1. What is the aim of Kidney-PATCH (Pediatric Accelerator Trial Clearing House)?

This project seeks to optimize planning of pediatric kidney disease therapeutic trials by:

a. Enabling feasibility assessment of the available patient populations through data sharing and access to chronic kidney disease (CKD) pediatric registries;

b. Facilitating centralized coordination with the various pediatric kidney clinical trial organizations in US and Europe; and

c. Assisting with identification of expertise that can provide consultation on pediatric study planning.

2. Why was Kidney-PATCH established?

Drug and device developers face major obstacles in conducting trials to advance diagnosis and treatment of pediatric kidney patients. Specifically, the rarity of pediatric patients with CKD, their broad dispersion across the US (and the globe), and the heterogeneity of the population have contributed to lack of new and effective therapies. The Kidney Health Initiative (KHI) and the pediatric clinical trial networks recognize these barriers and the need for innovation to improve health outcomes for children with CKD. As a result, the pediatric trial networks have come together under KHI to develop a charter and clearinghouse that will address the unmet need for coordination of pediatric studies in nephrology.

3. What are the benefits of using Kidney-PATCH?

The benefit to using Kidney-PATCH is efficiency. This centralized, coordinated clearinghouse will help determine feasibility and recommend a clinical trial network for consideration. Kidney-PATCH provides these resources in a pre-competitive space to create a more standardized process for sponsors to reach out to networks. Kidney-PATCH can also conduct feasibility assessments or provide expertise to review and assist with trial design.

4. How do I submit a request?

You will need to complete the application form which can be found at www.kidneyhealthinitiative.org.

5. What is the processing time from when I submit an application?

We anticipate the processing time to be 5-10 business days. Once the application has been processed a member of the committee will provide a list of capable networks to contact.
6. What if I have not completed a feasibility assessment?

Kidney-PATCH is designed to coordinate across pediatric clinical trial networks and assist sponsors with conducting a feasibility assessment.

7. How will I know which trial network is the best choice for me?

Kidney-PATCH has a governing body with representation from the many pediatric clinical trial networks in the US and Europe and has the ability to facilitate relationships globally, as needed. Once an application or request is received, this committee will review the need and provide a recommendation. The sponsor will be responsible for contacting the trial network and assessing their ability to assist with the request. This is a service of the Kidney Health Initiative; trial networks have not contributed any funding for the operation of this clearinghouse.

8. What is the cost associated with this service?

There is no cost associated with Kidney-PATCH during the initial pilot phase. There may be costs at a future date, once the pilot phase is complete. Please continue to check the KHI website for any updates.

9. What happens if there are not any networks who have the capacity to conduct my study?

We recognize the challenge conducting pediatric trials in nephrology, our ultimate goal is to optimize and efficiently conduct trials, the committee will work with sponsors to identify available networks able to conduct this study.