# HModEx®, a cloud-based, centralized health economic model marketplace to reduce costs and enhance equity in cancer

**Unique Protocol Identification Number: 1R43CA297808-01**

**National Clinical Trial (NCT) Identified Number:**

**Principal Investigator: Renée JG Arnold, PharmD**

**Sponsor:**

*Arnold Consultancy & Technology, LLC*

**Grant Title: HModEx®, a cloud-based, centralized health economic model marketplace to reduce costs and enhance equity in cancer**

**Grant Number: 1R43CA297808-01**

**Funded by: NCI**

**Version Number: v.0.010**

**20 August 2024**

## Summary of Changes from Previous Version:

| Affected Section(s) | Summary of Revisions Made | Rationale |
|---|---|---|
| Multiple | Used System Usability Scale in Aim 1, as well as in Aim 2 | Objective measurement of usability for Aim 1 |
| 6.2.1 and 10.1.9.1 | Substituted Mr. Philbin for Ms. Cooley as UX/UI expert | Better fit for the study |

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# Statement of Compliance

The trial will be conducted in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP), applicable United States (US) Code of Federal Regulations (CFR), and the National Cancer Institute Terms and Conditions of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the funding agency and documented approval from the Institutional Review Board (IRB), where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

## Investigator's Signature

**Principal Investigator or Clinical Site Investigator:**

Signed:  Date: November 20, 2025

Name*: Renée JG Arnold, PharmD
Title*: Principal Investigator

**Investigator Contact Information:**

Affiliation*: Arnold Consultancy & Technology, LLC
Address: 15 West 72nd Street – 23rd Floor, NY, NY 10023
Telephone: 917.945.3267
Email: rarnold@arnoldllc.com

**For multi-site studies, the protocol should be signed by the clinical site investigator who is responsible for the day to day study implementation at his/her specific clinical site:**

Signed:  Date: November 20, 2025

Name*: Renée JG Arnold, PharmD
Title*: Principal Investigator
Affiliation: Arnold Consultancy & Technology, LLC

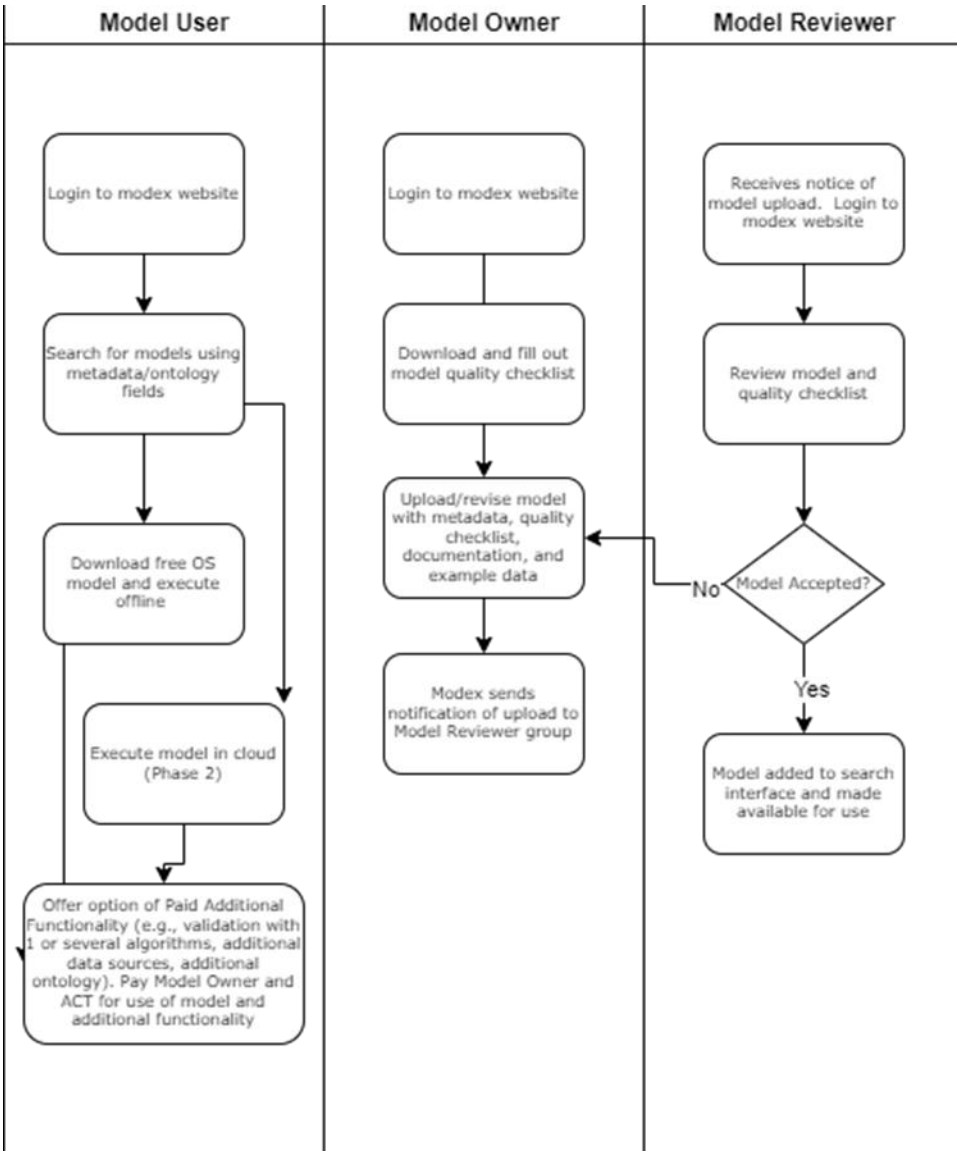
# 1 Protocol Summary

## 1.1 Synopsis

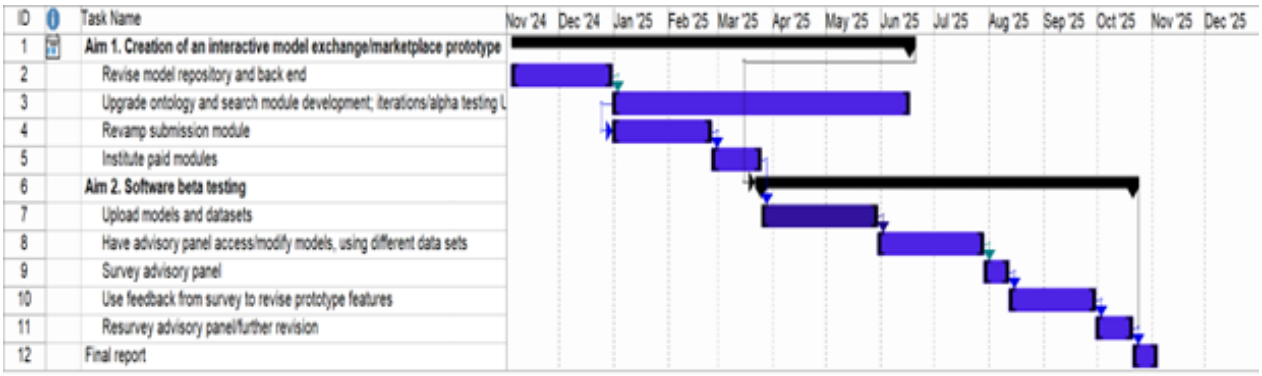
| | | |
|---|---|---|
| **Title:** | HModEx®, a cloud-based, centralized health economic model marketplace to reduce costs and enhance equity in cancer | |
| **Grant Number:** | 1R43CA297808-01 | |
| **Study Description:** | The investigators intend to create and test an interactive prototype of an online health economic model platform, HModEx®™, to house oncology models. | |
| **Objectives:** | Primary Objective: | Create the HModEx® health economic model platform |
| | Secondary Objectives: | Conduct usability testing of search, quality and collaboration on the HModEx® prototype for 20 oncology health economic models |
| **Endpoints:** | Primary Endpoint: | Iteratively unit test 4 tasks (A) Revise model platform and back end, (B) Refine the model taxonomy/characterization (i.e., ontology) and search module, (C) Revamp submission module, and (D) Implement paid modules) individually to ascertain 100% pass of common functionality (e.g., searching, uploading, and evaluating models) in the system back end and then iteratively perform integration testing via the front-end user interface until 100% pass using the System Usability Scale (SUS), a validated questionnaire. |
| | Secondary Endpoints: | Measure the success of Aim 2 by (1) completion of 80% of tasks in usability testing with scores of ≥68 on the SUS, and (2) satisfaction with the site. Testing will focus on user interaction with the system, emphasizing effectiveness, efficiency, engagingness, error tolerance, and ease of learning. Specifically, the investigators will assess the ability of the project team and Advisory Panel members to log into the platform, configure and manage their modeling projects, and annotate or categorize |

| | |
|---|---|
| | them in accordance with an ontological index. We will assign panelists to interact with at least 2 randomly selected models and associated data files, iterating on this milestone until the investigators achieve 100% success. |
| **Study Population:** | |
| **Phase* or Stage:** | National Institutes of Health (NIH) Small Business Innovation Research Phase I Study |
| **Description of Sites/Facilities Enrolling Participants:** | 9 Expert Advisory Panel Members (4 from US, 5 from UK/Netherlands) |
| **Description of Study Intervention/Experimental Manipulation:** | Development and test of HModEx® prototype health economic model platform with 9 Expert Advisory Panel members |
| **Study Duration*:** | 1 year |
| **Participant Duration:** | 8 months |

## 1.2 Schema


Model User
Model Owner
Model Reviewer
Login to modex website
Search for models using metadata/ontology fields
Download free OS model and execute offline
Execute model in cloud (Phase 2)
Offer option of Paid Additional Functionality (e.g., validation with 1 or several algorithms, additional data sources, additional ontology). Pay Model Owner and ACT for use of model and additional functionality
Login to modex website
Download and fill out model quality checklist
Upload/revise model with metadata, quality checklist, documentation, and example data
Modex sends notification of upload to Model Reviewer group
Receives notice of model upload. Login to modex website
Review model and quality checklist
Model Accepted?
No
Yes
Model added to search interface and made available for use

## 1.3 Schedule of Activities




# 2 Introduction

## 2.1 Study Rationale

Annually, healthcare stakeholders spend an estimated $1B on health economics and outcomes research (HEOR), much of it to create or recreate computerized health economic (HE) models. They use HE models to estimate the incremental costs and benefits of screening methods and treatments, thus identifying the most cost-effective care and facilitating healthcare decision-making in the United States and globally. Value assessment guidelines developed by practitioner organizations (e.g., the American Society of Clinical Oncology), independent technology assessment review groups (e.g., the Institute for Clinical and Economic Review (ICER)), academicians, managed care organizations (MCOs) and other healthcare institutions often incorporate measures of cost (affordability) and/or cost-effectiveness. Decision-makers are increasingly seeking HE models for use across multiple technologies, as demonstrated by the renal cell carcinoma and non-small cell lung cancer pathway pilots led by the National Institute for Health and Care Excellence (NICE) in the UK. We use the term “HE model” to encompass cost-effectiveness analyses (CEAs), budget impact models (BIMs), and the like. Unfortunately, a significant barrier to using HE models has been insufficient access and transparency. Authors often create models for a single purpose, after which they languish in journal archives, health authority databases or various proprietary settings. With appropriate adaptation and validation, these models can be valuable in their application to other decision problems. The dearth of platforms and standards to facilitate the sharing of computer models makes the models inaccessible to peer reviewers, expert readers, public health officials, and decision makers. When the need arises for a new evaluation to inform health policy or value-based pricing (VBP), such as the need to set a drug’s maximum fair price, stakeholders must reinvent HE models instead of updating or reusing existing work. The creation and management of new models produces a siloed process, requiring considerable time (up to a year) and expense. An open source model (OSM) platform and exchange mechanism that catalogs vetted

models with adequate documentation and is agnostic of model software eradicates many barriers to access. Several initiatives have attempted to address this issue; however, a unifying mechanism for HE model sharing remains an unmet need, as highlighted by multiple entities, such as ISPOR, Health Technology Assessment International (HTAi), and the Society for Medical Decision Making (SMDM).

## 2.2 Background

New cancer drugs have long been at the forefront of research and debate about rising healthcare expenditure in the United States; researchers and decision-makers rely on evidence to support fair pricing and ensure patient access. Health economic (HE) models enable decisions about the pricing and reimbursement of new technologies in the US and globally and support efficient and equitable investments. A significant challenge is that decision-makers perceive HE models to lack credibility because of their “black box” nature and lack of validation, preventing evidence from informing practice. Annually, stakeholders spend an estimated $1B on health economics and outcomes research (HEOR), and there is substantial waste in producing HE models because analysts routinely “reinvent the wheel” for similar decision problems. Sharing models by making their source code openly available would increase credibility and reduce waste for both modelers and Pharma stakeholders. However, prior initiatives have had limited success, partly due to a lack of incentives for model developers to share HE models.

## 2.3 Risk/Benefit Assessment

### 2.3.1 Known Potential Risks

There are no known potential risks to the proposed research.

### 2.3.2 Known Potential Benefits

The benefits are that decision makers will have access to vetted models, which will be more rapid than the typical 9-12 months it takes to develop a model.

### 2.3.3 Assessment of Potential Risks and Benefits

N/A

# 3 Objectives and Endpoints

The prototype will accomplish 4 tasks: (A) Revise model platform and back end, (B) Refine the model taxonomy/characterization (i.e., ontology) and search module, (C) Revamp submission module, and (D) Implement paid modules.

| OBJECTIVES | ENDPOINTS | JUSTIFICATION FOR ENDPOINTS | PUTATIVE MECHANISMS OF ACTION |
|---|---|---|---|
| Primary | | | |
| Create an interactive prototype of HModEx®™ using infrastructure from the Tufts CEVR Open-Source Model Clearinghouse framework. | The prototype will accomplish 4 tasks: (A) Revise model platform and back end, (B) Refine the model taxonomy/characterization (i.e., ontology) and search module, (C) Revamp submission module, and (D) Implement paid modules. | To evaluate the endpoints, the investigators will Iteratively unit test all 4 tasks individually to ascertain 100% pass of common functionality (e.g., searching, uploading, and evaluating models) in the system back end and then iteratively perform integration testing via the front-end user interface until 100% pass using the System Usability Scale. | N/A |
| Secondary | | | |
| Conduct usability testing of search, quality and collaboration on the HModEx® prototype. | We will use a convenience sample of 20 existing oncology OS models from GitHub, the literature and the Advisory Panel (using a combination of existing ontologies), accessed and analyzed using new settings/populations by 8 of a 10-member Advisory Panel (2 are Pharma only) and evaluated using the AdViSHE validation assessment tool to document model quality. | Measure the success of Aim 2 by (1) completion of 80% of tasks in usability testing with scores of ≥68 on the System Usability Scale, a validated questionnaire, and (2) satisfaction with the site. Testing will focus on user interaction with the system, emphasizing effectiveness, efficiency, engagingness, error tolerance, and ease of learning. Specifically, | N/A |

| OBJECTIVES | ENDPOINTS | JUSTIFICATION FOR ENDPOINTS | PUTATIVE MECHANISMS OF ACTION |
|---|---|---|---|
| | | the investigators will assess the ability of the project team and Advisory Panel members to log into the platform, configure and manage their modeling projects, and annotate or categorize them in accordance with an ontological index. We will assign panelists to interact with at least 2 randomly selected models and associated data files, iterating on this milestone until the investigators achieve at least 75% success. | |
| Tertiary/Exploratory | | | |
| | | | |

# 4 Study Design

## 4.1 Overall Design

This is a single-arm study that will build and evaluate a health economic model platform prototype using a 10-member expert advisory panel of health economists from the US and Europe. For aim 1, Panelists will be randomly assigned to interact with several models according to key use cases (e.g. model publishing, model searching, user registration, user profile updating, payments, etc.), create wireframes for each of these using Axure RP (or equivalent tool), and create a high level click through prototype of the UI for feedback from Advisory Panel (AP) members. Once the UI has been defined, the investigators will code up each use case and alpha test those with 5 AP members. We plan to build unit tests and end user test scripts to help identify bugs as early as possible in the development process and to aid in debugging. A satisfaction questionnaire, using a Likert-like scale, will be devised to ensure that the Advisory Panel finds that 90% of this key functionality is stable; then, the investigators will begin beta testing with selected end users to gather additional feedback.

For aim 2, a primary test dataset comprising 20 oncology OSMs from the AP members, CISNET and websites will be uploaded into the HModEx® platform, annotated, searched for (using a combination of existing ontologies), accessed, and analyzed. Models that meet the vetting criteria will be triaged to one or more AP members based

on their expertise/interests for further validation. The models will be accessed and evaluated for quality using the CADTH validation assessment tool by our 9 modeler AP members. This validation process will include annotation using the ontology module (Aim 1) and activation of a paid module for premium content; for this first phase, the premium content will be simulated and the paid module will be manually administered. The success of Aim 2 will be assessed via the ability to retrieve a model with the requested search characteristics 90% of the time (Aim 2A, 2B) and complete 80% of tasks in usability testing with scores of ≥68 on the System Usability Scale, a validated questionnaire[83], and satisfaction with the site (Aim 2C). Testing will focus on how users interact with the system, emphasizing effectiveness, efficiency, engagingness, error tolerance, and ease of learning [83, 84]; remote usability testing will be conducted using screen-sharing technology. Specifically, the investigators will assess the ability for the project team and AP members to log in, configure/manage their modeling projects, annotate or categorize them according to an ontological index and for each AP member to modify/evaluate at least 2 of the 20 oncology models and associated data files (Figure 4). Panel members will be randomly assigned to thus interact with multiple models; the investigators will iterate on this milestone until 100% achieved. A brief report will be produced that will review quantitative results, qualitative findings, and design recommendations for addressing problem areas. This report will be shared with our AP and will inform any necessary product modifications. The Advisory Panel will be charged with the following responsibilities during alpha and beta testing of our proposed platform:

--6 members alpha testing for 1 hour each@$200/hr, which includes uploading an oncology model of your choosing
--5 members beta testing for 2 hours each for 2 models, which includes interacting with 5 models on the platform

The total remuneration for each Advisory Panel member is up to $2,000 ($200/hr*2 hrs*5 models) over the course of 6-12 months after formal awarding of the project.

## 4.2 Scientific Rationale for Study Design

See Study Rationale above.

## 4.3 Justification for Intervention

N/A

## 4.4 End-of-Study Definition

Achievement of milestones, as above.

# 5 Study Population

## 5.1 Inclusion Criteria

10 Expert Advisory Panel members

## 5.2 Exclusion Criteria

Those not within our already recruited Expert Advisory Panel

## 5.3 Lifestyle Considerations

None

## 5.4 Screen Failures

N/A

## 5.5 Strategies for Recruitment and Retention

The Advisory Panel members have already been recruited from the PI's knowledge base and the ISPOR Open Source Model Special Interest Group.

# 6 Study Intervention(s) or Experimental Manipulation(s)

## 6.1 Study Intervention(s) or Experimental Manipulation(s) Administration

### 6.1.1 Study Intervention or Experimental Manipulation Description

See Overall Design above.

### 6.1.2 Administration and/or Dosing

See Overall Design above.

## 6.2 Fidelity

### 6.2.1 INTERVENTIONIST TRAINING AND TRACKING

The user experience (UX)/user interface (UI)/human factors expert, Mr. Kevin Philbin, has 19 years of experience in this field. He will be developing clickable grayscale wireframes – sufficient to begin evaluating the product against key user tasks. Mr. Philbin will then evaluate this prototype via UX study sessions with 6 AP members. An informal summary of findings and observations will be provided, with learnings incorporated into the following iterative prototype. Second Iteration Prototyping and Testing: Based on learnings from the UX studies of the first iteration prototype, Mr. Philbin and company will collaborate with the programmer to evolve the (or create a new) prototype of the HModEx® platform. The prototype will have higher levels of content, interactive, and/or visual fidelity than the previous prototype, sufficient to validate design changes and continue to evaluate the product against key user tasks. Mr. Philbin will then evaluate this prototype via UX study sessions with 9 Advisory Panel members. Each participant will be asked to complete a System Usability Scale (SUS) questionnaire at the end of their session. Mr. Philbin will provide an informal summary of findings and observations, with all learnings incorporated into a final recommendation for Content, Information Architecture, Screen Layout, Interactive Design, and Visual Design for the initial launch of HModEx®.

## 6.3 Measures to Minimize Bias: Randomization and Blinding

The models will be assigned so as to make sure that the Advisory Panel member to which they are assigned has not previously interacted with this model and has interest in the model subject matter.

## 6.4 Study Intervention/Experimental Manipulation Adherence

N/A

### 6.5 Concomitant Therapy

N/A

#### 6.5.1 Rescue Therapy

N/A

## 7 Study Intervention/Experimental Manipulation Discontinuation and Participant Discontinuation/Withdrawal

### 7.1 Discontinuation of Study Intervention/Experimental Manipulation

Upon achievement of all endpoints for both study aims.

### 7.2 Participant Discontinuation/Withdrawal from the Study

N/A

### 7.3 Lost to Follow-Up

N/A

## 8 Study Assessments and Procedures

### 8.1 Endpoint and Other Non-Safety Assessments

See study design.

### 8.2 Safety Assessments

N/A

### 8.3 Adverse Events and Serious Adverse Events

#### 8.3.1 Definition of Adverse Events

N/A

### 8.3.2 Definition of Serious Adverse Events

N/A

### 8.3.3 Classification of an Adverse Event

N/A

#### *8.3.3.1 Severity of Event*

N/A

#### *8.3.3.2 Relationship to Study Intervention/Experimental Manipulation*

N/A

#### *8.3.3.3 Expectedness*

N/A

### 8.3.4 Time Period and Frequency for Event Assessment and Follow-Up

N/A

### 8.3.5 Adverse Event Reporting

N/A

### 8.3.6 Serious Adverse Event Reporting

N/A

### 8.3.7 Reporting Events to Participants

N/A

### 8.3.8 Events of Special Interest

N/A

### 8.3.9 Reporting of Pregnancy

N/A

## 8.4 Unanticipated Problems

### 8.4.1 Definition of Unanticipated Problems

### 8.4.2 Unanticipated Problems Reporting

A Data Safety and Monitoring Plan (DSMP) will be developed that will include a brief description of the study design, potential risks and benefits for participating in the study, procedures for data review and reportable

events, roles and responsibilities of study staff and the monitoring entity (PI and PhD student), and data management, quality control and quality assurance.

### 8.4.3 Reporting Unanticipated Problems to Participants

This will be within the DSMP.

# 9 Statistical Considerations

## 9.1 Statistical Hypotheses

- Primary Efficacy Endpoint(s):

  To evaluate the primary endpoints, the investigators will Iteratively unit test all 4 tasks individually to ascertain 100% pass of common functionality (e.g., searching, uploading, and evaluating models) in the system back end and then iteratively perform integration testing via the front-end user interface until 100% pass using the System Usability Scale (SUS), a validated questionnaire.

- Secondary Efficacy Endpoint(s):

  We will measure the success of the secondary endpoint by (1) completion of 80% of tasks in usability testing with scores of ≥68 on the SUS, and (2) satisfaction with the site. Testing will focus on user interaction with the system, emphasizing effectiveness, efficiency, engagingness, error tolerance, and ease of learning. Specifically, the investigators will assess the ability of the project team and Advisory Panel members to log into the platform, configure and manage their modeling projects, and annotate or categorize them in accordance with an ontological index. We will assign panelists to interact with at least 2 randomly selected models and associated data files, iterating on this milestone until the investigators achieve at least 75% success.

## 9.2 Sample Size Determination

This is a convenience sample of 20 models to be evaluated by 9 of our Expert Advisory Panel members.

## 9.3 Populations for Analyses

Expert Advisory Panel.

## 9.4 Statistical Analyses

### 9.4.1 General Approach

See above. These are established methods of evaluating UX/UI and software usability.

### 9.4.2 Analysis of the Primary Endpoint(s)

See above.

### 9.4.3 Analysis of the Secondary Endpoint(s)

See above.

### 9.4.4 Safety Analyses

N/A

### 9.4.5 Baseline Descriptive Statistics

Descriptive statistics of the Expert Advisory Panel will include age, sex, primary geography, years of practice in the health economics field, modeling expertise characteristics, and specific expertise in the oncology area.

### 9.4.6 Planned Interim Analyses

N/A

### 9.4.7 Sub-Group Analyses

N/A

### 9.4.8 Tabulation of Individual Participant Data

N/A (Data will be aggregated).

### 9.4.9 Exploratory Analyses

N/A

# 10 Supporting Documentation and Operational Considerations

## 10.1 Regulatory, Ethical, and Study Oversight Considerations

### 10.1.1 Informed Consent Process

N/A

#### *10.1.1.1 Consent/assent and Other Informational Documents Provided to participants*

N/A

#### *10.1.1.2 Consent Procedures and Documentation*

N/A

### 10.1.2 Study Discontinuation and Closure

When all study aims/milestones have been achieved.

### 10.1.3 Confidentiality and Privacy

Participant data will be collected using initials only and all data will be kept in a secure Box file with access only on a need-to-know basis.

### 10.1.4 Future Use of Stored Specimens and Data

All data will be saved in the Box file to inform an SBIR Phase II submission.

### 10.1.5 Key Roles and Study Governance

| **Principal Investigator** | **Medical Monitor or Independent Safety Monitor** |
|---|---|
| Renée JG Arnold, PharmD | |
| | |
| | |
| | |
| | |

### 10.1.6 Safety Oversight

See above about the DSMP.

### 10.1.7 Clinical Monitoring

This will be accomplished by Drs. Arnold and Minhas, as well as by Ms. Wang.

### 10.1.8 Quality Assurance and Quality Control

See above for DSMP.

### 10.1.9 Data Handling and Record Keeping

#### *10.1.9.1 Data Collection and Management Responsibilities*

UX/human factor testing data will be collected by Mr. Philbin and analyzed by Dr. Arnold, Dr. Minhas and Ms. Wang.

#### *10.1.9.2 Study Records Retention*

Study records will be retained in a secure Box account.

### 10.1.10 Protocol Deviations

Protocol deviations will be reported to the IRB within 72 hours, according to the seriousness of the deviation, as delineated in the DSMP.

### 10.1.11 Publication and Data Sharing Policy

Results of the study will be presented and published in a timely fashion.

### 10.1.12 Conflict of Interest Policy

N/A

## 10.2 Additional Considerations

None

## 10.3 Abbreviations and Special Terms

| | |
|---|---|
| AE | Adverse Event |
| ANCOVA | Analysis of Covariance |
| CFR | Code of Federal Regulations |
| CLIA | Clinical Laboratory Improvement Amendments |
| CMP | Clinical Monitoring Plan |
| COC | Certificate of Confidentiality |
| CONSORT | Consolidated Standards of Reporting Trials |
| CRF | Case Report Form |
| DCC | Data Coordinating Center |
| DHHS | Department of Health and Human Services |
| DSMB | Data Safety Monitoring Board |
| DRE | Disease-Related Event |
| EC | Ethics Committee |
| eCRF | Electronic Case Report Forms |
| FDA | Food and Drug Administration |
| FDAAA | Food and Drug Administration Amendments Act of 2007 |
| FFR | Federal Financial Report |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practices |

| | |
|---|---|
| GMP | Good Manufacturing Practices |
| GWAS | Genome-Wide Association Studies |
| HIPAA | Health Insurance Portability and Accountability Act |
| IB | Investigator's Brochure |
| ICH | International Council on Harmonisation |
| ICMJE | International Committee of Medical Journal Editors |
| IDE | Investigational Device Exemption |
| IND | Investigational New Drug Application |
| IRB | Institutional Review Board |
| ISM | Independent Safety Monitor |
| ITT | Intention-To-Treat |
| LSMEANS | Least-squares Means |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MOP | Manual of Procedures |
| NCT | National Clinical Trial |
| NIH | National Institutes of Health |
| NIH IC | NIH Institute or Center |
| OHRP | Office for Human Research Protections |
| PI | Principal Investigator |
| QA | Quality Assurance |
| QC | Quality Control |
| SAE | Serious Adverse Event |
| SAP | Statistical Analysis Plan |
| SMC | Safety Monitoring Committee |
| SOA | Schedule of Activities |
| SOC | System Organ Class |
| SOP | Standard Operating Procedure |
| UP | Unanticipated Problem |
| US | United States |

## 10.4 Protocol Amendment History

| Version | Date | Description of Change | Brief Rationale |
|---|---|---|---|
| 20 November, 2025 | 20 November, 2025 | See page 1 | Better study alignment with endpoints and personnel |

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