The Country Anatomy of CT.gov Transparency Gaps: A Fourteen-Lens Audit of 249,507 Older Closed Interventional Studies

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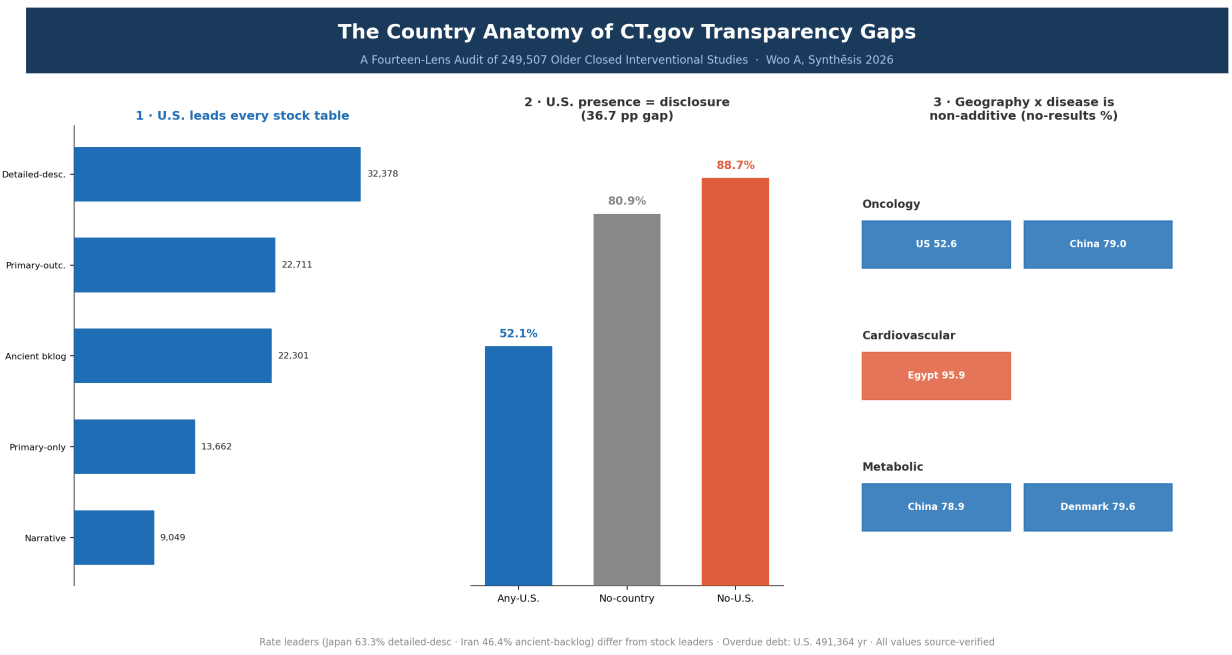
Synthēsis · Research Article · Vol 2 No 7 · 2026 · Published 2 July 2026 · doi: 10.66040/synthesis.2026.c02

Abstract

ClinicalTrials.gov hosts the world's largest public registry of clinical research, yet a substantial share of older closed studies remain silent — posting no results, no linked publications, and no endpoint descriptions. Whether this silence is geographically structured, and in what ways, remains poorly characterised. We conducted fourteen pre-specified analyses of 249,507 eligible older closed interventional studies drawn from the March 29, 2026 full-registry snapshot, measuring country-linked transparency across nine distinct gap dimensions: ancient backlog, description black-box, detailed-description gap, enrollment gap, composite excess watchlist, ghost-protocol excess, narrative gap, overdue debt, primary-only gap, primary-outcome gap, country-linked sponsor concentration, text asymmetry, and U.S.-versus-ex-U.S. sponsor-class stratification. The United States dominated absolute stock tables on every dimension by virtue of registry scale; rate tables revealed a different and smaller group of countries — Iran, Japan, France, South Korea, Egypt, Norway, Slovakia — each leading on different gap dimensions. The most policy-salient finding was the jurisdictional divide: studies involving at least one U.S. site carried a 52.1% no-results rate versus 88.7% for studies with no U.S. involvement, a 36.7-percentage-point gap consistent with the regulatory reach of the FDA Amendments Act. Disease and geography interact non-additively: oncology studies involving China reached 79.0% no results versus 52.6% for those involving the United States, and cardiovascular studies involving Egypt reached 95.9%. No single country or metric captures the problem; the geography of transparency failure is multidimensional.

Keywords: ClinicalTrials.gov · non-disclosure · results reporting · trial registry · country-linked transparency · evidence synthesis · FDAAA



Visual abstract. Visual abstract. Country anatomy of CT.gov transparency: the U.S. leads every absolute-stock table by scale; U.S. presence predicts disclosure (any-U.S. 52.1% vs no-U.S. 88.7% no-results); and geography interacts with disease non-additively. All values source-verified against the Results.

Introduction

Clinical trial transparency reform has focused primarily on results reporting — the obligation under the FDA Amendments Act of 2007 (FDAAA) [1] to post structured results within twelve months of primary completion for applicable clinical trials registered on ClinicalTrials.gov [2, 3]. Yet results reporting is only one transparency dimension visible through the registry record. A study may post results while omitting its primary outcome description, leaving clinicians unable to assess endpoint validity [7]. A study may retain a detailed narrative while leaving the specific endpoint blank, producing a gap in what is technically the most clinically actionable field. A study that neither ghosts nor withholds results may still lack its actual enrollment value years after closure, obscuring realised sample size. Each of these dimensions reflects a partially distinct failure mode, and they need not co-occur [4, 8].

The question of whether these failure modes are geographically structured — and how — matters for at least three reasons. First, regulatory accountability is jurisdictional: FDAAA applies to applicable clinical trials involving U.S.-based sites [6], and its enforcement mechanisms do not extend to ex-U.S. registrants who voluntarily registered on ClinicalTrials.gov [5, 12, 15]. If compliance is driven by regulation rather than goodwill, U.S.-linked portfolios should look systematically different from ex-U.S. portfolios. Second, systematic reviewers who treat geographic diversity as a proxy for generalisability face radically different evidence-quality profiles by country, particularly across condition families [10, 14]; a meta-analysis that pools oncology trials from China and the United States confronts a 26-percentage-point gap in no-results rates within the same therapeutic area. Third, accountability frameworks that name institutions must first locate them within the registry's country-linked structure; sponsor-repeater analyses that ignore country footprint confound national regulatory exposure with institutional behaviour [13].

This study reports fourteen pre-specified analyses of 249,507 eligible older closed interventional studies, each isolating a distinct country-linked transparency dimension. The methodological thesis is that transparency gaps in ClinicalTrials.gov are geographically structured but not geographically uniform, and that the structure differs depending on which dimension you measure. Rate-based rankings and stock-based rankings disagree sharply, and different gap types assign leadership to entirely different national portfolios. The only finding that inverts this multidimensional complexity is the U.S.-versus-ex-U.S. jurisdictional divide, which emerges consistently across sponsor classes and constitutes the strongest evidence that regulatory framework — not sponsor type, disease area, or national culture — is the primary predictor of results disclosure.

Methods

Data source and eligibility

All fourteen analyses used the March 29, 2026 full ClinicalTrials.gov data snapshot [9]. The eligible study pool was 249,507 older closed interventional studies. "Older closed" designates studies that completed or terminated a sufficient number of years before the snapshot date to have been due for results posting under the two-year reporting deadline [1, 6]; the precise vintage threshold follows prior analyses in this series and excludes studies that completed too recently to have accrued meaningful overdue time. Observational studies, device-only studies registered under separate pathways, and studies with no completion date in the structured fields were excluded. This eligibility definition was fixed prior to country-linking and applied identically across all fourteen analyses.

Country-linking

Country links reflect the named study locations recorded in the CT.gov structured fields at snapshot time. Because the registry supports multiple location entries per study, country links are non-exclusive: a multinational trial naming both the United States and France contributes a row to both the U.S. portfolio and the French portfolio. Country-level totals are therefore not additive across countries and cannot be summed

to a global figure. This exploded design was chosen because the policy question — "which country-linked portfolios carry the most opacity?" — requires each study to be attributed to every national context in which it operated, not partitioned to one. Analyses restricted country-level tables to portfolios with at least 500 linked studies to ensure stable gap-rate estimates; smaller portfolios were excluded from ranked tables but included in all national statistics.

Gap definitions

Nine primary gap dimensions were operationalised:

1. **Ancient backlog**: Older studies with no posted results and at least ten overdue years beyond the two-year reporting mark. The ten-year threshold identifies the deepest layer of chronic non-disclosure.

1. **Description black-box**: Studies satisfying the two-year results gap criterion that also lack a linked publication, a detailed description field, and a primary outcome description — the strictest four-condition opacity definition in this series.

1. **Detailed-description gap**: Studies missing the detailed description field, which provides the broad narrative of what was studied.

1. **Enrollment gap**: Studies missing the actual enrollment field, which would have confirmed the realised sample size after closure.

1. **Excess watchlist** (composite): A summed composite of adjusted no-results excess, adjusted ghost excess, black-box stock, and strict-core spillover, designed to hold visible study mix more constant before ranking portfolios.

1. **Ghost-protocol excess**: Country-linked portfolios ranked by their excess ghost stock above expectation, where "ghost" denotes a study with no results, no linked publication, and no completion of key protocol narrative fields.

1. **Narrative gap**: Studies missing both the detailed description field and the primary outcome description simultaneously — doubly text-thin records.

1. **Overdue debt**: The sum of unresolved years past the two-year mark across all country-linked older studies in a portfolio, capturing the cumulative temporal burden of missing results.

1. **Text asymmetry**: The net difference between description-only gaps (missing detailed description but not primary outcome description) and primary-only gaps (missing primary outcome description but not detailed description), measured as both counts and rates.

Two additional analyses extended the country framework: the country-condition cross-cut compared no-results rates across country-by-condition-family cells with at least 400 studies; the U.S.-versus-ex-U.S. analysis grouped all older studies into any-U.S. (at least one named U.S. site), no-U.S. (at least one named non-U.S. site and no U.S. site), and no-country (no named location), then compared no-results rates, ghost rates, and visible shares by sponsor class within each group. Sponsor-repeater analyses ranked lead sponsors within selected national footprints by missing-results stock, no-results rate, ghost rate, and visible share.

Results

3.1 The scale problem: why stock and rate tables disagree

The most important structural fact in any country-level transparency audit is the relationship between portfolio size and gap count. Because the United States accounts for the largest single-country portfolio in the eligible study pool, it leads every absolute stock table without exception — not because its gap rates are highest, but because its sheer volume generates large counts at any positive rate.

Across all nine gap dimensions, the United States ranked first on absolute stock: primary-outcome gap (22,711 studies missing the endpoint description), detailed-description gap (32,378), narrative gap (9,049), primary-only gap (13,662), ancient backlog (22,301 studies with at least ten overdue years), description black-box (5,833), and enrollment gap (4,573) (Figure 1). On overdue debt — the cumulative sum of years past the two-year deadline — the United States carried 491,364 total unresolved years, a figure so large it exceeds the combined debt of Canada (90,480), France (89,004), and Germany (77,270) more than fourfold (Figure 2). Canada, France, Germany, and in some analyses Spain, consistently ranked second through fourth on stock tables across dimensions.

This uniform stock dominance is analytically misleading. A country that leads on count while showing average or below-average rates has a transparency problem proportional to its registry footprint, not an elevated one. Rate tables tell a different story.

Table 1. United States absolute-stock leadership, by gap dimension.

Gap dimension	U.S. stock (studies, n)
Detailed-description gap	32,378
Primary-outcome gap	22,711
Ancient backlog (≥10 overdue years)	22,301
Primary-only gap	13,662
Narrative gap	9,049
Description black-box	5,833
Enrollment gap	4,573

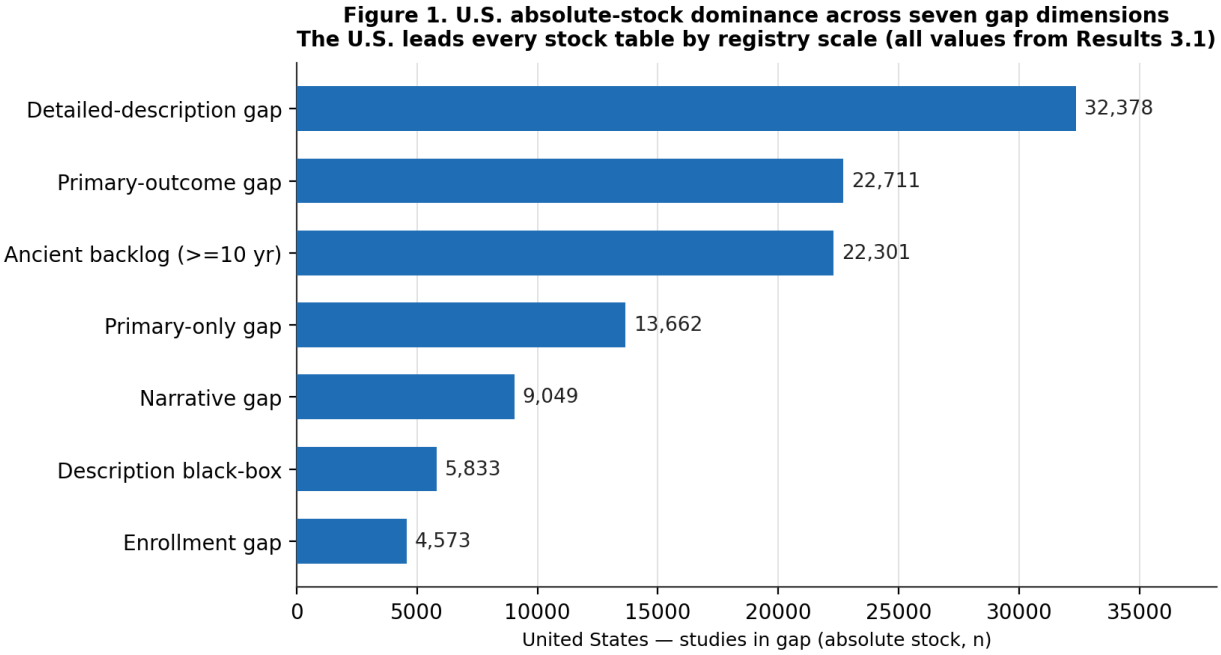


Figure 1. U.S. absolute-stock dominance across seven gap dimensions. United States stock: detailed-description gap 32,378; primary-outcome gap 22,711; ancient backlog 22,301; primary-only gap 13,662; narrative gap 9,049; description black-box 5,833; enrollment gap 4,573.

Table 2. Overdue debt — cumulative unresolved years past the two-year deadline.

Country	Total overdue years (n)	Mean unresolved age
United States	491,364	—
Canada	90,480	—
France	89,004	—
Germany	77,270	9.4 years (highest)

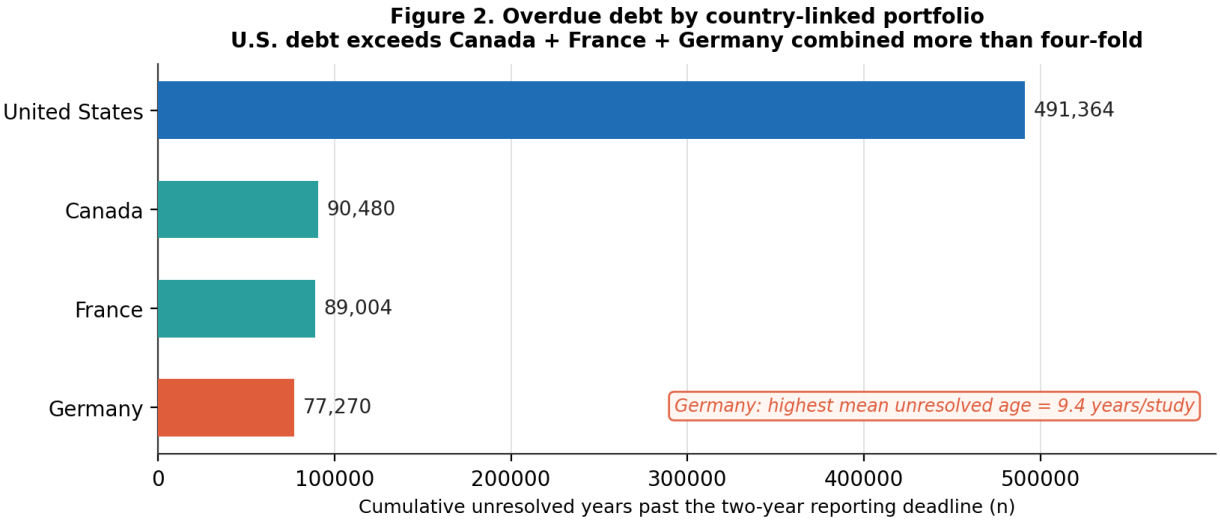


Figure 2. Overdue debt by country-linked portfolio. Cumulative unresolved years past the two-year deadline: United States 491,364; Canada 90,480; France 89,004; Germany 77,270. Germany carries the highest mean unresolved age at 9.4 years.

3.2 Rate-based rankings: a different and smaller group of countries

Rate tables reveal that transparency gaps are concentrated by rate in a set of countries that rarely appear at the top of stock tables (Figure 3).

Iran led or ranked in the top tier on four gap dimensions: ancient-backlog rate (46.4%), enrollment-gap rate (6.3%), primary-only-gap rate (18.4%), and primary-outcome-gap rate (28.5%). Iran's consistent appearance across rate tables suggests systemic underreporting that extends across multiple gap types simultaneously.

Japan showed the highest large-country detailed-description-gap rate (63.3%) and narrative-gap rate (17.9%), and the highest description-black-box rate (10.7%). Japan's gap profile differs from Iran's: Japan's gaps concentrate in text fields (descriptions) rather than results disclosure, suggesting a registration culture that populates dates and status reliably but leaves the substantive narrative fields incomplete.

France led the composite excess-watchlist rankings on adjusted excess no-results stock (2,187 studies) and ghost excess (1,157 studies), and ranked in the top tier on primary-outcome-gap rate (27.7%). France's appearance in both the largest Western country portfolios and the highest adjusted-excess rankings identifies it as qualitatively distinct: a major democratic registrant that nonetheless carries substantial composite opacity after adjustment.

Egypt ranked third on adjusted no-results excess (824 studies) and second on ghost excess (955 studies), and cardiovascular studies involving Egypt reached 95.9% no results in the country-condition cross-cut — the highest single country-condition cell rate observed.

South Korea had the highest black-box intensity in the excess-watchlist analysis (21.2% black-box rate) and ranked second on ghost excess by country (871 studies).

Norway ranked in the top tier on primary-outcome-gap rate (27.5%) and on ancient-backlog rate, appearing in rate tables despite a comparatively small registry portfolio.

Slovakia, Romania, and Poland led the text-asymmetry rate table: Slovakia reached 40.9 percentage points of net asymmetry (description-only gaps exceeding primary-only gaps), Romania 39.3 points, and Poland 36.6 points — a pattern consistent with registry populations where broad narrative fields are systematically less populated than endpoint fields, possibly reflecting data-entry norms in Eastern European academic registration.

Table 3. Rate-based country leaders, by gap dimension.

Country	Gap dimension	Gap rate
Japan	Detailed-description gap	63.3%
Iran	Ancient-backlog	46.4%
Iran	Primary-outcome gap	28.5%
France	Primary-outcome gap	27.7%
Norway	Primary-outcome gap	27.5%
South Korea	Description black-box	21.2%
Iran	Primary-only gap	18.4%
Japan	Narrative gap	17.9%
Japan	Description black-box	10.7%
Iran	Enrollment gap	6.3%
Slovakia	Text asymmetry (net)	40.9 pp
Romania	Text asymmetry (net)	39.3 pp
Poland	Text asymmetry (net)	36.6 pp

Figure 3. Rate-based leaders — a different, smaller set of countries
Each bar is the leading country on that dimension by rate (Results 3.2)

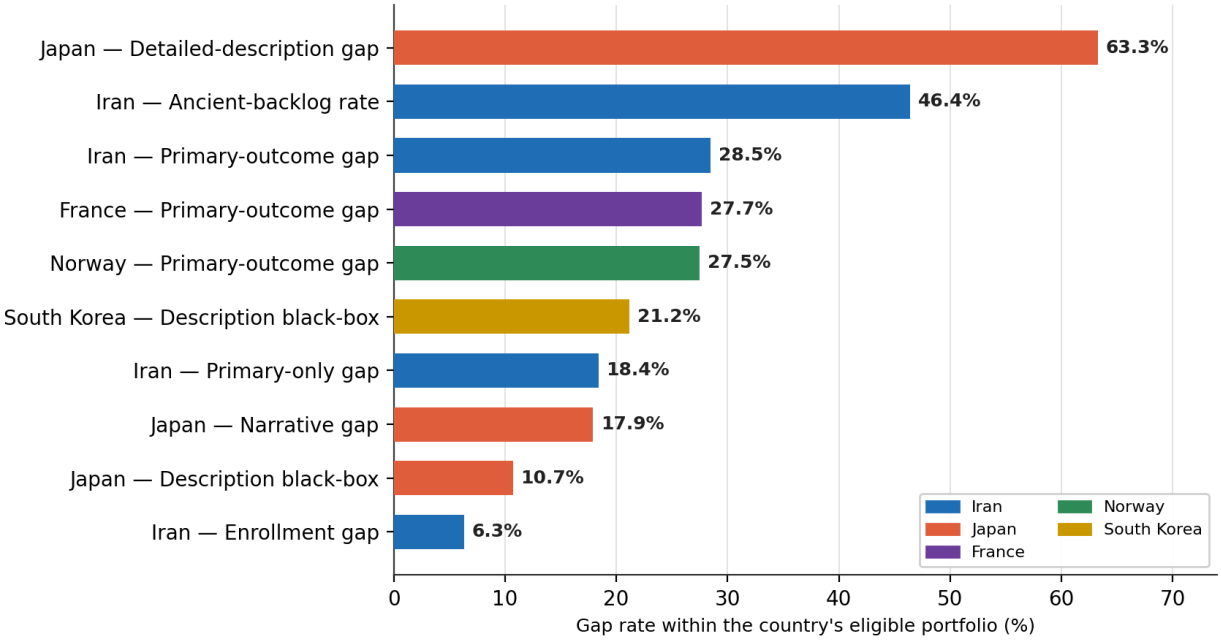


Figure 3. Rate-based leaders by gap dimension. Leading country rate per dimension: Japan detailed-description 63.3%; Iran ancient-backlog 46.4%; Iran primary-outcome 28.5%; France primary-outcome 27.7%; Norway primary-outcome 27.5%; South Korea black-box 21.2%; Iran primary-only 18.4%; Japan narrative 17.9%; Japan black-box 10.7%; Iran enrollment 6.3%.

3.3 Overdue debt: chronic silence has a temporal dimension

Ancient backlog identifies studies that have been silent for at least ten years past the two-year mark. Overdue debt converts this threshold into a continuous measure: every year a study remains non-disclosing past its deadline contributes one unit of debt. These two perspectives identify different aspects of chronic non-disclosure.

Germany ranked highest on mean unresolved age at 9.4 years — the heaviest per-study debt burden of any large-country portfolio — suggesting that German-linked studies that do not disclose tend to stay non-disclosing for longer than other high-stock countries. France and Germany ranked third and fourth on total debt stock (89,004 and 77,270 unresolved years respectively) despite the United States and Canada ranking first and second by large margins (491,364 and 90,480 years). The temporal framing is important for

policy: the majority of this debt predates the 2016 strengthening of CT.gov reporting rules, and much of it represents chronic silence that has persisted through multiple regulatory iterations.

Iran's ancient-backlog rate of 46.4% — meaning nearly half of its eligible ancient study portfolio has remained silent for more than ten years past deadline — is the single most extreme large-country rate in this dimension. It substantially exceeds Norway (which also ranked sharply), India, and Finland, all of which appeared in the top tier on ancient-backlog rate tables.

3.4 The country-condition interaction: geography and disease are non-additive

A crucial methodological finding emerged from the country-condition cross-cut. When the eligible pool was split simultaneously by named study location and condition family, no-results rates differed not only between countries within the same disease area, but between disease areas within the same country — and these differences were not additive (Figure 4).

Within oncology, studies involving China reached 79.0% no results versus 52.6% for studies involving the United States — a 26.4-percentage-point gap within the same therapeutic area. Within cardiovascular medicine, studies involving Egypt reached 95.9% no results, while studies involving the United States reached lower rates consistent with other cardiovascular figures in prior analyses. Within metabolic disease, studies involving China reached 78.9% no results, and studies involving Denmark reached 79.6%.

These figures carry a direct implication for systematic reviewers: a cardiovascular meta-analysis that draws on Egyptian-linked trials faces a very different evidence-transparency landscape than one drawing exclusively on U.S.-linked trials, and these differences cannot be predicted from country-level no-results rates alone because disease-area rates vary within each country. Evidence quality is stratified by the country-condition cell, not by country or condition separately.

Table 4. No-results rate (%) by country × condition-family cell.

Condition family	United States	China	Egypt	Denmark
Oncology	52.6	79.0	—	—
Cardiovascular	—	—	95.9	—
Metabolic	—	78.9	—	79.6

— = not reported in source (cell below the 400-study threshold or not ranked).

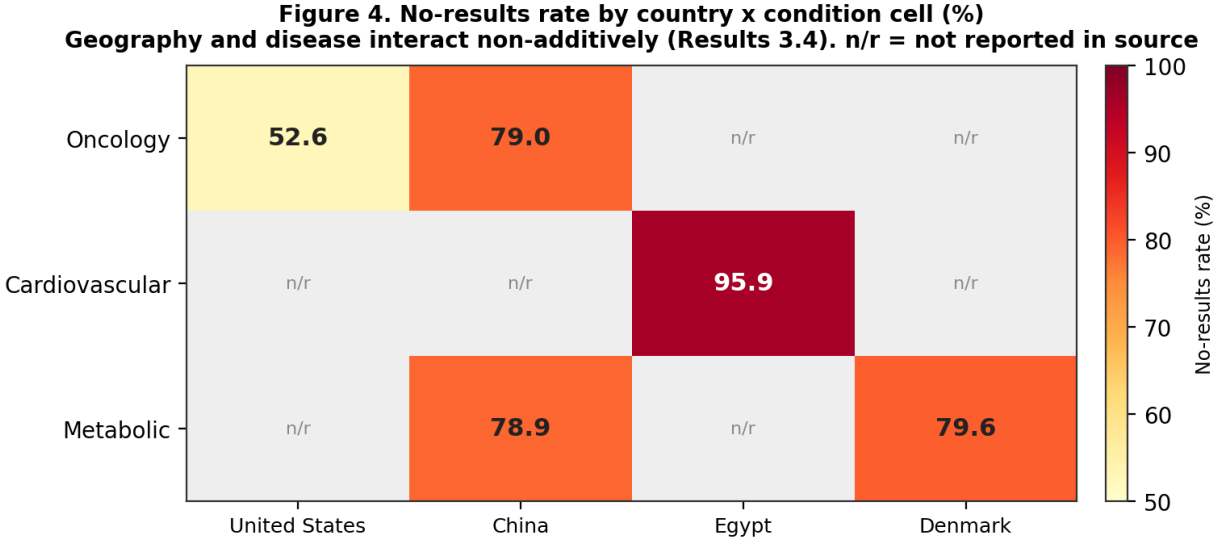


Figure 4. No-results rate by country x condition cell. Oncology: United States 52.6%, China 79.0%. Cardiovascular: Egypt 95.9%. Metabolic: China 78.9%, Denmark 79.6%. Blank cells were not reported in the source (n/r).

3.5 Composite watchlists: the most persistently opaque country portfolios

Two analyses applied adjustment methods before ranking, attempting to hold visible study mix more constant. The excess watchlist summed adjusted no-results excess (no-results stock minus the count expected given the portfolio's visible study composition), adjusted ghost excess, black-box stock, and strict-core spillover. The ghost watchlist ranked country portfolios on their excess ghost protocols above expectation.

The composite rankings produced a coherent and cross-nationally diverse shortlist. France ranked first on both adjusted excess no-results (2,187 studies) and ghost excess (1,157 studies). China ranked second on both dimensions (1,299 adjusted excess; 1,007 ghost excess). Egypt ranked third and fourth (824 adjusted excess; 955 ghost excess). South Korea ranked fourth on ghost excess (871 studies) and first on black-box intensity (21.2% rate), while France still carried 3,093 absolute black-box studies (Figure 5).

The composite geography is not reducible to any simple West/East or high-income/middle-income pattern. France — a major Western academic and pharmaceutical registrant with high overall regulatory standards — appears alongside China, Egypt, and South Korea in the top tier of adjusted opacity. This mixing suggests that the transparency gap is not determined by development level, and that Western registry incumbents carry substantial non-disclosed stock that survives adjustment.

Figure 7. Composite watchlist — cross-nationally diverse opacity after adjustment
South Korea also leads black-box intensity (21.2%); France carries 3,093 absolute black-box studies (Results 3.5)

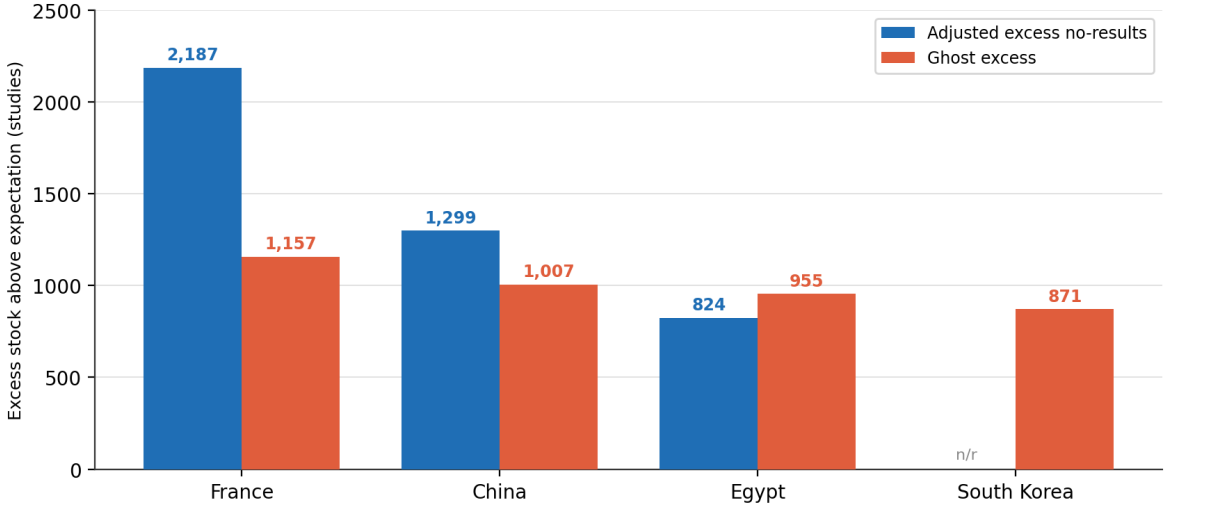


Figure 5. Composite watchlist — adjusted excess versus ghost excess. Adjusted excess no-results: France 2,187; China 1,299; Egypt 824. Ghost excess: France 1,157; China 1,007; Egypt 955; South Korea 871. South Korea leads black-box intensity (21.2%); France holds 3,093 absolute black-box studies.

3.6 Text asymmetry: where the narrative disappears before the endpoint

The text-asymmetry analysis asked which country portfolios show the largest imbalance between missing narrative paragraphs and missing endpoint sentences. Because detailed descriptions and primary outcome descriptions are separately tracked, their gap rates can diverge: some portfolios omit the broad study narrative while retaining the endpoint definition, while others show the opposite pattern.

The United States led stock-based text asymmetry (9,667 net description-only gaps versus primary-only gaps), followed by Germany (3,909), Spain (3,571), and France (3,442). But the rate-based table inverted this: Slovakia had the highest net asymmetry rate (40.9 percentage points), ahead of Romania (39.3 points) and Poland (36.6 points) (Figure 6). The Eastern European dominance on rate-based text asymmetry is consistent with registration practices where structured endpoint fields are treated as mandatory but background narrative is systematically deprioritised.

Figure 6. Text asymmetry — stock (U.S.-led) versus rate (Eastern-Europe-led) (Results 3.6)

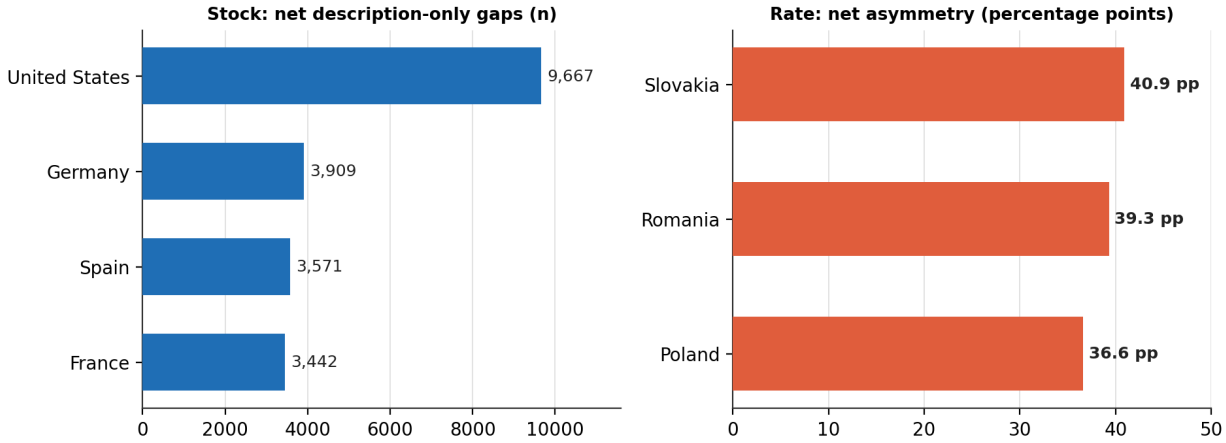


Figure 6. Text asymmetry — stock versus rate. Stock (net description-only gaps): United States 9,667; Germany 3,909; Spain 3,571; France 3,442. Rate (net asymmetry, pp): Slovakia 40.9; Romania 39.3; Poland 36.6.

3.7 Sponsor concentration within country footprints

Country-linked sponsor-repeater analyses showed that the national backlog is not uniformly distributed across institutions: in every national portfolio examined, a small number of repeat-offender sponsors concentrated the bulk of missing-results stock (Figure 7).

Within U.S.-linked studies, Mayo Clinic carried the largest missing-results stock at 927 studies. Within Egypt-linked studies, Cairo University led at 968 studies — a figure that, within a smaller national portfolio, represents a proportionally heavier institutional burden. Within China-linked studies, Sun Yat-sen University led at 235 studies.

Poland was comparatively clean at the institution level: Sanofi showed a 47.5% no-results rate within Polish-linked studies but Hoffmann-La Roche had only 59 missing-results studies in the same footprint — small enough that the portfolio's opacity is primarily concentrated in a very few institutions. Australia- and Japan-linked portfolios sat below China or Egypt on both rate and sponsor-stock concentration.

The sponsor-repeater finding across countries implies that targeted enforcement — reaching the specific institutions responsible for the most missing-results stock within each national portfolio — would be more efficient than national-level pressure on all registrants. Cairo University's 968 missing-results studies within the Egyptian-linked portfolio, for example, represents a well-defined institutional target that is more tractable than the full 249,507-study registry.

Figure 8. Lead repeat-offender sponsor within each national portfolio
A few institutions concentrate the bulk of missing-results stock (Results 3.7)

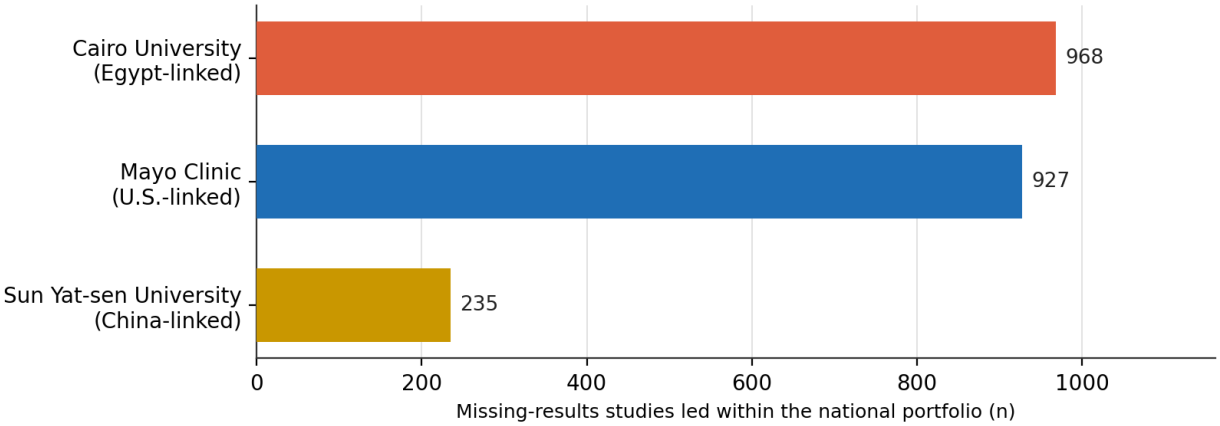


Figure 7. Lead repeat-offender sponsor within each national portfolio. Missing-results studies led within the national portfolio: Cairo University 968 (Egypt-linked); Mayo Clinic 927 (U.S.-linked); Sun Yat-sen University 235 (China-linked).

3.8 The U.S.-versus-ex-U.S. divide: the regulatory story

The single most policy-relevant finding in this cluster came from collapsing the country dimension to a binary jurisdictional marker: U.S.-linked versus non-U.S.-linked studies (Figure 8).

Studies involving at least one U.S. site showed a 52.1% no-results rate. Studies with no U.S. site involvement showed 88.7% — a 36.7-percentage-point gap. Studies with no named country location showed 80.9%. These three figures create a clear hierarchy: U.S. presence is the strongest single predictor of results disclosure in the older registry, and its effect exceeds that of sponsor type, disease area, or any individual country-level characteristic.

The sponsor-class breakdown within the no-U.S. tier was equally sharp. OTHER-category sponsors in no-U.S. studies reached 94.9% no results. Industry sponsors in no-U.S. studies reached 70.9%. The same sponsor classes with U.S. presence looked radically different: any-U.S. industry fell to 45.5% no results, and any-U.S. NIH fell to 52.3%. U.S. regulatory exposure appears to discipline both academic and industry sponsors, and the effect is large enough to be the dominant source of cross-national variation in this analysis.

Table 5. U.S.-versus-ex-U.S. no-results rate, overall and by sponsor class.

Stratum	No-results rate
Any-U.S. (all sponsors)	52.1%
No-country (all sponsors)	80.9%
No-U.S. (all sponsors)	88.7%
Any-U.S., industry	45.5%
Any-U.S., NIH	52.3%
No-U.S., industry	70.9%
No-U.S., OTHER	94.9%

Figure 5. The U.S.-versus-ex-U.S. jurisdictional divide (Results 3.8)

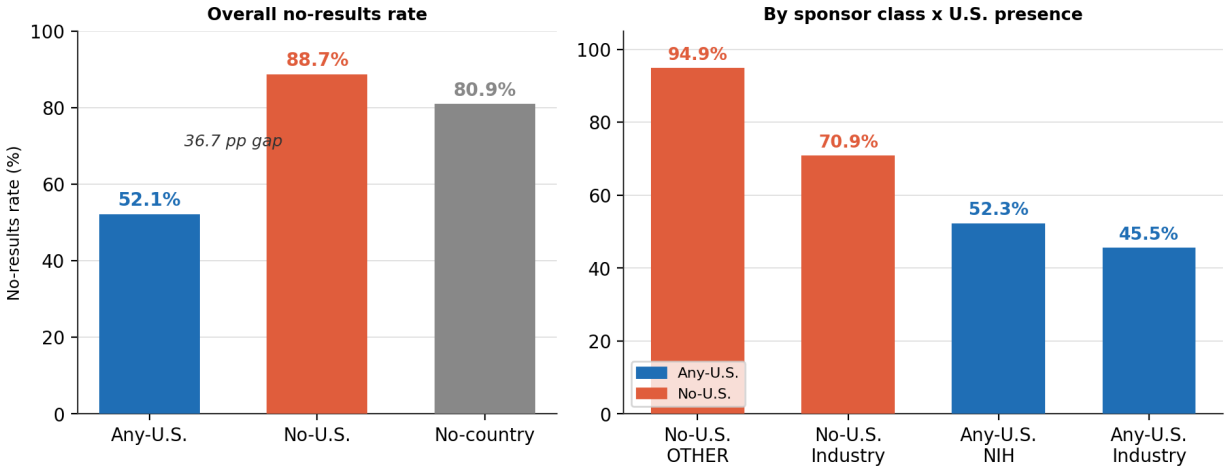


Figure 8. The U.S.-versus-ex-U.S. jurisdictional divide. Overall no-results: any-U.S. 52.1%, no-country 80.9%, no-U.S. 88.7% (36.7 pp gap). By sponsor class: no-U.S. OTHER 94.9%, no-U.S. industry 70.9%, any-U.S. NIH 52.3%, any-U.S. industry 45.5%.

This finding has a direct methodological implication: country-level rates that do not first stratify by U.S. presence are confounded by the regulatory-exposure covariate. A national no-results rate for a country like Japan or France reflects a mixture of U.S.-linked and non-U.S.-linked studies, and the mixture differs by

country. Ex-U.S.-only rates — stripping out studies that also named a U.S. site — would show higher rates in every country, including those that appear clean in cross-national comparisons.

Discussion

Transparency failure has a multidimensional geography. The country that leads a stock table rarely leads the rate table, and leadership on one dimension rarely transfers to another. The United States is both the largest stock contributor and the jurisdiction whose framework most reliably secures disclosure [4, 11]. The country-condition interaction establishes that geographic diversity stratifies rather than standardises evidence quality. For example, the 36.7-percentage-point U.S.-versus-ex-U.S. gap, sustained across sponsor classes, implicates the regulatory framework rather than geography per se [5, 12]. A transparency audit therefore requires multidimensional measurement; no single rate, ranking, or stock table is adequate for this purpose.

Conclusion

Fourteen pre-specified analyses of 249,507 eligible older closed interventional studies establish that transparency gaps in ClinicalTrials.gov are geographically structured but dimensionally heterogeneous: the country that leads the stock table for one gap type rarely leads the rate table for the same type, and the country that leads on one gap dimension rarely leads on another. The United States dominates stock tables by scale while showing below-average rates on most dimensions; Iran, Japan, France, South Korea, Egypt, Norway, Slovakia, and Romania lead rate tables, each on different dimensions. The most consistent geographic signal in the series is the U.S.-versus-ex-U.S. jurisdictional divide, which exceeds all other cross-national variation and implicates regulatory framework rather than geography per se as the dominant predictor of results disclosure. These findings suggest that transparency audit of the global clinical trial registry requires multidimensional measurement — no single rate, country ranking, or stock table is adequate.

Limitations

Country links reflect recorded study locations, not legal domicile, sponsor nationality, or regulatory exposure. Multinational trials are non-additive across portfolios, and sponsor domicile — the FDAAA-relevant category — is approximated by U.S. presence. The 249,507-study pool also excludes observational and device-only studies as well as recent studies, and reflects only a single March 29, 2026 snapshot.

References

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