Biomarker Commercialization Guide AVAILABLE FREE OF CHARGE IN SUMMER 2020 biomarker.nu

Technical development Commercial track Regulative aspects Biomarker discovery Research phases TRL-1 Basic principles observed Verification and preliminary scientific validity studies TRL-2 Proof of principle studies Development of a spesific biomarker assay (prototype) TRL-3 Proof of concept assay established Clinical performance of the prototype in laboratory settings TRL-4 Proof of concept studies with prototype assay Tech Transfer 5 Pre-industrial maturation phase TRL-5 Configuration to industrial application (Beta Prototype) TRL-6 Technology demonstrated in relevant environment Industrial and market phase Industrial assay development TRL-7 Clinical validation of IVD assay Commercial launch and clinical implementation TRL-8 Commercial launch of IVD assay TRL-9 Post launch monitoring of IVD assay

From discovery to market

The BIC project will provide you:

- a process tool for biomarker commercialization
- a screening and selection guide for TTOs
- a compilation of the best practices in commercializing IVD-applicable biomarkers



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Research phase

dustrial and market phase

Technical development

- Biomarker discovery
- 2 Verification and preliminary scientific validity studies

Commercial track

Regulative aspects

- 3 Development of a spesific biomarker assay (prototype)
- 4 Clinical performance of the prototype in laboratory settings
- 5 Pre-industrial maturation phase
- 6 Industrial assay development
- Commercial launch and clinical implementation

From bench to bedside

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