during the healthcare transition period and offered actionable suggestions improving current processes through young adult friendly trial designs. Additionally, reaching a national consensus on the term "young adult" and the age range it signifies would be an essential step toward disaggregating safety and efficacy data within finer age brackets. Improving and standardizing the transition from pediatric to adult care would provide young adult patients with clarity and predictability, thereby making clinical trial participation more feasible. Making clinical trial participation easier for young adults requires a comprehensive redesign of the process, encompassing everything from initial recruitment and reconsent procedures to long-term follow-up. With clinical trials that reflect their experiences, young adults and their medical providers will be better equipped to make informed healthcare decisions. For clinical trials to increase their benefit to young adult patients, clinical trial sponsors and regulatory authorities must first recognize young adults as a unique population and then make incremental progress towards more young adult friendly trial designs.

Acknowledgments

We would like to thank Meghan Didier for her support coordinating this roundtable.

Funding

This work was funded by the David and Lucile Packard Foundation.

Disclosure

Ms Sneha Dave reports grants to Generation Patient from Responsible Technology Youth Power Fund, WITH Foundation, Grantmakers for Girls of Color, Disability Frontlines Fund, Commonwealth Fund, Arnold Ventures, Disability Inclusion Fund; consulting fees from Robert Wood Johnson Foundation; payment as part of the Midwest CEPAC from Institute for Clinical and Economic Review, outside the submitted work. Dr Katherine Melton reports honoraria for consulting work from Generation Patient, outside the submitted work. The authors report no other conflicts of interest in this work.

References

1. Watson KC. *Chronic conditions among adults aged 18–34 years — United States, 2019*. *Morbidity and Mortality Weekly Report*. 2022.
2. Puthenpura VAO, Ji L, Xu X, et al. Loss to follow-up of minorities, adolescents, and young adults on clinical trials: a report from the children's oncology group. *Cancer*. 2023;129(10):1547–1556. doi:10.1002/cncr.34701
3. Ghazal LV, Wentzell K, Blanchette JE. Mobilizing research to understand the impact of financial toxicity among adolescents and young adults diagnosed with chronic diseases. *J Adolesc Health*. 2023;73(3):403–405. doi:10.1016/j.jadohealth.2023.05.020
4. Jiao W, Chang A, Ho M, Lu Q, Liu MT, Schulz PJ. Predicting and empowering health for generation Z by comparing health information seeking and digital health literacy: cross-sectional questionnaire study. original paper. *J Med Internet Res*. 2023;25:e47595. doi:10.1002/cncr.34701
5. Mittal N, Saha A, Avutu V, Monga V, Freyer DR, Roth M. Shared barriers and facilitators to enrollment of adolescents and young adults on cancer clinical trials. *Sci Rep*. 2022;12(1):3875. doi:10.1038/s41598-022-07703-5
6. Lewin J, Bell JAH, Wang K, et al. Evaluation of adolescents' and young adults' attitudes toward participation in cancer clinical trials. *JCO Oncol Pract*. 2020;16(3). doi:10.1200/JOP.19.00450
7. Generation Patient. Building global consensus for young adults with chronic conditions and non-communicable diseases. Available from: https://generationpatient.org/global. Accessed April 1, 2026.