



Company Update – June 2020
Michael Winlo – MD & CEO

Evidence Generating Care
www.emeraldclinics.com.au

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Presentation release authorised by Michael Winlo, CEO and Managing Director

Emerald | Real-world clinical evidence

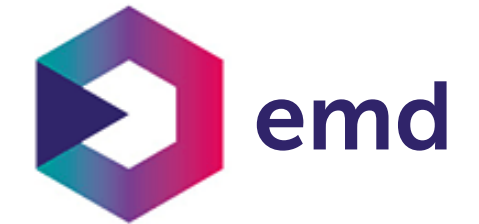
Emerald is a team of **medical doctors**, clinical researchers and **data scientists**.

We provide data-driven patient care across our network of clinics.

We develop digital health technologies that help generate accurate and actionable clinical evidence.

Our goal is to translate real-world patient experiences into evidence-based healthcare and accelerate access to new treatments in a safe, robust and ethical way.

Funding History & Focus



- ▶ Listed on the ASX, 12 February 2020 (ticker: EMD)
- ▶ IPO funding \$6m | Last reported cash position (Q1, 2020): \$5.018M | Market cap: \$9.38M (24 Jun 2020)
- ▶ Milestones since listing:
 - ▶ 1000 + patients to 6 months, commercialised data, completed trials, consulting, extended data platform
- ▶ Primary focus – commercialising **Real World Evidence (RWE)** leveraging our **clinical** and **data** expertise

Real-World Evidence (RWE) is becoming more important in treatment development

April 21, 2020

The surge in FDA approvals supported by RWE: A look at three recent FDA decisions

Christina Purpura
Contributing writer, Aetion



The U.S. Food and Drug Administration (FDA) is approving more drugs with the help of real-world evidence (RWE) than ever before. Between 1995 and 1997, 19.4 percent of the FDA's approvals came from having one adequate and well-controlled study plus confirmatory evidence, such as RWE. Between 2015 and 2017, that figure jumped to 47.2 percent.

Investment highlights



Experienced clinical team delivering a unique care model

Strong patient and referrer demand
Patient-centric, telehealth-supported
Robust, ethically captured clinical evidence

How we create and capture value

Unique treatment insights (what works?, for who?)
Capabilities to support care, trials and data insights

Value of the Emerald data platform and proprietary position

Proprietary platform supports development, validation and commercialisation of new treatments and technologies

Experienced board with medical focus

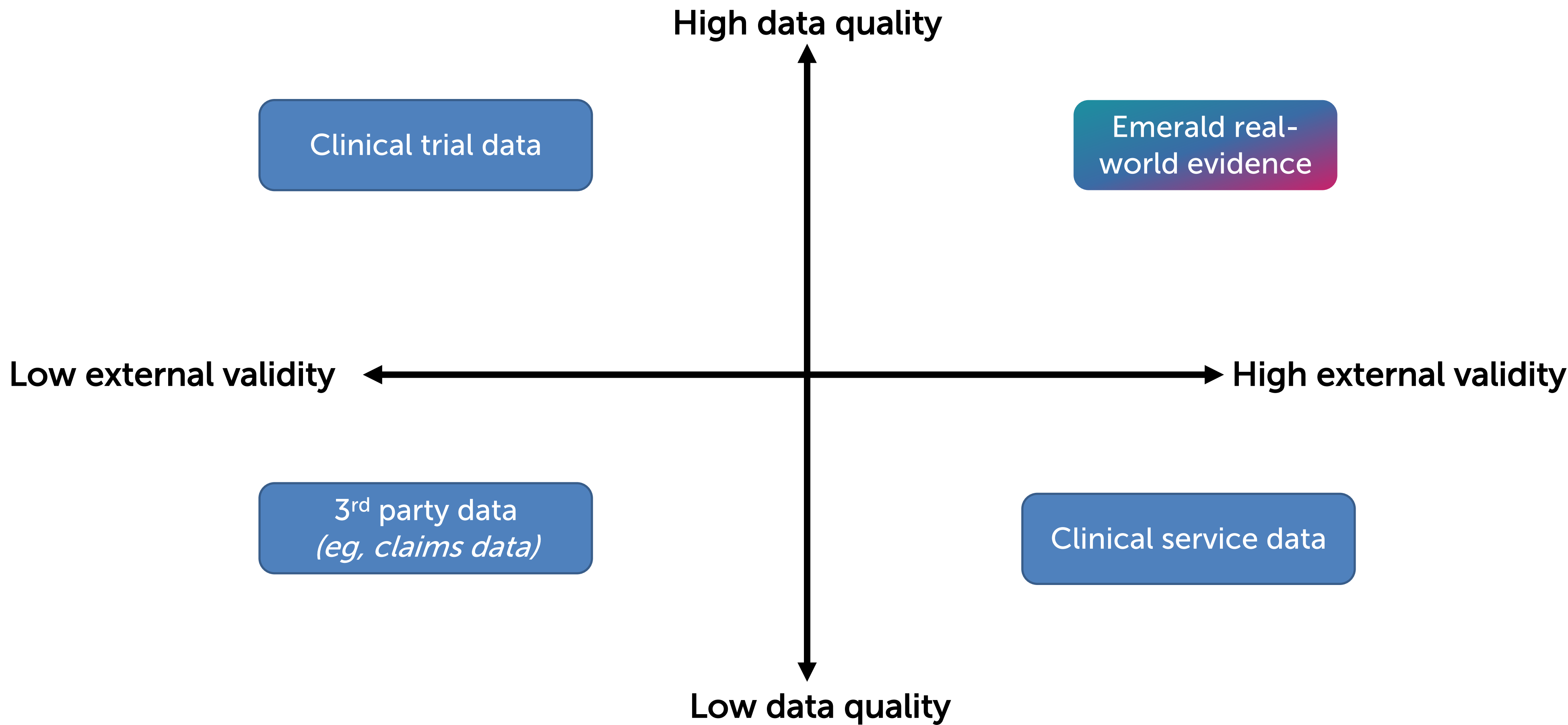
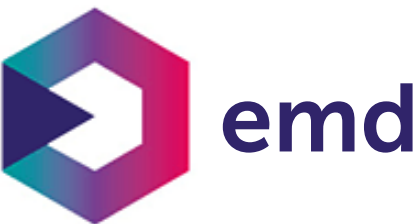


Key Person		Role	Previous Experience
	Dr Stewart Washer	Non-Executive Chairman / Founder	30 years of CEO and Board experience in medical and agrifood biotech companies. Chairman of Orthocell Ltd (ASX:OCC), regenerative medicine company, Founding Chairman and current Director of Cynata Therapeutics Ltd (ASX:CYP) stem cell therapies. Founder of AusCann Ltd (ASX:AC8), medical cannabis manufacturing, Co-founder of Zelda Therapeutics Ltd (ASX:ZLD) medical cannabis clinical studies and research. Stewart has held a number of Board positions in the past, including Chairman of Hatchtech that was sold in 2015 for A\$279m and was a Director of iCeutica Inc. that was sold to a US Pharma. He was also a Senator with Murdoch University and was a Director of AusBiotech Ltd
	Dr Michael Winlo	Chief Executive Officer / Managing Director	Former CEO of rapid growth clinical trial organisation, Linear Clinical Research, serving biotech start-ups through to multinational pharmaceutical companies across the USA, Europe, Japan and China. Previously, Health Lead at Palantir (a Peter Thiel founded company based in Silicon Valley) working on complex data integration and analysis for Fortune 50 companies; as well as the US and UK Governments. Holds multiple patents in data analysis as well as a Bachelor of Medicine and Bachelor of Surgery (MBBS) and an MBA from Stanford University Graduate School of Business. Member of AICD and has completed director's course.
	Dr Alistair Vickery	Chief Medical Officer / Executive Director	Specialist general practitioner with >30 years' experience in general practice. Associate Professor of Primary Health Care at the University of Western Australia and Deputy Chair of the Postgraduate Medical Council of WA and the clinical lead of the research group CHASM (The Collaborative for Health Care Analysis and Statistical Modelling) - providing high-level analysis and statistical modelling to inform clinical service evaluation and planning for WA Health. Chair of Black Swan Health, one of the largest primary health care service providers in WA and Fellow of the Australasian College of Health Service Management and AICD graduate.
	Matt Callahan	Non-Executive Director / Founder	Founder of Botanix Pharmaceuticals (ASX:BOT), iCeutica Inc. and Orthocell (ASX:OCC). Successfully developed 4 products through FDA approval. More than 20 years' legal, intellectual property and investment management experience. Former investment director for 2 venture capital firms in life sciences and was GM and general counsel with technology and licensing company Ipernica Limited, now Nearmap Limited (ASX:NEA), where he was responsible for licensing programs that generated more than \$120M in revenue.
	Professor Sir John Tooke	Independent Non-Executive Director	Senior Independent Director, BUPA Chile, Chair of Collaboration for the Advancement of Sustainable Medical Innovation (CASMI), UCL. Sir Tooke was Head of the School of Life and Medical Sciences at University College London (UCL) as Vice Provost (Health) and Academic Director of UCL Partners. Immediate past President of the Academy of Medical Sciences in the UK where he Chaired a report titled Enhancing the use of scientific evidence to judge the potential benefits and harms of medicine. Previous member of Google DeepMind Health's Independent Review Board. Leading advisor to the UK Government regarding health policy and was knighted in the United Kingdom in the 2007 New Year Honours for Services to Medicine.

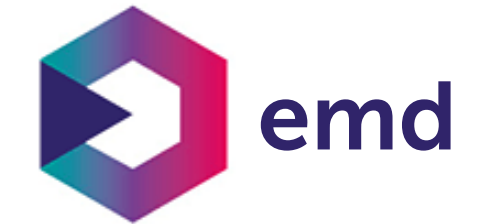
Real-world evidence (RWE):
*Emerald's model generates
valuable clinical evidence
during clinical care*



Sources of clinical evidence



RWE can shorten treatment development times & costs

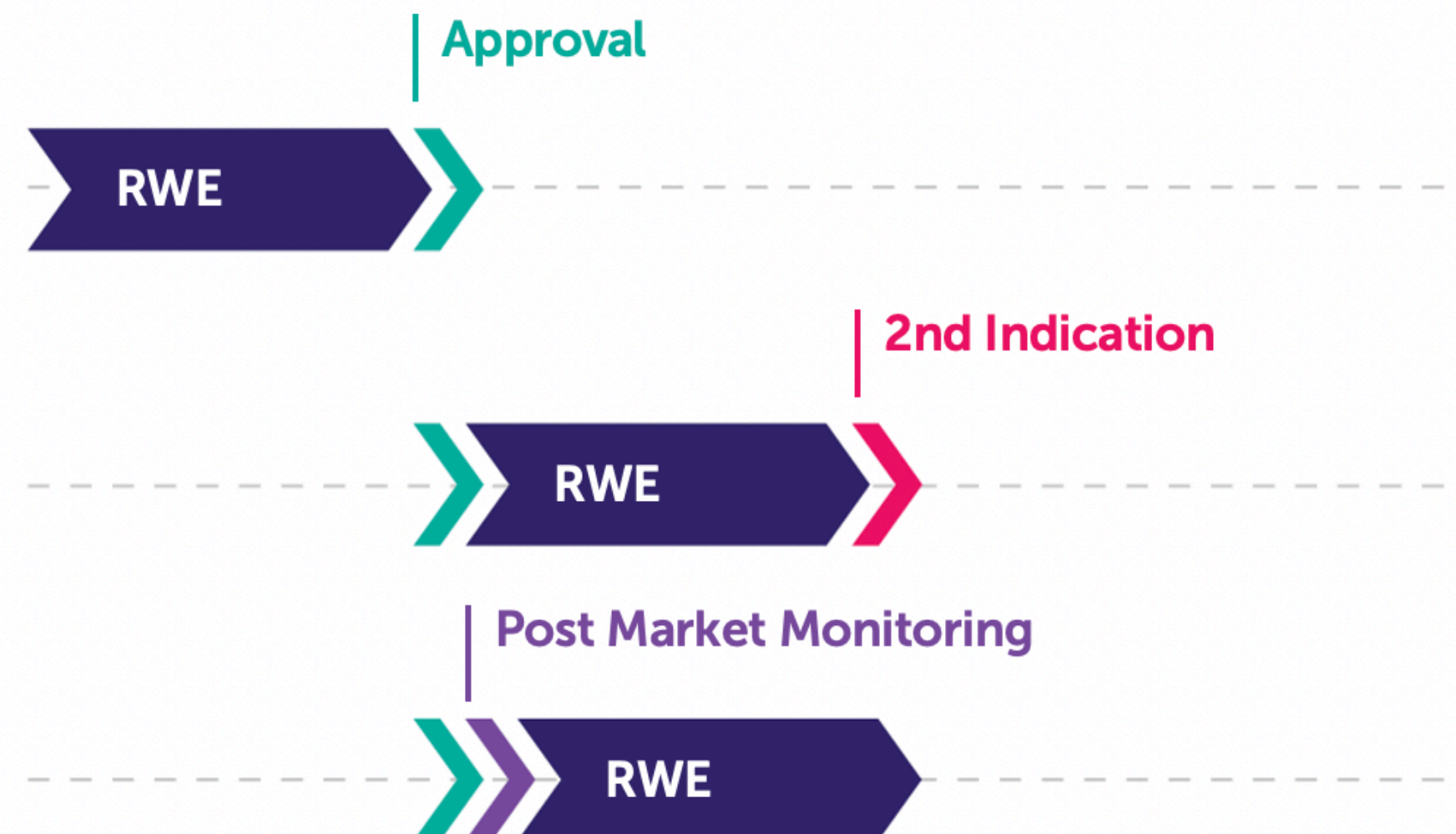


Traditional Model:



Real-World Evidence Model:

- Primary Approvals
 - Faster initial authorisation
- Indication Expansions
 - Rapid indication expansion
- Safety Monitoring
 - RWE supports payer coverage decisions

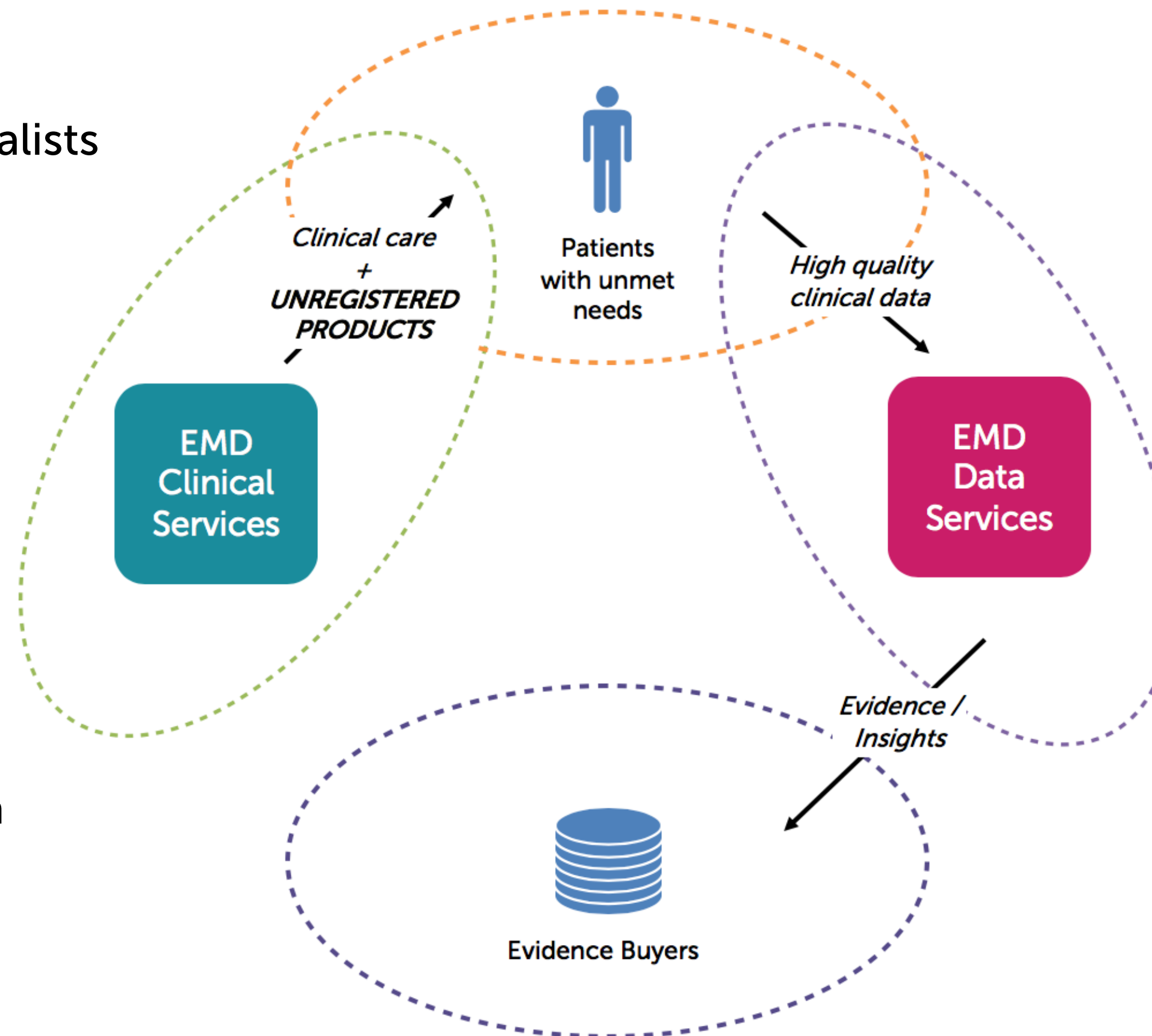


Emerald's Real World Evidence (RWE) care model



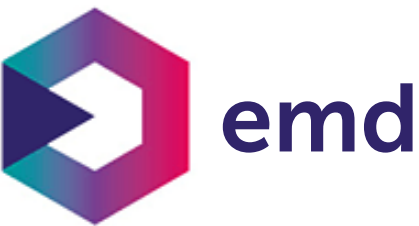
- ▶ 16 GPs and Specialists
(all GCP-trained)

- ▶ 4 locations
around Australia



- ▶ Proprietary data model and system
- ▶ In-house data management, integration & analysis

Emerald revenue streams



1 Clinical care
(patients & health insurers)

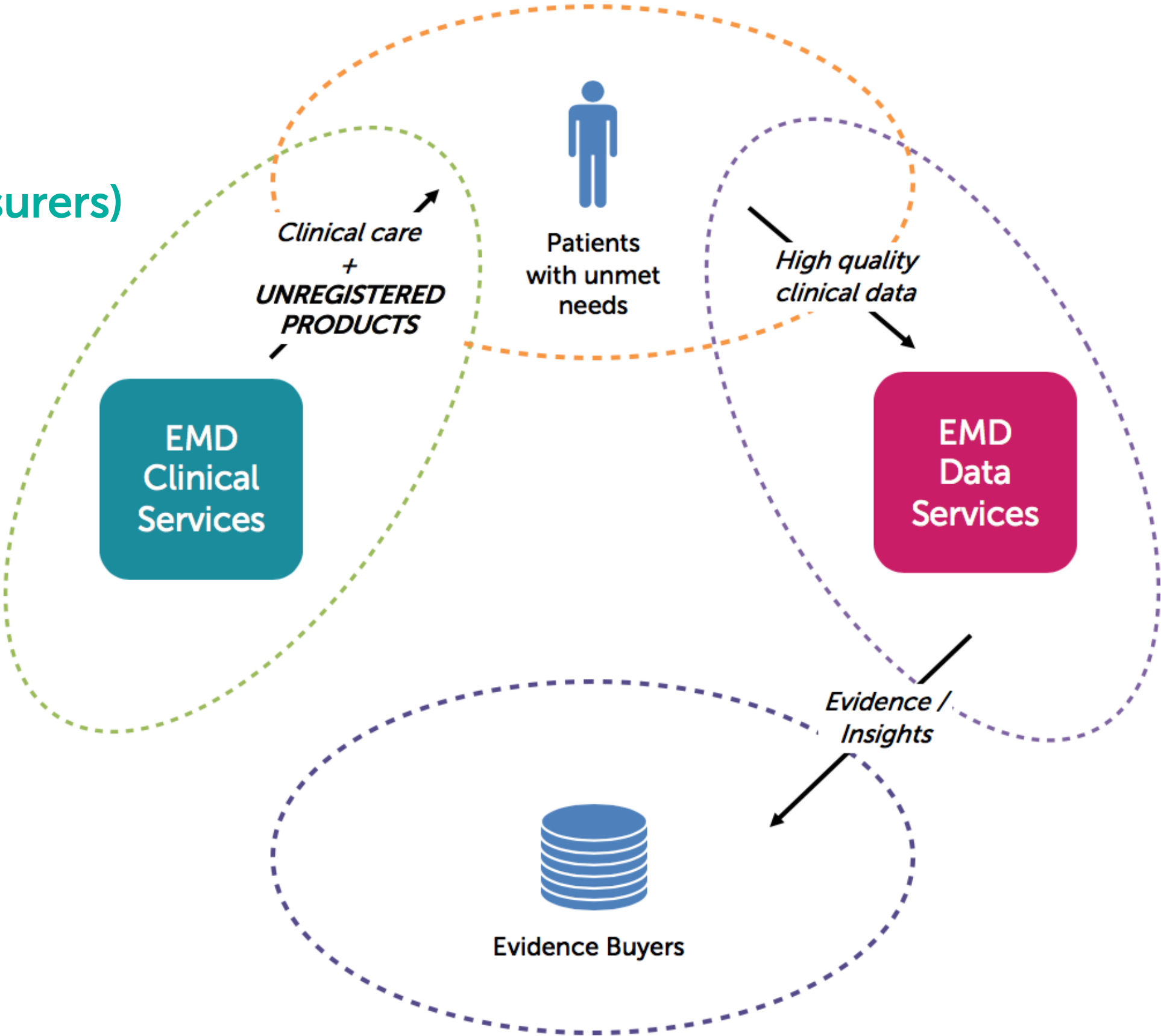
2 Clinical trials



3 Consulting services



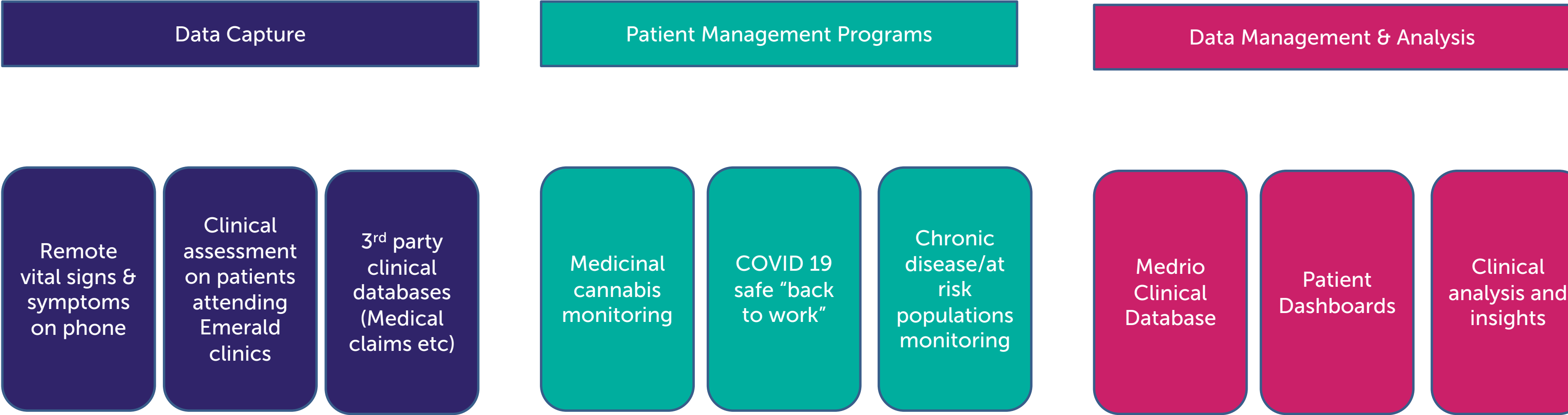
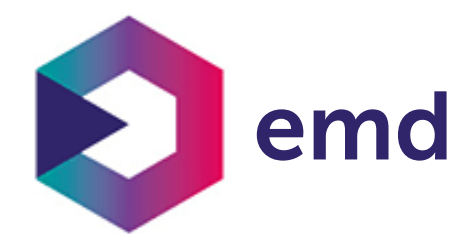
4 MAJOR FOCUS:
RWE insights



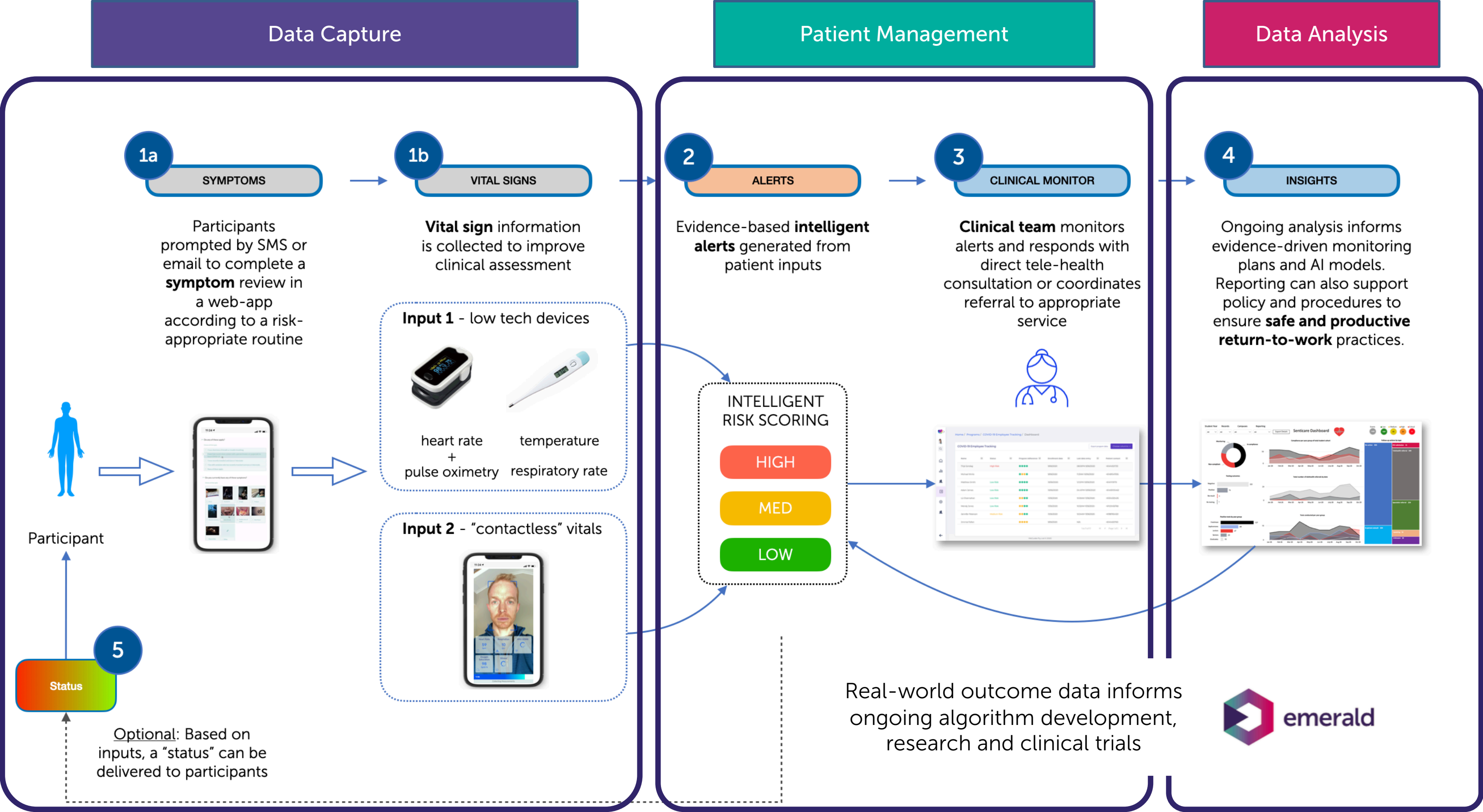
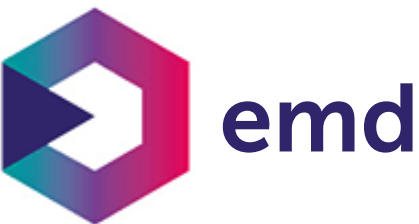
A photograph of three people in a modern office setting. On the left, a man with a beard and glasses, wearing a white shirt and khaki pants, sits in a light green armchair. In the center, a man with short blonde hair, wearing a dark blazer and khaki pants, sits in a similar chair, holding a tablet and looking at it. On the right, a woman with long dark hair and glasses, wearing a black top and dark pants, sits in a third chair, looking towards the man with the tablet. They are all engaged in a discussion. The background features a light-colored wall and a dark wood panel. A small red horizontal bar is visible in the top left corner of the image.

Development pipeline
*Emerald develops digital
health tools that support
RWE generation*

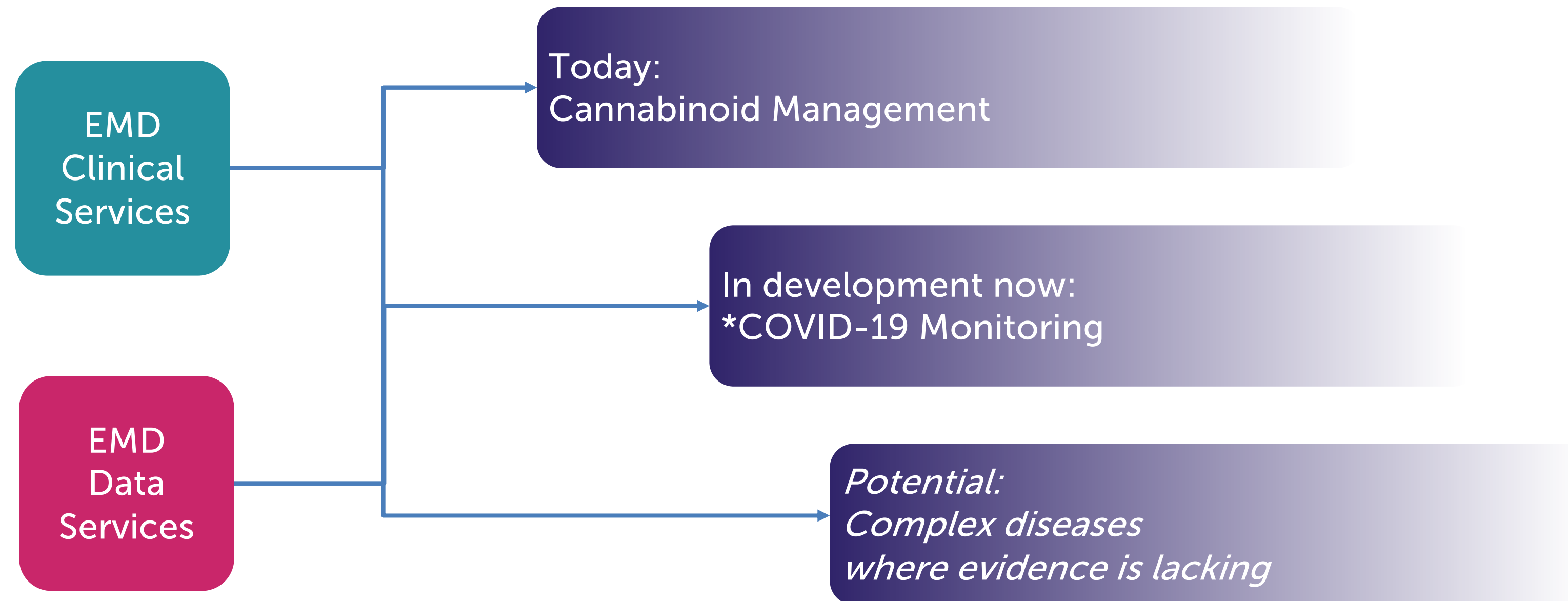
Overview of Emerald's RWE engine



Emerald's RWE architecture

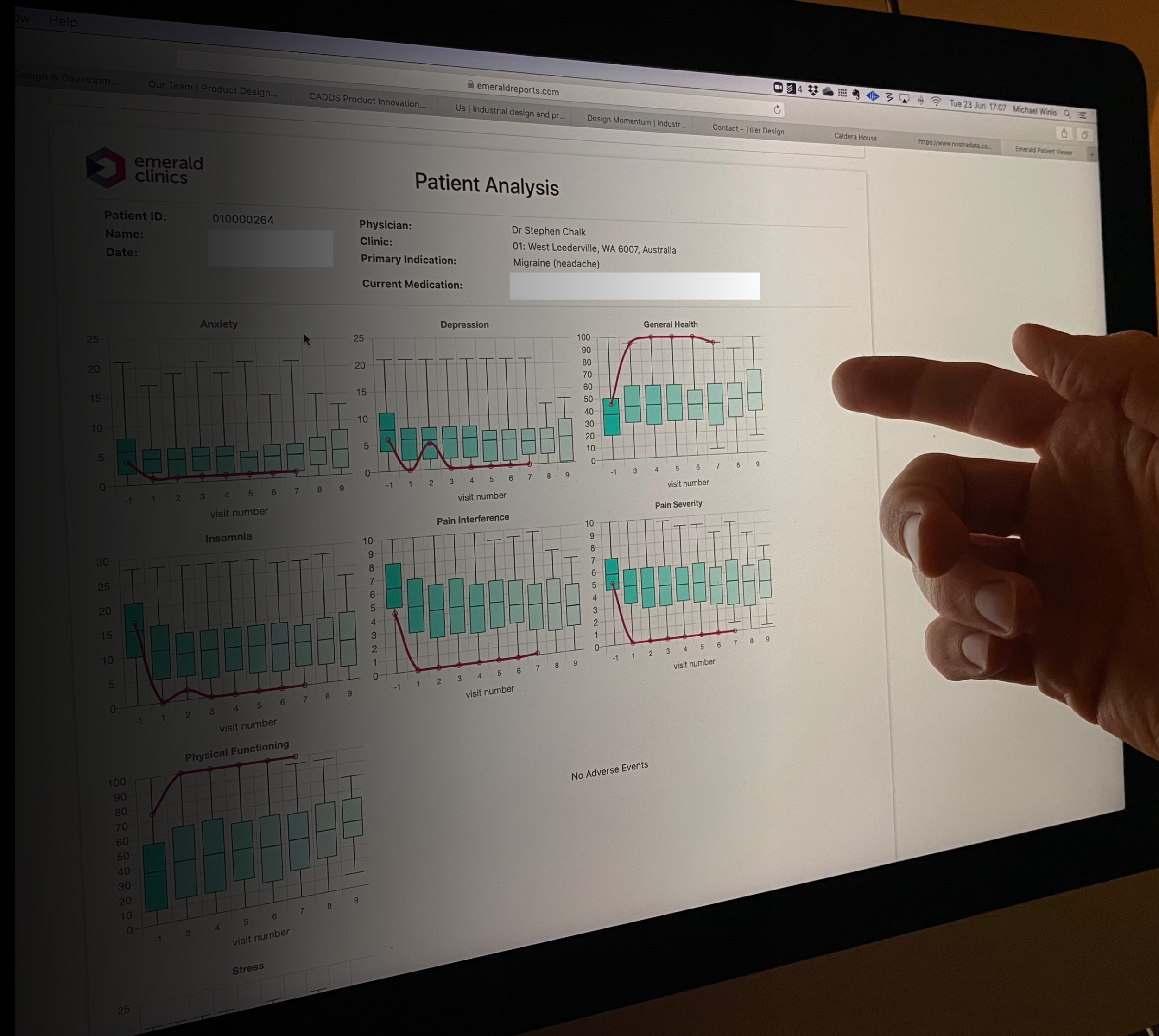


Emerald's RWE programs



*For further details, please see ASX Announcement of 22 June 2020

Real-world evidence for cannabinoid-based medicines (CBMs)



Emerald's cannabinoid medicine RWE asset



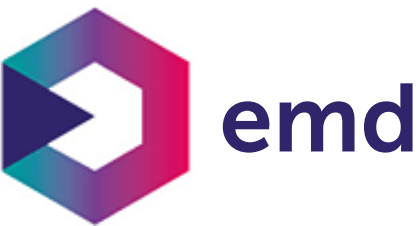
► CHALLENGE:

- Cannabinoid-based medicines (CMBs) lack high-quality, product-specific, clinical evidence to guide prescribing, registration and payment coverage decisions

► APPROACH:

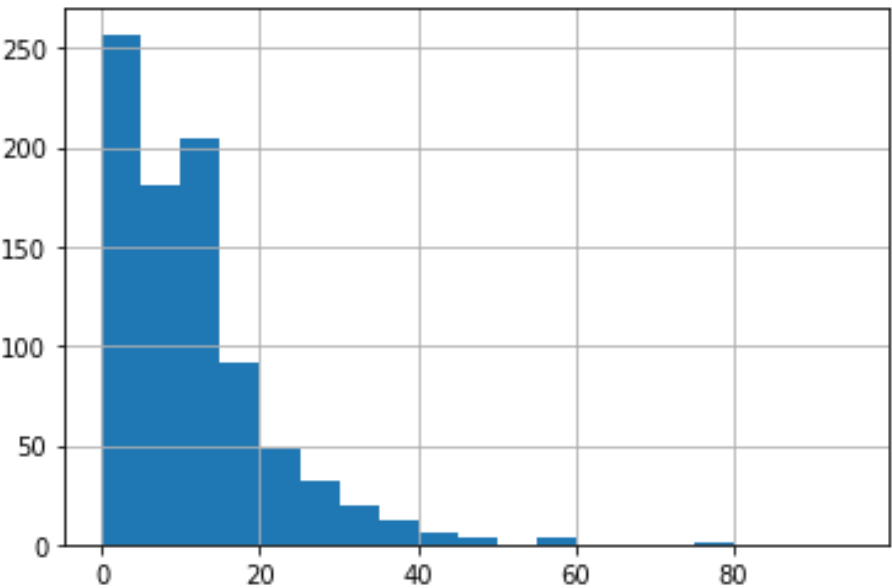
- Build and deploy a RWE platform within an independent clinical service
- Capture patient-reported and clinician data
- Use validated, licenced assessments *(the same tools used in clinical trials)*
- Use regulator-grade data standard
- Work within patients' usual care teams
- All patients screened to ensure they had "failed standard of care" and were suitable for treatment

Emerald's cannabinoid medicine RWE asset

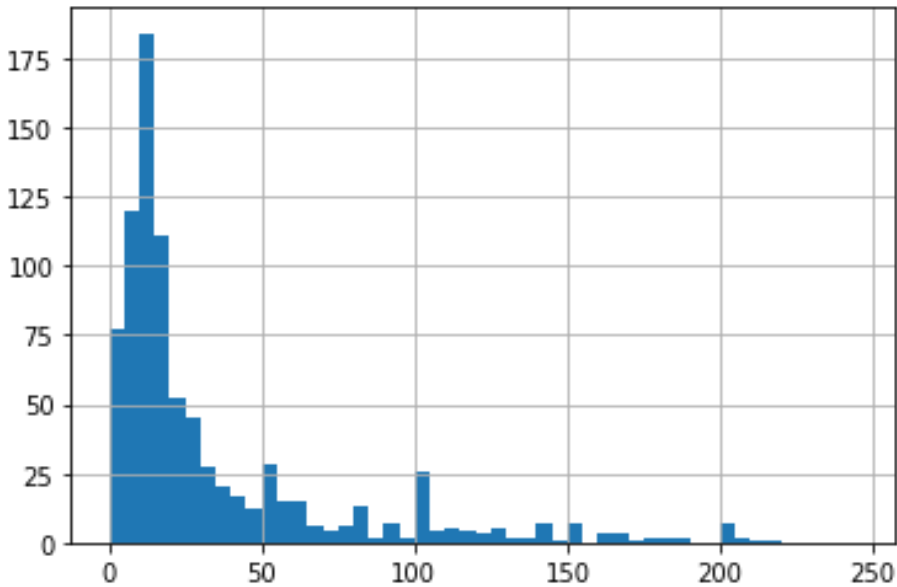


	Top indications
1	Chronic non-cancer pain
2	Cancer Pain
3	Other Indications
4	Insomnia
5	Neurological Spasticity
6	Parkinson's Disease
7	Migraine (headache)
8	PTSD
9	Epilepsy
10	Chemotherapy induced nausea and vomiting
11	Alzheimer's Disease
12	Anorexia and wasting due to chronic illness
13	Dementia
14	Inflammatory Bowel Disease

- Clinical-trial grade data capture
- Licensed and validated clinical assessments
- We covert all data into standardised models



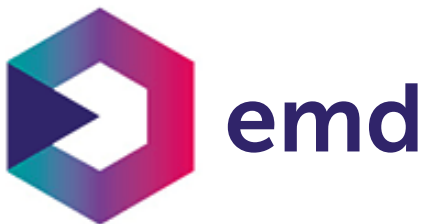
Histogram of average CBD dose/day/patient



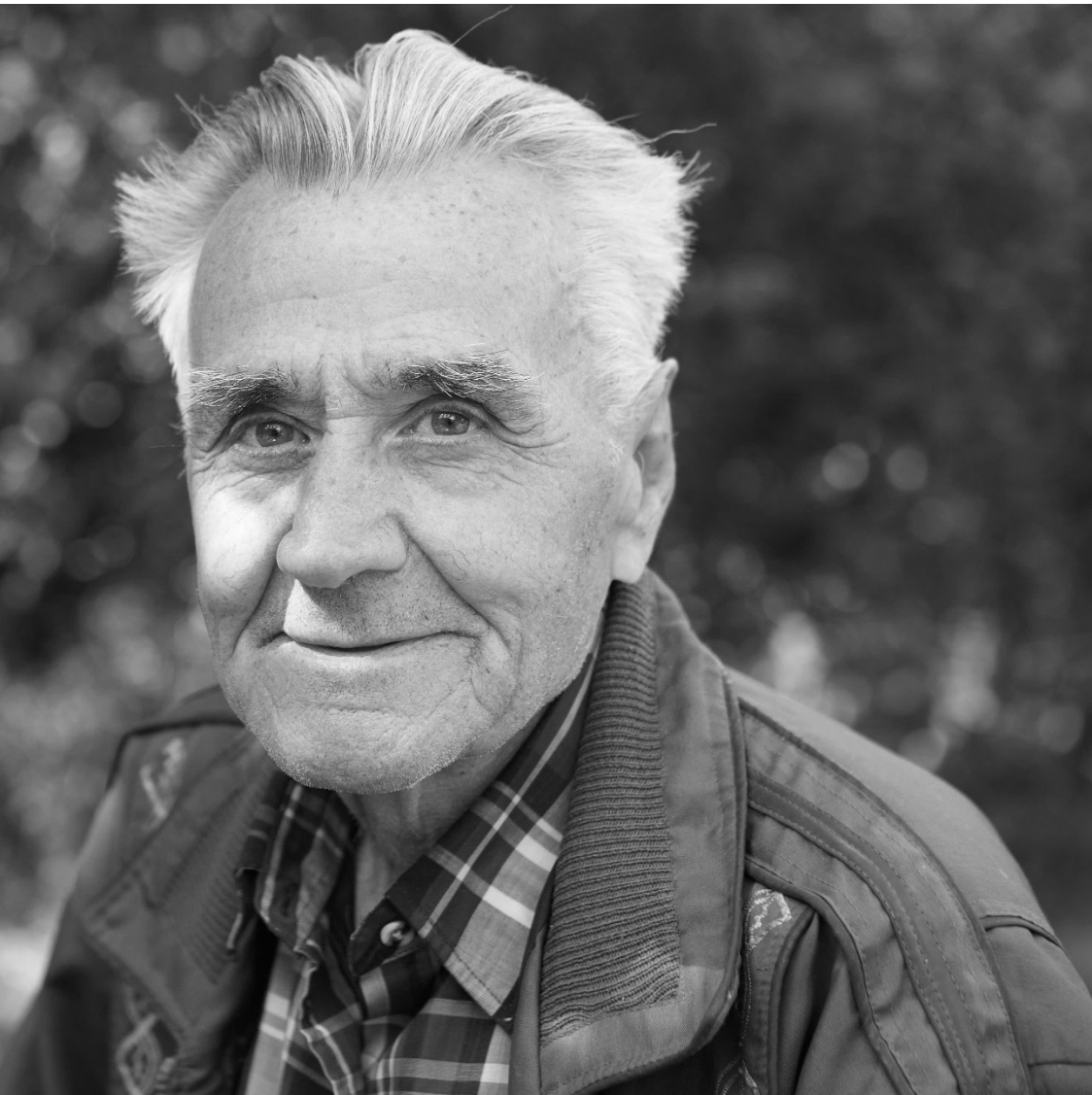
Histogram of average THC dose/day/patient



Case Study - Bob

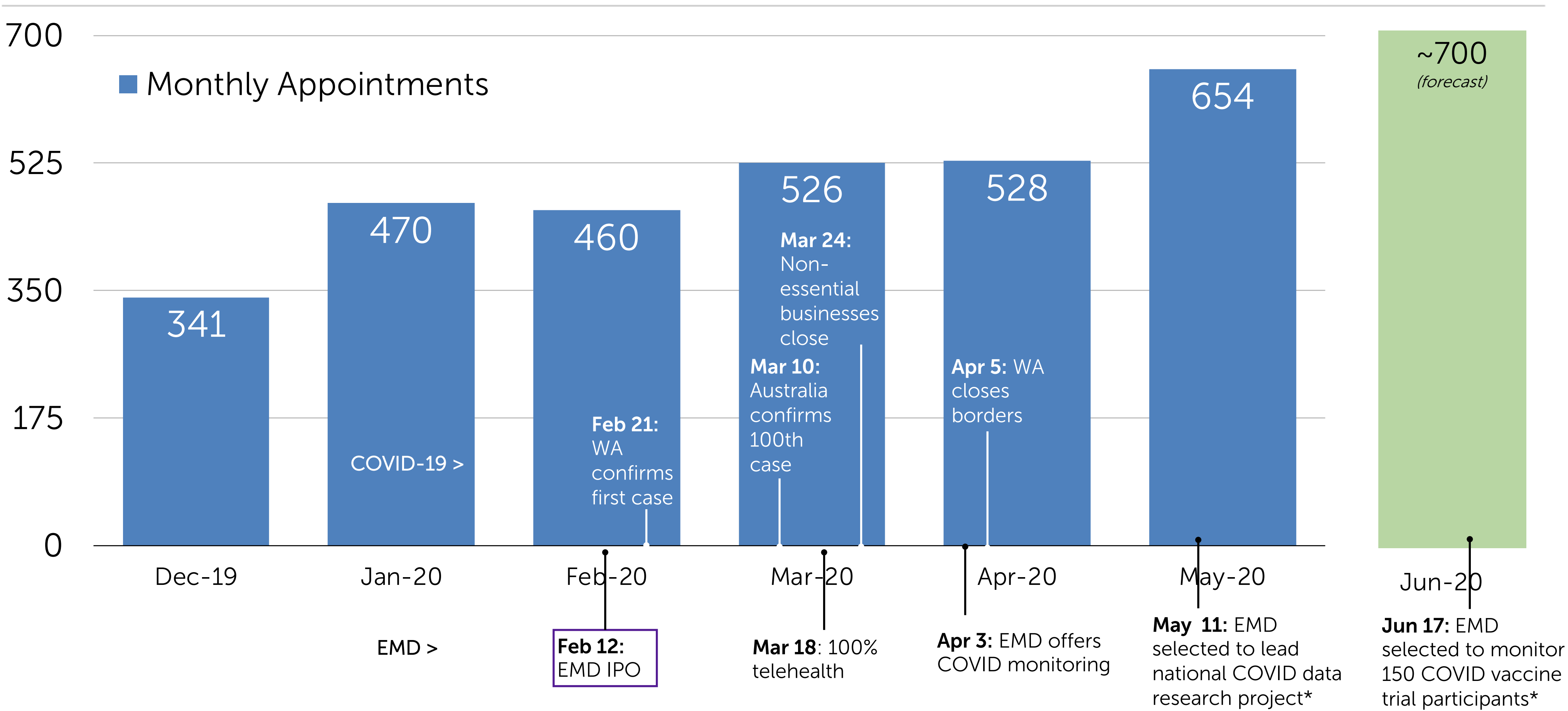
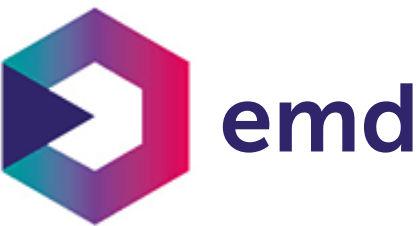


- ▶ Vietnam Veteran injured by large tree fall in 1969 causing multiple fractures
- ▶ Long-standing chronic back pain, developed peripheral neuropathy thought to be due to exposure to Agent Orange with history of PTSD
- ▶ Under care of pain specialists using oxycontin, buprenorphine, pregabalin, gabapentin, PEA, duloxetine –with little relief and/or poorly tolerated side effects.
- ▶ Now: *Stable dose of 15mg 1:1 THC/CBD oil, ceased all opiates, pregabalin and PEA*



Scores	Initial assessment	Visit 5
BPI Pain severity score	5.0	1.75
BPI Pain interference score	5.29	0.86
Visual analogue scale	5.0	1.0
Insomnia severity score	12.0	1.0
DASS 42 Depression	14	4
DASS 42 Anxiety	16	2
DASS 42 Stress	16	12

Clinical growth during COVID-19



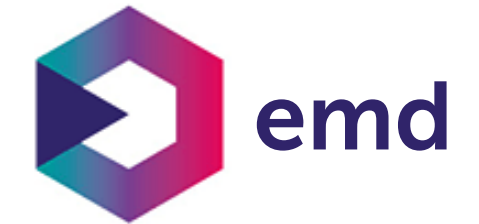
*For further details, please see ASX Announcement of 11 May 2020, at present, EMD has not yet commenced monitoring vaccine participants

Fighting COVID-19 with Real-World Evidence

The map displays the following states and cities:

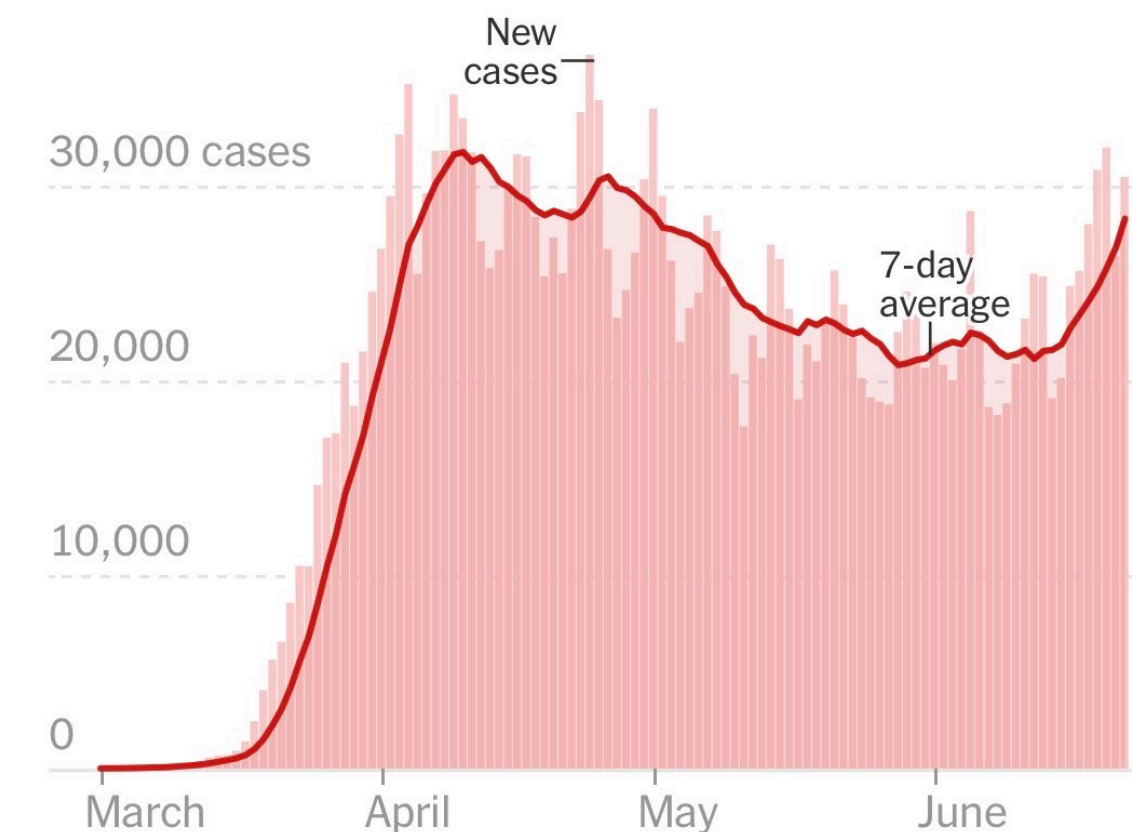
- States: Oregon, Idaho, Nevada, Utah, Wyoming, Colorado, New Mexico, Arizona, California, Alaska, Hawaii, New Hampshire, Massachusetts, New Jersey, Delaware, Virginia, North Carolina, South Carolina, Georgia, Florida, Texas, Oklahoma, Arkansas, Missouri, Illinois, Indiana, Michigan, Wisconsin, Minnesota, South Dakota, Nebraska, Kansas, Iowa, Kentucky, Tennessee, Mississippi, Alabama, Louisiana, New Orleans, Houston, Dallas, and Puerto Rico.
- Cities: San Francisco, Los Angeles, Chicago, New York, Miami, and Anchorage.

Why do we need better COVID-19 monitoring?



- ▶ COVID-19 is here to stay as a global pandemic
 - ▶ *Social distancing may be necessary into 2022 in the US¹*
- ▶ Development of a vaccine is by no means certain
 - ▶ *100+ vaccine candidates entering trials² however, no coronavirus vaccines have been developed before and the upper respiratory tract is a difficult target*
- ▶ Testing & tracing is problematic
 - ▶ *Sensitivity and specificity can vary greatly leading to false positives and false negatives³*
 - ▶ *Viral genome may be detected up to 28 days from symptom resolution further complicating testing and quarantine practices due to positive test results⁴*
- ▶ Development of a treatment is by no means certain
 - ▶ *Drug repurposing studies underway focused on reducing severity of disease^{5,6}*
- ▶ Unknown long-term health impacts of infection
 - ▶ *Early data suggests post recovery negative impact on lungs, heart, stroke risk, neurological dysfunction, inflammatory responses.^{7,8}*
- ▶ **An unqualified perception of risk is the biggest threat to businesses and educational establishments and hence economic recovery^{9,10}**

New reported cases by day in the United States



Note: The seven-day average is the average of a day and the previous six days of data.

<https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html> (June 24th, 2020)

1. Projecting the transmission dynamics of SARS-CoV-2 through the postpandemic period by Stephen M. Kissler et al. Published online in Science : 14 APR 2020 [Link](#)

2. World Health Organisation Draft landscape of COVID 19 candidate vaccines [Link](#)

3. Correlation of Chest CT and RT-PCR Testing in Coronavirus Disease 2019 (COVID-19) in China: A Report of 1014 Cases [Link](#)

4. Humoral immune response and prolonged PCR positivity in a cohort of 1343 SARS-CoV 2 patients in the New York City region [Link](#)

5. World Health Organisation International Clinical Trials Registry Platform [Link](#)

6. US listed Clinical Trials [Link](#)

7. Potential Effects of Coronaviruses on the Cardiovascular System A Review [Link](#)

8. Neurologic Features in Severe SARS-CoV-2 Infection [Link](#)

9. How Employees Feel About Coronavirus Now: A PandemicEX Survey Update [Link](#)

10. Qantas workers fear virus safety: survey [Link](#)

The Emerald approach

- A clinician-led monitoring service:
 - Our extended RWE platform can now help monitor symptoms *and* vital signs using just a smartphone
 - Intelligent alerts help identify patients requiring further clinical review by our clinical team
 - Our team of trained GPs and specialists provide clinical evaluation and review, as required

NOTE: EMD has commenced vital signs monitoring generally, but has not commenced vital signs monitoring for the sole purpose of COVID-19 monitoring, nor has it received revenues in respect of vital signs monitoring for the purposes of identifying COVID-19.



Home / Programs / COVID-19 Employee Monitoring 1 / Dashboard

COVID-19 Employee Monitoring 1 [Export program data](#) [Choose columns](#)

Name	Medical History	Status	Program Adherence	Temp	He
Melissa Johnson		High Risk	●●●●●	42	
Thijs Sondag	Diabetes	Medium Risk	●●●●●	39.2	
Tim Warren	Dia			40.5	
Hazel Wilson			●●●●●	40.6	
Mark Jones	High blood pressure	Low Risk	●●●●●		
Matt Callahan		Low Risk	●●●●●	37.8	
Adam James	None of the above	Low Risk	●●●●●		
Willie Wilson	High blood pressure	High Risk	●●●●●		

< Representative data only >

▶ Cannabinoid medicine RWE:

- ▶ Ongoing commercialisation of RWE
- ▶ Clinical trials
- ▶ Expansion into UK

▶ COVID-19 Opportunities:

- ▶ Clinical monitoring - COVID-19 Vaccine trial (150 participants, 2 years)
- ▶ A tool to assist organisations to get “back to business” with a clinician-guided COVID-19 monitoring service



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