DRL Canvas

Diagnostics Readiness Levels v1.0 | Jose Pereira Leal | pereiraleal.com/drl

Project:		**Date:**	
Assessor:		**Version:**	

Scorecard

Stream	DRL	1	2	3	4	5	6	7	8	9	10	11	12	13
Scientific & Technical														
Clinical														
Regulatory & Quality														
Commercial & Market														
Strategic & Systemic														

P = Pass (gate fully evidenced)	F = Fail (gate not met)	- = Not assessed	Stream DRL = highest consecutive fully-passed level

Overall DRL (weakest-stream rule):		Notes:	

Stream 1 - Scientific & Technical

PHASE 1 - CONCEPT

DRL-1	Has a specific biological parameter been named, with its molecular nature described and a plausible mechanism linking it to a clinical condition cited in published evidence? **Required artefact:** *One-page hypothesis document referencing at least one published source.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-2	Has the candidate biomarker been fully characterised at the conceptual level and have the technologies capable of detecting it been described? **Required artefact:** *Biomarker characterisation document listing molecular parameters, measurement complexity, and candidate platforms.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 2 - DEVELOPMENT

DRL-3	Has the biomarker been detected in the relevant sample type using the identified technology platform, with positive and negative controls defined and the detection limit estimated? **Required artefact:** *Laboratory record of first detection experiment with controls, signal data, and detection limit estimate.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-4	Does the assay detect the biomarker reproducibly across a meaningful set of real samples (>=20), including normal and pathological specimens, with preliminary sensitivity, specificity, and dynamic range estimated? **Required artefact:** *Data table or summary showing assay performance across >=20 real samples with preliminary sensitivity/specificity.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-5	Has analytical validation been completed with all performance parameters characterised under real-world conditions, with all data generated in the intended final assay format? **Required artefact:** *Full analytical validation report meeting the applicable IVDR/regulatory performance standard, generated in the final assay format.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

DRL-6	Has the assay been transferred to at least one external setting and performed within specification without direct support from the originating laboratory? **Required artefact:** *External site transfer report showing performance data within specification, generated by operators outside the development team.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-7	Has the assay been validated across multiple independent clinical centres (>=2 sites) with consistent performance and a dataset sufficient for regulatory submission and guideline consideration? **Required artefact:** *Multi-centre validation study report with statistical analysis confirming consistent performance, of sufficient size and design for regulatory submission.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 3 - MARKET ENTRY

DRL-8	Is manufacturing validated under ISO 13485 and producing consistent product at the required scale, and is post-market surveillance infrastructure operational? **Required artefact:** *ISO 13485 certification, batch release records from >=3 consecutive batches, and PMS plan with active reporting structure.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-9	Is the assay performing within its validated specifications in external clinical settings operated by staff with no involvement in its development and without on-site support? **Required artefact:** *Real-world performance data report from >=1 external site (operated independently), showing performance within validated specifications.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 4 - SYSTEMIC INTEGRATION

DRL-10	Is product quality demonstrably consistent across multiple manufacturing batches at commercial scale, and is real-world performance data being analysed and informing product iteration? **Required artefact:** *Batch release records from >=5 commercial batches plus at least one documented product iteration decision driven by real-world data.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-11	Has manufacturing capacity been demonstrated to be scalable to projected demand without quality degradation, with a documented scale-up plan and no single-source supply chain vulnerabilities? **Required artefact:** *Scale-up plan with qualified additional manufacturing capacity, and supply chain risk assessment confirming no single-source critical dependencies.*	Status: [ ] Pass [ ] Fail [ ] Not assessed

		Evidence / notes:
DRL-12	Has the assay been analytically and clinically validated in the specific patient populations of at least two geographies beyond the original validation cohort? **Required artefact:** *Analytical and/or clinical validation reports for >=2 additional geographies, explicitly addressing population-specific performance.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-13	Is post-market surveillance at population scale generating real-world performance data actively informing next-generation product development? **Required artefact:** *Published or submitted population-scale PMS data paper, plus documented R&D pipeline entry derived from PMS insights.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

Stream 2 - Clinical

PHASE 1 - CONCEPT

DRL-1	Has at least one specialist clinician who routinely faces the target decision confirmed that a clinical gap exists, and articulated what happens to patients today because of it? **Required artefact:** *Written or recorded confirmation from a clinician (email, meeting note, or signed statement).*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-2	Has the biomarker's intended clinical role been classified, the target population and comparator defined, and the minimum evidence level (I, II, or III) required for adoption determined and documented? **Required artefact:** *Evidence level decision document, signed off and treated as a binding constraint on the development programme.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 2 - DEVELOPMENT

DRL-3	Is a clinical partner actively engaged and has access to patient samples suitable for feasibility testing been confirmed, with the clinical validation programme designed in outline? **Required artefact:** *Signed or written confirmation of clinical partnership and sample access, plus outline study design document.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-4	Has a clinical partner reviewed the preliminary assay results and explicitly confirmed that the signal levels correspond to clinically meaningful differences between patient groups? **Required artefact:** *Written confirmation from a clinician that the performance profile is clinically relevant for the target decision.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-5	Have clinical partners confirmed that measurement precision is sufficient, the positivity threshold is clinically defensible, and the result format is actionable, and has the clinical validation programme design been finalised? **Required artefact:** *Clinical partner sign-off on analytical performance parameters plus finalised study protocol with ethics application in preparation.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-6	Has a retrospective or prospective-retrospective study on at least 50-100 representative subjects demonstrated the test distinguishes clinically	Status:

	meaningful patient groups, and has the real market objection been documented? **Required artefact:** *Clinical proof of concept study report (>=50 subjects) plus documented record of first market objection.*	[ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-7	Does prospective or prospective-retrospective evidence from independent multi-centre cohorts demonstrate clinical utility at the evidence level determined at DRL-2, and has a health economics model been reviewed by independent collaborators? **Required artefact:** *Clinical validation study meeting the required evidence level, plus health economics model with independent reviewer confirmation.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 3 - MARKET ENTRY

DRL-8	Have clinical evidence gaps identified during regulatory review been documented and has a post-market clinical follow-up programme been established with data collection infrastructure operational? **Required artefact:** *PMCF plan documenting open clinical questions and data collection protocol, filed with or accepted by the regulatory authority.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-9	Are real clinicians using the test to inform clinical decisions in routine care and is real-world clinical feedback being systematically captured? **Required artefact:** *Evidence of routine (non-research) clinical use at >=1 site, plus feedback capture system.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 4 - SYSTEMIC INTEGRATION

DRL-10	Is the test demonstrably influencing clinical decisions with measurable patient benefit, and is a plan for publishing real-world outcome evidence in place? **Required artefact:** *Case series report (>=10 patients) or equivalent real-world outcome data, plus publication plan with target journal and timeline.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-11	Has real-world evidence been published or presented at a major clinical conference, and are KOLs citing the test in their practice and in guidelines discussions? **Required artefact:** *Published peer-reviewed paper or major conference presentation of real-world evidence, plus written evidence of KOL citation or endorsement.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

DRL-12	Has the test been included in, or formally submitted for inclusion in, clinical guidelines in at least one geography, and is a population-level outcomes evidence programme active? **Required artefact:** *Guideline submission confirmation or inclusion certificate in >=1 geography, plus active real-world evidence programme.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-13	Is the test part of standard of care in at least one national clinical pathway, and is population-level outcomes data being generated, published, and cited in guideline documents? **Required artefact:** *National clinical pathway inclusion documentation, plus >=1 published population-level outcomes paper cited in a guideline.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

Stream 3 - Regulatory & Quality

PHASE 1 - CONCEPT

DRL-1	Has a structured record of all decisions, data sources, and rationale been initiated, and has the likely regulatory category of this diagnostic been identified in outline? **Required artefact:** *Dated laboratory or project notebook entry, shared folder, or version-controlled document.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-2	Has a freedom-to-operate assessment been completed and has the likely regulatory classification under IVDR or the relevant framework been identified? **Required artefact:** *FTO assessment report (internal or from IP counsel) and regulatory classification note.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 2 - DEVELOPMENT

DRL-3	Are laboratory practices compatible with Good Laboratory Practice, has the intended purpose statement been drafted, and has the regulatory pathway been identified in sufficient detail? **Required artefact:** *GLP compliance statement and draft intended purpose statement, with regulatory pathway note.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-4	Is assay development being documented in a format compatible with a future regulatory technical file, with version-controlled protocols, reagent records, instrument logs, and sample inventories maintained? **Required artefact:** *Confirmation of version-controlled documentation system in use, with at least one complete assay protocol on file.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-5	Has the regulatory pathway been confirmed with a diagnostics-specific regulatory advisor, and has the ISO 13485 QMS roadmap been initiated? **Required artefact:** *Written confirmation from a qualified diagnostics regulatory advisor of the applicable pathway, plus QMS implementation plan.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

DRL-6	Are all clinical study samples and associated data being collected and documented in a regulatory-compatible format such that this evidence will be usable in the regulatory dossier without repetition? **Required artefact:** *Ethics approval certificate, informed consent template, and site agreement template on file.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-7	Is the regulatory technical file in preparation or complete, and has the regulatory submission strategy been confirmed by a qualified diagnostics-specific advisor including geographic sequencing? **Required artefact:** *Regulatory technical file (or documented preparation plan) and written confirmation from qualified advisor of submission strategy.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 3 - MARKET ENTRY

DRL-8	Has market authorisation been obtained in the primary target geography, is the post-market surveillance plan operational, and has the regulatory sequencing strategy for secondary geographies been defined? **Required artefact:** *Market authorisation certificate plus PMS plan with active reporting and secondary geography sequencing roadmap.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-9	Is each new user site being onboarded with documented training, QC verification, and performance confirmation before clinical use begins? **Required artefact:** *Site onboarding protocol with training checklist, QC verification records from >=1 site, and PMS data collection log.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 4 - SYSTEMIC INTEGRATION

DRL-10	Is post-market surveillance data being systematically analysed and feeding back into the regulatory dossier, and are periodic safety update reports being filed on schedule? **Required artefact:** *Most recent PSUR filed on schedule, plus documentation of at least one product development decision informed by PMS data.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-11	Have regulatory submissions been filed in at least one secondary geography and is post-market surveillance generating outcome evidence of sufficient quality for HTA dossiers? **Required artefact:** *Regulatory submission confirmation in >=1 secondary geography plus PMS outcome data report of HTA-relevant quality.*	Status: [ ] Pass [ ] Fail [ ] Not assessed

		Evidence / notes:
DRL-12	Is market authorisation in place or on a confirmed timeline in at least three geographies, with each geography's specific regulatory requirements met? **Required artefact:** *Market authorisation certificates (or confirmed submission timelines) for >=3 geographies with geography-specific compliance documentation.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-13	Are all active market authorisations being maintained and renewed on schedule, and is post-market surveillance being used proactively to update labels, inform guideline submissions, and support next-generation development? **Required artefact:** *Current market authorisation renewal records for all active geographies, plus documented instances of PMS data driving product or regulatory action.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

Stream 4 - Commercial & Market

PHASE 1 - CONCEPT

DRL-1	Has the intended clinical setting, user type, and required turnaround time been documented and confirmed to represent a commercially viable use case in principle? **Required artefact:** *One-page use-case brief documenting setting, user, turnaround, and preliminary market viability rationale.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-2	Have the constraints imposed by the biomarker type on the commercial format been assessed, at least one comparable product identified with its price point noted, and the primary target geography selected? **Required artefact:** *Commercial constraints note documenting biology-to-format compatibility, comparable product benchmark, and target geography rationale.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 2 - DEVELOPMENT

DRL-3	Has a preliminary business model been documented with its compatibility with the platform, setting, and target geography assessed, and have logistics of sample handling been estimated? **Required artefact:** *Preliminary business model canvas or one-pager, with logistics estimate including shipping cost per test.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-4	Has a preliminary cost-of-goods estimate been produced and the gap between current COGS and commercially viable COGS been assessed, and has the logistics map been completed? **Required artefact:** *COGS estimate spreadsheet and logistics map document.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-5	Has the business model been made and locked as a binding commitment with its regulatory, manufacturing, distribution, and capital implications acknowledged? **Required artefact:** *Signed internal decision record locking the business model, plus early access niche description.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

DRL-6	Has at least one attempt been made to convert clinical interest into a concrete commitment, and has a preliminary health economics argument been constructed? **Required artefact:** *Record of commitment conversation documenting the real objection, plus preliminary health economics argument document.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-7	Has the reimbursement pathway been mapped for the primary target market, the relevant HTA body identified, and the critical question answered: does this test require a new reimbursement mechanism or can it use an existing one? **Required artefact:** *Reimbursement pathway map document naming the HTA body, evidence requirements, and existing vs. new mechanism determination.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 3 - MARKET ENTRY

DRL-8	Has the reimbursement and market access strategy been developed for each primary target market, is the distribution model operational with signed agreements and trained partners, and has pricing been validated in real transactions? **Required artefact:** *Reimbursement strategy document per target market, signed distribution agreement(s), and evidence of at least one real pricing transaction.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-9	Is there at least one paying customer paying for the test at a defined price in a routine transaction, and is the laboratory adoption protocol working without the founding team? **Required artefact:** *Invoice or purchase order from a paying customer plus evidence that >=1 site was onboarded without founding team involvement.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 4 - SYSTEMIC INTEGRATION

DRL-10	Is the business model generating positive unit economics, is distribution scaling through multiple accounts or geographies, and is the reimbursement pathway active? **Required artefact:** *Unit economics calculation from real transaction data, plus evidence of >=3 paying accounts and active HTA dossier submission.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-11	Has the commercial model been validated across at least two geographies, has reimbursement been obtained or entered active final-stage application in the primary market, and has the HTA dossier been completed? **Required artefact:** *P&L data from >=2 geographies, reimbursement approval certificate or final-stage application, and completed HTA dossier.*	Status: [ ] Pass [ ] Fail [ ] Not assessed

		Evidence / notes:
DRL-12	Is the test commercially available in at least three geographies with reimbursement secured in at least two markets, and is the commercial operation no longer dependent on the founding team? **Required artefact:** *Commercial availability evidence in >=3 geographies, reimbursement documentation for >=2 markets, and regional partner or distributor agreements.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-13	Is the business generating sustainable margins across multiple geographies with diversified revenue streams, and has commercial independence from any single market, customer, or revenue stream been demonstrated? **Required artefact:** *Multi-year P&L showing sustainable margins across >=3 geographies with >=2 revenue stream types and no single entity representing >50% of revenue.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

Stream 5 - Strategic & Systemic

PHASE 1 - CONCEPT

DRL-1	Have the key stakeholders beyond the ordering clinician been identified and their likely roles in the adoption process described? **Required artefact:** *Stakeholder map (table or diagram) with role annotations.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-2	Has the national and regional policy context been documented, the funding landscape mapped, and the strategic implications of the evidence level decision understood? **Required artefact:** *Policy and funding landscape note for the primary target geography, with instruments identified for this stage.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 2 - DEVELOPMENT

DRL-3	Has at least one funding instrument accessible at this stage been applied for or entered active preparation, and have the key partnerships required been mapped? **Required artefact:** *Grant application submission confirmation (or draft in preparation), and partnership map with named institutions and individuals.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-4	Has the capital required to reach analytical validation been confirmed as accessible, and have the broader capital requirements to reach clinical validation been estimated? **Required artefact:** *Confirmation of active funding instrument for this stage plus a capital requirements estimate for the clinical validation phase.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-5	Has a capital requirements map covering the full path to clinical validation been produced, the appropriate funding instrument identified and actively pursued, and the investor landscape for diagnostics at this stage been mapped? **Required artefact:** *Capital requirements map and investor landscape document, with evidence of active fundraising activity.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

DRL-6	Has the investor landscape for diagnostics at clinical PoC stage been documented, and have key partnership dependencies before regulatory submission been identified with conversations underway? **Required artefact:** *Investor landscape document for this stage plus evidence of at least one partnership conversation initiated.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-7	Is a Series A investment narrative in place and has the partner landscape (pharma, platform, distribution) been mapped? **Required artefact:** *Series A investor deck or narrative document, plus partner landscape map with named targets.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 3 - MARKET ENTRY

DRL-8	Have institutional and sovereign procurement conversations been initiated in at least one target market, and is a Series B narrative in place? **Required artefact:** *Record of at least one institutional procurement conversation plus Series B narrative document.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-9	Are early commercial relationships being used to inform the institutional procurement strategy, and are relationships being built with institutional buyers above the level of individual clinical departments? **Required artefact:** *Evidence of >=1 institutional-level relationship with procurement, HTA, or health agency contacts.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:

PHASE 4 - SYSTEMIC INTEGRATION

DRL-10	Is a Series B process active or complete with an investment case built on commercial traction, and are partnership conversations with large diagnostics or pharma companies underway? **Required artefact:** *Series B term sheet or evidence of active fundraising, plus record of >=1 strategic partnership conversation.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-11	Has supply chain resilience been confirmed with no single-source critical dependencies, and are in-country manufacturing or fill-finish partnerships being explored in primary markets? **Required artefact:** *Supply chain resilience assessment report plus documented engagement with >=1 potential in-country manufacturing or fill-finish partner.*	Status: [ ] Pass [ ] Fail [ ] Not assessed

		Evidence / notes:
DRL-12	Is the test embedded in a national procurement framework in at least one geography, and is at least one in-country manufacturing or fill-finish partnership operational? **Required artefact:** *National procurement framework contract or tender award in >=1 geography, plus operational in-country manufacturing or fill-finish partnership agreement.*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes:
DRL-13	Is the company demonstrably contributing to a national or regional diagnostics value chain, and is policy influence documented? **Required artefact:** *Documentation of local contribution (manufacturing, workforce, technology transfer) plus policy influence evidence (official strategy document or government report).*	Status: [ ] Pass [ ] Fail [ ] Not assessed Evidence / notes: