FREQUENTLY ASKED QUESTIONS

ISSUE 2

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This FAQ is supplemental to the FAQ page on the XPRIZE Healthspan website at www.xprize.org/prizes/healthspan/faq and made available for competing teams on www.pop.xprize.org/prizes/healthspan/resources. Please also reference our first FAQ edition previously released on 09/24/2024 (link here).

Please note, the FAQs below are exclusive to the Healthspan track of the competition. For teams competing in the FSHD Bonus Prize, the FSHD Bonus Prize Rules and Regulations containing specific protocols and guidelines for data collection, as well as a companion FAQ document will be released in Q4 2025.

SEMI-FINALS TESTING AND STUDY ENROLLMENT

1. For biomarker analyses, can we use a qualified laboratory of our choice, or must analyses be performed in an XPRIZE-designated laboratory? Will this approach remain the same for the Finals Testing phase?

You may use your laboratory of choice for Semi-Finals. We will have a central laboratory (to be determined) that teams will be required to use for Finals.

2. Are there any specific laboratory standards, accreditations, or certifications required for the laboratory performing these biomarker analyses to ensure data acceptance by XPRIZE?

Please continue to refer to the Competition Guidelines and FAQ 1 to inform how to conduct the PoC studies for this Semi-Finals phase, and what is expected to be submitted in your Finals application. Please review all mentions of SOP (Standard Operating Procedures) throughout the Competition Guidelines.

3. Regarding the XPRIZE Data Coordinating Center (DCC), is there any specific software or system we need to adopt at the Semi-Finals phase, or does the centralized data submission requirement apply only for Finals Testing?

The Data Coordinating Center only applies for the Finals Testing phase, not Semi-Finals.

At the end of Semi-Finals, teams will submit their enrollment reports, analyses, and de-identified raw data as part of their Finals Application. Only the Top 10 Teams selected for the Finals will have DCC reporting requirements. Please refer to Question #16 in our FAQ 1.

4. Do teams need to include specific endpoints in their PoC studies during the Semi-Finals phase?

No, teams are not required to include any of the specific endpoints listed in Section 9 of the Competition Guidelines, but may do so if they wish. Teams have the freedom and flexibility to define their own endpoints for the Semi-Finals phase of the competition. We do recommend that teams use the Semi-Finals phase to demonstrate plurality of effect, however they choose to do so.

5. Do teams need an IRB even in Semi-Finals?

Yes; see question #15 in the FAQ 1. While teams are only required to conduct small-scale proof-of-concept studies during Semi-Finals, they must provide enrollment reports and de-identified data with their Finals application in 2026. That means the teams must provide evidence that a safety or ethics board (IRB or equivalent for their clinic location) has reviewed and approved BEFORE they conduct human subjects research.

6. Is the use of a Contract Research Organization (CRO) required or strongly recommended?

No, the use of a CRO is not required; that decision is dependent on each team's resources and clinical capabilities should they decide to work with a CRO to achieve the requirements for submitting the Finals application in 2026.

7. Is it acceptable that our patient population will all have slightly different diagnoses, pathologies etc. and be given slightly different protocols personalized to their needs?

Yes, as long as a description of said protocols are provided in your Finals application.

8. Can the proof-of-concept studies be conducted in special populations (e.g. persons with life-limiting illness, physical or cognitive disability, progressive disease, or patients with newly diagnosed clinical disease for whom treatment is not stable, etc.), or are only healthy populations allowed?

Per Competition Guidelines (Section 8, p. 31), *"during Semi-Finals teams are expected to engage the clinical center that will be used in Finals and conduct a small study to demonstrate likelihood of successful completion of a 1-year clinical trial in Finals. Teams will be responsible for submitting regulatory and human subjects safety approvals, engaging a clinical center for testing, acquiring and administering the therapeutic solution, collecting and managing data, and submitting reports to XPRIZE."* By these guidelines there is no requirement that teams test their therapeutic in healthy populations during the Semi-Finals, and thus special populations would be acceptable per competition rules.

However, teams should consider that the Finals will require testing the therapeutic in persons without major life-threatening illness. Section 9 of the Guidelines states: *"Participants in the finalists' trials must be 50-80 years of age. Potential participants with treatable diseases such as hypertension or diabetes will need to have those diseases managed successfully to within acceptable limits prior to enrollment. Research participants may have evidence of some non-disabling, mild, age-related decline in function or health, which may increase the likelihood of measurable improvements with a 1 year therapeutic intervention time frame. Suggested specific eligibility criteria are described in Appendix B, as are example recruitment and monitoring guidelines (Appendix C)."*

By these rules teams must provide suitable evidence that the pre-existing chronic disease condition is stable and well-managed for Finals (not Semi-Finals). The challenge for teams recruiting special populations due to risk / safety concerns in the general population is that they must provide convincing evidence to the independent panel of judges (XPRIZE Healthspan Judging Panel) that the safety profiles and potential effects will translate to a generalized population for Finals.

9. Do we need to include a statement in the informed consent form allowing "data access, use, and material transfers to XPRIZE for judging and future analyses" during the Semifinal phase, or is this only required for the Finals?

Yes, Teams must include statements in informed consent or participation waivers to allow data access, use, and material transfers to XPRIZE as needed for judging and future analyses. This applies to the studies conducted during the Semi-Finals as well.

10. Are teams allowed to charge the participant to cover (part of) the financial expenses of their participation in the trial?

The Competition does not dictate how teams operate their PoC studies in this regard.

11. For the cognitive function endpoint assessment, what if the recommended measures currently outlined in the Competition Guidelines or the FAQ 1 are not fully available translated in the language of our patient population?

We will be consulting with our Scientific Advisory Board and Judging Panel on further guidance on testing for cognitive function assessment available in non-English languages, and get back to the teams once we are able to provide more information and guidance on this.

FINALS APPLICATION (MILESTONE 2) AND FINALS TESTING

12. What is the deadline for submitting an application for Finals?

To be eligible for Milestone 2, all Healthspan Qualified Teams must submit their Finals application by **13 April 2026**. The Healthspan Judging Panel will determine the Top 10 Finalist Teams receiving a Milestone 2 Award of US $1,000,000 (awarded Summer 2026; exact date TBD).

13. Will there be Finals Submission Guidelines and reporting templates to reference for the Finals application?

Yes, reporting requirements and a recommended template will be published for the Finals Application by October 2025 or earlier. Similar to how Guidelines for Qualifying Submissions were previously provided to teams, XPRIZE Healthspan Prize Operations will be publishing these reference documents on the prize website at www.xprize.org/prizes/healthspan/resources.

14. Have complete endpoint measurement criteria been released yet for the Finals of the Healthspan track of the Competition?

Updated endpoints have not yet been released for the Finals testing. Please note that for Healthspan's Semi-Finals proof-of-concept study phase, teams are to select and test their own endpoints as they've previously proposed in their Qualifying Submission application. We recommend teams to continue to refer to the information provided in the Competition Guidelines until we release further updates in the near future.

For Healthspan, the Rules and Regulations will be available prior to the start of Finals (in Q1 2026; exact release date TBD). The Prize Operations staff is working with our Scientific Advisory Board (SAB) to define the exact thresholds needed for teams to achieve for all three functional domains. Teams will be notified as soon as they are published. We will also hold office hours in the future during which we will talk about endpoints.

15. In the Finals, would it be acceptable to collect data from certain clinics that have fewer testing capabilities than others, e.g. one clinic can collect VO2 max capability while another cannot?

XPRIZE Healthspan will help Finalist teams standardize their data through the Data Coordinating Center.

16. In the Finals, will XPRIZE help cover the costs for certain tests (once they become confirmed via the Rules & Regulations)?

Not currently, but XPRIZE as a non-profit organization is working on negotiating favorable cost structures that we hopefully can pass over to our teams as a resource. The NIH Toolbox is currently free for U.S. teams.

TEAM MERGERS AND PARTNERSHIPS

17. If two or more teams decide to join forces, must they completely merge into a single competing entity?

If a team decides to operate under the legal entity of another team or if a team agrees to form a new entity with another team, each team must provide XPRIZE within ten (10) business days, prior written notice of any such acquisition or merger and the status of the surviving Team, which will stay active in the Competition.

A team that has not formally merged and collaborates with another team as a separate entity, is not required to formalize any agreement with XPRIZE.

18. Should two or more teams decide to collaborate together for sharing of resources such as data and trial support, yet still opt to maintain separate team identities, can each team still submit their own entry/application for the Finals?

Yes, a team may collaborate with another team as a separate entity and submit an entry as a separate entity. XPRIZE Healthspan Judges will review all entries independent of each other and make a determination on how the entry meets the required criteria.

However, we strongly encourage teams to please inform our Prize Operations staff and keep us updated at healthspan@xprize.org of any intra-team collaborative engagements planned in case we do need to request more information or any additional documentation of the resources that are being shared.

19. Prior to making a determination on whether a full merger is in the best interests of the teams involved, is there flexibility to enter into provisional collaboration agreements?

Outside of the terms outlined in the Competitor Agreements, any separate agreements entered between the teams is not subject to XPRIZE's approval.

20. Should two or more teams decide it is in their best interest to fully merge, does XPRIZE require the (new) team to form an entirely new legal entity?

No, Teams either have the option to merge with an existing team and be jointly represented by the legal entity of the primary team, or merge and create a new legal entity. In either case, the now merged team must assign one Team Lead/PI for their updated team structure.

Each team also must provide XPRIZE within ten (10) business days, prior written notice of any such acquisition or merger and the status of the surviving Team which will stay active in the Competition.

21. Are there guidelines or recommended frameworks (e.g. template agreements, governance proposals) available to help teams navigate the legal and administrative aspects of such a merger?

XPRIZE does not provide guidance on agreements between teams or governance proposals. XPRIZE remains a neutral facilitator of the XPRIZE Healthspan and is not in the position to provide legal counsel to teams. Please seek independent legal counsel.

DISCRETIONARY LATE REGISTRATION

22. Do late Qualifying Submissions qualify for the first $10M milestone prize?

Late submissions are not eligible for a Milestone 1 Award, which was awarded in May 2025.

The Competition's Primary Registration period occurred from 31 July - 20 December 2024. All submissions received beyond this Primary Registration timeframe are subject to the Discretionary Late Registration process. For these late-applying teams, your eligibility to be qualified into this current Semi-Finals period of the Competition needs to be evaluated by the Judging Panel on a case-by-case basis. Approved teams will then need to submit a Finals Application by April 2026.

Any new Team approved to advance during this Discretionary Late Registration period will be in the running alongside all other existing Qualified Semi-Finalist Teams competing for a spot in the Top 10 Finalist Teams selected to win a Milestone 2 Prize ($10M Milestone Purse divided amongst 10 teams) and advance to a 1-year clinical trial of their therapeutic.

22. I'm interested in entering the Competition now as a late applicant. Where do I start?

Start by submitting a 1-page Letter of Intent to: healthspan@xprize.org. Make sure to summarize these key pieces of information in your Letter of Intent:

- Brief overview of your team
- Description of your proposed therapeutic
- Rationale for its use in XPRIZE Healthspan
- Any available supportive data
- Clearly mention if your team is affiliated with a University, Non-Profit, or other academic/public research institution (you may qualify for waived or discounted fees)

All submitted Letters of Intent will be reviewed by the Executive Director of XPRIZE Healthspan for approval to formally enter into the Competition. If approved, the team will be permitted to complete all other registration requirements (Registration Form, Registration Fee, sign the Competitor Agreement) and submit their Qualifying Submission in the XPRIZE Prize Operations Platform. Please refer to the "Discretionary Late Registration" section within www.xprize.org/prizes/healthspan/resources for more detailed guidance on Late Registration.

All registration requirements must be completed by approved teams before your Qualifying Submission will be shared with judges. Judging for Discretionary Late Registration teams occurs on a Quarterly basis.

23. What is the current Registration Fee for the Healthspan track?

Per the Competition Guidelines, the Late Registration Fee is currently US$10,000 unless your team has special conditions to be eligible for a reduced rate or waiver of this fee. Generally, eligibility for a consideration of financial difficulty only applies to teams that have either of the following:

- The team's legal entity has a not-for-profit status,
- Are a mostly student-led team based within an academic institution, or
- The team is geographically based in a LMIC (Low and Middle-Income Country).

To request for a fee discount or waiver, the Team's Lead Point of Contact must submit a request to healthspan@xprize.org, providing sufficient explanation for why they qualify. XPRIZE reserves the right to deny any requests based on insufficient or non-eligible reasons.

24. My team's Letter of Intent has been approved and we're now working on completing Team Registration and submitting in a Qualifying Submission. What is the timeline for our application to get reviewed by the Judges?

Please refer to the following deadlines and timelines to receive a determination on your application being qualified for the Final submission.

First round of discretionary review of late applications:

- For teams that complete registration and submit a Qualifying Submission in POP by: **31 July 2025, 12pm PST**
    - Judges will review the submitted application in August 2025
    - Submitted teams will receive notification of whether they are qualified to advance as a Semi-Finalist team by early September

Second round of discretionary review of late applications:

- For teams that complete registration and submit a Qualifying Submission in POP by: **30 November 2025, 12pm PST**
    - Judges will review the submitted application in December 2025
    - Submitted teams will receive notification of whether they are qualified to advance as a Semi-Finalist team by early January 2026

Third/final round of discretionary review of late applications:

- For teams that complete registration and submit a Qualifying Submission in POP by: **13 March 2026, 12pm PST**
    - Judges will review the submitted application in April 2026
    - Submitted teams will receive notification of whether they are qualified to advance as a Semi-Finalist team by early May 2026

IMPORTANT: All qualified teams whose Qualifying Submissions have been approved by the Judging Panel within any of the above three review cycles must also submit a Finals application by **13 April 2026** to be considered for a spot in the Top 10 Teams advancing to the Finals.

25. Can I still apply for the FSHD Bonus Prize track?

Yes! The FSHD Bonus Prize is still open for registration. The Registration Fee for new teams for the Bonus Prize still remains at our previous rate of US$1,000 (compared to the increased $10,000 fee to register for the Healthspan track).

For our pre-existing Qualified/Semi-Finalist Teams in our Healthspan track, if you had not previously submitted a Qualifying Submission for the FSHD track during Primary Registration and would now be interested in doing so, we encourage you to consider applying via a cross-over application. Please message healthspan@xprize.org so we can discuss and coordinate options with your team on crossing over an application to the FSHD track.