

# Biotech Launch Readiness Checklist

A practical, cross-functional tool for commercial leaders preparing for launch.

## Why this checklist matters

Launch success is rarely determined by one workstream. Strong launches build the core team early, align medical, access, and commercial decisions before day one, and treat launch as a cross-functional process that continues through early uptake, patient acquisition, and course correction.

## How to use it

Use this checklist 12-24 months before launch and revisit it monthly. Mark each item as not started, in progress, or complete, then flag any open decisions that could delay readiness, weaken execution, or create early access friction.

## Readiness dimensions

This checklist is organized around six dimensions: strategic readiness, evidence and access, medical and stakeholder engagement, field and execution readiness, patient acquisition and support, and measurement and course correction.

## 1. Strategic readiness

Checklist item	Not started	In progress	Complete
Target patient segments and priority accounts are clearly defined.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Key adoption barriers and competitor risks are documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The core value story is aligned across leadership, medical, and commercial teams.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Critical launch decisions, owners, and approval paths are explicit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scenario planning exists for upside, base, and downside launch trajectories.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## 2. Evidence and access readiness

Checklist item	Not started	In progress	Complete
The payer value proposition is pressure-tested and evidence-backed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HEOR, RWE, and evidence gaps are mapped against access needs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coverage, policy, and reimbursement risks are identified by priority segment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bridge, affordability, and patient support assumptions are defined early.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medical, market access, and commercial teams are aligned on the evidence story.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## 3. Medical and stakeholder engagement

Checklist item	Not started	In progress	Complete
Medical affairs engagement starts early enough to gather meaningful insight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Key opinion leaders, advocacy groups, and priority stakeholders are mapped.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Disease education and scientific narrative are tailored to stakeholder needs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Internal escalation paths exist for feedback from the field and medical teams.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pre-launch stakeholder engagement informs both access and commercialization plans.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#### 4. Field and execution readiness

Checklist item	Not started	In progress	Complete
Core messaging and objection handling are finalized and field-tested.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sales, medical, and access roles are coordinated with clear handoffs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Launch governance cadence and escalation routines are active.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
External vendors and channel partners are onboarded and launch-ready.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Teams are sequencing the highest-impact activities rather than overloading the plan.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#### 5. Patient acquisition and support

Checklist item	Not started	In progress	Complete
Patient acquisition strategy is defined using patient and journey data, not only sales targets.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient support services are designed to reduce access and adherence friction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Priority demand-generation tactics are funded early enough to influence launch trajectory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Measures exist for initiation, conversion, leakage, and persistence.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Commercial, access, and patient teams agree on what early patient success should look like.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#### 6. Measurement and course correction

Checklist item	Not started	In progress	Complete
Leading indicators are defined for access, demand, activation, and persistence.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Data feeds and dashboards are set up to spot launch risks early.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The team has a launch control-tower or equivalent decision forum.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trigger points for tactical adjustment are agreed in advance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Post-launch learning loops exist across commercial, medical, and access teams.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### **Five common launch mistakes**

1) Building the core team too late. 2) Treating access as a downstream workstream. 3) Confusing message approval with message effectiveness. 4) Overloading execution instead of sequencing priorities. 5) Waiting too long to course-correct when early data signals risk.

### **Monthly review prompts**

Use the checklist in leadership reviews to ask three questions: Where are we red today? Which open decisions could create launch friction in the next 60 days? What needs to be escalated now across medical, access, commercial, or patient support?

### **Suggested launch-room metrics**

Track a small set of leading indicators: access wins and restrictions, stakeholder engagement quality, message pull-through, patient initiation, patient leakage, persistence, and any execution issues requiring course correction.

### **How Route Consulting can help**

Route Consulting helps biotech teams pressure-test launch strategy, align cross-functional priorities, sharpen value story and positioning, and build practical launch operating rhythms before and after day one.