## OPTIONAL TEMPLATE FOR QUALIFYING SUBMISSIONS

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

- *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 our Qualifying Submissions portal.*

**Contents and Page Limits:** *NOTE – Subsections must be saved and uploaded individually*

- **Summary:** **1 page**
- **Team:** **2 pages**
- **Environment & Clinical Center(s):** **2 pages**

- **Technical Application:** **5 pages**
  Subheadings:
  1. Scientific Rationale
  2. Preliminary Data
  3. Approach to Semi-Finals Testing
     - Study Design for Semi-Finals
     - Ethical Issues
     - Data Management & Statistical Analyses
     - Sample Size Justification

- **Study Timeline:** **1 page**
- **Scale & Accessibility** **1 page**

**Appendices for Judge Considerations:** ***no page limits***

- References
- Plan for Safety of Human Research Subjects
- Biohazards (if applicable)
- Trial Resourcing Plan (if applicable)
- Regulatory materials and informed consent documents (if available), or assurance that such materials will be prepared

**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**.

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

**Clinical Center**.

*Briefly (1-2 sentences) describe type (CRO, academic medical center, private clinic, etc.), location(s), and experience of the clinical center(s) the team will use for clinical trials testing.*

**Semi-Finals Approach.**

*Provide a succinct overview of testing approach for Semi-Finals. List primary objectives or aims for the study, and hypotheses or expected outcomes. Please note the study design, patient population, approximate sample size, intervention group(s), control group (if used), primary and exploratory endpoints to be used, and duration. If the early stage trial was conducted previously and data and results will be submitted for judging with a Finals Application in 2026, please describe the study briefly, explain how it is relevant to the XPRIZE competition, and provide references. Provide a sentence stating how the findings in the early-stage proof of concept or feasibility study will inform the prospective single-crossover trials to be conducted in the XPRIZE Healthspan Finals.*

**Scale & Accessibility**.

*Describe the ability of the team to advance from research and development to 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, scaled for use in larger trials, or used in the general population. If there are financial implications to administer, abundant compound availability, or commercial incentives for use please note*.

TEAM - 2 PAGES

**Team Overview**.
*Provide an overview of the team and team experience. As relevant please describe the team composition and attributes generally – individuals, academic / non profit, student group, research network or collaborative, or commercial company. Describe any unique features and expertise of the team most relevant to judges.*

**Team Leader**. Role, affiliation(s), experience / expertise.
*Please add a narrative description of the Team Leader. Include attributes and expertise necessary for judging the team's qualifying submission and likelihood to successfully advance in the prize.*

**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. Though the competition only recognizes one Team Leader as point of contact for communications, teams are allowed to engage a multi-person leadership team as necessary. These persons are analogous to co-inventors or multi-Principal Investigators, depending on the context.*

**Other Key Personnel** (optional). Roles, affiliation(s), experience(s).
*Please describe key team members, biostatisticians, regulatory consultants, advisory board members, staff, or other key persons engaged team relevant to judging the team's qualifying submission. These persons may not be "co-inventors" but likely have intellectual contribution or important operational roles on the team and decision making capability.*

**Leadership Strategy & Communications**
*For multi-person teams, especially those with one or more Team Co-Leaders, please briefly describe the team organization, communications (especially for teams with more than one site or company), and strategies for conflict resolution. If team has collaborated successfully before, or conducted complex multi-site projects, or if a company has experience that may reflect potential for success in competition, please note.*

**Team Expertise & Experience**
*List the Team's Key Publications, Projects, Patents, or Companies Related to Therapeutic that may be relevant to judging the team if not provided in sections above.*

ENVIRONMENT(S) & CLINICAL CENTER(S) - 2 PAGES

**XPRIZE Clinical Center Overview**

*Provide an overview of 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. If you have yet to select clinical centers that will be engaged for testing, please describe how they are or will be selected.*

*Suggested sections are provided below, but only include descriptions as relevant to your team.*

**Facilities Description**

*Describe facilities and resources available in the clinical center(s), testing environment(s), or facilities(s) where the testing will take place. Also provide an overview of the organizational and administrative infrastructure at the center to develop, implement, and evaluate the team's proposed therapeutic solution in clinical studies.*

**Clinical Center Expertise and Leadership** *(if different than descriptions in Team section)*

*Highlight key research conducted at center, especially those studies relevant to competition (if not described in Team section). Describe relevant experience performing proposed protocols or administering the therapeutic(s).*

**Participant Recruitment Support**

*Describe the experience of the center's success in recruiting the population to be enrolled in Semi-Finals and/or Finals, or relevant recruitment tools or registries that will be employed at the center.*

**Study or Safety Monitoring and Oversight**

*Succinctly provide clinical trials oversight committees available, including Institutional Review Board (IRB), Study Monitoring Committees, or other protocol submission and review processes available at the center(s), or if a central review board will be contracted.*

**Information Technologies**

*Describe clinical center access to computing, digital data management systems, and software packages or electronic data capture systems (e.g. REDCap, Medidata Rave, Medrio, etc).*

**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**

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

TECHNICAL APPLICATION - 5 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. A potential additive effect was observed in persons taking Other Intervention (OI) in our MEDX trial. We propose to test MEDX and OI in early stage trials to identify the appropriate combined dosing strategy to optimize pharmacologic metrics and maximize potential physiologic effects in the XPRIZE Healthspan Finals in persons with well-managed chronic condition Z.*

## I. SCIENTIFIC RATIONAL

### Background & Rationale

*Please describe your therapeutic solution, and the rationale for use in XPRIZE Healthspan. You may include a mix of text narrative and figures as needed. If video is necessary to demonstrate your therapeutic solution, you may include a link. However, judges are not required to follow links outside the Qualifying Submission or view extra materials, so please provide sufficient detail in text and figures to fully describe the therapeutic solution.*

### 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.*

### Supporting Evidence (optional)

*Support rationale using basic research, epidemiologic or clinical studies that suggest effects on endpoints relevant to prize: lifespan / mortality risk, age-related disease, or muscle, cognitive, or immune health. These studies can be conducted by the team or published research generated by others.*

## II. PRELIMINARY DATA

*Prioritize findings by the competing team or partners. Provide preliminary data to support use of the selected therapeutic solution(s) from drug discovery, effect in animal models, or use in clinical studies. Please include a mix of text narrative and data results – tables, graphs, figures, pictures / representative data, etc. If video is necessary to demonstrate effects, you may include a link. However, judges are not required to view or follow links outside the Qualifying Submission, so please provide sufficient detail in text and figures to fully describe the preliminary data. Subsections below are suggestions but may not be relevant to your team's solution.*

### Discovery and Early Therapeutic Development

*Describe early research and discovery to identify the therapeutic, if relevant. This could include use of computer simulation or other in silico approaches, hypothesis-driven target-based approaches, high-throughput screening or molecular techniques, lead-optimization, or cell-based studies.*

### Pre-Clinical Research or Animal Models

*Describe testing in preclinical models or animal models, if relevant.*

### Evidence in Humans (clinical trials, clinical use, or case study)

*Describe testing in humans done to date, if relevant. If regulatory approval to proceed to clinical testing was obtained for clinical studies used as preliminary evidence, please provide relevant approval numbers (investigational new drug, FDA- or EMA-approval, or other). Or, if regulatory approval was not needed to proceed to trials, please note (e.g. supplement, nutritional intervention, exercise or lifestyle approach, IND-exemption, or similar).*

## III. APPROACH TO SEMI-FINALS TESTING

### Overview

*Please provide a brief overview of the study you will conduct during Semi-Finals and how it will inform testing during Finals. If you have already completed your proof of concept / feasibility study in human subjects*

*previously, please provide an overview of the study and how it is relevant to XPRIZE Healthspan. For more information about testing and judging expected in the Semi-Finals, refer to Section 8 of the Competition Guidelines.*

**Study Design Characteristics** (for Semi-Finals)

- Population
- Intervention(s)
- Control (if relevant to your study)
- Outcomes
- Timeline

**Laboratory Methods**

*If biospecimen-based biomarkers or other laboratory methods will be used during the Semi-Finals, describe collections, assays, and other relevant methods.*

**Statistical Methods**

*Describe statistical methods that will be used to analyze data in the Semi-Finals studies.*

**Sample Size**

*Provide rationale and assumptions that inform sample sizes proposed for Semi-Finals.*

**Interpretation of Results**

*Describe possible results and how they interpreted or used to inform the next stage of the competition. If you are screening multiple therapeutic agents describe how you will determine which therapeutic agent or combination will be determined to go forward based on data from Semi-Finals.*

**Safety Monitoring**

*Describe how safety will be monitored during the Semi-Finals and risks minimized.*

**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.*

## TIMELINE - 1 PAGE

*See XPRIZE Healthspan Semi-Finals Timeline Example.*

*If using XPRIZE example timeline template or your own timeline format, please describe anticipated timing for anticipated key milestones, like start-up activities, recruitment, planned assessments, and lab measures or analyses needed. Ensure that activities can be completed and data submitted by early 2026 for Milestone 2 judging prior to Finals. If there are foreseeable challenges that may impact the timeline, please provide alternative approaches or solutions.*

# SCALABILITY & ACCESSIBILITY - 1 PAGE

**Scalability**

*Briefly describe how testing of the therapeutic solution can scale from small early-stage studies to one-year clinical trials in a larger number of research participants (e.g., n > 100). If foreseeable challenges may be encountered in scaling from small 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 discussion of ability to increase the production while maintaining quality and efficiency for commercialization or phase III clinical trials. Beyond physical production, please note prospects for commercial pathways or funding the further development of the therapeutic solution, 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 or phase III clinical trials testing, 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.*

# APPENDIX: REFERENCES

## 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 Qualifying 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

# APPENDIX: SAFETY OF HUMAN RESEARCH SUBJECTS

## I. RISKS TO HUMAN SUBJECTS

### Human Subjects Involvement / Participants Characteristics

*Provide characteristics of subject population (number enrolled, age range, and health status) and inclusion/exclusion criteria if not articulated in Qualifying Submission main text.*

### Collection of Materials, Data, and Information

*Briefly describe what research material, data, and information will be collected in human subjects. If personally identifiable information will be collected and retained, please describe how this information will be managed or protected*.

### Potential Risk(s)

*Describe potential risks to subjects (physical, psychological, financial, legal, or other) by participating in the Semi-Finals studies. Please include likelihood that this risk will be encountered and its seriousness*.

## II. PROTECTION AGAINST RISKS TO HUMAN SUBJECTS

### Participant Recruitment and Informed Consent

*Describe research participant recruitment strategies and Informed Consent process.*

### Plans to Minimize Potential Risks

*For risks described in I. Risks to Human Subject, please note how these will be minimized.*
*Provide detail regarding how medical or professional intervention will be provided for adverse events.*

## III. POTENTIAL BENEFITS AND KNOWLEDGE TO BE GAINED

*Describe anticipated benefits to individuals participating in proposed clinical studies, and how potential risks to subjects are justified in relation to these anticipated benefits.*

*Alternatively, if no direct benefits to individual participants are expected, describe importance of knowledge to be gained, and how potential risks to subjects are justified in relation to the knowledge to be gained.*

## IV. DATA AND SAFETY MONITORING PLAN

### Monitoring and Reporting Plan

*Describe monitoring plan for the clinical study, including who will be responsible for monitoring, and process by which Adverse Events (AEs) and Anticipated or Unanticipated Problems will be reported to appropriate regulatory bodies.*

### Commitment to Communicate Safety Reports to XPRIZE

*Affirm that reports of AEs and Unanticipated Problems will be communicated to XPRIZE as part of Milestone 2 Judging and consideration for continuing to Finals.*

# APPENDIX: BIOHAZARDS

*(IF APPLICABLE) Biohazards are biological organisms or their products (such as toxins) that pose a threat to human health. If team's solution or clinical studies include potential biohazards and other hazards* that may pose a significant risk to research personnel and/or the environment, then please describe how proper handling procedures and adequate protections will be approached.*

**Examples of biohazards or other hazards: radioactivity, dangerous chemicals, or recombinant DNA. Please also see select biologic agents and toxins (e.g. botulinum neurotoxins, Ebola virus, SARS-CoV or SARS-CoV2; see https://www.selectagents.gov/sat/list.htm for list).*

*If NOT applicable and Biohazards are not used in study, please omit this appendix section.*

## APPENDIX: SEMI-FINALS RESOURCING PLAN

*Conducting studies in human research subjects requires appropriate resourcing and financial support. Initiate studies in humans without sufficient support may be ill-advised as it could place enrolled human research participants at risk.*

*Please provide an estimated high-level budget to complete proposed prospective Semi-Finals clinical studies, and resourcing plan to meet budget. The resourcing plan could include existing in-kind support, grants, investors, private research funds, or other funding support.*

*If your team already has sufficient funds in place to support Semi-Finals clinical studies, please state. For in-kind support (received or anticipated), teams are encouraged -- but not required -- to obtain a Letter of Support from the service provider.*

*If there is a gap between existing resources and funds needed to conduct proposed research, please describe a resourcing plan and timeline to fund the Semi-Finals study.*

# APPENDIX: REGULATORY MATERIALS

*Please provide regulatory approval documentation and informed consent documents (if available). If such approvals are not yet received, please provide statement of assurance that such materials will be prepared.*