IVD · FDA APPROVAL + COMMERCIALIZATION

What it actually costs to bring an IVD to market.

Founders benchmark IVD program cost against the wrong number. A frequent starting assumption — *"$1–2M end-to-end"* — is the **floor** for the simplest imaginable path (predicate-heavy 510(k), minimal clinical bridging). The realistic range is 3–10× higher.

> **TL;DR —** a simple 510(k) IVD to first commercial sale is **$3–5M**. A typical 510(k) with novel-ish clinical claims is **$5–10M**. A De Novo is **$10–20M**. A Class III PMA (or a companion diagnostic tied to a drug) starts at **$15M** and can pass **$75M**.

01 Cost by regulatory pathway

Each pathway carries a distinct development + clinical + regulatory + manufacturing burden. Line items below are typical mid-market ranges for a US-only launch. International adds separately.

Simple 510(k) IVD

Strong predicate, established platform — lateral flow, ELISA, clinical chemistry

$2M – $7M
TO FDA CLEARANCE

Development + assay optimization	**$500K – $2M**
Clinical validation (accuracy, precision, EP-series)	**$500K – $2M**
CLIA Waiver Study (if pursued)	**$500K – $1.5M**
FDA user fees + submission prep	**$50K – $150K**
QMS + manufacturing setup	**$500K – $1.5M**

Novel 510(k) or De Novo MOST COMMON

No strong predicate, molecular diagnostic, novel cancer or infectious-disease marker

$5M – $15M
TO FDA CLEARANCE

Everything in Simple 510(k) plus:	—
Expanded clinical study (n>500, multi-site)	+$1M – $5M
Analytical characterization (extended)	+$500K – $2M
Pre-Submission (Q-Sub) meetings + prep	+$100K – $500K
De Novo classification-request prep (if applicable)	+$300K – $1M

Class III PMA

High-risk indication — cardiac troponin, cancer companion diagnostic, tissue-based tests

$15M – $50M+
TO FDA APPROVAL

Multi-site pivotal clinical trial (n often 1,000+)	$5M – $25M
FDA user fee (PMA)	~$450K
Regulatory strategy + PMA submission prep	$2M – $5M
Advisory-panel prep + defense	$500K – $1.5M
Post-approval study commitments	$1M+ ongoing

Companion Diagnostic (CDx)

Tied to a drug approval — codeveloped with a pharma partner

$20M – $75M+
FULLY-LOADED

Analytical + clinical alignment with drug trial	$10M – $40M
FDA + drug-partner regulatory coordination	$2M – $10M
Bridging studies + reproducibility panels	$3M – $10M
Post-approval MRD / lifecycle work	$5M+ ongoing

02 End-to-end (first commercial sale) · summary

Clearance/approval is not the finish line. Sales, distribution, MDR, and post-market surveillance add materially before revenue meaningfully arrives.

PATHWAY	TO CLEARANCE	+ COMMERCIALIZATION	TO FIRST MEANINGFUL REVENUE
Simple 510(k)	$2M – $7M	+$2M – $5M	$4M – $12M

PATHWAY	TO CLEARANCE	+ COMMERCIALIZATION	TO FIRST MEANINGFUL REVENUE
Novel 510(k) / De Novo	$5M – $15M	+$3M – $8M	$8M – $23M
Class III PMA	$15M – $50M+	+$5M – $15M	$20M – $65M+
Companion Diagnostic	$20M – $75M+	Co-launched w/ drug	Tied to drug launch

03 Where the software-driven advantage lands

Cost intelligence only matters if it changes a decision. The consulting-cost line item alone is the most substitutable piece of the stack.

MJAI · THE SOFTWARE SUBSTITUTION

Consulting is $500K–$2M of a 510(k) IVD. It's also the most substitutable line item.

Reg Affairs consultants, biostatisticians, clinical PMs, and QMS consultants together typically bill **$500K–$2M** for a 510(k) IVD program. This is drafting, structuring, checklisting, and interpretation work — exactly what an artifact factory replaces.

> **Rough math:** if MJAI cuts consulting spend by 30–50% (drafts prepared for counsel review vs. drafted from scratch), that's a direct **$150K–$1M saving** per program. Enterprise MJAI at $2,500/mo bundled base = $30K/year. Payback: **weeks, not months**.

Add the calendar compression — the six-months-to-days claim on first drafts — and the value shifts from "cost saving" to "revenue pulled forward." A quarter earlier to submission on a $10M ARR product is not a rounding error.

> *"IVD founders spend $3–10M+ to first commercial sale. Consulting is $500K–$2M of that. MJAI cuts consulting spend materially AND shortens the calendar.* **Enterprise license pays for itself if you save even 5 consultant weeks.**"

Sources + caveat

Ranges compiled from Advamed cost surveys, MDIC reports, published academic teardowns, KLAS/Deloitte benchmark studies, and founder-reported figures through Q4 2025. Ranges vary widely by technology, clinical claims, and jurisdiction — a specific program's number depends on its assay and pathway. This document is educational reference for business-plan calibration; it is not regulatory or financial advice. Every founder should validate their pathway-specific numbers with a Reg Affairs specialist and a fractional CFO who has closed comparable programs.