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## Sathanandam pioneers FDA trial of minimally-invasive device for premature infants with heart defects



Le Bonheur Interventional Cardiologist Shyam Sathanandam, MD, FSCAI, has pioneered a new technique to close PDAs in extremely low birth weight (ELBW) infants participating in a 10-site, FDA trial for the device using the closure. That device, Abbott's Amplatzer Piccolo Occluder, received FDA pre-market approval last month to treat PDAs in ELBW infants.

The minimally invasive technique performed in the hospital's hybrid catheterization lab was designed to shorten the length of stay for premature infants and improve the premature infant's recovery time.

The Amplatzer Piccolo Occluder is the first transcatheter cardiac device to earn FDA-approval for premature infants. The device, developed by the global health care company Abbott, is a self-expanding, wire mesh device inserted through a small incision in the leg and guided through vessels to the heart, where it is placed to seal the opening of the heart.

"We believe this will change the field of cardiology and improve care for the tiniest neonates," Sathanandam said. "The transcatheter closure allows babies to grow and heal faster."

To date, Sathanandam has performed 140 closures on neonates weighing two kilograms or less and played a key role in the multisite Abbott trial, which closed enrollment Feb. 1. Le Bonheur has enrolled more neonates than any other center in the study. In February, Le Bonheur Children's Hospital implanted the first commercial FDA-approved transcatheter device for PDA patients. Shyam and his team closed the PDA in the first patient post-approval, a 2-week old baby girl, born at 28 weeks and weighing one kilogram.

## Black receives award for hepatology research



Dennis Black, MD, CFRI Scientific Director and J. D. Buckman Professor of Pediatrics, is the lead investigator of a 12-center research study funded by the FDA Office of Orphan Product Development evaluating the role of the medication ursodeoxycholic acid in treating children with primary sclerosing cholangitis, a rare liver disorder leading to end-stage liver disease with liver transplantation as the only proven effective treatment.

An abstract reporting the findings of the study was awarded the Gerard Odell Prize for Excellence in Pediatric Hepatology Research and selected for a platform presentation at the Annual North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) meeting. Gerard Odell, MD, a Professor of Pediatrics at the Johns Hopkins School of Medicine, was a pediatric liver specialist and established the pediatric gastroenterology division at the University of Wisconsin.

## Save the date for Research Day 2019



The Annual Pediatric Research Day hosted by Le Bonheur Children's Hospital, University of Tennessee Health Science Center and Children's Foundation Research Institute will be held

on Sept. 18. The theme of this year's Pediatric Research Day is gastroenterology. Research Day will showcase our pediatric investigators and their ongoing research activities, highlighting the latest findings, medical advances and scientific innovations.

### Register studies with [clinicaltrials.gov](http://clinicaltrials.gov)

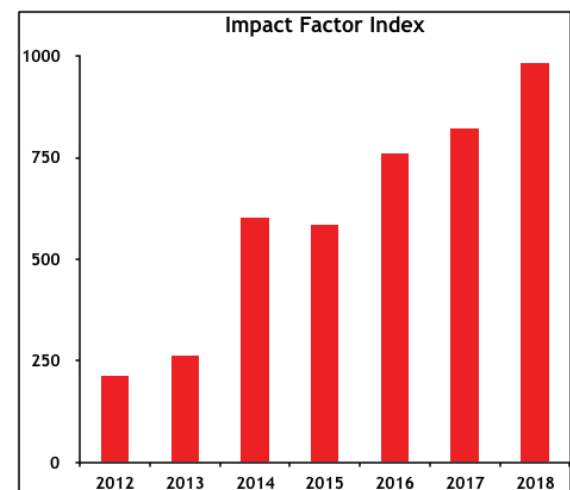
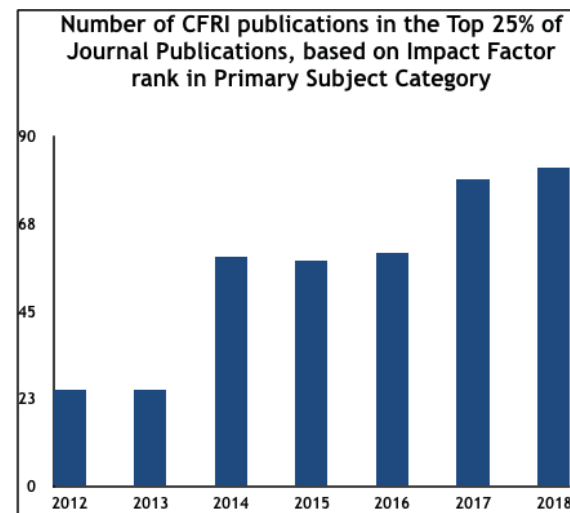
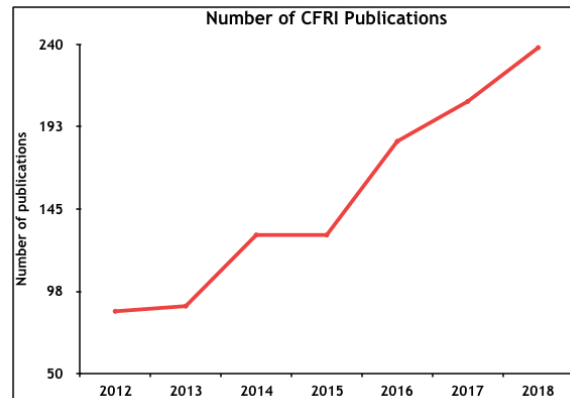
All researchers conducting investigator-initiated studies are required to register and report results of clinical trials at [clinicaltrials.gov](http://clinicaltrials.gov), a publicly-accessible registry. Registration is required to promote responsible dissemination of information about clinical trials to the public, ensure compliance with pertinent federal and state law and funding agency requirements and meet professional publication standards. Most journals will not accept manuscripts reporting results from clinical studies that are not posted on [clinicaltrials.gov](http://clinicaltrials.gov). For industry-sponsored trials, the sponsor is responsible for providing this information for the web site.

Le Bonheur has designated Kerry Moore, CFRI manager of Compliance and Regulatory Affairs, as the administrator for the Le Bonheur's Protocol Registration System (PRS) account.

CFRI will provide assistance with determining if a study is an applicable clinical trial, account set up or password reset, registration of trials and results reporting. It is the responsibility of the principal investigator to ensure that registration and results reporting are completed and updated in a timely manner.

If you need assistance or would like more information about the registration process, please email Kerry Moore ([kerry.moore@lebonheur.org](mailto:kerry.moore@lebonheur.org)).

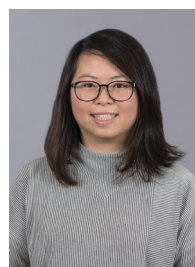
## CFRI publishes 240 articles in 2018



## CFRI welcomes new staff members



**Ashley Thompson, MHA, CCRP** joins CFRI as the new IRB regulatory coordinator. Ashley has more than 10 years of clinical research experience with a focus on leukemia, lymphoma, diagnostic imaging, epidemiology and public health. Prior to joining the CFRI, she gained extensive knowledge in clinical trial coordination, regulatory compliance and quantitative data analysis at St. Jude Children's Research Hospital.



**Celine Wu, MSc**, joins CFRI as a clinical research coordinator. Celine gained experience in clinical trial management, including patient enrollment, event reporting and compliance from her previous role as a clinical research practitioner at the National Institute for Health Research Centers in London, England. Celine also has clinical and basic research experience in the field of immunology.

## Neurosurgery paper on survival for rare tumor receives CNS paper of the year



Pediatric neurosurgeon Paul Klimo, MD, was awarded the Pediatric Paper of the Year from the Congress of Neurological Surgeons (CNS) at the 2018 CNS Annual Meeting in Houston, Texas. His paper, published in *Neurosurgery*, titled “Pineoblastoma – The Experience at St. Jude Children’s Research Hospital,” documented the outcomes of 41 patients with pineoblastoma who underwent multimodal therapy and evaluated the impact surgical resection had on survival.

Pineoblastomas are rare, malignant embryonal tumors that account for less than one percent of all pediatric brain tumors, according to Klimo. In addition, they are more common in young children.

Klimo’s study represents the largest pediatric series of pineoblastoma cases to date. The results of the study showed the effect of age and cancer metastasis on the likelihood of death or treatment failure. Of the 41 patients studied, 18 had succumbed to their tumor and 19 had experienced tumor recurrence or

progression. Children who experienced treatment failure were younger (less than 5 years old) and more likely to have metastatic disease at diagnosis. Patients 5 years or older who did not have metastatic disease and had 90 percent or more of their tumor removed had an excellent chance of survival. No patient in this subgroup died as a result of their cancer.

Klimo hopes that future studies will build on this research and uncover additional effective ways to improve outcomes for children with pineoblastoma.

“Our knowledge of molecular derangements that give rise to pineoblastomas will expand and may impact our surgical management,” said Klimo. “We hope that unraveling the molecular blueprint of pineoblastoma could lead to targeted chemotherapy and understanding genetic links.”

Le Bonheur is home to the nation’s largest pediatric surgical brain tumor program working in partnership with St. Jude Children’s Research Hospital. Approximately 200 brain tumor operations are performed each year. Children in Le Bonheur and St. Jude’s joint brain tumor program have some of the highest survival rates and have access to the most advanced technology available for treatment and support.

*Kara A. Parikh, Garrett T. Venable, Brent A. Orr, Asim F. Choudhri, Frederick A. Boop, Amar J. Gajjar, Paul Klimo; Pineoblastoma—The Experience at St. Jude Children’s Research Hospital, Neurosurgery, Volume 81, Issue 1, 1 July 2017, Pages 120–128, <https://doi.org/10.1093/neuros/nyx005>*

## K-Club changes to K-R0 Club, expands to include research project (R) awards

The scope of CFRI’s K-Club seminar series has recently expanded to assist investigators in preparing and submitting a broader range of NIH grant applications. Previously, K-Club focused on providing information and guidance for Career Development (K) award applications. Topics discussed will now also include information relevant to Research Project (R) Awards. The name of the seminar series has been changed to K-R0 club to reflect this change.

K-R0 Club meets on the second Tuesday of each month at noon in the third floor conference room of the CFRI and is open to all investigators at UTHSC, especially early career investigators and junior faculty, as well as investigators from St. Jude and the University of Memphis. Senior investigators are encouraged to attend to contribute to the discussion and provide perspective.



Topics that will be covered in K-R0 Club include “How I Built My Mentorship Team,” “Crystallizing Your Research Idea: What makes a good scientific question?,” “Advice and Red Flag Warnings for K Awards: From the Perspectives of a Review Panel Chair and a Standing Member” and “NIH Grant Peer Review: Demystifying the Process.” These topics are covered in a variety of

manners, including discussion groups, interactive seminars (some from outside speakers), and workshops.

Questions and comments regarding K-R0 Club should be directed to Dennis Black, MD ([dblack@uthsc.edu](mailto:dblack@uthsc.edu)). Further information and schedules can be found online at <https://www.lebonheur.org/research-and-education/research/investigator-resources/k-club/>

