STUDY PROTOCOL

Official Title

The MyLungHealth Study Protocol: A Pragmatic Patient-Randomized Controlled Trial to Evaluate a Patient-Centered, Electronic Health Record-Integrated Intervention to Enhance Lung Cancer Screening in Primary Care

Brief Title

Engaging Patients to Enable Interoperable Lung Cancer Decision Support at Scale

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Sponsor

University of Utah
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Principal Investigator

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Participating Institutions

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- NYU Langone Health, New York, New York, United States

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Confidentiality Statement

This document contains the IRB-approved study protocol for the clinical trial identified above and is submitted to ClinicalTrials.gov for regulatory compliance.

Engaging Patients to Enable Interoperable Lung Cancer Decision Support at Scale

Protocol Summary

IRB Approval Date of Current Version:	5/19/2025
University of Utah IRB #:	IRB_00153806
Sponsor:	DHHS AGNCY FOR HEALTHCARE RESH & QUALITY
Principal Investigator:	Kensaku Kawamoto
Internal Staff and Sub-Investigators:	**Site Name** / **Staff Names** University of Utah / Kensaku Kawamoto [redacted]

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This document was created using the ERICA Online System at the University of Utah. The document is created from study information approved by the IRB on the date listed above. Any alteration to the original content of this document may not be considered to represent the study as approved by the IRB.

Background and Introduction

Lung cancer is the leading cause of cancer-related deaths in the US, with over 135,000 deaths in 2020.[1] The US Preventive Services Task Force (USPSTF) recommends low-dose computed tomography (CT) screening to reduce mortality.[2] However, among eligible patients, there is wide individual variation in expected benefits vs. harms (e.g., biopsy complications after false-positive screens).[3] Thus, shared decision making (SDM) using a decision aid – a form of clinical decision support (CDS) – is required before low-dose CT screening, including by CMS for payment.[2,4] However, standalone CDS requires manual data entry and is not directly integrated into clinical workflows, while CDS developed with native electronic health record (EHR) tools have functional limitations and are difficult to disseminate across health systems and EHR platforms. These constraints limit the adoption of CDS to support SDM for lung cancer screening, which contributes to limited screening among eligible patients (~5%).[5] A critical need, therefore, is the wide adoption of CDS to support SDM for lung cancer screening. Our overall goal in this project is to improve lung cancer screening at scale through CDS. In addition to quantitative evaluation methods, we will use qualitative evaluated methods such as think-aloud with contextual inquiry, [6,7] critical incidence technique interviews[8] and focus groups[9] to support the design, implementation, and evaluation of the project interventions. The names of project interventions (e.g., MyLungHealth, Decision Precision+) may be updated as needed (e.g., based on feedback from user focus groups).

Acronyms used in this application are as follows:

AHRQ – Agency for Healthcare Research and Quality

CCET – Community Collaboration and Engagement Team

CDS – clinical decision support

CMS – Centers for Medicare and Medicaid Services

CFIR – Consolidated Framework for Implementation Research

CT – computed tomography

DP+ – Decision Precision+

EHR – electronic health record

FHIR – Fast Healthcare Interoperability Resources

GEE – generalized estimating equations

LDCT – low-dose computed tomography

NYU – New York University PHR

– personal health record RTA –

retrospective think-aloud SDM –

shared decision making

SMART – Substitutable Medication Applications and Reusable Technologies

USPSTF – United States Preventive Services Task Force

UUH – University of Utah Health

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Purpose and Objectives

This project is supported both operationally and by an Agency for Healthcare Research and Quality (AHRQ) R18 grant.

Our overall goal is to improve lung cancer screening at scale through clinical decision support (CDS). In pursuit of this goal, we have previously developed a CDS app using the "SMART on FHIR" interoperability standard for lung cancer screening with AHRQ support (Kawamoto R18HS026198) ("SMART on FHIR" is short for Substitutable Medical Applications and Reusable Technologies on Fast Healthcare Interoperability Resources). This app, known as Decision Precision+ (DP+), overcomes the limitations of traditional CDS, seamlessly integrating with the electronic health record (EHR) and providing patient-specific estimates of benefits and risks. *Our objective* is to build on DP+ and address 4 key remaining barriers: 1) providers have limited time to engage in shared decision making (SDM), 2) smoking history data in the EHR may be missing or inaccurate, 3) EHR vendors may not yet support the retrieval of all required smoking history data through their native FHIR data interfaces, and 4) there is currently no clear, replicable process for widely implementing interoperable CDS in real-world contexts where adoption sites are not paid to implement the CDS. To build on our achievements, address key remaining barriers, and fulfill our objective, we plan to pursue the following aims:

Aim 1. Adapt DP+ to include a patient-facing SMART on FHIR app (MyLungHealth). Using a user-centered design approach, we will engage patients, providers, and staff to identify how best to meet their needs while adhering to the CDS 5 Rights. MyLungHealth will be a SMART on FHIR app launched through the personal health record (PHR). MyLungHealth and associated PHR tools will enable patients to learn about lung cancer screening; review, update,

and augment their smoking history in the EHR; and review their individualized estimates of benefits and risks. MyLungHealth will be suggested to eligible patients via the PHR. As with the rest of DP+, MyLungHealth will be integrated with multiple EHR platforms. Human subjects research for this aim may include the following:

Aim 1a. Patient Focus Groups to Design MyLungHealth

Aim 1b. Patient Interviews to Design MyLungHealth

Aim 1c. Patient Participation in Pilot Implementation of MyLungHealth

Aim 1d. Patient Interviews to Evaluate Acceptability of MyLungHealth During Pilot Implementation

Aim 1e. Provider Interviews to Design MyLungHealth

Aim 1g. Provider and Staff Participation in Pilot Implementation of MyLungHealth

Aim 1h. Provider Interviews to Evaluate Acceptability of MyLungHealth in Pilot Implementation

Aim 1i. Patient Surveys to Evaluate MyLungHealth in Pilot Implementation

Aim 1j. Provider Surveys to Evaluate MyLungHealth in Pilot Implementation

Aim 2. Evaluate the impact of MyLungHealth. We will conduct a patient-randomized trial of MyLungHealth across primary care clinics at University of Utah Health (UUH) and New York University (NYU) Langone Health, with the current provider-facing DP+ serving as the baseline control. Human subjects research for this aim may include the following:

Aim 2a. Patient Participation in Clinical Trial

Aim 2b. Patient Surveys to Evaluate MyLungHealth in Clinical Trial Aim

2e. Provider and Staff Participation in Clinical Trial

Aim 2f. Provider Surveys to Evaluate MyLungHealth in Clinical Trial

Aim 2i. Patient Outcomes Assessment in Clinical Trial

Aim 2j. Provider and Staff Intervention Usage Assessment in Clinical Trial

Aim 2k. Data Quality Evaluation

Aim 2l. Stakeholder Interviews to Evaluate Implementation

Aim 2m. Stakeholder Focus Groups to Evaluate Implementation

Aim 3. Develop and Evaluate a Replicable Approach for Real-World Dissemination and Implementation of Interoperable CDS. Epic®, the nation's leading EHR vendor, prompts for documenting SDM within its base lung cancer screening module but does not provide any decision aid support; this Epic "Foundation" workflow is currently in use at over 100 health systems. For an upcoming release, based on the enthusiastic endorsement of its Pulmonology Steering Board, Epic plans to enhance this workflow by prompting for SDM using a decision aid and facilitating the implementation of DP+ if an EHR-integrated solution is desired.
Leveraging this decision, we aim to disseminate DP+ across at least 12 health systems. MyLungHealth will be added to DP+ following clinical validation. We will develop a Consolidated Framework for Implementation Research (CFIR)-informed approach to implementation that does not require payments to adoption sites. We will 1) assess adopters' perceptions of DP+, their implementation process, and their internal and external contexts; 2) enhance DP+ and develop self-service resources to address identified barriers; 3) assess implementation outcomes (adoption and usage) and correlate them with step 1 findings; and 4) iteratively refine DP+ and self-service resources based on the findings. Insights gained will be shared with peers engaged in CDS implementation. Human subjects research for this aim will consist of the following:

Aim 3a. Project Champion and Technical Lead Interviews to Assess Implementation Context

Aim 3b. Project Champion and Technical Lead Surveys to Assess Implementation Context

Aim 3c. Project Champion and Technical Lead Interviews to Evaluate Implementation

Aim 3d. Project Champion and Technical Lead Surveys to Evaluate Implementation

Study Population

Age of Participants: 18+

Sample Size:
At Utah:
All Centers: up to 81,684 participants

Inclusion Criteria:

Used throughout this application are the following definitions:

- *Patients with documented LCS eligibility.* A patient is eligible for lung cancer screening according to USPSTF criteria if they are 50 to 80 years old; have at least a 20 pack-year smoking history; if a former smoker, has quit within the last 15 years; and has no lung cancer diagnosis.
- *Patients with uncertain LCS eligibility.* A patient is *potentially* eligible for lung cancer screening according to USPSTF criteria if they are not eligible according to the available EHR data but may *potentially* meet the criteria if a complete and accurate smoking history were available. Patients will be considered to potentially meet the pack-year history criteria if they have an unknown pack-year history in the EHR or a 10-19 pack-year history (due to EHR data potentially being outdated). If a former smoker, patients will be considered to potentially have quit within the past 15 years (and therefore meet criteria) if they have an unknown quit date. Patients will also be considered to potentially meet the pack-year history criteria if they are a current or former smoker with a 0 pack-year smoking history, as this is not logically possible unless a data entry error occurred (e.g., with packs per day specified as 0 after quitting, even though that field is intended to capture average packs per day during the patient's lifetime of smoking vs. the current packs per day).
- A patient is in need of screening if they are 1) eligible for screening; 2) have not had a chest CT (low-dose or otherwise) in the past year; and 3) do not have structured EHR data indicating the patient had declined screening in the past 3 years.
- A patient is in need of screening education if they are 1) eligible for screening; 2) have not had a low-dose chest CT in the past 3 years; 3) do not have structured EHR data indicating the project's screening education has been provided in the past 3 years; and 4) do not have structured EHR data indicating shared decision making on lung cancer screening had been conducted with the patient in the past 3 years.
- Study clinic. A study clinic is a primary care clinic at University of Utah Health or NYU Langone Health. We may also include pulmonary clinics.
- Pilot clinic. A pilot site within the study clinics.
- Non-pilot study clinic. A study clinic that is not a pilot clinic.
- Project interventions. Project interventions will consist of 1) the patient-facing SMART on FHIR MyLungHealth app; 2) pre-visit PHR communications to patients; and 3) provider prompts regarding patient use of MyLungHealth. The MyLungHealth app will be available in the PHR and educate patients about lung cancer screening. The pre-visit PHR communications will be prior to study clinic visits and invite patients to learn about lung cancer screening through MyLungHealth. Also, for potentially eligible patients, patients will be educated on lung cancer screening eligibility criteria and asked about whether they meet these criteria; if they do, they will be offered the MyLungHealth intervention. The provider prompts will be in the EHR and inform providers regarding their patients' use of MyLungHealth and their potential interest in lung cancer screening. Project interventions may be referred to in short-hand as MyLungHealth.

Aim 1. Adapt DP+ to include a patient-facing SMART on FHIR app (MyLungHealth).

Aim 1a. Patient Focus Groups to Design MyLungHealth: We will recruit up to 60 patients who meet USPSTF lung cancer screening criteria and have Internet access. Patients will be recruited into cohorts which include (i) individuals who have had lung cancer screening and can reflect on what information would have been useful when making the screening decision; (ii) individuals who have not had screening; and (iii) individuals who can provide feedback on the Spanish version of MyLungHealth. We will seek to obtain as much racial and ethnic diversity as possible in our cohorts. We will also seek to recruit older participants from various backgrounds and health literacy levels.

Aim 1b. Patient Interviews to Design MyLungHealth: Up to 40 patients will be included in the interviews. Patients will be eligible if they meet USPSTF lung cancer screening criteria and have Internet access.

Aim 1c. Patient Participation in Pilot Implementation of MyLungHealth: We anticipate up to 1000 patients may be a part of the pilot implementation. This population will consist of individuals who are patients of a pilot clinic and who meet USPSTF lung cancer screening criteria or may potentially meet the criteria if a complete and accurate smoking history were available.

Aim 1d. Patient Interviews to Evaluate Acceptability of MyLungHealth During Pilot Implementation: Up to 40 patients will be included in the interviews. Patients will be eligible if they used MyLungHealth during the pilot implementation.

Aim 1e. Provider Interviews to Design MyLungHealth: Up to 40 providers will be included in the interviews. Providers will be eligible if they provide care related to lung cancer screening for the targeted patient population.

Aim 1g. Provider and Staff Participation in Pilot Implementation of MyLungHealth: Up to 200 providers and staff will participate in the pilot implementation. Providers and staff will be eligible if they provide care related to lung cancer screening for the targeted patient population at a pilot clinic.

Aim 1h. Provider Interviews to Evaluate Acceptability of MyLungHealth in Pilot Implementation: Up to 40 providers will be included in the interviews. Providers will be eligible if they provide care related to lung cancer screening for the targeted patient population at a pilot clinic and have at least one patient who uses MyLungHealth.

Aim 1i. Patient Surveys to Evaluate MyLungHealth in Pilot Implementation: Up to 1000 pilot participants may be invited to participate in an online survey.

Aim 1j. Provider Surveys to Evaluate MyLungHealth in Pilot Implementation: Up to 200 pilot participants may be invited to participate in an online survey.

Aim 2. Evaluate the impact of MyLungHealth.

Aim 2a. Patient Participation in Clinical Trial: We anticipate up to 70,000 patients will be enrolled.

This trial involves two studies:

Study 1 Primary Hypothesis: Among primary care patients aged 50–79 with uncertain LCS eligibility, MyLungHealth eligibility questionnaires and education will result in increased identification of LCS-eligible patients.

Study 2 Primary Hypothesis: Among primary care patients aged 50–79 with documented LCS eligibility, MyLungHealth education will result in increased LDCT ordering.

Inclusion criteria for both Study 1 and Study 2:

- aged 50-79

- a history of smoking (e.g., current or former tobacco use)

- seen in a study primary care clinic in the 12 months preceding the start of the trial

Inclusion criteria for Study 1:

- a 10-19 pack-year smoking history, an unknown pack-year history, unknown quit date for patients who quit smoking, or a 0 pack-year smoking history

Inclusion criteria for Study 2:

- at least a 20 pack-year smoking history and are a current smoker or have quit within the last 15 years

Secondary data analyses will be for other sub-populations of enrolled patients, including patients potentially eligible for screening at the start of the study period and subsets of populations according to key patient characteristics such as gender and race and ethnicity.

Aim 2b. Patient Surveys to Evaluate MyLungHealth in Clinical Trial: Up to 70,000 patients in the Aim 2 implementation trial will be surveyed. We will survey patients in the clinical trial with a recent lung cancer screening order or evidence of recent lung cancer screening SDM who have not previously undergone lung cancer screening.

Aim 2e. Provider and Staff Participation in Clinical Trial: Up to 10,000 providers and staff in the non-pilot study clinics will be included in the clinical trial. Providers and staff will be eligible if they provide care related to lung cancer screening for the targeted patient population at a non-pilot study clinic.

Aim 2f. Provider Surveys to Evaluate MyLungHealth in Clinical Trial: Up to 2,000 providers of patients who used MyLungHealth in the Aim 2 implementation trial will be invited to participate in an online survey.

Aim 2i. Patient Outcomes Assessment in Clinical Trial: Enrollment and eligibility criteria are the same as for participation in the clinical trial.

Aim 2j. Provider and Staff Intervention Usage Assessment in Clinical Trial: Enrollment and eligibility criteria are the same as for participation in the clinical trial.

Aim 2k. Data Quality Evaluation: We anticipate up to 70,000 patients will be enrolled. Patients will be eligible for inclusion in the trial if they are eligible or potentially eligible for lung cancer screening according to USPSTF criteria and are seen at a study clinic. Data quality evaluation will occur throughout the study, including in the trial preparation phase.

Aim 2l. Stakeholder Interviews to Evaluate Implementation: Up to 40 key stakeholders (e.g., project champions, technical leads, providers, administrative support, information technology personnel) who implemented the intervention will be interviewed regarding their experience.

Aim 2m. Stakeholder Focus Groups to Evaluate Implementation: Up to 40 key stakeholders (e.g., project champions, technical leads, providers, administrative support, information technology personnel) will be enrolled in focus groups.

Aim 3. Develop and Evaluate a Replicable Approach for Real-World Dissemination and Implementation of Interoperable CDS.

Aim 3a. Project Champion and Technical Lead Interviews to Assess Implementation Context: Up to 100 key stakeholders (e.g., project champions and technical leads) who are interested in implementing the intervention at the University of Utah or elsewhere will be interviewed with a goal of understanding the implementation context.

Aim 3b. Project Champion and Technical Lead Surveys to Assess Implementation Context: Up to 264 key stakeholders who are interested in implementing the intervention at the University of Utah or elsewhere will be surveyed with a goal of understanding the implementation context.

Aim 3c. Project Champion and Technical Lead Interviews to Evaluate Implementation: Up to 100 key stakeholders who implemented the intervention at the University of Utah or elsewhere will be interviewed with a goal of understanding their implementation experience.

Aim 3d. Project Champion and Technical Lead Surveys to Evaluate Implementation: Up to 264 key stakeholders who implemented the intervention at the University of Utah or elsewhere will be surveyed with a goal of understanding their implementation experience.

Exclusion Criteria:

Exclusion criteria for both Study 1 and Study 2 in Aim 2a. Patient Participation in Clinical Trial:

- >0 but < 10 pack-year smoking history or quit more than 15 years ago
- No use of the patient portal at least once in the year preceding the start of the study
- A lung cancer diagnosis at the start of the study
- LDCT completed in the past 3 years
- Another chest CT completed in the past year
- Structured EHR data indicating LCS SDM was provided in the past 3 years
- Exposed to the intervention during the pilot phase

Design

Randomized Trial
Prospective Social/Behavioral Intervention or Experiment

Study Procedures

Recruitment/Participant Identification Process:

University of Utah and NYU personnel will extend the initial invitation to participate to participants from their site. Site-specific recruitment requirements will be followed. Purposeful recruitment will be conducted as needed to help ensure balanced recruitment samples. All other recruitment and consent activities will be completed by University of Utah personnel.

For interviews and focus groups, screening surveys will be used to collect information on inclusion/exclusion criteria, demographic/background data, and other relevant information that supports the recruitment and inclusion of participants with diverse experiences. Information

relevant for the recruitment of participants with diverse experiences include whether the patient has already had lung cancer screening, patient health literacy, patient language, provider clinical specialty, and provider experience level.

For all recruitments, up to 2 reminder invitations will be sent to those who do not respond. If needed after initial invite, and at least a month following the initial invitation, up to 3 additional reminder invitations will be sent.

For all study aspects, Spanish translations will use professional medical translation services such as the University of Utah's research translation services (https://ctsi.utah.edu/cores-and-services/clinical-services-core/foreign-language-translation).

MyLungHealth will be available in both English and Spanish, as is already the case with DP+. In order to obtain input on the Spanish version of MyLungHealth, bilingual patients who speak both Spanish and English OR non-bilingual patients who speak Spanish, and who feel comfortable participating in a survey, interview, or focus group conducted in English or Spanish, will be recruited.

Aim 1. Adapt DP+ to include a patient-facing SMART on FHIR app (MyLungHealth).

Aim 1a. Patient Focus Groups to Design MyLungHealth: We may use the University of Utah's Community Collaboration and Engagement Team (CCET) to recruit focus group participants using the approach below. Alternatively, we may conduct some or all of the associated recruitment procedures through our own research team.

We may use word-of-mouth and flyers, which may be disseminated in clinics, by community organizations, and/or through social media. Flyers may also be sent to past or current CCET participants, with encouragement to share the opportunity with others who may fit the inclusion criteria. The flyer may contain a QR code and URL that links to a screener survey in REDCap. Interested individuals completing a screener will be contacted to ensure they meet inclusion/exclusion criteria, collect demographic data, provide information on the study, answer any questions, and verify their desire to proceed.

We may also use electronic health record data to identify patients eligible or potentially eligible for lung cancer screening. These patients may be recruited through personal health record messages or via mail or email contact inviting them to be screened for eligibility.

Aim 1b. Patient Interviews to Design MyLungHealth: We will use the same recruitment strategies as for the *Aim 1a. Patient Focus Groups to Design MyLungHealth*.

Aim 1c. Patient Participation in Pilot Implementation of MyLungHealth: We will seek a waiver of informed consent for targeted patients as described later.

Aim 1d. Patient Interviews to Evaluate Acceptability of MyLungHealth in Pilot Implementation: We will use the PHR, email, text message where allowed by local governance, or postal mail to recruit patients who have used MyLungHealth. Such patients will be identified through system logs.

Aim 1e. Provider Interviews to Design MyLungHealth: We will recruit providers from representative study clinics. Recruitment will be conducted in-person or via email, with invitations originating from respected clinical champions on the project team. Interviewees will be recruited from study clinics.

Aim 1g. Provider and Staff Participation in Pilot Implementation of MyLungHealth: Because the intervention is promoting standard of care, we will base our approach on how other health IT interventions are introduced in the clinical setting to promote standard of care. The PI is Associate Chief Medical Information Officer for University of Utah Health (UUH) and routinely introduces similar interventions for operational purposes outside of a research context. We will follow this usual process, including seeking approval from relevant governance groups such as the Community Physician Group Medical Directors or the EHR Operations committee. We will seek a waiver of informed consent for individual providers and staff as described later.

Aim 1h. Provider Interviews to Evaluate Acceptability of MyLungHealth During Pilot Implementation: We will recruit providers whose patients used MyLungHealth. Recruitment will be conducted in-person or via email by clinical leaders at the pilot clinics. Potential interviewees will also be identified by asking providers in the Aim 1i surveys if they would be interested in being interviewed.

Aim 1i. Patient Surveys to Evaluate MyLungHealth in Pilot Implementation: All pilot participants may be invited to participate in an online survey using the same methods described in 1d.

Aim 1j. Provider Surveys to Evaluate MyLungHealth in Pilot Implementation: All pilot participants may be invited to participate in an online survey using the same methods described in 1h. Providers will be given patient details in the recruitment email to help them remember and identify patients who have used the tool. HIPAA-compliant communication mechanisms will be used in the case that patient details include PHI.

Aim 2. Evaluate the impact of MyLungHealth.

Aim 2a. Patient Participation in Clinical Trial: Because the intervention is promoting standard of care, we will base our approach on how other health IT interventions are operationally introduced into the clinical setting to promote standard of care. The PI (Dr. Kawamoto) is Associate Chief Medical Information Officer for University of Utah Health (UUH) and routinely introduces similar interventions for operational purposes outside of a research context. We will follow usual processes for introducing health IT interventions promoting standard of care into the clinical setting, including seeking approval from relevant governance groups such as the UUH Community Physician Group Medical Directors or the UUH EHR Operations committee. We will seek a waiver of informed consent for individual providers and staff as described later. We will seek a waiver of informed consent for targeted patients as described later.

Aim 2b. Patient Surveys to Evaluate MyLungHealth in Clinical Trial: Survey study participants will be recruited electronically, including by text message where allowed by local governance, or via postal mail. Patients will be recruited if they received the project interventions, had an LDCT ordered, or had LCS SDM documented.

Aim 2e. Provider and Staff Participation in Clinical Trial: We will use the same approach as for the *Aim 1g. Provider and Staff Participation in Pilot Implementation of MyLungHealth*.

Aim 2f. Provider Surveys to Evaluate MyLungHealth in Clinical Trial: We will use email to recruit providers whose patients used MyLungHealth. Providers will be given patient details in

the recruitment email to help them remember and identify patients who have used the tool. HIPAA-compliant communication mechanisms will be used in the case that patient details include PHI.

Aim 2i. Patient Outcomes Assessment in Clinical Trial: The recruitment approach will be the same as for the patient participation in the *Aim 2a. Patient Participation in Clinical Trial.*

Aim 2j. Provider and Staff Intervention Usage Assessment in Clinical Trial: The recruitment approach will be the same as for the *Aim 2e. Provider and Staff Participation in Clinical Trial*.

Aim 2k. Data Quality Evaluation: We will conduct retrospective data analyses. We will seek a waiver of authorization as described later.

Aim 2l. Stakeholder Interviews to Evaluate Implementation: We will recruit key stakeholders of MyLungHealth implementation. Recruitment will be conducted in-person or via email, with invitations originating from informatics leaders well known to the stakeholders.

Aim 2m. Stakeholder Focus Groups to Evaluate Implementation: We will use the same recruitment methods described in 2l.

Aim 3. Develop and Evaluate a Replicable Approach for Real-World Dissemination and Implementation of Interoperable CDS.

Aim 3a. Project Champion and Technical Lead Interviews to Assess Implementation Context: We will recruit participants as a part of the process of on-boarding new adoption sites seeking to implement DP+.

Aim 3b. Project Champion and Technical Lead Surveys to Assess Implementation Context: We will use the same approach as for the *Aim 3a. Project Champion and Technical Lead Interviews to Assess Implementation Context*.

Aim 3c. Project Champion and Technical Lead Interviews to Evaluate Implementation: We will use the same approach as for the *Aim 3a. Project Champion and Technical Lead Interviews to Assess Implementation Context*.

Aim 3d. Project Champion and Technical Lead Surveys to Evaluate Implementation: We will use the same approach as for the *Aim 3a. Project Champion and Technical Lead Interviews to Assess Implementation Context*.

Informed Consent:

Description of location(s) where consent will be obtained:
For interviews and focus groups, it is expected that consent will be obtained virtually, at clinics, or in meeting rooms. For surveys, it is expected that consent will be obtained virtually, at the clinics, or at the respondents' homes.

Description of the consent process(es), including the timing of consent: For interviews and focus groups, we will provide a Consent Cover Letter and inform participants that proceeding with the interview or focus group will constitute consent. Participants will be informed that they can stop participating at any time. Surveys will begin with the contents of the Consent Cover Letter which will describe the study, make clear that participation is voluntary, and note that proceeding with the survey will constitute consent. Participants will be informed that they can stop participating at any time. For the pilot implementation and clinical trial, a waiver of informed consent for providers, staff, and patients is sought following assent of the clinical leadership (see Waiver request).

Requested Waivers/Alterations of Consent:

Waiver of Informed Consent	Request for waiver of consent for patient to have their providers and staff to have access to the IT intervention promoting standard of care, and to evaluate their data to assess intervention impact. The applicable aims are as follows: > Aim 1c. Patient Participation in Pilot Implementation of MyLungHealth > Aim 2a. Patient Participation in Clinical Trial
Waiver of Informed Consent	Request for waiver of consent for providers and staff to be exposed to the EHR-based intervention facilitating appropriate lung cancer screening based on USPSTF standard-of-care recommendations. The applicable aims are as follows: > Aim 1g. Provider and Staff Participation in Pilot Implementation of MyLungHealth > Aim 2e. Provider and Staff Participation in Clinical Trial

Procedures:

Listed below are the anticipated procedures for the human subjects research aspects of this project. Procedures for activities outside of humans subjects research are not listed, such as engagement with standards development organizations to advance relevant health IT standards; software development, implementation and monitoring undertaken to fulfill clinical operations and operational quality improvement responsibilities rather than for research purposes; and making the software developed in this project available in EHR app stores.

Participants will be recruited by research staff at their own institution. UUH research staff will conduct all interviews, focus groups, and surveys, although NYU research staff may participate. Recordings, transcripts, and surveys may be shared across the research teams. All sharing will be done using approaches that are HIPAA compliant. In general, interviews are expected to take approximately 1-2 hours, and focus groups are expected to take approximately 2 hours. When required by the site for employees, these activities will take place outside of their normal work hours. Focus groups and interviews will be recorded and professionally transcribed for analysis. Sample questions for all semi-structured interviews and focus groups are included in documents. Wording may be modified as the study progresses to meet study aims. Interviews and focus groups may be conducted online (e.g., via Zoom) or in person. Provision of gift certificates for both sites will be managed by UUH staff.

For focus groups and interviews, prepared scripts will be used. For focus groups, non-threatening group processes will be used, and Ground Rules shared with the participants will include the following:

- There are no right or wrong answers, only differing points of view.
- We are audio recording our session for later transcription.
- Please speak one at a time.
- You don't need to agree with others, but you must listen respectfully as others share their views.

Your responses are confidential. We request that you not share specific information about this conversation with others. No information linked to you directly will be used in any publication or report.

- My role as moderator will be to guide the discussion. Please talk to each other.

Aim 1. Adapt DP+ to include a patient-facing SMART on FHIR app (MyLungHealth).

Aim 1a. Patient Focus Groups to Design MyLungHealth: We will start with focus groups to guide the initial design of MyLungHealth. Spanish speakers will be included in the later phases of the design process following the translation of app contents into Spanish. The initial focus groups will take up to 2 hours. After a brief introduction to the purpose of the focus group, participants will be given a short synopsis of lung cancer screening, the challenges we are seeking to address (time pressures and missing or outdated smoking history), and the desire to adapt a clinic-based SDM tool into a tool that patients can access through their PHR to consider whether lung cancer screening is right for them. After obtaining the participants' initial thoughts, we will walk through representative clinical vignettes in conjunction with our initial proposal for MyLungHealth.

Once we assess that MyLungHealth is ready for clinical use, we will convene focus group cohorts to review the release candidate. Participants will be provided with a brief summary of the background materials and then review the application and provide feedback. The primary goal will be to confirm that the app has face validity, the information presented is clear, and patients will not experience undue stress from being provided access to MyLungHealth. Any final issues identified will be addressed prior to releasing the tool. Participants may also be asked to complete questionnaires regarding MyLungHealth.

Aim 1b. Patient Interviews to Design MyLungHealth: These interviews will be conducted as individual 2-hour cognitive walkthrough interviews. Participants will be asked to use a smartphone, tablet, and/or computer to use the tool and provide feedback. Clinical vignettes will be pre-configured in prototypes. The tool will be iteratively refined. The final set of interviews will include Spanish speakers following Spanish translation of the app.

If there is time, participants will also be asked to provide feedback on the planned patient survey of MyLungHealth, and adjustments will be made as necessary based on the feedback.

Aim 1c. Patient Participation in Pilot Implementation of MyLungHealth: We plan an up to 4-month pilot phase. During this phase, the project interventions will be deployed in the pilot clinics. Usage will be monitored to evaluate intervention acceptability. The feedback and insights obtained through the pilot implementation will be used to iteratively enhance the interventions prior to the Aim 2 implementation trial.

Aim 1d. Patient Interviews to Evaluate Acceptability of MyLungHealth During Pilot Implementation: We will ask patients about their experience with MyLungHealth. The feedback will be used to iteratively enhance the CDS intervention.

Aim 1e. Provider Interviews to Design MyLungHealth: The focus of the interviews will be on the entire MyLungHealth process, including proposed approaches for proactively reaching out to patients. The prototype will be refined based on the interview findings.

Aim 1g. Provider and Staff Participation in Pilot Implementation of MyLungHealth: The procedures are described under the *Aim 1c. Patient Participation in Pilot Implementation of MyLungHealth*.

Aim 1h. Provider Interviews to Evaluate Acceptability of MyLungHealth During Pilot Implementation: The critical incident technique will be used, involving asking the interviewee to describe their experience with MyLungHealth. The feedback will be used to iteratively enhance the CDS intervention.

Aim 1i. Patient Surveys to Evaluate MyLungHealth in Pilot Implementation. We plan to conduct online surveys covering three topics: the patient's recent visit with lung cancer screening discussion; the patient's understanding and feelings about lung cancer screening; and information about the patient and their smoking history. Surveys will be administered online through a HIPAA-compliant survey tool such as REDCap.

Aim 1j. Provider Surveys to Evaluate MyLungHealth in Pilot Implementation. Online surveys will focus on SDM quality and intervention usefulness. The survey will be administered through a HIPAA-compliant survey tool such as REDCap.

Aim 2. Evaluate the impact of MyLungHealth.

Aim 2a. Patient Participation in Clinical Trial: We will conduct a 1-year patient-randomized controlled trial of MyLungHealth. The provider-facing DP+ will be available to all providers, along with ancillary CDS to prompt providers and patients to consider lung cancer screening when eligibility criteria are met. For patients in study 2 (Study of patients with uncertain LCS eligibility), invitations to use MyLungHealth will be proactively sent through the PHR to

patients prior to primary care visits when they are eligible for and in need of lung cancer screening and lung cancer screening education. Study 1 patients (Study of patients with documented LCS eligibility) will also be sent a PHR message prior to primary care visits. These potentially eligible patients will be educated on lung cancer screening eligibility criteria and asked about whether they meet these criteria; if they do, they will be offered the MyLungHealth intervention. Provider prompts in the EHR will inform providers regarding their patients' use of MyLungHealth and their potential interest in lung cancer screening.

We will communicate with providers and staff at each intervention clinic to prepare them for the implementation trial. This may involve electronic, virtual, and/or in-person communications, presentations, and/or training. In these communications, we will describe the intervention and provide the opportunity to ask questions.

Following the roll-out, implementation facilitation activities will be conducted. These activities may include regular discussion with clinic leaders to share data on CDS adoption and lung cancer screening; address barriers to adoption; identify "implementation pearls" that facilitate adoption; and share these "pearls" among adoption sites. We will maintain a log of interactions to identify common issues, and issues will be prioritized and addressed.

Aim 2b. Patient Surveys to Evaluate MyLungHealth in Clinical Trial: We will use the same approach as for the *Aim 1i. Patient Surveys to Evaluate MyLungHealth in Pilot Implementation.*

Aim 2e. Provider and Staff Participation in Clinical Trial: The procedures will be the same as for the *Aim 2a. Patient Participation in Clinical Trial*.

Aim 2f. Provider Surveys to Evaluate MyLungHealth in Clinical Trial: The procedures will be the same as for the *Aim 1j. Provider Surveys to Evaluate MyLungHealth in Pilot Implementation.*

Aim 2i. Patient Outcomes Assessment in Clinical Trial: Data for analysis will be extracted from the data warehouse and system logs. Outcome measures are described under section 9 below. A PhD-level statistician co-investigator will oversee the statistical analyses.

Aim 2j. Provider and Staff Intervention Usage Assessment in Clinical Trial: The same approach will be used as for the *Aim 2i. Patient Outcomes Assessment in Clinical Trial*.

Aim 2k. Data Quality Evaluation: As part of standard quality assurance procedures, we will assess the quality of the underlying data used for the interventions and evaluations.

Aim 2l. Stakeholder Interviews to Evaluate Implementation: We will conduct interviews with key implementation stakeholders regarding their experience with the implementation.

Aim 2m. Stakeholder Focus Groups to Evaluate Implementation: We plan to conduct focus groups to evaluate the scalable dissemination of MyLungHealth. We will focus on facilitators and barriers to CDS adoption.

Aim 3. Develop and Evaluate a Replicable Approach for Real-World Dissemination and Implementation of Interoperable CDS.

Aim 3a. Project Champion and Technical Lead Interviews to Assess Implementation Context:

Pre-implementation assessments of health systems embarking on DP+ implementation will be conducted as virtual interviews with key implementation stakeholders. Initial assessments will be conducted via interviews using a CFIR-based interview guide.

Aim 3b. Project Champion and Technical Lead Surveys to Assess Implementation Context: Pre-implementation assessments of health systems embarking on DP+ implementation will be conducted as surveys designed to access inner setting characteristics of the adopting organizations and the initial perceptions of key stakeholders related to DP+.

Aim 3c. Project Champion and Technical Lead Interviews to Evaluate Implementation: Approximately one year after pre-implementation assessment, we plan to conduct post-implementation assessments with key implementation stakeholders to understand their experience of implementation. Interviews will be conducted using the critical incident technique, and surveys will be developed and validated based on interview findings.

Aim 3d. Project Champion and Technical Lead Surveys to Evaluate Implementation: Approximately six months to one year after pre-implementation assessments, we plan to conduct post-implementation surveys with 2-3 key implementation stakeholders to understand their experience of implementation. The surveys will include questions about feasibility, acceptability and sustainability of DP+ in the adopting organizations.

Our grant application matches the ERICA application in the following areas: study design, study population, study objectives and goals, and study test interventions and procedures. Sample recruitment emails and electronic messages, recruitment flyers, consent cover letters, focus group and interview guides, and surveys have been uploaded in the Document and Attachment section. In case of any edits, all of these materials will be submitted to the IRB via amendment for review and approval before they are used with participants.

Procedures performed for research purposes only:

Statistical Methods, Data Analysis and Interpretation

For Aims 2l, 2m, 3a, and 3c, we will augment interviews and focus groups with intervention implementation stakeholders through the review of a range of project documents, which may include project meeting minutes and other project materials (e.g., e-mail correspondence, slide presentations). Findings from the document review process will be analyzed along with qualitative and quantitative data.

Aim 1. Adapt DP+ to include a patient-facing SMART on FHIR app (MyLungHealth).

Aim 1a. Patient Focus Groups to Design MyLungHealth: As stated above, all interview and focus group sessions will be recorded and professionally transcribed. The transcripts will be analyzed using qualitative analysis software (such as ATLAS or NVivo), which can integrate transcripts, pictures, memos and other materials. We will use procedures recommended by Patton and others that focus on developing coding protocols to highlight issues, problems, and potential recommendations. The coding team will work together as a group to develop themes relating to MyLungHealth and its design.

Aim 1b. Patient Interviews to Design MyLungHealth: We will use the analysis methods as for the *Aim 1a. Patient Focus Groups to Design MyLungHealth.*

Aim 1c. Patient Participation in Pilot Implementation of MyLungHealth: Please see the analysis plan in the *Aim 2i. Patient Outcomes Assessment in Clinical Trial* below.

Aim 1d. Patient Interviews to Evaluate Acceptability of MyLungHealth During Pilot Implementation: We will use the analysis methods as for the *Aim 1a. Patient Focus Groups to Design MyLungHealth.*

Aim 1e. Provider Interviews to Design MyLungHealth: We will use the analysis methods as for the *Aim 1a. Patient Focus Groups to Design MyLungHealth.*

Aim 1g. Provider and Staff Participation in Pilot Implementation of MyLungHealth: Please see the analysis plan in the *Aim 2i. Patient Outcomes Assessment in Clinical Trial* below.

Aim 1h. Provider Interviews to Evaluate Acceptability of MyLungHealth During Pilot Implementation: We will use the analysis methods as for the *Aim 1a. Patient Focus Groups to Design MyLungHealth.*

Aim 1i.Patient Surveys to Evaluate MyLungHealth in Pilot Implementation. Descriptive data analysis will be conducted. Where relevant, we will examine survey data relating to usability and cognitive workload assessment; compare overall tool usability using norms (e.g., scores above 68 = above average usability); examine workload and how workload relates to roles and demographic characteristics; and use correlational analyses, regression analyses and univariate and multivariate methods. We may also examine psychometrics (e.g., Cronbach's alpha, factor analysis) of surveys. We may also compare patient and provider differences related to perceptions of shared decision making. We will evaluate the survey data along with existing information in the EHR, so as to reduce the amount of data that need to be collected from patients (e.g., detailed clinical information needed to calculate a patient's risk for lung cancer).

Aim 1j.Provider Surveys to Evaluate MyLungHealth in Pilot Implementation. We will use similar procedures as for Aim 1i.

Aim 2. Evaluate the impact of MyLungHealth.

Aim 2a. Patient Participation in Clinical Trial: Please see the analysis plan in the *Aim 2i. Patient Outcomes Assessment in Clinical Trial* below.

Aim 2b. Patient Surveys to Evaluate MyLungHealth in Clinical Trial: We will use similar procedures as for Aim 1i.

Aim 2e. Provider and Staff Participation in Clinical Trial: Please see the analysis plan in the *Aim 2i. Patient Outcomes Assessment in Clinical Trial* below.

Aim 2f. Provider Surveys to Evaluate MyLungHealth in Clinical Trial: We will use similar procedures as for Aim 1i.

Aim 2i. Patient Outcomes Assessment in Clinical Trial

Outcomes for patients who are potentially eligible for LCS will be assessed in study 1 and outcomes for patients with documented LCS eligibility at the start of the trial will be assessed in study 2. The primary hypotheses and outcomes for both studies are described below.

Study 1 Primary Hypothesis: Among primary care patients aged 50–79 with uncertain LCS eligibility, MyLungHealth eligibility questionnaires and education will result in increased identification of LCS-eligible patients.

Study 2 Primary Hypothesis: Among primary care patients aged 50–79 with documented LCS eligibility, MyLungHealth education will result in increased LDCT ordering among patients with documented LCS eligibility.

<u>Outcomes:</u>

The primary outcome for Study 1 will be the identification of LCS-eligible patients during the 1-year trial among patients with uncertain LCS eligibility at the start of the trial. Patients will be considered to fulfill this outcome if, at any point during the 1-year trial, the patient's EHR record indicates they meet smoking history eligibility criteria, or a patient affirms they meet eligibility criteria in the patient portal. Secondary outcomes for Study 1 will be LDCT ordering and completion during the 1-year trial among patients with uncertain LCS eligibility at the start of the trial.

The primary outcome for Study 2 will be LDCT ordering during the 1-year trial among patients with documented LCS eligibility as per EHR data at the start of the trial. A secondary

outcome for Study 2 will be LDCT completion during the trial. Another secondary outcome for Study 2 will be LCS care-gap closure, defined as the identification and completion of recommended care services among patients eligible for LCS according to the EHR. LCS care-gap closure could be achieved through LDCT completion, other chest CT completion, or documented SDM.

Other planned outcomes include estimated number of lung cancer deaths averted and life-year gains per 1,000 patients; estimated # of lung cancer deaths averted and life-year gains per major complication from screening; intervention use measures (e.g., invitations sent, app launches, viewing of app sections); patient knowledge, preferences, decisional conflict, and perceived SDM quality; smoking history measures (availability of complete and accurate smoking history, history updates); process measures including time spent by providers and patients with provider-facing DP+ and MyLungHealth (obtained from system logs); patient and provider assessment of intervention via SUS and NASA TLX surveys; and, to the extent allowed by governance, operating margin attributable to study patients during the study period.

Data Extraction and Management. Data for analysis will be extracted from the data warehouse. During the clinical trial, patient related data will be transformed into a limited dataset if data needs to be shared across institutional boundaries for data analyses in a HIPAA compliant manner. The sharing of the limited dataset will be from NYU to UUH, where the analyses will be conducted. Content of the limited data set are described in the NYU Data Use Agreement.

To the extent allowed by governance, return on investment analyses will be conducted at UUH and leverage a value analysis tool co-developed by PI Kawamoto to determine the true costs of care.

Covariates. Covariates will include patient demographics, Social Vulnerability Index (SVI), Rural Urban Commuting Area (RUCA), and other patient characteristics including PHR utilization, lung cancer risk factors, and clinic characteristics including health system affiliation, number of providers, and provider specialty.

Covariate Adjustment. The number of units of randomization may not be large enough to guarantee covariate balance. Thus, we will collect covariate data, assess for balance, and adjust for covariates as needed.

Statistical Analysis. The distribution of the primary outcome and other variables for enrolled patients eligible for LDCT screening will be summarized and compared using the chi-squared test for categorical variables or the two sample Student's t-test (or its non-parametric counterpart) for continuous variables. The primary analyses are to compare the population level differences in the primary outcomes between intervention and control arms. We will use generalized estimating equations (GEE) with appropriately selected link function based on the type of outcome to make the comparison after accounting for key confounders. We may adjust for key covariates using the inverse probability of treatment weighting with propensity score.

The difference estimation will be performed under the intention-to-treat principle. The health care system will be included in the model as an effect modifier.

Missing data frequently occur in pragmatic clinical trials with long study periods. If data can be assumed to be missing at completely random, standard GEE will be used. Otherwise, weighted GEE will be considered when a missing at random assumption is more realistic. If observations are neither missing at completely random nor missing at random, a more advanced multiple imputation approach will be used to draw valid inferences. All analyses will be conducted using R and statistical significance will be defined at alpha = 0.05.

Sample Size and Study Power. Empirical EHR data indicate that the number of distinct patients to be included in the primary analyses will be approximately 38,943 patients for Study 1 and 3,153 patients for Study 2. To estimate statistical power for Study 1, we assumed that the rate of identification of screening-eligible patients will be at least 20% in the MyLungHealth arm vs. 5% in the control arm. For Study 2, we assumed the rate of screening among eligible patients will be at least 30% in the intervention group vs. 20% in the control group. Given 1:1 allocation, we found that we would have >99% power to detect the estimated intervention effect with a two-sided test with a significance level of alpha = 0.05 for both Study 1 and Study 2.

Covariate Association Analyses. We will assess the association of covariates with study eligibility and study outcomes. For example, we will assess whether patients with a more disadvantaged background according to the SVI were more likely to not have used the patient portal in the year preceding the start of the study, and therefore were more likely to be excluded from the study. As another example, we will assess whether patients with a more disadvantaged background according to the SVI were less likely to engage with and benefit from the study intervention.

Subset Analyses. In prior research, we and others have found disparities in lung cancer burden and screening among women and racial/ethnic minority populations. Thus, we will conduct subset analyses to assess MyLungHealth's impact among subsets of patients including female and minority patients, as well as patients with different SVI and RUCA characteristics.

Aim 2j. Provider and Staff Intervention Usage Assessment in Clinical Trial: Utilization metrics will include the number of clinics, providers, and other empowered staff utilizing the intervention.

Aim 2k. Data Quality Evaluation. We plan to analyze data to find and address data quality issues such as missing data or potentially inaccurate data.

Aim 2l. Stakeholder Interviews to Evaluate Implementation: We will use the analysis methods as for the *Aim 1a. Patient Focus Groups to Design MyLungHealth.*

Aim 2m. Stakeholder Focus Groups to Evaluate Implementation: We will use the analysis methods as for the *Aim 1a. Patient Focus Groups to Design MyLungHealth.*

Aim 3. Develop and Evaluate a Replicable Approach for Real-World Dissemination and Implementation of Interoperable CDS.

Aim 3a. Project Champion and Technical Lead Interviews to Assess Implementation Context: We will use the analysis methods as for the Aim 1a. Patient Focus Groups to Design MyLungHealth.

Aim 3b. Project Champion and Technical Lead Surveys to Assess Implementation Context: Descriptive and correlational data analysis will be conducted.

Aim 3c. Project Champion and Technical Lead Interviews to Evaluate Implementation: We will use the analysis methods as for the *Aim 1a. Patient Focus Groups* to *Design* MyLungHealth.

Aim 3d. Project Champion and Technical Lead Surveys to Evaluate Implementation: Descriptive and correlational data analysis will be conducted.