HeSANDA Stakeholder Consultation Project: Pre-reading for stakeholder consultation participants

This information is for people participating in the HeSANDA Stakeholder Consultation Project. Your participation in the consultation will rely on you having a background understanding of the initiative.

Please read this document before attending one of the HeSANDA stakeholder consultation workshops run by the Australian Clinical Trials Alliance in June 2021.

You may also choose to attend the pre-consultation webinar about the HeSANDA initiative. Please check your invitation email for details of the webinar.

1. What is the HeSANDA initiative?

HeSANDA is the **He**alth **S**tudies **A**ustralian **N**ational **D**ata **A**sset.

HeSANDA is an Australian initiative designed to support sharing of data generated through health research studies. The initiative aims to build a national collection of data generated through Australian health research and support appropriate and ethical sharing of the data with other Australian researchers.

This is called **'secondary use of data'** or **'secondary data sharing'**.

By supporting secondary use of data from health research, HeSANDA aims to stimulate new research ideas, increase the impact of health research, increase the benefits of investment in health research, and ultimately improve the health and wellbeing of people in Australia.

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2. Who is leading the HeSANDA initiative?

The HeSANDA initiative is being led by the Australian Research Data Commons (ARDC). The ARDC is a Commonwealth initiative to support the national research sector and has been established under the National Collaborative Research Infrastructure Strategy (NCRIS).

The ARDC is working with the Australian health and medical research community to develop the HeSANDA initiative. An Advisory Committee has been established to oversee the initiative, with representatives from key project partners as well as consumer representation.

Key project partners

National Health and Medical Research Council (NHMRC)

Research Australia

Cochrane Australia

Australian Health Research Alliance (AHRA)

Australian New Zealand Clinical Trials Registry (ANZCTR)

Australian Clinical Trials Alliance (ACTA)

Population Health Research Network (PHRN)

Consumers Health Forum of Australia

The Australian Clinical Trials Alliance (ACTA) sits on the HeSANDA Advisory Committee and has been contracted by ARDC to deliver the stakeholder engagement consultation for the initiative.

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3. What is secondary use of data?

Health research studies collect information and data. This includes information about the people taking part in the research, their health condition(s) and their response to the intervention being studied in the research. There are national guidelines about how such data and information should be collected, stored, used and reported.

Information and data collected in one research study can be useful to inform other research activity. If the information is used for a purpose other than the original research for which it was collected, this is called **'secondary use of data'**.

Secondary use of data is different to the process of publishing results from a research study.

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4. What types of research activity are being considered in the HeSANDA initiative?

The HeSANDA initiative will use data and information collected from health research studies in Australia.

As a first step, the initiative is focusing on data and information collected from **investigator-initiated clinical trials**. These are clinical trials set up and managed by non-pharmaceutical / non-industry researchers, such as clinicians and researchers working in a health or medical research institution, independent research organisation or university.

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5. Why is secondary use of data important in clinical research?

Secondary use of data collected through clinical trials is a powerful way to make the most out of the data in a way that can inform future clinical care.

A clinical trial is designed to investigate a specific research question, or series of linked research questions. Making the data from one trial available to other researchers can help generate or answer different research questions and make connections between research studies that increase the strength and value of the research findings.

Consultation with Australian researchers about the HeSANDA initiative has highlighted three important uses of secondary data from clinical trials.

How secondary data from clinical trials can be used	What this means
Secondary research projects and analyses	Using the data from one clinical trial to generate ideas for and / or plan a different clinical trial or research study Analysing the data in a different way, perhaps combined with results from other research, to answer a different research question to the original clinical trial
Meta-analysis and systematic review	Including the data from a clinical trial as part of a bigger analysis of data from multiple research studies to look for trends, similarities or differences in research findings
Replication, reproducibility or peer review	An examination of whether the results from a clinical trial can be repeated in another trial using a similar group of trial participants

Each of these secondary uses of data can help to improve the design of new clinical trials, inform the development or review of health policy and clinical practice guidelines, and assist with the assessment of new health technologies.

6. What are some of the challenges with secondary use of data from clinical trials?

Researchers believe there can be significant benefits from sharing research data for secondary use. However, there are important issues that must be addressed. This includes sharing data in a way that respects the privacy and wishes of research participants, respecting the intellectual property of the original researchers, and managing data in a way that makes secondary use practical and efficient.

Challenge	What this means
Participant consent for secondary use of data is critical	Providing clear information to clinical trial participants about how and why data from a clinical trial may be shared and gaining consent for data sharing is critical. This means understanding and addressing the concerns people have about sharing of their personal data from a clinical trial.
Respecting the intellectual property of the original researchers is critical	Protecting the rights of researchers who put considerable effort and resources into the original research is critical. This means maintaining appropriate governance processes to ensure that the publication and intellectual property rights of the original researchers are adequately protected.
Storage of data from clinical trials is siloed	Data and information collected as part of a clinical trial is typically stored by the organisation that conducts the trial. The data and information are usually only available to other researchers through direct contact with the individual researcher or organisation leading the original trial.
Approaches to sharing data from clinical trials in Australia vary	The formats used to collect, enter and analyse data from clinical trials vary between researchers and organisations.
There is a lack of guidance about secondary use of data	While there are national guidelines for collecting, storing and analysing data from clinical trials, there is a lack of nationally agreed guidance about how to share data from clinical trials in an appropriate and ethical way.
Variations in approach and uncertainty are barriers to secondary use of data	Researchers encounter resource and efficiency issues due to variation in processes and a lack of clear guidance on how to implement the data sharing policies of funders, publishers, and other stakeholders.
The costs of data sharing are not consistently supported through research funding	The labour cost associated with data sharing is not consistently supported by research funders or institutions.

7. What kinds of data and information could be shared under the HeSANDA initiative?

The HeSANDA initiative is exploring what kinds of data and information from investigator-initiated clinical trials would be most useful for researchers if made available for secondary use. Examples of some of the kinds of data that could be shared are illustrated and described in the table below.

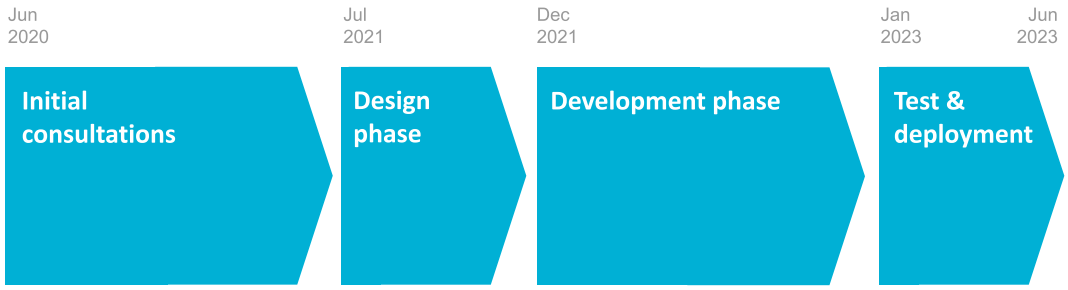
Type of data	Description
Study documentation	Study documentation may include: • **clinical trial protocol:** used to describe how the trial is run • **data dictionary:** a description of what each of the data items collected in the trial means • **ethics details:** information about the approval by a Human Research Ethics Committee of the trial, including any specific requirements for how the trial should be run and how data should be collected and used
Summary data	Summary information about the trial results, including: • **sample characteristics:** a summary of the group of people who participated in the trial • **aggregated results**: a collective summary of the results from the trial
Individual participant-level data (IPD)	Individual-level information about the trial results, including: • information about the age and sex of trial participants • results of any tests undertaken during the trial, including diagnostic tests and tests to assess response to treatment • responses to any surveys undertaken during the trial • information about any biomarkers studied during the trial Individual participant-level data does not include information such as the person's name, address, or other details that a researcher could use to contact the person or identify who they are.
Published data and results	Information about any publications arising from the clinical trial including: • publication details • data reported in journals.
Linked data	Some clinical trials link data collected through the trial to other available data about people taking part in the trial. This may include information about the person's health available in other health databases such as the Medicare database. Such data linkage is done with the permission of the people taking part in the trial.

Researchers have indicated that the most useful information for secondary use is **individual participant-level data (IPD)** from clinical trials, supported by information about the clinical trial protocol and information about the quality and type of data collected. Information about the purpose of the study and the ethics review and approval process for the study are also important contextual information.

8. How is HeSANDA being developed?

The development timeline for HeSANDA is 2020–2023. There are four development phases:

- **initial consultations** (to identify the needs and requirements of key stakeholder groups)
- **design phase** (where stakeholder needs and requirements will be used to inform the design of the data asset and infrastructure)
- **development phase** (where the design will be built into 'nodes' of groups of research institutions and networks interested in testing the initiative)
- **test & deployment** (where the network of nodes will be tested to make sure they operate correctly before roll-out).



ARDC is co-designing the initiative with key stakeholder groups. ARDC is working with researchers, institutions and health consumers so that the design process is informed by all relevant stakeholder requirements.

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9. Who has the ARDC consulted with so far about the HeSANDA initiative?

From August to October 2020, ARDC worked with the Australian Institute of Health and Welfare (AIHW) to run four online stakeholder consultation workshops. There was an open invitation to the clinical trials research community to join these workshops, and researchers, research managers, research funders, policy makers and a small number of research participants attended.

Each workshop focused on a specific issue to be considered by HeSANDA:

A. **Research purpose**: How do researchers wish to use shared data? What kinds of information are needed for these uses? Who would use shared data? How should these uses and purposes be prioritised?

B. **Data content & quality requirements**: Based on the purpose and uses identified in the first workshop, what data types and other primary research outputs need to be included in the data asset, and what are the quality requirements for these data?

C. **Existing data standards & practices**: Based on the data types, research outputs, and quality requirements identified in the second workshop, what data standards and practices exist or would need to be developed?

D. **Barriers, systems, & enablers**: What are the issues (e.g. ethics and consent, data governance, access arrangements, IT & infrastructure) that must be addressed in order for data sharing to be implemented successfully in Australia?

The feedback provided through these workshops has been summarised and used to develop a Research community consultation report on HeSANDA Development Priorities.

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9. What has been found so far?

The ARDC consultation with Australian researchers has found that:

- overall, the Australian research community supports having a coordinated national approach to sharing data from clinical trials research as a way of accelerating research and improving health outcomes for the Australian population
- approaches to sharing data from clinical trials in Australia vary
- researchers are uncertain about how to share data in an appropriate and ethical way, and this can be a barrier to sharing data from research studies in Australia
- the variation in approaches and uncertainty about how to share data appropriately makes the process of data sharing in Australia inefficient and expensive
- a national approach to data sharing that includes standards for appropriate data sharing will help to improve the efficiency and capacity for data sharing among Australian researchers.

Consultations have led to the development of:

- a set of 16 **key principles** that should underpin a national approach to secondary use of data
- three **suggested areas for future investment** that will help to enable sharing of data from clinical trials research in Australia.

The principles and areas for future investment have been designed to adhere to two key requirements:

- Data sharing should support the interests of people who take part in clinical trials or may take part in a trial in future, people running clinical trials, people who would like to use data from clinical trials and people funding clinical trials, as well as research organisations, institutions and policy makers. Support and endorsement from each of these groups about the HeSANDA initiative are important.
- While the potential scope for HeSANDA is boundless, a phased roll-out will help to make the process feasible. Roll-out can be informed by an understanding of current processes, including identification of key types of data, evaluation of data availability, and current clinical trial policies / procedures.

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10. What are the suggested areas for investment?

Consultation to date has identified three areas for investment to enable secondary use of data from investigator-initiated clinical trials in Australia:

1. Stakeholder-endorsed coherent data practices
2. Coordinated national network of data services to enable data sharing from clinical trials
3. Centralised data discovery and access tools.

Investment area	What this investment area would support / include
1. Stakeholder-endorsed coherent data practices	• Common standards for clinical trial data available for secondary use • Standardised descriptions of data available for secondary use • Standardised approaches to data governance, including standardised approaches to ensure compliance with ethics and participant consent for data sharing • Consistent and streamlined approaches for requesting and accessing data • Tools to facilitate data standardisation and compliance

2. Coordinated national network of data services to enable data sharing from clinical trials	• The development of a network of infrastructure nodes that adopt the coherent data practices
	• These nodes would be owned and operated by research institutions and networks and allow them to facilitate researchers' access to information from their clinical trials such as:
	  ○ individual participant-level data for secondary use
	  ○ summary information about research studies
	  ○ study protocols
	  ○ information about the types and quality of data from studies
	  ○ information about ethics approval for studies

3. Centralised data discovery and access tools	• Tools to support the discovery of relevant clinical trials and data held by the nodes • A streamlined process for requesting access to clinical trial data held by the nodes A coordinated and efficient approach to accessing clinical trial data held by the nodes

11. What are the proposed HeSANDA principles?

The 16 HeSANDA principles cover four main areas: Purpose; Data content and quality; and Stakeholder coordination.

Principle	What this means in practice
Purpose	
1. The capabilities delivered by HeSANDA must be informed by the core value proposition	The core value proposition of the HeSANDA initiative describes the main intent of the initiative. The core value proposition of the HeSANDA initiative is to improve the efficiency and impact of research and reduce the cost of research by supporting the sharing and secondary use of health research data. This core value proposition should be central to decisions about how the data asset is designed and the infrastructure required to support sharing and secondary use of data.

Principle	What this means in practice
2. The core research purpose of HeSANDA is to support research with a translational focus	The core research purpose of the HeSANDA initiative describes the main type(s) of research that would be supported through the initiative. Research with a 'translational focus' means research that can be used (or translated) to inform improvements in clinical care. This may include using research to inform health policy, clinical practice guidelines, assessment of new health technologies and / or to inform new research.
3. HeSANDA will facilitate the sharing of a range of clinical trial information	HeSANDA will support the sharing of different types of information associated with clinical trials. The emphasis will be on sharing individual participant-level data, as well as information about study protocols and summary data about the trial population and results.
4. HeSANDA will maximise the discoverability of the clinical trial information	HeSANDA will organise clinical trial data in a way that allows researchers to search for and find relevant information easily (subject to appropriate ethical controls).
5. HeSANDA will improve the efficiency and reliability of access to clinical trial data for secondary research	HeSANDA will implement a standardised approach to accessing data from clinical trials by other researchers, making secondary use of data easier and more efficient (subject to appropriate ethical controls). HeSANDA will explore options for efficient methods to store and search for data from clinical trials.
6. HeSANDA will reduce the barriers to data sharing for clinical trialists	HeSANDA will aim to align the approach to data sharing to fit in with the way researchers currently manage their data. This will help avoid asking researchers to take on additional burden by doing things in completely new ways that will not be useful. This will help to reduce the costs and inefficiencies associated with the secondary use of data.
Data content & quality	
7. HeSANDA will promote minimum reporting and data sharing requirements for clinical trials	HeSANDA will develop a set of minimum requirements for clinical trial data stored in the asset. This will include individual participant-level data and relevant contextual information about the trial (such as the trial protocol and descriptions of the trial data and data quality).
8. HeSANDA will support the current variety of IPD data standards but will encourage pathways to the adoption of stakeholder-endorsed data standards	HeSANDA should support access to clinical trial data in a range of formats. Over time, HeSANDA will aim to support the adoption of standard ways of capturing, storing, and reporting data from clinical trials to achieve a consistent approach.
9. 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.
Data governance	
10. HeSANDA should promote common approaches to data sharing and re-use by clinical trials researchers	The development of agreed protocols and procedures will improve the feasibility for data sharing to become standard research practice and improve the efficiency of these practices.

Principle	What this means in practice
11. HeSANDA should promote common approaches to participant consent requirements for data sharing and re-use	The HeSANDA initiative should develop a coordinated national approach for consent to secondary use of data from clinical trials to improve the feasibility of data sharing and, most importantly, address concerns and mitigate risk around the sharing of sensitive data.
12. HeSANDA should promote best practice guidelines for the handling and sharing of sensitive data	The HeSANDA initiative should develop guidance for researchers on specific data handling issues, such as de-identification of data and the security of sensitive data.
13. HeSANDA should be considerate of the labour cost to clinical trialists to facilitate access to data	While HeSANDA aims to improve the efficiency of data sharing, these improvements cannot entirely remove the labour cost associated with data sharing. Recognition of these costs within data sharing policy and infrastructure is fundamental to supporting the research community.
Stakeholder coordination	
14. HeSANDA should align its activities with existing structures and initiatives that support the national harmonisation of clinical trial activities	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 the administrative burden for researchers, HeSANDA should link to these and other existing structures to make it easier to search and access relevant data.
15. HeSANDA should attempt a nationally coordinated approach to address its data governance aspirations and principles	Data sharing and governance issues affect and involve a range of stakeholders, including research participants, researchers, research funders, institutions, and ethics committees. HeSANDA will facilitate a coordinated and collaborative approach that recognises and addresses common interests across the sector.
16. HeSANDA should leverage existing investment in data sharing infrastructure where possible	Researchers are required or incentivised to use the data management infrastructure provided by their organisations. HeSANDA will aim to develop strategies to avoid unnecessary duplication of effort and to maximise existing infrastructure investments.

12. Why is this additional consultation being undertaken?

Consultation to date has helped to:

- define the kinds of research and secondary use of data HeSANDA should support
- understand views of a broad group of stakeholders about practical issues for secondary data sharing that should be considered.

This next round of consultation will gather feedback from people who have taken part or may in future take part in clinical trials, and researchers who run clinical trials.

The consultation aims to understand the perspectives of people whose individual data or trial data may be shared through the HeSANDA initiative. This will help to ensure that the design of HeSANDA is acceptable to people who run and participate in trials, based on the feedback provided during the consultations.

13. What is the timing for HeSANDA?

Once the initial consultation phase is complete, ARDC will use the feedback from all of the consultations as the starting point for the design phase. The design phase will occur in the second half of 2021. The aim is to build the initial infrastructure in 2022 (i.e. the development phase), with testing in the first half of 2023 before the asset is launched (i.e. the Test & Deployment phase).

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14. What is the design process for HeSANDA?

ARDC is using a collaborative co-creation approach to develop HeSANDA. The design phase will be overseen by four working groups, each focusing on different aspects of the data asset.

Focus area	Areas for consideration

Information design	• What trial information (data, documents, other info) will need to be shared?
	• How should this information be organised and formatted?
	• Deliverables:
	  ○ Minimum reporting requirements, guidelines, & templates
	  ○ Informatics design
	  ○ Metadata model

Data access framework	• Who decides when trial info should be shared, and how do they decide?
	• Deliverables
	  ○ Types of access
	  ○ Workflow for accessing data
	  ○ Approach to data sharing agreements, licencing, & IP

Technology standards	• What technology is required to enable information design and data access? • This is a technical working group where ARDC's IT developers will design specific software technology to address the design requirements
Ethics & consent resources	• What ethics and consent are required to enable information design and data access? • Deliverables: ○ Recommendations, resources, and training materials for researchers, organisations, and ethics committees

ARDC will continue to seek stakeholder input at appropriate points throughout this process.

The scope of the HeSANDA initiative will be further refined by future engagement with the key stakeholder groups identified by the HeSANDA advisory committee.

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15. How will HeSANDA be rolled out?

ARDC is establishing an initial network of 10–15 infrastructure nodes through which data from clinical trials will be shared for secondary use. The nodes will be operated by clusters of research institutions and/or clinical trial networks that will develop their existing infrastructure to meet the national standards that will be established during HeSANDA's Design Phase. Research institutions and networks are currently applying to ARDC to establish nodes, and the initial network will be announced by the middle of the year.

The core functions of nodes within the HeSANDA network will be:

- to curate and provide descriptions of clinical trials research data and documentation and make that information available to the HeSANDA network (similar to a catalogue of research and data)
- to work with their data owners and custodians to implement common data access arrangements.

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16. Questions to think about

During the stakeholder consultation workshops, we will ask for your views on the HeSANDA initiative, including:

- is the intent of the initiative clear to you?
- do the proposed principles provide a useful foundation for the initiative?
- are there any groups of patients or types of trials that may need special consideration in the data asset?
- how likely would you (or members of your organisation) be to agree to your data (participants or triallists) being shared for use by other researchers through HeSANDA?