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GIGA-kids News & Updates

January 2020 Update

Happy New Year!

As of January 1st, 2020 there are 26 actively recruiting GIGA-kids sites. Total recruitment is presently at **N=516 participants**, including 504 cases and 12 healthy controls (Figure 1)! At the same time, we also note that our 2019 recruitment is lower compared to years 2015-2018 (Figure 2). We suspect that this may be partially because we have already enrolled all available prevalent patients at some sites, and the case recruitment now involves mainly newly diagnosed incident cases, nevertheless we would like to maintain a steady recruitment rate to ultimately reach our target of N=1,000 cases. Please note that we are still accepting new recruitment sites, and we are **actively enrolling** the following:

- **HSP cases** (IgAV without nephritis)
- **HSPN cases** (IgAV with nephritis)
- **IgAN cases** (biopsy-diagnosed)
- **Healthy Controls**

The GIGA-kids team is looking forward to the Spring PNRC (formerly the MWPNC) meeting in Salt Lake City, UT in March. Please feel free to pass along this newsletter to colleagues and collaborators or share via social media. And, as always, please let us know how we can best support your recruitment efforts by reaching out to Olivia Balderes with any questions, concerns, or suggestions.

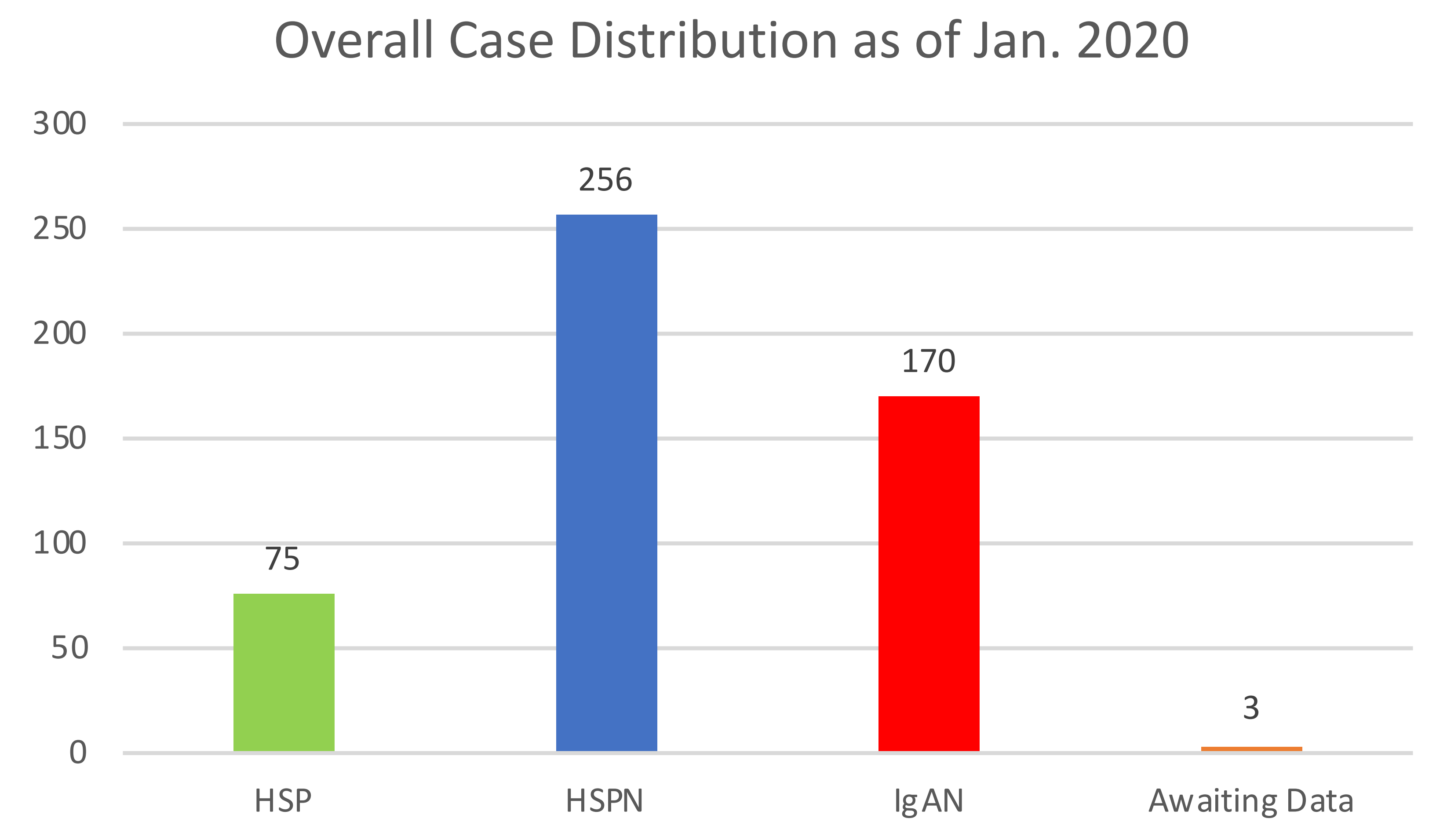

Figure 1: Overall case distribution as of January, 2020 (based on available clinical data).

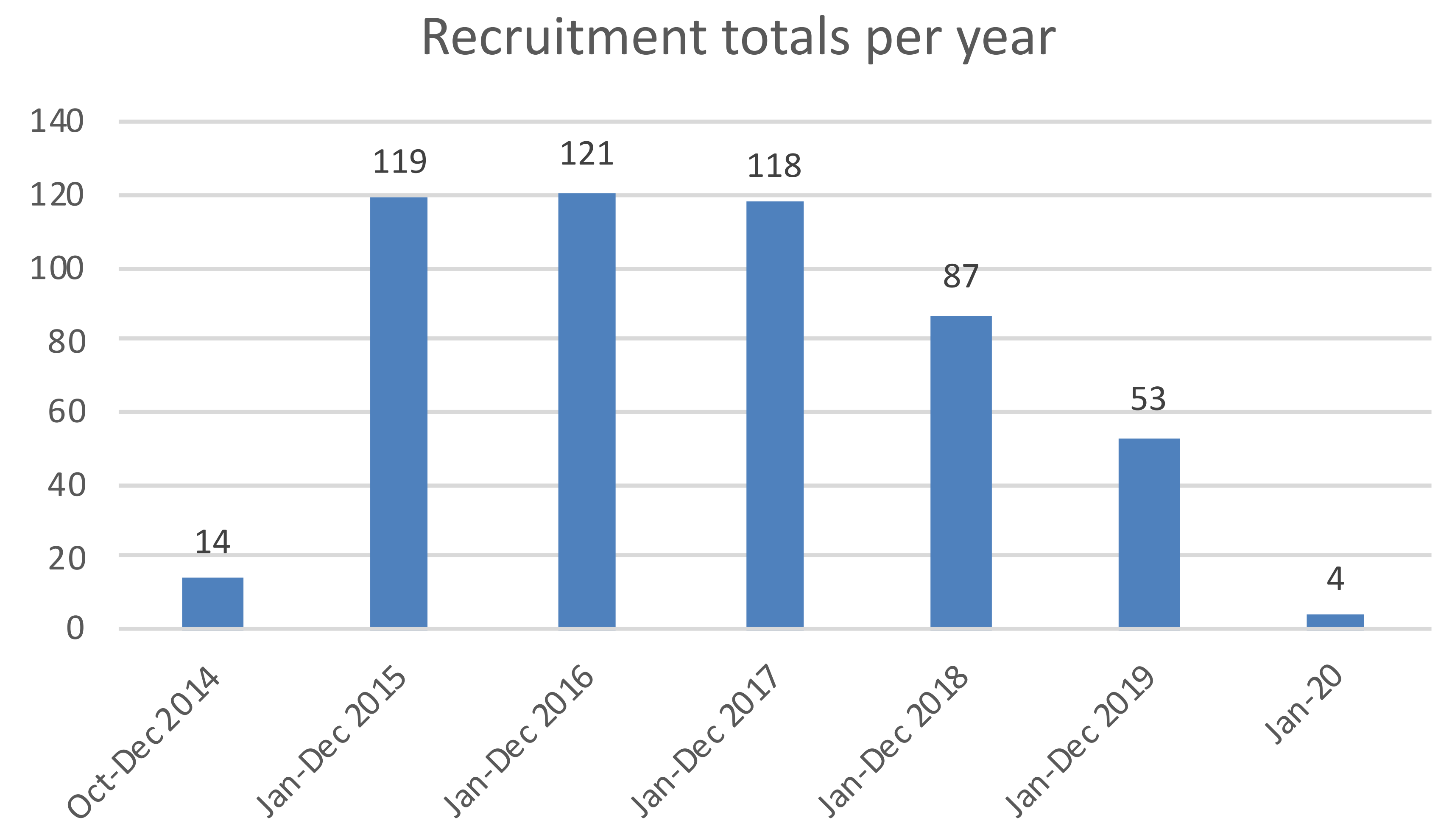

Figure 2: Cumulative annual recruitment as of January 2020.

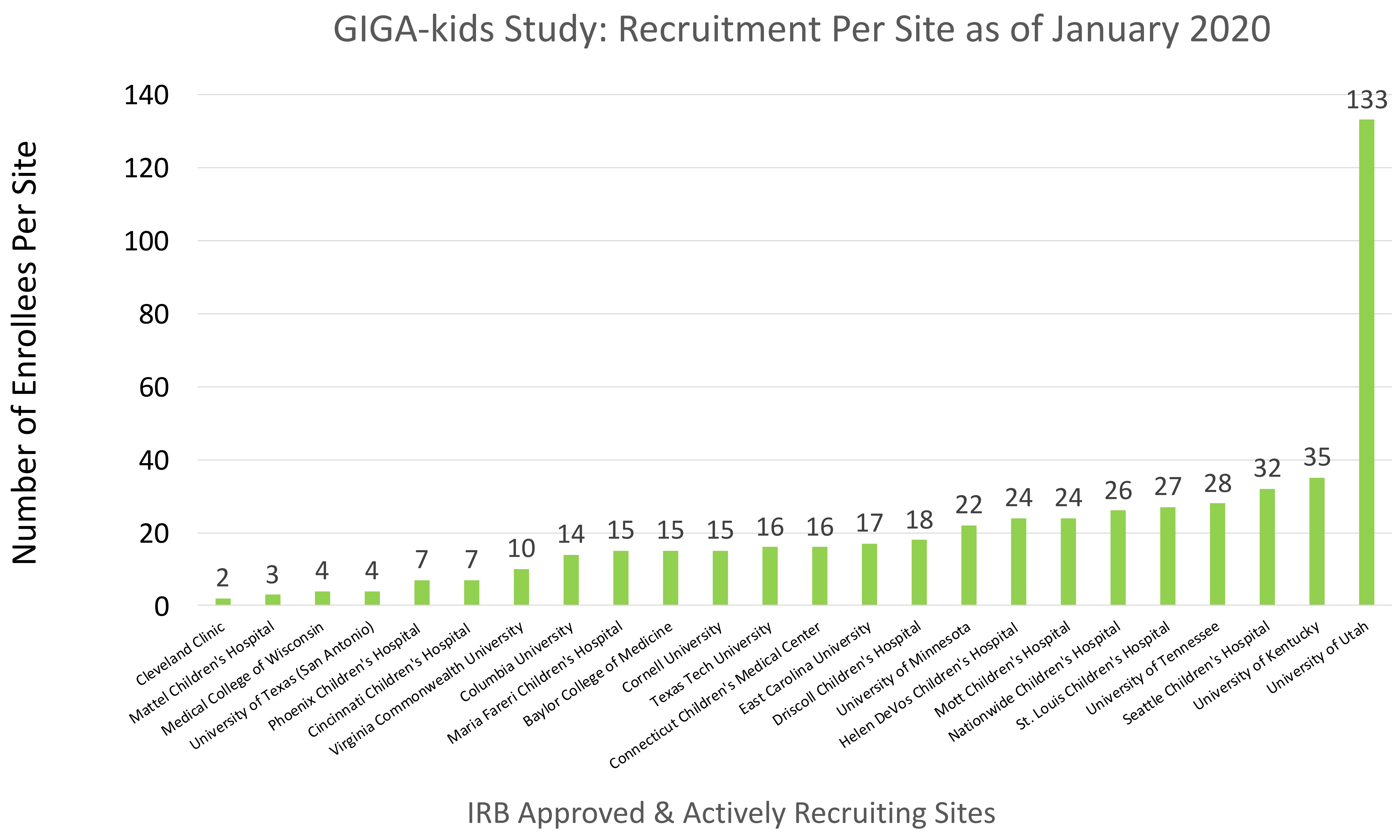

Figure 3: Cumulative Recruitment per site; October 2014 to October 2019.

How is GIGA promoting Genetic Health Literacy?

Health Literacy can refer to many things, but simply put being health literate refers to a person's ability to comprehend diagnoses and health outcomes, and to find and use appropriate health services. Genetic literacy is quickly becoming an important part of one's general health literacy with integration of clinical genetic testing into standard of care for many chronic diseases, and the increase in popularity of commercial genetic tests. As we recruit for genetic studies of chronic kidney diseases, we understand how important it is to prioritize a patients' understanding of a study's implications, potential outcomes, and goals, as well as to encourage informed engagement with their health.

It can be very difficult for patients being recruited into a study not to equate consent forms with the unreadable legal agreements that pop up on mobile devices, and computers. Lengthy and word-dense consent forms can result in reactions such as: 1) 'checking the box', hoping to move-on as quickly as possible, or 2) seeing the words "genetic study" and declining to participate out of fear. Both of these are easily avoided when we open up a dialogue about genetics, and provide people with appropriate resources and enough time to consider their options. Giving potential participants the tools to form their own opinions and to decide, with confidence, whether or not they are a good fit for a study has been shown to improve patients' relationships with the research team and retention in the study.

GIGA-kids families are often simultaneously struggling to understand a new diagnosis, eager to contribute to research on their child's illness, and wary of potential consequences. This is why we are working to make the GIGA-kids Study as participant friendly as possible. We are simplifying our website (see the notice below!), recruitment materials, and informational tools, and making them easy to pass along to other potentially interested parties.

We welcome any feedback on the changes we have made thus far, and suggestions on how we can continue to improve!

Reminders

- A reminder that the **window for reporting clinical data points** has been widened to 3 months preceding or following recruitment (if lab test dates are distinct from Date of Recruitment, this can be reported in the "Notes" section).
- A note on **OpenClinica**: If your site does not currently have an OC account, Olivia will be contacting you to get the account creation process started.
- **Thanks to all sites who have either completed the MTA and Protocol modifications, or are in the process of doing so!** If you have any questions regarding the 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.
- We will be **updating the GIGA-kids Website** in the coming weeks – an email will be sent out once it has been published!

New Website Features!

The GIGA website now has a dedicated 'For Patients' tab which includes a self-screening tool, and a brief description of the study, as well as the interactive site map. This will soon include a genetic "tool-kit" with links to useful websites, and definitions of key terms.

The screening tool is a series of branching questions which will help patients, parents/caregivers, and physicians determine whether or not someone is eligible for GIGA-kids. Additionally, the screening will help to streamline the process of getting families in touch with the appropriate parties. We encourage you to share this with colleagues and patients!

We are also working to develop more user-friendly remote recruitment materials which will be shared with all active GIGA sites once approved by the CUMC IRB.

Important Contact Information:

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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.

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