EQUITABLE HEALTH INNOVATION

Solution Development Toolkit



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INTRODUCTION



This toolkit is designed to help solution developers ensure that the health innovation products or services they are building are meaningfully advancing health equity.

It specifically aims to enable an understanding of how communities that have been historically marginalized by the U.S. healthcare industry have been and could be engaged in the design, development, testing, and evaluation of health innovations - to ensure positive health outcomes and avoid or mitigate harm.

This resource has been developed to support action in alignment with the *In Full Health* Principles for. Equitable Health Innovation and was guided and informed by three leading resources: Design Justice by Sasha Constanza-Chock, Race After. Technology by Ruha Benjamin, and RaceForward's Racial Equity Impact. Assessment Toolkit. We encourage use of this toolkit at multiple stages of the solution development lifecycle - from problem identification, to initial solution ideation, through ongoing evaluation and iteration.

This first version of the solution toolkit was developed in collaboration between the American Medical Association's <u>Center for Health Equity, The</u> <u>Greystone Group, the AMA External</u> <u>Equity & Innovation Advisory Group,</u> and the <u>In Full Health Collaborator</u> <u>Organizations</u>.

It is being made accessible via the Additional Terms (see end of toolkit for more detail).

We hope to evolve this toolkit over time with additional community feedback. We invite input and recommendations on how to strengthen the toolkit via <u>our website</u>.

→ VISIT OUR WEBSITE

TEN ACTIONS SOLUTION DEVELOPERS CAN TAKE TO CENTER EQUITY IN HEALTH INNOVATION

This toolkit is structured around the following ten actions that developers of health innovations can take to ensure equitable impact of their products or services:

Understand the demographics of your total potential market. Looking at your problem or opportunity statement, assess the communities represented within your total potential market among and at the intersection of different demographic groups.

a. Examples of total potential market definitions: all people living in a particular country, state, county, city, zip code, neighborhood; all employees of an organization; all members of a particular health plan; all people living in a hospital service area¹, all patients cared for within a particular hospital department/unit, or other defined population served by a hospital or clinic; all people with a particular health condition or health goal

b. Examples of demographic categories for which to assess % representation:

age, disability status, education level, employment status, ethnicity, gender identity, geographic location (rural, urban, suburban), health insurance coverage, household income, language, national origin, race, religion, sexual orientation Gather data on the difference in the health outcome of interest among and at the intersection of demographic subgroups, and root causes of that difference. Understand disparities in health conditions, treatment, and outcomes among and at the intersection of demographic groups and the structural and individual causes of these disparities.

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https://www.healthycommunities.org/resources/toolkit/files/step3-define-community

¹ Step 3: Define the community. ACHI. Accessed May 18, 2022.

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Be explicit about which demographic groups are represented among those you are engaging in solution design, and how you intend to address any inequities impacting those groups.

All solution designers have resource constraints and will need to prioritize target audiences. Once prioritization decisions are made explicit, we can understand representation gaps, decision making power imbalances, and information asymmetry that might render solutions ineffective for or harmful to demographic groups that are not engaged. 4

(If applicable) Ensure that priority demographic groups are represented in health data used to inform the solution design.

Conduct a review of clinical research or community health data used as an evidence base for your solution to understand and address any gaps in representation of priority groups. Address any gaps and define a plan for monitoring variances among groups to ensure efficacy and safety for all user groups. (If applicable) Ensure that priority demographic groups are represented in all AI / algorithm datasets used to create the solution.

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Conduct a review of the demographics of populations represented in datasets used to train and validate any Al / algorithms that are part of your solution. Address any gaps and define a plan for monitoring, reporting, and mitigating for any unintended consequences to ensure efficacy and safety for all user groups. Ensure that you understand what each variable in the algorithm is seeking to represent; be particularly cautious around how race and ethnicity data may be represented by the algorithm.

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TEN ACTIONS SOLUTION DEVELOPERS CAN TAKE TO CENTER EQUITY IN HEALTH INNOVATION

Seek out the insights and recommendations of marginalized communities via representation and power sharing in company decisionmaking roles impacting solution development.

Assess representation of historically marginalized demographic groups in *company leadership and governance groups, product/service design teams, and service delivery teams.* Seek representation of historically marginalized communities within your target audience and address any imbalances in decision-making power among individuals from and at the intersection of historically excluded or underrepresented demographic groups. Seek out the insights and recommendations of marginalized communities via representation and power sharing in formal user / participatory design opportunities impacting solution development.

Assess representation of historically marginalized demographic groups in formal user engagement opportunities, such as patient advisory groups, patient design councils, user research, and usability testing. Seek representation of historically marginalized communities within your target audience and address any imbalances in decision-making power among individuals from and at the intersection of historically excluded or underrepresented demographic groups and between those groups and those in company decision making roles.

Meaningfully engage, respond to, and value the contributions of marginalized communities by formally engaging a representative sample of priority users and stakeholders in all phases of solution design and development.

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Create structures for transparency, honesty, respect, and accountability in communication and decision making between solution developers and user groups. Provide space for users to inform *problem framing and* root cause analysis, solution design, prototyping, testing, evaluation planning, market selection and *implementation planning.* Provide clarity on any iterations of solution design and planning in response to user input. Compensate users for time, reimburse them for costs associated with participation, and secure consent for use and provide credit and mutually agreed upon compensation for any contributions and intellectual property shared or co-created with users. power differential and information asymmetry.

a. Problem framing and root cause analysis: Assess

and document inequitable structures and opportunities that have contributed to the health outcomes your solution seeks to solve. Acknowledge which root causes your solution will seek to address and where action from other stakeholders

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- b. Solution design, prototyping, testing: Engage users in testing of concepts and prototypes in a way that minimizes power differential and information asymmetry.
- c. Evaluation planning: Seek user guidance on how to define success metrics and establish accountability models for reporting, learning, and iterating on solution design and implementation plans.

d. Market selection and implementation planning:

Seek to understand community and patient needs to inform market opportunity, and be explicit about constraints or factors including company economic benefit that impact decisions about market prioritization. Engage users and other groups who will be impacted by the rollout of the solution including caregivers and health professionals to understand how implementation can be managed to support achievement of success metrics.

Ensure privacy of user data.

Develop and communicate policies, procedures, and controls that ensure the full protection of personal data of all users accessed or created by your solution. Conduct a review of privacy protocols and content with a representative sample of users - particularly those in historically marginalized demographic groups and iterate as needed to maximize privacy and control by all users. Be sure to develop and implement these safeguards at the start of your process rather than midstream or at the end.

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Evaluate and address any differential uptake and impact of your solution on users across and at the intersection of different demographic groups.

Plan to do this evaluation up front to facilitate real-time data collection and assessment to better understand who is and is not using your solution and how it is supporting the achievement of the success metrics defined with your representative group of users. Iterate upon your solution and its implementation to ensure that benefit is maximized and harm is mitigated for users from all priority demographic groups. Transparently communicate gaps or issues and mitigation efforts.



SOLUTION INVENTORY & RESOURCE MAP

This section of the toolkit provides a template that solution developers can use to take an inventory of progress to-date and identify new opportunities in alignment with the ten actions described above. It also provides a map of additional resources with supporting data, more detailed guidance, or other relevant information.

A few notes on the design of this inventory template:

- → It is recommended that the solution inventory be used to assess opportunities related to one specific product or service at a time. If you have multiple solutions you'd like to consider, it is recommended that you conduct a separate inventory for each.
- → This iteration of the solution inventory was developed for solutions that are used by patients or community members. If your solution is designed for health care providers or in a business-to-business capacity, many questions may not be relevant.
- → To get the most out of this inventory, we invite you to start by reading through all the questions and identifying sources of data or information needed to answer each question to the best of your ability, completely and accurately. Depending on the size and stage of your company and

product/service team, you may need to engage multiple departments or team members to provide input. For example, some questions may be best answered by your clinical leadership or advisory group, others by your development teams or IT department, and others by your market research or product management teams.

We encourage users to incorporate this inventory approach and template into existing organizational innovation development and review processes, embedding it into standard practice.

We'd love to learn how this inventory has supported your health solution development or evolution efforts - and welcome feedback and additional recommendations of relevant resources. Share case studies and input with the *In Full Health* team via <u>this form</u>.

→ VIEW FORM

SECTION I: GETTING STARTED: FRAMING YOUR SOLUTION & GOALS

QUESTION 1

What is the name of the product or service you are reviewing?

GUIDANCE & SUPPORTING INFORMATION

Tip: It is recommended that the solution inventory be used to assess opportunities related to one specific product or service at a time.

QUESTION 2

What specific problem does your solution seek to solve and/or health outcome do you seek to address?

GUIDANCE & SUPPORTING INFORMATION

Tip: We'll ask you to keep this problem or target health outcome in mind for the next sections of the inventory.

Examples: Improving blood pressure control rates, reducing inequities in maternal morbidity, reducing hospital readmission rates due to lack of safe and stable housing.

CASE STUDY: "DIABETES STOPPER"

Our hypothetical solution, "Diabetes Stopper" is aimed at helping U.S. adults with prediabetes reverse their diagnosis or prevent the onset of Type 2 diabetes with a combination of behavioral coaching, clinical protocols, and AI-based nudges via a mobile app. The health outcomes we would use as evidence of our solution's impact would be fasting plasma glucose test results below 100 mg/dL (reversal) or 126 mg/dL (prevent progression) or A1c test results below 5.7% mg/dL (reversal) or 6.5% mg/dL (prevent progression).



RELEVANT RESOURCES

Healthy People 2030 Foundation Health

The Role of Social Determinants of Health

in Promoting Health & Health Equity, KFF

Measures, Health & Human Services

Social Determinants of Health, CDC

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SOLUTION INVENTORY & RESOURCE MAP: SECTION I

QUESTION 3

Who could benefit from your solution? Specifically, how do you define and quantify the total potential community, or Total Addressable Market (TAM) that might use your product or service?

GUIDANCE & SUPPORTING INFORMATION

Tip: We'll ask you to keep this total potential audience in mind for the next sections of the inventory.

Examples: all people living in a particular country, state, county, city, zip code, neighborhood; all employees of an organization; all members of a particular health plan; all people living in a hospital or clinic service area; all people with a particular health condition or health goal

RELEVANT RESOURCES

- Defining the Community, Healthy Communities
- How to Do a Total Addressable Market Calculation, US Chamber
- What is a Total Addressable Market, MasterClass

CASE STUDY: "DIABETES STOPPER"

Our hypothetical solution, "Diabetes Stopper" seeks to eventually serve all of the approximately 96 million or roughly 38% of adults living with prediabetes across the US².



QUESTION 4

How would you describe the health equity aspiration of your solution?

- a. To improve health for all potential users with the goal of being inclusive of and avoiding or mitigating harm to historically marginalized communities
- b. To specifically improve health for one or more defined communities that have been historically marginalized or underserved by the health industry
- c. To close or narrow a specific health GAP or difference between your target population and an appropriate reference population

GUIDANCE & SUPPORTING INFORMATION

Tip: There is no best answer to this question, both aspirations are equally important. Being clear about intention for your product or service will help you frame the remainder of the solution inventory in the most relevant way.

Definitions:

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Health equity: Defined by the World Health Organization as "the absence of avoidable, unfair, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification. 'Health equity' or 'equity in health' implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential." Another definition is from Camara Jones MD, MPH, PhD: "Health equity is assurance of the conditions for optimal health for all people. Achieving health equity requires valuing all individuals and populations equally recognizing and rectifying historical injustice, and providing resources according to need."3

Historically marginalized communities: Groups of people that have faced historical disinvestment and exclusion from social, economic, political, educational, and/or cultural systems and opportunities based on characteristics including, but not limited to race, ethnicity, gender identity, sexual orientation, age, physical ability, language, religion, and/or immigration status. Marginalization occurs due to unequal power between social groups.

Examples:

Irth is an app developed to help Black and brown women and birthing people have a safe and empowered pregnancy through access to patient experience data from other parents of color. Irth's health equity aspiration would align with category (b).

Eleanor Health's mission is to help anyone concerned about their mental health or affected by addiction live amazing lives through whole-person, evidence-based treatment rooted in respect for their community member's values, culture, and life experiences. Eleanor Health's health equity aspiration would align with category (a).

RELEVANT RESOURCES

- Defining the Community, Healthy Communities
- How to Do a Total Addressable Market Calculation, US Chamber
- What is a Total Addressable Market, MasterClass



CASE STUDY: "DIABETES STOPPER"

"Diabetes Stopper" is not focused on one or more particular communities, but the founders want to ensure that it serves people of all communities well - especially given that they plan to make the service accessible to people through national health plans and employers who are accountable for the health of diverse populations. The "Diabetes Stopper" team is being asked to share in this accountability through a fee structure that includes incentives and/or penalties based on health outcomes across the population.

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SECTION II: DIGGING DEEPER: UNDERSTANDING DEMOGRAPHICS & INEQUITIES WITHIN YOUR USER POPULATION

LEARNING & ACTION OBJECTIVES

The following set of questions are intended to help you understand your current efforts and new opportunities related to Actions 1-3:

- → Understand the demographics of your total potential market. Looking at your problem or opportunity statement, assess the communities represented within your total potential market among and at the intersection of different demographic groups.
- → Gather data on the difference in the health outcome of interest among and at the intersection of demographic subgroups, and root causes of that difference. Understand disparities in health conditions, treatment, and outcomes among and at the intersection of demographic groups and the structural and individual causes of these disparities.
- → Be explicit about which demographic groups are represented among those you are engaging in solution design, and how you intend to address any inequities impacting those groups. All solution designers have resource constraints and will need to prioritize target audiences. Once prioritization decisions are made explicit, we can understand representation gaps, decision-making power imbalances, and information asymmetry that might render solutions ineffective for or harmful to demographic groups that are not engaged.



QUESTION 1

Looking at the problem statement or target health outcome and the total potential market you defined in Section 1, what is the composition of your total potential target audience across and at the intersection of the following demographic groups:

- age
- · disability status
- education level
- ethnicity
- employment status
- gender identity
- geographic location (rural, suburban, urban)
- health insurance coverage

GUIDANCE & SUPPORTING INFORMATION

Tip: The purpose of this question is to help you understand who is impacted by the problem or target health outcome you are seeking to address with your solution. By seeking data on the variance and intersectionality of identities within your total potential market, you can start to think about differences in experiences or needs that may impact solution design.

U.S. demographic data is included in the Appendix at the end of this toolkit for reference.

CASE STUDY: "DIABETES STOPPER"

According to this CDC report, these are the estimated demographics of the U.S. population with prediabetes:

Race and ethnicity:

- Asian, Asian American, and Pacific Islanders: 6.0M
- Black: **12.4M**
- · Latinx/Hispanic: 14.3M
- White: 62.4M

Sexual orientation and gender identity:

- Women: 43.7M
- Men: 52.3M

Age:

- · 18-44: 32.2M
- · 45-64: 37.4M
- 65 years and older: 26.4M

It is notable that this data is not comprehensive of all identities within the available demographic categories and does not include many demographic categories. Could potentially use data on demographics of those with type 2 diabetes to fill gaps.

- household income
- languages spoken
- national origin
- race
- religion
- sexual orientation

Consider % distribution and/or size of population.

RELEVANT RESOURCES

- National Health and Nutrition Examination Survey Data, CDC
- National Health Survey Interview Data, CDC
- Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality
- Healthy People 2030 Objectives and Data, U.S. Department of Health and Human Services
- PRAPARE Toolkit a national standardized patient risk assessment protocol designed to engage patients in assessing & addressing social determinants of health (SDOH)

QUESTION 2

What differences or inequities exist in the health outcome of interest among **and/or** at the intersection of the following demographic groups:

- age
- · disability status
- education level
- ethnicity
- employment status
- . gender identity
- geographic location (rural, suburban, urban)

GUIDANCE & SUPPORTING INFORMATION

Tip: The purpose of this question is to use data to understand inequities or differences in the health outcome of interest as experienced by people within and at the intersection of different demographic groups.

Definitions:

Intersectionality: Term coined by Kimberlé Krenshaw to describe the multiple social forces, social identities, and ideological instruments through which power and disadvantage are expressed and legitimized, as illustrated, for example by bias and oppression experienced by Black women in comparison to Black men or white women.⁴

CASE STUDY: "DIABETES STOPPER"

Given that data on health inequities for those with prediabetes was harder to come by, we can use Type 2 diabetes data to frame our understanding.

According to this analysis by the American Diabetes Association, the rate of diagnosed diabetes varies significantly by race and ethnicity:

American Indian/Alaskan Native: 14.5%

- Non-Hispanic Black: 12.1%
- Hispanic: 11.8%
- · Asian American: 9.5%
- White: 7.4%

Age: Data demonstrates 27.5% of Medicare Fee-for-Service beneficiaries had a diagnosis of diabetes in 2021, and heighted inequities based on race and ethnicity within that population.

Additional illustrative data from the National Center for Health Statistics database⁵ also highlights inequities by:

Disability status:

- With disability: 25.7%
- · Without disability: 7.7%

Education level:

- Less than high school diploma: 17.4%
- High school diploma or GED: 11.3%
- Some college: 11.1%
- College degree or higher: 6.3%

In addition to inequities demonstrated by variance in diabetes prevalence, there is also data demonstrating inequities in health outcomes (e.g. complications, death) experienced by those diagnosed with diabetes. One helpful source: American Diabetes Association: #HealthEquityNow initiative.

Additional data on inequities at the intersection of communities:

- More data on inequities impacting Medicare beneficiaries with lower education levels, lower income, and disabilities
- · Here is an illustrative example of a study highlighting intersectional inequities in diabetes screening and care impacting Black and Hispanic women.

- health insurance coverage
- household income
- languages spoken
- national origin
- race
- religion .
- sexual orientation

<u>G</u> **RELEVANT RESOURCES**

- National Health and Nutrition Examination Survey Data, CDC
- National Health Survey Interview Data, CDC
- Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality
- Healthy People 2030 Objectives and Data, U.S. Department of Health and Human Services'
- Health Equity Tracker, Satcher Health Leadership Institute, Morehouse School of Medicine

⁴Crenshaw K. On Intersectionality: Essential Writings. New Press; 2023. Kimberlé Crenshaw on intersectionality, more than two decades later. Columbia.edu. Accessed May 19, 2022. https://www.law.columbia.edu/news/archive/kimberle-crenshaw-intersectionality-more-two-decades-later 5 Summary health statistics. Cdc.gov. Published September 25, 2018. Accessed May 19, 2022. https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index.html

QUESTION 3

What information have you gathered on **root causes of the differences in the health outcome of interest** among and/or at the intersection of demographic groups?

GUIDANCE & SUPPORTING INFORMATION

Definitions:

Root causes of the differences in the health outcome of interest: Root causes of health inequities or differences in health outcomes include underlying systems and structures of social injustice that generate health inequity over time, including white supremacy, patriarchy, and class oppression. They interact with each other to produce social exclusion, marginalization, and exploitation.

CASE STUDY: "DIABETES STOPPER"

Continuing with our example above looking at people in the U.S. with type 2 diabetes, we can seek to understand the root causes of inequities in diabetes prevalence and outcomes impacting those within but not limited to American Indian/Indigenous, Black, Latinx/Hispanic, and other communities of color; people with disabilities; and communities with lower education levels. Below are a few illustrative sources of information:

- The Permanente Journal: Understanding Social Factors that Contribute to Diabetes
- Health Affairs: Misperceptions of People with Disabilities Lead to Low-Quality Care



🔮 RELEVANT RESOURCES

- AMA Prioritizing Equity.
 Series: The Root Cause
- AMA Prioritizing Equity
 Series: The Root Cause &
 Considerations for Health.
 Care Professionals
- <u>Medical Apartheid</u>, Harriet A. Washington

QUESTION 4

Considering the following categories, which demographic groups do you seek to design for? Please make note of intersectional identities or communities for whom you seek to design.

- age
- disability status
- education level
- ethnicity
- employment status
- gender identity
- geographic location (rural, suburban, urban)

GUIDANCE & SUPPORTING INFORMATION

Tip: The purpose of this question is to help you be explicit about which demographic groups are represented among those you are engaging in solution design. All solution designers have resource constraints and will need to prioritize target audiences. Once prioritization decisions are made explicit, we can understand representation gaps, decision-making power imbalances, and information asymmetry that might render solutions ineffective for or harmful to demographic groups that are not engaged.

U.S. demographic data is included in the Appendix at the end of this toolkit for reference.

CASE STUDY: "DIABETES STOPPER"

Case Study: "Diabetes Stopper": Given (1) the Diabetes Stopper team's equity goal of ensuring that their solution improves health for **all potential users** inclusive of and avoiding or mitigating harm to historically marginalized communities and (2) the data on prevalence and severity of Type 2 diabetes within the US, the Diabetes Stopper team wants to ensure that following communities are represented among those involved in solution design:

- Age: People above 65 (e.g., Medicare population)
- **Disability:** People with disabilities
- Race and ethnicity: American Indian / Indigenous, Black, Latinx / Hispanic, Asian American
- Education Level: communities with less than a college degree
- Income Level: communities with less than \$25,000 (e.g., Medicaid population)

- health insurance coverage
- household income
- languages spoken
- national origin
- race
- religion
- sexual orientation

RELEVANT RESOURCES

- <u>Design Justice</u>, Sasha Constanza-Chock
- <u>Race After Technology</u>, Ruha Benjamin
- <u>Racial Equity Impact</u>
 <u>Assessment Toolkit</u>,
 RaceForward

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SECTION III: INFORMING YOUR SOLUTION: REPRESENTATION OF TARGET USER POPULATION IN CLINICAL EVIDENCE & ANALYSIS

LEARNING & ACTION OBJECTIVES

The following set of questions are intended to help you understand your current efforts and new opportunities to:

→ Ensure that priority demographic groups are represented in health data used to inform the solution design. Conduct a review of clinical research or community health data used as an evidence base for your solution to understand and address any gaps in representation of priority groups. Address any gaps and define a plan for monitoring variances among groups to ensure efficacy and safety for all user groups.



QUESTION 1

(If applicable) Conduct a review of the demographics of the patient populations included in the **clinical research or community data used as the evidence base for your solution** and alignment with the demographic groups represented within your target audience. Are all demographic groups you seek to design for included in the data you're referencing? Are there any gaps?

GUIDANCE & SUPPORTING INFORMATION

Tip: The purpose of this question is to help you understand the demographics of the patient populations included in the evidence base being used in your solution design to ensure efficacy and safety of your solution for all demographic groups within your target audience.

RELEVANT RESOURCES

- Designing artifacts with biased data: The role of diversity in digital health innovation
- <u>Design Justice</u>, Sasha Constanza-Chock
- Race After Technology, Ruha Benjamin

CASE STUDY: "DIABETES STOPPER"

The behavioral coaching methods and clinical protocols used in Diabetes Stopper were developed with a clinical advisory board referencing peer-reviewed publications on effective weight management and diabetes prevention. Given that the team seeks to serve all people in the U.S. with prediabetes and given the higher prevalence of type 2 diabetes and poorer outcomes impacting people 65+; American Indian/ Indigenous, Black, Latinx/Hispanic, Asian communities; people with disabilities; and communities with lower education levels, communities with low income - the team should review the peer-reviewed studies upon which the Diabetes Stopper methods and protocols were developed to understand inclusion of these communities - and other reported demographics.

QUESTION 2

(If applicable) How have you explicitly and publicly described **any limitations of your solution in light of evidence gaps** that would impact the efficacy or safety of your solution for any demographic groups within your target audience?

GUIDANCE & SUPPORTING INFORMATION

Definitions:

Explicitly and publicly described: Being transparent and putting information regarding efficacy and safety where it is easily accessible to their users, i.e. on a website or app FAQ, as pop-up alerts during download, etc.

Context: There is currently a regulatory gap when it comes to health products and services. To ensure the safety of users, the FDA regulates devices, but defines devices as software/applications used for diagnosis, cure, mitigation, prevention or treatment of a recognized disease or condition. It does not include those used for maintaining or encouraging healthy lifestyles, or those used for administrative support or housing and dissemination of patient data. It also only considers software used in individualized traditional medical care settings.

This is problematic as many products/services fall outside of that scope (perhaps yours!) and are not being regulated. In addition, as technology advances, the distinction between solutions that improve wellness versus those that could be used in the context of traditional medical care are blurring and opening up further regulatory gaps.

Finally, the FDA's current definition of safety does not include notions of equity or disparity.

Thus, it is up to developers of such products/services to do their own due diligence to understand how one's products/services may differ in efficacy and safety across different demographic groups, and to be forthcoming with these differences so users can make educated choices about engaging with said product/service.

CASE STUDY: "DIABETES STOPPER"

If the Diabetes Stopper team learns that the studies upon which their solution's methods and protocols are based do not demonstrate efficacy among people 65+; American Indian/Indigenous, Black, Latinx/Hispanic, Asian communities; people with disabilities; and communities with lower education levels, communities with low income - the team should be transparent about these limitations when marketing their solution and develop a plan to address these gaps.

RELEVANT RESOURCES

 <u>Health Equity Tracker</u>, Satcher Health Institute, Morehouse School of Medicine

QUESTION 3

Describe your plan for collecting, analyzing, and reporting differences in health outcomes among all demographic groups within your target audience.

🗧 GUIDANCE & SUPPORTING INFORMATION

Tip: Collecting, analyzing, and reporting differences is important as it allows one to define a mitigation plan to address variances among groups to ensure efficacy and safety for all user groups. This is particularly critical for any demographic groups who are inadequately represented in clinical evidence or other data used to inform solution design.

RELEVANT RESOURCES

Improving Data on Race and Ethnicity: A Roadmap to Measure and Advance Health Equity, Grantmakers in Health, NCQA

CASE STUDY: "DIABETES STOPPER"

The Diabetes Stopper team should work with their clinical advisory group to ensure that any impact studies they conduct to understand and demonstrate health outcomes resulting from use of their solution among the health plan and employer populations for whom they are contracted include the collection of demographic data including but not limited to age, race, ethnicity, disability status, education level, income level. They should put in place a standard protocol for analyzing any variance in health outcomes correlated with demographics and partner with their clinical advisory group and customer (e.g., health plan or employer) to ensure the solution works well for all populations.

QUESTION 4

Describe your plan for collecting, analyzing, and reporting differences in **patient/user experience data** among all demographic groups within your target audience.

GUIDANCE & SUPPORTING INFORMATION

Tip: Same as above, this is focused on patient/user experience in addition to health outcomes.

CASE STUDY: "DIABETES STOPPER"

Same as above, except this is focused on patient/user experience data so may involve their product and service design teams in addition to clinical advisory group - with the goal of ensuring optimal experience for all populations.

SECTION IV: INFORMING YOUR SOLUTION: REPRESENTATION OF TARGET USER POPULATION IN AI / ALGORITHMS & MONITORING

LEARNING & ACTION OBJECTIVES

The following set of questions are intended to help you understand your current efforts and new opportunities to:

→ Ensure that priority demographic groups are represented in all AI / algorithm datasets used to create the solution. Conduct a review of the demographics of populations represented in datasets used to train and validate any AI / algorithms that are part of your solution. Address any gaps and define a plan for monitoring, reporting, and mitigating for any unintended consequences to ensure efficacy and safety for all user groups.



QUESTION 1

(If applicable) Conduct a review of the demographics of populations represented in **data sets used to train any AI** / algorithms that are part of your solution and alignment with the demographic groups represented within your target audience. Were all demographic groups you seek to design for included in creation of any AI / algorithms used in your solution? Are there any gaps? Are there any other potential biases associated with the development of the algorithms?

GUIDANCE & SUPPORTING INFORMATION

Definitions:

Al: Artificial intelligence is a segment of computer science that places an emphasis on developing advanced computers and applications with the goal of mimicking human intelligence.

In the context of health care, the American Medical Association uses the term augmented intelligence (AI) as a conceptualization of artificial intelligence that focuses on AI's assistive role, emphasizing that its design enhances human intelligence rather than replaces it.

Tip: A growing body of evidence is showing that AI algorithms perpetuate historic bias. To ensure efficacy and safety for all demographic groups within your target audience, it is critical to understand who is represented in the data used to train AI / algorithms and assess for other potential sources of bias.

RELEVANT RESOURCES

- Addressing bias in big data and Al for. health care: A call for open science
- Algorithmic Justice League
- Bias in data-driven artificial intelligence_ systems—An introductory survey
- <u>Coded Bias</u>
- Data Power and Bias in Al
- Dissecting racial bias in an algorithm used to manage the health of populations
- Latent bias and AI in Medicine
- Race After Technology, Ruha Benjamin

CASE STUDY: "DIABETES STOPPER"

The algorithm responsible for the "nudges" supporting users of the mobile app in the Diabetes Stopper program was developed by a third-party company who built the database from a variety of public and privately licensed sources (e.g. National Weight Control Registry, National Diabetes Prevention Program, and individual company any payer intervention and outcome data). Given that the team seeks to serve all people in the U.S. with prediabetes and given the higher prevalence of type 2 diabetes and poorer outcomes impacting people 65+; American Indian/Indigenous, Black, Latinx/Hispanic, Asian communities; people with disabilities; and communities with lower education levels, communities with low income - the team should ask the company who developed the algorithm to share information on the demographics of users in the database used to train the algorithm.

QUESTION 2

(If applicable) How have you explicitly communicated and/or addressed any limitations of your solution in light of any gaps in **the AI / algorithm training data sets or other inherent biases** that would impact the efficacy or safety of your solution for any demographic groups within your target audience?

CASE STUDY: "DIABETES STOPPER"

If the Diabetes Stopper team learns that the database used to train the "nudge" algorithm did not include a significant population of people 65+; American Indian/Indigenous, Black, Latinx/Hispanic, Asian communities; people with disabilities; and communities with lower education levels, communities with low income - the team should be transparent about these limitations when marketing their solution and develop a plan to address these gaps working with the third-party company who built the algorithm.

QUESTION 3

(If applicable) Describe your **plan for monitoring, reporting, and mitigating any unintended consequences of the AI / algorithms** built into your solution to ensure safety and efficacy among all demographic groups within your target audience.

CASE STUDY: "DIABETES STOPPER"

The Diabetes Stopper team should work with third-party company from whom they licensed the "nudge" algorithm to ensure that any analysis of its utility and impact among the health plan and employer populations for whom they are contracted include the collection of demographic data including but not limited to age, race, ethnicity, disability status, education level, income level. They should put in place a standard protocol for analyzing any variance in utility and impact correlated with demographics and partner with the algorithm developer to ensure the solution works well for all populations.

QUESTION 4

(If applicable) Provide the results of any third party algorithmic audits conducted to ensure for equitable and accountable AI.



Algorithmic Justice League

V

SECTION V: ENGAGING CRITICAL VOICES: REPRESENTATION OF TARGET USER POPULATIONS WITHIN YOUR COMPANY

LEARNING & ACTION OBJECTIVES

The following set of questions are intended to help you understand your current efforts and new opportunities to:

→ Seek out the insights and recommendations of marginalized communities via representation and power sharing in company decision making roles impacting solution development. Assess representation of historically marginalized demographic groups in *company board, product/service design team, and service delivery teams*. Seek representation of historically marginalized communities within your target audience and address any imbalances in decision making power among individuals from and at the intersection of historically excluded or underrepresented demographic groups.



QUESTION 1

Describe how demographic groups that make up the target audience you identified in Section II, Question 4 are represented within your **board or governance team**.

Who is represented currently? Who is missing? How might this impact how decisions are made? How can any gaps be addressed, with an emphasis on equity and avoiding tokenism?

GUIDANCE & SUPPORTING INFORMATION

Tips: Leaders who represent historically marginalized communities can bring observations, questions, concerns and solutions that may be overlooked by those in the dominant community, which in turn can be used to better address any gaps and create effective plans to ensure efficacy and safety for all user groups.

U.S. demographic data is included in the Appendix at the end of this toolkit for reference in understanding proportional representation.

Definitions:

Tokenism: the practice of making only a perfunctory or symbolic effort to do a particular thing, especially by recruiting a small number of people from underrepresented groups in order to give the appearance of sexual or racial equality within a workforce.

CASE STUDY: "DIABETES STOPPER"

In light of the Diabetes Stopper team's commitment to inclusion of the following communities in solution design, they should also assess representation of these groups within the **company board or governance team**:

- Age: People above 65 (e.g., Medicare population)
- **Disability:** People with disabilities
- Race and ethnicity: American Indian / Indigenous, Black, Latinx / Hispanic, Asian American
- Education Level: communities with less than a college degree
- Income Level: communities with less than \$25,000 (e.g., Medicaid population)

RELEVANT RESOURCES

- Delivering growth through diversity in the workplace, McKinsey & Company
- <u>Diversity improves</u> <u>performance and outcomes</u>, Journal of the National Medical Association
- Diversity in Digital Health.
 <u>Report</u>, Ivor Horn and Rock
 Health, 2020.
- Effective Change Requires. Proximate Leaders, Angela Jackson, John Kania, Tulaine Montgomery, Stanford Social Innovation Review, 2020.
- Toward a Racially Just. Workplace, HBR
- How Diverse Leadership. Teams Boost Innovation, BCG
- Onboard Health: Diverse Company Leadership
- Chicago Blend: BlendList Board Candidates
- 2021 CEO Blueprint for Racial Equity, PolicyLink
- MLT Black Equity at Work. Certification

EQUITABLE HEALTH INNOVATION SOLUTION DEVELOPMENT TOOLKIT

SOLUTION INVENTORY & RESOURCE MAP: SECTION V

QUESTION 2

Describe how demographic groups that make up the target audience you identified in Section II, Question 4 are represented within your company leadership team.

Who is represented currently? Who is missing? How might this impact how decisions are made? How can any gaps be addressed, with an emphasis on equity and avoiding tokenism?

GUIDANCE & SUPPORTING INFORMATION

Tips: See above.

CASE STUDY: "DIABETES STOPPER"

In light of the Diabetes Stopper team's commitment to inclusion of the following communities in solution design, they should also assess representation of these groups within the **company leadership team**:

- Age: People above 65 (e.g., Medicare population)
- **Disability:** People with disabilities
- · Race and ethnicity: American Indian / Indigenous, Black, Latinx / Hispanic, Asian American
- Education Level: communities with less than a college degree
- · Income Level: communities with less than \$25,000 (e.g., Medicaid population)



EQUITABLE HEALTH INNOVATION SOLUTION DEVELOPMENT TOOLKIT

SOLUTION INVENTORY & RESOURCE MAP: SECTION V

QUESTION 3

Describe how demographic groups that make up the target audience you identified in Section II, Question 4 are represented within your **product / service design team**.

How can any gaps be addressed, with an emphasis on equity and avoiding tokenism?

GUIDANCE & SUPPORTING INFORMATION

Tips: See above.

CASE STUDY: "DIABETES STOPPER"

In light of the Diabetes Stopper team's commitment to inclusion of the following communities in solution design, they should also assess representation of these groups within the **product / service design team**:

- Age: People above 65 (e.g., Medicare population)
- **Disability:** People with disabilities
- · Race and ethnicity: American Indian / Indigenous, Black, Latinx / Hispanic, Asian American
- Education Level: communities with less than a college degree
- Income Level: communities with less than \$25,000 (e.g., Medicaid population)

RELEVANT RESOURCES

- Design Justice, Sasha Constanza-Chock
- Race After Technology, Ruha Benjamin
- Ignoring Diversity Hurts Tech Products and <u>Ventures</u>, Mike Peña



QUESTION 4

(If applicable) Describe how demographic groups that make up the target audience you identified in Section II, Question 4 are represented within your **service delivery team**.

How can any gaps be addressed, with an emphasis on equity and avoiding tokenism?

GUIDANCE & SUPPORTING INFORMATION

Tips: See above.

CASE STUDY: "DIABETES STOPPER"

In light of the Diabetes Stopper team's commitment to inclusion of the following communities in solution design, they should also assess representation of these groups within the **service delivery team**:

- Age: People above 65 (e.g., Medicare population)
- **Disability:** People with disabilities
- Race and ethnicity: American Indian / Indigenous, Black, Latinx / Hispanic, Asian American
- Education Level: communities with less than a college degree
- Income Level: communities with less than \$25,000 (e.g., Medicaid population)

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SECTION VI: ENGAGING CRITICAL VOICES: REPRESENTATION & VALUING OF TARGET POPULATIONS IN USER DESIGN OPPORTUNITIES

LEARNING & ACTION OBJECTIVES

The following set of questions are intended to help you understand your current efforts and new opportunities to:

- → Seek out the insights and recommendations of marginalized communities via representation and power sharing in formal user / participatory design opportunities impacting solution development. Assess representation of historically marginalized demographic groups in *formal user engagement opportunities, such as patient advisory groups, patient design councils, user research, and usability testing*. Seek representation of historically marginalized communities within your target audience and address any imbalances in decision making power among individuals from and at the intersection of historically excluded or underrepresented demographic groups and between those groups and those in company decision making roles.
- Meaningfully engage, respond to, and value the contributions of marginalized communities by formally engaging a representative sample of priority users and stakeholders in all phases of solution design and development. Create structures for transparency, honesty, respect, and accountability in communication and decision making between solution developers and user groups. Provide space for users to inform *problem framing and root cause analysis, solution design, prototyping, testing, evaluation planning, market selection and implementation planning*. Provide clarity on any iterations of solution design and planning in response to user input. Compensate users for time, reimburse them for costs associated with participation, and secure consent for use and provide credit and mutually agreed upon compensation for any contributions and intellectual property shared or co-created with users.

QUESTION 1

Describe how demographic groups that make up the target audience you identified in Section II, Question 4 are represented within any **formal user/participatory design opportunities** such as patient and family/caregiver advisory groups, patient and family/caregiver design councils, user research, usability testing, etc.

GUIDANCE & SUPPORTING INFORMATION

Tip: Individuals who belong to historically marginalized communities can bring observations, questions, concerns and solutions that may be overlooked by those in the dominant community, which in turn can be used to better address any gaps and create effective plans to ensure efficacy and safety for all user groups.

U.S. demographic data is included in the Appendix at the end of this toolkit for reference in understanding proportional representation.

CASE STUDY: "DIABETES STOPPER"

In light of the Diabetes Stopper team's commitment to inclusion of the following communities in solution design, they should assess representation of these groups within **formal user/participatory design opportunities** such as patient and family/caregiver advisory groups, patient and family/caregiver design councils, user research, usability testing, etc:

- Age: People above 65 (e.g., Medicare population)
- Disability: People with disabilities
- Race and ethnicity: American Indian / Indigenous, Black, Latinx / Hispanic, Asian American
- Education Level: communities with less than a college degree
- **Income Level:** communities with less than \$25,000 (e.g., Medicaid population)

RELEVANT RESOURCES

- <u>Design Justice</u>, Sasha
 Constanza-Chock
- <u>Race After Technology</u>, Ruha Benjamin
- Equity and Inclusion Guiding Engagement Principles, PCORI Advisory Panel on Patient Engagement

QUESTION 2

How have you meaningfully engaged and incorporated recommendations from a representative group of target users and stakeholders in any of the following **problem definition** activities:

- a. Problem framing
- b. Root cause analysis

GUIDANCE & SUPPORTING INFORMATION

Tips: Assess and document inequitable structures and opportunities that have contributed to the health outcomes your solution seeks to solve. Acknowledge which root causes your solution will seek to address and where action from other stakeholders will be needed. Use an asset-based approach to understand what solutions already exist within your end user community and reframe the problem and opportunity statement as needed.

Definitions:

Meaningfully engage: Seek input in a way that makes people feel valued and heard. The International Association for Public Participation has developed a Spectrum of Public Participation, which illustrates a variety of ways to engage.

CASE STUDY: "DIABETES STOPPER"

After assessing **who** is represented in formal user/participatory design opportunities, this is an opportunity to look at **how** target users are engaged specifically in **problem definition** activities.

RELEVANT RESOURCES

Design Justice Principles

QUESTION 3

How have you meaningfully engaged and incorporated recommendations from a representative group of target users and stakeholders in any of the following **solution development** activities:

- a. Solution design
- b. Solution prototyping and testing

GUIDANCE & SUPPORTING INFORMATION

Tips: Engage users in testing of concepts and prototypes in a way that minimizes power differential and information asymmetry.

CASE STUDY: "DIABETES STOPPER"

After assessing **who** is represented in formal user/participatory design opportunities, this is an opportunity to look at **how** target users are engaged specifically in **solution development** activities.

RELEVANT RESOURCES

- Beyond Do No Harm: Structural Racism in Tech-Forward SDOH Solutions, Health Leads
- Designing consumer health. IT to enhance usability. among different racial. and ethnic groups within. the United States, Rupa S. Valdez, M. Chris Gibbons, Elliot R. Siegel, Rita Kukafka, Patricia Flatlely Brennan, Health and Technology, 2012.



EQUITABLE HEALTH INNOVATION SOLUTION DEVELOPMENT TOOLKIT

SOLUTION INVENTORY & RESOURCE MAP: SECTION VI

QUESTION 4

How have you meaningfully engaged and incorporated recommendations from a representative group of target users and stakeholders in any of the following solution evaluation activities:

- a. Defining target outcomes and impact metrics
- b. Impact data collection and/or research design (including clinical trials)

GUIDANCE & SUPPORTING INFORMATION

Tips: Seek user guidance on how to define success metrics and establish accountability models for reporting, learning, and iterating on solution design and implementation plan.

CASE STUDY: "DIABETES STOPPER"

After assessing **who** is represented in formal user/participatory design opportunities, this is an opportunity to look at how target users are engaged specifically in solution evaluation activities.

ଜ **RELEVANT RESOURCES**

Achieving health equity through digital health

QUESTION 5

How have you meaningfully engaged and incorporated recommendations from a representative group of target users and stakeholders in any of the following **market selection and implementation planning** activities:

- a. Pricing and Insurance coverage
- b. Customer, user, and caregiver training and support design

GUIDANCE & SUPPORTING INFORMATION

Tips: Seek to understand community and patient needs to inform market opportunity, and be explicit about constraints or factors including company economic benefit that impact decisions about market prioritization. Engage users and other groups who will be impacted by the roll out of the solution including caregivers and health professionals to understand how implementation can be managed to support achievement of success metrics.

🔮 RELEVANT RESOURCES

A framework for advancing health equity and value

CASE STUDY: "DIABETES STOPPER"

After assessing **who** is represented in formal user/participatory design opportunities, this is an opportunity to look at **how** target users are engaged specifically in **market selection and implementation planning** activities.

QUESTION 6

How have you **compensated users and stakeholders for their time and/or reimbursed them for any costs to support equitable participation** in formal user/participatory design opportunities, in accordance with need? How was the compensation calculated? What metrics or guidelines did you use?

CASE STUDY: "DIABETES STOPPER"

After assessing **who** is represented in formal user/participatory design opportunities, this is an opportunity to look at **how** users and stakeholders are compensated and for their time and any costs incurred as a result of their participation.



- <u>Research Design:</u>
 <u>Compensation Guidelines</u>,
 Poverty Action Lab
- <u>A Framework for Financial</u> <u>Compensation for Patient</u>. <u>Partners in Research</u>, PCORI Advisory Panel on Patient Engagement
- Principles for Compensating Patients for Patient Engagement Activities, The National Health Council
- When Does the Amount We Pay Research Participants Become "Undue Influence"?, AMA Journal of Ethics

QUESTION 7

How have you engaged in any of the following to **provide credit for the contributions of target users and stakeholders**:

- a. Explicitly and publicly provide credit for the contributions of target users and stakeholders
- **b.** Protect or allocate ownership of any intellectual property share or co-created by target users in design sessions

CASE STUDY: "DIABETES STOPPER"

After assessing **who** is represented in formal user/participatory design opportunities, this is an opportunity to look at **how** users and stakeholders are acknowledged, recognized, and attributed for their contributions during their participation in user/participatory design.



SECTION VII: ENSURING EQUITABLE PROTECTION OF USER DATA: PRIVACY PROTECTIONS

LEARNING & ACTION OBJECTIVES

The following set of questions are intended to help you understand your current efforts and new opportunities to:

→ Ensure privacy of user data. Develop and communicate policies, procedures, and controls that ensure the full protection of personal data and respect data use choices of all users accessed or created by your solution. Conduct a review of privacy protocols and content with a representative sample of users - particularly those in historically marginalized demographic groups - and iterate as needed to maximize privacy and control by all users.



QUESTION 1

Describe how your solution provides the following information to users about the personal data it is accessing, collecting, and processing, using clear, precise, and simple language that can be understood by those with elementary grade literacy in all languages supported by the solution:

- **a.** A public-facing privacy policy describing the solution's specific uses of data. Note that statements such as, "We may use and share this data to improve quality" are vague and do not advance an individual's understanding of how their data is managed by the solution.
- b. Disclosure of what specific data it is collecting prior to or at the point of collection
- c. Disclosure of the exact purpose of all data collected prior to or at the point of collection
- d. Disclosure of how often data elements are collected by the solution
- **e.** Disclosure of the specific types of entities with whom the solution shares an individual's data. Vague categories such as "our partners" are not appropriate.

GUIDANCE & SUPPORTING INFORMATION

Tips: It is critical to ensure that all users, and especially those from historically marginalized communities, understand who is collecting their data, who their data is being shared with, what will be done with it, and what control they have over it once provided to a health solution, digital platform, or mobile app. This is particularly important for demographic data being collected in order for the company to understand and address differential impact of the solution on distinct communities.

There are far too many examples of harmful consequences resulting from failures to protect data privacy, including the use of data to deny or or provide substandard care to historically marginalized communities. It is the responsibility of the solution developer to ensure that data privacy and transparency are upheld to ensure equitable impacts for all users.

CASE STUDY: "DIABETES STOPPER"

The product, data, and/or technology development teams would work together to ensure that the recommendations in this section are met, and address any gaps or changes needed.

RELEVANT RESOURCES

- Privacy is Good Business: A case for privacy by design in app development, American Medical Association.
- Privacy Principles, American
 Medical Association
- Data Justice Lab
- Race After Technology, Ruha
 Benjamin
- Improving Data on Race and Ethnicity: A Roadmap to Measure and Advance <u>Health Equity</u>, Grantmakers in Health, NCQA

EQUITABLE HEALTH INNOVATION SOLUTION DEVELOPMENT TOOLKIT

SOLUTION INVENTORY & RESOURCE MAP: SECTION VII

QUESTION 2

Describe how your solution provides configurable settings and functions to provide users with control over the use of their data, including by:

- a. Allowing users to define how their information is accessed, used, and processed
- b. Allowing users to set whether their personal data can be sold to or otherwise shared with third-parties
- c. Allowing users to share certain categories of data but not others (e.g., share medication lists but not diagnoses)
- d. Allow users to delete their data from within the solution's ecosystem (including deletion of data from a device, an application, and cloud storage)

QUESTION 3

Describe policies, procedures, and/or controls in place for your solution to prevent unnecessary data collection and discriminatory use, including ensuring:

- a. Collection of the minimum amount of information needed for a particular purpose? For example, a health app may collect an individual's general location data (e.g., zip code) to provide information about health services available in the user's geographic reason, but should not track an individual's precise location data or movements (e.g., GPS coordinates)
- b. Privacy protections do not vary based on fees for service or technology selections
- c. Data collected by your solution is not shared with employers or insurers absent explicit user consent
- d. Data collected by your solution is only shared with law enforcement following a court order or if the law enforcement entity has shown by clear and convincing evidence that the information is necessary to a specific and legitimate law enforcement inquiry
- e. Your solution does not use any data it collects, stores, or processes to aid or abet discrimination or the ability of the individual / their family to access products and services? For example, you do not allow any data collected, stored or processed by your solution to be used by data brokers to create "risk scores" or profiles.

QUESTION 4

Describe how your solution enables all users, including people with physical, sensory, or cognitive disabilities, to control how their data is accessed, used, processed, and disclosed, including:

- **a.** At least one mode of operation that does not require user vision/enables users to make use of limited vision.
- **b.** At least one visual mode of operation that does not require user perception of color.
- **c.** At least one mode of operation that does not require user hearing/enables users to make use of limited hearing.
- d. At least one mode of operation that does not require user speech.
- **e.** At least one mode of operation that does not require fine motor control or simultaneous manual operations.
- **f.** At least one mode of operation that is operable with limited reach and limited strength.

RELEVANT RESOURCES

<u>Functional Performance</u> <u>Criteria</u> in Section 255 of the Communications Act.

QUESTION 5

How does your solution support portability such that the user can transfer their data to a new platform in a common machine-readable and non-proprietary format?

QUESTION 6

How does your solution support portability such that the user can transfer their data to a new platform in a common machine-readable and non-proprietary format?

GUIDANCE & SUPPORTING INFORMATION

Definition:

De-identification: De-identification is a process of detecting identifiers (e.g., personal names and social security numbers) that directly or indirectly point to a person (or entity) and deleting those identifiers from the data.

SECTION VIII: EVALUATING FOR EQUITABLE IMPACT: SOLUTION DATA

LEARNING & ACTION OBJECTIVES

The following set of questions are intended to help you understand your current efforts and new opportunities to:

→ Evaluate and address any differential uptake and impact of your solution on users across and at the intersection of different demographic groups. Plan to do this evaluation up front to facilitate real-time data collection and assessment to better understand who is and is not using your solution and how it is supporting the achievement of the success metrics defined with your representative group of users. Iterate upon your solution and its implementation to ensure that benefit is maximized and harm is mitigated for users from all priority demographic groups. Transparently communicate gaps or issues and mitigation efforts.



QUESTION 1

Provide data demonstrating that **your solution improves health outcomes** for, among, and/or at the intersection of all demographic groups within your target audience?

GUIDANCE & SUPPORTING INFORMATION

Tip: Collecting, analyzing, and reporting differences is important as it allows one to define a mitigation plan to address variances among groups to ensure efficacy and safety for all user groups. This is particularly critical for any demographic groups who are inadequately represented in clinical evidence or other data used to inform solution design. While the initial plan was developed in response to Section III, Question 3, this section is focused on ongoing measurement and solution evolution in response to data and the evaluation plan that was ideally informed by a representative group of users from your target audience in Section VI, Question 4.

Definition:

Health outcomes: Health outcomes can include anything defined by your target audience that describes their state of health and well-being. It can be a clinical outcome, like blood pressure. It can also be a social determinant of health, like access to healthcare.

CASE STUDY: "DIABETES STOPPER"

Going back to the Diabetes Stopper team's **equity goal** provided in Section 1, Question 3 of ensuring that their solution improves health for all potential users inclusive of and avoiding or mitigating harm to historically marginalized communities and **intended community representation in solution design** described in Section II, Question 4, the Diabetes Stopper team should be monitoring the health outcomes of their solution by the following categories with attention to the groups for whom inequities in diabetes rates and outcomes exist:

- **Age:** People above 65 (e.g., Medicare population)
- Disability: People with disabilities
- Race and ethnicity: American Indian / Indigenous, Black, Latinx / Hispanic, Asian American
- Education Level: communities with less than a college degree
- Income Level: communities with less than \$25,000 (e.g., Medicaid population)

Differences in outcomes from use of the Diabetes Stopper solution should be transparently reported and mitigated through engagement with company team members, user/participatory design participants, community partners, and other stakeholders from within these communities.



- Improving Data on Race and Ethnicity: A Roadmap to Measure and Advance Health Equity, Grantmakers in Health, NCQA
- A Historical Overview of Health Disparities and the Potential of eHealth Solutions, M. Chris Gibbons, JMIR, 2005
 - Health Evolution Workgroup. & Industry Pledge: Leveraging Data to Improve. Health Equity

QUESTION 2

Provide data demonstrating that **your solution avoids or mitigates harm** for, among and/or at the intersection of all demographic groups within your target audience?

GUIDANCE & SUPPORTING INFORMATION

Tip: Same guidelines as above, this time with an emphasis on ongoing monitoring of **harm** experienced by users within prioritized and other historically marginalized communities and working with them to define mitigation and solution evolution plans.

RELEVANT RESOURCES

Human Factors Guidance to Prevent. Healthcare Disparities with the Adoption. of EHRs, M. Chris Gibbons, Svetlana Z. Lowry, Matthew T. Quinn, U.S. Department of Commerce, National Institute of Standards and Technology, 2011

QUESTION 3

Provide data demonstrating that **your solution generates positive patient/user experience** among and at the intersection of all demographic groups within your target audience?

GUIDANCE & SUPPORTING INFORMATION

Tip: Same guidelines as above, this time with an emphasis on ongoing monitoring of **differential patient/user experience** measures by users within prioritized and other historically marginalized communities and working with them to define mitigation and solution evolution plans.

RELEVANT RESOURCES

The Digital Divide in Healthcare: It's Not.
 Just Access, Lisa Fitzpatrick, Neal Sikka,
 Karin Underwood, HIMSS, 2021

QUESTION 4

Provide data demonstrating how **your solution is advancing health equity by addressing root causes** of differences of health outcomes of interest for, among and/or at the intersection of demographic groups within your target population?

GUIDANCE & SUPPORTING INFORMATION

Tip: Looking back at your root cause analysis of relevant inequities assessed in Section II, Question 3 and the problem framing and root cause analysis ideally conducted with a representative group of target users in Section VI, Question 2, provide any data on **how your solution addresses those root causes** and how you're continuing to work with users within prioritized and other historically marginalized communities to define mitigation and solution evolution plans in response to relevant ongoing data collection, as needed.

QUESTION 5

Describe and link to any peer reviewed journal publications or other **independent third party review conducted of your solution outcomes data**.

APPENDIX: U.S. PATIENT/ COMMUNITY DEMOGRAPHICS FOR REFERENCE IN DEMOGRAPHIC ASSESSMENT

Source of data is from the 2020 <u>US Census</u> unless otherwise noted.

Age:

- Persons under 5 years: 6.0%
- Persons between 5 and 18 years: 16.3%
- Persons between 18 and 65 years: 61.2%
- Persons 65 years and over: 16.5%

People with Disabilities, under age 65 years: 8.6%

Education Level:

- High school graduate or higher, percent of persons age 25+: 88.0%
- Bachelor's degree or higher, percent of persons age 25+: 32.1%

Employment Status:

- In civilian labor force, total, percent of population age 16+ years: 63.0%
- Civilian unemployment rate (source): 3.8%

Gender Identity (source)*:

- Male: 47.2%
- Female: 50.5%
- Transgender: 0.6%
- None of These: 1.7%

Geographic Location (source):

- Urban core: 31%
- Large suburban: 25%
- Smaller metropolitan: 30%
- Rural: 14%

Health Insurance Coverage (source):

- Private health insurance group: 55.4%
- Private health insurance non-group: 13.1%
- Medicare: 18.1%
- Medicaid/CHIP: 19.8%
- Military TRICARE: 2.7%
- Military VA Care: 2.2%
- Uninsured: 9.2%

Household Income (source)**:

- Households in lowest quintile, income of \$28,084 or less: 20%
- Households in second quintile, income between \$28,085 and \$53,503: 20%
- Households in third quintile, income between \$53,504 and \$86,488: 20%
- Households in fourth quintile, income between \$86,489 and \$142,051: 20%
- Households in highest quintile, income of \$142,052 or more: 20%



EQUITABLE HEALTH INNOVATION SOLUTION DEVELOPMENT TOOLKIT

APPENDIX: U.S. PATIENT/COMMUNITY DEMOGRAPHICS FOR REFERENCE IN DEMOGRAPHIC ASSESSMENT

Language Use (source and detailed list):

- Speak only English at home: 79%
- Speak a language other than English at home: 21%

National Origin:

- Foreign born persons: 13.6%
- US born persons: 86.4%

Race and Ethnicity:

- American Indian or Alaska Native alone (1.3%)
- Asian alone (5.9%)
- Black or African American alone (13.4%)
- Native Hawaiian or Other Pacific Islander alone (0.2%)
- Two or More Races (2.8%)
- Hispanic or Latinx (18.5%)
- White alone, not Hispanic or Latinx (60.1%)

Religion (source):

- Buddhist: 0.7%
- Catholic: 20.8%
- Hindu: 0.7%
- Jehovah's Witness: 0.8%
- Jewish: 1.9%
- Mormon: 1.6%
- Muslim: 0.9%
- Orthodox Christian: 0.5%
- Protestant: 46.6%
- Other: 0.7%
- Unaffiliated: 22.8%
- Don't Know: 0.6%

Sexual Orientation (source)*:

- Heterosexual: 86.7%
- Gay or Lesbian: 2.1%
- Bisexual: 3.1%
- Other (e.g., queer, same-gender-loving): 0.2%



** FAQs on poverty and low-income guidelines

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EQUITABLE HEALTH INNOVATION SOLUTION DEVELOPMENT TOOLKIT APPENDIX: U.S. PATIENT/COMMUNITY DEMOGRAPHICS FOR REFERENCE IN DEMOGRAPHIC ASSESSMENT

ADDITIONAL TERMS FOR IN FULL HEALTH EQUITABLE HEALTH INNOVATION SOLUTION TOOLKIT:

The In Full Health Equitable Health Innovation Solution Toolkit (Toolkit) constitutes an important work published by the AMA with the goal of advancing equitable opportunities in health innovation investment, solution development, and purchasing. The Toolkit includes questions, case studies, and resource links that promote understanding of the In Full Health principles.

We strongly believe that this information needs to be available to the public at no cost and encourage the use of the toolkit. In addition to scholarly research, debate, and commentary, you are encouraged to use and transform this information to help promote its spread and adoption as we seek to advance equitable health innovation opportunities.

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