# 2016–2021 Strategic plan









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# VISION FOR THE FUTURE

St. Jude Children's Research Hospital is a remarkable place of innovation with a legacy of success and a culture that allows it to achieve the extraordinary. Our focused vision of finding cures and saving children has led to the development of a world-renowned institution that has made a lifesaving difference to countless families around the globe.

With the 2016–2021 Strategic Plan, St. Jude has an exciting blueprint on which to build the institution's future. My gratitude is owed to the executive team, the more than 180 faculty and staff, and the leadership of the Board of Governors and ALSAC who lent their time, energy and talent to help shape this new strategic plan. The programs detailed within this plan will help St. Jude lead a new era of advancements in the research and treatment of pediatric catastrophic diseases.

ames K gran James R. Downing, MD President and Chief Executive Officer

2) ST. JUDE 2016–2021 STRATEGIC PLAN

THE **MISSION** OF ST. JUDE CHILDREN'S RESEARCH HOSPITAL IS TO ADVANCE CURES, AND MEANS OF PREVENTION, FOR PEDIATRIC CATASTROPHIC DISEASES THROUGH RESEARCH AND TREATMENT. CONSISTENT WITH THE VISION OF OUR FOUNDER, DANNY THOMAS, NO CHILD IS DENIED TREATMENT BASED ON RACE, RELIGION OR A FAMILY'S ABILITY TO PAY. OUR **VALUES** ARE AN INTEGRAL PART OF OUR IDENTITY AND GUIDE OUR DAILY ACTIONS AND DECISIONS. THE INCORPORATION OF THESE VALUES DIRECTLY IMPACTS OUR ABILITY TO MAKE PROGRESS TOWARD ACHIEVING THE MISSION OF ST. JUDE CHILDREN'S RESEARCH HOSPITAL.

**EXCELLENCE:** We embrace a culture of excellence, incorporating honesty, integrity and accountability in every action and decision.

**INNOVATION:** We foster an environment of discovery, collaboration and creativity.

**COMPASSION:** We demonstrate sensitivity to the physical and emotional needs of our patients, families, staff and supporters.

**DIVERSITY:** We respect ethnic, cultural, religious and lifestyle differences of all people.

# INTRODUCTION TO THE FY16–FY21 STRATEGIC PLAN

St. Jude Children's Research Hospital is recognized as one of the leading medical institutions in the world. Central to its success is its focused mission to advance cures and means of prevention for pediatric catastrophic diseases through research and treatment; its seamless integration of outstanding patient care and world-class clinical and laboratory research; its unique culture where every employee is part of a team that places the child and their family at the center of everything; and its financial strength and stability, which stem from a unique structure of two interdependent but separate institutions, St. Jude and ALSAC, working together with a highly engaged Board. We can be very proud of the legacy of accomplishments and the great work done every day to advance the St. Jude mission.

As stewards of this extraordinary institution, however, we must continuously ask, "Are we doing enough in the war against pediatric catastrophic diseases?" We are at a point in our hospital's history where it is clear that we can do more. St. Jude has a unique opportunity to step up and become the recognized world leader of pediatric medicine for the diseases we treat. In this role, we can establish a global clinical care and research agenda that will accelerate progress toward accomplishing our mission and improving lives for countless families. St. Jude has the talent, institutional culture, resources and public support to effectively lead the field.

To address these goals, the institution embarked on a seven-month planning process to develop a new six-year strategic plan (FY16–FY21). That process is described in Appendix I at the end of this document. Members of the Strategic Planning Oversight Group, the 15 Strategic Planning Working Groups, and the St. Jude Board of Governors Strategic Planning Committee are listed in Appendix II.

## OUR NEW SIX-YEAR STRATEGIC PLAN IS CENTERED ON 11 SPECIFIC GOALS.

## **OUR CLINICAL CARE PRIORITIES**

- Increase the number of patients treated on St. Jude-led clinical trials both on our campus and around the globe to accelerate progress in advancing cures, while minimizing therapyrelated toxicities
- Set the standard for pediatric cancer care delivery and the experience patients and their families have throughout their cancer treatment journeys
- Advance our clinical care programs for children with non-malignant hematological diseases, including sickle cell disease, coagulation disorders and bone marrow failure syndromes

## **OUR RESEARCH PROGRAMS**

- Strengthen our basic laboratory research programs, which serve as the foundation for our understanding of disease pathogenesis and therapeutic responses
- Enhance our clinical research programs and the infrastructure that supports them so that St. Jude continues to effectively develop and run high-complexity protocols that advance cures
- Establish the benchmark for the use of precision medicine in pediatric oncology for diagnosis, treatment selection, disease-response monitoring, diagnosing and managing therapy-related toxicities and for identifying patients who would benefit from cancer-surveillance screenings
- Determine the optimal application of proton beam therapy in the treatment of pediatric patients with brain tumors, solid tumors and Hodgkin lymphoma
- Develop a world-class cancer immunotherapy program focused on pediatric cancers

## **OUR GLOBAL LEADERSHIP POSITION**

- Expand our International Outreach Program so that it can lead a global effort to ensure that cures for pediatric cancer are rapidly made available throughout the developing world
- Develop a St. Jude-funded global clinical research consortium that can rapidly advance therapeutic trials for pediatric cancer
- Organize global teams of scientists who will collaboratively address high-priority scientific questions identified as gaps in knowledge that are currently limiting progress against pediatric catastrophic diseases

In the sections that follow, we detail the programs required to achieve the 11 specific goals. This strategic plan is based on the belief that St. Jude—with its history of achievement, exceptional faculty and staff, and support from ALSAC and its millions of donors across the United States—is poised for an era of unprecedented discovery. As such, we must do what others cannot do. We must continually ask, "If not St. Jude, then who?"



# OUR CLINICAL CARE PRIORITIES

St. Jude is committed to providing the best medical care and supportive services for children with hematological malignancies, brain tumors, solid tumors, non-malignant hematopoietic diseases or select infectious diseases. Our models of care for the treatment of these diseases must set the standards to which other institutions aspire. During the next six years, St. Jude will continue to focus 75 percent of its overall efforts toward advancing cure rates for pediatric cancer and 25 percent toward non-malignant hematological diseases and select infectious diseases.



The St. Jude cancer program is one of the largest in the world. Our efforts during the last five decades have contributed to many of the advancements made in pediatric oncology. As a result, the overall cure rate for pediatric cancer today is 80 percent, with some cancers like acute lymphoblastic leukemia (ALL) exceeding 90 percent. Nevertheless, pediatric cancer remains the leading cause of death from disease among children ages 1 to 14 in the U.S. One in five children with cancer still succumbs to his or her disease. Moreover, for some pediatric cancers, such as diffuse intrinsic pontine glioma, acute megakaryoblastic leukemia and metastatic neuroblastoma, cure rates remain very low. In addition, survivors of pediatric cancer are at risk for a variety of long-term side effects, many of which are being accurately identified for the first time through the efforts of St. Jude. Our focus for the future must be not only to advance the cure rate for every child with cancer, but also to develop more tailored treatment approaches that will increase cure rates, while decreasing therapy-related toxicities.

To accelerate progress during the next six years, St. Jude will make a concerted effort to enroll more patients on St. Jude-led therapeutic and non-therapeutic clinical studies. Our faculty and staff have the talent, creativity and infrastructural support to develop novel clinical protocols for the most aggressive forms of pediatric cancer. By increasing patient volume, we will be able to complete protocols more rapidly and use our results to inform the next round of clinical innovation. To accomplish this, we will need to expand the infrastructure for both clinical care and clinical research.

On the next page, we describe the clinical care efforts required to effectively treat an expanded number of patients on our campus. In the section titled "Our Research Programs" (page 12), we lay out the expansion in research efforts that will drive progress in advancing cures, while decreasing therapy-related toxicities. We then address our global leadership position and describe the significant expansion planned in our International Outreach Program, the creation of a St. Jude-led Clinical Research Consortium and the development of global teams of scientists working collaboratively to address the most pressing scientific problems in the field of pediatric catastrophic diseases.

## ENHANCING CARE ON OUR CAMPUS

## By FY21, our goal is to have a 20 percent increase in the number of new cancer patients treated each year on the St. Jude campus.

This will require a substantial increase in the infrastructure for clinical care delivery, including growth in faculty and staff, expansion of inpatient and outpatient facilities, and new office space for the workforce involved in the multidisciplinary care teams that are a hallmark of our clinical care models.

Along with the planned expansions in workforce and facilities, St. Jude will further enhance its focus on quality and safety practices. We have named Dr. Pat Flynn as chief quality officer and Dr. James Hoffman as chief patient safety officer to lead a team focused on education and the use of data analytics to continuously improve the quality and safety of the care we deliver. The analytic efforts will interact extensively with our Clinical Informatics group, allowing the institution to take full advantage of the large data sets within the electronic medical record.

## IMPROVE THE PATIENT AND FAMILY EXPERIENCE

Patients deserve the best treatment in a caring environment that makes their journeys as comfortable and supportive as possible. We will evaluate the total patient and family experience, including initial contact with St. Jude, arrival on campus, registration, clinic scheduling, waiting areas, methods of communication both on and off campus, inpatient admissions, discharge processes and housing. St. Jude will address this from the perspective of space planning, information systems, scheduling and process reengineering and will implement recommended improvements across the hospital's operational units. With the move of all inpatients into the Chili's Care Center and the Kay Research and Care Center and the construction of a new outpatient facility, St. Jude will be able to address



this in a holistic manner. A new Office of Patient and Family Experience will be established in FY16 and will be charged with leading the effort to reengineer the patient treatment journey at St. Jude. This team will work closely with a new Office of Strategic Planning and Decision Support to conduct the detailed studies that will be required to effectively introduce changes that will most benefit patients and their families. A patient and family Town Square will be incorporated into designs for the new outpatient facilities and renovated Patient Care Center. This will be a one-stop center where families receive assistance with their various needs, ranging from housing to travel requests to shopping for basic items (both on-site and through an online purchasing option) to assistance with reservations for local events. Together with the Family Advisory Council and our established culture of familycentered care, we can set the standard for the experience patients and their families have as they move through their cancer treatment.

## INCREASE RECRUITMENT OF PATIENTS

Our goal is to become the center of choice for children with high-risk forms of cancer and select non-cancer diseases for which we have unique clinical trials. To better promote our clinical and research expertise, we will need to invest in strengthening our Physician/Patient Referral Office.

St. Jude will also need to enhance its effort to directly inform families about the treatment options available through our programs. A key effort toward accomplishing this goal will be to develop a Web-based resource for the families of children recently diagnosed with cancer. This source will inform parents about diseases, current treatment options, what St. Jude offers and what treatment options can be obtained within their local regions. This site will have a direct link to contact St. Jude for consultation or referral and will ensure that a hospital representative replies within 24 hours. Our hope is to make this website the only resource a family will need to visit for key information about pediatric cancer. Creation of such a site and the associated consultation service and informational efforts will require additional personnel, but will ultimately serve as an invaluable resource to parents of pediatric cancer patients worldwide.

## ENHANCE OUR CLINICAL PROGRAMS FOR CHILDREN WITH NON-MALIGNANT HEMATOLOGICAL DISEASES

Efforts to increase the number of patients treated on our campus will extend to children with sickle cell disease, coagulation disorders and bone marrow failure syndromes. Since its beginning, St. Jude has served as a prominent source of care for pediatric patients with sickle cell disease in the greater Memphis area. Our program has a legacy of innovation and is responsible for the first cure of sickle cell disease through allogeneic bone marrow transplantation. St. Jude must carry this torch forward by continuing to advance the management of ongoing disease complications, while developing true cures. The St. Jude clinical program will strengthen its efforts to provide children with the best care available, expand the number of therapeutic trials available and develop a leading bone marrow transplantation program for patients whose disease severity requires this aggressive form of therapy.

In conjunction with the University of Tennessee Health Science Center and regional hospital systems, we will work toward enhancing the care received by our patients as they transition into the adult care environment. We will also focus our efforts on becoming an international referral center for children with coagulation disorders and bone marrow failure syndromes. These latter efforts will significantly benefit from the Department of Hematology's gene therapy program and our expanded efforts in genomic medicine that are described in the next section.



# OUR RESEARCH PROGRAMS

At St. Jude, our responsibility is to learn from every patient treated on campus and to use this information to advance treatment. This can only be achieved through the constant exchange of information between the clinic and the basic research laboratories. Investigators must take observations made within the clinic and move them into fundamental studies within our research laboratories. Simultaneously, scientists must take observations and methodologies from the labs and move them to the clinic. Only by combining outstanding patient care with sophisticated, biologically driven therapeutic trials will we accelerate progress in developing cures for pediatric catastrophic diseases.



## ENHANCING BASIC LABORATORY RESEARCH ON OUR CAMPUS

To strengthen basic laboratory research, St. Jude will increase the number of its faculty dedicated to fundamental discovery and enhance the infrastructure that supports laboratory research. This effort has begun with the creation of two new basic science departments: Cell and Molecular Biology under the leadership of Dr. J. Paul Taylor, and Computational Biology under the leadership of Dr. Jinghui Zhang. During the next six years, these departments will recruit a total of 14 new faculty and more than 50 staff members. Their combined efforts will enhance our understanding of the normal biology of molecular, cellular and organ systems and help define how alterations within these systems lead to diseases. St. Jude will also appoint new leadership to the Departments of Developmental Neurobiology and Structural Biology. During the last decade, these departments have been two of the most prominent scientific forces within the institution. The fundamental work performed by their laboratories must remain at the cutting edge of science and incorporate the most advanced experimental systems and methodologies. Their work must be innovative, investigator initiated and directed only by their commitment to advance our understanding of human biology. The appointment of new leadership for both departments will be a priority during the first two years of our strategic plan. Near the end of the strategic-planning process, we will need additional laboratory space to accommodate these and other growing laboratory efforts. To meet these demands, we will build a new laboratory research building as part of our six-year vision. A key interface between basic and clinical science is the Department of Chemical Biology and Therapeutics (CBT). This effort has brought great strength to the institution and has made a significant impact on the kind of research pursued at St. Jude. CBT has successfully engaged both laboratory and clinical investigators and is making important progress to assess available drugs for potential use in the treatment of pediatric cancers an effort termed drug repurposing.

During the next six years, our focus will be to coordinate this work across campus. This will include efforts to gain early access to new agents, which are being tested in the clinic for uses unrelated to pediatric catastrophic diseases. The department will also expand its efforts to develop chemical probes that can be used both to explore fundamental biological processes, as well as serve as lead compounds for drug development, which if warranted, could be pursued through partnerships with pharmaceutical and biotechnology companies. Together, our preclinical-to-clinical drug development efforts will help define the most effective drugs and drug combinations for the treatment of pediatric cancer and other catastrophic diseases.

One new laboratory-based initiative that was identified through the strategic-planning process is to build a coordinated program that focuses on the biological processes that control gene expression. We will recruit four new faculty members to develop a cross-departmental program that will not only broaden the scientific expertise on campus but also complement the current work that is being pursued in cancer biology, non-malignant hematopoietic diseases and infectious diseases.

Success in laboratory-based research requires deep scientific knowledge mixed with creativity and a fearlessness to tackle what are often believed to be unsolvable problems. Creating an environment that fosters success requires engaging individuals at different stages of their career, including experienced scientists as well as graduate students. Bright graduate students bring energy, a commitment to learn and a naiveté that can fuel new insights. St. Jude benefits from a close relationship with the University of Tennessee Health Science Center's graduate program as well as other informal arrangements with programs around the world. We currently have 71 graduate students from universities across the nation pursuing their doctoral degrees on our campus.

To further enhance the role of graduate students in laboratory-based research programs, St. Jude will establish a new graduate school for a PhD in biomedical research. This program will capitalize on the hospital's unique and unparalleled translational research environment. The program will take 10 to 12 students a year for four to five years of graduate work, leading to a PhD. Formal planning for this program has begun, and the goal is to have an initial entering class for FY18.



## ENHANCING CLINICAL AND TRANSLATIONAL RESEARCH ON OUR CAMPUS

St. Jude was built on the idea that research and clinical care are a continuum, and progress can only be made by having world-class laboratory investigators continuously interacting with clinicians schooled in the science of clinical investigation. To continue this legacy, we will strengthen and expand our clinical and translational research programs and the systems that support these efforts.

### St. Jude cancer research programs

St. Jude is the only National Cancer Institutedesignated Comprehensive Cancer Center solely dedicated to pediatric patients. Under the leadership of a new director, Dr. Charles Roberts, the St. Jude Cancer Center contains one basic science program (Cancer Genetics, Biochemistry, and Cell Biology), one population science program (Cancer Prevention and Control), and three clinical/translational programs (Developmental Biology and Solid Tumors, Hematological Malignancies, and Neurobiology and Brain Tumor). Strengthening our three clinical/ translational programs is a top priority, which will be accomplished by focusing on three interrelated efforts: 1) elucidate the molecular mechanisms underlying tumor formation, heterogeneity and therapeutic resistance; 2) identify therapies that exploit the identified molecular mechanisms; and 3) develop therapeutic trials based on the identified biological principles, with a particular emphasis on refractory and relapsed disease. As part of this, St. Jude will expand its clinical trial portfolio to cover a broader range of molecularly defined tumor subtypes. In addition, St. Jude will enhance its Phase I efforts to assess new drugs in the treatment of pediatric cancers.

An essential component of our clinical/ translation research efforts will be to **establish the benchmark for the use of precision medicine in pediatric oncology** for diagnosis, treatment selection, disease-response monitoring, diagnosing and managing therapy-related toxicities and for identifying patients who would benefit from cancer-surveillance screenings. St. Jude has taken a leading role in the National Institutes of Health Pharmacogenomics Research Network and has led clinical initiatives to incorporate host pharmacogenetic testing into routine patient care at St. Jude through the PG4KDS protocol and internationally through the Clinical Pharmacogenetics Implementation Consortium.

The St. Jude Children's Research Hospital-Washington University Pediatric Cancer Genome Project (PCGP) was a game changer in pediatric oncology. It helped to define new genetic subtypes of pediatric cancer; gave new insights into the underlying genetic lesions that drive the formation of cancer, intra-tumor heterogeneity, metastatic behavior and therapeutic resistance; and led to the identification of potential new therapeutic targets against which new agents could be developed. The discovery phase of the PCGP continues, and we have included resources to not only continue to sequence additional pediatric cancer samples, but also to make sure the extensive expertise developed through the project is available to all basic and clinical research programs at St. Jude.

A major challenge for the immediate future will be to define how to move DNA sequencing into the clinic. During the last 18 months, St. Jude established the infrastructure required for clinical genomics. We now have a CLIA-certified DNA sequencing laboratory, analytical pipeline and an informatics environment that allows integrated interpretation of DNA and RNA sequencing data, as well as reporting of medically significant genetic lesions identified in either tumor DNA or the patient's normal tissue. In addition, we have developed a clinical genomics team of pediatric oncologists, molecular pathologists, medical geneticists, pharmacists, genetic counselors, ethicists, computational biologists and data analysts. This group works collaboratively to enroll patients, obtain tissue samples, perform analyses, interpret data and communicate the results to patients, their families and their primary physicians.

The St. Jude clinical genomics team and infrastructure are second to none. Our precision medicine studies will be performed under a new clinical research protocol, Genomes for Kids, which opened in July of FY16. This is a feasibility study to help establish the benchmark for the application of precision medicine to pediatric oncology. Based on the experience obtained through this study, we will then move DNA-based sequencing analysis into the routine workup of every cancer patient admitted to St. Jude. It is our expectation that we will also extend this level of analysis to all consenting patients enrolled in our collaborative clinical research trials, including patients treated beyond our campus.



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During the next six years, St. Jude will initiate four new cancer-focused programs: (1) a clinical service dedicated to the diagnosis and care of children with hereditary predispositions to cancer; (2) a national referral clinic for rare pediatric cancers; (3) a proton beam therapy program; and (4) a cancer immunotherapy program.



### 1. TheCancer Predisposition Program

under the leadership of Dr. Kim Nichols, a recent recruit from the Children's Hospital of Philadelphia, will be an integral part of the St. Jude clinical genomics effort. Dr. Nichols will serve as the principal investigator of the Genomes for Kids (G4K) protocol. This program will manage the work-ups of all children expected of having hereditary predispositions to cancer. It will also perform surveillance testing so that the presence of any developing cancer can be detected at the earliest possible time, when the chances for a cure are highest.

Work performed as part of the PCGP has demonstrated that almost 10 percent of St. Jude pediatric cancer patients have genetic lesions in their normal tissue predisposing them to the development of cancer. When these patients are identified, we will perform comprehensive genetic testing and offer counseling for the entire family. In addition, St. Jude will manage the care for any sibling found to carry a genetic lesion. We anticipate the G4K program will grow significantly during the next several years and by 2021, 200 to 250 children annually will be under the care of physicians and genetic counselors from this program.

2. Within the general classification of pediatric solid tumors, a variety of rare tumor types continue to have poor outcomes. The rarity of each individual tumor type and the inability of any single institution to develop significant expertise in its treatment contribute to poor outcomes. To advance cures for these rare tumors, St. Jude will develop a referral clinic for rare tumors, bringing in patients from around the globe beginning in early 2016. We will begin this effort focused on pediatric melanoma, a tumor type that is uniformly lethal once it spreads. Through the PCGP, researchers have made important

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insights into the genetic lesions that drive the growth of pediatric melanoma. We will use this information to develop new therapeutic protocols and enroll a sufficient number of patients so that the studies can be completed as quickly as possible. St. Jude will not limit its efforts to melanoma but, over time, will expand the clinic to include other rare types of pediatric cancer. By developing this effort, St. Jude will accelerate improvements in therapy for some of the most aggressive and least studied childhood tumors.

3. In 2009, St. Jude started to use proton beam radiation therapy to treat a subset of its cancer patients through a collaborative arrangement. Patients have been treated on St. Jude protocols at the University of Florida's Proton Therapy Institute in Jacksonville. At the same time, St. Jude invested \$100 million in building the St. Jude Red Frog Events Proton Therapy Center, a state-of-the-art proton therapy facility, which will treat its first patient before the end of 2015. This center will contain three treatment rooms equipped with uniquely advanced technology.

Earlier this year, we appointed Dr. Thomas E. Merchant chair of the newly created Department of Radiation Oncology. Under his leadership, **St. Jude will develop**  the leading proton therapy program for children in the world. This program will incorporate advanced treatment and imaging modalities with a sophisticated computational infrastructure so that St. Jude can define the best use of this treatment for pediatric cancer patients. We are convinced that proton therapy will offer better tumor control, while decreasing toxicities - an overarching goal for St. Jude cancer treatment programs. The first child will be treated in the facility before the end of this year. We will gradually increase the number of children treated within the facility so that by 2018, 80 percent of children receiving radiation therapy at St. Jude will be treated in the center. The remaining patients will receive photon-based radiation therapy delivered in the Department of Radiation Oncology.

4. The field of cancer immunotherapy is a new and rapidly advancing area of cancer therapeutics. This approach redirects and/ or enhances the immune system so that it attacks cancer cells, leading to their elimination. Work is being pursued not only by academic laboratories but also by biotechnology companies and several major pharmaceutical corporations. A variety of approaches are being explored, including inhibiting endogenous signals (so-called immune checkpoints), which serve as natural



brakes of cellular immune reactions; delivering therapeutic doses of autologous or allogeneic naturally occurring immune cells, or immune cells genetically modified to enhance their targeting of cancer cells; tumor vaccines that stimulate the patient's immune system to react against cancer-specific antigens; and the use of antibodies directed against a variety of cancer-associated targets, from naturally occurring growth signals to cancerspecific tumor antigens. Each of these approaches has shown positive benefits in the treatment of a variety of adult cancers. In addition, genetically modified T cells engineered to express a chimeric antigen receptor (CAR) directed against the CD19 antigen seen on acute lymphoblastic leukemia (ALL) cells has resulted in remissions in some children with refractory B-lineage ALL.

Importantly, the CD19-CAR technology used in ALL was developed by Dr. Dario Campana and Dr. Chihaya Imai at St. Jude. This CAR technology is now being used by the biotechnology and pharmaceutical industries to develop genetically modified immune cells specifically targeted against a variety of cancer types. St. Jude will now invest in establishing a new cancer immunotherapy program that will involve faculty and staff from a variety of academic departments, including Bone Marrow Transplantation and Cellular Therapy, Hematology, Immunology, Infectious Diseases, Pathology and Oncology.

In addition to the therapeutic efforts outlined above, St. Jude will increase its investment in defining, and ultimately, decreasing the long-term toxicities of pediatric cancer therapies. The goal of these efforts is to ensure that every child cured of cancer has the best possible chance to live a long and full life, free of serious treatment-induced medical complications.

In 2007, Drs. Les Robison and Melissa Hudson in the Department of Epidemiology and Cancer Control, and within the Cancer Control and Prevention Program of our Cancer Center, developed the St. Jude LIFE long-term follow-up study. This program involves about 4,500 St. Jude childhood cancer survivors, who are invited back to our campus on average every three years for medical testing to determine if they have long-term side effects related to their cancer treatments.

In its relatively short history, St. Jude LIFE has become one of the nation's most significant survivorship research efforts. It has demonstrated that the majority of childhood cancer survivors have at least one chronic health condition, including new cancers, heart abnormalities, abnormal lung function and/ or neurocognitive dysfunction. Importantly, however, St. Jude researchers have also demonstrated that the overall frequency of these complications has decreased as our pediatric cancer therapies became more individualized to patients and their tumor types. Moreover, in collaborative studies with investigators from the Department of Pharmaceutical Sciences, biomarkers have been discovered that identify patients who are at an increased risk of developing toxicities from specific drugs. Discoveries such as these help researchers design new therapies that will maintain high cure rates, but will reduce treatment-related side effects by individualizing the type and/or the dose of drug each patient will receive.

With the tremendous success realized by the St. Jude LIFE study, we will expand this study to 6,000 pediatric cancer survivors. By increasing the number of patients being followed, St. Jude will significantly improve its ability to define risk factors, including genetic risk, for the development of long-term adverse consequences of cancer therapy. This new information will influence not only the way we follow current patients, but will also change how we treat future patients so that every survivor of pediatric cancer has a chance for a bright and full future.

## NON-MALIGNANT HEMATOLOGY RESEARCH PROGRAMS

St. Jude is committed to significantly advancing cures for some of the most devastating pediatric non-malignant hematological disorders. Dr. Mitchell Weiss, recently recruited from the Children's Hospital of Philadelphia, is leading this effort as chair of the Department of Hematology. The department will focus on several disease categories: sickle cell anemia and related hemoglobinopathies, coagulation disorders, select immunodeficiencies and bone marrow failure disorders (both sporadic and inherited). Researchers will use clinical genomics and genesequencing programs to better understand how gene mutations cause blood diseases and influence their outcomes. St. Jude will provide these patients with the best available care and access to novel therapeutic trials.

Home to one of the largest sickle cell anemia programs in the nation, St. Jude manages care for the majority of children with this disease from the greater Memphis area and its affiliates. Current sickle cell treatments are aimed at preventing sickling crises; relieving symptoms; and preventing complications, such as strokes and transfusion-related toxicities. St. Jude is the first to use routine pharmacogenetic testing to apply precision medicine principles to analgesic prescribing for sickle cell patients.

Our future focus will be to preserve vital organs damaged by the disease and to develop curative treatments, while improving symptomatic disease management. The only curative treatment for sickle cell anemia is allogeneic bone marrow transplantation, a discovery first made at St. Jude. It is time to advance this form of treatment for children whose disease severity requires this intensive therapy. This will take a coordinated effort between the Hematology and Bone Marrow Transplantation and Cellular Therapy departments to define the patients who will most benefit from this treatment option and to develop transplantation protocols that improve

C. Jude Childrens Assearch Hospital engraftment rates and decrease transplant-related toxicities. In parallel, investigators will expand their efforts to explore the role of gene editing and gene therapy as potential curative treatments for sickle cell anemia. These efforts will be focused on preclinical studies, but with success, will move into the clinic.

Working in collaboration with investigators from the Pediatric Cancer Genome Project and Computational Biology, the Sickle Cell Program will also sequence the germ line DNA from 1,000 St. Jude sickle cell patients. The resultant data will be analyzed to gain insights into the role genetic variations play in influencing disease severity. The research will be coupled with a new long-term, follow-up study of sickle cell patients transitioning to adult care. Although the majority of sickle cell patients survive to adulthood, they have a markedly shortened life expectancyabout 45 years. To gain a better understanding of the natural history of the disease, the influence of treatments during childhood on disease progression and the role genetic factors play in disease severity and life expectancy, St. Jude, working collaboratively with the University of Tennessee Health Science Center and regional hospital systems, will follow these 1,000 St. Jude sickle cell patients throughout their lives. The study will be modeled after the St. Jude LIFE program and will serve as an invaluable resource for advancing treatment.

The St. Jude Bone Marrow Failure Program is a new multidisciplinary effort, involving faculty and staff from the Hematology, Bone Marrow Transplantation and Cellular Therapy, Oncology, Pathology, Pharmaceutical Sciences, Nursing and Computational Biology departments. The program will define the underlying genetic causes of inherited bone marrow failure syndromes and optimize treatment so that children with these conditions can live normal lives. Serving as a global resource, the program will soon begin to recruit patients from around the world to be evaluated and treated at St. Jude. The expanded

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clinical sequencing effort described above will work closely with this program to carry out DNA sequencing and data analysis.

In addition to these programs, St. Jude will continue to invest in its Gene Therapy Program, an effort that is focused on treating diseases caused by a single gene defect that primarily manifests as an abnormality of the hematopoietic and immune system. This program benefits from the St. Jude Therapeutic Production and Quality Program and the associated Good Manufacturing Practice (GMP) facility and Human Applications Laboratory (HAL). Using these facilities, St. Jude has made groundbreaking advances in treating hemophilia B (Factor IX deficiency), demonstrating that gene therapy using an adeno-associated viral vector engineered to express human factor IX can significantly ameliorate disease severity. The program is now working on improving this form of gene therapy and expanding its use to treat hemophilia A (Factor VIII deficiency), the more common form of this disease.

## RESEARCH PROGRAMS IN INFECTIOUS DISEASES

The Childhood Infection Defense Center (CIDC) is the cornerstone of St. Jude's multidisciplinary clinical and research efforts in infectious diseases. The center includes teams from the Infectious Diseases consultation service, critical for the management of children with cancer or non-malignant hematological diseases; the HIV program; the hospital's infection control program; and our internationally recognized efforts in studying influenza, pneumococcal pneumonia, antimicrobial and malarial drug development, vaccine development, and the role of inflammatory and cellular immune systems in controlling and eliminating infectious organisms. In total, the center draws talent from six departments-Infectious Diseases, Immunology, Chemical Biology and Therapeutics, Pathology, Pharmaceutical Sciences and Structural Biology.

# During the next six years, the CIDC will focus on improving infectious disease diagnostics

by using sequencing-based methodologies and applying these new approaches to individual patients. The approaches will also aid infectioncontrol efforts, including tracking infections and monitoring for drug-resistant organisms. In addition, analysis of the microbiome and virome of children undergoing cancer treatments will be assessed, and studies will be performed to determine whether the biomes influence patients' therapeutic responses and risks of drug-related toxicities. The CIDC will also **bolster work to develop antimicrobial agents**, with particular attention on multi-drug–resistant organisms. Lead compounds developed will be assessed using preclinical models, and if promising candidates are identified, drug development will be pursued through collaborative efforts with biotechnology or pharmaceutical companies. Lastly, the CIDC will continue its ongoing effort to **develop effective vaccines** against a variety of infectious diseases that occur in our patient population.

## TRAINING CLINICAL FELLOWS

Since its inception, the goal for the clinical educational programs at St. Jude has been to train physician-scientists to become the next generation of leaders in the range of pediatric specialties required to care for children with catastrophic diseases. To accomplish this goal, St. Jude has developed innovative fellowship programs across 12 medical specialties: pediatric hematology/oncology, infectious diseases, bone marrow transplantation and cellular therapy, neuro-oncology, cancer survivorship, hospice and palliative care, diagnostic imaging, radiation



oncology, pediatric surgical oncology, pathology, pharmacy and psychology.

Our flagship training program is our three-year fellowship in pediatric hematology/oncology. This program recruits from around the globe the best pediatric senior residents interested in pursuing formal training in pediatric hematology and oncology.

As we look to the future, we will further enhance our commitment to training pediatric clinical fellows. These fellows play an important role in caring for our patients, and their learning experience is rooted in delivering that care. St. Jude will expand upon this educational base by offering an increasing number of didactic and mentoring sessions where the fellows can directly interact with senior faculty members who are master clinicians. In addition, during the second and third year of fellowships, St. Jude will significantly strengthen the fellows' training and educational experience by creating specific focus tracks, including clinical investigation, palliative care, international medicine and laboratory investigation. Each track will have a designated faculty leader who will define the curriculum. Some tracks will include an opportunity to pursue an advanced degree through universitybased programs. St. Jude will cover all costs for enrollment in the degree-granting programs. For the international medicine track, St. Jude

will explore developing its own degree-granting program in global medicine, which will be run jointly by the International Outreach Program and the St. Jude graduate program in biomedical sciences.

A particular area of strength at St. Jude is the integration of laboratory and clinical research. Our world-class basic and translational scientists routinely interact with the clinical investigators who care for our patients. Moreover, the infrastructure for translational research is unparalleled. This unique environment provides an optimal setting for training the physician-scientist interested in leading a laboratory-based research program. The St. Jude graduate program in biomedical research will aid in the recruitment of these individuals. Increasingly, pediatric residents want to pursue formal training in laboratorybased science, often leading to a PhD. Our graduate program will be structured to offer spots specifically reserved for St. Jude clinical fellows each year.

Lastly, to enhance the training programs' oversight, St. Jude will increase its investments in the Office of Academic Programs in Biomedical Sciences and the Clinical Education and Training Office. These offices help identify and recruit promising, nationally competitive fellows as well as oversee the development of a more robust clinical education culture throughout the institution.



# OUR GLOBAL LEADERSHIP POSITION

St. Jude is committed to helping establish a global clinical care and research agenda that will accelerate progress toward advancing cures for pediatric catastrophic diseases. To accomplish this goal, St. Jude needs to expand its footprint across the world by enhancing its International Outreach Program and by developing two new innovative programs: the St. Jude Clinical Research Consortium and the St. Jude Collaborative Research Program. On the following pages, we briefly describe these efforts.

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# THE INTERNATIONAL OUTREACH PROGRAM

During its existence, the St. Jude International Outreach Program (IOP) has made important inroads in improving care for children with cancer around the world. Despite progress, the need for help continues to increase. More than 80 percent of children with cancer live in low- and middle-income countries, where access to care is suboptimal. Even more worrisome, during the next decade, the number of pediatric cancer cases in developing countries will rapidly rise as improvements in public health and basic medical services increase the percentage of children who survive infancy and grow to an age at which they are at a higher risk of developing cancer. This is happening in countries unprepared to provide the level of care required to effectively treat pediatric cancer. This disparity is one of the most significant challenges in pediatric medicine-and one that St. Jude is in a position to effectively address.

Our goal during the next decade is to ensure childhood cancer patients around the globe have access to care through programs instilled with the knowledge, support and leadership to continuously improve the level of care provided. This goal can be reached and sustained only if St. Jude uses the same principles that successfully guided the hospital since its foundation in 1962: deliver the highest level of patient care within the context of research protocols designed to generate continuous improvement in clinical outcomes.

St. Jude has recruited a new physician leader for the IOP, Dr. Carlos Rodriguez-Galindo. He will also serve as chair of a new Department of Global Medicine. This department will recruit physicians and investigators with expertise in international medicine, health economics, health policy and implementation research. In addition, we will create new faculty positions within the Departments of Biostatistics, Diagnostic Imaging, Hematology, Infectious Diseases, Oncology, Pathology, Pediatric Medicine, Radiation Oncology and Surgery, who will devote a portion of their time to the IOP. Similarly, our commitment to training and supporting nurses in developing countries will receive additional resources.

Under IOP's new leader, a formal strategic planning process will be initiated during FY16 to define the overall vision for the program and the specific goals and objectives for the ensuing five years.



## ST. JUDE CLINICAL RESEARCH CONSORTIUM

St. Jude has many collaborative therapeutic research protocols. To broaden our reach across the United States and the world, our goal is to double the number of non-St. Jude patients enrolled on these studies. To accomplish this, we will develop a St. Jude-funded Clinical Research Consortium, which will generate protocols for pediatric cancers, non-malignant hematological diseases and other life-threatening disorders. Ten to 12 of the world's top pediatric programs will be invited to join the consortium. Faculty from these institutions will work collaboratively to develop high-complexity clinical research protocols. St. Jude will fund the infrastructure required to run these protocols and will lead the overall consortium. Leadership of the individual protocols will be decided by the consortium membership and can include faculty from any of the participating institutions. The institutions selected to form the consortium will be committed to opening a majority of the protocols run by the group. If other institutions are interested in opening select protocols, they will be allowed to join the consortium as limited members.

St. Jude will not only fund the development and clinical research costs of the protocols, but also work to augment the translational and correlative biological studies conducted as part of the protocols. This effort will take additional dedicated personnel to identify appropriate partners, establish the collaborations and then manage the regulatory, informatics and clinical interactions involved.



Collaborating centers worldwide for high-visibility St. Jude clinical trials: AML08 (acute myeloblastic leukemia), SJYC07 (infant brain tumors), SJMB12 (medulloblastoma > 3 yrs old)

## ST. JUDE COLLABORATIVE RESEARCH PROGRAM

The concept behind this program is to form St. Jude-funded scientific teams across the globe to work collaboratively to address knowledge gaps that need to be filled to allow progress against pediatric cancer and other pediatric catastrophic diseases. Performing the research required to answer these questions will require expertise outside our institution. Acquiring these skills through recruitment is slow, difficult, and in some areas of science, such as engineering and biomedical physics, especially difficult, if not impossible.

Our approach will be to identify the best talent around the globe to work as part of a St. Judefunded international team collaborating to answer the most pressing scientific questions. This will not only coalesce members of the pediatric scientific medical community around efforts to fill in key knowledge gaps but will also result in experts from outside the small pediatric catastrophic disease community joining together. This program would place St. Jude at the center of a global collaborative network of investigators from academia, pharmaceutical and biotechnology companies and government agencies.

The focus of the work carried out by these teams could range from fundamental basic science questions that have emerged from our own work to frontline clinical trials that are designed to assess new therapies. Specific questions will be developed by a senior faculty oversight group composed of the leaders of St. Jude cancer programs, non-malignant hematology programs, CIDC and our basic science departments. The program would fund three to four collaborative teams, each for a period of five years, with the level of funding being based on the nature of the work performed. Each team's membership will be expected to visit St. Jude twice a year, once for a project-specific meeting and again where all teams assemble to foster cross-team interactions. The St. Jude Collaborative Research Program will instill significant new funds into advancing research on pediatric catastrophic disease and, thereby, accelerate progress in advancing cures.



# RESOURCES REQUIRED TO ACHIEVE OUR VISION

Our goal is to ensure an environment where employees can do their best work, make the most of their careers and get the most satisfaction from their jobs. Employees are our most valuable assets, and it is only through their knowledge, skills, energy, commitment and compassion that St. Jude will achieve Danny Thomas' dream that no child dies in the dawn of life. In order to realize the strategic plan's bold vision, St. Jude will increase its staff by 25 percent and its faculty by 28 percent. Significant construction will occur as part of several key efforts to expand the infrastructure for clinical and research programs.



## MAJOR CONSTRUCTION AND RENOVATION PROJECTS

To support the planned growth, major construction and renovations will occur during the next six years. These include completion of the St. Jude Red Frog Events Proton Therapy Center and three inpatient floors in the Kay Research and Care Center; expansion of the Tamer-Rashid Building for ALSAC; and new construction of a Data Center, Domiciliary Housing Facility, Outpatient and Clinical Office Building, Research Building and Parking Garage. In addition, we will renovate key existing buildings across our campus.



# EMPLOYER OF CHOICE

To achieve its ambitious goals, St. Jude must remain the global employer of choice. Our institution is blessed with a mission that engenders a level of employee pride second to none. Its workforce is composed of many who have been with the hospital for 20, 30 or 40 years. St. Jude has been ranked as one of the 100 best places to work in the United States for five consecutive years. Millennials have also named St. Jude as one of the top places they aspire to work for the past three years. To maintain this legacy, St. Jude must continuously foster an environment that allows employees to do their best work. We must recruit, retain and develop the brightest talent in all areas. As a top workplace, St. Jude needs to constantly assess benefits to effectively compete with other employers. We must recognize our employees for the work they do and celebrate their excellence. We also have to

listen to our employees because they are on the front lines. It is essential to trust their assessments and work as partners to achieve our mission. This philosophy will stem from the highest levels of the institution. In this spirit, the CEO will initiate monthly town hall meetings to solicit input on key institutional efforts and issues. This new program will incorporate a page on the St. Jude intranet for employees to submit questions, rank the priority of the questions and see what questions will be discussed at upcoming town hall meetings. Our hope is to cultivate a community discussion on issues key to the institution and to facilitate channels for new and innovative ideas to enhance the work performed at St. Jude.



# CONCLUSION

This strategic plan represents the work of more than 180 faculty and staff across the institution, along with members of the Board of Governors and the senior leadership team of ALSAC.

This document serves as a roadmap for a six-year journey of growth, discovery and, most importantly, enhanced treatment for children at St. Jude. An implicit goal in our strategic planning effort was to not make the development of this plan an end in itself, but a beginning. We are committed to making formal strategic planning a part of our culture.

By formalizing strategic planning into a highly visible and continuous process that includes many voices from faculty and staff, we ensure that our path and priorities enable us to carry forward the great legacy of St. Jude.

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# APPENDIX $\mathbf{I}$ – STRATEGIC PLANNING PROCESS

The 2016–2021 Strategic Plan was developed through the efforts of a Central Strategic Planning Committee, which included the St. Jude Executive Committee, ALSAC's CEO, chief administrative officer, chief marketing officer and chief financial officer; the St. Jude Board of Governors' chair and first vice chair; and the Boards' Strategic Planning Committee's chair and vice chair—as well as 15 Working Groups, representing St. Jude clinical, research, educational and administrative activities.

Four retreats and follow-up meetings were held during a seven-month planning period. The detailed schedule of meetings and retreats is shown below.



## St. Jude Executive Committee

## St. Jude Senior Leadership



James R. Downing, MD President and Chief Executive Officer



Larry E. Kun, MD Executive Vice President Clinical Director Chair, Radiological Sciences



Mary Anna Quinn Executive Vice President Chief Administrative Officer



#### Charles Roberts, MD, PhD Executive Vice President Scientific Director Director, Comprehensive Cancer Center



Carlos Rodriguez-Galindo, MD Executive Vice President Director, International Outreach Program

Gerard C. Grosveld, PhD

Mitchell J. Weiss, MD, PhD

Douglas R. Green, PhD

Elaine I. Tuomanen, MD

Chair, Genetics

Chair, Hematology

Chair, Immunology

## Academic Department Chairs



James M. Boyett, PhD Chair, Biostatistics



J. Paul Taylor, MD, PhD Chair, Cell & Molecular Biology



R. Kiplin Guy, PhD Chair, Chemical Biology & Therapeutics



Jinghui Zhang, PhD Chair, Computational Biology



James I. Morgan, PhD Chair, Developmental Neurobiology



Larry E. Kun, MD Interim Chair, Diagnostic Imaging



Leslie L. Robison, PhD Chair, Epidemiology & Cancer Control

## Administrative Leaders



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Robyn Diaz, JD Senior Vice President Chief Legal Officer



Mary V. Relling, PharmD Chair, Pharmaceutical Sciences



Sean Phipps, PhD Chair, Psychology



Thomas Merchant, DO, PhD Chair, Radiation Oncology



Stephen W. White, DPhil Chair, Structural Biology



Andrew M. Davidoff, MD Chair, Surgery



Charles J. Sherr, MD, PhD Chair, Tumor Cell Biology



Keith Perry, MBA Chief Information Officer

Ching-Hon Pui, MD Chair, Oncology

Chair, Infectious Diseases

Chair,



Amar J. Gajjar, MD Co-Chair, Oncology Interim Chair, Pediatric Medicine

David W. Ellison, MD, PhD Chair, Pathology

## Chair of the UT Department of Pediatrics



Jonathan A. McCullers, MD Chair, Pediatrics, University of Tennessee Health Science Center Pediatrician-in-Chief, LeBonheur Children's Hospital Adjunct Member, Infectious Diseases

## Medical Executive Committee Chair



**Ulrike Reiss, MD** Director, Division of Clinical Hematology Director, Hemophilia Treatment Center

## Cancer Center Program Leaders



Suzanne J. Baker, PhD Developmental Neurobiology



Michael A. Dyer, PhD Developmental Neurobiology



Melissa M. Hudson, MD Oncology



Charles G. Mullighan, MBBS(Hons), MSc, MD Pathology



Alberto S. Pappo, MD Oncology



Martine F. Roussel, PhD Tumor Cell Biology



Victor M. Santana, MD Oncology



Brenda A. Schulman, PhD Structural Biology

## International Outreach Program



Terrence Geiger, MD, PhD Pathology Interim Co-Director, International Outreach Program



Matthew J. Krasin, MD Radiological Sciences Interim Co-Director, International Outreach Program

## **ALSAC Senior Leadership**



Richard C. Shadyac Jr. President and Chief Executive Officer



Emily Greer Chief Administrative Officer



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Terry Burman Chair



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Camille Sarrouf Jr. Second Vice Chair



George Simon Chair, Strategic Planning Committee



Ann Danner Vice Chair, Strategic Planning

## Strategic Plan Working Groups

Administration Basic Laboratory Education and Training Basic Sciences Bone Marrow Transplant Cellular Therapy and Cancer Immunotherapy Brain Tumor Cancer Prevention and Control Childhood Infectious Disease Center Clinical Care Clinical Education and Training Hematological Malignancies Hematology Information Sciences Patient Experience Solid Tumor

# Strategic Planning Committee of the ALSAC/St. Jude Boards of Directors and Governors\*

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\*This listing reflects membership as of October 2015.

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# APPENDIX II – ST. JUDE BOARD OF GOVERNORS AND SCIENTIFIC ADVISORY BOARD\*

# St. Jude Board of Governors

## **Board Members**

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\*This listing reflects membership as of October 2015.

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### David H. Rowtich, MD, PhD

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### Michel Sadelain, MD, PhD

Memorial Sloan Kettering Cancer Center, Stephen and Barbara Friedman Chair, Director of Center for Cell Engineering, New York, NY





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