Synthesis
METHODS NOTE (E156 entry 677)

Two reporting requirements, divergent compliance: results-posting rises while PCR-correction stalls in 2,039 registered malaria trials

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Primary estimand: P01 = fraction of completed malaria trials posting results within 12 months of primary completion; P03 = fraction declaring PCR-correction in primary outcomes.

Abstract

Do malaria trials registered on ClinicalTrials.gov comply with two reporting requirements — the FDAAA results-posting mandate and the WHO PCR-correction declaration in primary outcomes? The AACT 2026-04-12 snapshot of 2,039 registered malaria trials, 2004–2024 by primary completion date, was analyzed. P01 = the fraction posting results within 12 months; P03 = the fraction declaring PCR-correction (strict regex plus ACPR-inclusive broad regex), with Wilson 95% CIs. Compliance was below target: P01 = 5.3% [4.2, 6.6] of 1,407 completed trials; P03 strict = 5.4% [4.3, 6.7] / broad = 9.0% [7.6, 10.7] of 1,302 drug-efficacy trials. Trajectories diverged: FDAAA results-posting rose 2.5% → 10.1% pre/post-2017 (Fisher p<0.001), whereas WHO PCR-correction did not significantly change, 6.8% → 5.1% pre/post-2009 (p = 0.43). Malaria-specific FDAAA compliance trails the ~41% cross-disease benchmark ~eightfold; the WHO methodological standard has not moved without enforcement infrastructure. P03 strict is a lower bound; trials registered only in PACTR/CTRI/ISRCTN are outside this corpus.

FIGURES

Figure 1. Compliance point estimates with Wilson 95% CIs (P01; P03 strict; P03 broad) against the ~41% cross-disease FDAAA benchmark (DeVito 2020).

Figure 2. Pre/post trajectories: FDAAA results-posting (rose, p<0.001) versus WHO PCR-correction (no significant change).

Visual abstract.

METHODS NOTE

Source: AACT 2026-04-12 static snapshot of ClinicalTrials.gov. Corpus: 2,039 registered malaria trials (any-field text match), year-binned 2004–2024 by primary completion date. P01: among 1,407 completed trials, results first submitted within 365 days. P03: among 1,302 interventional drug/biological trials, primary-outcome PCR-correction declaration (strict regex; ACPR-inclusive broad regex). Statistics: Wilson 95% CIs; two-sided Fisher exact; year-binned denominators. Independently cross-validated in R 4.6 binom/fisher.test and awk recount.

DATA & CODE AVAILABILITY

AACT 2026-04-12 public export; recompute scripts in analysis/. No patient-level data. Analysis derived from publicly available aggregate records. Reporting checklist: STROBE (observational audit variant). AI disclosure: AI-assisted tooling for pipeline and independent verification; manuscript human-authored, reviewed, and approved. Funding: None. Competing interests: None declared.

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