



iCAN is seeking 2 pediatric patients of varying ages (and their caregivers) and 1 young adult, to share their experience managing a cardiac condition due to congenital heart disease using a medical device to speak to the U.S. Food and Drug Administration (FDA), Office of Cardiovascular Devices in the Center for Devices and Radiological Health (CDRH).

Examples of patient experience may include ventricular assist devices (VADs) that have helped provide a bridge to transplant for young patients; pacemakers and ICDs for treating life-threatening cardiac arrhythmias; or transcatheter pulmonary valves as an option to avoid open-heart surgery to help treat tetralogy of Fallot.

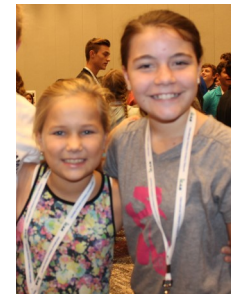
What you need to know

The patients and caregivers will participate in a panel discussion addressing topics such as what their experience has been using a medical device to manage their cardiac condition, what treatment options and risks they considered, and how they were informed about the treatment options and benefit/risk trade-offs of using the medical device. This event is for CDRH staff only, primarily for the Office of Cardiovascular Devices.

The meeting has been tentatively planned for August 9th, 1:30 pm. – 3:30 pm. (EST).

In advance of the meeting, we will provide questions for the patients and caregivers that are likely to be asked.

- **Must be willing to share a patient experience**
- **Use a medical device**
- **May or may not have participated in a clinical trial using the medical device, and**
- **Would be open to sharing their personal experience for about 5-10 minutes and participate in the panel discussion.**



To help improve pediatric patient care, please send names and contact of interested families to Amy Ohmer, Director, iCAN by Monday, July 19th at info@icanresearch.org

