

Management of Linkage Variables in Clinical Trials

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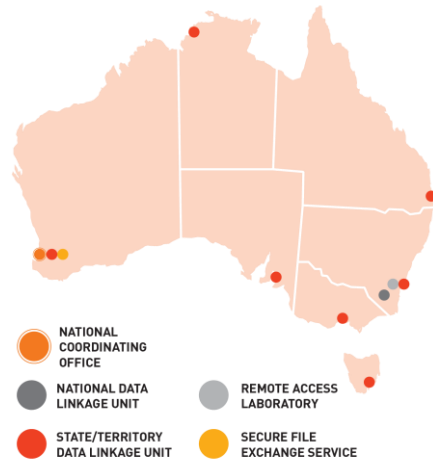
What is Data Linkage?

Data linkage, in simple terms, is a method of bringing together information derived from different sources, but relating to the same individual or event into a single file

What is a Data Linkage Unit?



- ❖ A specialised unit or facility which brings together information derived from different sources, but relating to the same individual or event into a single file



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Benefits

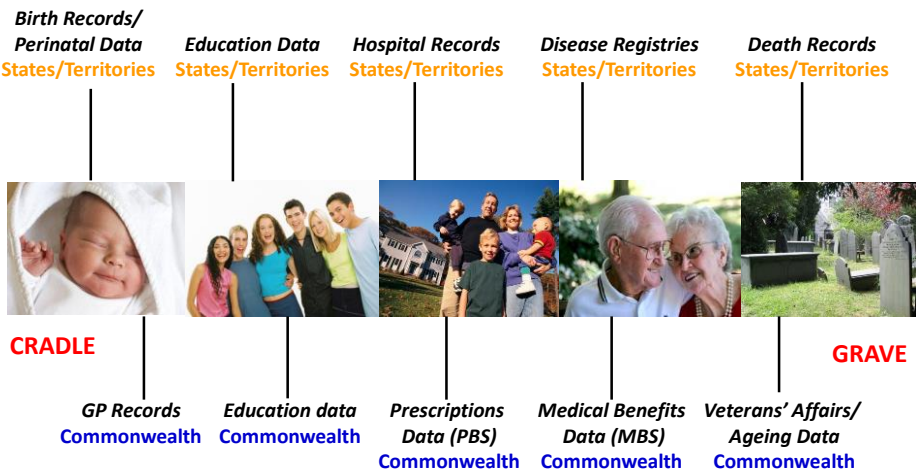


Linked data can be used to augment or replace data collection in the following ways:

- ❖ Long term follow-up (all participants or only those lost to follow-up)
- ❖ Pre-recruitment hospitalisation as a measure of trajectory to care
- ❖ Measurement of healthcare and/or pharmaceutical use before and after an intervention
- ❖ Measurement of primary and secondary endpoints
- ❖ Identification of eligible individuals or communities
- ❖ Economic analysis
- ❖ Disease prevalence, comorbidities, ethnicity and race
- ❖ Pragmatic or implementation clinical trials

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Data across the lifespan



Example

Using a specialist data linkage unit

The data collections



- ❖ Clinical trial data
- ❖ The Registrar of Births, Deaths and Marriages collects a record of every birth, death and marriage.

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Data Custodians



Clinical Trial Site

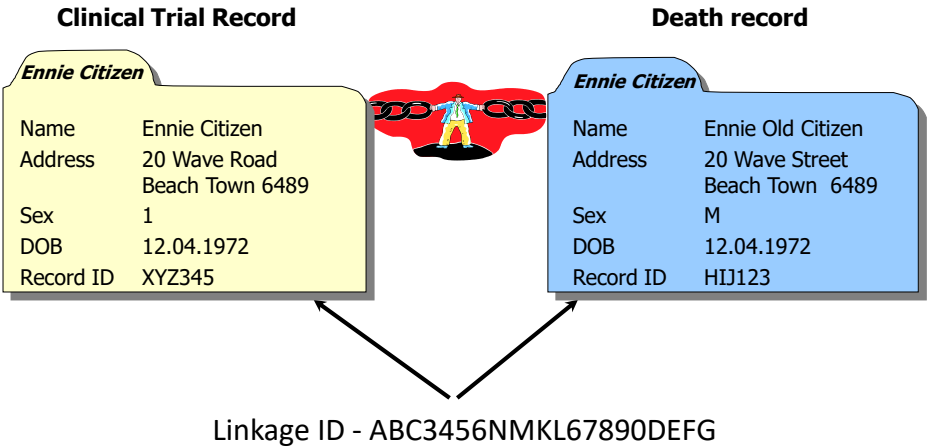
Ennie Citizen	
Name	Ennie Citizen
Address	20 Wave Road Beach Town 6489
Sex	1
DOB	12.04.1972
Record ID	XYZ345
ATSI	4
Marital	3
Diagnosis	F30.2
Ad Date	09.05.2008
Sep Date	15.05.2008

Registry of Births Deaths & Marriages

Ennie Citizen	
Name	Ennie Old Citizen
Address	20 Wave Street Beach Town 6489
Sex	M
DOB	12.04.1972
Record ID	HIJ123
Aborig	N
DOD	26.05.2008
COD	Y350

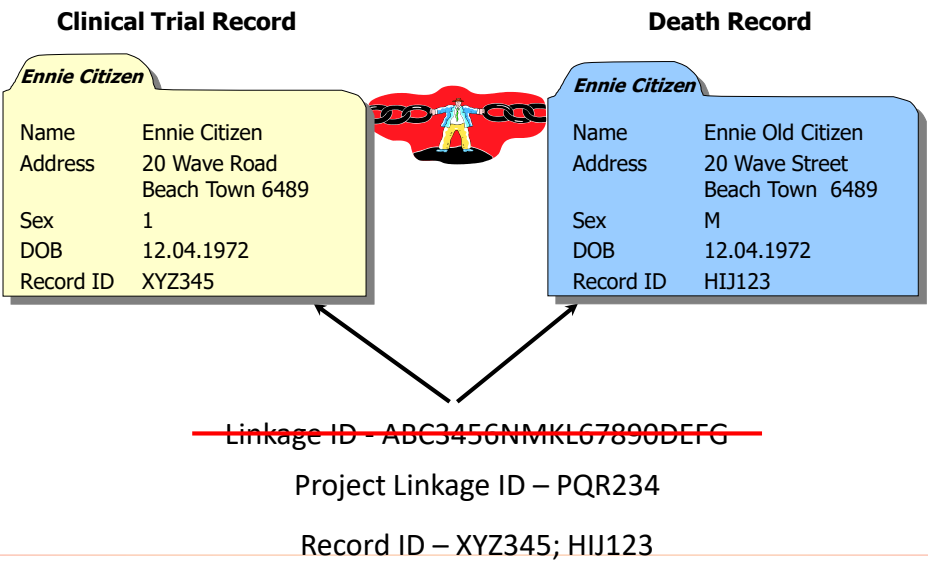
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Data Linkage Unit



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Data Linkage Unit



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Data Custodians



Clinical Trial Site

Ennie Citizen	
Name	Ennie Citizen
Address	20 Wave Road Beach Town 6489
Sex	1
DOB	12.04.1972
Project ID	PQR234
ATSI	4
Marital	3
Diagnosis	F30.2
Ad Date	09.05.2008
Sep Date	15.05.2008

Registry of Births
Deaths & Marriages

Ennie Citizen	
Name	Ennie Old Citizen
Address	20 Wave Street Beach Town 6489
Sex	M
DOB	12.04.1972
Project ID	PQR234
Record ID	HLR123
Aborig	N
DOD	26.05.2008
COD_	Y350

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Researcher merges
and analyses records



hospital record		Study data		death record
Project ID	PQR234	Project ID	PQR234	PQR234
Sex	1	Sex	1	M
ATSI	4	ATSI	4	N
Age	36	Age	36	36
Marital	3	Marital	3	26.05.2008
Diagnosis	F30.2	Diagnosis	F30.2	Y350
Sep Date	15.05	Sep Date	15.05.2008	
		DOD	26.05.2008	
		COD_Code	Y350	

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Access to Linked Data



❖ If you a linking to a clinical trial cohort each site will need to collect linkage variables.

Data format	Character-separated text (e.g. .csv, .tab), fixed-width text or Excel spreadsheet
Data fields supplied for linkage Every record must have a unique ID	Project record ID, First name, Middle name, Surname, Address, Suburb, Postcode, State, Date of birth (day), Date of birth (month), Date of birth (year), Sex

Example



Long term follow up of a clinical trial cohort (5 years post treatment completion).

Linkage to hospital admission and death data.

Assumptions

- ❖ Participants have provided consent for data linkage
- ❖ A central national hospital admission data repository not available

Questions to consider



- ❖ What is the likelihood that participants will have been admitted to a hospital or died outside the jurisdiction they were recruited in?
 - Link only to data in the same state/territory as the site
 - Link to data in all states/territories

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Data Linkage Units



Data Linkage Unit	Jurisdictions	URL
Centre for Health Record Linkage (CHeReL)	Australian Capital Territory & New South Wales	http://www.cherel.org.au/
SANT DataLink	Northern Territory & South Australia	https://www.santdatalink.org.au/
Data Linkage Queensland	Queensland	https://www.health.qld.gov.au/hsu/link/datalink
Tasmanian Data Linkage Unit	Tasmania	http://www.menzies.utas.edu.au/research/research-centres/data-linkage-unit
Centre for Victorian Data Linkage	Victoria	https://www2.health.vic.gov.au/about/reporting-planning-data/the-centre-for-victorian-data-linkage
WA Data Linkage Branch	Western Australia	https://www.datalinkage-wa.org.au/
AIHW	Australian Government	https://www.aihw.gov.au/our-services/data-linkage

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Linkage in one state/territory

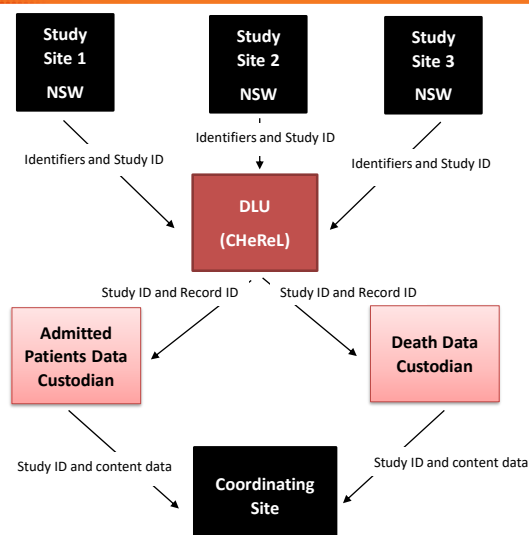


❖ Linkage variable management

- Each site collects and stores the linkage variables for their site
- Option 1 – coordinating site notifies each site when to send linkage variables to the DLU. DLU conducts the linkage.
- Option 2 – when each site completes recruitment or treatment they send linkage variables to DLU. DLU store and manage linkage variables until all sites ready for linkage.

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Linkage in One State/Territory



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Linkage in all states/territories

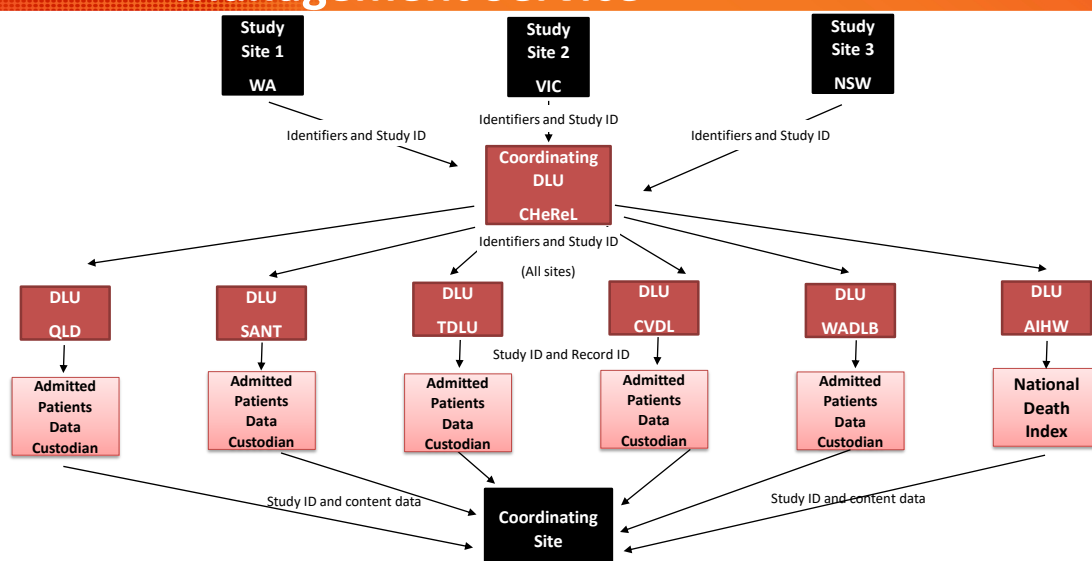


❖ Linkage variable management

- Each site collects and stores the linkage variables for their site
- One DLU nominated to be linkage variable coordinating DLU
- Each site sends linkage variables to coordinating DLU for collation and storage
- When time for linkage, coordinating DLU sends linkage variables from all sites to each state/territory DLU and to AIHW for linkage to National Death Index

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Hypothetical Linkage Variable Management Service



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Resources



- ❖ <https://www.phrn.org.au/>
- ❖ ACTA/PHRN Guide for Clinical Trials
http://www.clinicaltrialsalliance.org.au/wp-content/uploads/2019/07/Linked-data-guidance_final.pdf
- ❖ ACTA/PHRN webinars
<https://www.youtube.com/playlist?list=PLH5JZhNGOhzZyGt8ylqadnb3W25BvYSEU&spfreload=5>

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