Accelerated Approval Confirmatory Trial Status 2026

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Data cutoff: FDA live-status tables and time-sensitive regulatory-status statements in this article were checked on August 1, 2026. FDA notes that an indication can remain on a status page until product labeling is updated or a Federal Register notice is published.

Executive Summary

The **accelerated approval** (AA) pathway, created by the U.S. Food and Drug Administration (FDA) in 1992 in response to the HIV/AIDS crisis, lets the agency approve a drug on a **surrogate endpoint**, a laboratory or radiographic measure reasonably likely to predict clinical benefit, while a **confirmatory trial** verifies that benefit after the product reaches the market (Source: www.fda.gov). As of August 2026, published cohorts put the pathway's long-run conversion rate to full approval between roughly 50% and 64%, its withdrawal rate between 5% and 23%, and the share still pending confirmatory verification between 15% and 40%, with the range reflecting different cohort periods and denominators rather than a single disputed number (Source: link.springer.com) (Source: friendsofcancerresearch.org).

FDA's own **Project Confirm** database, run by the Oncology Center of Excellence (OCE), showed 56 oncology indications classified as ongoing accelerated approvals—meaning they had not yet converted to traditional approval—and 125 indications with verified clinical benefit as of this report's research window (Source: www.fda.gov) (Source: www.fda.gov). Withdrawals have accelerated sharply since 2021: a Lancet Oncology analysis found 74% of all cancer-indication withdrawals through April 2023 occurred in just the prior three years (Source: www.thelancet.com, and FDA's own withdrawal tables list further pulls through mid-2026, including Xpovio's diffuse large B-cell lymphoma indication (withdrawn April 30, 2026) and Tazverik's epithelioid sarcoma and follicular lymphoma indications (withdrawn June 22, 2026, after a safety signal in the confirmatory SYMPHONY-1 trial) (Source: www.fda.gov) (Source: www.ipsen.com).

The regulatory framework itself changed materially in December 2022, when the Consolidated Appropriations Act, 2023 (commonly called FDORA, the Food and Drug Omnibus Reform Act) amended Section 506(c) of the Food, Drug, and Cosmetic Act to let FDA require confirmatory trials to be **underway before or shortly after approval**, and to streamline the process for withdrawing approvals when sponsors fail to conduct required studies with due diligence (Source: uscode.house.gov). A January 2025 HHS Office of Inspector General (OIG) review of 24 accelerated approval drugs found concerns in

three, two of which are now off the market (Source: oig.hhs.gov), and the pathway remains under active policy debate, with BIO (the Biotechnology Innovation Organization) stating it "strongly opposes efforts to restrict access to innovative therapies approved under the Accelerated Approval Pathway" (Source: www.bio.org) even as Senate oversight continues to press for tighter enforcement.

Multiple named drugs illustrate the range of 2026 outcomes: Leqembi (lecanemab) converted from accelerated to traditional Alzheimer's approval in July 2023 based on the CLARITY AD trial (Source: www.fda.gov), while Aduhelm's accelerated approval was withdrawn in November 2024 after Biogen discontinued the drug and terminated its confirmatory ENVISION trial (Source: investors.biogen.com). In 2026 alone, Bristol Myers Squibb's Krazati (adagrasib) saw its confirmatory Krystal-10 trial miss both primary endpoints in colorectal cancer (Source: endpoints.news), Genentech's Columvi (glofitamab) lost an ODAC vote on extending its lymphoma indication (Source: www.roche.com), and FDA also continued granting fresh accelerated approvals outside oncology, including Otsuka's VOYXACT (sibeprenlimab-szsi) for IgA nephropathy in November 2025 (Source: www.otsuka-us.com). This report walks through the legal architecture governing confirmatory trials, quantifies conversion and withdrawal rates across the major peer-reviewed cohorts, tabulates the withdrawal record and the current at-risk pipeline, compares FDA's pathway to the European Medicines Agency's (EMA) conditional marketing authorisation, and profiles five named case studies to give life-sciences organizations a current, source-verified picture of where accelerated approval confirmatory trial status stands in 2026.

Introduction and Background

FDA's accelerated approval pathway occupies an unusual place in U.S. drug regulation: it grants marketing authorization based on evidence that is, by design, incomplete. Codified for drugs at 21 CFR Part 314, Subpart H and for biologics at 21 CFR Part 601, Subpart E, the pathway allows approval based on a surrogate or intermediate clinical endpoint reasonably likely to predict clinical benefit rather than on a direct measure of how a patient feels, functions, or survives. The tradeoff at the center of the pathway is that sponsors must then complete a **confirmatory trial**, sometimes called a postmarketing requirement (PMR), that verifies the anticipated clinical benefit actually materializes. FDA credits the pathway with getting cancer patients access to anti-cancer therapies a median of 3.1 years earlier than they would otherwise have had (Source: www.fda.gov), but the same design means a meaningful share of approvals eventually prove to lack the promised benefit, or worse, prove harmful.

By August 2026, the accelerated approval pathway has been in continuous use for more than three decades, expanded from its HIV/AIDS origins into oncology (where the large majority of approvals now occur), rare disease, neurology, infectious disease, and other therapeutic areas. Independent tallies put the cumulative total of accelerated approvals granted somewhere between roughly 253 (FDA's own count through December 2020) and 344 (a nonprofit policy analysis through December 2024), reflecting different counting conventions for drug-indication pairs versus individual products (Source: www.fda.gov) (Source: friendsofcancerresearch.org).

This report exists because the pathway has entered a genuinely new regulatory era.

The Consolidated Appropriations Act, 2023, known in the industry as FDORA, gave FDA authority, as appropriate, to require confirmatory trials to be underway before approval or within a specified period afterward, and created an expedited withdrawal process when sponsors fail to pursue required studies with due diligence (Source: uscode.house.gov). Since then, the pace of withdrawals has visibly accelerated: an HHS OIG review found that 13% of all accelerated approvals had been withdrawn as of May 2022, with half of those withdrawals occurring since January 2021 alone (Source: oig.hhs.gov). Life-sciences organizations tracking regulatory intelligence, whether inside a sponsor's regulatory affairs function or an outside advisory practice, now need a current accounting of which drugs converted, which were pulled, and which remain in limbo. This analysis draws on FDA's own Project Confirm database and withdrawal tables, HHS OIG and Government Accountability Office (GAO) reports, EMA's parallel conditional marketing authorisation record, advisory committee transcripts, professional-society and patient-advocacy comment letters, and peer-reviewed cohort studies published through mid-2026 to answer exactly that, section by section: the legal mechanics of confirmatory trial requirements, the program's aggregate conversion and withdrawal statistics, a detailed withdrawal record, a segment-level analysis of where risk concentrates, an international comparison, five named case studies, and the implications for sponsors and regulatory strategy going forward.

The Legal Architecture: How Accelerated Approval and Confirmatory Trials Work

Accelerated approval regulations for drugs sit at 21 CFR Part 314, Subpart H, titled “Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses”; the parallel biologics regulations are at 21 CFR Part 601, Subpart E. The pathway itself was developed in 1992 in response to the HIV/AIDS crisis and was later codified into statute by the FDA Modernization Act of 1997 and expanded by the FDA Safety and Innovation Act (FDASIA) of 2012 (Source: www.fda.gov). Under the pathway, a **surrogate endpoint** (for example, tumor response rate) or an **intermediate clinical endpoint** (for example, progression-free survival) substitutes for a direct measure of clinical benefit such as overall survival, on the premise that the surrogate is "reasonably likely" to predict that benefit.

The critical second half of the bargain is the confirmatory trial. Historically, sponsors could receive accelerated approval with only a general commitment to eventually complete a confirmatory study, and FDA's ability to force the issue when trials stalled was limited. That changed with the Consolidated Appropriations Act, 2023, enacted in December 2022 and commonly known in the industry as FDORA. Section 3210 of that law amended Section 506(c) of the Food, Drug, and Cosmetic Act to state that the Secretary "may require, as appropriate, a study or studies to be underway prior to approval, or within a specified time period after the date of approval, of the applicable product" (Source: uscode.house.gov). FDORA also gave FDA a faster, more explicit withdrawal mechanism, described by industry legal commentary as new regulatory "teeth to ensure that confirmatory trials are conducted expeditiously" (Source: www.thefdalawblog.com), when a "sponsor fails to conduct any required postapproval study of the product with due diligence, including with respect to conditions specified by the Secretary," such as enrollment targets and interim milestones (Source: uscode.house.gov). Notably, industry legal analysis has observed that FDA had never previously defined what "due diligence" means in this context even though the condition "was included in the final rule for the original regulations" back in 1992, and that the years of ambiguity following FDORA's enactment left sponsors facing real uncertainty about how the new authorities would be applied in practice (Source: www.thefdalawblog.com).

FDA has since worked to operationalize these new authorities, issuing two draft guidances in close succession: one from CDER in December 2024, titled "Accelerated Approval - Expedited Program for Serious Conditions," describing procedures for expedited withdrawal and the revisions FDORA made, and a companion Oncology Center of Excellence guidance in January 2025 interpreting exactly what "underway" means for a confirmatory trial at the time of approval (Source: www.fda.gov). FDA's Accelerated Approval Program page also references an Accelerated Approval Coordinating Council report covering 2025 activities required under FDORA Section 3210, and the agency now publishes quarterly reports on accelerated and restricted approvals under both Subpart H (drugs) and Subpart E (biologics) (Source: www.fda.gov), indicating the law also established a standing internal body to oversee the program.

The Oncology Center of Excellence's own transparency initiative, **Project Confirm**, predates FDORA but has become the public face of confirmatory trial tracking. Launched to "promote the transparency of outcomes related to accelerated approval for oncology indications," it maintains a searchable database of all oncology accelerated approvals granted since 1992, organized into ongoing, verified-benefit, and withdrawn categories, and uses the term "dangling" accelerated approval to describe an approval whose confirmatory trial did not verify clinical benefit but whose marketing authorization nonetheless continues (Source: www.fda.gov); a separate 2021 OCE annual report describes the database as listing "all Accelerated Approvals granted in oncology since 1992" (Source: www.fda.gov). FDA's guidance states the agency "may require the confirmatory trial(s) be underway at the time of accelerated approval," a shift toward front-loading confirmatory evidence generation rather than allowing it to begin only after the product is already on the market.

Oversight bodies have continued to scrutinize how these authorities are used in practice. A January 2025 HHS OIG report (OEI-01-21-00400) reviewed 24 accelerated approval drugs and "identified concerns about FDA's use of the accelerated approval pathway in 3 of the 24 drugs" it examined, including instances where FDA evaluated analyses not in a sponsor's original analysis plan or approved a product despite reviewer or advisory committee reservations (Source: oig.hhs.gov). Two of those three flagged drugs are now off the market, and the confirmatory trial for the third has been delayed, according to that same OIG review (Source: oig.hhs.gov). FDA's advisory committee process itself has been in flux during this period: Fierce Biotech reported that the overall number of FDA advisory committee meetings declined by 65% amid Oncology Center of Excellence leadership turnover, before ODAC resumed meeting in April 2026 under new leadership (Source: www.fiercebiotech.com).

Where the Program Stands in 2026: Conversions, Withdrawals, and the Pending Pipeline

FDA's Project Confirm database offers the closest thing to a real-time scoreboard for oncology accelerated approvals. As of this report's research window in 2026, the "Ongoing Cancer Accelerated Approvals" list contained 56 entries (Source: www.fda.gov), while the "Verified Clinical Benefit" list, meaning indications converted to traditional approval, contained 125 entries (Source: www.fda.gov). “Ongoing” identifies an indication that has not yet moved to the verified-benefit or withdrawn category; the label alone should not be used to determine the precise status or completion date of an individual confirmatory trial. FDA directs readers to its Postmarket Requirements and Commitments database and current product information for the status of specific requirements. Because these are live, continuously updated database pages rather than a static annual report, the counts shift as new approvals, conversions, and withdrawals occur. The two lists report distinct status categories and do not supply a defined denominator for calculating the share of an active oncology portfolio that remains pending.

Withdrawal headlines aside, the pathway continues to be used for new approvals outside oncology. FDA's ongoing accelerated-approval table lists Voyxact (sibeprenlimab-szsi), approved November 25, 2025 for reduction of proteinuria in adults with primary IgA nephropathy; Loargys (pegzilarginase-nbln), approved February 23, 2026 for hyperargininemia in patients with Arginase 1 Deficiency; and Kresladi (marnetegragene autotemcel), approved March 26, 2026 for severe leukocyte adhesion deficiency-I (FDA ongoing-indications table.

Table 1 below summarizes how several independent cohort studies, spanning different time windows and using different denominators, have quantified the pathway's overall conversion, withdrawal, and pending rates.

SOURCE	COHORT AND PERIOD	CONVERTED TO FULL APPROVAL	WITHDRAWN	STILL PENDING	MEDIAN TIME TO CONVERSION
FDA-authored 25-year review (Source: pubmed.ncbi.nlm.nih.gov)	93 malignant hematology-oncology indications, Dec. 1992 to May 2017	55% (51 of 93)	5% (5 of 93) (Source: pubmed.ncbi.nlm.nih.gov)	40%	3.4 years
Amgen policy analysis / Springer Ther Innov Regul Sci (Source: link.springer.com) (Source: pmc.ncbi.nlm.nih.gov)	278 total accelerated approvals, all areas, through Dec. 31, 2021	50% (139)	12% (32) (Source: link.springer.com)	38% (107) (Source: link.springer.com)	3.2 years
Cancer-drug 5-year cohort, PMC (2024) (Source: pmc.ncbi.nlm.nih.gov)	46 cancer indications approved 2013 to 2017, followed 5+ years	63% (29)	22% (10)	15% (7)	6.3 years
International Journal of Cancer (2025) (Source: doi.org)	138 oncology indications with completed post-approval assessment, Dec. 1992 to Jan. 2025	77.5%	22.5%	n/a (completed only)	not reported
Friends of Cancer Research (2024) (Source: friendsofcancerresearch.org)	344 total accelerated approvals, all areas, June 1992 to Dec. 2024	54% (189)	13% (45) (Source: friendsofcancerresearch.org)	32% (110) (Source: friendsofcancerresearch.org)	not reported
Peer-reviewed journal analysis (2026) (Source: www.sciencedirect.com)	328 total indications, all areas, through 2024	64%	not reported	not reported	not reported

No two of these cohorts use identical inclusion criteria: some count individual drug-indication pairs, others count unique products; some restrict to oncology, others span all therapeutic areas; and follow-up windows range from a few years to more than three decades. Read together, however, they converge on a consistent picture. Roughly half to two-thirds of accelerated approvals eventually convert to traditional approval, a meaningful minority (5% to 23%, depending on cohort and era) are withdrawn, and the remainder had not converted or been withdrawn at the cohorts' stated cutoff dates. Individual confirmatory-trial progress must be checked separately. The oldest, most mature cohorts (the FDA 25-year review and the Springer 278-approval analysis) show lower withdrawal rates simply because they include the earliest, least scrutinized decades of the program; the newer analyses that emphasize the post-2013 oncology surge show both higher conversion rates and higher withdrawal rates, consistent with a program that resolves cases faster in both directions than it once did.

The Withdrawal Record: Which Accelerated Approvals Have Been Pulled

Withdrawal has become markedly more common, and markedly faster, in the years following the 2021 industry-wide reassessment of checkpoint-inhibitor accelerated approvals and the 2022 FDORA reforms. A Lancet Oncology analysis found that of 23 cancer-indication accelerated approvals withdrawn as of April 2023, 17, or 74%, had been withdrawn in just the preceding three years (Source: www.thelancet.com. The proximate trigger for much of that wave was FDA's April 2021 review of six checkpoint-inhibitor indications whose confirmatory trials had not yet verified clinical benefit, covering products from Bristol Myers Squibb, AstraZeneca, Merck, and Roche (Source: fda.report). Four companies voluntarily withdrew indications even before FDA's Oncologic Drugs Advisory Committee (ODAC) convened (Source: www.raps.org), and the ODAC panel itself voted against continuing pembrolizumab's (Keytruda) gastric cancer indication among others under review (Source: www.healio.com).

Table 2 below lists notable accelerated approval withdrawals dated between 2020 and 2026, drawn directly from FDA's own withdrawn-approvals tables and corroborating primary sources, to illustrate both the pace and the range of therapeutic areas affected.

DRUG (INDICATION)	ACCELERATED APPROVAL GRANTED	WITHDRAWAL DATE	REASON / SOURCE
Opdivo (nivolumab), hepatocellular carcinoma	9/22/2017	7/23/2021	Confirmatory trial did not verify benefit (Source: www.fda.gov)
Imfinzi (durvalumab), urothelial carcinoma	not specified	2/19/2021	Confirmatory trial did not verify benefit (Source: www.fda.gov)
Keytruda (pembrolizumab), gastric/GEJ adenocarcinoma	not specified	2/4/2022	Confirmatory trial did not verify benefit (Source: www.fda.gov)
Tecentriq (atezolizumab), urothelial carcinoma	4/17/2017	12/2/2022	Confirmatory trial did not verify benefit (Source: www.fda.gov)
Makena (hydroxyprogesterone caproate), preterm birth prevention	2011	4/6/2023	Confirmatory Trial 003 failed to show benefit (Source: www.fda.gov)
Pepaxto (melphalan flufenamide), multiple myeloma	2/26/2021	2/23/2024	Confirmatory OCEAN trial showed increased mortality (Source: www.fda.gov)
Trodelvy (sacituzumab govitecan), urothelial cancer	4/13/2021	11/22/2024	Confirmatory trial did not verify benefit (Source: www.fda.gov)
Aduhelm (aducanumab), Alzheimer's disease	6/7/2021	11/1/2024	Sponsor discontinued drug and confirmatory ENVISION trial (Source: investors.biogen.com)
Ocaliva (obeticholic acid), primary biliary cholangitis	2016	11/24/2025	Withdrawn at FDA's request after years without verified benefit (Source: www.reuters.com)
Andexxa (andexanet alfa), anticoagulation reversal	5/3/2018	12/23/2025	FDA reported that ANNEXA-I found more thrombosis with Andexxa than usual care (14.6% versus 6.9%) and concluded the product's risks outweighed its benefits (FDA safety communication.
Elevidys (delandistrogene moxeparvovec), non-ambulatory DMD	6/20/2024	1/12/2026	FDA removed the non-ambulatory indication following reports of fatal acute liver failure and revised the labeling to limit use to ambulatory patients (Source: www.fda.gov) (Source: www.fda.gov)
Xpovio (selinexor), diffuse large B-cell lymphoma	not specified	4/30/2026	Confirmatory trial did not verify benefit (Source: www.fda.gov)
Tazverik (tazemetostat), follicular lymphoma and epithelioid sarcoma	2020	6/22/2026	FDA reported an increased rate of hematologic second primary malignancies in SYMPHONY-1 and stated that the treatment risks outweighed its benefits (FDA safety alert.

Table 2 makes two patterns visible. First, non-oncology withdrawals (Makena, Ocaliva, Andexxa, Elevidys) now occur alongside the oncology-heavy withdrawal wave, showing that confirmatory trial scrutiny has broadened beyond the checkpoint-inhibitor cohort that dominated 2021 and 2022 headlines. Ocaliva had carried its primary biliary cholangitis accelerated approval since 2016 before FDA recorded its withdrawal effective November 24, 2025 (FDA withdrawal table. FDA's Andexxa safety communication reports thrombosis in 14.6% of patients receiving Andexxa versus 6.9% receiving usual care in ANNEXA-I, as well as higher thrombosis-related deaths at day 30; FDA concluded that the product's risks outweighed its benefits (FDA safety

communication. Second, the interval between accelerated approval and withdrawal has compressed for the most recent cases: Elevidys's expanded, non-ambulatory Duchenne muscular dystrophy (DMD) indication was formally withdrawn roughly 19 months after it was granted, after FDA limited use following reports of fatal acute liver failure, a far shorter span than the historical median of 9 to 10 years documented in earlier program eras. Not every scrutinized approval ends in withdrawal, however. Lumakras (sotorasib), for instance, remains under accelerated approval as of 2026 despite a Complete Response Letter denying full approval; Amgen instead received a new postmarketing requirement for a confirmatory trial with a deadline no later than February 2028 (Source: investors.amgen.com), illustrating that FDA's expanded authority under FDORA is being used to reset and enforce timelines, not only to withdraw.

Not every 2025-era confirmatory trial dispute plays out through FDA's withdrawal tables; some now surface first at ODAC itself. In May 2025, the committee voted 8 to 1 that confirmatory STARGLO trial data did not support extending Genentech's Columvi (glofitamab) accelerated approval to a broader U.S. population of diffuse large B-cell lymphoma patients, noting that only 25 of the trial's 274 patients were enrolled in North America (Source: www.targetedonc.com). FDA subsequently issued a Complete Response Letter on the resulting supplemental application in July 2025, but Columvi retains its original 2023 accelerated approval for third-line-or-later disease while a new confirmatory trial is discussed (Source: www.roche.com). At the same session, the committee split narrowly, 4 to 5, over whether a single-arm trial design for UroGen's mitomycin (UGN-102) could support accelerated approval at all, a debate that foreshadowed FDA's broader 2025 push toward requiring randomized rather than single-arm confirmatory evidence (Source: www.lungevity.org).

Analysis of Key Segments: Oncology Concentration, Endpoint Choice, and Timing

Four structural factors explain most of the variation in confirmatory trial outcomes: therapeutic area concentration, the choice of endpoint used in the confirmatory trial, the rigor of the underlying trial design, and the timing of when the confirmatory trial begins relative to approval.

Oncology dominates the pathway, but is not the whole of it. A Government Accountability Office (GAO) review of FDA expedited-program applications from 2006 through 2014 found oncology was already the single most common product area, accounting for 19% of applications across all expedited pathways combined (Source: www.gao.gov). That concentration has only grown: a peer-reviewed analysis found oncology indications accounted for 80% of accelerated approvals granted between 2010 and June 2021 (Source: www.sciencedirect.com), and a University of Pennsylvania health policy analysis puts oncology drugs at more than 85% of all accelerated approvals, with 172 approvals in the most recent decade alone (Source: haclab.org). A JAMA Health Forum analysis of Medicare spending from 2015 through 2019 similarly found that 66 drugs carried at least one accelerated approval indication during that window, of which 49, or 74%, were oncologic (Source: jamanetwork.com) (Source: jamanetwork.com). The remaining, non-oncology quarter spans a genuinely wide range of disease areas, including infectious disease indications such as Arikayce and pediatric Chagas disease treatment, and congressional testimony in early 2026 pointed to non-oncology conversion successes as evidence the pathway works as intended, naming sparsentan for IgA nephropathy, agalsidase beta for Fabry disease, and delandistrogene moxeparvovec for Duchenne muscular dystrophy as accelerated approvals that reached full approval (Source: www.govinfo.gov).

Endpoint choice strongly predicts outcome. A 2025 International Journal of Cancer analysis of 138 oncology accelerated approvals with completed post-approval assessments found that confirmatory trials using a consistent endpoint type as the original approval, for example, overall survival confirmed by overall survival, had zero associated withdrawals, while trials that used a surrogate to confirm a different endpoint type showed materially higher withdrawal rates (Source: doi.org). The same analysis found that solid tumor indications converted to regular approval more often than hematologic malignancies (82% versus 71%), while hematologic malignancies were withdrawn more often (29% versus 18%). Separately, a JAMA Network Open cohort of 102 cancer accelerated approval indications from 1992 through 2022 found that among trials completed by August 2024, only about a third, 34 of 102, or 33%, demonstrated a statistically significant overall survival improvement in the confirmatory trial (Source: jamanetwork.com), underscoring that even a "successful" conversion frequently rests on endpoints short of a direct survival benefit. Within the broader converted-indication set, a similar cancer-focused cohort found that 19 conversions, or 40%, relied on overall survival while 21, or 44%, relied on progression-free survival, with the remainder based on response-rate measures (Source: pmc.ncbi.nlm.nih.gov).

Trial design rigor is itself becoming a distinct axis of scrutiny, separate from endpoint choice. A December 2024 cross-sectional study found that the share of accelerated approvals resting on single-arm pivotal trials had risen sharply before partly reversing, concluding that "measures should be taken to further improve the strength of evidence in Accelerated Approvals" (Source: link.springer.com). A May 2025 BMJ Oncology analysis of 181 postmarketing requirement statements for oncology accelerated approvals found that "PMR statement specificity for oncology AAs varies substantially," with vaguer requirement language linked to faster completion but weaker methodological rigor (Source: bmjoncology.bmj.com). A 2025 eClinicalMedicine cohort study similarly found that "higher withdrawal rates were associated with low ESMO-MCBS scores," meaning drugs with weak clinical-benefit scores at approval were more likely to fail confirmation later (Source: www.thelancet.com, while a December 2024 statistical methodology review found persistent disagreement among researchers over "when single-arm trials remain acceptable" to support accelerated approval, given the broader regulatory push toward randomized confirmatory designs (Source: nejsds.nestat.org).

Timing of trial initiation is the strongest lever FDA now controls. A cohort study of non-oncology accelerated approvals from 2002 through 2018 found that indications whose confirmatory trials were already underway before approval showed markedly higher resolution rates (conversion or withdrawal) than those whose trials had not yet started (Source: pmc.ncbi.nlm.nih.gov). Among approvals where the confirmatory trial started only after the product reached the market, trial initiation itself took a median of 18.5 months to begin, effectively adding a year and a half of delay before confirmatory evidence generation even started (Source: pmc.ncbi.nlm.nih.gov). A separate analysis of the 1992-through-2024 oncology cohort found that the share of accelerated approvals with confirmatory studies already underway at the time of approval rose from 63% in the 1992-to-2013 period to 85% in the 2014-to-2024 period (Source: europepmc.org), alongside median time to conversion falling from 4.3 to 2.3 years and median time to withdrawal falling from 9.5 to 3.2 years across those same two periods (Source: europepmc.org). Together, these figures associate earlier confirmatory-trial initiation with faster resolution times. FDORA gives FDA authority, as appropriate, to require studies to be underway before approval or within a specified period afterward; it does not establish a universal preapproval-trial requirement.

International Context: FDA Accelerated Approval versus EMA Conditional Marketing Authorisation

Life-sciences organizations operating across both U.S. and European markets often ask how FDA's accelerated approval compares with the EMA's parallel mechanism, **conditional marketing authorisation** (CMA). The two pathways share a common logic, approval on "less comprehensive clinical data than normally required" for medicines addressing an unmet medical need (Source: www.ema.europa.eu), but differ sharply in structure. A CMA is "valid for one year and can be renewed annually" until full data are available, forcing an annual reassessment that FDA's accelerated approval does not require in the same explicit way (Source: www.ema.europa.eu), and holders "must fulfil specific obligations within defined timelines" before a CMA can be "converted into a standard marketing authorisation" (Source: www.ema.europa.eu) (Source: www.ema.europa.eu). EMA's own accounting found that in the CMA pathway's first decade, a total of 30 medicines had received a conditional marketing authorisation, and no medicine with a CMA had to be revoked or suspended for safety or efficacy reasons in that period (Source: www.ema.europa.eu) (Source: www.ema.europa.eu), a far lower early-era attrition rate than FDA's program showed over a comparable span.

A real transatlantic difference persists, but the available record does not support describing the withdrawal-rate gap as having narrowed on the basis of both later EU events. A BMJ Open cross-sectional study covering 2006 through 2021 found a measurable "difference in the use of the FDA AA and the EMA CMA," including how the two agencies prioritize postmarketing obligations (Source: bmjopen.bmj.com), while a JAMA Health Forum cohort spanning 2007 through 2021 found nearly identical proportions of indications later rated as having high added therapeutic value by national health technology assessment bodies, 38.9% for FDA accelerated approvals versus 37.5% for EMA CMAs (Source: doi.org). For oncology, the cited Lancet Oncology analysis reported two withdrawn EU CMAs as of April 2023, compared with 23 withdrawn FDA cancer accelerated approvals over a similar period (Source: www.thelancet.com. Ocaliva's later EU revocation followed a failed confirmatory study and is a comparable evidence-related action; Beqvez's withdrawal was requested for commercial reasons and is not evidence about confirmatory-trial enforcement. A 2025 review of EU oncology CMAs found 23 conditional authorisations for advanced or metastatic solid tumors from 2006 through 2024, of which 11 (48%) converted to regular approval and two were withdrawn (Source: www.tandfonline.com).

Ocaliva's 2024 EU revocation shows that EMA can act when post-authorisation evidence fails to confirm benefit; Beqvez's 2025 commercial withdrawal should be considered separately. The European Commission revoked Ocaliva's EU conditional marketing authorisation in 2024 after its confirmatory study, numbered 747-302, "failed to show that Ocaliva was more effective than placebo," a mirror image of the drug's parallel U.S. accelerated approval withdrawal the following year (Source: www.ema.europa.eu). Separately, Beqvez (fidanacogene elaparvovec), granted EU conditional marketing authorisation on July 24, 2024 for haemophilia B, was withdrawn in May 2025 at the holder's own request for commercial reasons before ever reaching the market (Source: www.ema.europa.eu), illustrating that not every EU withdrawal reflects a confirmatory trial failure in the way most FDA accelerated approval withdrawals do. For multinational sponsors and the regulatory affairs teams that support them, the practical takeaway is that CMA's mandatory annual renewal cycle forces a more frequent, formal touchpoint with EMA than FDA's accelerated approval typically requires, even as FDA's post-FDORA reforms are now closing much of that structural gap.

Data Analysis and Evidence

The quantitative record on accelerated approval outcomes has grown substantially richer since 2022, driven by a combination of FDA's own transparency initiatives, congressional and inspector-general oversight, and an active academic literature. Several figures are worth isolating because they recur across independent analyses and because they bear directly on how sponsors and regulatory strategists should model confirmatory trial risk.

On program scale, GAO's earliest comprehensive review found FDA had approved 90 drug applications through the accelerated approval pathway from the program's 1992 creation through late 2008 (Source: www.gao.gov). By December 2020, FDA's own tracking put the cumulative total at 253 (Source: www.fda.gov), and by December 2024 an independent nonprofit analysis counted 344 total drug-indication accelerated approvals (Source: friendsofcancerresearch.org). The pathway also remains a large share of overall FDA activity: in 2024, CDER approved 33 of its 50 new therapies, or 66%, using at least one FDA expedited program (accelerated approval, fast track, breakthrough therapy, or priority review), according to the agency's own year-end summary (Source: www.fda.gov), part of a decades-long compression in FDA review timelines across all pathways that a 2024 Scientific Reports analysis traces back to the original Prescription Drug User Fee Act reforms (Source: www.nature.com).

On confirmatory trial delay specifically, a 2022 HHS OIG review found that of all 278 accelerated approval applications then on record, 104 had incomplete confirmatory trials (Source: oig.hhs.gov), and 35 of those 104 were past their originally planned completion date, including four applications with confirmatory trials that were, in the OIG's words, "significantly late, ranging from more than 5 years to nearly 12 years past their original completion dates" (Source: oig.hhs.gov). That same review found 13% of all accelerated approvals had been withdrawn by that point, half since January 2021 (Source: oig.hhs.gov). An independent University of Pennsylvania health policy analysis cites a similar 23% cumulative withdrawal rate for accelerated approvals granted since 2009, alongside an average 18.5-month delay before sponsors initiate confirmatory trials post-approval (Source: haclab.org) (Source: haclab.org).

On the quality of confirmatory evidence once trials do complete, an April 2026 white paper from the Institute for Clinical and Economic Review (ICER) found that one-third of oncology drugs approved via accelerated approval based on progression-free survival between 2013 and 2017 later converted to full approval without ever demonstrating an overall survival benefit (Source: icer.org). Within the 46-drug, 2013-to-2017 cancer cohort discussed above, fewer than half, 20 of 46, or 43%, actually demonstrated a clinical benefit such as improved overall survival or quality of life in their confirmatory trials (Source: pmc.ncbi.nlm.nih.gov). Conversion to traditional approval is not synonymous with a demonstrated survival or functional benefit. Under 21 U.S.C. § 356(c), FDA must determine, based on postapproval studies, that the product has been shown to verify and describe its clinical benefit. Whether a particular endpoint supports that determination depends on the indication and the totality of the evidence; statistical robustness alone is not the stated standard.

Finally, non-oncology data, while less studied than oncology, shows a comparable pattern: a 2026 peer-reviewed analysis of 328 total accelerated approval indications through 2024 found that 30% were non-oncology (implying roughly 70% oncology across the full historical dataset) and that 64% of the full 328-indication cohort had converted to full approval (Source: www.sciencedirect.com). Taken together, the data-side evidence supports three conclusions relevant to 2026 regulatory strategy: the program's overall conversion rate has likely improved modestly over time even as its withdrawal rate has also risen, largely because faster resolution (in either direction) has replaced the multi-decade limbo state that characterized approvals from the program's first ten to fifteen years; earlier confirmatory-trial enrollment is consistently associated with faster resolution, and FDA may, as appropriate, require a trial to be underway before approval or within a specified period afterward; and a meaningful share of "successful" conversions still rest on surrogate rather than hard clinical endpoints, meaning today's converted approval is not automatically immune from the kind of confirmatory scrutiny that produced the 2021 checkpoint-inhibitor wave.

Case Studies and Real-World Examples

The aggregate statistics above describe a distribution of outcomes; the following five cases illustrate what sits at each end of that distribution, and in the middle, as of 2026.

Aduhelm and Leqembi: Two Alzheimer's Drugs, Two Outcomes

Biogen's Aduhelm (aducanumab) and Eisai and Biogen's Leqembi (lecanemab) both targeted amyloid-beta plaque in Alzheimer's disease and both entered the market through accelerated approval within roughly eighteen months of one another, yet they arrived at opposite outcomes. FDA granted Aduhelm accelerated approval on June 7, 2021, with a required post-approval trial to verify that the drug delivered the expected clinical benefit (Source: www.prnewswire.com) (Source: www.prnewswire.com). On January 31, 2024, Biogen announced it would discontinue Aduhelm entirely and terminate the confirmatory ENVISION study, which the company itself described as "a requirement of FDA accelerated approval" (Source: investors.biogen.com), a decision Biogen attributed to portfolio prioritization rather than safety or efficacy concerns; FDA's own withdrawn-approvals table lists Aduhelm's indication as formally withdrawn effective November 1, 2024 (Source: www.fda.gov).

Leqembi, by contrast, took the fastest possible path through the same pathway. FDA approved Leqembi under accelerated approval in January 2023 and, by July 6, 2023, less than seven months later, converted it to traditional approval based on the confirmatory Study 301, known as CLARITY AD, a Phase 3 randomized controlled trial, calling it the first amyloid beta-directed antibody to be converted from accelerated to traditional approval (Source: www.fda.gov). The contrast between the two drugs illustrates that the pathway's outcome depends far more on whether a confirmatory trial was already positioned to read out quickly (CLARITY AD was substantially complete before Leqembi's accelerated approval) than on the underlying disease area itself.

Makena: A Decade-Long Confirmatory Trial Failure

FDA approved Makena (hydroxyprogesterone caproate) under accelerated approval in 2011 to reduce the risk of preterm birth in women pregnant with one baby who had a history of spontaneous preterm birth. The drug's postmarketing confirmatory study, known as Trial 003, ultimately failed to show that Makena reduced neonatal morbidity and mortality from preterm birth complications (Source: www.govinfo.gov). On April 6, 2023, twelve years after the original approval, FDA's Commissioner and Chief Scientist jointly announced the final decision to withdraw approval of Makena (Source: www.fda.gov). Makena stands as one of the clearest illustrations of the pre-FDORA problem: a full decade separated approval from final resolution. Under current law, FDA may, as appropriate, require confirmatory studies to be underway before approval or within a specified period afterward.

Pepaxto: When the Confirmatory Trial Shows Harm

Pepaxto (melphalan flufenamide) received accelerated approval for relapsed or refractory multiple myeloma on February 26, 2021, for patients who had received at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. Unlike Makena or Aduhelm, whose confirmatory trials simply failed to demonstrate benefit, Pepaxto's confirmatory Phase 3 OCEAN trial showed the drug actually increased the risk of death compared with the active comparator, pomalidomide (Source: www.hematologyadvisor.com). FDA issued its final decision withdrawing approval on February 23, 2024, stating that "the confirmatory study conducted as a condition of accelerated approval did not confirm Pepaxto's clinical benefit" (Source: www.fda.gov). Pepaxto illustrates the sharpest end of confirmatory trial risk: rather than a merely inconclusive result, the trial produced evidence of net harm, the strongest possible justification for FDA's expedited withdrawal authority.

The Sarepta DMD Franchise: Exondys 51, Amondys 45, and Vyondys 53

Sarepta Therapeutics' exon-skipping franchise for Duchenne muscular dystrophy illustrates how long an accelerated approval can remain unresolved even absent a negative safety signal. Exondys 51 (eteplirsen) received accelerated approval on September 19, 2016, "approved under the provisions of accelerated approval regulations (21 CFR 314.500)" (Source: www.accessdata.fda.gov), and its current FDA label still states that "continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials," meaning it remains under accelerated approval roughly a decade after being granted (Source: dailymed.nlm.nih.gov).

The related exon-skipping products, Amondys 45 (casimersen) and Vyondys 53 (golodirsen), reached a confirmatory trial readout in late 2025. Sarepta announced on November 3, 2025 that the confirmatory ESSENCE study "did not achieve statistical significance on its primary endpoint" (Source: investorrelations.sarepta.com), a 4-step ascend velocity measure at 96 weeks that missed significance narrowly, at P equals 0.309 (Source: investorrelations.sarepta.com). Rather than accepting withdrawal, Sarepta stated it intends to meet with FDA "to discuss the possibility of converting from accelerated to traditional approval" despite the missed endpoint (Source: investorrelations.sarepta.com), a request whose outcome remained pending as of this report. The Sarepta franchise underscores that a "failed" confirmatory endpoint does not automatically trigger withdrawal; FDA retains discretion to weigh the totality of evidence, and sponsors can and do contest a strict endpoint-based reading of confirmatory trial results.

Tazverik Withdrawal and Zepzelca’s Unresolved Confirmatory-Trial Failure

Two of the most recent developments in accelerated approval confirmatory trial status both unfolded in the first half of 2026. Ipsen's Tazverik (tazemetostat) received U.S. accelerated approval in 2020 for adults with relapsed or refractory follicular lymphoma, and separately for epithelioid sarcoma (Source: www.ipsen.com). On March 9, 2026, Ipsen voluntarily withdrew Tazverik from all markets, including both indications, after a Data Monitoring Committee reviewing the confirmatory SYMPHONY-1 trial flagged a signal for secondary hematologic malignancies, with SYMPHONY-1 itself having

served as the confirmatory trial required under the follicular lymphoma accelerated approval; FDA's own table lists June 22, 2026 as the formal effective withdrawal date, roughly three and a half months after the voluntary announcement, reflecting the administrative process FDA follows to convert a voluntary market withdrawal into a formal approval withdrawal (Source: www.ipsen.com).

Jazz Pharmaceuticals' Zepzelca (lurbinectedin), meanwhile, illustrates a case still unresolved as of mid-2026. FDA granted Zepzelca accelerated approval for second-line small cell lung cancer in June 2020 based on a single-arm Phase 2 study. On June 12, 2026, Jazz announced that the confirmatory Phase 3 LAGOON trial "did not meet its primary endpoint of overall survival," whether evaluating Zepzelca as monotherapy or in combination with irinotecan (Source: www.prnewswire.com). Trade press coverage noted the failure puts the drug's original accelerated approval "in jeopardy" once again, since an earlier confirmatory trial had also failed to demonstrate an overall survival benefit without triggering withdrawal at that time (Source: www.fiercepharma.com). Notably, the companies emphasized the LAGOON result "does not impact lurbinectedin approval in the first-line maintenance setting," a separate, traditionally approved indication based on the unrelated IMforte trial (Source: pharmamar.com). As of this report, FDA had not yet announced a final withdrawal decision for the second-line accelerated approval indication, leaving Zepzelca as a live example of a confirmatory trial failure working its way through FDA's post-FDORA review process in real time. A comparable dynamic is playing out for Bristol Myers Squibb's Krazati (adagrasib) in colorectal cancer. The KRYSTAL-10 registry identifies progression-free survival and overall survival as primary outcome measures. Trade-press reporting from the 2026 ESMO Gastrointestinal Cancers Congress said the trial did not achieve statistical significance on either endpoint; this preliminary result should not be treated as an FDA determination. FDA's live table continues to list the colorectal-cancer indication as an ongoing accelerated approval, with KRYSTAL-10 as its required postmarketing trial (Source: ClinicalTrials.gov) (FDA ongoing cancer accelerated approvals.

Implications and Future Directions

The confluence of the 2022 statutory amendments, draft agency guidance, and active oversight points toward continued scrutiny of accelerated approvals through the remainder of this decade. Sponsors planning to pursue accelerated approval should plan for the possibility that FDA will require, as appropriate, a confirmatory trial to be underway before approval or within a specified period afterward. FDA's January 2025 draft guidance is nonbinding and describes the agency's interpretation of when a confirmatory trial is "underway." Earlier trial initiation is associated with faster resolution, but outcomes remain product- and indication-specific.

That tighter enforcement is not without internal friction or external pushback. Reporting in late 2025 indicated that Richard Pazdur, CDER's newly appointed director, raised concerns internally about the legality and safety implications of other FDA initiatives aimed at accelerating drug review timelines even further, reflecting real disagreement within the agency about how far expedited review authority should extend (Source: www.biospace.com). Industry groups have pushed in the opposite direction: PhRMA formally asked FDA to "withdraw the Draft Guidance and consolidate all guidance related to accelerated approval into a single document" rather than layering successive rulemakings on top of one another (Source: friendsofcancerresearch.org), while the Senate HELP Committee's February 2026 FDA reform report framed the opposite concern, that "unnecessary bottlenecks slow patients and consumers getting the products they need" (Source: www.help.senate.gov). A February 2026 Senate Special Committee on Aging hearing record cited testimony that FDA had issued at least 23 complete response letters for rare disease therapies since the start of 2025, many considered under accelerated approval, underscoring how contested the pathway's current pace of both approvals and rejections has become (Source: www.govinfo.gov).

Professional societies and patient organizations have weighed in as well, often talking past each other on what "faster" enforcement should mean. ASCO's (American Society of Clinical Oncology) February 2025 formal comments on FDA's draft guidance pressed the agency to "require the confirmatory trials be underway prior to granting accelerated approval" with clearer, more enforceable timelines (Source: www.asco.org), while the National Organization for Rare Disorders (NORD) argued in February 2025 letters to two insurers that "accelerated approval did not create a different standard for drug approval," pushing back against payer policies that delay coverage of accelerated-approval therapies for up to eighteen months after launch (Source: rarediseases.org). The two positions are not strictly contradictory, tighter confirmatory-trial enforcement on the front end and full-approval-equivalent payer treatment on the back end can coexist, but they illustrate how differently clinicians, insurers, and patient groups read the same set of 2025 and 2026 reforms.

FDA's scrutiny is also extending earlier in the development timeline, beyond confirmatory trials into the design of pivotal studies that might later support accelerated approval in the first place. In July 2026, FDA reviewers publicly questioned Replimune's pivotal trial design for its investigational melanoma therapy RP1 ahead of an advisory committee meeting, writing that the study design had not adequately proven the drug's effect (Source: endpoints.news), a case study in how the post-FDORA scrutiny culture is spreading from confirmatory-trial enforcement into pre-approval evidentiary standards more broadly, a pattern consistent with the same single-arm-versus-randomized debate that split ODAC over UGN-102 in 2025. Sponsors and life-sciences organizations should read this combination, tighter confirmatory trial enforcement, industry pushback on guidance proliferation, professional-society and patient-advocacy engagement, and now earlier-stage trial-design scrutiny, as a signal that the current posture, evident in the Tazverik, Andexxa, Ocaliva, and Columvi cases, is likely to persist even as it remains genuinely contested inside and outside the agency.

Looking ahead, three developments are likely to shape accelerated approval confirmatory trial status through 2027 and beyond. First, FDA has published its Accelerated Approval Council Activities Report: CY 2025, which describes the Council's 2025 work and reports 14 new accelerated approvals as of December 4, 2025. It is not, however, a single-source tally of aggregate conversion, withdrawal, and pending figures across all therapeutic areas. Second, the current wave of 2026 confirmatory trial failures, Krazati, Zepzelca, and the Sarepta DMD franchise among them, will test how consistently FDA applies its expedited withdrawal authority when a confirmatory trial narrowly misses statistical significance versus when it shows a clear negative or harmful signal, a distinction that so far has produced different outcomes (Sarepta's continued negotiation versus Tazverik's rapid withdrawal). Third, continued OIG oversight, following the pattern of the 2022 and January 2025 reports, and EMA's 2024 Ocaliva revocation show continued scrutiny of post-authorisation evidence. Beqvez's commercial withdrawal does not establish comparable enforcement tightening or international convergence; the legal mechanisms remain structurally distinct, with FDORA's expedited withdrawal authority on one side of the Atlantic and CMA's mandatory annual renewal on the other.

Frequently Asked Questions (FAQs)

What is FDA's accelerated approval pathway? It is a regulatory pathway under 21 CFR Part 314, Subpart H for drugs and 21 CFR Part 601, Subpart E for biologics. It permits approval for serious or life-threatening conditions based on a surrogate or intermediate clinical endpoint reasonably likely to predict clinical benefit, subject to required post-approval studies.

What are FDA's confirmatory trial requirements under accelerated approval? Since FDORA took effect in December 2022, FDA can require a confirmatory trial to be underway before approval or within a specified period afterward, and can pursue expedited withdrawal if a sponsor fails to conduct that trial with due diligence, including missing agency-specified enrollment or milestone conditions (Source: uscode.house.gov).

What percentage of accelerated approvals convert to full approval? Published cohorts place the figure between roughly 50% and 64% depending on the period studied and the therapeutic area included, with oncology-only cohorts of completed post-approval assessments running as high as 77.5% (Source: link.springer.com).

How many accelerated approvals have been withdrawn, and is a list publicly available? Yes; FDA maintains separate, continuously updated public tables for withdrawn cancer accelerated approvals and withdrawn non-malignant, hematological, neurological, and other disorder accelerated approvals. Independent tallies put the cumulative withdrawal rate between roughly 5% (in the earliest, most mature cohorts) and 23% (in cohorts weighted toward the post-2009 oncology surge) (Source: haclab.org).

What is FDA's Project Confirm tracker? Project Confirm is an Oncology Center of Excellence initiative maintaining a public database of oncology accelerated approvals granted since 1992, sorted into ongoing, verified-benefit, and withdrawn categories. “Ongoing” indicates that an approval has not yet converted to traditional approval; it does not, by itself, establish the status of a particular confirmatory trial.

How does FDA's accelerated approval compare with the EMA's conditional marketing authorisation? Both allow approval on incomplete data for unmet medical needs, but EMA's CMA requires formal annual renewal and has historically shown lower early-era withdrawal rates. Ocaliva's 2024 EU revocation followed unconfirmed clinical benefit, whereas Beqvez's 2025 withdrawal was requested for commercial reasons; the latter should not be used to infer a change in comparative confirmatory-trial enforcement (Source: www.ema.europa.eu).

What happens when a confirmatory trial fails? Outcomes are indication-specific. FDA may withdraw the accelerated approval when the required study fails to verify clinical benefit or is not conducted with due diligence; the applicable statutory framework and the current FDA withdrawal tables are discussed above.

Are more accelerated approvals being withdrawn now than in the past? Yes. A Lancet Oncology analysis found 74% of all cancer-indication accelerated approval withdrawals recorded through April 2023 occurred within just the preceding three years (Source: www.thelancet.com, and FDA's own tables show additional withdrawals continuing into 2026, including Xpovio and Tazverik.

Conclusion

The accelerated approval pathway in 2026 looks structurally different from the pathway that existed even five years ago. Recent observational oncology cohorts report shorter median times to both conversion and withdrawal in more recent approval periods, alongside FDA's new authorities under the 2022 statutory amendments and its January 2025 draft guidance. Those differing cohorts and periods show an association, not proof that the reforms themselves caused faster resolution (FDA draft guidance on confirmatory trials (PubMed: Trends in time to withdrawal and full approval of accelerated approval cancer drug indications. The cohort-specific conversion, withdrawal, and pending estimates are summarized in Table 1.

The cases in this report show that accelerated-approval status remains dynamic: FDA’s public tables record both newly approved indications with outstanding postmarketing requirements and indications withdrawn after subsequent review. For sponsors, confirmatory-trial planning and enrollment should be treated as a core part of an accelerated-approval program. Regulatory, commercial, and medical-affairs teams should monitor FDA's public

status tables and product labeling because an indication’s status can change after launch.

Tags: accelerated approval, confirmatory trial, fda accelerated approval, project confirm, accelerated approval withdrawal, fdora, oncology drug approval, fda regulatory pathway, confirmatory trial requirements, drug approval 2026

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