HeSANDA

Health Studies Australian National Data Asset

HeSANDA Sydney Node
First test case

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CRICOS 00026A TEQSA PRV12057



Steps to add my trial into Health Data Australia

1. Willing to seek for ethics approval after a data request comes through (if the request is approved and sharing data for secondary use was not originally requested)
2. Update ANZCTR/CT.gov and its data sharing statement
3. Upload protocol, data dictionary, publication(s) in ANZCTR
4. Complete the Sydney node metadata collection form in REDCap



Ethics approval

- Check PICF wording
- Wait until a data request is submitted and approved

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. All paper documents will be kept in a locked filing cabinet in the study coordinators office. Staff only have access to the building and the office. Data saved on computer files will be entered in an unidentifiable format. Access to the computer files requires staff login and password and files are only accessible to the study coordinators. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the institution relevant to this Participant Information Sheet and The University of Sydney, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Data Sharing Statement

Will individual participant data (IPD) for this trial be available (including data dictionaries)?	Yes
What data in particular will be shared?	IPD underlying published results only
When will data be available (start and end dates)?	From 1st July 2023 data will be available for an indefinite time
Available to whom?	Researchers from not-for-profit organisations. All data requests will be considered by the primary sponsor on a case by case basis. Requests must include a methodologically sound proposal. Specific conditions of use may apply and will be specified in a data sharing agreement (or similar) that the requester must agree to before access is granted.
Available for what types of analyses?	Any approved protocol/proposal
How or where can data be obtained?	As of 1st July 2023, access can be requested via the Health Data Australia catalogue (https://www.researchdata.edu.au/health). Search for the ACTRN number in the catalogue to find datasets associated with this trial.

What supporting documents are/will be available?

Type	Citation	Link	Email	Other Details	Attachment
Study protocol	Palacios T, Vitetta L, Coulson S, Madigan CD, Denyer GS, Caterson ID. The effect of a novel probiotic on metabolic biomarkers in adults with prediabetes and recently diagnosed type 2 diabetes mellitus: study	https://pubmed.ncbi.nlm.nih.gov/28069054/			

Data Sharing Statement

- Guide to complete ANZCTR's data sharing statement
- HeSANDA resource developed by ANZCTR, ARDC and HeSANDA nodes

Question	Description	Sample Response
What data will be shared? * (Mandatory when 'Yes' is selected for IPD question in Step 11)	Please describe what data will be shared e.g. all of the individual participant data collected during the trial, after de-identification; individual participant data underlying published results only, etc.	Nominated Trials should indicate at least one of the following: • All participant data collected • Participant data supporting the publication results • Participant data relating to primary outcomes • Participant safety data *Sample response* *"Participant data supporting the publication results Participant data relating to primary outcomes"*
When will data be available (start and end dates)? * (Mandatory when 'Yes' is selected for IPD question in Step 11)	Please outline the timeframe of data availability, i.e. beginning and end dates for when the data is expected to be available, e.g. Immediately following publication, no end date; Beginning 3 months and ending 5 years following main results publication; no end date determined etc.	Nominated Trials should describe when the data will be made available. Options/examples include: (Optional) Pick one from the following: • Data are available straight after publication • Data are available ['x' months] after publication Pick one from the following: • Data are available for a finite time • Data are available for an indefinite time Add the following information (approximate dates are ok): • Start date: [insert date] • End date: [insert date] / [if "data are available for an indefinite time" then insert "Unknown"] If dates are subject to change (e.g. if funding ends/is extended) then your trial registration must be updated (as per the general requirements for updating ANZCTR records) *Sample response* *Example 1:* *"Data are available 5 months after publication*

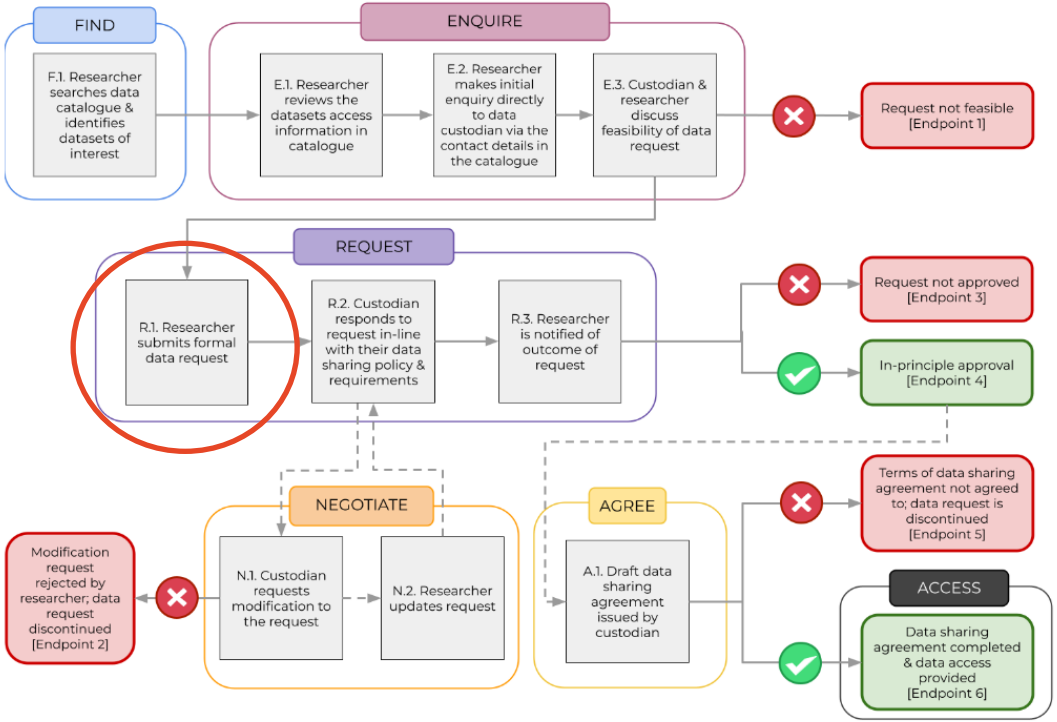
Metadata collection form

- Takes 5-10 minutes to complete
- Some fields are already populated
- Information about the dataset not available in ANZCTR/CT.gov

REDCap



Data Access Workflow



See how to manage data requests video in:
https://sydneyhealthpartners.org.au/resources/hesanda/

Data Request or Data Access Application

Dataset Requested	
DOI	http://doi.org/10.25910/KWKH-HJ77
Title	T2DM probiotic intervention clinical data
Reason for request	Our group would like to use the data for research training purposes (early career researchers at the Faculty of Health and Medical Sciences), as we are planning to expand work in the field of clinical trials. The dataset will be used to replicate the results in the published paper.
Bio Sample	No biological samples, only the de-identified dataset.
Applicant Details	
Researcher Name	David Gonzalez-Chica
Researcher Email	david.gonzalez@adelaide.edu.au
Researcher Position	Hed of Research in Primary Care
Researcher ORCID	0000-0002-7153-2878
Researcher organisation	The University of Adelaide

Project Design	
Background or Rationale	Early and middle career researchers at the Faculty of Health and Medical Science at the University of Adelaide lack the analytical skills to complete analyses in their studies. They have requested the provision of additional training resources using real health data from clinical trials.
Aims	To improve analytical skills of early and middle career researcher to conduct data analysis independenlty
Hypotheses	The use of real data and replication of results in previous studies is the best approach to improve analytical skills
Outcomes and Endpoints	At least 20 early and middle-career researchers completed 3 levels of research and analytical training using statistical software.
Data Security Strategy	All data will be stored in the internal servers at the University of Adelaide, and only academics attending these session will get access to de-identified data as part of the training sessions. The data will not be used for secondary purposes.
Project Outputs	
Output Type	No any paper or Ip will be developed using this data
Output Title	No output will be obtained
IP Arrangements	There are no outputs requiring IP arrangements

Questions

1. Do I want to share my data for training purposes? *Yes*
2. What if my findings cannot be reproduced?
3. Do I need to submit a full ethics application or will HREC provide a waiver of consent?
4. Does the data transfer agreement available at my institution requires any amendments? *No*
5. Will sharing my data for training purposes will benefit me? *No, but it will benefit others*





- A formal letter addressed to the HREC Chairman requesting a waiver of consent to share de-identified data

- A completed SLHD Privacy Compliance form - Requesting a waiver of the usual requirement for consent (2-page form)

- A list of the data fields requested
- Data request form
- Data Transfer Agreement

Ethics and Governance resources

- **Consent for secondary data use:** CT:IQ inFORMed project
  - Develop a simplified, participant-friendly national PICF
  - Template with wording for future sharing of data (and samples and genomic information)
  - Beta version available: https://www.informedpicf.com.au/
  - Final version to be released in June 2024

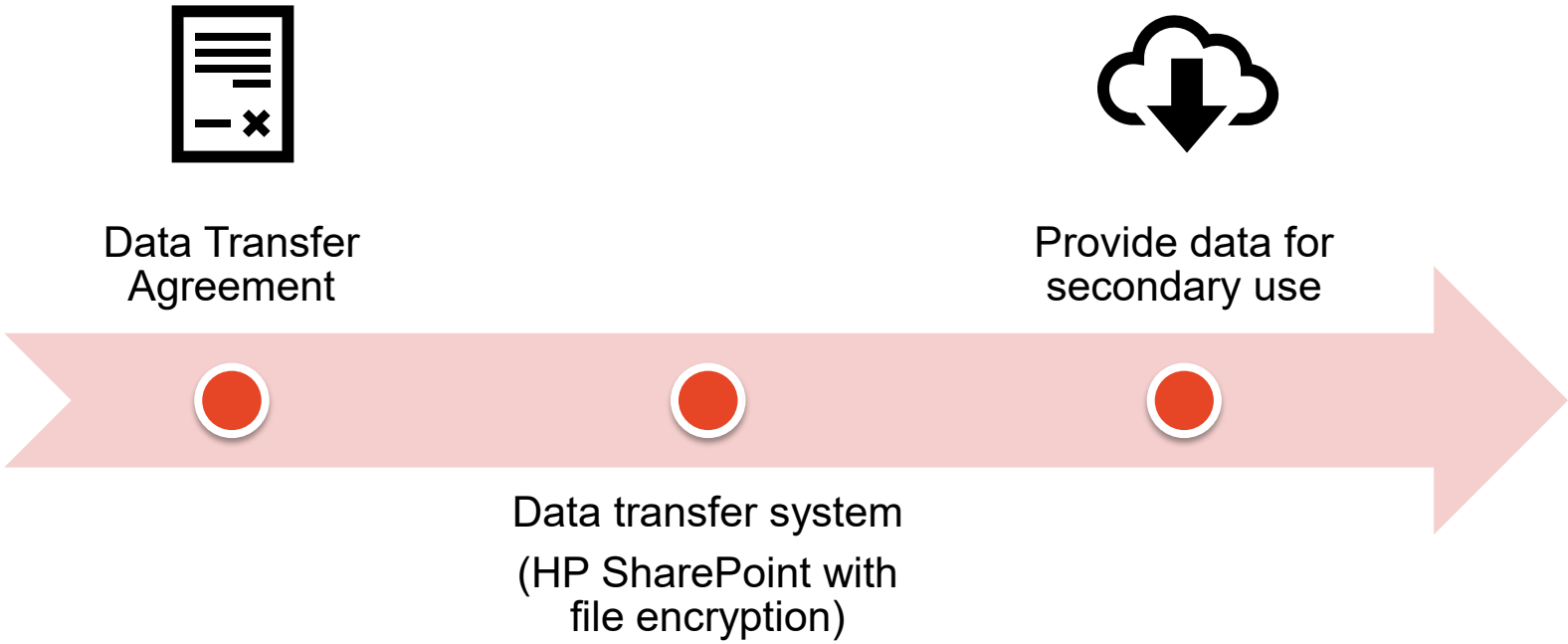
- **Clinical Research Data Sharing Frameworks project**
  - Improve efficiency and quality in the application of requirements for the secondary sharing of research data







Next steps


Data Transfer Agreement
Provide data for secondary use
Data transfer system
(HP SharePoint with file encryption)

Health Data Australia Portal
https://researchdata.edu.au/health

Sydney Node website
https://sydneyhealthpartners.org.au/resources/hesanda/

Contact HeSANDA Sydney Node
hesanda.shp-ctcnode@sydney.edu.au

Add your trial dataset to HDA

REDCap form

Sydney HealthPartners

NHMRC Clinical Trials Centre

THE UNIVERSITY OF SYDNEY

ARDC
Australian Research Data Commons