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| **FOR OFFICIAL USE** | |
| Proposal received date: | |
| Approval date: | Approval Number: |
| **SECTION A: ORGANISATION (MAIN APPLICANTS) DETAILS**  All communications to and from PRECISE-SG100K will be through the Main Applicants | |
| Name of **Lead Principal Investigator** in full (Dr/Mr/Ms\*): | Designation/Position: |
| Department/ Organisation: | |
| Email: | Contact number: |
| CV  please attach with submission | |
| Name of **Co-Lead Principal Investigator** in full (Dr/Mr/Ms\*): | Designation/Position: |
| Department/ Organisation: | |
| Email: | Contact number: |
| CV  please attach with submission | |
| Name of **Co-Lead Principal Investigator** in full (Dr/Mr/Ms\*): | Designation/Position: |
| Department/ Organisation: | |
| Email: | Contact number: |
| CV  please attach with submission | |
| \*Delete where appropriate | |
| **SECTION B: DETAILS OF PROPOSAL**  Please fill out information relevant only to this proposal | |
| Title of Proposal: | |
| Proposed Start Date: | Proposed End Date: |
| Indicate which datasets from TRUST and PRECISE-SG100K will be used for this proposal:   |  |  | | --- | --- | | **TRUST Dataset** | **Y/N** | | Death (with cause) |  | | National disease registries |  | | Prescriptions |  | | Laboratory investigations |  | | Diagnoses (with ICD codes) |  | | Outpatient and primary care episodes |  | | Inpatient care episodes |  | | Surgical interventions and outcomes |  |  |  |  | | --- | --- | | **PRECISE-SG100K Dataset** | **Y/N** | | Whole Genome Sequencing |  | | SG100K Phenotype tables |  | | 1. Core |  | | 1. Assays |  | | 1. Bioimpedance |  | | 1. Cognitive\_test |  | | 1. Carotid\_ultrasound\_imaging |  | | 1. DXA\_Hip\_Lumbar |  | | 1. DXA\_Whole\_Body |  | | 1. Eyes |  | | 1. FFQ |  | | 1. HLQ |  | | 1. Medications |  | | 1. Skin |  | | 1. Spirometry |  | | 1. Treadmill |  | | 1. Vicorder |  | | |
| Please carefully list the bioinformatics tools and resources that you will need for this proposed research (add extra rows as needed):   |  |  | | --- | --- | | **Tool / resource** | **Comment (e.g. rationale)** | |  |  | |  |  | |  |  | |  |  | |  |  | | |
| Will you need the Electronic Health Records in the fused dataset?  ☐Yes  ☐No  If “**Yes**” is selected, please note the application will need data access from TRUST Data Access Committee (DAC) before it starts. | |
| Is this study/ data analysis funded?  ☐Yes  ☐No  If “**Yes**” is selected, please provide grant or funding details.  If “**No**” is selected, please provide details on how computing resources would be supported. | |
| Does this study/ data analysis involve rare diseases and sensitive data info (SHI) as shown in the checklist **Annex A**?  ☐Yes  ☐ No  If “**Yes**” is selected, please list the disease and/or SHI below. Do ensure that the justification for the listed data is provided in Section C. | |
| Particulars of key Co-Investigators/ User applicants (suggest limit to 5-10)  Persons who are co-applicants on this proposal. PRECISE-SG100K will keep listed personnel in all correspondence. Persons who will have access to PRECISE-SG100K dataset. Please state the role (e.g. data analyst) of the person who will have access and the data governance related courses (e.g. institutional data governance course) that individual has taken. **If more than 10, please provide justification for the number of applicants required.**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **S/N** | **Name** | **Designation / Department / Organisation / Contact Details** | **Role** | **Data Governance course attended** (e.g. course mandated by organisation) | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  |   Justification: | |
| Information on industry partner(s) (“**Company**”)  *If there is/are industry partner(s) listed above, please work with your industry partner(s) to provide inputs to the questions listed in the* ***Annex B****. Information provided will be used to evaluate the industry’s contribution to PRECISE-SG100K and Singapore to justify for their request to access data.* | |
| Conflict of interest (if any) between any of the research personnel and the Company (consultancy, shareholding, options, etc.). *Please describe the nature of the conflict of interest as well as explain how it will be managed.* | |
| **SECTION C: PROPOSAL PLAN**  *Please provide in detail the purpose of the proposal, and the detailed steps to be used in the proposal. Use a separate sheet if necessary* | |
| Research Question: Please describe the research in detail, include the potential public benefits and justification for the data requested, the period and the fusion with other datasets (if applicable). | |
| Background: | |
| Specific Aim(s): | |
| Research Variables: | |
| Quality Control and Data Pre-processing: | |
| Main analysis: | |
| Key references (Up to 10): | |
| **SECTION D: DELIVERABLES** | |
| What is/are the intended and potential future use(s) for the PRECISE-SG100K approved data output?  *Please provide details on plans for publications, public communications or commercialisation based on the potential insights that will be derived for the above-mentioned aim(s) etc.* | |
| **SECTION E: REQUISITE CONSENT/APPROVAL** | |
| Does existing SG100K consent provide approval for the research proposed in Section C?  ☐Yes  ☐No  If “**Yes**” is selected, no action.  If “**No**” is selected, please provide the basis on which you think the research proposed can be carried out. | |

**Annex A: Rare Disease and Sensitive Health Info (SHI) Checklist**

**Rare Diseases**[[1]](#footnote-1)

Table 1: List of rare diseases

|  |  |
| --- | --- |
| **Condition** | **Medicine (s)** |
| Primary bile acid synthesis disorder | Cholic acid |
| Gaucher disease (Type 1 or 3) | Imiglucerase (Cerezyme)  Velaglucerase alfa (VPRIV)  Taligucerase alfa (Elelyso) |
| Hyperphenylalaninaemia due to tetrahydrobiopterin (BH4) deficiency | Sapropterin dihydrochloride (Kuvan) |
| Pompe Disease | Alglucosidase alfa (Myozyme) |
| Mucopolysaccharidosis type VI (MPS VI) | Mucopolysaccharidosis type VI (MPS VI) |

**Sensitive Health Info (SHI)**[[2]](#footnote-2)

**Clinical Information in Medical Records**

Table 2: Prescribed classes of medical information in PDPA Regulations

|  |  |
| --- | --- |
| **PRESCRIBED CLASSES OF SPECIFIED MEDICAL INFORMATION IN PDPA REGULATIONS** | **SPECIFIC DATA TYPES/EXAMPLES** |
| The assessment, diagnosis, treatment, prevention or alleviation by a health professional of any of the following affecting an individual: |  |
| (a) any sexually transmitted disease, such as Chlamydial Genital Infection, Gonorrhoea and Syphilis; | * Chlamydial genital infection * Gonorrhoea * Syphilis |
| (b) Human Immunodeficiency Virus Infection; | * HIV |
| (c) Schizophrenia or delusional disorder; | * Schizophrenia * Delusional disorder |
| (d) substance abuse and addiction, including drug addiction and alcoholism. | * Substance abuse (opioid abuse, inhalant abuse) * Substance addiction (drug addiction, alcoholism) |
| 19. The provision of treatment to an individual for or in respect of  (a) the donation or receipt of a human egg or human sperm; or | * Sperm donor * Sperm recipient * Egg donor * Egg recipient |
| (b) any contraceptive operation or procedure or abortion. | * Contraception operation or procedure * Abortion information |
| 20. Any of the following:  (a)   subject to section 4(4)(b)[[3]](#footnote-3) of the Act, the donation and removal of any organ from the body of the deceased individual for the purpose of its transplantation into the body of another individual;  (b)   the donation and removal of any specified organ from the individual, being a living organ donor, for the purpose of its transplantation into the body of another individual;  the transplantation of any organ mentioned in sub paragraph (a) or (b) into the body of the individual. | * Organ donation and receipt (identity of organ donor, identity of organ recipient) * Transplant, transplant-related complications (e.g. liver transplant rejection) |

**Other Types of Non-Clinical Information in Medical Records**

Table 3: Types of non-clinical information that can be found in medical records in PDPA Regulations

|  |  |
| --- | --- |
| **PRESCRIBED CLASSES OF NON-CLINICAL INFORMATION IN PDPA REGULATIONS** | **SPECIFIC DATA TYPES/EXAMPLES** |
| Subject to section 4(4)(b)3 of the Act, the suicide or attempted suicide of the individual. | * Suicide or attempted suicide |
| Domestic abuse, child abuse or sexual abuse involving or alleged to involve the individual. | * Domestic abuse, child abuse or sexual abuse |

**Annex B: Industry Contribution Evaluation Questions**

1. Company’s collaboration with Main Applicant (local research partner)

Please provide details that address the following questions:

* Please provide details on research collaboration
* What is/are the project outcome(s) of this collaboration?
* How would this collaboration benefit Singapore and impact the company’s operations in Singapore?
* What is/are the factor(s) that draw the company to work with collaborators in Singapore?

2. Company’s direct contribution(s) to Singapore through the collaboration with Main Applicant.

* *If company is contributing data to Singapore through PRECISE-SG100K, please answer questions under part i.*
* *If company is making other contributions to Singapore (non-data), please answer questions under part ii.*

i. Data contribution to Singapore through PRECISE-SG100K   
*It could be data that the company is contributing to Singapore or data that would be co-generated with the local research partner(s) i.e. applicant.*Please provide details on the data contribution that address the following questions:

1. Please provide details on the data that the company is contributing *i.e. data elements, data format, sample size, coverage in terms of age, gender, ethnicity*
2. What is the data management process to ensure data completeness, accuracy and uniqueness *i.e. no duplication*?
3. Is there standardised data documentation? Please share a sample of meta-data and data dictionary.
4. Is the data permissible for prospective research? Is consent from participants obtained?
5. Does the data contain identifiers (i.e. NRIC/FIN) and are available to be shared with PRECISE-SG100K? *Please note that identifiers are crucial for fusion to PRECISE-SG100K dataset. Identifiers will be de-identified prior to data transfer to PRECISE-SG100K. No direct identifiers would be shared to User(s).*

ii. Non – Data contribution to Singapore

*It could be investment for the collaboration, new capabilities/knowledge developed, set up of new facilities i.e. centre of excellence and new roles under the company and localisation of business.*

Please provide details on the non-data contribution that address the following questions:

1. What is/are the expertise(s) that the company will be bringing in through the collaboration? *This may include notable researchers who will be working on the projects and unique capabilities of the company.*
2. What is the knowledge/capabilities that will be shared with local collaborators, and how will it be shared? *This may include co-development of new solutions, transfer/teaching of techniques/methodology.*
3. What is the size of the company’s team that will be involved in the collaboration? *Please provide estimated number of individuals that will be based in Singapore and/or the estimated number of individuals that will travel to Singapore across the collaboration.*
4. What are the investments that the company will be making in Singapore as part of this collaboration? *This can include industry research spend (cash and in-kind) into the project, the setup of new functions/teams/roles by the company, or investments in fixed assets that will expand the company’s presence in Singapore (e.g. setting up centres of excellence). Please provide further details and quantify the scope of investments where possible (e.g. types of roles, no. of FTEs, IRS, expected business spend).*

3. Company’s activity in Singapore (if any)

Please provide an overview of the company’s current operations in Singapore. *This should include a description of the company’s overall headcount and key functions in Singapore.*

1. <https://www.kkh.com.sg/giving/Documents/Rare-Disease-Fund/index.html> [↑](#footnote-ref-1)
2. <https://www.moh.gov.sg/resources-statistics/dbn-list-2021> [↑](#footnote-ref-2)
3. Section 4(4)(b) of the PDPA – 4(4) This Act shall not apply in respect of - (b) personal data about a deceased individual, except that the provisions relating to the disclosure of personal data and section 24 (protection of personal data) shall apply in respect of personal data about an individual who has been dead for 10 years or fewer. [↑](#footnote-ref-3)