

# ASX Announcement

07/06/2021

# emyria

myriad data.  
individual care.

## Emyria data validated, care model reduces opioids, opening new opportunities

### Highlights:

- **Analysis of large drug community dispensing data shows a significant reduction in opioid use** following commencement of a personalised treatment program involving cannabinoid medicine at Emyria's Emerald Clinics
- Opioid prescription dispensing data provided by **IQVIA (NYSE: IQV)** and **NostraData** validates the quality and utility of Emyria's proprietary clinical data
- The data show that, on average **opioid consumption reduces after commencing care** at Emerald Clinics from a previous 12 month steady-state of opioid-use
- Opioid abuse continues to be a major health issue worldwide, with nearly 50,000 people dying per year in the USA alone from opioid-involved overdoses [1]
- Emyria will further and deeply analyse the data to **assess potential for new registered treatments with the FDA** for opioid-sparing<sup>[AV1]</sup>.
- **Emyria to present data to health insurers and payers** for increased clinic and patient funding and expansion support for better health outcomes and potential health economic benefits
- Emyria has engaged **Professor David Preen**, Chair of Public Health at UWA and Chief Investigator for the **Centre of Research Excellence in Medicines Intelligence** to continue independent research on Emyria Data [2]
- Emyria to continue investment in **care model innovation** and proprietary, **software-powered clinical decision support tools** backed by Emyria Data

**Emyria Limited (ASX: EMD)** (Emyria or the Company), a data-backed treatment development and clinical services company, is pleased to share preliminary results of an engagement between Emyria, IQVIA and NostraData. Emyria Managing Director and CEO, Dr Michael Winlo, will present these findings on Monday, June 7th 2021 at the Annual National Summit of the Association of Regulatory and Clinical Scientists (ARCS). The ARCS presentation covering the first phase of analysis accompanies this ASX release.

Emyria engaged the Real World Evidence (RWE) analytics team of IQVIA - a \$44B contract research organisation - and NostraData, to validate Emyria's medication tracking data and build comparison patient cohorts. Comparison cohorts can be used as external controls and improve the analysis of Emyria's care models and drug development programs.

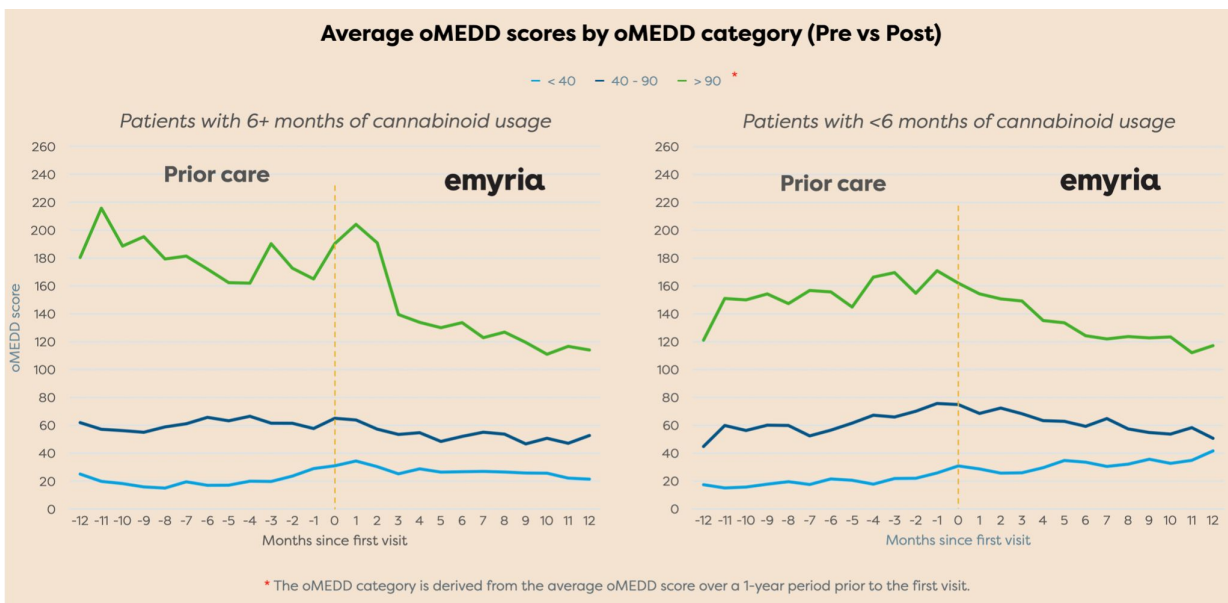
# emyria

**Emyria's Managing Director, Dr Michael Winlo**, said: "I'm very pleased to present the early findings of a world-first data-linkage project combining Emyria's clinical data with prescription drug dispensing data from partners IQVIA and NostraData.

This project allowed us to understand the historical opioid usage patterns of our patients in the 12 months prior to receiving personalised care at our Emerald Clinics through an anonymous matching process.

The analysis shows that patients receiving personalised care at Emerald Clinics reduce their opioids substantially while also gaining improvements in pain symptoms and quality of life measures. Importantly, the analysis demonstrates both the validity, reach and richness of Emyria Data assets as well as the effectiveness of Emyria's Care programs.

Emyria has engaged academic partners to continue independent research and will further analyse the data for intellectual property, potential treatments for the USA and the development of proprietary clinical decision support software tools."



**Figure 1.** Average oral morphine equivalent daily dose (OMEDD) scores for Emyria patients 12 months before and 12 months during care.

The company expects to produce further reports on the data analysis in due course.

This announcement has been approved and authorised by the Board of Emyria Limited.

For further information on **Emyria**:

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## REFERENCES

- [1] <https://www.cdc.gov/mmwr/volumes/70/wr/mm7015a1.htm>
- [2] <https://newsroom.unsw.edu.au/news/health/new-centre-monitors-medicine-use-and-safety>

# emyria

## Investor Webinar

Emyria's Managing Director and CEO, Dr, Michael Winlo will present an overview of today's release "EMD's care model reduces opioid use" and provide the latest preliminary results of a collaboration between Emyria, IQVIA and NostraData.

### Details of the event are as follows:

- **Event:** Emyria Investor Webinar
- **Webinar Presenter:** Emyria's Managing Director, Dr, Michael Winlo
- **Date and Time:** Tuesday 8 June 2021, 11:45am AEDT
- **Where:** Zoom Webinar - details to be provided upon registration

To register your interest in the webinar please click through to the link below.

### Registration Link:

[https://janemorganmanagement-au.zoom.us/webinar/register/WN\\_qCzy0GPsT0ivAYi4RgjLVw](https://janemorganmanagement-au.zoom.us/webinar/register/WN_qCzy0GPsT0ivAYi4RgjLVw)

After registering your interest, you will receive a confirmation email with information about joining the webinar. Participants will be able to submit questions via the panel throughout the presentation, however, we encourage shareholders and investors to send through questions via email beforehand to Lexi O'Halloran at: [lexi@janemorganmanagement.com.au](mailto:lexi@janemorganmanagement.com.au)

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## About Emyria ([www.emyria.com](http://www.emyria.com))

Emyria Limited is a data-backed, drug development company. **Emyria's Treatments** target unmet needs and are focused on obtaining approval from major global regulators. Emyria's drug development programs are informed by insights generated from extensive analysis of **Emyria Data** - deep, ethically-sourced clinical evidence that is gathered with patients across Emyria's independent clinical services (**Emerald Clinics** - [www.emeraldclinics.com.au](http://www.emeraldclinics.com.au))

**Emyria Data** provides deep treatment insights and is therefore a source of unique IP, strategically designed drug development and personalised care programs.

Emyria's first drug development program, **EMD-003** is targeting unmet needs in mental health. Specifically psychological distress and the symptoms of anxiety, depression and stress.

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## Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for its product candidates. In addition, the forward-looking statements included in this press release represents the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

From pandemic to recovery –  
building Australia's competitive advantage  
post COVID

# Innovation in Real World Evidence: Pioneering new frontiers

*Bridging the clinic to  
the community*

**Dr Michael Winlo, Managing Director, Emyria**

**emyria**

  
NostraData



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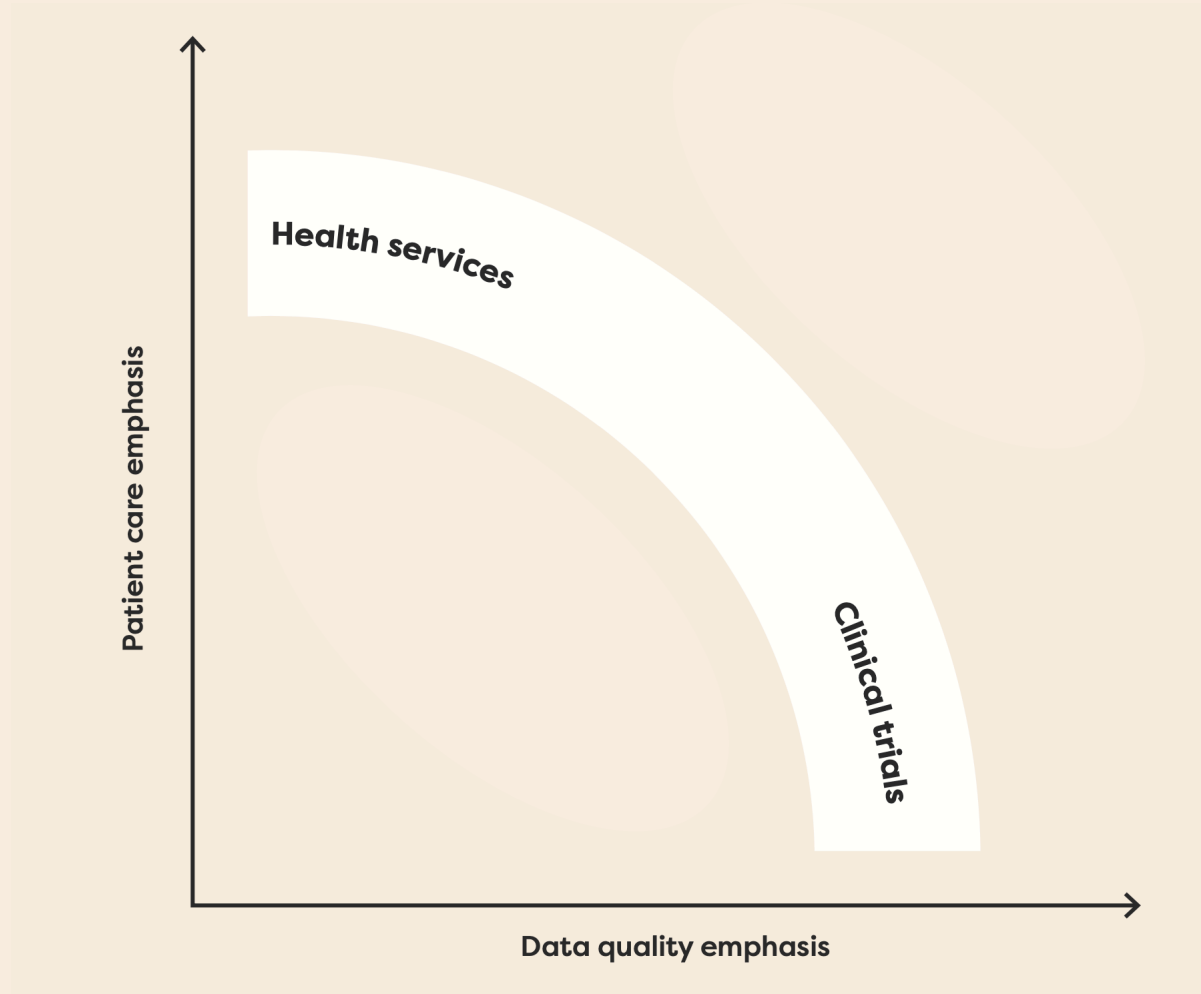
## Disclaimer and notices

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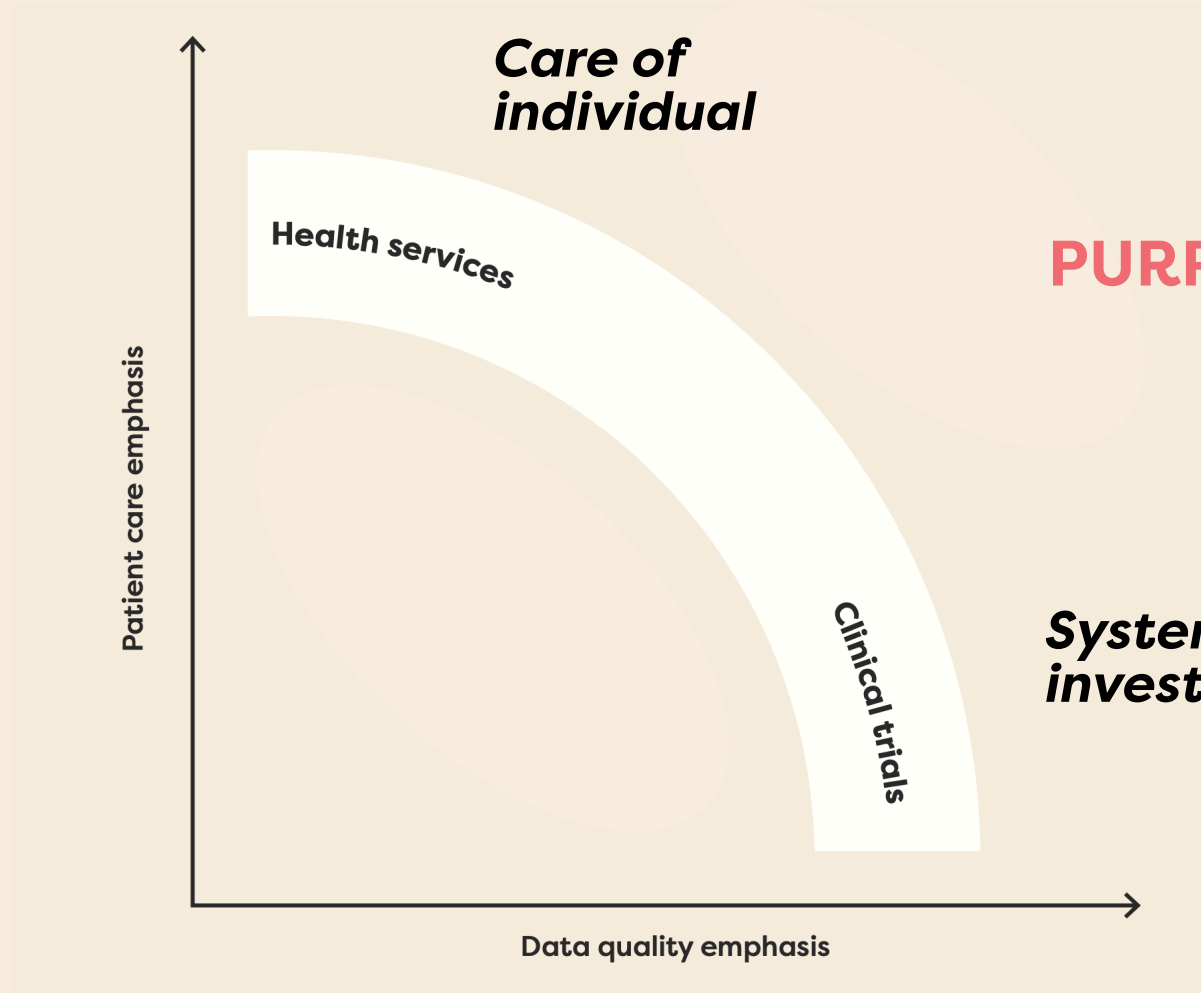
Presentation release authorised by **Michael Winlo, CEO and Managing Director**

# Tensions between Care + Research:



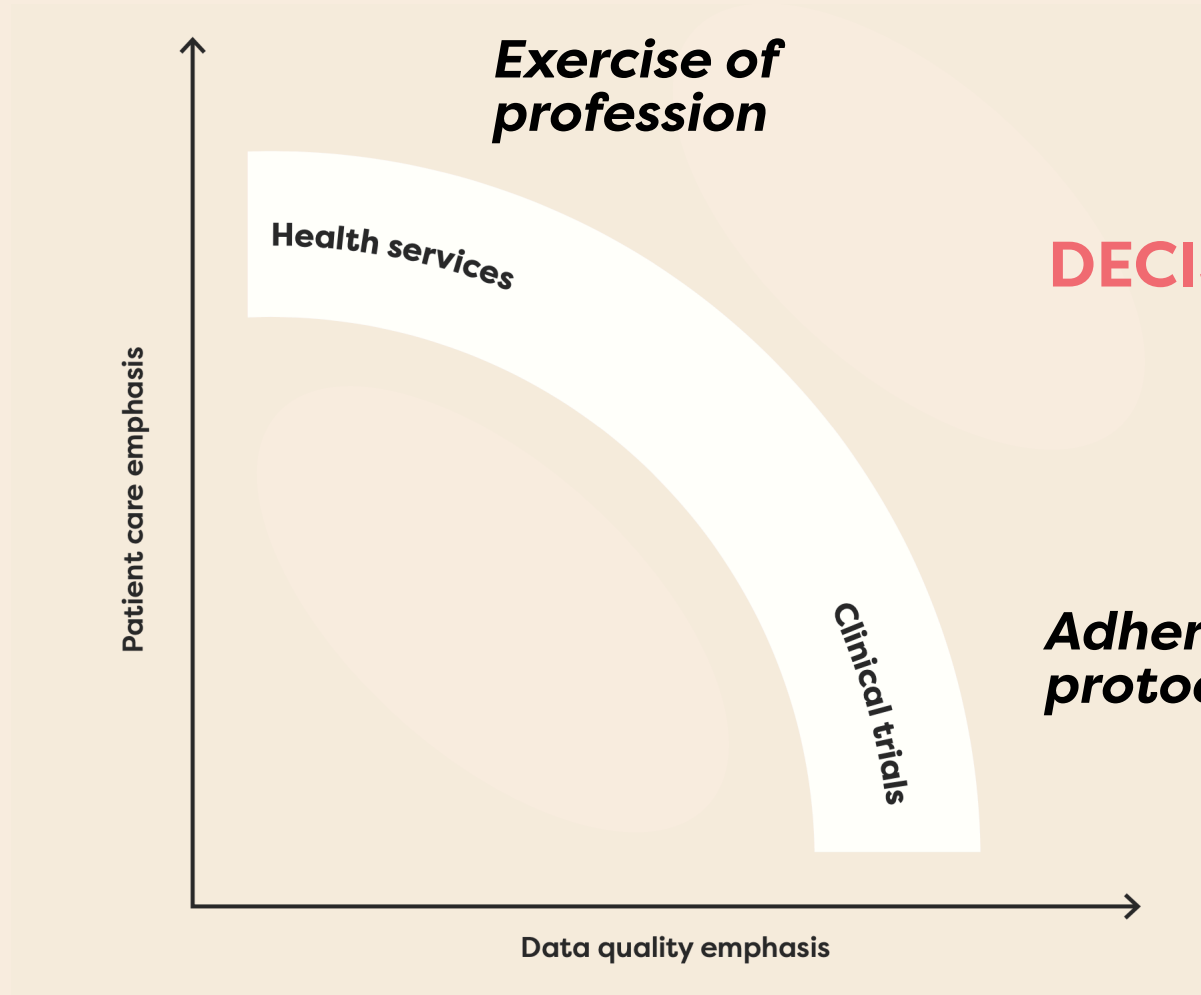
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# Tensions between Care + Research:



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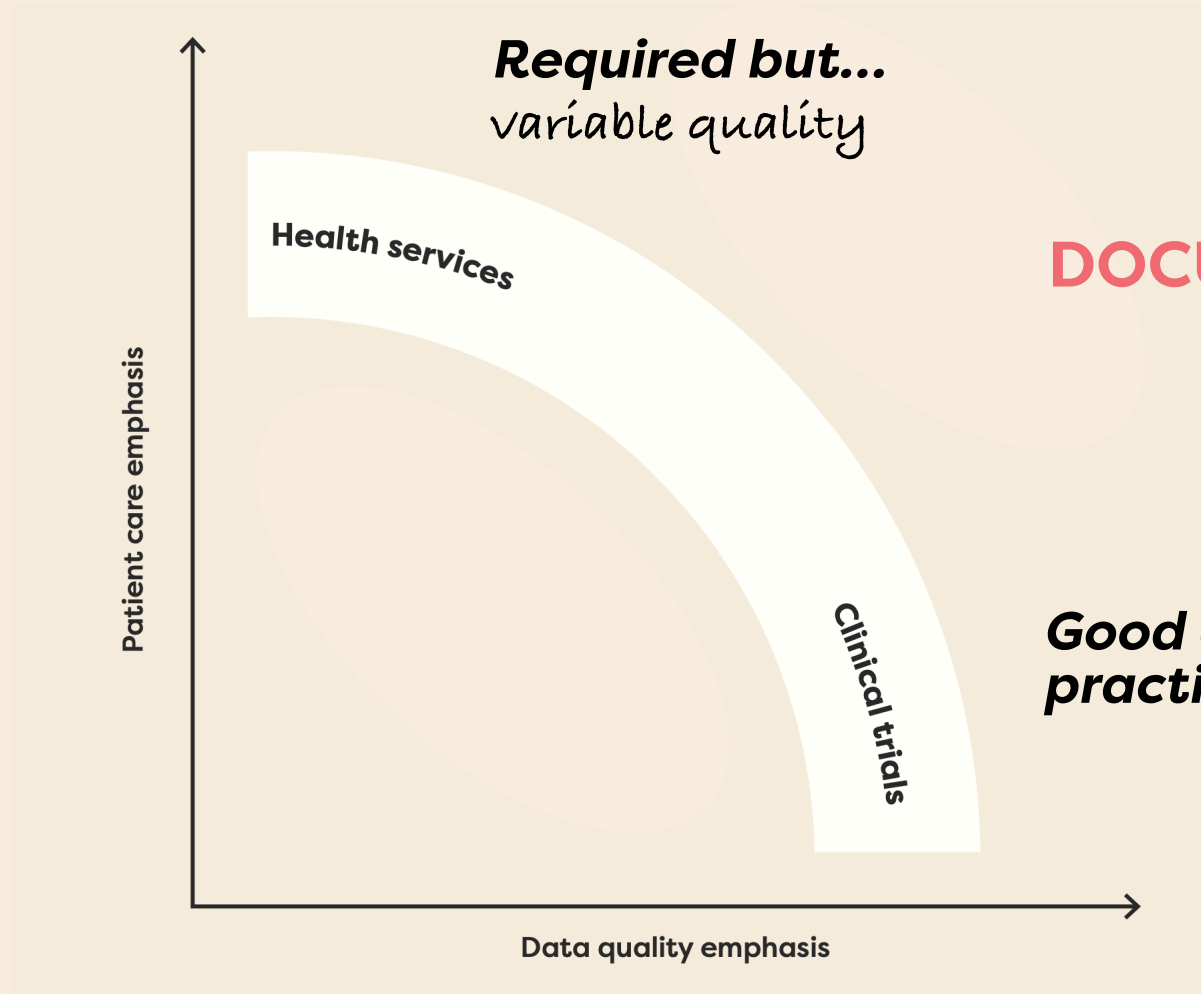


# Tensions between Care + Research:



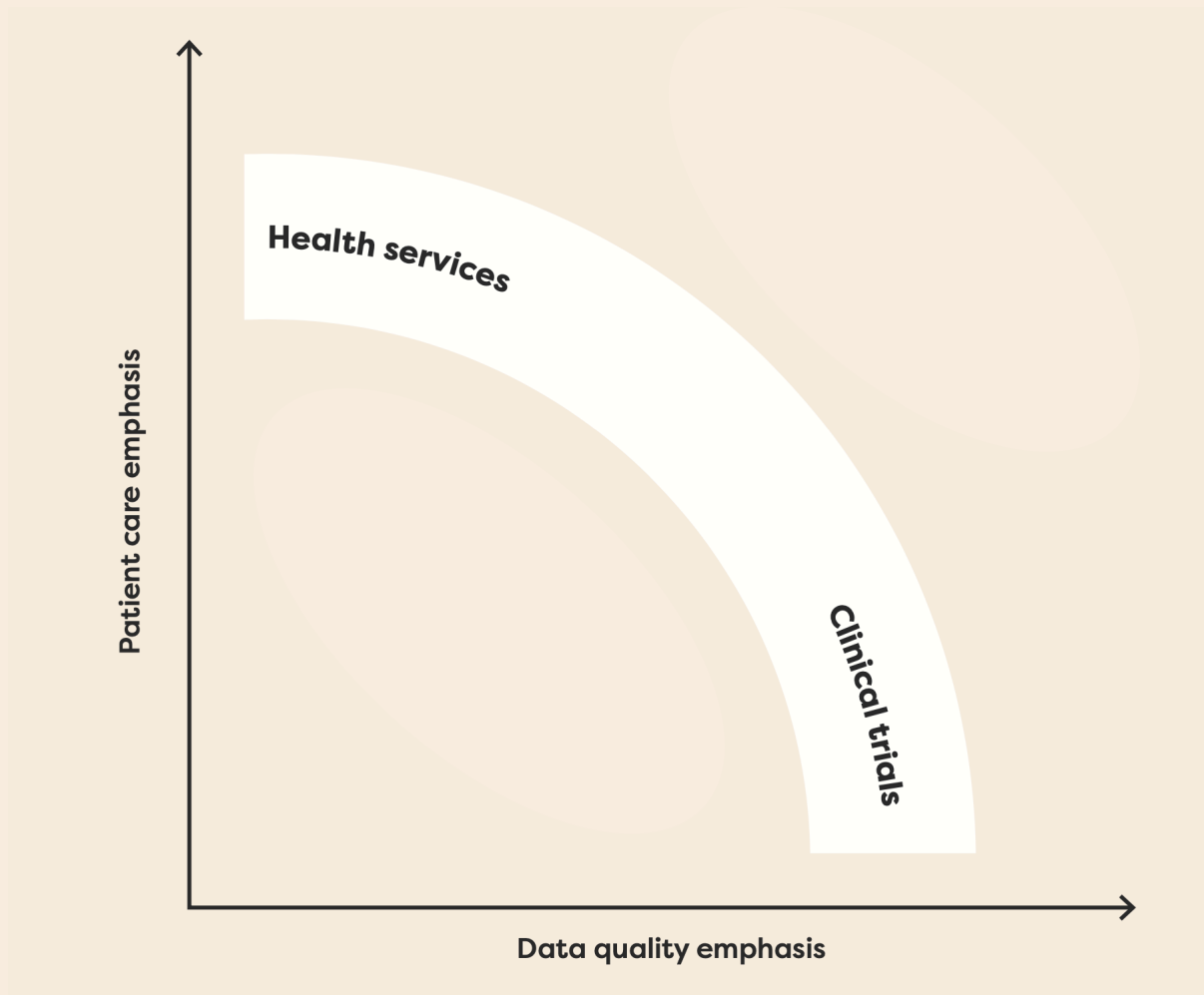
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# Tensions between Care + Research:



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# Tensions between Care + Research: Advancing the frontier



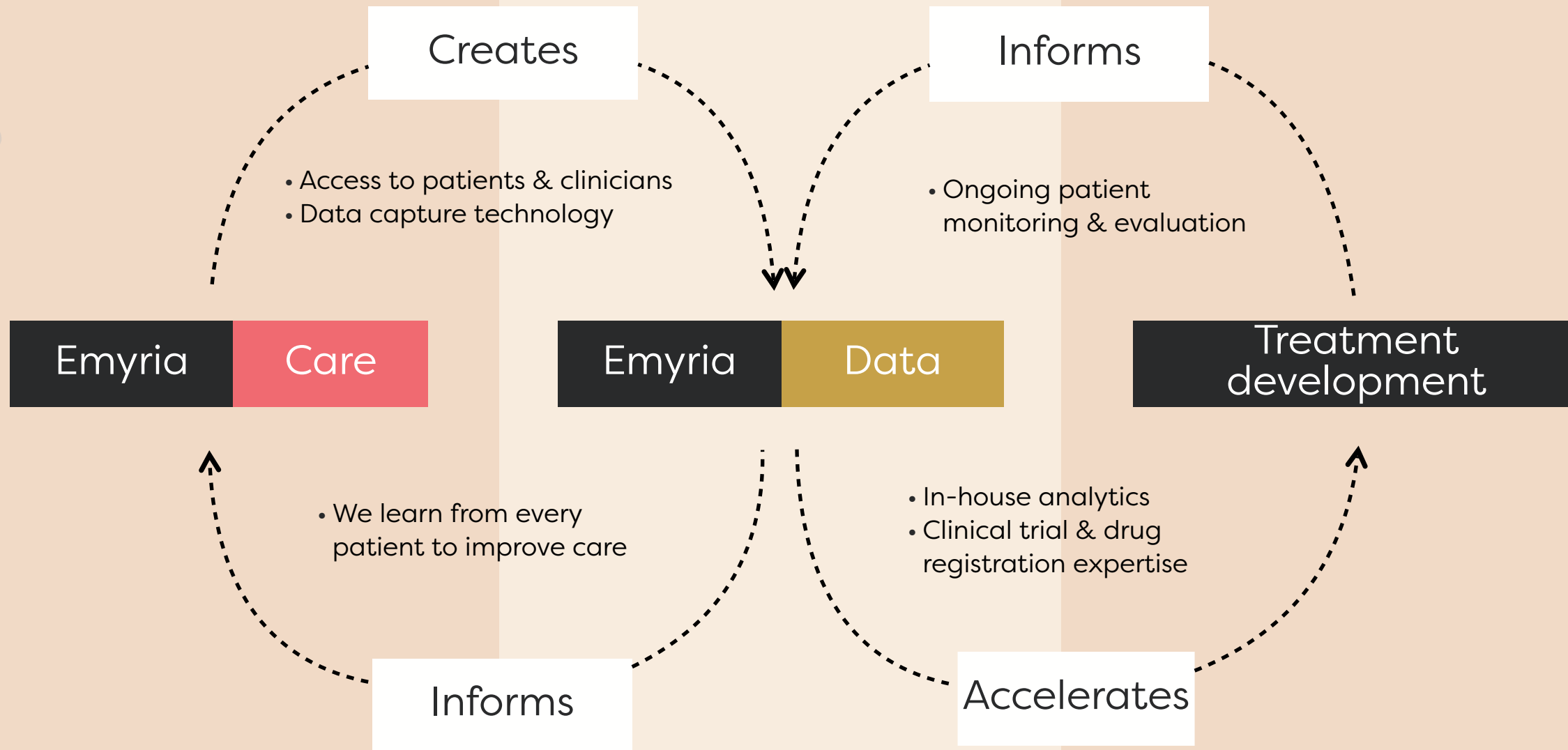
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**Emyria creates registered treatments  
for under-served populations using our  
proprietary clinical evidence**



*“Emyria owns clinics, cares for patients, invests in technology, generates data, creates evidence and develops programs to accelerate the registration of new treatments, including our own.”*

**Dr Michael Winlo, MD and CEO**



Emyria

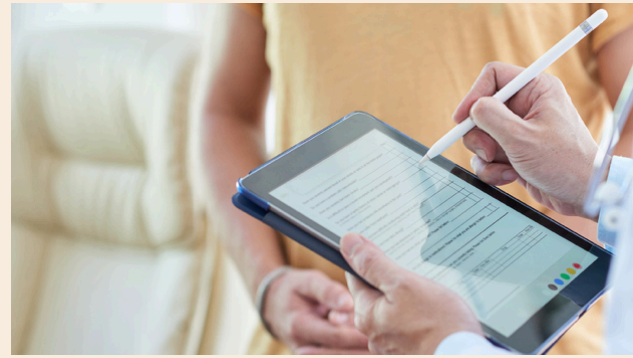
Care



- **7 sites** around Australia
- **GCP-trained** clinical team
- **4,000 patients** and growing
- Patients aged **2 - 96years**
- Over **40 clinical indications**

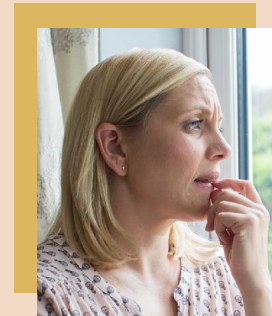
Emyria

Data



- **Validated** assessments
- **Clinical-trial-grade** data
- **Millions of data points**
- Unique **dose response** insights
- Source of **IP**

Emyria's current treatment development programs



#### Mental health

- *CBD medicine*
- *Entering clinical outcomes studies*
- *Seeking Schedule 3 registration*

EMD-003



#### Others

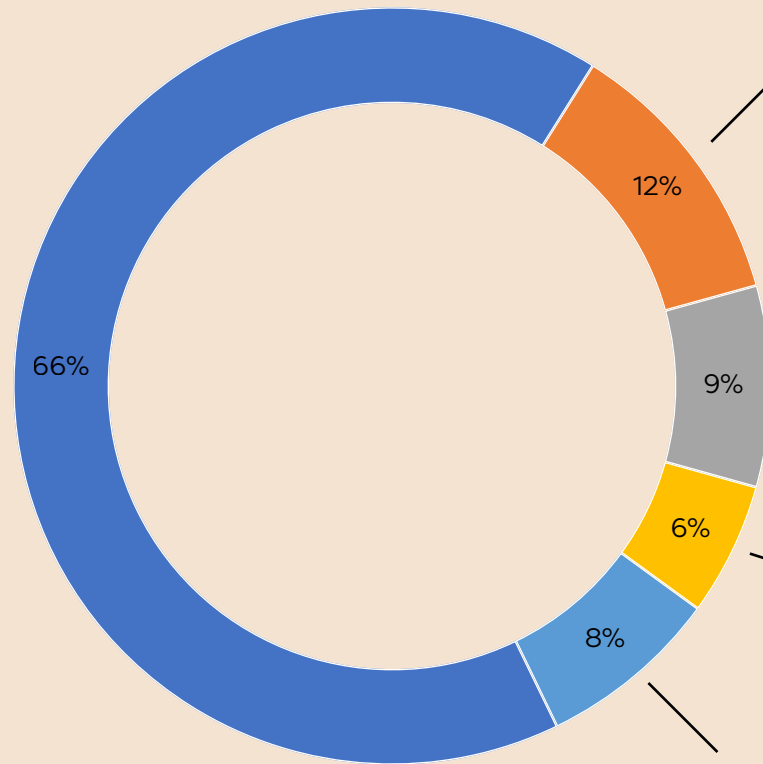
- *Irritable Bowel Syndrome (EMD-004)*
- *Chronic Pain*

EMD-00X

# Emyria patients: Primary indication seeking care

## Chronic Non-Cancer Pain

- Neuropathic
- Inflammatory
- Mixed
- Migraine



## Mental Health

- Insomnia
- PTSD
- Anxiety disorders

## Cancer symptoms

- Pain
- CINV
- Anorexia

## Neurological disorders

- Dementia
- Multiple Sclerosis
- Parkinson's Disease
- Epilepsy

## Other

- Irritable Bowel Syndrome
- Inflammatory Bowel Disease
- Fibromyalgia
- Alcohol and other drug abuse

# Chronic pain patients at Emyria



• **Age** 60.1 years (SD 17.01)

• **FT work** 19%

• **Gender:** 61.4% female

• **CNCP:**

• Neuropathic (55.9%),

• Inflammatory (5.6%),

• Mixed (30.6%),

• "other" (7.9%)

• **>2 years** 90% (>5 yrs 63%)

• **Multi-morbidity**

• Insomnia 76.1%

• OA 45.1%

• MH disorders 43.1%

• GI disorders 35.4%

• others 42.1%

• **Poly-pharmacy**

• opiates:

• *synthetic* 49.3%,

• *non-synthetic* 77.3%

• paracetamol 74.4%

• antidepressants 54.7% (including duloxetine, amitriptyline)

• anticonvulsants 35.8% (pregabalin, gabapentin, valproate)

• benzodiazepines 38.8%

• **Interventions** 38.4%

• facet joint injections 39.8%

• cryorhizotomies 21.7%

• surgery 34.6%

• **Recent cannabis use** 15.1%

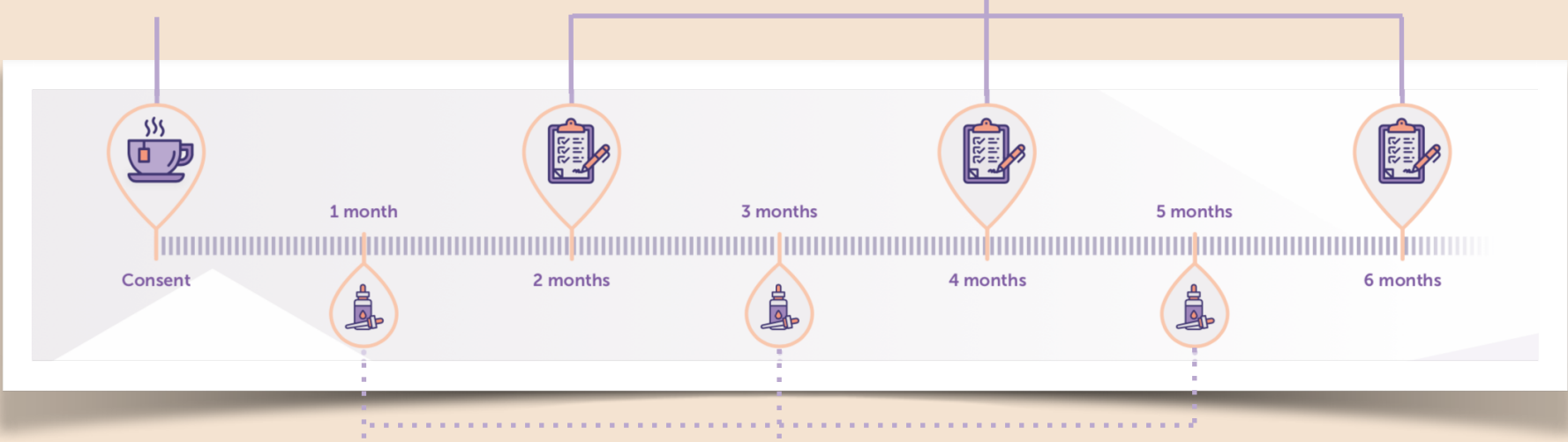


# Emyria's chronic pain care model:



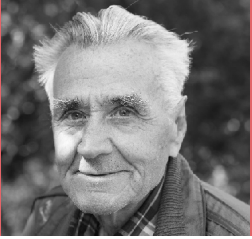
*Detailed patient consent*

*Regular, in-depth assessments and reviews to measure what's working*



*Personalised treatment schedule - informed by our data and the prior experience of similar, "patients like you"*

Personal use only



# Case Study - Bob



- Vietnam Veteran | injured by fall in 1969 | multiple fractures
- Chronic back pain | peripheral neuropathy from Agent Orange | PTSD
- **At initial visit:** oxycontin | buprenorphine | pregabalin | gabapentin | PEA duloxetine - with little relief and side effects.
- **Now:** Stable at 15mg 1:1 THC/CBD | **ceased all opiates**, pregabalin and PEA




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

# Opioid use disorder: Massive global problem

## Opioids for chronic pain

As many as **1 in 4 PEOPLE\*** receiving prescription opioids long term in a primary care setting struggles with addiction.



\* Findings from one study [1]

## Australia

**WHAT DOES EXTRA-MEDICAL OPIOID USE COST AUSTRALIA?**

Extra-medical opioid use includes the illegal use of heroin and the misuse of pharmaceutical opioids (use not as prescribed)

**645,260** Australians USE extra-medical opioids  
**104,000** Australians are DEPENDENT on extra-medical opioids  
**2,203** Australian DEATHS are attributable to extra-medical opioid use

The tangible costs of extra-medical opioid use amount to **\$5.63 BILLION**

- \$2.48 billion Premature death
- \$936 million Drug-related crime
- \$481 million Road traffic accidents
- \$1.08 billion Healthcare costs
- \$459 million Workplace costs
- \$194 million Other (including prevention programs)
- \$311 million Pharmaceuticals for treatment of medical conditions related to opioid use
- \$127 million Specialist drug treatment including opioid substitution therapy
- \$85 million Other health costs
- \$249 million Inpatient hospital treatment
- \$234 million Primary healthcare treatment
- \$41 million Ambulance and Emergency Department services
- \$31 million Outpatients

The intangible cost of extra-medical opioid use is **\$10.13 BILLION** due to the premature death of 2,203 people and over 70,000 years of life lost

**THE TOTAL COST OF EXTRA-MEDICAL OPIOID USE IS \$15.76 BILLION**

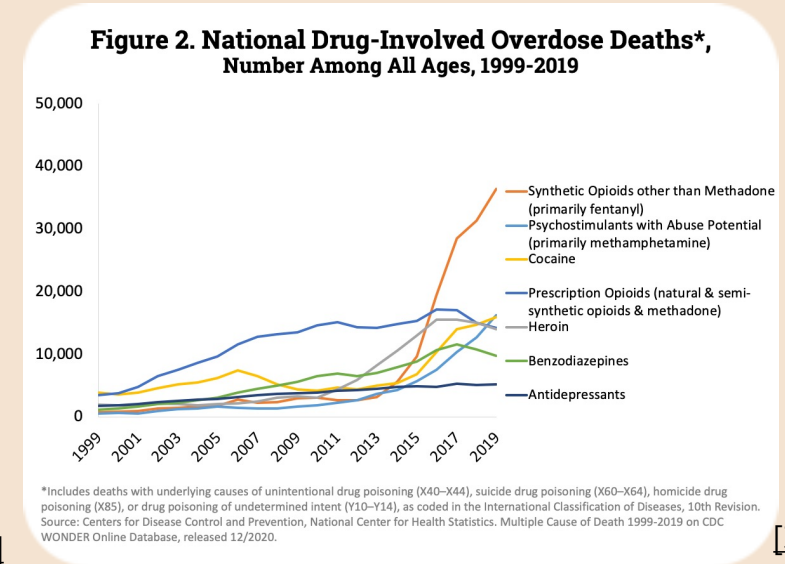
Data from 12-month period July 2015 to June 2016

Whetton, S., Tali, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Makhtar, A., Zahra, E., Campbell, G., Degenhardt, L., Day, T., Hallin, S.A., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A. and Alkay, S. (2020). Quantifying the social costs of pharmaceutical opioid misuse and illicit opioid use to Australia in 2015/16. National Drug Research Institute, Curtin University, Perth, Western Australia.

ndri.curtin.edu.au [2]

## USA

The U.S. economic cost of opioid use disorder (**\$471B**) and fatal opioid overdose (**\$550B**) during 2017 totalled **\$1,021 billion**.



Sources:

[1] <https://ndri.curtin.edu.au/news-events/ndri-news/media-release-the-cost-of-opioid-use-to-australia>

[2] <https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates>

[3] <https://www.cdc.gov/mmwr/volumes/70/wr/mm7015a1.htm>

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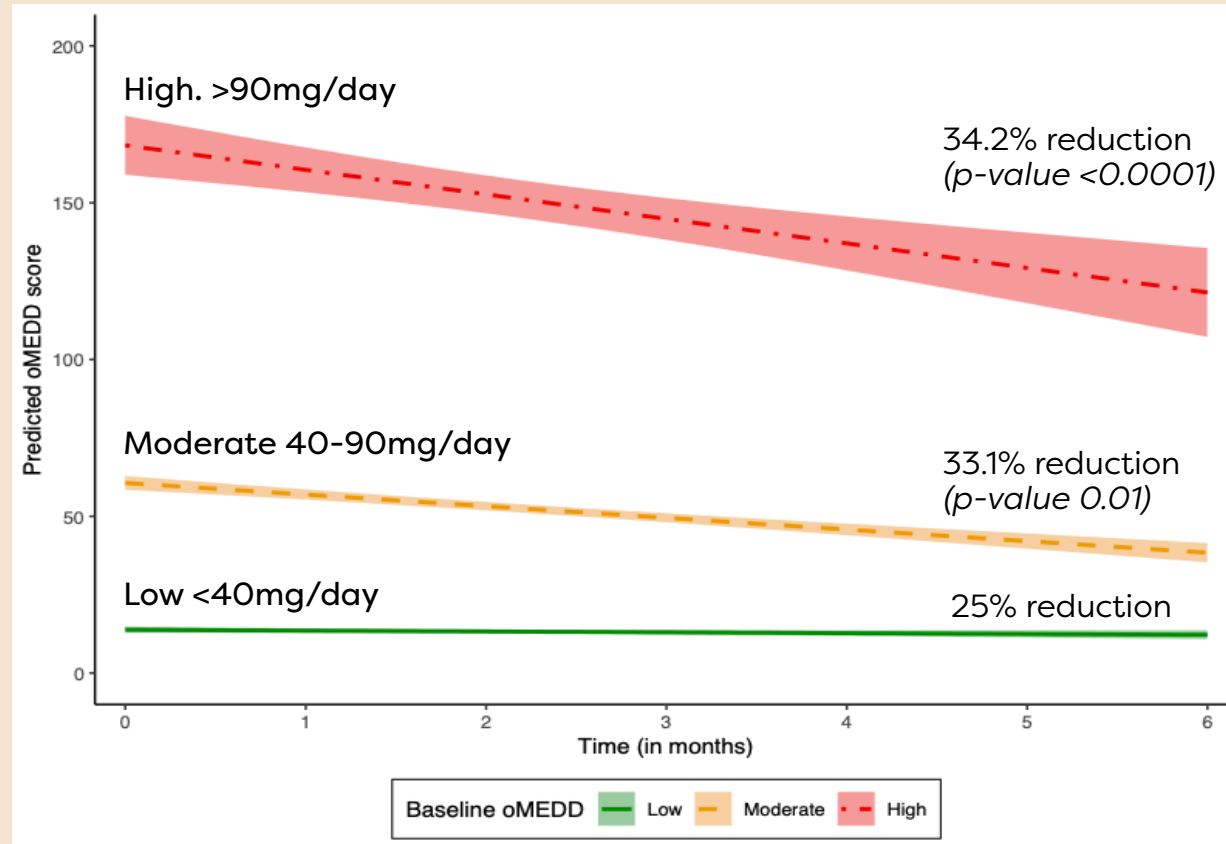
**CASE STUDY:**



**How effective is *Emyria's unique care model* at *reducing opioid use*\*?**

\* measured via average oral morphine equivalent daily dose ("OMEDD")

# Emyria Care: OMEDD Results over 6 months (n=503)

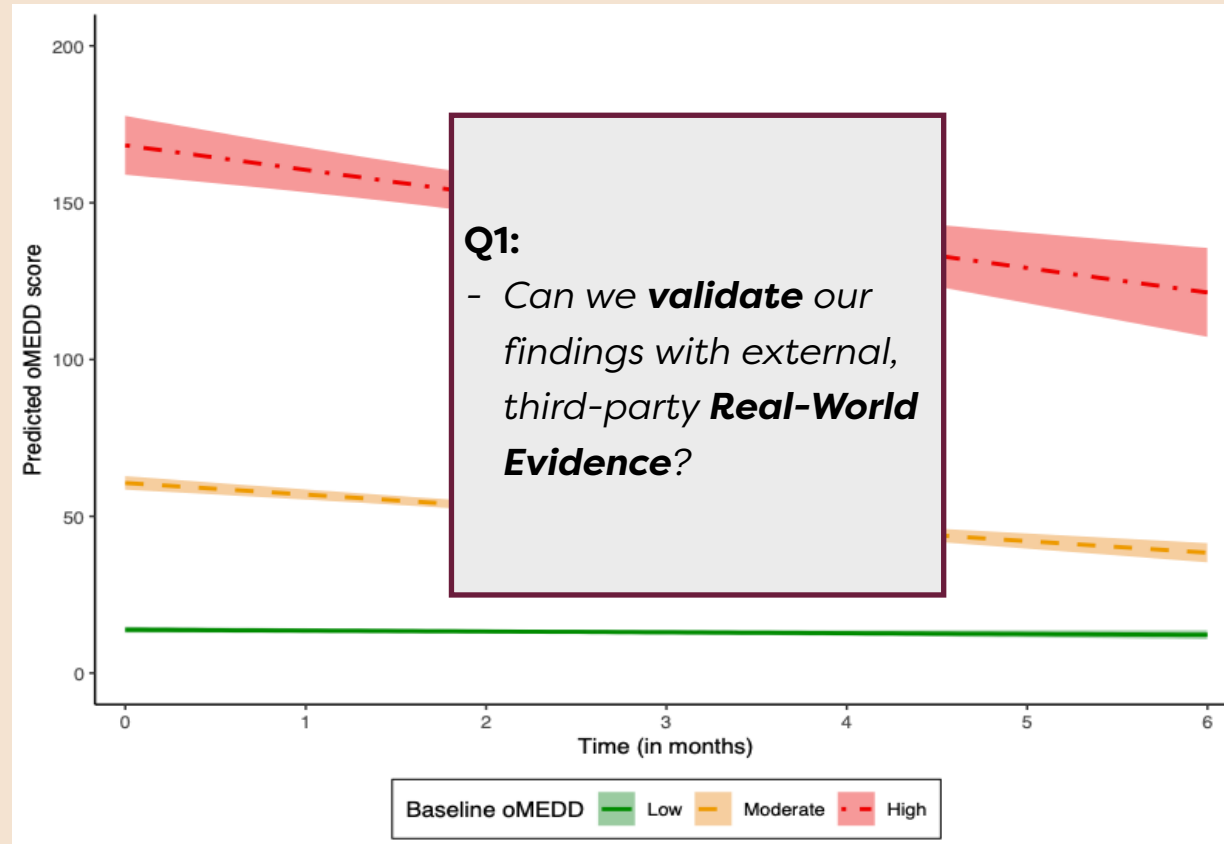


- Patients also reported:**
- Decreased pain severity + interference
  - Improvements in psychological distress and quality of life (QoL)

# Emyria Care: Questions?

## Q2:

- What is the **OMEDD trend** of our patients, “before” they receive Emyria Care?



## Q1:

- Can we **validate** our findings with external, third-party **Real-World Evidence**?

## Q3:

- What happens to patients once they stop treatment?
- Can we make a control?

# The TEAM!

**emyria**



- NostraData collects dispensed **prescription data** from over **4,500 retail community pharmacies** across Australia
- Using **special technology**, NostraData can safely and securely collect the cleanest and most accurate data in the industry
- NostraData can then load, cleanse, map, stack and rack the data in visually stunning **reports** and **datasheets**



- IQVIA is a global (NYSE: IQV) **biopharmaceutical development company** focussed on Phase I-IV clinical trials, laboratory and **analytical services**
- **IQVIA Real World Solutions** enables customers to **generate and disseminate real world evidence** to answer crucial questions
- IQVIA has a network of more than 70,000 employees in more than 100 countries

# Linking the DATA: Is it RESEARCH-GRADE?

**emyria**

NostraData 

## Data quality

**Source verification** (can you trust it?)

**Completeness (QMS)** (can you use it?)

**Standards** (can you link + generalise results?)

## Data Governance

**Patient consent** (are patients involved? Can you share data?)

**De-identification process** (is privacy protected?)

**Secure transfer + tracking** (can you manage cyber risk?)



# STEP 1: LINK THE DATA

**emyria** Data

Patients provided by Emyria

1029 patients

Patients found with Master Patient IDs in ND

1020 patients

Patients with more than 1 visit

786 patients

Patients with at least 1 dispensation of analgesics (ATC N02) or opioids between the first visit +/-  $n$  days where  $n$  can be either 365 days or the cannabinoid treatment duration, whichever is the greatest. \*

\* Ensures the ND panel captures dispensations of analgesics or opioids in the proximity of the first visit of each active patient.

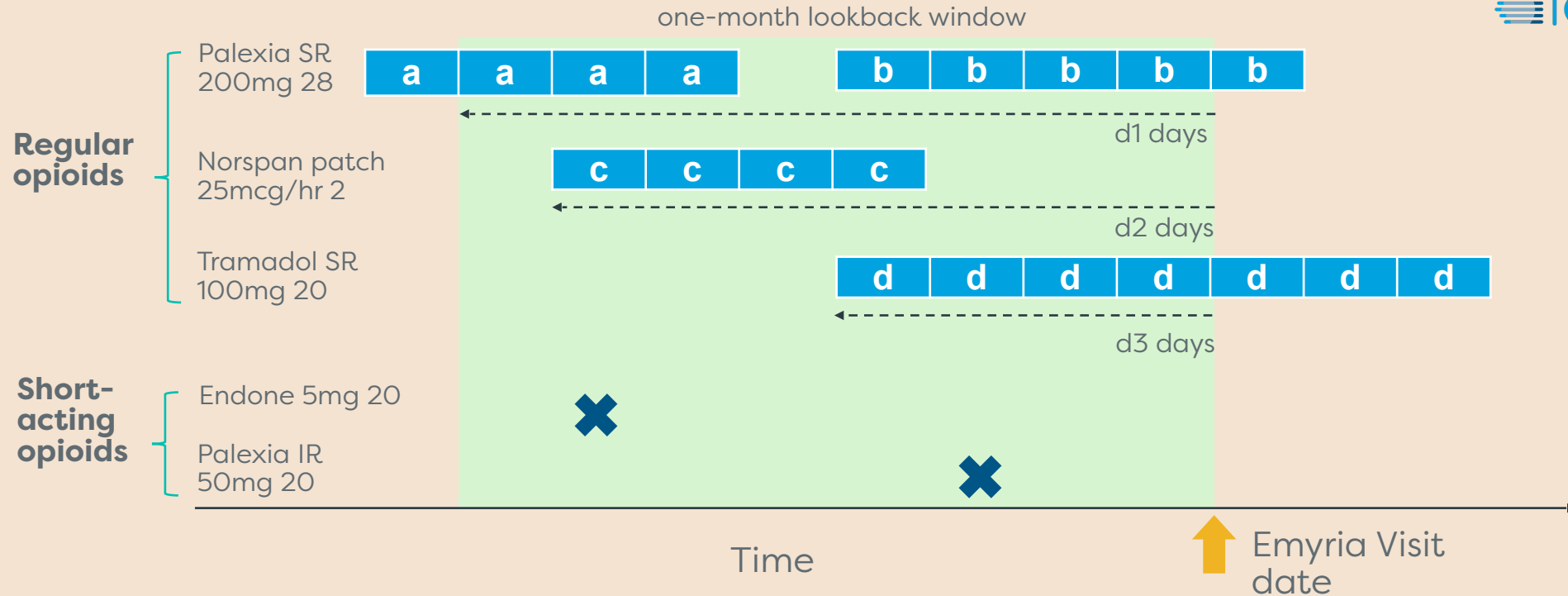
711 patients

Patients with analgesics dispensations for at least 50% of the months in the observation period

470 patients

NostraData  
IQVIA  
LRx

# STEP 2: BUILD AN OMEDD MODEL FOR LRx



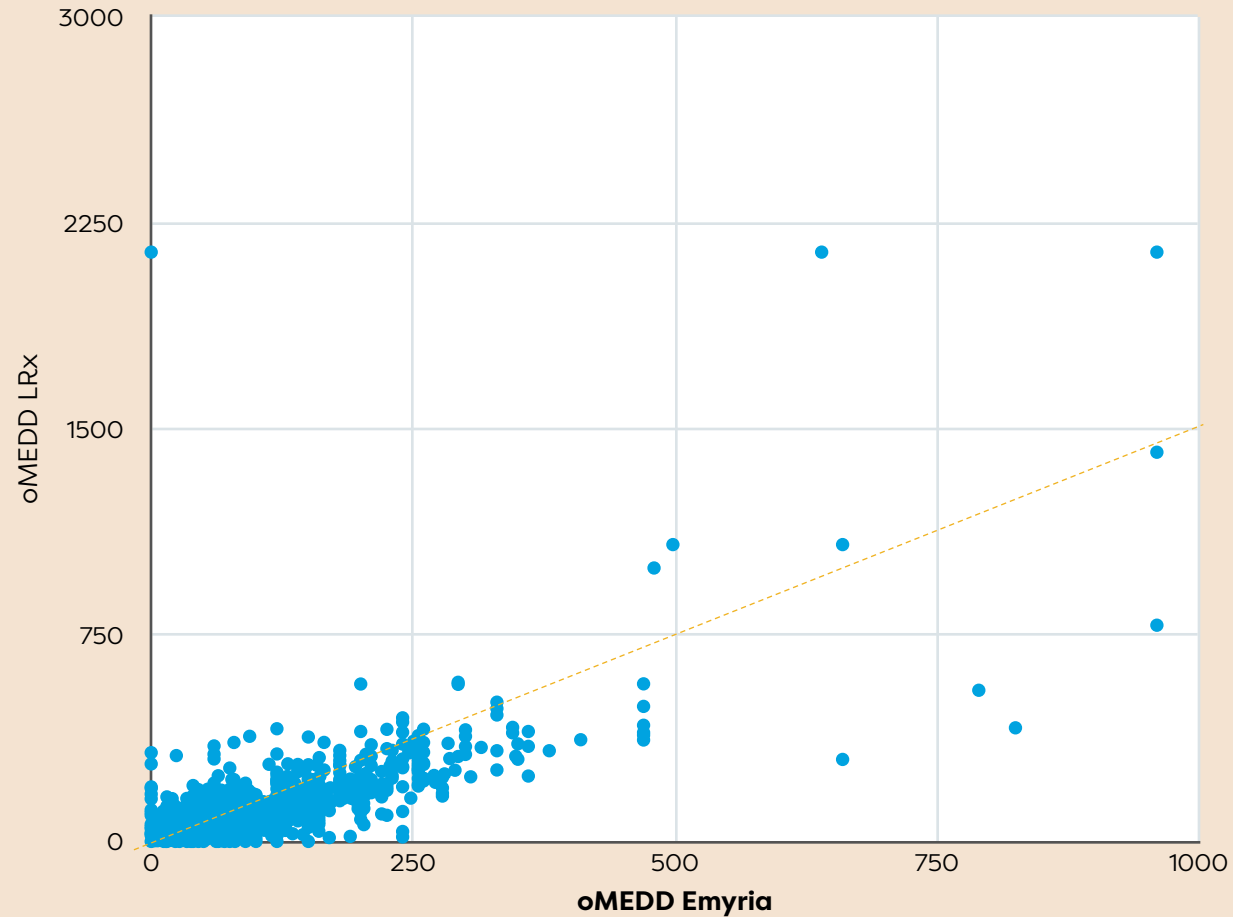
1. Look back one month prior to the Emyria visit date.
2. For each regular opioid dispensation, calculate the oMEDD score based on the SKU strength and the label instruction. The theoretical days of supply are calculated based on the number of packs dispensed and the daily dose decoded from the label instruction. As shown above, the blue rectangles and the letters represent the days of supply and the oMEDD scores respectively. If the label instruction does not give any useful daily dose (e.g. "Use as directed"), the most common day of supply for that SKU is used.
3. For each regular opioid SKU, determine the longest span ended on the visit date, which are denoted as d1, d2 and d3 days above. The average oMEDD score for each SKU is calculated by dividing the sum of the scores within the span by the span in days.
4. For the short-acting opioids, label instructions might not be indicative of the actual daily doses because patients are likely to use the drugs "when required", e.g. Take two capsules four times a day when required. Therefore, a 30-day supply is assumed and the average oMEDD score is derived from the total mg dispensed divided by 30 days.
5. Sum all the average oMEDD scores from all SKUs.

Personal use only

# STEP 3: ANALYSIS



oMEDD LRx vs oMEDD Emyria



**Correlation coefficient = 0.76**

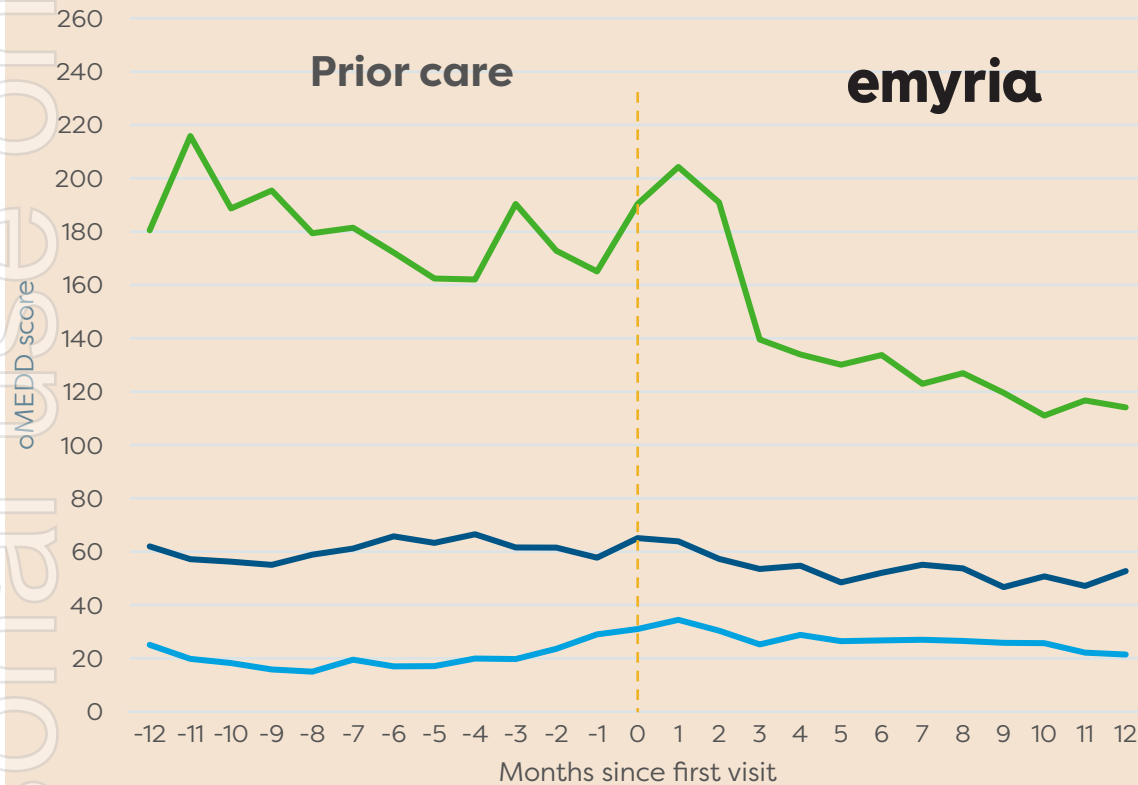
# EARLY RESULTS - significant decrease in oMEDD



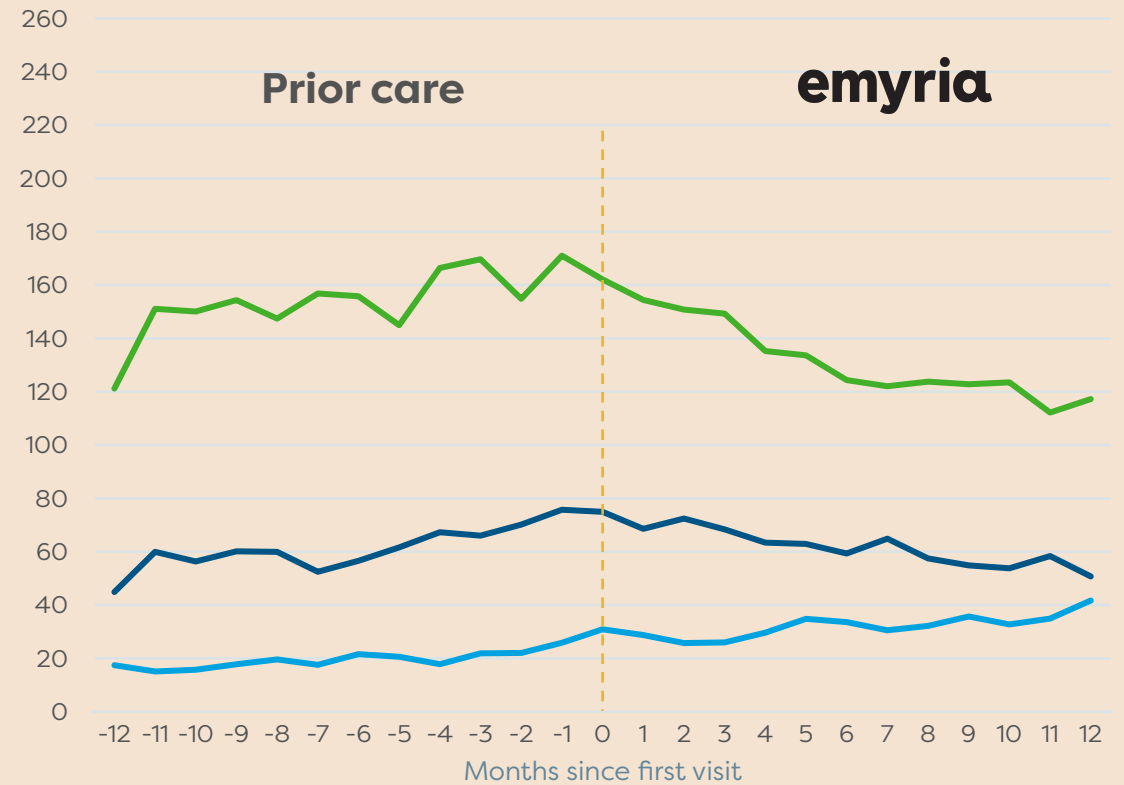
Average oMEDD scores by oMEDD category (Pre vs Post)

— < 40 — 40 - 90 — > 90 \*

Patients with 6+ months of cannabinoid usage



Patients with <6 months of cannabinoid usage



\* The oMEDD category is derived from the average oMEDD score over a 1-year period prior to the first visit.

# Commentary

## • Emyria's personalised care model appears effective

- Emyria patients reduce opioid use against background of improving symptoms and Quality of Life (“QoL”) measures and this is sustained beyond 6 months

## • Emyria's data has high validity

- Demonstrated ability to link Emyria's data to third-party sources securely to support robust analysis
- Implications for future research, treatment and care model innovation

# + Take-Aways

## • INVEST IN DATA

- People
- Technology
- Data governance

## • WORK WITH PARTNERS

- IQVIA + NostraData

## • SCALE CARE MODEL

- Approach payers
- Continue to refine models to maximise benefit

# What's possible with research-grade data and what's next?

- **Produce deeper analysis + publications**

- Cost and service utilisation analysis
- Peer-reviewed publications
- ENGAGED UWA

- **Create data-backed assets**

- Emyria will launch new Rx programs
- Emyria is building clinical decision support tools

- **Develop innovative care models**

- Emyria to approach payers and insurers to present findings of model of care
- Continuous refinement of care models to maximise benefit



**Prof. David Preen** - Chair of Public Health at UWA  
- working on a coordinated research program to accelerate the development and translation of evidence about real-world medicine use and outcomes to improve the quality use of medicines and reductions in medicine-related harm.

ersonal use only

**Thank-you and QUESTIONS?**

