

GIGA-kids News & Updates

October 2019 Update

Happy Fall, All!

As of October 1st, 2019 there are 25 actively recruiting GIGA-kids sites. Total recruitment is presently at **N=497 participants**, including 485 cases and 12 healthy controls.

The GIGA-kids study will be represented at the American Society of Nephrology Conference (ASN) in Washington D.C. on November 8th. This is the fourth year a GIGA-kids poster is on display as an informational poster at ASN. Please stop by to say hello! We will include the content of the poster in the next newsletter.

GIGA-kids is currently accepting new recruitment sites, and is actively enrolling all HSP/N (IgAV), and IgAN cases, and healthy controls. Please feel free to pass along this newsletter to colleagues and collaborators or share via social media.

As always please let us know how we can best support your recruitment efforts, and do not hesitate to reach out to Olivia Balderes (ob2214@cumc.columbia.edu) with questions, concerns, or suggestions.

GIGA-kids: Overall Distribution of Disease

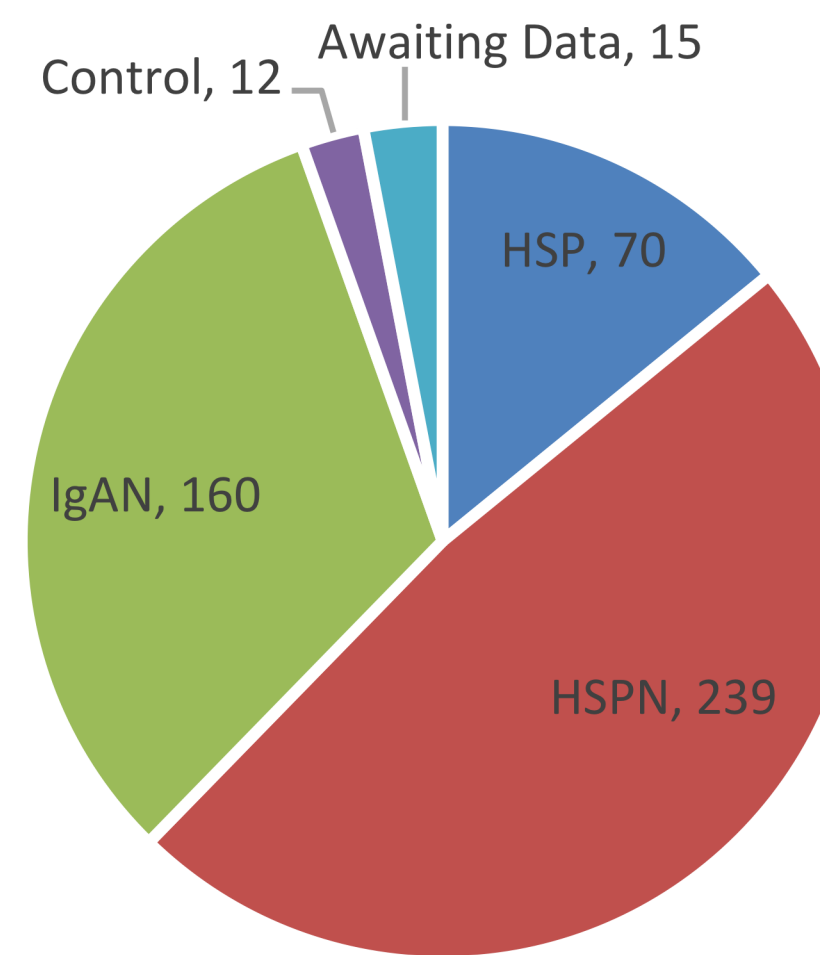


Figure 1: Overall case distribution as of October, 2019 (based on available clinical data).

Recruitment totals per year

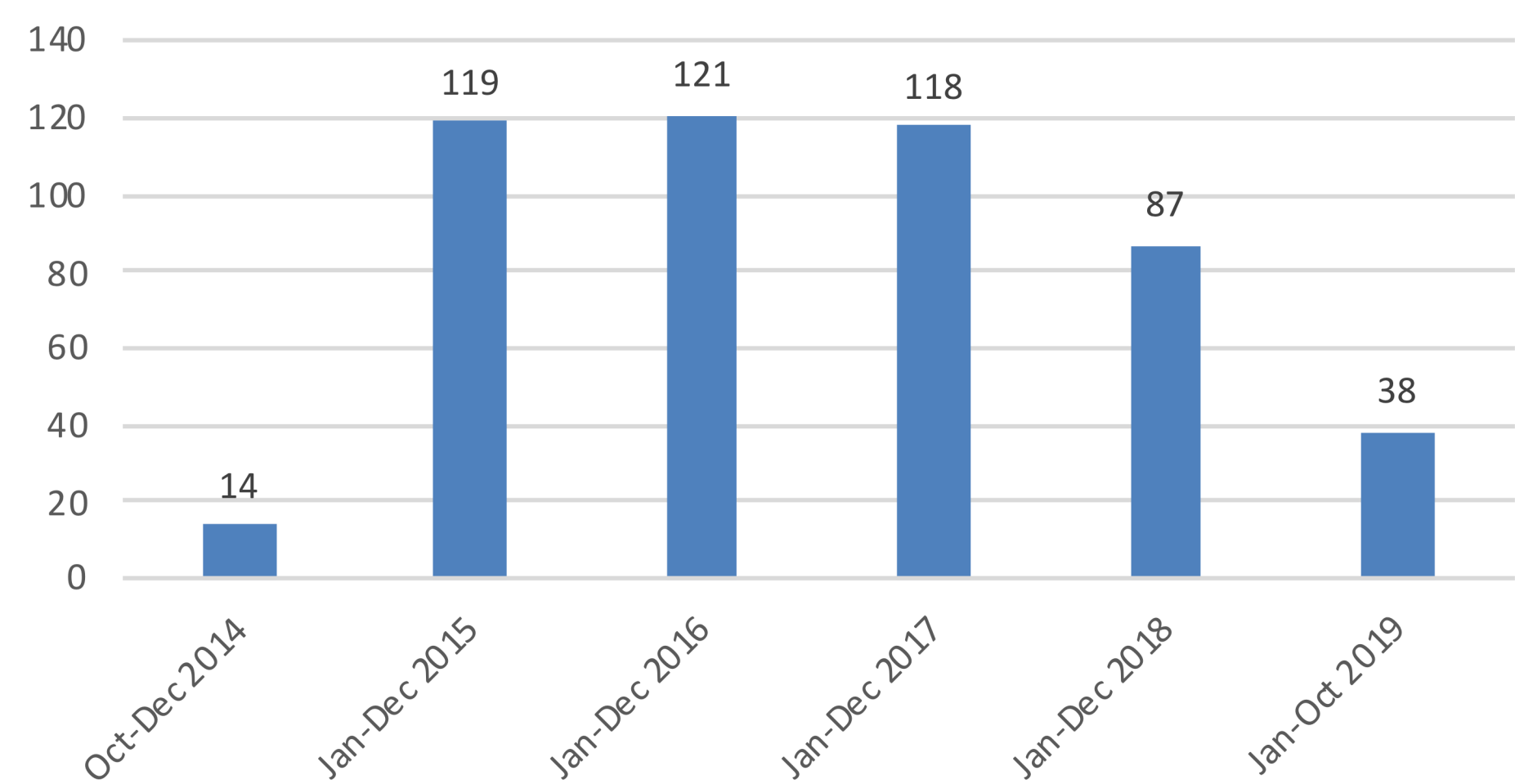
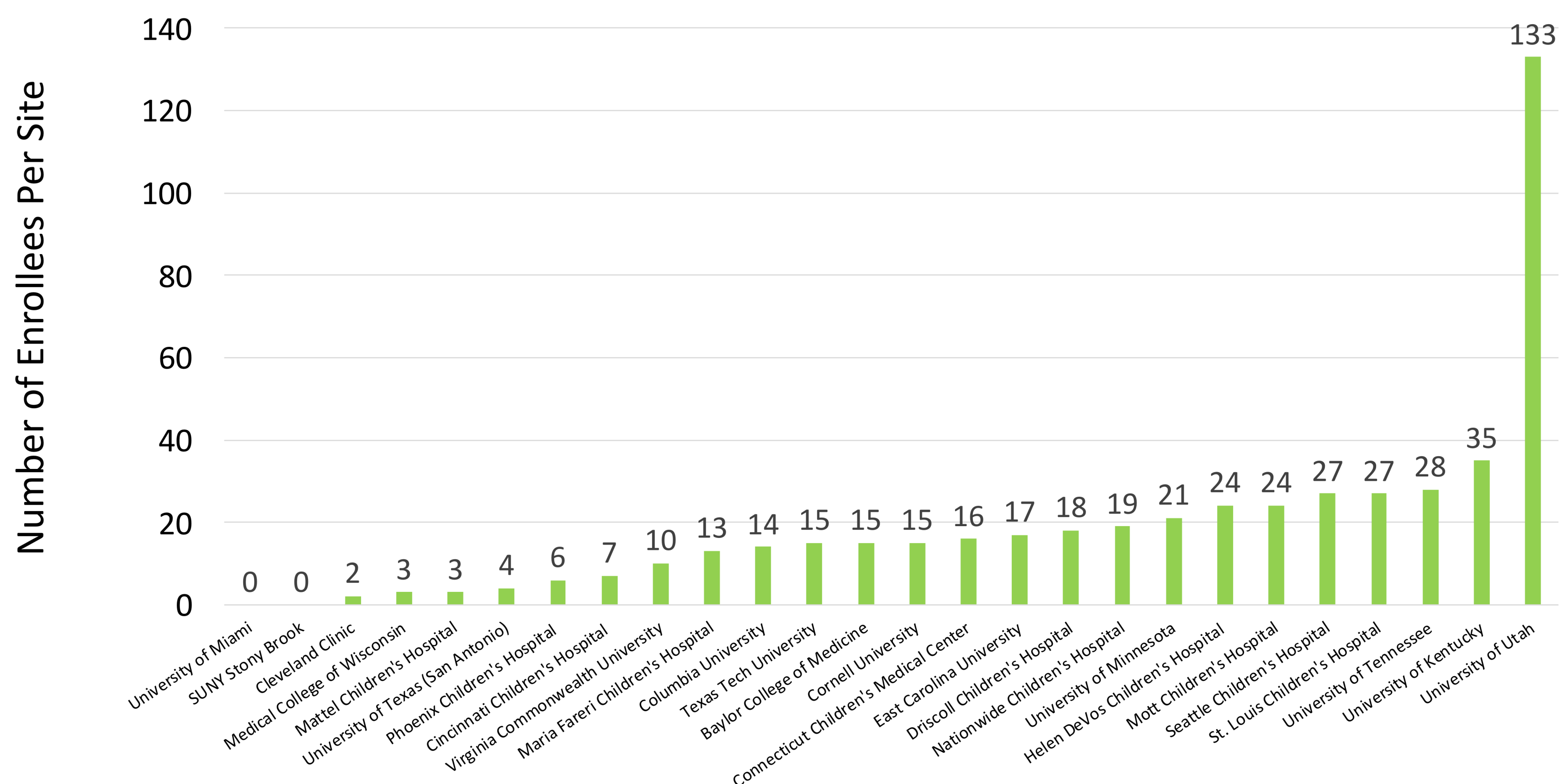


Figure 2: Cumulative annual recruitment as of October 2019.

GIGA-kids Study: Recruitment Per Site as of September 2019



IRB Approved & Actively Recruiting Sites

Figure 3: Cumulative Recruitment per site; October 2014 to October 2019.

Fall 2019 PNRC Meeting -- St. Louis, MO



The 32nd PNRC (formerly MWPNC) meeting marks the beginning of an exciting new chapter for the consortium – new studies expand upon successful past studies, and collaborations between physician-scientists, RNs, and CRCs from different sites are reinforced and expanded upon. The new PNRC website, which is to be unveiled in the coming months, will provide the perfect platform for lively discussion, recruitment troubleshooting, and generation of new hypotheses and solutions.

A big thank you to Dr. Vikas Dharnidharka of WUSTL for hosting, and to Corinna Bowers for organizing such successful and thought provoking conferences year after year. Very much looking forward to seeing everyone at the next meeting in Salt Lake City, UT in March 2020!



Above: St. Louis' Gateway Arch at dusk; Center: CRCs enjoying the dinner at the Museum Under the Arch; Far right: Drs Mahan and Dharnidharka opening the 32nd PNRC Meeting.

Reminders

- A reminder that the **window for reporting follow-up data points** has been widened to 3 months preceding/following recruitment (if lab test dates are distinct from Date of Recruitment, this can be reported in the "Notes" section).
- A note on **OpenClinica**: OC allows for a centralized dataset, which can be amended and updated as new information comes in. If your site does not currently have an OC account, please make sure to start the process of requesting one as soon as possible, by emailing both [Olivia Balderes](mailto:Olivia.Balderes@nationwidechildrens.org) and [Corinna Bowers](mailto:Corinna.Bowers@nationwidechildrens.org). If, in the past, your site sent hard-copy CRFs for GIGA participants, please make sure there are corresponding OC profiles for these individuals.
- A **new tool** was rolled out over the summer to allow for a streamlined document and kit request pipeline. The link to this form will be on the GIGA website, and in the signature of Olivia's emails.

MTA Modifications & Protocol Revisions

As most of you know, as part of the GIGA-kids project we are planning to establish collaborations with selected industry partners in order to generate sequence and/or biomarker data for the cohort (e.g. to perform whole genome sequencing on all participants). Although all current informed consents are fully compatible with such collaborations, our present MTA language needs to be revised, and a minor modification to the protocol is to be made. All sites should have received emails regarding these modifications beginning in July.

If you have any questions regarding the **MTA or protocol** revision process, please do not hesitate to reach out to **Olivia Balderes**. She will help to guide you through this process, and is more than happy to communicate with local legal teams, and/or signing officials.

Thanks to all sites who have either completed the MTA and Protocol modifications, or are in the process of doing so!

In addition, we have determined that all DUAs should include a clause about de-identified data being shared with our industry partners. For **DUA modifications** (between Nationwide and all sites), **Corinna Bowers** will be the individual coordinating the modification roll-out effort. Her team will be reaching out to each site's PIs and/or coordinator(s) with details sometime in the coming weeks.

Important Contact Information:

DUA/OpenClinica – Nationwide: Corinna Bowers
Corinna.Bowers@nationwidechildrens.org

IRB/MTA – CUMC: Melanie Foley
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Interested in participating in the GIGA Kids Study?

Our Coordinator for the GIGA-kids study, Olivia Balderes, can guide you through the IRB application process, and help to answer any questions you may have regarding study protocol, or recruitment.

Email: ob2214@cumc.columbia.edu
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