OPTIONAL TEMPLATE FOR FINALS APPLICATIONS

*INSTRUCTIONS FOR USE: This is an **optional** template for teams to use for their Finals Application.*

- *Please omit instructions, page limits descriptions, and formatting on this page (do not submit).*
- *Gray italicized fonts are suggestions for materials to be included in each section. Please delete all instructions prior to submission.*
- *Teams may retain, omit, or revise suggested subsection headings (in bold) as needed to customize the template for their team's submission.*
- *Note page limits per section below. Please save each subsection separately for upload on the Prize Operations Platform (POP).*

Contents and Page Limits: *NOTE – Bolded subsections and additional submission components must be saved and uploaded individually*

PRIMARY APPLICATION

- **Summary** **1 page**
- **Summary of Changes to Team or Environment (if relevant)** **2 pages**
- **Scaling Plan & Accessibility** **2 pages**
- **Technical Application** **8 pages**
  1. Updated Scientific Rationale
  2. Review of Preliminary Data and Semi-Finals Study Analyses
  3. Plan for Finals Testing
     A. Population Description
     B. Therapeutic Approach
     C. Control or Standard of Care Group
     D. Randomization and Masking or Blinding Procedures
     E. Anticipated Risks and Safety Monitoring Plan
     F. Regulatory and Ethical Considerations
     G. Study Timeline

Submission Components with No Page Limits

- Regulatory Approval Notice or Ethical Assurance for Semi-Finals Studies
- Recruitment and enrollment reports for Semi-Finals
- Primary analyses from Semi-Finals (if additional space is needed)
- De-identified data set for Semi-Finals (to support enrollment numbers and analyses in final reports)
- References
- Regulatory Approval Letter(s), Informed Consent, or plan for submission for Finals (if available)

Formatting:

Adherence to spacing, font size, type density, and text color requirements is necessary to ensure readability and fairness

- Margins: Must be 0.5 inch (1.27cm) or larger
- Font size: Must be 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible.
- Font type: Sans serif font (Arial, Helvetica, or Calibri preferred)
- Text color: Though not required, black or other high-contrast text colors are recommended.

- No specified citation formatting; the use of "et al." in place of listing all authors of a publication is acceptable.

SUMMARY - 1 PAGE

Overview.
Provide a succinct overview of the therapeutic(s), molecular target (if appropriate), rationale for use in XPRIZE Healthspan, and supportive data available. If the team proposes more than one therapeutic agent, please briefly describe each and the rationale for their combined use. If the team will conduct a screening study during semi-finals to identify the therapeutic / combination / dose / administration / etc. out of a set of therapeutics or molecular targets, please briefly describe the agents to be screened and tested, approach to screening, and provide a supportive rationale.

Team and Clinical Center.
Briefly (2-3 sentences) describe the composition of the competing team, experience of the Team Leader(s), and Clinical Center the team will use. Include only the most relevant expertise or capabilities. If a multi-person leadership team is engaged, describe previous collaborative experience, synergies between leaders, or administrative / organizational structure.

Semi-Finals Findings.
Provide a high-level overview of findings from proof-of-concept clinical studies conducted to meet Semi-Finals stage of competition. Please note the study design, patient population, approximate sample size, intervention, and endpoints as appropriate. If the early stage trial was conducted previously and results are already published, please provide references. Provide a sentence stating how these findings inform the prospective randomized controlled single-crossover trials to be conducted in the XPRIZE Healthspan Finals.

Finals Plan.
Provide a succinct overview of testing approach for Finals. Please note the patient population, describe the intervention group(s), control or standard of care group, primary and other relevant details. Include the number of participants with a summary of a sample size estimate.

Scale & Accessibility.
Describe the ability of the team to scale to one-year trials and resources available to aid ability to advance through prize. Provide a brief statement regarding potential for scalability or accessibility. Teams can note the aspects of the therapeutic(s) that allow it to be tested efficiently, commercialized, or used in the general population. If there are financial implications to administer, abundant compound availability, or commercial incentives for use please note.

SUMMARY OF CHANGES TO TEAM OR CLINICAL CENTER (if needed) - 2 PAGES

Overview of Changes to Team or Clinical Center.
Provide an overview of the team and team experience and note any major changes from Qualifying Submission. As relevant please describe the team composition and attributes and any unique features and expertise of the team or clinical center most relevant to judges.

Below, provide brief rationale for changes from Qualifying Submission as needed:

Team Leader. Role, affiliation(s), experience / expertise.

Team Co-Leader(s) (optional). Role, affiliation(s), experience.
For multi-leader teams, please add a brief narrative description as above for as many team leaders as needed. These persons are analogous to co-inventors or multi-Principal Investigators, depending on the context. The competition only recognizes one Team Leader as point of contact for communications, however teams are allowed to engage a multi-person leadership team or change their leadership team as necessary.

Other Key Personnel (optional). Roles, affiliation(s), experience(s).
Please describe any notable changes to key personnel that would benefit judges review.

Updated Team Expertise & Experience
Update list of the Team's Key Publications, Projects, Patents, or Companies Related to Therapeutic that may be relevant to judging the team if not provided previously or as beneficial to judges.

Overview of Changes to Clinical Center
Provide an overview of updates to the clinical center(s), environment(s), or facilities where the clinical testing or procedures will take place. If you will use multiple clinical centers, please briefly describe each and any unique features and expertise.

Please update below only if needed and relevant to judging for Finals.

Facilities Description
Describe facilities and resources available in the clinical center(s), testing environment(s), or facilities(s) where the testing will take place.

Participant Recruitment Support
Describe the experience of the center's success in recruiting the population to be enrolled in Finals, or relevant recruitment tools or registries that will be employed at the center. Describe the assumptions about screening and enrollment within the timeline. Describe contingency plans for slower than necessary recruitment.

Laboratory Support
Describe laboratory or translational research space and equipment needed to support study protocols or proposed therapeutic solution. For example, phlebotomy services, clinical lab space and support, specialized support for cell collection or isolation of cell subpopulations from peripheral blood mononuclear cells, resources for stem cell or molecular biology approaches, freezers and biorepository.

Other Facilities / Resources Available

SCALING & ACCESSIBILITY - 2 PAGES

Describe other infrastructure or resources needed to support activities proposed in pursuit of the prize not already noted above. This could include biostatistical cores or services or other specialized resource centers.

NOTE: If your scaling and accessibility descriptions have not changed, you may resubmit existing information from your Qualifying Submission.

Scalability

Briefly describe how testing of the therapeutic solution can scale to one-year clinical trials in approximately 100-150 research participants. If foreseeable challenges may be encountered in scaling from the team's small proof of concept Semi-Finals trial to larger trials, please describe how these challenges will be overcome.

Also describe potential to scale the therapeutic solution beyond the prize. This could include production processes, distribution, quality control, and production increases that may be required to test in larger settings or phase III clinical trials or deploy in clinics with 100's to 1000's of participants. For companies, please note scaling objectives for commercialization if relevant to your team, for example - manufacturing and supply chain development, capital and financial resources, market access and commercialization strategy, organizational development, or strategic partnerships and business developments, if available.

If there are potential pitfalls in scaling the therapeutic solution, please discuss how these will be managed or alternative approaches that the team may consider.

Accessibility.

Briefly describe potential accessibility of therapeutic to general population following XPRIZE Healthspan competition, if relevant. Considerations for accessibility include but are not limited to:

- *Cost / affordability*
- *Geographic location and Transport*
- *Consistent product quality*
- *Global supply chain for therapeutic solution components*
- *Burden of administration or required provider format*
- *Potential for overuse of misuse of therapeutic*
- *Ability for target population to adhere to therapeutic solution*

If foreseeable challenges may be encountered in accessibility of the therapeutic solution, please describe how these challenges will be overcome.

TECHNICAL APPLICATION - 8 PAGES

Overview. *EXAMPLE: Our team, XPRIZE HEROES, helped pioneer the use of MEDICINE X (MEDX) that targets biological process Y to extend lifespan and healthspan in animals and rare patient populations. Our Semi-Finals study demonstrated that a combined therapeutic strategy of three weeks daily dosing of MEDX + Other Intervention (OI) resulted in improved biomarkers in 10 middle-aged and older adults with well-managed chronic condition Z. Moreover, our 10 participants were able to successfully adhere to our dosing strategy with no adverse safety events associated with MEDX+OI and minimal negative symptom reporting.*

Based on our regulatory approval and these early findings supporting the feasibility of our approach, we propose to test the effects of MEDX + OI versus standard of care on XPRIZE Healthspan determined Muscle, Cognitive, and Immune endpoints in older adults with stable health condition Z.

I. UPDATED SCIENTIFIC RATIONALE

NOTE: If your rationale and proposed mechanisms have not changed from your Qualifying Submission, you may minimize or omit this section.

Background & Rationale

Please describe your therapeutic solution, and the rationale for use in XPRIZE Healthspan.

Mechanism of Action (optional)

If your therapeutic solution has a known mechanism of action, please describe. You may include graphical representation of the pathways targeted by the therapeutic.

II. REVIEW OF PRELIMINARY DATA AND SEMI-FINALS STUDY ANALYSES

Provide primary findings from your Semi-Finals study to support your proposed therapeutic approach. This must include recruitment of human subjects and intervention testing with regulatory approvals as relevant. You may also include preliminary data to support use of the selected therapeutic solution(s) from drug discovery, animal models, or use in previous clinical studies. Please include a mix of text narrative and data results – tables, graphs, figures, pictures / representative data, etc. Subsections below are suggestions but may not be relevant to your team's solution.

Preliminary Evidence in Humans from Semi-Finals Studies

Describe testing in humans done to date. If regulatory approval to proceed to clinical testing was obtained, please provide relevant approval numbers – e.g. Institutional Review Board number, investigational new drug (IND) application / approval, Clinical Trials Application, Clinical Trials Notification, or similar as relevant. Or please note if study was exempted or regulatory approval otherwise not needed to proceed.

NOTE: enrollment reports, data analyses results, and de-identified data will be submitted separately. These subsequent submissions do not have specific page limits, but brevity is appreciated. This section should be an overview and presentation of key findings useful to judging this competition round, and teams may reference supplemental results / reports.

Please briefly describe the following:

- **Semi-Finals Study Design Overview** *State design in one sentence or less.*
- **Study Recruitment** *Please report the primary method of recruitment and eligibility criteria. Report the number of participants recruited or contacted, the number screened out, and the final number ultimately enrolled in the Semi-Finals study as relevant.*
- **Patient Demographics and Baseline Characteristics.** *Present detailed information about enrolled patients including age, sex, relevant health status or underlying disease severity, comorbidities, concurrent medications or treatments, and other relevant baseline characteristics. May present in text or table format. Please see Competition Guidelines, Appendix B.*

- **Key Preliminary Results**. *Examples include but are not limited to the following; use sections as relevant to your Semi-Finals study:*
    - Quality & Rigor - *e.g. evidence that the data is high quality and rigorously collected?*
    - Feasibility - *e.g. Adherence to therapeutic schedule, dosing strategy, or assessments.*
    - Recruitment - *e.g. Characteristics of the patient population and number of participants who were either enrolled in or completed the study relative to the number of participants expected*.
    - Ethical / Safety Issues and Tolerability - *e.g. comprehensive data covering adverse events (frequency, severity, relationship to treatment), serious adverse events, unanticipated problems, protocol revisions,laboratory abnormalities, vital signs, and any dose-limiting toxicities. Methods used to mitigate risks and evaluate risk:benefit ratio.*
    - Study Outcomes, Data and Analyses - *this section will depend on the team's individual study design and stage of testing proposed in Qualifying Submission, but could include:*
        - Measurement Characteristics and Estimates of Effects - *e.g. estimates of effects on study endpoints relevant to Finals testing, such as measures of muscle, cognitive and immune function, or other data demonstrating a potential plurality of effect on multiple systems relevant to Finals.*
        - Pharmacokinetic and Pharmacodynamic Data – *e.g. drug exposure levels, dose-response relationships, and any biomarker changes that demonstrate target engagement or mechanism of action. Include population PK analysis if applicable.*
        - Biomarker and Translational Data - *e.g. correlative studies that support the mechanism of action, such as target engagement biomarkers, pathway modulation markers, or predictive biomarkers that might inform participant selection or estimates of effect in Finals.*
        - Other Clinical Study Results - *e.g. results as aligned with stated design and approach to Semi-Finals. For very small studies and pilot trials, when possible show individual patient responses alongside group means to demonstrate consistency and identify potential subgroups that may be relevant to the design of your team's Finals trials.*
        - Patient-Reported Outcomes - e.g. *if applicable, include questionnaire data that captures the patient experience and potential clinical meaningfulness of observed short-term changes.*
        - Comparative Context - *if appropriate, position the results within the context of existing treatments, historical controls, or published literature to help interpret the clinical significance of the findings.*
- **Finals Development Implications** - Describe how the Semi-Finals stage will inform your Finals testing, e.g. *dose selection rationale for Finals studies, optimal patient population, potential combination strategies, and any protocol modifications based on the PoC results*

Additional Supportive Evidence: Discovery and Early Therapeutic Development, Pre-Clinical Research or Animal Models

Describe or update your progress in research and discovery to identify the therapeutic, if relevant. This could include use of computer simulation or other in silico approaches, high-throughput screening or molecular techniques, lead-optimization, or cell-based studies. Describe results from testing in preclinical models or animal models over the previous year that support your approach, if relevant.

III. PLAN FOR FINALS TESTING

Overview

Provide a brief overview of your Finals study approach. Assessment measures for judging the Grand Prize will be set by XPRIZE and clinical data will be submitted by teams prospectively via electronic data capture and analyzed centrally by XPRIZE-partner Utah Data Coordinating Center. A clinical protocol with endpoint assessment measures and specimen collections to be followed by teams will be included in a Rules &

Regulations book and prepared for comment by Qualified Teams comment in January 2026. For more information about testing and judging expected in the Finals, refer to Section 9 of the Competition Guidelines.

Study Design Characteristics (for Finals)
Provide a detailed description of the following study design components for your Finals study:

- **Population Description**
- **Intervention(s) or Therapeutic Approach**
- **Control or Standard of Care Group (required for Finals)**
- **Randomization and Masking or Blinding Procedures**
- **Anticipated Risks and Monitoring Plan**
- **Regulatory and Ethical Considerations**
- **Study Timeline**

Participant Recruitment and Retention
Finals testing is time limited and ability to recruit, enroll, and retain at least 100 participants is essential to team success. Please describe:

- *Recruitment resources available to ensure adequate and timely enrollment. Contingency plans if recruitment is slower than necessary to achieve the planned sample size.*
- *Anticipated participant attrition over 1-year intervention period, with realistic estimates based on team experience as applicable.*
- *Resources available to boost participant retention during testing and intervention periods, as well as any follow-up or management plans if relevant.*

Additional Assessments or Resources
If the team plans to conduct additional testing, including biospecimen-based biomarkers or other laboratory methods, describe collections, assays, and other relevant resources anticipated. Similarly, if the Finals study is a substudy of a larger clinical trial, please describe.

Problem Solving and Alternative Approaches
Describe potential pitfalls, and should problems arise how they will be solved. If there are alternative approaches that the team may consider in the face of challenges, please describe.

REGULATORY APPROVAL OR EXEMPTION NOTICE (SEMI-FINALS)

Provide appropriate notice, approval letter, approved application numbers, or other assurances that human subjects safety or ethics board approvals are met for the preliminary data reported in this application for Semi-Finals judging.

RECRUITMENT AND ENROLLMENT REPORTS FOR SEMI-FINALS STUDIES

XPRIZE Healthspan recommends teams to follow the CONSORT (Consolidated Standards of Reporting Trials) statement for reporting participant recruitment and enrollment information. This data is typically presented in the CONSORT flow diagram and accompanying text. Here's what needs to be included for evaluation:

CONSORT Flow Diagram Elements

- ***Initial Screening Phase*** *Report the total number of individuals assessed for eligibility, including how they were identified (e.g., database screening, referrals, advertisements).*
- ***Exclusions with Reasons*** *Document the number of individuals excluded and provide specific reasons for exclusion. Break this down by major exclusion categories such as not meeting inclusion criteria, declining to participate, or other reasons.*
- ***Enrollment and Randomization Numbers*** *Show the number of participants who were officially enrolled and started the therapeutic treatment or randomized to each treatment arm if relevant to the teams Semi-Finals study.*
- ***Participant Tracking*** *Track participants through each phase of the study including those who received allocated intervention, discontinued intervention (with reasons), were lost to follow-up (with reasons), and were analyzed for the outcomes described in the Finals Application.*
- ***Analysis Populations (if relevant)*** *Clearly identify how many participants were included in different analysis sets such as intention-to-treat, per-protocol, and safety populations.*

Accompanying Text Elements

- ***Recruitment Timeline and Methods*** *Describe the recruitment period (start and end dates), recruitment strategies employed, and any modifications to recruitment approaches during the study. Include information about recruitment sites for multi-site studies and any challenges encountered.*
- ***Baseline Characteristics*** *Present demographic and clinical characteristics of enrolled participants, typically in a baseline characteristics table, to describe the study population.*
- ***Protocol Deviations and Violations (if relevant)*** *Report significant protocol deviations and their potential impact on study integrity and results interpretation, if relevant.*
- ***Enrollment Rate Analysis*** *Include information about planned versus actual enrollment numbers and timeline.*
- ***Screening-to-Treated Ratio (or Screening-to-Randomized Ratio)*** *Represent the number of participants screened for eligibility relative to those who started the intervention, to show the selectivity of the study population in Semi-Finals.*
- ***Geographic and Temporal Distribution*** *For multi-site studies, consider including information about enrollment distribution across sites.*

PRELIMINARY DATA REPORT AND ANALYSES FOR SEMI-FINALS STUDIES

As noted in descriptions above for primary Finals Application, this is a supplemental section for teams to provide additional data or analyses done in support of their Semi-Finals studies. Though there is not a specific page limit, brevity is appreciated.

Key Preliminary Results. *Examples include but are not limited to the following; use sections as relevant to your Semi-Finals study:*

- **Feasibility** - *e.g. Adherence to therapeutic schedule, dosing strategy, or assessments. Number of participants who were either enrolled in or completed the study relative to the number of participants expected*.
- **Safety and Tolerability** - *e.g. comprehensive data covering adverse events (frequency, severity, relationship to treatment), serious adverse events, unanticipated problems, laboratory abnormalities, vital signs, and any dose-limiting toxicities*
- **Pharmacokinetic and Pharmacodynamic Data** - *e.g. drug exposure levels, dose-response relationships, and any biomarker changes that demonstrate target engagement or mechanism of action. Include population PK analysis if applicable.*
- **Biomarker and Translational Data** - *e.g. correlative studies that support the mechanism of action, such as target engagement biomarkers, pathway modulation markers, or predictive biomarkers that might inform participant selection or estimates of effect in Finals.*
- ***Other Clinical Study Results*** - *present results for primary endpoints with appropriate statistical analysis as aligned with your stated design and approach to Semi-Finals. For very small studies and pilot trials, when possible show individual patient responses alongside group means to demonstrate consistency and identify potential subgroups that may be relevant to the design of your team's Finals trials.*
- **Patient-Reported Outcomes** - e.g. *if applicable, include questionnaire data that captures the patient experience and potential clinical meaningfulness of observed short-term changes.*
- **Comparative Context** - *if appropriate, position the results within the context of existing treatments, historical controls, or published literature to help interpret the clinical significance of the findings.*

DE-IDENTIFIED DATA FOR SEMI-FINALS STUDIES

Teams are required to submit a spreadsheet (e.g. csv file) or electronic data record with de-identified participant data.

"De-Identified" means the data must not include: *legal names, specific geographic locators such as mailing addresses or subdivisions smaller than a state (e.g. zipcodes), all dates directly related to an individual (birth, hospital admission, hospital discharge, death), vehicle identifiers, telephone numbers, fax numbers, device identifiers and serial numbers, email addresses, web URLs, Social Security numbers, medical record numbers, biometric identifiers including fingerprints and voiceprints, health plan beneficiary numbers, full-face photographs and comparable images, account numbers, any other unique identifying number or code, and certificate/license numbers.*

Extent and Use of De-Identified Data during Judging: *The de-identified data is a limited data set and should only contain data to support the key data provided to support the Semi-Finals study reports. This data will be used ONLY to confirm key preliminary results during judging Finalists if necessary.*

A simplified example for an n=6 pilot study is below:

Pt Code	Age (y)	Sex	Treat Group Code	Pre 6min Walk (m)	Post 6min Walk (m)	Pre NIH Fluid Cognition Score	Post NIH Fluid Cognition Score	GrimAge Change	Vaccine-induced induction of T cell response (log max antibody titer)
001	72	F	Green	421	477	85	89	-6.1	6.8
002	78	M	Blue	417	380	102	100	-0.9	1.4
003	67	F	Green	538	602	110	116	-1.8	8.8
004	62	M	Blue	583	580	114	115	0.1	3.3
005	74	M	Green	527	585	96	101	-2.0	5.8
006	75	F	Blue	422	425	86	85	-0.5	4.9

.

REFERENCES

*Provide references used to support works above (journal article, webpage, book, book section or chapter, dissertation, monograph, official report, white paper, government document, etc.). Though most standard reference formats are acceptable, teams are encouraged to use **Vancouver Style** which is numeric for in text citation (parentheses or superscript) and references listed in this section are numbered in the order in which the corresponding citations appear in your Finals Submission, rather than listed alphabetically by author.*

For a full description of Vancouver Style and examples of formatted references, please see:
National Library of Medicine Samples of Formatted References
(https://www.nlm.nih.gov/bsd/uniform_requirements.html)

Instruction for most commonly encountered citations are below Journal Article, Books, Book Chapter, and Website are below:

Journal article references:
Author(s), Article title, *Journal Title Abbreviation*, Date of Publication, Volume and Issue number, Location (Pagination). DOI doi:10.xxxxxxxxx.

Entire Book, written or compiled by the same author(s)
Author(s). Title of book. Edition. Place of Publication: Publisher; Date.

Chapter of book compiled by an editor with various chapter contributors:
Author(s) of Contribution. Title of contribution. Editor(s) of Book. Title of book. Place of Publication. Edition. Place of Publication: Publisher; Date of Publication. Location of Contribution (page numbers).

Website references contain the following elements in order:
Author(s). Title [Internet]. Place of Publication: Publisher; Date of Publication [Date of Citation]. Available from: URL

OPTIONAL: INFORMED CONSENT OR REGULATORY APPROVAL (FINALS STUDY)

Please provide regulatory approval documentation and informed consent documents for your upcoming Finals study (if available). If such approvals are not yet received, estimated time to submit materials for approval should be indicated in the study timeline in Finals Application.