



**NephCure Kidney International
The Gateway Initiative**

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Dear Clinical Trial Recruitment Collaborators,

Welcome to the first edition of the Gateway Initiative eNewsletter. We are confident that you are as excited and motivated as we are to make significant positive change in patient recruitment for primary glomerular disease clinical trials in 2019. As we enter month six of this twelve-month, time-sensitive initiative towards Workgroup solutions, we remain focused on producing tangible results that have the power to provide a direct and immediate impact on trial recruitment.

We look forward to sharing with you the ongoing monthly updates from the six **Clinical Trial Recruitment Collaborative Workgroups**, in addition to news from the three other pillars of the Gateway Initiative:

- **KidneyHealthGateway.com**, a website that connects patients to trials near them;
- **Nephrotic Syndrome Specialists Program**, a public recognition and referral of patients to NS experts who regularly treat NS patients and recruit for clinical trials;
- **Nephrotic Syndrome Community Expansion**, the need for a shared sense of urgency across the globe and inclusion of all patient groups.

I would also like to take this opportunity to thank the sponsors of the Gateway Initiative, whose support and investments will make new treatments for Nephrotic Syndrome patients soon possible. We look forward to announcing the full list of sponsors at the official launch of KidneyHealthGateway.com on Feb. 19th.

Thank you all for your efforts towards addressing this long-awaited and time-sensitive opportunity to improve clinical trial recruitment and enable new therapies for Nephrotic Syndrome. We look forward to making positive changes in the field this year!

Warmly,

Lauren Lee
Chief Research Officer
NephCure Kidney International

Clinical Trial Recruitment Collaborative: Workgroup Updates

CLINICIANS WORKGROUP

- Develop a clinical trial curriculum to be presented on GlomCon, summer 2019
- Expand workgroup membership to be geographically inclusive & representative of private practices
- Work with NephCure to develop and market clinician-focused section of KidneyHealthGateway.com

CONSORTIA WORKGROUP

- Create library that summarizes available resources of all consortia/networks
- Explore possibility of a universal data dictionary
- Work with relevant Patient Advisory Boards to collect feedback on KidneyHealthGateway.com
- Explore feasibility of regional trial-readiness meetings

PATHOLOGY WORKGROUP

- Draft editorial that outlines the need for pathologists' involvement in clinical trials
- Collaborate with the Renal Pathology Society Workgroup to create a website with information about all ongoing clinical trials
- Explore possibility of a centralized pathology consultant group with 2 levels of consult: trial design and centralized data collection

STUDY OVERLAP WORKGROUP

- Explore telehealth solutions through case studies
- Create a model of master protocol for FSGS
- Create a resource that highlights the differences of each ongoing clinical trial
- Create a best practices list for engaging patients/families in trial design

PEDIATRIC INCLUSION WORKGROUP

- Understand industry perspective of pediatric inclusion in trials through a survey
- Document activities of workgroup through a white paper
- Understand patient/family barriers to trial participation & creating resources to address those barriers
- Collaborate with relevant groups to unify efforts around creating a trial-ready culture among the professional pediatric nephrology community / institutions
- Summarize the historical and current landscape of pediatric nephrology trials and making evidence-based suggestions on how to meaningfully include children in trials

EX-US INCLUSION WORKGROUP

- Create a rolodex/directory of key international contacts/resources
- Dedicate an upcoming World Kidney Day to FSGS
- Explore current international meetings that can showcase the trial landscape & Gateway initiative
- Collaborate with NephCure to make KidneyHealthGateway.com international-friendly

KEY:  COMPLETE  IN PROGRESS  NOT YET STARTED

KidneyHealthGateway.com

The first phase of the patient-friendly pre-screener/connector for all Nephrotic Syndrome clinical trials, KidneyHealthGateway.com, will publicly **launch February 19, 2019**. This initial version includes the following capabilities:

- Patients can quickly see the trials they are eligible for and connect directly with a study coordinator at recruiting site geographically closest to them.
- Hub for patients to learn about the importance of participation in clinical research and see stories from other patient peers who have research study experience.
- Patient-friendly pre-screening tool to better connect patients in all stages of their disease journey to trials that are right for them.
- Each site's study coordinator contact information available in real-time.
- Search tool for Nephrotic Syndrome Specialists (more information below).
- Patients will have immediate access to NephCure staff for questions, more information, and encouragement.
- Supported by a professional marketing campaign to drive all NS patients to the website.

We hope you will join us in promoting this website not only to your patients, but to your peers and other colleagues. We look forward to your feedback on the site as we implement further enhancements in future phases, which will include expanded global participation, a physician-access portal, daily health journal, and genetic screening opportunities.

Nephrotic Syndrome Specialists Program

Data indicates that non glomerular disease-focused nephrologists do not regularly see Nephrotic Syndrome patients. Delay in finding expert care can result in a lack of access to contemporary treatment approaches and a delay in gaining access to potentially relevant clinical trials.

The Nephrotic Syndrome Specialists program was created to address the importance of connecting patients to glomerular disease experts earlier in their diagnoses. The goal of this program is to simultaneously improve patients' quality of life and advance critical research. Each NS Specialist has been carefully selected through a rigorous nomination and vetting process.

The first phase of this program will include approximately 125 US-based NS Specialists and will launch in conjunction with the February 19th kick-off of KidneyHealthGateway.com. Through a simple zip code search, patients will see a list of specialists near them, sorted by Adult vs. Pediatric and Community Practice vs. Academic Medical Center. The nomination process is ongoing, and we expect to expand the list both in number and geographically over time.

Offering an NS Specialists Program has been a near-constant patient request for many years, and we are confident that the entire NS community will see the intrinsic value of providing such a service.

Nephrotic Syndrome Community Expansion

To address the need for a shared sense of urgency across the globe and the power of a unified Nephrotic Syndrome patient advocacy group, we are:

- Bringing together all parties to expedite recruitment into NS clinical trials;
- Expanding globally to implement solutions and facilitate progress on all fronts.

In alignment with the above needs, NephCure has expanded our mission to include all forms of rare, “protein-spilling” kidney diseases including IgAN and complement-mediated disorders like C3G. We have solidified mission alignment in our partnership with the IGA Nephropathy Foundation of America, with plans to complete a full organizational merger in the near future.

In an effort to truly be global in our approach, in December, we traveled to Europe and met with representatives from Kidney Research UK; Dr. Daniel Gale of the RaDaR Registry; the 2020 Int’l Podocyte Conference - Manchester, UK lead, Dr. Rachel Lennon; and the IPNA Committee for Establishment of Guidelines to Treat Steroid Resistant Nephrotic Syndrome. This past week, we presented a webinar in conjunction with Dr. Poyan Mehr, creator of GlomCon. Dr. Richard Glassock presented compelling information about treatment options for IgAN patients, Dr. Suneel Udani provided information on IgAN trials, and Chelsey Fix introduced KidneyHealthGateway.com to more than 300 viewers.

NephCure and the Gateway Team will also be in attendance at the following annual meetings to provide an NS Clinical Trial Recruitment call to action: ISN Meeting · ASN Meeting · ASPN Meeting · IPNA Meeting · ESPN Meeting

Save the Date - Next In-Person Meeting

Please save the date for our next in-person Clinical Trial Recruitment Collaborative Meeting, to be held **June 26th, 2019, at the Georgetown Marriott in Washington, DC**. We eagerly await the presentations of the six Workgroups, including their deliverables to date and details on how they will work through next steps. We will provide more information, including the agenda and hotel reservation details, in upcoming eNewsletters. Thank you in advance for making time for this pivotal meeting towards ensuring no Nephrotic Syndrome trial fails due to insufficient recruitment.

The Gateway Initiative: Clinical Trial Recruitment Collaborative

SEP. '18 Workgroup Landscape Analysis	OCT. '18 Workgroup Landscape Analysis (Completed)	NOV. '18 Nov. 15, 2018 Clinical Trial Collaborative Meeting - Washington, D.C.	DEC. '18 Workgroup Solutions Engagement	JAN. '19 Workgroup Solutions Engagement	FEB. '19 Workgroup Solutions Engagement	MAR. '19 Workgroup Solutions Engagement	APR. '19 Workgroup Solutions Engagement	MAY '19 Workgroup Solutions Engagement	JUN. '19 June 26, 2019 Clinical Trial Collaborative Meeting - Washington, D.C.
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