

## SCHEDULE ONE – PROPOSAL BRIEF

### 1. The Services

#### 1.1 Overview

Movember is creating a **RWE Network**, which will build upon existing Movember-funded international programs, collaborations, and partnerships across biomedical research, clinical quality registries, and survivorship. The Network will allow the collection, integration, and analysis of patient data (globally) to accelerate the development and implementation of personalised tests and treatments, and quality of care programs leading to early identification and treatment, as well as improvements in the survival and quality of life of men living with prostate cancer.

With the RWE Network having already commenced the migration of Prostate Cancer Outcomes Registry - Australia and New Zealand (**PCOR-ANZ**) into a central platform, Movember is now seeking a partner to co-design, co-develop and establish an integrated clinical, molecular and imaging analytical database to support its global collaborative biomedical research programs. The intention is that the database, subject to this RFP, will incorporate future biomedical research initiatives, as well as form part of the integrated RWE Network.

#### *Movember's Biomedical Research Programs*

Movember's biomedical research programs are established through the global collaboration of multidisciplinary teams that share data and knowledge to develop a unified approach to address the unmet clinical needs of men with prostate cancer. In alignment with Movember's biomedical research strategy, two global collaborative programs have already been launched:

- the *Preventing Disease Progression* program aims to reduce the number of men with high-risk, locally advanced prostate cancer and metastatic hormone sensitive prostate cancer who ultimately progress to advanced disease. Through the integration of existing databases on a global scale, this program seeks to gain a greater understanding of the unique biology of these cancers and to define the role of new and currently available therapies to deliver improved outcomes for men; and
- separately, the *Personalised Active Surveillance (AS)* program aims to develop a dynamic, risk-adapted approach to active surveillance to reduce unnecessary tests and treatments in men at lowest risk of disease progression.

#### *Development of An Integrated Analytical Database*

To support and underpin these concerted efforts, Movember is seeking a partnership to co-develop an integrated analytical database that will allow the integration and / or linkage of existing, global clinical, molecular and imaging datasets. This database will require an analytical layer implementing state-of-the-art machine learning, bioinformatics and computational biology methods to help drive discovery and a secure interface portal through which clinicians and researchers can access the Data, undertake analyses and generate clinical reports. It is anticipated that the development of this analytical database will provide Movember, together with the wider research and clinical community, the opportunity to personalise treatments and improve outcomes for men living with prostate cancer.

## 1.2 Service Requirements

It is critical that this database has the capability and capacity to:

- support the structured, standardised collection of real-world clinical, molecular and imaging Data from multiple, global databases (as detailed in **Table 1 in Schedule 1** below);
- ensure interoperability with clinical information systems to enable Data linkage from multiple, global sources and different systems;
- ensure and maintain information security and privacy standards where Data is managed and stored within a securely operated and protected infrastructure, ensuring confidentiality, integrity and availability. The platform must be fully compliant with global data protection and medical data protection legislative requirements (21 CFR part 11 / GDPR compliant);
- support the storage of Data through appropriate high performance computing and storage platforms;
- integrate analytics with Data and support advanced machine learning, bioinformatics and computational biology;
- provide a secure access portal that will support multiple levels of access, with an interactive interface to the Data provided for authorised users (with appropriate governance and control) to undertake analyses and generate clinical reports;
- align / complement other national and international efforts to generate federated datasets; and
- support scaling to host other cancers and / or registries (desirable).

The successful Respondent must develop a Data management plan before any Data is transferred to the database, which must be provided to Movember upon request.

**Table 1: Examples of Data that may be included in the database**

Type of Data	Examples
Clinical	Including, but not limited to: <ul style="list-style-type: none"> <li>▪ Annotated medical history</li> <li>▪ Treatment plans and progress notes</li> <li>▪ Patient outcomes</li> </ul>
Molecular	Including, but not limited to: <ul style="list-style-type: none"> <li>• Genomics</li> <li>• Proteomics</li> <li>• Epigenomics</li> <li>• Transcriptomics</li> <li>• Gene expression profiling</li> </ul>
Imaging	Including, but not limited to: <ul style="list-style-type: none"> <li>▪ Histology</li> <li>▪ Immunohistochemistry</li> <li>▪ PET</li> <li>▪ CT</li> <li>▪ MRI</li> <li>▪ Bone scans</li> </ul>

### 1.3 Database Requirements

Respondents are required to provide a Data infrastructure solution that meets the requirements of ISO 27001 certification, which includes, but is not limited, to the following components:

- **Analysis and Design** – Provide an effective solution design defining the nature of the solution including applications, technology, network, Data and support;
- **Configuration** – Provide configuration of the solution as required by Movember;
- **Applications** - Provide software applications and licenses forming the solution;
- **Infrastructure** – Provide a cloud hosted solution. If not housed onshore, then must prove that the storage of Data meets all Australian legal requirements. No on-site purchase of hardware;
- **Maintenance and upgrades** - Provide annual (minimum) maintenance services and upgrades of software, hardware and related infrastructure as part of the solution;
- **Integration Services** – Provide integration services to ensure that the solution integrates with Movember and third party processes and systems where required;
- **UAT Testing** – Work with Movember to test the solution to ensure it meets user needs;
- **Solution Testing** – Perform System and production testing to ensure the solution meets requirements;
- **Meets Requirements** - The solution will be expected to meet or exceed Movember's requirements including capacity, scalability, volumetric;
- **Training** – Provide services and documentation [softcopy and hardcopy] where needed for all end user staff training in the new solution;
- **Business Continuity** – Provide capability to meet Movember's requirements so that the functions can continue to operate during abnormal conditions and defined events;
- **Go Live and Warranty** – The successful Respondent will be expected to deploy and test the service solution components in the production environment and provide go-live support and warranty period;
- **Ongoing Service Support** – The successful Respondent are expected to provide ongoing service support according to the support agreement; and
- **Contractual** – Agreement to RFP conditions and statement of work relating to this solution including service level requirements if Respondent is successful.

### 1.4 Service Delivery Timelines

It is critical that this integrated analytical database can be delivered within 18-24 months from the commencement date.

### 1.5 Reporting Requirements

Report	Date for completion
Progress update reports and financial reports	6 months, 12 months and 18 months from commencement date
Final report	Upon completion of the database
Annual performance report	Annually; once the database is completed

## 1.6 Insurance Requirements

Prior to the Commencement Date, the Respondent must ensure that the following insurances are in place before the Commencement Date and for the duration of the agreement:

Insurance type	Amount
Professional Indemnity	\$10 million AUD
Public Liability	\$10 million AUD
Products Liability	\$10 million AUD

## 2. Proposal Requirements

### 2.1 General Requirements

Proposals submitted via this RFP must include the following:

- i. Respondent's contact details (name, position, contact number and email address);
- ii. Company details (name, business registration numbers, registered office address);
- iii. Information about the corporate profile of the Respondent including, but not limited to:
  - i. information on corporate and ownership structure, including information on related bodies corporate;
  - ii. information about how long it has been in business;
  - iii. confirmation that there is no past, current, pending or finalised litigation that would impact upon the Respondent's ability to perform the Services, or an explanation of such litigation;
  - iv. particulars of any petition, claim, action, judgement or decision which is likely to impact or affect the Respondent's performance of the Services; and
  - v. any other matters that are relevant to the Respondent's ability to perform the Services;
- iv. information about how the Respondent will meet each of the requirements set out in this Proposal Brief;
- v. details about the delivery of similar services which the Respondent has been involved in (and which are relevant to the Services);
- vi. details about the Respondent's management team and key personnel who will be involved in implementing the Services;
- vii. details about pricing for the Services which must be quoted in Australian dollars on a GST exclusive basis and include all contingencies. Specify the following:
  - a. Proposed project expenditure profile (e.g. employee and operating costs, software licence and maintenance, infrastructure, services,

- integration and interfaces, Data management, Data hosting, training and support, sustainability costs etc);
  - b. Demonstrated capacity to financially support the co-development and ongoing maintenance of the platform;
  - c. Demonstrated commitment of partners to the project and how they will support its successful delivery (through financial and / or in-kind contributions). Where applicable, provide MOU or letters of support/confirmation of the partnership; and
  - d. Potential co-funding opportunities that could be explored to support the development of the platform.
- viii. details about the Respondent's payment terms for the payment of all fees and costs in relation to the provision of the Services; and
- ix. signature of an authorised representative of the Respondent.

Respondents are also encouraged to include 'value add' services within its Proposal.

Respondents are also encouraged to provide any attachments, letters of support or documentation within its Proposal.

## 2.2 Specific Requirements

Proposals submitted via this RFP must include the following:

- i. *Information about Respondent's capabilities and capacities to deliver the proposed database.*
  - a. Respondents should provide information about previous experience and / or capabilities in:
    - working on programs and / or data with national and international consortia;
    - working with and / or developing integrated clinical, biological and imaging databases in an oncology setting;
    - establishing/supporting collaborative national and international consortia;
    - structured collection of data and translation to a uniform dataset; and
    - providing data security (e.g. ISO 27001, HIPPA, GDPR), disaster recovery and technical support
  - b. Where appropriate, Respondents should briefly describe any experience in utilising patient Data to improve research and / or patient outcomes.
- ii. *Information about Respondent's Project Methodology, Design and Timelines.*
  - a. Respondents should provide an outline of the proposed project plan (including timelines) that will be used to deliver the database, covering the architectural design, Data collection, Data processing/harmonisation, Data access, Data storage and

methodologies. Please include details on how the following will be addressed:

- Development of an integrated clinical, molecular and imaging database (specifically in the field of oncology), that is accessible globally;
  - Data harmonisation, transfer and / or linkage across datasets;
  - Governance and controls; and
  - Analysis pipelines and Data pre-processing.
- b. Respondents should provide a plan detailing how the platform will be managed, maintained and sustained.
- c. Respondents should highlight any challenges or obstacles that may arise in delivering this database, as well as any considerations that have not been identified in the objectives above, that should be addressed. List key technical and delivery risks associated with this project including proposed mitigation measures.

*iii. Information on Respondent's Resources*

- a. Respondents should provide details of existing resources that can be accessed to support the development of the Service.
- b. Respondents should provide details of the team's experience with, or access to, new technologies (e.g. artificial intelligence / machine-learning / deep-learning for data analysis).
- c. Respondents should provide details of any other relevant capabilities that have not been captured and will support the proposal.
- d. If applicable, given the complexities in the delivery and management of the data infrastructure, Respondents should define their ways of working if operating across multiple time zones.
- e. Where appropriate, Respondents should demonstrate whether the team includes individuals that bring diverse experience and expertise (e.g. across disciplines, genders, cultures, lived experience relevant to the research question, career stages, and research sectors).

*iv. Information on Respondent's Partners:*

- a. Respondents should provide details of partnerships with other service providers or technology suppliers relevant to this proposal.  
  
Respondents should describe how the project partner will work and contribute to successfully deliver the Data infrastructure i.e. outline roles and responsibilities, as well as any experience / expertise that the project partner will bring to the group.
- b. Where appropriate, Respondents should briefly describe any past or current partnerships (or funding received for projects) with similar scope that may be of relevance to this RFP.

## **2.3 Proposal Format**

- Proposals should be a single MS Word or PDF document: prepared in Arial font (regular), minimum 11 point and in single-spaced text (maximum of 25 pages, not including references and supporting documentation);

- on an A4-sized page 8.3” x 11.7” (21cm x 29.7cm) with 1” (2.54cm) margin on all sides of each page; and
- include a header on each page with the Respondent’s name in the top left-hand corner, and the page number in the top right-hand corner.

## **2.4 Evaluation Criteria**

The Evaluation Criteria for this RFP are:

- the Respondent's ability to prove that it is able to engage with Movember and partner in its strategic agenda;
- the Respondent’s previous experience and relevant expertise in:
  - working on programs and / or data with national and international consortia;
  - working with and / or developing integrated clinical, biological and imaging databases in an oncology setting; and
  - establishing collaborative national and international consortia
- the Respondent’s capability, capacity and key personnel to perform the Services and address the Requirements, as well as demonstrated previous experience in providing services similar to the Services, in accordance with the Proposal Brief;
- the Respondent’s proposed project plan, architectural design and methodologies (including timelines) to address the Requirements and perform the Services, in accordance with the Proposal Brief;
- the Respondent’s partnerships with other service providers or technology suppliers relevant to its proposal, including the nature of those relationships; and
- the proposed pricing structure and budget, including the ability and capacity to financially support the co-development and ongoing maintenance of the platform.