PHRN Strategic Priorities Project

Increasing Industry Visibility Final Report

Submitted by:

PHRN Program Office

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Contents

Executive Summary

A Strategic Project was commissioned by the Population Health Research Network (PHRN) to understand the requirements to increase visibility and accessibility of PHRN infrastructure to the clinical trials and medical products industry. The project was managed by the Program Office, with consulting company Future Friendly.

The project consisted of three phases, national consultations with clinical trialists and relevant experts to validate areas of opportunity, a strategy report presenting the key evidence from the consultations, and a three-horizons roadmap with a phased plan for delivering on the future vision.

Interviews with key experts revealed that the clinical trials sector faces too many barriers to engage with linked health data in its current form, making it out of reach, and limiting its impact. Key areas of focus identified were a lack of awareness, the complexity of the application and approval process and lengthy delays in getting access to data.

A three-horizon roadmap was developed to achieve the PHRN vision of increased awareness of the products and services available, guidance and support tailored to the clinical trials sector, and readily available datasets. Lowering the barriers to accessing linked data will improve health services and patient outcomes across Australia.

PHRN GOALS

World Class Research and Analysis

Facilitate and grow the use of linked data for world class, action-oriented research.

Successful Collaborations

Develop new collaborations and partnerships for the use of linked data.

Increasing Industry Visibility of Data Linkage

Background

This project supports the PHRN's strategic objective to "Develop new collaborations and partnerships for the use of linked data" and more broadly to "Facilitate and grow the use of linked data for world class, action-oriented research".

Australia has some of the world's richest population health data, yet this data is currently underutilised for medical product development and its potential to improve lives is often untapped. Internationally, linked health data has been used to support all phases of the medical product development pipeline. It has been found to be particularly valuable in assisting with clinical trial design {Tang, 2021 #7;Wang, 2022 #4}, site and participant selection {Hemkens, 2022 #17} post-market surveillance {Daniels, 2017 #8} and through the provision of longitudinal data, providing greater insight of an intervention's long-term risks and benefits {Fitzpatrick, 2018 #18;Hague, 2016 #5}.

Researchers working in epidemiology and health services research are aware of Australia's linked health data and have been using the PHRN data linkage infrastructure for many years. In contrast, consultations conducted by the PHRN indicate that industry awareness, especially in clinical trials and therapeutic development, of the opportunities offered using linked data is currently extremely limited.

To optimise the use of linked data to support clinical trials and medical product development in Australia, increased awareness among the therapeutic development sector of what linked data is available and how it can be used to support therapeutic development is needed urgently.

Project context

National priorities, including the National Science and Research Priorities (Health), the Modern Manufacturing Strategy (Medical Products), the Blueprint for Critical Technologies (opportunities for improved health and social outcomes), the Australian Medical Research and Innovation Priorities, and the 2021 National Research Infrastructure Roadmap have made it clear that clinical trials and the medical product pipeline are of critical importance to the national research infrastructure.

The existing PHRN infrastructure was initially conceived and developed to support epidemiological research. However, it is evident that the PHRN infrastructure needs to be more visible and accessible to industry and the mutual benefits from closer collaboration with the clinical trials and medical products sectors need to be promoted. The infrastructure will not be used to its potential for clinical trials and medical product development if users from these sectors are either unaware of or do not know how to access the national linked

health data infrastructure. As a result, the population health and economic benefits from the use of linked data may not be realised.

The PHRN has proposed a significant investment in new data linkage infrastructure to support the clinical trials sector. As an adjunct to this investment, increased visibility and accessibility of current and future health-related national research infrastructure is necessary. This is a critical pathway to increasing use of Australia's valuable linked health data resources and making them as widely available to industry as possible.

Project aim

The aim of the PHRN Increasing Industry Visibility project was to understand requirements to increase visibility and accessibility of PHRN infrastructure to the clinical trials and medical products industry. The project sought to identify use cases and requirements for industry use of Australia's linked population data including information, support and training needs, and commence a process to meet these needs.

Project activities and findings

Phase 1: Current State

The PHRN engaged the consulting company Future Friendly to conduct a series of initial interviews with experts from various organisations and jurisdictions to understand the current state and awareness of linked data within the clinical trials sector, identify the existing pain points in the data linkage process and the key opportunities for the Increasing Industry Visibility Project. The learning goals for the consultations are summarised in Figure 1 below. Researchers represented the various stages of the medical product development pipeline and had a diverse range of experience with linked data.

Figure 1: Consultation learning goals.

Expert interviews with clinical trialists confirmed that there was a general lack of awareness about the PHRN and linked data more broadly, the types of data that are available for linkage, the process involved in applying for and accessing data and their eligibility to access linked data. It was suggested that this was likely due to the fact that linked data has been focused on research as opposed to the clinical trials sector and so linked data is not as available to the clinical trials sector as it could be. Participants, however, grasped the value of linked population health data quickly and sought more details of what is involved to help evaluate its application in their specific context.

Participants were readily able to recognise a range of ways that linked data could be applied to their work in clinical trials, with pre-recruitment data, measurements of primary and secondary endpoints, and health economic analysis as some of the most consistently noted use cases.

For those that had used linked data previously, the complexity of the application and approval process was commonly reported. A lack of transparency and minimal upfront guidance to help navigate the process was noted. It was indicated that for linked data to be useful to the clinical trials sector, timely access to real-world data would be required. The lengthy lead times for PHRN's bespoke linked data often mean it's not feasible for clinical trialists to use. Most required data within 3-6 months, yet many reported delays of years to obtain data.

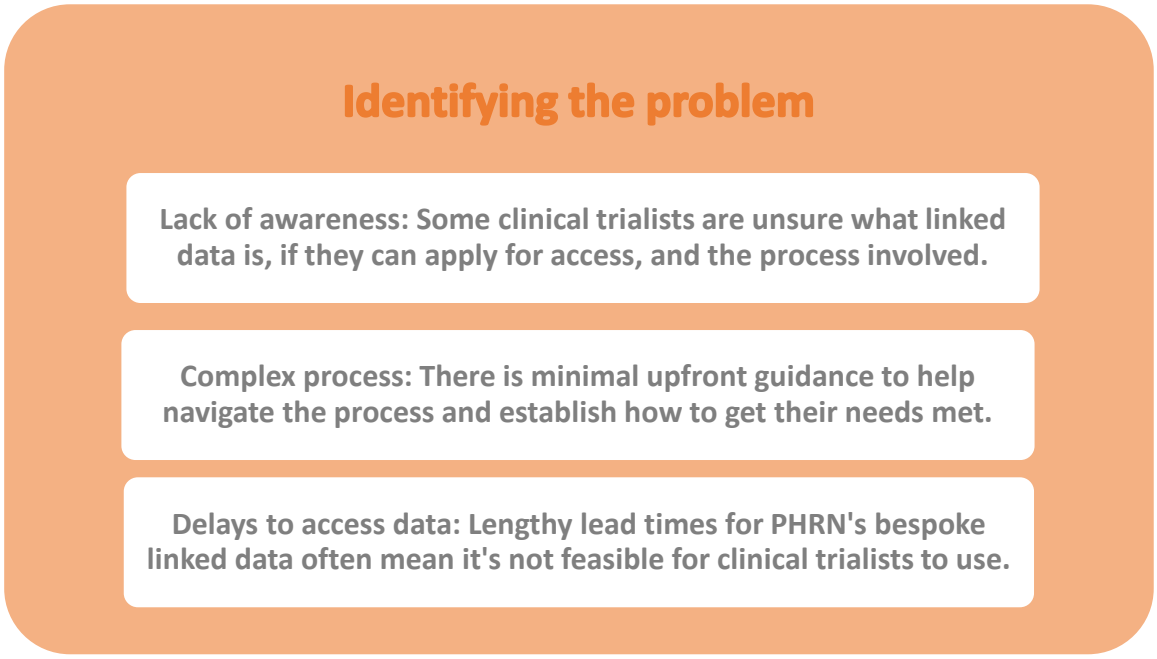

Figure 2: Key barriers identified in the consultations.

Overall, participants recognised the potential value of using linked health data within the clinical trials setting, particularly the benefit of having access to whole of population, real-world data. Participants expressed a high level of interest and willingness to try a refined set

of products and services to gain ready access to linked data. Key findings are summarised in Figure 3 below.

Figure 3: Key findings from consultations.

Phase 2: Opportunity Areas and Prototyping

Final Strategy Report is available in Appendix 1.

Value proposition

Future Friendly held 1:1 user testing sessions to develop, test and validate proposed products and services to support the clinical trials sector. Fourteen user testing sessions were held with clinical trialists from various roles including senior market access managers, project managers, clinician researcher, health economist and clinical research associates.

Participants in the consultations were presented with examples of the potential ways to use linked data, the benefits of using linked data and a demonstration of the current process for accessing linked data. Participants were then presented with a series of 'future' linked data products, services and training aimed at lowering the barriers to accessing linked data.

Each product and service were presented using tangible prototypes which underwent continuous iterations following each user testing until each concept was well refined. The products and services tested have been described briefly below.

Linked data products

Aggregate Data Collections: These were defined as pre-approved data summaries that provided simple, descriptive data to help with planning a clinical trial. It was proposed that the data would be pre-approved by data custodians and Human Research Ethics Committees and could be used to:

- Assess the feasibility of research
- Identify research populations and locations
- Build evidence for grants and funding
- Scope a linked unit record request

Routinely-linked Clinical Quality Registries: These were defined as data collections containing data on health care quality from specific clinical domains. It was proposed that these collections could be used to monitor the quality of care by collecting, analysing and reporting on health-related information.

Routinely-linked Clinical Datasets: These were defined as data collections that contain information about health conditions and/or care. It was proposed that access to linked clinical data such as pathology, imaging and omics be increased, and access timeframes to biobank data be minimised through routine linkage.

Synthetic data: These data were defined as computer-generated data, which retains the statistically relevant characteristics of the original data. It was proposed that synthetic data could be a valuable planning and modelling resource for training purposes, testing hypotheses or modelling multiple outcomes, using data that requires less rigorous approvals. Other proposed use cases included creating synthetic control groups, establishing target populations and predicting the cost-effectiveness of a new drug.

Mock data: Mock data was defined as raw or formatted randomised data. It was proposed that mock data could be used as a training and planning resource. Raw data would indicate the file format the researcher will receive the dataset; whilst the formatted data would provide a list of all included variables with several lines of data as an example of the format of each variable.

Metadata toolbox: The Metadata Toolbox was defined as a search and navigation tool for finding and evaluating data collections. Metadata included in the value proposition were a listing of routinely linked data collections, a summary description and the temporal scope of available datasets, the ability to compare the availability of datasets across jurisdictions, and related metadata to evaluate the relevance of a dataset for a specific research project.

Services to help get the most out of linked data

Ethics, law and social implications (ELSI) service: The ELSI service was defined a service that provides support and advice on the ethical and legal implications of proposed data uses. It was proposed that the service would consist of a team of experts who are dedicated to

identifying and resolving ethical issues that may arise during the application process, to ensure a smoother and faster HREC approval process, and ultimately, more timely access to the data requested.

Data Concierge: Data concierge was defined as specialist advisors who would assist with advising on feasibility and approval requirements for clinical trials data linkage requests.

Training: Several potential training programs were presented to participants. Topics related to:

- Linking Data and Protecting Privacy
- Navigating Application and Approval Requirements
- Using Linked Data to Inform Clinical Trial Design
- Analysis of Linked Health Data

Analytic services: Defined as an expert team available to analyse linked data for clinical trials.

Linkage variable management: Defined as a third-party service to manage the linkage variables for clinical trials, so that identifiers don't need to be shared with the central clinical trials analytics team.

Prioritised opportunities

Key evidence from consultations

Aggregate Data: Aggregate was a recognised format and seen as a useful source of high-level data. Having fast or immediate access was the highest aspect of desirability.

Routinely linked Clinical Quality Registries: Routinely linked Clinical Quality Registries were highly desirable, with recognised constraints to access in the current state.

Routinely linked Clinical Datasets: Access to routinely linked clinical datasets was seen as a useful way to access fundamental data to help inform research.

Synthetic Data: Synthetic data was a new concept to users, and many struggled to understand how it would work and were sceptical of its reliability. However, many users were also intrigued by the potential time savings enabled by avoiding the usual approval processes. Some saw value in accessing privacy-protected synthetic data ready for immediate use and were able to identify potential applications including feasibility assessments and getting snapshots of disease prevalence in an Australian context. Ultimately, technical complexity, limited ability to view and use the data, and a lack of real-world case studies limited comprehension of synthetic data's potential applications in clinical trials. This led to participants to prematurely dismiss the concept in most cases. Some expressed hesitation to use it in reimbursement or grant applications due to potential rejection and the resulting delay in getting therapeutics to market. Trust emerged as the pivotal factor in adopting synthetic data for the Australian therapeutics industry.

Participants sought assurance on the following: the methodology used to create synthetic data; whether it's been approved for use by regulators such as Pharmaceutical Benefits Advisory Committee (PBAC); and how patient privacy was maintained.

Mock Data: Some participants recognised the usefulness of mock data but it was not identified as having as high a value as other offerings.

Ethics, law and social implications service: Ethics approval was recognised as a vital but anxiety-inducing part of the data acquisition process. Users were keen to gain confidence in their approach to navigating ethics approval. Participants expected that speaking to someone with connections to ethics boards and committees would be helpful to ensure they were meeting requirements.

Participants expected that using the ELSI service would streamline their application and increase the chance of first-time approval. Responses, however, were mixed regarding whether the service need to be a separate service, as opposed to being absorbed by the role of the data concierge.

Metadata Toolbox: The Metadata Toolbox was recognised as a useful starting point for discovering what data collections are available. Users were keen to establish a more detailed view of what variables are included in each of the collections.

Data Concierge: Users recognised that having expert advice regarding the application and approval process as highly useful. The Data Concierge was seen as a collaborative partner with clinical trial expertise, helping translate ideas into strong applications.

Training: Users were keen to have modular training that could bolster their confidence and understanding of the application process, while not overlapping with in-house specialists.

Analytic Services: There was mixed interpretation of what this would include and when it would be used. Many clinical trialists indicated they either had the expertise themselves or were working in large companies that had these resources readily available (i.e., in-house analysts).

Linkage Variable Management: Comprehension of this service was low. Many clinical trialists were more concerned about accessing the required data rather than how it would be done whilst still meeting ethics requirements.

Prioritisation results

During each of the user testing sessions, participants were asked to prioritise and rate each of the products and services. A summary of the evaluation results is provided in Table 1.

Table 1 Evaluation results

	Desire	Value Attribution	Comprehension
Products			
Aggregate Data	High	High	High
Routinely linked Clinical Quality Registries	High	High	Medium
Routinely linked Clinical Datasets	High	High	Medium
Synthetic Data	Medium	Medium	Low
Mock Data	Low	Medium	Low
Services			
Ethics, law and social implications service	High	High	High
Metadata Toolbox	High	High	Medium
Data Concierge	Medium	High	High
Training	Medium	High	High
Analytic Services	Low	Medium	High
Linkage Variable Management	Low	Medium	Low

Phase 3: Three-Horizon Roadmap

The Three-Horizon Roadmap is provided in the Final Strategy Report (Appendix 1).

Future vision

An industry-first offering that lowers the barriers to accessing linked data to improve health services and outcomes across Australia.

A future experience was proposed that included three key focus areas. These included:

1. **Increased awareness**

   Support clinical trialists to understand linked data, where it fits in their workflow and how to apply.

   User need: Understand what products and services are available to the clinical trials sector and how to apply for linked data.

Solution: Create a bespoke landing page that clearly communicates the PHRN's value proposition for the clinical trials sector and products and services offerings, with tailored use cases and examples for the clinical trials sector.

2. **Tailored guidance and support**

   Provide expert support and a streamlined process to help clinical trialists navigate the application process with speed and confidence.

   User need: Guidance on preparing a successful linked-data application, including any requirements specific to clinical trials.

   Solution: Data concierge service that provides expert advice specific to clinical trialists. Access to a platform that provides access to online bookings, a checklist for trialists to prepare for the session, manage quotes, updates, session notes and next steps in one place.

3. **Timely Access**

   Offer ready-made and bespoke products to meet varying needs. Increase access to linked data for clinical trials with a light-touch application process for low-risk products.

   User need: Timely access to linked data for clinical trial planning, design and development.

   Solution: Explore making aggregate data, that is pre-approved by data custodians and human research ethics committees, more widely available, to dramatically reduce the time to apply and access data. Lay the foundations for synthetic data.

Roadmap

Horizon 1: Bring the sector along the journey.

Key outcomes

1. Raise awareness of PHRN and linked data in the therapeutics sector
2. Design, further validate and pilot a data concierge service as a one-stop-shop for enquires.
3. Assess the feasibility of new linked data products, including synthetic data.

Horizon 2 De-risk and scale future offerings.

Key outcomes

1. Provide access to routinely linked Clinical Quality Registries and Clinical Data.
2. Streamline access by identifying barriers to national adoption of the online application system.
3. Prototype a synthetic data proof of concept and deliver a pilot.

Horizon 3 A seamless integrated experience.

Key outcomes

1. Provide a single space to manage linked data requests, integrated with other PHRN products.
2. Develop a pricing model that enables quick quoting and cost estimation for our products.
3. Improve the wellbeing of all Australians through increased use of linked health data.

Project milestones and outputs

Project milestones and outputs for the three phases of the Increasing Industry Visibility Project are summarised in Table 2 below.

Table 2: Milestones and Project Outputs

Due Date	Milestones and Project Outputs	Status
Phase 1: Planning		
-	Establish steering committee for scoping study	Not completed*
25/01/2023	Retain a suitable resource to undertake study	Completed
Phase 2: Conduct scoping study		
29/03/2023	Undertake scoping consultations with clinical trialists and key industry experts	Completed
29/03/2023	Strategy Report	Completed
Phase 3: Final Strategy Report		
21/04/2023	3-horizon roadmap	Completed
21/04/2023	Final Strategy Report	Completed

*PHRN Program Office developed a Terms of Reference for a Project Control Group 26/02/2023, however due to the short project timeframe a formal PCG was not established. Key stakeholders and experts were consulted throughout the project.

Discussion

The Increasing Industry Visibility project was completed by the PHRN in collaboration with Future Friendly via a three-phase process that included a review of the current state, identification and validation of opportunity areas and the development of a 3-horizon roadmap.

The key findings from the project were that the clinical trial sector does see value in linked-data products and services, however timely access to real-world data is paramount. The time to apply for and access linked health data was a recognised pain point and the lengthy

process to access data currently limits the use of linked data within the sector. The application and approval process needs to be better streamlined and transparent and there is a role for expert help to navigate the process.

Prototypes of products and services were presented to key experts and clinical trialists during user testing to validate opportunities and to prioritise areas for the PHRN to focus on moving forward. Of the products we tested, aggregate data was the clear preferred data product followed by clinical quality registries and clinical datasets. There was mixed support for synthetic data, which was due in part to a low comprehension and concerns re its practical utility. The ELSI service and the metadata toolbox had the greatest appeal and value attribution among the services tested. Clinical trialists highly valued easy access to ethics and legal support. Notably data custodians and DLU staff were also supportive of an ELSI service that could provide guidance on the release of data to the private sector.

Insights from testing revealed three key opportunity areas including increased awareness of the PHRN value proposition for the clinical trials sector, tailored guidance and support and timely access to data.

Next Steps

Short term

Increased awareness

- Provide a recorded presentation introducing the PHRN and linked data for clinical trialists, which includes the value proposition to the sector.
- Develop a bespoke landing page to communicate PHRN's products and services, with tailored use cases and examples for the clinical trials sector.

Tailored guidance and support

- Launch the metadata toolbox.
- Launch the introductory researcher training for linked data.
- Investigate if the existing client services model differs from the expectations of the data concierge service and what changes, if any, would be required to meet the needs of clinical trialists.

Timely access

- Work with relevant stakeholders to open up access to clinical quality registries and clinical data.
- Prioritise data collections to be made available as aggregate data.

Medium term

Tailored guidance and support

- Explore the feasibility of an ELSI service.

- Investigate the barriers to the national uptake of the existing Online Application System by individual jurisdictions.

Timely access

- Develop a pricing model (quote builder) that enables quick quoting and cost estimation for data linkage projects.
- Provide access to routinely linked clinical quality registries.
- Provide access to routinely linked clinical data.
- Build a platform to enable access to linked aggregated data collections to fit study cohort requirements.

Long term

Timely access

- Make aggregate data collections available for priority data collections.
- Prototype a proof of concept for synthetic data.
- Develop a single space to manage linked data requests, integrated with other PHRN products.

Conclusion

The PHRN *Increasing Industry Visibility* project has been successfully completed. The project has delivered a three-horizon roadmap that reflects the needs of the clinical trials sector. This project demonstrated that the clinical trial sector recognises value in linked-data products and services. However, the current state of data linkage in Australia presents too many barriers for the clinical trials sector to be able to meaningfully engage with linked health data, making it out of reach for many triallists and limiting its impact.

Future uptake of data linkage within the clinical trials sector is dependent on improved efficiencies in the application and approval process in addition to timely access to real-world data, available in a variety of formats to meet user needs. Expert advice to assist in navigating data access as well as ethics and legal support will be essential if we are to see transformative growth in the utilisation of linked data for identified national priority purposes and to strengthen the Australian Therapeutic Pipeline.

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