



FULFILLED, GO ON



NOT FULFILLED, RE-THINK

CLINICAL NEED

COMMERCIAL VIABILITY

FEASIBILITY & IPR

1. Biomarker discovery

TRL-1 Basic principles observed

NOT AN IVD
-APPLICABLE
BIOMARKER

- 1. Is the clinical need sufficiently 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?"

2. Biomarker verification and preliminary scientific validity studies

TRL-2 Proof of Principle studies

- 1. Are your results consistent, reproducible 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 competitive landscape? What are the products addressing the same aim and how competitive 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

RE-DESIGN
WHERE FEASIBLE

- 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?"

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?

5. Pre-industrial maturation phase

"TRL-5 Configuration to industrial application (beta prototype)
TRL-6 Technology demonstrated in relevant environment
Pre-industrial maturation phase"

FURTHER MATURATION
WHERE FEASIBLE

- 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)?"

- "1. Have you selected your commercialization business model - start-up or licensing/full assignment?
- 2. Have you prepared a preliminary product plan and a plan for establishing industrial beta-prototype?
- 3. Have you investigated regulatory process from the commercial perspective and especially manufacturer obligations?"

SELECTION OF BUSINESS MODEL & INITIATION OF TECHNOLOGY TRANSFER