Australian Research Data Commons

HeSANDA Guiding Principles

Version	*Date*	*Authors*	*Notes*
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Background

The Health Studies Australian National Data Asset's (HeSANDA) guiding principles have been established through a process of consultation. The initial phase of the HeSANDA program involved two series of consultation workshops. The first of these was the 'data development' workshops. These were based on the Australian Institute of Health and Welfare's (AIHW) Guide to Data Development and were designed and run with the support of AIHW. These workshops were open to the clinical trials research community (e.g. trialists, research participants, health consumers, health researchers, research organisations and policymakers etc) and other relevant stakeholders. They established the business context, information needs, feasibility considerations, and consultation and collaboration requirements for HeSANDA. Importantly, the report from these workshops included a set of recommended principles for the HeSANDA program and infrastructure, which have matured into the guiding principles herein.

The second series of workshops was designed and run by the Australian Clinical Trials Alliance (ACTA) on behalf of the ARDC and delivered a targeted set of Stakeholder Consultations with clinical trialists, health consumers, and research participants. The purpose of these workshops was to build on the outcomes of the Data Development workshops and further inform the HeSANDA infrastructure's design. The consultations collected the perspectives of people whose data and/or intellectual property may potentially be shared using HeSANDA infrastructure and aimed to ensure that the purpose, design and governance of HeSANDA were acceptable to people who run and participate in clinical trials in Australia. The workshops provided ratification and refinement of the intent and guiding principles for HeSANDA, and the report from these workshops identified implementation considerations for the principles as well as the development and ongoing operation of the infrastructure. The report also identified specific groups of people and types of trials that may need special consideration regarding secondary data use. The consultations aimed to understand the factors from a trialist or consumer perspective that would influence an agreement to share data via HeSANDA.

These principles, implementation considerations, and special considerations informed the Design Phase of HeSANDA. During this phase, working groups reviewed and ratified these inputs and provided additional feedback. Based on this feedback and the guidance of an editorial consultant, revisions were made to improve the clarity of expression, reduce potential ambiguity in phrasing, and to allow for the synthesis of a coherent set of principles to guide the HeSANDA initiative. The consultative approach with the clinical trials research community and stakeholders that informed the guiding principles in this document is central to the ethos of HeSANDA and will continue as the initiative evolves.

Guiding principles

1. Purpose

	Principle	Statement, rationale, further information
1.1	The capabilities delivered by HeSANDA must be informed by the core value proposition	HeSANDA will enable the national infrastructure required to support the sharing and secondary use of health research data in order to improve research efficiency and quality, reduce cost and research waste, and increase research impact and translation.
1.2	The core research purpose of HeSANDA is to support research with a translational focus	HeSANDA will support access to the information and outputs from clinical trials necessary for: ● meta-analysis and systematic review ● replication, reproducibility, &/or peer review ● secondary research projects and analyses to facilitate the translation of research into the healthcare setting through improved clinical guideline and policy development, health intervention and technology assessment, and the development of new research.
1.3	HeSANDA will facilitate the sharing of a range of clinical trial information	To meet the needs of data producers and secondary users, HeSANDA will support the sharing of a variety of different types of information associated with clinical trials, with an emphasis on sharing individual participant-level data (IPD), study protocols, data dictionaries, and cohort summary data.
1.4	HeSANDA will maximise the discoverability of the clinical trial information	The information available through HeSANDA must be organised in a way that supports efficient search and discovery of clinical trial information (e.g. using the PICO[1] framework). HeSANDA will implement the FAIR data principles.
1.5	HeSANDA will improve the efficiency and reliability of access to clinical trial data for secondary research	Trial information is currently siloed, predominantly stored on institutional servers, and is accessible to secondary researchers through varying and often poorly defined approval processes. However, there is clear community enthusiasm for making this information accessible via more standardised and robust procedures that utilise potentially centralised mechanisms to achieve optimal research efficiencies.
1.6	HeSANDA will reduce the barriers to data sharing for clinical trialists	To reduce resource effort and facilitate development of HeSANDA, opportunities for leveraging or modifying current research practices of trialists that facilitate efficient data sharing must be identified.

[1] Richardson, S., Wilson, M. C., Nishikawa, J., & Hayward, R. S. (1995). The well-built clinical question: a key to evidence-based decisions. ACP journal club, 123(3), A12-13.

Implementation considerations

[a] Communication of scope

HeSANDA must be specific about its intent and scope when communicating about the asset and its development. This includes providing a clear description of:

- the types of data that will be available for secondary use, and the associated issues of privacy and identifiability
- the purposes for which secondary data sharing would be approved (i.e. for ethically-approved research use)
- the types of organisations/groups from whom applications for secondary data use would be considered
- the proposed benefits of supporting secondary data through HeSANDA.

[b] Ease of access and use

The uptake of HeSANDA will depend on its ease of access and use. The need to minimise the burden on researchers who are using HeSANDA and research groups who are asked to share data will be critical.

[c] Funding

Transparency around funding for HeSANDA will be important, including communication about any costs associated with its use and considerations for long-term sustainability.

[d] Evaluation

Ongoing evaluation and review will be important to ensure that HeSANDA is achieving its purpose with the flexibility to make refinements as required.

2. Data content & quality

	Principle	Statement, rationale, further information
2.1	HeSANDA will specify minimum requirements and best practices for sharing data from clinical trials	The implementation of minimum requirements maximises the utility of clinical trials data. Minimum data sharing requirements should include IPD and the study information that contextualises it (e.g. study protocol; data descriptions; data quality statements). Research and data descriptions to support Principle 1.4 must also be included. Enabling coherent data practices throughout the research journey can support these requirements.
2.2	HeSANDA will support the current variety of IPD data standards but will encourage pathways to the adoption of stakeholder-endorsed data standards	Currently, there is a wide variation in the data formats used to collect, enter, and analyse new data. As such, HeSANDA will need to facilitate the sharing of different data formats for IPD and metadata. However, HeSANDA will support the adoption of standardised data platforms and data standards for storing data and recording metadata (e.g. data dictionaries).
2.3	Data quality statements will underpin the utility of HeSANDA's content	In order to provide confidence in the data asset, data quality should be represented for each data collection.

Implementation considerations

[a] Standardised definitions

HeSANDA's facilitation of consistent approaches (e.g. through creation and promotion of standardised definitions for common data fields) will help to promote greater consistency in data collections and improve HeSANDA's value. Use and promotion of data dictionaries as tools to describe the data items available for secondary use will be important.

[b] Standardised data fields

Where appropriate, HeSANDA should promote the need for meaningful and usable data fields relating to individual trial participant characteristics that are not currently captured consistently, or in a meaningful way (e.g. language, ethnicity, culture, country of birth, gender diversity). While this is a broader issue for trials data overall and must be considered relative to the cost of trialists and privacy of participants, the consistent capture of

	meaningful data fields will support greater comparability across data sets when shared for secondary use.
[c] Contextual information	The provision of sufficient context and information about trials and their data within HeSANDA is important to ensure that interpretation of trial data is appropriate, and that secondary use retains the integrity of the original data.

3. Data governance

	Principle	Statement, rationale, further information
3.1	HeSANDA will promote common approaches to data sharing and re-use by clinical trials researchers	Researchers encounter resource and efficiency issues due to the lack of clear guidance on how to implement the data sharing policies of funders, publishers, and other stakeholders. The development of agreed protocols and procedures (e.g. information and data standards, data access workflows, etc) will improve the feasibility for data sharing to become standard research practice.
3.2	HeSANDA will promote common approaches to participant consent requirements for data sharing and re-use	Researchers agree on the fundamental importance of consent and community support for research practices such as data sharing but require guidance on how best to implement open science policies as they relate to participant consent. Developing a coordinated national approach to meet consent requirements will not only improve the feasibility of data sharing but address concerns and mitigate risk around the sharing of sensitive data.
3.3	HeSANDA will promote best practice guidelines for the handling and sharing of sensitive data	To complement the principles of common approaches to policy interpretation and application (above), researchers will benefit from guidance on specific data handling issues such as data security and the handling and reporting of identifiable data.
3.4	HeSANDA should be considerate of the labour cost to clinical trialists to facilitate access to data	The above principles seek to improve the efficiency of data sharing (either directly or indirectly), thereby reducing costs and improving feasibility. However, these improvements cannot entirely remove the labour cost of data sharing that is not consistently supported at the funder or institutional levels at present. Recognition of these costs within data sharing policy and infrastructure is fundamental to supporting the research community.

Implementation considerations

[a] Governance process and framework	A robust approach to data governance is a critical consideration for HeSANDA that will influence trust and confidence in both consumers and trialists about secondary data use. This might be achieved via a comprehensive and transparent data governance framework describing how, with whom, and for what purpose data from clinical trials can be reused.
[b] Consent	From a consumer perspective, the approach to gaining informed consent for secondary data use is critical. Stakeholder feedback highlights the need to develop standardised wording and tools to facilitate consent for secondary data sharing from clinical trials. The data governance framework for HeSANDA must be consistent with the National Statement and support clear, unambiguous and straightforward informed consent processes, or be consistent with the provisions for waivers of consent. The timing of consent will require careful consideration, noting that the requirement for and process of gaining consent for secondary use of data should not influence an individual's consent to participation in a clinical trial. Clear communication with a lay audience about the intent and benefits of secondary data use from clinical trials for research purposes will be important to overcome consumer concerns about consent. This includes a clear description of what data may be shared, whom data may be shared with, how data may be used, and any risks (actual or perceived) associated with secondary data use for research purposes.
[c] Linked data	It is crucial to consult with human research ethics committees and institutions around consent requirements for accessing linked data collected as part of a clinical trial, with particular caution around linkage to certain record types such as mental health records.

[d] Identification	From a consumer perspective, understanding the issues of individual identifiability in secondary data use are fundamental for informed consent. The need to consider and respond to questions in terms understandable by a lay audience will be essential. The need for consumer confidence and trust in the integrity of the process is paramount.
[e] Misuse	It is important to address data misrepresentation or misuse concerns, including reputational risk, in communication about HeSANDA as this may be a barrier to researchers making data available for secondary use.
[f] Intellectual property	It is vital to ensure the appropriate use and interpretation of data in a way that protects academic and commercial intellectual property.

4. Stakeholder coordination

	Principle	Statement, rationale, further information
4.1	HeSANDA will align its activities with existing structures and initiatives that support the national harmonisation of clinical trial activities	For example, currently, clinical trial researchers are required to enter common data regarding their trial in the human research ethics application (HREA) form, trial registration (e.g. via ANZCTR), and, where applicable, to the Therapeutic Goods Administration (TGA). To reduce administrative burden for researchers, HeSANDA will link to these and other existing structures where possible to support better knowledge discovery and easier meta-analysis.
4.2	HeSANDA will aim for a nationally coordinated approach to address data governance and principles	Issues of data sharing & governance impact multiple stakeholder groups, such as research participants, health consumers and people with lived experience, researchers, funders, institutions, and ethics committees. The research community desires cooperation and coordination between these groups to address their common interests.
4.3	HeSANDA will leverage existing investment in data sharing infrastructure where possible	Researchers are required or incentivised to utilise existing data management and sharing infrastructure provided by their organisations. HeSANDA should engage with research organisations and networks in order to develop strategies to avoid unnecessary duplication of effort and to maximise existing infrastructure investments.

Implementation considerations

[a] Co-design	Sector co-design of HeSANDA is critical. In particular, the need for full engagement of consumers in the design and development of HeSANDA.
[b] Consultation with specific population groups	Targeted consultation with population groups for whom special consideration will be required in relation to secondary data use for research is recommended. This includes but is not limited to Aboriginal and Torres Strait Islander peoples, culturally and linguistically diverse populations, and people identifying as LGBTIQA+.

[c] Communication	Provision of simple HeSANDA documentation in plain language, is important to ensure that consumers can understand the intent and contribute in an informed and meaningful way. Similarly, trialists require a clear understanding of the concepts and need for data sharing. Stakeholders also voice support for a clear value proposition for HeSANDA. The value proposition and communication about HeSANDA must use straightforward and unambiguous language. The value proposition should include a description of the benefits of HeSANDA over and above existing methods for accessing data from clinical trials for secondary use.
[d] Feedback	The need to strengthen feedback to trial participants about the outcome of trials in which they participate is an overall issue for the health research sector. HeSANDA should consider this need and how it might support it in relation to secondary data use.
[e] Understanding the evolving context	Acknowledgement and understanding of the context within which HeSANDA will be operating will be an important factor influencing uptake and use of HeSANDA. Ongoing engagement with key stakeholders and peak national organisations to understand potential system-level barriers and enablers will be essential. The potential to work with partners and HeSANDA node organisations to address critical barriers that will influence its use and usefulness could also be considered.
[f] Reporting	Public reporting of research successes catalysed through HeSANDA will provide research participants and the broader community (including research funders and government) with information reinforcing the value of secondary use of data.

Special considerations

Data relating to a range of population groups, health conditions and disease areas should be given careful consideration by HeSANDA. This includes data relating to:

- Aboriginal and Torres Strait Islander peoples
- people from culturally and linguistically diverse communities
- people who cannot read or write
- people for whom identification may be possible (e.g. people with rare diseases)
- paediatric populations
- people unable to give informed consent
- people who have died
- health conditions with high levels of stigma
- genetic/genomic information
- prison populations and people with a criminal history

Some novel clinical trial designs require careful consideration regarding the timing and approach to secondary use of data. These included platform trials or other trial designs where data release occurs while trials are ongoing, and the release of data related to translational sub-studies.

Each of these population groups and data types will require specific consideration when designing approaches to data field capture, consent for secondary data use, and reporting of data from secondary research studies. For some population groups there are likely to be limited data available for sharing due to clinical trial exclusion criteria, access to trials, inconsistent or inadequate data fields, and the fact that some people do not feel safe reporting aspects of ethnicity, culture, sexuality or gender identity. While these issues are outside the scope of HeSANDA, HeSANDA could help drive awareness of these issues, particularly when promoting the standardisation of data fields.

HeSANDA should also be wary of reinforcing stigma or making assumptions about capacity for decision making in its communications and data governance processes. Ongoing engagement with groups with specific expertise and insights relating to different population groups is important to ensure appropriate planning, design, and implementation processes that are sensitive to the needs and concerns of different population groups whose data may be shared through HeSANDA.