Hub PASREL 15th of March 2022

BMK TOOLS

Bridging biomarkers from the lab to the patient

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Agenda

1. A bit of context: Aviesan
2. What is actually a value chain ?
3. The biomarker value chain
4. The BMK TOOLS platform

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The National alliances

5 alliances

- Improve the coordination of players within the same research field
- Build a prospective thinking
- Increase performance, visibility and international influence
- Highlight French research

Energy

ANCRE
Alliance Nationale de Coordination de la Recherche pour l'Énergie

Human and social sciences

ATHENA
alliance nationale des sciences humaines et sociales

Environment

AllEnvi
Alliance nationale de recherche pour l'Environnement

Digital technologies

ALLISTENE
l'alliance des sciences et technologies du numérique

Life sciences and health

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Aviesan

The project started within the Alliance **Aviesan** (National French Alliance for life sciences and health)

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Associated members

Founders

Aviesan main objectives

- Scientific coordination
- Operational coordination

➔ **More visibility and reactivity**
➔ **To share priorities on structuring projects**

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CVT-Aviesan: A think tank to smooth knowledge transfer

The CVT « thematical valorization consortium » gathered the technology transfer offices of the Aviesan members with these aims:

- Understand the value chains of innovation: current and future
- Identify the barriers and opportunities
- Bet on the complementarity of the different players
- **Design and test tools among the ecosystem**

BMK TOOLS
Bridging Biomarkers from the lab to the patient

ParcoursDM
DISPOSITIFS MÉDICAUX INNOVANTS

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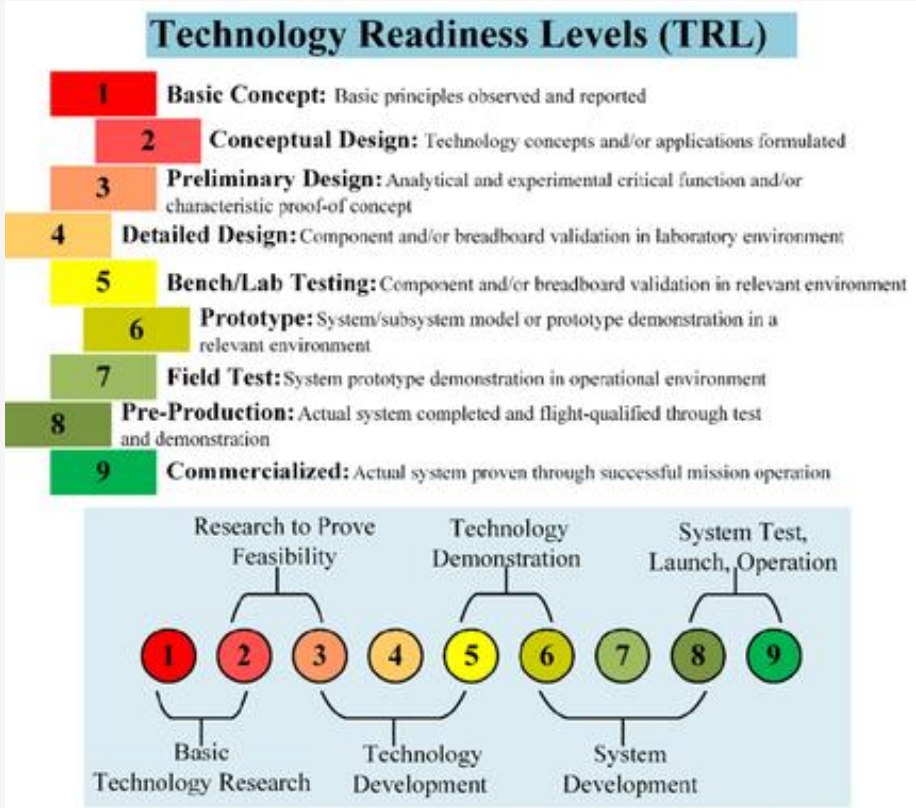
Beyond the « Technology readiness level »



- Technology readiness level (TRL) is a system used to estimate technology maturity
- The use of TRLs enables consistent, uniform discussions of technical maturity across different types of technology

➔ **Who are the key players involved ?**

➔ **Ecosystem definition / value chain understanding**

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What about biomarker ?

Definition:
A biomarker is a **biological characteristic** that can be **measured objectively** and that reflects a biological process (normal or pathological) or a biological response after a therapeutic intervention

The majority of medical decisions relies on biomarker and diagnostic tools

Increasing need to discover and develop new biomarker for a better care of the patients:

- Risk evaluation (genetic tests)
- Prevention
- Early diagnostic
- More accurate diagnostic
- Targeted therapies

➔ **Biomarkers are the best allies for the precision medicine !**

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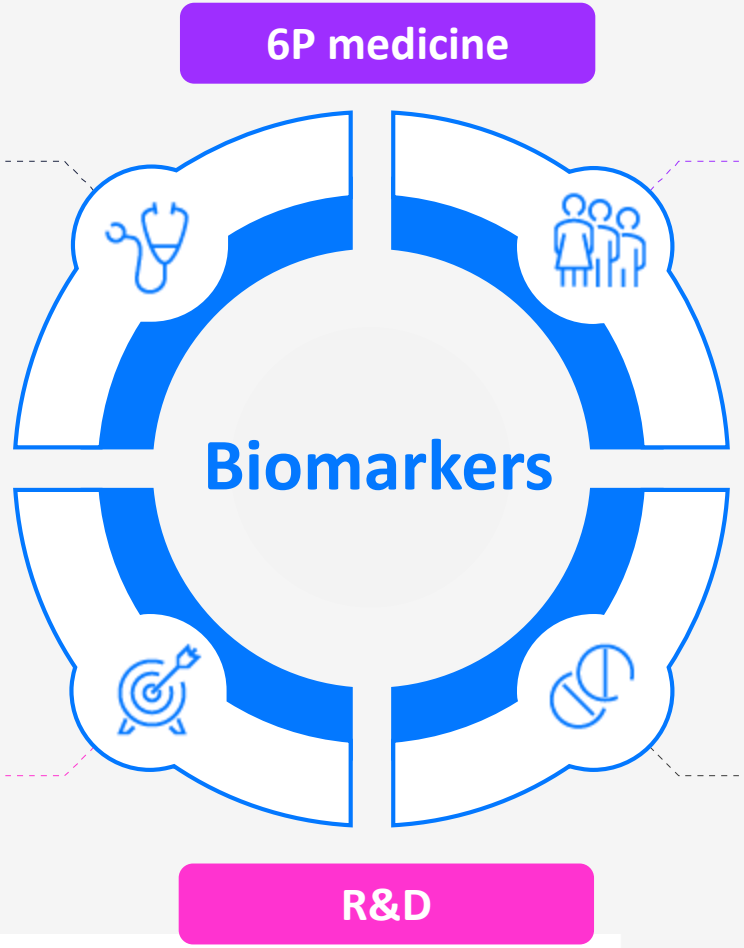
The central role of biomarkers

1

All along the healthcare organisation

- autotests
- point of care
- biomedical analysis
- diagnostic



2

All along the patient life

- prenatal diagnostic
- prevention
- diagnostic
- treatment follow up

3

Target validation

- reduce R&D costs
- compensate poor predictivity of animal models

4

For the development of new therapies

- patients stratification during clinical trials
- response to treatment
- efficacy
- toxicity
- surrogate endpoints

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The biomarker value chain: the steps

› THE BIOMARKER VALUE CHAIN

Development stages of a biomarker

STEP 1 Discovery of biomarker

STEP 2 Assay design

STEP 3 Development of test

STEP 4 Proof of concept

STEP 5 Analytical validation

STEP 6 Clinical validation

STEP 7 Regulatory, approval and launch

STEP 8 Reimbursement

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The biomarker value chain: the steps

Step 1 - Discovery of biomarker

The first step of the biomarker value chain is **the discovery of the biomarker.** During this step, the biomarker is identified, and the basic principles are described. A review of the scientific literature, patents, existing technologies, the pathologies concerned is important to fully characterise the biomarker. This includes a description of the nature, type of biomarker and its potential use in the clinic.

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The biomarker value chain: the steps

Step 2 - Assay design

At this stage, it is a matter of generating ideas, hypotheses and experimental plans for the **design of the diagnostic test** used to detect the candidate biomarker. During the development of a test, a comprehensive reflection on the biomarker and its test in the early stages of development allows the formulation of hypotheses and experimental plans in line with the possibilities for use in common practice.

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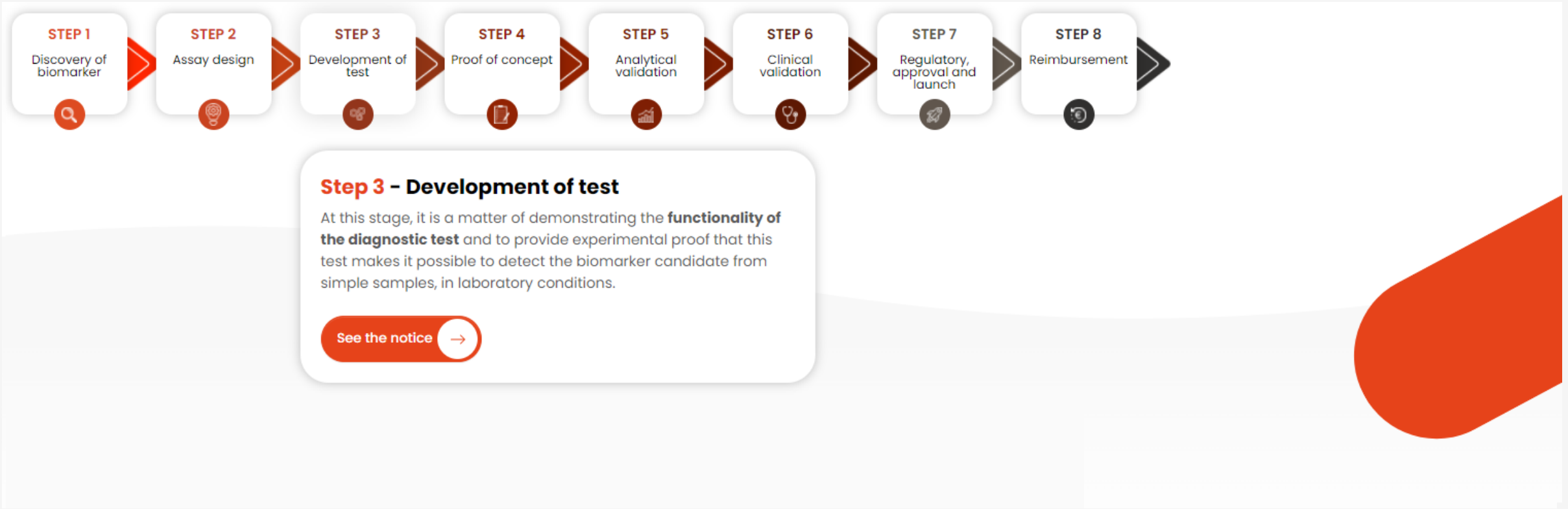
The biomarker value chain: the steps



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The biomarker value chain: the steps

Step 4 – Proof of concept

The **proof of concept stage** is a critical step to ensure the next steps of the proper development of a diagnostic test. The objective of this stage is to determine whether the test is useable in practice.

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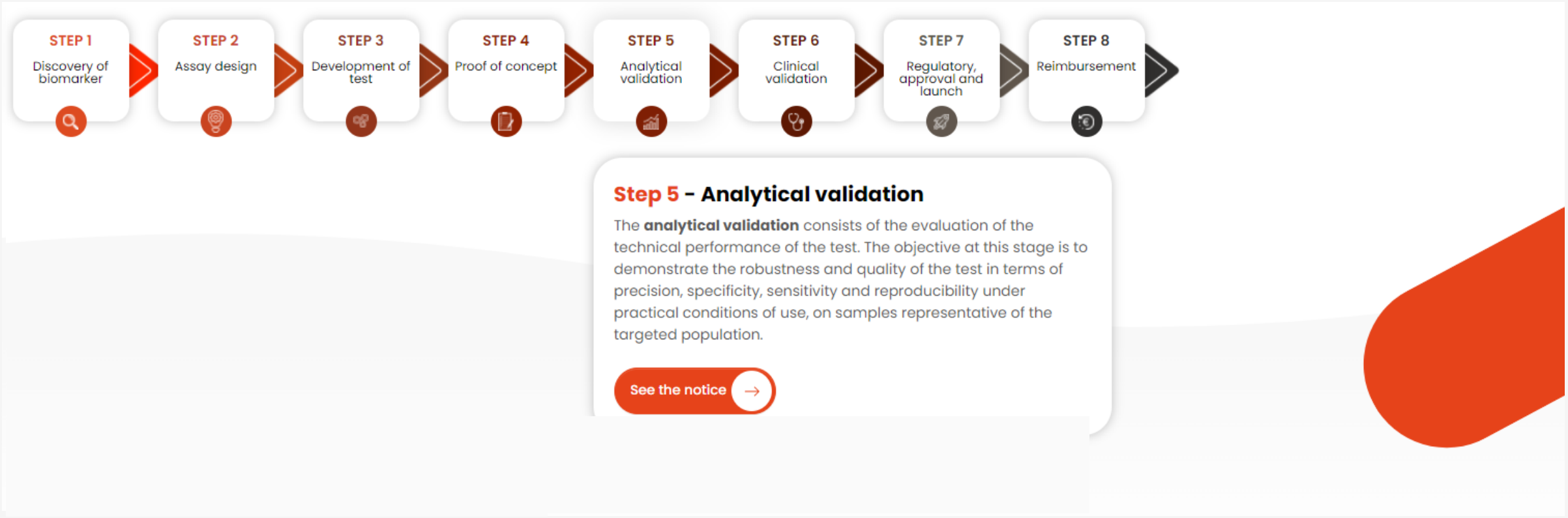
The biomarker value chain: the steps



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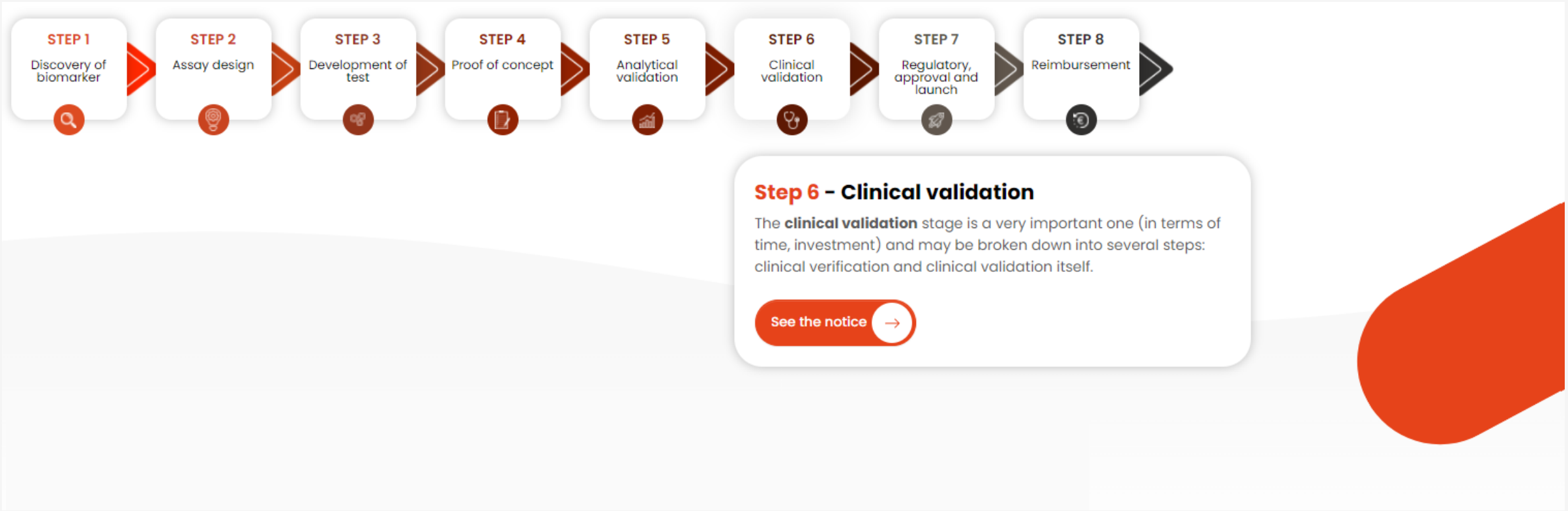
The biomarker value chain: the steps



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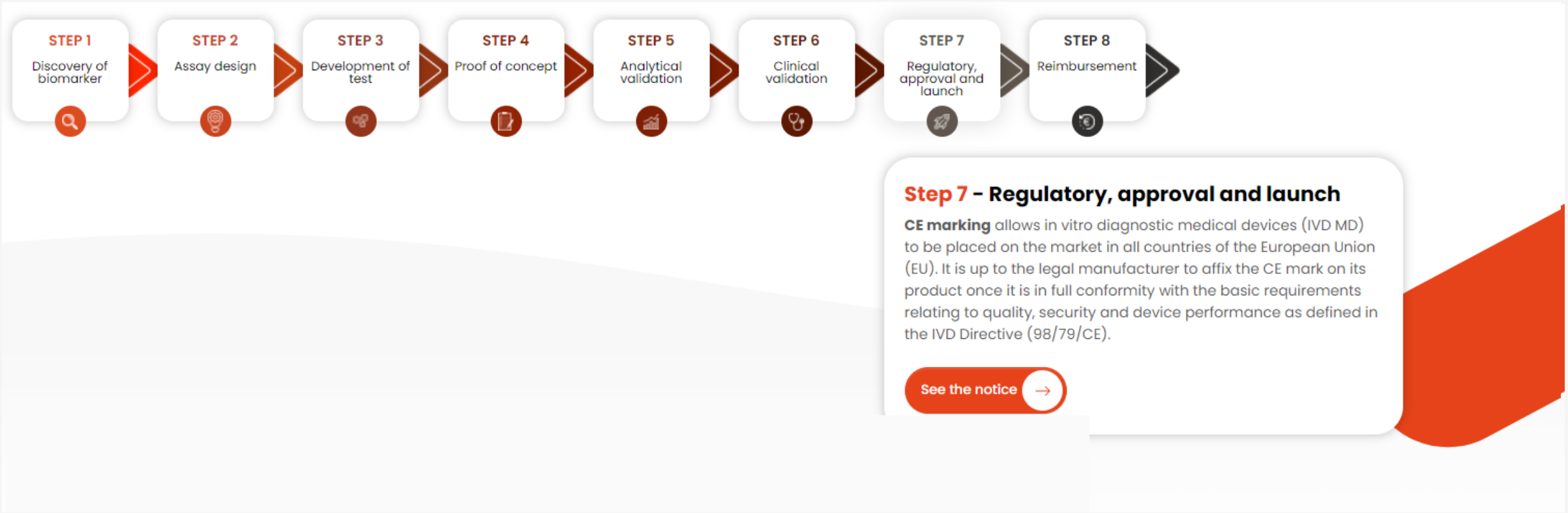
The biomarker value chain: the steps



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The biomarker value chain: the steps

Step 8 - Reimbursement

Throughout diagnostic development, testing and application, all steps of the product elaboration research and development can influence **reimbursement and market access strategies**. While most organizations start developing their approach to target markets once the diagnostic has obtained CE marking, proactive examination of requirements and reimbursement/market access pathways assists in having the test fit the system, which in turn speeds up reimbursement.

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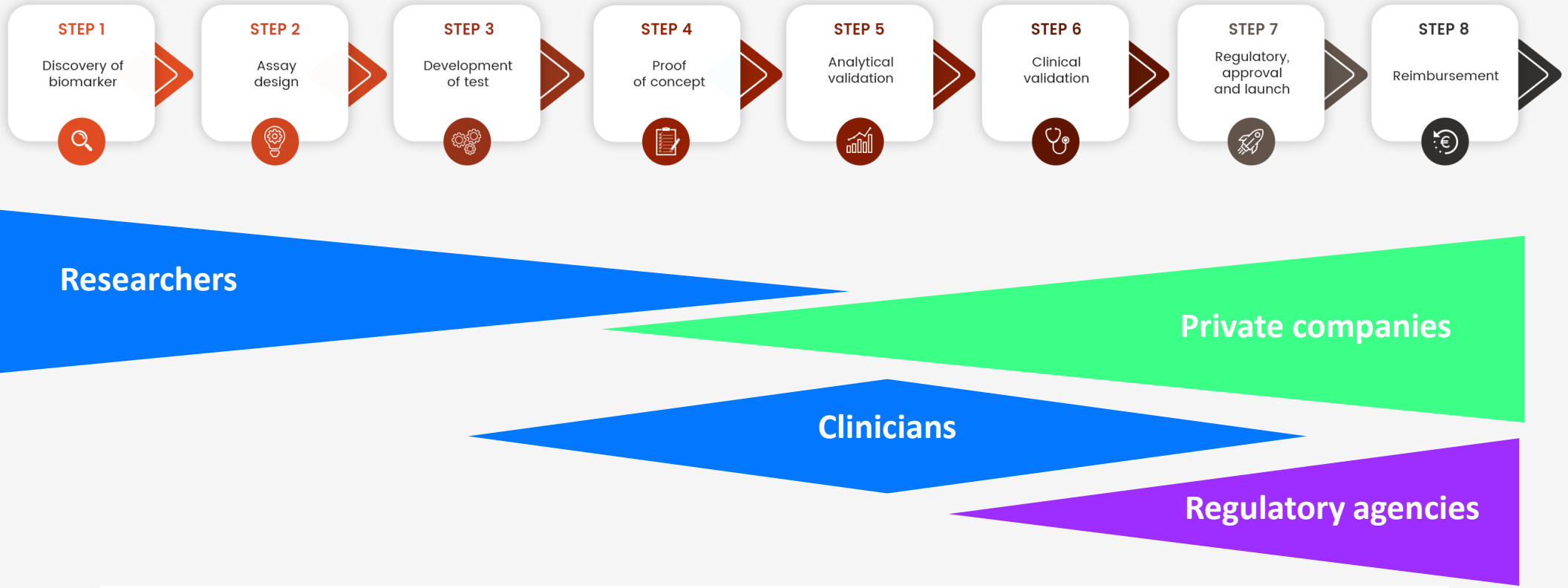
The biomarker value chain: the key players



Multiple steps and actors implying different goals, requirements and langages

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The biomarker value chain: the gap

There is a « translational » gap

- Despite the profusion of publications and patents, only a few (less than 1%) biomarkers are really used in clinical practices
- Market is difficult to address because of the divesity of the sectors: Pharma, IVD, Biotech, Medtech…

Need of coordination between the stakeholders

Importance of the public / private partnerships

Design a tool to brigde biomarkers from the lab to the patient

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The BMK TOOLS platform

Get informed: all the steps of the value chain

Position a project on the value chain

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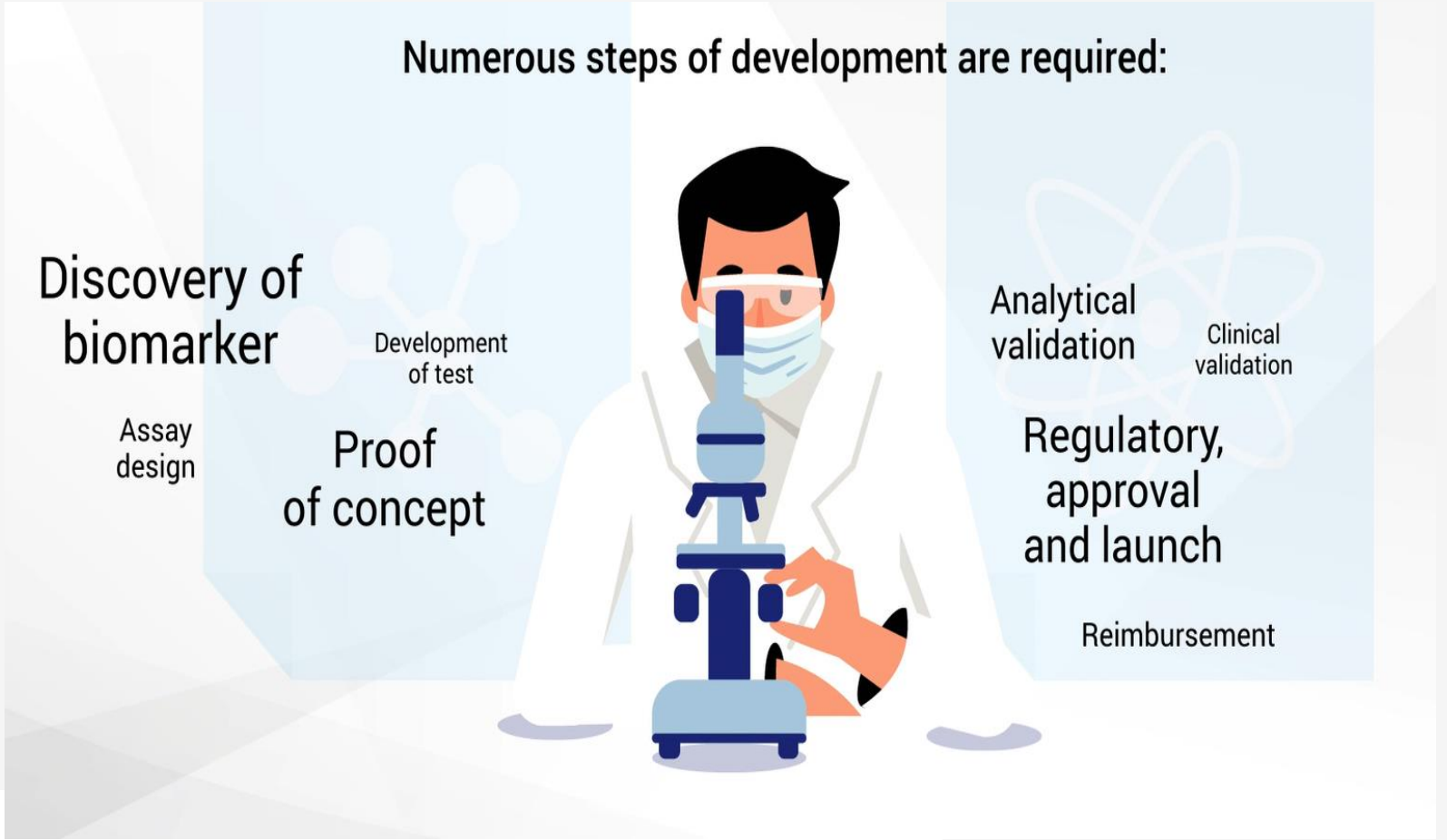
Align the players of the ecosystem



Align the players of the ecosystem

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The « education » module

Explanation sheet

- Step description
- Questions to investigate
- Definitions
- Links
- …

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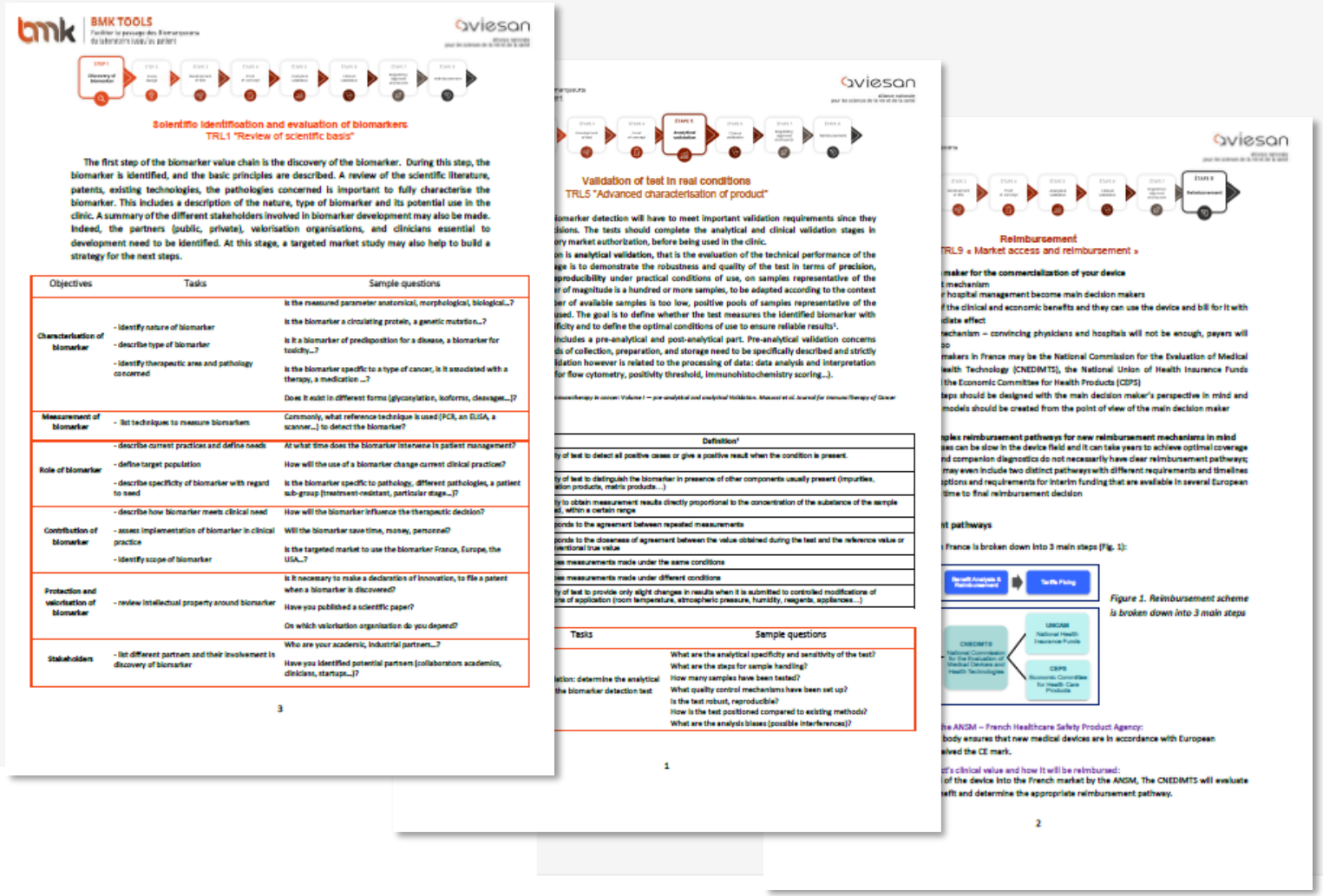
The « education » module

BMK TOOLS booklet



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The « education » module

→ **Facilitate the understanding of the different steps of the biomarker development**

→ **Allow the different communities to rely on the same language**

→ **Accelerate public / private partnerships**

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Position a project: the questionnaire

Personnal account:

A secure space

A dynamic questionnaire to position projects

A possibility to ask for support

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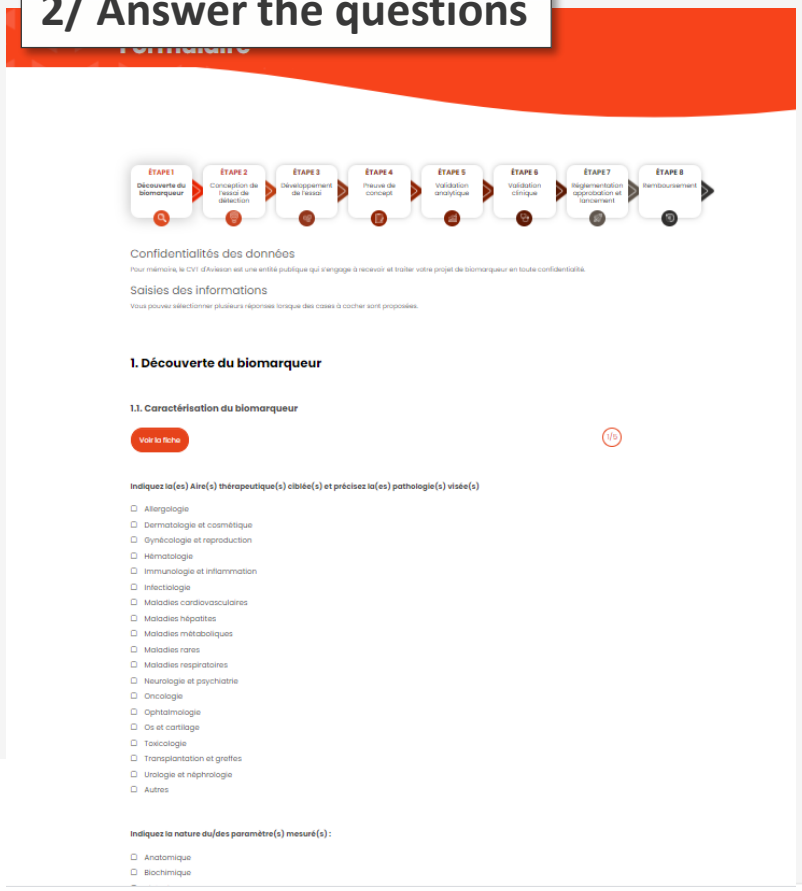
Position a project: the questionnaire

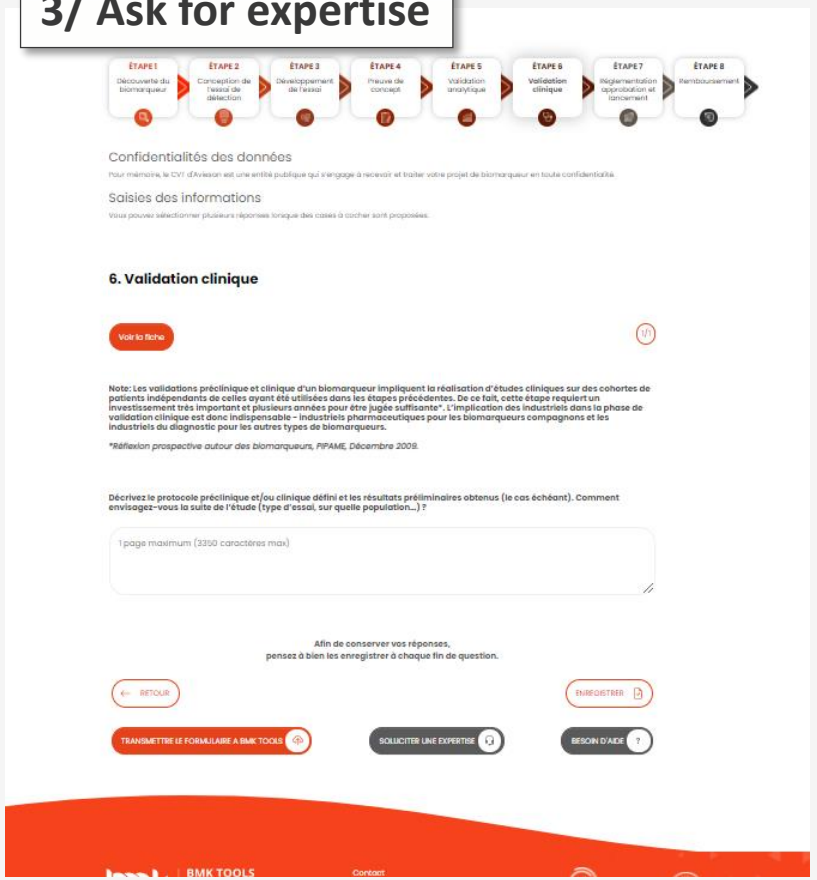
The dynamic questionnaire to position the research projects

1/ Fill a new form

2/ Answer the questions



3/ Ask for expertise



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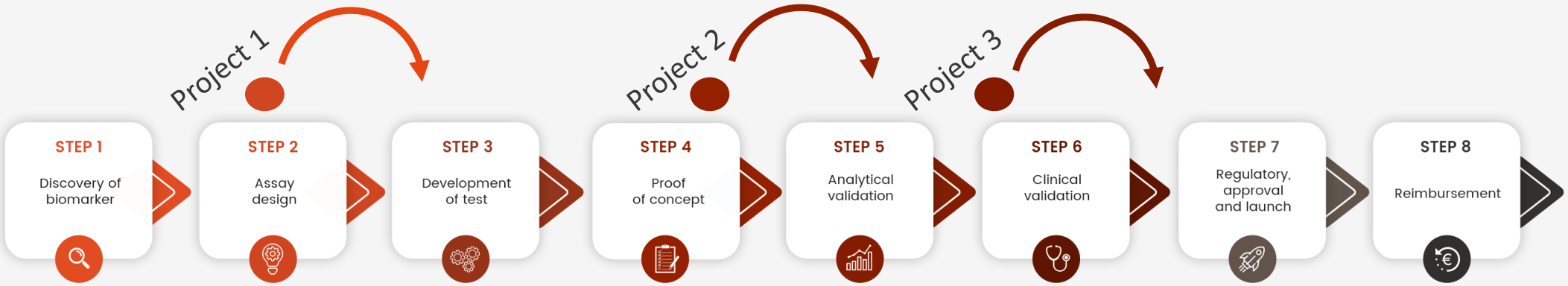
Position a project: the questionnaire



- Bridges between stakeholders
- Share expertise
- Connect the different communities

➔ **Help projects to move forward !**

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The support of experts

1 **Online projects filing**

2 **Autonomous use** or **Help** or **Advisory committee**

	Autonomous use	Help	Advisory committee
What ?	→ All the projects → Independant of the BMK Tools® team	→ Early projects → Questions adressed by the BMK Tools® team	→ Mature projects / specific needs → Advisory committee
Who ?			
When ?	→ Throughout the year	→ Throughout the year	→ 2 or 3 committees per year

3 **Researchers / Industrial meeting**

4 **Public / Private partnership**

Advisory committee

- **Alain Horvais :** Kurma Life Sciences
- **Catherine Larue** : EATRIS
- **Christophe Cans :** Sanofi
- **Daniel Laune :** KYomedINNOV
- **Jérôme Sallette :** Cerba Healthcare
- **John De Vos :** CHU Montpellier
- **Karine Kaiser :** Biomérieux
- **Patrick Rossignol :** CHU de Nancy
- **…**

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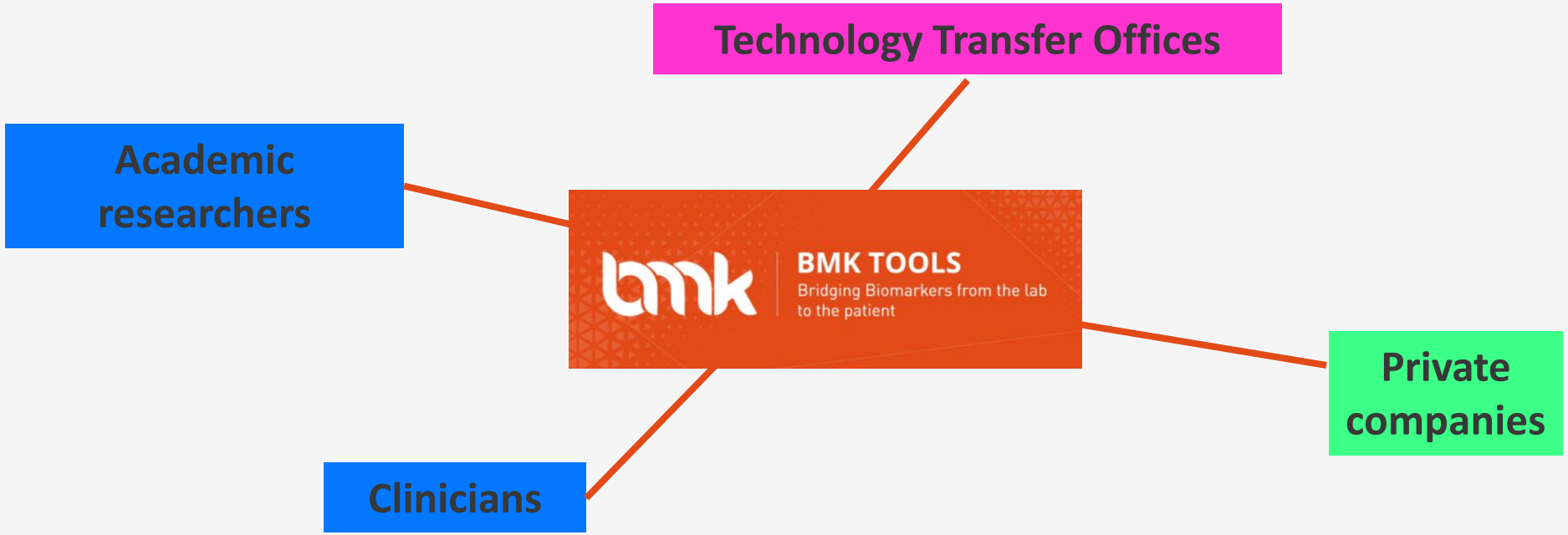
Connecting the dots…



Connecting the dots by creating a unique place to gather all the key players

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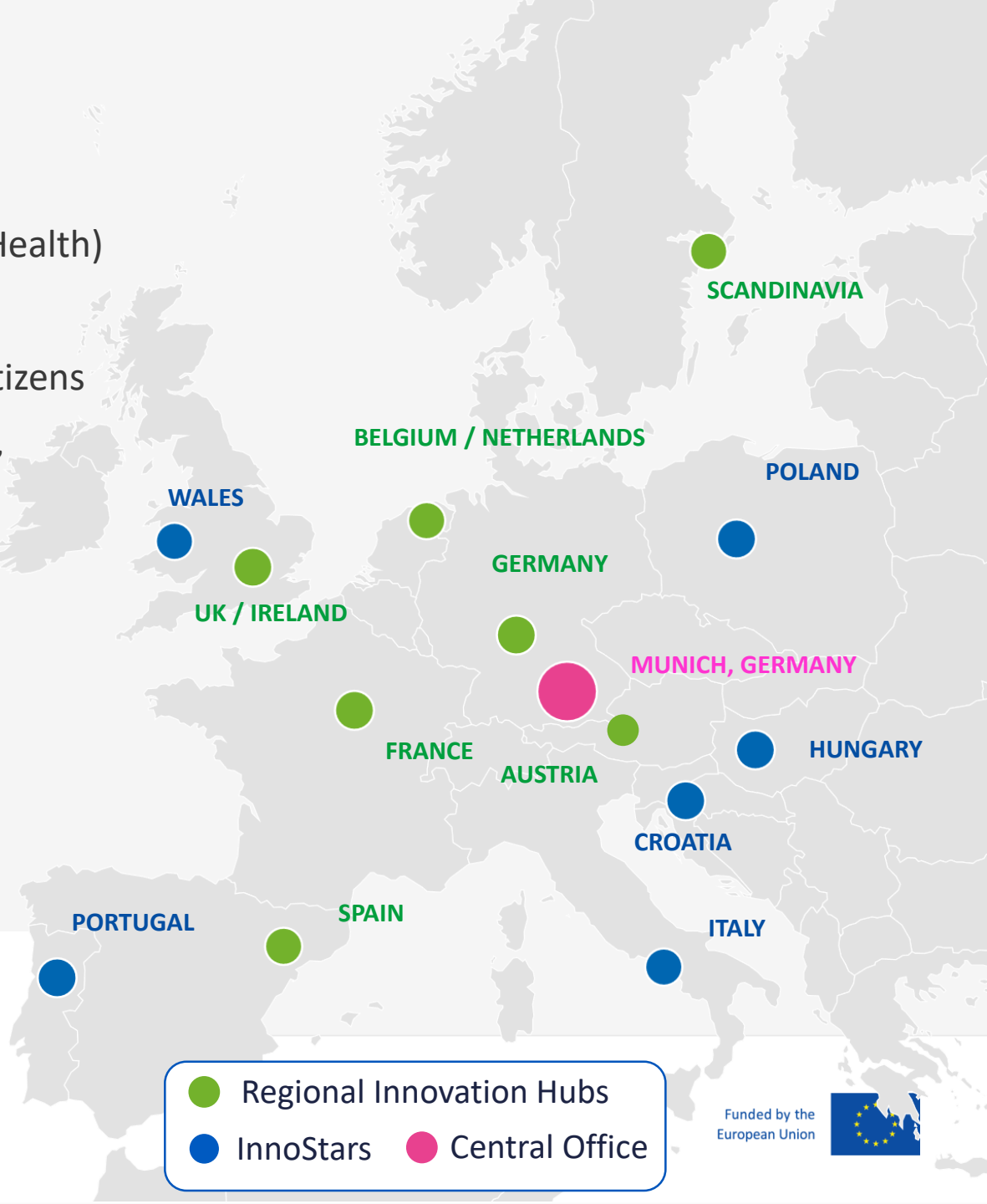
EIT Health involvment

EIT Health (European Institute of Innovation and Technology in Health)

- A network of public and private partners
- Programmes to support students, startups, research teams, citizens
- Develop and implement digital tools (WorkInHealth, Academy, RABBIT…)

Investments in the BMK TOOLS project

- Fundings
- Technological skills
- Partner network
- Experts all over Europe



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Bridging biomarkers from the lab to the patient

https://biomarqueurs.aviesan.fr

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