

BIC BIOMARKER
COMMERCIALIZATION

Biomarker Commercialization Guide

- From discovery to market

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Biomarker Commercialization - Challenges

- How do you translate a biomarker discovery from lab to clinical setting?
- How to ensure efficient validation phase and generation of valid data?
- How to ensure that the researchers have adequate knowledge about the commercialization of biomarkers?
- How does a TTO select the best biomarkers projects for commercialization?
- How to provide industry or investors relevant documentation?

BIC project deliverables

- **Biomarker Commercialization Guide**
 - a tool covering technical, business and regulatory aspects of commercialization
- **Best Practices Handbook**
 - compilation of the best practices & pitfalls in IVD commercialization
- **Screening and Selection Guide**
 - TTO Review Tool
 - self-evaluation tool for researchers

Biomarker Commercialization Guide

Available free of charge in summer 2020 at biomarker.nu

- Process divided in 7 phases and 3 main tracks: technical development, commercial and regulatory aspects
- Support documents for specific tasks
- Checklists, guides and possibility of self-evaluation at the end of each phase
- Links to useful material



Biomarker Commercialization Guide

Research
Phases

1. Biomarker discovery

TRL-1 Basic principles observed

2. Verification and preliminary scientific validity studies

TRL-2 Proof of principle studies

3. Development of a specific biomarker assay (prototype)

TRL-3 Proof of concept assay established

4. Clinical performance of the prototype in laboratory settings

TRL-4 Proof of concept studies with prototype assay

5. Pre-industrial maturation phase

TRL-5 Configuration to industrial application (Beta Prototype)

TRL-6 Technology demonstrated in relevant environment

6. Industrial assay development

TRL-7 Clinical validation of IVD assay

7. Commercial launch and clinical implementation

TRL-8 Commercial launch of IVD assay

TRL-9 Post launch monitoring of IVD assay

Tech
Transfer

Industrial and
Market Phase

BIC BIOMARKER COMMERCIALIZATION

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