



CAHS Research Education Program Research Skills Seminar

Innovation and Commercialisation

2nd December 2022

Co-presented by

Ashley Schoof

Commercialisation Officer - Telethon Kids Institute



and

Helga Mikkelsen

Investment Analyst – Brandon Capital Partners



**CAHS Research Education Program
Research Skills Seminar Series**

✉ ResearchEducationProgram@health.wa.gov.au

🌐 cahs.health.wa.gov.au/ResearchEducationProgram



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Department of Health, Government of Western Australia

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Innovation and Commercialisation

PRESENTATION SLIDES





Government of Western Australia
Child and Adolescent Health Service



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Innovation and Commercialisation

2nd December 2022

Presented by



Ashley Schoof
Commercialisation Officer
Telethon Kids Institute



Helga Mikkelsen
Investment Analyst
Brandon Capital Partners

Research Education Program | Research Skills Seminar Series

Proudly supported by
Perth Children's
Hospital Foundation

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Acknowledgement of country

I would like to acknowledge the
traditional custodians of the land,
the Noongar Whadjuk people,
and pay my respects to their elders,
past, present and future.

2




Proudly supported by the people of Western Australia through Channel 7's Telethon

Innovation & Commercialisation


Ashley Schoof & Helga Mikkelsen
Research Skills Seminar Series
December 2, 2022

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Agenda

- Introductions
- What is commercialisation and why do you need to know?
- How does commercialisation occur?
- What are the essential ingredients?
- What can commercialisation look like?
- Who can help?



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Ashley Schoof

- Commercialisation Officer at Telethon Kids Institute since 2017; Operations Manager for Inspiring
- 4 Spin Out companies, 2 licence deals from Telethon Kids research
- Work collaboratively with the researchers/innovators to:
 - Identify, Review and Protect valuable Intellectual Property
 - Identify and engage with potential partners
 - Strategic advice in the development of the IP
 - Negotiate and execute licence agreements with partners
 - Creation of spin out companies
 - Fundraising for investment into spin out companies

Email: Ashley.Schoof@telethonkids.org.au
Phone: 0432 848 547



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Helga Mikkelsen, PhD

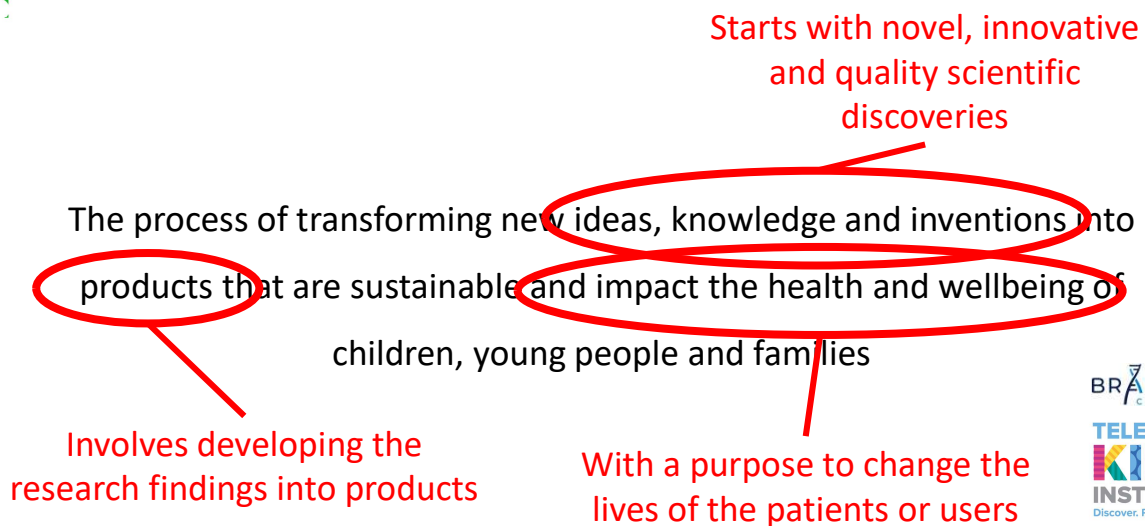
- Investment Analyst, Brandon Capital
- WA representative for Brandon BioCatalyst
- Work collaboratively with researchers, clinicians and commercialisation offices to translate discoveries into products/services that can change patient outcomes
- Director and co-founder of Respirion Pharmaceuticals (Telethon Kids spin-out)

Email: hmikkelsen@bcpvc.com
Phone: 0491 277 662



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What is commercialisation?



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Why commercialise?

- Relative to its size, Australia produces a large amount of high-quality medical science
 - Top 10 for discovery¹
 - Top 20 for innovation²
 - 79th for innovation efficiency²
- Many Australian discoveries never benefit patients
 - Patients are treated with medical products
 - Publishing doesn't produce products
 - Many findings are never published at all

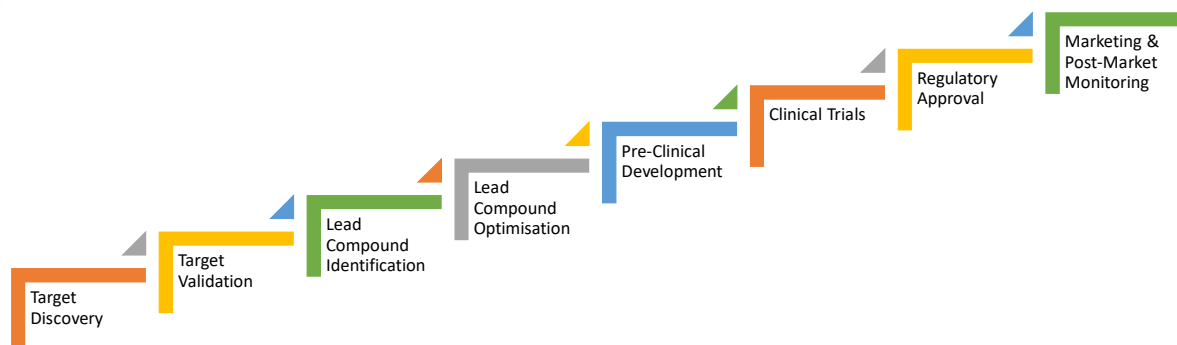
¹ No. 5 globally, Scientific American Biotechnology ranking (2016)
² No. 19, INSEAD Global Innovation Index (2016)

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Commercialisation in medical research includes

- Drugs/Therapeutics – Small Molecules, Antibodies, Gene Therapy, etc.
- Medical Devices
- Diagnostics
- Digital (Digital Medicine/Therapeutics, Telehealth, etc.)
- Training Methods/Programs

Drug Development Pathway

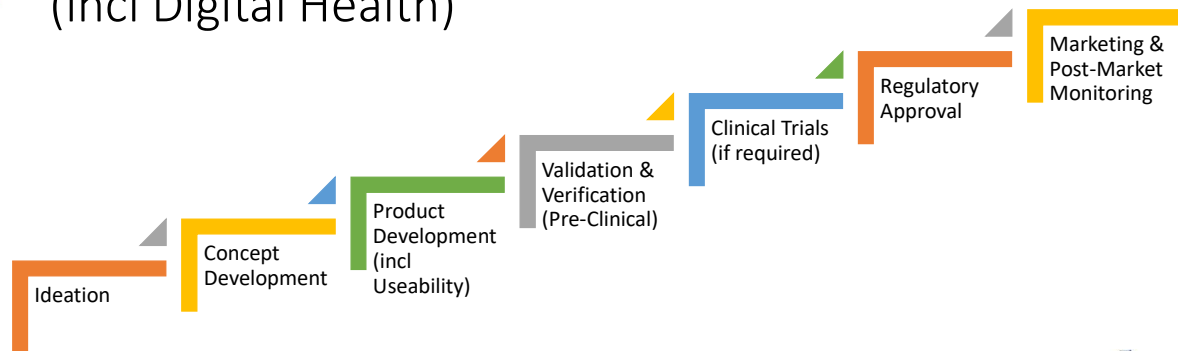


Time: 12-17 Years

Cost: Estimated from \$161m to \$4.54b*

* doi: 10.1007/s40273-021-01065-y

Medical Device Development Pathway (incl Digital Health)



Time: 4-12 Years

Cost: Estimated from \$3m to \$500m*



*<https://starfishmedical.com/assets/StarFish-Whitepaper-Cost-to-Develop-Medical-Devices-July-2020.pdf>

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Partners needed

Licencing

- IP Licenced to Industry Partner
- Industry Partner continues development
- Research Contracts & Consultancy back to Inventors
- Upfront, Milestone and Royalty Payments back to IP owners



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Partners needed

Start up Company

- IP assigned to new start up
- Investment secured
- Start up continues development
- Inventor engaged in start up
- IP Owner retains equity in start up
- Start up either develops through to Market or licences at late stage to Large Biotech/Pharma

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Any
questions so
far?


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What does it take to commercialise?


The essential ingredients

 Unmet medical need & market

 Value proposition

 Proprietary technology (IP)

 Competitive advantage

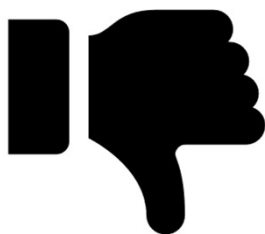
 A staged value creation plan



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Unmet medical need & market



“Our solution will treat cancer and generate a \$gazillion in revenue”

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Unmet need can be

- There are no approved drugs
- Few compounds in late phase clinical studies
- Where existing compounds are compromised by liabilities at efficacious dose
- Where there is an identifiable subset of patients who are currently underserved

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Unmet need



What is the problem?

- How well do we understand the disease state?
- What is standard of care?
- Is there consensus on the nature of the unmet need?



How many patients?

- What is the specific patient population?
- Clinical presentation
- Diagnostic criteria



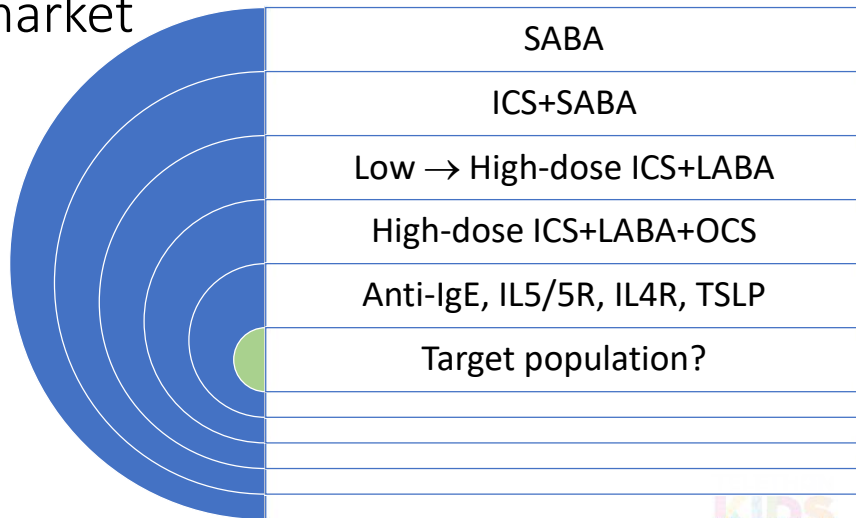
What is a meaningful outcome?

- What are the measurements / trial endpoints?
- What would the registration trial look like?

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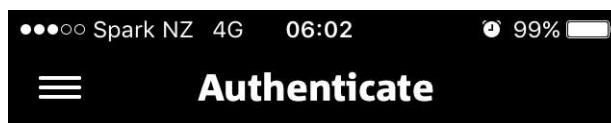
The asthma market

- 300 million people globally
- US\$25 billion market



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Value proposition



One-time password

Enter your PIN



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Value proposition

- How will it help patients?
- What is the label claim?



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Value proposition

- Clinical workflow fit?
- How much training is needed?
- Can we charge for it?



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Value proposition

- How much does it cost?
- Is it reimbursed?
- Is there an existing code?
- Positive health economics?



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Value proposition

- How many are there?
- Why and when would they be interested?
- How do they make money?
- Does it fit their strategy?



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Value proposition

- Is there a product?
- Can it be manufactured with QA, stored and distributed?
- Can it be offered as a service?
- Can it be scaled?



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Protecting your advantage

IP protection

- Developing medical products takes a lot of time and a lot of \$\$\$
- For most medical technologies, patent protection is crucial

Time: 12-17 Years

Cost: Estimated from \$161m to \$4.54b*

Time: 4-12 Years

Cost: Estimated from \$3m to \$500m*

Other protection

- Copyright
- Trade secrets
- Regulatory exclusivity (e.g. orphan indication)

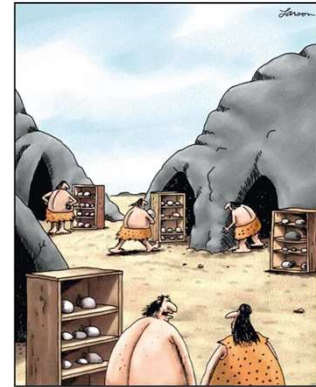
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Protecting your advantage

Who is your competition?

1. Standard of care and existing solutions
2. Recent approvals that provide new therapeutic options
3. Solutions in development / pipeline programs that may be ahead of yours

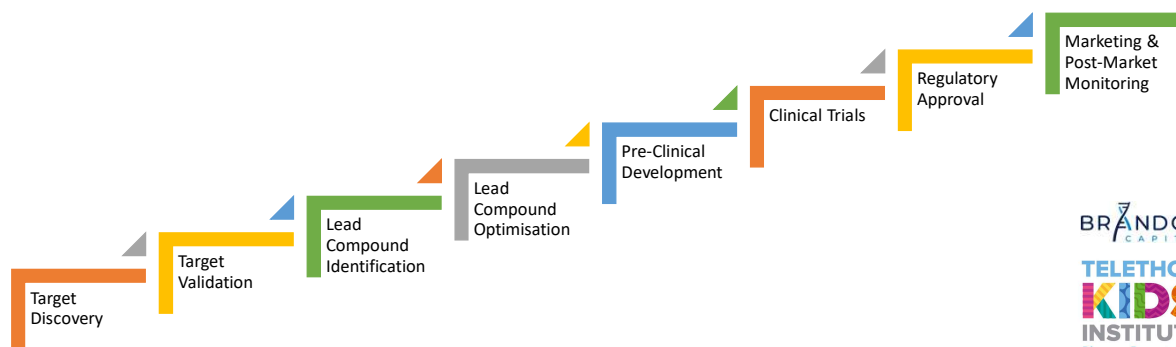


"You know, I used to like this hobby. ...
But shoot! Seems like *everybody's* got a
rock collection."

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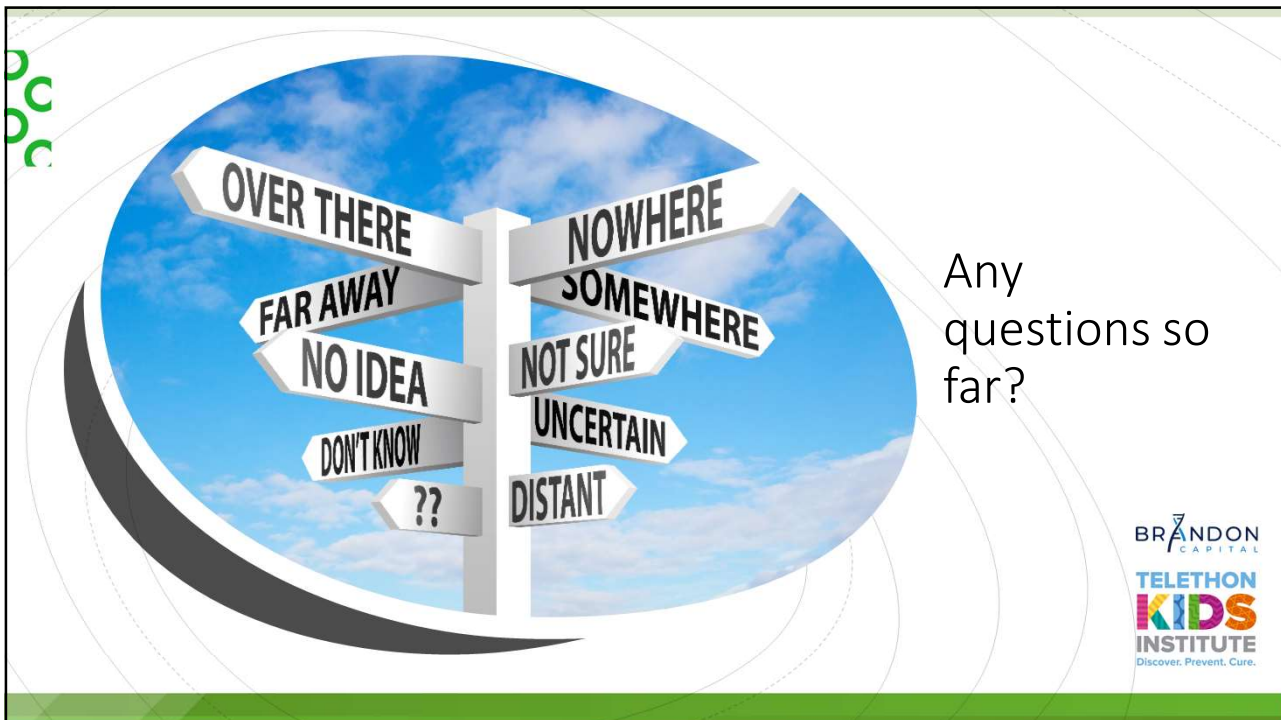
Value creation plan

- Value inflection occurs when a significant project risk is reduced
- A development plan should incrementally reduce project risk



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The SonoPlex Needle

Problem	Poor visibility during ultrasound-guided anaesthesia
Invention	Echogenic needle that is more visible at any angle
R&D	Multiple prototypes
IP	Provisional patent filing
Partner	Patent licenced to Pajunk Development, manufacturing, QA and distribution
Outcome	Multiple products that make clinician's life easier Improved patient safety

Dr Christopher Mitchell, SCGH

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Respirion Pharmaceuticals



Dr Barry Clements, PCH

Problem	Limited efficacy of inhaled tobramycin for Pseudomonas lung infections in CF; Biofilm formation and antibiotic resistance
Invention	Two adjuvants that chelate iron and break down bacterial biofilms and increase tobramycin efficacy
R&D	In vitro work showed efficacy Investigator-led clinical trial showed reduced bacterial load and improved FEV1
IP	Two provisional patents Regulatory exclusivity: orphan indication, QIDP
Partner	Brandon Capital and US Cystic Fibrosis Foundation (\$\$, expertise and trial sites) Multiple industry partners for drug and device development
Outcome	A product ready for testing in FDA-sanctioned clinical trials If all goes well, improved treatment of chronic lung infections

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Smileyscope



Dr Evelyn Chan, Royal Children's Hospital, Melbourne

Problem	75% of kids, 50% of adolescents and 25% of adults fear needles, preventing them from seeking medical care
Invention	VR headset with software that provides a tool to minimise stress
R&D	Medical grade hardware designed from scratch VR experience that aligns with procedure and physical sensation
IP	VR device, system and framework for generating VR experience choreographed to a physical procedure potentially inducing an anxiety or pain response
Partner	Initially Australian hospitals, extended to 40 hospitals in the US Investors from Silicon Valley and Australian Doctors
Outcome	Clinical trial shows reduced pain, distress and need for restraint Potential for improved health outcomes



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The final ingredient is people - We need you!!

- Inventors are needed throughout the commercialisation process:
 - New discoveries, ideas, inventions – always starts with quality scientific discoveries
 - Engagement with potential partners
 - Contribution of expertise (scientific, clinical, etc.)
 - Opportunity for employment in spin off or Consultancy/Contract Research
 - Potential funding back for to your research program
- Patents, Industry Engagement & Commercialisation are key impact metrics for many funding applications, especially philanthropy

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Who can help?

- Innovation Teams @ Health Services
- Commercialisation Teams @ Universities/MRIs
- WA DoH Research and Innovation Office
- Brandon Biocatalyst - Helga Mikkelsen
- MTP Connect Life Sciences Innovation Hub – Tracey Wilkinson, Dean Nedelkos, Rebecca Craggs
- ANDHealth (Digital Health) - Cath Resnick




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Advice

- Be careful with what you share publicly – prior disclosure can be problematic
- Use non-confidential conversations to validate/refine your ideas
- Consider commercialisation early – start with the end in mind
- Love the problem more than the solution – be prepared to fail
- It takes a village – reach out for advice and support
- Consider getting involved




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Thank You
Any questions?

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Ashley Schoof
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M: 0432 848 547



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Upcoming Research Skills Seminars

HOLIDAY BREAK

31st Jan 2023 REDCap Workshop 1 – Basic Walkthrough
with Dr Jane Mugure Githae, Research Fellow

Register → researcheducationprogram.eventbrite.com.au

We love feedback
A survey is included in the back of your handout, or complete online
<https://tinyurl.com/surveyInnovComm>

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Innovation and Commercialisation

RESOURCE NOTES



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1. Training Opportunities

- 1.1. [Centre for Entrepreneurial Research & Innovation](#) – Bootcamp, Concept to Creation
- 1.2. [On Prime](#) & [On Accelerate](#)
- 1.3. [BioDesign](#) – Bootcamp, Perth BioDesign for Medtech, Perth BioDesign for Digital Health
- 1.4. [ANDHealth](#) – BRIGHT:Ideate, BRIGHT:Innovate
- 1.5. [Australian Clinical Entrepreneur Program](#)
- 1.6. [Cicada MedLab – Commercialisation 101](#)
- 1.7. [Curtin Ignition](#)

2. Resources

- 2.1. [MTP Connect](#) – Funding, Newsletters, Podcasts
- 2.2. [WA Life Science Innovation Hub](#) – Newsletters, events, funding information
- 2.3. [Life Sciences WA](#) – Newsletters, events
- 2.4. [WA DoH Future Health Research & Innovation Fund](#) – Funding



CAHS Research Education Program

Research Skills Seminar Series

A free, open-access resource designed to upskill busy clinical staff and students and improve research quality and impact.

Interactive in pdf format
Last updated 22/11/22

2023 Seminar Schedule

	DATE	TOPIC	PRESENTER	ENROL	WATCH
1	3 Mar	Research Fundamentals	Dr Kenneth Lee, UWA	REGISTER	2021
2	10 Mar	Introduction to Good Clinical Practice	tba	REGISTER	2021
3	17 Mar	Introductory Biostatistics	Michael Dymock, TKI	REGISTER	2022
4	28 Apr	Scientific Writing	Dr Amy Page, UWA (tbc)	REGISTER	2021
5	5 May	REDCap for Data Capture and Management	Dr Jane Mugure Githae, CAHS	REGISTER	2021
6	12 May	Using Social Media in Research	Dr Amy Page, UWA (tbc)	REGISTER	2022
7	19 May	Getting the Most out of Research Supervision	A/Prof Sunalene Devadason, UWA/CAHS	REGISTER	2022
8	2 Jun	Survey Design & Techniques	Dr Jane Mugure Githae, CAHS	REGISTER	2021
9	9 Jun	Conducting Systematic Reviews	Prof Sonya Girdler, Curtin Uni	REGISTER	2022
10	23 Jun	Project Management	tba	REGISTER	2022
11	30 Jun	Sample Size Calculations	Michael Dymock, TKI	REGISTER	2022
12	21 Jul	Consumer & Community Involvement in Research	Belinda Frank, TKI	REGISTER	2022
13	28 Jul	Data Collection and Management	tba	REGISTER	2022
14	4 Aug	Rapid Critical Appraisal of Scientific Literature	Dr Natalie Strobel, Curtin Uni	REGISTER	2022
15	18 Aug	Media and Communications in Research	tba	REGISTER	2022
16	25 Aug	Oral Presentation of Research Results	Dr Jane Mugure Githae, CAHS	REGISTER	2022
17	1 Sep	Involving Aboriginal Communities in Research	Cheryl Bridge, Mara West and Mel Robinson – TKI and CAHS	REGISTER	2022
18	8 Sep	Knowledge Translation	A/Prof Fenella Gill, Curtin Uni/CAHS	REGISTER	2021
19	22 Sep	Research Impact	Dr Tamika Heiden, Vic (tbc)	REGISTER	2022
20	20 Oct	Grant Applications and Finding Funding	Dr Tegan McNab, TKI	REGISTER	2022
21	27 Oct	Statistical Tips for Interpreting Scientific Claims	Michael Dymock, TKI	REGISTER	2022
22	03 Nov	Research Governance	tba	REGISTER	2022
23	17 Nov	Ethics Processes for Clinical Research in WA	tba	REGISTER	2020
24	24 Nov	Qualitative Research Methods	Dr Shirley McGough, Curtin Uni	REGISTER	2022
25	1 Dec	Innovation and Commercialisation	Helga Mikkelsen/Ashley Schoof TKI	REGISTER	2022

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CAHS Research Education Program

2023 REDCap Workshop Series



The Research Education Program - supported by the Perth Children's Hospital Foundation and the Telethon Kids Institute - offers a series of hands-on workshops that focus on the most integral features of REDCap and its application to your research project data. Workshops aim to directly build user skills in a guided environment, with time to ask questions and work on your own project. Dates below are now confirmed - registrations will open in 2023.

Presented by: Research Education Program Research Fellow Dr Jane Mugure Githae

Location: PCH, TKI Seminar Room, Level 5 (West). ONLINE option may also be available.




Topic	Day	Date	Time	Max No (inperson)
Workshop 1 – Basic Walkthrough	Tuesday	31 January	1:00pm to 3:30pm	40 Register
Workshop 2 – Intermediate Walkthrough	Tuesday	21 Feb	1:00pm to 3:30pm	40 Register
Workshop 3 – Advanced REDCap - Creating Surveys	Tuesday	28 March	1:00pm to 3:30pm	40 Register
Workshop 4 – Basic Walkthrough	Tuesday	2 May	1:00pm to 3:30pm	40 Register
Workshop 5 – Intermediate Walkthrough	Tuesday	6 June	1:00pm to 3:30pm	40 Register
Workshop 6 – Advanced REDCap - Creating Surveys	Tuesday	27 June	1:00pm to 3:30pm	40 Register
Workshop 7 – Basic Walkthrough	Tuesday	1 August	1:00pm to 3:30pm	40 Register
Workshop 8 – Intermediate Walkthrough	Tuesday	29 August	1:00pm to 3:30pm	40 Register
Workshop 9 – Advanced REDCap - Creating Surveys	Tuesday	19 Sep	1:00pm to 3:30pm	40 Register


IMPORTANT

Attendance is open to all Department of Health and Telethon Kids Institute staff.

Places are strictly limited and offered on a first-come, first-serve, basis. If you are not able to attend a workshop for which you have registered, please contact Research Education Program support via phone or email to cancel your reservation and/or be placed in another workshop or on the waitlist.

 Click here to
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CAHS Research Education Program

2023 REDCap Workshop Series

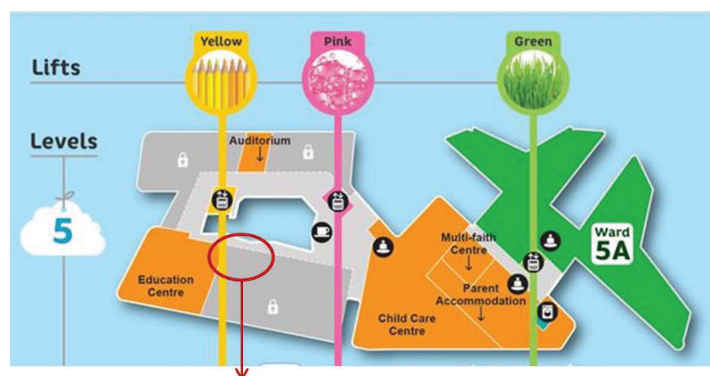
REDCap Workshop 1: Basic Walkthrough

31st January 2023 • **1.30 - 3.30pm** • **PCH, TKI Level 5 Seminar Room**

Workshops aim to directly build user skills in a guided environment, with time to ask questions and work on your own project.

This workshop offers an introduction to building databases in REDCap and covers basic concepts and best practices to equip researchers in building a database for their research project.

Workshop 1 is most useful to anyone building a new project in REDCap and those who have been tasked with managing an existing database.



Location of the TKI Seminar Room

Accessible via yellow or pink lifts

About the Presenter

Dr Jane Mugure Githae
REP Research Fellow



Mugure joins us from Kenya where she practiced as a General Surgeon & Honorary Lecturer in General Surgery. She has experience in clinical research, clinical audits and medical education. She is keen to simplify the process of integrating day-to-day clinical work with research.



Register via Eventbrite

View our online REDCap resources

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Places are strictly limited and offered on a first-come, first-serve basis. If you are unable to attend a workshop for which you have registered, please contact Research Education Program support via email to cancel your booking and/or be placed in another workshop or on the waitlist.

Laptops are available if required

Contact Us



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REDCap Workshops are presented by the Research Education Program in partnership and with support from the PCH Foundation and Telethon Kids Institute as part of the Research Education Program REDCap Workshop Series, presented by the CAHS Department of Research, WA Department of Health.





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Research Skills Seminar Series

A free, open-access resource designed to upskill busy clinical staff and students and improve research quality and impact.

Innovation and Commercialisation

Thank you for your interest in this seminar

Please complete this 1-minute evaluation.

Your feedback will help guide future presentations and educational activities.

How did you attend the seminar?

- ☐ Live seminar at Perth Children's Hospital
- ☐ Hosted video-conference on-site (e.g. FSH, Lions Eye, RPH etc.)
- ☐ Online via Avaya or Teams
- ☐ Viewed online recording

Please rate your agreement with the following statements:

	N/A	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
The aims and objectives were clear	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The session was well structured	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Presentation style retained my interest	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The speaker communicated clearly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The material extended my knowledge	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The additional resources were helpful	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

What were the best aspects of the seminar?

What changes or improvements would you suggest?

How did you hear about the seminar?

(you can select multiple answer)

- ☐ Email invitation from Research Education Program
- ☐ CAHS Newsletters e.g. The Headlines, The View, CAHS Research Newsletter
- ☐ "Health Happenings" E-News
- ☐ Healthpoint Intranet Upcoming Events
- ☐ Collegiate lounge screen or other posted promotional material
- ☐ Telethon Kids Institute screen or other posted promotional material
- ☐ Telethon Kids Institute Newsletter
- ☐ Other

Thank you!



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Healthy kids, healthy communities

Compassion

Excellence

Collaboration

Accountability

Equity

Respect

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