

Patient Global Impression (PGI) and Clinician Global Impression (CGI) Measures: Adoption Patterns Across CNS Clinical Research

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What is the Methodological Issue Being Addressed? PGI and CGI scales are increasingly incorporated into CNS clinical trial endpoint strategies and are frequently used as anchors for evaluating clinically meaningful change. Despite their widespread use, adoption patterns across indications, development phases, and research settings have not been systematically characterized. This study provides a quantitative landscape analysis of PGI and CGI utilization across registered CNS clinical trials (TrialTrove, 2021-2025) and published literature (PubMed, 2016-2025), examining adoption by indication, sponsor type, age group, and endpoint role. These findings provide an evidence base to guide indication-appropriate selection of global impression measures and inform future regulatory and endpoint strategy discussions.

Introduction Background: PGI and CGI scales are increasingly recognized as important clinical anchors in endpoint strategies. No systematic analysis has characterized adoption patterns, disease-specific utilization, or temporal trends.

Aims: To characterize PGI and CGI scale utilization across registered clinical trials of CNS indications (2021-2025) and PubMed publications (2016-2025), identifying disease-specific patterns, trial design characteristics, and differences between patient- and clinician-rated approaches.

Methods Methods: A cross-sectional analysis of 14,072 CNS trials starting in 2021-2025 was conducted using TrialTrove. PGI and CGI utilization was identified from registered primary and secondary endpoint fields. Descriptive analyses examined adoption by trial phase, sponsor type, disease indication, patient age group, endpoint role (primary vs secondary), scale co-utilization, and start year. A parallel PubMed search characterized publication trends across 10 CNS disease indications from 2016 to 2025.

Results Results: Of CNS clinical trials initiated between 2021 and 2025, 1,322 (9.4%) used a CGI or PGI measure. CGI was used approximately twice as often as PGI (7.1% vs 3.6% of all trials). CGI adoption was highest in ADHD (33.1%), autism spectrum disorder (26.8%), and bipolar disorder (24.9%), whereas PGI adoption was highest in migraine (8.5%), PTSD (6.7%), and anxiety disorders (4.9%). Global-impression scales were typically used independently: only 189 trials (14.3%) used both, while 812 used CGI only and 321 PGI only. CGI more frequently served as a primary endpoint than PGI (13.4% vs 5.7% of CGI- and PGI-using trials, respectively). Pediatric-inclusive trials showed greater CGI than PGI use (16.0% vs 2.8%) compared with adult-only trials (6.1% vs 3.7%). Adoption was highest in Phase III/II-III studies, reaching 16.0% for CGI and 7.5% for PGI. Similar rates were observed in Phase I/II and Phase II studies, with CGI use of 14.7% and PGI use of 7.5%.

Industry-sponsored trials demonstrated higher adoption, reaching 25.3% for CGI and 11.5% for PGI in Phase III/II-III studies and 20.6% and 10.9%, respectively, in Phase I/II and Phase II studies. Overall adoption remained relatively stable from 2021 to 2025 (CGI approximately 7%-8%; PGI approximately 3%-4%).

Among 4,045 PubMed publications, CGI predominated the literature accounting for 3,382 publications versus 663 for PGI (5.1:1). However, PGI demonstrated greater relative growth, increasing from 46 publications in 2016 to 95 in 2025 (+107%; slope $\approx$ +5.6/year), whereas CGI increased from 327 to 395 publications (+21%; slope $\approx$ +8.7/year). By indication, CGI was used most often in depression (34.7%), schizophrenia (25.3%), and anxiety (20.5%), whereas PGI was most frequently used in depression (27.7%), anxiety (20.0%), and multiple sclerosis (15.6%).

Conclusion Conclusion: CGI and PGI scales appear to fulfill distinct but complementary roles within CNS endpoint strategies. CGI predominates in clinical trials and publications, particularly in psychiatric disorders and pediatric-inclusive populations. In contrast, PGI was frequently adopted in conditions characterized by substantial subjective symptom burden. Despite substantial growth in PGI-related publications, adoption in registered CNS clinical trials remained stable between 2021 and 2025. This divergence suggests increasing scientific interest has not yet translated into broader implementation. These findings may inform indication-specific selection of global impression measures and support patient-centered assessment strategies in CNS research.

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Guidelines I have read and understand the Poster Guidelines

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