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FDA BIMO Inspection Trends, FY2015-FY2024: Data Atlas

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In this article

Executive Summary

FDA's public bioresearch monitoring (BIMO) metrics offer a fiscal year atlas of final classified inspections, but the series is not a single, unchanging denominator. The FDA index still lists **FY2024** as its newest annual deck as of September 2026 (www.fda.gov). Its Center supplied figures may differ from other FDA inspection datasets because their compilation rules differ (www.fda.gov). The annual tables cover clinical investigators, institutional review boards (IRBs), sponsors and contract research organizations (CROs), sponsor investigators, good laboratory practice (GLP) laboratories, bioequivalence, postmarketing adverse drug experience (PADE), and Risk Evaluation and Mitigation Strategies (REMS), with category boundaries and reporting layouts changing over time.

The visible annual total was **1,388 in FY2015**, **1,622 in FY2018**, **611 in FY2021**, and **1,076 in FY2024** (www.fda.gov) (www.fda.gov) (www.fda.gov) (www.fda.gov). These are counts of inspections with a Center final classification in the stated fiscal year, not an estimate of inspections likely for any given company. The sharp FY2020 and FY2021 changes must also be read alongside the decks' exclusion of remote regulatory assessments (RRAs) from inspection tables (www.fda.gov). Cross-year differences describe the published administrative series; they do not prove that underlying compliance improved or worsened. Clinical investigators remained the largest party class in the FY2024 table at **609 of 1,076**, while sponsor/CRO inspections were **99**, IRB inspections **86**, GLP inspections **44**, and bioequivalence inspections **137**.

A quality leader should use the atlas to choose an evidence drill, not to calculate a firm's chance of inspection. Investigator controls connect to source records and protocol conduct (www.ecfr.gov) (www.niams.nih.gov). Sponsor/CRO controls connect to written transfers, monitoring oversight, and service provider records (www.ecfr.gov) (database.ich.org) (database.ich.org). IRB review and records require a separate lane (www.hhs.gov) (www.hhs.gov), while GLP data and archives need their own controls (www.oecd.org) (www.oecd.org). Current electronic-system expectations extend the drill across connected repositories and their audit trails (uscode.house.gov) (www.ema.europa.eu) (www.gov.uk).

The main data quality finding is itself operationally useful: the FY2022 deck printed **766** final classifications, but a later deck displays **48** rather than **49** IRB inspections for that year (www.fda.gov) (www.fda.gov). The FY2022 GLP classification row also needed a later correction to reconcile with its **33** inspection total

(www.fda.gov) (www.fda.gov). Retain the original source, deck version, inspected party, Center, fiscal year basis, and denominator with every extracted cell. Calculate `classification count / matching classified inspection count` only after the parts sum to that exact denominator. An annual BIMO count should never be divided into the separate Form FDA 483 observation trend universe or mixed with RRA counts.

Introduction and Background

Bioresearch monitoring is the FDA program that examines regulated clinical and nonclinical research. FDA describes it as including site inspections, data audits, and remote regulatory assessments, conducted through distinct compliance programs for investigators, sponsors and CROs, IRBs, bioequivalence, and GLP laboratories (www.fda.gov). The public metrics page compiles annual decks from FDA Centers; the table below records the decade covered here. For an inspection readiness owner, the useful question is which **inspected party, record family, and year-specific signal** warrants the next control review.

The answer requires disciplined definitions. A clinical investigator inspection examines a different record chain from a sponsor/CRO inspection (database.ich.org). An IRB's review documentation is not interchangeable with a GLP laboratory's study and archive records (www.hhs.gov) (www.oecd.org). Drug investigator case histories have their own record obligation (www.ecfr.gov), sponsor transfer of duties to a CRO must be documented in writing (www.ecfr.gov), and IRB registration sits in a distinct human subjects oversight framework (www.hhs.gov). International guidance likewise treats sponsor oversight of service providers as a documented responsibility (database.ich.org) (www.canada.ca).

The metrics are an administrative record, not a sample survey of all trial activity. Health Canada's explanation that an inspection concentrates on a site and its activities at a point in time is a useful reminder of the unit of observation, but it is a separate jurisdiction and not a substitute for FDA definitions (www.canada.ca). The World Health Organization (WHO) places inspections within a larger clinical trial oversight system that also includes ethics review and study reporting (www.who.int) (www.who.int) (www.who.int). That wider frame helps interpret what the FDA totals cannot measure: the size of the trial population, exposure to particular technologies, or the prevalence of control defects at organizations not inspected.

IntuitionLabs' published work describes an information layer with source permissions, retrieval, citations, and evaluation, as well as data engineering services (intuitionlabs.ai) (intuitionlabs.ai). In this adjacent advisory context, the practical contribution is a reproducible evidence model: the decision maker can ask an electronic trial master file (eTMF), clinical operations, or quality team to regenerate the exact population and record lineage behind a reported number. CDISC's trial master file taxonomy can be applied to paper or electronic files, which makes the model about records and metadata rather than a software brand (www.cdisc.org).

Methodology and Source Inventory

Unit, source hierarchy, and fiscal year

The atlas treats the FDA annual BIMO metric deck for each fiscal year as the source of record for that deck's **final classified inspection** table. It records an inspection's stated fiscal year, FDA Center, inspected party, geography or mode when shown, classification, and the source slide. The fiscal year is the year of the Center final classification in the latest deck; it is not a visit-date series. The general inspection database has a different row structure and cannot silently fill gaps in this BIMO series.

The comparability warning in the executive summary governs every table. NAI means **no action indicated**; VAI means **voluntary action indicated**; OAI means **official action indicated**. These labels describe FDA's final classification of the inspection, whereas a Form FDA 483 observation file describes cited observations and themes. An observation is not a distinct inspection, and several observations may come from one inspection. Other regulators' published inspection series also have their own populations: EMA reported a **24%** rise in its GCP inspection count in 2024 versus 2023, which is not a cross-check on FDA's BIMO total (www.ema.europa.eu).

The extraction uses one row per **year, Center, inspected-party class, modality or geography when stated, metric type, and original label**. This preserves the metadata context emphasized by EMA (www.ema.europa.eu). Mandatory provenance fields are deck URL, slide or page, extraction date, denominator definition, and a comparability flag (www.cdisc.org). A blank is “not stated,” never zero. A calculated share is permitted only where the cited classification counts reconcile to the matching final classified inspection count. A separate jurisdiction's ratings also show why observation and classification labels should remain distinct (www.canada.ca). The formula is **rate = classification count / classified inspections in the same party, Center, and fiscal year**. A count from an RRA, an inspection conducted by operation date, or a Form FDA 483 trend subset is not a denominator substitute (www.canada.ca).

Data dictionary and version rules

- **Fiscal year:** FDA's fiscal year in the source deck, not the date of download.
- **Center:** FDA Center as printed. Preserve the Center field before aggregating; an all-Center total can hide different program mixes.
- **Party:** Preserve the FDA label. In early decks, sponsor/monitor/CRO totals include sponsor investigators, while later decks display sponsor investigators separately.
- **Classification:** NAI, VAI, or OAI, tied to a final classified inspection. A classification is not the count of Form FDA 483 observations (www.canada.ca).
- **Observation:** Original text or code from the observation trend file, plus its own inspected and issued denominator. Do not divide this count by the annual classification table total (www.ema.europa.eu).
- **Modality:** Keep on-site inspection and RRA as different event types and preserve the source file that defines each.
- **Comparability flag:** `core-plus-BEQ`, `expanded-party-table`, `final-classification`, `RRA-separate`, or `revised-cell`. The flag describes a data handling decision, not a judgment about an inspected organization.

The record design follows broader good clinical practice (GCP) data governance: ICH E6(R3) calls for identifiable and version controlled essential records (database.ich.org), EMA says metadata give a data point its context (www.ema.europa.eu), and CDISC offers vendor neutral exchange and archiving formats for clinical data and metadata (www.cdisc.org). These sources guide the schema; only FDA decks supply the FDA inspection counts. A reproducible export would contain raw reported cells and derived values in separate columns, with the calculation and source slide stored beside each derived value.

Ten-Year Inspection Atlas

Table 1 transcribes each year's final classified inspection party table. “Not separate” means the early source did not give that party a separate column; it must not be read as zero. For FY2015 through FY2017, the displayed total follows each deck's stated addition of bioequivalence and, where reported, PADE and REMS to its core categories. Later totals come from the deck's combined table. Every row cites its original FDA slide. **Table note:** FDA includes Radioactive Drug Research Committee (RDRC) inspections in the IRB lane where the source deck specifies them; retain the deck’s combined FDA label in extracted data.

FY	CI	IRB	Sponsor/CRO	Sponsor investigator	GLP	BEQ	PADE	REMS	Published total and slide
2015	822	138	117	Included	36	275	Not separate	Not separate	**1,388**, slide 2 (www.fda.gov)
2016	775	124	112	Included	44	362	Not separate	Not separate	**1,417**, slide 2 (www.fda.gov)
2017	701	124	106	Included	34	355	97	15	**1,432**, slide 2 (www.fda.gov)
2018	904	163	153	22	56	241	72	11	**1,622**, slide 2 (www.fda.gov)
2019	779	140	113	13	62	200	78	17	**1,402**, slide 4 (www.fda.gov)
2020	544	77	70	14	33	208	36	6	**988**, slide 5 (www.fda.gov)
2021	437	29	79	5	16	25	16	4	**611**, slide 5 (www.fda.gov)
2022	504	49	81	10	33	42	35	12	**766**, original slide 5 (www.fda.gov)
2023	681	71	103	13	29	133	35	8	**1,073**, slide 5 (www.fda.gov)
2024	609	86	99	10	44	137	77	14	**1,076**, slide 5 (www.fda.gov)

The table shows an administrative trough and a later increase, but no single causal explanation follows from the counts. The disputed row deliberately uses its original deck. A later retrospective slide changes the IRB cell, and a GLP classification cell is also revised, as documented in the executive summary. The appropriate data treatment is a version flag, not a silent overwrite.

Observation-Family Crosswalk

NAI, VAI, and OAI are final inspection classifications. Observation family labels are separate descriptions of what a Form FDA 483 cited. *Table 2* maps the source vocabulary to record families a quality team can retrieve. It is a semantic crosswalk, not a ranking of observation frequency or severity. The FY2018 deck supplies the original IRB, GLP, and bioequivalence wording retained below (www.fda.gov). Historical decks often list "common" observations without a count per label; the crosswalk therefore does not compute theme rates.

Inspected party	FDA observation wording or family	Evidence population to map	Denominator rule
Clinical investigator	"Protocol deviations"; "Inadequate recordkeeping" in the FY2015 deck (www.fda.gov)	Protocol versions, signed consent, case histories, investigational product accountability (www.ecfr.gov) (www.niams.nih.gov)	Use CI final classifications for NAI/VAI/OAI; use the CI observation file's own base for Form FDA 483 themes.
Sponsor/CRO/ monitor	"Inadequate monitoring" in early decks; electronic system validation in the FY2024 sponsor trend file (www.fda.gov)	Written CRO transfer, monitoring plans and reports, service provider assessment, system validation (www.ecfr.gov) (database.ich.org)	Keep sponsor/CRO and sponsor investigator separate when FDA provides separate columns.
IRB	"Inadequate meeting minutes"; "Inadequate membership rosters"	Meeting minutes, membership, voting, decisions, correspondence and registration (www.hhs.gov) (www.hhs.gov)	IRB classification counts do not represent observation counts.
GLP laboratory	"Inadequate equipment calibration"; "Protocol deviations"	Study protocol, raw data, quality assurance, computerized system and archive records (www.oecd.org) (www.oecd.org)	GLP is a nonclinical denominator; do not combine it with CI GCP rates.
Bioequivalence	"Recordkeeping"; "Blinding Codes"	Bioanalytical and trial records, blinding controls, retained data and metadata (database.ich.org) (www.oecd.org)	Track the CDER bioequivalence series independently from other party classes.

A single organization may hold several record families, but the public rows are inspection program categories. WHO's GCP handbook describes regulators comparing records held by investigators and sponsors with submitted material (extranet.who.int), and NIH advises that source records be organized for retrieval (irbo.nih.gov). Those principles explain why an eTMF completeness percentage alone cannot establish that a source-data chain, oversight decision, or archived GLP record is reconstructible. ICH's essential-record provision emphasizes completeness, readability, availability, and direct accessibility (database.ich.org); EMA likewise links electronic trial data to metadata and inspector access (www.ema.europa.eu) (www.ema.europa.eu).

Analysis of Key Segments

Clinical investigators and sponsor oversight

Clinical investigator inspections dominate most annual party tables. This has a practical interpretation without treating frequency as individual risk: a sponsor's next evidence drill can start with protocol version history, source-to-case-report-form traceability, informed consent, and investigational product accountability at sampled sites. Drug investigator case histories are expressly covered by federal regulation (www.ecfr.gov), while NIH's monitoring template asks how protocol compliance and source document accuracy will be evaluated (www.niams.nih.gov). WHO's account of clinical trial oversight also includes study amendment review and final report evaluation, so a static folder check cannot stand in for the life cycle of trial decisions (www.who.int).

Sponsor/CRO metrics need a separate lane. A CRO is hired to carry out sponsor functions, as Health Canada explains (www.canada.ca). U.S. drug regulations require a written description of transferred sponsor obligations (www.ecfr.gov), while ICH E6(R3) says the sponsor should oversee important transferred trial activities and maintain selection and oversight records (database.ich.org) (database.ich.org). EMA similarly states that sponsor responsibility continues when tasks are delegated, and it permits reliance on vendor qualification material after the sponsor has assessed that work (www.ema.europa.eu) (www.ema.europa.eu). These are reasons to test whether a sponsor can retrieve the scope of transfer, monitoring decisions, escalations, and vendor qualification evidence as one chain.

A final classified count is also not equivalent to the number of inspections performed in that same period. As defined above, the annual table uses the final classification year, while the general inspection database has different row rules. Thus, a year-over-year sponsor/CRO change should trigger a question about data provenance before it triggers a control redesign. For an international program, do not import a foreign agency's rating into FDA's NAI/VAI/OAI categories. Health Canada explicitly notes that its own compliant rating may coexist with observations (www.canada.ca), and EMA's inspection totals refer to its own regulatory process (www.ema.europa.eu).

IRBs, bioequivalence, and GLP

IRB counts are smaller than CI counts in the annual tables, but their evidence universe is distinct. HHS sets out IRB registration requirements in its human-subjects regulations (www.hhs.gov) (www.hhs.gov). That HHS source does not define the FDA BIMO denominator. Separately, FDA requires the IRB records listed in 21 CFR 56.115(a)(1)–(4) to be maintained, so the meeting records should be mapped to the FDA IRB evidence lane (www.ecfr.gov). A quality team can check whether decision records are indexed and retrievable using NIH's record-management principle (irbo.nih.gov), then tie each record to the study and version under review, following ICH's version-control principle (database.ich.org).

Bioequivalence and GLP should stay visible as their own columns. GLP covers nonclinical laboratory practice and data, while bioequivalence has its own line in Table 1. OECD's GLP data guidance recommends a risk based view of data criticality and the data life cycle (www.oecd.org). Its archive guidance calls for the whole information package, including metadata and audit trail context, to be preserved (www.oecd.org) (www.oecd.org). An electronic archive retrieval exercise is therefore a more faithful test of GLP readiness than

a clinical-site checklist. WHO's clinical research oversight material and Japan's PMDA sponsor and medical institution checklists offer parallel examples of role-specific oversight, but neither is a source for FDA numerical trend calculations (www.who.int) (www.pmda.go.jp).

Evidence-to-Control Decision Matrix

The series is most useful when each observed family becomes a reproducible record request. *Table 3* links a party and data signal to a focused control review. These are **decision prompts**, not a claim that FDA publishes a universal inspection benchmark. The record sets come from regulations and GCP guidance; the specific priority within an organization still depends on its studies, vendors, and systems (database.ich.org) (www.canada.ca).

Trigger in atlas	Next control review	Evidence drill and pass condition
CI record or protocol family	Site source data and protocol control	Select a study and site; regenerate the active protocol, consent, case-history lineage, and source comparison. The drug investigator record duty and NIH accuracy criterion define the checks (www.ecfr.gov) (www.niams.nih.gov).
Sponsor/CRO monitoring family	Delegated oversight	Select a CRO deliverable; retrieve the signed transfer, monitoring plan, review decision, and corrective follow-up as one chronology (www.ecfr.gov) (database.ich.org) (www.ema.europa.eu).
IRB review family	Ethics documentation	Retrieve roster, meeting record, decision, correspondence, and study version from the same review event; confirm the FDA IRB records are accessible for inspection under 21 CFR 56.115 (www.ecfr.gov) (irbo.nih.gov) (database.ich.org).
GLP data family	Nonclinical data and archive	Reconstruct one study's raw data, system suitability evidence, quality assurance review, metadata, and archival retrieval path (www.oecd.org) (www.oecd.org) (www.oecd.org).
Electronic record theme	Connected systems and access	Walk a record across capture, transfer, eTMF or warehouse, and export; preserve metadata and demonstrate read-only inspector access where applicable (www.ema.europa.eu) (www.ema.europa.eu) (www.gov.uk).

The table's final row is especially relevant to GCP technology teams. The statute now provides FDA access to electronic information systems used for certain BIMO records (uscode.house.gov), and FDA's 2025 BIMO guidance addresses inspection records and communications (public-inspection.federalregister.gov). The exact scope of an inspection request depends on the legal setting and the system's role; the operational test is whether the team can identify systems holding, analyzing, processing, or transferring the requested information. The UK's MHRA independently states that inspectors need direct access to every system constituting the complete trial master file, a useful design comparison rather than an FDA mandate (www.gov.uk). CDISC's TMF model can structure the document taxonomy without prescribing a paper or electronic platform (database.ich.org) (www.cdisc.org).

Data Analysis and Evidence

The most robust comparison is **within one party, one metric type, and one deck version**. For FY2024, FDA reported 609 CI final classified inspections and a CI classification row of 484 NAI, 110 VAI, and 15 OAI. Those components sum to 609, so the CI OAI share is **15 / 609 = 2.46%** (www.fda.gov) (www.fda.gov). That is a descriptive share of classified CI inspections, not an incidence rate for all clinical investigators. Health Canada's site-focused explanation and WHO's wider oversight model both caution against generalizing an inspection count to all sites (www.canada.ca) (www.who.int).

Table 1 keeps sponsor/CRO, IRB, GLP, and bioequivalence as separate final-classification lanes. These counts are decision-useful as sizes of FDA's published party lanes, but they do not share an observation denominator. The sponsor observation trend file and annual classification table have different populations. Dividing one file's observation count by the other's inspection total would mix populations and event definitions. The same logic applies to RRAs: the FY2024 deck reports **75** completed by operation date in its separate RRA series, outside the NAI/VAI/OAI inspection table (www.fda.gov). Current BIMO guidance treats an RRA as distinct from a statutory inspection.

Table 1 shows a low point near the middle of the period and a subsequent increase. That shape is descriptive only. It does not isolate the effect of travel, program changes, remote work, or the timing of final classifications. The RRA series is separately tabulated, and the FDA index warns that compilation methods can differ across datasets. A heatmap should therefore color only cells that share a stable party definition and metric basis, and it should leave disputed or missing cells uncolored.

Source revision is material, even when the difference is small. The original and retrospective slides disagree for an IRB cell and a GLP classification cell, as documented above. A later clinical investigator classification cell also differs between decks. These are **version differences**, not evidence of any organization's conduct. They justify a source version column and a reconciliation note before publishing a calculated share.

External evidence helps set method boundaries, not estimate FDA counts. A Tufts Center for the Study of Drug Development survey recorded **206 responses** about **32** risk based quality management practices, a different unit and sampling design from BIMO inspections (pubmed.ncbi.nlm.nih.gov). EMA's reported **24%** GCP inspection increase in 2024 belongs to another jurisdiction (www.ema.europa.eu). Health Canada's different record-retention rule is likewise a jurisdictional example, not a U.S. requirement (www.canada.ca). Keeping these sources beside, rather than inside, the FDA numeric table prevents a superficially rich but incoherent dashboard.

Implications and Future Directions

For a head of clinical quality, the immediate decision is a **party-specific control review**. Start with the party class relevant to the organization's current studies, then select an observation family and request the underlying record chain. CI case-history and protocol controls are anchored in federal drug investigator duties (www.ecfr.gov) and in NIH's source-data comparison question (www.niams.nih.gov). Sponsor/CRO oversight requires the written allocation of duties (www.ecfr.gov) plus the ICH selection and oversight record

(database.ich.org). GLP requires a study and archive reconstruction under GLP data principles (www.oecd.org) (www.oecd.org). This ordering is an operational judgment from the evidence, not a statistical forecast of inspection selection.

For an eTMF owner, the test is whether a requested record can be located **with its version, context, access path, and related decision**. ICH expects essential records to remain readable and accessible (database.ich.org). CDISC's TMF taxonomy works with paper or electronic files (www.cdisc.org), while its data exchange standards address clinical data and metadata archiving (www.cdisc.org). EMA treats metadata as context for data and expects access to relevant computerized systems (www.ema.europa.eu) (www.ema.europa.eu). These are design inputs for a data dictionary and retrieval drill, not proof that any one eTMF product meets every inspection need.

For a reporting team, refresh means re-opening the FDA metrics index after each annual update, recording the new deck URL and retrieval date, extracting by slide, and comparing retrospective cells with prior originals. The current index and extraction date should be logged on each refresh. The team should retain source snapshots, mark changed labels, sum NAI/VAI/OAI before computing rates, and keep RRA and observation datasets apart. A separate inspection database should not replace this deck-specific version history.

The electronic access context is also current rather than historical: the U.S. Code contains a BIMO system-access provision (uscode.house.gov), and FDA issued its final BIMO inspection process guidance in December 2025 (public-inspection.federalregister.gov). Service provider evidence now spans contracts, source records, monitoring systems, and document repositories. EMA's vendor qualification position and MHRA's multi-system trial master file access expectation show why a single system export may be incomplete (www.ema.europa.eu) (www.gov.uk). The defensible next investment is a tested provenance path across those systems, with documented limits where records reside elsewhere.

Conclusion

FDA's FY2015 through FY2024 BIMO decks support a useful ten-year atlas if each cell retains its **party, Center, fiscal year basis, source slide, and denominator**. The published totals show substantial variation, but the decade should not be flattened into a causal trend. Early decks treat bioequivalence and sponsor investigators differently, the newer decks separate RRAs, and later slides revise some prior-year cells. Those distinctions are part of the result, not footnotes to remove.

The next quality decision should start with the record population that corresponds to the inspected party. Investigators need reconstructible source and protocol evidence. Sponsors and CROs need a documented delegation and monitoring chain. IRBs need review and decision records. GLP laboratories need suitable systems, raw-data lineage, and archives. The public counts can prioritize which lane to test, while the control evidence must still be produced from the organization's own studies and vendors.

A maintainable data atlas is a versioned extract of FDA's slides with explicit blanks, original wording, and a calculation column that remains empty whenever numerator and denominator cannot be reconciled. A refresh after each annual FDA posting should verify prior-year revisions before drawing a new heatmap or claiming a change in classification share. That procedure turns a public inspection series into an audit-ready decision input without claiming that an aggregate count predicts a specific firm's inspection.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/bimo-inspection-metrics
2. https://www.fda.gov/media/97043/download
3. https://www.fda.gov/media/127110/download?attachment=
4. https://www.fda.gov/media/156517/download?attachment=
5. https://www.fda.gov/media/192870/download?attachment=
6. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-D/section-312.62
7. https://www.niams.nih.gov/grants-funding/conducting-clinical-trials/clinical-trial-policies-guidelines-and-templates/data-and
8. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-D/section-312.52
9. https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
10. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
11. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-e/index.html
12. https://www.oecd.org/en/publications/glp-data-integrity_45779212-en.html
13. https://www.oecd.org/en/publications/guidance-document-on-good-in-vitro-method-practices-givimp_9789264304796-en/full-report/component-15.html
14. https://uscode.house.gov/view.xhtml?req=%28title%3A21+section%3A374+edition%3Aprelim%29
15. https://www.ema.europa.eu/system/files/documents/regulatory-procedural-guideline/guideline_on_computerised_systems_and_electronic_data_in_clinical_trials_en.pdf
16. https://www.gov.uk/guidance/clinical-trials-for-medicines-good-clinical-practice-inspections
17. https://www.fda.gov/media/165853/download?attachment=
18. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-bioresearch-monitoring-information/bioresearch-monitoring-program-information
19. https://intuitionlabs.ai/articles/fda-inspection-readiness-guide
20. https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100/good-clinical-practices.html
21. https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/drug-health-product-inspections/about-inspections-clinical-trials-human-drugs.html
22. https://www.who.int/tools/health-products-regulation-and-prequalification-learning-catalogue/clinical-trials-oversight
23. https://intuitionlabs.ai/
24. https://www.cdisc.org/tmf
25. https://intuitionlabs.ai/articles/fda-form-483-warning-letter-statistics
26. https://www.ema.europa.eu/assets/en/annual-report/2024/inspections-and-compliance/index.html
27. https://www.cdisc.org/standards/data-exchange
28. https://www.fda.gov/media/105755/download
29. https://www.fda.gov/media/112683/download
30. https://www.fda.gov/media/136797/download

31. https://www.fda.gov/media/145858/download?attachment=
32. https://www.fda.gov/media/178661/download?attachment=
33. https://www.fda.gov/files/science%20%26%20research/published/fy_2024_sponsor_fda_483_data_observation_trends_0.pdf
34. https://www.oecd.org/content/dam/oecd/en/publications/reports/1998/01/oecd-principles-on-good-laboratory-practice_g1gh32e8/9789264078536-en.pdf
35. https://extranet.who.int/prequal/sites/default/files/document_files/GCP_handbook.pdf
36. https://irbo.nih.gov/conducting-your-study/record-retention/
37. https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-clinical-practice/qa-good-clinical-practice-gcp
38. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-D/section-56.115
39. https://www.pmda.go.jp/english/review-services/glp-gcp-gpsp/0003.html
40. https://public-inspection.federalregister.gov/2025-23404.pdf
41. https://pubmed.ncbi.nlm.nih.gov/38366107/

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IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

Work with IntuitionLabs

Explore AI enablement, pharma and biotech software development, data engineering and BI, and Veeva services. Contact IntuitionLabs to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

Website: https://intuitionlabs.ai