**PROGRAM APPLICATION**

**SECTION I: GENERAL INFORMATION**

|  |  |
| --- | --- |
| Company Name: |       |
| Head Office Address: |       |
| Head Office Telephone: |       |
| Company Website URL: |       |
| Main Contact Name & Title: |       |
| Main Contact Address(if different from above): |       |
| Main Contact Telephone: |       |
| Main Contact Email: |       |
| Company Twitter Handle: | @      |
| Other Relevant URL: |       |
| Is your company a Multi-National Enterprise (MNE) or a MaRS Venture Client? | [ ]  YES If yes, complete sections I, II and V only.[ ]  NO If no, complete all sections. |

**SECTION II: TECHNOLOGY**

|  |  |
| --- | --- |
| 1.  | Proposed Name of Technology: |
|  |       |
| 2. | Describe the problem the technology aims to solve and how the technology works. |
|  |       |
| 3. | Provide a brief description of the health claim(s) of the technology, and the potential value the technology could deliver to patients, clinicians and health systems. |
|  |       |
| 4. | What is the primary target patient population (gender, age, medical condition(s), care setting, stratification, etc.)? Describe. |
|  |       |
| 5. | Does the product/technology have a clear competitive advantage from the end user’s perspective? Describe. |
|  |  |       |
| 6. | What kind of market research has been done to validate the pain-point(s) and/or needs of patients, clinicians or health systems? Describe. |
|  |       |
| 7. | What types of Key Opinion Leaders or Clinical Experts have been engaged by the Company with respect to the technology? Describe the feedback. |
|  |       |
| 8. | Have proof-of-concept studies have been conducted to validate product-market fit? Describe. |
|  |  |       |
| 9. | What is the estimated size of the target market in Ontario? Globally? |
|  | Ontario: $      CADGlobally: $      CAD |
| 10. | At what stage of development is the product/technology? |
|  |  |
| 11. | Are there any plans for product improvements, extensions or future versions? Describe. |
|  |  |       |
| 12. | Does the Company have provisional or pending patents on the technology? If yes, provide patent details; if no, describe why not. |
|  |  |       |
| 13. | What entity is the owner or assignee of the Intellectual Property (IP)? |
|  |       |
| 14. | Does the Company plan to secure IP in multiple markets? Which ones? |
|  |  |       |
| 15. | Are alternative interventions currently available in Ontario to serve this purpose? (i.e. is a current standard of care poised to be disrupted or obsolesced?) |
|  |  |
| 16. | If you answered Yes to Question 15, please state if this technology either substitutes or supplements current technologies/drugs/standard of care, explaining how differentiated the product/technology is to existing options in the market. |
|  |       |
| 17. | Is this technology licensed/authorized by Health Canada? If "In Process", what stage is the submission at? |
|  |  |       |
| 18. | How does Health Canada classify this device? |
|  |  |
| 19. | Is this technology licensed/authorized for use by a regulatory body in any other jurisdiction? If yes, please list jurisdiction(s): |
|  |  |       |
| 20. | Have any constituents from the Ontario health system been made aware of the technology? If yes, please list who: |
|  |  |       |
| 21. | Are there any patients, clinicians, or institutions that have used or are currently using this technology in Canada or globally? If yes, please briefly describe who and where here: |
|  |       |
| 22. | Have any animal, safety or early feasibility studies been completed? Please describe below and submit any available reports from these studies with your application. |
|  |  |       |
| 23. | Have any previous studies been reviewed by a Research Ethics Board (REB)? If yes, list Boards: |
|  |  |       |
| 24. | Have any publications, abstracts, or posters been completed? If yes, please submit relevant documents with application. |
|  |  |
| 25. | Does the technology have an Instructions for Use document? If yes, please submit with application. |
|  |  |
| 26. | Are any clinical research studies using this technology currently in progress or anticipated to take place in the next 24 months? If yes, please describe briefly including status of Health Canada Investigational Testing Authorization letter, if applicable. |
|  |  |       |
| 27. | Does the Company keep records of device performance / safety data? |
|  |  |
| 28. | Outside of Ontario, does the applicant intend to use the data collected through the EXCITE evaluation for licensing or reimbursement approval purposes in any of the following jurisdictions? If yes, rank in order of priority. |
|  |  |  Canada  United States Australia Europe (specify)       Other (specify)       |
| 29. | The EXCITE evaluations comprise a minimum Core Evidentiary Bundle, which includes a clinical evaluation of efficacy, safety and clinical utility, systematic review, economic analysis, and human factors review. EXCITE also offers additional optional services. Please indicate whether you wish to explore any of the following options: |
|  | 1. Technology usability and human factors analysis\*
2. An analysis of uptake efficiency
3. A comprehensive education program for training end users in the use of the technology
4. The development of a registry to track post-adoption effectiveness and long-term safety outcomes
5. Patient Preferences analysis

*\*may be a requirement based on human factor review outcome* |  |
| 30. | Does the Company have the ability to manufacture or provide the technology in sufficient quantities for an EXCITE evaluation? |
|  |  |
| 31. | Who manufactures the device? Where is manufacturing taking place? |
|  |       |
| 32. | Does the manufacturing facility have an establishment license from Health Canada or other regulatory agency? |
|  |  |
| 33. | Does the manufacturing facility have a Quality Management System (QMS) in place? |
|  |  |
| 34. | Have validation studies been done on equipment and software (if applicable)? If yes, please submit relevant documents. |
|  |  |
| 35. | EXCITE evaluations are expected to cost between $1 million to $5 million CAD depending on complexity. The bulk of the funds would begin to be dispersed approximately 1 year after the EXCITE application process. Does the Company currently have line of sight to raising the necessary funds? Please describe your plans to raise capital from grants or private sources, including timelines. |
|  |       |

**SECTION III: BUSINESS**

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| 36. | How many full-time equivalents (FTEs) are currently employed by Company? |
|  |       |
| 37. | How many members are in the Company’s founding team? |
|  |       |
| 38. | Are any of the Company’s founders repeat entrepreneurs? |
|  |  |
| 39. | Are all the founders engaged full-time in the venture? Describe. |
|  |  |       |
| 40. | Describe the composition of the Management Team. |
|  |       |
| 41. | Describe the composition of the Board of Directors. |
|  |       |
| 42. | Does the Company have an advisory board or other cadre of mentors? Describe. |
|  |  |       |
| 43. | Does the Company have any strategic partnerships with industry players or other key partners? If so, please describe. |
|  |  |       |
| 44. | What is the total capital requirement to bring the product to market? |
|  | $       CAD |
| 45. | What is your go-to-market plan? (e.g. do you expect to bring the product to market yourselves, direct sale, 3rd party distribution, or license to a third party? |
|  |       |

**SECTION IV: ADDITIONAL INFORMATION ABOUT EXCITE APPLICATION PROCESS**

1. All reviews, assessments, and evaluations that comprise the EXCITE program will be conducted in an evidence-based and objective manner.
2. EXCITE will ensure that its process is conducted in a fair, transparent, and objective manner (subject to its’ stated prioritization criteria), and will strive for consistency in its decision-making.
3. Decisions by the EXCITE Management Board are final.
4. Companies that meet the EXCITE criteria but are not selected for participation may be considered for later selection by EXCITE.
5. Where applicable, copies of all confidentiality/non-disclosure agreements in force that you wish to be executed in advance of the EXCITE review should be submitted with this application. The details of the confidentiality claimed and the parties who sign the confidentiality/non-disclosure agreement must be explained precisely. Omission of this information will be assumed by EXCITE to mean that the applicant has no confidentiality concerns. Any information submitted that is considered to be proprietary or confidential must be identified.
6. Confidentiality, non-disclosure and proprietary information agreements submitted to EXCITE as outlined above will be respected by all EXCITE participants.
7. Applicant names and affiliations will remain confidential during the Application Phase.
8. Applicant names and affiliations will be released publicly only once the Application Phase is complete, and upon execution of a signed participation agreement between Company and MaRS.
9. The EXCITE Management Board and members of its Secretariat disclaim liability, consequential or otherwise, arising from the use of a technology that has been evaluated by EXCITE, including, but not limited to, bodily injury alleged or sustained, or any other adverse event alleged or sustained by a patient or other participant in the evaluation of the technology, or any adverse event or claim arising from the conduct of the study.
10. While EXCITE strives to conduct each evaluation promptly and efficiently, it disclaims liability for any unforeseen event associated with the evaluation, including failure to complete the study or the prolongation of the study beyond original estimates.
11. Successful applicants may be subject to additional terms and conditions.

**SECTION V: ACKNOWLEDGEMENTS & SIGNATURE**

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| 46. | I acknowledge the information provided in Section IV above. | [ ]  |
| 47. | I confirm that I have completed and am submitting an Executive Summary using the template provided on the MaRS EXCITE webpage. | [ ]  |
| 48. | I confirm that this application contains all existing reports, papers, articles, and other materials to support claims. *Note: Applicants should present all positive and negative outcomes of early work together with this application, as later stages of the evaluation will require that all existing data be presented. Failure to disclose data (include adverse event reports and information) that proves material to the overall analysis may result in EXCITE cancelling a project.* | [ ]  |
| 49. | I understand that all materials accompanying this application must comply with the applicable privacy and intellectual property laws and regulations. | [ ]  |
| 50. | I understand that the application materials submitted must not contain any information that identifies, or could reasonably be used to identify, individual patients. | [ ]  |
| 51. | I acknowledge that any materials that accompany this application may be shared with the EXCITE Secretariat, the EXCITE Management Board, applicable Research Ethics Board(s), and with members of the Health Technology Review Sub-committee, Scientific Collaborative in support of discussions, evaluations, proposals and business transactions pertaining to this application. | [ ]  |
| 52. | If my technology is selected for participation in the EXCITE program, and Company elects to continue to the Consultation & Design stage, I understand the following fee schedule will be applicable: | [ ]  |
| 53. | I understand that the cost of each evaluation is predicated on the complexity of the technology and the evaluation protocol, including the sample size required; I understand that it is expected that the cost of the evaluations will range from $1 million to $5 million CAD including the EXCITE Program Management Fee. | [ ]  |
| 54. | I understand that, should Company elect to proceed through the EXCITE program, Company will provide the technology being evaluated at no cost to EXCITE or the Scientific Collaborative partners for the purposes of the agreed-upon evaluations. | [ ]   |
| 55. | I understand that the applicant and any affiliates should not publicize their participation in the EXCITE program until all applicable agreements have been fully executed. *Note: Exceptions may be made if Company wishes to disclose they have been selected for participation in the EXCITE program, however the company must follow guidelines and language set by MaRS EXCITE and gain approval on a case-by-case basis.* | [ ]  |
| 56. | I attest that, as the Applicant, I have authority to submit an application on behalf of Company to the EXCITE program. | [ ]  |

MaRS recognizes your need for privacy. By submitting personal information to MaRS, you agree to our collection and use of such personal information to keep a record of the applicants to the EXCITE program and contact them with updates as we assess each application. MaRS will keep the personal information secure and only use or disclose it for the purposes identified above or as required by law.

By signing below, the Applicant attests that all information provided in this application is accurate and complete to the best of the Applicant’s knowledge.

|  |  |
| --- | --- |
| Applicant Signature *(insert image file of signature)*: |  |

|  |  |
| --- | --- |
| Applicant Name & Title: |       |
| Date (dd MMM yyyy): |       |

Applications and supplementary information can be submitted by email to EXCITE@marsdd.com