KIDNEY HEALTH INITIATIVE

1510 H Street NW | Suite 800 | Washington, DC 20005
p 202.640.4660 | f 202.637.9793 | khi@asn-online.org

Memorandum

To:

Shantanu Agarwal, MD
Robbie Barbero, PhD
Joseph V. Bonventre, MD, PhD
Joseph L. Charest, PhD
Andrew Davenport, MD
Iain Drummond, PhD
Jennifer Erickson
Mike Flessner, MD, PhD
Gregory G. Germino, MD
Gema Gonzalez, PhD
Kate Goodrich, MD
Daniel Gossert, PhD
Raymond Harris, MD, FASN
Rosemarie Hunziker, PhD
Frank Hurst, MD, FASN
Dean G. Johnson, PhD
Kris Kandarpa, MD, PhD
Richard Knight, MBA
Edward F. Leonard, PhD
Peter Linde, MD, FASN
Richard McFarland, PhD, MD
Sharon Moe, MD
Jonathan Morse, JD
Guiseppe Orlando, MD, PhD
Harald Ott, MD
Jesse Roach, MD
David Sachs, MD
Murray Sheldon, MD
Doug Silverstein, MD
Robert Star, MD
Jason Wertheim, MD, PhD
Dave White
Celia Witten, MD, PhD
Iwen Wu, PhD

From: Prabir Roy-Chaudhury, MD, PhD, FASN
Melissa West, KHI Project Director

Re: Kidney Health Initiative Advisory Meeting on Monday, November 7, 2016

Date: Thursday, November 3, 2016

On behalf of the Kidney Health Initiative (KHI), thank you for accepting our invitation to participate in the KHI Advisory Meeting focused on developing an innovative roadmap for future renal replacement therapy (RRT). As previously mentioned in an attempt to significantly change the landscape of renal replacement therapy, KHI submitted a commitment at a White House Summit on Organ Donation in June 2016, to "develop a Roadmap that will allow the medical product development community to understand the challenges and milestones needed to achieve the goal of a successful alternative to dialysis." (White House Organ Summit Fact Sheet)

The KHI Advisory Meeting will begin our process to shape and define this roadmap for future development of an artificial or bio artificial kidney, which may include cells, mechanical components, or a combination of both. Our goal is to discuss the state of the science in cellular and mechanical therapies and determine the scientific challenges and milestones for bench and animal studies for any future portable, wearable or implantable product.

In advance of the meeting, please review the background material that is provided in the attached PDF. Please respect our request to not distribute these materials to anyone not

attending the meeting. We would like to focus your attention to Tab 4 and ask that you consider the following questions:

1. Since the attachment was developed to provide examples and not be comprehensive, what is additions or changes would you recommend to this initial list of scientific challenges?
2. What prioritization, level of importance, or level of complexity would you assign to each challenge (both our examples and your own)?
3. What timeline to resolving the challenge would you assign? (eg. 1 year, 3 year, 5 year) Are there potential intermediate milestones for the more complex issues?

We will discuss your answers to these questions during our afternoon breakout and group discussion. Additional questions to support our discussion on Monday are provided on the agenda.

Thank you again for agreeing to participate in the meeting, especially with such short notice. This one day meeting will provide initial structure to the roadmap, which will be further developed in a public workshop in February 2017.

Following is logistical information for your review:

Meeting Schedule

9:30 AM	Arrivals and Coffee Break
10:00 AM	Meeting Begins
4:00 PM	Meeting Adjourns

Please see the detailed agenda in Tab 1

Hotel and Meeting Location

Double Tree by Hilton Hotel – Washington, DC – Silver Spring
8727 Colesville Road
Silver Spring, Maryland 20910
(301) 589-5200

Room: Pinnacle Ballroom

Transportation

The DC Metro is scheduled to have several station closures on the Red Line. We encourage you to have a taxi or car service to the hotel from the DCA, BWI, or Union Station. If you are interested in more information on the DC Metro track work, please visit http://www.wmata.com/

Please retain any receipts for taxis, travel, and food for the meeting. Complete the attached reimbursement and we will reimburse your for any meeting-related expenses.

Attire

The dress for the meeting is business casual.

Background Materials/ Attachments

Tab 1	Meeting Agenda
Tab 2	List of Participants
Tab 3	Project Proposal
Tab 4	Examples of Scientific Challenges
Tab 5	Kidney Disease Prize Description
Tab 6	Expense Reimbursement Policy and Form

KHI Staff Contact

If you have any questions, please do not hesitate to contact Melissa West at mwest@asn-online.org or 202-740-7891.

If you need assistance the day of the meeting, please contact Melissa or Ryan Murray at 908-752-5667.

CC: Tod Ibrahim, ASN Executive Vice President
Rachel Meyer, ASN Director of Policy and Government Affairs
Ryan Murray, KHI Senior Project Associate
Elle Silverman, KHI Project Associate

KHI Advisory Meeting
"Roadmap Development for Innovative Renal Replacement Therapies"

Monday, November 7, 2016
10:00 a.m. – 4:00 p.m. ET

DoubleTree by Hilton Hotel
Room: Pinnacle Ballroom
8727 Colesville Road
Silver Spring, MD 20910

Agenda

9:30 a.m. – 10:00 a.m. Arrivals and Continental Breakfast

10:00 a.m. – 12:00 p.m. Introduction

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30 min. **Welcome and Opening Remarks**
Prabir Roy-Chaudhury, MD, PhD, FASN
Kidney Health Initiative Co-Chair

Center for Devices and Radiological Health, FDA

Center for Biologics Evaluation and Research, FDA

White House Office of Science and Technology and Policy (Tentative)

30 min. **Presentation of ASN/XPrize Ideation Report and Discussion**
Sharon Moe, MD
Indiana University School of Medicine

30 min **State of the Science: Cellular Technologies and Discussion**
Joseph V. Bonventre, MD, PhD, FASN
Brigham and Women's Hospital

30 min. **State of the Science: Mechanical Technologies and Discussion**
Andrew Davenport, MD
Royal Free Hospital (United Kingdom)

12:00 p.m. – 4:00 p.m. Translating State of the Science into Future Development Efforts for RRT

Lunch will be provided

Topic discussions include:

- What technologies are likely to come to trial in 5 years?
- What design principles or characteristics are deemed to be most important?
- What scientific challenges need to be considered for bench and animal studies?
- What level of complexity, timeline for resolution and prioritization would you apply to the scientific challenges?
- What hybrid technologies need to be considered and accommodate in the Roadmap?
- How should patients participate in this process?
- For industry, what guidance would you provide to ensure the RRT roadmap secures confidence through to commercialization?
- What stakeholders are not represented and should be invited to the public workshop?

4:00 p.m.	**Adjourn**

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KHI Advisory Meeting
Monday, November 7, 2016
Meeting Participants

1. Shantanu Agarwal, MD, *Center for Program Integrity, Centers for Medicare and Medicaid Services*
2. Robbie Barbero, PhD, *White House Office of Science and Technology Policy*
3. Joseph V. Bonventre, MD, PhD, FASN, *Brigham and Women's Hospital*
4. Joseph L. Charest, PhD, *Draper Laboratory*
5. Andrew Davenport, MD, *Royal Free Hospital (United Kingdom)*
6. Iain Drummond, PhD, *Massachusetts General Hospital*
7. Jennifer Erickson, *White House Office of Science and Technology Policy*
8. Mike Flessner, MD, PhD, *National Institute of Diabetes and Digestive Kidney Diseases, National Institutes of Health (KHI Board of Directors Member)*
9. Gregory G. Germino, MD, *National Institute of Diabetes and Digestive Kidney Diseases, National Institutes of Health*
10. Gema Gonzalez, PhD, *Center for Devices and Radiological Health, US Food and Drug Administration*
11. Kate Goodrich, MD, *Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services*
12. Daniel Gossert, PhD, *National Institute of Diabetes and Digestive Kidney Diseases, National Institutes of Health*
13. Raymond Harris, MD, FASN, *Vanderbilt University Medical Center (ASN President)*
14. Rosemarie Hunziker, PhD, *National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health*
15. Frank Hurst, MD, FASN, *Center for Devices and Radiological Health, US Food and Drug Administration*
16. Dean G. Johnson, PhD, *University of Rochester*
17. Kris Kandarpa, MD, PhD, *National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health*
18. Richard Knight, MBA, *Kidney Transplant Recipient, American Association of Kidney Patients*

19. Edward F. Leonard, PhD, *Columbia University*

20. Peter Linde, MD, FASN, *Acceleron Pharma (KHI Board of Directors Member)*

21. Richard McFarland, PhD, MD, *Center for Biologics Evaluation and Research, US Food and Drug Administration*

22. Rachel Meyer, *American Society of Nephrology*

23. Sharon Moe, MD, *Indiana University School of Medicine*

24. Jonathan Morse, JD, *Center for Program Integrity, Centers for Medicare and Medicaid Services*

25. Ryan Murray, *Kidney Health Initiative*

26. Guiseppe Orlando, MD, PhD, *Wake Forest Baptist Medical Center*

27. Harald Ott, MD, *Massachusetts General Hospital*

28. Jesse Roach, MD, *Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services (KHI Board of Directors Member)*

29. Prabir Roy-Chaudhury, MD, PhD, FASN, *University of Arizona (KHI Co-Chair)*

30. David Sachs, MD, *Massachusetts General Hospital*

31. Murray Sheldon, MD, *Center for Devices and Radiological Health, US Food and Drug Administration*

32. Jeff Shuren, MD, JD, *Center for Devices and Radiological Health, US Food and Drug Administration*

33. Elle Silverman, *Kidney Health Initiative*

34. Doug Silverstein, MD, *Center for Devices and Radiological Health, US Food and Drug Administration*

35. Robert Star, MD, *National Institute of Diabetes and Digestive Kidney Diseases, National Institutes of Health*

36. Jason Wertheim, MD, PhD, *Northwestern University*

37. Melissa West, *Kidney Health Initiative*

38. Dave White, *Kidney Health Initiative Patient and Family Partnership Council*

39. Celia Witten, MD, PhD, *Center for Biologics Evaluation and Research, US Food and Drug Administration (KHI Board of Directors Member)*

40. Iwen Wu, PhD, *Center for Biologics Evaluation and Research, Food and Drug Administration*

Development of a Roadmap for Innovations in Renal Replacement Therapy (RRT)

Problem

There are over 600,000 patients with end stage renal disease (ESRD) in the United States receiving various forms of Renal Replacement Therapy (RRT), including 450,000 on dialysis [hemodialysis (HD) or peritoneal dialysis (PD)] and 193,000 with a kidney transplant. Patients who have ESRD are eligible for Medicare regardless of age, and the cost of ESRD to Medicare is nearly $34 billion per year (2013). This is more than the entire budget of NIH ($29 billion in 2013) and represents 7% of the total Medicare payments, despite the ESRD population representing less than 1% of the total Medicare population. Most agree that renal transplantation is the best available option for RRT and most closely mimics native kidney function. Indeed, the rates of survival are highest in patients with a functioning allograft compared to those on maintenance hemodialysis or peritoneal dialysis. Kidney transplantation is also the least costly at $29,920 per person per year (PPPY) compared with HD ($84,550 PPPY) and PD ($69,919 PPPY).[1]

Unfortunately, transplantation is not an option for all patients with ESRD due to several limitations, including a shortage of viable organs or high levels of antibodies in sensitized patients. There are currently more than 120,000 people in the United States on the organ waiting list, and more than 80 percent of those patients are waiting for kidneys.[2] Each year approximately 17,000 Americans receive kidney transplants while a further 80,000+ are on the waiting list. It is this shortfall of transplant organs which makes the search for innovative forms of renal replacement so critical. Each month, 3,000 new patients are added to the kidney waiting list, making it critical for the government and all stakeholders to support and catalyze innovation in the search for effective modalities of renal replacement for both these patients and to the health care system.

Given that the etiologies of ESRD (hypertension and diabetes) are increasing in the United States and world-wide [see World Health Organization's report: (http://apps.who.int/iris/bitstream/10665/204871/1/9789241565257_eng.pdf?ua=1) suggesting that over the period from 1980 to 2014 "diabetes rates nearly doubled" and currently "one in 12 people living in the world today have the disease"], it seems likely that the prevalence of dialysis therapy will continue to grow with the cost becoming unmanageable possibly within the next decade. It is therefore imperative to expedite development of alternative therapies that can provide improved solute clearance and better health outcomes in a cost effective manner based on sound science.

[1] United States Renal Data System. 2015 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.
[2] https://www.unos.org/data/

Background and Significance

The purpose of this proposal is to develop a Roadmap that will allow the medical product development community to understand the challenges and milestones needed to achieve the goal of a successful alternative to dialysis as RRT. There are multiple innovative technologies being pursued as improvements and/or replacements for traditional dialysis therapies, including external miniaturized dialysis systems and implantable artificial organs in various configurations. These technologies could potentially increase the RRT options for patients, as well as fill in the current gap that exists between organs available for transplant and those who need them. With the right processes and support in place, including dedicated stakeholder coordination, a functional alternative to traditional dialysis may be on the horizon; however currently there does not exist a consensus Roadmap to develop such an alternative. Although such a Roadmap does not exist, we believe that the knowledge from which to construct such a Roadmap resides in the many disparate areas of the field. Scientific, engineering, and clinical expertise exists in NIH, professional medical societies, academic and industry researchers. Regulatory expertise exists at FDA, in particular CDRH and CBER, which have extensive experience and knowledge regarding the regulatory pathways needed to allow clinical trials for RRT products. Payers (CMS is the primary payer for U.S. patients with ESRD) have expertise that is critical for widespread implementation of novel RRT products. A Roadmap as proposed will enable more robust understanding of the challenges and milestones throughout the field that can be used as a common reference for developers and regulators.

Kidney Health Initiative (KHI) Resources Needed

KHI administrative support and expenses associated with engaging with stakeholders and drafting the Roadmap including facilitation and support for a Workshop/Consensus Conference to gather information and perspectives for the Roadmap.

Project Outline

The overall activities of the project will be managed by a Steering Committee, which will include Senior Officials from organizations and agencies who are ESRD stakeholders including Government [the Food and Drug Administration Center for Biologics Evaluation and Research (FDA/CBER) and Center for Devices and Radiologic Health (FDA/CDRH), the National Institutes of Health/ National Institute of Diabetes and Digestive and Kidney Diseases (NIH/NIDDK), and National Institute of Biomedical Imaging and Bioengineering (NIH/NIBIB), the Centers for Medicare and Medicaid Services (CMS)], Academia, Industry, Healthcare providers and professional medical Societies such as American Society of Nephrology (ASN), Patients and Caregivers from various KHI participants such as the National Kidney Foundation (NKF), the American Association of Kidney Patients (AAKP), and others.

The initial steps toward a Roadmap will be to plan and hold a Workshop aimed on gathering information and perspectives on technologies which are considered to be innovative forms of RRT. The Workshop

should focus on technologies that have advanced beyond the concept stage and should represent major technological leaps and/or vastly improved patient experience compared with currently available ESRD technologies.

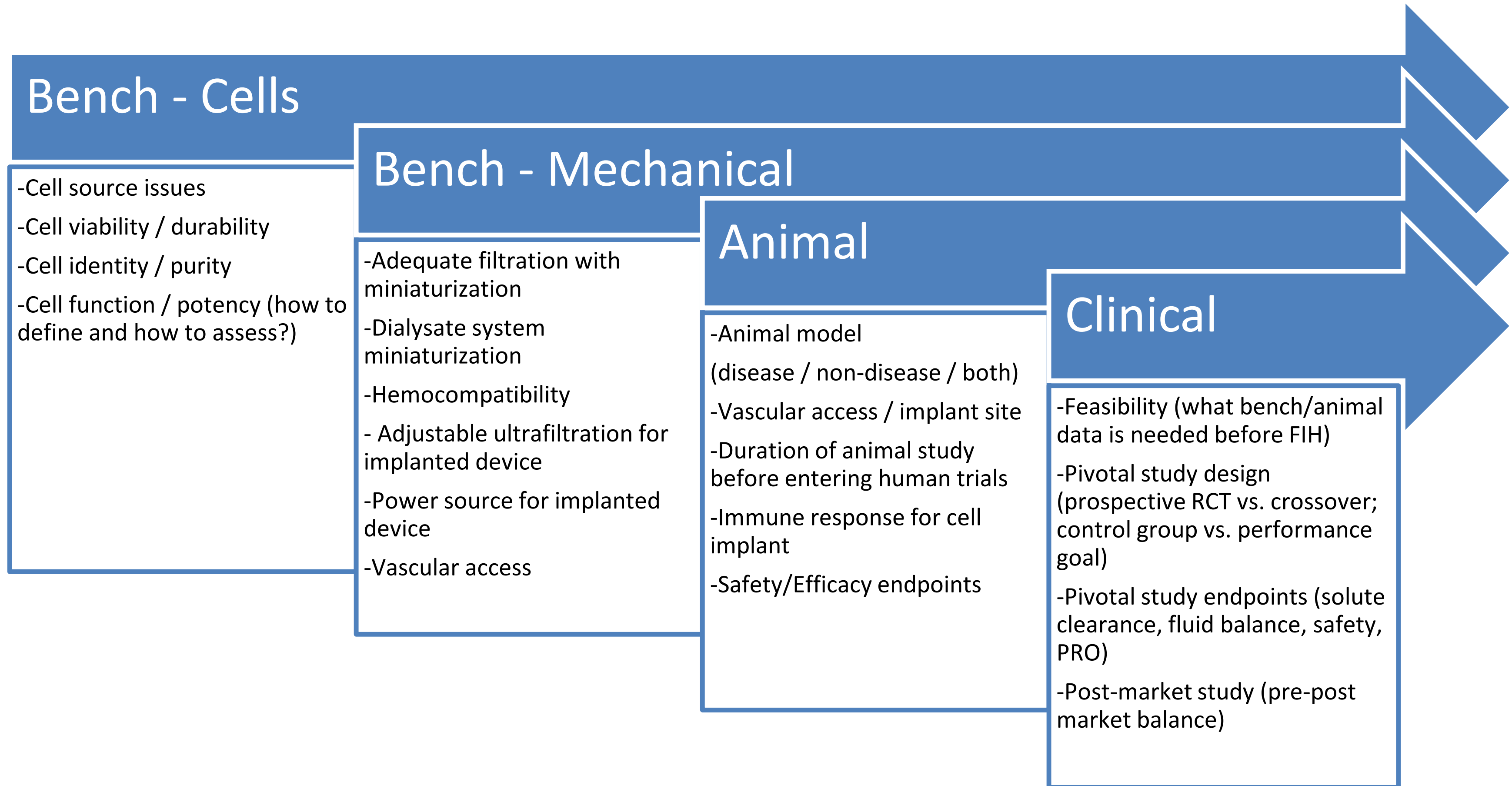
The Steering Committee will prioritize and focus on technology areas which have the best chance of success in terms of actually being available to patients in the near future (~5 years). Medical products requiring highly advanced technologies may be prioritized to allow stepwise development starting with common technologies or platforms. Considerations include, but are not limited to, external miniaturized dialysis systems, implantable artificial organs with mechanical and cellular components, and bioengineered organs with cells grown on a scaffold. The innovative RRT technologies could be intended to treat patients with ESRD or those with predialysis CKD similar to a preemptive kidney transplant.

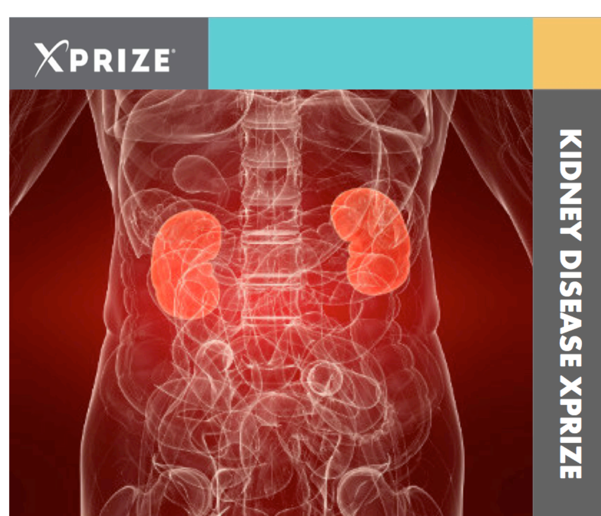
Once the technological areas are determined, the workshop will be structured in such a way as to determine a development/regulatory Roadmap for these innovative RRT technology areas to include detailed recommendations for additional bench testing, as well as animal and clinical studies. Additionally, knowledge gaps will be determined during the workshop planning sessions and/or workshop proceedings which can be used to determine research priorities for expanding knowledge in critical areas of the Roadmap. Identifying and consolidating these research priorities should help to advance the science, as well as identify areas in which funding would have the most impact in terms of making the technology available to patients.

Project Goals and Deliverables

The Project Goal and final deliverable will be the publication of a "Development and Regulatory Roadmap for innovative forms of RRT". In order to ensure that the Roadmap benefits from the input and interaction of a broad spectrum of stakeholders, the project will also conduct a Workshop/Consensus Conference to engage stakeholders, identify research priorities to alleviate critical knowledge gaps and advance the science of alternatives to dialysis for ESRD prior to writing the Roadmap.

Scientific Challenges (examples)





KIDNEY DISEASE XPRIZE COMPETITION

The $11 million Kidney Disease XPRIZE competition addresses the lack of effective, patient-centric treatments for end-stage renal disease (ESRD). The competition will:

- Incentivize innovation in a stagnant field that has only seen incremental innovation in the past three decades;
- Bypass perverse incentives that hinder innovation; and
- Develop new technologies for treating ESRD that lead to improved patient outcomes and a reduced social burden.

THE KIDNEY DISEASE XPRIZE

The Kidney Disease XPRIZE will challenge teams to overcome decades of stagnation in ESRD treatment. This prize will create a fundamental shift in the way we treat kidney disease by focusing on patient-centric therapeutic devices that improve patients' quality of life. The winning team will develop a wearable or implantable, tether-free, needle-free, and self-regulating renal replacement therapy (RRT). The winning device will revolutionize ESRD treatment by improving uremic solute clearance, fluid and electrolyte regulation, and endocrine regulation, while addressing the challenge of vascular access and the associated problems of bleeding, clotting, and biofouling.

The Kidney Disease XPRIZE is a 52-month competition. XPRIZE will allow teams to join the competition late—up to 12 months after launch—at a significant registration premium. This will encourage teams to register early, while still allowing for teams that do not enter the competition early but have breakthroughs relevant to the competition. Milestone prizes will be awarded at Month 24, and the top 30 teams will be selected to continue their device development to compete for the grand prize. At Month 43, XPRIZE will determine which teams move directly into the

[143] Kjellstrand, C. M. & Blagg, C. R. (2003, January 1). Differences in dialysis practice are the main reasons for the high mortality rate in the United States compared to Japan. *Hemodialysis International, 7(1),* 67–71.
[144] Ibid.

Laboratory Testing phase. Laboratory Testing will be limited to 10 teams. Once testing is complete, judges will determine the winning team.

This competition structure serves the following functions:

- Provides funding to teams with promising technologies midway through the competition in the form of milestone prizes
- Encourages a rapid technological development cycle to accelerate innovation by setting audacious competition deadlines
- Rewards the best technological advancement rather than the fastest developed

A snapshot of the Kidney Disease XPRIZE appears below in Table 6. Each element of the prize snapshot is discussed in greater detail below the table.

Table 6. Kidney Disease XPRIZE Snapshot

$11 MILLION KIDNEY DISEASE XPRIZE	
Grand Challenge	More than 20 million Americans suffer from chronic kidney disease (CKD). Of these individuals, approximately 400,000 suffer from end-stage renal disease (ESRD) and are on some form of dialysis at a public cost of more than $35 billion annually.[145] The lack of effective, patient-centric treatments for ESRD that result in improved patient outcomes and a reduced social burden is a Grand Challenge that must be remedied.

[145]United States Renal Data System (USRDS). (2013). *Costs of end-stage renal disease*. Ann Arbor, MI: USRDS. Retrieved from www.usrds.org/2013/pdf/v2_ch11_13.pdf

$11 MILLION KIDNEY DISEASE XPRIZE	
Prize Purse	Total: $11 million <u>Milestone Prizes</u> Total: $1 million • 1st place: $500,000 • 2nd Place: $300,000 • 3rd Place: $200,000 <u>Grand Prize</u> $8 million <u>Bonus Prizes</u> $1 million (if winning device is implantable) $1 million (if winning device provides endocrine function)
Goals	• Incentivize innovation in a stagnant field that has only seen incremental innovation over the past three decades • Bypass perverse incentives that hinder innovation • Develop new technologies for treating ESRD that lead to improved patient outcomes and a reduced social burden
The Winning Team Will…	Develop a wearable or implantable, tether-free, needle-free, and self-regulating renal replacement therapy (RRT)

$11 MILLION KIDNEY DISEASE XPRIZE	

Guidelines/Metrics	The winning team will develop a device that will:
	• Perform the following physiologic functions of kidneys:
	  ○ Filtration rate of at least 30 liters (L) per day
	  ○ Uremic solute clearance of at least one solute in each of the classes described in Table 7 at 20 percent efficiency
	  ○ Fluid balance
	    ▪ Maintain smooth, consistent fluid pressure
	    ▪ Normalize sodium, potassium, and calcium levels to the following:
	      • Sodium: 135–145 milliequivalents per liter (mEq/L)
	      • Potassium: 3.5–5.0 mEq/L
	      • Calcium: 8.8–10.7 milligrams per deciliter (mg/dL)
	  ○ Endocrine function (to be eligible for the bonus prize)
	    ▪ Maintain homeostasis of the following endocrine molecules:
	      • Calcitriol (to 20–50 nanograms per milliliter)
	      • Erythropoietin (to 4–24 milliunits per milliliter)
	• Provide needle-free vascular access
	  ○ Reduce likelihood of infections
	• Reduce bleeding, clotting, and biofouling
	  ○ Prevent any significant bleeding, clotting, or biofouling at vascular access points or within the device
	• Internally monitor and regulate physiologic parameters
	• Improve "quality of life" criteria, including:
	  ○ Weight
	  ○ Water requirements
	  ○ Needle-free vascular access (number and type), if not internal
	  ○ Ease of use and comfort
	    ▪ Number of times used per day/week or continuous?
	    ▪ Length of each use or continuous?
	  ○ Ease of setup
	    ▪ Ability of patient to set up device without assistance

$11 MILLION KIDNEY DISEASE XPRIZE	
Timeline	Month -3: Pre-Launch Month 0: Launch • Draft competition guidelines issued for public comment • Teams may submit intent to compete • Registration begins Month 3: Final Competition Guidelines Issued Month 9: Medical Device Testing Rig Update • Teams receive detailed technical specifications for the medical device testing rigs (the rigs are discussed in more detail below) Month 12: Registration Deadline Month 18: Team Summit #1 Month 22: Technology Assessment #1 Deadline • Teams submit Technology Assessment #1 to judging panel Month 24: Technology Assessment #1, Team Summit #2, and Milestone Prize Award • Three-day event, including team presentations, Team Summit #2, a judging summit, a down-select to the top 30 teams, and the Milestone Prize Award event Month 43: Technology Assessment #2 • Judges select up to 10 finalist teams Month 44: Laboratory Testing • Teams are tested in a staggered fashion (one team every seven days) on standard medical device testing rigs Month 47: Judging • Teams are assessed using the metrics listed under "Guidelines/Metrics" Month 48: Award Ceremony • Winner announced and grand prize purse awarded Month 49: Post-Prize Industry Activities Month 52: Formal Prize Activities End

The Kidney Disease XPRIZE will incentivize teams to develop innovative RRTs that will address patients' quality of life, improve health outcomes, and reduce the social burden of ESRD. The competition does not presuppose a solution. XPRIZE does not know what the winning device will look like or how it will be designed. Teams will likely develop a wide range of innovative approaches to this Grand Challenge.

KEY PRIZE CONSIDERATIONS

In designing this prize, XPRIZE considered the following:

- How to determine metrics for the competition that enable a proof of concept without being prohibitively difficult to achieve in the time frame set by the competition
- How to measure the impact an innovative device would likely have on a patient's quality of life
- How to appropriately test and validate teams' devices without requiring costly and time-consuming animal or human trials

Each of these considerations is discussed in detail below.

Competition Metrics

Metrics for the Kidney Disease XPRIZE have been designed to require functionality beyond that of current dialysis technologies. This requires significant innovation in the time frame allotted by the competition.

- *Filtration rate*. The filtration rate for the competition is set at 30 L/day, which is 20 percent of the functionality of an average, normally functioning human kidney. Once a kidney falls below approximately 15 percent functionality, dialysis is required to extend a person's life; therefore, this metric is set above that threshold, but low enough as to not be prohibitively difficult for teams to achieve.

- *Uremic solute clearance*. Three classes of uremic solutes that cause vascular damage were selected for this competition. Urea, the standard uremic solute cleared by traditional dialysis, was also selected (see Table 7 below). Teams must select at least one solute in each of the classes listed in Table 7 for clearance by their devices. This metric will require teams to develop innovative filtration technologies that can successfully clear different uremic solute classes. The devices must clear these solutes at 20 percent efficiency. Once a kidney falls below approximately 10 percent efficiency in uremic solute clearance, dialysis is required to extend a person's life; therefore, this metric is set above that threshold, but low enough as to not be prohibitively difficult for teams to achieve.

Table 7. Selected Uremic Solute Classes

Uremic Solutes	Description
Urea	Urea is a waste product from protein metabolism. The buildup of urea interferes with normal metabolic processes.[146]

Middle molecules	Middle molecules are difficult to remove by standard dialysis treatments. These include the following:[147]
	• Advanced glycation end products (AGEs)
	• Angiotensin A (Ang A)
	• Dinucleotide polyphosphates
	  ○ Diadenosine pentaphosphate (Ap_5A)
	  ○ Diadenosine hexaphosphate (Ap_6A)
	• Leptin
	• Tumor necrosis factor-alpha (TNFα)

Protein-bound molecules	Protein-bound molecules are difficult to remove by standard dialysis treatments. These include the following:[148]
	• Advanced glycation end products (AGEs)
	• Dinucleotide polyphosphates
	  ○ Diadenosine pentaphosphate (Ap_5A)
	  ○ Diadenosine hexaphosphate (Ap_6A)
	• Homocysteine
	• Indoxyl sulfate
	• Leptin
	• P-cresyl sulfate (pCS)
	• Phenylacetic acid
	• Tumor necrosis factor-alpha (TNFα)

Small water-soluble compounds	The following small water-soluble compounds "have a different kinetic behavior compared with the prototypic water-soluble compound urea:"[149] • Asymmetric dimethylarginine (ADMA) • Guanidine acetic acid • Methylguanidine

[146]Casiday, R. & Frey, R. (1999). Maintaining the body's chemistry: Dialysis in the kidneys—Membranes and proteins: Dialysis, detergents, and proton gradients experiment [Tutorial]. Washington University. Retrieved from www.chemistry.wustl.edu/~edudev/LabTutorials/Dialysis/Kidneys.html

[147]Vanholder, R., Baurmeister, U., Brunet, P., et al. (2008). A bench to bedside view of uremic toxins. *Journal of the American Society of Nephrology, 19(5),* 863–870. Retrieved from http://jasn.asnjournals.org/content/19/5/863.full.pdf

[148]Ibid.

[149]Ibid.

- *Fluid and electrolyte balance.* Maintenance of osmotic balance in a living being is vitally important. Fluid load and electrolyte balance are interlinked. To test the devices' functionality in a medical device testing rig, XPRIZE will measure two things:
    - Fluid load and fluctuations
        - Devices will be expected to maintain smooth, consistent fluid pressure
    - Electrolyte balance
        - Devices will be expected to normalize levels of sodium, potassium, and calcium to the following levels:
            - Sodium: 135–145 mEq/L
            - Potassium: 3.5–5.0 mEq/L
            - Calcium: 8.8–10.7 mg/dL

- *Endocrine function.* The endocrine system secretes hormones that regulate metabolism, tissue function, growth, sleep, mood, and many other activities. The kidneys play an important role in that system by regulating three key elements of endocrine function: renin, erythropoietin, and calcitriol. The functionality of renin, which regulates blood pressure, fluid levels, and mineral balance, will most likely be replaced through the use of filtering membranes and pressure regulators within the device. Erythropoietin, which regulates red blood cell production, is commercially available under the brand name Epogen. Epogen is expensive, however, so this competition requires teams to develop devices that can provide and maintain erythropoietin. The remaining endocrine molecule, calcitriol—the active form of vitamin D—is a necessary component of renal function and can be easily measured. Therefore, this competition uses the maintenance (increase/decrease) of erythropoietin and calcitriol to measure endocrine functionality.

- *Needle-free vascular access.* Dialysis machines access the body's circulatory system through needles at vascular access points. Infections are common and patients report significant pain and discomfort at these sites. No significant innovation has been developed to make vascular access points less painful, more robust, or less susceptible to infection. Therefore, a key element of improving patient outcomes and increasing patient quality of life is developing needle-free vascular access.[150]

- *Reduction in bleeding, clotting, and biofouling.* Bleeding, clotting, and biofouling are common problems at vascular access points and within early prototypes of wearable or implantable RRTs.[151] Minerals, proteins, and other molecules and compounds accumulate and cause blockages and infections. Addressing these issues is critical for any truly functional

[150] XPRIZE interviews with experts. (2014).
[151] Ibid.

wearable or implantable RRT.[152,153] Therefore, the winning device must include mechanisms, technologies, or processes that address these issues.

Measuring Potential Impact on Quality of Life

The structure of the Kidney Disease XPRIZE requires testing the teams' devices on the medical device testing rig described below. Therefore, XPRIZE is unable to ask real patients how the devices make them feel, if their side effects have decreased/increased or remained at the same level, and if the devices are easy or difficult to use. In lieu of real patient data, XPRIZE has devised a list of physical and usage characteristics to serve as proxies for determining the effect a device is likely to have on a patient's quality of life. Scoring for this portion of the competition will be determined during the Design and Planning phase.

The following characteristics of the devices will serve as proxies for the Judging Panel when assessing the likely impact of the device on a patient's quality of life:

- Weight
- Water requirements
- Needle-free vascular access points (number and type), if not internal
- Ease of use and comfort
    - Number of times used per day/week or continuous?
    - Length of each use or continuous?
- Ease of setup
    - Ability of patient to set up device without assistance

Testing and Validation

Success of the Kidney Disease XPRIZE relies on a robust testing and validation strategy.

To accelerate innovation in the medical device sphere and address the cost and regulatory challenges of animal and human trials, XPRIZE proposes the development and production of standardized medical device testing rigs. The rigs will benefit the competition and the follow-on market in the following ways:

- Reduce barriers to entry into the competition

[152]Ibid.

[153]Martins, M., Rodrigues, A., Pedrosa, J. M., et al. (2013, September). Update on the challenging role of biofilms in peritoneal dialysis. *Biofouling: The Journal of Bioadhesion and Biofilm Research, 29(8),* 1015–1027. Retrieved from www.tandfonline.com/doi/full/10.1080/08927014.2013.824566

- Innovators who may not otherwise have access to testing facilities may use the open-source design to build their own medical device testing rigs
    - New innovators and innovators from tangential industries that have little experience with the FDA and testing protocols will be able to easily compete; their focus will be on technology development rather than on meeting the insurance and regulatory criteria for conducting animal and/or human testing

- Reduce operational costs of the competition by using easily replicable rigs for testing instead of animal models

- Reduce competition risks and uncertainties by using standardized rigs for all teams instead of animal models

- Encourage innovation in the follow-on market by improving access to low-cost testing options beyond the scope of the competition via open-source rig design and assembly instructions

Medical device innovators would still be required to prove both the safety and efficacy of their devices in animal and human testing conducted at later stages of device development outside the scope of this competition.

Some laboratories have developed testing rigs similar to what XPRIZE proposes developing. At least one of these rigs can be used to test kidney function and filtration in a laboratory setting. A similar rig would provide an ideal testing environment for the devices that teams develop for the Kidney Disease XPRIZE.[154]

Under the direction of the Scientific Advisory Board, XPRIZE will contract with a firm to design and build rigs made specifically to test the criteria set forth in this prize. Potential partners for this endeavor include StarFish Medical, General Electric, and Lawrence Livermore National Laboratory. The rig design will be open source, and XPRIZE will publish this information as soon as the rigs are validated. This will allow teams the opportunity to build their own rigs to XPRIZE's specifications for testing their devices prior to the competition's Laboratory Testing phase. It will also provide a tool and protocol as a legacy of the prize competition for any kidney researcher to use in testing their technologies.

XPRIZE will contract with a third party to begin developing the rigs prior to the launch of the competition. Upon registering for the competition, teams will receive the rig's basic design parameters. By Month 9 of the competition, teams will be provided with detailed technical specifications that will allow them to build their own testing rigs (if they choose to do so).

[154] XPRIZE interviews with experts. (2014).

The medical device testing rig will be able to measure the following:

- Blood filtration capacity (a minimum of 30 L/day)
- Fluid pressure and fluctuations (through the use of osmotic pressure sensors)
- Electrolyte balance
- Selective water/sodium reabsorption (biological or non-biological)
- Hormone levels (biological or non-biological)
- Bleeding, clotting, and biofouling

Technical Elements

While the technical specifications of the rig have yet to be determined, the rig will function as a closed circuit, presenting fluid (blood analogs) to the devices for filtration. The chemical composition of this fluid will be closely controlled and monitored as the devices are tested.

Minimum technical elements are listed below:

- Closed circuit of fluid (blood or blood analogs) that mimics the human circulatory system
- Rig/device interface designed to be usable for both wearable and implantable devices
    - Ports that allow the device to connect to the rig and receive fluid
- Pumps to manage fluid flow rate and pressure
- Sensors to measure bleeding, clotting, and biofouling
- Temperature monitoring to ensure stable temperature
- Access ports for collecting samples of pre-dialyzed and post-dialyzed fluid for laboratory analysis
- User interface (control display) that allows technicians real-time access to basic data such as flow rate, filtration rate, and pressure

Estimated Costs

After discussions with potential providers, XPRIZE estimates the following costs:

- One-time design and development costs of $400,000
    - Includes the following: open-source concept, design, sensors, fluidics, housing, control display, electronics, project management, and assembly
- Additional per unit costs of $100,000

Other Considerations

In addition to the required technical elements, the aesthetics ("look and feel") of the rigs may be a factor worth considering. Designing a human-shaped rig with a user-friendly display, for example, would increase design and production costs but could make the testing more telegenic.

COMPETITION STRUCTURE

The Kidney Disease XPRIZE consists of seven primary components:

1. Pre-Launch
2. Launch and Recruitment
3. Device Development
4. Technology Assessment #1 and Milestone Prizes
5. Technology Assessment #2 and Down-Select
6. Laboratory Testing
7. Award and Post-Prize Activities

These components are outlined below. See Figure 7 for a complete prize timeline.

Each of these components will be further developed and refined during the Design and Planning phase of the prize design process if XPRIZE and the American Society of Nephrology choose to continue to develop this competition.

To ensure that the competition is fair to the teams competing and addresses all possible risks and concerns, XPRIZE will appoint the following three panels:

- Scientific Advisory Board. XPRIZE will recruit a Scientific Advisory Board composed of experts in the following fields: nephrology, bioengineering, biomaterials, and innovation. The Scientific Advisory Board will assist XPRIZE staff with development of the competition guidelines to ensure that the competition is robust and has a high likelihood of success.

- Ethics Review Board. XPRIZE will recruit three ethicists to comprise an Ethics Review Board that will review and oversee the Kidney Disease XPRIZE. We will ensure that the final competition is designed and operated in a manner that addresses all potential ethical considerations.

- Judging Panel. XPRIZE will recruit judges with expertise in nephrology, bioengineering, biomaterials, and innovation. Judges will convene a minimum of three times to collaborate,

review guidelines, ask questions, ensure that they are fully able to judge the competition in a fair and appropriate manner, and judge the teams' submissions.

XPRIZE will also contract with laboratory technicians to form a Validation Team that will be responsible for overseeing the Laboratory Testing phase.

Pre-Launch

Prior to launching the Kidney Disease XPRIZE, we will engage in three months of pre-launch planning. During this period, XPRIZE will hire operational staff to manage the competition, refine the competition guidelines, plan the launch event, and prepare for prize operations.

Launch and Recruitment

XPRIZE will publicly announce the Kidney Disease XPRIZE at an in-person launch event in Washington, D.C., with its sponsor, the American Society of Nephrology. Launching the competition "above the line of super credibility" will be critical to attracting teams from around the world and generating public excitement for the prize. The event will include sponsors, doctors, researchers, policy makers, government agencies, students, celebrities, and others who will share their thoughts about the challenge of kidney disease in the United States. This broad array of participants will also help ensure that the competition has widespread appeal and credibility.

The launch event will be complemented by a comprehensive marketing strategy and social media campaign that creates high-profile visibility for the event and the competition. The competition website and registration portal will also publicly launch along with the competition announcement.

Concurrent with the launch, XPRIZE will release a draft version of the competition rules for public comment. The comment period will last 30 days, during which the public may submit comments online. Within 90 days of the launch of the prize, XPRIZE will publish the final competition rules, which will include detailed device performance requirements.

XPRIZE will invite teams from around the world to enroll in the competition by completing a registration form and submitting a fee. The registration materials will include descriptions of the following:

- The competition phases and time requirements for teams
- Formal guidelines outlining required performance metrics for the devices
- Formal guidelines outlining design specifications and hardware requirements
- Materials to be submitted by teams

Teams will be permitted to register anytime within 12 months of the launch. The registration fee will increase as the registration deadline nears. Teams that register early in the registration window will pay an "early bird" registration fee, while those that wait until the end of the registration window will pay a "late registration" fee. Registration fees will be determined during the Design and Planning phase. Each team lead must be designated at registration, and teams may include any number of members. Teams may add additional team members throughout the competition.

To ensure that competitors are qualified to compete, teams will be required to provide a Technology and Business Plan along with their registration fee. This document must describe, at minimum, a preliminary overview of the devices and standard business plan elements for design, production, regulatory approvals, sales, and markets.

XPRIZE will evaluate these competition plans against the basic technical parameters of the prize. Teams with plans that sufficiently address all parameters will be permitted to compete. XPRIZE expects that the low threshold for registration and the potential value of developing investor and partner relationships during Team Summits, combined with the marketing and promotion associated with being involved in the prize and the prize purse, will create an incentive for diverse teams to compete.

All registered teams will also be promoted through a competition website featuring team profiles and updates, background on the Grand Challenge, potential impact of the prize, and interactive elements that engage the public. During the Design and Planning phase, XPRIZE will investigate how a leaderboard may be used to create anticipation and engage the public throughout the competition.

Device Development

Teams are expected to begin developing their devices as soon as they register. Upon registration, each team will be provided with detailed technical requirements for developing their devices, including the basic design parameters of the testing rigs. By Month 9 of the competition, teams will be provided with detailed technical specifications that will allow them to build their own testing rigs for testing purposes if they choose to do so. XPRIZE will refine these detailed guidelines and technical requirements during the Design and Planning phase of prize development.

Team Summit #1

At Month 18, registered teams will participate in a mandatory Team Summit, potentially held in conjunction with an existing conference or industry event to maximize attendance and reduce operations costs. This event will be designed to update teams about competition goals and guidelines, provide educational lectures on important prize considerations, and set expectations for the communication of progress and confidentiality of shared data. XPRIZE staff will be available to

answer questions, and teams will have the chance to network with XPRIZE staff, experts, and each other.

Technology Assessment #1, Down Select, and Milestone Prizes

At Month 22, teams will submit Technical Submissions to the judging panel for consideration during Technology Assessment #1. This assessment will be used to select the top 30 teams that will continue in the competition and to determine the winners of the three Milestone Prizes. The Milestone Prizes have been developed to both incentivize novel innovators in this space and to assist the three teams with the most innovative and promising devices in raising financial capital to support their device development.

Technical Submissions must include the following information, which will be reviewed and assessed by the Judging Panel:

- Technical schematics of the device
- Technology overview that addresses planned technical feasibility in the following areas:
  - Filter at least 30 L/day of fluid
  - Uremic solute clearance of at least one solute in each of the solute classes described in Table 7 at 20 percent efficiency
  - Fluid and electrolyte balance
  - Endocrine function (to be eligible for the bonus prize)
  - Prevention of bleeding, clotting, and biofouling
- Physical and usage characteristics of the device that will serve as proxies for the Judging Panel when assessing the likely impact of the device on a patient's quality of life:
  - Weight
  - Water requirements
  - Needle-free vascular access (number and type), if not internal
  - Ease of use and comfort
    - Number of times used per day/week or continuous?
    - Length of each use or continuous?
  - Ease of setup
    - Ability of patient to set up device without assistance

Table 8. Milestone Prize Parameters and Scoring

PARAMETER	PLANNED FEASIBILITY METRIC	SCORING
Filtration rate	Device can filter a minimum of 30 L/day	10-point scale
Uremic solute clearance	Device can remove at least one solute in each of the solute classes described in Table 7 at 20 percent efficiency	10-point scale
Fluid and electrolyte balance	Device can regulate fluid quantity and sodium, potassium, and calcium levels. Target electrolyte levels are: • Sodium: 135–145 mEq/L • Potassium: 3.5–5.0 mEq/L • Calcium: 8.8–10.7 mg/dL	10-point scale
Endocrine function	Device can maintain erythropoietin homeostasis within a normal range (4–24 milliunits per milliliter) and calcitriol homeostasis within a normal range (20–50 nanograms/milliliter).	10-point scale
Needle-free vascular access	Device provides needle-free vascular access and reduces the likelihood of infections.	10-point scale
Bleeding, clotting, and biofouling	Device prevents any significant bleeding, clotting, or biofouling of the vascular access points or device itself.	10-point scale

PARAMETER	PLANNED FEASIBILITY METRIC	SCORING

Improvement in Quality of Life (QoL)	Technology schematics show consideration of the following physical and usage characteristics, which serve as proxies for a QoL measure:
	• Weight
	• Water requirements
	• Ease of use and comfort
	    o Number of times used per day/week or continuous?
	    o Length of each use or continuous?
	• Ease of setup
	    o Ability of patient to set up device without assistance
		10-point scale

A detailed scoring rubric will be developed during the Design and Planning phase.

The three teams with the highest scores will win Milestone Prizes in the following amounts:

1st Place: $500,000
2nd Place: $300,000
3rd Place: $200,000

Fourth- and fifth-place teams will earn honorable mentions. The top 30 teams will advance in the competition.

Table 9. Milestone Prizes Award Structure

PRIZE CATEGORY	PURSE	SCORING
1st Place	$500,000	Highest-ranking team out of 70 possible points
2nd Place	$300,000	Second highest-ranking team out of 70 possible points
3rd Place	$200,000	Third highest-ranking team out of 70 possible points
Honorable Mention	N/A	Fourth- and fifth-highest ranking teams out of 70 possible points

Milestone Prizes will be awarded during Month 24, on the last day of a three-day event that will include the following:

- Day 1: Teams arrive and attend a two-day Team Summit #2 during which they will share their progress, socialize, learn about updated guidelines, and ask questions of XPRIZE staff. Judges arrive and attend a one-day Judges' Summit.
- Day 2: Judges review their decisions based on the teams' Technology Assessment #1 submissions and deliberate while teams attend the second day of Team Summit #2. Judges select the top 30 teams to move forward and the winners of the three Milestone Prizes.
- Day 3: The top 30 teams that will move forward in the competition are announced, and Milestone Prizes are awarded to the top three teams.
    - Media will conduct interviews of teams and XPRIZE staff.
    - XPRIZE film production staff will conduct interviews of teams for use in a documentary film.
    - XPRIZE will conduct a public demonstration of the medical device testing rig that will be used to test teams' technologies during the Laboratory Testing phase. The demonstration will be open to the media, key stakeholders, teams, and the general public via live stream.

The Milestone Prizes will address the challenge of raising significant research funding by supporting teams with promising technologies. It will infuse capital into the competition at the halfway point, when significant time remains for these teams to finalize development of their technologies.

Technology Assessment #2 and Down Select

At Month 43, the top 30 teams will submit Revised Technical Submissions to XPRIZE for the Technology Assessment #2. The Revised Technical Assessment will update the planned technical feasibility elements submitted at Month 22 with the final technical elements of the teams' technologies, including the following:

- Final technical schematics of the technology
- Technology overview detailing technical utility in the following areas:
    - Filter a minimum of 30 L/day of fluid
    - Uremic solute clearance of at least one solute in each of the solute classes described in Table 7 at 20 percent efficiency
    - Fluid and electrolyte balance
    - Endocrine function (to be eligible for the bonus prize)
    - Prevention of bleeding, clotting, and biofouling
- Physical and usage characteristics of the technology that will serve as proxies for the Judging Panel when assessing the likely impact of the technology on a patient's quality of life:
    - Weight
    - Water requirements
    - Needle-free vascular access (number and type), if not internal
    - Ease of use and comfort
        - Number of times used per day/week or continuous?
        - Length of each use or continuous?
    - Ease of setup
        - Ability of patient to set up device without assistance

The Judging Panel will use this assessment to select 10 of the 30 teams to move forward to the Laboratory Testing phase. These 10 teams will move immediately into Laboratory Testing. Teams that do not submit Revised Technical Submissions by the due date will not be eligible to be considered for participation in the Laboratory Testing phase and will be eliminated from the competition.

In addition to selecting the 10 finalist teams for the Laboratory Testing phase, judges will use the Revised Technical Submissions to determine whether a team's technology is eligible for the $1 million Bonus Prize for an implantable device.

To be eligible for the Bonus Prize for an implantable device, the technology must do the following:

- Access the body's native circulatory and urinary tract systems for blood filtration and waste disposal
- Be designed without external access ports for the addition of water or removal of waste
- Fit comfortably within the human body

Detailed criteria for the Bonus Prize will be refined during the Design and Planning phase.

Laboratory Testing

The Laboratory Testing phase will take place at a world-class facility contracted by XPRIZE. XPRIZE staff and laboratory technicians will be present during all testing. Each of the 10 finalist teams will have seven days at the testing facility with no other teams present.

Testing procedures for each team will be as follows:

- Validation Team sets up medical device testing rig and performs standard calibration
- Validation Team takes first set of samples of filtrate
- Team sets up technology inside medical device testing rig with Validation Team oversight
- Technology runs for required length of time (specific to each device)
    - Measurements taken during the run time include:
        - Filtration rate (milliliters/minute)
        - Fluid balance of medical device testing rig circuit
        - Clotting and biofouling, if any
- Validation Team takes the second set of samples of filtrate
- Samples are removed to a remote location for testing
    - Each set of samples is tested for:
        - Uremic solute load
        - Endocrine balance
        - Bleeding

Table 10. Grand Prize Parameters and Scoring

PARAMETER	MEASUREMENT	SCORING
Filtration rate	Device can filter a minimum of 30 L/day	TBD
Uremic solute clearance	Device can remove at least one solute in each of the solute classes described in Table 7 at 20 percent efficiency	TBD
Fluid and electrolyte balance	Device can regulate fluid quantity and sodium, potassium, and calcium levels. Target electrolyte levels are: • Sodium: 135–145 mEq/L • Potassium: 3.5–5.0 mEq/L • Calcium: 8.8–10.7 mg/dL	TBD
Endocrine function	Device can maintain erythropoietin homeostasis within a normal range (4–24 milliunits per milliliter) and calcitriol homeostasis within a normal range (20–50 nanograms/milliliter).	TBD
Needle-free vascular access	Device provides needle-free vascular access and reduces the likelihood of infections.	TBD
Bleeding, clotting, and biofouling	Device prevents any significant bleeding, clotting, or biofouling of the vascular access points or device itself.	TBD

A detailed scoring methodology will be developed during the Design and Planning phase.

Judging

At the end of the Laboratory Testing phase, the Validation Team will organize and submit each team's data to the Judging Panel. That data will include the following:

- Medical device testing rig results
  - Filtration rate (milliliters/minute)
  - Fluid and electrolyte balance of medical device testing rig circuit
  - Clotting and biofouling, if any
- Pre-filtration test results
  - Results from first set of filtrate samples, which serve as the baseline for each team's test
- Post-filtration test results
  - Results from the second set of filtrate samples, which will show the change, if any, in uremic solute load, endocrine balance, and evidence of any bleeding.

The Judging Panel will use the data above to determine the effectiveness of each technology at filtering fluid at the required rate, maintaining fluid and electrolyte balance, removing uremic solutes, maintaining endocrine balance, and preventing bleeding, clotting, and biofouling. In addition to the data gathered during the Laboratory Testing phase, the Judging Panel will take into consideration the QoL factors discussed above. Detailed scoring for the competition will be determined during the Design and Planning phase.

ASN REIMBURSABLE EXPENSE REPORT

Mail completed form with ORIGINAL receipts to:
American Society of Nephrology
1510 H Street, NW, Suite 800
Washington, DC 20005
Attn: _______________

Name ____

Address ____

____

City ______________________ State/Province __________ Postal Code ____________ Country __________________

Telephone ______________________________ Email ____________________________________

Dates/Destination/Purpose of Trip ____

SS# (*required for individuals filing US tax returns*) ______________________________

Expenses:	Air fare	$ ____________		
	Train	$ ____________		
	Automobile	$ ____________		
	Taxi/Limo/Subway	$ ____________		
	Parking	$ ____________		
	Tolls	$ ____________		
	Other	$ ____________		
	TOTAL TRANSPORTATION		**$ ____________**	
	Meals	$ ____________		
	Hotel	$ ____________		
	Tips	$ ____________		
	Miscellaneous	$ ____________		
	TOTAL MEALS/LODGING		**$ ____________**	
	TRIP TOTAL			**$ ______________**

For ASN Office Use Only:

Approval: ____________________________________ Account Number: ____________________________________

01/2016

ASN Guidelines for Travel Reimbursement

These guidelines are for those traveling at ASN's expense so that travel arrangements are made with full understanding of what will be reimbursed.

ASN wishes its representatives/guests to travel with comfort and as little inconvenience as possible. However, that desire must be balanced by the knowledge that travel is reimbursed by a non-profit membership society, meant to create programs of value for members. ASN reimburses a large number of trips each year, so savings in individual travel costs translate into significantly more dollars available for member services such as educational programs, grants, and publications.

Guidelines for Reimbursement in US Dollars:
ASN reimburses expenses incurred for ASN business in US dollars only. International travelers should submit their expenses in US dollars at the exchange rate on the day expenses are submitted to ASN, or ASN will calculate the exchange rate of the international currency to US dollars on the date expenses are processed by ASN's accounting department. **ASN issues reimbursement as a check in US dollars only. ASN does not issue wire transfers.** Any additional costs to cash or deposit an ASN expense reimbursement check are the responsibility of the traveler.

Guidelines for Reimbursable Expenses:
Those being reimbursed are expected to make every effort to limit their travel costs. Travel by car, train, and airplane is acceptable. Car travel will be reimbursed at the IRS standard mileage rate ($0.54/mile), the cost not to exceed that of roundtrip economy, non-refundable airfare.

Only economy, non-refundable airfare will be reimbursed, and **travelers must make their reservations well in advance** to qualify for a heavily discounted fare and full reimbursement. Those who do not make their reservations at least 21 days in advance will only be reimbursed for the price of a 21-day advance ticket fare. If a traveler books with a preferred airline, at a higher cost, reimbursement will be limited to the lower, equivalent travel cost.

In addition to travel, ASN will pay for lodging at the official meeting hotel(s) only. **ASN will also pay actual expenses for meals**, not to exceed $75 per day. **Meal receipts must be provided to ASN.** ASN will pay for transportation to and from the airport in both home and destination cities, and for airport parking. Travelers are asked to take advantage of the most economical transportation services available, such as hotel or airport shuttles and low-cost (satellite) airport parking.

In the case where one is traveling for more than one group, ASN requires that expenses be apportioned between or among the sponsoring groups. A traveler may wish to make interim stops when traveling to or from an ASN function. In that case, ASN will identify the roundtrip coach or excursion fare from the traveler's home city to the meeting site and reimburse that amount only. ASN will not pay for interim lodging.

Examples of expenses that **ASN will not reimburse**:

- Mini-bar expense.
- Cabs/limousines for personal entertainment.
- Valet/dry-cleaning.
- Bar tabs.
- Long distance phone calls.
- Recreational costs such as court fees.
- Expenses of traveling companion(s).

In addition, if a traveler chooses to make personal dining arrangements rather than attend an ASN planned meal function, ASN will not reimburse that expense.

Procedure for Reimbursement:
The traveler must complete an ASN Reimbursable Expense Report, following the procedures given on the form. **Include original bills, receipts, and ticket coupons.** Then, the traveler should mail form and supporting documentation to the ASN office in Washington, DC within 10 business days of travel dates.