



Hello TRIDENT Consortium! It is our pleasure to share with you our **2020 Fall Quarterly Bulletin** updating you on all things **TRIDENT**.

The air is getting chilly, foliage is changing, and the days are getting shorter. It is now the Fall season and Covid-19 continues to impact our daily lives. However, our clinics have stepped up and are doing a great job in keeping patients and staff safe and allowing research to continue! Most of our sites have resumed research activities and are able to recruit new patients, remote activities are encouraged whenever possible, and the show goes on! This bulletin will feature the continued impacts of the crisis on our study as well as provide some general updates.

Featured Personnel:

Randy Luciano, MD, PhD has been a nephrologist at Yale University School of Medicine for the last 7 years. Dr. Luciano completed his residency and fellowship training at Yale. Prior to that, he studied at Wake Forest University in North Carolina for his undergraduate studies, at New York University for his PhD graduate work in biomedical sciences, and at University of Connecticut where he earned his medical degree.



Dr. Luciano is an active clinical nephrologist seeing patients most days of the week, either inpatient, in his dialysis units, or in one of his outpatient clinics. He is especially interested in the role of the kidney biopsy in diagnosis and prognostication of kidney disease. Apart from TRIDENT where Dr. Luciano serves as the site PI, he is also involved in KPMP (through the NIDDK) and collaborates with a Yale Professor in Laboratory medicine obtaining extra cores to validate a multi-photon microscope in the clinical setting. His other area of interest is establishing and expanding a glomerular clinic at Yale.

When not practicing medicine, Dr. Luciano enjoys spending time with his three children, staying fit with exercise and weightlifting, and working or hiking outside. Dr. Luciano can be found on Twitter sending tweets about exciting biopsies and medical cases. Be sure to follow him @RandyLucianoMD.



Updates on Research Activities due to Covid-19:

- **Active recruitment.** All sites that have resumed recruitment activities, should be sure to inform the DCC; this information will be updated on ClinicalTrials.gov. Sites are encouraged to follow their local clinic guidelines with regard to resumption of research activities and new recruitment.
- **Use of Remote Consent.** If needed, the use of remote consent is allowed due to the impacts of Covid-19. This is approved for all relying sites, non-relying sites will need to seek local approval for the use of remote consent. See below for guidance on the use of remote consent:
 - o Ensure patient has a printed copy of the ICF (mail or email); review details of ICF together with patient.
 - o If patient agrees to participate, patient signs the ICF and returns signed copy to site (site personnel to sign and date). Patient will also need to send proof of the signed document (photo, scan, fax, etc.) for immediate documentation of obtaining consent.
 - o A Note to File is written by site to document the remote consent process.
- **Research Visits should be conducted with limited in-person patient contact.** Labs and physical measures require the patient to come into the clinic, however in order to reduce patient-staff contact, other elements of the research visits that can be completed remotely should be done so. This includes medical updates, concomitant medications, and medical history survey.
- **Tracking Visit Activity and Documenting Deviations.** Please continue to track visits that are incomplete or completed remotely due to Covid-19 and document these under the Deviation Reports CRF.

Reminders and Updates

Annual Steering Committee Meeting: We will be holding our annual Steering Committee this year as a virtual meeting. Please mark your calendars for **Friday December 18th**! An official Save-the-Date will be coming out soon with more details



regarding timing. Thank you to everyone who provide their availability, we will do our best to accommodate everyone's schedule and consider our members in various time-zones.

Budget Amendment. If not already completed, be sure to follow-up with your business and contracting offices to ensure the Budget Amendment is signed and executed. Future payments will be unable to be processed until this is completed at your site. Questions pertaining to the amendment can be sent to [Shira Blady](#).

Publications and Presentations Committee: If you have an interest in writing a paper with TRIDENT data, would like to present on TRIDENT, or have any questions about manuscript proposals, abstracts, etc. please reach out to the P&P liaison [Shira Blady](#). The next P&P committee call is scheduled for Monday October 26, 2020. **All new proposals must be submitted no later than Thursday October 22, 2020 at 8am EST.** Submit proposals to P&P liaison [Shira Blady](#) and cc the [TRIDENT](#) account.

Summary of Executive Committee Conference Calls: Each month the TRIDENT Core team holds a conference call with the Executive Committee to review study progress and site updates. Below is a summary of the recent calls:

- A monthly review of active sites' recruitment and enrollment progress – including changes due to the Covid-19 pandemic;
- Data QC plans and timeline;
- Study project data updates including but not limited to RNA sequencing, urine single cell and pathology analysis;
- Review of possible ancillary studies and new projects;
- Discussion of new protocol and study design changes.

Coordinator Conference Calls: We are now conducting our calls via Blue Jeans and they are held at the on the second Wednesday of each month at 2pm ET. The next call will be Wednesday October 14th, 2020. A coordinator or representative from each site is required to be on the monthly calls and provide an update on site recruitment and enrollment.

TRIDENT
Transformative Research
In Diabetic Nephropathy



TRIDENT Site Personnel:

Recruitment Site	Principal Investigator	Co-Investigator(s)	Research Coordinator(s)
University of Pennsylvania	Jonathan Hogan, MD	Abdallah Geara, MD	Antonia Brown, MPH
University of North Carolina, Chapel Hill	Amy Mottl, MD, MPH		Emmie Cole, MSOT Anne Froment, BS Jordan Ormond Foster, BA Sandy Grubbs, MSN Ian McInnis, BS
Stanford University	Richard Lafayette, MD		Kshama Mehta, PhD Tamar Emily Tatoian, BS
University of Michigan	Matthias Kretzler, MD		Amanda Williams, BS Chrysta Lienczewski, BS Jamie Bixler, BS
Northwestern University	Tamara Isakova, MD, MMSc	Shikha Wadhvani, MD, MS Rupal Mehta, MD Rebecca Frazier, MD	Carlos Martinez, BS Patrick Fox, BS Rachel Phillips, BS Alexis Stevenson, BS
Icahn School of Medicine Mount Sinai Hospital	Kirk Campbell, MD	John Cijiang He, MD, PhD Lili Chan, MD Kristin Meliambro, MD Fadi Salem, MD Joji Tokita, MD Shuchita Sharma, MD	Stephanie Pagan, BA Samantah Sun, BA Isabella Perez-Pecchio, BS
University of New Mexico	Christos Argyropoulos, MD, MSc, PhD	Jonathan Owen, MD Saeed Kamran Shaffi, MD, MS Mark Unruh, MD, MS	Hugo Vilchis, BS Claudia Rice, BS Monica Bajana, BA, BS Christopher Zima, BS Arel Hurwitz, BS
Columbia University	Pietro Canetta, MD, MSc	Woojin Ahn, MD, PhD Gerald Appel, MD Andrew Bomback, MD, MPH Wai Lau, MD	Anup Pradhan, MBBS, MPH Michael Toledo, BA, RN Irma Orbe
University of Texas Health at San Antonio	Shweta Bansal, MD	Christopher Dyer, MD Tareq Nassar, MD Manoj Bhattarai, MD Yanli Ding, MD	Chakradhar Velagapudi, PhD Christy Luna, BS Subratha Debnath, MPH, PhD
Baylor Research Institute	Harold Szerlip, MD, MS(Ed)		Jon Thammavong, BS Felecia Jones Dianna Robinson, LVN
Yale University	Randy Luciano, MD, PhD	Neera Dahl, MD, PhD Jeffrey Turner, MD	Nicolas Page, BS Katrina Blount, PhD Lauren Liberti, MS Hari Nair, BA

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Recruitment Site	Principal Investigator	Co-Investigator(s)	Research Coordinator(s)
Ohio State University	Salem Almaani, MD, MS	Samir Parikh, MD Brad Rovin, MD Isabelle Ayoub, MD Udayan Bhatt, MD Rima Kang, MD	Melissa Riley, MS Vijay Rings, BS Laci Bloomfield, BSN Ryan Watson, BS
University of Miami	Oliver Lenz, MD, MBA		Carlos Bidot, Jr. BS Jacqueline Vassallo
Albert Einstein School of Medicine	Michal Ross, MD	Jyotsana Thakkar, MD Deep Sharma, MD	Lisandra Villalba, BA
MetroHealth	Jeffery Schelling, MD		Marleen Schachere, RN
Oregon Health & Science University	Rupali Avasare, MD	Nicole Andeen, MD Jessica Weiss, MD Jose Rueda, MD Raghav Wusirika, MD Robert Rope, MD	Claire Dorfman, BA Amber Gordon, MHS, MLS Kelsey Zionskowski, BS Brian Booty, BS
University of Arizona	Frank Brosius, MD	Bijin Thajudeen, MD	Ana Florea, MPH Alexandra Shilen, MPH
Lehigh Valley Health Network	Nelson Kopyt, DO		Mary Sobotor, CLA-ASCP Debra Walicki, BS Jean Novak, BA Lauri Centolanza Meghan Ilasi
University of Arkansas for Medical Sciences	Manisha Singh, MD	John Michael Arthur, MD, PhD	Giuseppina Dusio, PhD
University of Southern California	Yan Zhong, MD	Philip Carpenter, MD	Laura Salguero Nudell, MS Anton Akulov, MD
University of Virginia	Julia Scialla, MD, MHS	Kambiz Kalantari, MD Jitendra Gautam, PhD Helen Cathro, MBChB, MPH Corey Cavanaugh, DO	Igor Shumilin, PhD, MS Tracey Blount, RN, MSN
Georgia Nephrology	James Tumlin, MD		Erika Jodice