IP28 Innovate or Continuously Be Outdated: The Need for a ‘Living’ Approach to HTAs

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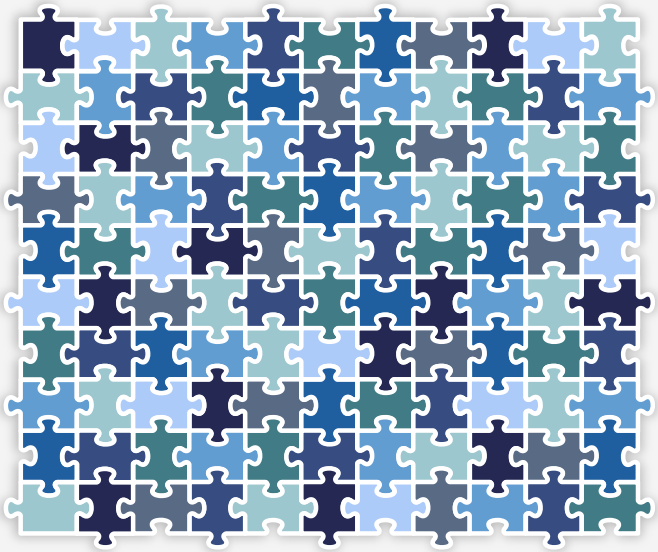


Recognised Challenges of the Current HTA Ecosystem

- Missed opportunities for healthcare system efficiencies by utilising the fast-evolving, technological advances in evidence identification, generation and economic modelling
- Coverage with evidence development only addresses this issue with single re-assessment of technologies.
- Static (single) technologies assessment ignores the increasing volume of rapidly produced evidence from different sources.
- Increased public pressure for early patient access of promising technologies
- For new technologies, decisions are often made by outdated evidence whereas there are no opportunities for disinvestment of existing technologies in the market which don't produce the promising benefit at launch.

Moving from a Static HTA To a Dynamic Living HTA Process

Static, single timepoint assessment

Costs to healthcare systems/providers, wider societal impact

Clinical (and economic) value to patients, caregivers

Dynamic, real-time LiveHTA process

Initial HTA

Price renegotiations, disinvestment decisions

Living approach to market access arrangements

Living evidence reviews

Resolution of uncertainty

Incorporating new evidence (RWE, RCT) as it becomes available

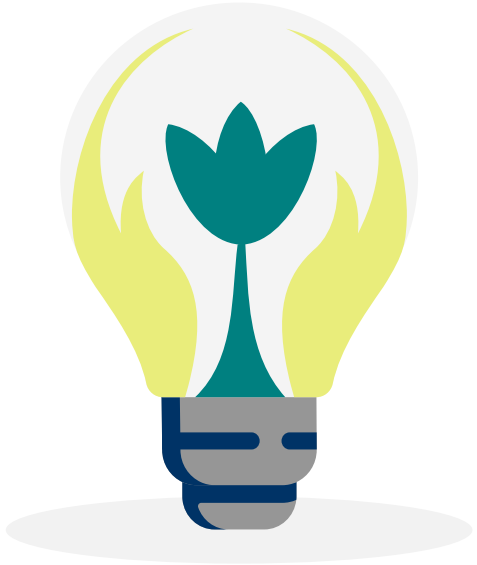
From both technology under assessment and comparators

Considering changes in care pathway

Mitigate model uncertainties with new evidence signals

Regular update of clinical and cost-comparative effectiveness analyses

‘Living’ HTA can provide the setting to maintain continuous, cost-effective clinical practice by rapidly disinvesting in technologies that have not maintained their reimbursement value in light of new evidence.



Panel discussion

Innovate or Continuously Be Outdated: The Need for a 'Living' Approach to HTAs

Moderator

Grammati Sarri, PhD
Head of RWAA External Research Partnerships/ Senior Research Principal, Cytel

Speaker 1

Seye Abogunrin, MBBS, MPH, MSc
F. Hoffmann-La Roche

Speaker 2

Gaugarin Oliver, MSc
CapeStart

Speaker 3

Saskia Cheyne, MSc
Australian Living Evidence Consortium

Cytel Roche capestart your dev & data partner AUSTRALIAN LIVING EVIDENCE CONSORTIUM Cochrane Australia

Polling question 1

Considering the current healthcare system, what would be the strongest driver to push for HTAs moving toward a 'living' approach?

(Please select the most important)

A.	Need for wider evidentiary base to resolve uncertainties in clinical and cost-effectiveness estimates	**C.**	Need for overburdened healthcare systems to identify ways to make efficiencies in spending
B.	HTA decision-making closer to regulatory submissions so that there is not enough time to generate robust evidence for reimbursement technology assessments	**D.**	Need for more transparent pricing negotiations

Polling question 2

How likely is it that decision-makers will incorporate the use of technological tools to support a 'living' HTA process within the next five years?

(Please select one)

A. Unlikely, due to resistance of decision-makers to automated, online tools and completely restructure of their process

B. Maybe, depending on the development of international methodological standards on automation in decision-making

C. Very likely, as there will be no other way to disinvest technologies that are not maintaining their value for money

D. Depends on the country, HTA body

Polling question 3

What are the main obstacles toward implementation of a 'living' HTA?

(Please select more than one as you feel appropriate)

A. Resistance to change by different stakeholders (e.g., HTA bodies, industry, patients)

B. Lack of understanding of how this new approach can fit with the increasing number of technologies entering the market

C. Issues around data sharing, validation of online tools and platforms

D. Difficult decisions for patients and caregivers around disinvestment of technologies already in the market

Panel discussion

Speaker 1

Seye Abogunrin, MBBS, MPH, MSc
F. Hoffmann-La Roche

What is the industry perspective to the new paradigm of ‘living HTAs’?

Is it really a viable solution to efficiently respond to the rapidly evolving and complex treatment and evidence landscape?

Innovate or Continuously be Outdated: The Need for a “Living” Approach to HTAs

Industry perspective to the new paradigm of “Living” HTAs

Dr. Seye Abogunrin, MB BS, MPH, MSc
Global Access Evidence Leader

9 November 2022 | For external use

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Background and challenge *1/2*

01

Evidence base of data needed for healthcare decision-making continues to grow

- There is an increase in the number of health technologies being investigated, largely driven by medical advancement
- Approximately 20,000 studies are active on clinicaltrials.gov with another 68,000 recruiting or enrolling by invitation
- It also takes a relatively long time for many biotechnology/pharmaceutical companies to move from data read out to reimbursement approval in many countries.

02

Rapidly evolving and complex treatment and evidence landscape

- Uncertainty as to whether the correct comparators and most up to date evidence is considered when defining clinical practice.
- Lack of standardization of processes and final documentation which prevents reuse of information.

03

Recency of the evidence included in payer submissions is important

- Often required to be 3 to 6 months old

Background and challenge *2/2*

04

Need for adaptability

- Current approaches and methodologies for reassessment or updates to previous assessments may be unsuitable in the face of increasing costs as several governments continue to seek ways to decrease the cost of treating patients.

05

Quicker access to more effective technologies

- These challenges are increasingly problematic in the context of a general drive for faster patient access to effective health technologies especially in patient populations with significant unmet needs when new technologies are often assessed based on an immature and highly uncertain evidence base.

Overview of effort required by HEOR researchers to prepare HTA documentation

- HEOR work is dependent on a lot of factors.
  - Single assessments are easier in the short term but as more and more interventions are investigated and approved, it becomes tougher to update HTA assessments for multiple assessments.
  - Work is often done at risk in anticipation of a positive trial readout and if negative results in wasted efforts
- Table shows some of the most time consuming activities when generating evidence for an HTA submission.

HTA Deliverables	Duration
Systematic literature review	6 months to 24 months
Indirect treatment comparison*	3 months to 6 months
Economic evaluation^	6 months to 12 months
Value dossiers/payer submission summaries	6 months to 12 months

HEOR: health economics and outcomes research; HTA: health technology assessment; * Not always necessary; ^Cost-effectiveness analysis (including cost-utility analysis), cost-minimisation analysis, cost-benefit analysis.

How can “Living” HTAs make the existing process more efficient?

Faster generation of insights to inform early decision making

Conversion of the 'wasted generated evidence' into reusable scientific evidence

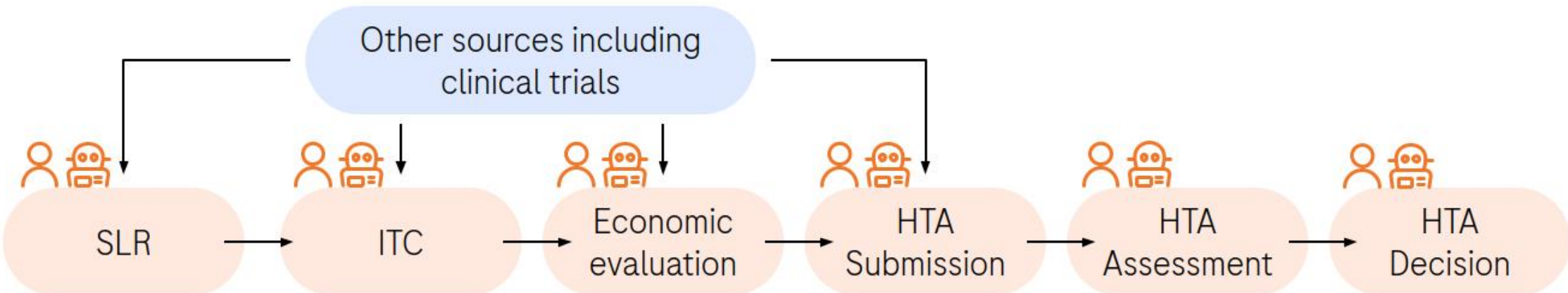
Provision of transparent, consistent and FAIR information

Fit for purpose HTA decisions

FAIR: findable, accessible, interoperable and reusable; HTA: health technology assessment

What could a potential approach look like?

It is debatable as to whether these processes should all be integrated or not, and how they should be if they should be. Whatever the case, an integrated approach of some sort is required.



HTA: health technology assessment; ITC: indirect treatment comparison; SLR: systematic literature review

Potential factors that can influence the “Living” HTA process *1/2*

01 Transparency and data sharing

- Transparency with the availability of data from these deliverables
- Consider best practices for sharing data and develop data-sharing agreements for all of these activities which can enable transparency of the data used in these projects.
- Standard is to provide a summary of the data without the provision of the actual datasets or models

02 Standardization and accuracy

- Accuracy and timing of the data and the information provided for such if there are multiple collaborators
- Standardization of the data, FAIR Transparent, reusable and standardized process.

03 Cross-industry collaboration

- Synergy across the industry will be important
- A single application where individual company data connected to each other may solve this problem but the true value lies in being able to share information that will enable reuse and easy update of the data.

Potential factors that can influence the “Living” HTA process *2/2*

04 Updates

- Frequency of conducting the assessments - real time or using other timing, and triggers
- Automatic update with the latest treatments

05 Data governance process

- Who owns the data?
- Management of the solution, if is technologically driven

06 Uncertainty on how to approach the solution

- Unknown terrain
- Practicality of navigating this approach.

Thank You

Seye Abogunrin

 seye.abogunrin@roche.com

Doing now what patients need next

Panel discussion

Speaker 2

Gaugarin Oliver, MSc
CapeStart

How can automated software companies and industry facilitate transparency and acceptance in the use of technology in the ‘living HTA’ approach?

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CAPESTART OVERVIEW

PharmaNLP

Platform for SLR &
other Natural Language Processing Pharma Tasks

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AI & Living HTA? NLP-aided Living SLR

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PHASE 1: PLAN REVIEW

Specify Research Questions

Develop Review Protocol

Validate Review Protocol

PHASE 2: CONDUCT REVIEW

NLP based Screening & Data Extraction

Develop Search Strategy

Define Inclusion & Exclusion Criteria

Studies

Remove Duplicates

Title & Abstract Screening

Full Text Screening

Data Extraction

Relevant Studies

PHASE 3: META - ANALYSIS

Calculation of Effect Sizes & Outcome Measures

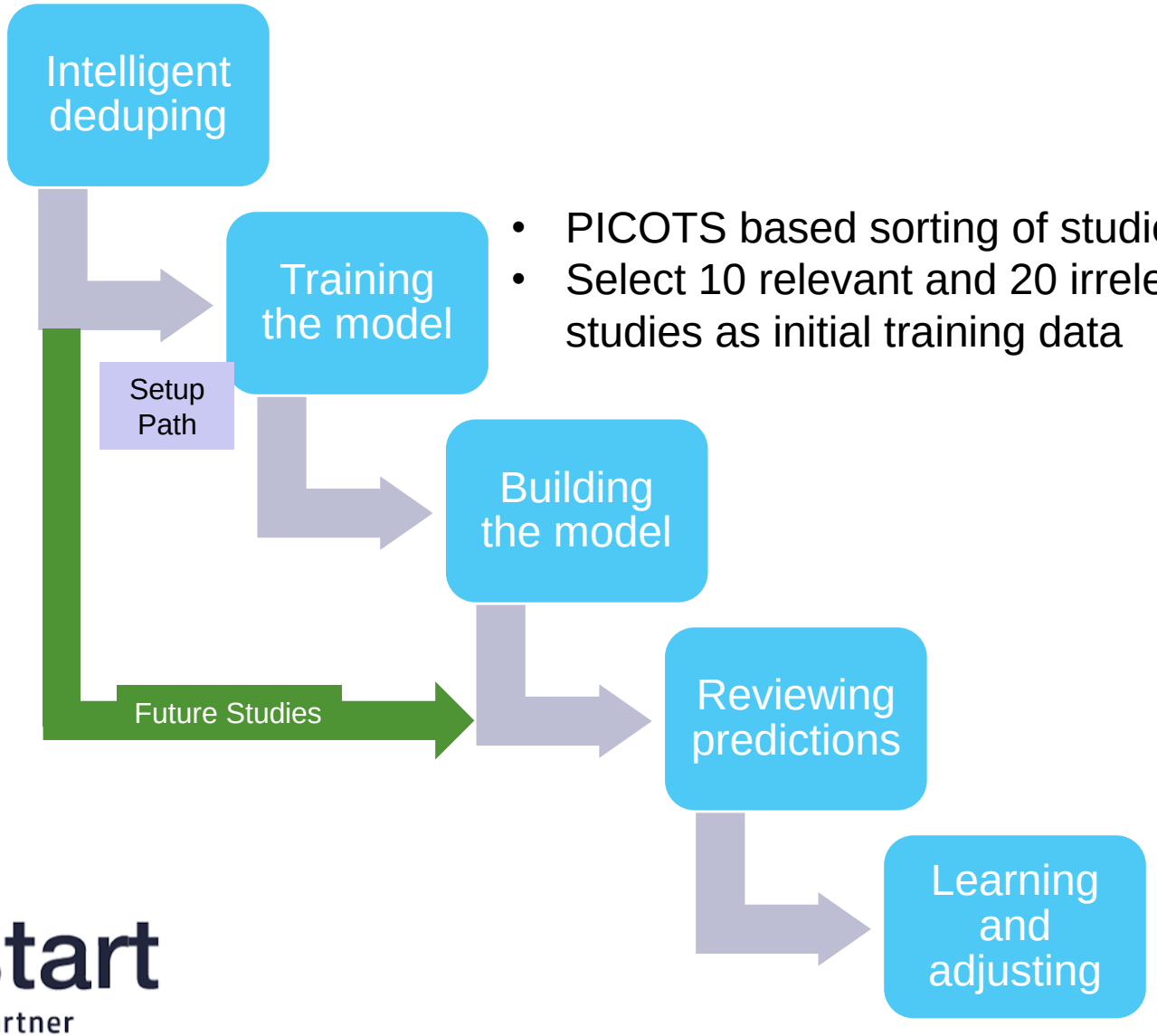
Representing the results in plots and figures

PHASE 4: REPORT GENERATION

Quality Assessment

Structure evidence and draw conclusions

An Example- Living Title & Abstract Screening Process



- PICOTS based sorting of studies
- Select 10 relevant and 20 irrelevant studies as initial training data

Significant Time Savings

No ML Engineer or Data Scientist Required

Consistent, Quick, Repeatable Process

After reviewing 20% or so of results, high probability that all remaining classifications will be accurate

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Adopting AI - Critical Factors for Success

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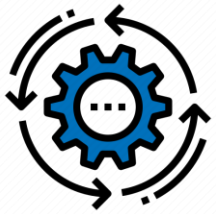
- AI Results are Probabilistic – Accept and plan
- From Data Scientist Language to Simple Terms

- Transparency – Able to export, drill down
- Accountability - Log of factors that lead to decision



- Continuous Learning & Adapting – Retrain with additional data
- Human in the Loop – Supervision and feedback
- Periodic Re-certification of the Models

Panel discussion

Speaker 3

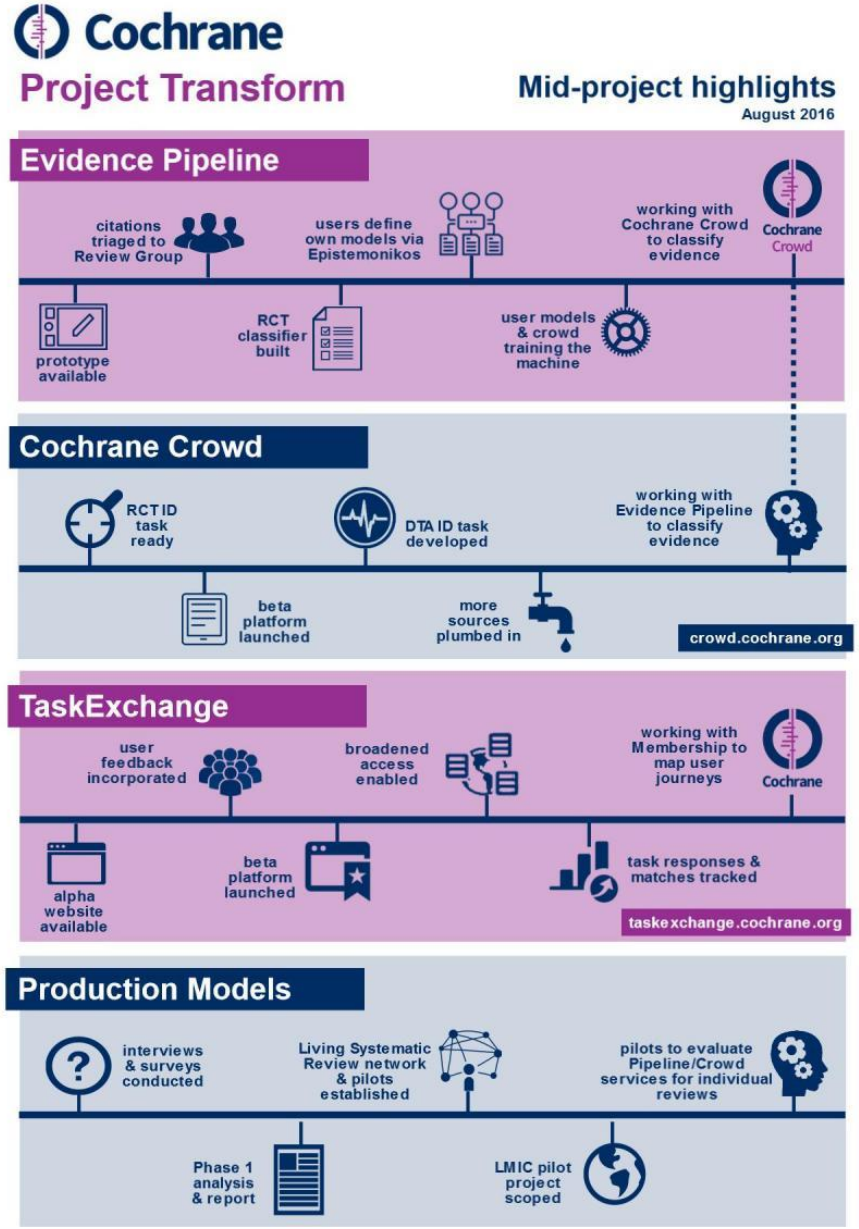
Saskia Cheyne, MSc
Australian Living Evidence Consortium

What is the experience of the Australian Living Evidence Consortium?

How can we establish a set of methodological standards to minimise analytical time to process data, while optimising certainty in decision-making?

2015: It all began with… Project Transform

- Cochrane Game Changer/NHMRC Partnership project led by Cochrane Australia
- Development of data science/machine learning/automation tools and processes for ‘living evidence’
- Citizen science platform for crowd sourcing
- Pilot living systematic reviews



2018: The Australian Living Evidence Consortium was born

Scope expansion of Project Transform into living guidelines

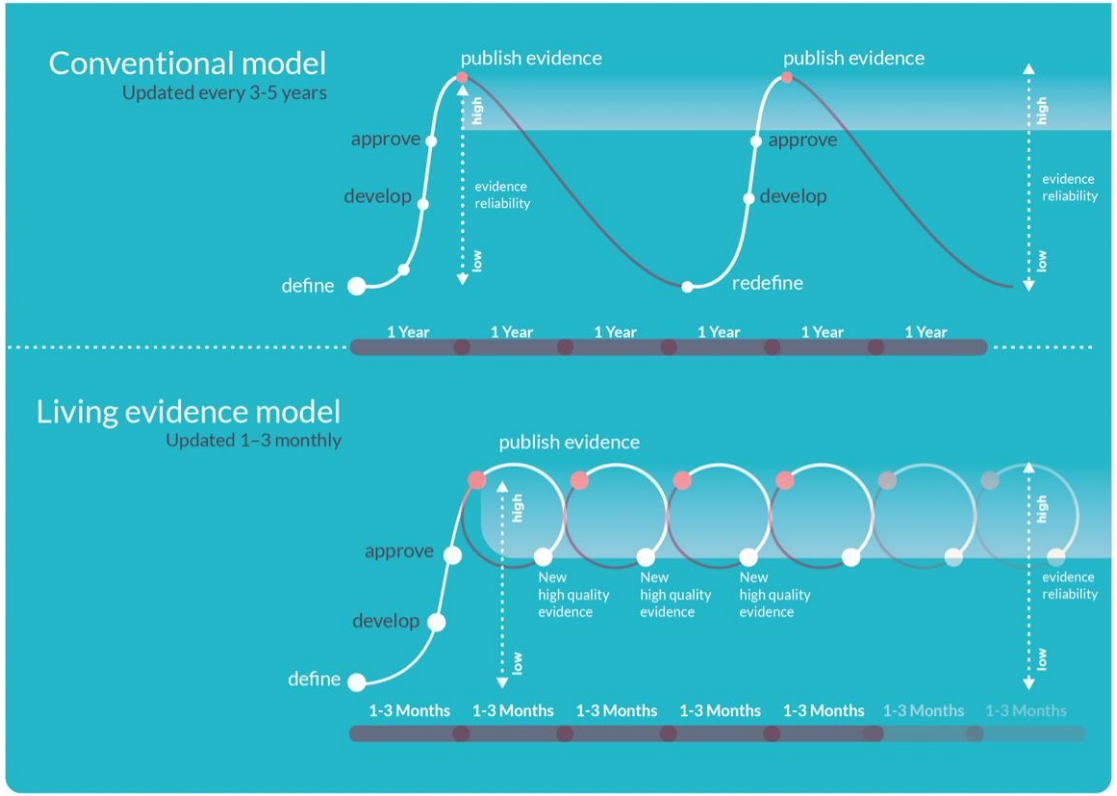
- 2018: the world's first living guidelines on Stroke
- Later living guidelines focused on diabetes, heart disease, and musculoskeletal conditions

Pillar 1: Establishing a National Living Evidence Support Hub

Pillar 2: Building a Living Evidence Digital Technologies Platform

Pillar 3: Producing Living Guideline Recommendations

Pillar 4: Getting the latest evidence to where it's needed



AUSTRALIAN LIVING EVIDENCE CONSORTIUM

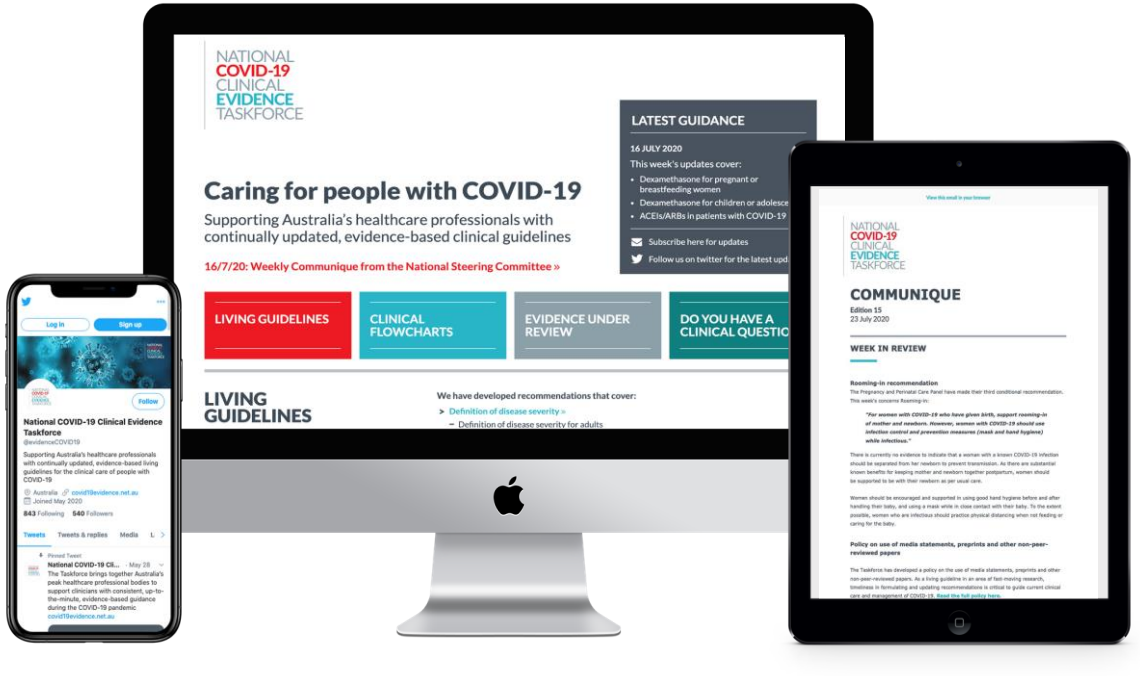
Cochrane Australia · Stroke Foundation · ads Australian Diabetes Society · Heart Foundation · Kidney Health Australia · KHA-CARI Guidelines · CARI Guidelines

Australasian Paediatric Endocrine Group · diabetes australia · ADEA · ANZSN · ANZMUSC · Arthritis Australia · Cancer Council Australia

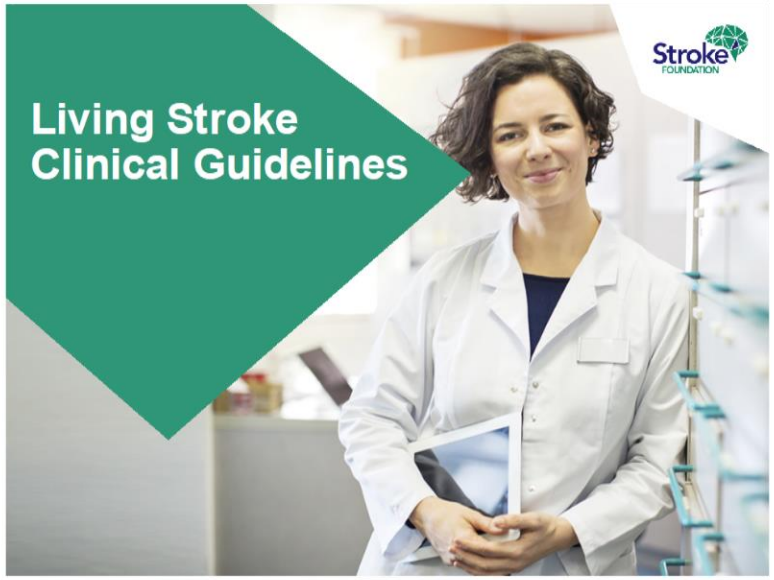
2020: Australian Living Guidelines for care of people with COVID-19

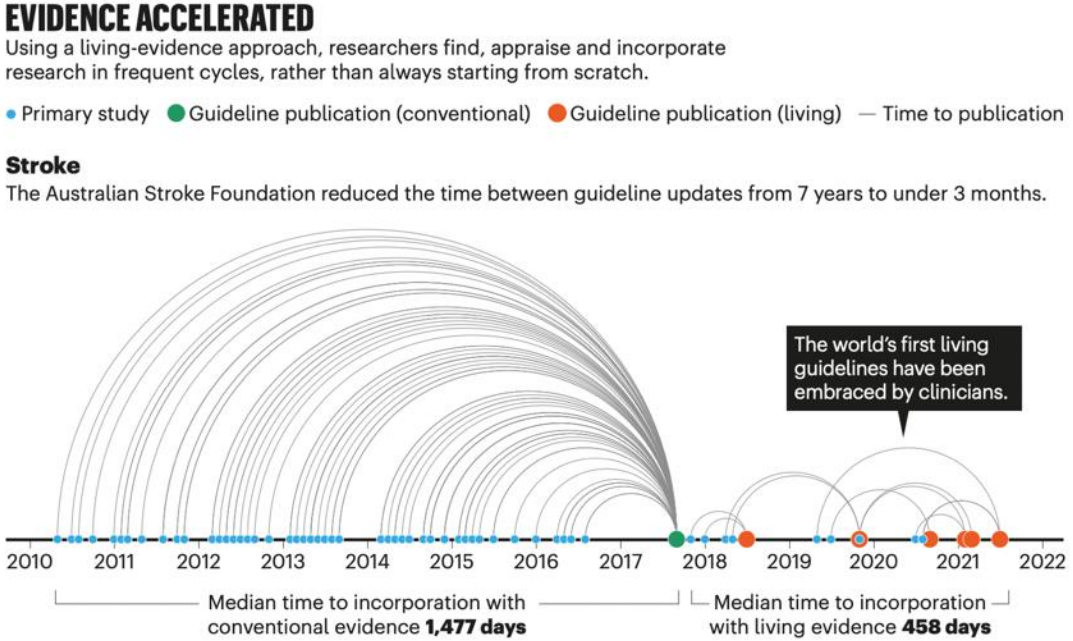
NATIONAL COVID-19 CLINICAL EVIDENCE TASKFORCE

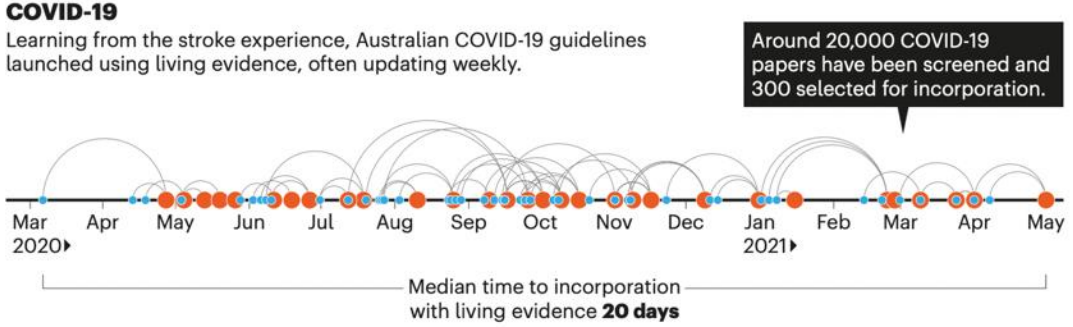
- Literature searches for any treatment for COVID-19 [Daily]
- Publications screened using Covidence, included studies appraised, Evidence Profile and Summary of Findings tables developed or added to using MAGICapp [Weekly]
- Guideline Panels consider new evidence and draft guidance – recommendations and Flowcharts [as required]
- Contains over 180 recommendations
- Has been updated more than 100 times.



Phase 1: World's first living guidelines in stroke & COVID-19 led to 99% reduction in time from research to point-of-care





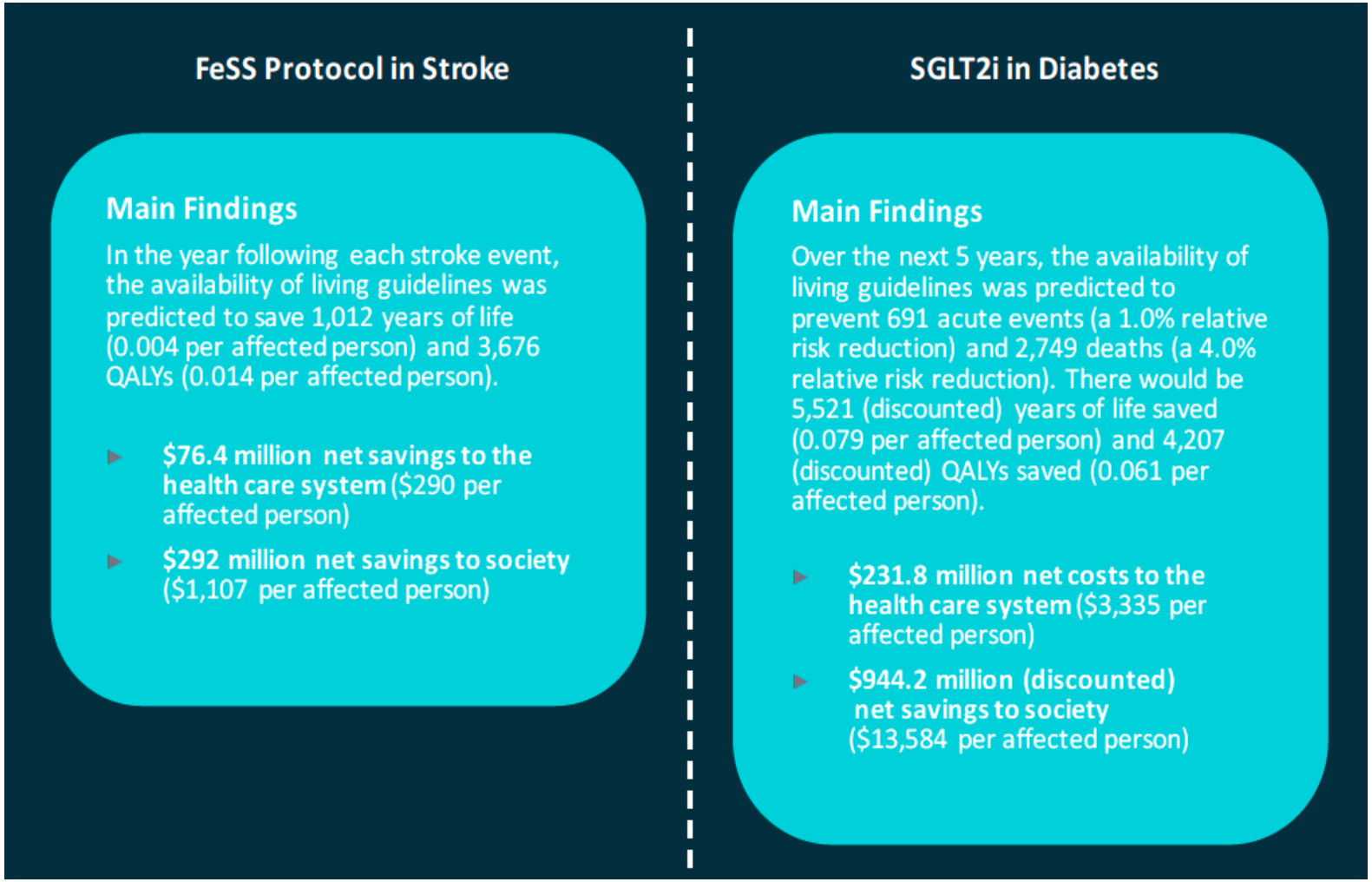


Elliott JH, Lawrence R, Minx JC, et al. Decision makers need constantly updated evidence synthesis. Nature 2021;600:383-385

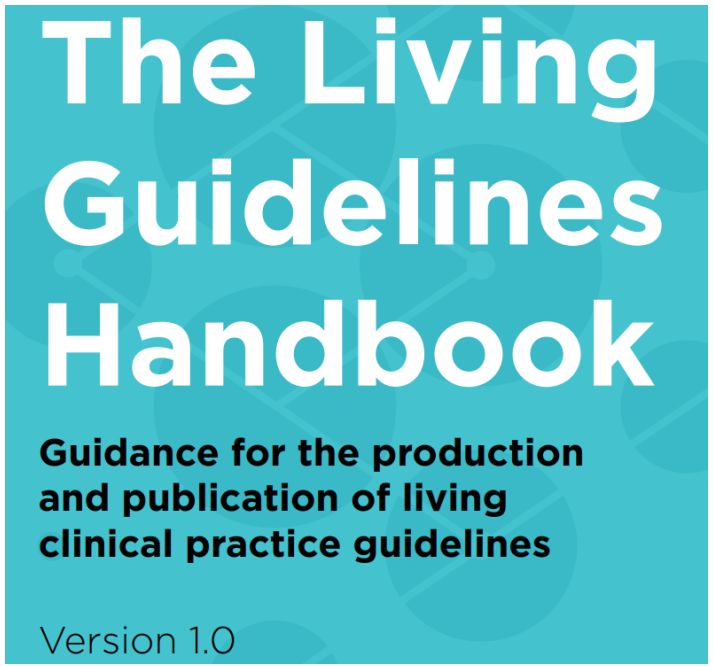
Economic modelling estimated net societal benefit of $1.2B from living guideline recommendations in just two topics

- Economic model evaluating the potential impact of living versus conventional updating of guidelines after publication of practice-changing evidence

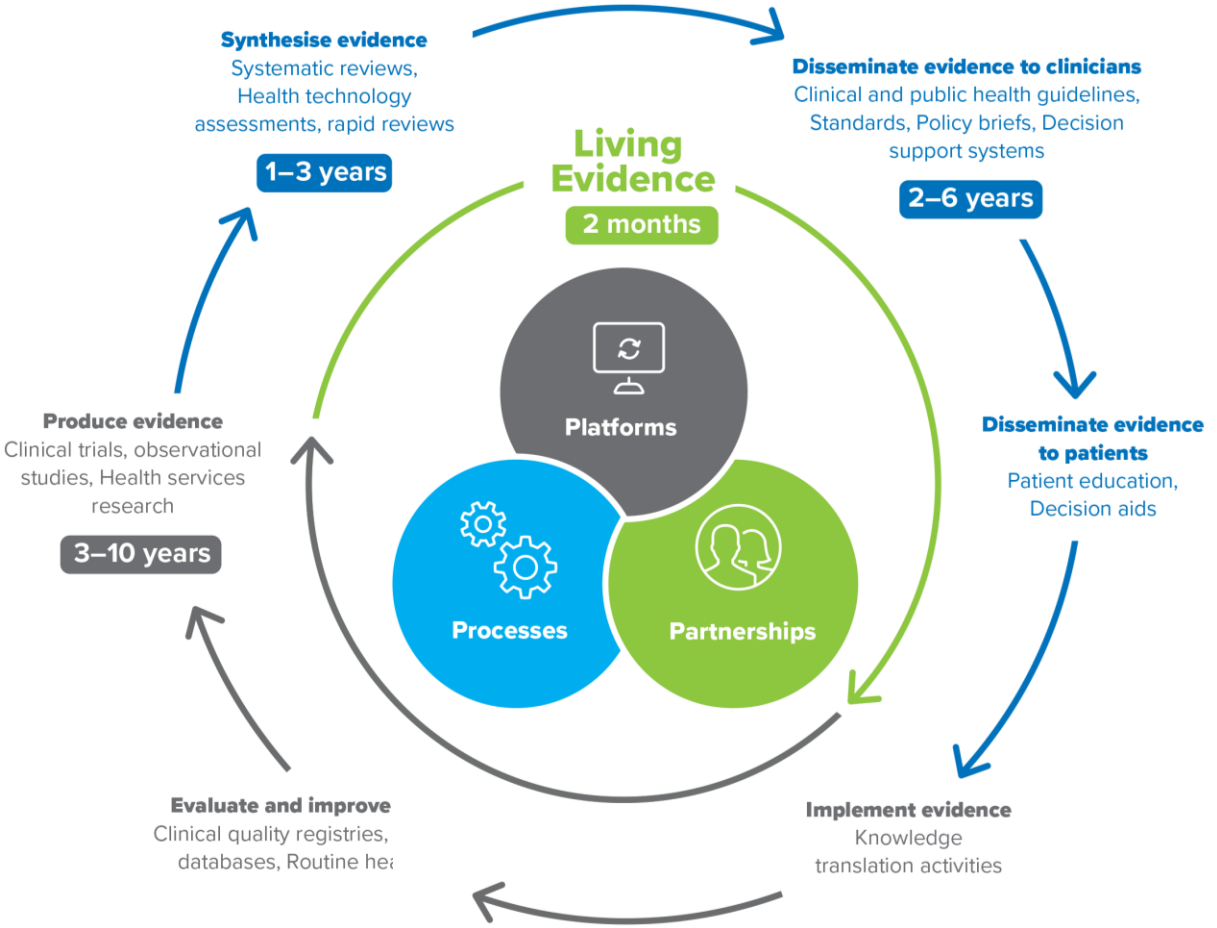
- Two case studies were used:
  - The FeSS Protocol: a nurse-led intervention for managing fever, high blood sugar and swallowing after stroke
  - SGLT2 inhibitors: addition of a new drug class to standard care for people with type 2 diabetes and cardiovascular disease



The Australian Living Evidence Consortium uses innovative novel technologies, methods development, processes and partnerships



Available at: https://livingevidence.org.au/key-publications



Thank you!