Utilization Patterns of Patient Global Impression (PGI) and Clinician Global Impression (CGI) Scales in CNS Clinical Trials

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INTRODUCTION

BACKGROUND

- Global-impression scales (CGI, PGI) are widely used clinical anchors, yet their adoption in CNS trials and clinical development programs has never been systematically studied.
- It remains unclear whether clinician-rated (CGI) and patient-reported (PGI) measures serve distinct, condition-specific roles.

AIMS

- **Prevalence:** how frequently CGI and PGI are used, individually and relative to one another, in Trialtrove registered CNS trials.
- **Indication patterns:** the CNS conditions in which the clinician versus the patient perspective predominates.
- **Co-utilization:** how often both perspectives are used together versus independently.
- **Trial context:** where the scales sit as endpoints (primary vs secondary/other) and how use varies by trial phase and age group (adult vs pediatric-inclusive).
- **Temporal patterns** — trends in registered-trial adoption (2021–2025) and in publication activity (2016–2025).

TWO COMPLEMENTARY DATA SOURCES

	TRIAL REGISTRY	LITERATURE
Source	Trialtrove	PubMed
Time frame	Actual start 2021–2025	2016–2025
Unit	Registered trial	Publication
Denominator	14,072 CNS trials	4,045 publications

METHODS

TRIAL REGISTRY · Trialtrove

- Cross-sectional, descriptive analysis of CNS trials with actual start dates 2021–2025. Trialtrove was used since it aggregates ClinicalTrials.gov with other national registries into a single curated source, giving broader coverage than any single registry.
- Scale use identified from registered primary and secondary/other endpoint fields.
- CGI terms: CGI, CGI-S, CGI-I, CGI-C, Clinician/Clinical Global Impression.
- PGI terms: PGI, PGI-S, PGI-I, PGI-C, Patient Global Impression.
- Variables: trial phase, CNS indication, age group, endpoint position, co-utilization, actual start year.
- Trials using both scales contributed to each scale-specific analysis and were separately identified in the co-utilization analysis.
- Denominators are stated with every figure (all CNS trials; scale-using trials; indication-, phase-, sponsor- or age-specific totals).

LITERATURE · PubMed

- PubMed searches conducted separately for CGI and PGI across 10 CNS indications.
- Publications counted by year of publication, 2016–2025; 2026 excluded as a partial year.
- Trends described using annual counts and absolute and relative change; no slope estimation or inferential testing was performed.
- Overlap between the CGI and PGI searches was possible; counts are publications, not unique clinical trials.
- Results reflect only terminology captured by the prespecified search strategy.

SCOPE AND DEFINITIONS

CNS indications included in analysis: ADHD, Alzheimer disease, Anxiety, Autism, Bipolar, Depression, Epilepsy, Insomnia, Migraine, Multiple sclerosis, OCD, Pain, Parkinson disease, PTSD, Schizophrenia, Stroke.

Scale definitions used for identification. CGI: clinician-rated global impression of severity, improvement or change. PGI: the corresponding patient-reported global impression. ObsGI (observer- or caregiver-reported global impression): excluded by design; Identification reflects registered endpoint wording or indexed publication terminology; it does not confirm how an instrument was administered, scored or interpreted within a given study.

RESULTS

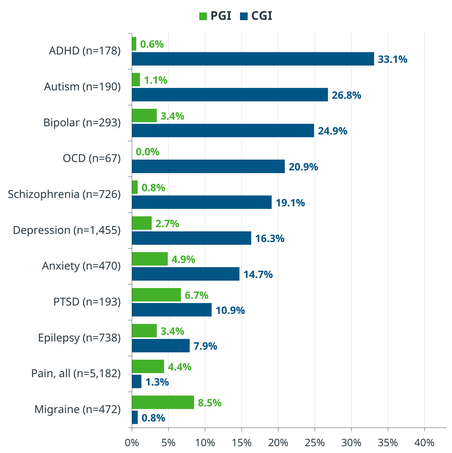
A · TRIAL REGISTRY RESULTS

Trialtrove | CNS trials with actual start 2021–2025 | Unit of analysis: registered trial

14,072	1,322	7.1%	3.6%
CNS trials screened	used CGI, PGI or both (9.4%)	CGI, of all CNS trials	PGI, of all CNS trials

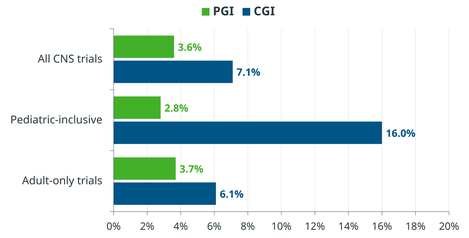
Overall adoption and co-utilization: CGI was identified approximately twice as often as PGI (ratio 2.0:1; 1,001 CGI trials and 510 PGI trials). Scales were largely used independently — 189 trials (14.3% of the 1,322 scale-using trials) applied both.

FIGURE 1 CGI and PGI adoption across the top ten CNS indications by number of trials (% within each indication)



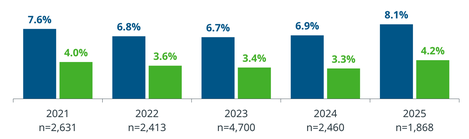
Denominator: all trials within the indicated condition. CGI adoption was highest in psychiatric and neurodevelopmental indications; PGI exceeded CGI only in migraine and pain. Indications are not mutually exclusive.

FIGURE 2 CGI and PGI adoption across trial contexts



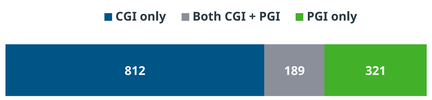
Denominators differ by row: all CNS trials n = 14,072; pediatric-inclusive n = 1,371; adult-only n = 12,701.

FIGURE 3 Annual adoption by actual start year, 2021–2025



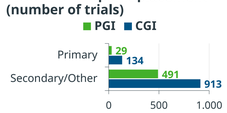
Denominator: all CNS trials with an actual start in the stated year. Adoption was comparatively stable across the period (CGI 6.7–8.1%; PGI 3.3–4.2%); no inferential test for trend was performed.

FIGURE 4 Scale co-utilization among 1,322 trials



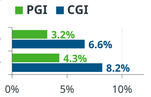
812 CGI-only + 321 PGI-only + 189 both = 1,322 scale-using trials; both measures were applied in 14.3% of them, indicating largely independent use.

FIGURE 5 Endpoint placement (number of trials)



Both scales were used predominantly as secondary or other endpoints; Primary use may be sole or co-primary; this was not distinguished here.

FIGURE 6 Adoption by trial phase (%)



Early phase = Phase I, I/II and II (n = 7,154); late phase = Phase II/III, III and IV (n = 6,174).

B · LITERATURE RESULTS

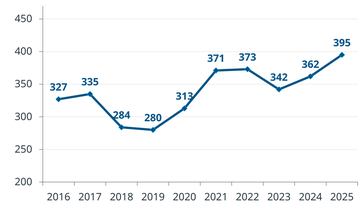
PubMed | Publications 2016–2025 | Unit of analysis: publication

4,045	3,382	663
publications retrieved	CGI publications	PGI publications

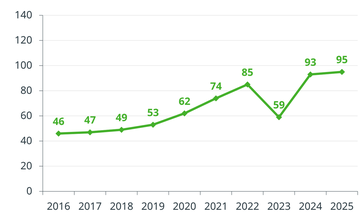
- **Total volume:** CGI-associated publications outnumbered PGI-associated publications by approximately 5:1 (3,382 vs 663; 3,382 + 663 = 4,045).
- **Relative growth:** CGI 327 (2016) → 395 (2025), +21%; PGI 46 → 95, +107%. PGI share of annual retrieved publications moved from 12.3% to 19.4%.
- **Interpretation caveat:** counts are publications retrieved by the prespecified search, not unique trials, and higher volume does not indicate greater validity.

FIGURE 7 Annual PubMed publications, 2016–2025 (counts of publications, not trials)

CGI · 327 → 395 publications · +21%

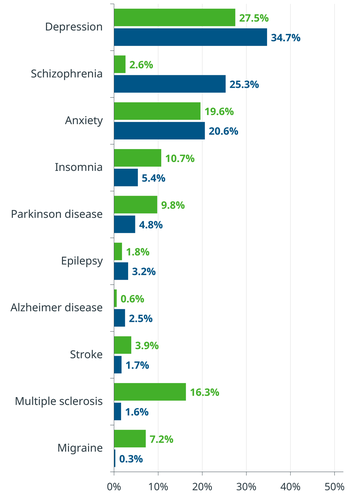


PGI · 46 → 95 publications · +107%



Two aligned panels with independent y-scales are used because the ~5:1 volume difference would render the PGI series flat on a shared axis; no dual y-axis is used. CGI and PGI searches were run separately and overlap was possible, so the panels should not be summed by year.

FIGURE 8 Publications by CNS indication — % of each scale's own publication total



Percentages are calculated separately within each scale's own publication set (CGI n = 3,382; PGI n = 663), so each series sums to 100%; CGI and PGI values in a row are not comparable in absolute volume. CGI publications were most frequent in depression, schizophrenia and anxiety; PGI in depression, anxiety and multiple sclerosis.

CONCLUSIONS

- **PGI-related publications grew more than CGI-related publications (2016–2025; +107% vs +21%), while adoption in registered trials remained comparatively stable (2021–2025).** This divergence between the two sources is not readily explained and merits further investigation.
- **Clinician-rated global impressions predominated across both data sources.** CGI was more frequently represented than PGI in registered CNS trials (7.1% vs 3.6%) and in retrieved publications (3,382 vs 663).
- **Co-utilization of CGI and PGI within the same trial appeared low.** The two were seldom deployed together, which may warrant further examination.
- **Representation varied by indication in a direction consistent with symptom observability.** PGI showed relatively greater representation in indications where symptoms are predominantly subjective and self-report may be considered reliable (e.g., migraine, pain, multiple sclerosis); CGI was comparatively more represented where insight may be limited or behavior is externally observed. No PGI use was identified in OCD.
- **In pediatric-inclusive trials, CGI appeared more frequently, but this observation should be interpreted with caution.** Observer-reported global impressions were excluded by design, so any caregiver-rated contribution in these trials falls outside the scope of this analysis.
- **The indications in which global scales serve as primary endpoints remain to be characterized.** This is an open question not resolved by the current analysis.
- **Use appeared to be slightly more common in later-phase trials,** potentially serving an interpretive (anchor) role rather than as exploratory early-phase measures.

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Color convention throughout: CGI = dark blue, PGI = green. Database is identified by panel design and heading, not by scale color. All values are descriptive; no statistical testing was performed.

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