

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Chief Technology Officer (OCTO)

Announcement of Requirements and Registration for ‘KidneyX: Redesign Dialysis’

Authority: 15 U.S.C. 3719

The Kidney Innovation Accelerator (KidneyX) is a partnership between the U.S. Department of Health and Human Services (HHS) and the American Society of Nephrology (ASN). HHS and ASN plan to hold a series of KidneyX prize competitions to develop innovative solutions that can prevent, diagnose, and/or treat kidney diseases. Prize competitions challenge individuals, communities, businesses, institutions, and non-profit organizations, among others, to achieve defined goals in a defined timeframe. In KidneyX prize competitions, HHS and ASN plan to offer cash prizes and other incentives to increase the number and variety of problem-solvers addressing critical issues in kidney health. Every KidneyX prize competition will define a problem, without a pre-conceived notion of what the solution(s) should be, and ask participants to find solutions. Think better, think bold, think big.

Through this notice, HHS and ASN are updating the announcement of KidneyX’s initial prize competition, “KidneyX: Redesign Dialysis.” Phase 1 of the competition, now concluded, asked participants to develop innovative ideas for potential solutions or components of solutions. Phase 2, which this announcement will describe in greater detail, asks participants to build and test a prototype solution. **Participants do not need to have participated in Phase 1 in order to submit a Phase 2 entry.** This prize competition is being run under the authority of section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719), as added by the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

HHS and ASN reserve the right to change or update this notice at any time.

Dates for KidneyX: Redesign Dialysis, Phase 2

Submission period begins: November 11, 2019

Submission period ends: January 31, 2020, 5:00 p.m. ET

Awardees announced by: May 18, 2020

Sections of this announcement:

- A. Background
- B. Subject of Prize Competition
- C. Prize Competition Structure
- D. Prize Competition Scope
- E. Submission Rules, Judging Criteria, Eligibility, and IP Rights
- F. Technological and Scientific Needs in Potential Renal Replacement Therapies
- G. Details on Redesign Dialysis Phase 1 [Completed]

A. Background

Over 700,000 adults in the U.S. have kidney failure, also called End Stage Renal Disease (ESRD), a debilitating condition that is quickly fatal without treatment. To survive, people with ESRD must receive some form of renal replacement therapy (RRT). For more than half a

century, people with kidney failure have had only one treatment option other than a kidney transplant: dialysis.¹ Dialysis, a type of RRT, clears excess fluid and filters out some of the toxins that the kidney normally excretes, but dialysis replicates only the kidney's filtration function, and only while the patient is on dialysis. Dialysis is a life-saving technology, but it still leaves patients with substantial morbidity, mortality, and a decreased quality of life.

Most dialysis in the United States is performed in hemodialysis units, where patients with kidney failure are connected to machines for three to five hours, three times a week. Some advances on in-clinic dialysis have occurred, including home treatment and peritoneal dialysis, but key limitations of in-center dialytic therapy as currently practiced include its intermittent nature, the need for patients to travel to receive treatment, and the failure to restore other kidney functions besides filtration clearance.

Kidney transplantation can extend lifespan and improve quality of life, but the number of kidney donations is not remotely close to meeting the current demand. Furthermore, while kidney transplantation best duplicates native kidney function, the potential for organ rejection is ever present, requiring life-long immunosuppression with its risks of life-threatening infections and the need for multiple medications.

Dialysis treatment of ESRD is extremely expensive for the Federal government: Medicare alone spends more than \$35 billion per year for beneficiaries with ESRD.² Despite the high cost of dialysis treatment, dialysis patients' 5-year life expectancy is worse than that of most cancer patients.³ Alternatives to current RRT for people with ESRD are long overdue.

B. Subject of Prize Competition

The "KidneyX: Redesign Dialysis" prize competition seeks solutions or components of solutions that offer patients significant alternatives to dialysis as it is generally practiced today. The competition is intended to attract a wide range of ideas and participants and thus to catalyze development of new, improved classes of renal replacement therapeutic options. The goal is not necessarily to build a better dialysis machine or to provide iterative improvements to dialysis: other possibilities may include constructs that do not resemble dialysis as it is currently practiced, but rather shift the paradigm for how kidney failure is managed. Of particular interest is applying advanced technologies currently used in non-kidney areas to current or potential RRT technologies. Section D of this announcement provides more information about the scope of "KidneyX: Redesign Dialysis."

This prize competition seeks ideas and participants from within and from outside the field of kidney health. Many potential prize competition participants may have applicable technologies,

¹ Of American adults currently with ESRD, 200,000 have received kidney transplants, while 500,000 require chronic dialysis to survive. United States Renal Data System, *2017 USRDS Annual Data Report*, 6.

² United States Renal Data System. *2018 USRDS Annual Data Report: Epidemiology of kidney disease in the United States*, 2018. https://www.usrds.org/2018/view/v2_09.aspx.

³ Kirsten L. Johansen. "Life Expectancy Gains for Patients with ESRD," *Clin. J. Am. Soc. Nephrol.* 2018 13: 11-12; United States Renal Data System. *2018 USRDS Annual Data Report: Epidemiology of kidney disease in the United States*, 2018. https://www.usrds.org/2018/view/v2_05.aspx; Centers for Disease Control and Prevention: *Cancer Survival Data: 5-Year Relative Survival by Selected Primary Site, Race, Sex, and Age Group*, 2017.

concepts, or expertise from domains that have not previously been considered in improving RRT. Similarly, there may be innovators working on component technologies or discrete concepts that may have utility as one part of a novel renal replacement therapy solution. As such, HHS and ASN encourage participation from participants with concepts for specific kidney replacement therapeutic options as well as participants who believe their concept might be a component in developing a successful renal replacement therapeutic option.

Phase 1 of this prize competition is now concluded. For public record, details about Phase 1's judging criteria can be found in Section G, below. Participants may submit a solution in Phase 2 even if they did not participate in Phase 1.

C. Prize Competition Structure

Redesign Dialysis Phase 2 is open to all eligible participants (for eligibility requirements, see Section E, below). You do **not** need to have submitted a Phase 1 solution in order to participate in Phase 2. Submissions open November 11, 2019, and close January 31, 2020. Phase 2 asks participants to build and test a prototype (submission and judging criteria are located in Section E, below). At the end of Phase 2, judges will review submissions and an authorized official will select up to 3 winners, with each eligible winner receiving a cash prize of \$500,000 (note: the HHS Chief Technology Officer will approve the distribution of HHS prize money, while an ASN representative will approve the distribution of ASN prize money). Eligibility rules are described in Section E.

D. Prize Competition Scope

Redesign Dialysis Phase 2 seeks prototype solutions, or components of solutions, that can replicate normal kidney functions, thereby improving quality of life for patients. For the purposes of this prize competition, a “*prototype*” is a testable device (even if a first iteration) that can perform one or more of the functional areas described below (blood filtration, electrolyte homeostasis, volume regulation, toxin removal and secretion, filtrate drainage and connectivity, and dialysis access). Prototype solutions do not have to address more than one of these functional areas. Testing in animals or humans is not required, but some demonstration or documentation of the prototype's operating capacity is necessary. Any research conducted in the development of the submission must abide by all local, state, and federal laws regulating [the welfare of animals](#) in research and [protections for human subjects in research](#).

The functional areas listed below comprise the scope of this prize competition: solutions must address at least one of these functional areas. Additional details about current technical and scientific needs can be found in the [Kidney Health Initiative's “Technology Roadmap for Innovative Approaches to Renal Replacement Therapy.”](#)

Listed after each functional area are technical design targets a solution in that functional area should be working towards. **Successful submissions will demonstrate progress towards or achievement of the relevant technical design targets.**

- [Blood Filtration](#) (filtering blood to remove waste and excess fluid)

1. *Target #1*: Non-fouling and able to maintain continuous performance (duration defined by product and clinical context)
 2. *Target #2*: Generates a filtrate of at least 40L/day (~30mL/minute for 24-hour therapy)
 3. *Target #3*: Size selective, with no loss of essential blood proteins (e.g., albumin)
 4. *Target #4*: Component materials and design are biocompatible and hemocompatible
- Electrolyte Homeostasis (maintaining appropriate levels of key minerals in the blood)
 1. *Target #1*: Normalizes and maintains commonly measured or needed electrolytes (e.g., sodium, potassium, calcium, magnesium, and phosphate) within clinically acceptable ranges, potentially with the aid of pharmacological interventions
 - Volume Regulation (regulating the amount of and/or removing excess fluid)
 1. *Target #1*: Has the capacity to remove excess fluid and is adjustable based on the needs of the patient
 2. *Target #2*: Allows patient to self-manage and monitor volume status separate from monitoring of other functions (electrolyte and toxin removal)
 - Toxin Removal and Secretion (removing, limiting or preventing toxins in the bloodstream). Applicants should describe and justify specific toxins in each of the targets.
 1. *Target #1*: Maintains clearance/reduction of small, non-protein bound uremic toxins (clearance of 40L/day)
 2. *Target #2*: Maintains clearance/reduction of small, protein bound uremic toxins (reduction in blood concentration)
 3. *Target #3*: Maintains clearance/reduction of "middle molecule" uremic toxins (reduction in blood concentration)
 4. *Target #4*: Capable of secreting non-filtered toxins
 - Filtrate Drainage and Connectivity (removing excess filtrate after processing; connectivity issues for filtration, processing, and exterior drainage)
 1. *Target #1*: Composed of biocompatible materials
 2. *Target #2*: Removes remaining processed filtrate—up to 3L/day
 3. *Target #3*: Processed filtrate storage/removal apparatus is acceptable to the patient
 - Dialysis Access (vascular, peritoneal, blood circuit, or alternative (e.g., GI tract) access)
 1. *Target #1*: Provides access to the blood (either direct or indirect via peritoneal membrane or GI tract) for filtration in a continuous manner
 2. *Target #2*: Composed of biocompatible materials
 3. *Target #3*: Maintains patency over usable life, reducing incidence of stenosis and thrombosis
 4. *Target #4*: Lowers incidence of infectious complications
 5. *Target #5*: Patient-friendly (low/no maintenance, easy and quick connection/disconnection, painless access)
 6. *Target #6*: Mitigates blood loss or other complications in the event of an unintentional disconnection

E. Submission Rules, Judging Criteria, Eligibility, and IP Rights

Amount and Payment of the Prize:

For the “KidneyX: Redesign Dialysis” prize competition, \$2,625,000 in total prize funds are available. Phase 1 offered \$1,125,000 in total prize money, and Phase 2 offers \$1,500,000 in total prize money. HHS is contributing \$655,000 to the total prize pool and will pay 24.9% of each prize; ASN is contributing \$1,970,000 to the prize purse.

Prizes awarded under this prize competition will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS and ASN will comply with the Internal Revenue Service withholding and reporting requirements, where applicable. Prizes offered by ASN will be paid directly by ASN to prize recipients, and prize money offered by HHS will be paid directly by HHS to prize recipients. If ASN fails to pay any portion of the monetary prize it has indicated it intends to pay, HHS does not have the legal authority to pay the amount on their behalf.

Phase 2 Submission Requirements:

Phase 2 submissions open on November 11, 2019. In advance of that date, **HHS and ASN will update this announcement with details on the process for submitting entries.**

Phase 2 asks participants to build a testable prototype that can perform at least one desired function described in Section D, “Prize Competition Scope.” A participant’s Phase 2 submission, which will be used to determine Phase 2 winners, must consist of a written description of the prototype, its performance with rigor, reproducibility, statistical analysis, and a visual (photographic or video) presentation of the prototype. The written description must be 10 pages or less, 8.5 x 11 inch page, 10-point font or greater and one inch margins. Finally, Phase 2 participants must include a publicly-shareable abstract summary (no more than 200 words) of the prototype solution. By submitting an entry, Phase 2 participants automatically agree to allow this abstract to be published on the KidneyX.org site. Phase 1 winners that wish to participate in Phase 2 must submit a separate Phase 2 application.

Basis upon which Phase 2 winners will be selected:

A multi-disciplinary judging panel will review submissions for “KidneyX: Redesign Dialysis” Phase 2 and recommend winners from the submissions received; the HHS Chief Technology Officer will approve the distribution of HHS prize money, while an ASN representative will approve the distribution of ASN prize money.

Judges will evaluate Phase 2 submissions in accordance with the following **Phase 2 evaluation criteria (weight of criteria in parenthesis)**:

- **Demonstration of a testable prototype whose function addresses one or more functional areas of the prize competition scope described in Section D, above (50%). If a prototype addresses more than one functional area, judges will determine at their discretion which functional areas to consider.**
 - Clear description of which functional area(s) the prototype addresses
 - Degree to which prototype progresses towards achieving the technical design targets (listed in Section D, above) for the relevant functional area(s)

- Number of design targets the solution addresses in the functional area(s)
- Rigor, reproducibility, and statistical analysis of tests/evaluations of the prototype's function or performance in achieving or progressing towards design targets
- References to supporting evidence from the literature where appropriate
- **Demonstration of patient input in the design of the prototype (20%)**
 - Degree to which input from patients has informed the development of the prototype
 - Degree to which prototype as currently designed or in a future integrated device addresses [one or more aspects of patient quality of life described on page 9 of the RRT roadmap](#)
- **Extent of innovation from past solutions, including demonstrated knowledge of past approaches to the problem the solution addresses (15%)**
- **Clarity and feasibility of next steps for development and plans for future commercialization (15%)**
 - Clear description of next steps and awareness of potential challenges in the prototype development process (e.g., what gaps exist in the proposed solution, how might the design fit with existing approaches or other complementary technologies not yet developed to offer a new solution)
 - Discussion of current gaps in team expertise or technological capabilities (to better inform and position HHS and ASN to offer assistance if appropriate)
 - Current or planned collaborations with industry or other entities (participants may choose not to disclose all such collaborations if they wish)
 - Plans to meet with FDA regarding the prototype, either through the Pre-submission Program or another approach
 - Long-term vision for product development of the prototype, including plans for animal and human trials and potential pathways for commercialization

Eligibility Rules:

To be eligible to win a prize under the KidneyX: Redesign Dialysis prize competition, an individual or entity—

- (1) Shall have registered to participate in the prize competition;
- (2) Shall have complied with all the requirements set forth in this announcement for participation in this prize competition;
- (3) For prize money from HHS and/or ASN, who are jointly sponsoring this prize competition - In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States **Note:** Non-U.S. citizens and nonpermanent residents can participate as a member of a team that otherwise satisfies the eligibility criteria but will not be eligible to win a monetary prize (in whole or in part); however, their participation as part of a winning team, if applicable, may be recognized when results are announced;
- (4) May not be a Federal entity or Federal employee acting within the scope of their employment (all non-HHS federal employees must consult with their agency Ethics Official to determine whether the federal ethics rules will limit or prohibit acceptance of a KidneyX prize);
- (5) Shall not be an HHS employee;

(6) Federal grantees may not use Federal funds to develop submissions unless consistent with the purpose of their grant award; and

(7) Federal contractors may not use Federal funds from a contract to develop KidneyX prize competition applications or to fund efforts in support of a KidneyX prize competition submission.

Additional Requirements:

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

Each individual (whether participating singly or in a group) or entity agrees to follow all applicable federal, state, and local laws, regulations, and policies.

Participants must also agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from their participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

Participants are not required to obtain liability insurance or demonstrate financial responsibility in any specified amount for claims by a third party for death, bodily injury, or property damage or loss resulting from an activity carried out in connection with participation in a prize competition, but are encouraged to consult with their advisors with respect to the level of insurance that is prudent for each participant. Registered participants agree to indemnify the Federal Government against third party claims for damages arising from or related to prize competition activities, and further indemnify the Federal Government for damage or loss to Government property resulting from such activities.

HHS reserves the right to cancel, suspend, and/or modify this prize competition, or any part of it, for any reason, at HHS's sole discretion. HHS reserves the right not to award any prizes if no entries are deemed worthy. ASN may also discontinue its participation in the prize competition at its discretion. If ASN elects to discontinue its participation, every effort will be made to announce that decision promptly on the KidneyX.org website.

Intellectual Property (IP) Rights:

- Participants are free to discuss their submission and the ideas or technologies that it contains with other parties, are encouraged to share ideas/technologies publicly, are encouraged to collaborate or combine with other teams to strengthen their solutions, and are free to contract with any third parties. Participants should be aware that any agreement signed or obligation undertaken in regard to their participation in this prize competition that conflicts with the prize competition rules, terms, and conditions may result in disqualification of the participant's submission.
- By participating in this prize competition, each participant (whether participating singly or in a group) warrants that he or she is the sole author or owner of, or has the right to

use, any copyrightable works that the submission comprises, that the works are wholly original with the participant (or is an improved version of an existing work that the participant has sufficient rights to use and improve), and that the submission does not infringe any copyright or any other rights of any third party of which participant is aware. In addition, each participant (whether participating singly or in a group) and each entity grants to HHS an irrevocable, paid-up, royalty-free nonexclusive worldwide license to reproduce, publish, post, link to, share, and display publicly (e.g., on websites) the abstracts on the web or elsewhere. Each participant will retain all other intellectual property rights in their submissions, as applicable. To participate in the prize competition, each participant must warrant that there are no legal obstacles to providing the above-referenced nonexclusive licenses of participant rights to the federal government. To receive an award, winners will retain ownership of their intellectual property rights in the solution, but must grant to the federal government the nonexclusive, nontransferable, irrevocable, paid up license to practice, or have practiced for or on its behalf, the solution throughout the world for federal purposes. Each participant also warrants that the work is free of security threats and/or malware.

- Each participant must clearly delineate any Intellectual Property (IP) and/or confidential commercial information contained in a submission that the participant wishes to protect as proprietary data.
- All materials submitted to HHS as part of a submission become HHS agency records. Any confidential commercial or financial information contained in a submission must be clearly designated at the time of submission.
- If the submission includes any third party works (such as third party content or open source code), the participant must be able to provide, upon request, documentation of all appropriate licenses and releases for use of such third party works. If the participant cannot provide documentation of all required licenses and releases, HHS and ASN reserve the right, at their sole discretion, to disqualify the submission.

F. Details on Redesign Dialysis Phase 1 [completed]

Phase 1 Submission Requirements:

For Phase 1, now concluded, participants were asked to submit designs for potential solutions or components of solutions.

Phase 1 submissions, which were used to determine Phase 1 winners, were 6 pages or less, 8.5 x 11 inch page, 10-point font or greater and one inch margins. Participants included a publicly shareable abstract describing the proposed solution or component technology. By submitting an entry, all Phase 1 participants automatically agreed to allow this abstract to be published on the KidneyX.org site. Participants were also allowed to submit a visual supplement as part of their Phase 1 submission (e.g., a link to video, a website, or design specs)

Basis upon which Phase 1 winners were selected:

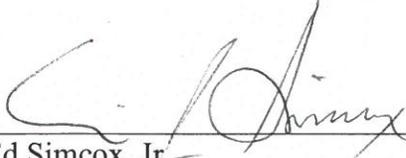
A multi-disciplinary judging panel reviewed submissions for Phase 1 of “KidneyX: Redesign Dialysis;” and authorized officials selected the winners from the submissions received (the HHS Chief Technology Officer approved the distribution of HHS prize money, while the ASN Council approved the distribution of ASN prize money).

Phase 1 evaluation criteria were:

- **Potential to significantly improve or add to the landscape of solutions to manage kidney failure**
 - Clearly demonstrates a vision for medical product development, which should include a clear articulation of the problem being addressed/solved.
 - Clearly demonstrates that the proposed design includes new components, technologies, or approaches that have not previously been part of renal replacement therapies
- **Nature and extent of anticipated benefit(s) to patients,**
 - Clearly demonstrates efforts to incorporate patient feedback into the design
 - Clearly addresses one or more of the “Improving Patient Quality of Life” objectives discussed in Section D, above
- **Feasibility of producing a functional prototype (including scientific and technological rigor)**
 - Clear descriptions of technological or scientific needs, if any, for potential development of a prototype (e.g., what gaps in the proposed solution exist, how might your design fit with existing approaches to create a solution, where do you need additional input?), to better inform and position HHS and ASN to offer assistance if appropriate
 - Clear explanation of additional challenges or potential pitfalls that need to be considered or addressed
 - Feasibility of development milestones over one year
 - Feasibility of regulatory approval of the proposed solution
 - Clear explanation of the knowledge or expertise the participant/participant team brings to the development of the proposed solution.
- **Quality of evidence supporting the design**

For Further Information Contact:

Ross Bowling, Ph.D. (ross.bowling@hhs.gov, 202-260-7158) or
Sandeep Patel, Ph.D. (Sandeep.patel@hhs.gov, 202-205-0355).



Ed Simcox, Jr.
HHS Chief Technology Officer

4/29/19
Date