

ORIGINAL RESEARCH

Geographic Distribution and Scope of US FDA Good Clinical Practice (GCP) Inspections for Marketing Applications: A Six-Year Update (FY2019–2024)

Courtney S. McGuire, Jenn W. Sellers, Kassa Ayalew and Laurie B. Muldowney

Background: The US FDA conducts Good Clinical Practice (GCP) inspections to help ensure clinical trial data integrity and participant safety. This study characterizes the geographic distribution and scope of GCP inspections from fiscal years (FY) 2019–2024 and inspection outcomes by region.

Methods: We extracted data from FDA internal databases and analyzed GCP inspections supporting marketing applications from FY2019–2024. We characterized application characteristics, inspection distribution by location, establishment type, and therapeutic area, and summarized inspection outcomes and deficiency areas by region. We integrated previously published data and compared annualized inspection rates across FY2016–2024.

Results: From FY2019–2024, sponsor and contract research organization inspections increased from 9% to 19.2%. US inspections peaked at 89.2% in FY2020 before declining to 59.3% by FY2024. In aggregate, non-US inspections had a slightly higher No Action Indicated (NAI) percentage than US inspections (86.2% vs. 82.7%), though the percentage of Voluntary Action Indicated (VAI) varied across specific non-US regions (9.0%–20.7%). Protocol deviations and inadequate recordkeeping were the most common deficiencies in both US and non-US inspections. Oncology was the predominant therapeutic area, accounting for 26.9% of US inspections, and 70.7% in Asia. Comparing pre- to post-pandemic periods, inspection rates increased by 52.8% in Asia but decreased by 8.1% in Eastern Europe, with marked heterogeneity at the country level.

Conclusion: Post-pandemic recovery of FDA GCP inspections has been highly heterogeneous, shaped by the complex interplay of risk-based site selection, therapeutic area priorities, geopolitical events, and sponsor trial location decisions, underscoring the need for adaptive inspection strategies in an increasingly globalized clinical trial environment.

Keywords: US FDA; Good clinical practice; inspection; clinical investigator; sponsor; contract research organization

Introduction

The US Food and Drug Administration's (FDA) Bioresearch Monitoring (BIMO) program ensures the integrity of clinical trial data and the protection of human subjects in trials supporting applications for US marketing approval.^{1,2} Within this program, Good Clinical Practice (GCP) inspections of clinical investigators, sponsors, and contract research organizations (CROs) verify data reliability and compliance with federal regulations.³ The findings from these inspections and the subsequent GCP assessments directly inform the agency's regulatory decisions. Understanding the trends in how this oversight is deployed, including where inspections are conducted, which therapeutic areas are prioritized, and how the

program adapts to global events, is therefore essential for all stakeholders, including sponsors, regulators, and the public.

The FDA selects clinical investigators for inspection using a risk-based approach, considering factors such as enrollment volume, data criticality to regulatory decision-making, and prior compliance history. Similar risk-based approaches guide the selection of sponsors and CROs for inspection. Inspections reflect both the FDA's risk-based priorities and the geographic distribution and characteristics of clinical investigators chosen by sponsors during trial design and implementation.

Previous comprehensive analyses of FDA GCP inspections have provided valuable insights into inspection scope and geographic distribution through fiscal year (FY) 2018.⁴ This work examined operational details at the clinical trial site level, establishing key metrics such as inspection coverage, duration, and the geographic distribution of clinical trials and inspections.⁴ However, the impact of the COVID-19 public health emergency and major subsequent

Office of Scientific Investigations (OSI), Office of Compliance (OC), Center for Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA), US

Corresponding author: Courtney S. McGuire
(courtney.mcguire@fda.hhs.gov)

geopolitical events has raised critical questions about trends in the volume and location of global inspections. While high-level shifts in inspection volume have been reported by McGuire et al, a detailed, granular analysis of the post-pandemic recovery and its geographic and clinical research areas remains lacking.⁵

This study addresses this gap by analyzing FDA GCP inspection patterns from FY2019 to 2024, spanning pre-pandemic, pandemic, and post-pandemic periods. Using the FY2016–2018 baseline established by Ayalew et al.,⁴ we focused on two specific aims: (1) to quantify geographic shifts in inspection distribution from pre-pandemic to post-pandemic periods, and (2) to characterize the evolving landscape of global clinical research across regions and countries. We also describe inspection outcomes across regions and deficiency area distributions between US and non-US inspections.

Methods

This retrospective descriptive study analyzed FDA GCP inspections conducted for marketing applications in the Center for Drug Evaluation and Research (CDER) from FY2019 to 2024. We extracted data from FDA internal databases: Document Archiving, Reporting & Regulatory Tracking System (DARRTS), Compliance Program Information System (COMPLIS), and Enterprise Content Management System (ECMS).

The marketing applications included New Drug Applications (NDAs), Biologics License Applications (BLAs), and Emergency Use Authorizations (EUA). During the study period, EUAs were primarily submitted under associated Investigational New Drug Applications (INDs) in response to the COVID-19 public health emergency.¹

We identified GCP inspection requests dated between FY2019–2024 through data queries in COMPLIS. The analysis included all requests with at least one completed GCP inspection for marketing applications. We excluded GCP inspection requests if all FDA-conducted GCP inspections were canceled, identified as duplicates or for-cause inspections, or involved Bioavailability (BA) and Bioequivalence (BE) studies.

Geographic and therapeutic area distributions were compared across three periods: pre-pandemic (October 1, 2015–January 29, 2020), during pandemic (January 30, 2020–May 10, 2023), and post-pandemic (May 11, 2023–September 30, 2024).^{6,7}

Descriptive statistics were generated using JMP 17 and Microsoft Excel. The following variables were extracted for analysis:

- **Application-level data:** application type (NDA, BLA, or EUA), submission type (original or supplement), review designation (priority or standard), indication and therapeutic area.
- **Inspection-level data:** establishment type (clinical investigators, sponsors, or CROs), geographic location (US or non-US), duration of assessment, final inspection classification (NAI [No Action Indicated], VAI [Voluntary Action Indicated], or OAI [Official Action Indicated]), and deficiency area (adherence to trial protocol, adequacy of records, monitoring/trial over-

sight, reporting safety information, informed consent, drug accountability, or Institutional Review Board (IRB) approval).

For regional analyses, all non-US countries were grouped into seven geographic regions: Western Europe (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, Switzerland, and United Kingdom), Eastern Europe (Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Georgia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Serbia, Slovakia, and Ukraine), Asia (China, India, Japan, Philippines, South Korea, Taiwan, Thailand, and Vietnam), North America (excluding US; Canada, Mexico, and Panama), South America (Argentina, Brazil, Chile, and Peru), Middle East (Israel and Turkey), Africa (South Africa), and Pacific (Australia and New Zealand). The percentage of NAI, VAI, and OAI were calculated as the number of inspections with the respective classification out of the total inspections for the region.

Country-level analyses included countries with ≥ 20 total inspections within the analysis timeframes to ensure adequate sample sizes for meaningful trend analysis.

To assess the impact of the COVID-19 public health emergency, we integrated data from a prior analysis covering FY2016–2018 to enable evaluation across the three pandemic time periods.⁴ Annualized inspection rates (i.e., the total number of inspections in each time period divided by the number of months in that period, multiplied by 12) were calculated to compare inspection trends across these distinct periods. The rate difference and percentage change between the pre- and post-pandemic periods were calculated as follows:

$$\text{Inspection rate difference} = \text{post-pandemic annualized rate} - \text{pre-pandemic annualized rate}$$

$$\text{Percentage change} = \frac{\text{inspection rate difference}}{\text{pre-pandemic rate}} \times 100\%$$

Results

1. Summary of Data Collected for Analyses

Database queries identified 770 NDA/BLAs from FY2019 to 2024, for which the FDA review division requested GCP inspections (referred to as GCP inspection requests). From this initial group, 57 GCP inspection requests were excluded from the analysis because their requested inspections were canceled, duplicates, for-cause inspections, follow-up Official Action Indicated (OAI) inspections, or Remote Regulatory Assessments (RRAs). The final cohort of 713 GCP inspection requests resulted in 2,206 completed inspections.

2. Characteristics of Study Cohort (FY2019–2024)

The 713 GCP inspection requests primarily supported NDAs ($n = 466$, 65.4%), with most being for original submissions ($n = 475$, 66.6%) rather than supplements. Priority review designations ($n = 381$, 53.4%) slightly outnumbered standard review designations ($n = 332$, 46.6%).

Table 1: GCP Inspection Requests by Location of Inspected Establishments*, by Year (N = 713).

Year	Inspection Requests (N)	Inspected Establishment Location(s)		
		US Only n (%)	Non-US Only n (%)	Both US and non-US n (%)
All	713	403 (56.5%)	100 (14.0%)	210 (29.5%)
2019	133	58 (43.6%)	20 (15.0%)	55 (41.4%)
2020	106	87 (82.1%)	5 (4.7%)	14 (13.2%)
2021	114	90 (78.9%)	7 (6.1%)	17 (14.9%)
2022	118	65 (55.1%)	19 (16.1%)	34 (28.8%)
2023	129	59 (45.7%)	20 (15.5%)	50 (38.8%)
2024	113	44 (38.9%)	29 (25.7%)	40 (35.4%)

Note: Percentages are calculated as n/N, where N is the total number of GCP requests in the row.
*Only includes establishments that were selected and assessed.

Most inspection requests (613, 86.0%) involved inspection of at least one US establishment, and 310 (43.5%) involved inspection of at least one non-US establishment. Requests involved a mean of 1.6 countries (range: 1 to 6). Nearly all requests (680, 95.4%) included at least one clinical investigator inspection; 212 (29.7%) and 104 (14.6%) requests included sponsor and CRO inspections, respectively.

Geographic scope and inspected establishment type varied by application type. BLAs more frequently included non-US inspections compared to NDAs (54.7% vs. 37.6%). Sponsor inspections were also more common in BLAs than NDAs (38.8% vs. 25.5%), as were CRO inspections (21.5% vs. 11.2%).

3. Inspection Requests by Location and Year

The geographic scope of inspection requests changed substantially during the study period (**Table 1**). The data show a sharp but temporary shift toward US-only requests, which peaked in FY2020 before declining steadily to below pre-2020 levels by FY2024. In contrast, non-US-only requests reached their lowest point in FY2020 before increasing substantially through FY2024.

4. Inspection Number and Type by Year

The 713 requests generated 2,206 completed GCP inspections over the study period, averaging 3.1 inspections per request (range: 1 to 10). Annual inspection numbers declined from 469 in FY2019 to 277 in FY2020 (41.0% decrease), then partially recovered to 354 by FY2024.

The distribution of inspection types shifted during the study period. Clinical investigator inspections remained the most common type but decreased from 91.0% of all inspections in FY2019 to 80.8% in FY2024. Conversely, the combined proportion of sponsor and CRO inspections increased from 9.0% in FY2019 to 19.2% in FY2024.

5. Overall Geographic Distribution of Inspections

During FY2019–2024, the FDA conducted 2,206 inspections, of which 1,588 (71.9%) were in the US and 618 (28.1%) were in non-US locations.

When examined within each establishment type, the majority of inspections were US-based: 90.2% of sponsor inspections, 85.0% of CRO inspections, and 69.1% of clinical investigator inspections were conducted in the US. The proportion of all inspections conducted in the United States varied by fiscal year, from 65.9% in FY2019, peaking at 89.2% in FY2020, and declining to 59.3% by FY2024.

The most frequent non-US regions were Western Europe (230, 37.2%), Eastern Europe (178, 28.8%), and Asia (92, 14.9%), which together comprised 80.9% (500) of non-US inspections.

6. Inspection Outcomes by Region

Non-US inspections had a slightly higher percentage of NAI compared to US inspections (533, 86.2% vs. 3,313, 82.7%), with a correspondingly lower percentage of VAI (82, 13.3% vs. 271, 17.1%). OAI classifications were rare in both groups. Among regions with ≥50 inspections during FY2019–2024 (**Table 2**), the percentage of VAI classifications ranged from 9.0% in Eastern Europe (16/178) to 20.7% in North America (12/58).

Table 2: Inspection Outcome by Region (FY2019–2024).

Region	NAI (%)	VAI (%)	OAI (%)
United States (n = 1588)	82.7%	17.1%	0.3%
Non-US ^a (n = 618)	86.2%	13.3%	0.5%
Western Europe (n = 230)	86.1%	13.5%	0.4%
Eastern Europe (n = 178)	90.4%	9.0%	0.6%
Asia (n = 92)	80.4%	19.6%	—
North America ^b (n = 58)	77.6%	20.7%	1.7%

Note: A dash (—) indicates no inspections with that classification. Table includes only regions with ≥50 total inspections. Regions are defined in Methods.

Abbreviations: NAI, No Action Indicated; VAI, Voluntary Action Indicated; OAI, Official Action Indicated.

^aNon-US represents the aggregate of all non-US inspections, including regions with fewer than 50 inspections not shown separately.

^bNorth America excludes the United States.

Table 3: Deficiency Areas Among VAI and OAI Inspections by US and non-US Locations (FY2019–2024).

Deficiency Area	US n (%) N = 275	Non-US ^a n (%) N = 85	All n (%) N = 360
Adherence to trial protocol	187 (68.0%)	53 (62.4%)	240 (66.7%)
Adequacy of records	114 (41.5%)	36 (42.4%)	150 (41.7%)
Monitoring/trial oversight	32 (11.6%)	3 (3.5%)	35 (9.7%)
Reporting safety information	26 (9.5%)	6 (7.1%)	32 (8.9%)
Informed consent	22 (8.0%)	2 (2.4%)	24 (6.7%)
Drug accountability	15 (5.5%)	5 (5.9%)	20 (5.6%)
Institutional Review Board (IRB) approval	10 (3.6%)	1 (1.2%)	11 (3.1%)

Note: N, total number of inspections with VAI or OAI classification in each group; n, number of inspections with the cited deficiency area. Percentages calculated as n/N within each column. Each inspection may have findings in more than one deficiency area, so percentages do not sum to 100%. Table only presents deficiency areas with ≥1% of all inspections with deficiencies.

^aNon-US represents the aggregate of all non-US inspections.

Among the 360 inspections with VAI or OAI classifications, adherence to trial protocol and adequacy of records were the most commonly cited deficiency areas in both US and non-US inspections (66.7% and 41.7% of all deficient inspections, respectively), with comparable percentages between groups. Modest differences in the percentage of monitoring/trial oversight and informed consent deficiency areas were observed between US and non-US inspections (**Table 3**).

To further contextualize the geographic differences in deficiency area distributions, deficiency areas were also examined by establishment type. Monitoring/trial oversight was the only deficiency area predominantly identified in sponsor and CRO inspections (combined;

30/35, 85.7%). At least 88% of all other deficiency areas were identified in clinical investigator inspections, with informed consent and IRB approval exclusively so.

7. Therapeutic Area Distribution by Region

Therapeutic area distribution varied across regions (**Table 4**). In the US, the most common therapeutic areas were oncology (427, 26.9%), neurology (149, 9.4%), and endocrinology (138, 8.7%).

Oncology was also the most common therapeutic area in most non-US regions, but proportions varied: Western Europe (101, 43.9%), Middle East (4, 44.4%), Asia (65, 70.7%), and Pacific (8, 88.9%). Infectious diseases were the most common area in Eastern Europe (36, 20.2%) and Africa (5, 62.5%).

Table 4: Therapeutic Area Distribution by Region (FY2019–2024).

Region	Onc (%)	Endo (%)	Neuro (%)	ID (%)	Derm (%)	Psych (%)	GI (%)	Others (%)
United States (n = 1588)	26.9%	8.7%	9.4%	7.0%	6.6%	7.5%	5.7%	28.2%
Non-US ^a (n = 618)	36.3%	11.3%	7.9%	12.1%	6.8%	3.2%	4.8%	17.7%
Western Europe (n = 230)	43.9%	7.8%	7.4%	8.3%	5.2%	3.0%	2.6%	21.7%
Eastern Europe (n = 178)	11.8%	11.8%	9.6%	20.2%	10.7%	4.5%	8.4%	23.0%
Asia (n = 92)	70.7%	10.9%	5.4%	5.4%	—	—	1.1%	6.5%
North America ^b (n = 58)	27.6%	17.2%	10.3%	5.2%	17.2%	3.4%	5.2%	13.8%
South America (n = 34)	17.6%	26.5%	5.9%	14.7%	—	8.8%	11.8%	14.7%
Middle East (n = 9)	44.4%	11.1%	11.1%	22.2%	—	—	11.1%	—
Pacific (n = 9)	88.9%	—	—	—	11.1%	—	—	—
Africa (n = 8)	12.5%	12.5%	12.5%	62.5%	—	—	—	—

Note: Table displays the seven most common therapeutic areas overall; “Others” represents all remaining therapeutic areas combined. A dash (—) indicates no inspections were recorded in this category. Regions are defined in Methods.

Abbreviations: Derm, Dermatology; Endo, Endocrinology; GI, Gastroenterology; ID, Infectious Diseases; Neuro, Neurology; Onc, Oncology; Psych, Psychiatry.

^aNon-US includes all individual non-US regions.

^bNorth America excludes the United States.

Table 5: Therapeutic Area Distribution by Country (FY2019–2024).

Country	Onc (%)	Endo (%)	Neuro (%)	ID (%)	Derm (%)	Psych (%)	GI (%)	Others (%)
United States (n = 1588)	26.9%	8.7%	9.4%	7.0%	6.6%	7.5%	5.7%	28.2%
Bulgaria (n = 22)	–	18.2%	9.1%	50.0%	4.5%	9.1%	4.5%	4.5%
South Korea (n = 25)	72.0%	8.0%	4.0%	4.0%	–	–	–	12.0%
United Kingdom (n = 25)	32.0%	8.0%	16.0%	16.0%	–	4.0%	–	24.0%
Italy (n = 31)	64.5%	3.2%	9.7%	6.5%	–	–	–	16.1%
China (n = 32)	100.0%	–	–	–	–	–	–	–
Germany (n = 40)	22.5%	12.5%	–	7.5%	12.5%	10.0%	–	35.0%
France (n = 41)	61.0%	7.3%	9.8%	2.4%	4.9%	–	2.4%	12.2%
Spain (n = 41)	51.2%	7.3%	7.3%	7.3%	2.4%	4.9%	2.4%	17.1%
Canada (n = 44)	27.3%	13.6%	13.6%	–	20.5%	2.3%	6.8%	15.9%
Poland (n = 80)	8.8%	7.5%	7.5%	5.0%	20.0%	2.5%	16.2%	32.5%

Note: Table displays the seven most common therapeutic areas overall; “Others” represents all remaining therapeutic areas combined. A dash (–) indicates no inspections were recorded in this category. Table includes countries with ≥20 total inspections during FY2019–2024.

Abbreviations: Derm, Dermatology; Endo, Endocrinology; GI, Gastroenterology; ID, Infectious Diseases; Neuro, Neurology; Onc, Oncology; Psych, Psychiatry.

8. Therapeutic Area Distribution by Country

Country-level therapeutic area distributions are shown in **Table 5**. Among the 10 non-US countries with ≥20 inspections during FY2019–2024, oncology proportions ranged from 0% (Bulgaria) to 100% (China). All inspections in China (32/32) and 72.0% in South Korea (18/25) were for oncology products.

Within Western Europe, oncology proportions varied: Italy (20/31, 64.5%), France (25/41, 61.0%), and Germany (9/40, 22.5%). In Eastern Europe, Bulgaria showed the highest proportion of infectious diseases inspections (11/22, 50.0%), while Poland showed inspections distributed across multiple therapeutic areas.

9. Annualized Inspection Rates Pre-, During and Post-Pandemic Period in non-US Regions (FY2016–2024)

Annualized inspection rates changed heterogeneously across non-US regions from pre-pandemic to post-pandemic periods. This analysis combines current data (FY2019–2024) with the published pre-pandemic baseline data (FY2016–2018) from Ayalew’s study.⁴ Overall, non-US inspection rates increased by 8.3% (from 141.5 to 153.3 inspections/year).

Three regions showed increases: Asia (+52.8%, from 18.9 to 28.9 inspections/year), North America excluding the US (+37.0%, from 11.1 to 15.2 inspections/year), and Western Europe (+25.3%, from 46.2 to 57.8 inspections/year).

The remaining regions experienced varying degrees of decline with the Middle East showing the most pronounced reduction (–100.0%, from 2.8 to 0 inspections/year).

10. Annualized Inspection Rates Pre- to Post-Pandemic Period by non-US Country (FY2016–2024)

Annualized inspection rates for non-US countries with at least 20 total inspections during FY2016–2024 (n = 18

countries) are shown in **Table 6**. The rate trends for these countries varied across the pre-pandemic, during, and post-pandemic periods. Notably, China and the United Kingdom were the only two countries to show an increase in inspection rates during the pandemic period.

Net changes from pre- to post-pandemic period were highly divergent for individual countries. The largest increases in annualized number of inspections per year occurred in Poland (+9.4), South Korea (+7.9), and Spain (+6.1). In contrast, the largest decreases occurred in Ukraine (–4.6), Hungary (–3.7), and Romania (–3.6).

The divergence was even more pronounced when considering the relative (percentage) change. The largest increases occurred in Bulgaria (+220.0%), South Korea (+213.5%), China (+125.0%), Spain (+98.4%), and Poland (+59.1%), while the largest relative decreases occurred in Ukraine (–100.0%), Hungary (–84.1%), and Romania (–62.1%).

Discussion

This analysis of 713 FDA GCP inspection requests from FY2019–2024 characterized geographic and therapeutic area patterns spanning pre-, during, and post-pandemic periods. Building upon the established pre-pandemic baseline, which characterized inspection scope and geographic distribution from FY2016 through FY2018, our findings indicate the recovery of GCP inspections after the pandemic was not uniform and appeared to be influenced by regulatory site selection for inspections, therapeutic area priorities, geopolitical events, and sponsor trial location decisions.⁴ We did not re-examine operational metrics such as inspection duration and inspection coverage (including number of trial participants and volume of source documents reviewed), which were hypothesized to remain stable due to the consistent BIMO program framework.^{1,2}

Table 6: Annualized Inspection Rates Pre- to Post-Pandemic Period for the Top 18 Non-US Countries (FY2016–2024).

Country	Annualized Inspection Rate (inspections/year)			Pre- to Post-pandemic Rate Change	
	Pre-pandemic	Pandemic	Post-pandemic	Rate Difference (inspections/year)	Percentage Change (%)
Bulgaria	2.5	1.9	8.0	+5.5	220.0%
South Korea	3.7	1.6	11.6	+7.9	213.5%
China	3.2	6.3*	7.2	+4.0	125.0%
Spain	6.2	3.4	12.3	+6.1	98.4%
Poland	15.9	8.1	25.3	+9.4	59.1%
United Kingdom	2.3	3.8*	3.6	+1.3	56.5%
India	3.5	0.3	5.1	+1.6	45.7%
Denmark	2.8	0.9	3.6	+0.8	28.6%
Canada	9.5	5.9	11.6	+2.1	22.1%
Italy	6.9	4.4	8.0	+1.1	15.9%
France	10.4	4.1	10.8	+0.4	3.8%
Netherlands	3.5	1.3	3.6	+0.1	2.9%
Germany	7.8	5.9	7.9	+0.1	1.3%
Brazil	3.5	1.3	2.2	−1.3	−37.1%
Czech Republic	3.5	1.3	2.2	−1.3	−37.1%
Romania	5.8	0.9	2.2	−3.6	−62.1%
Hungary	4.4	0.3	0.7	−3.7	−84.1%
Ukraine	4.6	0.9	0.0	−4.6	−100.0%

*Denotes countries that exhibited an increase in annualized inspection rate from the pre-pandemic to the pandemic period.

Note: The table displays the mean annualized inspection rate (inspections/year) for each of the three defined periods. The final two columns present the rate difference and the relative percentage change between the pre-pandemic and post-pandemic periods. Countries are sorted in descending order based on percentage change. The table includes countries with ≥20 total inspections during FY2016–2024.

Defined Periods: Pre-pandemic period is defined as Oct 2015–Jan 2020; pandemic period is defined as Jan 2020–May 2023; post-pandemic period is defined as May 2023–Sep 2024.

The increase in US-based inspections to nearly 90% in FY2020 is consistent with international travel restrictions during the COVID-19 public health emergency and aligns with high-level trends reported by McGuire et al.^{5,8} During this period, the FDA employed alternative assessment tools, such as RRAs, to maintain regulatory oversight when on-site inspections were not feasible.⁹ The subsequent decline in US proportion indicates resumption of international inspections, though the distribution across regions was heterogeneous.

Asia demonstrated the largest relative increase in post-pandemic inspection rates, driven primarily by South Korea and China (Table 6). This growth was highly concentrated in oncology across the region. All inspections in China and most in South Korea involved oncology trials (Table 5). Notably, China showed an increase in its annualized inspection rate during the pandemic period itself, an exception to the broader pandemic-period slowdown (Table 6).

These patterns coincide with several developments in the region. China's accession to the International Council for Harmonisation (ICH) in 2017 streamlined pathways for international clinical trials, and the region

has experienced growth in domestic biotechnology industries that conduct trials to support both Chinese and US marketing applications.^{10–13} The region also offers large patient populations and established clinical research infrastructure.¹⁴

Eastern Europe showed an overall decline in post-pandemic inspection rates, with marked heterogeneity across countries (Table 6). Ukraine, which accounted for 3.7% of all non-US inspections from FY2016–2018,⁴ had zero post-pandemic inspections. This cessation coincided with the February 2022 US State Department Level 4 (“Do Not Travel”) advisory and reports of clinical trial disruption.^{15–19} Several of the countries that border Ukraine also showed declines, including Hungary and Romania. Industry reports from this period describe sponsors relocating trials from the region due to perceived geopolitical risk, operational challenges including staff departures and supply chain disruptions, and travel advisories affecting site access.^{16,20,21}

While some industry data point to a decline in the region's share of clinical trials from 2019 to 2024, our data show a 59.1% increase in post-pandemic inspection rates in Poland through FY2024 (Table 6),

with inspections during FY2019–2024 distributed across multiple therapeutic areas.²² This growth is consistent with industry reports of Poland as an attractive research hub, noted for its operational stability, European Union (EU) membership, and established infrastructure.^{23–26} This increase may reflect the completion of previously initiated pivotal trials during the study period and the country's role in ensuring the continuity of research activities disrupted in Ukraine.^{16,27}

Bulgaria showed a 220% relative increase in inspection rates (from 2.5 to 8.0 inspections/year), though this represents a smaller absolute change given the low baseline (**Table 6**). Bulgaria also showed a distinct therapeutic area profile for FY2019–2024, with infectious diseases comprising the highest proportion among countries with ≥ 20 inspections (**Table 5**). These included trials for COVID-19, bacterial infections, and fungal infections conducted by multiple sponsors. Industry participants have identified Bulgaria as a key hub for clinical research, valued for its cost-effectiveness and harmonized regulatory environment within the EU.^{28,29}

The key therapeutic patterns observed in this study, including the global concentration in oncology and regional prominence of infectious diseases, are consistent with broad distributions reported previously.^{4,30} Our analysis provides new, regional granularity to these findings. While oncology was the leading category across most regions, its proportion varied substantially. In contrast, Eastern Europe and Africa presented distinct profiles, where infectious diseases were the leading categories (**Table 4**).

This geographic variation reflects several factors. For oncology, regional differences in cancer incidence, treatment patterns, and availability of treatment-naïve patients influence where sponsors conduct oncology trials. Regulatory requirements may contribute to geographic diversity in oncology development.³¹ Similarly, the concentration of infectious disease inspections in certain regions may reflect regional expertise or temporal clustering of trials for pathogens of global concern, such as COVID-19. More broadly, operational considerations such as enrollment timelines, costs, and infrastructure also influence sponsor trial location strategies.²² FDA risk-based site selection may prioritize high-enrollment sites and those generating critical or complex data.

Final inspection classifications, including cited deficiency areas, reflect the compliance status of the individual inspected establishment and should not be interpreted as an assessment of overall GCP compliance in a given region. The predominance of NAI classifications is consistent with previously published data, suggesting broadly comparable levels of GCP compliance across geographic regions.⁵ Similarly, where deficiencies were observed, rates of nonadherence to trial protocol and inadequacy of records were also consistent with previously published findings.⁵ OAI classifications were too infrequent for meaningful regional comparison. The higher percentage of monitoring/trial oversight deficiencies in US inspections may reflect the concentration of sponsor and CRO inspections domestically, given that

these deficiencies are predominantly associated with inspections of these establishments.

Several limitations should be noted. First, the analysis is limited to the FDA's review-based BIMO inspections for CDER marketing applications and excludes alternative tools like RRAs.⁹ Second, the number of inspections reflects where the FDA conducted oversight, not total trials conducted in each region; geographic trends therefore reflect both FDA site selection and sponsor trial location decisions, which cannot be distinguished with available data. A small number of inspections in South America, Africa, and the Middle East preclude meaningful interpretation of changes in these regions; similarly, small sample sizes in most non-US regions precluded a regional breakdown of deficiency areas. Finally, the observed differences in inspection classifications and deficiency areas should be interpreted with caution, as this descriptive analysis was not designed to evaluate the underlying factors contributing to these differences.

The observed geographic shifts have important implications for the FDA's global inspection strategies and resource allocation. The substantial regional variation in post-pandemic inspection patterns reflects the dynamic nature of the global clinical trial landscape and the need for flexible regulatory approaches.

Several avenues for future research could build upon these findings, including analysis of the broader geographic distribution of clinical trial sites supporting marketing applications, which would help distinguish trends in sponsor trial location decisions from the FDA's risk-based site selection for inspection. As the post-pandemic period (May 2023–September 2024) was relatively short, longitudinal analyses extending beyond this period would clarify whether observed patterns represent recovery of temporary disruptions or sustained shifts in global trial conduct. Understanding these evolving patterns is essential for maintaining robust oversight of global clinical trial activities.

Conclusions

This analysis of 713 FDA GCP inspection requests from FY2019–2024 demonstrated substantial shifts in geographic distribution and scope following the COVID-19 pandemic. Post-pandemic inspection rates increased in Asia and decreased in Eastern Europe, with marked heterogeneity at the country level. In aggregate, the inspection classifications and cited deficiency areas were broadly comparable between US and non-US inspections. The observed variation may reflect differences in site selection, site characteristics, or other factors not assessed in this study. Therapeutic area distribution varied substantially by region, with oncology predominating in Asia and infectious diseases in Eastern Europe.

These patterns reflect the complex interplay of the pandemic, geopolitical events, therapeutic area priorities, and sponsor trial location decisions. As the global clinical research landscape continues to evolve, the FDA's GCP inspection program should maintain adaptive strategies that can respond to shifting geographic and therapeutic priorities while ensuring robust oversight of an increasingly dynamic international trial environment.

Note

- ⁱ In 2020, the Secretary of Health and Human Services issued a determination of a public health emergency due to the COVID-19 pandemic, enabling the use of EUAs for unapproved medical products, which were typically submitted under an associated IND.

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Competing Interests

The authors declare no conflicts of interest. The views expressed in this article are the personal views of the authors. They may not be understood or quoted as being made on behalf of or reflecting the FDA's position with which each author is affiliated.

Author Contributions

JS, KA, and CM conceived the study design. CM was responsible for data collection, quality control, and data verification. CM also conducted the data analysis and generated all tables. CM, JS, and KA drafted the manuscript, and all authors provided critical revisions and intellectual content.

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