Australian Research Data Commons

Australian Clinical Trials Alliance

HeSANDA STAKEHOLDER CONSULTATION PROJECT: SUMMARY OF CONSULTATION FEEDBACK

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CONTENTS

EXECUTIVE SUMMARY

This report provides a summary of key themes emerging from a targeted consultation process facilitated by the Australian Clinical Trials Alliance (ACTA) on behalf of the Australian Research Data Commons (ARDC) to inform the planning and design of the Health Studies Australian National Data Asset (HeSANDA) initiative. Feedback was sought from clinical trialists and consumers across Australia with experience and insights in a range of health and research areas. Consultations gathered insights from 116 people through four virtual workshops and an online survey during May and June 2021.

Consultations were designed to gain insights into a series of questions with a view to ratifying and adding detail to feedback provided through the initial consultations undertaken to inform the initiative. A summary of insights is provided below.

OVERALL FINDINGS

Overall findings from the consultation process included:

- support from participating consumers and trialists for the goal of facilitating secondary use of data from clinical trials for research purposes, with a strong emphasis placed on the need for secondary sharing and use of data to be facilitated in an appropriate, effective and efficient way
- reinforcement by clinical trialists of the need for the design and implementation of HeSANDA to consider data governance and ethics; to include simple and standardised processes and to ensure that commercial and academic intellectual property is protected
- reinforcement by consumers of the importance of informed consent for sharing data from clinical trials and the need to protect individual identification through shared data to protect against misuse or misrepresentation.

FEEDBACK ON THE HESANDA PRINCIPLES

Feedback gathered through the ACTA consultation process broadly aligns with and supports the principles previously proposed to underpin the development of HeSANDA.

Feedback suggests three additional principles that are focused on: that are focused on:

- the importance of evaluation to understand whether HeSANDA is meeting its goals and to make refinements as required (‘Purpose’ principle)
- the importance of ensuring appropriate use and interpretation of data in a way that protects academic and commercial intellectual property and guards against misuse or misrepresentation of data (‘Data governance’ principle)
- reinforcement of a commitment to the inclusion of consumers/people with lived experience within all aspects of planning, design and implementation (‘Stakeholder coordination’ principle).

In addition, feedback provided further nuance and considerations for implementing the existing principles under the four theme areas of: Purpose; Data content and quality; Data governance; and Stakeholder coordination. While some of the issues identified (e.g. issues under the ‘Data content and quality’ theme) may be beyond the scope of HeSANDA itself, HeSANDA could act as a catalyst for sector-wide action to address these issues.

SUMMARY OF IMPLEMENTATION CONSIDERATIONS

The table below summarises feedback relevant to the implementation of the HeSANDA principles gathered through the ACTA consultation process. Feedback is themed according to the four principle areas.

Principle area	Theme	Implementation consideration
Purpose	Communication of scope	Stakeholder feedback highlights the need to be specific about the intent and scope of HeSANDA 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, including the fact that identified data for individual research participants will not be made available for sharing • the **purposes** for which secondary data sharing would be approved (i.e. for research use) • the **types of organisations/groups** from whom applications for secondary data use would be considered (i.e. researchers and research organisations) • the **proposed benefits of supporting secondary data through HeSANDA** (above existing mechanisms such as through peer-reviewed publications, Australian and New Zealand Clinical Trials Registry (ANZCTR) or direct contact with research teams).
	Ease of access and use	The uptake of HeSANDA will depend on ease of access and its ease of use. The need to minimise the burden on researchers who are using it and researchers who are asked to share data through the asset will be critical.
	Funding	Transparency around funding for HeSANDA will be important, including communication about any costs associated with using the asset and considerations for long-term sustainability.
	Evaluation	Ongoing evaluation and review will be important to ensure that HeSANDA is achieving its purpose with the flexibility to make refinements as required.
Data content and quality	Standardised definitions	The opportunity to facilitate consistent approaches (e.g. through creation and promotion of standardised definitions for common data fields) through HeSANDA will help to promote greater consistency in data collections and improve the value of the data asset. Use and promotion of data dictionaries as tools to describe the data items available for secondary use will be important.
	Contextual information	Feedback highlights the importance of providing sufficient context and information within HeSANDA to ensure that interpretation of trials data is appropriate, and that secondary use retains the integrity of the original data.
	Standardised data fields	There is an opportunity through HeSANDA to promote the need for meaningful and usable data fields relating to individual trial participant characteristics that are not currently captured in a meaningful or consistent way (e.g. language, ethnicity, culture, country of birth, gender diversity). While this is a broader issue for trials data overall,

Principle area	Theme	Implementation consideration
		the consistent capture of meaningful data fields will support greater comparability across data sets when shared for secondary use.
Data governance	Governance process and framework	A robust approach to data governance is a critical consideration for HeSANDA that will influence trust and confidence in the data asset by both consumers and trialists. A comprehensive and transparent data governance framework is needed describing how, with whom, and for what purpose data from clinical trials are shared through HeSANDA.
	Consent	From a consumer perspective, the approach to gaining informed consent for secondary use of data is critical. Stakeholder feedback highlights the need to develop standardised wording and tools to facilitate consent for secondary sharing of data from clinical trials. The data governance framework for HeSANDA must support clear, simple and unambiguous informed consent processes. 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 use of data 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, who data may be shared with, how data may be used, and any risks (actual or perceived) associated with secondary use of data for research purposes.
	Linked data	The need to consult with human research ethics committees around consent requirements for accessing linked data collected as part of a clinical trial was noted, with particular caution around linkage to certain record types such as mental health records.
	Identification	From a consumer perspective, the fact that individual, identifiable information will not be available through HeSANDA may go some way to allaying concerns about consent. However, the need to consider and be able to answer each question in terms understandable by a lay audience will be important. Feedback highlights the need to clearly explain what may happen with data collected, if permission is given for secondary use of data, so that consumers feel sufficiently reassured that personal information is protected. The need for consumer confidence and trust in the integrity of the process is paramount.
	Misuse	Feedback highlights the need to address concerns about the potential for misinterpretation or misuse of data, including reputational risk, in communication about HeSANDA as this may be a barrier to researchers making data available for secondary use.
Stakeholder coordination	Co-design	Co-design of HeSANDA with the sector is seen to be critical. In particular, the need for full engagement of consumers in the design and development of HeSANDA.

Principle area	Theme	Implementation consideration
	Consultation with specific population groups	Targeted consultation and representation within design working groups of population groups for whom specific consideration will be required in relation to secondary use of data 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+.
	Communication	Provision of simple documentation in plain English, not only once HeSANDA has been designed, but during the planning and design phases, is important to ensure that consumers can understand the intent and contribute in an informed and meaningful way. Stakeholders also voice support for a clear value proposition for HeSANDA. The value proposition and communication about HeSANDA must use simple 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.
	Feedback	The need to strengthen feedback to trial participants about the outcome of trials in which they participate was highlighted as an overall issue for the health research sector. Recognition by HeSANDA of this need and how to manage feedback in relation to secondary data use was noted.
	Understanding 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 Advisory Committee members to understand potential system-level barriers and enablers will be important. The potential to work with partners and HeSANDA node organisations to address critical barriers that will influence the use and usefulness of the data asset could also be considered.
	Reporting	Public reporting of research successes catalysed through HeSANDA would provide research participants and the broader community with information reinforcing the value of secondary use of data.

Special considerations

Data relating to a range of population groups and health conditions/disease areas were identified as needing careful consideration by HeSANDA. These included 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.

Stakeholders also noted that novel clinical trial designs may raise questions about the timing for 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 the population groups and data types identified by stakeholders will require specific consideration when designing approaches to consent for secondary use of data, data fields and reporting of data from secondary research studies. It was noted that while data sharing is a laudable goal, for some population groups there are likely to be limited data available for sharing because of 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, it was noted that HeSANDA could help drive awareness of these issues, particularly when promoting the standardisation of data fields.

The feedback also highlighted the importance of taking proactive steps to avoid reinforcing stigma or making assumptions about capacity for decision making through HeSANDA communications and data governance processes. Ongoing engagement with groups with specific expertise and insights related to different population groups will be 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.

1. INTRODUCTION

The Health Studies Australian National Data Asset (HeSANDA) is an Australian initiative being led by the Australian Research Data Commons (ARDC) to support sharing of data generated through health research studies. The initiative aims to facilitate access to data generated through Australian health research by other Australian health researchers and to support appropriate and ethical sharing of the data for the purposes of research.

By supporting the 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.

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 and deployment** (where the network of nodes will be tested to make sure they operate correctly before roll-out).

ARDC is working with researchers, institutions and health consumers so that the design process is informed by all relevant stakeholder requirements. Initial consultation by ARDC 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 clear standards will help to improve the efficiency and capacity for data sharing among Australian researchers.

Consultations to date 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.

The phased roll-out of HeSANDA will initially focus on the secondary use of data from investigator-initiated clinical trials. During March to June 2021, the Australian Clinical Trials Alliance (ACTA) facilitated targeted consultation with the Australian clinical trials sector to build on these consultation findings and inform the design of the asset.

Consultations gathered insights from:

- **clinical trialists** – people and organisations involved in designing and running investigator-initiated clinical trials in Australia
- **consumers** – including people from consumer organisations with an interest in clinical research, people with lived experience of different health conditions, and members of consumer advisory groups from clinical trial organisations
- **research participants** – people who are currently or who have previously taken part in a clinical trial in Australia.

These categories are not mutually exclusive. The aim of the consultation process was to understand the perspectives of people whose data may be shared through HeSANDA with a view to ensuring that the purpose, design and governance of the asset are acceptable to people who run and participate in clinical trials in Australia. In broad terms, the consultation aimed to sense check or ratify the intent and draft principles for HeSANDA, identify specific groups of people or types of trials that may need special consideration in the data asset, and understand factors from a trialist or consumer perspective that would influence agreement to share data via HeSANDA.

This report provides a summary of key themes from the consultation process together with implementation considerations for the design groups taking the HeSANDA initiative forward.

2. ABOUT THE CONSULTATION PROCESS

2.1 CONSULTATION OVERVIEW

The consultation process was developed and facilitated by ACTA, with input from a multidisciplinary Working Group comprising research and consumer experts with an interest in data sharing (see Appendix I).

A stakeholder consultation framework was developed to underpin the consultation process.

Ratification	Expansion of directions	Collaboration and buy-in
1. Is the intention/purpose of HeSANDA clear for clinical trialists, consumers and research participants? 2. Do the draft principles provide a robust foundation on which to base HeSANDA? Are there any principles that miss the mark? Are there any principles that could be added?	3. Are there any critical considerations for specific population/community groups that need to be factored into HeSANDA directions? 4. Are there any clinical trial questions/designs that will require specific consideration as HeSANDA is developed?	5. What interest and enthusiasm is there among clinical trialists to add data to/use data from a national data asset such as HeSANDA? 6. What concerns and questions do current research participants have about how data provided to a national data asset will be used in future?
7. What outstanding questions and issues are there that will need further consideration by ARDC / working groups and / or require further targeted consultation?		

Review of this framework prioritised four key questions for consultation:

1. Is the intent of the HeSANDA initiative clear to you?
2. Do the proposed principles provide a useful foundation to underpin secondary data sharing from clinical trials?
3. Are there any population groups or types of trial data that may need special consideration in the data asset?
4. What would make you (or members of your organisation) confident/more confident about data from a clinical trial you are running or taking part in being shared for use by other researchers?

2.2 WORKING GROUP

Potential Working Group members were identified through the ACTA network with targeted invitations emailed to individuals with known interest and expertise in data and data sharing. Eleven members agreed to participate in the Working Group, meeting virtually on three occasions to plan the consultation process and provide expert comment on the synthesis of consultation findings (see Appendix I for Working Group and Project Team members).

2.3 PROMOTION AND INVITATIONS

The consultation was promoted through the ACTA network, including via targeted emails and phone calls to:

- ACTA's Special Interest Group for Network Managers (SIGNET)

- ACTA's Statistics in Trials Interest Group (STInG)
- ACTA organisational members from Clinical Trial Networks (CTN), including established and emerging CTNs
- ACTA Reference Group members (volunteers contributing to ACTA's project-based initiatives)
- ACTA Board members and individual members with a known interest in data.

Members were also asked to share the email with their consumer advisory panels.

External stakeholders were also invited to participate through targeted emails. This included consumer organisations and organisations representing specific population groups.

The consultation was promoted via the ACTA website and through a regular newsletter and social media posts.

2.4 PRE-CONSULTATION EDUCATION

Pre-consultation education was undertaken to ensure that participants joined the consultation with the same baseline understanding of the intent of HeSANDA and work to date. A background paper written in plain English provided an overview of the benefits of secondary use of data in research, the purpose of HeSANDA, proposed scope, draft principles and investment areas.

A 1-hour online webinar was also held one week prior to the first consultation. The webinar was recorded and posted on a dedicated webpage hosted by ACTA to support the consultation process.

Reading the background paper and/or attending the webinar was a pre-requisite for all consultation participants. People who participated in the consultation process indicated on registration or as part of survey completion that they had read the background paper. A total of 49 people attended the pre-consultation webinar.

2.5 CONSULTATION WORKSHOPS

Four 90-minute virtual consultation workshops were held via zoom during June 2021. Two workshops focused on gaining insights from clinical trialists, and two focused on gaining insights from consumers and research participants. The decision to hold separate sessions for researchers and consumers was deliberate, with the aim of ensuring even time was given to hearing both views. However, consumers were not prevented from attending the trialist sessions and vice versa. Individuals could attend more than one session.

Workshops were co-facilitated by ACTA and the professional facilitator who was engaged to support the consultation process. Workshop discussions used open questions and encouraged participation by all attendees. A workshop scribe captured notes, and sessions were recorded for completeness. In addition to contributing to discussions, participants were encouraged to use the 'chat' function in zoom to provide written comments.

Brief details about participants (perspective, role, organisation and location) were captured as part of the registration process for the workshop.

2.6 SURVEY

An online survey was open for six weeks in May and June 2021 to gather insights from people unable to attend a workshop and from people who attended a workshop but wanted to provide additional feedback.

Survey questions and questions about participant details mirrored those used during the consultation workshops (see Appendix II).

2.7 SYNTHESIS AND OUTPUT TESTING

Notes from all workshops were analysed thematically together with the survey responses. A summary report was developed and discussed with the Working Group to gain input on the implementation considerations. The summary report was also circulated to all registered workshop participants and survey respondents who provided an email address. Consultation participants were invited to comment on whether the report captured the main points from the consultation they attended/survey input they provided and to identify any gaps or ambiguous information in the report.

Alongside the output testing, two follow-up conversations were held to elicit feedback related to particular population groups not represented strongly through the consultation (LGBTIQA+ people and people from culturally and linguistically diverse backgrounds).

2.8 LIMITATIONS OF THE METHODOLOGY

While the consultation process was open and promoted widely, participation relied on people's awareness of and interest in secondary use of data from clinical trials and motivation to provide feedback on HeSANDA. A review of a brief evaluation survey circulated to participants highlighted that people were motivated to take part to find out more about HeSANDA and because they have an interest in seeing such an initiative progress. People with less interest in secondary use of data and/or opposed to secondary use of data or the concept of HeSANDA may not have been motivated to participate.

Conduct of consultations on four different dates and at different times of day provided options for participants but relied on people available to participate in a 90-minute consultation during office/clinic hours. This may have limited the option for participation by some people. The availability of the survey aimed to overcome this issue, providing a mechanism for participation by people unable to attend a consultation workshop.

The open format of the virtual consultations aimed to draw out insights from participants. Effort was made during the consultations to seek input from all participants, including prompting individuals for comment and inviting comment using the meeting platform 'chat' function. However, as with all consultations, it is possible that some people were reluctant to express views that diverged significantly from the overall group perspective.

See also *Section 3.3 Gaps in consultation insights*.

3. CONSULTATION PARTICIPANTS

3.1 CONSULTATION PARTICIPANTS

The consultation process aimed to target around 100 people. In total, 116 unique perspectives were provided. This included 93 people who provided input by attending at least one workshop and 36 who provided input via the online survey (noting that some people attended a workshop and completed the survey).

The consultation aimed to capture insights from trialists and consumers. People who participated brought a range of perspectives (see Table 3.1). Overall, 67% of participants provided a researcher/trialist perspective (n=78) and 27% of participants (n=31) provided a consumer/research participant perspective.

Table 3.1: Perspective of consultation participants (n=116)*

Perspective	Number of participants	Percentage of participants
I work for an organisation that runs clinical trials	63	54%
I am a researcher involved in the design/conduct of clinical trials	53	46%
I have previously been a participant in a clinical trial	9	8%
I am considering participating in a clinical trial	8	7%
I am currently a participant in a clinical trial	5	4%
I am a consumer (patient, carer or person who uses healthcare services) and have been involved in the design/conduct of clinical trials	22	19%
I am a consumer representative in a clinical trials organisation	13	11%
Other†	10	9%
No category chosen	5	4%

*People could nominate more than one category

† Other perspectives: Technology provider for clinical trials; Research/trials manager (not for a clinical trials organisation); Researcher (non-trials related); provide molecular screening; systematic reviewer; ethics committee member/organisation; interested in clinical trials; other NGO; research participant (not clinical trial)

The consultation process aimed to incorporate a diverse range of insights, including:

- people from different states and territories
- clinical trialists working within small and large research networks/organisations and within established and new research networks/organisations
- diverse disease areas
- diverse community perspectives (cultural identity and background, age, geography, health literacy, gender/gender identity).

Perspectives were provided from different states and territories of Australia (Table 3.2). Organisations/affiliations listed by participants are summarised in Appendix III.

Table 3.2: Geographic location of consultation participants (n=116)

State/Territory	Number of participants	Percentage of participants
Australian Capital Territory	1	1%
New South Wales	40	34%
Northern Territory	1	1%
Queensland	9	8%
South Australia	10	9%
Tasmania	0	0%
Victoria	34	29%
Western Australia	7	6%
Not stated	14	12%

A range of health/disease areas were represented, including cancer, cardiovascular disease, child health, drug and alcohol, eye health, immune disorders, intensive care, kidney disease, mental health, orthopaedics, palliative care, population health, rare diseases, skin diseases, women's health. Other perspectives included data and data governance, human research ethics, statistics and biostatistics, and technology providers.

3.3 GAPS IN CONSULTATION INSIGHTS

The goal of gathering perspectives from different geographic locations and from a range of disease and health areas (including more common and rare disease areas) was achieved. Perspectives were provided during consultations (survey and workshops) about specific considerations regarding secondary use of data from trials involving Aboriginal and Torres Strait Islander peoples and people from culturally and linguistically diverse communities. However, the number of participants identifying within one of these population groups is unknown.

Effort was made to contact specific organisations and researchers with specific interest and expertise in research involving Aboriginal and Torres Strait Islander peoples, culturally and linguistically diverse populations and research involving people identifying as LGBTIQA+. Two follow-up discussions were held during output testing (with the Federation for Ethnic Communities' Councils of Australia and researchers from Telethon Kids who are running clinical trials involving LGBTIQA+ youth). Contacts for the newly established National First Nations Research Network have been provided to ARDC for follow-up.

While an effort was made to provide information about the consultation process in plain English, and separate sessions run for trialists and consumers; participation in the consultation process required a level of overall literacy and of health and research literacy.

Implementation consideration: further consultation

Targeted consultation and representation within design working groups of population groups for whom specific consideration will be required in relation to secondary use of data 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+.

4. STAKEHOLDER VIEWS ON INTENT OF HeSANDA

Overall, participating clinical trialists and consumers voiced strong support for the goal of facilitating secondary use of data from clinical trials for research purposes. Stakeholders emphasised the need for such secondary sharing and use of data to be facilitated in an appropriate, effective and efficient way.

Survey snapshot: Survey respondents indicated a high likelihood of agreeing to data from a clinical trial being shared through HeSANDA (average rating of 72/100 where zero indicated very unlikely and 100 very likely).

4.1 CONSUMER VIEWS ON INTENT OF HeSANDA

Participating consumers were overwhelmingly positive about the intent of HeSANDA to facilitate secondary use of data from research. Their feedback highlights the sense of altruism and beneficence that underpins the decision to participate in a clinical trial and the importance of making optimal use of data generated through research. The most common feedback and questions highlighted the importance of informed consent for sharing of data from clinical trials, concerns about potential identification of individuals through data shared, and concerns about misuse or misrepresentation of shared data.

Participating consumers indicated the need to ensure that the potential for secondary sharing of data be clearly communicated to trial participants as part of informed consent and the need to ensure protection of privacy and appropriate use of data.

4.2 RESEARCHER VIEWS ON INTENT OF HeSANDA

Participating clinical trialists supported the need for an efficient and consistent approach to secondary use of clinical trial data. They highlighted a range of issues for consideration in the design and implementation of HeSANDA. Common issues raised related to data governance, ethics, the need for simple and standardised processes and, and the need to protect commercial and academic intellectual property.

Participating researchers highlighted that while data from clinical trials can be accessed through peer-reviewed publications or direct contact with principal investigators, the process of accessing data is time-consuming and administratively burdensome. An assumption underpinning support for HeSANDA was that the process of accessing data for secondary use would be easier and quicker through this asset than it is currently.

Implementation considerations: value proposition and communication

Stakeholders voiced support for a clear value proposition for HeSANDA. The value proposition and communication about HeSANDA must use simple 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, such as the Australian and New Zealand Clinical Trials Registry (ANZCTR).

5. FEEDBACK ON GUIDING PRINCIPLES

Feedback gathered through the ACTA consultation process broadly aligns with and supports the 16 principles proposed to underpin HeSANDA (under the four themes: Purpose; Data content and quality; Data governance; Stakeholder coordination). The strongest feedback related to Data governance.

Survey snapshot

- 94% of 34 survey participants (n=32) indicated that the HeSANDA principles provide a useful foundation to underpin secondary data sharing from clinical trials.

5.1 PURPOSE OF HeSANDA

Stakeholder feedback suggested that the intention and purpose of HeSANDA were clear to the trialists and consumers who participated in the consultation. Consistent support was provided for the value of maximising the use of available data from clinical trials for the purposes of health research and reducing the risk of duplication of research activity.

During consultations, stakeholders raised a number of questions about the scope of HeSANDA. Questions were raised in relation to the types of research covered by HeSANDA and whether the asset will include data from past trials, and whether linked data would be accessible. Access questions related to whether data would only be accessible to researchers in Australia, whether users would need to pay to access HeSANDA, and whether industry/commercial access would be supported (Table 5.1). The need for clear communication of a value proposition was noted. This includes describing how HeSANDA will differ from existing data assets such as the ANZCTR.

Some standard answers were provided to participants in response to initial questions about scope and purpose raised during the webinar (see Appendix IV).

Table 5.1: Stakeholder questions about the scope and purpose of HeSANDA

Theme	Questions for consideration
Types of research	• What is the definition of 'investigator-initiated clinical trials'? What types of trials and research does this definition include and exclude? • Is the focus on experimental data only (i.e. involving an intervention), or could it include observational data? • Does the scope include treatment case studies as well as registered clinical trials?
Timeframe for included research	• Will HeSANDA only make data available from future clinical trials, or will data from historical clinical trials be made available? (*Links to consent and data governance*)
International data	• Will HeSANDA only include data about Australian trial participants? • How will data sharing be managed for the Australian arm of international clinical trials?
Differentiation from other data assets	• How does HeSANDA differ from other data assets (e.g. ANZCTR, Research Data Australia, data available through peer-reviewed publications)? • Would this asset meet the requirements of Open Source for international publications?
Data linkage	• Will ANZCTR records link to the data asset? • Will there be any interface with AIHW or jurisdictional health data custodians? • Would it be possible to link trial data with administrative datasets such as the ABS?

Theme	Questions for consideration
Role of industry	• What role should/could industry have in HeSANDA? (*While some stakeholders flagged concerns over industry having access to secondary data, others noted the potential of allowing industry access, including a business case to make the initiative self-sufficient through industry funds*).
Access	• Who will be able to gain access to secondary data through HeSANDA? • Will researchers need to pay to access HeSANDA? • Will HeSANDA be available to industry/commercial organisations? • Will HeSANDA be accessible by international researchers? • Will HeSANDA include a version for consumers/support access to trial data by consumers?
Cost of access	• Will people have to pay to access HeSANDA? • How will HeSANDA be funded? Over what time period is funding confirmed?
Ease of access	• How will the data practically be shared? Will the investigator have to approach each data custodian separately (i.e. will the asset really just highlight where to find the data)? • What administrative requirements are expected for the original research team/data custodians in relation to making data available for sharing through HeSANDA? • Will any tools or funding be made available to researchers to streamline or facilitate the process of data sharing? (e.g. inclusion of funding to support secondary use of data within research grants)
Evaluation	• How will HeSANDA be evaluated? • How will process improvement be managed over time?

Implementation considerations: Communication of scope

Stakeholder feedback highlighted the need to be specific about the intent and scope of HeSANDA when communicating about the asset and its development. This included providing a clear description of:

- the **types of data** that will be available for secondary use, including the fact that identified data for individual research participants will not be made available for sharing
- the **purposes** for which secondary data sharing would be approved (i.e. for research use)
- the **types of organisations/groups** from whom applications for secondary data use would be considered (i.e. researchers and research organisations)
- the **proposed benefits of supporting secondary data through HeSANDA** (above existing mechanisms such as through peer-reviewed publications, ANZCTR or direct contact with research teams).

Implementation considerations: ease of access

Uptake of HeSANDA will depend on ease of access and ease of use. The need to minimise the burden on researchers who are using it and researchers who are asked to share data through the asset will be critical.

Implementation considerations: funding

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

Implementation considerations: evaluation

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

5.2 DATA CONTENT AND QUALITY

Stakeholders discussed a range of considerations and questions in relation to data content and quality. Clarification was sought by stakeholders about how issues of data quality, data currency, data linkage and data interpretation will be managed within HeSANDA. Opportunities to consider standardisation of approaches to collection and reporting of data were highlighted.

Stakeholders highlighted the significant variability that exists in data definitions, data standards and quality of data generated through clinical trials and the impact of such variation on comparability and/or suitability of data for meta-analysis. Key questions raised about data content and quality are listed in Table 5.2. In addition, the opportunity to use HeSANDA as a catalyst to improve data quality and consistency was noted.

Table 5.2: Stakeholder questions about data content and quality

Theme	Questions and considerations
Data quality	• Will HeSANDA set criteria/minimum standards relating to methodological rigour for trials for which data will be made available? • Does ARDC have any influence over setting an expectation of mandatory patient co-design in clinical trials as a requirement of accessing data? • Who will be responsible for data cleaning for data made available through HeSANDA?
Data currency	• Will there be a time limit within which trial data will be made available for sharing? • How will outdated data be identified and removed from the asset? • For trials generating data in stages, when is the optimal timeframe for making data available for secondary use (noting that staged release data may change over time, influencing conclusions)?
Data comparability	• Will data standards be implemented across the HeSANDA network so that data are easily compared (e.g. CDISC)?
Data integrity	• It is important for researchers to understand the context in which clinical trial data have been generated in order to ensure appropriate interpretation. • There is a risk of affecting the integrity of ongoing trials if data from platform trials are shared for secondary use while the original trial is ongoing.
Data linkage	• How will linked data from other repositories (e.g. primary health data, newborn blood spot results) be managed through HeSANDA? • How will HeSANDA ensure that the requirements/conditions associated with approval for linkage of clinical trial data to other data sets are preserved and respected in secondary use?

Implementation considerations: standardised definitions

While issues identified in relation to data content and quality may be beyond the scope of HeSANDA itself, these issues will influence the value of sharing data through HeSANDA. The opportunity through HeSANDA to facilitate 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 the value of the data asset.

Use and promotion of data dictionaries as tools to describe the data items available for secondary use will be important.

Implementation considerations: contextual information

Stakeholder feedback also highlights the importance of providing sufficient context and information within HeSANDA to ensure that interpretation of trials data is appropriate, and that secondary use retains the integrity of the original data.

5.3 DATA GOVERNANCE

Data governance was a key area highlighted and discussed during the consultation workshops. Questions raised covered data identification, consent, data custodianship, ethics, data security, intellectual property and appropriate use of shared data.

Questions raised by stakeholders about data governance are listed in Table 5.3.

Issues around consent were a particular concern for consumers who participated in the workshops with consumers raising questions about how their individual data will be used. Stakeholders highlighted the complexity and length of current participant information sheets and consent forms and raised issues around accessibility for people with low health literacy, overall literacy and those for whom English is not a first language.

The potential for identification of personal information through HeSANDA was also a significant concern for consumers. During discussions, the fact that it is not the intent of HeSANDA to share personal/identifying information through the asset was reiterated. However, the risk of identifiable data that could affect an individual's life in the event of a security breach or if data were given to a third party with malicious intent was noted as a concern.

The issue of data sovereignty was raised in relation to Aboriginal and Torres Strait Islander data (see Section 6) and more broadly. It was noted that some legal and regulatory considerations relevant to collection and use of clinical trial data differ by jurisdiction (and internationally). Given that HeSANDA is not aiming to be a repository in its own right, a number of the issues raised around data governance are likely to remain the responsibility of the primary investigators who hold the source data. However, it was noted that data governance and custodianship is not an area that is standardised in Australia, and that HeSANDA will need to consider issues carefully in order to ensure the value and utility of the asset.

Table 5.3: Stakeholder questions about data governance

Theme	Questions and considerations

Governance (overall comments)	• Who will decide what data can be shared and with whom?
	  ○ Will HeSANDA provide guidance on what types of data should not be shared?
	• What review and assessment processes will be used to assess the suitability of secondary data requests and users?
	  ○ How will HeSANDA ensure that data are not accessed by untrustworthy or unethical users?
	  ○ How will HeSANDA ensure that data area only accessed for research purposes and not by, for example, insurance companies or the police?
	  ○ What quality assurance method will be put in place to ensure that those that are using the data are following guidelines?
	  ○ How will HeSANDA account for differences in international laws and regulations around data governance and access?
	• Who will have governance over data once it has been accessed for secondary use?
	• How will HeSANDA overcome differences in institutional requirements regarding data management and sharing?
	• Will HeSANDA provide guidance around appropriate data governance for less experienced research groups to ensure data are shared and accessed appropriately?

Identification of personal data	• What level of identifying information will be made available through HeSANDA? i.e. is there any risk an individual would be identifiable through the data shared and/or through combinations of data shared? • What risk is there if individuals are identified through the data shared (given the focus on using data for research purposes only)? • How will potential identification of individuals (e.g. for small/rare disease populations) be managed? • What communication is needed to reassure research participants about the level of data that will be made available for secondary use through HeSANDA?
Consent	• How will HeSANDA ensure that including consent for secondary use of data does not add to the complexity of the existing consent process for clinical trials? • Will people be able to give criteria for which they consent to secondary use (i.e. will consent be for unlimited sharing?) • Will there be an option for people to withdraw consent for secondary use of data and how will this be managed? • How will consent be factored into the range of clinical trial consent processes in use (paper-based, e-consent, dynamic consent, waiver of consent)? • Can data be made available for secondary use if the original trial consent process did not specify the potential for secondary use? • Could HeSANDA generate a national consent statement that includes consent for secondary use? • NHMRC patient information and consent form (PICF) templates do not address data sharing/access and need updating.
Consent for linked data	• The need to consult with human research ethics committees around consent requirements for accessing linked data collected as part of a clinical trial was noted, with particular caution around linkage to certain record types such as mental health records.
Data custodianship	• How will HeSANDA determine who ‘owns’ the data generated through clinical trials? • For the Australian arm of international clinical trials, how will HeSANDA consider international governance and regulatory frameworks that govern data custodianship and access?

Theme	Questions and considerations
	• If HeSANDA is not a data repository, who will determine who can access the data from a specific clinical trial? And how will this process be managed once principal investigators are no longer in their original roles? • Clinical trials wind up after completion. Who then becomes data custodian?

Theme	Questions and considerations
Ethics	• How will the requirement for ethics approval for secondary use of data be managed? Will each study apply independently for ethics approval? Will this be the responsibility of the principal investigators for the original trial? How will this process be managed/resourced? Would all Human Research Ethics Committees (HRECs) be familiar with the meta-repository? (Links to considerations for historical trials and trials where the PI is no longer in their role). • There will be a need to provide guidance for addressing the potential for secondary use of data in ethics applications.
Data security	• What considerations need to be in place around data security?
Intellectual property	• How will original researchers be recognised and rewarded when their data are used in secondary research? • How will the intellectual property rights (commercial or academic) for research funders and researchers be protected? • What guidance or requirements will be included about acknowledgement of the primary researchers and funders in publications?
Data interpretation	• Will controls be in place to stop groups without methodological training using data for purposes that will detract from the primary research purpose and/or create false narratives?
Respect for legacy	• How will HeSANDA ensure that respect is given to the legacy that research participants/families leave through data generated through research in which they have participated?

Implementation considerations: data governance

A robust approach to data governance is a critical consideration for HeSANDA that will influence trust and confidence in the data asset by both consumers and trialists.

A comprehensive and transparent data governance framework is needed describing how, with whom and for what purpose data from clinical trials are shared through HeSANDA.

Implementation considerations: consent

From a consumer perspective, the approach to gaining informed consent for secondary use of data is critical. Stakeholder feedback highlights the need to develop standardised wording and tools to facilitate consent for secondary sharing of data from clinical trials. 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 use of data from clinical trials for research purposes will be important to overcome consumer concerns about consent. This includes a clear description about what data may be shared, who data may be shared with, how data may be used, and any risks (actual or perceived) associated with secondary use of data for research purposes.

Implementation considerations: identification

The fact that individual, identifiable information will not be available through HeSANDA may go some way to allaying the concerns about consent. However, the need to consider and be able to answer each question in terms understandable by a lay audience will be important. Feedback highlights the need to clearly explain what may happen with data collected if permission is given for secondary use of data so that consumers feel sufficiently reassured that personal information is protected. The need for consumer confidence and trust in the integrity of the process is paramount.

Implementation considerations: protecting against misuse

Feedback highlighted the need to address concerns about the potential for misinterpretation or misuse of data, including reputational risk, in communication about HeSANDA as this may be a barrier to researchers making data available for secondary use.

5.4 STAKEHOLDER COORDINATION

Stakeholders appreciated the opportunity to contribute views to inform the design and development of HeSANDA. The need for ongoing collaboration with the sector is seen as critical.

Specific emphasis was given during consultations to the importance of co-design and involvement at all steps of design and implementation with people with lived experience, given that informed consent of research participants is critical to secondary use of data.

Questions raised in relation to stakeholder coordination are listed in Table 5.4.

Comments about stakeholder coordination also reflected the need to avoid duplication/reinventing the wheel and to learn from and build on activities already underway within Australia and internationally (see Appendix V).

While potentially outside scope for HeSANDA itself, the need to improve the process for providing feedback to trial participants about research outcomes was noted.

Table 5.4: Stakeholder questions about stakeholder coordination

Theme	Questions and considerations
Co-design and consumer involvement	• Will HeSANDA have a consumer advisory panel throughout the development and into the future?
Feedback to trial participants	• Can consumers see (for example through My Health Record) where their data are being used and what are the results of those research trials?

Implementation considerations: co-design

Co-design of HeSANDA with the sector is seen to be critical. In particular the need for full engagement of consumers in the design and development of HeSANDA.

Implementation considerations: information

Provision of simple documentation in plain English, not only once HeSANDA has been designed, but during the planning and design phases is important to ensure that consumers can understand intent and contribute in an informed and meaningful way.

Implementation considerations: feedback

The need to strengthen feedback to trial participants about the outcome of trials in which they participate was highlighted as an overall issue for the health research sector to continue. Recognition by HeSANDA of this need and how to manage feedback in relation to secondary data use was noted.

Implementation considerations: reporting

Public reporting of research successes catalysed through HeSANDA would provide research participants and the broader community with information reinforcing the value of secondary use of data.

5.5 ADDITIONAL PRINCIPLES

A comparison of the feedback provided by stakeholders against the list of 16 principles highlights three additional principles that could be included:

- a principle regarding the importance of evaluation to understand whether HeSANDA is meeting its goals and to make refinements as required ('Purpose' principle)
- a principle about the importance of ensuring appropriate use and interpretation of data in a way that protects academic and commercial intellectual property and guards against misuse or misrepresentation of data ('Data governance' principle)
- a principle reinforcing commitment to including consumers/people with lived experience within all aspects of planning, design and implementation ('Stakeholder coordination' principle).

6. SPECIAL CONSIDERATIONS

Stakeholders highlighted a number of trial populations and data types for which HeSANDA may need to give special consideration.

Table 6.1 lists issues for consideration in relation to different population groups and trial/study designs. This table includes feedback from email and telephone consultation undertaken with relevant organisations outside the workshops and survey.

Table 6.1: Populations and data types requiring special consideration as HeSANDA is designed

Population/data types	Issues for consideration
Population groups	
Aboriginal and Torres Strait Islander populations	• Consider Indigenous data sovereignty and cultural sensitivities for First Nations people. • Aboriginal and Torres Strait Islander peoples will want to see tangible benefits from sharing their data. • The AIATSIS Code of Ethics specifically addresses secondary use of data. • The AIATSIS CARE principles highlighted in the AIATSIS Code of Ethics provide guidance for implementing principles of Indigenous data sovereignty.
People from culturally and linguistically diverse communities	• Consider understanding of consent processes, including translations of consent information and forms. • Ensure translations avoid misinterpretation or ambiguity. • Consider cultural considerations related to consent processes.
People who cannot read or write	• Given the integral importance of informed consent, the need to consider how consent processes are managed for people who cannot read and write and/or have low levels of digital literacy (for e-consent) will be important.
People where identification is likely to be possible	• Reporting of data from trials involving people with rare diseases or health conditions increases the risk of individuals being identifiable. • Data linked to identified data sets (e.g. organ donor health registries) will also need consideration.
Paediatric populations	• Consider how consent will be managed for secondary use of data from trials involving children. • This includes implications for consent to use data when the person transitions into adulthood.
Trans, gender diverse and intersex people	• People with intersex variations are frequently misrepresented in clinical and other health research. • It will be important for HeSANDA to establish, reflect and promote consistent approaches to terminology. • Concerns about consent, who can access data and how data will be used may influence willingness to consent to secondary use of data. • Consent for adolescents may be challenging if they do not feel safe discussing their sexuality or gender identity with their parents.
People who are unable to consent	• A range of population groups were identified for whom gaining consent for trial participation is already challenging, and for whom consent for secondary use of data will raise additional challenges. • These include people with dementia or other conditions causing cognitive decline, and people who are in emergency or intensive care settings where waiver of consent applies.

Population/data types	Issues for consideration
People who have died	• Gaining consent/re-consent from families of people who have passed away may need consideration.
Data about health conditions that carry high levels of stigma or sensitivity	• The need for sensitivity when describing and sharing certain types of health data was noted. • Examples identified by stakeholders included data related to mental health issues, data about alcohol or drug issues, data about health conditions that carry high levels of stigma such as HIV/AIDS and data about certain population groups, such as prisoners.
Genetic/genomic data	• Genetic data has implications for whole families as opposed to individual research participants. • Technology to analyse genomic data is rapidly evolving, meaning that a person's data could be analysed in a way that was not possible when they first consented to participate in the original trial.
Research/data types	
First in man studies	• Early phase research where products are being developed for commercial (as well as medical) gain.
Platform trials	• There is a risk of affecting the integrity of ongoing trials if data from platform trials are shared for secondary use while the original trial is ongoing.
Community-based research	• Clinical trials that are conducted in community settings (schools, workplaces, online) rather than in hospitals or health services may need special consideration around consent processes, comparability and the types of data collected.
Translational research	• The return of research findings/raw data from biospecimen analyses undertaken through translational research (as a sub-study within a clinical trial) will be valuable for building a knowledge base, but how this is best done in a quality assured way would need consideration.

Feedback about population groups for whom special consideration is needed emphasises the importance of informed consent.

A key point made in relation to clinical trials data from trials involving certain population groups is that, while data sharing is a laudable goal, for some population groups, there are likely to be limited data available for sharing. This may be because:

- clinical trials exclude certain population groups (based on age, ability to speak English, ethnicity)
- cultural considerations or geographic location may influence a person's access to or decision to take part in a trial
- data about individual characteristics including ethnicity, country of birth, language, culture, gender diversity are not captured routinely or consistently in trial or administrative data sets
- people do not feel safe reporting aspects of ethnicity, culture, sexuality or gender identity.

These issues were flagged in particular for people from culturally and linguistically diverse backgrounds and people with intersex variations but are likely to be relevant for other population groups, including Aboriginal and Torres Strait Islander peoples.

While these issues are outside the scope of HeSANDA, it was noted that HeSANDA could help drive awareness of these issues. From a culturally and linguistically diverse perspective, this may involve including key data fields for country of birth, ethnicity, culture, language spoken at home in agreed

minimum data fields. The need for multiple fields reflects the fact that limiting data fields to country of birth or language spoken at home does not provide the depth of information needed to be able to interpret and use the data (e.g. ethnicity has an impact on biology, which influences susceptibility to diseases and response to certain drugs; culture and beliefs do not necessarily align with the country of birth).

Implementation considerations: standardisation of terminology (part of the Data content and quality principle)

There is an opportunity through HeSANDA to promote the need for meaningful and usable data fields relating to individual trial participant characteristics that are not currently captured in a meaningful or consistent way. While this is a broader issue for trials data overall, consistent capture of meaningful data fields will support greater comparability across data sets when shared for secondary use.

Implementation considerations: consent (part of the Data governance principle)

Each of the population groups and data types identified by stakeholders will require specific consideration when designing approaches to consent for secondary use of data, data fields and reporting of data from secondary research studies. This may include the need for translations and/or access to interpreters.

The data governance framework for HeSANDA must support clear, simple and unambiguous informed consent processes.

Implementation considerations: avoiding stigma (part of the Stakeholder coordination principle)

Feedback also highlights the importance of taking proactive steps to avoid reinforcing stigma or making assumptions about capacity for decision making through HeSANDA communications and data governance processes.

Implementation considerations: engagement (part of the Stakeholder coordination principle)

Ongoing engagement with groups with specific expertise and insights related to different population groups will be 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.

7. FEEDBACK ON BARRIERS AND ENABLERS

In addition to feedback on Principles, stakeholders highlighted a number of barriers and enablers that will influence the success of HeSANDA (Table 7.1).

Some of the barriers and enablers highlighted may be beyond the scope of HeSANDA itself. However, HeSANDA may be able to act as a catalyst for sector-wide action to address these issues.

Table 7.1: Barriers and enablers influencing the success of HeSANDA

Theme	Issues for consideration
Resourcing	• The administrative burden on managing and assessing requests, as well as the need to clean data prior to sharing, may pose a barrier to this initiative from the perspective of clinical trials organisations. • The ability of research teams to share research health data may depend on the resources of the institute or research team. • Supporting resourcing for secondary data sharing may be an area that funding bodies need to consider and could form part of grant funding.
Currency/flexibility	• HeSANDA will need to be flexible to enable it to remain up-to-date and relevant given rapid changes in IT, data analyses, ethics and ethics interpretations, legal interpretations, societal expectations and laws around intellectual property. • It will be important to consider how ethics committees and legal advisors can best liaise with HeSANDA and share knowledge (theoretical and practical). • As secondary use of data becomes 'business as usual', expectations and requirements are likely to change.
Standardisation and alignment	• Data standardisation and standardised definitions will be helpful. • Providing clear guidance through HESANDA is an opportunity to align practice for the research sector and HREC decision-making across institutions. • A broader end goal of a national standard for all data and uniform database structuring would be valued by the sector.
Commercial and IP sensitivities	• Issues of commercial sensitivity, academic confidentiality and the competition for grants and publications may all be barriers to the sharing of data for secondary use.
Sustainability	• The need to consider how the asset will be funded and maintained beyond 2023 is important.

Implementation considerations: understanding context (part of the Stakeholder coordination principle)

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 Advisory Committee members to understand potential system-level barriers and enablers will be important. The potential to work with partners and HeSANDA node organisations to address critical barriers that will influence the use and usefulness of the data asset could be considered.

APPENDIX I: WORKING GROUP AND PROJECT TEAM

Working Group members

Name	Organisation
Heath Badger	Chief Operating Officer, Breast Cancer Trials
Merryn Carter	Consumer Advisory Panel member, Breast Cancer Trials
Ian Davis	Professor of Medicine and Head of the Eastern Health Clinical School, Monash University and Eastern Health, Chair Australia New Zealand Urogenital and Prostate Cancer Trials Group
Liz Hutchings	PhD student, University of Sydney
Kristan Kang	HeSANDA Program Manager, ARDC
Donna Long	Regional Trial Network Program Manager, Border Medical Oncology
Mitch Messer	Consumer Advocate, Telethon Kids
Jonathon Morris	Professor of Obstetrics and Gynaecology, University of Sydney and Head of Women's and Babies Research the Kolling Institute for Medical Research
Christopher Reid	Cardiovascular epidemiologist, Curtin University, Chair, Australian and New Zealand Alliance for Cardiovascular Trials
Nicole Scholes-Robertson	Consumer, University of Sydney
Simone Yendle	Chief Executive Officer, Australian Clinical Trials Alliance

Project team

Name	Organisation
Fiona Nemeh	Project Officer, Australian Clinical Trials Alliance
Sharon Lloyd	Program and Operations Manager, Australian Clinical Trials Alliance
Kristan Kang	HeSANDA Program Manager, ARDC
Alison Evans	Principal Consultant, Alison Evans Consulting and Sensus Health Group
Jen Henwood	Health Communications Consultant, Sensus Health Group

APPENDIX II: SURVEY QUESTIONS

1. Have you read the HeSANDA initiative background paper?
2. Is the intent of the HeSANDA initiative clear to you?
    - If no, what questions do you have about the initiative?
3. Do the proposed principles described in the background paper provide a useful foundation to underpin secondary data sharing from clinical trials?
    - If no, what could be improved?
4. Please list any groups of patients or types of trial data that may need special consideration in the data asset.
5. How likely would you (or members of your organisation) be to agree to data from a clinical trial you are running or participating in being shared for use by other researchers through HeSANDA?
6. What would make you (or members of your organisation) more confident about data from a clinical trial you are running or taking part in being shared for use by other researchers?
7. If you have any other questions or comments about the HeSANDA initiative please share them below.
8. Which of the following categories best describes you? Please check all that apply.
    - I am a researcher involved in the design/conduct of clinical trials
    - I work for an organisation that runs clinical trials
    - I am a consumer representative in a clinical trials organisation
    - I am a consumer (patient, carer or person who uses healthcare services) and have been involved in the design/conduct of clinical trials
    - I am currently a participant in a clinical trial
    - I have previously been a participant in a clinical trial
    - I am considering participating in a clinical trial
    - Other (please specify)
9. If you are a researcher or a member of a consumer or other health organisation, please provide details below.
10. Which state/territory do you live/work in?
11. Please provide your name and contact details if you would like to be updated about consultation workshop dates and outcomes or if you have a question and would like the project team to contact you with a response.
12. Has your organisation applied to be one of the HeSANDA nodes?

APPENDIX III: ORGANISATIONS REPRESENTED IN THE CONSULTATION

The table below summarises the organisations listed by workshop and survey participants. Participants took part in the consultation as individuals, not necessarily as representatives for their organisation(s). Organisations are listed to provide an indication of the breadth of perspectives provided. In addition to the people working for organisations listed, participants included individual consumers who were not part of a network or research group and individuals who did not list any affiliation.

Organisations listed by participants		
Alfred Health	Griffith University	Regional Trials Network - Victoria
ANZUP Cancer Trials	Health CAN SA	Royal Darwin Hospital / ANZICS CTG
Australian Genomic Cancer Medicine Centre	Hume Regional Integrated Cancer Service	SA Health
Australia New Zealand Gynaecological Oncology Group	Hunter Medical Research Institute	Sanfilippo Children's Foundation
Australasian Gastrointestinal Trials Group	Intersex Human Rights Australia	Skin Health Institute
Australasian Kidney Trials Network	IQVIA	South Australian Health and Medical Research Institute
Ballina Shire Dementia Friendly Community Alliance	Jean Hailes for Women's Health	Swinburne University of Technology
Bellberry Limited	Macquarie University	Sydney Local Health District
Black Dog Institute	Melanoma Patients Australia / Melanoma Research Victoria	Sydney Health Partners
Breast Cancer Trials	Melbourne Academic Centre for Health	Telethon Kids Institute
Carli Sheers Consultancy	Mental Health Australia	The Australian National University
Central Adelaide LHN	Menzies School of Health Research	The George Institute
Centre for Eye Research Australia	Monash University	The University of Newcastle
Chrysalis Clinical	MS Research Australia	TROG Cancer Research
Cochrane Breast Cancer Group	Murdoch Children's Research Institute	University of Melbourne
Cooperative Trials Group for Neuro-Oncology (COGNO)	NeuRA	University of New South Wales
Consumer Health Forum	Northern Sydney Local Health District Drug and Alcohol Services	University of Newcastle
Curtin University	NSW Drug and Alcohol Clinical Research and Improvement Network	University of Queensland
Deakin University	Peter MacCallum Cancer Centre	University of Sydney
Duchenne Australia	Oracle	University of Technology Sydney
Epworth Hospital	Orygen	University of Western Australia
Federation of Ethnic Communities' Councils of Australia	Queensland Centre for Mental Health Research	University of Wollongong
Flinders University	Queensland Children's Hospital	West Australian Health Translation Network
Genetic Alliance	Queensland University of Technology	WriteSource Medical Pty Ltd
Genomics Queensland	Rare Voices Australia	

APPENDIX IV: ANSWERS TO STAKEHOLDER QUESTIONS ABOUT SCOPE

Stakeholder questions raised during the webinar that preceded the consultation, during the consultation workshops and through survey feedback reflect the importance of clear information about the scope of HeSANDA. Key points of clarification given in response to initial questions raised about HeSANDA by participants are summarised below.

1. Is HeSANDA a new data repository?

HeSANDA is not a new data repository and participant data ('IPD') will not be handed over to a third party to manage. HeSANDA is a 'data asset'. This is a broad term which in this context refers to a catalogue of information about clinical trials and the data collected through these trials (effectively a clinical trial 'metadata' asset). The documents and data collected in clinical trials will stay with the researchers who conduct the trial. These researchers will provide the descriptions of those documents and data into the 'metadata' asset.

2. Is HeSANDA an open data asset?

HeSANDA will focus on supporting secondary use of data where consent has been given by trial participants and by the original investigators. It is not intended to be an open data asset. A researcher may browse through this catalogue and may see a trial that has collected data that will be valuable for their new research project (e.g. writing a clinical practice guideline or systematic review). However, they will not be able to access the data without first getting permission from the original researcher who conducted the trial. Permission may be needed from an institution and/or university and/or health service rather than an approval sought from the relevant human research ethics committee(s).

3. Will HeSANDA support sharing of data from research other than clinical trials?

ARDC recognises the value of sharing all kinds of health data for research. HeSANDA is starting with a focus on supporting secondary use of data collected as part of investigator-initiated clinical trials. Clinical and health service records are also important for research, as are cohort studies, clinical quality registries etc, and in the future, HeSANDA will consider how to incorporate these and how the standards designed for sharing clinical trials data might be extended to these other data types and research areas.

Some information used in clinical trials may come from clinical or health service settings. HeSANDA will consider the appropriate consent needed to allow secondary research to make use of the range of data used in the original trial.

APPENDIX V: RELEVANT INFORMATION / RESOURCES REFERENCED BY STAKEHOLDERS

- AIATSIS Code of Ethics specifically addresses secondary use of data
- CARE principles for Indigenous data governance
- CDISC standardised fields for data linkage
- European Commission survey on data use (currently open)
- FAIR principles for data management and stewardship
- Federation of Ethnic Communities' Councils of Australia report If We Don't Count It Doesn't Count: Towards Consistent National Data Collection and Reporting on Cultural, Ethnic and Linguistic Diversity
- Health Expectations article on citizens juries run in 2020 with community members about conditions under which they would support data sharing
- Infectious Diseases Data Observatory
- WAHTN Survey of Consumer and Community Involvement Program Community Members' Attitudes to COVID-19 Research and Consent

APPENDIX VI: ABBREVIATIONS

Abbreviation	
ACTA	Australian Clinical Trials Alliance
AIATSIS	Australian Institute of Aboriginal and Torres Strait Islander Studies
AIATSIS CARE	AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research
ANZCTR	Australian New Zealand Clinical Trials Registry
ARDC	Australian Research Data Commons
CDISC	Clinical Data Interchange Standards Consortium
CTN	Clinical Trials Network
HeSANDA	Health Studies Australian National Data Asset
HREC	Human Research Ethics Committee
IT	Information technology
LGBTIQA+	Lesbian, Gay, Bisexual, Transgender/gender diverse, Intersex, Queer and Asexual
NHMRC	National Health and Medical Research Council
PICF	Patient Information and Consent Form
SIGNET	ACTA's Special Interest Group for Network Managers
STING	ACTA's Special Interest Group for Statisticians