

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Announcement of Requirements and Registration for “Artificial Intelligence Health Outcomes Challenge”

Authority: 15 U.S.C. 3719; 42 U.S.C. 1315a

Update: August 13, 2020

The Centers for Medicare & Medicaid Services’ (CMS’) Center for Medicare and Medicaid Innovation (Innovation Center) announced the Artificial Intelligence (AI) Health Outcomes Challenge on March 27, 2019, in collaboration with the American Academy of Family Physicians, and the Laura and John Arnold Foundation (now known as “Arnold Ventures”). The CMS AI Health Outcomes Challenge provides an opportunity for innovators to demonstrate how AI tools, such as deep learning and neural networks, can be used to predict unplanned hospital and skilled nursing facility (SNF) admissions and adverse events based on Medicare Fee-for-Service (FFS) Parts A and B administrative claims data. Solutions developed through the Challenge are for potential use by the Innovation Center in testing innovative payment and service delivery models under the authority of section 1115A of the Social Security Act (42 U.S.C. 1315a).

The CMS AI Health Outcomes Challenge will offer monetary prizes to encourage further progress in AI for health and health care and to accelerate development of real-world applications by the Innovation Center. Participants will analyze large health data sets and respond to a clinical problem description provided by CMS to predict clinical outcomes.

CMS announced the AI Health Outcomes Challenge through a previous version of this notice and is carrying out this challenge under the authority of Section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719), as amended, to stimulate innovation that has the potential to advance the mission of CMS, in particular the Innovation Center. The purpose of the Innovation Center within CMS is to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs.

This challenge is also authorized under section 1115A of the Social Security Act (42 U.S.C. 1315a), which created the Innovation Center within CMS. The Innovation Center already provides data feedback to model participants as part of testing its models under section 1115A. Through this competition, we are seeking to enhance these data feedback tools with useful predictions that are actionable and can lead to improvements in quality and reduced cost of care.

CMS reserves the right to change or update this notice at any time. We may provide further details about the competition in future updates.

Activity dates (subject to change)

CMS worked diligently to establish policies and issue guidance to assist those responding to the Coronavirus disease 2019 (COVID-19) pandemic. CMS has taken numerous steps to address the pandemic, such as issuing an array of new rules and waivers of federal requirements to ensure

that local hospitals and health systems have the capacity to absorb and effectively manage potential surges of COVID-19 patients. On April 7, 2020, CMS informed AI Health Outcomes Challenge Stage 1 participants of a temporary pause in the challenge, with a resume date of Monday, June 29, 2020. CMS emphasized that during the pause, the Limited Data Set (LDS) files participants already received (and all derivative data) are for use in the context of the Challenge only, and such use is subject to the terms of the Data Use Agreement (DUA) that they signed. Following the pause, the following timeline for the remainder of the AI Challenge was established.

- Launch Stage
 - Participants submitted applications from March 27 - June 18, 2019, 5 p.m. ET
 - CMS announced participants that advanced to Stage 1 on October 30, 2019 (previously projected date in the initial publication of this Announcement was August 2, 2019)

- Stage 1
 - Stage 1 participants submitted the CMS DUA requests for Limited Data Set (LDS) files by December 2, 2019
 - CMS provided LDS files to Stage 1 participants qualified to receive the data on December 5, 2019
 - Participant Stage 1 project packages due July 2020
 - CMS announces participants that will move on to Stage 2 (“finalists”) in October 2020

- Stage 2
 - Stage 2 finalists submit requests for LDS files with additional data by the end of November 2020 (precise date to be determined by CMS)
 - CMS provides LDS files with additional data to Stage 2 finalists qualified to receive the data by November 2020
 - Finalist Stage 2 project packages due by the end of January 2021 (precise date to be determined by CMS)

CMS announces awardees by April 2021.

A. Background

Over 2,000 exabytes (1 exabyte = 1 billion gigabytes) of health care data will be produced in 2020, up more than 1,400 percent since 2013.¹ Yet, medical decision-making and population health management have not significantly changed. AI tools, applied to such needs as diagnostics, precision medicine, and patient monitoring have the potential to transform large volumes of structured and unstructured data into actionable insights that can reduce inefficiencies and enable transformations in healthcare practice and delivery.

¹ Stanford Medicine. (2017) Stanford Medicine 2017 Health Trends Report: Harnessing the Power of Data in Health. Available online at: <https://med.stanford.edu/content/dam/sm/sm-news/documents/StanfordMedicineHealthTrendsWhitePaper2017.pdf>

Recent advances in deep learning and neural networks have shown some success in predictions for health outcomes, but many barriers remain to implement these tools at scale.^{2,3} Quality and availability of data limit the range of questions that AI models can effectively answer, and the current health care payment system that often pays for volume instead of value does not provide incentives to utilize advanced data science in improving beneficiary health outcomes. CMS is actively working to address both of these barriers. In 2018, CMS launched the MyHealthEData Initiative and Blue Button 2.0 to break down barriers that contribute to preventing patients from being able to access and control their medical records and other health data. As part of MyHealthEData, providers are encouraged to share health data and support health IT interoperability, which supports value-driven health care across all settings.

CMS recognizes that AI can transform the role of data in the health care system. Although the use of simple heuristics in medical decision-making is well-established, sophisticated predictive models and more innovative handling of large administrative claims data sets have the potential to improve risk stratification to help health care providers better target interventions and care management resources for Medicare, Medicaid, and CHIP beneficiaries.

Through its models, the Innovation Center provides frequent feedback to model participants in order to support continuous quality improvement, with the understanding that learning and adaptation are essential to enable health care providers and health systems to achieve the greatest efficiencies and improvements possible in each new payment model. The Innovation Center also analyzes claims data to deliver actionable feedback to model participants about their performance, and encourages model participants to use this feedback to drive continuous improvement in their outcomes. With AI, there is the potential to do more. CMS, by virtue of its large data sets, the size and complexity of its beneficiary populations, and its role in testing innovative payment and service delivery models, is an ideal testing ground for AI and related technologies that have the potential to be scaled to the entire health care market.

B. Subject of Challenge Competition

Background

The Innovation Center tests models with the goals of reducing program expenditures and preserving or enhancing the quality of care for Medicare, Medicaid, and CHIP beneficiaries. Reducing unnecessary hospital and SNF admissions and adverse events are key components of improving quality and reducing the overall cost of care.

High rates of unplanned admissions and adverse events are not only costly to the health care system, but they can also indicate low-quality care during a prior hospital stay, or contribute to poor care coordination in post-acute care. Unnecessary institutionalization can also expose

² Hinton, G. (2018). Deep Learning—A Technology With the Potential to Transform Health Care. *JAMA*, 320(11), 1101-1102. Available online at: <https://jamanetwork.com/journals/jama/fullarticle/2701666>.

³ Roski, J.; Gillingham, B.; Just, E.; Sohn, E.; Sakarcan, K. (2018). Implementing And Scaling Artificial Intelligence Solutions: Considerations For Policy Makers And Decision Makers. Health Affairs, Blog. Available online at <https://www.healthaffairs.org/doi/10.1377/hblog20180917.283077/full/>.

patients to medical risk, and can result in adverse events, including hospital-acquired infections and death.

The rise of value-based payment programs in the U.S. health care system has increased the focus on reducing unnecessary admissions and other measures of quality and utilization.^{4,5} Commonly accepted strategies to reduce avoidable admissions and adverse events include improved communication during transitions of care, such as: patient/resident discharge instructions; coordination with post-acute care providers and primary care physicians; reducing complications such as hospital-acquired conditions; and referrals to home health and home and community-based services and social supports. In support of these strategies, physicians and other clinicians in value-based payment programs now receive a tremendous amount of data and alerts about these quality and utilization measures from government programs, accountable care organizations (ACOs), and electronic health record systems, which can be overwhelming and difficult to interpret.

Physicians and other clinicians need actionable data and more accurate predictive capabilities so that they can provide appropriate resources to patients at the right time. The Innovation Center is interested in better leveraging technology in testing its models, including improving the care quality and utility of the data feedback provided to model participants in an effort to improve quality and reduce costs as part of its model tests. Enhancing data feedback to model participants could drive individually-tailored interventions by model participants, such as care management or home visits, while also providing valuable insights on the success of these interventions for Medicare beneficiaries. This information, in turn, could be used to develop new Innovation Center models that could result in even more effective and more efficient care for Medicare beneficiaries. As a note, we are focusing on only Medicare beneficiaries and data in the AI Health Outcomes Challenge due to the quality, validity, and availability of Medicare data.

Competition Objectives

1. For Stage 1, use AI, including but not limited to deep learning methodologies,⁶ to predict unplanned hospital and SNF admissions, and adverse events within 30 days⁷ for Medicare beneficiaries, based on a data set of Medicare administrative claims data, including Medicare Part A (hospital) and Medicare Part B (professional services).
2. For Stage 2, use AI, including but not limited to deep learning methodologies, to predict unplanned hospital and SNF admissions, and adverse events, within 30 days for Medicare

4 McCarthy, C; Pandey, A. (2018). Predicting and Preventing Hospital Readmissions in Value-Based Programs. *AHA Journals – Circulation: Cardiovascular Quality and Outcomes*, 11(10). Available online at: <https://www.ahajournals.org/doi/full/10.1161/CIRCOUTCOMES.118.005098>

5 Ryan, A.; Krinsky, S.; Adler-Milstein, J. (2017). Association Between Hospitals' Engagement in Value-Based Reforms and Readmission Reduction in the Hospital Readmission Reduction Program. *JAMA Internal Medicine*, 177(6):862-868. Available online at: <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2617280>

⁶ Deep learning is part of a broader family of machine learning methods based on learning data representations, as opposed to task-specific algorithms.

⁷ Participants should be aware of the lag inherent in claims submission and processing, which would implicitly limit the inputs of a real-time AI model to claims that actually were processed and visible to the Medicare claims system. In practice this means that claims would not be visible to the AI engine until the claim effective date (and most likely not until the 'IDR load date' several days after the claim effective date). Many claims would therefore not be available to an AI engine until weeks or months after the 30 day window has passed. Participants should be aware of this limitation so that models take into account when claims would actually become visible to the claims system.

beneficiaries, as well as a standard target to be established by CMS, based on a Part A and Part B data set.

3. For both Stage 1 and Stage 2, develop innovative strategies and methodologies to: explain the AI-derived predictions to front-line clinicians and patients to aid in providing appropriate clinical resources to model participants; and increase use of AI-enhanced data feedback for quality improvement activities among model participants.

Data Set and Challenge Stages

Throughout the three stages of the competition, participants will be asked to prepare supporting materials (e.g., white papers, slide presentations) to explain their proposed solutions and methodologies. Stage 1 and Stage 2 participants will be asked to create algorithms, using the structured Medicare claims data sets provided. (Section C describes the submissions required for each stage.) The winning solution(s) may be considered for future development and use within data support tools at the Innovation Center and throughout CMS.

Participants who are selected for Stage 1 of the competition, based on their Launch Stage applications, may request an LDS with a prescribed set of Medicare beneficiary data, encompassing around 2.5-3 million unique beneficiaries. (LDS files contain beneficiary-level health information, but exclude specified direct identifiers as outlined in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR 164.514(e).) Participants who are selected for Stage 2 of the competition will be provided additional data by CMS from the same beneficiary sample. Additional information regarding Stage 2 data will be provided at a later date at the AI Health Outcomes Challenge web page.

Stage 1 and 2 participants will be able to request access to the LDS files for “research,” defined in the HIPAA Privacy Rule as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” (See 45 CFR 164.501). Stage 1 and 2 participants deemed qualified to receive the data are required to sign and comply with a Data Use Agreement (DUA) in order to receive the LDS. The DUA will include specific rules and requirements to receive, store, and protect the LDS. The LDS will be provided free of charge to the Stage 1 and 2 participants deemed qualified to receive it. Stage 1 and 2 participants may not augment or link the LDS at the beneficiary level for competition use, but may use and link other de-identified public data sets to the LDS (e.g., Census data). Participants are not required to use other de-identified public data, however, they will be evaluated on their ability to identify other data sets and types of information that will be useful to further refine their solutions following the competition.

Because research, as defined under the HIPAA Privacy Rule, must “develop or contribute to generalizable knowledge,” CMS requires the results of research using CMS data to be made publicly available; therefore, participants will be required to publicly share their findings and/or solutions in compliance with the requirements of the DUA. This could be accomplished through, for example, a presentation at a CMS public meeting, posting findings on a challenge-related or participant-associated website, or publication in a scientific journal.

C. Challenge Structure

The AI Health Outcomes Challenge is operating in three stages: the Launch Stage, Stage 1, and Stage 2. The Launch Stage was open to all eligible participants and the competition was intended to attract a wide range of ideas and participants (e.g., large and small entities, individuals and teams, etc.). (Section G describes the eligibility rules.) The top 25 participants of the Launch Stage advanced to Stage 1; up to 7 of the top participants of Stage 1 will move to Stage 2. More details about Stages 1 and 2 may be provided at a later date to participants and may be posted to the AI Health Outcomes Challenge web page.

The **Launch Stage** was an entry stage where participation was open to the general public and entrants completed an online application and submitted a brief slide deck providing information about the participants and their proposed solution and describing their concept, based on application instructions available at the AI Health Outcomes Challenge web page. Evaluation panels (described in Section F, below) reviewed entries based on defined evaluation criteria, and 25 Launch Stage participants were selected to progress to Stage 1. (See Sections F and G, below, for entry rules and evaluation criteria.)

Stage 1 is a design stage that asks participants to submit their ideas and solutions related to the clinical problem description, and an associated white paper describing a proof-of-concept algorithm, and other required elements of the entry. Additionally, participants will run an analysis using the LDS to demonstrate that their solution works. Participants were only permitted to participate in Stage 1 if they submitted an application during the Launch Stage and were selected to advance to Stage 1. The evaluation panels will review entries based on defined evaluation criteria, and up to 7 Stage 1 participants will be selected to progress to Stage 2, and will receive an \$60,000 monetary prize.

Stage 2 of the challenge asks finalists to further refine their algorithm related to the clinical problem description, to develop algorithms to meet a standard target to be established by CMS, and to provide an associated white paper describing the algorithm and other required elements of the entry. Additionally, finalists will be required to run a series of analyses using the LDS to prove that their algorithms work, and demonstrate predictive power. Participants may only participate in Stage 2 if they have submitted a design solution in Stage 1 and been selected to advance to Stage 2.

At the end of Stage 2, the evaluation panels will review entries based on defined evaluation criteria and award-approving officials will select a grand prize winner and a runner-up (see Sections E and F, below, for entry rules and evaluation criteria). Each Stage 2 finalist may be invited to present their algorithms at an open public meeting with an audience that may include stakeholders from across government, investors, patients, industry representatives, academics, and non-profit organizations. The grand prize winner will receive \$1 million and the runner-up will receive \$230,000, as described in and subject to Section D, below. More information on Stage 2 may be available at a later date at the AI Health Outcomes Challenge web page.

D. Amount and Payment of the Prizes

For the CMS AI Health Outcomes Challenge, \$1.65 million in total prize funds will be available. The up to seven selected finalists who advance to the final stage of the competition (i.e., Stage 2)

will each receive prizes of \$60,000 (for a total of up to \$420,000). The grand prize winner and runner-up will be awarded at the end of Stage 2. The grand prize winner will receive \$1 million and the runner-up will receive \$230,000. CMS is contributing \$1,010,000 to the CMS prize purse and the American Academy of Family Physicians and Arnold Ventures are contributing a total of \$640,000 to the prize purses.

Prizes awarded under this challenge will be paid by electronic funds transfer and may be subject to Federal income taxes. CMS, the American Academy of Family Physicians, and Arnold Ventures will comply with the Internal Revenue Service withholding and reporting requirements, where applicable. CMS, the American Academy of Family Physicians and Arnold Ventures will each distribute their prize money directly to award recipients. Arnold Ventures will not tender funds under the AI Health Outcomes Challenge to individuals. If either or both Arnold Ventures and the American Academy of Family Physicians fail to pay any portion of the monetary prize it has indicated it intends to pay, CMS does not have the legal authority to pay the amount on their behalf.

E. Entry Requirements

Launch Stage Entry Requirements:

For the Launch Stage, participants were asked to submit an online application describing themselves and their concept. Entries were due by June 18, 2019, at 5:00 pm. The Launch Stage of the CMS AI Health Outcomes Challenge opened on March 27, 2019. On that date, an application for the challenge was available on the AI Health Outcomes Challenge web page. Complete instructions for entry were provided on that page.

The Launch Stage entry was used to determine the top-scoring participants that advanced to Stage 1. The entry consisted of the online application through which participants provided information about themselves and their proposed solutions. Additionally, participants were required to submit a brief PowerPoint presentation with an introduction to their proposed solution, according to specific criteria that was made available on the AI Health Outcomes web page. The presentation could not exceed 10 slides in total length.

Stage 1 and 2 Entry Requirements:

More information about Stage 2 entry requirements may be made available at the AI Health Outcomes Challenge web page at a future date.

F. Selection of Winning Submissions and Evaluation Criteria

All Launch Stage submissions were reviewed to ensure that they met eligibility and other requirements (described in Sections G and H, below). A multi-disciplinary (i.e., expert) evaluation panel reviewed and scored qualified entries for all stages of the AI Health Outcomes Challenge, based on defined evaluation criteria stated in this announcement and on the AI Health Outcomes Challenge web page. The expert evaluation panel was composed of experts selected by CMS, in its sole and absolute discretion. Based on the scores of the expert evaluation panel, final decisions were made by CMS award-approving officials.

Participants have no right to observe the deliberations of the evaluation panels, or to be informed of other participants' calculations, measurements, and results, unless such information is made publicly available by CMS.

In order to assist the evaluation panels in evaluating Launch Stage entries, participants were asked to ensure that their entry provided sufficient detail and information to allow evaluation panels to evaluate the entry in accordance with the following:

High level evaluation criteria for the Launch Stage included:

- *Impact and innovation of proposed solution (60%)*
 - To what extent is the proposed approach operationally feasible for CMS?
 - How likely is it to succeed in predicting unplanned hospital and SNF admissions and adverse events?
 - Did the participant identify potential roadblocks to implementation and suggest ideas to facilitate resolution of such roadblocks?
 - To what degree is the proposed design innovative, creative, and original?
 - To what extent did the participant demonstrate how the proposed solution can outperform existing approaches?
 - To what extent has the participant identified other data sets and/or types of information that would be useful to further refine their solutions following the competition?
- *AI-Human Collaboration (40%)*
 - To what extent has the participant explained how the proposed AI tool will work with humans (clinicians and patients) to achieve the desired results?
 - To what extent has the participant identified strategies and tools to explain AI predictions to clinicians and patients to build trust and drive transparency?
 - To what extent has the participant demonstrated a link between the proposed solution and benefit to the Medicare population and potential impact on current health care practice and delivery methods?
- *Participant qualifications/history (Assessed and scored, but not included in the weighted score)*
 - Experience of participant in AI/deep learning with complex data sets.
 - Participants' experience with health care-specific data, including experience with and knowledge in hospital admissions data and measures of clinical quality. Note that specific experience with health care data is not required, but will help participants understand and interpret the competition subject and goals.
 - High-level timeline and business plan—has the participant presented an appropriate plan to meet the deadlines and requirements for the competition?
 - Participants' backgrounds, including with respect to location, professional background, and approach.

Evaluation criteria for Stage 1 include the following:

- Evaluation of the participant's solution performed by a neutral third party. This will require participants to submit their solution to a third party, which will evaluate the performance of the solution on the basis of defined criteria, and relative to the CMS baseline.

- An analysis of the interpretability/explainability of the participant’s solution. The analysis will reveal insight into how the participant’s solution is using the data on which they have been trained to achieve the Competition Objectives (described in Section B, above).

Additional information regarding evaluation criteria for Stage 1 and Stage 2 will be provided via updates to this announcement and the AI Health Outcomes Challenge web page.

G. Eligibility

To be eligible to win a prize under the AI Health Outcomes Challenge, an individual or entity--

1. Shall have timely submitted an entry to participate in the relevant stage of the challenge;
2. Shall have complied with all the requirements described in this announcement for participation in this challenge;
3. For prize money from CMS and/or partners, who are jointly sponsoring this challenge: 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 individuals or 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 his or her employment (all non-HHS Federal employees must consult with their agency Ethics Official to determine whether the Federal ethics rules will limit or prohibit the acceptance of the AI Health Outcomes Challenge prize);
5. Shall not be a HHS employee;
6. Federal grantees may not use Federal funds to develop entries unless consistent with the purpose of their grant award; and
7. Federal contractors may not use Federal funds from a contract to develop AI Health Outcomes Challenge applications or to fund efforts in support of an AI Health Outcomes Challenge entry.

H. Additional Requirements

1. 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.
2. 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 my participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.
3. Participants are not required to obtain liability insurance or demonstrate financial responsibility 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 the AI Health Outcomes Challenge.

4. Participants must also agree to indemnify the Federal Government against third party claims for damages arising from or related to AI Health Outcomes Challenge activities.
5. CMS reserves the right to cancel, suspend, and/or modify the AI Health Outcomes Challenge, or any part of it, for any reason, at CMS's sole discretion.

I. Intellectual Property (IP) Rights

1. Participants are free to discuss their entry 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 participants 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 the AI Health Outcomes Challenge that conflicts with the challenge rules, terms, and conditions may result in disqualification of the participant's entry.
2. By participating in this challenge, each participant (whether individuals, participating singly or in a group, or entities) 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 individuals, participating singly or in a group, or entities) grants to CMS an irrevocable, paid-up, royalty-free nonexclusive worldwide license to reproduce, publish, post, link to, share, and display publicly (e.g., on websites) the submission and abstracts on the web or elsewhere. Each participant will retain all other intellectual property rights in their submissions, as applicable. To participate in the challenge, 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 participants 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 government purposes. Each participant also warrants that the work is free of security threats and/or malware.
3. Each participant must clearly delineate any Intellectual Property (IP) and/or confidential commercial information contained in an entry that the participant wishes to protect as proprietary data.
4. All materials submitted to CMS as part of an entry become CMS agency records. Any confidential commercial or financial information contained in an entry must be clearly designated at the time of entry.
5. If the entry 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, CMS and Partners reserve the right, at their sole discretion, to disqualify the entry.

J. Supplementary Information

Participants will be required to follow the CMS process for requesting the LDS and sign a DUA with CMS in order to receive a claims data set that encompasses Medicare FFS Parts A/B data for a random 5% sample of Medicare beneficiaries (i.e., the LDS). This data set is expected to contain continuous data for approximately 2.5-3 million beneficiaries.

- In Stage 1, the participants may request certain LDS data, defined by CMS.
- In Stage 2, the finalists may request certain additional, continuous LDS data, defined by CMS.

The DUA will include specific rules and requirements to receive, store, and protect the LDS. Participants should note that all requests for the LDS will be granted or denied at CMS' sole discretion, and that in offering this LDS, CMS does not represent that the participant has met all applicable HIPAA requirements for requesting the data. Participants should consult with their own counsel to make those determinations prior to requesting this data from CMS.

Use of the LDS will be provided free of charge to the Stage 1 and 2 participants deemed qualified to receive it. Stage 1 and 2 participants may not augment or link the LDS at the beneficiary level for competition use, but may use and link other de-identified public data sets to the LDS (e.g., Census data). Participants are not required to use other de-identified public data, however, they will be evaluated on their ability to identify other data sets and types of information that will be useful to further refine their solutions following the competition. Participants will only be allowed to use the LDS for the purposes of the challenge and will be expected to destroy the files and submit a Certificate of Disposition (COD) form to close their DUA once the competition is complete.

AI Health Outcomes Challenge participants may not use in the Challenge any LDS data that they obtained outside of the AI Health Outcomes Challenge. Participants may use only the LDS data that they were provided as part of the AI Health Outcomes Challenge for purposes of the AI Health Outcomes Challenge. CMS may provide further guidance to participants on data use issues at a later date.

- [LDS data dictionaries/description of files](#)
- [LDS denominator file](#)
- [Comparison of RIE, LDS, and PUF](#)

K. For Further Information

Questions related to the challenge should be directed to cmsaichallenge@sensisagency.com or to [an email address that is subsequently established by CMS](#). CMS will notify participants of updates via email. CMS and its contractors also may engage participants directly via points-of-contact identified in their entries. However, these interactions with single participants only will be for logistical purposes only.