

THE RARE ROUNDUP

The official Newsletter of Rare Disease Research, LLC

"If you are working on something that you really care about,
you don't have to be pushed; the vision pulls you."

- Steve Jobs

WE FINALLY MOVED!

After a VERY LONG wait, we have finally fully transitioned to our new site! The process started as we received approval from study sponsors to move our trials one by one. Our staff had to go back and forth for a short period of time to accommodate the demands of each study and to ensure that there was no interruption in the schedule of events. Gradually, each study was transitioned over. We are now very excited to begin working in the new center, as it provides much more space to conduct our trials and additional room for us to grow as an organization.

RDR STAFFING NEWS



- RDR is excited to announce that our research assistants **Angela Seymour**, a recent graduate of Clark Atlanta University, and **Genevieve Wilson**, a recent graduate of Emory University, have fully transitioned from clinical research assistants to clinical research coordinators (CRCs). Congratulations, ladies, on your achievements!
- RDR also welcomes **Trisha Sundaram**, our new intern from Emory University. Trisha is in her third year majoring in Biology with a minor in Ethics.
- It was also bittersweet for us to say goodbye to our CRC of two and a half years, **Tu Tran**, as he accepted a Clinical Research Associate position with PPD. Congratulations, Tu, and best wishes in your new adventure!
- This spring, we are fortunate to welcome two new staff members:
 - **Deanna Baker**: Deanna comes to RDR from Northside Hospital where she worked as a clinical oncology research data specialist. She obtained her undergraduate degree from Georgia State University and a Master of Public Health from Mercer University. Deanna has joined our growing team at RDR as a CRC!
 - **Savanna Westmoreland**: A graduate of the University of South Florida with a degree in Mass Communication and Public Relations, Savanna is our first executive administrative assistant whose primary focus is helping the study start up team to maintain and follow up communications with sponsors, keeping track of leads, and ensuring that there is a great path of communication between RDR and sponsors. She also manages numerous other administrative duties at RDR and keeps

RARE DISEASE UPDATES

The Safe Step Act (H.R. 2163/S. 464) has been reintroduced in Congress! This legislation would ensure that rare disease patients have access to treatments they need by improving step therapy protocols.

Step therapy, often called "fail first," is a process that requires patients to take one or more alternative medications before they can access the medication prescribed by their doctor. While this is done to control high drug costs, step therapy has been increasingly applied without sufficient regard for a patient's medical history.

The Safe Step Act would protect millions of Americans who are on federally regulated insurance by establishing a clear exemptions process, requiring certain exceptions to the step therapy protocols, and requiring plans to respond to exception or appeal requests in specific time period.

Ask your members of Congress to cosponsor this important legislation today!

More than half of state legislatures have already passed stronger patient protections for step therapy in state regulated plans. Congress must act now.

Take Action!

Together we are strong,
The NORD Policy Team



REGULATORY CORNER

To keep pace with the advancement in drug development, from the technology for next-generation gene sequencing to CRISPR/Cas9, the FDA is focusing on several areas of regulatory science this year:

1. Patient-Centricity and Real-World Evidence;
2. Biomarker Research
3. Artificial Intelligence (AI) and Computer Modeling
4. Advanced Manufacturing
5. The Power of Data

From Chatterjee, Bikash. (2021, March 19) FDA's 2021 Focus Areas of Regulatory Science: 5 Trends to Watch. Clinical Leader. Retrieved April 24, 2021

NATIONAL CLINICAL TRIALS DAY- MAY 20TH 2021

We recognized National Clinical Trials Day on May 20th to support the people who conduct clinical trials and to say thank you for the advancement in the medical field that they provide. National Clinical Trials Day is celebrated on May 20th in commemoration of the first-ever clinical trial, conducted by a surgeon named James Lind aboard the HMS Salisbury. He established a connection between citrus fruits and scurvy, a condition common among sailors caused by severely low Vitamin C intake. By recruiting 12 men to participate in his trial he observed that scurvy could be quickly improved with consumption of citrus fruits. It is said that he created the foundation of how clinical trials are designed today.

About #CTD2021. Clinical Trials Day. (n.d.).
<https://www.clinicaltrialsday.org/about>.

STAFF HIGHLIGHT

Our very own **Genevieve Wilson** was awarded the 2021 Marion Luther Brittain Award from Emory University. This award is the highest honor that a student can receive at Emory University. She received this honor for her acts of service without expectation of recognition or reward and for her impact in her community.

As a director of Volunteer Emory, Genevieve organized 20-30 service trips every single week for students to volunteer with critical nonprofits around the Atlanta area. Genevieve was also the president of the Emory Neuroscience Association, through which she built bridges between the Emory Brain Health Center and the University in order to provide networking opportunities for students.

As president of Emory Food Chain, Genevieve directed the redistribution of 7,000 pounds of food annually. She also co-founded Rice, Beans, and Southern Greens, a budding nonprofit which strives to increase access to fresh produce for residents of Atlanta food deserts.

Following her graduation, Genevieve will be a clinical research coordinator here at Rare Disease Research. She plans to work for approximately a year and then enroll in medical school to become a neurologist. It wasn't enough for Genevieve to simply go to school and complete her studies. She wanted to be engaged in important work that brought a deep sense of meaning to her life and benefitted her community. She embodies the definition of the Brittain Award, having performed "significant, meritorious, and devoted service". Emory has been greatly changed from her time there.

Contributed by: Savanna Westmoreland Jones, S. (2021, May 10). Undergraduate Brittain Award recipient lauded for stellar service across campus and beyond. Emory University | Atlanta, GA. https://news.emory.edu/stories/2021/05/er_commencement_award_brittain_undergrad_wilson/campus.html.

Editors-in-Chief

The content and design of this newsletter are produced by our very own **Trang Vo, Genevieve Wilson, and Savanna Westmoreland**. If you have any ideas you would like to see implemented, please let us know! trang.vo@rarediseaseresearch.com, genevieve.wilson@rarediseaseresearch.com, savanna.westmoreland@rarediseaseresearch.com

ALL IN A RARE DAY'S WORK

It was another end-of-day meeting at RDR. Everyone took turns to talk about his or her day and here was what Nick had to say: "Yeah, it has been a hot dog kinda day. Just plain ketchup!" Good luck trying to copy that. Nick has already had the phrase copyrighted!

At RDR, we often receive safety reports for the investigational products through electronic means. One day, Trang received a notification to download a safety report, and to her surprise, it was all in Chinese!!! Well, according to our SOP, the safety report has to be reviewed and signed by the principal investigator and clinical significant information will be discussed during our staff meeting. So, Trang followed the procedure and dropped it in Dr. Phan's box with a sticker that said "Please review and sign". For all we know, Dr. Phan has probably started learning additional languages since we'll be receiving safety reports from all over the world.

RECENT EVENTS: RDR STAFF APPRECIATION DAY

We finally had our "Christmas Party" on April 9th at Pricci Italian Restaurant, as our original Christmas party plan was cancelled last year due to COVID. We had so much fun getting to know each other in a different setting. We played games, enjoyed good food, and good company! Dr. Phan saved the best surprise for last—at the end of the night we learned that **Eduardo (Jona) Comix**, our regulatory specialist/pharmacy technician/research coordinator, has received an RDR scholarship to pursue his undergraduate degree in nursing. Congratulations, Jona!

