



Hub PASREL 15<sup>th</sup> of March 2022

# BMK TOOLS

**Bridging biomarkers from the lab to the patient**

Funded by the  
European Union



# 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<sup>4</sup>
- Highlight French research

## Energy



## Human and social sciences



## Environment



## Digital technologies



## Life sciences and health



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



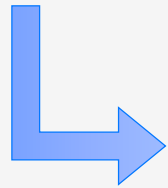
## Aviesan main objectives

- Scientific coordination
  - Operational coordination
- More visibility and reactivity
- To share priorities on structuring projects

# 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**

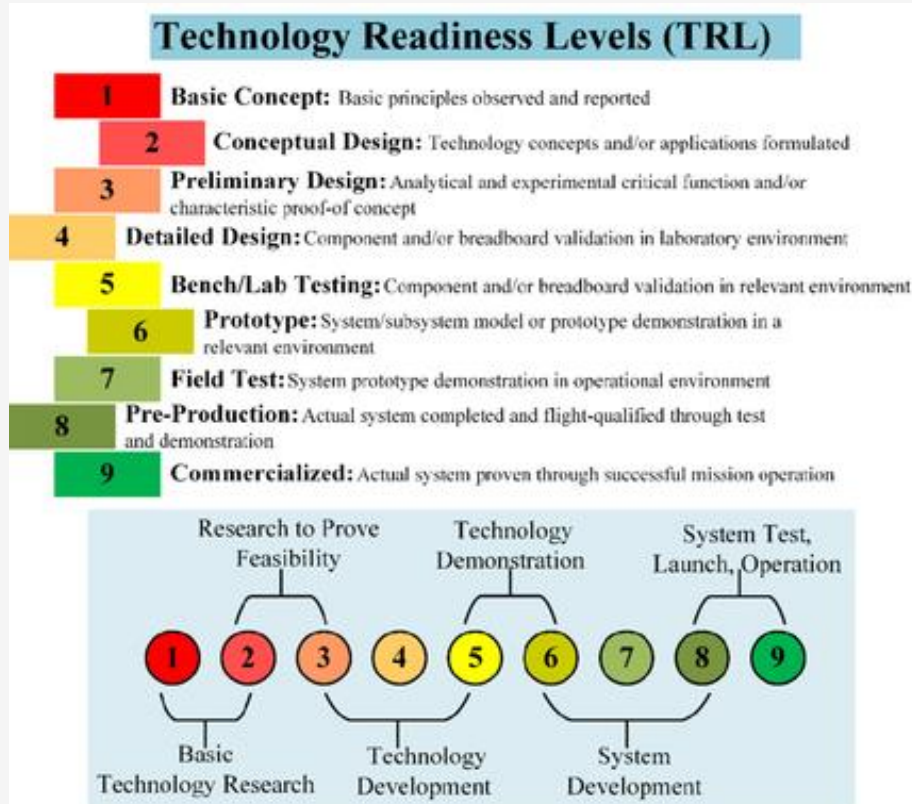
Bridging Biomarkers from the lab  
to the patient



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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

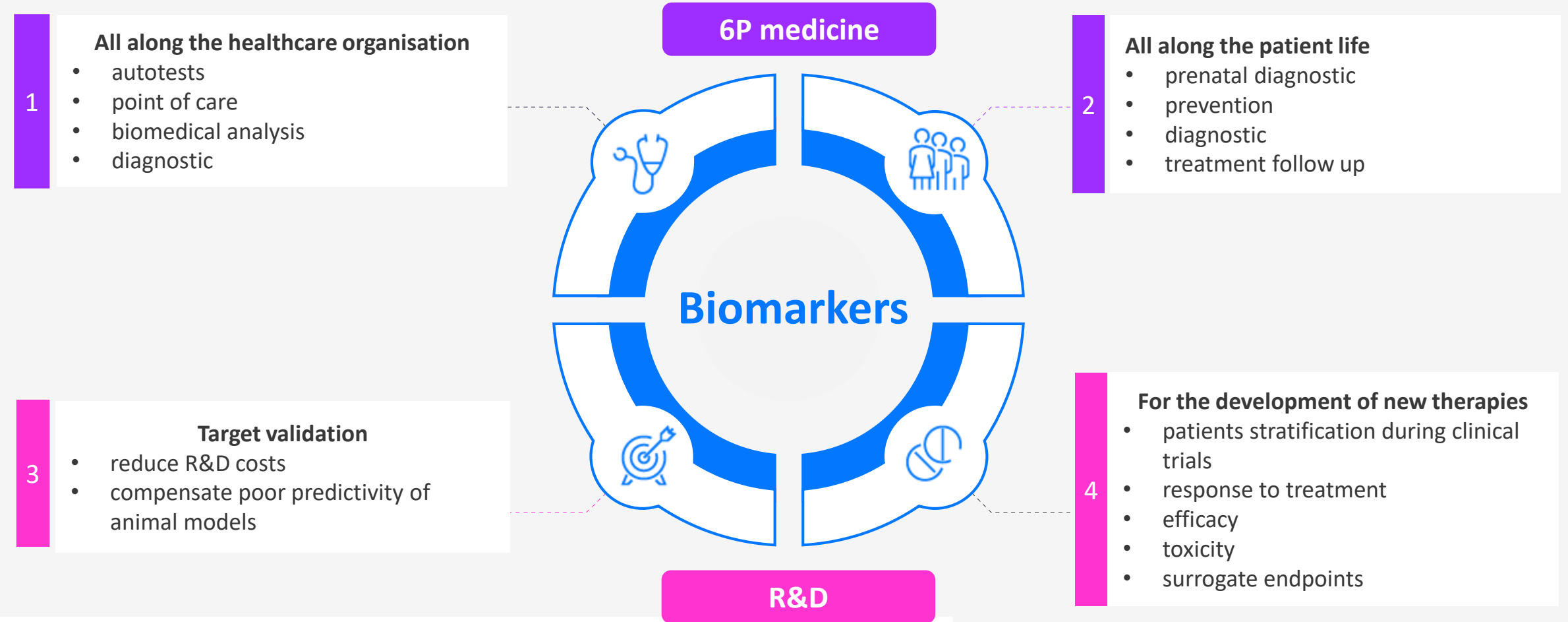
The majority of medical decisions relies on biomarker and diagnostic tools

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 !

# The central role of biomarkers



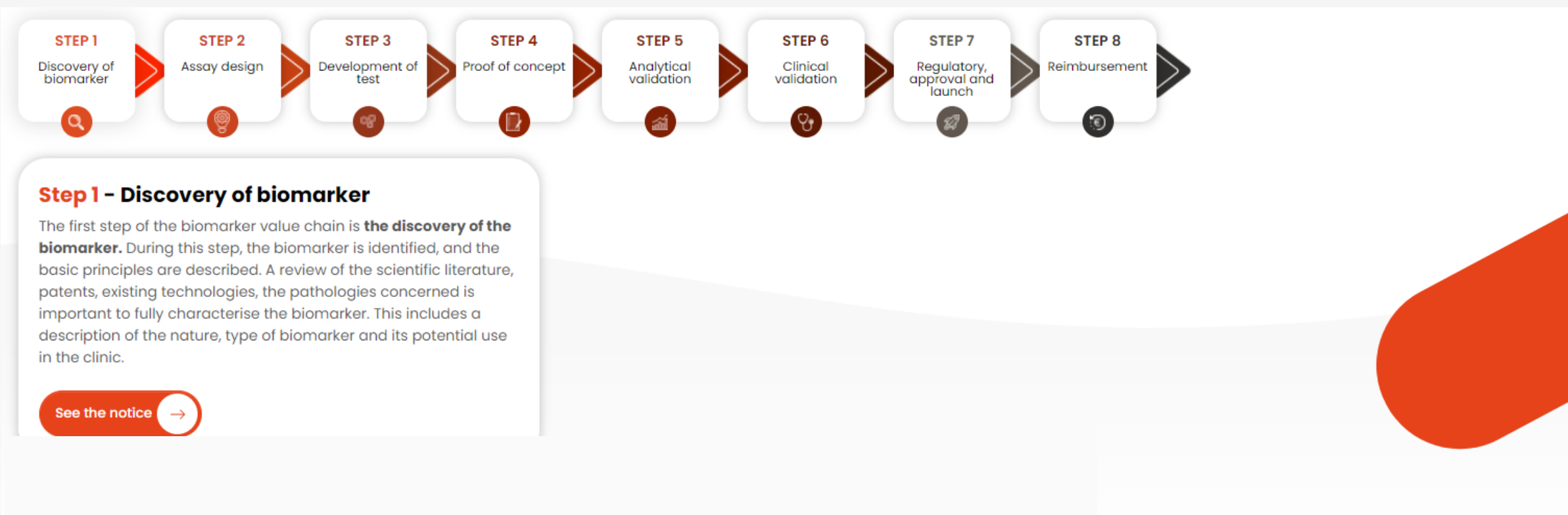
# The biomarker value chain: the steps

## > THE BIOMARKER VALUE CHAIN

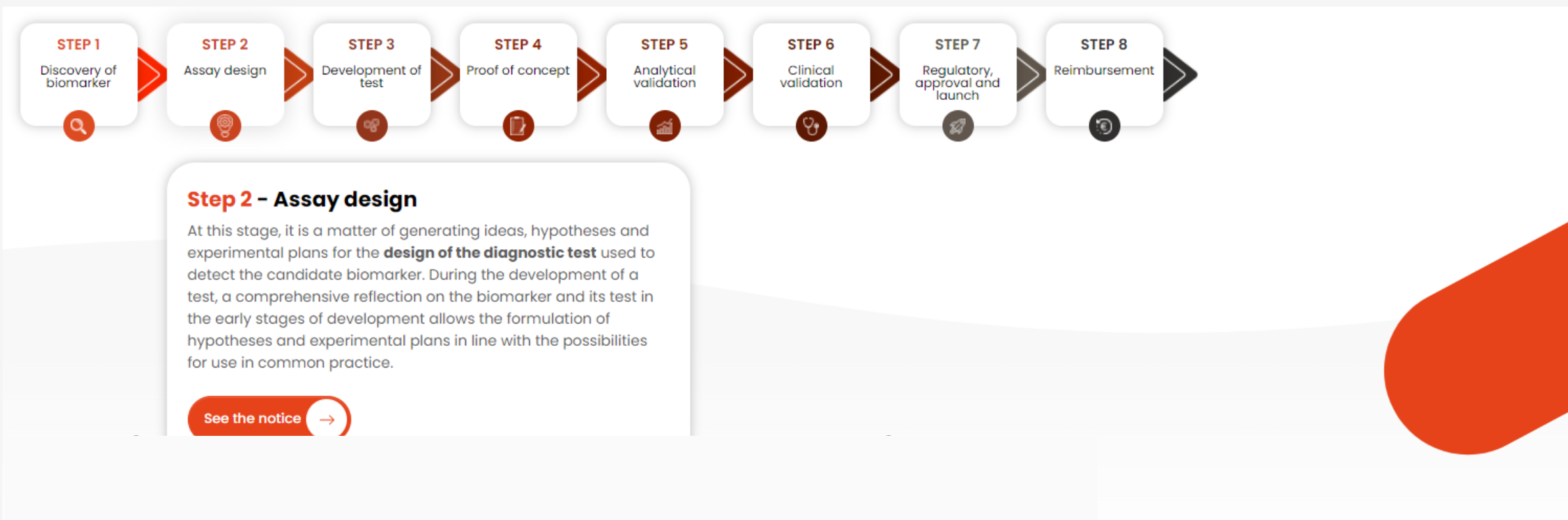
### Development stages of a biomarker



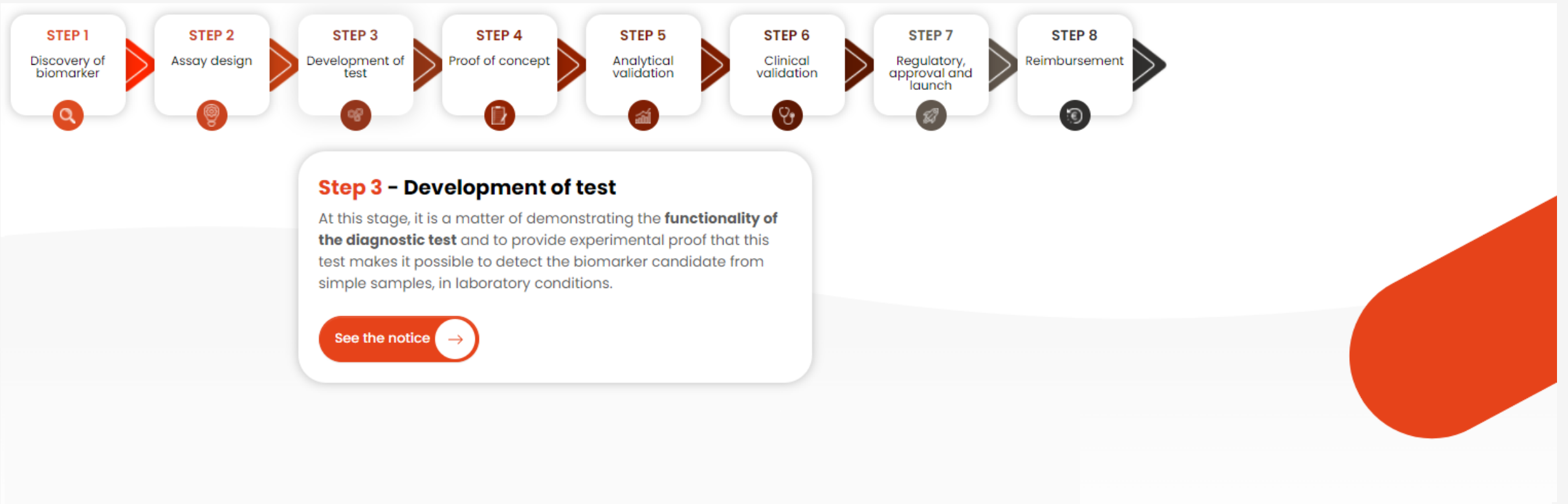
# The biomarker value chain: the steps



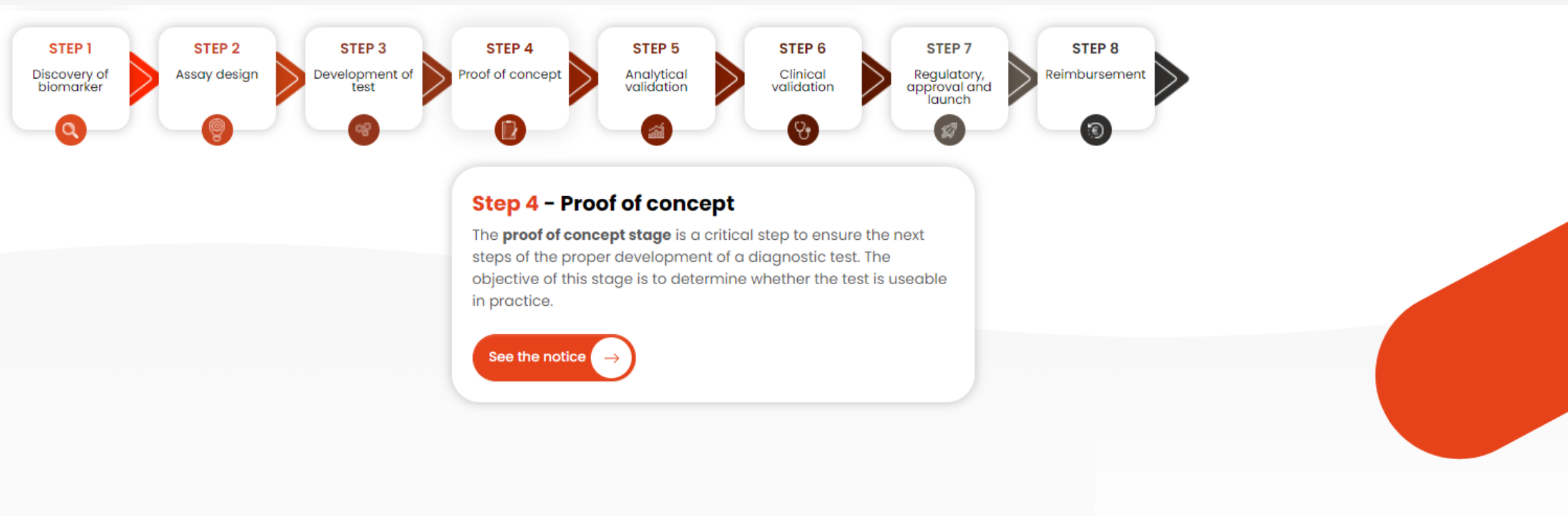
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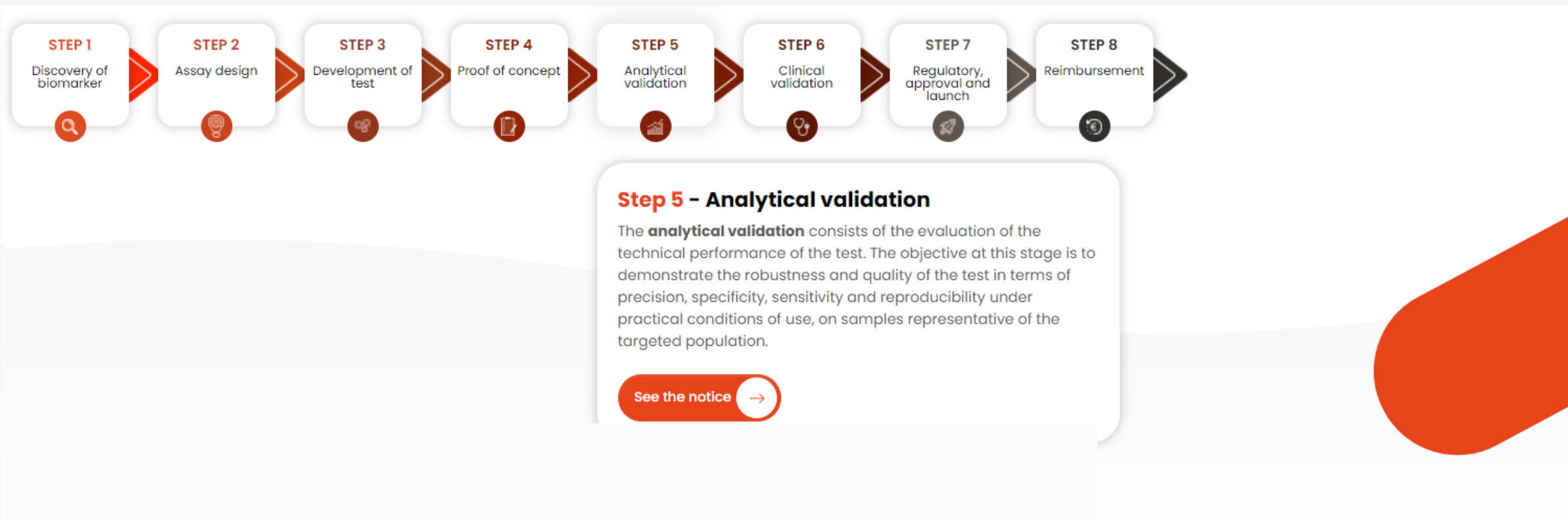
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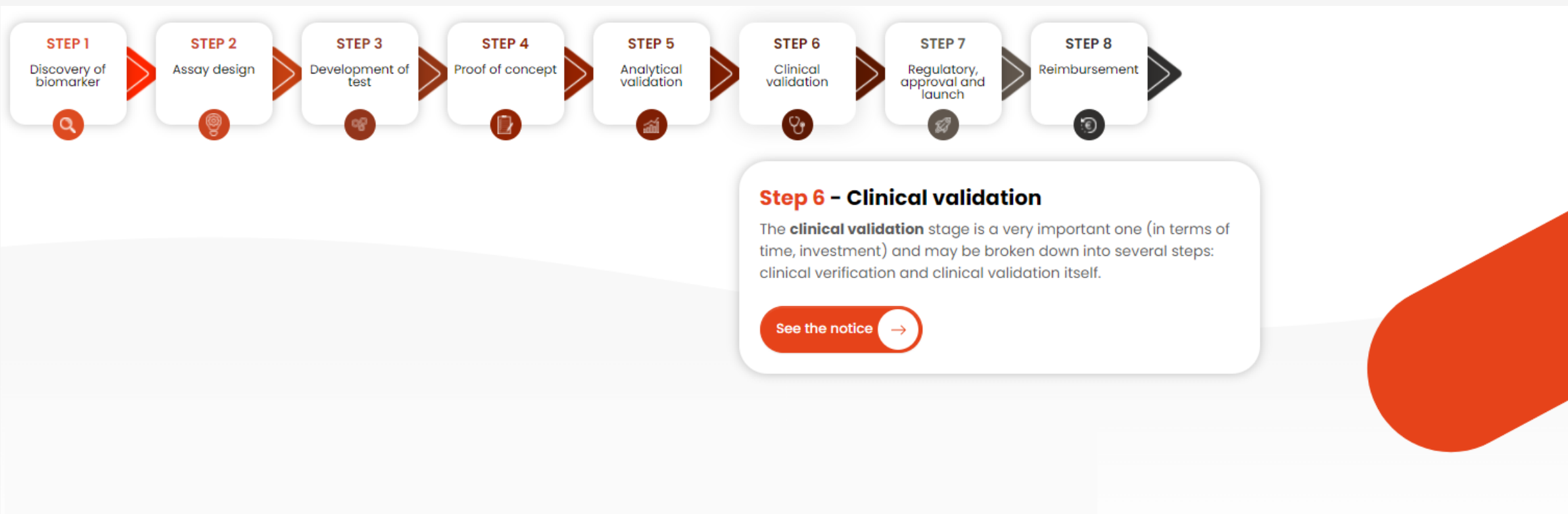
# The biomarker value chain: the steps



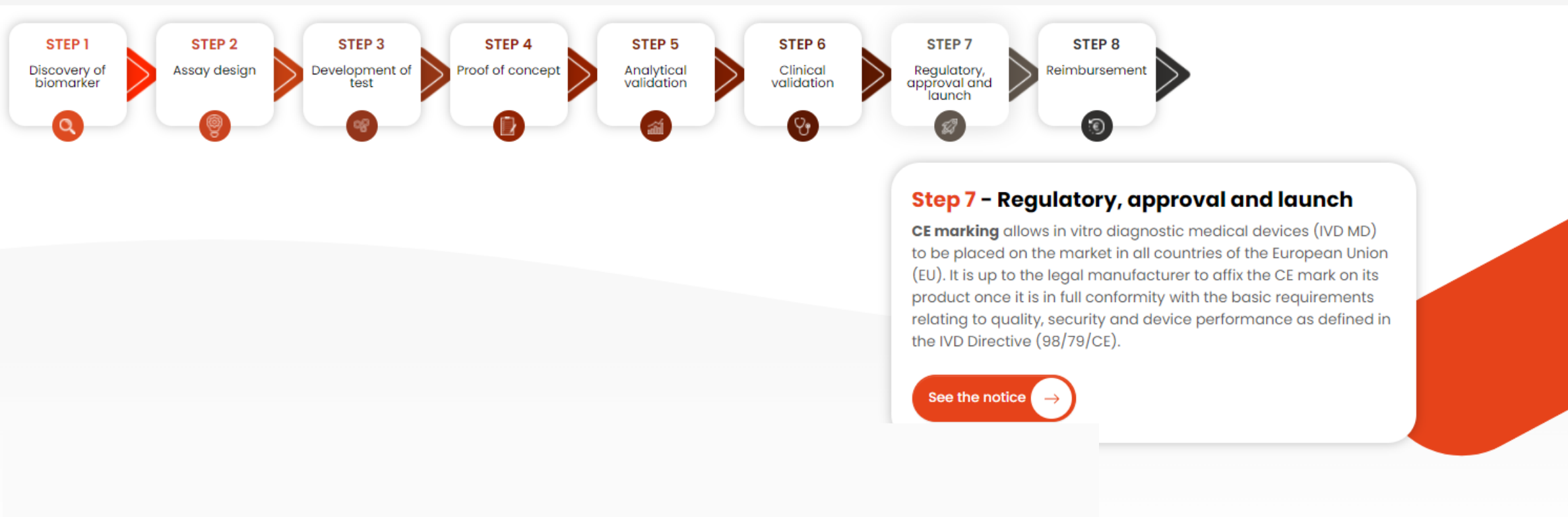
# The biomarker value chain: the steps



# The biomarker value chain: the steps



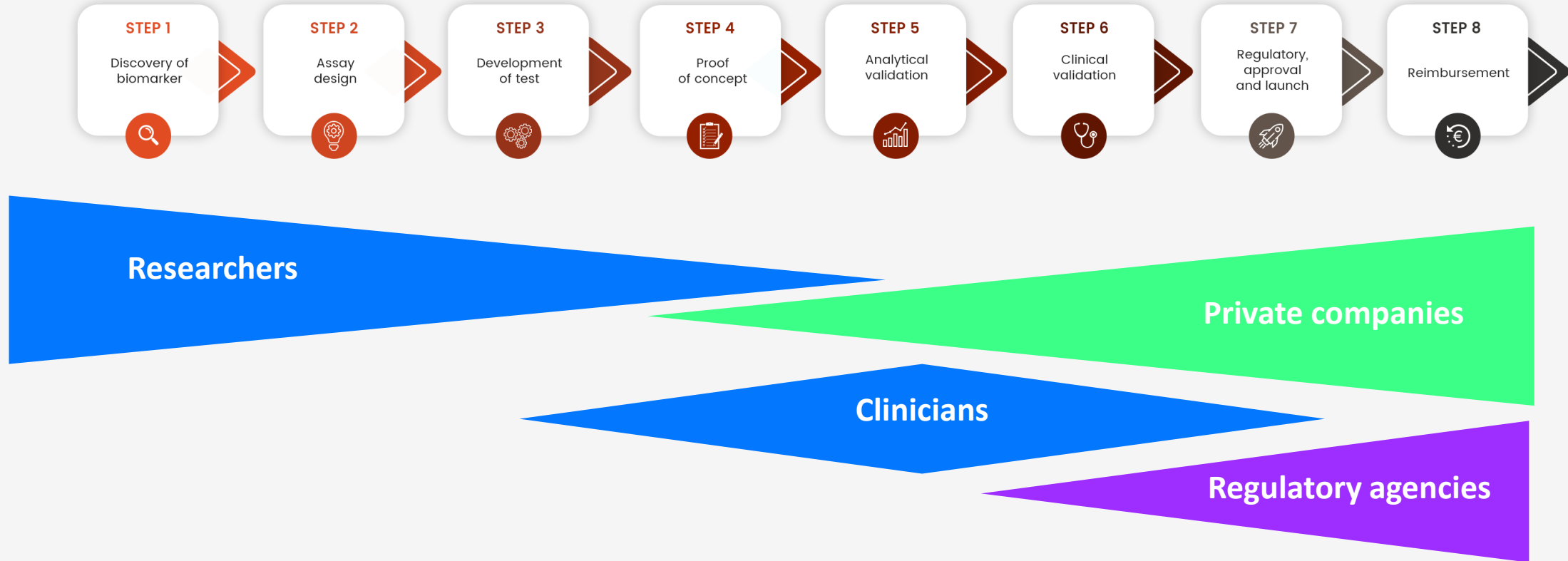
# The biomarker value chain: the steps



# The biomarker value chain: the steps



# The biomarker value chain: the key players



Multiple steps and actors implying different goals, requirements and languages

# 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 diversity of the sectors: Pharma, IVD, Biotech, Medtech...



**Need of coordination between the stakeholders**



**Importance of the public / private partnerships**



**Design a tool to bridge biomarkers  
from the lab to the patient**

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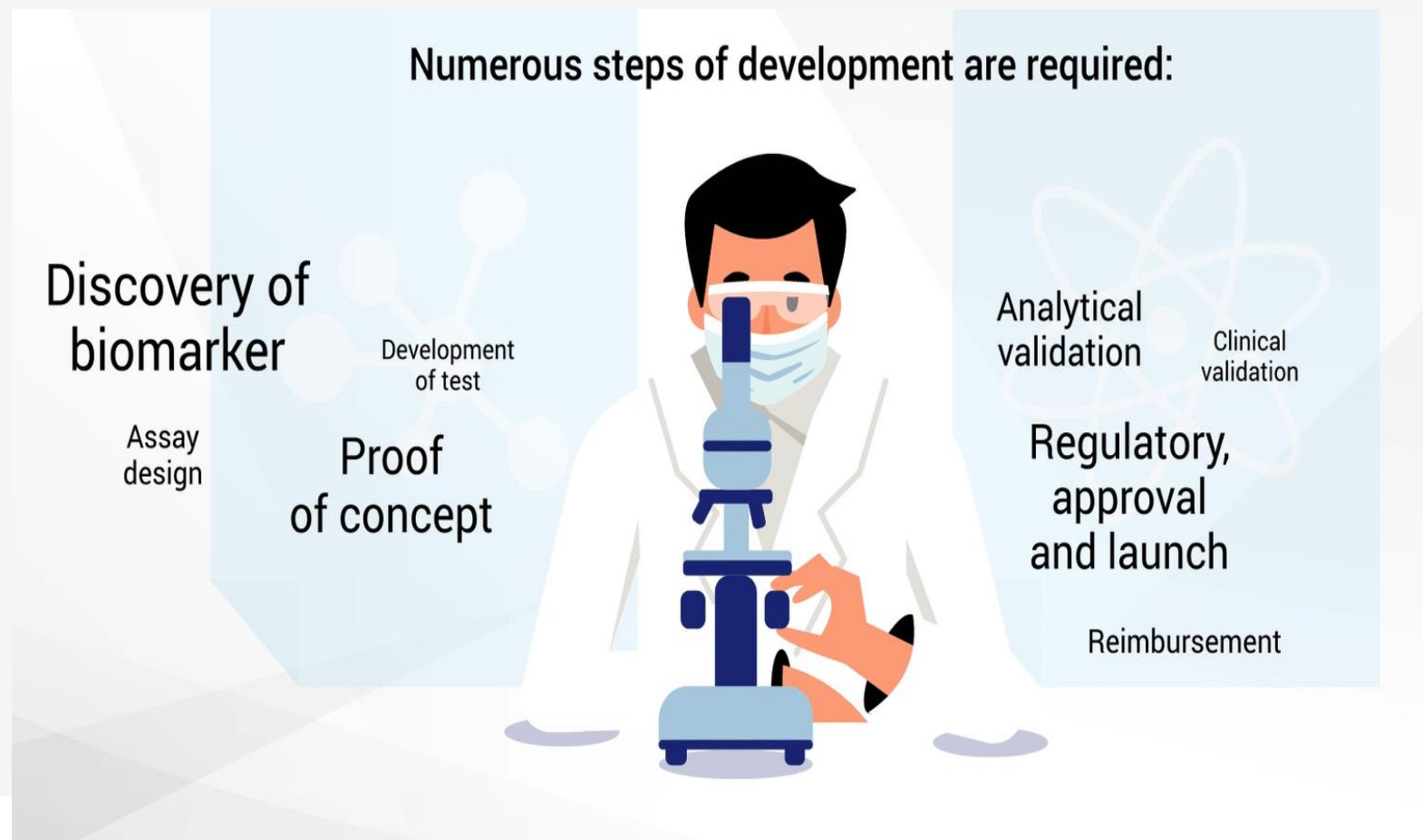
# The BMK TOOLS platform



Get informed: all the steps of the value chain

Position a project on the value chain

# Align the players of the ecosystem



# Align the players of the ecosystem

A long way to come, involving many partners and expertises



# The « education » module



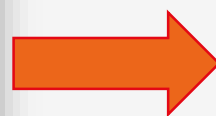
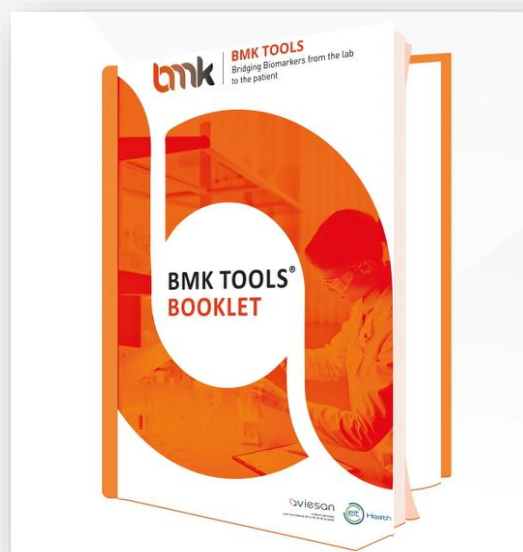
## Explanation sheet



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

# The « education » module

## BMK TOOLS booklet



**bmK** | **BMK TOOLS**  
Faciliter le passage des Biomarqueurs  
du laboratoire à l'usage clinique

**Aviesan**  
Alliance nationale pour les sciences de la vie et de la santé

**Scientific identification and evaluation of biomarkers**  
TRL1 "Review of scientific basis"

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. A summary of the different stakeholders involved in biomarker development may also be made. Indeed, the partners (public, private), valorisation organisations, and clinicians essential to development need to be identified. At this stage, a targeted market study may also help to build a strategy for the next steps.

Objectives	Tasks	Sample questions
<b>Characterisation of biomarker</b>	<ul style="list-style-type: none"> <li>Identify nature of biomarker</li> <li>Describe type of biomarker</li> <li>Identify therapeutic area and pathology concerned</li> </ul>	<p>Is the measured parameter anatomical, morphological, biological...?</p> <p>Is the biomarker a circulating protein, a genetic mutation...?</p> <p>Is it a biomarker of predisposition for a disease, a biomarker for toxicity...?</p> <p>Is the biomarker specific to a type of cancer, is it associated with a therapy, a medication...?</p> <p>Does it exist in different forms (glycosylation, isoforms, cleavage...)?</p>
<b>Measurement of biomarker</b>	<ul style="list-style-type: none"> <li>Set techniques to measure biomarkers</li> </ul>	Commonly, what reference technique is used (PCR, an ELISA, a scanner...) to detect the biomarker?
<b>Role of biomarker</b>	<ul style="list-style-type: none"> <li>Describe current practices and define needs</li> <li>Define target population</li> <li>Describe specificity of biomarker with regard to need</li> <li>Describe how biomarker meets clinical need</li> </ul>	<p>At what time does the biomarker intervene in patient management?</p> <p>How will the use of a biomarker change current clinical practice?</p> <p>Is the biomarker specific to pathology, different pathologies, a patient sub-group (treatment-resistant, particular stage...)?</p> <p>How will the biomarker influence the therapeutic decision?</p>
<b>Contribution of biomarker</b>	<ul style="list-style-type: none"> <li>Assess implementation of biomarker in clinical practice</li> <li>Identify scope of biomarker</li> </ul>	<p>Will the biomarker save time, money, personnel?</p> <p>Is the targeted market to use the biomarker France, Europe, the USA...?</p>
<b>Protection and valorisation of biomarker</b>	<ul style="list-style-type: none"> <li>Review intellectual property around biomarker</li> </ul>	<p>Is it necessary to make a declaration of innovation, to file a patent when a biomarker is discovered?</p> <p>Have you published a scientific paper?</p> <p>On which valorisation organisation do you depend?</p>
<b>Stakeholders</b>	<ul style="list-style-type: none"> <li>List different partners and their involvement in discovery of biomarker</li> </ul>	<p>Who are your academic, industrial partners...?</p> <p>Have you identified potential partners (collaboration academic, clinicians, startups...)?</p>

3

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**Validation of test in real conditions**  
TRL5 "Advanced characterisation of product"

Biomarker detection will have to meet important validation requirements since they are used. The tests should complete the analytical and clinical validation stages in order to demonstrate the robustness and quality of the test in terms of precision, reproducibility under practical conditions of use, on samples representative of the target population. This is analytical validation, that is the evaluation of the technical performance of the test. The goal is to demonstrate the robustness and quality of the test in terms of precision, reproducibility under practical conditions of use, on samples representative of the target population. This is analytical validation, that is the evaluation of the technical performance of the test. The goal is to demonstrate the robustness and quality of the test in terms of precision, reproducibility under practical conditions of use, on samples representative of the target population.

Definition
Ability of test to detect all positive cases or give a positive result when the condition is present.
Ability of test to distinguish the biomarker in presence of other components usually present (impurities, other products, matrix products...)
Ability to obtain measurement results directly proportional to the concentration of the substance of the sample tested, within a certain range
Ability to obtain the same result between repeated measurements
Ability to obtain the same result between the value obtained during the test and the reference value or theoretical true value
Ability to obtain the same result under different conditions
Ability of test to provide only slight changes in results when it is submitted to controlled modifications of the conditions of application (room temperature, atmospheric pressure, humidity, reagents, appliances...)

Tasks	Sample questions
Validation: determine the analytical performance of the biomarker detection test	<p>What are the analytical specificity and sensitivity of the test?</p> <p>What are the steps for sample handling?</p> <p>How many samples have been tested?</p> <p>What quality control mechanisms have been set up?</p> <p>Is the test robust, reproducible?</p> <p>How is the test positioned compared to existing methods?</p> <p>What are the analysis biases (possible interferences)?</p>

1

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**Reimbursement**  
TRL8 "Market access and reimbursement"

Reimbursement for the commercialization of your device

In France, the reimbursement of a medical device is a complex process. It involves several stakeholders: the National Commission for the Evaluation of Medical Health Technology (CNEDIMTS), the National Union of Health Insurance Funds (UNAF), the Economic Committee for Health Products (CEHP), and the French Healthcare Safety Product Agency (ANSM). The reimbursement process is broken down into 3 main steps (Fig. 1):

- Step 1: Evaluation of the device by the CNEDIMTS.
- Step 2: Evaluation of the device by the UNAF.
- Step 3: Evaluation of the device by the CEHP.

Figure 1. Reimbursement scheme is broken down into 3 main steps

2

# 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

# Position a project: the questionnaire



## Personnal account:

A secure space

A dynamic questionnaire to position projects

A possibility to ask for support

# Position a project: the questionnaire

The dynamic questionnaire to position the research projects

## 1/ Fill a new form

### Formulaires



### Bienvenue sur votre compte BMK Tools

Depuis votre compte, remplissez de nouveaux formulaires et modifiez-les à tout moment. Une fois soumis vous pouvez les télécharger aux formats excel ou pdf.

Pour vous préparer à remplir un formulaire, vous pouvez télécharger le formulaire et prendre connaissance des différentes informations dont vous avez besoin. Des fiches explicatives sont également disponibles.

[Remplir un nouveau formulaire](#) [Formulaire téléchargeable](#) [Fiches explicatives](#)

#### Mes formulaires

Date	Titre	État	Action
Aucun formulaire de trouvé.			



**BMK TOOLS**  
Faciliter le passage des Biomarqueurs  
du laboratoire pour le patient

Contact  
BMK TOOLUP  
Avelon 8, rue de la Croix Jarry  
75018 Paris



BMK TOOLUP a été créé pour faciliter la maîtrise et la complétion, par choix, des différentes étapes de développement d'un biomarqueur.

[Mentions légales](#) | [Cookies](#) | [Conditions Générales d'Utilisation](#) | [Données personnelles](#) | [Contact](#)



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## 2/ Answer the questions



### Confidentialité des données

Pour mémoire, le CVI d'Aviesan est une entité publique qui s'engage à recevoir et traiter votre projet de biomarqueur en toute confidentialité.

### Saisies des informations

Vous pouvez sélectionner plusieurs réponses lorsque des cases à cocher sont proposées.

### 1. Découverte du biomarqueur

#### 1.1. Caractérisation du biomarqueur

[Voir la fiche](#)

Indiquez la(es) Aire(s) thérapeutique(s) ciblée(s) et précisez la(es) pathologie(s) visée(s)

- ☐ Allergologie
- ☐ Dermatologie et cosmétique
- ☐ Gynécologie et reproduction
- ☐ Hématologie
- ☐ Immunologie et inflammation
- ☐ Infectiologie
- ☐ Maladies cardiovasculaires
- ☐ Maladies hépatites
- ☐ Maladies métaboliques
- ☐ Maladies rares
- ☐ Maladies respiratoires
- ☐ Neurologie et psychiatrie
- ☐ Oncologie
- ☐ Ophtalmologie
- ☐ Os et cartilage
- ☐ Toxicologie
- ☐ Transplantation et greffes
- ☐ Urologie et néphrologie
- ☐ Autres

Indiquez la nature du/des paramètre(s) mesuré(s) :

- ☐ Anatomique
- ☐ Biochimique

## 3/ Ask for expertise



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### Saisies des informations

Vous pouvez sélectionner plusieurs réponses lorsque des cases à cocher sont proposées.

### 6. Validation clinique

[Voir la fiche](#)

Note: Les validations préclinique et clinique d'un biomarqueur impliquent la réalisation d'études cliniques sur des cohortes de patients indépendants de celles ayant été utilisées dans les étapes précédentes. De ce fait, cette étape requiert un investissement très important et plusieurs années pour être jugée suffisante. L'implication des industriels dans la phase de validation clinique est donc indispensable - industriels pharmaceutiques pour les biomarqueurs compagnons et les industriels du diagnostic pour les autres types de biomarqueurs.

\*Réflexion prospective autour des biomarqueurs, PIPAME, Décembre 2008.

Décrivez le protocole préclinique et/ou clinique défini et les résultats préliminaires obtenus (le cas échéant). Comment envisagez-vous la suite de l'étude (type d'essai, sur quelle population...) ?

1 page maximum (3200 caractères max)

Afin de conserver vos réponses,  
pensez à bien les enregistrer à chaque fin de question.

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[TRANSMETTRE LE FORMULAIRE A BMK TOOLS](#)

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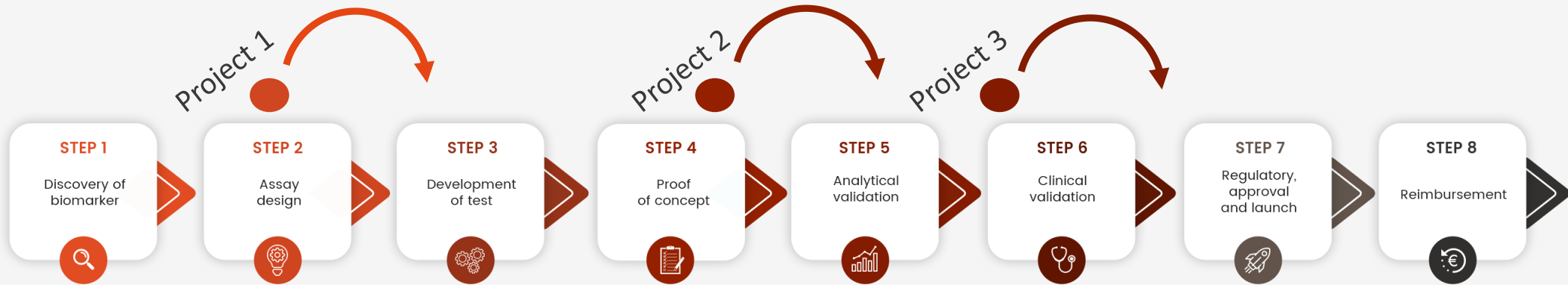
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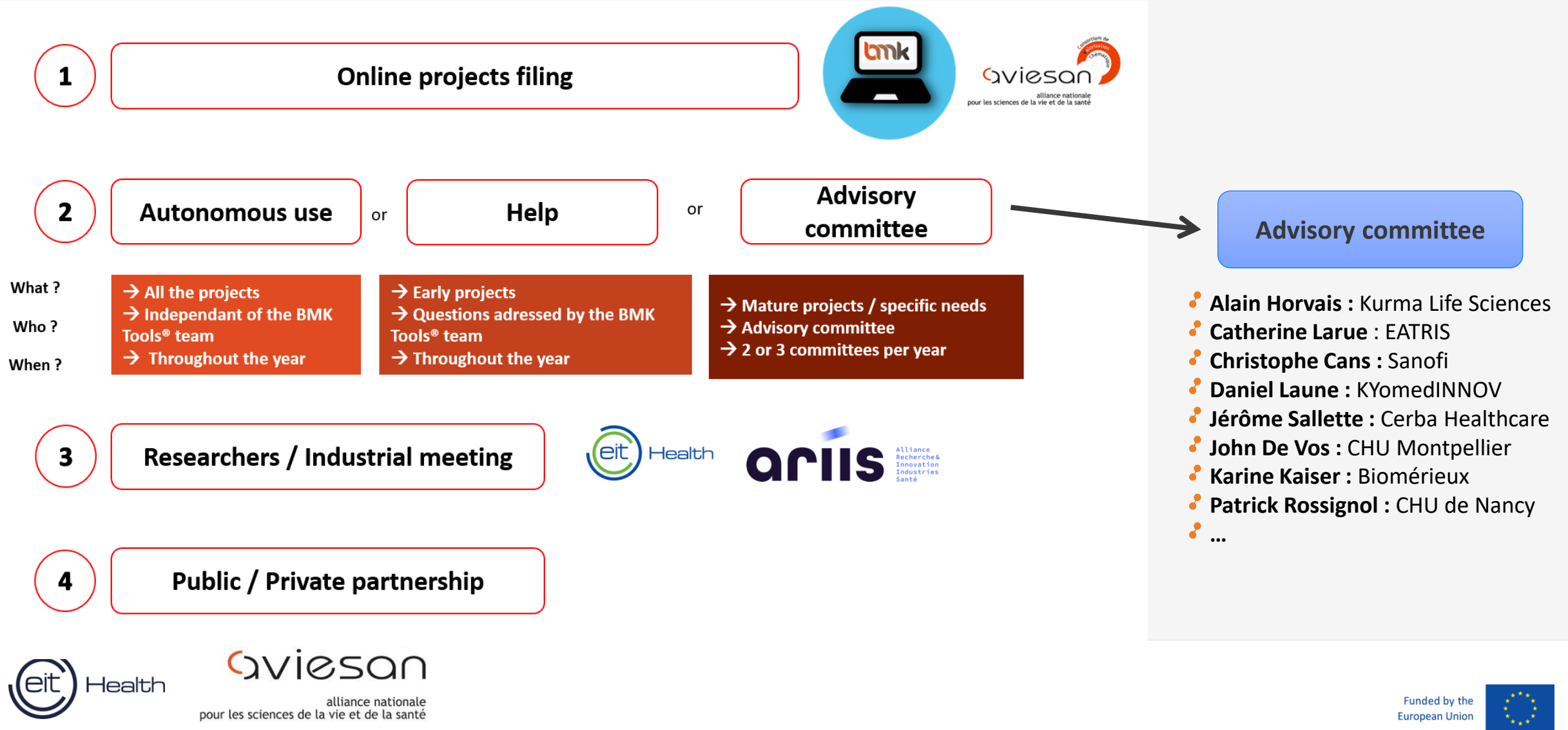
# Position a project: the questionnaire



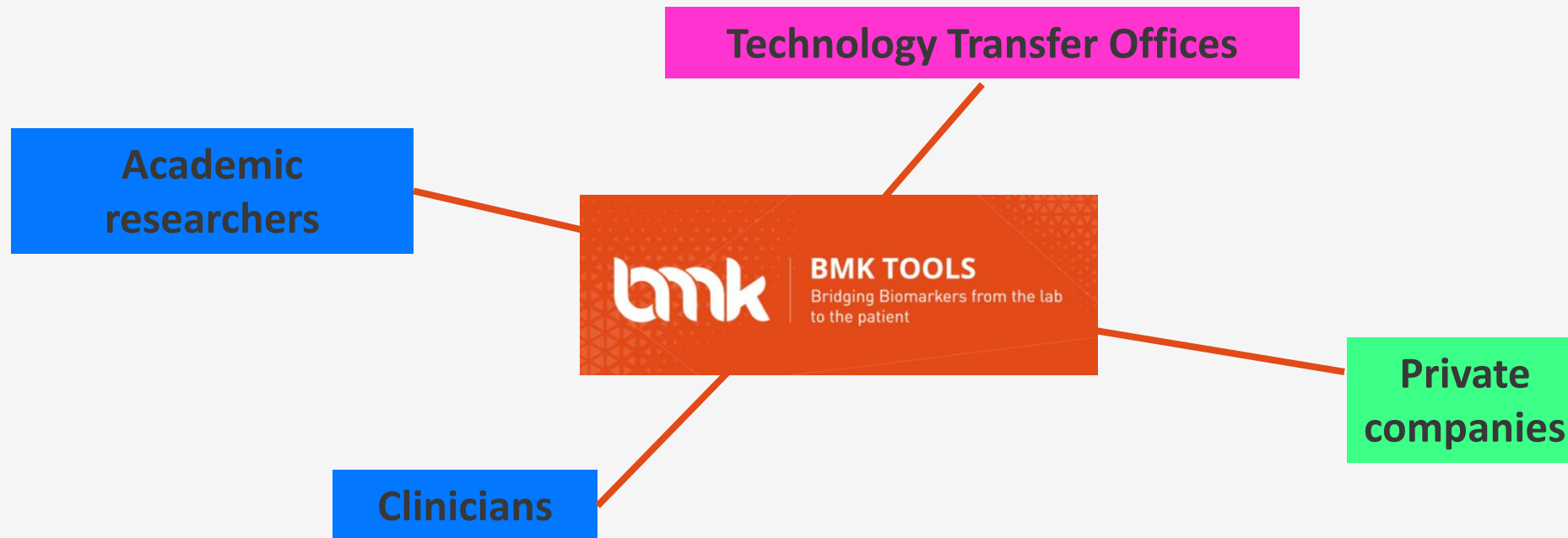
- Bridges between stakeholders
- Share expertise
- Connect the different communities

→ Help projects to move forward !

# The support of experts



# Connecting the dots...



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

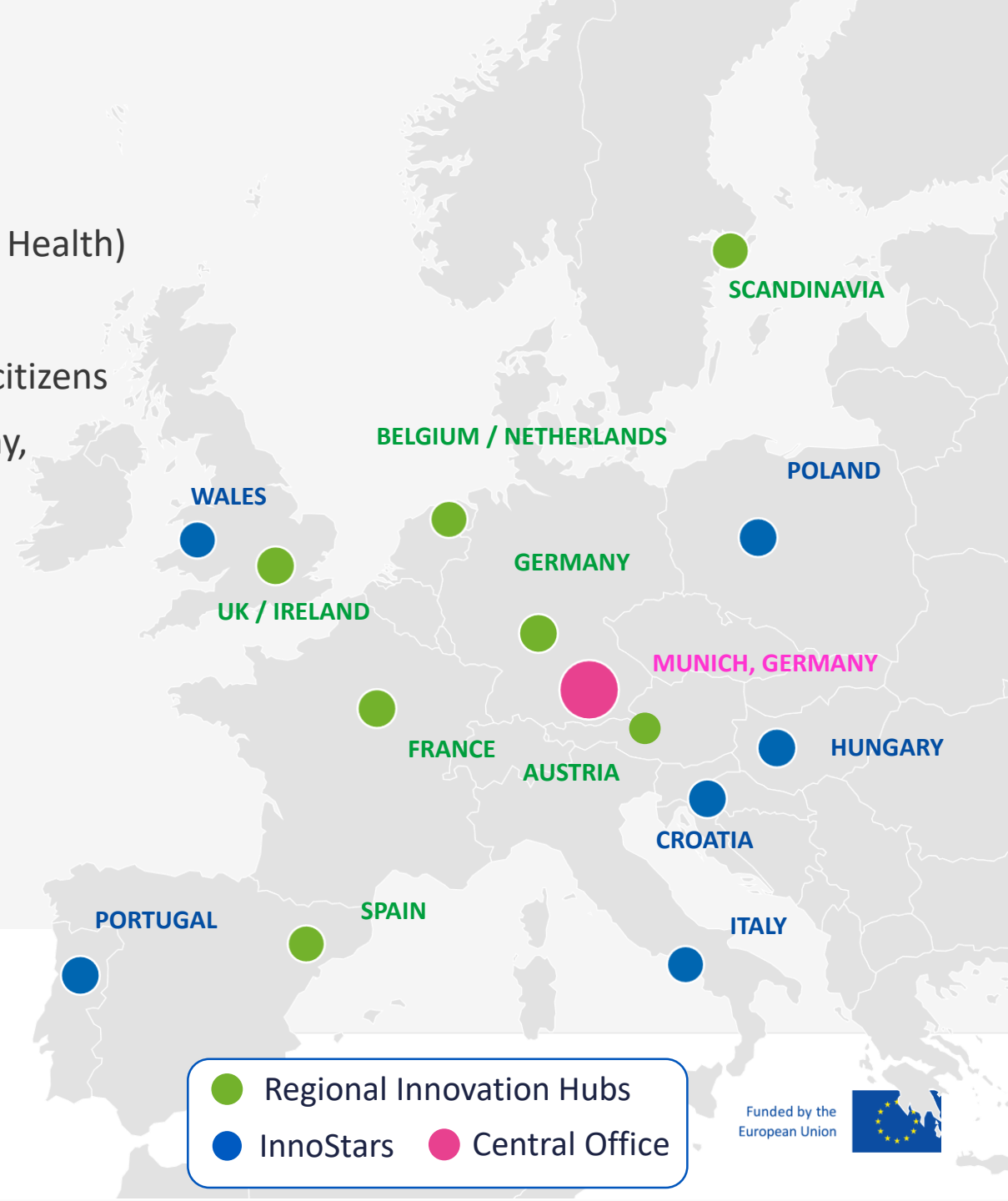
# EIT Health involvement

## 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



# Bridging biomarkers from **the lab to the patient**



<https://biomarqueurs.aviesan.fr>

Marie Anson

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www.eithealth.eu | info@eithealth.eu



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