

# The Kidney Project

# FAQ

Version 2.0

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Frequently asked questions sourced from and designed for patients living with end stage renal disease (ESRD) answered by Drs. Shuvo Roy and William Fissell.

## The Basics – The Device & Its Function

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### **How does the device work?**

The bioartificial kidney consists of two modules that work together to get rid of wastes. First, a hemofilter module processes incoming blood to create a watery ultrafiltrate that contains dissolved toxins as well as sugars and salts. Second, a bioreactor of kidney cells processes the ultrafiltrate and sends the sugars and salts back into the blood. In the process, water is also reabsorbed back into the body, concentrating the ultrafiltrate into “urine,” which will be directed to the bladder for excretion.

### **How big is the device?**

The device is the size of a coffee cup.

### **What is the surgical process like to insert the device? Where can I have the procedure done?**

The procedure will be similar to kidney transplant surgery and it will be performed under general anesthesia.

### **How will the filter be cleaned?**

The filter is coated with a special thin biocompatible film to prevent fouling and blood clots. Additionally, the blood flowing over the coated filter surface will also help to keep the membrane free of debris accumulation.

### **How long will the device survive after implantation? Will it have to be replaced?**

The device is meant to be permanent and that is what our efforts are pushing towards. Current testing and research suggest that it could be possible for the device to operate for many years, without failure. However, if failures occur, the replacement of the filter and/or cells would involve a minimally invasive surgery.

### **Will there be a risk of blood clotting? Will patients still have to take immunosuppressive drugs or anticoagulant after implantation?**

The possibility of having to take immunosuppressive drugs or anticoagulants is minimal, and even non-existent. While we will certainly have better insight as we progress through the pre-clinical trials phase, the cells in the bioreactor are isolated from the patient’s immune system and the surface coating on the device will work to prevent blood clotting.

### **Will it also help Polycystic Kidney Disease and Focal Segmental Glomerulosclerosis (FSGS)?**

Yes. In any case where a kidney transplant is needed, our device will be a viable option.

### **Can you still get this device if you still have 15% kidney function? Or is it exclusive to those whose kidneys have totally failed?**

This is case-specific, so it would depend on the details of a particular patient’s case and will be decided by both the patient and physician.

## **The Basics – The Device & Its Function (Continued)**

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### **Will this be available internationally? Or will international patients have to go to United States for procedure?**

Once the device is released commercially, it will be available to all patients in need, domestic or international. Clinical trials, however, will likely be conducted in the United States initially because it is where the key research is taking place as well as needing to adhere to all FDA guidelines.

### **Any predicted side effects?**

Adverse side-effects that might occur would be similar to side effects known in other procedures involving implanted medical devices, and would possibly associated with surgical traumas and infections. Additionally, there might be a need for increased fluid consumption.

### **How much will this device cost?**

We are unable to say with certainty how much the device will cost, due to what the business and economic climate will be like by the time it is released. Though, we are anticipating that the device will cost no more than what transplant maintenance currently costs.

### **What are the challenges (long term and short term)?**

The Kidney Project is an ambitious project and is not without its challenges. In the short term, our primary challenge is funding the research. A significant hurdle is procuring enough money in order to proceed through the preclinical studies, which would allow us to build full-scale prototypes to generate data for the first round of in-human studies.

The long term challenges center around keeping the device operating trouble-free after implantation beyond a few months. Some of problems we won't hit until we do clinical trials, so for now, we are looking at ways to increase the lifetime of cells as well as ways to minimize, or even eliminate, thrombus formation (blood clotting). We will get a better handle on the long-term challenges once we transition to preclinical studies and begin to gather clinical-scale data.

## The Timeline

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### **What can be done to speed up the research and development process?**

More funding would significantly help to speed up both research and development. *See below for more details on funding.*

### **If you had full funding, when would the device be ready for clinical trials?**

If we successfully raise all of the necessary funding, mentioned above, and we do not encounter any unanticipated development challenges, we expect to have a device released for commercialization by the middle the year 2017.

### **When will the device be ready after clinical trials?**

Typically, there are at least two cycles of clinical testing required for all medical devices. The nature of the results of the first round of clinical trials will largely influence the timing of release and industrial-scale manufacturing.

That being said, we estimate that the clinical trials will be complete by the year 2020. During the clinical trials, we will be working with manufacturers to discuss and manage the details of production. Once the clinical trials are complete, the device will be immediately available for patients.

## The Funding

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### **Is there an estimate as to the cost of funding to ensure timely completion of Phase 2?**

Currently, we estimate that we need around 10 million US dollars to complete Phase 2, preclinical studies, in a timely manner.

### **What kind of federal funding do you receive? How do you get more?**

To date, we have received almost \$7 million from various federal agencies in the United States, namely National Institute of Health (NIH), National Aeronautics and Space Administration (NASA) and the Department of Defense (DOD), who provided funds for the basic research and groundwork behind the artificial kidney. We have since received very positive feedback from these federal agencies, recognizing our success with the fundamental proof-of-concept work. In order to proceed to the next steps in commercialization, we now need the help of industry partners and investors. However, as mentioned below, the challenge with procuring these industry partners and investors is that they want to see more data from preclinical studies before they invest.

### **Why do you not have a lot of investors? Is it too risky for them?**

Investors have expressed interest in the concept of our project and have indicated their understanding of its potential. Additionally, they have also commented that their comfort with investing in our project would increase significantly once we can show them evidence of the device working in an animal for at least 30 days. This is what we are currently working on.

### **Is it worth contacting our government officials to ask for more funding to your project?**

Yes, absolutely! The Kidney Project's artificial kidney will enhance patient outcomes and reduce treatment costs, which provides an overall improvement to the patients' quality of life and current healthcare costs.

### **How can I make a donation? (Domestically and Internationally)**

For domestic donations, use the following link:

[Make a Donation Here!](#)

International donations have experienced issues with the above system. So, if the above link does not work, use one of the following options:

- Email [onlinegiving@ucsf.edu](mailto:onlinegiving@ucsf.edu) to give a donation
- Call +1-877-499-8273
- Email Stephanie Brummett at [stephanie.brummett@ucsf.edu](mailto:stephanie.brummett@ucsf.edu)

## Clinical Trials – Before & After

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### **When will the first animal trials occur using the final implantable design?**

As we've mentioned above, with full funding, we anticipate testing the final implantable kidney prototype in animals by the beginning of the year 2017.

### **What is the status of animal testing?**

Currently, we have tested components of the device successfully, but we still need to integrate these components into a single device that will be implanted and operated for at least 30 days.

### **What are the criteria for choosing first group of clinical trials patients?**

For the initial clinical trials, we will be looking for patients who exhibit high levels of antibodies and have been on the transplant wait list for a long time.

### **Will stage 4 patients be accepted?**

Initially, clinical trials will concentrate on End Stage Renal Disease patients.

### **Will international patients be considered?**

International patients will certainly be considered. However, it is likely that the first round of patients will be domestic due to operating under FDA (Food and Drug Administration) guidelines.

### **Will there be a trial for pediatric patients?**

Safety will be our main concern during the initial phase of clinical trials, so we do not intend to expose vulnerable populations, such as children, until after we have positive and consistent data from clinical trials with adults.

### **Will patients have to relocate to Bay Area for duration of clinical trials?**

At this stage of the project, logistics of the clinical trials are not certain. That being said, the trials will likely be held at multiple sites, including the Bay Area, so the patient will not be required to relocate to the Bay Area.

### **Will the clinical trials be fully funded or will the patients need to help with funding their participation?**

Ideally, if we have procured all necessary funding, the clinical trials should be fully funded. We will know more details as we get closer to clinical trials and will update everyone accordingly.

## Getting Involved

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### **Will there be routine updates regarding the progress of the project?**

Our Facebook page is a great place to stay informed about our progress:

<http://facebook.com/ArtificialKidney>. In addition, we keep an archive of news stories on our site: <http://kidney.ucsf.edu>

### **Is there a way to help get the artificial kidney closer to reality?**

There are two main ways: firstly, by directly helping with funding either through organized fundraisers in your community or direct donations to the project. You can donate on our website: [kidney.ucsf.edu](http://kidney.ucsf.edu). Secondly, by raising awareness by sharing our website and Facebook page, publicizing our efforts in the press, and reaching out to interested people or communities.

### **How will the first group of people for clinical trials in 2017 be selected?**

For the first studies, we are focused on safety. Need will likely not play a large role in selection. While we do not have an official “clinical trial candidate list,” we are keeping track of all interested parties. Please send an email to our Project Coordinator, Stephanie Brummett at [Stephanie.brummett@ucsf.edu](mailto:Stephanie.brummett@ucsf.edu).