

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Chief Technology Officer (OCTO)

Announcement of Requirements and Registration for “KidneyX COVID-19 Kidney Care Challenge”

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 preconceived notion of what the solution(s) should be, and ask participants to find solutions. Think better, think bold, think big.

Through this announcement (also referred to herein as “the Official Rules, Terms, and Conditions”), HHS and ASN are announcing KidneyX’s prize competition, the “KidneyX COVID-19 Kidney Care Challenge” (referred to herein as “the Competition”). KidneyX is launching the COVID-19 Kidney Care Challenge to identify and share solutions that reduce SARS-CoV-2 transmission and risk among people with, or at risk of, kidney injury or disease.

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.

The COVID-19 Kidney Care Challenge anticipates disbursing the prize purse over two rounds. A third round may occur at the discretion of HHS and ASN. The below dates are subject to change.

Round 1

Submission period begins: November 6, 2020

Submission period ends: December 4, 2020 4:59 p.m. ET

Winners announced: January 2021

Round 2

Submission period begins: December 9, 2020

Submission period ends: January 20, 2021 4:59 p.m. ET

Winners announced: February 2021

Round 3 (potential)

Submission period begins: February 17, 2021

Submission period ends: March 17, 2021 4:59 p.m. ET

Winners announced: April 2021

Sections of this announcement:

- A. Background
- B. Subject of the Prize Competition
- C. Prize Competition Structure
- D. Registration and Submission Requirements
- E. Eligibility, Evaluation Criteria, and Judging
- F. Additional Rules, Terms, and Conditions

A. Background

According to the Centers for Disease Control and Prevention, there have been more than 5.7 million confirmed cases of COVID-19 and more than 175,000 deaths in the United States as of August 2020. The COVID-19 pandemic has created unique risks and challenges for the estimated 37 million Americans living with kidney disease, as well as their families and caregivers. Several groups appear to be at particularly high risk: those who receive in-center dialysis treatments and are unable to self-isolate; those with a kidney transplant, who are likely on immunosuppression drugs; those with early onset acute kidney injury; and, those with chronic kidney disease. Patients with kidney disease also typically have other COVID-19 risk factors, such as diabetes, hypertension, and cardiovascular disease. There is also growing evidence to suggest that COVID-19 can lead to kidney damage, even among patients with no kidney problems prior to infection by the novel coronavirus. As a disproportionate number of people living with kidney disease are of African, Latin, and Native American descent, the COVID-19 pandemic is also worsening existing health disparities and social determinants of health.

To address these challenges, patients, caregivers, frontline medical professionals, and organizations have rapidly developed novel solutions or adapted existing solutions to ensure continuity of kidney care during the initial phases of the pandemic. These solutions have the potential to be replicated in other areas of the country or settings to benefit the many people living with kidney disease, as well as those who may be at risk for kidney injury or disease after contracting an infection by SARS-CoV-2. The COVID-19 Kidney Care Challenge will identify and share the best of these solutions so they can be more widely adopted.

This Competition is an initiative from KidneyX, a public-private partnership between the U.S. Department of Health and Human Services (HHS) and the American Society of Nephrology (ASN), that aims to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases. KidneyX seeks to improve the lives of patients by expediting the development of drugs, devices, biologics, and other therapies across the spectrum of kidney care. To date, KidneyX has completed three prize competitions that have awarded over \$4,000,000 to innovators.

B. Subject of the Prize Competition

The COVID-19 Kidney Care Challenge aims to increase the safety of kidney care during the COVID-19 pandemic, including potential future surges. The Competition aims to identify and share solutions that reduce SARS-CoV-2 transmission and risk among people with, or at risk of, kidney injury or disease.

The Competition will seek a broad range of demonstrated solutions from healthcare providers, staff, patients, caregivers, and other organizations and stakeholders. Solutions that reduce the impact of the COVID-19 pandemic on people and caregivers seeking care for kidney diseases, kidney failure, and kidney transplant, who are also members of communities facing existing health disparities and social determinants of health, are encouraged. These solutions could be applicable in settings such as dialysis centers, clinics, hospitals, homes, and transport. Of particular interest are solutions that consider the patient experience, and could be implemented without requiring significant time, expertise, money, or other resources.

Solutions may include, but are not limited to:

- data collection and dissemination methods,
- approaches to patient management and monitoring;
- education, training and communication;
- supply chain and resource management; and
- care setting logistics.

C. Prize Competition Structure

The Competition will award \$300,000 in cash prizes to recognize demonstrated solutions that could have a positive impact in other settings. The total prize purse will be distributed to a maximum of fifteen (15) winners in up to three (3) rounds, at the discretion of HHS and ASN. HHS is contributing the total prize purse; eligibility to receive monetary prizes from HHS is further detailed in Sections E and F of this announcement. All winning solutions will also be recognized publicly by the KidneyX partnership.

Rounds 1 and 2 will be administered by Luminary Labs, LLC (Luminary Labs). Luminary Labs has been contracted to assist and support HHS and ASN in organizing and managing the Competition.

- **Round 1 (November 2020 - January 2021)**

Round 1 will be open to all entrants who meet the eligibility requirements defined in Sections E and F of this announcement. In their submissions, entrants will be asked to provide an overview of the solution; available data or justification to demonstrate the solution has, or could, have a positive impact; and additional information to assess how the solution may be implemented in other settings. Round 1 submissions open on November 6, 2020 and close at 4:59 p.m. ET on December 4, 2020.

Winners will be recommended by the judging panel according to the evaluation criteria defined in Section E of this announcement. Winners will each receive a \$20,000 cash prize. Additional entrants may be selected to receive honorable mentions (no cash prize).

As part of their submissions, all entrants agree to have synopses or abstracts of their submissions published by the KidneyX partnership to share knowledge with other practitioners and stakeholders. Please see Section F, Additional Competition Rules, Terms, and Conditions for more details.

- **Round 2 (December 2020 - February 2021)**

Round 2 will be open to all entrants who meet the eligibility requirements defined in Sections E and F of this announcement. Entrants will not be required to have participated in Round 1 to participate in Round 2. Entrants who submitted in Round 1 are permitted to submit revised or new solutions in Round 2.

All Round 2 requirements are anticipated to be the same as Round 1 including submission content, evaluation criteria, and prize awards. As part of their submissions, Round 2 entrants will also agree to have synopses or abstracts of their submissions published by the KidneyX partnership. Round 2 submissions are expected to open on December 9, 2020 and close at 4:59 p.m. ET on January 20, 2021.

- **Potential Round 3 (February - April 2021)**

A third round may be implemented at the discretion of HHS and ASN. If executed, requirements are anticipated to be the same as Rounds 1 and 2 including submission content, evaluation criteria, and prize awards.

D. Registration and Submission Requirements

Registration

To participate in the Competition, entrants must:

1. Register for the Competition via the KidneyX website;
2. Enter a submission to the Competition via the KidneyX website (the submission form will be made available when Round 1 submissions open on November 6, 2020);
3. Comply with all requirements in this announcement and on the KidneyX website;
4. Provide affirmation upon submission to the Competition that the entrant is eligible under the Eligibility section below;
5. Agree to:
 1. Assume any and all risks and waive claims against the Federal government, its related entities, ASN, and Luminary Labs; 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 the Competition, whether the injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arises through negligence or otherwise;
 2. Indemnify the Federal government, ASN, and Luminary Labs against third-party claims for damages arising from, or related to, Competition activities, patents, copyrights, and trademark infringements; and
 3. Comply with and abide by the Official Rules, Terms, and Conditions noted in this announcement and on the KidneyX website, as well as the decisions of HHS and ASN which shall be final and binding in all respects.

Upon submission, entrants will be asked to affirm they have read, understand, and fully agree to the Competition Rules, Terms, and Conditions, including granting an irrevocable and royalty-free license to HHS, ASN, and Luminary Labs to store, access, modify, reproduce, and distribute submissions in perpetuity, however, entrants retain ownership of their concepts, including any software, designs,

research, or other intellectual property (IP) that they develop in connection therewith. Please refer to “Intellectual Property (IP) rights” in Section F for more information.

In advance of any submission period, HHS and ASN may update this announcement with additional details on the process for submitting entries.

E. Eligibility, Evaluation Criteria, and Judging

Eligible entrant profile

Pursuant to the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358), this Competition is open to all individuals (non-felons) over the age of 18, United States Citizens or legal permanent residents at the time of entry and to all validly formed legal U.S. entities whose primary place of business is in the U.S. that have not declared or been declared in bankruptcy.

To be eligible to receive any monetary prizes, participants, whether participating singly or as a team, must register for the Competition on Luminary Lightbox™ and designate an individual or entity as the official entrant. Pursuant to 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), to be eligible to receive monetary prizes awarded by HHS, an entrant must be a citizen or permanent resident of the United States, or a legal entity with its primary place of business in the United States. Monetary prizes will be awarded to the extent allowed under US law, including US trade and economic sanctions and US government restrictions on dealing with specified parties. In particular, entrants are not eligible to receive any monetary or nonmonetary prize in the Competition if they are a resident or entity designated by the United States Treasury’s Office of Foreign Assets Control (see <https://www.treasury.gov/resource-center/sanctions/programs/pages/programs.aspx> for additional information). Complete eligibility requirements are noted Section F below.

Evaluation criteria and judging

A multi-disciplinary judging panel will evaluate eligible submissions.

Members of the judging panel will assign up to 5 points for each of the criteria below, for a maximum of 20 points. Based on their evaluation, the judging panel will recommend winners; a representative of HHS will approve the distribution of HHS prize money.

Submissions will be evaluated using the following four equally-weighted criteria below:

- **Impact:** The confidence in the solution to reduce SARS-CoV-2 transmission among people with kidney disease and/or reduce the risk of kidney injury/disease among people who contract COVID-19.
- **Feasibility:** The ease with which the solution could be implemented, considering factors such as expertise, money, or other resources required.
- **Adaptability:** The extent to which the solution could be adapted for other people or used in other care settings and/or geographies.

- **Ingenuity:** The degree to which the submission offers a new solution, demonstrates an improvement on an existing solution, or applies an existing solution in new ways.

To achieve KidneyX programmatic goals, ASN and HHS may consider the diversity of solutions when selecting winners from top-scoring submissions recommended by the judging panel.

F. Additional Competition Rules, Terms, and Conditions

Eligibility

Pursuant to 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):

1. The Competition is open to all individuals (non-felons) over the age of 18, United States Citizens or legal permanent residents at the time of entry and to all validly formed legal U.S. entities whose primary place of business is in the U.S. that have not declared or been declared in bankruptcy, subject to the additional eligibility requirements listed below. Eligibility is subject to verification by HHS before monetary prizes are awarded.
2. An individual or entity shall have registered to participate in the Competition under the rules promulgated by HHS, ASN, and Luminary Labs in accordance with the description provided on the KidneyX website. Entrants shall have complied with all of the requirements on the official KidneyX website.
3. Entrants are not eligible to receive any monetary or non-monetary prize in the Competition if they are a person or entity designated or sanctioned by the United States Treasury’s Office of Foreign Assets Control (see <http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx> for additional information).
4. To be eligible to win prize money from HHS under the Competition, a private entity shall be incorporated in and maintain a primary place of business in the United States; and 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 from HHS (in whole or in part); however, their participation as part of a winning team, if applicable, may be recognized when results are announced. Please refer to the “Monetary Prizes” section of these Rules, Terms, and Conditions for additional information on HHS prizes.
5. HHS and ASN employees directly supporting the development or execution of the Competition and support contractors directly supporting the development or execution of the Competition, Luminary Labs and its contractors (with the express exception of Luminary Labs’ authorized solver community), and judges are ineligible to compete in this Competition. Likewise, members of their immediate family (spouses, children, step-children, siblings, step-siblings, parents, step-parents), and persons living in the same household, whether or not related, are not eligible to participate in any portion of this Competition. Note: The members of an individual’s household include any other person who shares the same residence as such individual for at least three months out of the year.
6. Individuals and entities, otherwise eligible to win a monetary or non-monetary prize, may form and submit a team entry; however, each team member must be clearly identified on the team’s submission form for the team to be eligible. Failure to follow this procedure as outlined on the

KidneyX website will disqualify the contest submission. Team winnings, as determined by the Competition sponsor, will be distributed to the designated team lead for further distribution to team members. In the event a dispute regarding the identity of the entrant who actually submitted the entry cannot be resolved to HHS and ASN's satisfaction, the affected entry will be deemed ineligible. If the submission includes the work of any third party (such as third-party content or open source code). The entrant must identify the work and be able to provide, upon the request of HHS and ASN, and/or Luminary Labs, documentation of all appropriate licenses and released for such third-party works. If the entrant cannot provide documentation of all required licenses and relates, HHS and ASN reserve the right to disqualify the applicable submission, or direct the entrant to secure the licenses and relates for HHS and ASN's benefit within three (3) days of notification of the missing documentation and allow the applicable submission to remain in the Competition.

7. Entrants to this Competition must agree to be bound by the rules of the Competition, agree that the winner selection decisions for the Competition are final and binding, and acknowledge that their submissions may be the subject of a Freedom of Information Act (FOIA) request and that they are responsible for identifying and marking all business confidential and proprietary information in their submissions.
8. Entrants selected as monetary prize winners must submit all required taxpayer identification and bank account information required to complete an electronic payment of the monetary prize. Failure to provide Luminary Labs, HHS, or ASN required documents for electronic payment within 30 days of notification by Luminary Labs, HHS, or ASN will result in a disqualification of the winning entry.
9. Entrants in the Competition agree, as a condition for winning a monetary or non-monetary prize, to complete and submit all required winner verification documents to Luminary Labs, HHS, or ASN within 3 days of notification. Failure to return all required verification documents per return instructions by the date specified in the notification may be a basis for disqualification of the winning entry.
10. Entrants to the Competition must agree and consent, as a condition for receiving a monetary or non-monetary prize, to the use of their name, affiliation, city and state, likeness or image, comments, and a synopsis or abstract of their winning solution as a part of HHS and ASN's promotion of this Competition.
11. Entrants must own or have access at their own expense to a computer, an Internet connection, and any other electronic devices, documentation, software, or other items that entrants may deem necessary to create and enter a submission.
12. The following entrants (including any individuals participating as part of a team or entity) are not eligible regardless of whether they meet the criteria set forth above:
 - a) Any HHS employee.
 - b) Any Federal entity or Federal employee acting within the scope of his or her employment or otherwise prohibited by Federal law. Federal employees should consult their agency ethics officials to determine whether the federal ethics rules will limit or prohibit acceptance of a prize under the Competition. Note: Federal ethical conduct rules may restrict or prohibit federal employees from engaging in certain outside activities; any federal employee not excluded under this paragraph seeking to participate in this

Competition outside the scope of employment should consult his/her agency's ethics official prior to developing a submission

- c) Any individual or entity that used Federal funds to develop a submission, unless such use is consistent with the grant award, or other applicable Federal funds awarding document. If a grantee using Federal funds enters and wins this Competition, the monetary prize must be treated as program income for purposes of the original grant in accordance with applicable Office of Management and Budget Circulars. Federal contractors may not use Federal funds from a contract to develop a submission for the Competition, or to fund efforts in support of a Competition submission.
13. An individual or entity shall not be deemed ineligible under these eligibility rules 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.
 14. Each individual (whether participating singly or in a group) or entity (whether participating singly or in a group with other individuals and/or entities) agrees to follow all applicable federal, state, and local laws, regulations and policies.
 15. Use of Marks: Except as expressly set forth in the Competition Rules, Terms, and Conditions, entrants shall not use the names, trademarks, service marks, logos, insignias, trade dress, or any other designation of source or origin subject to legal protection, copyrighted material or similar intellectual property (“Marks”) of the organizers or other Competition partners, sponsors, or collaborators in any way without such party’s prior written permission in each instance, which such party may grant or withhold at its sole and absolute discretion.
 16. By participating in the Competition, each entrant represents, warrants, and covenants that entrants are the sole authors, creators, and owners of the submission; and that:
 - a) The entrant’s submission:
 - i. Is not the subject of any actual or threatened litigation claim
 - ii. Does not, and will not, violate or infringe upon the intellectual property rights, privacy rights, publicity rights, or other legal rights of any third party
 - iii. Does not, and will not, contain any harmful computer code (sometimes referred to as “malware,” “viruses,” or “worms”)
 - b) The submission and entrant’s use of the submission does not, and will not, violate any applicable laws or regulations of the United States.
 - c) An individual or entity that is determined to be on the GSA Excluded Parties List (www.sam.gov) is ineligible to receive a monetary or non-monetary prize award and will not be selected as a Competition winner.

Entrants must comply with and abide by these Official Rules, Terms and Conditions and the decisions of HHS and ASN which shall be final and binding in all respects. HHS and ASN and Luminary Labs reserve the right to disqualify any submission that HHS and ASN and/or Luminary Labs in their discretion, deem to violate these Official Rules, Terms and Conditions.

Monetary prizes

HHS is contributing the total prize pool for the Competition of \$300,000. This total prize purse will be awarded across up to three rounds of competition.

The judging panel will recommend winners according to official evaluation criteria. The monetary prizes will be distributed across winners, at the discretion of HHS and ASN. Competition entrants must agree and consent, as a condition for receiving a monetary prize, to the use of their name, affiliation, city and state, likeness or image, and a synopsis or abstract of their winning solution as a part of HHS and ASN's promotion of this Competition, as stated in the Eligibility section, and below in the Publicity Release section.

If any potential winner is found to be ineligible, has not complied with the Official Rules, Terms and Conditions, or declines the monetary prize for any reason prior to award, an alternate winner may be selected.

Monetary prizes awarded will be paid by electronic funds transfer and may be subject to local, state, and/or Federal income taxes. Award recipients will be responsible for any applicable local, state, and Federal taxes and reporting that may be required under applicable tax laws. HHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable. Prizes will be awarded directly by HHS to prize recipients.

Registration and submission requirements

To enter the Competition, entrants must go to the KidneyX website and complete all required fields of the Competition registration and submission form on the KidneyX website before the close of open submissions in each round. Each entrant must complete all of the required fields in the Competition registration and submission form in accordance with these Official Rules, Terms and Conditions.

All entrants are required to provide consent to these Official Rules, Terms and Conditions upon submitting an entry. Submissions must be received during the open submissions period of the Competition in order to be eligible. Round 1 open submissions officially begin on November 6, 2020. Open submissions will last from this date through the close of Round 1 open submissions, currently scheduled for 4:59 p.m. ET on December 4, 2020. Round 2 open submissions are expected to begin on December 9, 2020. Open submissions will last from this date through the close of Round 2 open submissions, currently scheduled for 4:59 p.m. ET on January 20, 2021. A potential Round 3 is anticipated to begin on February 17, 2021. Open submissions will last from this date through the close of Round 3 open submissions, anticipated to close at 4:59 p.m. ET on March 17, 2021. Luminary Labs is the official timekeeper for the Competition. Once submitted, a submission may not be altered during open submissions. HHS and ASN, and Luminary Labs reserve the right to disqualify any submission that HHS and ASN, or Luminary Labs deem inappropriate.

Individuals and entities, otherwise eligible to win a monetary prize, may form and submit a team entry. Each team member must be clearly identified on the team's submission form for the team to be eligible. Team winnings will be distributed to the designated team lead for further distribution to team members. In the event that a dispute regarding the identity of the entrant who actually submitted the entry cannot be resolved to HHS and ASN's satisfaction, the affected entry will be deemed ineligible.

All entry information submitted on the KidneyX website and all materials, including any copy of the submission, becomes the property of HHS and ASN and will not be acknowledged or returned by

Luminary Labs, or HHS and ASN; however, entrants retain ownership of their concepts, including any software, designs, research, or other intellectual property (IP) that they develop in connection therewith, subject to the licenses granted to HHS and ASN to use submissions as set forth in the Intellectual Property of Submissions section below.

Proof of submission is not considered proof of delivery to or receipt of such entry. Furthermore, HHS and ASN, and Luminary Labs shall have no liability for any submission that is lost, intercepted, or not received by HHS and ASN, and/or Luminary Labs. HHS and ASN and Luminary Labs assume no liability or responsibility for any error, omission, interruption, deletion, theft, destruction, or unauthorized access to, or alteration of submissions.

Round 1 open submissions close at 4:59 p.m. ET on December 4, 2020. Round 2 open submissions close at 4:59 p.m. ET on January 20, 2021. Potential Round 3 open submissions would be anticipated to close at 4:59 p.m. ET on March 17, 2021. Entrants should submit at least one hour before the deadline to ensure the completed submission is received. Entrants who submit an application after the deadline date because of a technical problem with the KidneyX website system must immediately contact kidneyx@asn-online.org and provide an explanation of the technical problem experienced on the KidneyX website system. HHS and ASN, and Luminary Labs will accept your application if HHS and ASN and Luminary Labs can confirm that a technical problem occurred with the KidneyX website system and that the technical problem affected your ability to submit an application by close of submissions. HHS and ASN and/or Luminary Labs will contact you when a determination is made on whether the application will be accepted.

Note: These extensions apply only to the unavailability of, or technical problems with, the KidneyX website system. HHS and ASN will not grant an entrant an extension if the entrant failed to submit an application in the system by the application deadline date and time, or if the technical problem experienced is unrelated to the KidneyX website system.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact: [Luminary Labs, 61 Broadway, Suite 2800, New York, NY 10006] or by email: [add Competition email address]. Entrants who use a TDD or a TTY may call the Federal Relay Service (FRS), toll free, at 1-800-877-8339. If Luminary Labs provides an accommodation or auxiliary aid to an individual with a disability in connection with the entry submission process, the entry remains subject to all other requirements and limitations in these Official Rules, Terms, and Conditions.

Publicity release

By participating in the Competition, each entrant hereby irrevocably grants to HHS and ASN and Luminary Labs the right to the use of their name, affiliation, city and state, likeness or image, and a synopsis or abstract of their winning solution as a part of HHS and ASN's promotion of this Competition, as stated in the Eligibility section.

Disqualification

HHS and ASN reserve the right in their discretion to disqualify any entrant who is found to be tampering with the entry process or the operation of the Competition, the KidneyX website, or other KidneyX-

related websites; to be acting in violation of these Official Rules, Terms and Conditions; or to be acting in an unsportsmanlike or disruptive manner, or with the intent to disrupt or undermine the legitimate operation of the Competition; or to annoy, abuse, threaten, or harass any other person; and HHS and ASN reserve the right to seek damages and other remedies from any such person to the fullest extent permitted by law.

Links to third-party websites

The KidneyX website may contain links to third-party websites that are not owned or controlled by HHS and ASN or Luminary Labs. HHS and ASN and Luminary Labs do not endorse or assume any responsibility for any such third-party sites. If you access a third-party website from the KidneyX website, you do so at your own risk and expressly relieve HHS and ASN and / or Luminary Labs from any and all liability arising from use of any third-party website content.

Notice to winner(s)

Attempts to notify winner(s) will be made using the email address associated with the Team Lead's Luminary Lightbox™ account. HHS and ASN and Luminary Labs are not responsible for email or other communication problems of any kind.

If, despite reasonable efforts, a potential winner does not respond within three (3) days of the first notification attempt regarding selection as a winner (or a shorter time as exigencies may require), or if the notification is returned as undeliverable to such entrant, that entrant may forfeit the entrant's winner status and any associated prizes, and an alternate winner may be selected.

If any potential winner is found to be ineligible, has not complied with these Official Rules, Terms and Conditions, or declines the applicable prize for any reason prior to award, such potential winners will be disqualified, and alternate winners may be selected.

Intellectual Property (IP) rights

Entrants retain all ownership in intellectual property of their submissions, subject to the licenses referenced herein.

- Entrants are free to discuss their submissions and their ideas or technologies that it contains with other parties, are encouraged to share ideas and technologies publicly, are encouraged to collaborate or combine with other teams to strengthen their solutions, and are free to contract with any third parties. Entrants should be aware that any agreement signed or obligation undertaken in regard to their participation in the Competition that conflicts with the Competition rules, terms, and conditions may result in disqualification of the entrant's submission.
- By participating in the 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. Each entrant is responsible for consulting with legal counsel of his/her/its choice as to whether publication of his/her/its abstract will jeopardize his/her/its ability to secure patent protection of his/her/its invention. Neither HHS nor ASN nor Luminary

Labs shall be liable for any loss of IP rights or protection that results from publication of any entrant's abstract by the KidneyX partnership. In addition, each participant (whether participating singly or in a group) and each entity grants to HHS an irrevocable, paid-up, royalty-free non exclusive worldwide license to reproduce, publish, post link to, share, and display publicly (e.g., on websites) the submission and related synopses or abstracts. To participate in the Competition, each entrant 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 must grant to the federal government a nonexclusive, non transferable, irrevocable, paid up license to practice, or have practiced for or on its behalf the solution throughout the world for federal purposes. Winners must also grant to the federal government and others acting on its behalf, a fully paid, nonexclusive, irrevocable, worldwide license in any copyrightable works that the submission comprises, including the right to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly said copyrightable works. By participating in the Competition, each entrant hereby grants an irrevocable and royalty-free license to HHS and ASN and Luminary Labs to store, access, modify, reproduce, and distribute submissions in perpetuity. Each entrant also warrants that the work is free of security threats and/or malware.

- All materials submitted to HHS as part of a submission become HHS agency records.
- If the submission includes any third party works (such as third party content or open source code), the entrant must be able to provide, upon request, documentation of all appropriate licenses and releases for use of such third party works. If the entrant cannot provide documentation of all required licenses and releases, HHS and ASN reserve the right, at their sole discretion, to disqualify the submission

Dates and deadlines

HHS and ASN reserve the right to modify any dates or deadlines set forth in these Official Rules, Terms and Conditions or otherwise governing the Competition.

Competition termination

HHS reserves the right to cancel, suspend, and/or modify the 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 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.

General liability release

By participating in the Competition, each entrant hereby agrees that:

Without limiting the generality of the foregoing releases, HHS, ASN, and Luminary Labs are not responsible for incomplete, illegible, misdirected, misprinted, late, lost, postage-due, damaged, or stolen entries or prize notifications; or for lost, interrupted, inaccessible, or unavailable networks, servers, satellites, Internet Service Providers, websites, or other connections; or for miscommunications, failed, jumbled, scrambled, delayed, or misdirected computer, telephone, cable transmissions or other

communications; or for any technical malfunctions, failures, difficulties, or other errors of any kind or nature; or for the incorrect or inaccurate capture of information, or the failure to capture any information.

These Official Rules, Terms and Conditions cannot be modified except by HHS and ASN in their absolute discretion. The invalidity or unenforceability of any provision of these Official Rules, Terms and Conditions shall not affect the validity or enforceability of any other provision. In the event that any provision is determined to be invalid or otherwise unenforceable or illegal, these Official Rules, Terms and Conditions shall otherwise remain in effect and shall be construed in accordance with their terms as if the invalid or illegal provision were not contained herein.

Insurance

Based on the subject matter of the Competition and the type of work that it will possibly require, entrants 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 participating in a prize competition, but are encouraged to consult with their own advisors with respect to the level of insurance that is prudent for each entrant.

Privacy, data security, ethics, and compliance

Entrants are required to identify and address privacy and data security issues in their proposed projects and describe specific solutions for meeting them. In addition to complying with appropriate policies, procedures, and protections for data that ensures all privacy requirements and institutional policies are met, use of data should not allow the identification of the individual from whom the data was collected.

Entrants are responsible for compliance with all applicable federal, state, local, and institutional laws, regulations, and policies. These may include, but are not limited to, Health Information Portability and Accountability Act (HIPAA) protections, Department of Health and Human Services (HHS) Protection of Human Subjects regulations, and Food and Drug Administration (FDA) regulations. If approvals (e.g., from an Institutional Review Board) will be required to initiate any activities associated with submission development in Round 1, 2 or potential Round 3 of the Competition, it is recommended that entrants apply for approval at or before that round's submission deadline. The following links are intended as a starting point for addressing potentially applicable regulatory requirements but should not be interpreted as a complete list of resources on these issues:

HIPAA

Main link: <http://www.hhs.gov/ocr/privacy/index.html>.

Summary of the HIPAA Privacy Rule: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>.

Summary of the HIPAA Security Rule: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html>.

Human Subjects—HHS

Office for Human Research Protections: <http://www.hhs.gov/ohrp/index.html>.

Protection of Human Subjects Regulations: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

Policy & Guidance: <http://www.hhs.gov/ohrp/policy/index.html>.

Institutional Review Boards & Assurances: <http://www.hhs.gov/ohrp/assurances/index.html>.

Human Subjects—FDA

Clinical Trials: <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>.

Office of Good Clinical Practice: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191>.

Consumer Protection—Federal Trade Commission

Bureau of Consumer Protection: <http://business.ftc.gov/privacy-and-security>.

Exercise

The failure of HHS and ASN to exercise or enforce any right or provision of these Official Rules, Terms and Conditions shall not constitute a waiver of such right or provision.

Governing law

All issues and questions concerning the construction, validity, interpretation, and enforceability of these Official Rules, Terms and Conditions shall be governed by and construed in accordance with U.S. Federal law as applied in the federal courts of the District of Columbia if a complaint is filed by any party against HHS and ASN, and the laws of the State of New York as applied in the New York state courts in New York City if a complaint is filed by any party against Luminary Labs.

Privacy policy

By participating in the Competition, each entrant hereby agrees that occasionally, HHS and ASN and Luminary Labs may also use the entrant's information to contact the entrant about federal Competition and innovation related activities, and acknowledges that the entrant has read and accepted the Privacy Policy published on the KidneyX website.

Additional terms that are part of the rules, terms and conditions

Please review the Luminary Lightbox Terms of Service at <http://www.LuminaryLightbox.com/terms> for additional rules that apply to your participation in the Competition and more generally your use of the KidneyX website. Such Terms of Service are incorporated by reference into these Official Rules, Terms and Conditions. If there is a conflict between the Terms of Service and these Official Rules, Terms and Conditions, the latter terms shall control with respect to this Competition only.

Participation in the Competition constitutes the entrant's full and unconditional agreement to these Official Rules, Terms and Conditions. By entering, an entrant agrees that all decisions related to the Competition that are made pursuant to these Official Rules, Terms and Conditions are final and binding, and that all such decisions are at the sole discretion of HHS and ASN and/or Luminary Labs.

Luminary Labs collects personal information from entrants to the Competition. The information collected is subject to the Privacy Policy located here: <<http://www.LuminaryLightbox.com/privacy>>

Winner list, Official rules, and Contact

To obtain a list of winners (after the conclusion of the Competition) or a copy of these Official Rules, Terms and Conditions, send a self-addressed envelope with the proper postage affixed to: Luminary Labs, 61 Broadway, Suite 2800, New York, NY 10006. Please specify “Winner List” or “Rules, Terms and Conditions” and the name of the specific Competition in your request.

For Further Information Contact:

Kidneyx@asn-online.org.