

Blockbuster Anticlotting Drug Approved on Flawed Studies

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STORY AT-A-GLANCE

- › Ticagrelor, a blockbuster anticlotting drug, was approved despite FDA scientists warning it looked less safe and effective than older, cheaper alternatives like clopidogrel
- › The landmark PLATO trial used to secure approval showed U.S. patients had worse outcomes on ticagrelor, yet those results were overridden by FDA leadership
- › An investigation by The BMJ revealed serious problems with the trial, including altered death records, missing data, and inconsistent monitoring that favored ticagrelor
- › Follow-up platelet studies were also misreported, with non-significant results published as significant and some listed authors denying participation
- › Knowing these flaws allows you to ask your cardiologist informed questions about your treatment and the evidence behind it, and to reduce your underlying cardiovascular risk through lifestyle alongside your prescribed treatment

Ticagrelor (Brilinta) has been promoted for years as a breakthrough in heart care, generating billions in sales and earning top placement in treatment guidelines across the world. It was positioned as a safer, more effective option than older blood thinners, and its reputation gave doctors reason to prescribe it widely.

However, an investigation by The BMJ, published in 2024, renewed concerns about the integrity of the data underlying the drug's popularity. If you are currently taking ticagrelor or another antiplatelet drug, do not stop it based on this controversy. The U.S. Food and Drug Administration (FDA) label for ticagrelor carries a boxed warning stating that

stopping it increases the risk of subsequent cardiovascular events.¹ The risk is best documented in patients with stents.^{2,3} Current guidelines call for dual antiplatelet therapy for at least 12 months after acute coronary syndrome in patients not at high bleeding risk.⁴ The questions raised below are worth taking to your cardiologist, but not a reason to stop a prescribed medication on your own.

FDA Scientists Warned Ticagrelor Was Less Safe Than Advertised

An in-depth investigation published in The BMJ revealed that the blockbuster anticlotting drug ticagrelor was approved over the strong objections of FDA medical reviewers who warned the trial data was unreliable.⁵ The approval hinged on the PLATO trial — the massive study that secured ticagrelor's worldwide approval, which enrolled 18,624 patients across 43 countries.

While the published results claimed a reduction in cardiovascular deaths, heart attacks, and strokes, U.S. patients actually fared worse on ticagrelor compared to clopidogrel (Plavix). This raised serious questions about whether the benefits touted by ticagrelor's maker AstraZeneca were real or manufactured.

- **U.S. patients had worse outcomes** — The FDA's analysis revealed that patients in the U.S. had a 27% higher risk of major cardiovascular events when given ticagrelor, the exact opposite of what was seen in Europe and other regions. AstraZeneca argued that high aspirin doses in the U.S. explained this difference, but FDA scientists rejected that explanation as insufficient. This is a regional subgroup finding rather than the trial's primary result, which is why AstraZeneca was able to contest it. Subgroup analyses are normally treated as hypothesis-generating rather than conclusive; what made this one hard to set aside was that the FDA's own reviewers found the sponsor's explanation for it insufficient.

This matters if you were prescribed ticagrelor in the U.S., the region where the drug performed poorly in this analysis. It is worth raising with your cardiologist, who is best placed to weigh it against your own history.

- **Lead FDA reviewer sounded the alarm** — Dr. Thomas Marciniak, a medical officer at the FDA known for his rigorous reviews, concluded in a 47-page memo that ticagrelor appeared inferior in both safety and efficacy. He described AstraZeneca's submission as “the worst in my experience regarding completeness of the submissions and the sponsor responding completely and accurately to requests.”

His recommendation was to deny approval. Despite this, FDA leadership approved the drug.

- **Data monitoring raised red flags** — Another alarming detail from the investigation was that AstraZeneca monitored most trial sites themselves, except in four countries where independent organizations oversaw the process. In those four independently monitored countries — including the U.S. — ticagrelor performed worse than clopidogrel.

Where the sponsor oversaw data collection, ticagrelor appeared superior. This inconsistency suggests that oversight and data handling may have shaped the reported outcomes.

- **Endpoint adjudication errors** — The BMJ also confirmed that adjudicators — those tasked with classifying patient outcomes — correctly added 45 heart attacks (myocardial infarctions) to the clopidogrel group but none to the ticagrelor group. As noted in the BMJ paper:

“In his now unsealed legal complaint from 2012, Victor Serebruany alleged that PLATO’s adjudicators added 45 MIs to the clopidogrel group, ‘and precisely zero additional MIs for . . . ticagrelor.’ The BMJ was able to confirm Serebruany’s numbers. FDA records show that according to site reports there were 504 subjects with MIs on ticagrelor compared with 548 on clopidogrel. Following adjudication, the count increased only for clopidogrel—to 593.

Using trial datasets first obtained from the FDA by Serebruany and subsequently verified through a freedom of information request by The BMJ—which contains both pre-adjudication and post-adjudication judgments—we also found an imbalance among 20 death category decisions that the adjudication committee was in ‘major’ disagreement over and ultimately could not resolve: 17 were in the clopidogrel arm while only 3 were in ticagrelor. The disparity raises questions over the possibility of unblinding.

Despite unresolved disagreements over the 20 deaths, a final post-adjudication cause of death classification was recorded. But in six cases, it flipped whether or not the event met the primary endpoint definition compared with the cause of death attribution provided by site investigators. In every case, The BMJ found the change in attribution favoured ticagrelor.”

- **Mechanism of harm tied to bleeding and misclassified events** — The trial design used a primary endpoint that combined death from vascular causes, heart attack, or stroke. This meant even small shifts in how events were classified could tip the scales.

When deaths or heart attacks were reclassified in ticagrelor's favor, the appearance of benefit emerged. For you, this demonstrates how outcome definitions — not just biology — determine whether a drug is labeled a “life saver” or a “risky bet.”

What you can take from this is not just about ticagrelor but about the system itself. If a multibillion-dollar drug could be approved over scientific objections, it shows how important it is to ask questions, look at alternatives, and demand transparency in how medical data is reported.

Key Platelet Studies Were Riddled with Errors

The 2024 BMJ investigation exposed major data integrity problems in the PLATO trial, casting doubt on whether the drug truly offers an advantage over cheaper rivals.⁶ A year later, as generic versions were set to hit the market, The BMJ conducted a follow-up

investigation focused on the two smaller platelet studies — ONSET/OFFSET and RESPOND — that AstraZeneca used to defend ticagrelor's effectiveness in acute coronary syndrome.⁷ They too appear to have some problems.

- **Studies were inaccurately reported, casting serious doubt on AstraZeneca's claims** — These trials were central to convincing regulators and doctors that ticagrelor worked better, yet the primary endpoint results were misstated in *Circulation*, a leading cardiology journal.^{8,9}
- **Participants faced extreme and unusual demands** — Patients in these platelet studies, who had stable coronary artery disease, were required to give large amounts of blood — up to 604 milliliters across visits, which is more than a full unit donated at a blood bank. Typically, platelet studies involve just one or two blood draws, but AstraZeneca's required six within a single eight-hour period.

As one trial investigator admitted, only the most committed participants could endure that burden. This unusual setup raises questions about whether the data reflected typical patients or only those willing to undergo intense procedures, which directly impacts whether the results apply to real life.

- **Data gaps and missing records weakened credibility** — The BMJ investigation found that more than 60 platelet readings were missing from the datasets submitted to the FDA. Even worse, some of the excluded results showed significantly higher platelet activity, suggesting ticagrelor did not inhibit clotting as strongly as advertised.

Implausible readings, such as platelet activity increasing after treatment, were included in final analyses, but instead of being flagged, they were hidden through unpublished “data adjustments.” The findings show that key data was either mishandled or left out.

- **Authorship was misrepresented** — Several individuals listed as study authors later denied involvement, while others who actively recruited patients were excluded. For example, Tonny Nielsen, identified as a Danish investigator and author, stated

outright, “I did not participate in the RESPOND study.” Conversely, a Baltimore physician who enrolled 12 patients wasn't credited.

Even the Study Methods Introduced Bias

Platelet aggregation, the lab test used to measure clotting, is notoriously sensitive to timing and technique. Experts told The BMJ that such tests are best done at a single site to ensure consistency, yet AstraZeneca spread them across 10 sites in multiple countries.¹⁰

The investigation could not confirm whether all staff received proper training, increasing the chance of inconsistent results. This has safety implications, because if platelet function was measured improperly, the claims about ticagrelor's effectiveness lose validity.

RESPOND originally showed non-significant results, meaning ticagrelor did not reliably outperform clopidogrel. But by changing the definition of the primary endpoint, the published paper reported it as significant. That single shift turned ticagrelor into a “winner.” Victor Serebruany, a Johns Hopkins pharmacologist and one of ticagrelor's earliest critics, summarized it bluntly: “If doctors had known what happened in these trials, they would never have started using ticagrelor.”¹¹

This means that the trust placed in ticagrelor's science was misplaced, and potentially safer drugs like clopidogrel were pushed aside based on faulty evidence. One caution on the comparison: What these investigations undermine is the claim that ticagrelor is superior to clopidogrel. That is not the same as establishing that clopidogrel is the safer choice for any particular patient — it has its own limitations, including reduced effectiveness in people who metabolize it poorly. Which antiplatelet suits you is a clinical question, not one this evidence settles.

How to Protect Yourself from Flawed Drug Approvals

The truth about ticagrelor's approval process is unsettling. When a drug is pushed through despite serious doubts about safety and effectiveness, you're left vulnerable. But you're not powerless here. If you've been prescribed an anticlotting drug after a heart procedure, or if you're caring for a loved one in that position, these steps can help you move forward. None of them involves changing, reducing, or stopping a prescribed medication on your own — every one of those decisions must be discussed with and supervised by your cardiologist.

- **Question the strength of the evidence** — Before starting any drug, look into whether the key studies supporting it had problems with data accuracy, missing information, or conflicting results. In this case, ticagrelor's studies were riddled with errors and misreporting, and concerns about the data were not secret. Several post-licensure studies have also reported disappointing results. When you ask “What does the cumulative evidence suggest?” you set yourself up for better decisions.
- **Reduce your underlying cardiovascular risk** — Lowering your cardiovascular risk through diet, movement, and reducing toxic exposures is worth doing on its own terms. (One distinction matters, though: Ticagrelor is prescribed after acute coronary syndrome or a stent, to stop a clot forming on a damaged or stented artery wall. Improving your diet does not remove the need for it.) For general health, cut vegetable oils from your diet, avoid ultraprocessed foods, increase your intake of whole-food carbohydrates, and build strength through daily walking and regular resistance training. These changes support cardiovascular health over the long term.
- **Track your progress with the right markers** — Instead of relying on outdated measures like total cholesterol, focus on health tests that actually reflect your metabolic health. Monitor your HOMA-IR score to track insulin resistance, check fasting glucose, and keep an eye on your triglyceride-to-HDL ratio.

You can also use a simple blood pressure cuff at home to watch for improvements in circulation. Treat these numbers like checkpoints — improvement is a sign your daily choices are moving in the right direction.

- **Stay informed and proactive about drug safety** — Don't assume that just because a drug is FDA-approved, it's the best choice. The ticagrelor case shows that approval does not guarantee the underlying evidence was sound. Read investigations, follow updates from independent researchers, and ask yourself whether the benefits outweigh the risks. Knowledge puts you in charge, not the system.

FAQs About the Anticlotting Drug Ticagrelor

Q: What is ticagrelor and why is it prescribed?

A: Ticagrelor, sold as Brilinta, is an anticlotting drug widely prescribed for patients with acute coronary syndrome, which includes heart attacks and unstable chest pain. It was marketed as superior to clopidogrel, an older and cheaper drug, based on clinical trial data that is now under serious scrutiny.

Q: Why are experts questioning the approval of ticagrelor?

A: The FDA's own medical reviewers warned that ticagrelor performed worse than clopidogrel in U.S. patients and flagged major data quality issues in the landmark PLATO trial. Despite those warnings, FDA leadership approved the drug. Later investigations found missing data, altered death records, and inconsistencies that all favored ticagrelor.

Q: What problems were uncovered in follow-up studies?

A: A 2025 BMJ investigation revealed that key platelet function studies used to support ticagrelor's approval were misreported. Non-significant results were published as significant, more than 60 platelet test results were missing from FDA datasets, and some study authors denied involvement. These flaws raise serious

doubts about whether ticagrelor truly offers benefits.

Q: How does this affect me if I've been prescribed ticagrelor?

A: If you're on ticagrelor, you should know that its supposed advantages are not backed by consistent or reliable science. Patients in the U.S. — the very population where the drug was most heavily promoted — actually experienced worse outcomes, including higher risks of heart events. What it does not mean is that you should stop taking it. Ticagrelor's label carries a boxed warning that stopping increases the risk of cardiovascular events, and stopping antiplatelet therapy early after a stent carries a well-documented risk of stent thrombosis. Bring your concerns to your cardiologist and decide together.

Q: What steps can I take to protect myself?

A: You can reduce reliance on flawed drugs by asking your cardiologist about the alternatives and the evidence behind them, questioning the quality of evidence before starting new prescriptions, lowering your cardiovascular risk through diet and lifestyle, tracking your progress with simple health tools, and staying informed about drug safety investigations.

This article is for informational purposes only and does not constitute medical advice. Consult a qualified healthcare provider before making changes to your health regimen. Do not stop or change a prescribed medication without speaking to the clinician who prescribed it.

Sources and References

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