

EU & Swiss market access for emerging biotech — evidence strategy, JCA readiness, and the value at stake.

The 10-Point JCA & Market Access Readiness Checklist

In the 2026 landscape, an EMA approval is no longer enough — the EU Joint Clinical Assessment now gatekeeps your European price, and under Most-Favored-Nation rules a weak result can drag down your US floor too. This is the same red-flag scan I run for clients. Work through the ten points below to see where your asset stands today.

I EVIDENCE & CLINICAL ALIGNMENT

- ☐ **Shadow PICO Audit.** Have you mapped your Phase III trial against the up-to-27 national treatment inputs (PICOs) EU Member States can require?
- ☐ **Comparator Validity.** Does your trial use the local Standard of Care — not a placebo or a convenient comparator — to avoid a "No Added Benefit" finding?
- ☐ **MCID Thresholds.** Is your primary endpoint statistically significant *and* above the Minimum Clinically Important Difference HTA bodies expect?
- ☐ **Population Sub-groups.** Have you identified whether specific sub-groups (e.g. ApoE4 carriers, specific mutations) will trigger reimbursement exclusions or label restrictions?

II VALUATION & FINANCIAL RISK

- ☐ **P(access) Calibration.** Is your rNPV model using a realistic blended likelihood of access for Europe — or still assuming the "FDA average"?
- ☐ **MFN Contagion Modelling.** Have you calculated how a price rejection in Germany would contaminate and erode your US Medicare/Medicaid price floor?
- ☐ **Launch-Delay Impact.** Does your valuation account for the ~18-month revenue gap caused by HTA rejections and mandatory arbitration?

III STRATEGIC EXECUTION

- ☐ **The "Gold Standard" Review.** Have you stress-tested value with the full formula — $rNPV = (\text{Revenue by price potential, not market share}) \times P(\text{success}) \times P(\text{access}) - \text{Costs}$?
- ☐ **Early-Access Strategy.** For French, Swiss or CEE markets, have you initiated the pre-launch dialogue (e.g. Art. 71 KVV, or HZZO early filing) to secure earlier revenue?
- ☐ **Evidence-to-Value Mapping.** Do you have a plan to use Real-World Evidence or emulated trials to fill the gaps your Shadow PICO audit surfaces?

Scored a few blanks?

Those blanks are where value quietly leaks. A short, confidential briefing can tell you what they're worth.

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