

Redesign Dialysis FAQ

Popular Questions

Do I have to submit a Phase 1 application in order to participate in Phase 2?

No, you can submit a Phase 2 solution even if you did not participate in Phase 1. A major benefit of Phase 1 participation, in addition to prize money, is publicity. Phase 1 winners will be highlighted in outreach material and on KidneyX.org; Phase 1 winners may also be invited to present their ideas at an open public KidneyX meeting planned for April or May, 2019. Attendees at this meeting are anticipated to include investors, stakeholders from across government, patients, industry representatives, academics, and non-profit organizations.

When are submissions due?

Submissions for Phase 1, which asks solvers to design a solution, are due February 28, 2019 at 5:00 pm EST. Phase 2 will ask solvers to demonstrate a prototype solution, and Phase 2 submissions will be due January 31, 2020.

Where should I submit my solution?

You should e-mail your solution, as an attachment, to kidneyx@hhs.gov, with the subject heading "Redesign Dialysis Phase 1 submission -- [Individual/Team name]". Each submission should include only a 6-page description/discussion of your solution and a publicly shareable abstract (not longer than 1 page) describing the proposed solution. If you want to submit multiple solutions, please send each submission in a separate e-mail.

KidneyX encourages collaboration, but I am concerned about my Intellectual Property (IP) rights; how does KidneyX deal with IP?

Full information regarding intellectual property for can be found in the [KidneyX Redesign Dialysis prize announcement](#).

Who owns the intellectual property in KidneyX submissions?

Each participant will retain ownership of all intellectual property rights in their submissions and solutions.

Does the U.S. Department of Health and Human Services (HHS) require participants to grant use licenses?

Yes. 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. Additionally, 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. A nonexclusive license means that the grantors of the licenses are free to grant licenses in their submissions and solutions to other parties as they see fit.

How much funding is available in Redesign Dialysis?

The [Redesign Dialysis](#) prize has a total prize purse of \$2,625,000. Phase 1, which asks participants to design solutions or components of solutions, will award up to 15 prizes of \$75,000 each. Phase 2, anticipated to begin in April, 2019, asks participants to develop initial prototypes; this phase will award up to 3 prizes of \$500,000 each.

Who can participate in KidneyX: Redesign Dialysis? Can non-US citizens participate?

Anyone can submit solutions for Redesign Dialysis, although by law prize money can only be awarded to citizens or permanent resident of the United States or private entities that are incorporated in and maintain a primary place of business in the United States. However, provided that a participant team contains at least one U.S. citizen or permanent resident/US incorporated entity, that team can be awarded prize money. Specifically, the prize money in such a scenario will be given to the U.S. citizen/entity. Additionally, compelling solutions from non-U.S. citizens/entities may also be recognized and promoted by KidneyX even if HHS and ASN cannot award them prize money.

Requests for Assistance

How can I, as a participant, get feedback on my ideas from FDA, CMS, and/or NIH?

If you have questions about regulatory or payment pathways or would like scientific feedback on an idea, please e-mail your inquiry to KidneyX@hhs.gov. We will route your question as appropriate to experts at FDA, CMS, and/or NIH. Please note that the participation of government entities is not a guarantee of any particular result (e.g., premarketing authorization approval or clearance by FDA, coverage or payment under Medicare, or the award of an NIH grant).

Can you connect me with potential investors?

Phase 1 winners may be invited to present their ideas at an open public KidneyX meeting planned for April or May, 2019. Attendees at this meeting are anticipated to include investors, stakeholders from across government, patients, industry representatives, academics, and non-profit organizations. In addition, awardees will be featured on a KidneyX.org webpage and may, with their permission, be referenced in KidneyX presentations and talks going forward.

How can I get patient input and feedback on my submission/design?

KidneyX has identified a diverse subset of patients representing various national patient organizations that have volunteered to serve as a resource for KidneyX participants. If you are interested in receiving feedback from this group of expert patient volunteers, please email KidneyX at KidneyX@asn-online.org with your idea, topic area and question to connect you with the volunteer that best suits your needs.

How can I connect with others interested in this topic to possibly form a team?

KidneyX encourages open collaboration and exchange of ideas. We are currently determining the most effective method for connecting participants who are interested in finding partners, and we will update this space once the method is finalized.

Can people living with kidney diseases who aren't submitting solutions help KidneyX?

HHS and ASN have designed KidneyX to be patient-driven. We actively collaborate with people living with kidney diseases and have developed a patient engagement strategy to ensure that KidneyX is not only patient-centered but also patient-driven. Going forward, as we continue to build KidneyX, people living with kidney diseases will have representation throughout the KidneyX governance structure and judging process. People living with kidney diseases that are interested in volunteering to serve as an

expert resource to KidneyX participants are asked to contact KidneyX by emailing KidneyX@asn-online.org.

Where can I learn more about current technical or scientific needs in renal replacement therapy, or how the kidney functions?

The Kidney Health Initiative's (KHI) [Technology Roadmap for Innovative Approaches to Renal Replacement Therapy](#) provides the scientific and technological foundation for the Redesign Dialysis prize and is an excellent first resource. HHS and ASN are also currently working to develop scientific overview sheets for the Redesign Dialysis prize, and those documents will be added to KidneyX.org when they are complete. In the meantime, if you have scientific questions, please reach out to kidneyx@hhs.gov.

Submissions

Can I submit multiple entries for Phase 1? For Phase 2?

Yes, you may submit more than 1 solution for a Phase (each solution should be a separate submission).

How do I register to participate in this competition?

When you submit a solution for the prize competition to kidneyx@hhs.gov, you will automatically be registered as a participant.

Who should apply for Phase 1 of Redesign Dialysis?

Phase 1 is focused on rewarding participants for coming up with promising designs for future alternatives for dialysis. These designs can either be component parts that would enable a wearable, implantable, or other form of dialysis – or they can be whole prototypes. We want to incentivize creative planning. Participants who already have prototypes are also encouraged to apply for Phase 1 funding, and we would expect that their submissions would focus on the work needed to advance or perfect these prototypes.

I have an idea or solution related to kidney health, but not related to renal replacement therapies. Should I submit it to Redesign Dialysis?

Redesign Dialysis is looking for ideas and solutions that will drive new options/approaches in renal replacement therapy. However, HHS and ASN are planning to run a wide range of KidneyX prize competitions on topics across the kidney health spectrum. These might include medications (a variety of treatments for kidney disease, including drugs and biologics), diagnostics (point-of-care or at-home testing kits, better tools to measure kidney function), patient-centered tools (electronic health record tools designed to identify and track disease, applications to empower patients to manage kidney disease), and more. If you have an idea, a solution, or a question related to kidney health and are looking for input or trying to find potential partners, you can reach out to us at KidneyX@hhs.gov.

Part of the judging criteria is “feasibility of regulatory approval of the proposed solution”—should submissions address this issue?

Submissions may but do not have to address this issue: the judging panel will be able to assess feasibility based on its own expertise.

Do design specs and data sets count towards the 6-page limit for the Phase 1 submissions?

To ensure a timely review of submissions by judges, any design specs and data sets will count towards the total of 6 pages for Phase 1 submissions (the required one-page abstract, however, does not count towards the total).

Judging

How are the judging criteria weighted?

The judging criteria for Phase I as well as Phase II of Redesign Dialysis, detailed in the [prize announcement](#), are weighted equally (i.e., 25% each).

Who are the judges for Redesign Dialysis?

HHS and ASN are currently identifying a group of experts with diverse scientific, medical, investment, and technical expertise, including patient representation. Once judges are determined, the Redesign Dialysis judges will be identified on [KidneyX.org](#)

Funding

How will checks be distributed to Phase 1 prize competition recipients?

Prize recipients will receive two checks. HHS will pay 24.9% of the prize funding and ASN will pay 75.1%. Payment from HHS will be provided through electronic funds transfer. Payment from ASN can be done electronically or by check.

Will the prize awards be subject to Federal income taxes?

Prize awards may be subject to Federal income taxes. HHS and ASN will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Can prize awards be paid to an organization?

The intent of the prize competition is to award individuals or teams who produce the best solution to a problem presented in the challenge. However, we recognize that submissions may be made on behalf of an existing institution/organization. Therefore, payments may be made to that entity at the request of the individual or team. Please keep in mind that the intent of the prize is to reward the individual or teams who presented the solution and not to be used to support overhead costs of an institution.

Other Questions

How does KidneyX and the Redesign Dialysis prize intersect with the Kidney Health Initiative?

The [Kidney Health Initiative](#) (KHI) is a public-private partnership between ASN and the U.S. Food and Drug Administration. Established in 2012, KHI has nearly 100-member organizations. KHI has developed a [Technology Roadmap for Innovative Approaches to Renal Replacement Therapy](#) that is the scientific foundation for the Redesign Dialysis prize: the scientific and technological renal replacement therapy needs that the [prize announcement](#) identifies come directly from the KHI Roadmap.

Do you think \$75,000 or \$500,000 prizes are sufficient to drive significant advances in dialysis?

HHS and ASN understand that the prize award amounts for Redesign Dialysis Phase 1 and Phase 2 alone are orders of magnitude smaller than what would ultimately be needed to bring products to market. The goal of these prize awards is to build momentum on promising ideas, drawing the attention of potential investors with the resources to nurture and commercialize products. The recognition and validation Redesign Dialysis prize winners earn—from the most relevant U.S. Federal agency and the largest nephrology health professional organization in the world—should send potential investors a powerful signal, potentially de-risking investment in these participants in particular and sending a signal about the opportunity in the kidney space more broadly.

Additionally, the goal of KidneyX prize competitions is to build a stronger, more vibrant ecosystem of ideas in kidney health. We believe Redesign Dialysis funding will not only provide additional resources to innovators currently in the kidney space, but will also attract junior innovators and experts currently outside of the nephrology field.

Will these products take decades to develop?

The Redesign Dialysis judging criteria considers the feasibility of commercializing proposed solutions, and we will be prioritizing solutions that have greater likelihood of becoming a product (or a component of a product). More broadly, KidneyX is designed to build a thriving ecosystem of innovation in kidney health, which requires supporting products in all phases of development. This spectrum of development is best exemplified by the Kidney Health Initiative's [Technology Roadmap for Innovative Approaches to Renal Replacement Therapy](#).

How can my organization support KidneyX?

KidneyX is seeking additional partners. Organizations interested in supporting KidneyX (whether by providing financial resources, scientific expertise or other means) are encouraged to contact KidneyX staff at kidneyx@asn-online.org.

How can I stay informed about KidneyX?

To receive updates on KidneyX, please sign up for our e-mail list on KidneyX.org; you can also follow KidneyX on Twitter (@Kidney_X).

How can I contact KidneyX?

You can contact KidneyX via e-mail at kidneyx@asn-online.org.