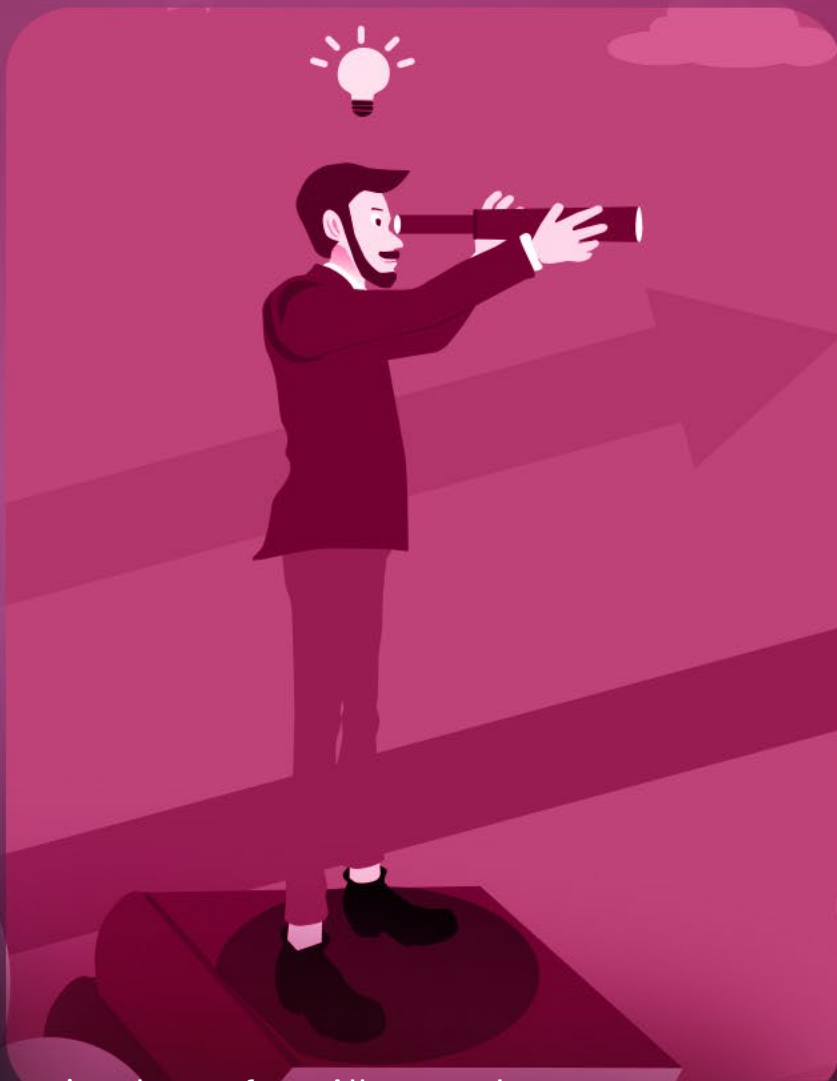




Seeing the Bigger
Picture: **How to
Evaluate Real-World
Evidence** Along with
RCTs in Psychiatric
Treatment Decisions

MasterClass

Supported by an educational grant from Alkermes, Inc

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Faculty Disclosures

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Disclosures

- The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational use(s) of drugs, products, and/or devices (any use not approved by the US Food and Drug Administration)
- Applicable CME staff have no relationships to disclose relating to the subject matter of this activity
- This activity has been independently reviewed for balance

Learning Objectives

- Assess the general methodological strengths and limitations of randomized controlled trials versus real-world studies in psychiatric treatment research
- Differentiate common real-world study designs in psychiatric treatment research
- Evaluate the clinical implications of available RWE on FDA-approved psychiatric treatments
- Integrate evidence from both RCTs and RWE studies to individualize treatment selection and improve treatment effectiveness for patients in psychiatric practice

Overview of Randomized Controlled Trials (RCTs) and Real-World Evidence (RWE) in Psychiatry

1800s: When Medicine Started Counting

Medicine trusted tradition

Treatments were guided by theory and clinical impression

Dr. Pierre Louis began counting outcomes

and compared groups with similar illnesses

The numbers challenged intuition

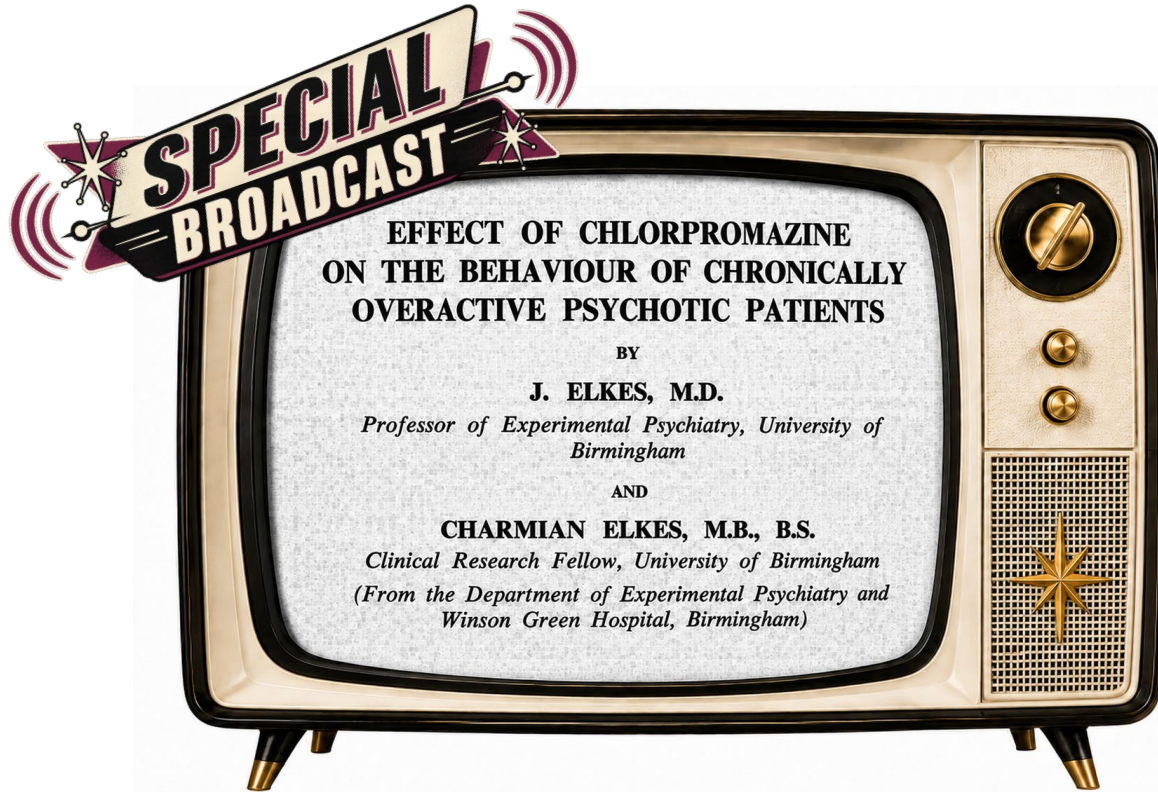
Earlier bloodletting led to faster recovery, *but higher mortality*

Counting added objectivity to medicine

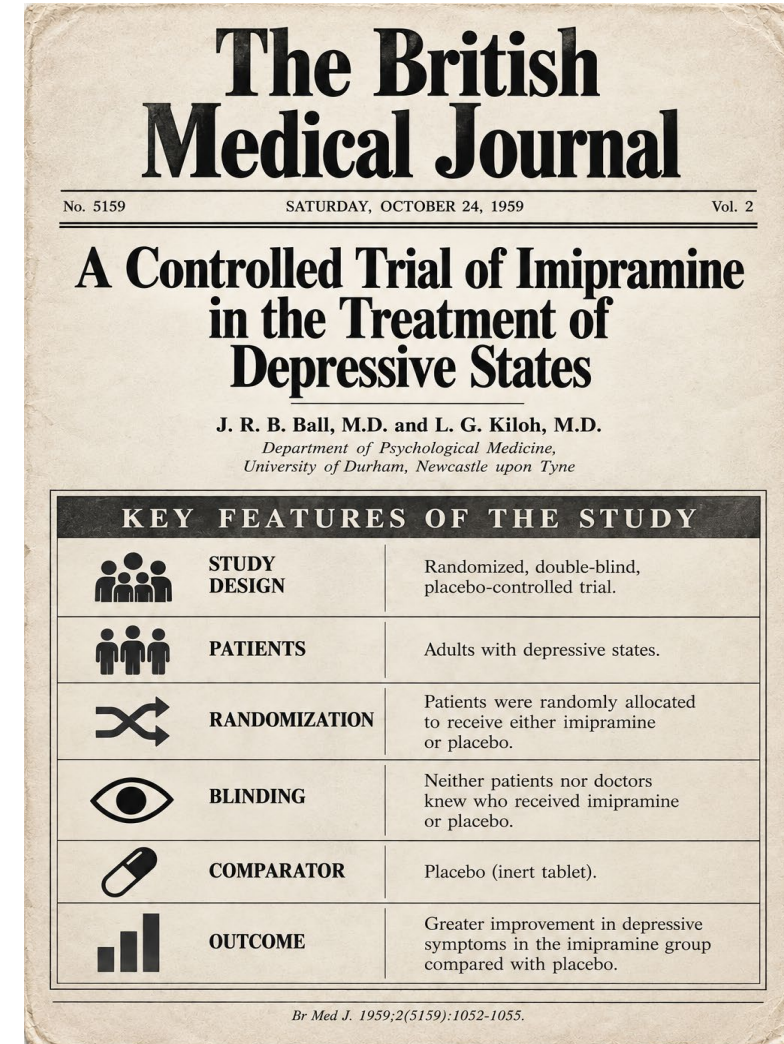
Clinical impression gave way to measurable outcomes



1950s: Psychiatry Meets the Controlled Trial



Chlorpromazine for Schizophrenia (N=27)



Imipramine for Depression (N=55)

1970s-1990s: The RCT Becomes the Gold Standard



But Gold Isn't Always Golden...



2009: Who Actually Gets Represented in an Antidepressant RCT?

Out of 2,855 STAR*D participants with MDD...

Only
22%
would have been
considered RCT-eligible

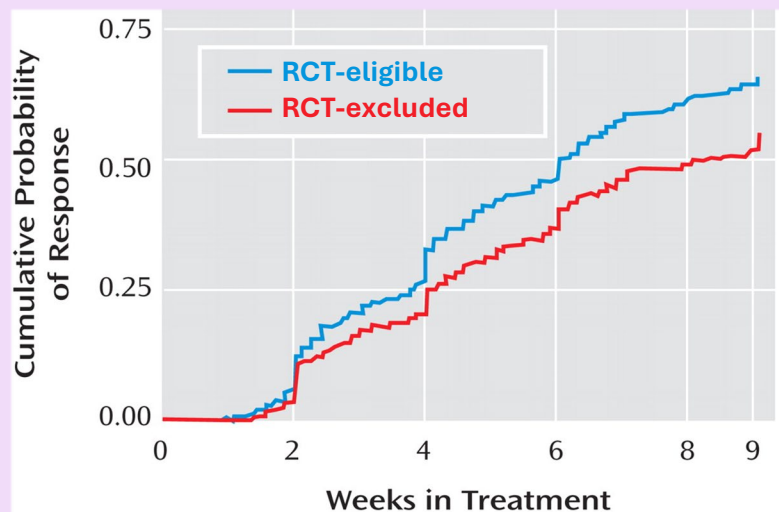
~78%
would have been excluded from a
typical Phase 3 antidepressant trial

The Excluded Participants Had Worse Clinical Outcomes

THE 78% EXCLUDED HAD:

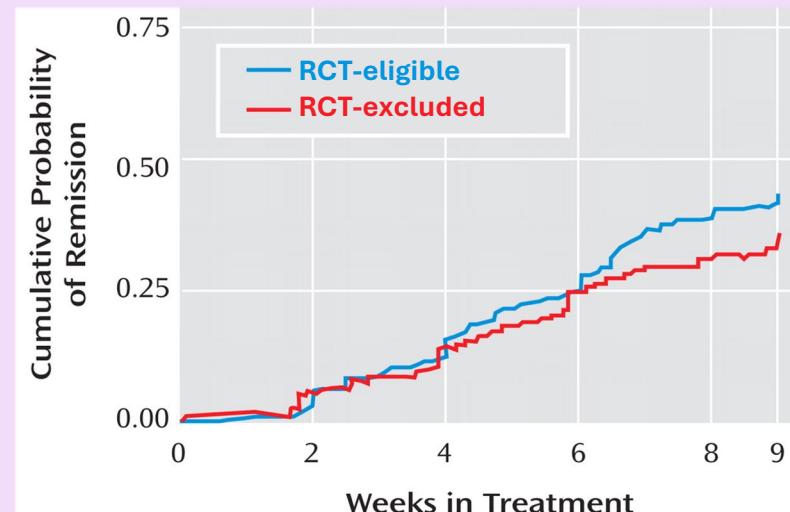
Lower Response

39.1% in the excluded sample vs
51.6% in the eligible sample



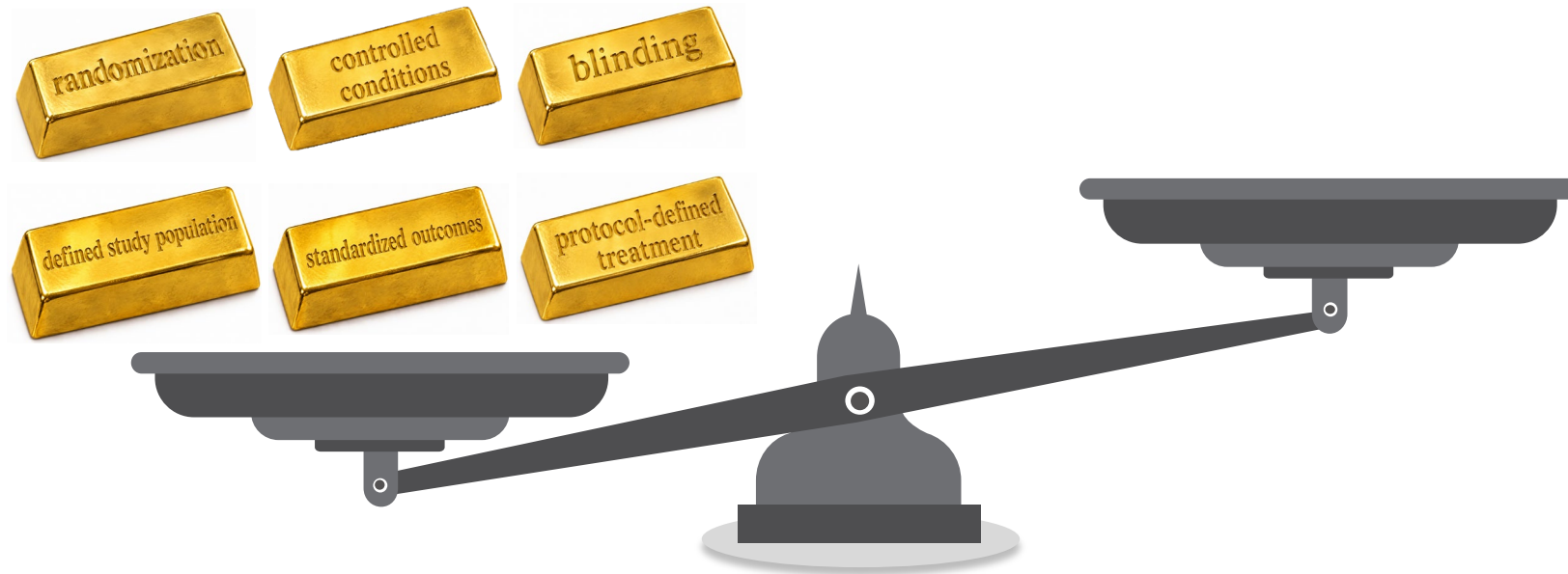
Lower Remission

24.7% in the excluded sample vs
34.4% in the eligible sample



The gold standard isn't equally golden for everyone

Today: Modern RCTs Are Rigorous and Valuable...



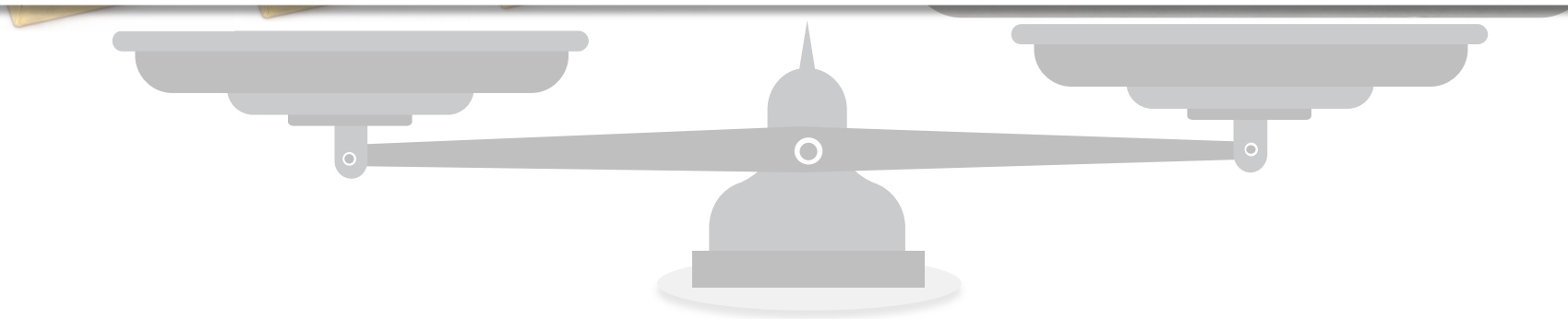
...But RWE Adds Complimentary Strength



...But RWE Adds Complimentary Strength

It's not about choosing between **RCTs** and **RWE**...

It's about finding the right balance of evidence to answer the questions that matter for our patients



Key Learning Points



- RCTs rigorously establish treatment efficacy through randomization, controlled conditions, standardized outcomes, and protocol-defined treatment
- ***Gold-standard RCTs aren't golden for everyone***: restrictive criteria may exclude many real-world patients
 - Example: **Approximately 78% of STAR*D participants with MDD** would have been excluded from a typical phase 3 antidepressant RCT due to restrictive eligibility criteria
- RWE complements RCTs by showing how treatments perform in broader clinical populations

Evidential Strengths and Limitations of RCTs and the Importance of RWE in Psychiatry

Strength of RCTs:

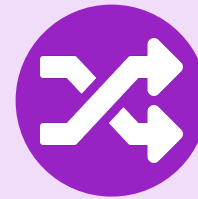
High Internal Validity

High Internal Validity (Strong Causal Inference)

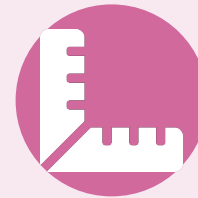
The RCT remains **the methodological gold standard** for establishing that an intervention (not by chance or confounding variables) caused the observed outcome

Two design features drive this strength:

-  **Randomization** attempts to neutralize known and unknown confounders
-  **Prespecified, standardized tools** ensure outcomes are measured consistently across every participant and site



**Randomization &
Confounder Control**

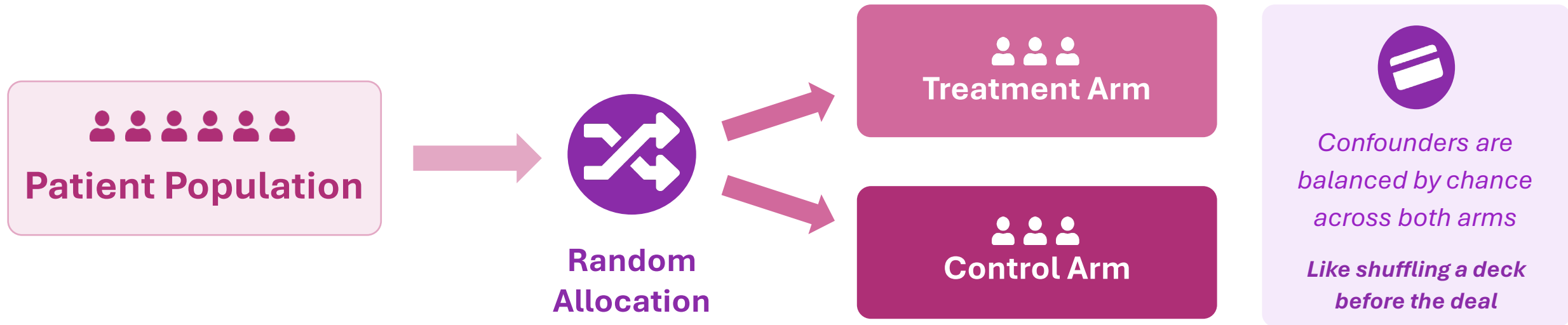


**Standardized
Measurement**

Mechanism 1:

Isolation of Treatment Effects via Randomization

Random allocation distributes both known confounders (age, illness severity, comorbidity) and unknown confounders equally across arms **by chance**, so any difference in outcome can be attributed to the intervention itself



Outcome differences between arms can be interpreted as **causal effects of the treatment**, not artifacts of unequal baseline characteristics.

Mechanism 2:

Measurement via Prespecified, Standardized Tools

Outcomes are defined before the trial begins and captured the same way for every participant (the same ruler applied to every patient, every time), which is what makes results comparable across sites and reproducible across studies



Primary Endpoints Set *A Priori*

The key outcome and analysis plan are locked before enrollment begins, reducing the risk of post-hoc reinterpretation.



Validated Rating Scales

Instruments, such as the HAM-D or MADRS, provide a common, psychometrically tested metric of symptom change.



Blinded Outcome Assessment

Raters unaware of treatment assignment reduce expectation bias in symptom scoring.



Fixed Assessment Timepoints

Protocol-driven visit schedules ensure every participant is measured at the same intervals.

Limitation of RCTs:

Low External Validity

Low External Validity (Limited Generalizability)

The same design features that maximize internal validity often **narrow how well trial results translate to the patients actually seen in day-to-day psychiatric practice.**

Two limitations to weigh:



Restrictive inclusion/exclusion criteria may yield unrepresentative samples



Protocol-adherent procedures could create artificial treatment conditions



Unrepresentative Samples



Artificial Conditions

Limitation 1:

Unrepresentative Samples from Restrictive Criteria

Strict inclusion and exclusion criteria protect internal validity, but each layer of exclusion narrows the sample further from the patients seen in routine psychiatric care.



Real-world psychiatric patients

Excl.: active substance use, suicidality

Excl.: psychiatric/medical comorbidity

Excl.: polypharmacy,
age extremes

RCT Sample

Who gets left out of trials?

The more eligibility filters applied, the fewer real-world patients remain represented

- Patients with significant comorbid conditions
- Active substance use disorders
- Suicidality or high-acuity presentations
- Complex polypharmacy regimens
- Pediatric, geriatric, or pregnant patients

Limitation 2:

Artificial Conditions from Protocol-Adherent Procedures

The structured monitoring that keeps a trial rigorous also produces a treatment experience that looks little like routine outpatient care

Think of it as a greenhouse versus the open field: both grow the same plant, under very different conditions.



RCT Protocol Conditions



Frequent, scheduled monitoring visits



Structured adherence tracking & pill counts



Concomitant medications tightly restricted



Heightened attention from research staff



Routine Clinical Practice



Visits driven by symptoms & availability



Adherence largely self-reported



Comorbidities managed with polypharmacy



Standard visit time and attention

Beyond the Trial: **Why Real-World Evidence Matters**

The Importance of Real-World Evidence

RWE captures how a treatment actually performs once it leaves the trial setting across the full diversity of patients, comorbidities, and everyday conditions that RCTs are designed to exclude.

Sources of RWE:



Electronic health records & clinical registries



Insurance claims & administrative datasets



Patient-reported outcomes from everyday care (e.g. surveys)

*Think of it as the treatment's track record in the real world,
not just its performance on the test!*



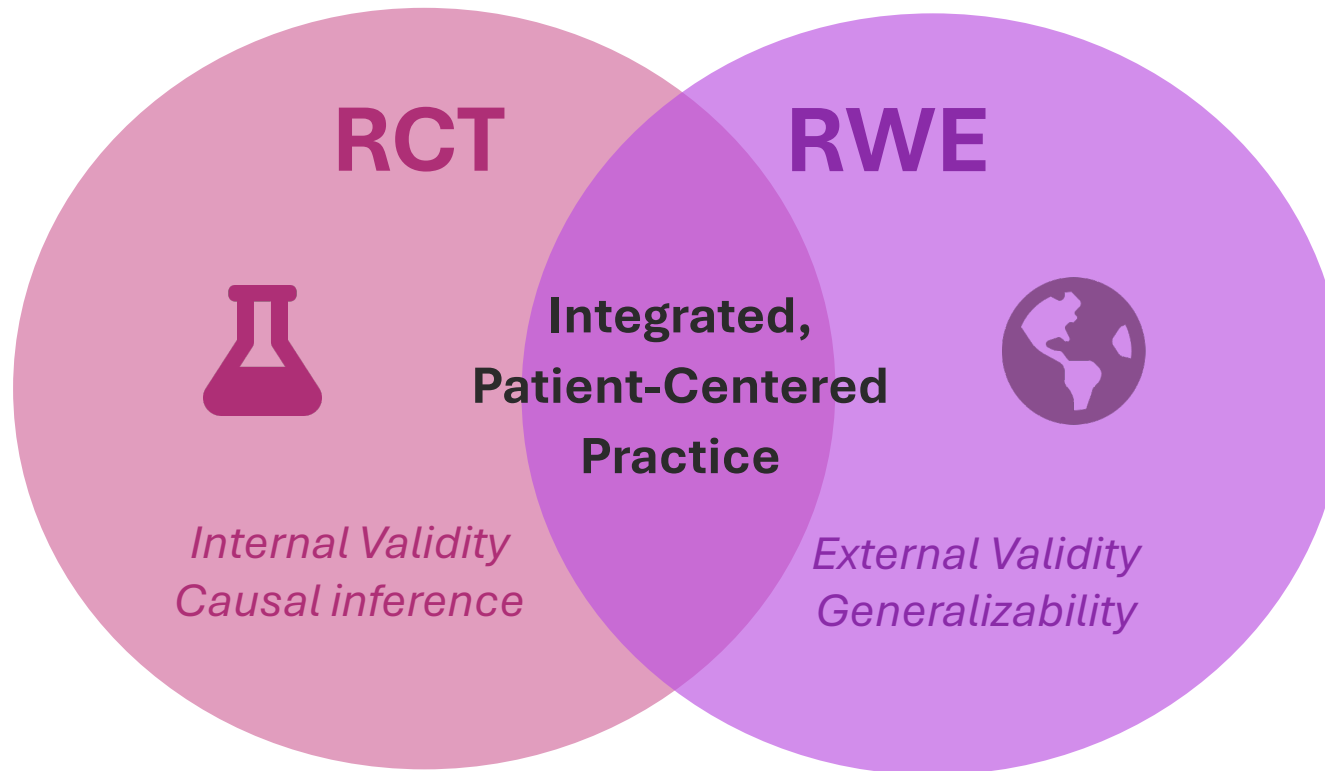
Reflects Real,
Diverse Populations



Captures Long-Term,
Real-World Outcomes

Bringing It Together:

The Importance of RCT-RWE Integration



Neither evidence type is sufficient alone.
Psychiatric practice should draw on **both** to inform
decisions for the patient in front of you.



***RCT evidence is the map;
real-world evidence is the
compass that adjusts for the terrain.***



THE CRUCIAL QUESTION



Are these patients like your patients?

-  Demographics and comorbidity profile comparable?
-  Illness severity and chronicity similar?
-  Prior treatment history and treatment resistance aligned?
-  Concomitant medications the trial excluded now needed?

Key Learning Points

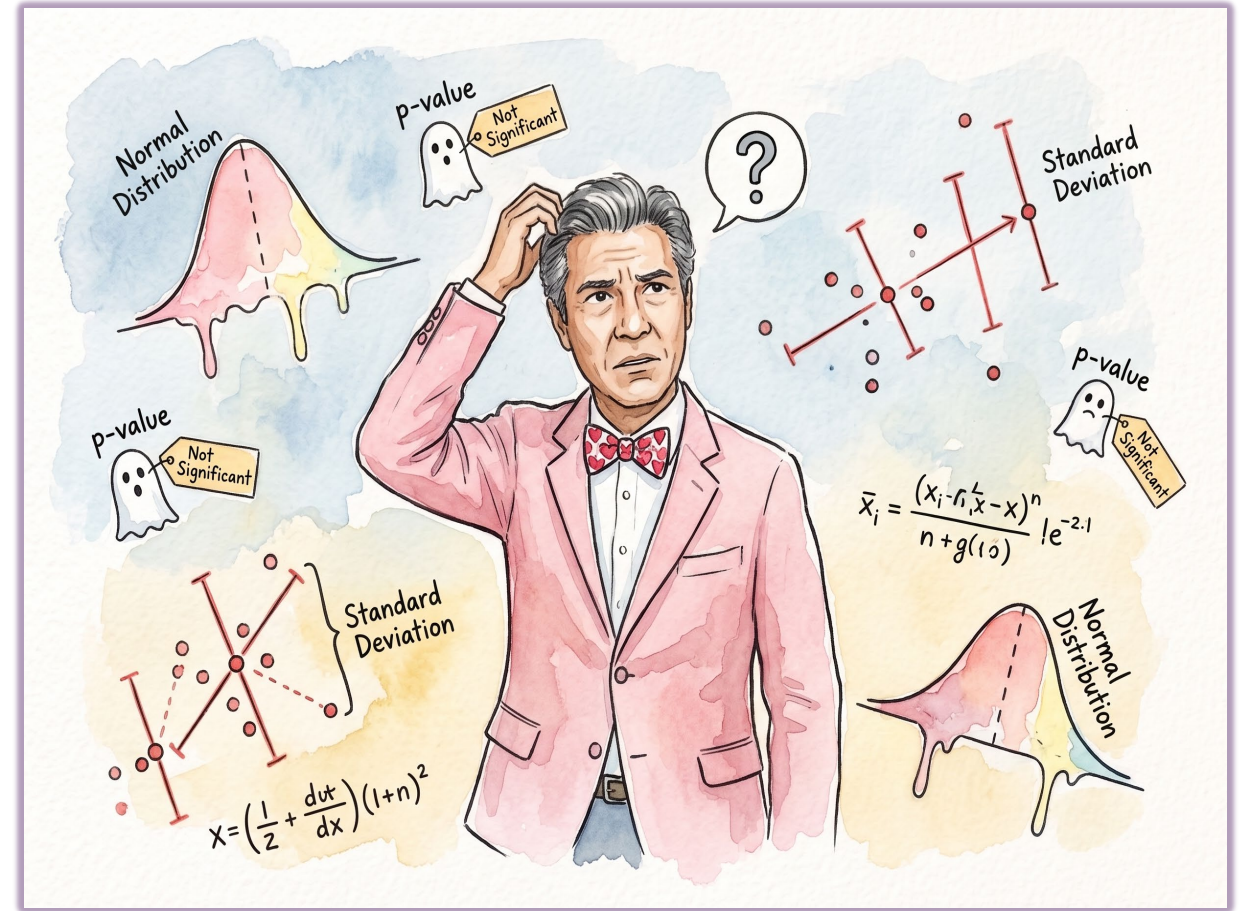
- RCTs remain **the gold standard** for causal inference, due to randomization and standardized, prespecified measurement.
 - That same rigor narrows the sample; restrictive criteria and protocol-driven care limit generalizability to routine practice.
- **Real-world evidence** (pragmatic trials, registries, EHR cohorts) fills the external validity gap that RCTs leave behind.
- Always ask: ***are these patients like your patients?***
 - Match demographics, severity, comorbidity, and treatment history before extrapolating.
- Best psychiatric practice **integrates RCT and RWE findings**, applied through individualized clinical judgment.

Design and Interpretation of Real-World Studies in Psychiatry

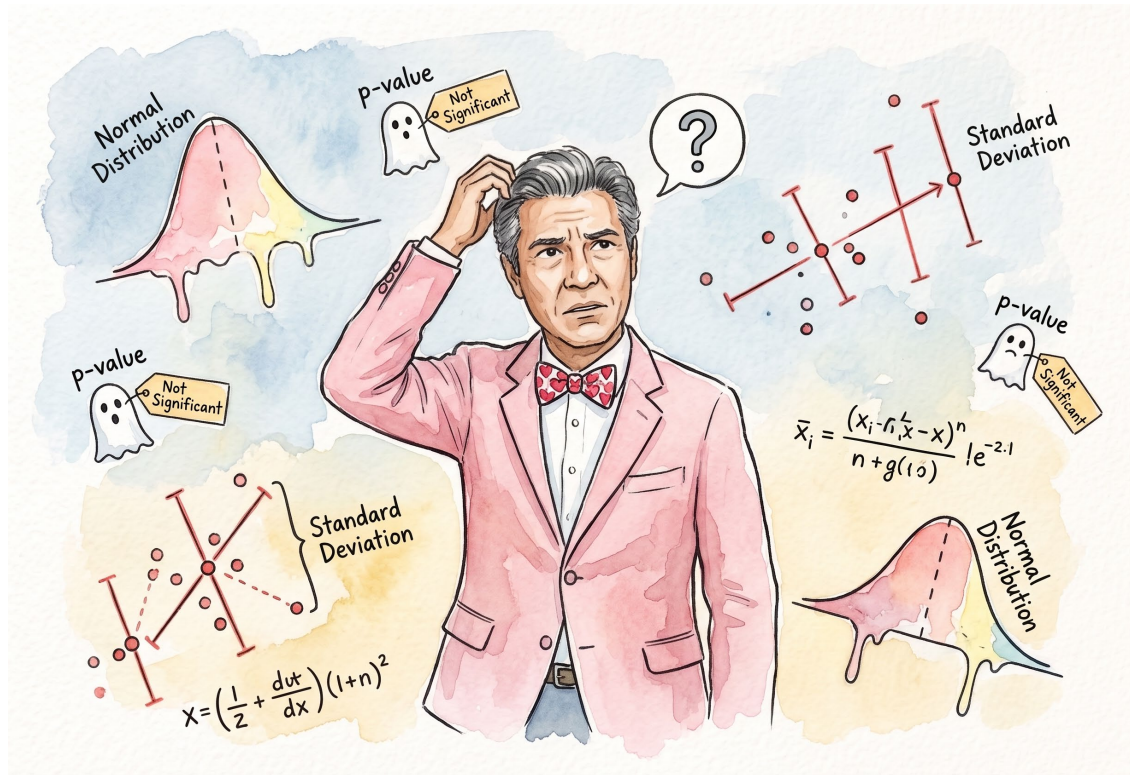
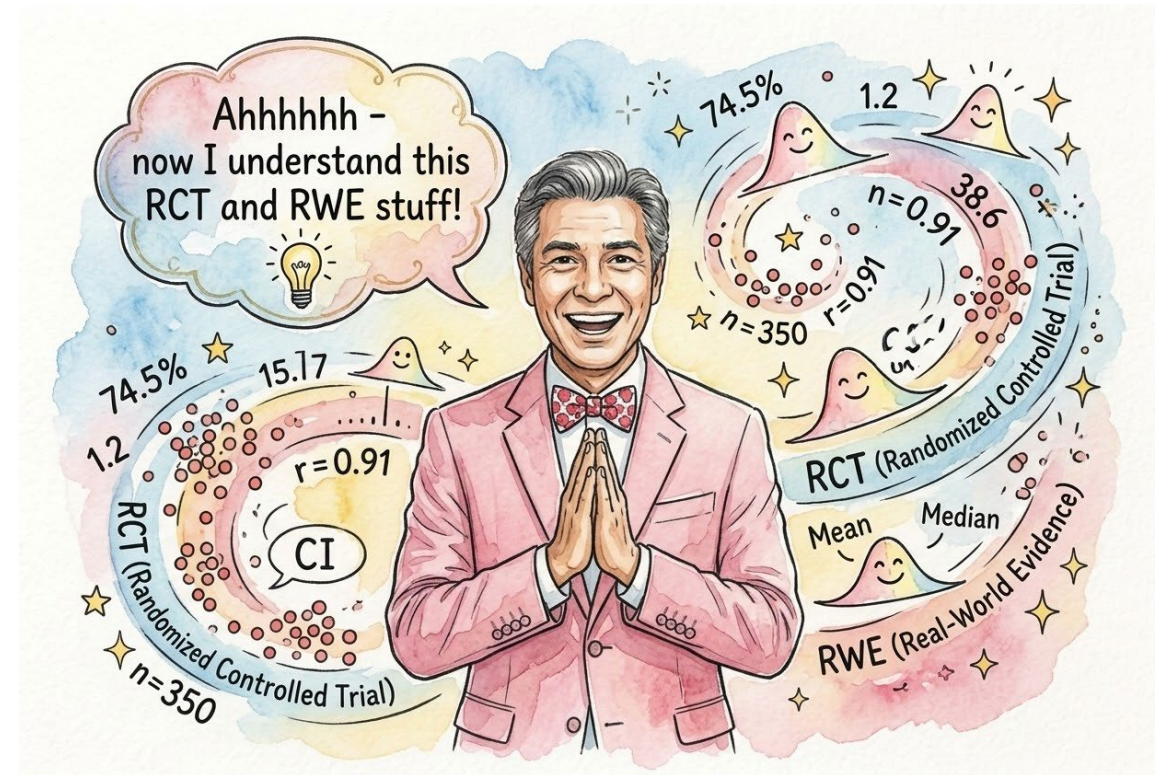
Let's Be Real – This Is Confusing S@#!!*

Being Real -

- Most of us got a minimum education on stats
- Most of us have no/very little instruction on Real World Evidence
- Most of us, therefore, find it intimidating and miss out on valuable information
- But – we are ready to change things
- Let's GOOO.... !



State of Clarity



**Let's Start by Hearing It Straight from
the Horse's Mouth**

The FDA

FDA Statement is Deeply Supportive of RWE

“FDA is committed to realizing the full potential of fit-for-purpose RWD to generate RWE that will advance the development of therapeutic products and strengthen regulatory oversight of medical products across their lifecycle.

Definitions

Real-world data are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status.

Real-world evidence (RWE) is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.”

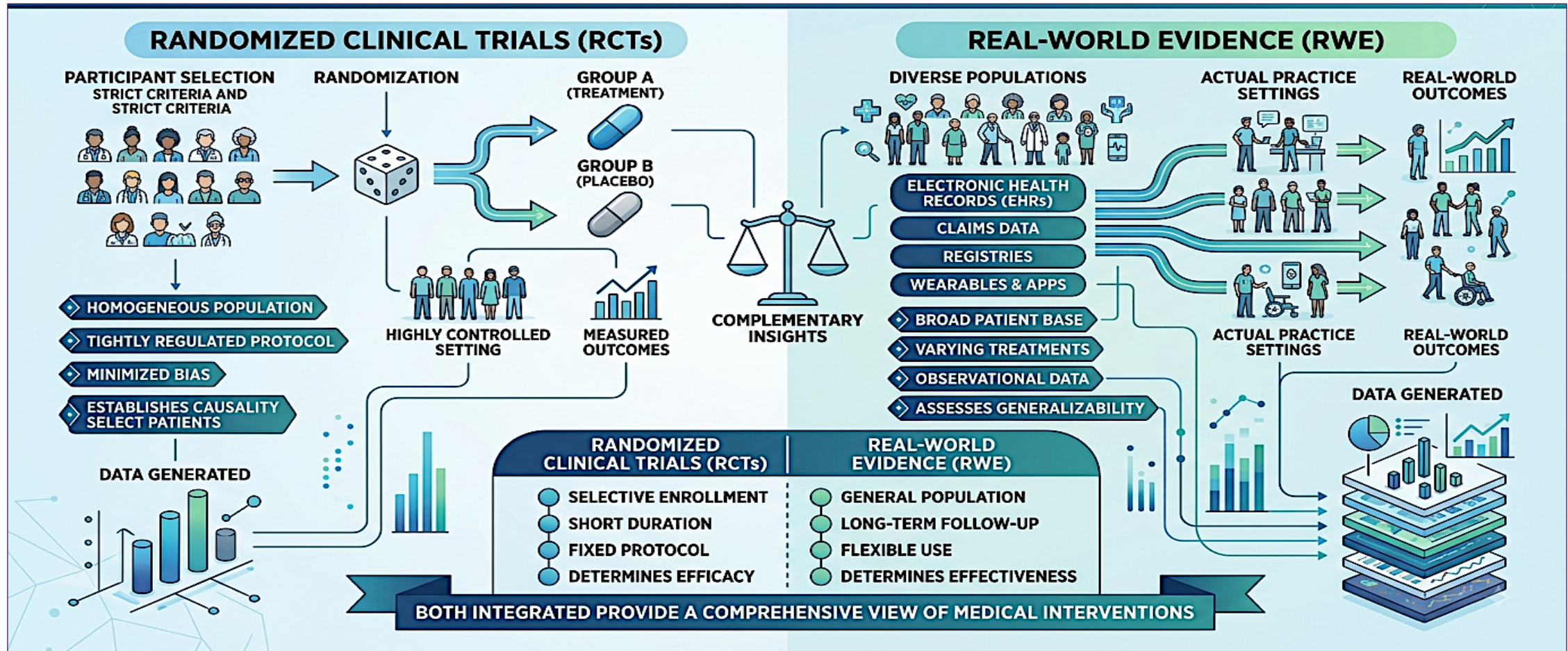
RWD = real-world data.

U.S. Food and Drug Administration. *Real-World Evidence*. Updated June 3, 2026. [FDA: Real-World Evidence](#)

**Let's Start by Putting
RCT and RWE Side By Side**

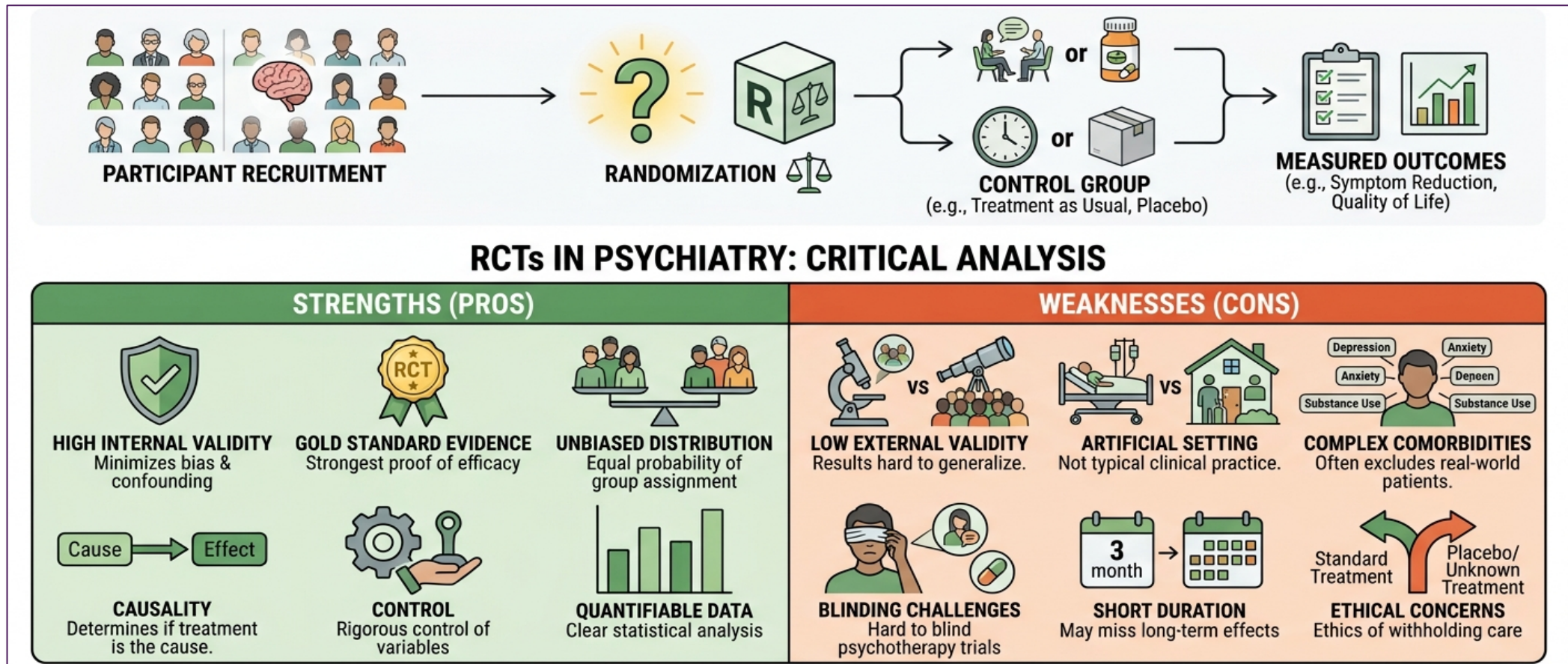
***Then We Will Do a Deep Dive
Into Each***

Let's Do a Side-by-Side Comparison of RCT and RWE



Deep Dive Into RCT (Randomized Clinical Trial)

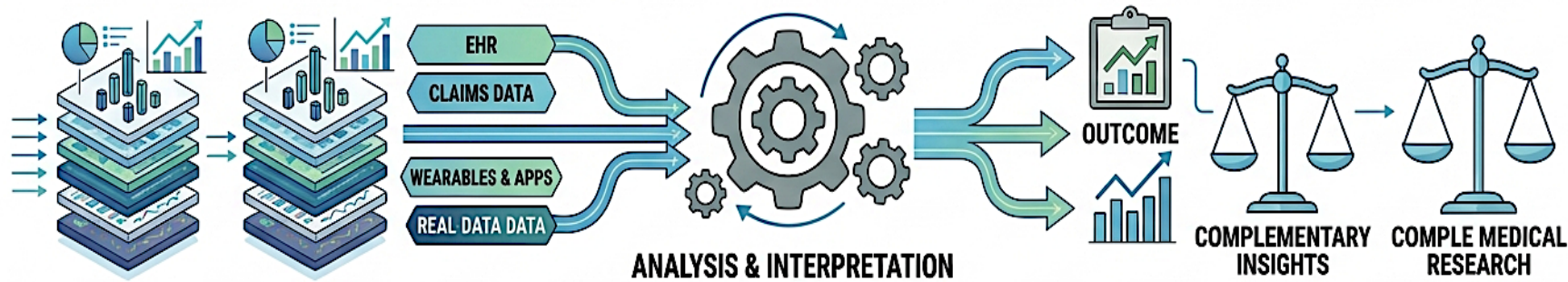
Structure, Strengths, Weaknesses



Now we Turn Our Attention to RWE

(Real World Evidence)

Structure, Strengths, Weaknesses



RWE Data Sources Include

- EHRs
- Medical Claims
- Registries

STRENGTHS (PROS) OF RWE			WEAKNESSES (CONS) OF RWE		
 HIGH GENERALIZABILITY Reflects results in diverse, real patient populations (broad patient base from <IMAGE0>)	 LONG-TERM FOLLOW-UP Tracks long-term safety and effectiveness over extended periods (duration from <IMAGE1>)	 REAL-WORLD EFFECTIVENESS Assesses how interventions perform in actual practice settings	 CONFOUNDING & BIAS Observational nature leads to potential selection bias and confounding	 DATA QUALITY & HETEROGENEITY Inconsistent data quality and disparate formats across sources	 CAUSALITY CHALLENGES Determining cause-and-effect is more difficult than in RCTs
 COMPLEX COMORBIDITIES & POPULATIONS Includes patients with multiple	 COST-EFFECTIVE DATA GENERATION Uses existing data sources, potentially reducing resource intensity	 LARGE SAMPLE SIZES Enables detection of rare adverse events in huge datasets	 PATIENT-REPORTED OUTCOMES Harder to collect standardized PROs outside controlled trials	 DATA PRIVACY & ETHICS Complex rules for accessing and using secondary patient data	 UNMEASURED CONFOUNDERS Relevant variables might not be recorded in datasets

EHR = electronic health record

Concato, J., et al *The Lancet*, 2020. 396(10260), 1385–1387.

Are We All Now On the Same Page?!

Let's Do a Quick Recap

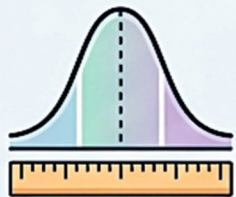
Feature	Randomized Controlled Trials (RCT)	Real-World Evidence (RWE)
Primary Goal	Assess efficacy under ideal, strictly controlled conditions	Assess effectiveness and safety in routine clinical practice
Study Design	Prospective, experimental, interventional	Observational, non-interventional (retrospective or prospective)
Data Source	Dedicated clinical trial case report forms (CRFs)	Electronic health records (EHRs), claims data, registries, wearable devices
Patient Population	Highly selected, homogeneous (strict inclusion/exclusion criteria)	Broad, heterogeneous (comorbidities, diverse demographics, polypharmacy)
Treatment Allocation	Randomized and blinded (to eliminate selection bias and confounding)	Clinician- or patient-determined (reflects real-world practice patterns)

**There Are Two Statistical Concepts
We Need to Be The Boss Of:**

***Statistical Deviation
&
P Value***

Standard Deviation and P-Value: Definitions, Uses, and Misuses

STANDARD DEVIATION (SD)



SD Measures
VARIABILITY
(SPREAD).

SD Measures **VARIABILITY** (SPREAD).



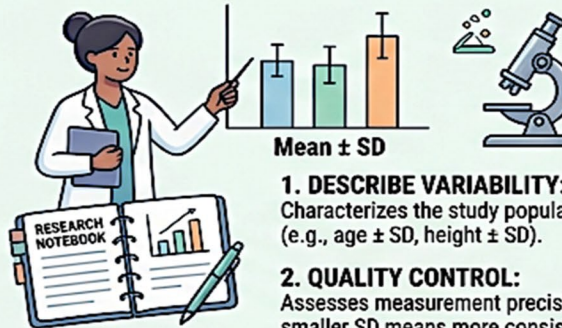
Small SD



Large SD

Tells us how
bunched or spread
out the data points
are around the
MEAN (AVERAGE).

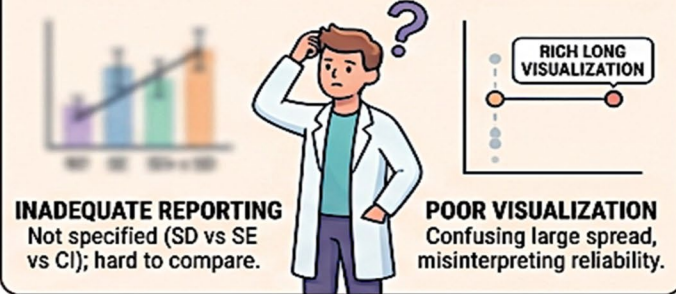
STANDARD DEVIATION



Mean $\pm$ SD

- 1. DESCRIBE VARIABILITY:**
Characterizes the study population
(e.g., age $\pm$ SD, height $\pm$ SD).
- 2. QUALITY CONTROL:**
Assesses measurement precision;
smaller SD means more consistent.

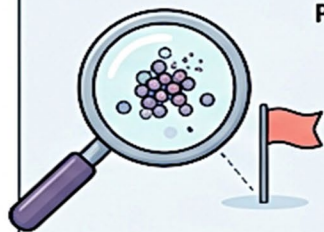
STANDARD DEVIATION



INADEQUATE REPORTING
Not specified (SD vs SE
vs CI); hard to compare.

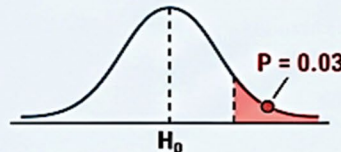
POOR VISUALIZATION
Confusing large spread,
misinterpreting reliability.

P-VALUE



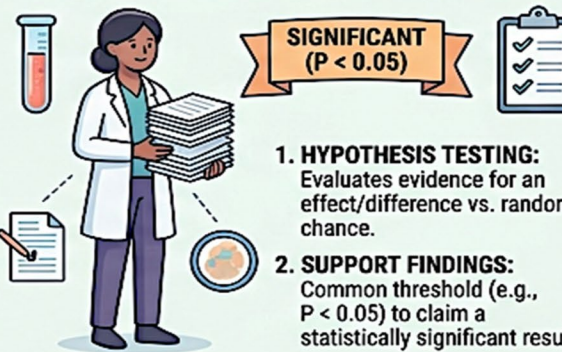
The probability of seeing
results this extreme,
ASSUMING H_0 IS TRUE.

P-VALUE Measures **SURPRISE** against
the **NULL HYPOTHESIS (H_0)**.



Think of it as a **"SURPRISE METER."**
Small P = "Very Surprising,"
evidence against H_0 .
Large P = "Not Surprising,"
no evidence.

P-VALUE



SIGNIFICANT
($P < 0.05$)

- 1. HYPOTHESIS TESTING:**
Evaluates evidence for an
effect/difference vs. random
chance.
- 2. SUPPORT FINDINGS:**
Common threshold (e.g.,
 $P < 0.05$) to claim a
statistically significant result.

P-VALUE

P-HACKING:
Actively searching data
or changing tests just
to get $P < 0.05$.



PUBLICATION BIAS:
Only "significant" results
are published,
"non-significant" (H_0 not
rejected) are buried.

NEGATIVE RESULTS



WARNING: THESE VALUES TELL ONLY PART OF THE STORY.
Context, study design, and effect size are crucial.

There Are A Few More Statistical Concepts We Can Explore:

- ***Odd Ratio (OR)***
- ***Relative Risk (RR)***
- ***Hazard Ratio (HR)***

Make Note: These Are Slightly Different Concepts, And Nearly All RWE Articles Report Them

ODDS RATIO (OR)



Definition: Ratio of ODDS of an event occurring

Exposure	
Outcome	Exp
	Unexp
	Yes
	No

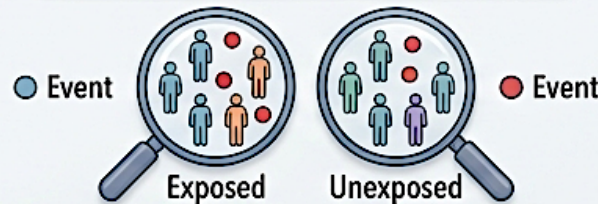
Focus: Relative ODDS at one point in time

OR = 1	(No Association)
OR > 1	(Increased Odds)
OR < 1	(Decreased Odds)



Key Caveat: Misinterpreted as Risk

RELATIVE RISK (RR)



Definition: Ratio of RISK of an event occurring



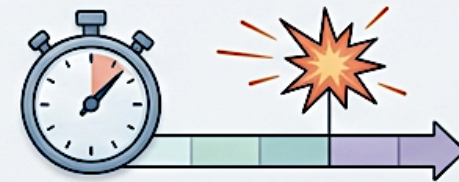
Focus: Cumulative RISK over a specified time

RR = 1	(No Difference)
RR > 1	(Increased Risk)
RR < 1	(Decreased Risk)

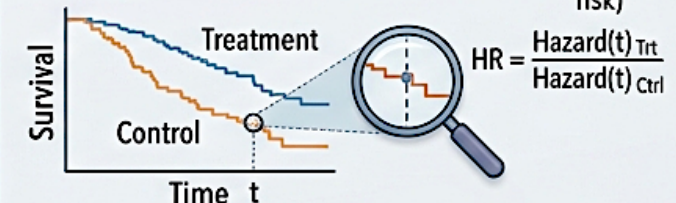


Convergence: Converges with OR when event is RARE (<10%)

HAZARD RATIO (HR)



Definition: Ratio of HAZARD RATES (instantaneous risk)



Focus: Time-to-Event and INSTANTANEOUS RATE

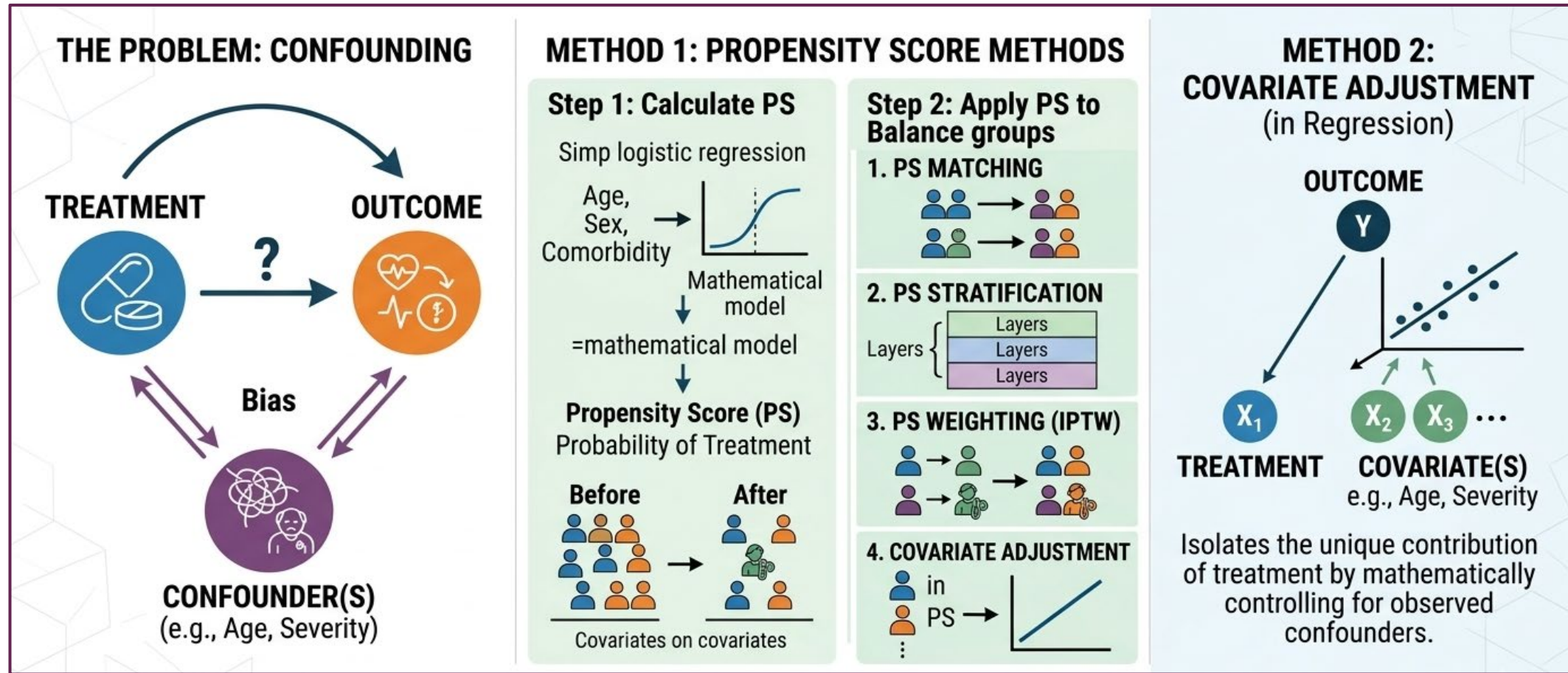
HR = 1	(No Difference)
HR > 1	(Increased Rate)
HR < 1	(Decreased Rate)



Survival Analysis: Captures TEMPORAL nuance

How Do We Reduce Bias in RWE Studies?

Two Methods to Reduce RWE Studies: Propensity Score Method & Covariate Adjustment



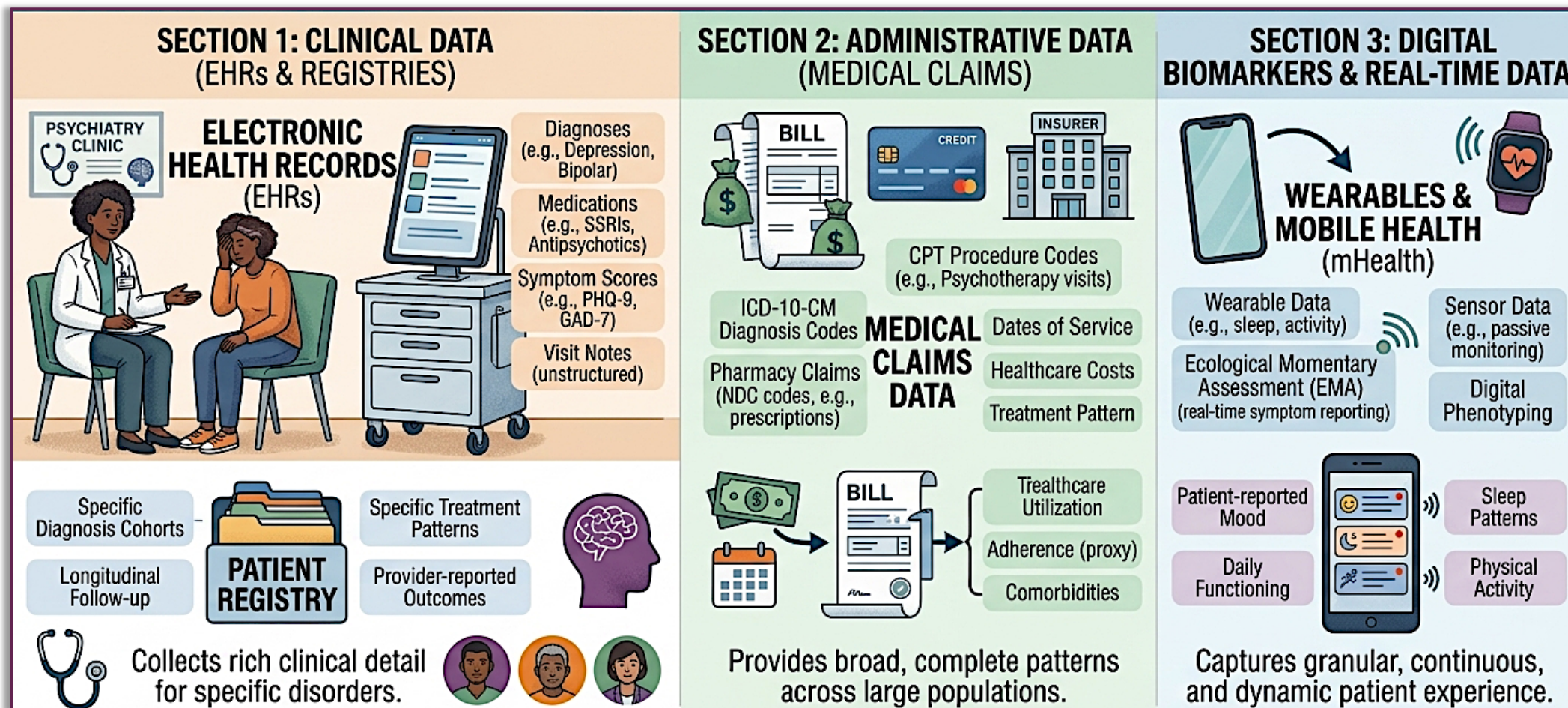
**No, we do not need to be experts at
reducing bias**

***But we do need to look for it in articles
on RWE we read and posters we view***

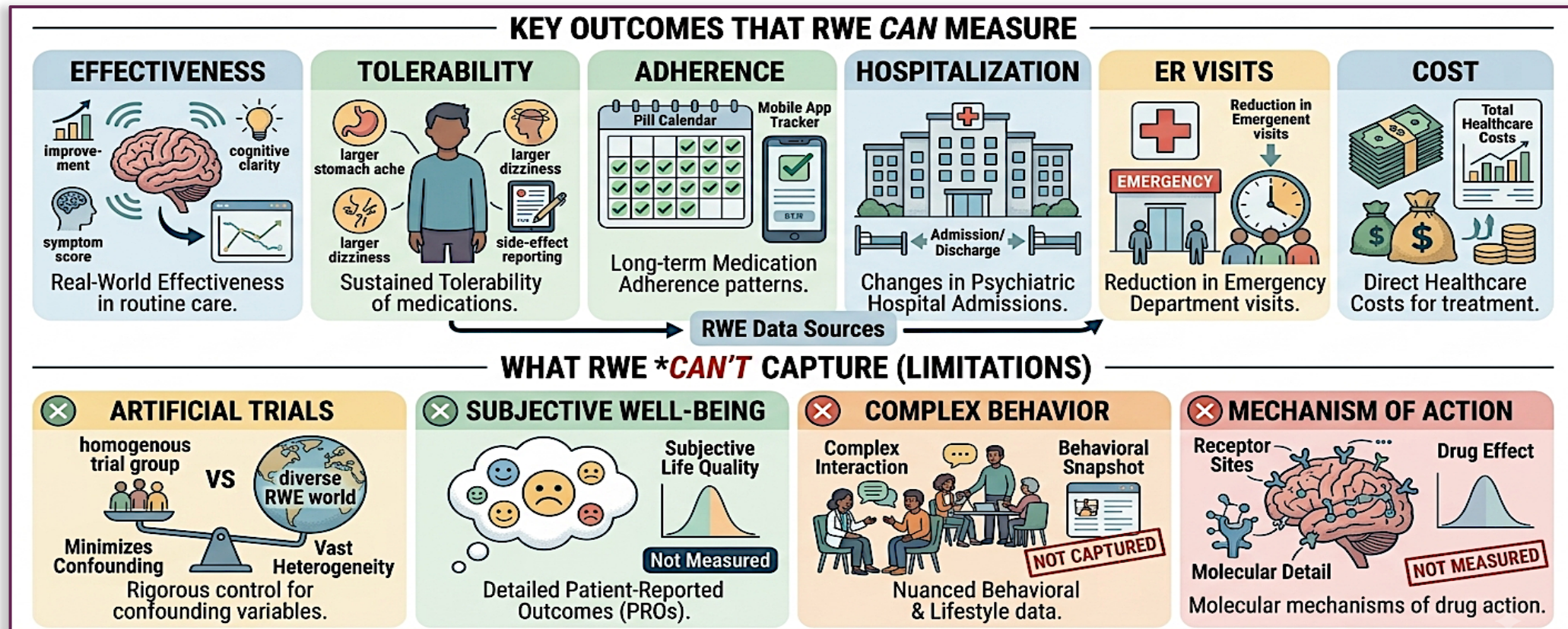
***Ok – Time For a Deeper
Dive into RWE***

Where Does RWE Data Come From?

There are Three Main Sources of Data for RWE



RWE: What It Can, & What It Can't Measure



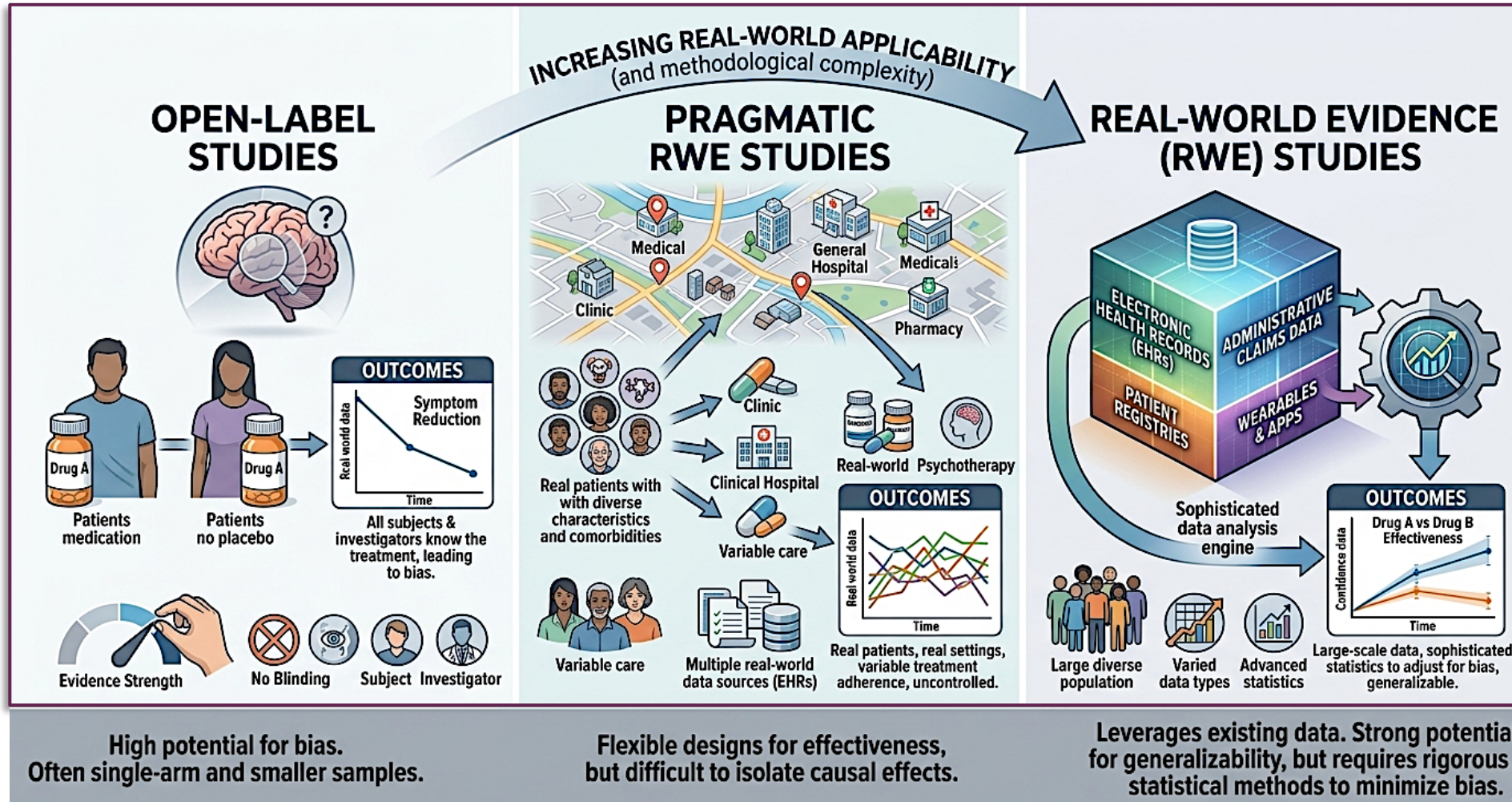
This is Why the Combination of RCTs and RWEs Best Improves Our Understanding of An Intervention

The 'Spectrum' of Studies

- *Open Label Studies*
- *Pragmatic RWE Studies*
- *RWE Studies*

The Spectrum of Studies

(FDA Only Recognizes the Third Group as RWE)

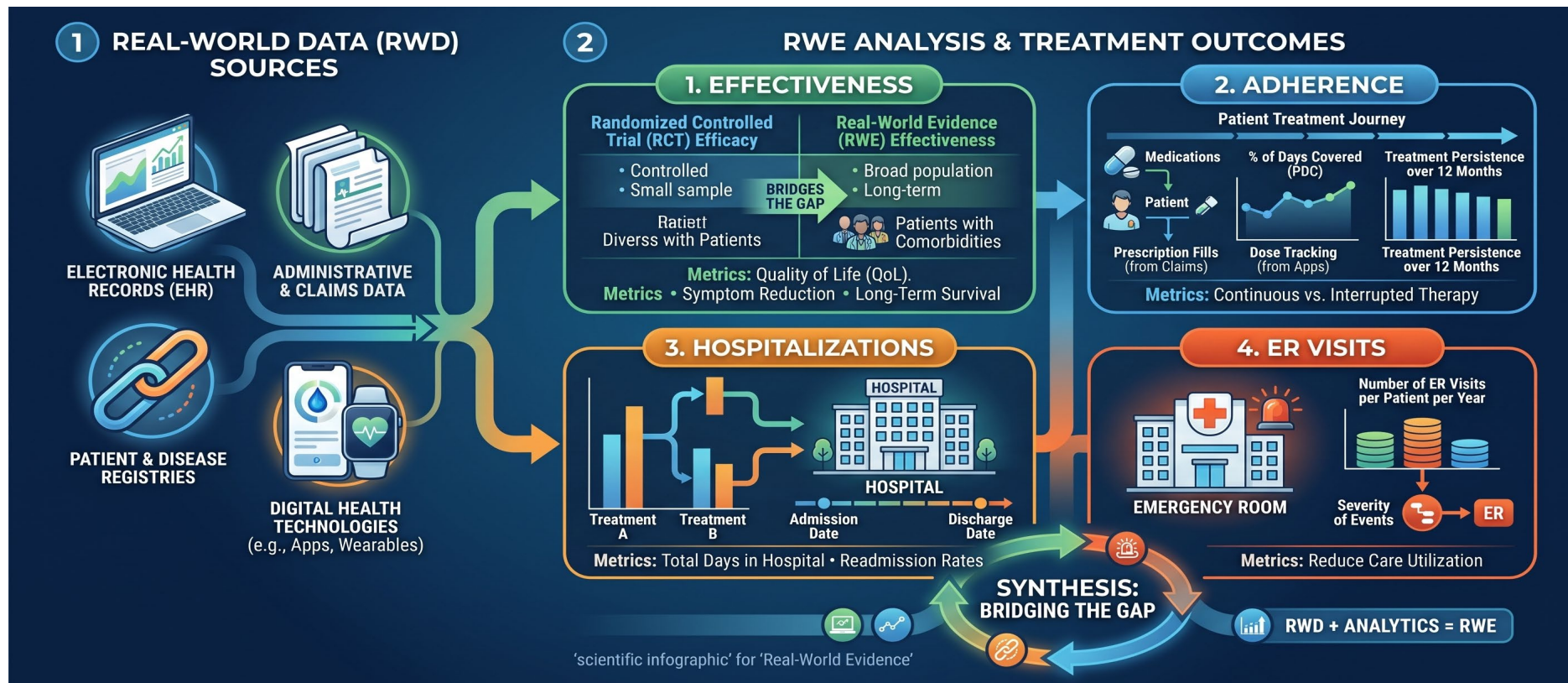


OLE Studies are often an extension of double-blind studies

Pragmatic Studies examples: CATIE, Star D

RWE: defined by the FDA

RWE Studies Can Reveal the 'Actual' Effectiveness, Adherence, Hospitalization Rates, ER Visits, etc. Associated with a Medication's Use 'Out There'

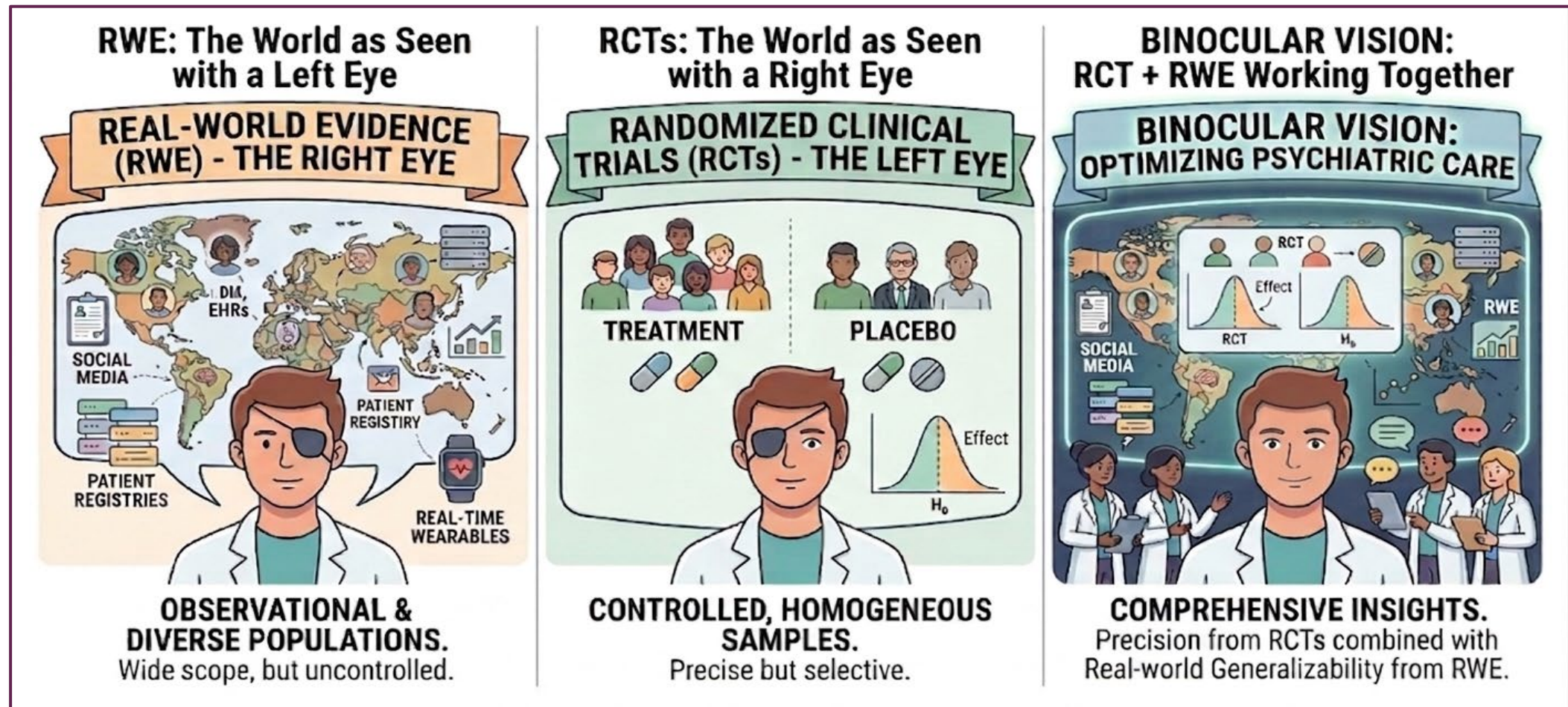


***So, Which Is Better –
RCT or RWE?***

Who's the Winner?!

Truth – Neither is ‘Better’

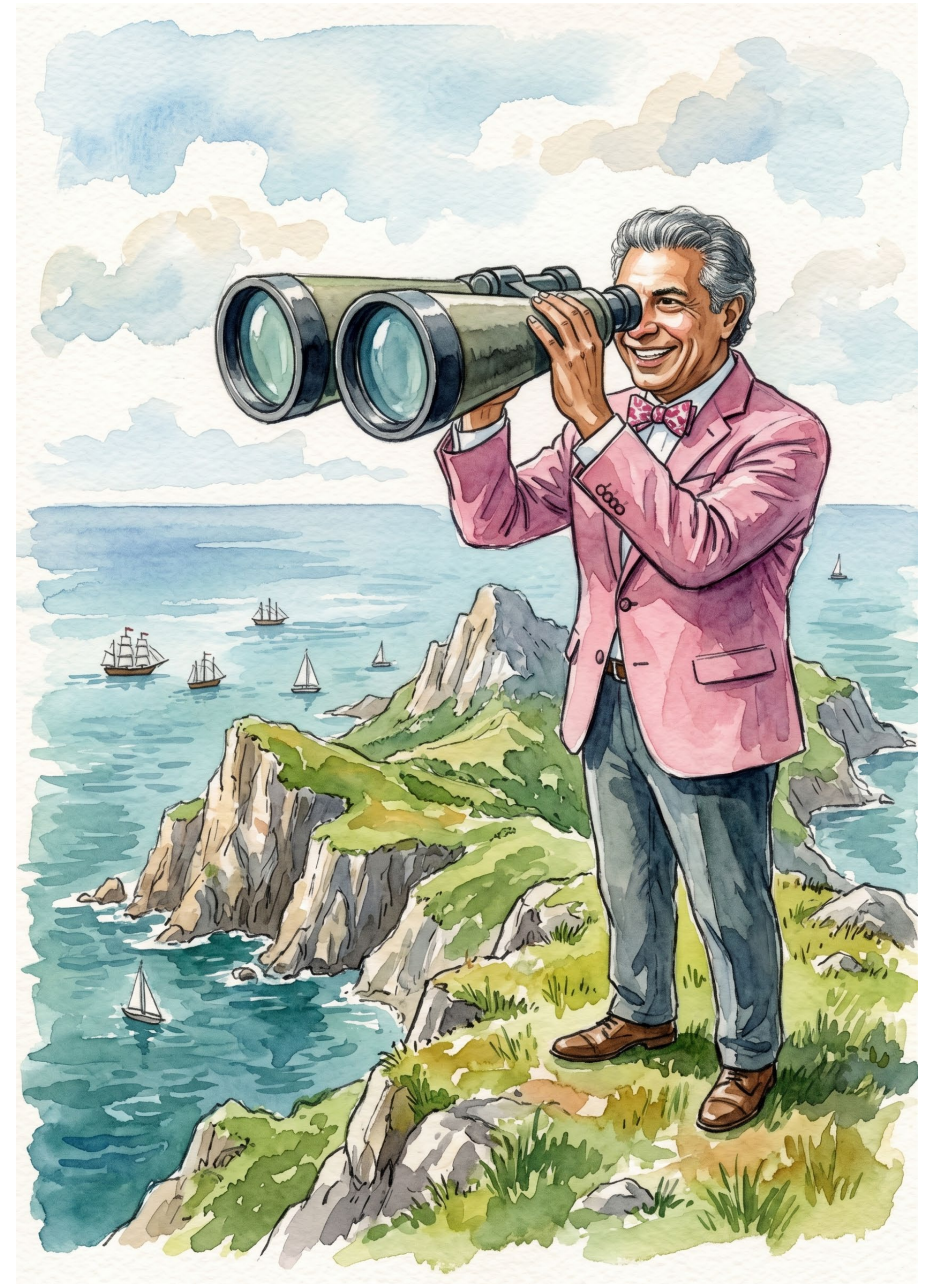
Both Have Individual Strengths and Weaknesses



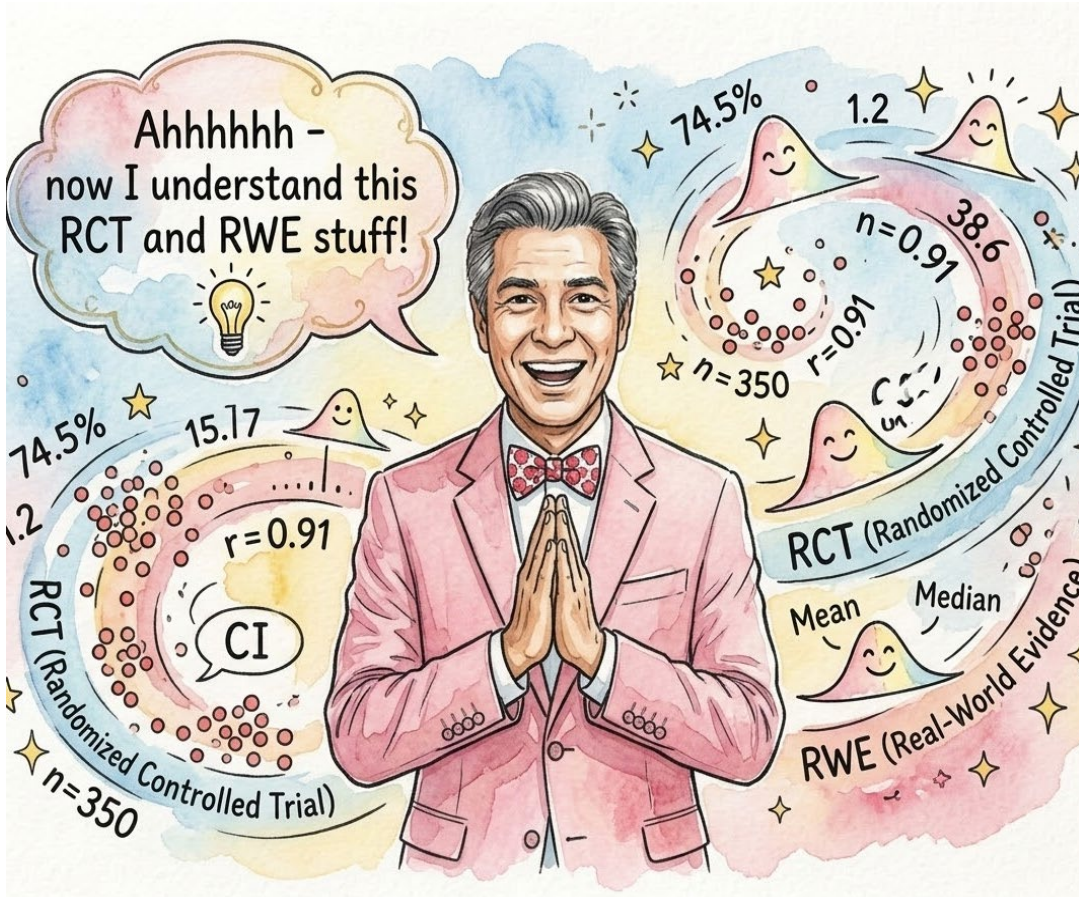
**Let's Not Look For the
'Winner' or 'Better' Approach**

Let's Use Both!

***This 'binocular' vision gives us
the best understanding of any
treatment's strengths and
weaknesses***



In Conclusion



**RWE answers many
questions that RCTs can't**

- RWEs are essential in our FULL understanding of data and treatments
- RCTs are critical, but by definition, are narrow in scope and not generalizable to entire populations
- FDA-recognized RWE includes observational studies using EHRs, claims, and registry data
- FDA is VERY supportive of RWE studies, so they will become increasingly important in the literature



Case-Based Psychiatric Treatment Questions That RWE Can Help Answer

**“Which of These Medications Is
Likely to Be More Effective for
My Patient?”**

Craig Chepke

Real-World Patient #1



- 40-year-old woman with schizophrenia whose symptoms are causing her to struggle to get along with her roommate at the group home and keep her “job” as a food pantry volunteer
- Distrusts healthcare clinicians and recently experienced a near-crisis after skipping a week of her medications
- Open to a monthly long-acting treatment, and is a candidate for either AOM or PP1M
 - (tolerated past trials of oral aripiprazole and risperidone)
- **Which medication is more likely to be effective for this patient**

AOM Was Associated With Lower 1-Year Treatment Discontinuation vs PP1M

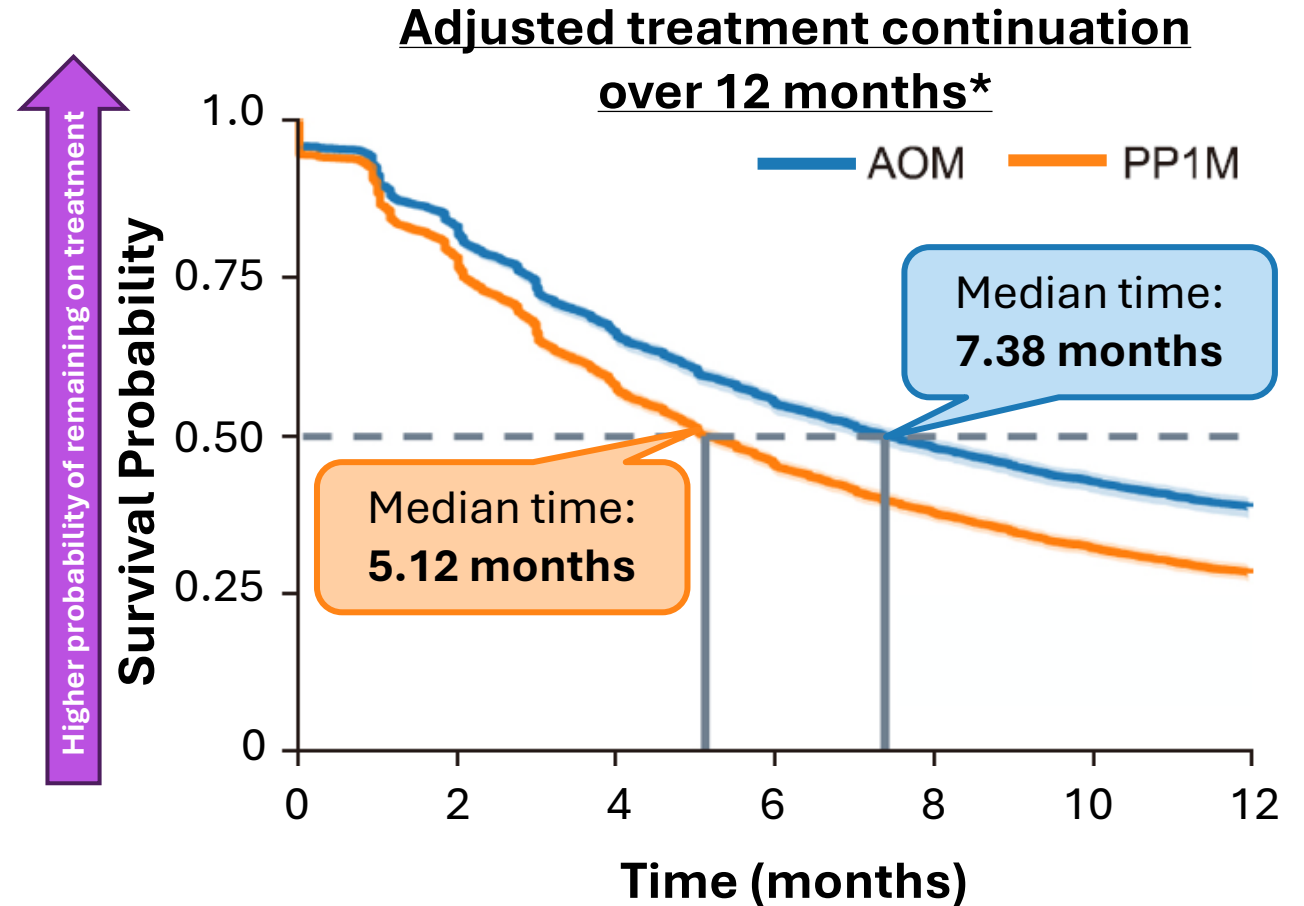
Study snapshot

- Nationwide Korean claims database, 2016–2023
- Adults with schizophrenia spectrum disorders initiating an LAI
- **Aripiprazole once-monthly (AOM):** n=6,454
- **Paliperidone palmitate once-monthly (PP1M):** n=9,118
- Follow-up: 12 months

Lower discontinuation[†] at 12 months

62.7% AOM vs **74.1% PP1M**

Adjusted HR, **1.322** (95% CI, 1.270–1.376); $P < 0.0001$



*Adjusted for age, sex, number of concomitant psychotropics, and baseline EPS-related adverse events [†]Discontinuation was defined as switching to another LAI, switching to an oral antipsychotic, or a treatment gap longer than 60 days.

Pae CU, Gwon SH, Kim H, et al. *Clin Psychopharmacol Neurosci*. 2026;24(3):627-640.

**“My Patients are So Different from
the Ones in the Clinical Trials: How
Will this Medication Work for Them?”**

Hara Oyedeji

Real-World Patient #2



- 41-year-old with schizophrenia and multiple comorbidities, including anxiety, hypertension, and obesity
 - Taking several concomitant medications
 - Have a history of inconsistent adherence to antipsychotic treatment due to significant weight gain from olanzapine
 - 2 previous ED visits, 1 hospitalization
- **Clinical trials establish efficacy and safety, but how well do those results translate to a patient with multiple psychiatric and medical comorbidities?**

Real-World OLZ/SAM Use Includes Patients With Substantial Psychiatric and Medical Comorbidity

Retrospective claims analysis
(commercial/Medicaid/Medicare Advantage)

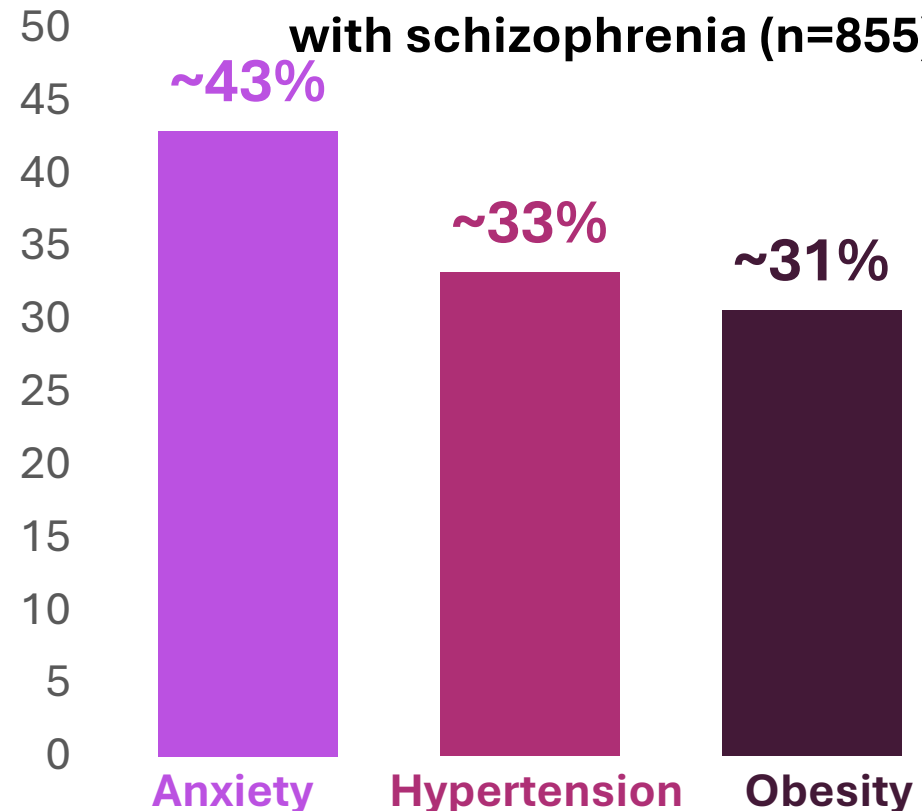
N=1546 (schizophrenia: n=855, bipolar I: n=691)
initiating olanzapine/samidorphan

In patients with schizophrenia (despite high comorbidity rate) 6-mo after OLZ/SAM initiation:

28.2% ↓ relative decrease in inpatient admissions

11.5% ↓ relative decrease in ED visits

Prevalence of comorbidities in cohort
with schizophrenia (n=855)



RWE captured outcomes in patients with medical and psychiatric complexity
encountered in routine schizophrenia care

**“How Likely is it That My Patient
Will Take this Medication
Consistently?”**

Rakesh Jain

Real-World Patient #3

- 25-year-old female with bipolar disorder and panic disorder is on 4 different medications for her disorders
 - Takes them only when reminded by her mother
 - Often forgets to pick up medications at pharmacy
 - Motivated to get better but is inconsistent with her meds, and says – “Well, at least I do take my medicine most days. Is that not good enough??”
- **Clinical Trials establish efficacy and side effects, but what happens ‘out there’ in terms of risk with irregular taking of medications?**



Poor Adherence May Lead to Poorer Outcomes

In a 12-month study of N=619 individuals with a severe and persistent mental illness:

Irregular medication users had significantly...

more
hospitalizations
42% vs 20%

more
hospital days
16 days vs 4 days

higher
hospital costs
\$3,992 vs \$1,048

*Irregular medication use remained the strongest predictor of hospital utilization and costs
after adjustment for clinical and demographic factors*

**“Which Medication Is More Likely
to Keep My Patient Out of
the Hospital?”**

Craig Chepke

Real-World Patient #4

- 36-year-old man with bipolar disorder with comorbid anxiety, ADHD, alcohol use disorder, and obstructive sleep apnea; taking multiple medications
 - Experienced a prolonged, severe manic episode—he walked several miles in 6°F weather wearing golf cleats, intending to provoke police into shooting him
 - Prior hospitalization was traumatic for the patient and his family; wanted to avoid another hospitalization
 - Treatment was complicated by antipsychotic-induced movement symptoms, substantial weight gain, and reluctance to continue medication
 - Managed intensively as an outpatient with visits 3-4 times weekly for several months
- **How can we achieve sustained mood stabilization while minimizing adverse effects and avoiding hospitalization?**

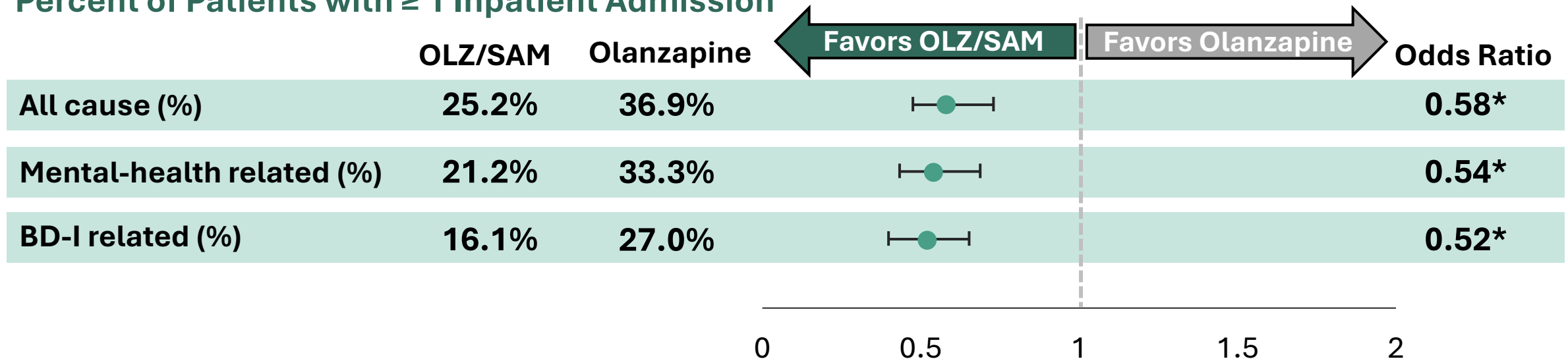


OLZ/SAM Was Associated With Fewer Hospitalizations vs Olanzapine



Retrospective administrative claims analysis | Medicaid-insured adults with BD-I | PSM n=504 per group | 12-month follow-up

Percent of Patients with ≥ 1 Inpatient Admission



Longer treatment persistence

150 vs 90 days median persistence

Spent fewer days hospitalized

2.3 vs 5.5 days/patient for BD-I-related hospitalization

* $P < 0.001$; PSM = propensity score-matched.

Jain R, Panchmatia HR, Hughes AG, et al. Real-world comparison of olanzapine/samidorphan vs olanzapine: an assessment of treatment patterns and acute care events among patients with bipolar I disorder. Poster presented at: Psych Congress 2025, San Diego, CA.

**“My Patient Needs More Than
Symptom Reduction.**

**Will This Medication Help Improve Their
Functioning and Quality of Life?”**

Hara Oyedeji

Real-World Patient #5

- 58-year-old with schizophrenia and clinician-rated mild tardive dyskinesia after years of antipsychotic treatment
- Movements are subtle on exam, but the patient has stopped attending church and family gatherings out of embarrassment
- **The exam findings look like ‘mild’ tardive dyskinesia (TD)...is treatment worth it, or are the movements having an impact on how the patient is living their life and their daily functioning?**



Valbenazine Treatment Was Associated With Clinically Meaningful Improvements in TD-Related QoL

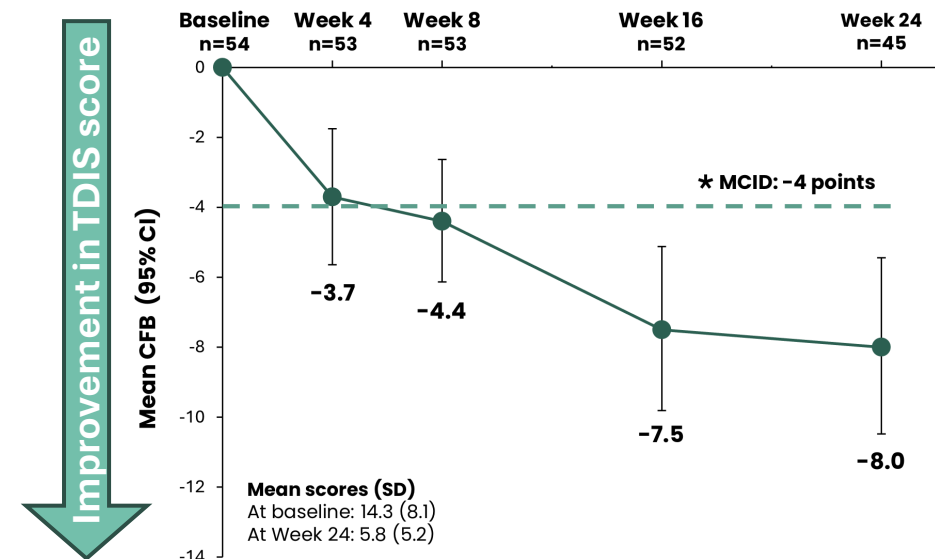
Phase 4, open-label study of valbenazine designed to reflect real-world TD practice

N=59 (mild TD n=24, moderate/severe n=35) across schizophrenia, schizoaffective, bipolar, and MDD diagnoses

What does the Tardive Dyskinesia Impact Scale (TDIS) measure?

Physical, social, and emotional impacts of *patient-reported, TD-specific QoL burden*

TDIS improvement exceeded the MCID by Week 8 and was sustained through Week 24, with benefits also observed in patients with mild TD



Take-home: Patient-reported benefits of valbenazine extended beyond movement improvement to meaningful changes in TD-related quality of life.

QoL = quality of life, MCID =

Correll CU, Perez-Rodriguez M, McEvoy JP, et al. CNS Spectr. 2026;doi:10.1017/S1092852926101138.

Key Learning Points



- **RWE helped us understand (case summaries):**
 - AOM was associated with lower treatment discontinuation than PP1M at 1-year.
 - Real-world OLZ/SAM use includes patients with substantial psychiatric and medical comorbidity.
 - Poor adherence may lead to poorer outcomes.
 - OLZ/SAM was associated with fewer hospitalizations than olanzapine.
 - Valbenazine treatment was associated with clinically meaningful improvements in TD-related quality of life.
- **RWE complements RCT data by showing how treatments perform in diverse patients across outcomes that matter in practice, including persistence, adherence, healthcare utilization, and quality of life.**

Faculty Panel Discussion

Integrating RWE with RCT Evidence in Clinical Decisions

The Future of RWE in Psychiatry

Practical Take-Aways

01

Use RCT and RWE findings together to assess both treatment efficacy and real-world effectiveness

02

Consider outcomes beyond symptom control, including persistence, adherence, hospitalization, functioning, and quality of life

03

Apply RWE to individualize treatment decisions for patients whose comorbidities and circumstances may not be represented in clinical trials



Q&A