SUBMISSION

aamri
Association of Australian Medical Research Institutes

STATUTORY REVIEW OF THE DATA AVAILABILITY AND TRANSPARENCY ACT 2022

30 May 2025

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Overview

The Association of Australian Medical Research Institutes (AAMRI) and its members welcomes the opportunity to provide input into the statutory review of the *Data Availability and Transparency Act 2022* (DAT Act).

AAMRI's members are not currently eligible to participate in the DATA Scheme (the scheme implemented under the Act) so our response:

- seeks the extension of the DAT Act to include research organisations, including medical research institutes
- highlights the benefits of including medical research institutes
- notes some of the challenges that medical research institutes currently face in accessing Commonwealth datasets that could be mitigated by the expansion of the DAT Act
- covers some observations on the current operation of the DAT Act.

1. Has the operation of the DAT Act advanced its objectives?

The purpose of the legislation includes the safer, better and faster access to Commonwealth Data to encourage research and development.

The DAT Act does not currently meet this objective – research organisations such as medical research institutes are not included in the definition of Australian entities that are eligible to participate.

AAMRI seeks the expansion of the types of entities eligible to participate in the DATA Scheme under the DAT Act to include all Australian research organisations, including medical research institutes.

Stated purpose of the legislation

Under the data sharing scheme, Commonwealth bodies are authorised to share their public sector data with accredited users, and accredited users are authorised to collect and use the data, in a controlled way. Data may be shared with an accredited user directly, or through an intermediary accredited for the purpose (accredited data service provider (ADSP)). The data sharing scheme is based on the Five Safes framework to ensure safe access and use of Commonwealth Data.

The stated purpose of the legislation is to increase the use of Commonwealth data in a safe way to encourage its use for the delivery of government services, informing government policies and programs, and research and development (the 3 data sharing purposes – see clause 15(1) of the DAT Act).

Current limitations of the legislation

The key provisions setting up access to data are as follows:

> *13A Authorisation for accredited user to collect and use data*
>
> *An entity (the user) is authorised to collect data shared with the user under, or purportedly under, section 13 as part of a project, or to use output of the project, if all of the following apply:*
>
> *(a) the project is covered by a registered data sharing agreement that is in effect and that meets the requirements of this Act;*
>
> *(b) the collection or use is in accordance with the data sharing agreement;*
>
> *(c) the user is satisfied that the project is consistent with the data sharing principles;*
>
> *(d) **the user is an accredited user** and its accreditation is not suspended;*
>
> *(e) if the data shared with the user includes personal information—the privacy coverage condition in section 16E is met in relation to the user;*
>
> *(f) if the sharing by the sharer is not authorised by section 13—the user does not know and could not reasonably be expected to know that.*
>
> *74 Accreditation*
>
> *(1) If an entity applies for accreditation as an ADSP or an accredited user under section 76, the accreditation authority for the entity may grant the entity the accreditation applied for if:*
>
> *(a) **the entity is an Australian entity** and not an excluded entity; and*
>
> *(b) the authority is satisfied that the entity meets the criteria for accreditation under section 77, to a standard appropriate for the accreditation; and*
>
> *(c) the authority considers it appropriate, in all the circumstances, to grant the accreditation.*
>
> ***Australian entity** means an entity that is any of the following:*
>
> *(a) a Commonwealth body, a State body or a Territory body;*
>
> *(b) the Commonwealth, a State or a Territory;*
>
> *(c) an Australian university.*

Access to data utilising the benefits of the DAT Act is limited to accredited users and an accredited user must be an Australian entity. While Research Organisations and medical research institutes were consulted extensively in the development of the DAT Act and the DATA Scheme, **only Australian Universities and government research organisations were included**. This leaves a significant section of the research providers in Australia unable to be an Accredited User or Accredited Data Service Provider.

How could a research organisation be defined?

In Australia, a research organisation is typically defined as an entity, often a university, medical research institute, or government agency, that undertakes scientific research. Scientific research means any activity in the fields of natural or applied science for the extension of knowledge. **A medical research institute is an independent legal entity that primarily conducts health and medical research.**

How would the addition of Research Organisations change how medical research institutes access Commonwealth data?

It would allow medical research institutes to become an Accredited Data User or an Accredited Data Service Provider.

- If you have been Accredited as a Data User, assessment then isn't required each time you make a data access request to the Commonwealth.
- An Accredited Data Service Provider can receive data from the Commonwealth. The Commonwealth will only release data to an Accredited Service Provider, so medical research institutes need to partner with these to use the data in their research.
- If you consider the Five Safes Framework:
    - An Accredited Data User has been assessed as Safe People
    - An Accredited Data Service Provider has been assessed as a Safe Settings and Safe Data. That is a secure environment to house Commonwealth Data with appropriate controls and access in place.
- The DATA scheme provides a portal for requests and a consistent data sharing framework. There is also a level of transparency and accountability in how Commonwealth Data is shared. Costs are reduced and more consistent and the process is streamlined.

Research undertaken by medical research institutes helps to inform government policies and programs.

Medical research institutes support the development of government policies and programs through more effective and efficient treatments, economic growth and quality of life. Examples include:

- **More effective and efficient treatment**: Due to both the Gardasil vaccine and improved testing methods, Australia is the first county in the world to be on track to eliminating cervical cancer – currently forecasted for 2035. This is an incredible win for patients and Australia's healthcare system.
- **Economic growth**: AAMRI conducted a study in 2018 that showed that for every dollar invested into medical research, $3.90 is returned to the population. Medical research creates jobs and a larger, more productive workforce by improving the health and well-being of the population.
- **Quality of life**: Newborn hearing screening can diagnose deafness at birth allowing for early intervention and better learning pathways. Whereas previously deafness or hearing problems often weren't detected until speech was significantly delayed and the family had faced many struggles not understanding what the child was experiencing. A simple diagnostic tool greatly changing a life path.

AAMRI members effect change through their research and related activities.

Medical research institutes effect changes through:

- Creating guidelines on best practice through research
- Discovery of new treatment pathways, tested in clinical trials and taken to market
- Outreach programs in remote and vulnerable communities
- Mental health programs
- School programs educating families and children about health and science
- Capacity building in remote communities through health care training
- Student training
- Virus and contagious disease monitoring and control advice
- Genetic testing
- World health impact by advancing treatment of underserved populations.

Are medical research institutes appropriately experienced data users to be included as Accredited Data Users or an Accredited Data Service Providers?

Applying the Five Safes framework

The "Five Safes" framework is *an internationally recognised risk management model* developed by the Office for National Statistics (UK).[1] It is used by Australian state and federal agencies to assess risks related to data management, including data access and release.[2] Research staff employed by Medical research institutes already operate within the Five Safes framework, and for this reason, should be accorded the definition of "accredited entity"[3] and trusted data users in the same way that Australian universities are.

Specifically, Australian medical research institutes operate as follows within the Five Safes Framework[4]:

1. **Safe People** (can the users be trusted to use it in an appropriate manner?)

   Medical research institute staff routinely deal with sensitive information of both adults and children. As such, research staff have "*the knowledge, skills and incentives to act in accordance with required standards of behaviour*". Research staff undergo regular training, are knowledgeable in the use of a variety of relevant data storage options and are required to submit their proposed research for review (where necessary). This minimises risks potentially associated with human interest or error (e.g. creating the conditions in which a data breach might occur).

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[1] https://blog.ons.gov.uk/2017/01/27/the-five-safes-data-privacy-at-ons/.

[2] https://alswh.org.au/for-data-users/applying-for-data/the-five-safes-framework/?__cf_chl_tk=mu0o068aLZFgLYODxt9L2O.nP1m1LRTQBZKOTHuBlhw-1748228475-1.0.1.1-YWctYdrahrbzl4i_huFO1wTZEPHfMMI9p788tVRL1KU#:~:text=The%20Five%20Safes%20framework%20is%20used%20by%20Australian%20state%20and,data%2C%20settings%2C%20and%20output.

[3] *Data Availability and Transparency Act 2002* (Cth), s 11(4).

[4] https://www.aihw.gov.au/about-our-data/data-governance/the-five-safes-framework

2. **Safe Projects** (is the use of the data appropriate?)

   The projects undertaken within medical research institutes, where they deal with relevant types of human data, are subject to Human Research Ethics Committee (HREC) review and approval and are bound by the resulting approved protocol and any internal legal and compliance requirements. As such, use of human data is legal and ethical, and the research projects are expected to deliver public benefit. Requiring review of research that proposes to utilise human data ensures that there is a record of requirements attached to said research. Institutional oversight in this respect supports researchers to maintain compliance with HREC expectations and privacy frameworks. As such, risks associated with the research (e.g. breach of HREC approval conditions) are minimised.

3. **Safe Data** (is there a disclosure risk in the data itself?)

   Staff employed by medical research institutes are bound, where relevant, by the *Privacy Act 1988* (Cth),[5] the *National Statement on Ethical Conduct in Human Research* (the National Statement),[6] and/or state health records/privacy legislation. Furthermore, where possible, data is "treated appropriately to minimise the potential for identification of individuals".[7] Medical research institute staff are routinely required to undertake education and training exercises with respect to privacy and the management of data to ensure they remain cognisant of their obligations.

   Medical research institutes often collaborate with overseas entities, including the European Union (EU) and the United States (USA). The EU operates according to particularly stringent privacy requirements as outlined in the General Data Protection Regulation (GDPR).[8] Medical research institutes who collaborate with EU entities must therefore also operate within the GDPR framework, as well as the Australian privacy and ethics framework. Working with the data of collaborating entities has ensured that the staff of medical research institutes have developed a strong understanding of the need to adequately protect the sensitive data that is made available for research purposes.

   Continuous improvement efforts are a core aspect of the functioning of medical research institutes in this regard. Regular handling of data within relevant privacy frameworks, along with professional services support for researchers, ensures researchers can recognise the potential risks associated with data management (e.g. data linkage, insufficient deidentification etc.) and provide rectification if required.

4. **Safe Settings** (does the access facility prevent unauthorised use?)

   All medical research institutes operate in an environment in which "*There are practical controls on the way the data is accessed – both from a technology perspective and considering the physical environment*". For example, at the Walter and Eliza Hall Institute (WEHI), there is a dedicated team responsible for providing bespoke storage solution for laboratories depending on the requirements attached to their datasets. These solutions include software options such as Sharepoint (a Microsoft product), VAST, RedCAP, StorNext, Electronic Lab Notebooks (ELNs) (LabArchives), Dotmatics (LabArchives), password-protected and two-factor log-in requirements, and locked physical storage.

[5] https://www.legislation.gov.au/C2004A03712/latest/text.

[6] https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023.

[7] https://www.aihw.gov.au/about-our-data/data-governance/the-five-safes-framework.

[8] https://gdpr-info.eu/.

The Murdoch Children's Research Institute (MCRI) has a review committee comprised of representatives from Cybersecurity, Technology, Data, Legal and Privacy teams to oversee all data transfers (in and out of MCRI) and new uses of software and technology. The use of software with security protections commensurate to the safety measures required for the data in question, as well as physical protection mechanisms, reduces risks associated with data management (e.g. unauthorised data access).

As part of the scheme outlined in the DAT Act, much of the information accessed by medical research institutes would not leave the control of the Accredited Data Service Provider. As such, it would remain in an approved secure environment with appropriate protection settings utilised.

5. **Safe Outputs** (are the statistical results non-disclosive?)

   Medical research institute staff also understand the importance of ensuring that research outputs protect the sensitive and health information of individuals. Where researchers are not already working with deidentified datasets, it is routine practice to review pre-published outputs to ensure there is no identifying information contained within. This reduces risks associated with research outputs failing to meet privacy requirements.

The level of adherence by medical research institutes to the Five Safes Framework is already at a very high level and will likely only increase if they are included in the scheme. The DAT Scheme itself also introduces many improvements in this area, which, if medical research institutes were included in the scheme, would require their compliance.

The expansion of the DAT Act and DATA Scheme to include Research Organisations and Medical Research Institutes will assist the DAT Act to meet its purpose of increasing the use of Commonwealth data in a safe way for the delivery of government services, informing government policies and programs, research and development.

2. Does the DAT Act improve information flow between public sector bodies and accredited entities?

While medical research institutes are not currently accredited entities, they have made the following observations in interactions with Commonwealth and State entities and their data sharing under the DAT Act:

- The willingness to share data in a safe way has increased
- More uniform processes and data sharing agreements are being used
- While there are still delays in the sharing of information between key data custodians in the Commonwealth and between the Commonwealth and the States, this could be supported and encouraged by a national data sharing system with parallel legislation enacted in each state and territory.
    - In terms of medical research, Australia is a relatively small country and if researchers are working with rare conditions or require a cohort that represents the diversity of our population – scale is required to see patterns. It is often necessary to bring together information from across the country to see that scale.

- There is still a reluctance to share data outside of the relevant government departments secure environment (or usual accredited data service provider). This presents a challenge when trying to bring together data from multiple Commonwealth and State datasets and other data sources.
- The data sharing processes fail to consider consent for research. Often applications for access to data with the consent of the relevant individuals are not treated differently to other applications for data access. If a party has explicitly given consent in writing for a research organisation to access their data (including data with identifiers to enable linkage and data matching) this should be considered. There should be a streamlined process to deal with consented research and the wishes of the individual to share their data for a particular purpose should be recognised.
- Further work on common data formats and data handling for certain fields of data will reduce data cleansing and increase the interoperability of systems over time.
- Australia needs to remain competitive in research and its ability to source overseas funding and research partners. In the EU the exchange of information is facilitated by the GDPR legislation. In many countries, such as Norway, there is a single government authority who can grant access to all of its health data.

3. How does the DAT Act add value in the wider data sharing context?

For medical research in Australia, the DAT Act offers a better path to access to the significant amount of data already collected by the Commonwealth and the States.

Linking to data that is already collected for research enables:

- follow up of many research participants in a cost-effective way
- the ability to get access to data at scale and with diversity and equity
- reduced costs of research – utilising data already collected elsewhere by other organisations
- low burden for research participants – no need to contact participants to collect additional data or to collect data that they have already provided to another organisation
- reduced reliance on response rates for data collection e.g. surveys of research participants
    - currently response rates can be as low as 30-40% for large longitudinal cohort studies
    - this is because response rates drop over time
    - compare this to accessing data that is already collected by government and you will have an almost complete set of data on an ongoing basis for those fields of data
- access to systematically collected data for health outcomes
- minimised reporting and recall bias
- access to data historically before recruitment.

To effectively and efficiently conduct medical research, researchers need access to existing patient data relevant to their studies. Without access, if research programs had to ask for information from each research participant it would:

- increase the budget (and grant funds needed) to establish a study

- limit the effectiveness of the study as obtaining large numbers of participants would have many barriers
- create negative relationships with participants who would be constantly contacted by each research program looking at the data
- defer large population studies which allow for greater understanding and insight due to the mass amount of data already collected.

Medical researchers need to be eligible data users to effectively and efficiently do their work, which benefits the healthcare system and the Australian economy.

Included below is a Case Study that outlines some of the challenges medical research institutes face and how the DAT Act (with some improvements) could facilitate and improve research in Australia.

4. Should the DAT Act be allowed to sunset?

The DAT Act should not be allowed to sunset.

It should be expanded to allow medical research institutes to participate and to continue to remove barriers to bringing together Commonwealth and State data for the benefit of the community. The improvements put in place needs to be expanded and refined.

The DAT Act has increased the level of accessibility to Commonwealth datasets in a safe and secure way. Under the DAT Act, the Commonwealth Data Custodians and Accredited Data Service Providers working with the Office of the National Data Commissioner are working toward a more uniform and simplified processes to apply for Commonwealth data, data linkage, and use of the data for research.

The DAT Act encourages data sharing with users to be done in accordance with the data sharing principles (developed by the ONDC – based on the Five Safes Framework) under data sharing agreements (based on templates prepared by the ONDC and registered with the ONDC). Further development of data sharing on this basis should be developed further. A standard process and clearer costings will allow researchers to appropriately plan the costs of their research when applying for funding. In the past, costs associated with data linkage and access to secure environments have varied significantly.

While medical research institutes cannot currently access the benefits of the DATA Scheme, AAMRI members are seeing some benefits of the scheme when accessing Commonwealth Data by alternate pathways.

5. Conclusion

Enabling medical research institutes to participate in the DATA Scheme will have many benefits for the community. It will reduce costs of research if we can:

- streamline access to both Commonwealth and State/Territory data
- some AAMRI members are accredited to hold data – so they no longer must pay for access to an Accredited Data Authority's secure environment
- institutes can access Commonwealth, State/Territory and other collected data in one secure environment for research.

Case Study – GenV project, Murdoch Children's Research Institute

GENV Let's make this our healthiest generation ever

Medical research institutes use data linkage in many of our research projects – particularly in studies that track children, families and adults over part of their Lifecourse journey. Our largest Lifecourse study is the **GenV project led by the Murdoch Children's Research Institute (MCRI).**

GenV provides a useful example of barriers to linkage that at times feel insurmountable - despite the explicit consent of its 123,000 participants to access their administrative and services data to benefit current and future generations.

Including medical research institutes as eligible users under the DAT Act, in addition to universities, would enable Australia to experience the needed benefits of the substantial investment in GenV. This is consistent with the stated purpose of the DAT Act - to safely increase the use of Commonwealth data to deliver government services, inform policies and programs, and drive research and development.

About Generation Victoria (GenV)

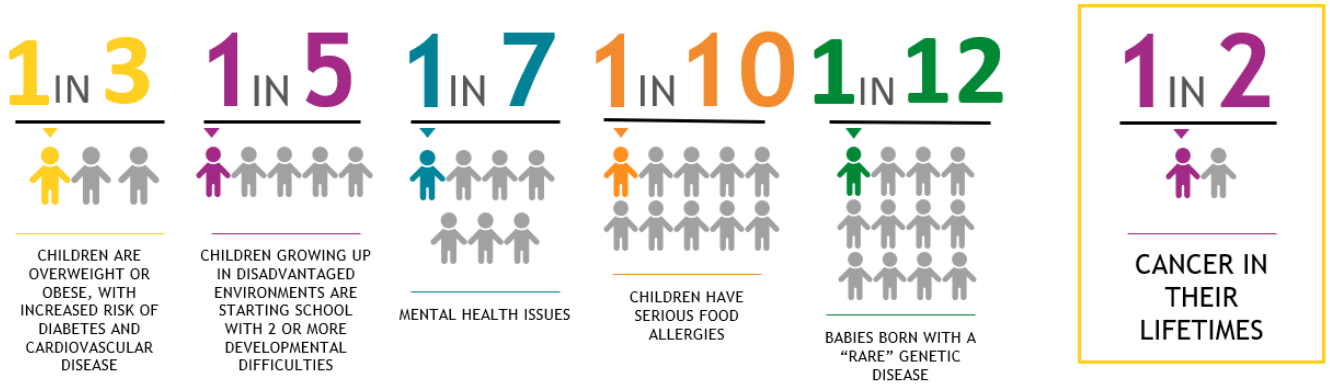
Over a two-year period, GenV asked the parents of newborns across Victoria to be a part of GenV by safely and securely sharing information with us about their own and their child's health, well-being and development of their newborn. This will create an ongoing data resource that brings together GenV collected data, Commonwealth State and hospitals data, and data from its collaborators and users.

GenV includes over 123,000 consented participants from across Victoria, including many under-represented groups. With its 'cell-to-society' approach, it also hosts Australia's largest child and adult biobank and rich geospatial and policy data. This enables actionable insights (such as how heat exposures affect mental and physical health, physiology, functioning and service needs) at whole-of-state scale, covering 25% of the Australian population. A key strength of GenV is that it minimises burden on families by leveraging existing data.

To government-collected data on service usage, GenV adds vital missing pieces, capturing everyday life, health and wellbeing across entire communities, including for people who don't need or can't access services. Through discovery research and embedded trials, GenV will enable a richer, more complete understanding of population health and how we can predict, prevent and treat health and wellbeing problems better than we can today.

For the first time ever, this will give us a complete picture of the health and wellbeing of a whole generation, and to unlock discoveries that improve the lives of all families.

We are focused on solving the modern epidemics faced by children and adults, now and for their futures

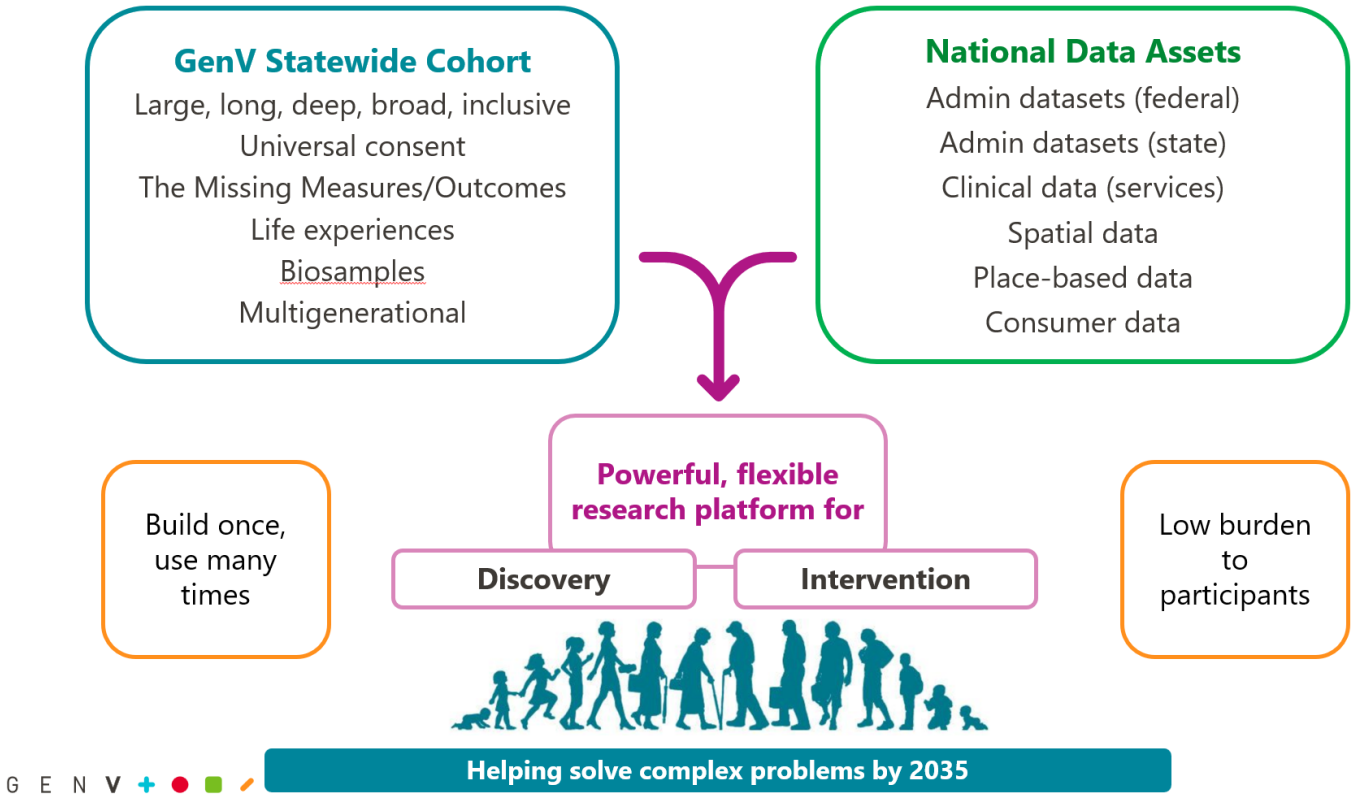


For further information see www.genv.org.au.

GenV access to Commonwealth and State datasets

Under its existing consent, GenV is in the process of arranging access to data that is already collected by both Commonwealth and State Government Departments on an ongoing basis – setting up enduring access to data rather than a one-off data access request.

From the Commonwealth, GenV is seeking to access datasets such as Medicare and Pharmaceutical Benefits Schemes, Centrelink, the Australian Immunisation Register. GenV will bring this together with Victorian Government health and education datasets held by the Centre for Victorian Data Linkage (CVDL).



Accessing Commonwealth Data – when medical research institutes are excluded from the operation of the DAT Act

GenV has already brought together GenV-collected data with Victorian datasets in the secure environment at CVDL.

GenV has consent for data linkage and more explicitly to access Medicare data and numbers. Because it is not eligible for the DATA Scheme, GenV has had to work in existing systems of access and approval for Commonwealth Data. This involves negotiating with individual data custodians via approval processes designed for smaller one-off research projects. Experience shows that this is costly, slow and may even prove impossible – despite the consent from nearly 125,000 Australians. The current structure will also see data sit in multiple secure environments rather than being brought together in one place. (Many Data Custodians prefer to use a particular Accredited Data Service Provider and require that the data does not leave that Data Service Providers secure environment.)

The result is a time consuming and costly process, delaying the real-world impact of this research. GenV currently has pilot research projects that are seeking to utilise data collected by GenV and bring it together with Commonwealth Data. The GenV research collaborators cover topics such as congenital cytomegalovirus testing to reduce lifelong hearing and neurodevelopment impairment, maternal vaccine safety in pregnancy, rapid new tests for rare genetic disorders, and the role of medication use in pregnancy and lactation in later-life asthma of mothers and children. All these projects are run by experts in their fields, funded by peer-reviewed competitive grants or government funding and have ethics approval.

Under the current processes, each researcher must prepare a separate application for data access to the Commonwealth Data Custodian, which typically takes approximately six months to approve. Following this, they must obtain a project-specific Public Interest Certificate to authorise access to protected datasets, validating the purpose and necessity of the request. Data Stewards then extract and securely transfer a project-specific dataset, tailored to the requested variables and time periods, to the nominated Accredited Data Service Providers for cohort linkage and permit access. Additional governance instruments include a deed poll and/or a terms and conditions agreement, which specify the conditions of release and use.

Such processes create a substantial workload and administrative burden for both researchers and data custodians. It also increases the cost and duration of research projects, limiting the ability to build data assets once and reuse them multiple times.

Accessing Commonwealth Data – if medical research institutes could utilise the process set out in the DAT Act

Data from Commonwealth datasets can be transferred to Accredited Data Service Providers for use for approved purposes by Accredited Data Users.

CVDL is currently an Accredited Data Service Provider under the DAT Act. If MCRI was an Accredited Data User, the institute could work with CVDL to arrange access to a variety of Commonwealth datasets via data sharing agreements under the new data sharing scheme. CVDL would put in place a single access agreement with each Commonwealth data custodian for access to datasets, making them available to Accredited Data Users faster and more cost effectively.

To aid data linkage, CVDL and GenV are seeking to use the existing Medicare Consumer Directory/Medicare Identifiers held by the Commonwealth. This would facilitate more accurate, efficient and secure data linkage with State and Commonwealth datasets using fewer personal identifiers in the data linkage process for GenV.

The aim of GenV is to build once and use many times, a concept that can be equally applied to the provision of linked data. A new data flow of Commonwealth data to an Accredited Data Service Provider like CVDL (within the appropriate Five Safes framework), which is updated regularly and able to be accessed through a streamlined data access application, would remove much of the repetition and burden of existing processes and build the GenV Research program for the future for end-user access.

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