

HSE Universal Healthcare Products and Services Extension v2.0

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.

Scope

Covers consumer wellness, medical devices and diagnostics, laboratory and digital health, OTC and prescription drugs/biologics, telehealth, clinical services, care delivery, home health, medical logistics, and combinations. The framework applies generically; obligations vary by intended use, claims, jurisdiction, operator and patient population.

Operating model

HSE-Global and HSE-USA may coordinate commercialization. The product/service owner, manufacturer, provider, regulator-designated sponsor, CRO, facilities and partners remain responsible according to applicable law and actual contracts. Do not infer sponsor status from location or incorporation.

H1–H5 interpretation

Healthcare scores are independent from CVA and TCRLAS. H1 regulatory/legal, H2 clinical/service evidence, H3 payer/purchaser access, H4 channels and delivery, H5 healthcare execution. Higher scores mean more demonstrable capability. NE allowed.

Category and jurisdiction first

Assess service versus product, general wellness versus regulated claims, human intervention, intended users, delivery location, professional licenses, protected data, reimbursement and safety. Unknown category is an explicit classification blocker for any restricted activity.

H1 — Regulatory and legal pathway

0: No credible lawful pathway for proposed activity, or known prohibitive legal issue.

- 1: Possible product/service category and governing authorities hypothesized.
- 2: Preliminary intended use, jurisdiction, classification and required permissions identified.
- 3: Documented category-specific compliance plan, qualified owners and evidence requirements.
- 4: Key regulatory assumptions supported by qualified review/interactions; required preparations underway.
- 5: Applicable requirements for the specific proposed activity substantially verified and fulfilled or controlled, with documented gaps.
- 6: Applicable permissions, quality/legal obligations and continuing compliance demonstrated for ongoing defined operations.

H2 — Clinical / service effectiveness and safety evidence

- 0: No credible evidence for essential claims, or reliable evidence contradicts essential claims.
- 1: Health benefit or service outcome hypothesized.
- 2: Relevant scientific rationale, baseline performance and evidence plan drafted.
- 3: Credible measurement framework with appropriate preliminary analytical/clinical/service evidence.
- 4: Independent or relevant-environment evidence supports intended claims and safety for the defined stage.
- 5: Strong externally reviewed evidence and adverse-event/service-safety controls support proposed scope.
- 6: Robust repeatable clinical/service performance and continuing monitoring appropriate to claims demonstrated.

H3 — Payer, purchaser and access

- 0: No viable purchaser, payment route or access path identified.
- 1: Potential payer, consumer, employer, provider or public purchaser posited.
- 2: Coverage, cash-pay, contracting and/or procurement options preliminarily researched.
- 3: Credible buyer and payment route documented with price, adoption barriers and access assumptions.
- 4: External customer, purchaser or payer feedback supports meaningful payment and adoption possibility.
- 5: Payment contracts or strongly supported ability/willingness to pay and practical market access demonstrated.
- 6: Repeatable payment and equitable, operationally sustainable market access demonstrated.

H4 — Commercial delivery and channels

- 0: No credible route to intended customers/patients/providers.
- 1: Potential clinical, direct-to-consumer, employer, public or distribution pathway identified.
- 2: Candidate delivery, referral, procurement, support and distribution entities identified.
- 3: Working channel plan with buyer journey, fulfillment, data flows and support responsibilities.
- 4: Credible commitments or pilots from delivery/channel participants; service logistics mapped.
- 5: Verified functioning customer access and delivery with appropriate support and responsible parties.
- 6: Repeatable geographically/operationally relevant service or product delivery at scale.

H5 — Healthcare execution system

- 0: Indispensable qualified clinical, quality, operational or contracting capability absent without solution.
- 1: Candidate qualified parties and organizational structure hypothesized.

- 2: Initial accountable roles for clinical/regulatory/quality/delivery identified.
- 3: Documented execution matrix, partner plan, agreements needed, funding and governance for next milestone.
- 4: Qualified parties, essential agreements and resources demonstrably committed for next milestone.
- 5: Execution network delivers safely, with relevant qualified systems, contingencies and documented oversight.
- 6: Repeatable resilient multi-party operation and required continuing healthcare oversight demonstrated.

Service-specific checks

Telehealth: professional licensure, jurisdiction of patient/provider, care standard, privacy, prescribing as applicable. Clinical practice: facility/provider credentials, scope, consent, continuity and emergencies. Labs: applicable lab licensing/quality, test validity and reports. Medical logistics: chain of custody, cold-chain where needed, transport safety, data exchange and responsibility.

Product-specific checks

Medical devices/diagnostics: intended use, classification, regulatory route, quality, analytical/clinical performance as relevant, labeling. Medicines/biologics: regulatory development and marketing route, trial oversight, manufacturing controls and pharmacovigilance. Consumer wellness: claims and consumer protection.

Payment models

Payer insurance reimbursement is not universal. Document payer, provider, employer, government, consumer cash pay, or blended purchase route. Separate user, prescriber, purchaser and funding source.

HSE accountable partner matrix

Owner/product developer | HSE-Global coordinator | HSE-USA coordinator | regulatory/legal professional | sponsor where applicable | CRO where applicable | healthcare provider | manufacturer/logistics | distributor/channel | payer/purchaser. Record a named accountable entity for each applicable task.

HSE evidence pack

Five scores and supporting links; product/service classification; jurisdiction and intended use; credentials/licensing; clinical/service performance; safety; payer/payment evidence; distribution; sponsor/CRO/partner matrix; blockers and decision authority.

STATUS: PROPOSED WORKING DRAFT — not externally validated.