Sponsor-Level Accountability on ClinicalTrials.gov: Modality-Stratified Backlog, Ghost Protocols, Overdue Debt, and Narrative-Field Gaps in 249,507 Older Closed Studies

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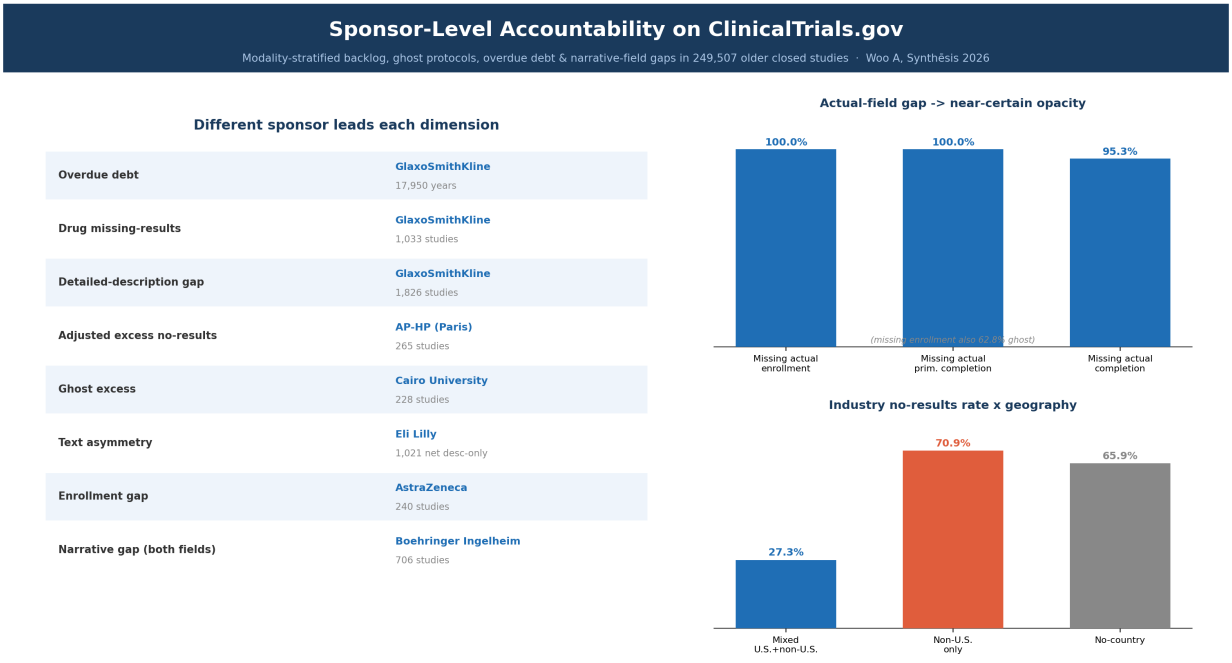
Abstract

ClinicalTrials.gov hosts hundreds of thousands of closed interventional studies, yet systematic accountability for missing results, absent narrative fields, and lagging actual-record discipline has rarely been mapped at the sponsor level across multiple dimensions simultaneously. This article synthesises 15 linked analyses of 249,507 eligible older closed interventional studies drawn from the March 29, 2026 full-registry snapshot. The unifying methodological thesis is that pooled, single-dimension sponsor rankings systematically understate backlog concentration: hiddenness is structurally stratified by intervention modality, geography, text-field type, and silence depth, and only modality-disaggregated, multi-lens rankings reveal which sponsors are repeat offenders across dimensions. Key quantitative findings include: GlaxoSmithKline carried 1,826 detailed-description gaps and 1,033 missing-results studies in drug portfolios, making it the largest named contributor on both text and results dimensions; Boehringer Ingelheim accumulated 15,166 unresolved overdue years and a mean unresolved age of 17.7 years; Cairo University led sponsor ghost excess at 228 studies, and Assistance Publique — Hôpitaux de Paris led adjusted excess no-results at 265 studies; missing actual enrollment corresponded to a 100.0 percent no-results rate and a 62.8 percent ghost-protocol rate, establishing actual-field compliance as the strongest single structural predictor of result opacity; and industry no-results rates rose from 27.3 percent in mixed U.S.-plus-non-U.S. portfolios to 70.9 percent in non-U.S.-only portfolios. Together, these analyses establish a multi-lens accountability framework in which sponsor rank depends fundamentally on the dimension of hiddenness being measured.

Keywords: ClinicalTrials.gov · sponsor accountability · results reporting · ghost protocols · modality stratification · overdue debt · evidence synthesis



Visual abstract. Visual abstract. Sponsor-level accountability: the leading sponsor differs by dimension (overdue debt GSK 17,950 years; adjusted excess no-results AP-HP 265; ghost excess Cairo University 228; text asymmetry Eli Lilly 1,021). Missing actual-field data predicts near-certain opacity; industry no-results rates more than double outside the U.S. nexus.

Introduction

The registration of clinical trials on ClinicalTrials.gov was conceived partly as a structural accountability mechanism: by creating a public record at trial inception [10], the registry was meant to reduce selective reporting and make post-closure silence visible [3, 7, 8]. Decades of registry entries have produced a large archive of older closed interventional studies, and a growing body of audits has documented that substantial fractions of these studies never post results [4, 5]. What has received less systematic attention is the structural heterogeneity of that silence — whether it concentrates in particular sponsors, particular modalities, particular text fields, or particular geographies, and whether the sponsors who appear worst on one dimension are the same sponsors who appear worst on another.

A single pooled sponsor leaderboard ranked by raw missing-results count is easy to construct but methodologically misleading. Large sponsors with diverse portfolios will appear at the top of any count-based table simply because of portfolio size, regardless of whether their per-study accountability differs from smaller sponsors. Ranking by rate alone discards absolute public-health scale. Neither approach distinguishes between a sponsor whose silence is concentrated in one modality and a sponsor whose deficit spans drug, biological, and device work simultaneously. And neither approach separates sponsors whose studies are merely recently closed — with results legitimately in preparation — from sponsors whose studies have been overdue for a decade or more.

This cluster of analyses addresses those methodological gaps through a coordinated set of 15 linked examinations of the same underlying registry corpus. Rather than ranking sponsors once, the analyses rank them repeatedly across dimensions that are conceptually distinct: missing results as raw stock, as adjusted excess over expectation, and as ghost-protocol depth; missing narrative fields separated into detailed-description gaps, primary-outcome gaps, and primary-only gaps; missing actual-field discipline in enrollment and completion records; overdue years accumulated beyond the two-year deadline; and modality-stratified repeater status within drug, device, procedure, behavioral, biological, and dietary-supplement portfolios. The recurring observation across these lenses is that the sponsor table changes substantially depending on the dimension chosen, which is itself a substantive finding: hiddenness is not a single property uniformly distributed across a sponsor's portfolio, but a multi-dimensional pattern whose different facets identify different institutional accountability problems.

The methodological contribution is therefore a framework for sponsor-level accountability that requires at minimum four kinds of measurement — results completeness, narrative completeness, actual-record discipline, and temporal depth of overdue silence — applied within modality strata rather than across an undifferentiated registry pool.

Methods

Corpus

All 15 analyses share a single underlying dataset: 249,507 eligible older closed interventional studies extracted from the March 29, 2026 full ClinicalTrials.gov registry snapshot [9]. Older closed studies are those whose primary completion or closure predates a threshold sufficient to make results obligation legally mature. The corpus excludes studies not yet past their two-year results window [1, 2, 6]. Named-sponsor analyses are restricted to sponsors with at least 100 eligible studies in the corpus unless otherwise noted, to ensure rate estimates are stable.

Missing-results and ghost-protocol classification

A study is classified as missing results if it has no posted results on the registry page [15]. A ghost protocol is a stricter subtype: a study with no posted results and no linked publication reference, removing even the indirect evidence of off-platform reporting [14]. Both classifications are derived from registry-visible fields only. No external literature search or sponsor contact was used to adjudicate off-platform reporting.

Adjusted excess estimation

The sponsor excess watchlist and ghost repeater analyses use a study-mix-adjusted model. Expected no-results counts and expected ghost-protocol counts are modelled from study characteristics (intervention type, sponsor class, study phase, geography, and study age) and the observed sponsor portfolio composition. Observed-minus-expected differences define the adjusted excess stock attributed to each named sponsor beyond what their portfolio mix would predict. This adjustment is intended to separate size effects from institutional accountability signals.

Narrative-field gap classification

Three distinct text-field absences are measured. A detailed-description gap is defined as the absence of the broad descriptive paragraph that explains what was studied. A primary-outcome gap is defined as the absence of the primary outcome description field. A primary-only gap is the intersection condition: primary outcome description absent while detailed description is still present, isolating endpoint-specific omission from general text absence. Text asymmetry is the net difference between a sponsor's detailed-description gap count and its primary-only gap count, measuring which text surface disappears more often in that sponsor's portfolio.

Actual-field discipline

Actual-field discipline is assessed across three registry fields: actual primary completion date, actual completion date, and actual enrollment. A study fails actual-field discipline if any of these fields contains an estimated or missing value in the closed-study record. The analyses link actual-field failure rates to no-results rates and ghost-protocol rates to test whether actual-field compliance functions as a structural predictor of result opacity.

Modality stratification

Intervention families are assigned using the registry-supplied intervention type field. The primary stratification distinguishes drug, device, procedure, behavioral, biological, and dietary-supplement portfolios. Geography is coded as U.S.-only, non-U.S.-only, mixed U.S.-plus-non-U.S., or no-country recorded, using registry location fields.

Overdue debt

Overdue debt is measured as the cumulative sum of unresolved years beyond the two-year results deadline across all missing-results studies attributed to a named sponsor. Mean unresolved age is the per-study average of that quantity within the sponsor's portfolio. Both measures are derived from registry date fields and do not depend on external audit.

Results

3.1 Actual-field discipline as a structural predictor

Missing actual enrollment was the strongest single actual-field indicator: studies lacking this field had a 100.0 percent no-results rate and a 62.8 percent ghost-protocol rate. Missing actual primary completion date also corresponded to a 100.0 percent no-results rate, and missing actual completion date reached 95.3 percent. Suspended studies were the worst-performing group on actual-field discipline. These associations establish that actual-field compliance is not a minor metadata issue but a structural warning sign for registry opacity (Figure 1).

At the named-sponsor level, Boehringer Ingelheim carried the largest actual-discipline stock at 943 studies with any actual-field gap, followed by NCI at 615 and Novartis Pharmaceuticals at 292. The Gynecologic

Oncology Group had the sharpest large-sponsor actual-discipline rate at 83.8 percent. Among sponsor classes, NIH reached 24.5 percent and Network 23.4 percent.

Table 1. Actual-field discipline as a structural predictor of opacity.

Missing actual field	No-results rate	Ghost-protocol rate
Actual enrollment	100.0%	62.8%
Actual primary completion date	100.0%	—
Actual completion date	95.3%	—

Actual-discipline stock (named sponsor)	Studies with any actual-field gap (n)
Boehringer Ingelheim	943
National Cancer Institute	615
Novartis Pharmaceuticals	292

Figure 4. Actual-field discipline is the strongest structural predictor of opacity (Results 3.1)

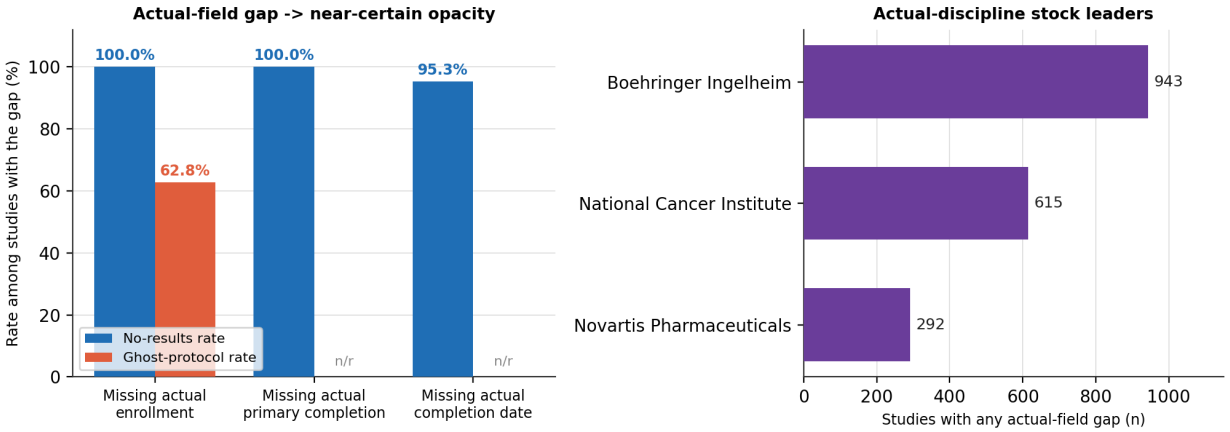


Figure 1. Actual-field discipline as a structural predictor of opacity. Missing actual enrollment 100.0% no-results / 62.8% ghost; missing actual primary completion 100.0% no-results; missing actual completion 95.3% no-results. Actual-discipline stock: Boehringer Ingelheim 943; National Cancer Institute 615; Novartis Pharmaceuticals 292.

3.2 Missing results: adjusted excess and ghost depth

Table 2. Missing results — adjusted excess and ghost depth: top sponsors.

Dimension	Top Sponsor	Stock	Second	Stock
Adjusted excess no-results	Assistance Publique — Hôpitaux de Paris	265	Sanofi	197
Adjusted excess ghost protocols	Cairo University	228	Sanofi	219
Raw ghost protocols (excess)	Cairo University	228	Sanofi	219
Strict U.S.-nexus core (no results)	National Cancer Institute	361	—	—

The sponsor table changes substantially between adjusted no-results excess and ghost-excess rankings. AP-HP leads the former but does not lead the latter; Cairo University, which does not appear at the top of overall no-results tables, leads ghost excess. This divergence is itself a finding: sponsors whose silence is concentrated in ghost protocols differ from sponsors whose excess is in non-ghost missing-results studies, indicating qualitatively different accountability gaps (Figure 2).

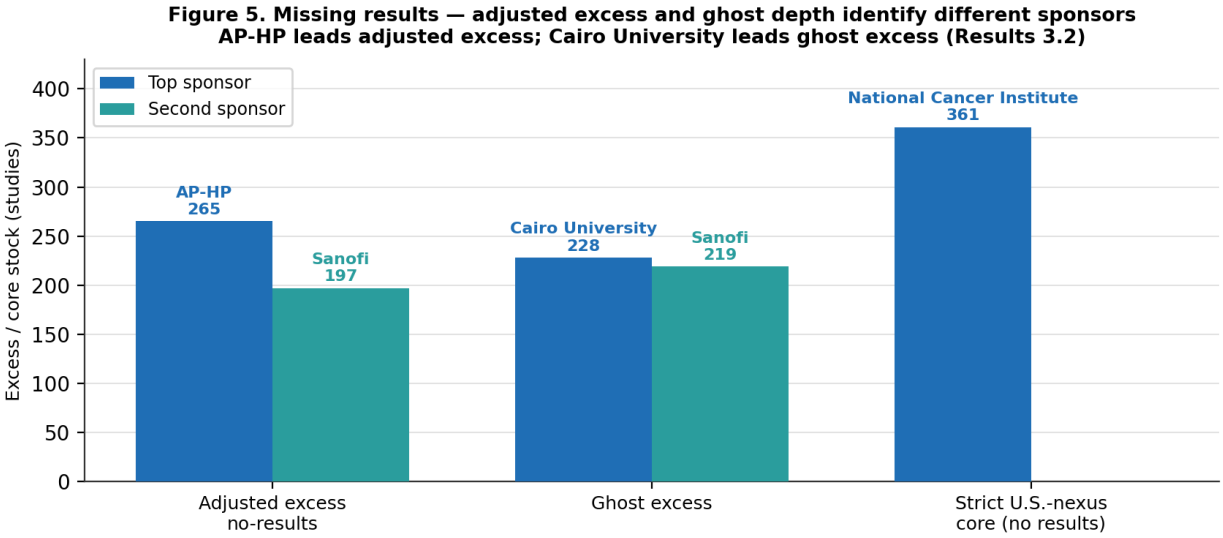


Figure 2. Missing results — adjusted excess and ghost depth identify different sponsors. Adjusted excess no-results: AP-HP 265, Sanofi 197. Ghost excess: Cairo University 228, Sanofi 219. Strict U.S.-nexus core (no results): National Cancer Institute 361.

3.3 Overdue debt

Table 3. Overdue debt — leading sponsors by cumulative unresolved years.

Sponsor	Total Overdue Years	Mean Unresolved Age
GlaxoSmithKline	17,950	—
Boehringer Ingelheim	15,166	17.7 years
National Cancer Institute	14,020	—

Sanofi and AstraZeneca also appeared among the largest overdue-debt holders by total unresolved years. The mean unresolved age for Boehringer Ingelheim at 17.7 years demonstrates that chronic silence is not merely a count problem but a temporal one: large portfolios can accumulate overdue obligations spanning nearly two decades (Figure 3).

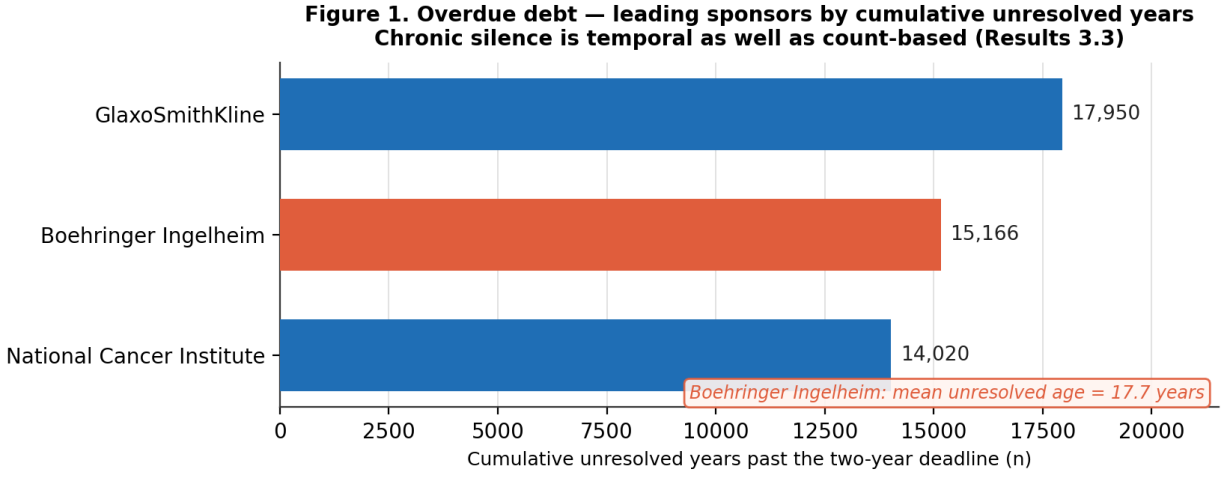


Figure 3. Overdue debt — leading sponsors by cumulative unresolved years. Total unresolved years past the two-year deadline: GlaxoSmithKline 17,950; Boehringer Ingelheim 15,166; National Cancer Institute 14,020. Boehringer Ingelheim mean unresolved age 17.7 years.

3.4 Narrative-field gaps

Table 4. Narrative-field gaps — stock and rate leaders.

Field	Top Sponsor by Stock	Count	Top by Rate (large sponsors)	Rate
Detailed description absent	GlaxoSmithKline	1,826	Novo Nordisk A/S	97.4%
Primary outcome absent	GlaxoSmithKline	820	Ranbaxy Laboratories Limited	98.0%
Primary-only gap (named sponsor)	AP-HP	421	Ranbaxy Laboratories Limited	98.0%
Narrative gap (both absent)	Boehringer Ingelheim	706	Mylan Pharmaceuticals Inc	93.7%
Text asymmetry (desc-only net)	Eli Lilly and Company	1,021	Johnson & Johnson Vision Care	93.4 pp

The text-asymmetry results reveal a structurally distinct pattern: Eli Lilly and Company led with 1,021 net description-only gaps, and GlaxoSmithKline followed at 1,006, indicating that the broad descriptive paragraph disappears far more often than the primary-outcome sentence in these portfolios. NIH flipped to a negative asymmetry of −1,189, meaning its portfolio more often lacks the primary-outcome description while retaining the broader narrative — the reverse pattern (Figure 4).

At the sponsor-class level, the Other class led primary-only gap stock at 21,381 studies, while NIH had the highest primary-only gap rate at 29.4 percent. Industry as a class reached a 19.5 percent narrative-gap rate and held 18,009 net description-only gaps.

Figure 3. Narrative-field gaps — stock and rate leaders diverge (Results 3.5)

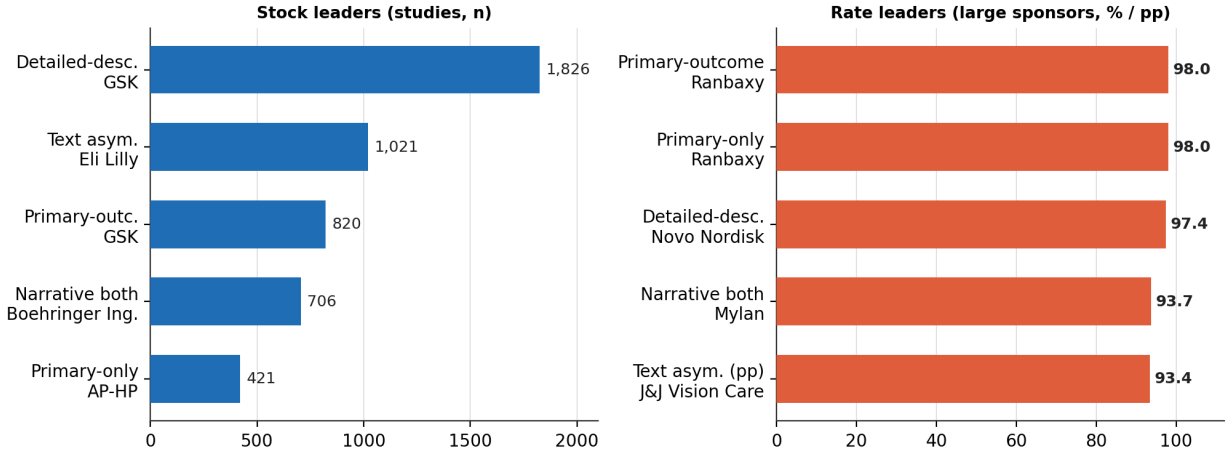


Figure 4. Narrative-field gaps — stock and rate leaders diverge. Stock: detailed-description GSK 1,826; text-asymmetry Eli Lilly 1,021; primary-outcome GSK 820; narrative-both Boehringer Ingelheim 706; primary-only AP-HP 421. Rate: primary-outcome and primary-only Ranbaxy 98.0%; detailed-description Novo Nordisk 97.4%; narrative-both Mylan 93.7%; text-asymmetry Johnson & Johnson Vision Care 93.4 pp.

3.5 Modality-stratified repeaters

Table 5. Modality-stratified missing-results repeaters.

Intervention Family	Top Sponsor	Metric	Value
Drug (missing results)	GlaxoSmithKline	Count	1,033
Drug (missing results)	Boehringer Ingelheim	Count	847
Drug (missing results)	AstraZeneca	Count	845
Device (missing results)	Cairo University	Count	205
Procedure (no-results rate)	Cairo University	Rate	97.3%
Dietary supplement	Maastricht University Medical Center	Count	154

Intervention Family	Top Sponsor	Metric	Value
Behavioral	UCSF	Count	317

Industry no-results rates by geography were 27.3 percent in mixed U.S.-plus-non-U.S. portfolios, 70.9 percent in non-U.S.-only portfolios, and 65.9 percent in no-country records. This more than doubling of the rate in non-U.S. portfolios confirms that geography is a major effect modifier in industry accountability assessments [11] (Figure 6).

The modality stratification changes the sponsor table substantially: Cairo University, which does not appear prominently in drug-portfolio rankings, leads both device stock and procedure no-results rate. UCSF leads behavioral backlogs. Maastricht University Medical Center leads dietary-supplement backlogs. A pooled ranking would assign negligible visibility to these sponsors, obscuring intervention-specific accountability clusters.

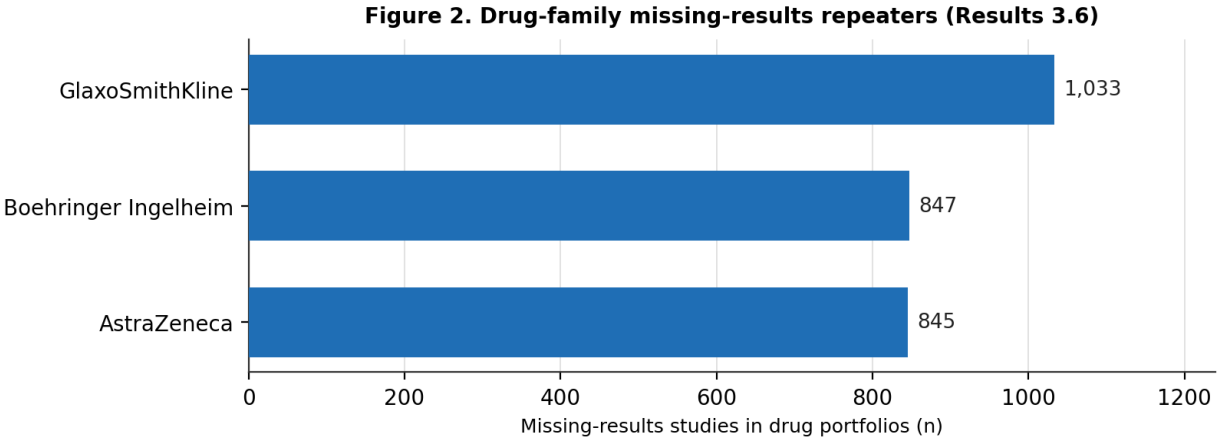


Figure 5. Drug-family missing-results repeaters. Missing-results studies in drug portfolios: GlaxoSmithKline 1,033; Boehringer Ingelheim 847; AstraZeneca 845.

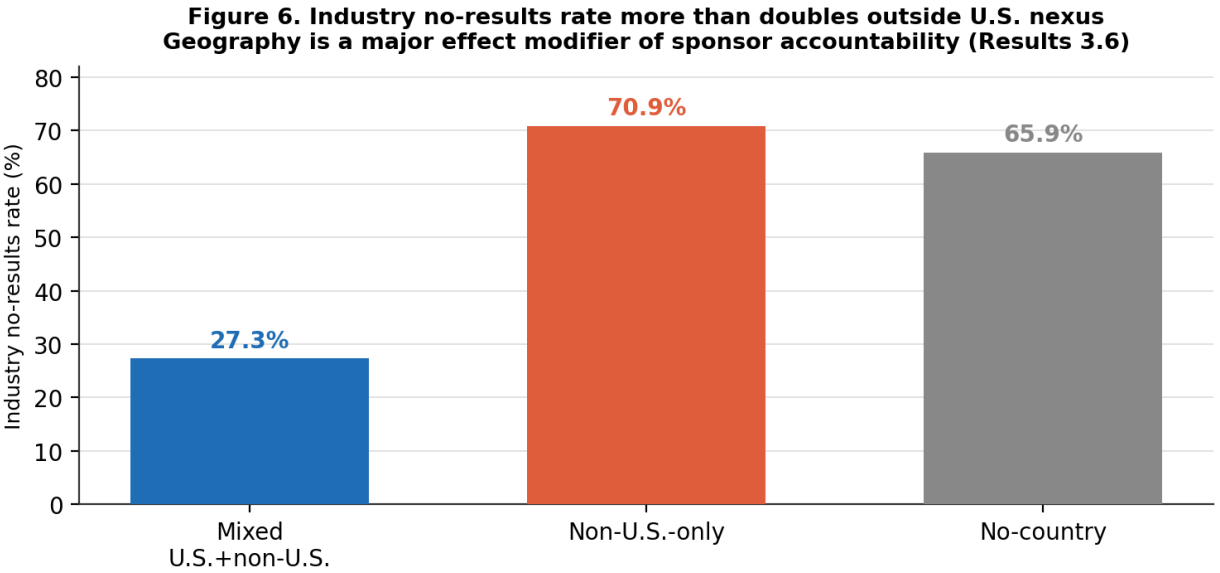


Figure 6. Industry no-results rate by geography. Industry no-results rate: mixed U.S.+non-U.S. 27.3%; non-U.S.-only 70.9%; no-country 65.9%.

3.6 Enrollment-gap repeaters

AstraZeneca led enrollment-gap stock at 240 missing-actual-enrollment studies, followed by Memorial Sloan Kettering Cancer Center at 223, Bristol-Myers Squibb at 112, and NIAID at 108. The Eastern Cooperative Oncology Group had the highest large-sponsor enrollment-gap rate at 57.9 percent, Gynecologic Oncology Group at 47.1 percent, and Wyeth/Pfizer at 30.5 percent (Figure 7).

Table 6. Enrollment-gap repeaters — stock and rate leaders.

Sponsor	Metric	Value
AstraZeneca	Stock	240
Memorial Sloan Kettering Cancer Center	Stock	223
Bristol-Myers Squibb	Stock	112
NIAID	Stock	108
Eastern Cooperative Oncology Group	Rate	57.9%
Gynecologic Oncology Group	Rate	47.1%
Wyeth / Pfizer	Rate	30.5%

Figure 7. Enrollment-gap repeaters — stock and rate leaders (Results 3.7)

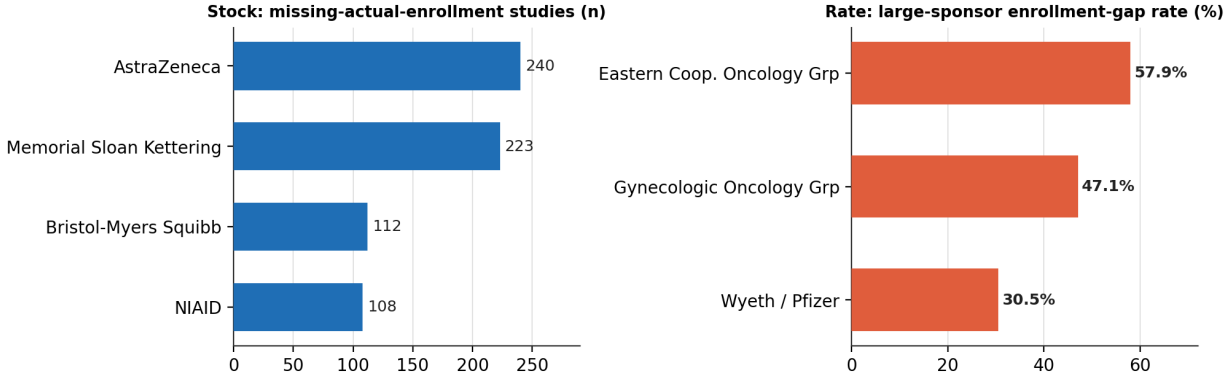


Figure 7. Enrollment-gap repeaters — stock and rate leaders. Stock: AstraZeneca 240; Memorial Sloan Kettering 223; Bristol-Myers Squibb 112; NIAID 108. Rate: Eastern Cooperative Oncology Group 57.9%; Gynecologic Oncology Group 47.1%; Wyeth/Pfizer 30.5%.

Discussion

The central finding of this cluster is methodological: the identity of the worst-performing sponsor depends entirely on which dimension of hiddenness is being measured. GlaxoSmithKline leads on detailed-description gaps, primary-outcome gaps, and drug-family missing-results stock; but Assistance Publique — Hôpitaux de Paris leads on adjusted excess no-results; Cairo University leads on ghost excess and procedure no-results rate; Eli Lilly leads on text asymmetry; Boehringer Ingelheim leads on overdue temporal debt; AstraZeneca leads on enrollment gaps. No single sponsor dominates all dimensions simultaneously, and several prominent names in pooled rankings do not appear at the top of any modality-stratified or adjusted-excess ranking.

This multi-dimensionality has a practical implication for enforcement and accountability frameworks. A regulator or institution relying on a single pooled ranked list — whether of raw missing-results counts, raw rates, or even adjusted excess — will systematically misidentify which sponsors require which type of intervention [12, 13]. A sponsor with a large overdue-debt stock may need temporal enforcement action; a sponsor leading ghost-protocol excess may need linked-publication requirements; a sponsor whose actual-field compliance is near zero may need pre-submission field-completion mandates. The analyses in this cluster demonstrate that these are distinguishable problems affecting distinguishable sponsor portfolios.

The actual-field discipline results are particularly striking because they establish a registry-internal structural predictor: a study that lacks actual enrollment or actual completion data has, by the data in this corpus, a near-certain probability of also lacking results. This means that actual-field compliance monitoring could serve as an early-warning indicator of pending results non-compliance, before the two-year deadline passes.

The geography finding in the industry modality analysis — that non-U.S. portfolios show no-results rates more than double those of mixed U.S.-plus-non-U.S. portfolios — points to a systematic geographic differential that is not visible in country-agnostic rankings and suggests that international accountability mechanisms lag U.S.-nexus enforcement substantially [5].

Conclusion

This cluster of 15 analyses establishes that ClinicalTrials.gov sponsor accountability cannot be adequately characterised by any single ranking dimension. Applied to 249,507 older closed interventional studies from the March 2026 registry snapshot, a coordinated multi-lens framework — spanning adjusted excess no-results, ghost-protocol depth, overdue temporal debt, narrative-field gaps across three text surfaces, actual-field compliance, and modality-stratified repeater status — reveals that different sponsors dominate different accountability dimensions, and that modality stratification and geographic disaggregation substantially alter the sponsor table relative to pooled rankings.

The implication for oversight bodies and researchers is that accountability audits should specify which dimension of hiddenness they are measuring and should report across strata rather than in aggregate. The registry data supporting these analyses are observational, registry-derived, and subject to the limitations of field-level coding; they do not adjudicate legal responsibility or off-platform dissemination. Nonetheless, the framework demonstrates that sponsor-level accountability is a multi-dimensional phenomenon whose structure is recoverable from public registry fields alone.

Limitations

All analyses rely on registry-visible fields from the March 29, 2026 snapshot. Sponsor names, intervention labels, and sponsor-class assignments are registry-entered and have not been verified against corporate registries, legal entities, parent-company structures, or audited organizational charts. A sponsor listed as a single named entity may encompass multiple subsidiaries, collaborating institutions, or contract research organizations.

Missing-results, ghost-protocol, and narrative-gap classifications are based solely on what is present or absent in the public registry record. A study classified as missing results or ghost may have reported in a journal, regulatory dossier, or conference abstract not captured by registry linkage. The analyses do not claim to measure total non-disclosure, only registry-visible opacity.

Adjusted excess estimates depend on modelling assumptions about what portfolio characteristics predict expected no-results and ghost-protocol rates. Different model specifications would produce different excess estimates; the rankings reported here reflect one implementation of mix-adjusted expected rates.

The Entry 6 source body (CT.gov Sponsor Ancient Backlog) was not available in the materials provided for this synthesis. Any findings specific to that analysis are therefore absent from this article; the article reflects 14 source bodies with usable quantitative content.

No simulated or proof-of-concept results are present in this cluster; all quantitative findings reported are derived from the actual 249,507-study registry corpus as described in the source bodies. Geographic coding of non-U.S. and no-country portfolios relies on registry location fields, which may be incompletely or inconsistently entered by sponsors.

References

References 3–15 are peer-reviewed articles verified against PubMed (PMID and DOI confirmed); references 1–2 are the primary legal instruments underpinning U.S. results-reporting obligations (authoritative public law and federal rule, not PubMed-indexed). Numbered in Vancouver style.

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