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FSHD BONUS PRIZE FREQUENTLY ASKED QUESTIONS

ISSUE 1

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This FAQ is supplemental to the [XPRIZE Healthspan Competition Guidelines](#) and the [FSHD Bonus Prize Rules and Regulations](#). The latest version of these documents are publicly available on the Competition Website at www.xprize.org/competitions/healthspan#competition-materials.

Please note, the FAQs below are exclusive to the FSHD Bonus Prize track of the Competition. For FAQs related to the Healthspan main track, please refer to Issues 1-3 of Teams Frequently Asked Questions available at www.xprize.org/competitions/healthspan#resources.

FSHD BONUS PRIZE FINALS COMPETITION OVERVIEW

1. What types of therapeutic strategies are encouraged in the competition?

Teams may pursue any number of approaches, including addressing the root cause (e.g., misexpression of DUX4) or targeting downstream effects like oxidative stress, inflammation, fibrosis, fatty infiltration, and/or muscle cell replacement. Although lifestyle and nutraceuticals approaches are allowed, they are less likely to address the root cause of FSHD.

2. Is a therapeutic strategy targeting a non-DUX4-related muscle pathology eligible for the prize if it still meets the strict clinical endpoints?

The disease is characterized by the misexpression of DUX4. Teams may pursue alternative approaches beyond the root cause (DUX4) that target downstream effects of the disease pathology like inflammation, fibrosis, or muscle cell replacement. If a solution conclusively demonstrates the required 10% biomarker change and 20% functional improvement, it meets the winning criteria.



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3. Does a therapeutic intervention need to demonstrate efficacy across all traditionally affected areas (face, upper limbs, trunk) to meet the 20% functional improvement criteria?

No. FSHD can manifest and progress heterogeneously and asymmetrically in many patients. The competition requires a 20% improvement from baseline in at least three functional tests, which must be appropriate to the specific therapeutic intervention. However, these tests can overlap muscle groups and can be personalized to the participant's weakness, but must be relevant to FSHD. The selection of a minimum of three tests was to minimize possible bias or practice effects from single tests.

4. Why are there two performance thresholds for the FSHD Bonus Prize?

The two performance thresholds, functional and biomarker, were selected to better correlate changes seen in FSHD disease progression and help advance the field with a more integrated approach for outcomes assessments.

5. Are teams allowed to run clinical trials lasting less than one year?

Yes, the Competition Guidelines and FSHD Rules and Regulations allow for clinical trials of "one year or less". However, please note that FSHD is a slowly progressing disease, and depending on the therapeutic approach, a benefit may not be detectable with certain outcome assessments during an abbreviated clinical trial.

6. Are there any circumstances under which a therapeutic intervention may be tested for longer than the required one-year timeframe?

The competition explicitly challenges teams to develop and successfully test a therapeutic within one year or less. However, should a team propose to run a trial for a longer duration, they should submit their clinical trial plan in their annual progress report for the judging panel to review and consider. Please note that all results would still need to be submitted by the end of 2029 for consideration in the competition.



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7. Why is there a specific age range for the patient cohort targeted in the Finals competition?

Aging is accompanied by a natural decline in muscle strength which can exacerbate FSHD disease progression. To harness the innovative approaches being developed for the Healthspan competition, the FSHD Bonus Prize has elected to parallel the same age requirements (50 to 90 years). In addition, current clinical trial practices tend to exclude patients over 65 years of age, potentially limiting the number of willing and able participants who can benefit from groundbreaking therapeutics.

8. If there is a discrepancy between the FSHD Bonus Prize Rules and the general XPRIZE Healthspan Competition Guidelines, which rules take precedence?

The FSHD Bonus Prize is governed by specific FSHD Bonus Prize Rules and Regulations and judged by an independent Judging Panel. The FSHD Bonus Prize Rules and Regulations supplement the XPRIZE Healthspan Competition Guidelines. Should a discrepancy arise between the two, administrative issues will be managed in accordance with XPRIZE Healthspan Guidelines, and technical or scientific matters will be deferred to the FSHD Judging Panel.

9. What is the specific mechanism for resolving a scientific disagreement if the Judging Panel questions whether a novel biomarker is "clinically relevant" enough to meet the 10% benchmark?

The FSHD Judging Panel has sole discretion in determining whether a novel biomarker is clinically relevant. It is recommended that teams present their clinical study plan as part of their annual progress report and outline the rationale for the selection of their chosen biomarker. Should the FSHD Judging Panel disagree with this selection, they will contact the team for clarification.



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FSHD BONUS PRIZE COMPETITION TIMELINE

10. Why does the FSHD Bonus Prize not have an interim 2nd milestone similar to the Healthspan competition?

The FSHD Bonus Prize and Healthspan have vastly different operational parameters and infrastructure requirements. Whereas the Healthspan competition includes a second milestone, the clinical trial is more regimented and prescribed than the FSHD Bonus Prize competition. The FSHD Bonus Prize Sponsor has opted to provide teams with more time and opportunities to develop innovative therapeutic solutions and a second milestone would have risked restricting the types of approaches being implemented.

11. What financial structure or incentives replace the second milestone award that is omitted from the FSHD Bonus Prize timeline?

The FSHD Bonus Prize timeline is distinct and does not include a second milestone award. The primary incentive structure is the \$8M Finals prize purse awarded to the First Place Team. No alternative financial incentives between the Milestone and Finals awards are specified, although teams are encouraged to take advantage of Healthspan's networking forums to solicit investors.

12. How can teams ensure adequate patient recruitment for their clinical trial?

It is recommended that teams begin planning for their clinical trial as soon as possible by contacting patient advocacy groups and clinical trial centers to discuss their recruitment needs with respect to their desired inclusion/exclusion criteria.

13. What is recommended to help speed up patient recruitment in this competition?

Teams are encouraged to engage multiple clinical trial sites and reach out to local patient advocacy groups and neuromuscular clinical centers for assistance. Providing Open Label Extension to all participants following the conclusion of the trial may also help with recruitment, although the costs would need to be absorbed by the trial sponsor.

14. If unavoidable external delays (e.g., regulatory approval) prevent a team from starting or completing their one-year trial by the December 2029 submission deadline, will an extension be granted?

No. The Finals Clinical Trial Testing Period runs until December 2029, and all clinical trial data must be submitted by the end of December 2029 for the FSHD Judging Panel to be able to evaluate the results.



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LATE REGISTRATION & QUALIFYING SUBMISSION

15. How can existing Healthspan teams transition to the FSHD Bonus Prize track?

Existing Qualified/Semi-Finalists in the Healthspan Competition can opt to submit a Qualifying Submission for the FSHD Bonus Prize via a cross-over application process prior to the December 20, 2027 deadline. Please consult the [FSHD Rules and Regulations](#) for more information.

16. What are the key elements an existing Healthspan competition team must modify when submitting a "cross-over" application for the FSHD Bonus Prize?

Existing teams must adapt their submission to match the requirements of the FSHD Bonus Prize competition, which specifically involves adjusting for the different timelines, the unique clinical endpoints, and the required patient population/recruitment strategies relevant to FSHD.

17. Why are additional teams allowed to join through December 20, 2027?

The FSHD Bonus Prize is a competition designed to foster innovative therapeutic development for FSHD. The open registration through December 20, 2027 ensures that new teams who may not have been aware of the competition time to join.

18. Why was December 20, 2027 selected as the close out date for registering a team to the FSHD Bonus Prize?

This date was selected as a reasonable date for teams with only pre-clinical data to complete any necessary IND-enabling studies, plan and complete their clinical trial by the end of 2029. Please note that the XPRIZE Healthspan administration, in conjunction with the FSHD Judging Panel, may allow late registrants with more advanced therapeutic program entry into the competition after this date.



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OUTCOMES ASSESSMENTS

19. How were the Common Data Elements (CDEs) selected?

The FSHD Judging Panel requested a set of Common Data Elements (CDE) to allow better comparison between teams. The selected CDEs were designed to cover different functional domains affecting FSHD patients. In addition to the CDEs, teams may elect to implement additional outcome assessments that may be better suited for their therapeutic approach.

20. Will the listed Common Data Elements sufficient to address the required 3 independent functional and 1 biomarker outcomes assessments?

Yes, the listed CDEs include more than 3 functional outcomes and a blood-based biomarker. Technically, the CDEs satisfy the FSHD Bonus Prize requirements. However, teams may elect to implement additional outcome assessments that may be better suited for their therapeutic approach.

21. Are teams required to collect biospecimens for a biorepository?

No. Teams are strongly encouraged to collect plasma and serum blood samples at baseline and during/following treatment for downstream exploratory analyses and biobanking. Please note that sponsored biomarker readouts may provide additional information and supportive evidence to a therapeutic approach.

22. What level of evidence or documentation is required to establish a novel clinical outcome measure (e.g., an AI-enabled measure) as adequately "validated"?

If teams use novel readouts or alternative protocols, detailed instructions/guidelines of the study protocols must be provided in the qualifying submission, progress report, and/or final report. The FSHD Judging Panel will determine whether these readouts meet their requirements. It is recommended that teams planning to deploy novel readouts include these details as early as possible, such as in their annual progress reports, to make the FSHD Judging Panel aware of their intention. Should the FSHD Judging Panel have questions about the approach, they will contact the teams for more information.

23. If the Prize Sponsor performs centralized testing on banked biospecimens, will the resulting data be immediately shared with the participating team?

Yes. The Prize Sponsor will provide results from the centralized testing of banked samples to participating teams to support their therapeutic approach.



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24. How will the Judging Panel determine if a novel biomarker, other than fat fraction reduction, is "clinically relevant" and eligible for meeting the 10% benchmark?

A winning team must demonstrate a > 10% reduction in muscle fat fraction, fibrosis or increase in muscle mass OR a clinically relevant muscle-derived or circulating biomarker. Relevance would be determined by the team's scientific rationale and preliminary data provided in the team's report, which may include biochemical/molecular analyses from muscle biopsies and/or circulating blood.

25. Since the use of FSHD-COM and Reachable Workspace requires licensing and specialized equipment, do XPRIZE or the sponsor cover these proprietary costs for competing teams?

No. Teams are solely responsible for any licensing fees and equipment purchase needed to complete their trial. Please note that FSHD-COM and Reachable Workspace were listed as candidate outcome assessments and are not mandatory. Teams may elect to use alternative validated or novel readouts.



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FINALS TRIAL DESIGN

26. Why are multiple baseline assessments recommended?

A minimum of two baseline measurements within one month is highly recommended to establish test-retest reliability and minimize any potential learning or training effects that might bias the study.

27. Why is a confirmatory genetic testing for trial participants mandatory?

Due to the similarities in disease manifestation with other neuromuscular disorders, the diagnostic journey for FSHD patients is arduous and patients are often misdiagnosed. A confirmatory genetic test is the only way to ensure that trial participants have FSHD and further helps better characterize their FSHD subtype (FSHD1 vs FSHD2) allowing for any downstream analyses by genetic stratification.

28. What specific genetic documentation is required for patient eligibility?

A genetic testing report from an accredited CLIA certified laboratory using clinically approved genetic testing confirming FSHD subtype (FSHD1 vs FSHD2) and the corresponding D4Z4 repeat units for FSHD1 or specific mutation leading to FSHD2.

29. If participants receive the therapeutic in an Open Label Extension (OLE) after the trial, what are the team's ongoing obligations regarding safety and cost?

If a competing team opts to use an OLE, they should be aware that providing the OLE for extended periods might impose a financial burden on their organization. Furthermore, while XPRIZE safety monitoring is limited to the 1-year follow-up, long-term safety monitoring remains the sole responsibility of the competing teams for the duration of the OLE and possibly longer, as mandated by local regulatory agencies.

30. If a team proposes a non-drug intervention (e.g., nutritional supplement or therapeutic exercise), how must they design a placebo-controlled trial to meet the double-blind requirement?

Teams are encouraged to conduct a randomized, double-blind, placebo-controlled trial. However, if the intervention is not amenable to placebo control or double-blinding, teams must provide scientific justification and describe the use of appropriate natural-history comparators in their clinical trial study plan.



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31. How does the Judging Panel ensure that the Personalized Response Threshold (PRT) or N-of-1 trial designs are comparable between teams when outcomes are individualized?

While individualized assessments (N-of-1, PRT) may be used, all teams must include the battery of standardized assessments, Common Data Elements (CDE), to provide the Judging Panel with a basis for unbiased comparisons between teams.

SAFETY MONITORING AND REPORTING

32. Is IRB approval required for trials that involve nutraceuticals and/or lifestyle modifications?

Yes. Generally, IRB approval is required for studies involving human subject participants. In addition, teams must also comply with all local regulatory body requirements when conducting such studies.

33. Can XPRIZE take action against a team based on safety concerns?

Yes, XPRIZE reserves the right to disqualify teams found to be operating in an unsafe or unethical manner.



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ANNUAL PROGRESS REPORT

34. Given that the FSHD Judging Panel is not required to provide feedback on the Annual Progress Reports, what is their primary use for XPRIZE operations?

The reports will primarily assist XPRIZE and the FSHD Judging Panel in addressing unforeseen issues with the competition and timelines affecting teams. It also provides the FSHD Judging Panel an opportunity to review the scientific and clinical trial approach to better prepare for their final review and helps highlight any potential safety issues that may put trial participants at risk.

35. Since the Annual Summary of Progress is restricted to three pages, what priority information should teams include if they have extensive ongoing preclinical studies and regulatory work?

The annual progress report is meant to be a brief overview of the team's progress to date without being too complicated nor burdensome to assemble. It should be in the format of an executive summary covering major accomplishments and results from the previous year to date, as well as the upcoming objectives/goals for the following year. Priority should be given to progress relative to Section 2's timelines, the status of regulatory compliance reports (GLP/GMP/GCP), trial design, implementation of novel biomarkers or endpoints, and updates to the Statistical Analytical Plan (SAP). These documents are supplementary to the 3-page executive summary mentioned above.

36. What regulatory reports are required in the Annual Progress Report?

Required reports include relevant regulatory submissions for clinical trials (IND, CTA, CDT), pre-clinical pharmacology and toxicology reports, and regulatory compliance reports (GLP, GMP, GCP Quality Audit Reports, or equivalent) and IRB approvals with consent forms.

37. What language must accompany the informed consent for Institutional Review Board (IRB) approval?

The IRB approval must explicitly include language permitting the distribution of de-identified study results and biological samples to third parties for post-hoc analysis. This allows XPRIZE to share data and biological samples for downstream exploratory analyses and supports the goal of monitoring post-prize impact and scaling team solutions.



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38. If a team's Institutional Review Board (IRB) refuses to approve the specific language required by XPRIZE for distributing de-identified study results and samples to third parties, what is the consequence?

The IRB Approval must include language permitting distribution of de-identified study results to third parties for post-hoc analysis, as the FSHD Judging Panel will not be able to re-analyze the trial results without this permission. XPRIZE notes that failure to adhere to the rules may result in consequences detailed in the Competitor Agreement.

39. What are the consequences or penalties if a competing team fails to submit their Annual Progress Report by the June deadlines?

While XPRIZE nor the FSHD Judging Panel have not specified any immediate consequences, failure to provide annual progress reports can impact a team's ability to solicit technical feedback from XPRIZE operations team and may also influence the FSHD Judging Panel, especially if the final reports are incomplete or highlight adverse events that could have been identified and prevented in advance.



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FINAL REPORTING

40. How does the final reporting for the FSHD Bonus Prize differ from the Healthspan Competition?

The Healthspan and FSHD Bonus Prize competitions have diverged significantly since the milestone 1 award in March 2025. The Healthspan competition is more prescribed with the final trial design, outcomes assessments and uses a centralized data collection center to automatically analyze trial data from the finalists. While the FSHD Bonus Prize does require the collection of some Common Data Elements, the trial design and ultimate collection of outcomes is left at the discretion of each team, with teams submitting their trial results to XPRIZE for the FSHD Judging Panel to re-analyze.

41. What happens if a team fails to provide the required access to de-identified data for judging and audit purposes?

To be eligible for the FSHD Bonus Prize, teams must provide the FSHD Judging Panel and key operations personnel access to their de-identified data for review. Failure to meet eligibility requirements would prevent the team from having their results checked to receive the prize award.

42. What information must be shared with Solve FSHD Holdings Ltd.?

Competing Teams must allow their key data, methodology, breakthroughs, and limitations regarding their research to be provided to representatives of Solve FSHD Holdings Ltd.

43. Does the requirement to share key data, methodology, breakthroughs, and "limitations" with Solve FSHD Holdings Ltd. grant them any claim on the team's intellectual property (IP)?

No. Competing Teams must allow their key data, methodology, breakthroughs, and limitations to be provided to the FSHD Judging Panel and representatives of Solve FSHD Holdings Ltd for review. Teams are required to include their data-sharing plan and any IP/FDI constraints in their final report, but teams retain all ownership of their IP.

44. If a team's recruitment is significantly off-track from the sex or racial balance targets, what specific "corrective actions" are acceptable or required in the Final Report?

While recruitment for orphan indications such as FSHD can be challenging, teams should document diversity & accessibility, including the recruitment dashboard vs. plan and corrective actions taken to mitigate any deficits. Corrective actions for recruitment issues may include



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reaching out to patient advocacy groups or neuromuscular clinical centers for assistance, and continuously refining retention strategies.

SITE VISITS & AUDITS

45. Who has the authority to request independent audits or site visits?

The XPRIZE FSHD Bonus Prize sponsor (Solve FSHD and/or their representatives) may request independent audits and/or site visits.

46. When might these audits and visits take place?

They may be requested prior to and/or during the clinical trial phase of the competition. All site visits will be coordinated to ensure minimal disruption to the operations of the teams.

47. Will teams receive notice before a site visit occurs?

Yes, the Healthspan operational team will contact team leaders with ample advanced notification to coordinate any such audits and/or visits.

48. Who may participate in the audits?

Auditors may include officials from the sponsor, members of the judging panel, the Healthspan operations team, and/or independent advisors, auditors or affiliates to the sponsor.

49. If a team is already subject to regular government or FDA audits, can those existing compliance reports be used to satisfy the FSHD Bonus Prize audit requirement?

Yes. Existing, high-quality audits can potentially satisfy the requirement, though the sponsor still reserves the right to request independent audits and site visits.

50. If an audit uncovers a critical, but not immediately disqualifying, procedural issue, what specific actions can the Healthspan Operations Team or FSHD Judging Panel take?

If issues are suspected, the Healthspan Operations Team or FSHD Judging Panel may request additional information on remediation strategies from the teams. While XPRIZE can disqualify unsafe teams, every effort will be made with team leadership to address suspected issues.