

Commercial Launch Decision Guide v1.0

TCRLAS Refinement v2.0 | Working methodology | 15 October 2026

Definition and boundaries

TCRLAS assigns demonstrated milestone level independently. CVA evaluates forward-looking commercial viability. CDA authorizes a specific next action. Launch authorization is an additional, separately documented decision. Neither scores nor charts grant permission to market healthcare offerings.

Evidence and uncertainty

Date all evidence; identify evaluator, source, verification status, jurisdiction, scope and confidence. NE means not evaluated; zero is a justified adverse score, never a substitute for missing information.

Scoring policy

Scores 0–6 are ordinal evidence anchors. Do not interpret the arithmetic mean as probability or validated investment return. No required CVA or HSE numeric threshold controls advance or launch. Record blockers separately.

Preservation

Keep nine original TCRLAS milestones and their minimum conditions unchanged. Preserve legacy TCI as experimental and do not apply it automatically to new CVA scores.

Purpose

A separate, explicit authorization to offer a defined product OR service to defined buyers/patients in a defined jurisdiction with specified intended use, claims, distribution and delivery model.

Gate 1: scope

Confirm offering version, intended use, target users, claimed effects, channel, geography and launch mode.

Gate 2: lawful and safe

Determine applicable licenses, market authorizations, permissions, medical/consumer claims, privacy/security, quality, professional practice, safety and ethics. Obtain specialist verification. Unresolved mandatory permission blocks relevant launch.

Gate 3: benefits and evidence

Validate claims and performance/clinical service outcomes at an evidence standard appropriate to product/service and proposed claims.

Gate 4: operational readiness

Demonstrate delivery capacity, accountable owners, vendors, complaints, adverse-event routes, service continuity, support and incident escalation.

Gate 5: commercial viability

Check pricing, contract/payment route, service or unit economics, cash available for launch, customer acquisition and contingency.

Gate 6: decision authority

Named authorized person/board records GO, CONDITIONAL ONLY FOR ACTIVITIES ALREADY PERMITTED, HOLD, or NO-GO, including scope limitations and signed evidence.

Post-launch review

Define monitoring, adverse-event and quality controls, outcome/financial performance triggers and rollback/stop rules.

Launch record template

Offering | version | intended use | jurisdiction | claims | buyer/payer | channel | mandatory obligations | evidence links | controls | responsible officers | decision | permitted scope | launch date | recheck trigger.

STATUS: PROPOSED WORKING DRAFT — not externally validated.