emerald clinics

Evidence Generating Care
www.emeraldclinics.com.au

Investor Presentation – March 2020

Michael Winlo – MD & CEO
Adam James – COO

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Presentation release authorised by Michael Winlo, CEO and Managing Director

There is a massive evidence gap for cannabinoid products

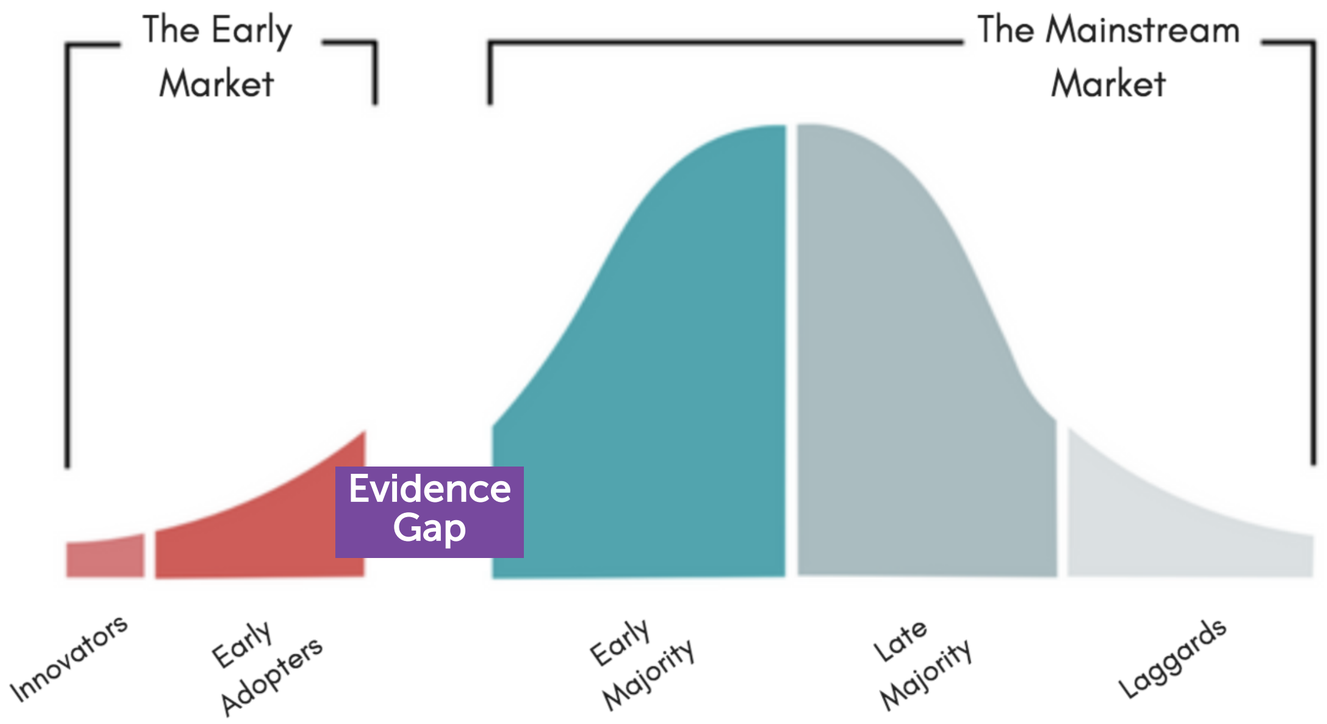
Evidence gap creates a chasm to mainstream adoption

Forces constrained access through special access schemes

Restricts patient access and clinical studies

Constrains the commercial potential of the industry

Limits the potential benefits to patients



This gap creates significant challenges for stakeholder adoption

SPONSORS

CBMP Sponsors can't access **patients**

REGULATORS

Won't **authorise**

Lack of quality clinical evidence. Apprehension for clinical use.

PAYERS

Won't **pay**

Lack of quality clinical evidence. Apprehension for clinical use.

CLINICIANS

Won't **prescribe**

Lack of quality clinical evidence. Apprehension for clinical use.

PATIENTS

Patients can't access **CBMs**

Obtaining an "authorisation" from a major regulator is a critical first step

Robust clinical evidence required to support market authorisations (aka "product registrations")

Regulators are now taking action on unsubstantiated claims (i.e. evidence gaps)

Food Standards Agency sets deadline for the CBD industry and provides safety advice to consumers

The FSA has set a deadline for CBD businesses to provide more information about CBD products and their contents. It also advises vulnerable groups not to take CBD, and healthy adults to take no more than 70mg a day.

Emily Miles, Chief Executive of the Food Standards Agency UK, said:

'CBD products are widely available on the high street but are not properly authorised. The CBD industry must provide more information about the safety and contents of these products to the regulator before 31 March 2021, or the products will be taken off the shelves.

'Also today, we are advising that CBD could be risky for vulnerable groups, and suggesting an upper limit of 70mg a day for everyone else taking the product.

13 February 2020

https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers?navref=search-news-alerts-news-5

FDA NEWS RELEASE

FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns

Violations include marketing unapproved new human and animal drugs, selling CBD products as dietary supplements, and adding CBD to human, animal foods

https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details

1. CBD has the potential to harm you, and harm can happen even before you become aware of it.
    - CBD can cause liver injury.
    - CBD can affect the metabolism of other drugs, causing serious side effects.
    - Use of CBD with alcohol or other Central Nervous System depressants increases the risk of sedation and drowsiness, which can lead to injuries.

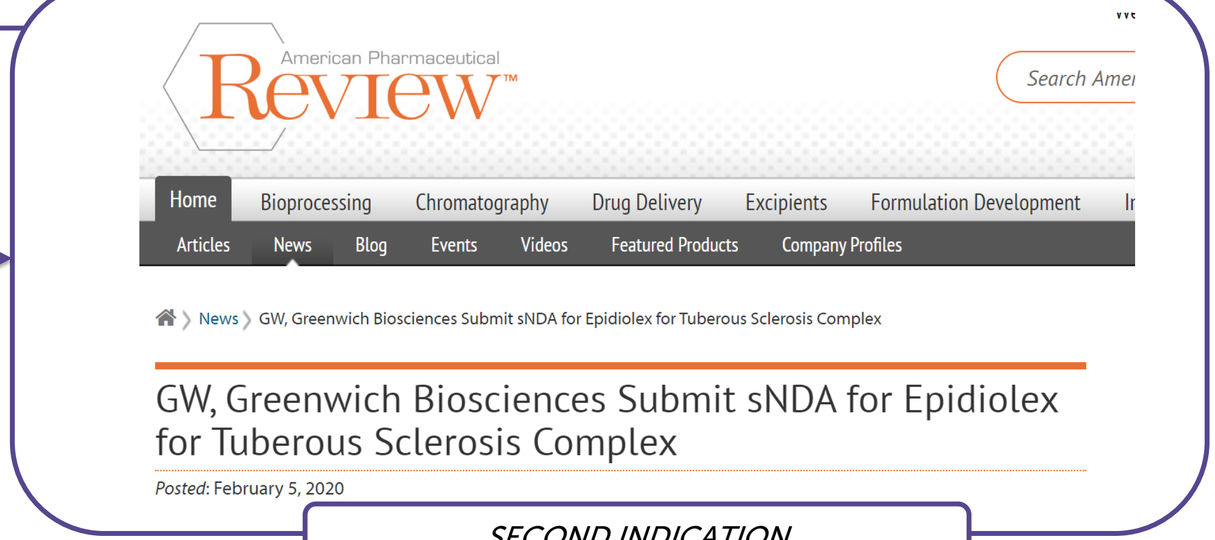
https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis

CBM's supported by evidence are entering mainstream

FDA-backed CBD drug brings in $296 million in 'incredible launch year,' GW Pharma CEO says

PUBLISHED THU, JAN 16 2020•7:10 PM EST

FIRST INDICATION



SECOND INDICATION

https://www.cnbc.com/2020/01/16/cbd-epilepsy-drug-does-incredible-296-million-in-sales-gw-pharma-ceo.html

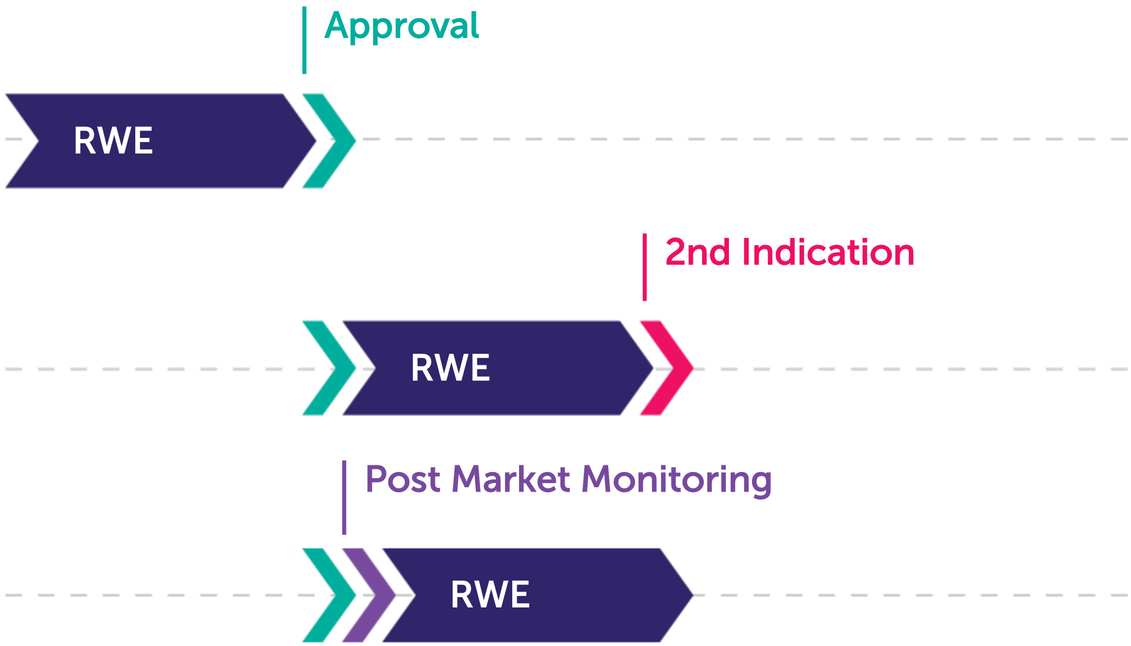
https://www.americanpharmaceuticalreview.com/1315-News/560474-GW-Greenwich-Biosciences-Submit-sNDA-for-Epidiolex-for-Tuberous-Sclerosis-Complex/?catid=6262

Real-World Evidence (RWE) accelerates evidence generation

Traditional Model:

Real-World Evidence Model:

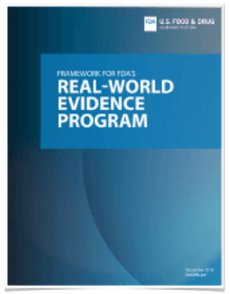
- Primary Approvals
  - Faster initial authorisation
- Indication Expansions
  - Rapid indication expansion
- Safety Monitoring
  - RWE supports payer coverage decisions



Real-World Evidence (RWE) is already critical for pharma

Regulators increasing acceptance of RWE

Major regulators across US, Europe and Canada all developing guidance on Real World Evidence to support faster drug approvals



"As the breadth and reliability of RWE increases, so do the opportunities for FDA to make use of this information."

Scott Gottlieb, FDA Commissioner
National Academies of Science, Engineering, and Medicine, Examining the Impact of RWE on Medical Product Development, September 19, 2017

Framework for FDA's Real-World Evidence Program, available at https://www.fda.gov/media/120060/download

Big pharma investing in RWE


FINANCIAL REVIEW

Home Companies Markets Street Talk Politics Policy World Property Technology Opinion Wealth Work &

Companies Healthcare And Fitness Healthcare

CSL bets on real-world evidence, builds digital strategy

https://www.afr.com/companies/healthcare-and-fitness/csl-bets-on-real-world-evidence-builds-digital-strategy-20200212-p5404s

RWE companies achieving valuable exits

flatiron

Ex CMO at Flatiron, Dr. Amy Abernethy, is current Principal Deputy Commissioner and Acting CIO at FDA

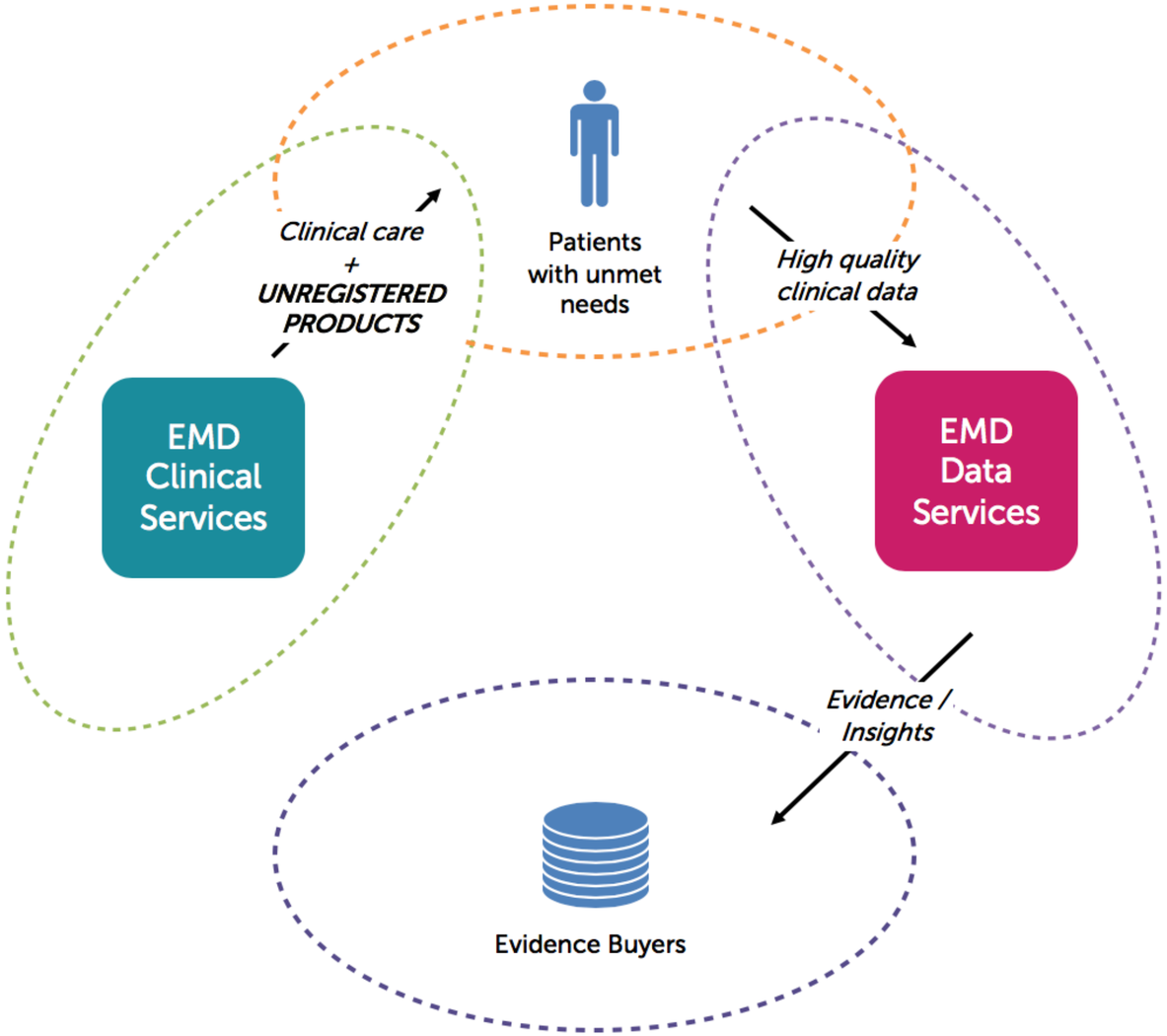
Emerald's evidence generating care model

Emerald's CLINICAL SERVICE:

- Trained multidisciplinary team **provides care** across Australia (Perth, Sydney, Melbourne and Northern Rivers region of NSW)
- Harmonised clinical service ensures consistent care and high quality data
- Independent of all treatment producers and Sponsors
- Doses of CBMs are 10-30 times lower than inhaled cannab

Emerald's DATA SERVICE:

- Creates robust and ethically sourced **real-world evidence (RWE)** *with* patients
- Emerald RWE can help **assess the safety and efficacy of unregistered medicines including cannabinoid medicines (CBMs)**



Emerald's clinical service boosts RWE quality and value

High data quality

RCT Data

- Limited population, controlled environment
- Demonstrates safety and efficacy for a specific population
- Limited health economic insights
- Expensive - driven by assessment and data management costs
- Limited generalisability to "real world" care
- *Data owned by pharma sponsor with specific consent for use*

EMD RWE

- Represents "real world" patients with unmet needs – generalisable
- Real world therapy compliance
- Can help evaluate safety and efficacy in an active clinical service
- Can help reveal health economic benefits
- Standardised data collection and validated clinical assessments
- *Data owned by EMD patient who provide informed consent for use*

Low External validity

High External validity

Other data sources

- Disparate data sources
- Lack of standardisation and interoperability
- Requires significant cleaning limiting utility in regulatory review
- Limited applicability to clinical care or economic evaluation
- *Data owned by commercial entities with limited consent for use*

Typical RWE

- Representative of population
- Demonstrates safety and efficacy in everyday practice
- Can be used for understanding economic benefit
- Limited by low data quality requiring significant investment in cleaning
- *Data owned by clinic or health service with limited consent for use*

Low data quality

Careful monitoring of adverse events is critical

Emerald's CLINICAL SERVICE

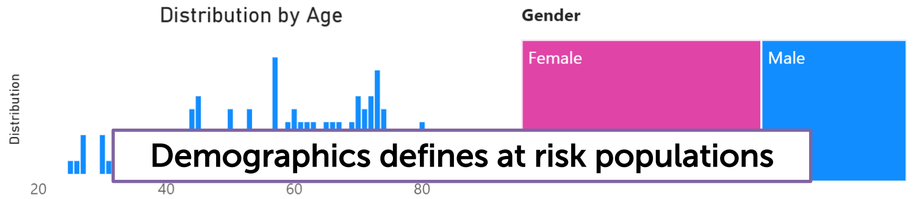
- Monitors and manages adverse events as part of routine care
- Determines if event was related or unrelated to the unregistered medicine

Emerald's DATA SERVICE

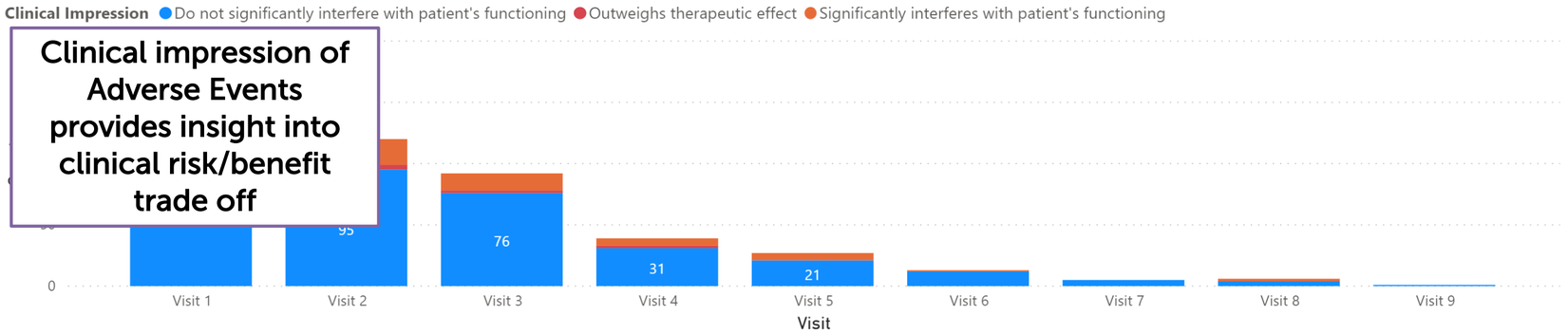
- Maps the event to standardised terms for reporting
- Provides insights to clinical service to improve care

Insight into when Adverse events are occurring informs prescribing and monitoring guidelines

Patients with an AE | Adverse Events



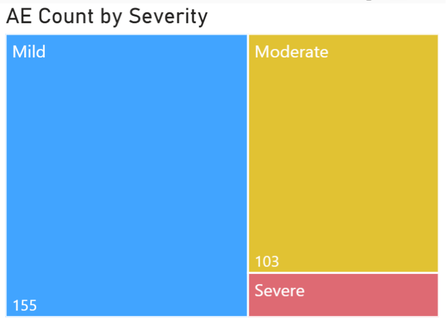
Demographics defines at risk populations

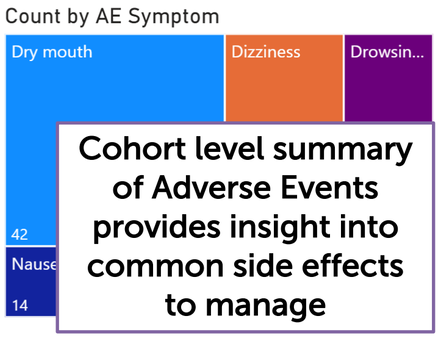


Clinical impression of Adverse Events provides insight into clinical risk/benefit trade off

Date	Symptom	Severity	Action	End Date
02-Jun-2019	Anxiety	Severe	Dose discontinued	30-Jun-2019
04-Feb-2019	Memory Loss	Severe	Other	04-Feb-2019
04-Feb-2019	Pulse Increase after change in dose	Severe	Dose discontinued	09-May-2019
06-Dec-201				
06-May-20				
09-Sep-201				
11-Dec-201				
12-Jun-201				

Detailed reporting of specific events including attribution to inform regulators





Cohort level summary of Adverse Events provides insight into common side effects to manage

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.
- Under care of pain specialists using oxycontin, buprenorphine, pregabalin, gabapentin, PEA, duloxetine –with little relief and/or poorly tolerated side effects.
- <u>Now</u>*: Stable dose of 15mg 1:1THC/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

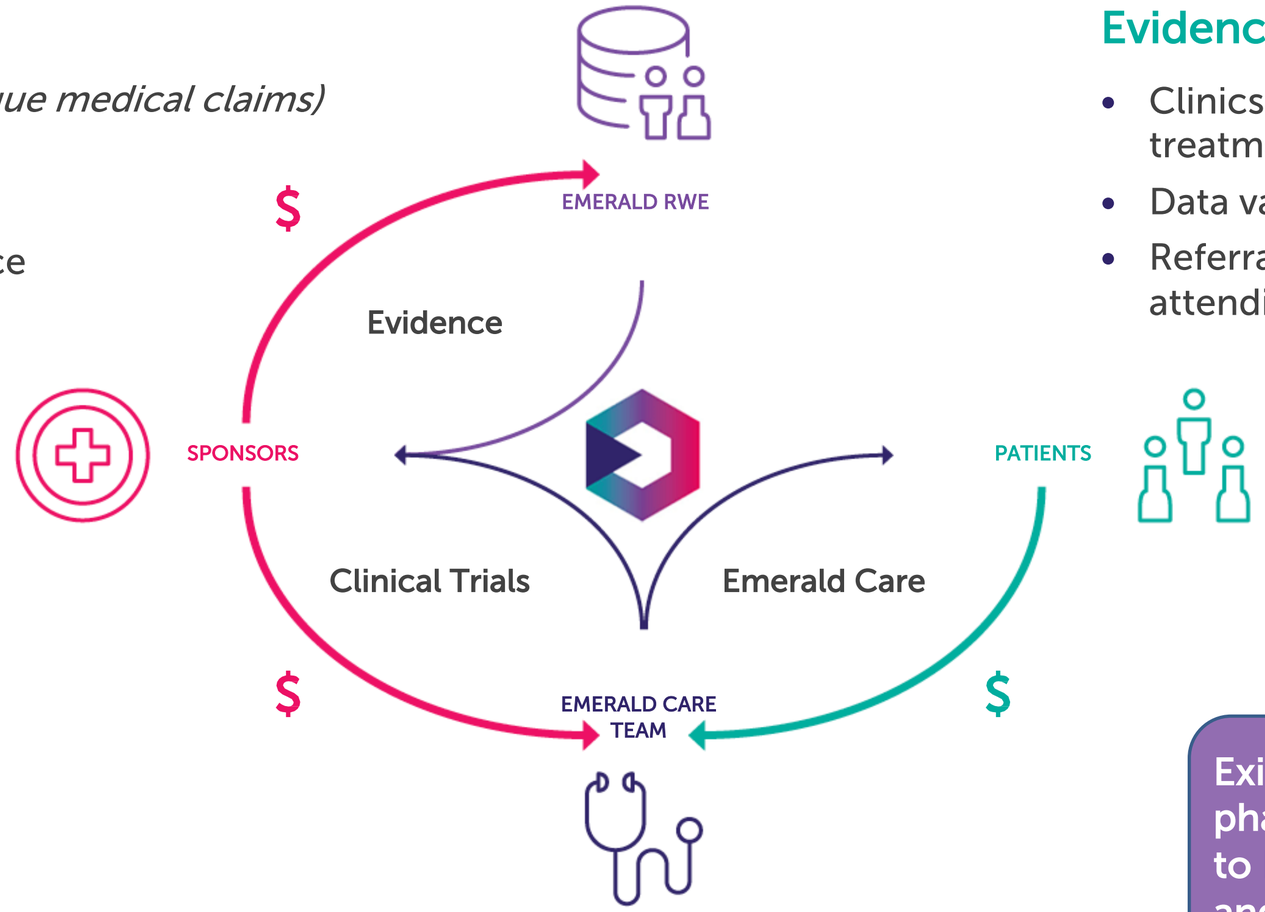
Emerald's RWE derived from our own clinical service

	flatiron	Verana Health	AETION	emerald clinics
Therapy area	Cancer	Eye disease + neurology	Diverse	Initially pain and sleep
Delivers clinical service?	NO	NO	NO	YES
Able to control clinical routines	NO	NO	NO	YES
Data quality	Electronic Medical Records (needs cleaning)	Patient Registries (needs cleaning)	Insurance claims data (needs cleaning)	**Direct input from patient** (means minimal cleaning, regulatory-grade)

Emerald potential revenue streams

Sponsors pay for Emerald's RWE to support:

- Product registrations *(unique medical claims)*
- Coverage decisions
- Drug development
- Product/market intelligence



Patients Pay for Emerald's Evidence Generating Care:

- Clinics approaching cost-neutral treatment expense
- Data value justifies operational overhead
- Referral model ensures all patients attending have high unmet needs

Sponsors pay for Emerald's unique trial capability:

- Trial design
- Trial delivery
- Post-market surveillance

Exit opportunities range from pharma M&A (eg Flatiron - $2.9B to Roche) to insurance companies and other data companies

Emerald's clinical service

London Clinic

- Emerald investigating options for a London clinic
- LOI with UK partner

Data Platform

- Validated assessments active
- Linear Clinical Research supporting data management in FDA-compliant system
- Completed data deals confirm value

Australian Roll-Out

- 4 clinical services operating across Australia
- Several new sites under consideration for 2020

Emerald's data service revenue model

(1) Initial Engagement:

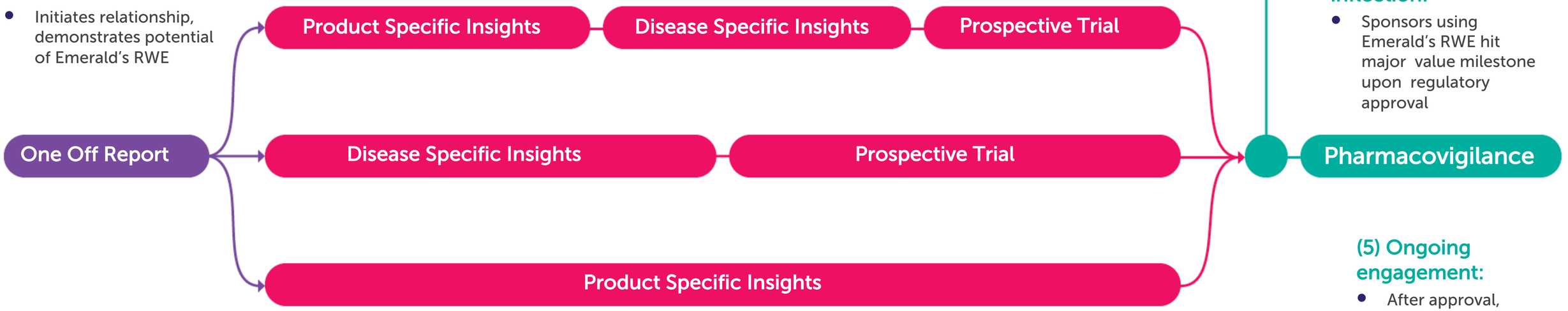
- Sponsors purchase a one-off report (narrow subset of data)
- Initiates relationship, demonstrates potential of Emerald's RWE

(2) Data subscription model:

- Sponsors subscribe to continuous data on own products and / or specific clinical indications which informs drug development and future trial designs

(3) Clinical trials:

- Emerald runs end-to-end clinical trials across network



(4) Major value inflection:

- Sponsors using Emerald's RWE hit major value milestone upon regulatory approval

(5) Ongoing engagement:

- After approval, Sponsors pay Emerald to support post-market surveillance and indication expansion programs

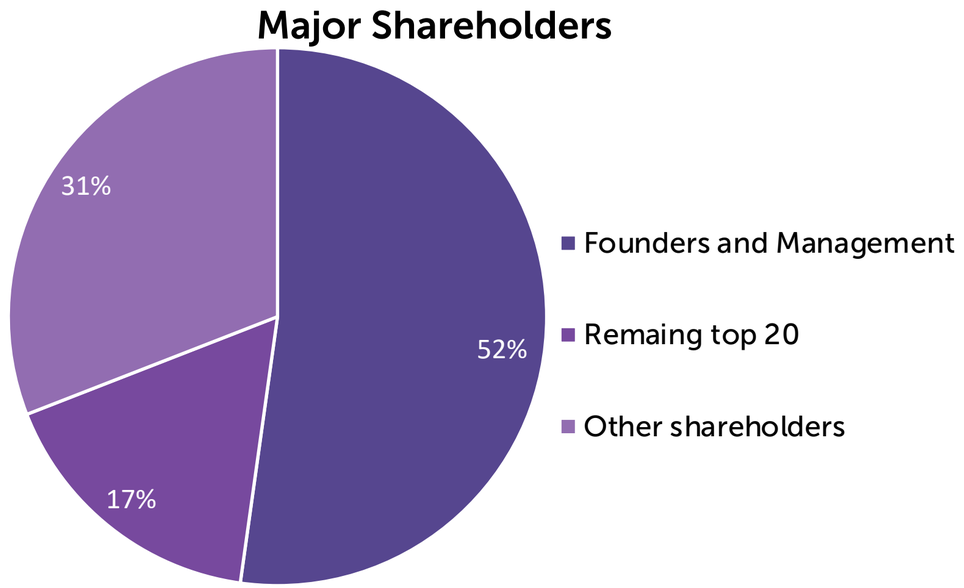
Time >

Experienced board with medical focus

	Key Person	Role	Previous Experience
	Dr Stewart Washer	Non-Executive Chairman / Founder	>25 years of CEO and Board experience in medical and agrifood biotech companies. Founder of AusCann Ltd (ASX:AC8), medical cannabis manufacturing, Co-founder of Zelda Therapeutics Ltd (ASX:ZLD) medical cannabis clinical studies and research, Chairman of Orthocell Ltd (ASX:OCC), regenerative medicine company, Founding Chairman and current Director of Cynata Therapeutics Ltd (ASX:CYP) stem cell therapies and Chairman of Minomic International cancer diagnosis and treatment. 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.
	Sir Professor 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.

Corporate Snapshot

Key Corporate and Financial Data	
ASX Code	**EMD**
Shares on issue	183.9 M
Unlisted Options	18.4M
Current share price	$0.095
Market Capitalisation	**$17.5M**
Share price range	$0.155 - $0.095
Debt	Nil
Cash (as at 28/2/20)	**$5.5M**
Enterprise Value	$16.5M



Board of Directors	
Dr Stewart Washer	Non Executive Chairman
Sir Professor John Tooke	Independent Non Executive Director
Matt Callahan	Non Executive Director
Dr Alistair Vickery	Executive Director/Medical Director
Dr Michael Winlo	CEO/Managing Director

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Appendix

The value of RWE case study: Ibrance

In April 2018, Roche acquired Flatiron for US$1.9B[3]

Primary Indication 31/03/18 | **2nd Indication 04/04/19**

Clinical Trials (13 years) → **RWE (1 year)**

Approval journey for “Ibrance” (palbociclib) for breast cancer

By using Real-World Evidence from Flatiron, Pfizer was able to obtain accelerated FDA approval for a second indication **3.8 years faster** than the median for other drugs[1]

April-July 2019 sales of Ibrance were US$1.28B/ quarter (up 25% on previous quarter)[2]


Breast Cancer Research

RESEARCH ARTICLE Open Access

Real-world evidence analysis of palbociclib prescribing patterns for patients with advanced/metastatic breast cancer treated in community oncology practice in the USA one year post approval

1 https://www.analysisgroup.com/Insights/ag-feature/health-care-bulletin/winterspring-2019/expanded-role-real-world-evidence/
2 https://www.cnbc.com/2019/10/29/reuters-america-update-2-pfizer-raises-2019-forecast-on-surging-cancer-drug-sales.html
3 https://www.roche.com/media/releases/med-cor-2018-04-06.htm

Recent examples of RWE-driven approvals at FDA

Sponsor & Product	Indication	Real-World Evidence Used In Efficacy Decision
Recordati/Orphan Europe's Carbaglu (carglumic acid)	Hyperammonemia due to NAGS deficiency	Retrospective case series summary data on plasma ammonia reductions
Asklepion's Cholbam (cholic acid)	Bile acid synthesis disorders	Retrospective chart review of treatment IND and expanded access program patients; Historical control from retrospective literature review
BTG's Voraxaze (glucarpidase)	Methotrexate toxicity	Data from NIH treatment protocol; Historical control based on well-characterized methotrexate excretion curves from 40+ years of clinical trials
Wellstat's Vistogard (uridine triacetate)	5-FU overdose	External historical control based on cases in literature and review of safety reports submitted to FDA regarding fluorouracil overdoses
Fresenius Kabi's Omegaven (fish oil triglycerides)	Pediatric patients with parenteral nutrition-associated cholestasis	Pair-matched historical controls
Provepharm's ProVay Blue (methylene blue)	Acquired methemoglobinemia	Retrospective case reports from multicenter chart review and literature search
Aegerion's Myalept (metreleptin)	Lipodystrophy	NIH protocol and treatment IND patient data
Advanced Accelerator Application (Novartis)'s Lutathera (lutetium dotatate LU-177)	GEP-NET	Expanded access protocol data supported broader indication than was supported by clinical trial
Vertex' Kalydeco (ivacaftor)	Expansion of cystic fibrosis indication to include an additional 23 mutations	Registry data and mechanistic information from lab studies

Omegaven addresses a highly specialized niche market and has long been available under an expanded access protocol, making conventional clinical trials a challenge. FDA's approval history suggests the agency prefers to bring products out of the expanded access/personal importation gray market and into light of the FDA review process, even if the reviewers have to make do with less-than-ideal data.

Source: A Baker's Dozen of US FDA Efficacy Approvals Using Real World Evidence Pink Sheet, Aug 7, 2018
https://pink.pharmaintelligence.informa.com/PS123648/A-Bakers-Dozen-Of-US-FDA-Efficacy-Approvals-Using-Real-World-Evidence

Sponsor & Product	Indication	Real-World Evidence Used In Efficacy Decision
Amgen's Blincyto (blinatumomab)	Relapsed or refractory B-precursor acute lymphoblastic leukemia	Matched historical control data and model-based projection study to justify response rate efficacy threshold for accelerated approval; pediatric label expansion relied on retrospective cohort and model-based analysis
EMD Serono/Pfizer's Bavencio (avelumab)	Merkel cell carcinoma	Matched historical controls from retrospective electronic health record review, supported by literature review including a retrospective case series
BioMarin's Brineura (cerliponase alfa)	Late infantile neuronal ceroid lipofuscinosis type 2	Natural history cohort
Genzyme's Lumizyme and Myozyme (algucosidase alfa, produced at different scales)	Pompe disease	Lumizyme: Clinical outcomes data for infantile-onset patients from international Pompe Registry supplemented placebo-controlled trial in late-onset disease; Myozyme: historical control group

13 recent FDA efficacy approvals where:

FDA used RWE to make a decision on efficacy where:

- Data has come from "registry-like case series" and;
- "registry data used as controls"

Chronic pain patients in Australia – market size

70% of Emerald's patients present for management of chronic non-cancer pain

The total cost of chronic pain in Australia in 2018 was estimated to be $73.2 billion

Pain Australia estimated that 3.24 million Australians were living with chronic pain in 2018 with 68.3% of working age

The report estimated that chronic pain was associated with 340,384 disability adjusted life years (DALYs) which represents a cost of $66.1 billion

Source: https://www2.deloitte.com/au/en/pages/economics/articles/cost-pain-australia.html