

# Duke STAR Program and the Pediatric Trials Network

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**ABBREVIATIONS** DCRI, Duke Clinical Research Institute; PTN, Pediatric Trials Network; STAR, Summer Training in Academic Research

**KEYWORDS** clinical research education; internship; mentorship; pediatric research

J Pediatr Pharmacol Ther 2026;31(1):118–119

DOI: 10.5863/JPPT-25-00143

In 2010, the pediatrics group at the Duke Clinical Research Institute (DCRI) was awarded leadership of the Pediatric Trials Network (PTN; <https://pediatrictrials.org/>),<sup>1</sup> a network sponsored by the National Institute of Child Health and Human Development and made possible by the Best Pharmaceuticals for Children Act. The PTN conducts studies on the formulation, dosing, efficacy, and safety of drugs and the development of medical devices used in pediatric patients. In addition to the research led by the PTN, the DCRI pediatrics faculty was interested in creating a summer program to introduce students to clinical research. They designed a summer internship program that initially recruited local high school students from Durham, NC. The success of the original summer internship program led to the creation of the Duke STAR (Summer Training in Academic Research) Program, which provided ~20 local high school or college students per summer the opportunity to learn about clinical research and work closely with researchers and practicing pediatric clinicians. Recruiting efforts prioritized schools in Durham that had a high proportion of students receiving free/subsidized school lunches, and focused on including strong students who were interested in the medical sciences or research who may not otherwise have the opportunity to pursue an academic summer experience.

The STAR Program has evolved considerably during the past 15 years. By 2017, the program was recruiting students throughout North Carolina and by 2021, the program was receiving applications from students across the United States. In 2023, the decision was made to expand the program to include a greater proportion of medical school and other graduate students, especially those interested in providing health care services in rural areas of the country. The STAR Program now includes students in high school, college, medical and pharmacy school, and those in graduate school pursuing PhD degrees. In addition, residents,

fellows, and junior faculty serve as near-peer and junior mentors for program participants.

Grant funding provides for student stipends, thereby allowing for the recruitment of students who may need financial support. The program goals for the next 2 years include expansion through collaboration with other institutions to create a similar program for medical students. First-year medical students will be able to apply for admission into STAR the following summer.

The STAR Program uses a team-based, project-centered approach to introduce students to clinical research. PTN and DCRI faculty provide a research project and mentorship for the summer and subsequent academic year. Research projects are secondary analyses of existing PTN (or PTN-partner) data, and are often related to dosing, safety, and use of therapeutics; however, clinical epidemiology and health services research are also frequently studied. In addition, the program's partnership with the Pediatric Medical Group<sup>2</sup> has been especially important. The Pediatric Medical Group provides care for more than 20% of newborn infants hospitalized in intensive care units in the United States. Information from these infants' electronic health records (including laboratory tests, diagnoses, and treatments) are assembled in a clinical data warehouse. These data have been the basis for more than 100 publications authored by faculty from PTN and Duke in partnership with Pediatric; the results from these publications are used by PTN to provide the rationale in the design of studies conducted in infants—for example, frequency of use of therapeutics, the need (or lack thereof) for required laboratory tests for safety monitoring.

The primary goals when creating the STAR Program were to design a curriculum of sufficient quality and rigor to ensure students were trained in appropriate research methods and to make certain that research projects resulted in participants authoring a research manuscript published in a peer-reviewed journal indexed in PubMed. This supplement of the *Journal of Pediatric Pharmacology and Therapeutics* includes manuscripts authored by STAR Program participants

Submitted October 23 2025; Accepted January 20 2026

and reflect the program's focus on therapeutics and other areas of pediatric research.

STAR is a hybrid program that includes up to 8 weeks of in-person instruction and remote (video call) follow-up throughout the subsequent academic year as needed to finish research projects. During the in-person, hands-on experience in research methodology and writing, participants are grouped in teams and matched with Duke clinical fellows and faculty mentors who volunteer their time to work on an original, hypothesis-driven project. Students spend their days immersed in an academic research environment while also receiving advice and guidance on practical skills that can be applied as they enter the workforce. In the morning, students attend lectures focusing on the diseases and conditions they are studying. In the afternoon, students are assigned to groups and partnered with a faculty member to complete literature searches and identify research questions. The faculty also work with students to generate statistical output, figures, and tables for their research manuscript. Students also attend midday seminars led by faculty that focus on practical how-to advice and cover a variety of topics, including communication in a professional setting, drafting a resume, preparing for interviews, and effective negotiation strategies.

A key component of the STAR Program is publishing research findings. Students receive instruction on professional scientific writing, including writing and submitting an abstract and guidance on how to design and present scientific posters and oral platform presentations. Students are responsible for drafting a manuscript based on the research question they identified with their small groups. The students draft the introduction, methods, results, and discussion sections; the faculty are responsible for reviewing and submitting the manuscript to a peer-reviewed journal. All STAR Program students who meet criteria for authorship as defined by the International Committee of Medical Journal Editors are listed as authors on the manuscript.

The STAR Program is extramurally funded and extremely successful; more than 300 students have completed the program since 2013 and 97% have been authors on a peer-reviewed publication. In 2024, there were 1127 applicants for the program.

As we look to the future of pediatric pharmacology and therapeutics, the overarching goal of the Duke STAR Program in 2026 is the same as when it started: to seek out and develop undiscovered talent.

## Article Information

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**Disclosures.** All authors attest to meeting the four criteria recommended by the ICMJE for authorship of this manuscript. Daniel K. Benjamin Jr disclosures available at <https://scholars.duke.edu/person/danny.benjamin/research#external-relationships>. Sarah C. Armstrong has nothing to report. Rachel G. Greenberg disclosures available at <https://scholars.duke.edu/person/rachel.greenberg1/research#external-relationships>.

This work was supported by the Biogen Foundation and Duke Clinical Research Institute's R25 Summer Training in Academic Research (STAR) Program (grant No. 5R25HD076475-10), the National Institute of Child Health and Human Development (NICHD) contract (HHSN2752010000031) for the Pediatric Trials Network (PI: Daniel K. Benjamin Jr), the Duke Clinical Research Institute (DCRI), and the Kiser-Arena Distinguished Professorship, Department of Pediatrics (Daniel K. Benjamin Jr). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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