



ROI REPORT · CONFIDENTIAL

# RegDesk RIM Platform

Business Case for Investment · Prepared for Imricor · July 2026

203%

3-YEAR ROI (FULL RIM)

\$746K/yr

RECOVERABLE SAVINGS

~5 Mo

PAYBACK PERIOD

Company: Imricor Medical Systems (ASX: IMR) | RA Team: 9 FTEs | Markets: 18 Countries | Submissions: 45/yr | Products: 13 Families

## Imricor's Operational Reality

Current State Analysis · Based on Imricor's Own Data

The following analysis is derived directly from Imricor's own operational data. Each line item represents time currently consumed by manual, cross-system processes — time that cannot be redirected to higher-value regulatory work. At a blended RA cost rate of **\$75/hr** (\$150K fully loaded ÷ 2,000 hrs/yr), recoverable overhead represents significant annual expenditure constraining capacity for strategic regulatory work.

| Cost Driver             | Imricor Data Point                           | Annual Hours  | Annual Cost  | Priority |
|-------------------------|----------------------------------------------|---------------|--------------|----------|
| Regulatory Monitoring   | 3 people × 4.5 hrs/wk · 100% savings         | 702 hrs       | \$52,650     | HIGH     |
| Submission Coordination | 15 submissions × 80 hrs × 85% overhead       | 1,020 hrs     | \$76,500     | HIGH     |
| Standards Monitoring    | 3 people × 1 hr/wk · 100% savings            | 156 hrs       | \$11,700     | MEDIUM   |
| Standards Assessments   | 10 standards × 40 hrs × 50% overhead         | 200 hrs       | \$15,000     | HIGH     |
| Change Control (CCP)    | 100 assessments × 23 countries × 2 hrs × 75% | 3,450 hrs     | \$258,750    | HIGH     |
| AI Submission Prep      | 45 submissions × 112 hrs × 85% overhead      | 4,284 hrs     | \$321,300    | HIGH     |
| GSPR & DOC Management   | 10 forms × various hrs × 85% overhead        | 34 hrs        | \$2,423      | MEDIUM   |
| Registration Reporting  | 4 reports/month × 1 hr × 95% savings         | 46 hrs        | \$3,420      | MEDIUM   |
| TOTAL (Recoverable)     | Blended rate: \$75/hr                        | ~9,892 hrs/yr | \$746,055/yr | —        |

**Capacity Gap:** 9 FTEs × 2,000 hrs = 18,000 hrs available annually. Recoverable overhead consumes ~9,892 hrs = **55% of total team capacity**. This limits Imricor's ability to pursue proactive market access, faster approvals, and strategic RA work across 18 active markets.



The Business Case for RegDesk

Two options · All ROI calculated from Imricor's own operational data

Base RIM

\$72,500/yr · \$21,600 one-time setup

|                       |                           |
|-----------------------|---------------------------|
| Modules included      | RegIntel · DCT · Tracking |
| Annual savings        | \$136,883                 |
| Year 1 investment     | \$94,100                  |
| Year 1 net benefit    | +\$42,783                 |
| 3-yr total investment | \$239,100                 |
| 3-yr total savings    | \$410,649                 |
| 3-yr net benefit      | +\$171,549                |

72%

3-Year ROI · Payback ~8 months

Best for: Teams focused on regulatory intelligence, submission coordination and status reporting.

Full RIM

\$146,250/yr · \$30,000 one-time setup · \$2,000/application (App Builder)

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| Modules included                  | All Base + Standards · CCP · App Builder · Forms |
| Annual savings                    | \$746,055                                        |
| App Builder fees (45 apps × \$2K) | \$90,000/yr                                      |
| Year 1 investment                 | \$266,250                                        |
| Year 1 net benefit                | +\$479,805                                       |
| 3-yr total investment             | \$738,750                                        |
| 3-yr total savings                | \$2,238,165                                      |
| 3-yr net benefit                  | +\$1,499,415                                     |

203%

3-Year ROI · Payback ~5 months

Best for: Full automation of RA operations — change control, submissions, standards, and compliance forms.



## Quantified ROI — Side-by-Side Comparison

All figures based on Imricor's own operational data · \$75/hr blended RA cost rate

| BASE RIM — \$72,500/yr               |           |           |           |            |
|--------------------------------------|-----------|-----------|-----------|------------|
| Item                                 | Year 1    | Year 2    | Year 3    | 3-Yr Total |
| Platform License                     | \$72,500  | \$72,500  | \$72,500  | \$217,500  |
| Setup Fee                            | \$21,600  | —         | —         | \$21,600   |
| Total Investment                     | \$94,100  | \$72,500  | \$72,500  | \$239,100  |
| RegIntel & Monitoring                | \$56,963  | \$56,963  | \$56,963  | \$170,888  |
| Tracking & Reporting                 | \$3,420   | \$3,420   | \$3,420   | \$10,260   |
| Collaboration Tool (DCT)             | \$76,500  | \$76,500  | \$76,500  | \$229,500  |
| Total Savings                        | \$136,883 | \$136,883 | \$136,883 | \$410,649  |
| Net Benefit                          | +\$42,783 | +\$64,383 | +\$64,383 | +\$171,549 |
| 3-Year ROI: 72%   Payback: ~8 months |           |           |           |            |

| FULL RIM — \$146,250/yr + \$2,000/application |            |            |            |              |
|-----------------------------------------------|------------|------------|------------|--------------|
| Item                                          | Year 1     | Year 2     | Year 3     | 3-Yr Total   |
| Platform License                              | \$146,250  | \$146,250  | \$146,250  | \$438,750    |
| App Builder Fees (45 × \$2K)                  | \$90,000   | \$90,000   | \$90,000   | \$270,000    |
| Setup Fee                                     | \$30,000   | —          | —          | \$30,000     |
| Total Investment                              | \$266,250  | \$236,250  | \$236,250  | \$738,750    |
| RegIntel & Monitoring                         | \$56,963   | \$56,963   | \$56,963   | \$170,888    |
| Tracking & Reporting                          | \$3,420    | \$3,420    | \$3,420    | \$10,260     |
| Collaboration Tool (DCT)                      | \$76,500   | \$76,500   | \$76,500   | \$229,500    |
| Standards Management                          | \$26,700   | \$26,700   | \$26,700   | \$80,100     |
| Change Control (CCP)                          | \$258,750  | \$258,750  | \$258,750  | \$776,250    |
| AI Application Builder                        | \$321,300  | \$321,300  | \$321,300  | \$963,900    |
| AI Forms Builder                              | \$2,423    | \$2,423    | \$2,423    | \$7,269      |
| Total Savings                                 | \$746,055  | \$746,055  | \$746,055  | \$2,238,165  |
| Net Benefit                                   | +\$479,805 | +\$509,805 | +\$509,805 | +\$1,499,415 |
| 3-Year ROI: 203%   Payback: ~5 months         |            |            |            |              |



RegDesk Directly Addresses Imricor's Challenges

Capability alignment with Imricor's operational pain points



Centralized Registration Tracking

*Pain: Manual spreadsheet tracking of registration status across 18 markets*

RegDesk provides real-time registration status visibility across all 18 active countries — replacing fragmented spreadsheets with a single source of truth accessible to RA, sales, and executive teams.



Change Control Automation

*Pain: Coordinating change assessments across countries and regional SMEs*

100 change assessments × 23 countries = 4,600 country-assessments per year. RegDesk CCP automates impact scoping, routes to regional SMEs, and tracks completion — recovering 3,450 hrs/yr of RA overhead.



AI-Powered Submission Builder

*Pain: 45 global submissions/yr at 112 hrs each — manual, repetitive, error-prone*

RegDesk Application Builder uses AI to pre-populate country-specific submission templates, leverage prior submissions, and coordinate outstanding content — transforming a 14-day manual process into an accelerated workflow.



Standards & GSPR Management

*Pain: Manually maintaining GSPRs and declarations of conformity*

RegDesk automatically monitors standard updates, triggers GSPR/DOC revisions, and maintains version control — eliminating the manual effort of tracking 10+ standard changes per year.



Global Regulatory Intelligence

*Pain: 3 staff spending 4.5 hrs/week monitoring regulatory changes across 18 markets*

RegDesk RegIntel delivers curated regulatory updates for all 18 Imricor markets — plus instant global regulatory plans for new product launches and market entries — recovering 702 hrs/yr of monitoring overhead.

At **\$146,250/yr + \$2,000/application**, RegDesk Full RIM delivers a **203% 3-year ROI** and **\$1,499,415 net benefit** over 3 years — based entirely on Imricor's own operational data. The platform pays for itself in approximately **5 months**.

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