MACH Clinical Trials Consortium HeSANDA Node

Health Studies Australian National Data Asset (HeSANDA) & Health Data Australia

Data Provider, Data Requestor Responsibilities & Guidelines

Purpose

The MACH HeSANDA Node responsibilities and guidelines document is intended to be used as guidance only for data providers and data requestors in the use and context of the Health Data Australia (HDA) portal to facilitate the secondary use of clinical trial data. It is the responsibility of the data requestor and data provider to refer to and adhere to their individual organisation/institutional governance requirements related to data sharing.

Responsibilities

MACH HeSANDA Node

- If required assist the data provider in submitting the clinical trial metadata record to HDA.
- If required support the data requestor in the process of submitting a data access request.
- Communicate an expression of interest (EOI) to the data provider when a data access request is received through the Health Data Australia (HDA) portal from a potential secondary researcher.
- Enable researchers to navigate the HDA platform and provide guidance on all phases of the provision of metadata and data access process.

Data Provider (Principal Investigator)

- Plan for and conduct clinical trials with the intention of facilitating data sharing and enabling secondary analyses.
- Ensure the management of clinical trial data and actual sharing of data is done so in accordance with any legal, regulatory, and ethical requirements.
- Stipulate your intention to share data within the clinical trial registration in ANZCTR.
- Establish a data management plan for the current and future management of clinical trial data and respective research outputs, record any potential restrictions or limitations.
- Ensure a data sharing agreement is completed and signed by both parties prior to the transfer of research data.
- Prepare and secure transfer of the datasets in accordance with the agreed terms outlined in the data sharing agreement.

Data Requestors (Secondary Researchers)

- Data requestors must be affiliated with a reputable academic institution or healthcare organisation with experience in medical research and the ability to successfully undertake the proposed research or secondary analyses.
- Additional ethics committee preparation and application for the purposes of the reuse of data is the responsibility of the data requestor unless otherwise agreed with the data provider.
- Arrange additional funding resources for the scope of the proposed secondary research.
- State any actual or potential conflicts of interest within their proposal and subsequent publications or presentations.
- In all publications resulting from secondary analyses the original study team must be acknowledged in accordance with agreed prior conditions with the data provider.

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This project received co-investment from the Australian Research Data Commons (ARDC).
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Ethical Considerations

- For prospective or current studies, data sharing and secondary reuse of data is required to be addressed and approved by an ethics committee and incorporated into the participant and information consent form (PICF) and signed by the clinical trial participants.
- For retrospective studies where informed participant consent was not originally obtained, the preparation of an amendment to the ethics committee for a waiver of consent could be considered.

Additional Resource Consideration

- Plan and budget for the management and sharing of data.
- Submit a data management sharing plan when applying for clinical trial grants or funding.
- In discussion and agreement with the data providers, data requestors may be responsible and required to cover the costs of providing the data including preparation of agreements, data processing and subsequent transfer.
- It is expected the data provider will specify any expected costs in association with the data provider's initial proposal.

Contact: hesanda-mach@unimelb.edu.au

References

- ARDC Data Sharing Agreement Development guidelines https://ardc.edu.au/resource/data-sharing-agreement-development-guidelines/
- NHMRC 'Principles for accessing and using publicly funded data for health research' https://www.nhmrc.gov.au/sites/default/files/documents/reports/principles-publically-fundeddata.pdf
- NHMRC 'Management of Data and Information in Research - A guide supporting the Australian Code for the Responsible Conduct of Research.' https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Dataand-Information-in-Research.pdf
- George Institute data sharing policy https://www.georgeinstitute.org.au/data-sharing-policy

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