FULFILLED, GO ON

NOT FULFILLED, RE-THINK

	CLINICAL NEED	COMMERCIAL VIABILITY	FEASIBILITY & IPR
1. Biomarker discovery TRL-1 Basic principles observed	1. Is the clinical need suffciently identified and described? 2. Have you performed initial statistical significance evaluation of the putative findings and clinical meaningfulness? 3. Do you have prepared a plan for testing the consistency of the results and stability?	1. Do you recognize a potential market for your biomarker? Does it fill a gap or otherwise improves current testing scheme? 2. Would your biomarker or biomarker panel improve the current gold standard? (If yes, is the effect of the improved clinically significant?)	1. Can you secure access to clinical specimens for further studies and whether existing ethics approvals cover further work? 2. Have you made a proper survey on novelty and potential limitations from existing IPR (prior art)? 3. Do you know, how to finance further steps of commercialization?
NOT AN IVD -APPLICABLE BIOMARKER			
2. Biomarker verification and preliminary scientific validity studies TRL-2 Proof of Principle studies	1. Are your results consistent, reproducable and significant? 2. Is the biomarker specific to the disease? 3. Do you have enough interest from healthcare professionals?	1. Have you defined in detail your target population and your target product profile? 2. Have you analyzed the competetive landscape? What are the products addressing the same aim and how competetive is your potential test? 3. Do you have positive, documented feedback from clinicians / clinical laboratories on need?	1. Is assay for biomarker / correlation inventive and patentable? 2. Are results consistent and scientifically valid in quantitative analyses?
3. Development of a specific biomarker assay (prototype) TRL-3 Proof of Concept assay established	1. Have the biomarker(s) specific assay prototype been established? 2. Are the analytical characteristics of the prototype satisfactory enough? 3. Can a sufficiently high throughput be achieved in the routine settings?	1. Can you formulate your competitive advantages, e.g. for a non-confidential technology presentation?	1. Has the freedom-to-operate search results been enabling for suggested methodology and components? 2. Do you have a plan for patenting of the invention? 3. Have you determined your assay under jurisdiction of EU IVDR?
RE-DESIGN WHERE FEASIBLE			

DECISION ON PATENTING

4. Clinical performance of the prototype in laboratory settings TRL-4 Proof of Concept studies with prototype assay	1. Have you accomplished comprehensive assessment of clinical performance of the established prototype incl. comparison with reference method? 2. Are aims set for clinical performance characteristics achieved (e.g. AUC, Clinical sens. / spec., NPV / PPV)? 3. Are evidence of health benefits (improved patient outcome) confirmed?	1. Have you performed your economic evaluation and cost effectiveness analysis? 2. Have you formulated your business case and commercial strategy? 3. Is positioning in clinical care pathway confirmed (e.g. new step, complementary step, replacement of old test)? 4. Is cost-effectiveness of test on appropriate level?"	1. Have you secured freedom-to-operate? 2. Have you estimated the risk class and the regulatory requirements for the assay?
FURTHER MATURATION WHERE FEASIBLE			
5. Pre-industrial maturation phase TRL-5 Configuration to industrial application (beta prototype) TRL-6 Technology demonstraded in relevant environment	1. Have you performed with satisfactory outcome refinement of biological characterization of the biomarker(s)? 2. Have you updated clinical performance indicators along new specimen cohorts? 3. Do you have further clinical evidence accumulated by collaboration with clinicians / industry? 4. Have you gathered further knowledge (e.g. link to condition, variation in sub-populations, cross-reactions)? 5. Have you estimated the clinical and technological suitability of the potential biomarker to your platform?	1. Have you selected your commercialization business model - start-up or licensing/ full assignment?	1. Have you prepared a preliminary product plan and a plan for establishing industrial beta-prototype? 2. Have you investigated regulatory process from the commercial perspective and especially manufacturer obligations?

SELECTION OF BUSINESS MODEL & INITIATION OF TECHNOLOGY TRANSFER

	TECHNICAL & COMMERCIAL DEVELOPMENT	REGULATORY APPROVALS
6. Industrial assay development TRL-7 Clinical validation of IVD assay	1. Have you finalized the business plan? 2. Have you estimated resources: staffing and budget?	1. What are the most important milestones and risk to plan? 2. Have you contacted your notified body?

DEVELOPMENT PHASE

7. Commercial launch and clinical implementation TRL-8 Commercial launch of IVD assay TRL-9 Post launch monitoring of IVD assay	1. Have you finalized your marketing plan? 2. Have you set up new or your existing distribution channels?	1. Have you registered to EUDAMED database? 2. Have you applied for CE-mark? 3. Have you prepared your post-market surveillance plan?

MARKET LAUNCH & POST-MARKET SURVEILLANCE