

Recruitment Numbers – New Sites Help Us Reach Our Goals

GIGA-kids continues to grow and expand the number of participating sites. Recently, we have engaged five new sites, including a new site in Alberta, Canada. Within the MWPNC, we have nearly reached 200 enrollees. As evident from **Figure 1**, our cumulative recruitment is growing steadily.

The total recruitment for all national sites is 185 as of the end of June 2016. This includes 181 patients with either IgAN, HSP or HSPN and 4 healthy controls -- note that we target 1 control per 10 cases, so we need to do better in this respect -- see page 2 for our suggestions on the best strategies for recruiting controls in and around your clinic. **Figure 2** shows the patient breakdown by disease type and sex.

Most all of the blood samples have already been processed and DNA has been extracted. We are now beginning to do some early genetic work with an aim to generate preliminary data for future funding applications. However, we already have a clear demonstration that our network recruits effectively, so big thanks to all of you for your commitment to this collaboration!

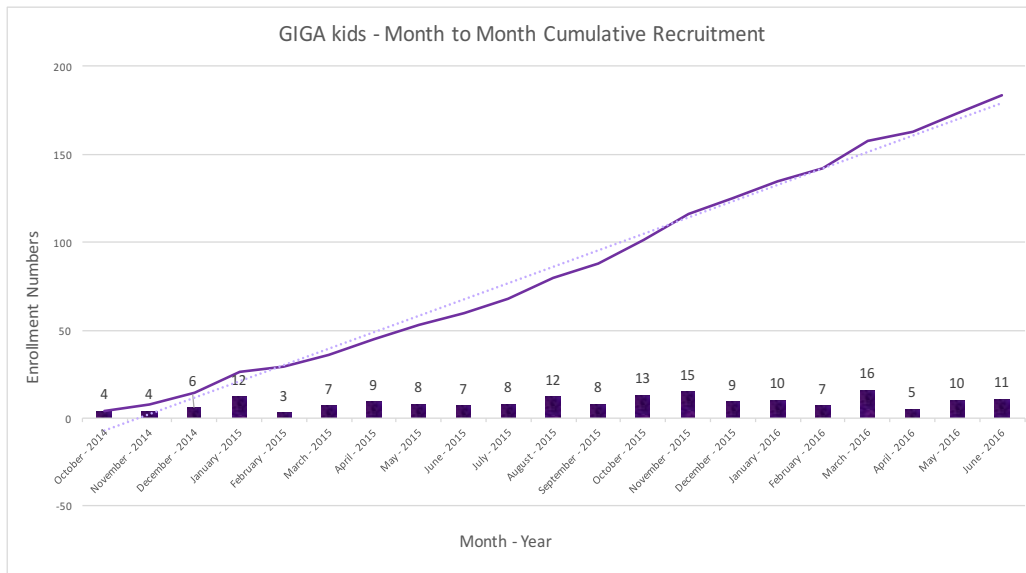


Figure 1 (above): Cumulative Recruitment as of June 2016

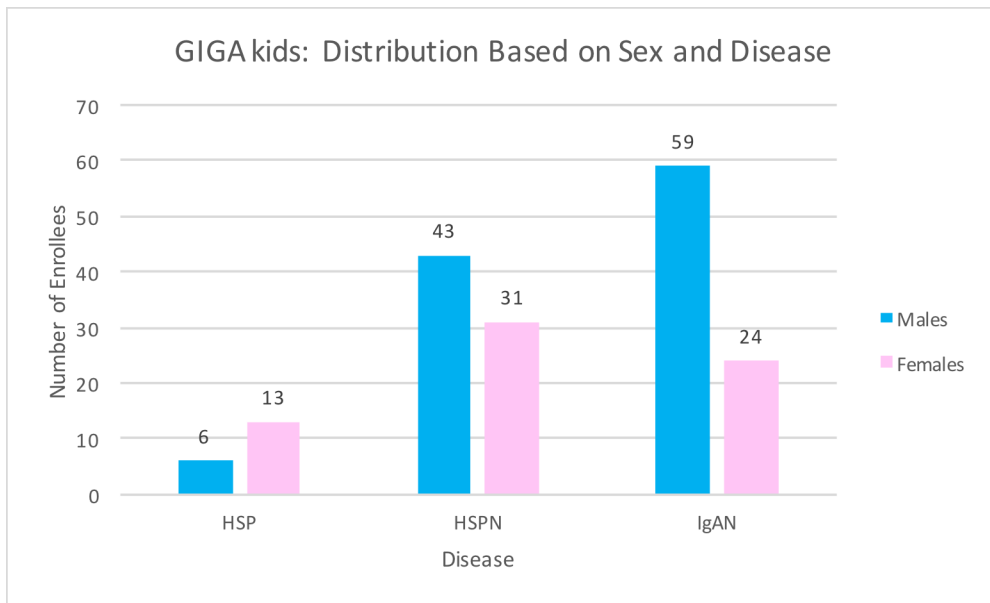


Figure 2 (above): Distribution of Disease Based on Sex as of June 2016

OpenClinica - Changes at Nationwide

There are some noteworthy changes happening at Nationwide Children’s Hospital that are important for all the sites to be alerted to.

Sarah Higgins, who had been in charge of managing OpenClinica for GIGA-kids, has moved on to another position. So, until a new person has filled this position, all inquiries regarding OpenClinica will be directed to Corinna Bowers.

As Nationwide strives to improve our data platform for GIGA, there will be some alterations made to the entry page for the VPN. This will not mean re-entry of previously entered data, but just a change in username and password. We will alert you with this will be in effect.

Healthy Controls – Suggestions, Criteria

As a reminder, we are also asking each site to recruit healthy controls for GIGA-kid Study. Our target is to recruit 100 healthy, age- and ethnicity-matched controls for the purpose of biomarker studies. Since we now have well over 20 sites recruiting, if each institution committed to recruiting 5 controls, we would be well on our way to the goal.

The inclusion criteria for controls includes age- and ethnicity-matched individuals unrelated to the cases and with no history of kidney disease or skin purpura, and no pre-existing diagnosis of autoimmune disease, liver disease, active HBV, HCV, or HIV infections.

Its been asked by some on what is the best way to recruit controls and we have had some suggestions from other sites. Some have proposed recruiting non-blood related family members and friends. Other sites are recruiting from neighboring pediatric clinics. If you have suggestions, please let us know. As usual, we want to make this study as convenient and practical as possible.

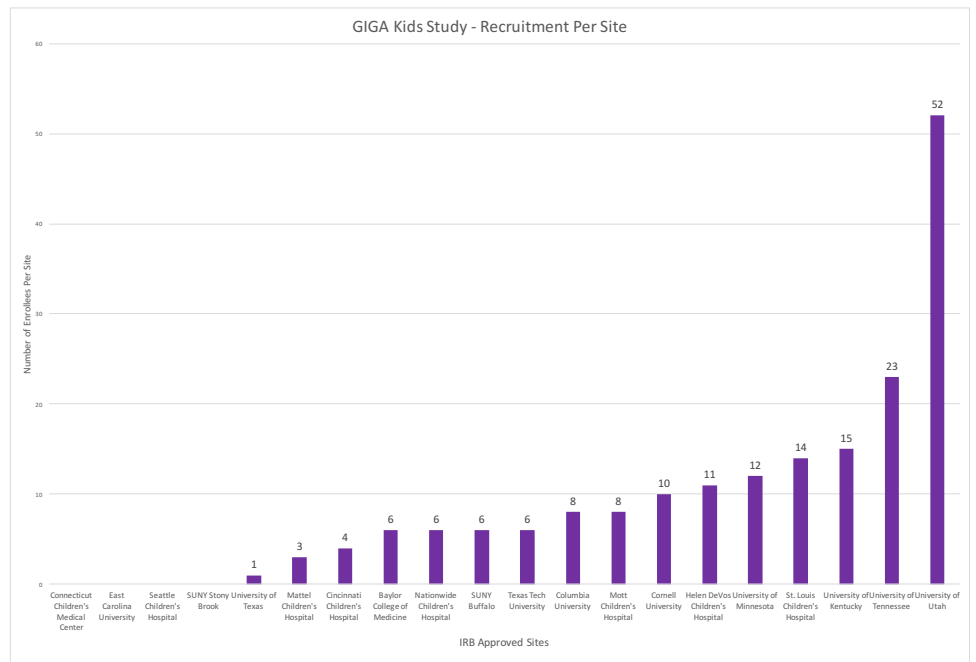


Figure 3: Recruitment per Institution/Site as of June 2016

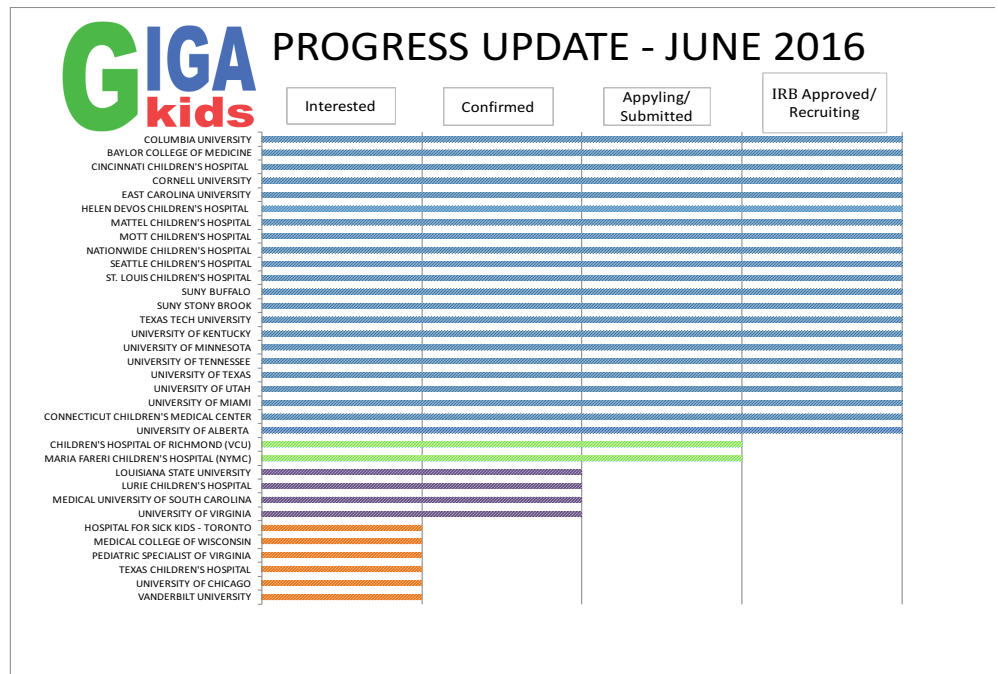


Figure 4 (below): Progress Update as of June 2016

Contact Information:

DUA – Nationwide
Corinna Bowers
Corinna.Bowers@nationwidechildrens.org

MTA – CUMC
Melanie Foley
mf2162@cumc.columbia.edu

Interested in participating in the GIGA Kids Study?

Our Clinical Research Coordinator, Drew Bradbury, can help and support you along the IRB application process. Contact her at:

dab2213@cumc.columbia.edu

Missing Samples – Following Up with Patients

We have several sites that were unable to receive the blood sample from a patient at the time of consent. Now we have a better understanding of the clinical flow and that sometimes families may not want bloods drawn outside

doctor's orders and/or they have their blood drawn at an outside laboratory. However, in order to keep up with this growing list, if this is your site, expect an email in the next coming weeks just to serve as friendly reminder to follow-up with these patients.