



Childhood Cancer
STAR ACT
Survivorship Treatment Access and Research

CHILDHOOD CANCER STAR ACT SECOND ANNIVERSARY REPORT ON PROGRESS JUNE 5, 2020

The Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act is the most comprehensive childhood cancer bill in history. It expands opportunities for childhood cancer research, improves efforts to identify and track childhood cancer incidences and enhances the quality of life for childhood cancer survivors.

The STAR Act was signed into law on **June 5, 2018** (Public Law No: 115-180). The legislation permits Congress to provide up to **\$30 million for the STAR Act programs each year for five years**. For the past two years, Congress has fully funded the STAR Act. Our Champions on Capitol Hill are working to ensure that the STAR Act is once again fully funded for the fiscal year that begins on October 1, 2020.

Here is a brief update on some of the key accomplishments over the past two years that were made possible by the STAR Act:

CHILDHOOD CANCER BIOREPOSITORIES (STAR Act Title 1, Sec 101)

The STAR Act provides that the National Institutes of Health (NIH) may make awards to build upon existing research efforts to collect biospecimens and clinical and demographic information of children, adolescents, and young adults with selected cancer subtypes (and their recurrences) for which current treatments are least effective, in order to achieve a better understanding of the causes of such cancer subtypes (and their recurrences), and the effects and outcomes of treatments for such cancers.

Amounts received under an award may be used to carry out the following:

- Collect and store high-quality, donated biospecimens and associated clinical and demographic information on children, adolescents, and young adults diagnosed with cancer in the United States, focusing on children, adolescents, and young adults with cancer enrolled in clinical trials for whom current treatments are least effective. Activities under this subparagraph may include storage of biospecimens and associated clinical and demographic data at existing biorepositories supported by the National Cancer Institute (NCI).

- Maintain an interoperable, secure, and searchable database on stored biospecimens and associated clinical and demographic data from children, adolescents, and young adults with cancer for the purposes of research by scientists and qualified health care professionals.
- Establish and implement procedures for evaluating applications for access to such biospecimens and clinical and demographic data from researchers and other qualified health care professionals.
- Provide access to biospecimens and clinical and demographic data from children, adolescents, and young adults with cancer to researchers and qualified health care professionals for peer-reviewed research

What Has Been Accomplished?

In his 2019 State of the Union Address, the President announced a new Childhood Cancer Data Initiative (CCDI) that would build on the biorepository provisions of the STAR Act. CCDI aims to establish more efficient ways to share and use childhood cancer data with an aggressive focus on data sharing.

According to the NIH website, “NCI anticipates that the CCDI will complement and enhance efforts aligned with the Childhood Cancer STAR Act.” Moreover, in 2019, NCI Acting Director Douglas Lowy noted that, “Data from specimens collected through the STAR Act efforts will contribute to the CCDI, and CCDI data resources will also enable future survivorship research.”

On May 13, 2019, the NCI hosted its first formal meeting to begin the implementation of the Biorepository provisions of the STAR Act. Leaders of the NCI and the childhood cancer community met to discuss the challenges and opportunities of childhood cancer biobanking.

For the current fiscal year, Congress provided \$50 million specifically for the CCDI. Moreover, Congress has directed the NCI to invest an additional \$25 million to implement the STAR Act biorepository provisions. The NCI Board of Scientific Advisors Working Group, which was created to provide general guidance for CCDI, is scheduled to present an initial report to NCI in June 2020. When this report is released, we expect to see a sustained action on the implementation of the STAR Act provisions related to biorepositories.

CDC SURVEILLANCE PROGRAM (STAR Act Title 1, Sec 102)

The STAR Act provides that the Centers for Disease Control and Prevention (CDC) may make awards to State cancer registries to enhance and expand infrastructure to collect information to better understand the epidemiology of cancer in children, adolescents, and young adults. Such registries may be updated to include each occurrence of such cancers within a period of time designated by the Secretary of Health and Human Services (HHS).

The grants may be used for:

- Identifying, recruiting, and training potential sources for reporting childhood, adolescent, and young adult cancer cases
- Developing practices to ensure early inclusion of childhood, adolescent, and young adult cancer cases in State cancer registries through the use of electronic reporting.
- Collecting and submitting deidentified data to the CDC for inclusion in a national database that includes information on childhood, adolescent, and young adult cancers
- Improving State cancer registries and the database described above, as appropriate, including to support the early inclusion of childhood, adolescent, and young adult cancer cases

What Has Been Accomplished?

In each of the past two years, Congress has provided the CDC with an additional \$2 million pursuant to the STAR Act to enhance childhood cancer surveillance.

In 2019, the CDC expanded the number of states that have comprehensive childhood cancer surveillance programs (expanding from 7 to 10 states) and began the to modernize cancer registries by creating a national cloud-based computing platform that will enable real-time reporting to central cancer registries.

On September 29, 2019, the CDC awarded a 5-year contract to develop a software tool that will aid pediatric cancer reporting facilities with rapidly submitting cancer incidence to Central Cancer Registries.

In February of 2020, the CDC gathered public health officials from 12 states to discuss the expansion of the Surveillance program. States included California, Florida, Georgia, Kentucky, Louisiana, Minnesota, Nebraska, New Hampshire, Ohio, Texas, Rhode Island and Utah.

The CDC has formed implementation and stakeholder advisory groups to inform its work. These groups held initial meetings in May and June 2020. The Alliance for Childhood Cancer is represented on the stakeholder advisory group.

PILOT PROGRAMS TO EXPLORE MODEL SYSTEMS OF CARE FOR PEDIATRIC CANCER SURVIVORS (STAR Act Title 2, Sec 201(a))

The STAR Act permits the Secretary of Health and Human Services to make awards to eligible entities to establish pilot programs to develop, study, or evaluate model systems for monitoring and caring for childhood cancer survivors throughout their lifespan, including evaluation of models for transition to adult care and care coordination.

What Has Been Accomplished?

This is the only provision of the STAR Act that has not yet begun. The STAR Act sets out a host of actions to be taken over five years and we understand that HHS must coordinate its works sequentially. When the work on Best Practices (below) is complete in 2021, we expect HHS will turn its attention to this provision of the STAR Act.

WORKFORCE DEVELOPMENT FOR HEALTH CARE PROFESSIONALS ON MEDICAL AND PSYCHOSOCIAL CARE

(STAR Act Title 2, Sec 201(b))

The STAR Act requires that the Secretary of Health and Human Services shall conduct a review of the activities of the Department of Health and Human Services related to workforce development for health care providers who treat pediatric cancer patients and survivors. Such review shall include:

- An assessment of the effectiveness of supportive psychosocial care services for pediatric cancer patients and survivors, including pediatric cancer survivorship care patient navigators and peer support programs
- Identification of existing models relevant to providing medical and psychosocial services to individuals surviving pediatric cancers, and programs related to training for health professionals who provide such services to individuals surviving pediatric cancers
- Recommendations for improving the provision of psychosocial care for pediatric cancer survivors and patients

What Has Been Accomplished?

Under the provisions of the STAR Act, the Secretary of Health and Human Services must conduct this review and report to Congress by June 5, 2020. With the final review in hand, we can then determine what actions and potential legislation may be appropriate to implement the recommendations.

RESEARCH ON PEDIATRIC CANCER SURVIVORSHIP (STAR Act Title 2, Sec 202)

The STAR Act provides that the Director of the NIH may conduct or support pediatric cancer survivorship research including in any of the following areas:

- Outcomes of pediatric cancer survivors, including within minority or other medically underserved populations and with respect to health disparities of such outcomes

- Barriers to follow-up care for pediatric cancer survivors, including within minority or other medically underserved populations
- The impact of relevant factors, which may include familial, socioeconomic, and other environmental factors, on treatment outcomes and survivorship
- The development of indicators used for long-term follow-up and analysis of the late effects of cancer treatment for pediatric cancer survivors
- The identification of risk factors associated with the late effects of cancer treatment; predictors of adverse neurocognitive and psychosocial outcomes; and the molecular basis of long-term complications
- The development of targeted interventions to reduce the burden of morbidity borne by cancer survivors in order to protect such cancer survivors from the late effects of cancer

What Has Been Accomplished?

On January 11, 2019, the NCI published an RFA: “Improving Outcomes for Pediatric, Adolescent and Young Adult Cancer Survivors.” The NCI anticipates funding 6-8 new research project grants to develop interventions to prevent, mitigate, and manage adverse disease- and treatment-related outcomes and/or to test and refine models of care for survivors of pediatric, adolescent, and young adult cancers across their lifespan.

In its first year, NCI is scheduled to provide a **\$4.8 million total annual set aside for the RFA (with a total of \$25 million to be invested over five years)**. The NCI has shown incredible good will in expediting the publication of this RFA and in funding these new research projects.

BEST PRACTICES FOR LONG-TERM FOLLOW-UP SERVICES FOR PEDIATRIC CANCER SURVIVORS (STAR Act Title 2, Sec 203)

The STAR Act permits the Secretary of Health and Human Services to facilitate the identification of best practices for childhood and adolescent cancer survivorship care and consult with individuals who have expertise in late effects of disease and treatment of childhood and adolescent cancers, which may include:

- Oncologists, which may include pediatric oncologists
- Primary care providers engaged in survivorship care
- Survivors of childhood and adolescent cancer
- Parents of children and adolescents who have been diagnosed with and treated for cancer and parents of long-term survivors
- Nurses and social workers
- Dental health professionals
- Allied health professionals, including physical therapists and occupational therapists

What Has Been Accomplished?

In January 2020, the HHS Secretary tasked the Agency for Healthcare Research and Quality (AHRQ) with conducting work to identify best practices for improving the effectiveness of care provided to childhood and adolescent cancer survivors.

AHRQ is planning to launch a series of AHRQ Evidence-based Practice Center (EPC) Program reviews to identify best practices for childhood and adolescent cancer survivorship care across several areas emphasized in the STAR Act. The EPC Program will conduct three separate evidence reviews. These will focus on: 1) The transition of care from pediatric to adult services for childhood and adolescent cancer survivors; 2) Models of pediatric survivorship care; and 3) Disparities and barriers to survivorship care and strategies that have been proposed to address these barriers.

AHRQ estimates the work will take approximately 18 months to complete, which will allow for a reporting date in the summer of 2021.

BARRIERS TO OBTAINING AND PAYING FOR ADEQUATE MEDICAL CARE FOR SURVIVORS OF CHILDHOOD CANCER

As part of the STAR Act, Congress included a provision in the Fiscal Year 2019 (FY2019) Labor, Health, and Human Services Appropriations bill that stated:

The Committee requests that GAO conduct a review and submit recommendations to Congress on existing barriers to obtaining and paying for adequate medical care for survivors of childhood cancer. This report would include identifying existing barriers to the availability of complete and coordinated survivorship care for survivors of childhood cancer and make recommendations to provide improved access and payment plans for childhood cancer survivorship programs and palliative care, including psychosocial services.

What Has Been Accomplished?

In August 2019, the U.S. Government Accountability Office (GAO) began work on this report. The Alliance for Childhood Cancer met with the GAO Team Leaders to discuss the report and invited the GAO to attend the October 2019 Alliance for Childhood Cancer Meeting to discuss this with all the Members of the Alliance.

On October 29, 2019, the GAO Team Leaders spent two hours with Alliance Members, listening and asking questions about a wide array of issues that could create barriers for childhood cancer survivors to getting the care they need.

The GAO has advised that its research is moving along briskly. It is currently developing a time frame for public release of the Final Report, which they estimate will be released in the summer of 2020. With these recommendations in hand, we can then determine what actions and potential legislation may be appropriate to enact the findings of the report.