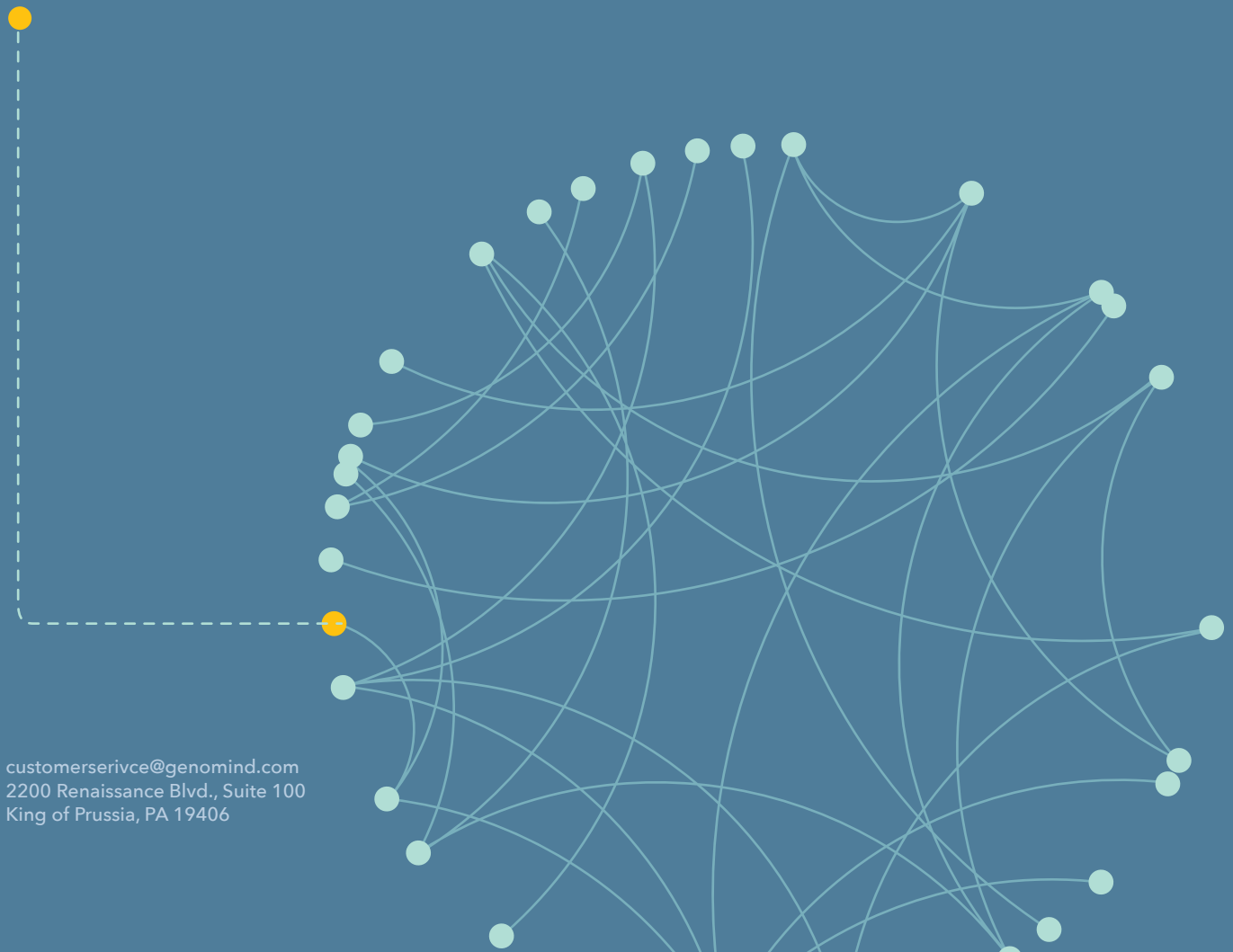
CLINICAL EVIDENCE SUMMARY

The value of PGx and precision medicine

An overview of the published data supporting the utility of pharmacogenetics (PGx) in precision medicine



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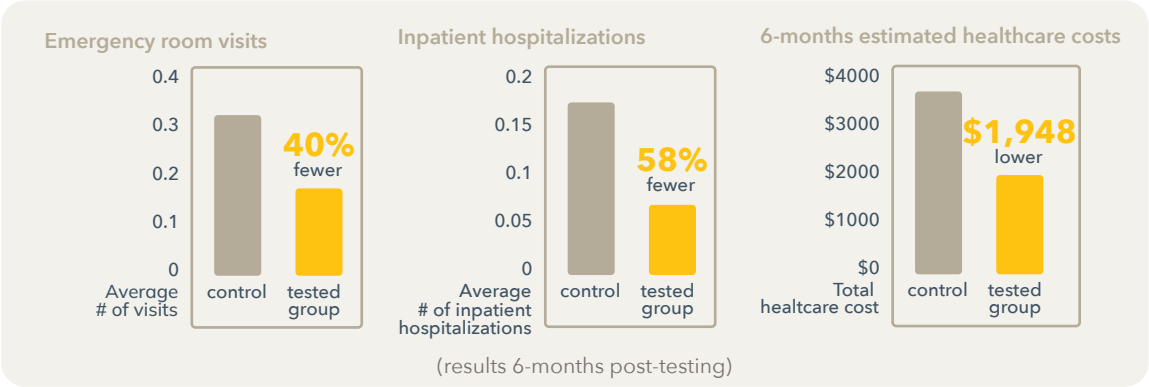
The Science Behind Better

AETNA CASE-CONTROL HEALTHCARE UTILIZATION STUDY

Pharmacogenetic testing among patients with mood and anxiety disorders is associated with decreased utilization and cost: A propensity-score matched study



Study design

Case-control study examining health care utilization and cost among patients with mood disorders following use of Genomind PGx testing (n=817) compared to a matched control group (n=2,745) whose treatment was not guided by Genomind PGx.

Key findings

Genomind PGx testing was associated with:

- 40% fewer emergency room visits
- 58% fewer inpatient hospitalizations
- Estimated $1,948 reduction in health care costs over 6-months

Genomind's Precision Health Platform was associated with decreased healthcare costs per individual over 6 months.

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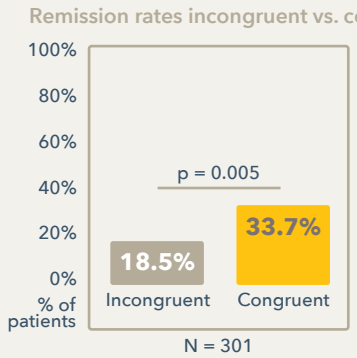
Perlis RH, et al. Pharmacogenetic testing among patients with mood and anxiety disorders is associated with decreased utilization and cost: A propensity-score matched study. Depression & Anxiety. 2018;35(10):946-952. doi:10.1002/da.22742

RANDOMIZED-CONTROLLED TRIAL PGx & DEPRESSION STUDY

Randomized, controlled, participant- and rater-blinded trial of pharmacogenomic test-guided treatment versus treatment as usual for major depressive disorder

Study design

Eight-week multicenter RCT examining the impact of Genomind PGx testing (n=151) versus treatment-as-usual (n=153) among outpatients with major depressive disorder. Both participants and raters were blinded to treatment conditions for the primary outcome (Hamilton Depression Rating Scale; SIGH-D-17).



There were no significant differences between groups on the primary outcome measure (change in SIGH-D-17).

Key findings

Post-hoc analyses revealed:

Significantly fewer individuals experienced worsening of depressive symptoms following Genomind PGx testing compared to treatment-as-usual

Individuals receiving treatment that was congruent with PGx recommendations were twice (OR 2.23; 95% CI 1.17-2.83) as likely to remit compared to patients who received incongruent treatment.

In a post-hoc analysis, patients assigned medications congruent with Genomind's PGx test were twice as likely to experience remission

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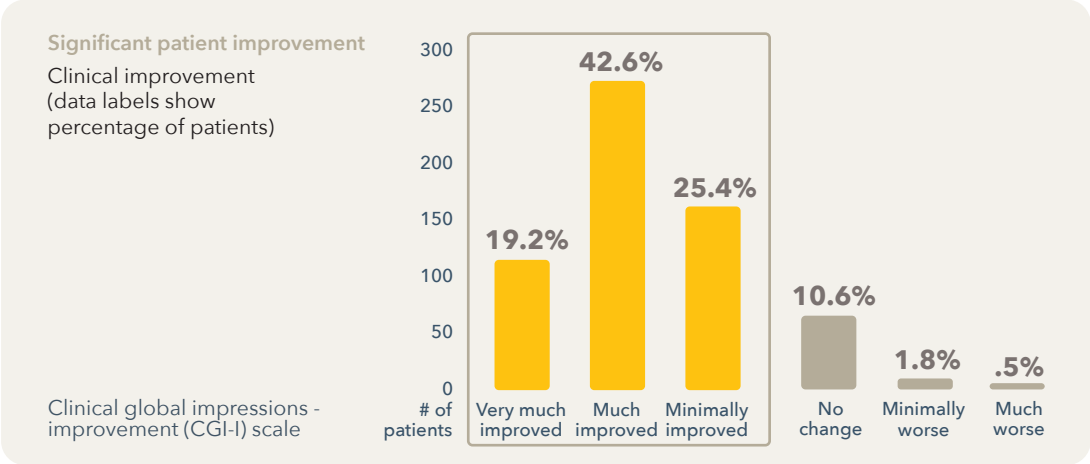
Perlis RH, et al. Randomized, controlled, participant- and rater-blind trial of pharmacogenomic test-guided treatment versus treatment as usual for major depressive disorder. Depress Anxiety. 2020;37(9):834-841. doi:10.1002/da.23029

A naturalistic study of the effectiveness of pharmacogenetic testing to guide treatment in psychiatric patients with mood and anxiety disorders



Study design

Naturalistic, open-label study of psychiatric patients who used Genomind PGx testing (n=685) and completed self-report questionnaires assessing depression (Quick Inventory for Depressive Symptoms), anxiety (Zung Self-Rated Anxiety Scale), and quality of life (Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form).

Key findings

Results demonstrated a substantial proportion of individuals receiving Genomind PGx testing showed:

- Significant decreases in depression, anxiety, and medication side effects
- Increased quality of life over 3-months (all $p<0.001$)

87% who used Genomind PGx testing saw clinically measurable mental health improvement

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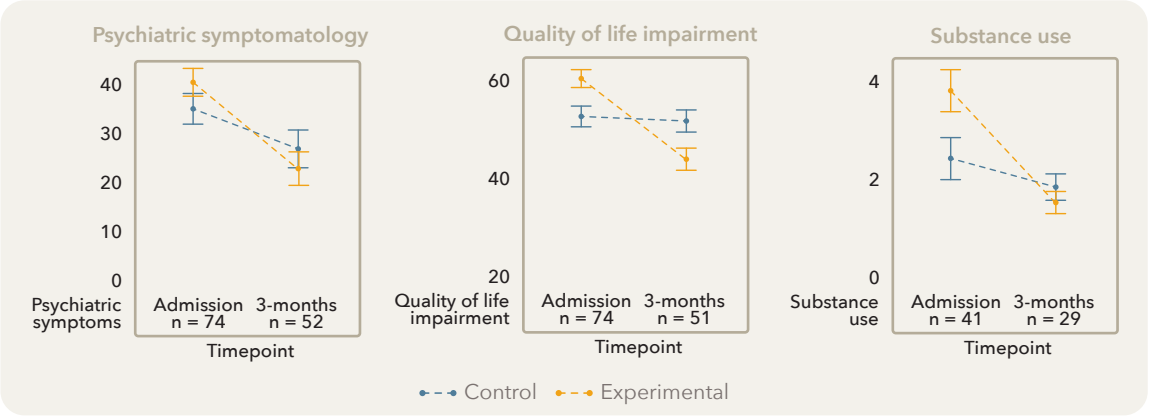
Brennan FX, et al. A naturalistic study of the effectiveness of pharmacogenetic testing to guide treatment in psychiatric patients with mood and anxiety disorders. Prim Care Companion CNS Discord. 2015;17(2).doi:10.4088/PCC.14m01717

Pharmacogenetic testing in an adult psychiatric inpatient population



Study design

Open-label pilot study examining the feasibility of Genomind PGx testing in an inpatient unit, examining clinical outcomes including the APA DSM-V Level 1 Cross Cutting Symptom Measure, APA DSM-V Level 2 Cross Cutting Symptom Specific Measure (8 specific symptoms), and the WHODAS 2.0 to assess quality of life, 3 months post-hospitalization in patients with anxiety and depression related diagnoses.

Key findings

Compared to a control group who did not have PGx testing, participants who received Genomind PGx testing reported:

- Significantly greater reductions in broad psychiatric symptomatology (p=.028) and substance use (p<.001)
- Improved quality of life (p=.004)

PGx testing linked to significant improvement in psychiatric symptoms and quality of life

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King CD, et al. Open-label pilot study of psychiatric pharmacogenetic testing in an adult psychiatric inpatient population. Elsevier. 2020. doi:10.1016/j.pmip.2020.100060

The effect of pharmacogenomic testing on response and remission rates in the acute treatment of major depressive disorder: A meta-analysis

Study design

Rosenblat and colleagues meta-analytic review examined the effect of PGx testing on remission and response rates specifically in the acute treatment phase of MDD on a total of six studies: four RCTs (also included in the Bousman meta-analysis), as well as two additional open-label, controlled cohort studies. A total of 735 participants were randomized to receive PGx-guided treatment (n=353) versus treatment as usual (n=383).

Key findings

40%
remission rate

Overall, the PGx-guided treatment participants had a remission rate of 40% as compared to the unguided group, with a pooled remission rate of 25%.

74%
increased odds of remission

In a random-effects meta-analysis examining 735 patients undergoing acute treatment for MDD across the included studies, the pooled risk ratio favored PGx-guided treatment, indicating a 74% increased odds of remission.

PGx testing is associated with increased odds of remission

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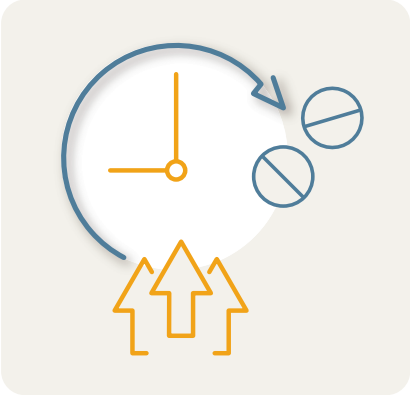
Rosenblat JD, et al. The effect of pharmacogenomic testing on response and remission rates in the acute treatment of major depressive disorder: a meta-analysis. J Affect Disord. 2018;241:484-491. doi:10.1016/j.jad.2018.08.056.

Pharmacogenetic tests and depressive symptom remission: a meta-analysis of randomized controlled trials



Study design

Bousman and colleagues performed a systematic review and meta-analysis examining five randomized controlled trials (RCTs) of the utility of PGx testing in major depressive disorder (MDD) patients (n=1,737). In each individual RCT included in the meta-analysis, patients were randomized to receive PGx-guided treatment (n=887) versus treatment as usual (n=850).

Key findings

71%
more likely to achieve remission

Depressed patients receiving PGx-guided treatment were 71% more likely to achieve remission on their medications compared to participants receiving treatment as usual.

PGx category data supports improved remission rates with PGx use

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Bousman CA, et al. Pharmacogenetic tests and depressive symptom remission: a meta-analysis of randomized controlled trials. Pharmacogenomics. 2019;20(1):37-47. doi:10.2217/pgs-2018-0142

DAVID META-ANALYSIS OF PGx & HOSPITAL ADMISSIONS STUDY

An analysis of pharmacogenomic-guided pathways and their effect on medication changes and hospital admissions: A systematic review and meta-analysis

Study design

Systemic review and meta-analysis examining the effect of PGx testing on medication changes and hospitalizations compared to treatment-as-usual (TAU).

Key findings

50%
less likely to be hospitalized

In the analysis of 5 studies evaluating hospitalizations, participants receiving PGx-guided treatment (n=2,957) were 50% less likely to be hospitalized compared to participants receiving treatment-as-usual (n=6,783).

91%
more likely to have medication changes

In the analysis of 5 studies evaluating medication changes, participants receiving PGx-guided treatment (n=749) were 91% more likely to have medication changes compared to TAU participants (n=825). Medication changes were a result of medication optimization (ex. medication switch, change of dose, or deprescribing).

PGx category data supports improved outcomes with PGx use

David V, et al. An analysis of pharmacogenomic-guided pathways and their effect on medication changes and hospital admissions: a systematic review and meta-analysis. Front. Genet. 2021;12:698148. doi: 10.3389/fgene.2021.698148

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