

# Advancing Molecular Diagnostics in the Dutch Eastern Region

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## **Development of a Vision**

September 2010

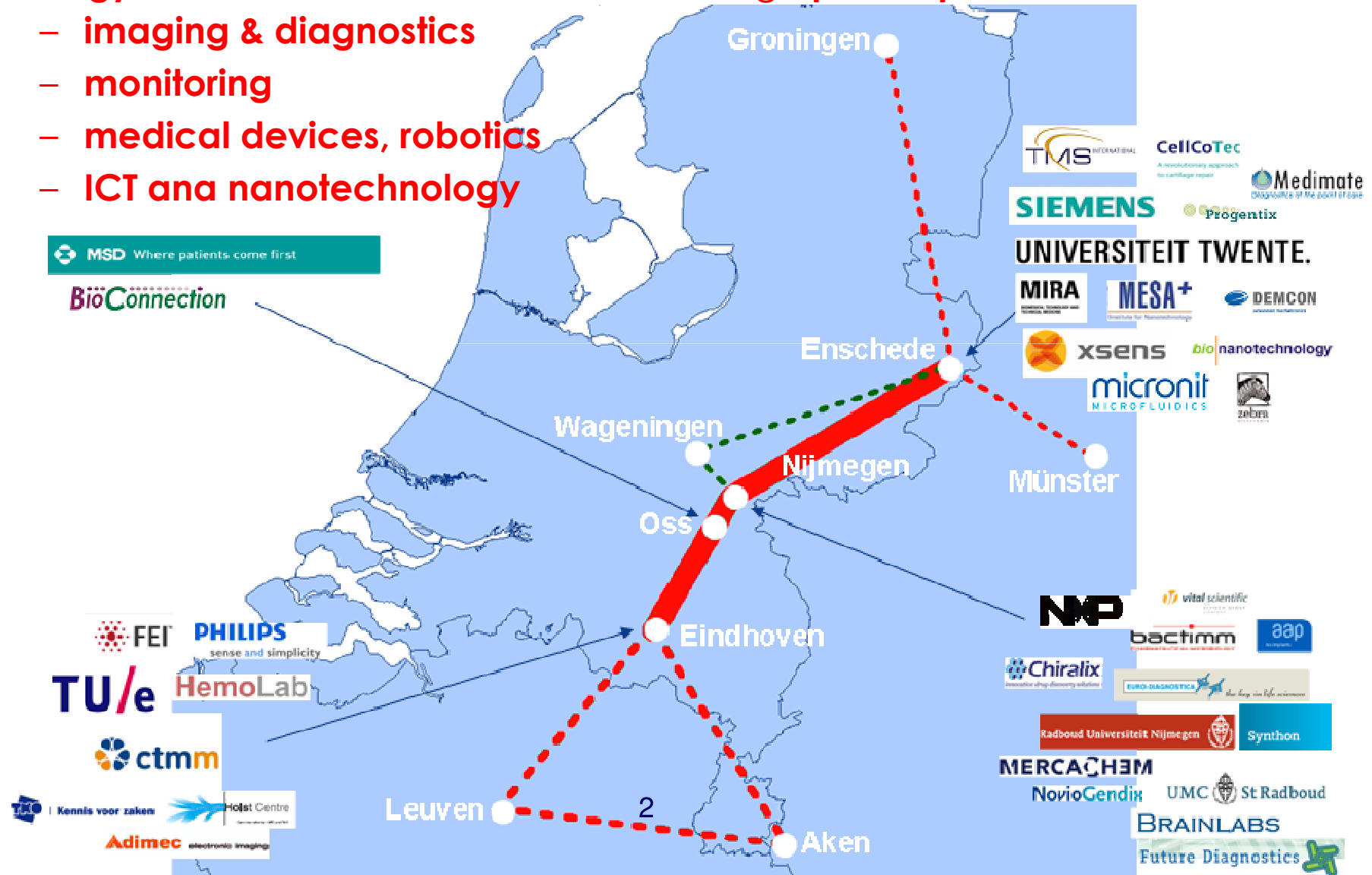


# Red MedTech Highway

## Health Valley

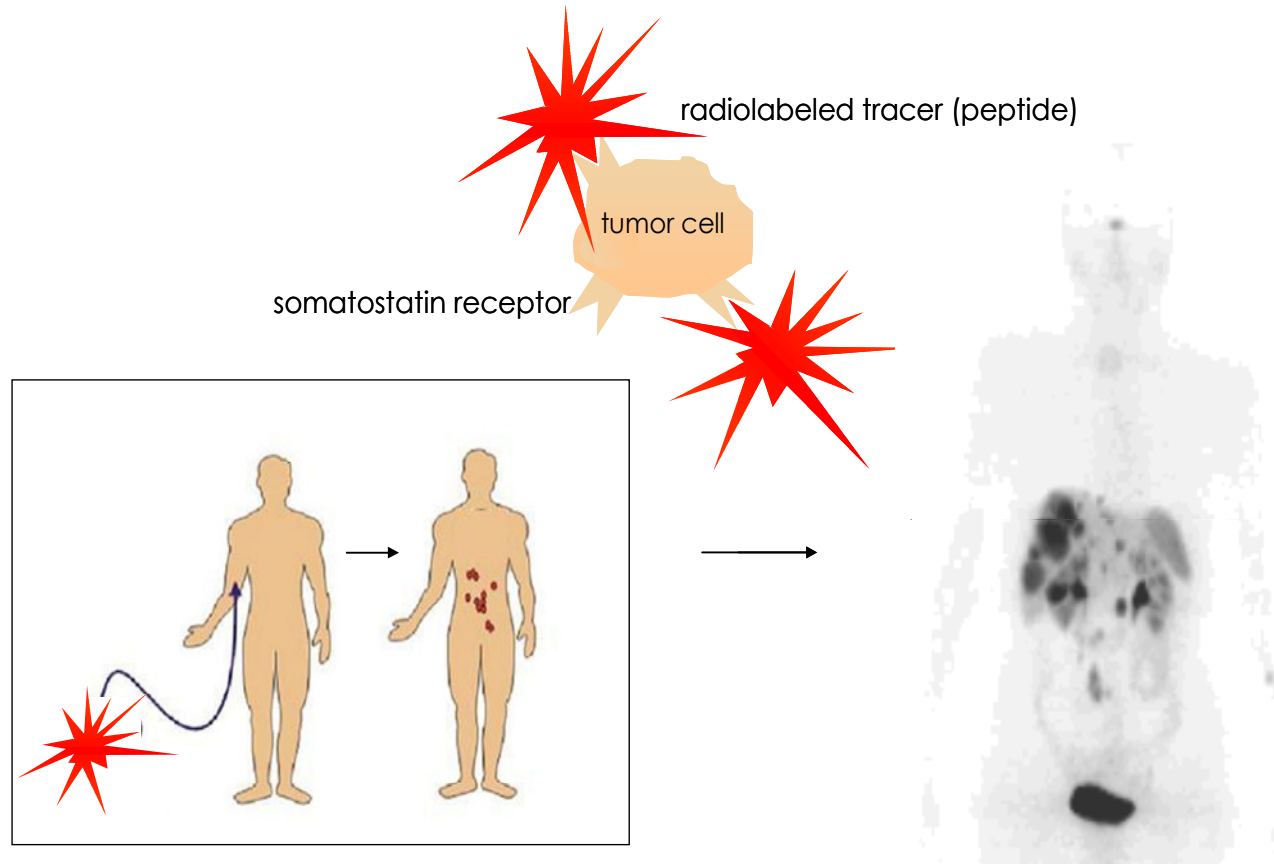
Technology driven, translational research through public-private collaborations in

- imaging & diagnostics
- monitoring
- medical devices, robotics
- ICT and nanotechnology



# Molecular medicine at work

## $^{177}\text{Lu}$ Lutetium labelled – Octreotate for GEPNET tumours



1. Diagnosis and staging
2. Patient selection
3. Targeted therapy
4. Dosing
5. Therapy effect monitoring

# Molecular diagnostics

## Definition

### Assessment of

- DNA sequence variations
- Relative RNA abundance

### Multiplex measurements of

- Proteins / peptides
- Metabolites

### For the detection of

- Genotypes
- Mutations
- Antigens
- Biochemical changes

### Assessment through

- Molecular Imaging
- Immunoassays
- Molecular Biology Techniques
- Clinical Chemistry

### Including, but not limited to

- *In situ* hybridization of chromosomes for cytogenetic analysis
- Oligonucleotide array sequence analysis of gene expression patterns
- Identification of pathogens via species-specific DNA/RNA sequences
- Identification of proteins and biomolecular interactions
- Detection of mutations with PCR

# Development VISION document and ACTION plan

Eastern region

To boost the **economic activity** in the Eastern Region  
in the field of molecular diagnostics,  
based on **in depth understanding of the present situation,**  
**ongoing developments,**  
and **future perspectives**

Sponsors

Health Valley, Provinces of Gelderland and Overijssel,

City of Nijmegen, UniHealth/Interreg project

# Molecular diagnostics in the Eastern Region

Numerous players at numerous sites



Arnhem  
Deventer  
Duisberg (Germany)  
Enschede  
Münster (Germany)  
Nijmegen  
Oss  
's-Hertogenbosch  
Twente  
Wageningen  
Zwolle

# The Eastern Region

Marked by numerous activities on MD

## 1. Strong cluster of companies and knowledge institutes

- Nijmegen Centre for Molecular Life Sciences (link between UMC St Radboud and Radboud University; **NCMLS**) and the Institute for Biomedical Technology and Technical Medicine (**MIRA**) in Enschede

## 2. Numerous public-private collaborations focusing on identification of new biomarkers

- Pieken in de Delta, Interreg / UniHealth, CTMM

## 3. **NovioMatch meetings** organized by Health Valley and Tweehuysen B.V. with industry and knowledge centers revealed need for a vision for the Eastern Region for MD

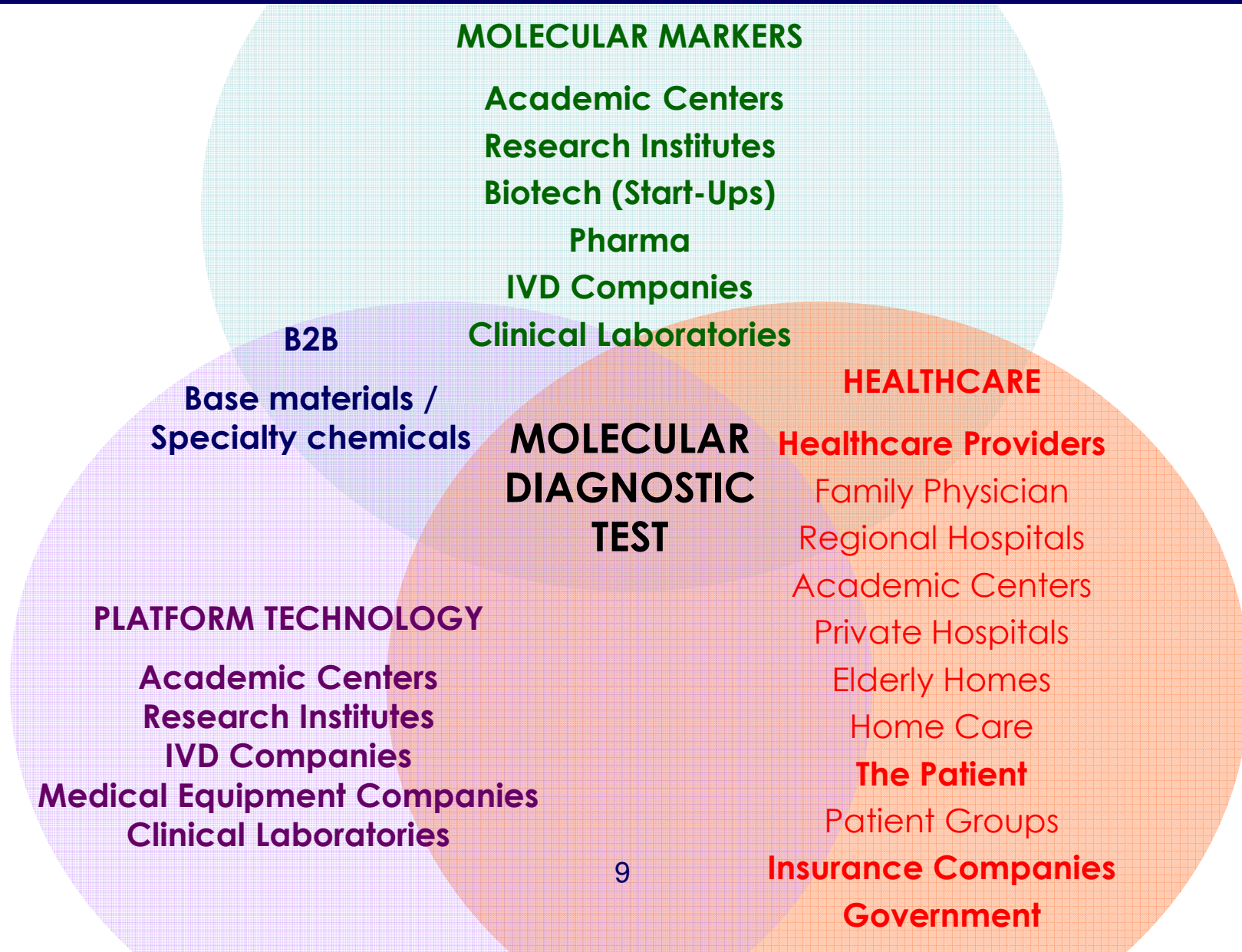
# Development VISION document and ACTION plan

## Key objectives

1. Support **strategic decision-taking** by all stakeholders
  - Identification of attractive combinations of technologies, markets and products & the creation of new business cases
2. Identify the requirements to create a successful Molecular Diagnostics **cluster**
  - Unique selling points, - business knowledge
3. Define **concrete follow-up opportunities** and prepare plan
  - Promotion of **entrepreneurial initiatives**, such as incubators, science parks, networks, business support
  - **Fund raising** for initiatives, e.g. setting up a private investment fund
  - **Public relations and lobbying** on national and EU level
  - Contribution to the **existing action plan** of BioFarmlnd, a network of companies in the field of biotech (a.o. Mol. Diagnostics)

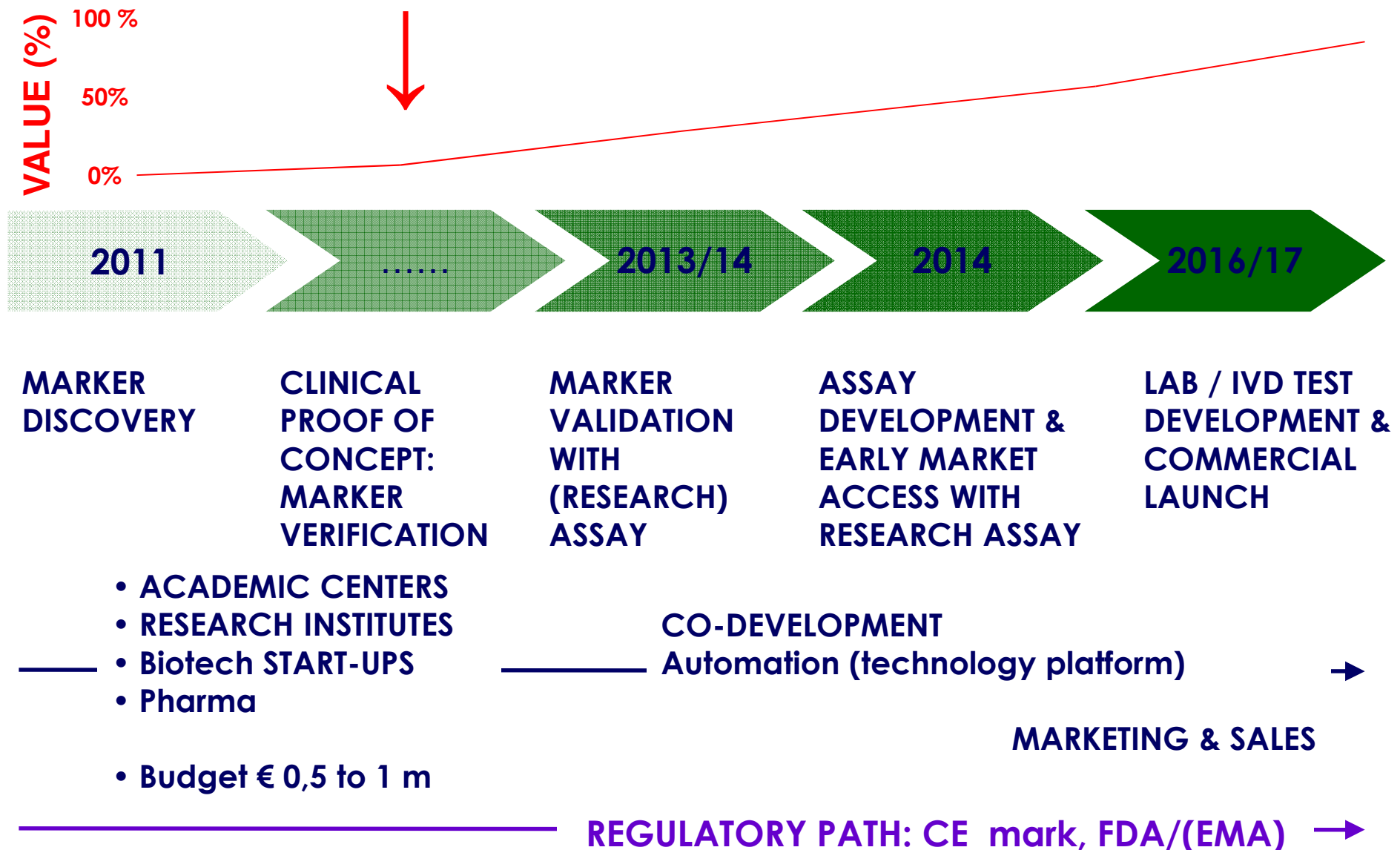
# Molecular diagnostics industry

Three pillars / many stakeholders



# Molecular diagnostic test

Value chain, business model and stakeholders



### **Political**

1. Consolidation of industrial activities into clusters
  - Public-private collaborations
  - Changing public funding (subsidies) landscape
2. Valorization at universities and knowledge institutes

### **Economic**

1. Increased pressure for cost-reduction pushes competition
2. Manufacturing of mature assays moving to low cost markets
3. Shift to specialty assays serving low volume markets with prices under pressure
4. Pressure on healthcare budgets results in reduced reimbursement

# Molecular diagnostics

## Economic trends and key drivers – 2

5. Need for improved patient management (personalized medicine)
  - Positive: demand for innovative diagnostics
    - Sensitivity, specificity, robustness and/or 'speed'?
    - Non-invasive or minimal-invasive procedures for biopsy
    - Cross-benefits: almost instant diagnostic results, more targeted therapies and shorter hospitalization times
    - Improved cost-effectiveness: automation and multiplex system development, centralization of clinical laboratories, increased point-of-care (at patient's bed site, home care, etc.)
  - Negative: switch to cheaper alternatives / price erosion

### **Social**

1. Increased awareness/involvement of patients
2. Strong need for improved patient care, for personalized medicine

### **Technology**

1. Advancing (IT) technologies
2. Increased understanding of molecular pathways

# Molecular diagnostic tests

End users are key stakeholders

<b>DISEASE AREA</b>	<b>Cardio-vascular</b>	<b>Oncology</b>	<b>Sepsis / Infectious diseases</b>	<b>Others</b>
<b>Reference labs</b>	=	↑	↑	↑
<b>Core labs</b>	=	=	=	↑
<b>Decentralized labs</b>	↑	-	↑	↑
<b>Point of care</b>	↑	-	↑, not yet	↑, PTH hormone
<b>Doctor's office</b>	↑, h-FABT	↑	↑, strep A	↑, urine
<b>Patient self testing</b>	-?	-	↑	↑, diabetes, hormones (pregnancy, fertility)

-: not applicable; =: no change in time;

↑: increase in time; ↓decrease in time

# Executive team and advisory committee



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## **Advisory committee:**

Representatives from BioFarmInd, companies, universities, support organizations