



**EXPRESSION OF INTEREST NOTIFICATION FROM
EMERGING TECHNOLOGY DIVISION, K-DISC
[Ref No: 1087/2024/K-DISC dated 6/11/2024]**

Project Name: KERALA BONE MARROW REGISTRY



KERALA DEVELOPMENT AND INNOVATION STRATEGIC COUNCIL

India Height, Govt. Women's College Road
Vazhuthacaud, Thiruvananthapuram – 695014

Phone 2332920/2334472

www.kdisc.kerala.gov.in

Table of Contents

| | |
|--|-----------|
| 1. INTRODUCTION..... | 3 |
| 2. TERMS OF REFERENCE | 4 |
| 3. SELECTION PROCESS..... | 4 |
| STEP 1: Submission of Expression of Interest (Eoi) | 4 |
| STEP 2: Project requirements clarification meeting and Eoi Response Sheet submission | 4 |
| STEP 3: Shortlisting of Startups for submission of Technical Proposal | 4 |
| STEP 4: Submission of Technical Proposal..... | 5 |
| STEP 5: Presentation / Demonstration by Startup and Technical Evaluation | 5 |
| STEP 6: Submission of Financial Proposal and Evaluation..... | 6 |
| 4. GUIDELINES FOR EOI RESPONSE SHEET | 6 |
| 4.1. Organization Particulars | 6 |
| 4.2. Organizational Capabilities | 7 |
| 4.3. Organizational structure and capacity | 7 |
| 4.4. Previous implementation experience..... | 7 |
| 4.5. Certifications..... | 8 |
| 5. GENERAL TERMS | 9 |
| 6. TERMS OF AGREEMENT | 12 |

Expression of Interest notification for the project- Kerala Bone Marrow Registry

1. INTRODUCTION

Kerala Development and Innovation Strategic Council (K-DISC) is the strategic think-tank advisory body of the Government of Kerala, formulating plans reflecting the latest in technology, product and process innovations for the development of the State. It seeks to address the challenges of providing holistic health care, employment, social security, infrastructure, food and nutrition security with a pro-poor bias, gender justice and inclusion of outliers, within severe fiscal constraints.

The Emerging Technology Division of K-DISC has been championing several Emerging Technology Projects for various Departments in the Government of Kerala, with cutting edge future technologies like Blockchain, Distributed Ledger, Big Data Analytics, Artificial Intelligence (AI), Machine Learning (ML), Internet of Things (IoT), Augmented Reality (AR), Virtual Reality (VR), Robotics etc. One of K-DISC's mission is to coherently work with the Government Departments in identifying potential areas for improving efficiency, process improvements and promoting innovation, by architecting and implementing Emerging Technology based solutions with suitable providers of such products/solutions, and hand-holding the Government through piloting these solutions.

The objective of this Expression of Interest (EoI) is to identify a qualified Technology Partner (a Startup recognized by the Department for Promotion of Industry and Internal Trade (DPIIT)) who can deliver a comprehensive solution for this project.

Brief description of the project:

The project Kerala Bone Marrow Registry is for setting up a web-based registry for automating and digitizing the patient–donor matching process. The registry will be integrated with the proposed Kerala Cancer Registry. The operations of the Kerala Bone Marrow Registry are closely linked to the Advanced Blood Collection centers, where the donors register their names and the Transplant centers, where the patients register and undergo transplantation. The registry does the donor matching for each patient based on a standardized globally accepted World Marrow Donor Association (WMDA) donor matching algorithm, and the list of matched donors is updated in the registry which can be accessed by the Transplant center. The proposed project will digitally transform the multi-step processes from donor and patient registration, donor-patient matching, the transplant process and post donation follow-ups. The proposed Kerala Bone Marrow registry will also integrate with the World Marrow Donor Association (WMDA) so that patients from Kerala can easily search for possible matching donors worldwide and vice versa. Artificial Intelligence and Machine Learning will be utilized to boost patient-donor matching, predict chances of transplant success and post-transplant complications. The bone marrow registry will be able to handle HLA typing using Next Generation Sequencing.

2. TERMS OF REFERENCE

Any startup recognized by the Department for Promotion of Industry and Internal Trade (DPIIT) can apply for the EoI process. However, the startup should have relevant experience and expertise in the requirements mentioned in the document.

The following are the terms of reference for the EoI: -

1. The startup should be registered with Department for Promotion of Industry and Internal Trade (DPIIT) as a startup and is currently holding the start-up status, valid for at least 2 years from the date of EoI response.
2. The startup should have previous implementation experience in developing a similar solution in Government or Private Sector.
3. The startup should have a successful completion certificate (End User Certificate) from the customer as proof of above (2) or should have obtained relevant patent certificate.
4. The startup should have sufficient dedicated manpower to lead both development and deployment within the time frame mentioned in the project proposal (Brief CVs to be attached mandatorily).
5. The startup should be willing to place their domain resources and technical resources at the implementation site for smooth project implementation, when required.
6. The providers should be willing to collaborate with K-DISC and other stakeholders to develop and deliver the project that meet the specific needs of K-DISC.
7. The startup should be willing to comply with the terms and conditions of K-DISC and provide regular updates on the progress of the project.

3. SELECTION PROCESS

The selection of the Technology partner will be a Quality Cost Based Selection (QCBS) process which consists of the following six steps:

STEP 1: Submission of Expression of Interest (EoI)

The Kerala Startup Mission (KSUM) will issue an Expression of Interest (EoI) to startups based on the requirement document submitted by K-DISC (Annexure 1). Interested Startups can express their interest through KSUM website.

STEP 2: Project requirements clarification meeting and EoI Response Sheet submission

An online meeting will be convened by KSUM with the startups who have expressed their interest in Step 1. Startups can clarify any relevant doubts regarding the project requirement document (Annexure 1). Interested startups can submit duly filled EoI response sheet (Annexure 2), along with all necessary supporting documents within the specified time.

STEP 3: Shortlisting of Startups for submission of Technical Proposal

In the third step, K-DISC shall shortlist the startups based on the submitted EoI response sheet. The criteria for shortlisting are as follows:

1. Must be registered with Department for Promotion of Industry and Internal Trade (DPIIT) as a startup and currently holding startup status valid for at least 2 years (proofs

- must be provided).
2. Should have previous implementation experience in developing solutions in Web development, Artificial Intelligence, Machine learning, Health care domain ERP projects, Database Management and Integration and, other advanced software systems in the Government/Private sector, within any states of India.
 3. Should possess a successful completion certificate from a customer as evidence of implementation experience in relevant technology (proof must be provided). Startup shall also specify any related patents/papers/ publications (proofs must be provided)
 4. Should have sufficient dedicated manpower to lead both development and deployment within the time frame mentioned in the project proposal with domain expertise in Web development, Artificial Intelligence, Machine learning, health care domain ERP projects, Database Management and Integration and, other necessary advanced software systems during the entire duration of the project. (brief CVs of Key personnels along with Linkedin profiles should be included).
 5. Should be willing to place their domain resources and technical resources at the implementation site for smooth project implementation, when required.

STEP 4: Submission of Technical Proposal

The shortlisted startups will be notified by KSUM to submit a technical proposal within a specified time. A standard template for submitting the technical proposal will be provided. Note that the technical proposal should be comprehensive and adhere to the standard template provided. All sections of the template should be filled in completely and no sections should be removed. No further chances will be given to update the proposal, once submitted.

STEP 5: Presentation / Demonstration by Startup and Technical Evaluation

The startups should provide a presentation on the technical proposal and if required a demonstration needs to be conducted. The technical proposals will undergo QCBS evaluation and will be assessed and scored based on the following criteria.

| Sl. No | Criteria | Max. Mark |
|--------|--|-----------|
| 1 | Project objective and scope covered | 20 |
| 2 | Proposed architecture and its Innovativeness in solving the proposed problem statement <ol style="list-style-type: none"> i. User centered design ii. Modularity iii. Technology stack – use of advanced technologies iv. Performance – response time and throughput v. Process cost optimization vi. Security | 15 |
| 3 | Proposal presentation/demonstration of similar solutions | 15 |
| 4 | Application flexibility <ol style="list-style-type: none"> i. Interoperability and ease of integration with existing system ii. Maintainability and ease of deployment | 10 |

| | | |
|---|---|-----|
| | iii. Ease of Integration with future systems | |
| 5 | Application scalability | 10 |
| 6 | Timeline proposed for Project implementation | 10 |
| 7 | Completeness of Technical Proposal (Clarity of technical approach, Architecture diagrams, Project schedule/Gantt chart, compliance with proposal requirement) | 20 |
| | Total | 100 |

Table 1

*Cut off mark for qualification shall be 60%

STEP 6: Submission of Financial Proposal and Evaluation

Startups who have qualified the cut off for technical evaluation shall be called for submitting financial proposal through KSUM. Startups will have to submit the financial proposal in the standard template provided by K-DISC. The financial proposal should be complete in all aspects and should cover the scale of the project and be reasonably quoted. The financial proposal should meet the terms and conditions of K-DISC detailed in the Terms and Conditions section in the proposal template.

KSUM will convene a financial bid meeting to evaluate the financial proposal. The evaluation will be completed using QCBS framework, with 60% weightage given to technical aspects and 40% weightage given to financials.

4. GUIDELINES FOR EOI RESPONSE SHEET

4.1. Organization Particulars

1. Name of the Project for which Eoi Response is submitted: [Name of the K- DISC project for which Eoi is notified]
2. Name of the Startup: [Name of the startup submitting Eoi response sheet]
3. Legal Name: [Name of the startup as registered with the relevant authority]
4. Legal Status: [Indicate the legal structure of the startup, such as a partnership, company, etc.]
5. Registration Number: [Provide the unique registration number assigned to the startup by the relevant authority if any (CIN)]
6. Date of Registration: [Indicate the date when the startup was registered with the relevant authority]
7. KSUM or DPIIT Unique ID: [Provide the KSUM or DPIIT Unique ID]
8. KSUM or DPIIT Startup Certificate Expiration Date: [Provide the validity date of KSUM or DPIIT Startup Certificate]
9. Registered Address: [Provide the complete postal address of the startup's registered office]
10. Website: [Website of the organization]
11. Full name of the contact person: [Provide the designation of the startup's main

contact person]

12. Designation of the contact person: [Provide the full name of the startup's main contact person]
13. Contact Mobile Phone Number: [Provide the mobile phone number the startup's main contact person]
14. Contact e-mail id: [Provide the email address for the startup's main contact person].

4.2. Organizational Capabilities

1. Introduction: [Provide a brief introduction to the startup, highlighting its key characteristics and purpose. This may include the startup's name, year of establishment, and core business activities. Be concise but descriptive (Word Limit- 150)]
2. Key products or services: [Provide an overview of the services offered by the startup, highlighting its key areas of expertise and its value proposition. This should describe the specific services that the startup offers and how they align with the objectives of the tender. Be sure to highlight any relevant experience or success stories related to similar projects. Also highlight relevant patents/papers/publications by the organization. (Word Limit- 250)]

4.3. Organizational structure and capacity

1.

1. Total number of Employees: [Provide the number of employees in the organization]
2. Details of the key personnels in the technical & management team: [Provide required information on the table with short CV of the employees] (Add rows on the table as required)
 - A. Name: [Provide the name of the key team member]
 - B. Designation: [Provide designation of the team member]
 - C. Skill Set: [Provide his/her relevant skill sets]

If shortlisted for submitting the technical proposal, the startup must provide the detailed CV.

4.4. Previous implementation experience

[Provide a brief of the relevant and recent project experience that are similar in scope and complexity to the current requirement, in the Government Sector. Please attach the experience certificate from customer for each of the customer]

- A. Customer: [Provide name of the customer]
- B. Customer Category: [Mention "Government" or "Private" accordingly]

- C. Location: [Mention “Inside Kerala” or “Outside” accordingly]
- D. Start Date: [Provide project started date]
- E. End Date: [Provide project completed date]
- F. Project Brief: [Provide a brief of the project including the size, objective, and outcomes of each project in 100 words]
- G. Scope of the Project: [Provide scope of the project in 150 words]
- H. Is the implemented project currently being used: [Provide “Yes” or “No” accordingly]
- I. Address of the customer: [Address of the customer where the project is implemented]
- J. Name of the person to be contacted: [Provide the name of an authorized person from the client/customer company, to be contacted]
- K. Designation of the person to be contacted: [Provide the designation of the authorized person from the client/customer company, to be contacted, if required]
- L. Contact Number: [Add contact number of the authorized person from the client/customer company to be contacted]
- M. Email address: [Add email id of the authorized person from the client/customer company to be contacted]
- N. Experience Certificate from customer attached: [Provide “Yes” or “No” accordingly, experience certificate from customer should be attached with EoI Response sheet]
- O. Relevant patents/papers/publications by the organization

4.5. Certifications

Certifications received: [Mention any relevant certifications such as regulatory approvals/ accreditations / Quality Management Frameworks/ Patents that your Startup / product or solution has Obtained.]

- A. Name of Certification: [Provide the name of the certification that the startup has obtained]
- B. Issuing Body: [Provide the name of the startup that issued the certification]
- C. Certification Number: [Provide the unique identification number assigned to the certification]
- D. Date of Issue: [Indicate the date when the certification was issued]
- E. Expiration Date: [Indicate the date when the certification will expire]
- F. Certification attached: [Provide “Yes” or “No” accordingly, listed certifications should be attached with EoI Response sheet]

The Potential Applicants should carefully review the Project Requirement Document (Annexure 1), Notification for the EoI and criteria set by the K-DISC before submitting their EoI Response sheet. The applicants should express their interest in the project within the specified deadline through Kerala Startup Mission.

Annexures

Annexure 1- Project Requirement Document

Annexure 2- EoI Response Sheet Template

5. GENERAL TERMS

By submitting an EoI for the project Kerala Bone Marrow Registry, the startup acknowledges and agree to comply with the below specified period of completion, make all reasonable efforts to ensure timely delivery of the project, adhere to the specified payment terms and milestones-based payment schedule, and be bound by the terms of the separate Confidentiality and Non-Disclosure Agreement (NDA) to be executed with K-DISC.

5.1. Period Of Completion

The bidder acknowledges and agrees that the period of completion for the project-Kerala Bone Marrow Registry shall be a maximum of one year from the date of contract execution. The period of completion includes all phases of the project, including but not limited to design, development, implementation, testing, training, and handover.

The bidder shall provide a detailed project timeline and schedule as part of its submission, outlining key milestones, deliverables, and estimated timelines for each phase of the project. Any proposed deviations from the agreed-upon timeline shall be subject to approval by the Emerging Technology Division of K-DISC.

Failure to adhere to the agreed-upon period of completion may result in penalties, liquidated damages, or termination of the contract, at the discretion of K-DISC.

5.2. Payment Terms

| PAYMENT TERMS | |
|---------------------------------------|--|
| Payment (% of the total project cost) | Particulars |
| 10% | Upon signing the agreement |
| 20% | Upon successful achievement and acceptance by the client of Milestone 1 TRL 2 – 3 Basic research and proof of concept |
| 20% | Upon successful achievement and |

| | |
|-----|--|
| | acceptance by the client of Milestone 2 TRL 4-5 Applied research and early-stage development |
| 20% | Upon successful achievement and acceptance by the client of Milestone 3 TRL 6-7 System and component design development, system integration and testing. |
| 30% | Upon successful achievement and acceptance by the client of Milestone 4 , with Bank-Guarantee from the Technology Partner, worth 5% of the Total Amount (Exclusive of GST) for Warranty. TRL 8 – Early-stage pilot deployment |

(Note: The payment terms can be restructured to 4-6 payments according to the project)

1. The Payment for the Project shall be released based on the Milestone Achievements, the specific milestones and associated payment release shall be detailed and executed through an Agreement between the Parties
2. Technology partner shall submit utilization certificate in the prescribed format along with the expenditure statement signed by the Head of the institution from the second instalment. Utilization Certificate along with the audited expenditure statement duly signed by both the Chartered Accountant and Head of the institution is compulsory for above Rs. 5 Lakhs.
3. Technology partner shall submit a Bank Guarantee worth 5% of the total amount, for warranty, and a warranty agreement shall be signed with the K-DISC. The final payment based on the completion of last milestone shall be released only after signing the warranty agreement.
4. A final audited utilization certificate for the entire project cost shall be submitted to K-DISC at the end of the project.

5.3. Confidentiality and Non-Disclosure Agreement (NDA) Execution

1. **Confidential Information:** The term "Confidential Information" shall include all information, data, documents, materials, or other proprietary information provided by either party to the other party in connection with the EoI process, including but not limited to project plans, technical specifications, financial information, and business strategies.
2. **Non-Disclosure Obligation:** The bidder agrees to treat all Confidential Information received from the Emerging Technology Division of K-DISC as strictly confidential and shall

not disclose, divulge, or communicate any Confidential Information to any third party without the prior written consent of K-DISC.

3. **Use of Confidential Information:** The bidder agrees to use the Confidential Information solely for the purpose of evaluating and preparing its submission for the project- Kerala Bone Marrow Registry and shall not use the Confidential Information for any other purpose without the prior written consent of K-DISC.
4. **Protection of Confidential Information:** The bidder agrees to implement reasonable measures to protect the confidentiality and security of the Confidential Information, including but not limited to restricting access to Confidential Information to authorized personnel only and preventing unauthorized access, use, or disclosure of Confidential Information.
5. **Non-Compete Obligation:** The bidder agrees that during the EoI process and for a period of five years following the submission of its EoI, it shall not directly or indirectly engage in any activities or business ventures that compete with the objectives of the project- Kerala Bone Marrow Registry without the prior written consent of K-DISC.
6. **Survival of Obligations:** The obligations of confidentiality, non-disclosure, and non-compete shall survive the conclusion or termination of the EoI process and shall remain in full force and effect for a period of 5 years specified herein.
7. **Governing Law and Jurisdiction:** This Confidentiality and Non-Disclosure Agreement shall be governed by and construed in accordance with the laws of India, and any disputes arising out of or in connection with this Agreement shall be subject to the exclusive jurisdiction of the courts of Thiruvananthapuram

5.4 Service Level Agreement Terms

The offer submitted should cover all details covered as per the requirements of K-DISC. The technology partner is required to adhere to the following guidelines while preparing and submitting financial proposals to K-DISC.

COMMERCIAL PROPOSAL

- a) If there are any one-time costs, recurring costs, etc., they should be explicitly stated in the relevant sections of the table.
- b) One-year free warranty, covering both the software and hardware, must be included in the proposal.
- c) The Annual Maintenance Charge (AMC) after warranty period should be within 10% of the total project cost.
- d) If any third-party services are involved and their costs impact the proposal, the details of these services shall be provided.
- e) The system will be hosted at the State Data Centre (SDC), and K-DISC will supply the necessary virtual machines (VMs) for the project. Technology partner should ensure the specifications for the VMs are included in the cost summary table. Technology partner should also account for the resource cost involved in deployment to the SDC, while preparing the financials.

- f) K-DISC will carry out a Security Audit and Load Testing through CERT empaneled agency. The Technology partner should take into account the efforts required to resolve any issues identified in the Vulnerability Assessment and Penetration Testing (VAPT) process and Load Testing until the Final VAPT and Load Testing certificate is obtained.
- g) The source code along with any other project related artifacts must be transferred to K-DISC before raising the final payment invoice.
- h) The Technology partner is responsible for covering expenses for promissory note and courier charges for the agreements and any addendums (if applicable).
- i) Technology partner shall submit the required utilization certificates in K-DISC format for processing payments other than advance payment.
- j) The Technology partner is responsible for any expenses related to SSL certificates, domain validation, etc.
- k) In manpower section the details of different types of resources should be provided along with duration of their engagement

6. TERMS OF AGREEMENT

An agreement shall be signed between K-DISC (Client) and the selected Technology Partner after receiving due approvals. The Technology Partner is required to adhere to the following key terms of the agreement, along with any other terms specified.

6.1. Termination of Contract

- a) Either Party may terminate the Agreement by giving notice in writing to the other Party if,
 - i. the other Party materially breaches the Agreement and does not remedy the breach within 15 (fifteen) days of receipt of such written notice, or
 - ii. the other Party is or appears likely to be unable to pay its debts or become insolvent, or
 - iii. breaches any applicable law or regulation for the time being in force.
- b) Upon expiration/termination of the Agreement, the Technology Partner shall promptly deliver/ return without any pre-condition to Client all documents, data, source code and other information acquired by them from the Client. If Client is desirous of getting any further documents, data prepared/generated/ developed by the Technology Partner pursuant to the Agreement or any Scope of Work, such documents/ data should be provided to Client after settling the payment dues, as per the agreed project milestones. The Technology Partner shall ensure Services to Client, for a reasonable period, to ensure a smooth transition.
- c) Upon early termination of the Agreement, the settlement shall be made after deducting any payments or other charges due from the client, as completed by Technology Partner and accepted by the Client, in accordance with payment milestone, to the Technology Partner under any of the clauses of the agreement.

- d) Termination based on non-delivery of products/services is not permitted, except in cases where Liquidated Damages (LD) and compensation are explicitly outlined as in clauses 5.2 below.

6.2. Liquidated Damage

The period of completion of the work, stipulated in the contract, is the essence of the contract. If the Technology Partner fails to complete the work within the time period(s), then K-DISC shall, without prejudice to its other remedies under the Contract, deduct from the Contract price, as liquidated damages, a sum equivalent to 2% of the contract value per week or part thereof, up to a maximum of 10%. Once, the maximum is reached, then K-DISC may consider termination of the contract. K-DISC may withhold any payment due to the consultant until the whole of the work is completed. This clause is without prejudice to the right of K-DISC to make risk purchase mentioned and the liability under that clause shall be in addition to liquidated damages.

6.3. Settlement of Disputes: -

(a) Amicable Settlement, -

If during the subsistence of the agreement, Parties have differences or disputes on any matter directly or indirectly related to and/or connected with the Agreement, the same would be resolved by mutual consultations and for which purpose the Parties shall engage with each other.

(b) Arbitration, -

In case the attempt to resolve differences and disputes does not result in amicable settlement within 21(twenty-one) days of such reference then, either Party may as per its position initiate disputes redressal by means of arbitration, in India, in accordance with the provisions of Arbitration and Conciliation Act, 1996(26 of 1996). The arbitration shall be presided upon by a sole arbitrator to be appointed by the mutual consent of the Parties. The venue of such arbitration shall be in Thiruvananthapuram, Kerala and the language of such arbitration proceedings and that of all documents and communications between the Parties shall be English. The decision of the arbitrator shall be final and binding on the Parties. The expenses of the arbitrator as determined by the arbitrator shall be shared equally by Client and the Technology Partner. However, the expenses incurred by each Party, in connection with the preparation, presentation of the documents shall be borne by the Party itself. All arbitration awards shall be in writing and shall state the reasons for such award.

6.4. Governing Law and Jurisdiction

The Agreement, its meaning and interpretation, and the relation between the Parties shall be governed by the laws of the state of India (“Applicable Law”). Subject to clause “Settlement of disputes” mentioned above, the Courts of Kerala shall have exclusive jurisdiction. (The Client reserves the right to modify the agreement as may become necessary in terms of Government orders/circulars issued from time to time, during the term of the assignment based upon mutual consultation between both the parties.)

6.5. Force Majeure

- a) The Technology Partner shall not be liable for forfeiture of its performance security, liquidated damages, or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Agreement is the result of an event of Force Majeure.

- b) For purposes of this clause, “Force Majeure” means an event beyond the control of the Technology Partner and not involving the Technology Partner’s fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the State Government in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.
- c) If a Force Majeure situation arises, the Technology Partner shall promptly notify the Client in writing of such condition and the cause thereof. Unless otherwise directed by the Client /Government of Kerala in writing, the Technology Partner shall continue to perform its obligations under the Agreement as far as reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.
- d) It is hereby agreed between the parties that Force Majeure is applicable when need arises.

6.6. Penalty

If the Technology partner abandons the project without fulfilling the terms and conditions of the agreement, they will be liable to return the amount received from the Client with interest (12% of the principal amount) and penal interest as applicable to the Government funds.

6.7. OEM Conditions

OEM, as a recipient, shall ensure that their sub-recipients understand and acknowledge conditions and potential requirements that may be placed upon undertakings as a result of provisions of the Agreement with K-DISC. OEM shall defend, indemnify and hold K-DISC, and K-DISC’s officers, directors, and employees and agents harmless against any and all third party claims against K-DISC, including, without limitation, claims of infringement or misappropriation of intellectual property rights, arising from: (a) the OEM Products or services provided by OEM in conjunction with the OEM Products excluding the Product, or (b) OEM’s additions or changes to the Products, or use of the Products in combination with other materials not furnished by K-DISC or with systems, products or components not reasonably anticipated to be used with the Product or part thereof; and OEM shall pay in all such cases the costs, including reasonable attorney’s fees, finally awarded against K-DISC, provided that K-DISC:

(i) timely notifies OEM of the claim, and (ii) gives OEM a copy of each communication relating to the claim, and (iii) gives OEM the authority, information, and assistance, at OEM’s expense, reasonably necessary to defend or settle the proceeding. OEM agrees that any and all warranties made to K-DISC and End User Department shall be made only by the OEM. OEM acknowledges and agrees that OEM will make no additional representatives or warranties. In connection with any sale of the licensed software bundled with the OEM products, OEM shall expressly and conspicuously disclaim all express or implied warranties of merchantability or fitness for a particular purpose shall exclude liability for consequential damages and loss of profits and information. In addition to its indemnity obligations hereunder, OEM shall indemnify and defend K-DISC against any loss or damages, including attorney fees, arising out of OEM’s failure to comply with its obligations regarding warranties.

6.8. Guarantee/Warranty

- a) During implementation period

During the implementation, the Technology Partner shall meet all conditions set forth in the

Agreement and follow the implementation schedule strictly, failure to comply with the same, shall attract application of penalty clause.

- b) During Warranty period
 - i. Software

As part of the warranty covered as part of the agreement, the Technology partner shall.

- 1) Provide and install, at Technology partner's sole expense, with bug fixes and code corrections to correct software malfunctions in order to bring the services into substantial conformity with the specifications set forth in the projects scope of work. Bug fixes shall be acknowledged within one hour of the client intimating them and fixed within reasonable time as agreed with the client as per the severity of the bug.
- 2) Provide and install relevant updates of the software released by the Technology partner within the warranty period, installing them within 48 hours of release, without causing any downtime. In the event the Technology Partner foresees downtime requirement, the same shall be carried out with permission of the client
- 3) Ensure that the database used in the Project will be managed with reasonable care and diligence, and that any updates or modifications to the database and related changes to application will be performed in a timely manner, without causing any downtime. In the event the Technology Partner foresees downtime requirement, the same shall be carried out with permission of the client.
- 4) Perform any updates or modifications related to changes in configuration (App server/Web server, DB server etc.)/ operating system (OS)/ other operating environment of virtual machine's hosted at SDC in a timely manner, without causing any downtime. In the event the Technology Partner foresees downtime requirement, the same shall be carried out with permission of the client.
- 5) Take necessary steps for maintaining SSL Certification and Domain validation and maintenance, including the initial purchase and any subsequent renewal during the Warranty Period.
- 6) The Technology Partner shall provide timely and adequate support to the Client whenever necessary, including technical support and customer service. Such support shall be provided within 12 hrs from the receipt of the support request from the Client.
- 7) The Technology Partner is responsible for implementing security measures to protect the application from unauthorized access and promptly addressing any security issues within 12 hours of identification.
- 8) The Technology Partner must provide monthly reports to the Client that outline the application's performance, availability, and incidents that occurred during the reporting period.
- 9) The Technology Partner is responsible for 24/7 monitoring of the application, proactively detecting and resolving any issues within 24 hours of detection.
- 10) The Technology Partner is responsible for providing training and documentation to the Client's staff on the proper use of the application, which must be provided after before handing over the project to the End User Department
- 11) The Technology Partner must maintain adequate staffing levels to provide timely and effective support for the application and provide a designated point of contact for the Client's staff to contact in the event of any issues.
- 12) All issues raised during the warranty period must be addressed and resolved by the Technology Partner.

- ii. Hardware
 - 1) The Technology Partner shall ensure that any hardware components supplied as part of the project will be free from defects in materials and workmanship. If any such defects arise during this warranty period, the Technology Partner will repair or replace the defective hardware at no additional cost to the Client.
 - 2) The Technology Partner shall ensure that
 - a. The hardware will meet the performance specifications specified in the Agreement throughout the warranty period
 - b. Periodic maintenance of the hardware is carried out as required.
 - c. If any issues arise due to the Technology Partner's improper actions or omissions, the Technology Partner shall promptly correct the issues at no additional cost to the Client
 - 3) The Technology Partner is responsible for providing training and documentation to the Client's staff whenever Hardware/ Equipment is repaired/upgraded during warranty period. The Technology Partner must maintain adequate staffing levels to provide timely and effective support for the Hardware/Equipment, and provide a designated point of contact for the Client's staff to contact in the event of any issues.
- c) During AMC period

The Technology Partner shall comply with all the conditions in the AMC Agreement to be signed upon mutual agreement.

6.9. Contract Period / Duration or Validity

The agreement shall valid for one year with effect from the date of signing of the Agreement, covering the installation and commissioning and the warranty period.

6.10. Change Orders / Management of Change in Scope of Work: -

The Agreement is based on the scope of work given in 'Schedule A', furnished as part of agreement as well as in the K-DISC Project proposal as approved by end user department. Any change in Scope of Work, and any delay from end user department/ K-DISC with respect to approvals, site readiness etc. or decisions of end user department/K-DISC which may result in:

- a) Enhancement to Geographical, Functional or Technical Scope of Work
- b) Postponement of the major milestones in Project Plan or
- c) Any other matter to be mutually identified and agreed by the parties and shall be subject to the following change management process:
 - i. A Scope Change Request ("SCR") as raised by either the Client or Technology Partner's Project Manager accompanied by suitable supporting documents.
 - ii. Technology Partner shall prepare a detailed estimate of actual efforts to be required together with an estimate of additional fees and likely impact on the Project Plan for each SCR
 - iii. Only upon formal written approval by Client of the SCR, together with cost and time estimates, Technology Partner shall commence any work arising out of the SCR(s).

On approval by K-DISC, a new appendix containing the changes to the Agreement shall be mutually signed and appended to the Agreement, which together with the existing Schedules, shall constitute the entire Agreement.

6.11. Subcontract

The Technology Partner shall notify K-DISC in writing of all subcontracts awarded under

the contract if not already specified in their bid. Such notification, in the original bid or later shall not relieve the Technology Partner from any liability or obligation under the contract.

6.12. Risk Purchase Clause

K-DISC shall reserve the right to terminate the order or contract and purchase from anywhere at the risk and cost of the Technology Partner, either the whole part of the system/goods which the Technology Partner has failed to deliver within the stipulated delivery period or if the same were not available, the best and the nearest available substitute(s) thereof. The Technology Partner would be liable to compensate the K-DISC for any loss, which the K-DISC may sustain by reason of such purchase. This clause will be operated only after completion of delivery period including extended period with penalty.

6.13. Project Monitoring and Feedback Collection

- a) The Technology Partner shall monitor and track the progress, milestones, and overall performance of the project. The project monitoring should include regular status meetings, progress reports, and key performance indicators (KPIs) to assess project success.
- b) The Technology Partner shall provide regular project status reports to the client, outlining the achieved milestones, deliverables, and any significant project updates. The frequency and format of the reports shall be defined and agreed upon by the client.
- c) The Technology Partner shall take necessary actions for collecting feedback from the client & end user department regarding the project's progress, quality, and adherence to requirements. Feedback collection methods may include surveys, meetings, or other communication channels to gather input from client & end user department.
- d) The Technology Partner shall review and analyze the feedback received from the client and end user department promptly. Based on the feedback, the Technology Partner shall develop an action plan to address any identified issues, concerns, or areas for improvement.
- e) The Technology Partner shall document the lessons learned from the project monitoring and feedback collection process.

Annexure 1

Requirement Document
For
KERALA BONE MARROW REGISTRY



**Kerala Development of Innovation and Strategic Council
(K-DISC)**

09.09.2024

Version 1.0

TABLE OF CONTENTS

| | |
|--|-----------|
| CONTENTS | 2 |
| 1 ORGANIZATION PROFILE | 4 |
| 2 INTRODUCTION | 4 |
| 2.1 BUSINESS CASE FOR THE PROJECT | 4 |
| 2.2 SUMMARY OF THE PROPOSAL..... | 4 |
| 3 PROJECT OBJECTIVES | 5 |
| 4 SCOPE OF THE PROJECT | 5 |
| 4.1 FUNCTIONAL REQUIREMENTS | 7 |
| 4.1.1 <i>User Management</i> | 7 |
| 4.1.2 <i>Collection Centre Module:</i> | 8 |
| 4.1.3 <i>Transplant Centre Module</i> | 13 |
| 4.1.4 <i>Patient – Donor Matching Module:</i> | 14 |
| 4.1.5 <i>Reports Module</i> | 15 |
| 4.1.6 <i>Public Dashboard</i> | 16 |
| 4.2 API INTEGRATION | 16 |
| 4.3 PAYMENT MODULE..... | 18 |
| 4.4 NON-FUNCTIONAL REQUIREMENTS | 18 |
| 5 IMPLEMENTATION STRATEGY | 19 |
| 5.1 TECHNICAL APPROACH | 19 |
| 5.2 KEY BENEFITS TO BE ACHIEVED | 19 |
| 6 PROJECT SCHEDULE | 19 |
| 7 SERVICE LEVEL AGREEMENT TERMS | 20 |
| 7.1 PROJECT MONITORING AND FEEDBACK COLLECTION | 21 |

List of Tables

| | |
|---|----|
| FIGURE 1: PROPOSED ARCHITECTURE OF KERALA BONE MARROW REGISTRY | 6 |
| FIGURE 2: WORKFLOW OF THE SAMPLE COLLECTION AND TESTING PROCESS FOR DONOR | 10 |
| FIGURE 3: THE DONOR HLA TYPING RESULTS ENTRY SHOULD BE IN THE FORMAT GIVEN ABOVE..... | 11 |
| FIGURE 4: DONOR JOURNEY (REFER 4.2 FOR API'S) | 11 |
| FIGURE 5: PATIENT DONOR MATCHING PROCESS 1 (REFER 4.2 FOR API'S) | 12 |
| FIGURE 6: PATIENT REGISTRATION PROCESS..... | 12 |
| FIGURE 7: DONOR PATIENT MATCHING PROCESS1 (REFER 4.2 FOR API'S)..... | 13 |
| FIGURE 8: PATIENT PROCESS FLOW..... | 15 |

List of Figures

| | |
|------------------------------|----|
| TABLE 1: DONOR STATUS..... | 17 |
| TABLE 2: PATIENT STATUS..... | 18 |

List of Abbreviations

| Sl. No | Abbreviation | Definition |
|--------|--------------|--|
| 1 | WMDA | World Marrow Donor Association |
| 2 | KBMR | Kerala Bone Marrow Registry |
| 3 | KCR | Kerala Cancer Registry |
| 4 | API | Application Programming Interface |
| 5 | UHID | Unique Health Identification. |
| 6 | ABHA | Ayushman Bharat Health Account |
| 7 | CMV | Cytomegalovirus |
| 8 | EBV | Epstein-Barr virus |
| 9 | HIV | Human Immunodeficiency Virus |
| 10 | PBSC | Peripheral Blood Stem Cell |
| 11 | HLA | Human Leukocyte Antigens |
| 12 | DNA | Deoxyribonucleic acid |
| 13 | NIMA | Non-Inherited Maternal Antigen |
| 14 | HAC | Health and Availability Check |
| 15 | ALT | Alanine aminotransferase |
| 16 | IDM | Infectious Disease Marker |
| 17 | EMDIS | European Marrow Donor Information System |
| 18 | SRS | Software Requirement Specification |
| 19 | MCC | Malabar Cancer Centre |
| 20 | EHR | Electronic Health Record |
| 21 | MVP | Minimum Viable Product |
| 22 | URL | Uniform Resource Locator |
| 23 | UI/UX | User Interface/User experience |
| 24 | UAT | User Acceptance Testing |
| 25 | VAPT | Vulnerability Assessment and Penetration Testing |
| 26 | AMC | Annual Maintenance Contract |
| 27 | CERT | Computer Emergency Response Team |

1 Organization Profile

Kerala Development and Innovation Strategic Council (K-DISC) is a strategic think-tank advisory body constituted by the Government of Kerala. It aims at bringing out path-breaking strategic plans that reflect new directions in technology, product and process innovations, social shaping of technology, and creating a healthy and conducive ecosystem for fostering innovations in the State. In the sphere of development, K-DISC is promoting and initiating new projects in Emerging Technologies such as Blockchain, Internet of Things, Machine Learning, Artificial Intelligence, Robotics, and soon that would enable transparent and cognitive advances in various departments of the State Government and deliver the ultimate benefit to the citizens. K-DISC would facilitate with different government departments that may need any of these technological advances to solve their critical problems and to arrive at the proof of concepts stage with adequate technical and financial resources to promote innovation. Also, K-DISC will ease the implementation by overseeing the same.

2 Introduction

eHealth Kerala, in collaboration with Kerala Development and Innovation Strategic Council (K-DISC) and Kerala Startup Mission had organized 'Hack 4 Health', a Hackathon event on November 22nd to 24th, 2021, soliciting start-ups to attempt 8 problem statements developed by the Department of Health and Family Welfare. "Single server data analytics dashboard with multiple forms for patient management" was one of the eight problem statements. On further meetings with domain experts to evolve a comprehensive project proposal, it was decided to focus specifically on building a digitized bone marrow registry. Accordingly, K-DISC has prepared this comprehensive project proposal with input from the domain experts at Malabar Cancer Centre, Thalassery.

Based on the suggestion from e-Health Kerala, the Bone Marrow Registry is envisaged to be developed and implemented as "Kerala Bone Marrow Registry", integrated with eHealth and the 'Kerala Cancer Registry' being developed by eHealth Kerala. Department of Health and Family Welfare vide G.O.(Rt)No.2034/2024/H&FWD dated 26-08-2024 accorded administrative sanction for the pilot implementation of the project in coordination with Malabar Cancer Center, Thalassery

2.1 Business Case for the Project

On average, around 50 patients reach Malabar Cancer Centre, Thalassery every year seeking Bone Marrow Transplant. Patients are matched with suitable donors through a multi-step process involving Patient Registration, Donor Registration and matching process. Marrow Donor Registry (India) website says that less than 30% of those in need of a transplant will find a suitable donor. Currently, State of Kerala does not have functional Marrow Donor Registry. Having such an indigenous registry can increase the number of registered donors, thereby increasing the chances of finding suitable donors for more patients. Currently Patient/Donor registration and matching processes are not fully digitized. Implementing a digital bone marrow registry will lead to ease of use by reducing manual errors and saving time.

Currently the private bone marrow registries charge between Rupees 6 - 8 Lakhs for patient-donor matching. The proposed Kerala Bone Marrow Registry will significantly reduce this cost and make patient-donor matching more affordable.

2.2 Summary of the Proposal

The project is for setting up a web-based Kerala Bone Marrow Registry which will be integrated with the proposed Kerala Cancer Registry. The operations of the Kerala Bone marrow registry are closely linked to the Advanced Blood Collection centers, where the donors register their names and the Transplant centers, where the patients register and undergo transplantation. The registry does the donor matching for each patient based on a standardized globally accepted World Marrow Donor Association (WMDA) donor matching algorithm, and the list of matched donors is updated in the

registry which can be accessed by the Transplant center. A set of confirmatory tests are carried out on the matched donors to identify the best fit. Transplant Centre will carry out the transplant process using the stem cell donated by the best fit donor.

The proposed project will digitally transform the multi-step processes from donor and patient registration, donor-patient matching, transplant process and post donation follow ups. The proposed Kerala Bone Marrow registry will also integrate with the World Marrow Donor Association (WMDA) so that the patients from Kerala can easily search for possible matching donors across the world and vice versa.

3 Project Objectives

1. Development and Implementation of Kerala Bone Marrow Registry (KBMR) integrated with eHealth and Kerala Cancer Registry (KCR) with bidirectional flow of information.
2. This will provide the facility for donor registration, patient registration and patient-donor matching for the registered individuals.
3. Donor registration can be done at the registered institutions or any other Advanced Blood Collection Centres across the State of Kerala or any registered private institutions through the KBMR registry.
4. Patient registration can be done through registered institutions such as Transplant Center.
5. Integration with World Marrow Donor Association (WMDA) registry through the annual membership details provided by Malabar Cancer Center (MCC) for one year. After this period, the membership information shall be migrated to the nodal agency recommended by the Government of Kerala.
6. Prediction of transplant success and post-transplant complications using Artificial Intelligence and Machine Learning

4 Scope of the Project

1. Development and deployment of a web-based application for Kerala Bone Marrow Registry to be hosted at the State Data Centre. Kerala Bone Marrow Registry will have the following modules:
 - a. Donor/Patient Registration Module
 - b. Collection Centre Module
 - c. Transplant Centre Module
 - d. Patient-Donor Matching Module
 - e. Admin Module
 - f. Reports Module
2. Digitize the process involved in donor registration, patient registration, patient-donor matching, and post-transplant follow ups. The current process flow is detailed in figure 4.
3. The Kerala Bone Marrow Registry shall be integrated with eHealth through APIs to ensure bidirectional flow of information. Those patients registering in KBMR should be automatically registered in KCR. The details of APIs required for integration with eHealth are provided in section 4.2 and 4.3.
4. The user login to the Kerala Bone Marrow Registry shall be based on Single Sign On using Key Cloak. (APIs for Key Cloak SSO to be provided by eHealth).

5. To establish an online tool to predict complications of allogenic HSCT in Indian setting as an additional tool in Blood and Marrow Donor Registry software
6. The following figure shows the proposed architecture of Kerala Bone Marrow Registry.

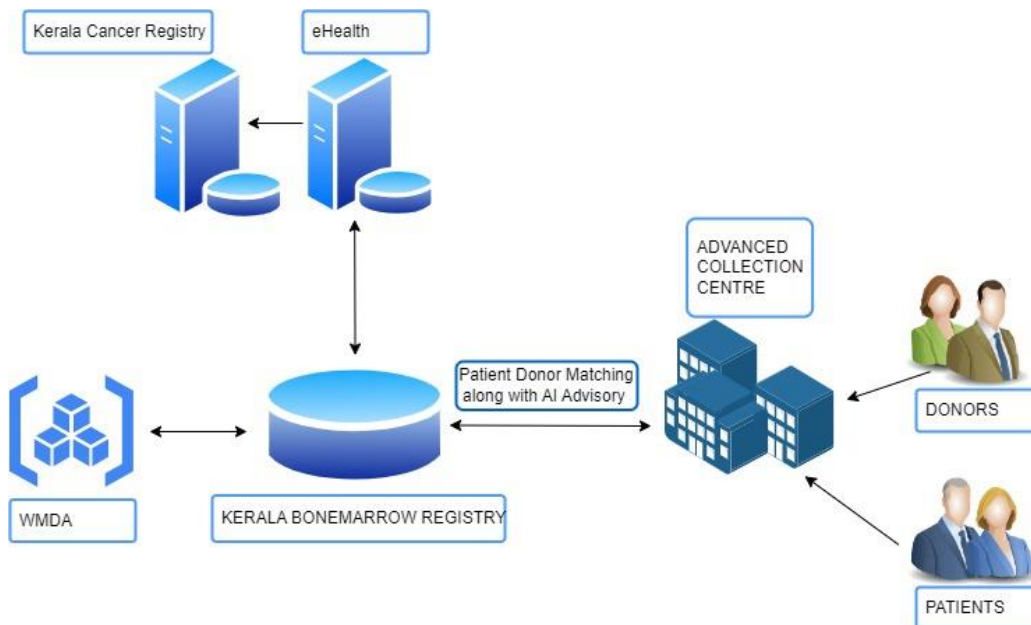


Figure 1: Proposed Architecture of Kerala Bone Marrow Registry

a. Donor/Patient Registration Module

- i. The Donor/Patient registration module in the Kerala Bone Marrow registry will perform the functionality to input donor/patient details into the registry. This will be done through ABHA/UHID of the donor/patient. The information is validated through the necessary API's from eHealth Kerala. If the UHID/ABHA ID's are already available in the eHealth database, then the available information from eHealth is auto filled otherwise a new registration.

b. Collection Centre Module

- i. The collection Centre module shall be accessed by Advanced Blood Collection Centres. The module shall incorporate the following functionalities.
- ii. Donor Registration –Using UHID / ABHA ID for Indian Citizens. WMDA ID to be used for non-Indian citizens
- iii. Sample Collection and Testing – Bar codes should be generated for sample labelling and tracking. Bar codes should be based on unique ID and time stamp. Integration for barcode printing should be done.
- iv. Donor Follow up.
- v. Payment Gateway to accept payments from patients for availing the services of the registry.

c. Transplant Centre Module

- i. The Transplant Centre module shall be accessed by various Transplant Centres across the state of Kerala. This module will have the functionalities
- ii. Patient Registration -Using UHID/ABHA ID
- iii. Preliminary Search Request

- iv. Confirmatory Tests
- v. Transplantation Details
- vi. Patient Follow-up
- vii. Payment Gateway to accept payments from patients for availing the services of the registry.

d. Patient-Donor Matching Module:

- i. Patient-Donor Matching module shall be an internal module of the Kerala Bone Marrow Registry that will act as the backbone for matching the patient to donor.
- ii. Possible donors will be displayed both from Kerala Bone Marrow Registry and World Marrow Donor Association (WMDA).
- iii. Prediction of transplant success and post transplant complications using Artificial Intelligence and Machine Learning
- iv. Transplantation Details
- v. Patient Follow-up
- vi. Payment Gateway to accept payments from patients for availing the services of the registry.

4.1 Functional Requirements

4.1.1 User Management

4.1.1.1 Register Institutions

Both Private and Public institutions can register themselves as Collection Centre, Transplant center or both in the registry portal. This information will be updated in the central registry and during the matching process the registry will classify the donors/patients based on the data provided by these institutions.

A. Register Users and Set access privileges.

1. Super Admin
 - Has the privilege to register/modify new institutions and the IT administrator users for that institution.
 - If required, they can also register/modify for particular institutions.
2. Institution specific roles
 - a. IT Administrator
 - Each registered institution will have a central IT administrator who will be the authorized personnel for managing the institution's registry and its users. This includes creation of users based on certain categories and assigning the necessary privileges and access control.
 - b. Doctor
 - Authorized Senior Doctors/ Consultants
 - c. Technician
 - Lab Technicians/Nurses -

For example, authorized Senior Doctors or Consultants may have the privilege to search and access the matched donor data for a particular patient and Lab technicians have the privilege to add lab test related data for a donor / patient.

4.1.2 Collection Centre Module:

Advanced Blood Collection Centres in Government Medical Colleges as well as private hospital centres (if required) will be acting as the collection centre where the following functions are carried out:

- Registering individuals willing to donate bone marrow, collecting samples for testing, and sending the samples for testing and updating the registry with the reports.
- During registration of a donor, the system should check if the citizen is already registered in eHealth system through API. If available, the required information is auto filled through API, else a manual registration is done for the donor. This information is also added to the eHealth system through upload API's.
- All samples need to be bar coded using Donor's Unique ID and Timestamp.
- Donor information to be integrated with World Marrow Donor Association (WMDA) registry through the annual membership information provided by Malabar Cancer Center.
- After successful registration, a WMDA ID is created for both donor and the patient.
- Facility to collect any payment through online payment gateway.
- Contact the potential donors who are shortlisted, collect the stem cell sample and send it to the testing centre.
- Periodic follow ups with a donor after stem cell donation.
- The system should have provision to collect the following details to create the Donor Database:
 - a. Unique registration identifier for donors -
 - i. Aadhaar number,
 - ii. UHID/ABHAID,
 - iii. donor centre ID,
 - iv. Recruitment/WMDA ID.
 - b. Demographics:
 - i. Name,
 - ii. Title,
 - iii. Gender,
 - iv. Date of birth,
 - v. Ethnic group,
 - vi. Mother tongue, and so on.
 - c. Contact details:
 - i. Permanent address,
 - ii. Temporary address
 - iii. Work address,
 - iv. E-mail,
 - v. Phone numbers,
 - vi. Social media networks,

- vii. Communication language,
 - viii. Preferred contact method,
 - ix. History of communication with the donor.
- d. Medical questionnaire:
 - i. Weight,
 - ii. Height,
 - iii. Blood group,
 - iv. Hemoglobin,
 - v. Number of pregnancies,
 - vi. Number of blood transfusions,
 - vii. Donor consent to different types of donations, and
 - viii. Past diseases.
- e. Recruitment:
 - i. Donor centre,
 - ii. Date of recruitment,
 - iii. Recruitment method (website, patient-draft, blood donor, indication of whether the donor is also a blood or platelet donor)
- f. Donor status:
 - i. Reservation of the donor,
 - ii. Temporary or permanent withdrawal,
 - iii. Reason of withdrawal (age, medical, personal).
- g. Infectious disease markers:
 - i. CMV status,
 - ii. Toxoplasmosis,
 - iii. EBV status,
 - iv. HIV status,
 - v. HIV p24 antigen, antibodies to HIV, hepatitis B and C status and antibodies, Lues status, ALT status, with dates of tests and laboratories that performed tests.
- h. Collection:
 - i. Date and place of collection,
 - ii. Date and place of transplant,
 - iii. Patient ID,
 - iv. Source of stem cells (bone marrow, PBSC, DLI, cord blood, other)
 - v. Barcode
- i. HLA data:
 - i. Separate fields for serology and DNA typing results,

- ii. Typing laboratory,
 - iii. Date of typing,
 - iv. Primary typing data includes HLA A, B, C, DRB1, DQB1, DPB1, with options for capturing KIR typing, MICA-129, HLA-E, CCR5,
 - v. NIMA, etc.
- j. Products:
- i. Information about the stored donor samples, their position in the freezer and so on.
- k. Relationships:
- i. Family or personal relations to other donors or patients, used for family reports of the patient.
- l. Donor follow-up details:
- i. It should be possible to identify the person who has created or modified the donor record and when, with a searchable history of changes to the donor record.



Figure 2: Workflow of the Sample collection and testing process for Donor

The sample testing involves:

- a) Sample Collection & Testing
- b) Testing Report Preparation
- c) Verification

The test results are added into the Kerala Bone marrow Registry based on the reports obtained from the testing centre.

There shall be provision for

- Donor Status Recordings at the time of requirements
- Donor reminder on specific days

Details of Donor Sample Testing:

1. Sample Received Date
2. DNA Extraction Date
3. HLA Testing Date
4. Validated by
5. Sample stored at
6. Kit Details
7. Barcode

| HLA results (HLA codes based on IMGT/HLA Release 3.40.0) | | | | | |
|--|----------------------|----------------------|-----------|----------------------|----------------------|
| Class I | | Class II | | | |
| HLA-A* | <input type="text"/> | <input type="text"/> | HLA-DRB1* | <input type="text"/> | <input type="text"/> |
| HLA-B* | <input type="text"/> | <input type="text"/> | HLA-DQB1* | <input type="text"/> | <input type="text"/> |
| HLA-C* | <input type="text"/> | <input type="text"/> | HLA-DPB1* | <input type="text"/> | <input type="text"/> |

bold = required
Additional results
 + Enter additional results

Figure 3: The Donor HLA Typing Results Entry should be in the format given above

The Donor journey is represented below:

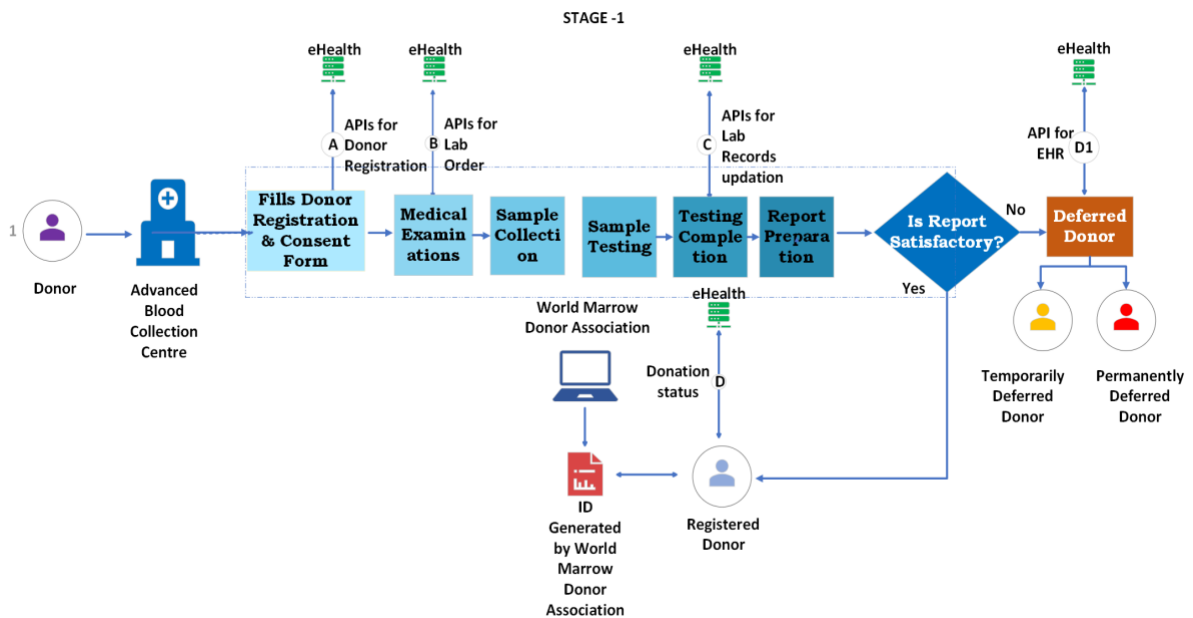


Figure 4: Donor Journey (Refer 4.2 for API's)

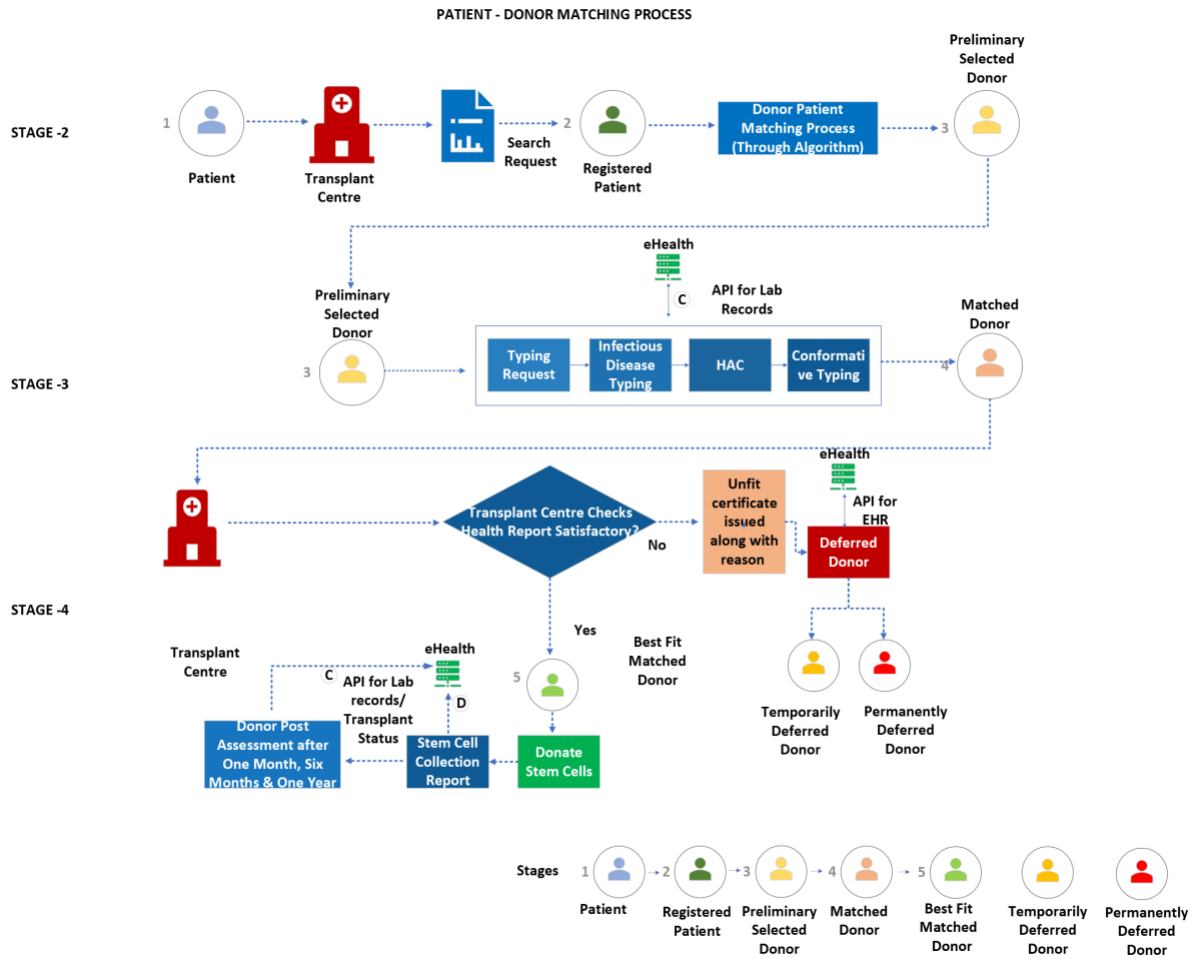


Figure 5: Patient Donor Matching Process 1 (Refer 4.2 for API's)

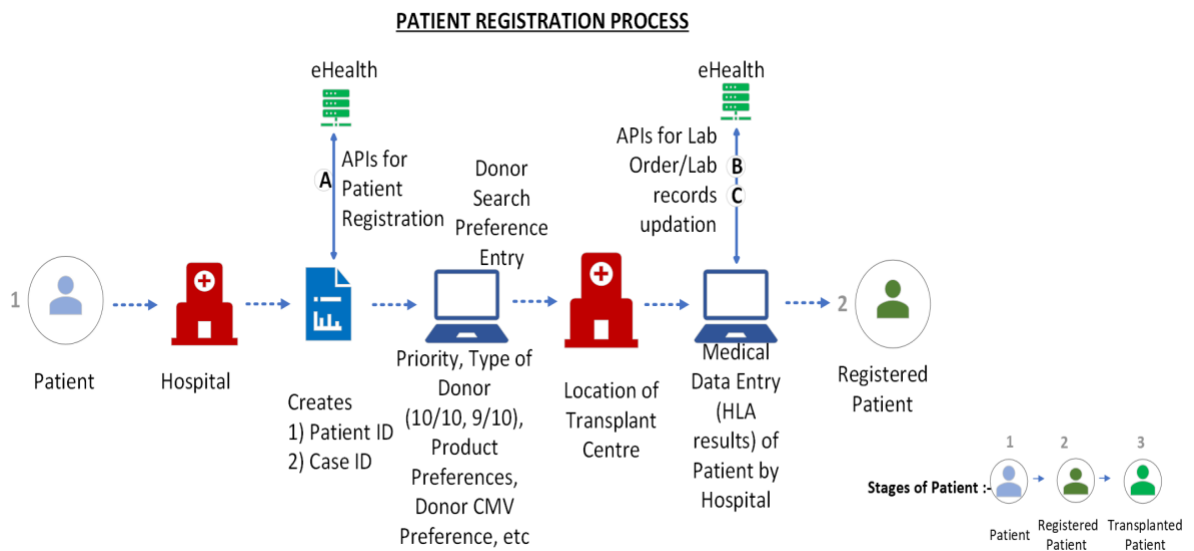


Figure 6: Patient Registration Process

DONOR PATIENT MATCHING PROCESS

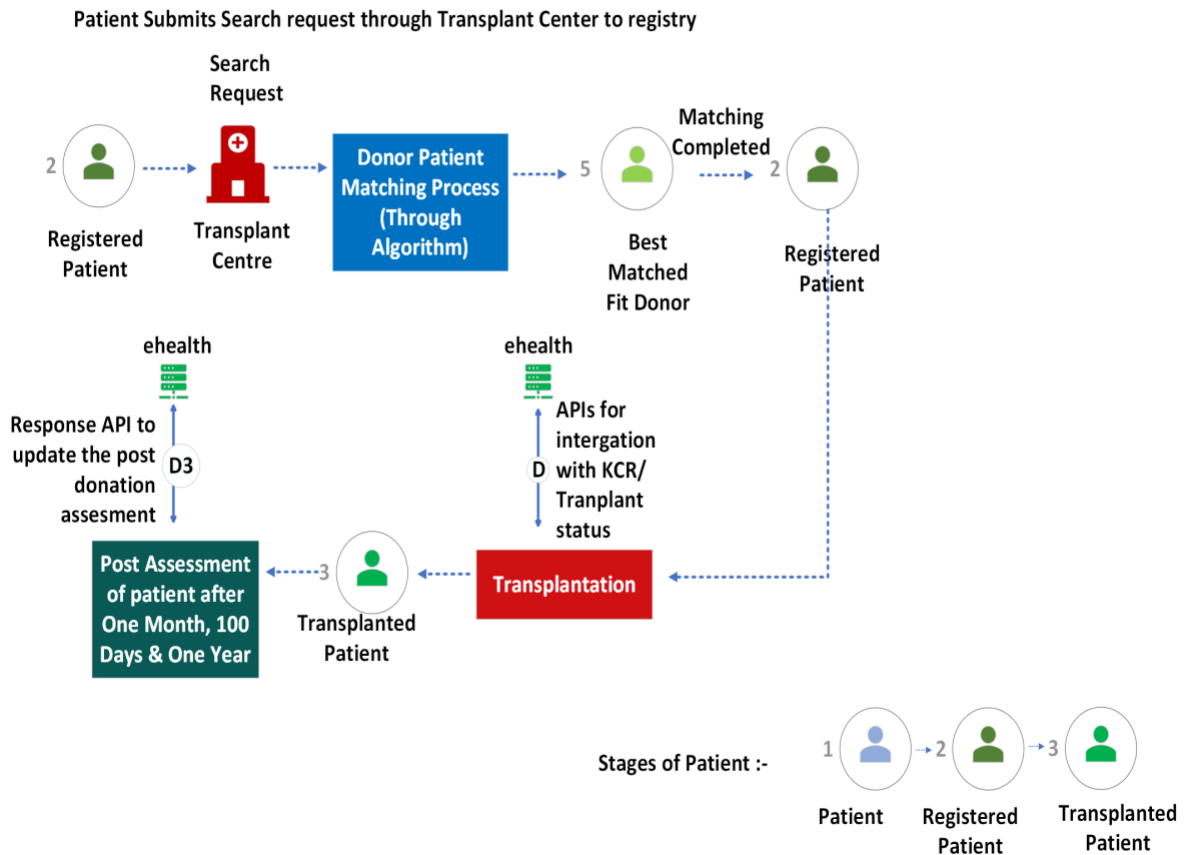


Figure 7: Donor Patient Matching Process1 (Refer 4.2 for API's)

4.1.3 Transplant Centre Module

The Transplant centre module will have the following functionalities:

- Provision for patient registration using UHID/ABHA ID
- During registration of a patient, the system should check if the citizen is already registered in eHealth system through API. If available, the required information is auto filled through API, else a manual registration is done for the patient. This information is also added to the eHealth system through upload API's.
- Provision for online payment to avail search facilities.
- Provision for preliminary searching of donors based on Patient Details including Patient ID, Search Preferences and Organizations/Institutions Involved
- While registering a patient, there should be provision to collect the following details:
 - A unique registration donor identifier (UHID / ABHA ID) for patient, but can also include Aadhaar number, transplant centre ID, hospital record ID, EMDIS ID and Physician
 - Demographics: name, title, gender, date of birth, insurance company and so on.

- Relationships: family or personal relations to donors, used for family reports of the patient.
- Patient status: donor search status, transplantation status, closure of the case (date, reason).
- Medical information: diagnosis, disease phase, weight, blood group, CMV status.
- HLA data: separate fields for serology and DNA typing results, typing laboratory, date of typing, primary typing data. Separate fields for historical HLA results.
- Transplants: date and place of collection, date and place of transplantation, donor ID, source of stem cells (bone marrow, PBSC, DLI, cord blood, other).
- Need customizable reports of donor and patient details, provision to export to PDF files, provision to send emails to donors through user-defined templates.
- It should be possible to identify who has created or modified the patient record and when, with searchable history of changes of the patient record. Both donor and patient database must be searchable by different attributes
- There should be no expired reservations of donors, no over-age donors that are marked as 'available for transplant purposes' on the searches, no donors missing critical data (Example-date of birth, gender)
- Provision for downloading the receipt of search report from the Registry.
- Request for blood sample from Donor registry for HLA Verification Typing, Receipt of Infectious Disease Marker testing results from Donor Registry during donor workup and Health and Availability Check (HAC)
- Receipt of donor's extended HLA typing test results and Infectious Disease Marker (IDM) Results from lab.

4.1.4 Patient – Donor Matching Module:

The matching process of a patient with a donor shall be based on the globally accepted matching WMDA algorithm provided by the Malabar Cancer Centre (MCC).

The matching algorithm uses HLA type matching.

- HLA Typing: The patient and potential donors are HLA typed using various methods such as DNA analysis, blood test or tissue typing.
- Searching for Donors: Once the patient's HLA type is determined, a search is initiated for potential donors who match the patient's HLA type.
- Potential donors are ranked based on how closely the HLA type of the donor matches the SLA type of the patient. Lower number of HLA mismatches indicate a closer match.
- Compatibility Assessment: Once potential donors are identified, further testing is done to confirm their compatibility with the patient. This usually includes additional HLA testing, blood tests, and medical evaluations to ensure the donor is healthy enough to donate.
- Selection of Donor: The most compatible donor is initially searched within the Kerala Bone Marrow Registry and if unavailable in the KBMR, then a search will be initiated in WMDA registry. Further, the transplant process is initiated.

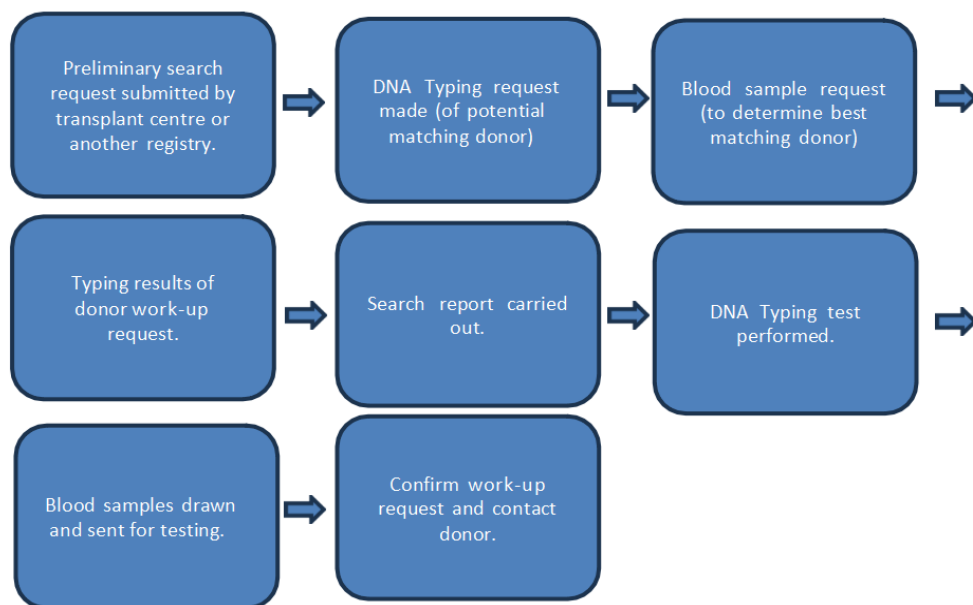


Figure 8: Patient process flow

The below listed reports can be generated from the Kerala Bone Marrow Registry

4.1.5 Reports Module

1. **Registry Overview Report:** This report provides a high-level summary of the registry's status, including the total number of registered donors, recipients, registered institutions and number of transplants done with options to filter based on different dates.
2. **Donor Report:** It details the effectiveness of donor recruitment efforts, including metrics such as the number of new donor registrations over time, demographics of registered donors, sources of donor referrals and the list of deferred donors.
3. **Recipient Needs Report:** This report outlines the current needs of patients awaiting transplantation, including the number of active patient profiles, their HLA characteristics, and the urgency of their cases.
4. **Transplant Report:** This gives a report on the number of transplants done at various registered institutions.
5. **Institutional Summary:** This report will include each participating institution's profile details such as its name, location, type and contact information.
6. **Payment Reports / Accounts Summary:** This report will include the transactions made to the registry for the selected period.
7. **Report module will be available for users based on their access privileges.**

4.1.6 Public Dashboard

The Kerala Bone Marrow Registry will include a public dashboard, with the following information accessible to everyone.

1. How to Register:
 - i. Clear instructions on how individuals can register as donors.
 - ii. Links to registration forms or sign-up events.
2. Donor Statistics:
 - i. Total number of registered donors.
 - ii. Breakdown by age, gender
 - iii. Number of new registrations.
 - iv. Matches and Transplants:
3. Number of successful matches made.
 - i. Number of transplants conducted.
 - ii. Waiting List Statistics:
4. Information on the number of patients currently on the waiting list for a bone marrow transplant, as well as their demographics
 - i. Geographic Distribution:
5. Regional distribution of donors and recipients.
6. FAQs and Resources:

Frequently asked questions about bone marrow donation, transplantation process, and for further information or support.
7. Contact Information:

Details on how to get in touch with the registry for inquiries assistance.

4.2 API Integration

The following is the list of APIs that will be provided by eHealth, Kerala for the seamless integration of Kerala Bone Marrow Registry with Kerala Cancer Registry through eHealth.

A. Donor / Patient Registration

1. Search eHealth from Bone Marrow Registry with UHID/ ABHA ID / Aadhaar.
2. Download API with Patient details if UHID/ ABHA ID is available in eHealth.
3. Upload API to eHealth with ABHA ID/ Aadhaar/ WMDA ID (in the case of foreign donors) and other details.
4. Download API with UHID /Temporary UHID (in case of foreign donors with WMDA ID) of the new patient registered at eHealth.
5. Upload API with Donor ID / Patient ID created in KBMR, to be stored in eHealth system as future reference.

B. Donor / Patient Lab Order

1. Search eHealth with UHID for medical records related to HLA Typing, Infectious Disease Marker (IDM), and confirmatory tests.
2. Download API to fetch test report of preliminary lab orders, HLA Typing, Infectious Disease Marker (IDM) and confirmatory tests (if already available in eHealth).
3. Upload API to initiate lab tests - preliminary tests, HLA Typing, Infectious Disease Marker (IDM), and confirmatory tests. (for hospitals under eHealth with lab facility). Upload API to update the test report of preliminary tests, HLA Typing, Infectious Disease Marker (IDM), and confirmatory tests (if tests are done in centers other than eHealth enabled hospitals).

C. Transplant Status

- eHealth should capture this information and store it against the patient record and KBMR donor ID in the main pages of the health system for easy visibility to the status of the Donor in KBMR.

1. Upload API to update the status of donor.

The following table shows the suggested statuses for the Donor in various stages of Donor Journey.

| SI No | Status | Description |
|-------|----------------------|--|
| 1 | Registered Donor | Donors registered in the Kerala Bone Marrow Registry with a UHID, Donor ID and WMDA ID |
| 2 | Approved donor | Donors approved for stem cell donation after preliminary tests |
| 3 | Temporary deferred | Donors deferred temporarily due to health conditions |
| 4 | Permanently deferred | Donors deferred permanently due to age, illness etc |
| 5 | Matched Donor | Donors Matched for a patient as per the matching algorithm |
| 6 | Best Fit donor | Best fit donor selected for a particular patient from the list of Matched Donors based on tests conducted. |
| 7 | Stem cell donated | Donor status after stem cell donation to a patient |

Table 1: Donor Status

2. Upload API to update the status of patients to eHealth from Kerala Bone marrow Registry.

The following table shows the suggested statuses for the Patient in various stages of Patient Journey.

| SI. No | Status | Description |
|--------|--------|-------------|
|--------|--------|-------------|

| | | |
|---|----------------------|---|
| 1 | Registered Patient | Patients registered in the Kerala Bone Marrow Registry with UHID and KBMR Patient ID. |
| 2 | Matched Patient | Patient matched with a donor as per the matching algorithm |
| 3 | Transplanted Patient | Transplant completed |

Table 2: Patient Status

- Further queries into the KBMR from eHealth can be made using the KBMR Donor ID and UHID as references to retrieve more information regarding the transplant/matching. The below APIs can be provided from KBMR, to eHealth for this. eHealth can list further requirements and corresponding APIs from KBMR shall be made available.
 1. Response API to provide stem cell donation details of donor to eHealth.
 2. Response API to provide information on successful transplantation completed in Transplanted donor's EHR.
 3. Response API to provide post donation assessment details of donor to EHR.
 4. Response API to provide post donation assessment details of patient to EHR.

D. For integration with Cancer Registry

1. Download API to retrieve medical records from Cancer Registry of donor/patients from KBMR (to be given by eHealth).
2. Response API to provide patient details, stem cell donation or transplant details can be provided from KBMR.

Further details regarding the API integration shall be included in the SRS during implementation stage.

4.3 Payment Module

A payment module shall be made available in the registry.

- Handle the payments to the registry by patients, to avail the donor search facilities.
- Department can add or modify the tariff. The Super Admin will have the access to add/modify tariffs.

The tariff shall be provided by the Department of Health and Family Welfare. The hospital and associated expenses related to the donor onboarding and donor selection will be covered by the registry using this amount.

4.4 Non-functional Requirements

1. Security
2. High Availability
3. Reliability
4. Data integrity
5. The application shall be deployed State Data Center

5 Implementation Strategy

5.1 Technical Approach

This **web-based** solution will be built using centrally accessible, cloud-based infrastructure at the State Data Centre, and using open-source elements for all major components of the application. Where external proprietary methods are employed, the service provider will make explicit mention of the technology used and provide necessary explanations as to why an open-source alternative was not considered.

Additionally, a detailed system study shall be conducted after project approval, based on which a software requirement specification (SRS) document shall be submitted to the Nodal Institution (e.g. MCC, Thalasseri) and eHealth for approval.

5.2 Key Benefits to be achieved

1. An indigenous web-based registry of bone marrow donors which can be easily searchable by transplant centres
2. Higher chances of finding best fit donor
3. For patients, the donor matching process becomes affordable.
4. Digitization of donor and patient registration process.
5. Integration of Donor data with World Marrow Donor Association (WMDA) registry.
6. Patient charges for using Bone Marrow Registry could be collected through online payment mode.
7. Bone Marrow Donor and Patient Matching automated.
8. Helps in systematic donor and patient follow up after stem cell donation or transplant.
9. Automatic report generation
10. Integration with eHealth and Kerala Cancer Care Registry

6 Conclusion

In conclusion, the Kerala Bone Marrow Registry project aims to digitally revolutionize the process of matching bone marrow donors with patients through a web-based platform. By integrating with the Kerala Cancer Registry and Advanced Blood Collection centers, the registry will automate and streamline donor and patient registration, as well as the matching process using the World Marrow Donor Association's standardized algorithms. This integration not only enhances accessibility to potential donors locally and globally but also ensures adherence to global standards in donor matching.

Utilizing Artificial Intelligence and Machine Learning, the registry will further refine the matching process, predicting transplant success rates and post-transplant complications. This innovative approach promises to significantly improve patient outcomes by facilitating more accurate and timely matches.

ANNEXURE 2

Expression of Interest Response Sheet for the project- Kerala Bone Marrow Registry

Instructions

Please carefully read through both the expression of interest notification for the project and the project requirement document before filling the EoI response sheet.

1. Organization Particulars

| Sl. No | QN | Response |
|--------|---|----------|
| 1 | Name of the Project for which EoI Response is submitted | |
| 2 | Name of the Startup | |
| 3 | Legal Name | |
| 4 | Legal Status | |
| 5 | Registration Number | |
| 6 | Date of Registration | |
| 7 | Registered Address | |
| 8 | KSUM or DPIIT Unique ID | |
| 9 | KSUM or DPIIT Startup Certificate Expiration Date | |
| 10 | Website | |
| 11 | Full name of the contact person | |
| 12 | Designation of the contact person | |
| 13 | Contact Mobile Phone Number | |
| 14 | Contact e-mail id | |

2. Organizational Capabilities

| Sl. No | QN | Response |
|--------|---|----------|
| 1 | Introduction (Word Limit 150) | |
| 2 | Key products or Services (Word Limit 250) | |

3. Organizational structure and capacity

| Sl. No | QN | Response |
|--------|---------------------------|----------|
| 1 | Total number of Employees | |

4. Details of the key personnels in the technical & management team *(Add rows as required)*

| Sl. No | Name | Designation | Skill Set |
|--------|------|-------------|-----------|
| | | | |
| | | | |
| | | | |
| | | | |

5. Previous implementation experience

| Sl. No | QN | 1 | 2 |
|--------|--|---|---|
| 1 | Customer Name | | |
| 2 | Customer Category | | |
| 3 | Location | | |
| 4 | Start Date | | |
| 5 | End Date | | |
| 6 | Project Brief (Word limit-100) | | |
| 7 | Scope of the Project (Word limit-150) | | |
| 8 | Is the implemented system currently being used by the customer | | |
| 9 | Address of the customer | | |
| 10 | Name of the person to be contacted | | |
| 11 | Designation of the person to be contacted | | |
| 12 | Contact Number | | |
| 13 | Email address | | |
| 14 | Experience Certificate from customer attached (Yes/ No) | | |
| 15 | Relevant Patent/ Papers /Publications by the organisation | | |

6. Certifications (Add rows as required)

| Sl. No | Name of Certification | Issuing Body | Certification Number | Date of Issue | Expiration Date |
|--------|-----------------------|--------------|----------------------|---------------|-----------------|
| | | | | | |
| | | | | | |

7. List of attachments (Short CVs of key personnel, Experience certificates, and other certifications)

(Please include the list of attachments)

- 1.
- 2.