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FDA PMR/PMC Tracker: Study Status, Milestones & Data Model

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Executive Summary

An **FDA postmarketing requirements and commitments (PMR/PMC) tracker** should begin with the agency's quarterly public extract, but it must keep the source snapshot, study text, application context, obligation category, status, and original milestone schedule together. A postmarketing requirement is a study or trial the sponsor must conduct under statute or regulation; a postmarketing commitment is a study or trial the sponsor agrees to conduct without that mandate. FDA's public database covers reportable PMRs and **506B PMCs** for clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology, rather than every operational promise associated with an approval. ([toolkit.ncats.nih.gov](https://www.ncats.nih.gov/toolkit)) ([toolkit.ncats.nih.gov](https://www.ncats.nih.gov/toolkit))

As of **October 2, 2026**, FDA's searchable page displayed **July 31, 2026** as its last update, while the downloadable page described a quarterly ZIP intended for import into a database or spreadsheet. The public release includes all open records but only fulfilled or released records closed within the prior year. That rolling closure window makes a saved quarterly snapshot essential to longitudinal work. The ZIP itself could not be inspected through the available readers during this research session, so this report does **not** assert its current row count, internal column names, or identifier stability. Its proposed crosswalk starts from FDA's documented search display and annual-status form, then requires validation against the next readable archive. (www.accessdata.fda.gov) (www.fda.gov) (www.w3.org)

The status field is a decision aid, not a sponsor score. FDA defines **delayed** against the original study schedule; a revised planning date must be retained separately, and a delayed study can return to schedule in a later phase. **Submitted** means the final report reached FDA but written fulfillment or release has not yet been communicated. Accordingly, a tracker should distinguish the FDA status, the next original milestone, any revised forecast, the annual-status-report event, and the date the public snapshot was observed. It should calculate days to the next original milestone, not an invented "overdue" or negligence metric. (www.fda.gov) (www.ecfr.gov) (www.ecfr.gov)

The newest annual report listed on FDA's reports index as of publication was **FY2024**, with a September 30, 2024 measurement date. It reported **1,636 open PMRs**, of which **1,147 (70%)** were on schedule, and **386 open PMCs**, of which **307 (80%)** were on schedule. Those are annual-report cohorts, not counts reproduced from the July 2026 public ZIP. FDA explicitly says the annual, backlog, and public website series are not directly comparable. A practical dashboard should therefore expose its denominator, snapshot date, source file hash, and inclusion filter beside each chart. (www.fda.gov) (www.fda.gov) (www.federalregister.gov) (www.federalregister.gov)

Introduction and Background

The business question behind an FDA PMR/PMC tracker is narrow and consequential: **which study obligations need a person to review the next event, evidence package, or status change?** Regulatory operations may own the approval letter and annual status report; clinical operations may own a trial; safety may own risk evaluation; medical affairs may use the emerging evidence. These teams need one cross-system view, yet their systems do not necessarily use the same unit of record. FDA's public search results group one application or supplement and then show one or more requirements or commitments beneath it. An application-level report is therefore not a study-level workload count. (www.federalregister.gov) (database.ich.org) (database.ich.org)

This report treats the public file as an **observation of FDA's published state**, not as the company's legal or clinical system of record. FDA says information about postmarketing requirements and commitments comes from agency letters and applicants' annual status reports. The practical result is a reconciliation workflow: compare the latest public observation with the approval letter, the current annual report, the protocol and study record, and any agency correspondence before escalating a mismatch. A missing public change can reflect a publication delay while FDA verifies information. (www.fda.gov)

The available evidence has a material boundary. FDA says the public download contains all open PMRs and reportable 506B PMCs but only recently fulfilled or released items; older closed records leave the display. FDA also identifies categories, such as chemistry and manufacturing commitments, that are outside this public clinical-study scope. A tracker built solely from today's ZIP cannot reconstruct all historical obligations, closure rates, or an application's complete internal commitment inventory. Preserving each quarterly file from the first run improves future trend analysis but does not recover records already outside the window. (www.federalregister.gov) (link.springer.com) (link.springer.com)

IntuitionLabs' documented work in data engineering and integration provides the adjacent implementation perspective: a tracker is useful when source lineage, permissions, and operational ownership are explicit. This is a workflow design recommendation, not a claim that the consultancy supplies an FDA database or a competing PMR product. (intuitionlabs.ai) (intuitionlabs.ai)

Source, Scope, and Reproducible Method

What the FDA searchable site and ZIP provide

FDA describes two public access paths: a searchable PMR/PMC website and a downloadable compressed archive. The page says the archive has a table of contents and Excel or text data that can be imported into a database, spreadsheet, or word-processing program. The searchable site displayed **July 31, 2026** as its last update when checked on **October 2, 2026**. FDA describes refreshes around the ends of January, April, July, and October; that cadence is a review schedule, not a guarantee that every annual-report change appears in the next quarter. (www.fda.gov) (www.fda.gov) (www.w3.org)

The analyst should store the original download as an immutable object and record retrieval timestamp, public display date, file name, byte size, content hash, parser version, and any table-of-contents notes. Each parsed row should retain its untouched source values alongside normalized columns. This preserves the ability to explain why an obligation appeared in a dashboard on a particular day. The World Wide Web Consortium's PROV model offers a useful vocabulary for relating a derived row to its source entity and generation time. That is an architecture option, not an FDA requirement. (www.w3.org) (www.w3.org) (www.w3.org) (www.w3.org)

A minimum snapshot manifest should make the following items inspectable:

- **Source URL:** Record the landing page and resolved archive link.
- **Capture time:** Record the retrieval timestamp in Coordinated Universal Time.
- **Display date:** Retain the FDA date shown to users.
- **File hash:** Calculate a digest of the untouched archive.
- **Parser version:** Identify the exact code that produced normalized rows.
- **Scope filter:** Save the inclusion rule used for every count.
- **Reject log:** Preserve rows the parser could not classify.
- **Approval record:** Name the reviewer who released the new snapshot.

For this publication, the archive landing page and searchable page were read, but the ZIP payload could not be opened with the permitted page readers. Accordingly, **no July 2026 public-file count is reported**. A future refresh can publish a count only after retaining the file and executable filter: one record per documented obligation key, explicit inclusion of open plus the allowed recent closed window, and separate figures by PMR or PMC and FDA status. It should also report unparseable rows and duplicate candidate keys. FDA's help page explains that the displayed requirement or commitment number comes from agency letters, but does not establish that every candidate composite key remains stable across quarterly files. (www.w3.org) (www.w3.org)

The scope boundary that prevents false comparisons

The searchable scope is **drugs and biologics**, with reportable studies and clinical trials in the four named areas. It should not be confused with device post-approval study or section 522 surveillance datasets. Even within drugs and biologics, the public extract is a subset of FDA's internal obligations. The annual report may contain records that have not yet been verified for public posting. Its denominator and cut-off date therefore differ from an analyst's downloaded snapshot. (www.fda.gov) (www.federalregister.gov)

FDA's report page listed FY2024 as the newest annual PMR/PMC performance report as of **October 2, 2026**. Its underlying status date was **September 30, 2024**, despite the later report availability notice. The historical backlog series has still another population: obligations open as of a fixed 2007 baseline. A chart joining these three series as though they were successive quarterly extracts would create a false trend.

(www.federalregister.gov) (www.federalregister.gov)

FDA Status Taxonomy and Escalation Meaning

FDA uses **pending, ongoing, delayed, terminated, submitted, fulfilled, and released** as public study-status categories. The definitions are study-level observations. They do not state the cause of a delay, predict whether a report will satisfy FDA, or grant a reader authority to close an internal task. Status history should be stored as dated observations, and internal disposition should have its own owner and audit trail. (www.w3.org) (hl7.org)

Table 1 maps each FDA label to a safe operational interpretation. The calculations are proposed tracker behavior. They are not replacement FDA status rules. (hl7.org)

FDA status	Operational interpretation	Permitted tracker calculation	Prohibited inference
Pending	Study has not begun and has not met FDA's delayed criterion. (www.fda.gov)	Show days to the next documented original milestone; flag missing source dates.	Treating pending alone as late or inactive.
Ongoing	Study is at or ahead of the original schedule. (www.fda.gov)	Group open work by next original event and owning team.	Assuming completion is assured.
Delayed	Progress is behind the original schedule; FDA says a later phase can return to schedule. (www.fda.gov)	Surface original and revised dates side by side and request context review.	Treating the label as evidence of negligence or a fixed duration of delay.
Terminated	Study ended before completion and the final report has not yet been submitted. (www.fda.gov)	Route for regulatory review of report and correspondence.	Treating termination as release from the obligation.
Submitted	Final report reached FDA; fulfillment or release has not yet been communicated in writing. (www.fda.gov)	Track agency decision and correspondence dates separately.	Counting submitted as fulfilled.
Fulfilled	FDA determined the terms were met after final-report review. (www.fda.gov)	Record the FDA decision and closure observation.	Inferring the decision date from the quarterly publication date.
Released	FDA determined the study need not continue because it is infeasible or no longer useful. (www.fda.gov)	Record the release decision and reason when sourced.	Treating release as evidence that the study was completed.

The table creates two distinct queues: **study execution** for pending, ongoing, and delayed items, and **regulatory disposition** for terminated and submitted items. Fulfilled and released require a closure record and evidence link, then retention in the internal history even after they fall off FDA's one-year public display.

FDA's FAQ says some status explanations are published for pediatric studies across statuses and for other obligations when delayed or terminated; that text should be kept separately from any internal explanation. (www.w3.org) (hl7.org)

FDA's delayed definition relies on the **original** schedule, not merely the latest revised date. The status may cease to apply after a later phase catches up. Conversely, a revised internal forecast does not rewrite the original baseline. The proper escalation trigger is therefore a review condition, such as a newly delayed FDA label, a material mismatch between public and internal schedules, or an approaching documented event, with a human deciding the response. (www.ecfr.gov) (database.ich.org) (www.ecfr.gov)

Field-Level Data Model and Identity

The data model should represent an **obligation**, not just a product. FDA's search help describes applicant, product, application number, supplement, approval and report dates, requirement or commitment number, text, authority, status, and final-report date in its display. FDA Form 3989 then supplies a richer submission-side model with establishment date, original milestones, revised milestones, and a center-specific PMR/PMC identifier format. These sources justify a field-level crosswalk, but the physical ZIP column names remain to be validated from the archive itself. (www.fda.gov) (www.federalregister.gov)

Table 2 is the proposed canonical schema. "Source" identifies where the value should be checked. A blank source field remains null; it should not silently inherit a date from another system. (www.w3.org)

Canonical field	Source crosswalk	Normalization and audit rule
snapshot_id, source_hash, observed_at	Download metadata plus FDA displayed update date.	Preserve the untouched file, parser version, and capture time. (www.nlm.nih.gov)
center, application_type, application_number, supplement_number	FDA search display; Form 3989 application identifier.	Keep leading zeros and a separate supplement field; never join on product name alone. (hl7.org)
applicant, product, approval_date	FDA application-level display.	Store source spelling and normalized display value separately. (www.federalregister.gov)
obligation_type, authority_category	PMR versus 506B PMC; "Required Under" for PMRs. (www.fda.gov)	Use explicit type and authority, with unknown category allowed. (toolkit.ncats.nih.gov)
obligation_number, established_at, study_text	Agency-letter number and text; establishment date from formal communication. (www.federalregister.gov)	Preserve raw text and exact source reference.
fda_status, status_explanation, status_observed_at	FDA status and available explanation.	Treat as a dated public observation, not an internal completion flag. (hl7.org)
milestone_type, original_due, revised_due, revision_reason	Form 3989 and approval or follow-up correspondence. (www.fda.gov)	One child row per milestone and schedule version. (www.ecfr.gov)

Canonical field	Source crosswalk	Normalization and audit rule
final_report_due, annual_report_due, annual_report_received	FDA displayed dates where available.	Distinguish study-event deadlines from the application annual-report cycle. (www.ecfr.gov)
nct_id, internal_study_id, rim_record_id, safety_plan_id	Verified links to trial and internal systems. (clinicaltrials.gov) (hl7.org)	Store evidence for each linkage; do not infer equivalence from title similarity.

The table separates **identity**, **state**, **schedule**, and **provenance**. That separation is important because an application can have several obligations, a single obligation can have several milestones, and a status can change without changing the underlying study text. The ClinicalTrials.gov NCT number is a unique identifier for its registered study record, but it is not an FDA PMR/PMC obligation identifier. The Health Level Seven ResearchStudy model likewise distinguishes a business identifier from a record version. (clinicaltrials.gov) (hl7.org) (hl7.org)

A field review should answer these questions before a join is accepted:

- **Center:** Is the record managed by the expected FDA center?
- **Application:** Does the identifier retain its leading zeros?
- **Supplement:** Is the supplement separate from the parent application?
- **Obligation number:** Does it match the controlling letter?
- **Study text:** Is the description preserved without truncation?
- **Establishment date:** Is the formal communication identified?
- **Schedule:** Are original and revised dates in separate fields?
- **Link evidence:** Is every external study match reviewable?

A reasonable candidate key is (center, application_type, application_number, supplement_number, obligation_number), with the original agency letter as a disambiguation aid. It must remain a **candidate** until tested against successive actual ZIPs. FDA documents the letter-derived obligation number, and Form 3989 documents different identifier formats for CDER and CBER; neither source guarantees that a synthesized key is globally persistent. Store a surrogate internal obligation_id and a mapping history so a correction or numbering change can be reconciled without overwriting older observations. (www.w3.org) (hl7.org)

Milestone Logic and Quarterly Change Detection

Normalize the baseline before computing dates

Form FDA 3989 identifies draft protocol, final protocol, study or trial completion, final report, and optional interim-report milestones. Its instructions call for **original milestone dates** and, if applicable, **revised milestone dates**, including the reason for a requested revision. The corresponding biologics regulation also asks for original and most recently revised schedules. A tracker should therefore make each event a row with type, source document, original date, latest acknowledged or proposed revision, date precision, and evidence reference. The revision must not overwrite the original field. (www.ecfr.gov) (www.ecfr.gov) (www.ecfr.gov)

The public display may omit a final-report due date. FDA says that date appears only when available and notes that its database did not begin capturing final-report due dates until **April 2001**. Null therefore means **unknown in this source**, not no milestone. Approval letters and Form 3989 can fill the internal schedule, but the public-data column should remain null if FDA did not publish a value. Likewise, an annual-status-report due date belongs to the application reporting cycle and should not be conflated with a study's final report deadline. (www.fda.gov)

The useful calculation is $\text{days_to_next_original_milestone} = \text{original_due_date} - \text{snapshot_date}$ for the earliest documented future event relevant to an open obligation. If the original date is past, show its signed distance and the FDA status side by side; label it “original event date passed,” not “sponsor overdue.” FDA defines delayed through the study's progress against the original schedule, not through this simplistic date subtraction. A completed prior phase or a formally extended pediatric deferral can alter interpretation. The dashboard should display the status explanation and correspondence before an owner escalates. (www.ecfr.gov)

For a reproducible quarterly diff, compare only records whose keys have been validated or manually crosswalked. In this conceptual, normalized view, each snapshot has at most one row per validated obligation and milestone type; count status or text changes by distinct obligation, because an obligation can have multiple milestones. Keep independent flags so simultaneous changes remain visible:

```
-- Conceptual normalized view; map ZIP fields only after archive inspection.
WITH paired AS (
  SELECT COALESCE(n.obligation_id, p.obligation_id) AS obligation_id,
         COALESCE(n.milestone_type, p.milestone_type) AS milestone_type,
         p.fda_status AS old_status, n.fda_status AS new_status,
         p.study_text_hash AS old_text_hash,
         n.study_text_hash AS new_text_hash,
         p.original_due AS old_original_due,
         n.original_due AS new_original_due,
         p.revised_due AS old_revised_due,
         n.revised_due AS new_revised_due,
         p.source_snapshot AS old_snapshot,
         n.source_snapshot AS new_snapshot
  FROM previous_snapshot p
  FULL OUTER JOIN current_snapshot n
    ON p.obligation_id = n.obligation_id
   AND p.milestone_type = n.milestone_type
)
SELECT *,
  CASE WHEN old_snapshot IS NULL THEN 'first_seen'
       WHEN new_snapshot IS NULL THEN 'not_in_current_extract'
       ELSE 'present_in_both' END AS row_state,
  CASE WHEN old_snapshot IS NOT NULL AND new_snapshot IS NOT NULL
       THEN old_status IS DISTINCT FROM new_status ELSE FALSE END AS status_changed,
  CASE WHEN old_snapshot IS NOT NULL AND new_snapshot IS NOT NULL
       THEN old_text_hash IS DISTINCT FROM new_text_hash ELSE FALSE END AS text_changed,
  CASE WHEN old_snapshot IS NOT NULL AND new_snapshot IS NOT NULL
       THEN old_original_due IS DISTINCT FROM new_original_due ELSE FALSE END AS original_due_changed,
  CASE WHEN old_snapshot IS NOT NULL AND new_snapshot IS NOT NULL
```

```
THEN old_revised_due IS DISTINCT FROM new_revised_due ELSE FALSE END AS revised_due_changed
FROM paired;
```

The code deliberately calls an absent row **not in current extract**. Because FDA removes fulfilled and released records after the public display window, disappearance is not proof of a new release, withdrawal, or data error. A separate match-and-review queue should look up the last observed status, FDA correspondence, and the file manifest before classifying the event. Retain `old_status`, `new_status`, both snapshot dates, and the raw source rows; the W3C provenance model supports documenting the derivation of a change record. (www.w3.org) (www.w3.org) (hl7.org)

Annual reporting is a separate clock

Section 506B reporting and FDA's guidance require annual progress reports for covered requirements and commitments until FDA gives written notice of fulfillment or release. FDA guidance generally places the annual status report within **60 days** of the U.S. approval anniversary unless an alternate reporting date applies. Form 3989 is an optional structured annual-report form, whereas Form 3988 is for other PMR/PMC-related submissions. These are submission workflow facts, not a substitute for the study milestone schedule. A tracker needs distinct events for annual-report preparation, submission, FDA receipt, final-study-report submission, and FDA disposition. (www.fda.gov) (www.ecfr.gov)

FDA states that updates based on annual status reports may not appear in the same quarter they are submitted. A reconciliation exception should therefore record when the organization sent a report, when FDA acknowledged it, and when a changed public status was first observed. That audit trail is more useful than a binary “FDA out of sync” label, because it can identify which clock differs without attributing a cause that the public file does not establish. (www.fda.gov)

Analysis of Key Segments and Portfolio Views

A portfolio dashboard should answer four questions: **what kind of obligation is this, who owns the next action, what changed, and how fresh is the public evidence?** The base pivot is obligation type by FDA status, with application and center filters. PMRs and 506B PMCs need separate columns because they have different legal origins. A second view groups original milestone events by calendar quarter and milestone type, and a third highlights status transitions between saved public snapshots. Each view must publish its numerator, denominator, as-of date, and inclusion filter. (www.w3.org) (database.ich.org)

The **application view** should list the source application number, supplement, product, applicant, annual report due and received dates, and the number of visible obligations. This is a work-planning view, not a count of all commitments an organization may manage: FDA's public scope excludes some categories, and several obligations can sit under one application. A reviewer should be able to open the raw FDA text and the internal letter from the same row. The establishment date belongs to the formal communication containing the final obligation, which may be at approval or afterward. (www.federalregister.gov) (www.federalregister.gov) (www.federalregister.gov)

The **status view** should make newly delayed and newly submitted items easy to review. It must preserve the last and current FDA labels, snapshot dates, and any explanation. It should not rank sponsors or infer negligence from delayed labels. FDA defines delayed relative to original phase scheduling and permits the label to stop applying if a later phase catches up. Similarly, submitted means a final report reached FDA but an agency disposition remains open. Those definitions make a transition log more informative than a single red/green status. ([hl7.org](#)) ([hl7.org](#))

The **workload view** should count open obligations with a documented next event in the current and following quarters, split by protocol, study completion, interim report, final report, and annual-status-report tasks. A null event date belongs in a **needs source review** bucket, rather than disappearing from the chart. The view should distinguish original milestones, revised forecasts, and reporting-cycle dates. ICH E2E advises milestone planning for pharmacovigilance evaluations and reporting; those plan milestones can be linked to, but should not silently replace, the FDA obligation schedule. ([database.ich.org](#)) ([database.ich.org](#)) ([database.ich.org](#))

Finally, the **freshness view** should show the FDA displayed update date, local retrieval date, and the age of each linked internal record. The public database's planned quarterly cadence does not mean all applicant submissions appear that quarter. ClinicalTrials.gov likewise distinguishes update submission from public posting. A cross-system dashboard should display each system's posted or extracted date, not a single synthetic "last updated" value. ([clinicaltrials.gov](#)) ([www.nlm.nih.gov](#)) ([www.nlm.nih.gov](#))

RIM, Safety, and Clinical Integration Blueprint

The integration design begins with an obligation registry owned by regulatory information management (RIM). Its authoritative links are the application and supplement, approval or follow-up letter, PMR/PMC number, study text, and original schedule. The public FDA feed is an observation layer. Clinical operations contributes protocol and trial identifiers; safety contributes pharmacovigilance-plan activities and evidence review; medical affairs may consume the resulting evidence map. Each system contributes a dated link and owner, while the obligation registry retains the legal context. FDA's form instructions and the public search fields support the identifiers and dates in that core. ([database.ich.org](#)) ([database.ich.org](#))

A ClinicalTrials.gov linkage should use an **NCT number** when a verified registered study corresponds to the obligation. ClinicalTrials.gov defines it as a unique code for a registered clinical-study record, and the National Library of Medicine documents an API lookup by nctId. Do not assume every PMR/PMC is a registered clinical trial or that two records with similar titles are the same study. One peer-reviewed historical analysis found **28 of 31** assessable PMCs for new clinical trials registered in its specified 2009 to 2012 approval cohort; that sample is context, not a current coverage estimate. ([clinicaltrials.gov](#)) ([www.nlm.nih.gov](#)) ([link.springer.com](#))

Use a relationship table with obligation_id, external_system, external_id, link type, evidence URL or document, reviewer, and effective dates. The NLM API's JSON and ISO 8601 date conventions make it practical to ingest trial metadata, but its posted dates should remain distinct from FDA observation dates. HL7 FHIR ResearchStudy supplies an optional interoperability model with business identifier, version, and status

timing. CDISC's Study Data Tabulation Model concerns clinical-study data representation; it is useful downstream for evidence exchange but should not be misused as a PMR status schema. (www.nlm.nih.gov) (hl7.org) (hl7.org) (www.cdisc.org)

Where a company uses **Veeva Vault**, documented Clinical Operations to RIM connections can move documents and data records between applications, and Veeva recommends treating the authoring Vault as the source. Its connection documentation also describes study and product-data synchronization. These are vendor-documented capabilities, not a claim that a native connection automatically reconciles FDA's public PMR/PMC file or supplies the proposed key. The same principles apply with other platforms: retain a source-system identifier, evidence of the mapping, a human review path, and an audit log of changed fields. (www.veeva.com) (www.veeva.com) (www.veeva.com) (www.w3.org)

The owner should also define explicit review outcomes:

- **Accepted match:** Public and internal obligations are linked with evidence.
- **Candidate match:** Similar records need a reviewer to confirm identity.
- **Status change:** Old and new FDA labels are both retained.
- **Date change:** Original and revised schedule fields are checked separately.
- **Text change:** The source wording and its prior version remain accessible.
- **Missing date:** The dashboard shows an unknown value.
- **Public omission:** The row is marked absent from this extract.
- **Publication lag:** The discrepancy is kept open with both timestamps.
- **Closure review:** Agency correspondence is linked before internal closure.

A quarterly operating cycle has five steps:

- **Capture:** Save the original FDA archive and its manifest around the expected refresh window, while recording the actual displayed date and retrieval time. (www.nlm.nih.gov)
- **Parse:** Preserve raw values, validate schema and types, and quarantine rows whose identity or dates cannot be interpreted. (www.w3.org) (www.w3.org)
- **Diff:** Compare validated obligation identities, statuses, study text, and schedule fields against the prior saved snapshot. (www.w3.org) (www.nlm.nih.gov)
- **Reconcile:** Match new or changed public rows to agency letters, the current annual status report, trial registry, and safety plan; document unresolved mismatches. (www.nlm.nih.gov) (database.ich.org) (www.nlm.nih.gov)
- **Publish:** Release a versioned workload view with its denominator, source age, owner, exceptions, and change log. (www.w3.org) (hl7.org)

Data Analysis and Evidence

The available quantitative benchmark is FDA's **FY2024 annual report**, measured at **September 30, 2024**, rather than a count extracted from the unreadable current ZIP. FDA reported **402 unique applicants** with open obligations under **826 unique new drug applications and biologics license applications**. It counted **1,636**

open PMRs, with **1,147 on schedule (70%)** and **489 off schedule (30%)**. It separately counted **386 open PMCs**, with **307 on schedule (80%)** and **79 off schedule (20%)**. These categories reflect the report's definitions and cohort at that date. (www.federalregister.gov) (www.federalregister.gov)

Table 3 keeps the three published units separate. Its figures come from the FY2024 report and are **not** a current public database tally. (www.federalregister.gov)

FY2024 measure	Reported value	Use in a tracker
Applicants with open PMRs or PMCs	402 (www.fda.gov)	Context for application-level reporting; not study workload.
Unique NDAs and BLAs with open PMRs or PMCs	826 (www.fda.gov)	Application denominator, not obligation denominator.
Open PMRs, on schedule / off schedule	1,147 / 489 , total 1,636 (www.fda.gov)	Separate required obligations from commitments.
Open PMCs, on schedule / off schedule	307 / 79 , total 386 (www.fda.gov)	Keep voluntary 506B commitments in their own cohort.
Annual status reports expected / on time	750 / 583 (www.fda.gov)	Application reporting workload, not milestone fulfillment.

The report's **750** expected annual-status reports were counted by application: **583** arrived on time, **66** outside the on-time window, and **101** were not received during the fiscal year. FDA explains that not all applications with open obligations had a report due that year. A tracker should therefore avoid dividing obligation counts by annual-report counts to create a pseudo-compliance rate. It should instead show each application's own reporting clock and each study's milestones. (www.federalregister.gov)

FDA also reported **172 NDA PMRs** and **65 BLA PMRs** closed during FY2024, plus **41 NDA PMCs** and **30 BLA PMCs**. Those are fiscal-year closure flows. They exclude records closed in earlier fiscal years and cannot be equated with fulfilled or released records still visible in a later quarterly public extract. The report itself warns that its internal figures and the public website counts are not directly comparable, and that the cohort of open items changes year to year. (www.fda.gov) (www.fda.gov)

The older backlog series illustrates why denominators matter. Its fixed historical cohort was **1,636** PMRs/PMCs open on **September 27, 2007**, and a later review reported **34** of that cohort still open. The numerical coincidence between that baseline size and the FY2024 open-PMR total does not make them the same population. One is a fixed historical set of PMRs and PMCs; the other is a contemporary, changing set of PMRs. They must occupy separate charts with explicit definitions. (www.fda.gov)

Implications and Future Directions

The first implementation decision is **whether the tracker is for public observation, internal obligation control, or both**. A public-only tool can report FDA labels, displayed dates, and text with transparent freshness and inclusion rules. An internal control tool additionally needs agency correspondence, sponsor submissions,

protocol versions, owner assignments, and evidence of each schedule revision. FDA's public file cannot supply every internal commitment or a complete historical closure cohort. That constraint should be visible on every dashboard, not buried in a methodology note. (www.federalregister.gov) (www.w3.org) (database.ich.org)

The second decision is whether a row can be linked confidently across quarters. Until actual ZIPs are compared, key stability remains an open empirical question. Use a candidate composite key, preserve the original obligation number and text, and create an adjudication queue for collisions or changed identifiers. A reviewer should be able to replay each quarterly diff from the saved raw file and parser version. W3C provenance vocabulary supports this lineage; HL7 ResearchStudy versioning provides a compatible concept for linked study records. (www.w3.org) (hl7.org) (hl7.org)

The third decision is escalation design. Escalate **newly delayed**, **terminated**, and **submitted awaiting disposition** obligations for review, but route them to different owners and evidence. A delayed label is FDA's schedule assessment; a submitted label is a report-received state; a terminated label is an ended study awaiting final-report handling. None justifies a universal sponsor-performance score. The calculation to automate is a transparent date difference or a transition count, with status and source context attached. (www.ecfr.gov) (www.ecfr.gov)

Future releases should publish a reproducible machine-readable data dictionary only after the ZIP's table of contents and files can be opened. They should report record counts by type, status, center, and snapshot date, plus unmatched and ambiguous keys. Until then, the more defensible output is the field crosswalk and processing recipe in this report, with the live-file unknowns stated plainly. A current extract may be analytically useful, but a precise number without the captured file and filter would not be auditable. (www.w3.org) (www.nlm.nih.gov)

Frequently Asked Questions (FAQs)

What is the difference between an FDA PMR and a PMC?

A **PMR** is a study or trial required under a statute or regulation. A **PMC** is one the sponsor agrees to conduct without that mandate. The public searchable database includes reportable **506B PMCs** within its specified study categories, so its PMC count is not necessarily an organization's total internal commitment count. (www.federalregister.gov) (toolkit.ncats.nih.gov)

Does delayed mean a sponsor missed a legal deadline?

No such conclusion follows from the label alone. FDA describes delayed as study progress behind the **original** schedule and says the status can cease to apply after a later phase catches up. Review the original milestones, any revised schedule, status explanation, and correspondence before interpreting a specific record. (www.ecfr.gov) (www.ecfr.gov)

Can the latest ZIP be used to calculate historical completion rates?

Not on its own. FDA retains all open public-scope records but only fulfilled or released records from the recent one-year window. Saved quarterly extracts can build a prospective history; the latest extract cannot restore older closed records that are no longer included. (link.springer.com) (www.w3.org) (link.springer.com)

Why do FDA annual-report and public-database counts differ?

They use different populations, dates, verification states, and retention rules. FDA explicitly warns against direct comparison with website search results and backlog-review counts. The FY2024 report is useful as a separately labeled benchmark, not as a validation total for a July 2026 extract. (www.federalregister.gov) (www.federalregister.gov)

Conclusion

An effective FDA PMR/PMC tracker is a **versioned obligation register with public-source lineage**. It keeps PMRs distinct from 506B PMCs; represents application, study, status, and milestone as different entities; and carries both original and revised schedules. Its most useful computations are transparent workload buckets, days to a documented original event, and a quarterly old/new status log. FDA's definitions and Form 3989 supply the semantic baseline, while the public extract supplies dated observations. (hl7.org)

The current public database must be handled within its limits. The displayed update was July 31, 2026 when this report was prepared, but the archive payload was not available to inspect here; no current-file record count or internal column inventory is claimed. FDA's own annual FY2024 figures describe a different cohort, and older fulfilled or released public records leave the rolling display. A trustworthy implementation stores every acquired snapshot, proves its filters, and makes missing or ambiguous mappings visible to the owner who can resolve them. (www.w3.org) (link.springer.com)

That approach makes the tracker useful for escalation and evidence planning without turning an FDA status into an unsupported judgment. It gives regulatory, clinical, safety, and medical-affairs teams a shared view of the next decision, the source behind it, and the age of that source. (database.ich.org) (hl7.org) (intuitionlabs.ai)

Source links

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

1. <https://toolkit.ncats.nih.gov/module/after-fda-approval/after-fda-approval/requirement-and-commitment/>
2. <https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm>
3. <https://www.fda.gov/drugs/postmarketing-requirements-and-commitments-introduction/postmarketing-requirements-and-commitments-downloadable-database-file>
4. <https://www.w3.org/TR/prov-overview/>
5. <https://www.fda.gov/drugs/postmarketing-requirements-and-commitments-introduction/postmarketing-requirements-and-commitments-status-and-fulfillment-categories>
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13. <https://www.fda.gov/drugs/drug-approvals-and-databases/about-postmarketing-requirements-and-commitments-searchable-database>
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25. <https://www.fda.gov/media/194349/download?attachment=>

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