RevRx AI Consulting

MEDTECH LAUNCH GUIDE

# From FDA Authorization to Sustainable Revenue

## Authorization is the starting line. Here is what to build next.

For MedTech CEOs and commercial leaders launching a newly authorized device.

Before launch · Launch · First accounts · Scale

# Authorization Is Not Revenue

FDA authorization lets you sell your device in the US. It does not get your device bought, paid for, or used. Those are separate jobs, and each one needs an owner.

QUESTION 1

## Can they buy it?

Hospital approval, a contract, and the device set up in the hospital's purchasing system.

CHECK **Do we know how each first account will buy?**

QUESTION 2

## Can they get paid?

The right codes, payer coverage, and payment for the procedure.

CHECK **Do sites know how to bill for it?**

QUESTION 3

## Will they use it?

Training, the first case, and support during the case.

CHECK **Who supports the first case?**

QUESTION 4

## Will they keep using it?

Outcomes, ongoing support, and reorders.

CHECK **How will we show results after case one?**

**If you cannot answer all four, you are not ready to launch. You are ready to plan.**

COPY THIS PROMPT INTO YOUR AI TOOL. FILL IN THE BRACKETS.

For **[device]** used in **[care setting]**, answer four questions: Can they buy it? Can they get paid? Will they use it? Will they keep using it? For each one, list what we know, what we still need to verify, and who should own it. Do not assume payer coverage or hospital approval. If you are missing information, ask me for it instead of guessing.

# Are You Ready to Launch?

Score each item before you spend on launch. Be honest. A “Missing” today costs less than a stalled launch later.

| ITEM | WHAT “READY” MEANS | READY | PARTIAL | MISSING |
|---|---|---|---|---|
| **Evidence** | You have data that answers the questions physicians, value analysis committees, and payers will ask | ☐ | ☐ | ☐ |
| **Reimbursement** | You know which codes apply, coverage status with key payers, and how sites will bill | ☐ | ☐ | ☐ |
| **Contract path** | You know whether each target account buys through a group purchasing organization (GPO), a local agreement, or a letter of access | ☐ | ☐ | ☐ |
| **Pricing** | You have a price and a value story that hospital finance can follow | ☐ | ☐ | ☐ |
| **Training** | You have a short, repeatable training plan for physicians and staff | ☐ | ☐ | ☐ |
| **Support** | You know who covers the first cases and how fast they can get there | ☐ | ☐ | ☐ |
| **Team** | You have a named owner for sales, clinical support, reimbursement, and contracting | ☐ | ☐ | ☐ |

Any “Missing” is a launch risk. **Fix it before you scale.**

COPY THIS PROMPT INTO YOUR AI TOOL. FILL IN THE BRACKETS.

Score our launch readiness for [device] using this checklist: evidence, reimbursement, contract path, pricing, training, support, and team. Mark each item Ready, Partial, or Missing, and give one next step for each. Use only these facts: [paste what you know]. Do not fill in gaps with assumptions. List any facts you would need to score an item with confidence.

# Your First Accounts Set the Pace

Your first accounts are where you prove the device works in the real world. Pick them for proof, not for big names.

| | |
|---|---|
| **Champion physician** | A physician who wants the device and will push for it inside the hospital. |
| **Case volume** | Enough procedures to build experience and results quickly. |
| **Contract access** | A clear way to buy, through a GPO, local agreement, or letter of access. |
| **A committee that moves** | A value analysis process that reviews new products on a steady schedule. |
| **Sister hospitals** | Part of a health system where one win can open the door to other sites. |

| CRITERIA | ACCOUNT A | ACCOUNT B | ACCOUNT C |
|---|---|---|---|
| **Champion physician** | | | |
| **Case volume** | | | |
| **Contract access** | | | |
| **A committee that moves** | | | |
| **Sister hospitals** | | | |
| **Total** | | | |

Scoring key: 1 = weak, 2 = some, 3 = strong

**A big name with no champion and a slow committee can stall your launch.**

COPY THIS PROMPT INTO YOUR AI TOOL. FILL IN THE BRACKETS.

Here is my list of target accounts with what I know about each: **[list accounts with champion, case volume, contract status, committee timing, and health system ties]**. Rank the best first launch accounts and explain why. Score each account 1 to 3 on champion physician, case volume, contract access, committee speed, and sister hospitals. Flag any missing data instead of guessing.

# Who Sells and Who Supports

Before you launch, decide how you will cover your territories and who owns each part of the work.

| | DIRECT REPS | DISTRIBUTOR | INDEPENDENT REPS |
|---|---|---|---|
| **Control** | High | Lower | Medium |
| **Speed to cover territory** | Slower to build | Fast, uses existing reach | Fast, uses existing relationships |
| **Cost type** | Mostly fixed (salary and benefits) | Variable (distributor margin) | Variable (commission) |
| **Training effort** | You train and manage fully | Shared; your product competes with others in their bag | Shared; your product competes for rep time |
| **Best when** | You have funding and need tight control | You need reach fast across many accounts | You need coverage in select territories |

### Name an owner for each part of the work

**Sales:** Owner _____ **Clinical support:** Owner _____

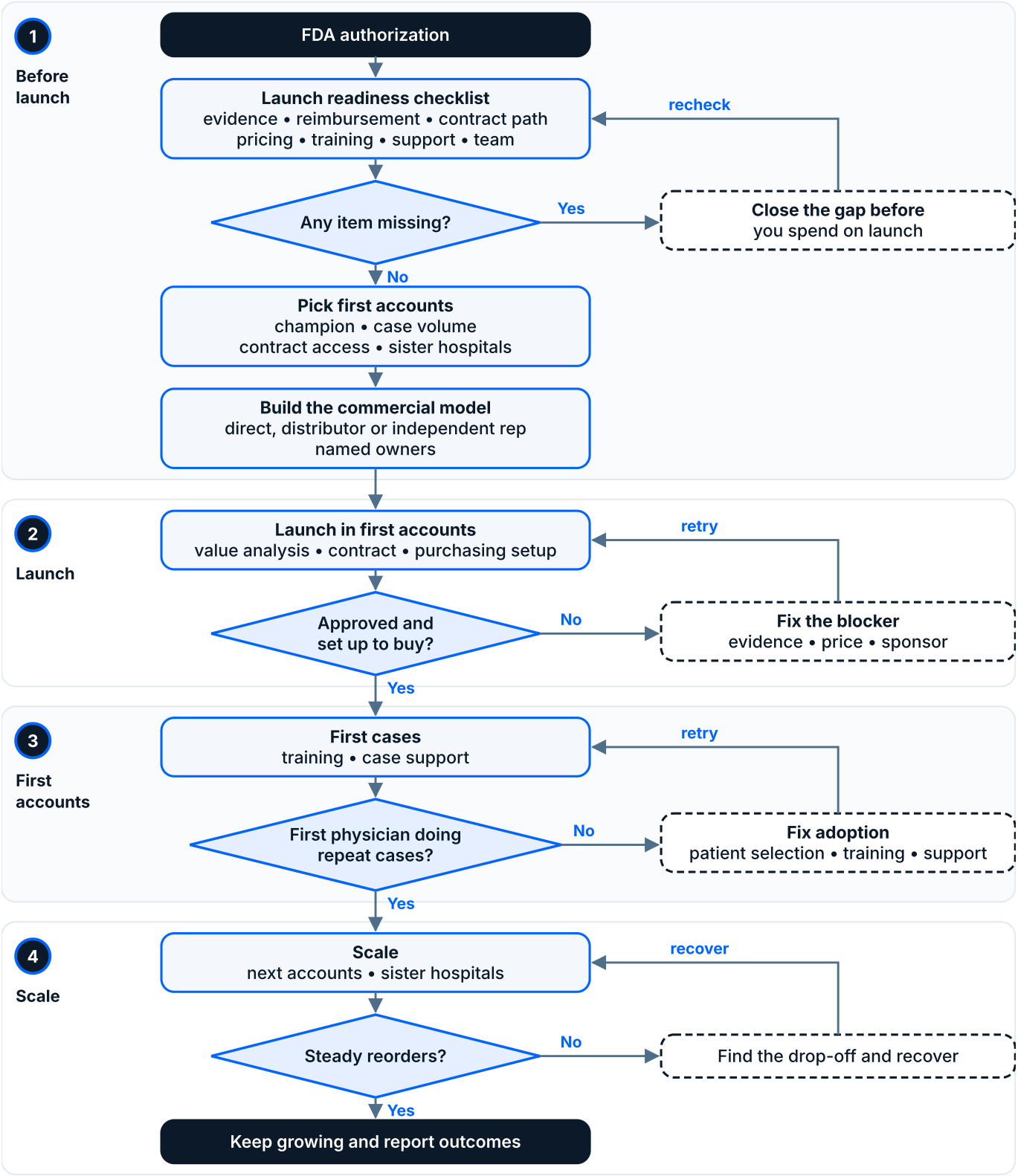
**Reimbursement:** Owner _____ **Contracting:** Owner _____

**Go deeper:** Distributor and Independent Rep Channel Strategy, and Sales Hiring, Onboarding and Comp Plans.

COPY THIS PROMPT INTO YOUR AI TOOL. FILL IN THE BRACKETS.

Compare direct reps, distributors, and independent reps for launching **[device]** in **[territories]** with **[team size and budget]**. List the tradeoffs in control, speed, cost type, and training effort. Then list the questions we should answer before choosing. Do not assume commission rates, distributor margins, or salary costs.

# Launch in Order, With a Gate at Every Stage




Do not move to the next stage until you pass the gate.

# Launch in Order, With a Gate at Every Stage

### 1 Before launch

Complete the readiness checklist and pick your first accounts.

GATE **No “Missing” items on the checklist.**

### 2 Launch

Go through value analysis, get the contract in place, and get the device set up in purchasing.

GATE **Approved and set up to buy.**

IF STUCK Find the blocker. It is usually evidence, price, or the sponsor.

### 3 First accounts

Run the first cases with training and case support in place.

GATE **The first physician is doing repeat cases.**

IF STUCK Fix adoption through patient selection, training, and support.

### 4 Scale

Expand to the next accounts and to sister hospitals.

GATE **Steady reorders.**

IF STUCK Find where usage dropped off and recover the account.

COPY THIS PROMPT INTO YOUR AI TOOL. FILL IN THE BRACKETS.

Turn this launch plan into a stage-by-stage sequence: **[paste your plan]**. Use four stages: before launch, launch, first accounts, and scale. For each stage, list the owner, the inputs needed, the deliverable, the gate to move on, and what to do if the gate is not met. Do not assume payer coverage or hospital approval.

# Five Launch Mistakes to Avoid

| MISTAKE | WHY IT HURTS | DO THIS INSTEAD |
|---|---|---|
| **Treating authorization as the finish line** | There is no plan for how the device gets bought, paid for, and used | **Answer the four questions on page 2** |
| **Hiring reps before shelf access** | Reps wait on committees and contracts instead of selling | **Build the contract path first** |
| **No reimbursement plan** | Sites hesitate when they do not know how to bill | **Know codes and coverage before launch** |
| **Picking the wrong first accounts** | Proof comes slowly and momentum stalls | **Use the scoring grid on page 4** |
| **No owner for first-case support** | A weak first case can cost you the physician | **Name a clinical support owner on page 5** |

COPY THIS PROMPT INTO YOUR AI TOOL. FILL IN THE BRACKETS.

Review our launch plan for **[device]**: **[paste your plan]**. Check it against these five mistakes: treating authorization as the finish line, hiring reps before shelf access, no reimbursement plan, picking the wrong first accounts, and no owner for first-case support. For each one, tell me if we are at risk, why, and what evidence would confirm it. Do not guess where you lack information. Ask me instead.

07 | NEXT STEP

# Find Where Your Launch Will Stall

RevRx AI helps MedTech teams build the commercial system after authorization.

STEP 1

## Take the Revenue Friction Scorecard

Answer 5 questions and see where friction is slowing your revenue path.

Take the Revenue Friction Scorecard

revrxai.com/medtech-tools

STEP 2

## Book a Discovery Call

A 30-minute call to walk through your launch plan and where it may stall.

Book a Discovery Call

https://api.revrxai.com/widget/bookings/30-minute-meeting-with-terryrovrku

RevRx AI Consulting

**Terry Coutsolioutsos**
Founder and Revenue Architect
linkedin.com/in/terry-coutsolioutsos/
revrxai.com | 941-400-1352