

## **The revolution of molecular diagnostics and personalized medicine**

Paris, 17<sup>th</sup> March 2011

# Content

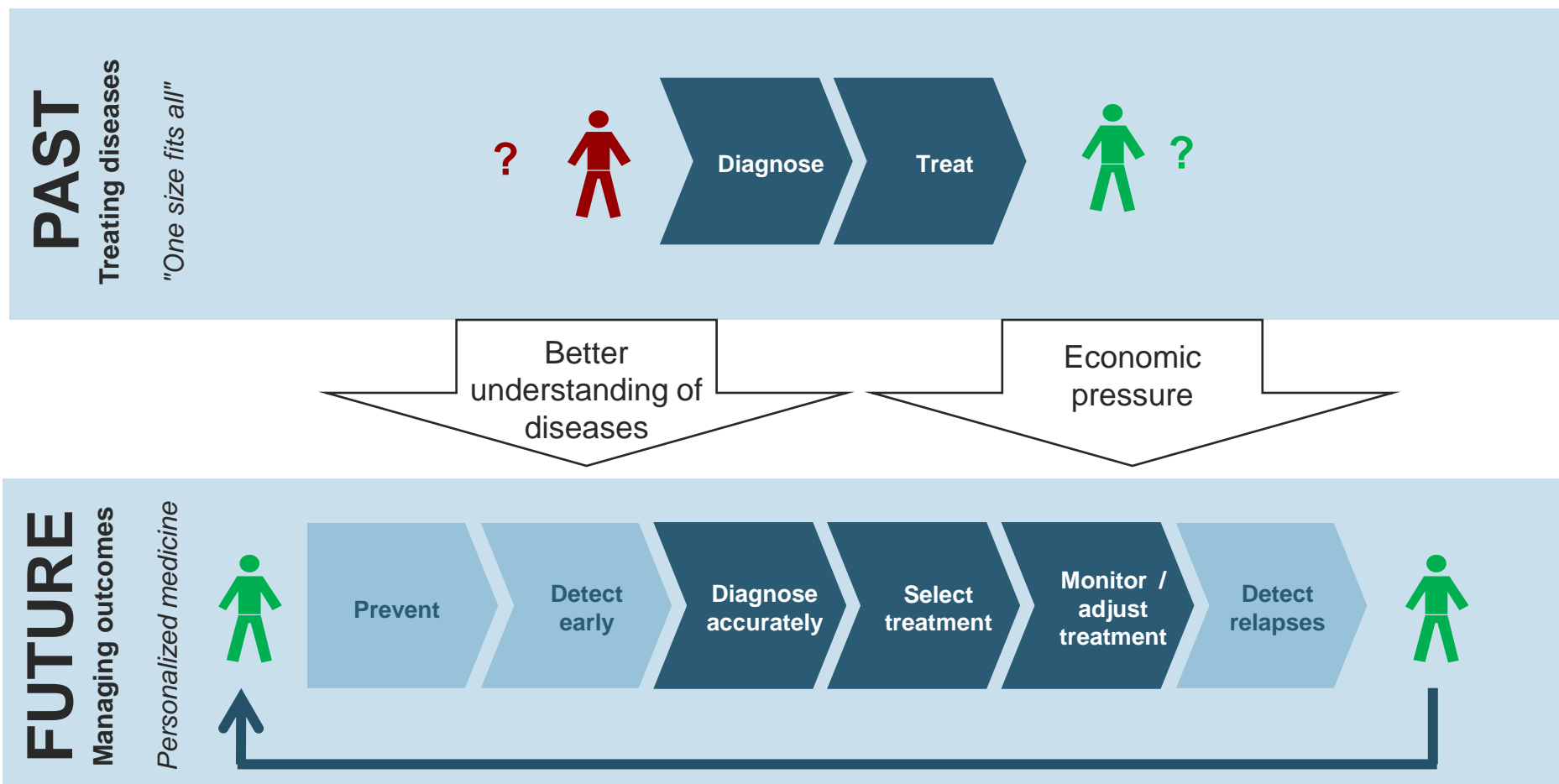
**A. Personalized medicine, biomarkers and molecular diagnostics**

**B. The revolution of molecular diagnostics: benefits for patients and impact on the pharmaceutical industry**

**C. About Cepton**

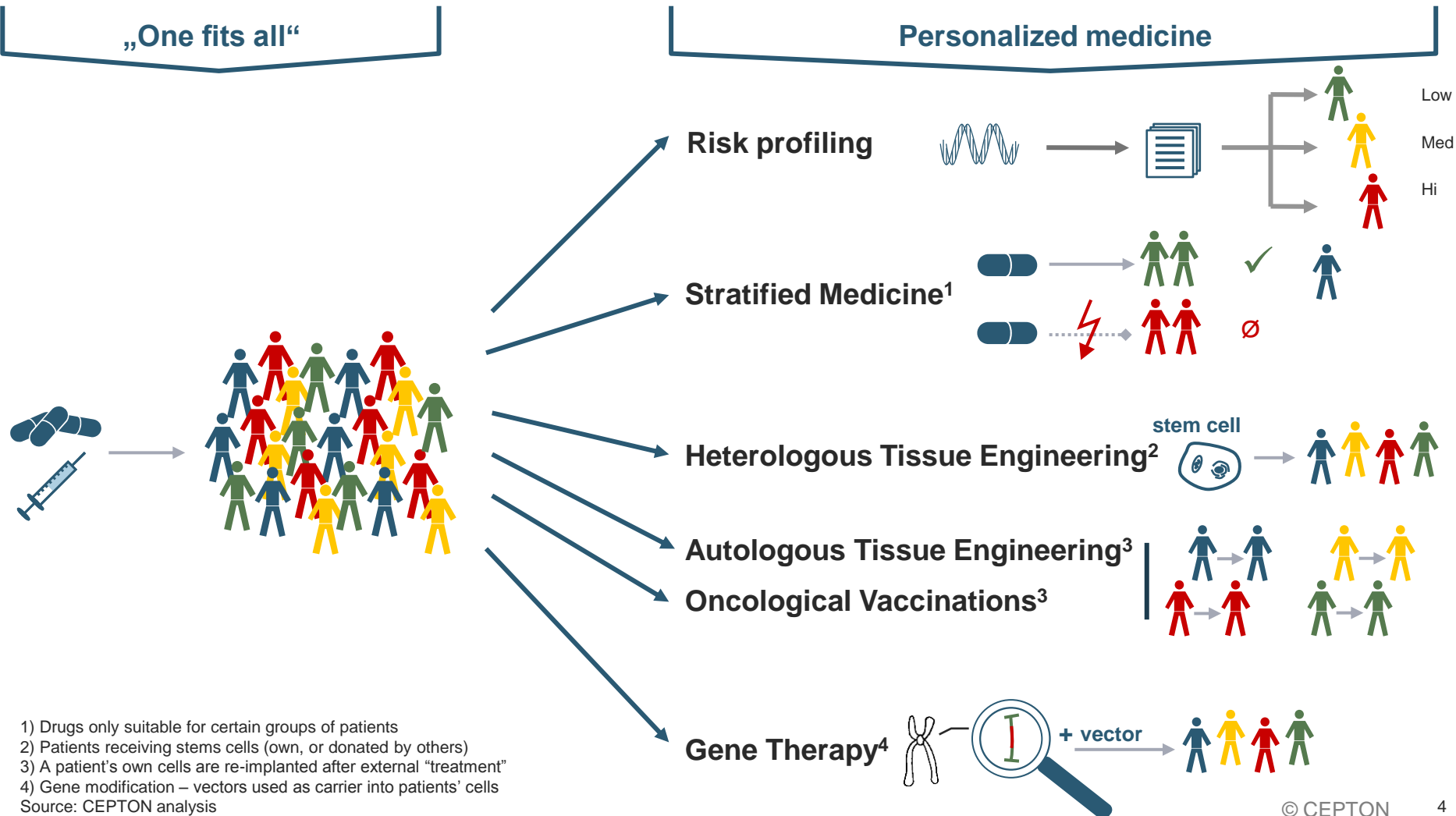
# Scientific progress and increasing economic constraints are forcing physicians to change their approach of medicine

From treating diseases to managing outcomes – A new approach in modern medicine



# Personalized Medicine covers Stratified Medicine, Tissue Engineering, Oncological Vaccinations and Gene Therapy

Scope of Personalized Medicine



# Stratified medicine and risk profiling rely on molecular biomarkers, hence the name "Molecular diagnostics"

## What does "molecular diagnostics" mean?

### Molecular target/biomarker

*In human body*



+



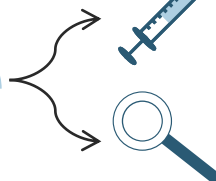
**Probe**

*Designed in laboratories*



**Complex**

*Detection or visualization using a specific molecular biology technique*



## What is a "Biomarker"?

"a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention"

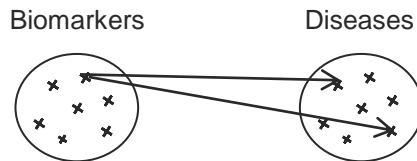
*National Institute of Health, 1998*

- Molecular diagnostics is used to detect and **measure specific molecular target/abnormalities** using **selective targeted probes** and corresponding visualization methods.
- The value of these targets is that they **correlate with disease** or ideally are causative for the disease.

Biomarkers can be **molecules** (DNA, RNA, peptides, proteins) or even **entire cells**

# Molecular biomarkers are key in the detection of a disease – However, there is often no direct causality between a biomarker and a disease

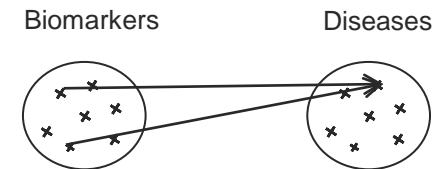
## One biomarker may detect several diseases



### Examples:

- **AZCP1:** cardiac hypertrophy, hypercholesterolemia, cirrhosis of liver, squamous cell carcinoma
- **CD46:** status epilepticus, rheumatoid arthritis, congestive cardiomyopathy, lung-transplant rejection

## Several biomarkers may be necessary to identify a disease



### Examples:

- **Breast cancer:** ENPP4, PFKP, THBD, IGFALS
- **AIDS:** PAPP4, TRADD, APRIN, MAP3K5

**Less than 20%** of measurable proteins in both blood plasma and urine proteomes are biomarkers

# Each type of biomarker is associated with one or more specific technologies

## Biomarker diagnostics

Biomarker		Method (common examples)
DNA <sup>1</sup>	Single Gene / defined mutation / single SNP <sup>3</sup>	<ul style="list-style-type: none"> <li>• PCR<sup>4</sup> (and variants like LCR<sup>5</sup>, ...)</li> <li>• Sequencing</li> <li>• FISH<sup>6</sup></li> </ul>
	Epigenetic modification (DNA <sup>1</sup> methylation)	<ul style="list-style-type: none"> <li>• Methylation specific PCR<sup>4</sup></li> <li>• Differential methylation microarray</li> </ul>
	Multiple genes / Genomic profile / SNP <sup>3</sup> profile	<ul style="list-style-type: none"> <li>• Microarray (DNA<sup>1</sup>-Chip)</li> </ul>
RNA <sup>2</sup>	Single gene expression	<ul style="list-style-type: none"> <li>• Quant. Reverse Transcriptase-PCR<sup>4</sup></li> </ul>
	Gene expression profile	<ul style="list-style-type: none"> <li>• Microarray (RNA<sup>2</sup>-Chip)</li> </ul>
Protein	Defined protein (Antibody, Enzyme, ...)	<ul style="list-style-type: none"> <li>• Immunochemistry, esp. ELISA<sup>7</sup></li> <li>• Mass-spectroscopy peptide profiling</li> </ul>
	Proteomic profiling	<ul style="list-style-type: none"> <li>• Mass-spectroscopy peptide profiling</li> </ul>
Cell	Cell types according to cell surface proteins	<ul style="list-style-type: none"> <li>• FACS<sup>8</sup></li> </ul>
Tissue	Abundance of protein in tissue	<ul style="list-style-type: none"> <li>• Immunohistochemistry</li> <li>• Molecular imaging (<i>in vivo!</i>)</li> </ul>
	Abundance of DNA/RNA <sup>2</sup> in tissue	<ul style="list-style-type: none"> <li>• FISH<sup>6</sup></li> </ul>

1) Desoxyribonucleic acid 2) Ribonucleic acid 3) Single nucleotide polymorphism 4) Polymerase chain reaction 5) Ligase chain reaction 6) Fluorescence in-situ hybridization

Source: CEPTON 7) Enzyme-linked Immunosorbent Assay 8) Fluorescence-activated cell sorting

# PCR, Micro-Arrays and FISH are the most widely used technologies in molecular diagnostics

Examples

	Description	Benefits	Weaknesses	Examples
<b>Polymerase Chain Reaction (PCR)</b>	<i>Chain amplification of a segment of DNA or RNA by polymerization</i>	<ul style="list-style-type: none"> <li>• Low quantity of raw material (exponential amplification)</li> </ul>	<ul style="list-style-type: none"> <li>• Too much information to make the interpretation easy for physicians</li> <li>• Risk of samples contamination</li> </ul>	<ul style="list-style-type: none"> <li>• Detection of breast and colorectal cancers by blood test</li> <li>• HBV &amp; HCV<sup>1</sup> diagnoses by plasmatic analysis</li> <li>• Prove-it™ Sepsis Streptococcus, salmonella and aureus staphilococcus screening</li> </ul>
<b>Micro-Arrays</b>	<i>Hybridization of a sample of DNA by DNA fragments placed on a coated quartz grid</i>	<ul style="list-style-type: none"> <li>• Numerous tests can be performed simultaneously (1 million)</li> <li>• Possibility of quantification of sample components</li> </ul>		<ul style="list-style-type: none"> <li>• Detection of genetic variations / Patient stratification</li> <li>• Cystic fibrosis detection</li> <li>• Detection and identification of respiratory diseases</li> </ul>
<b>Fluorescent in situ hybridization (FISH)</b>	<i>Identification of a target molecule by a system of coupled antibody / fluorescent site</i>	<ul style="list-style-type: none"> <li>• Useful technique for cells not in process of division</li> <li>• High sensitivity that allows its use for early detection of pathological processes</li> </ul>	<ul style="list-style-type: none"> <li>• Complex</li> <li>• 5 -10% error (false positives)</li> </ul>	<ul style="list-style-type: none"> <li>• Breast cancer prognosis</li> <li>• Trisomies 8 &amp; 12 prognoses</li> <li>• Validation of bone marrow donation among patients of opposite sex</li> </ul>

1- Hepatitis B & Hepatitis C Virus

Source: Business Insights, Desk research, CEPTON analysis



# However, new technologies keep emerging in this very innovative, not yet mature field

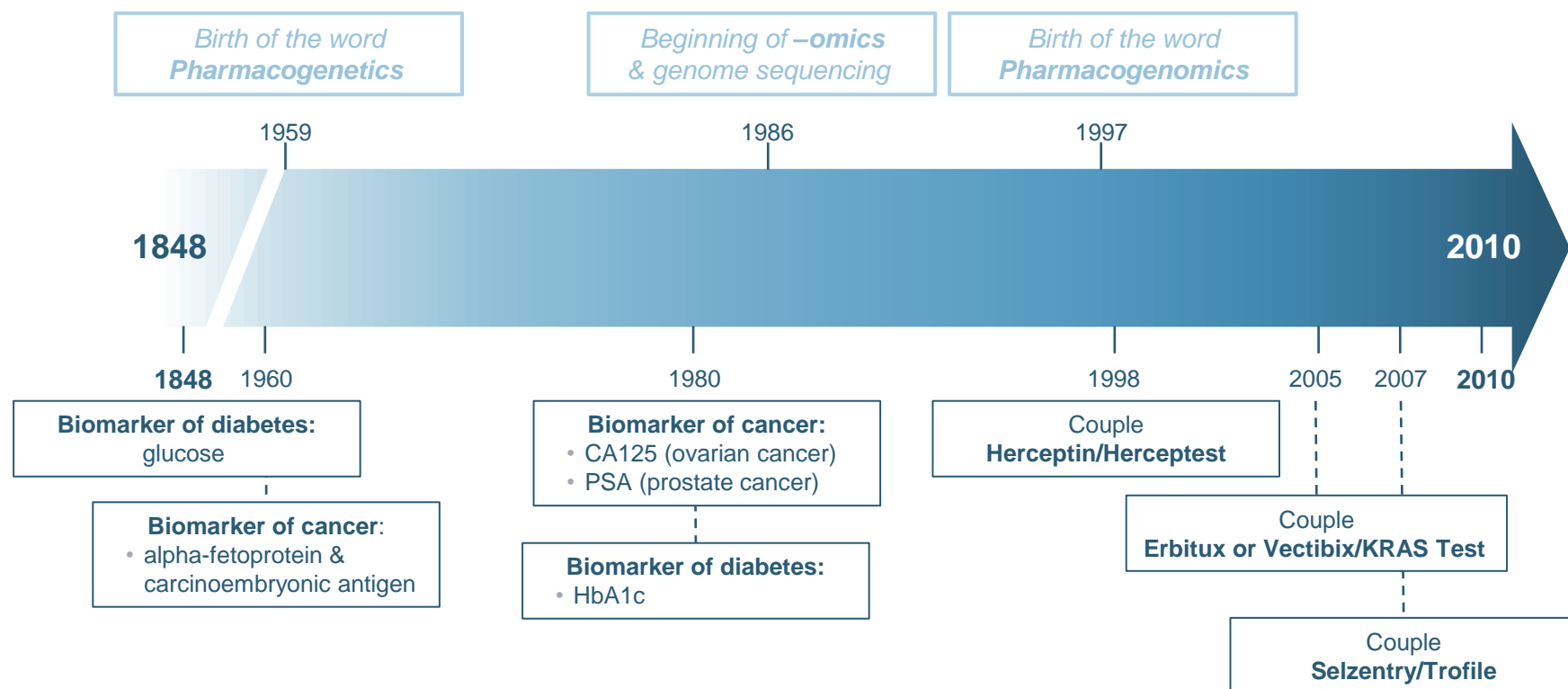
Examples of more recent in vitro technologies

Examples

	Description	Benefits	Prospects	Examples
<b>Biobarcode™ Nanosphere</b>	<i>Detection of proteins by amplification of a DNA sequence with a gold coated nanoprobe</i>	<ul style="list-style-type: none"> <li>• Higher sensitivity than FISH, ELISA and mass spectrometry</li> <li>• Cheaper than mass spectrometry</li> <li>• Practicable by hospital employees</li> </ul>	<ul style="list-style-type: none"> <li>• Diagnosis of ovarian, prostate and pancreas cancers</li> <li>• Diagnosis of neurological degeneration (Alzheimer's disease)</li> </ul>	<ul style="list-style-type: none"> <li>• Diagnosis of thrombophilia &amp; hypercoagulation problems</li> <li>• Cystic fibrosis diagnosis</li> </ul>
<b>DNA methylation</b>	<i>Observation and quantification of DNA methylation</i>	<ul style="list-style-type: none"> <li>• Detection of tumors before they actually exist</li> <li>• Prognosis of tumor aggressivity</li> <li>• Prognosis of response to treatment (in some cases)</li> </ul>	<ul style="list-style-type: none"> <li>• Classification of prostate, breast and colorectal cancers</li> <li>• Response to cancer treatments</li> <li>• Detection of lung cancer</li> </ul>	<ul style="list-style-type: none"> <li>• Colorectal cancer detection by blood analysis</li> </ul>

# Biomarkers have been used in laboratories & in hospitals for a long time – However they are now developing at a much faster pace

## History of biomarkers



# Content

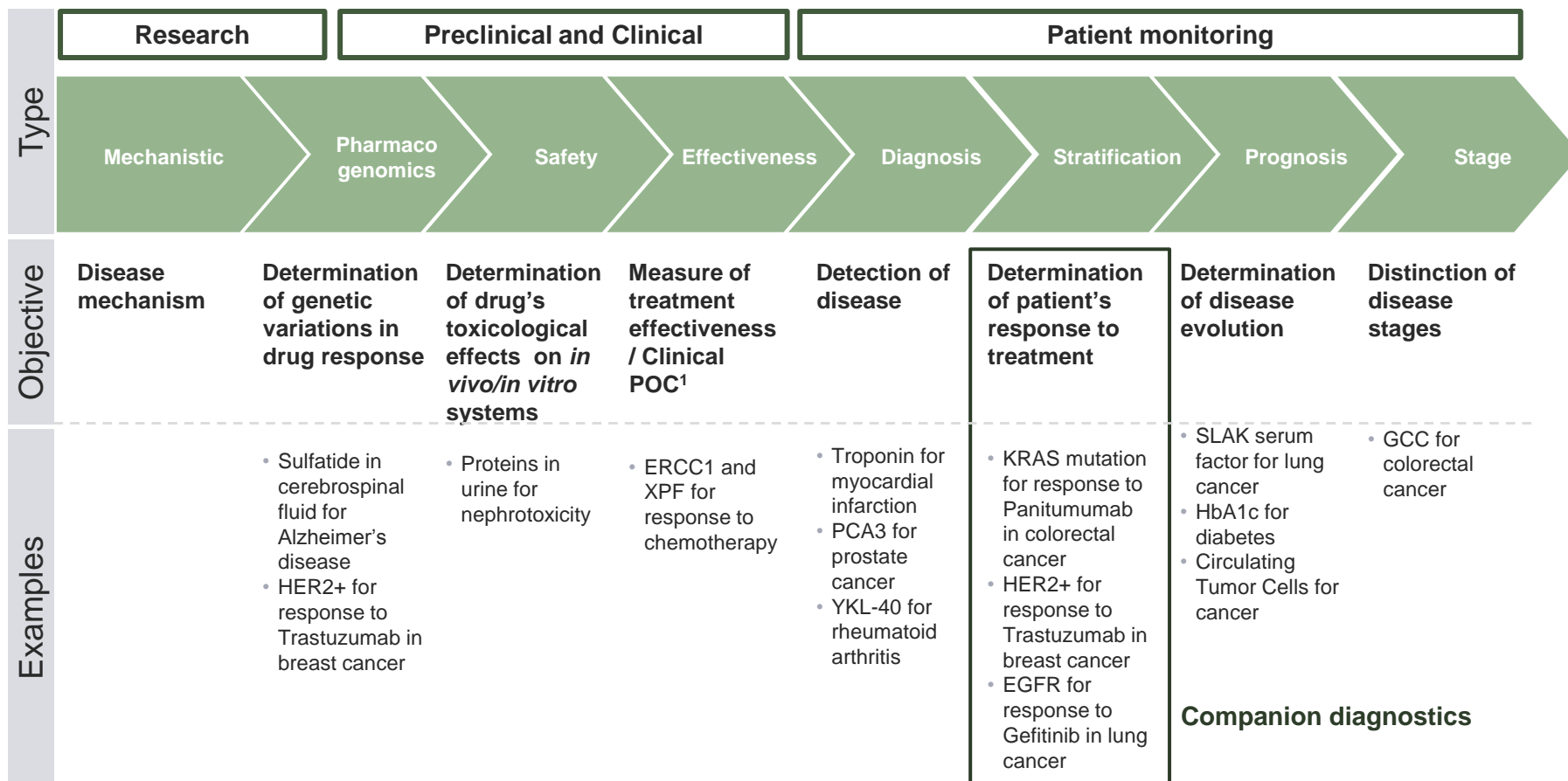
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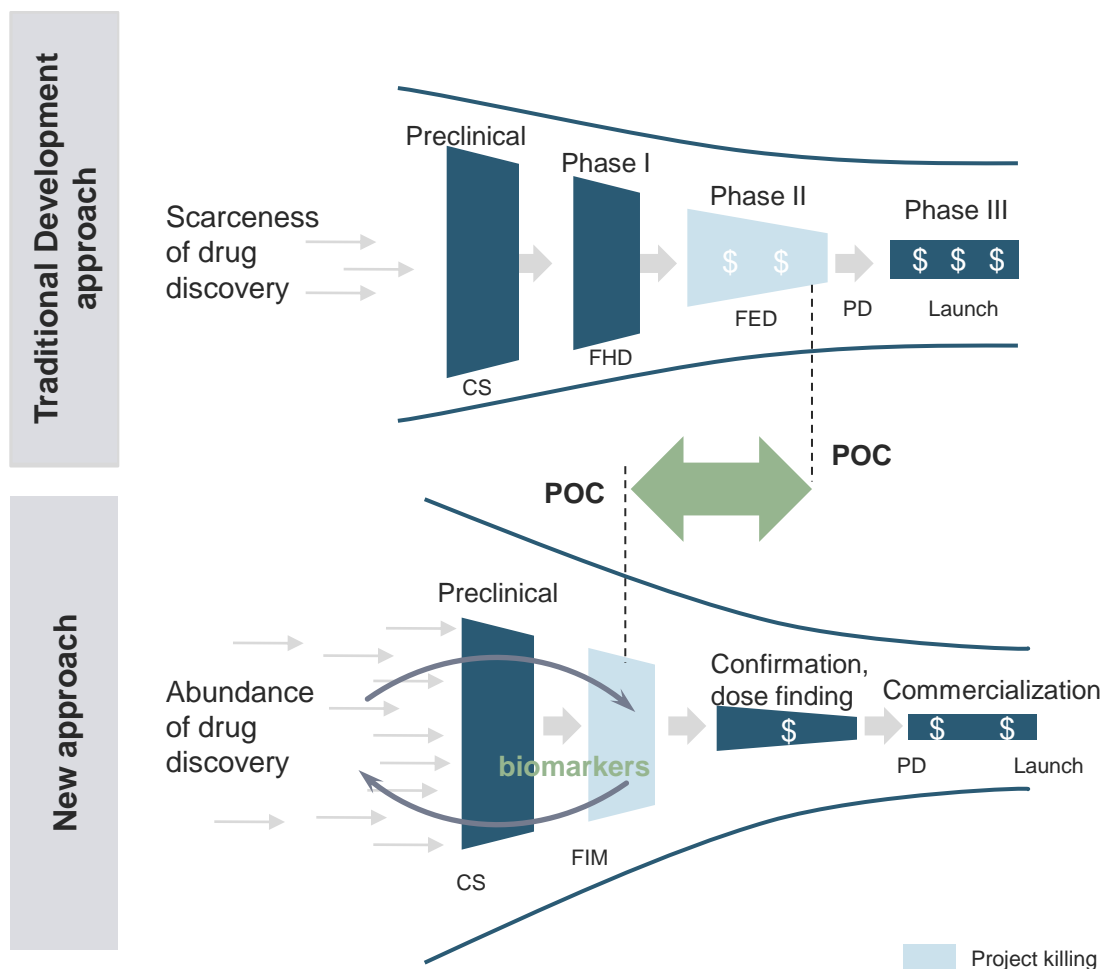
# Biomarkers may be used in a variety of situations, from drug discovery to patient monitoring, with different objectives

Possible roles of biomarkers



# Discovery biomarkers can significantly speed up the drug discovery process by reducing time to POC

## Discovery biomarkers - The new innovation cycle



## Benefits from the new approach

- **Clinical constraints are anticipated** at an early stage of Research
- The **waste of resources is reduced** as more failing Projects are « killed » earlier
- Projects entering Phase II-b have a **higher chance** of making it to the market

POC: Proof of Concept in Man  
CS : Candidate Selection  
FHD: First Human Dose  
FED : First efficacy dose  
FIM : First in Man  
PD : Product decision

# Development biomarkers reduce lead times in clinical phases, improve probability of success and stratify patients to optimize efficacy

Examples of development biomarkers

## Objective

## Examples

### Safety

- Predict or anticipate toxic side-effects
- Detect damage earlier

- Kidney's protein biomarkers which are specific to a kidney's region, thus enabling to better & earlier detect damage through urine analysis
  - clusterin
  - kim-1
  - bêta2 microglobulin

### Surrogate endpoints

- Measure the effect of a specific drug or therapy that may correlate with a real clinical endpoint

- **Circulating Tumor Cells (CTC)**, detectable in patients suffering from metastatic breast cancer
- **Prostate Specific Antigen (PSA)**, present in high quantities in patients suffering from prostate cancer

### Pharmacogenomics

- Determine genetic variations in drug response
- Stratify for better selection of patients in clinical trials

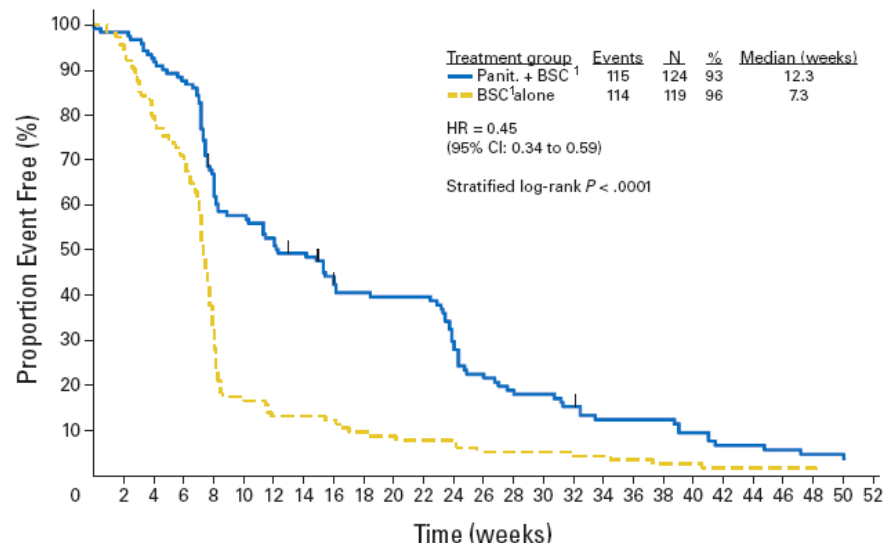
- **Sulfatide** in cerebrospinal fluid for response to AD<sup>1</sup> treatment
- **Her2/neu** for response to Herceptin®
- **KRAS mutation** for response to Erbitux® and Vectibix®

# Efficacy data of Vectibix® shows increased progression-free survival only in patients carrying the KRAS wild-type

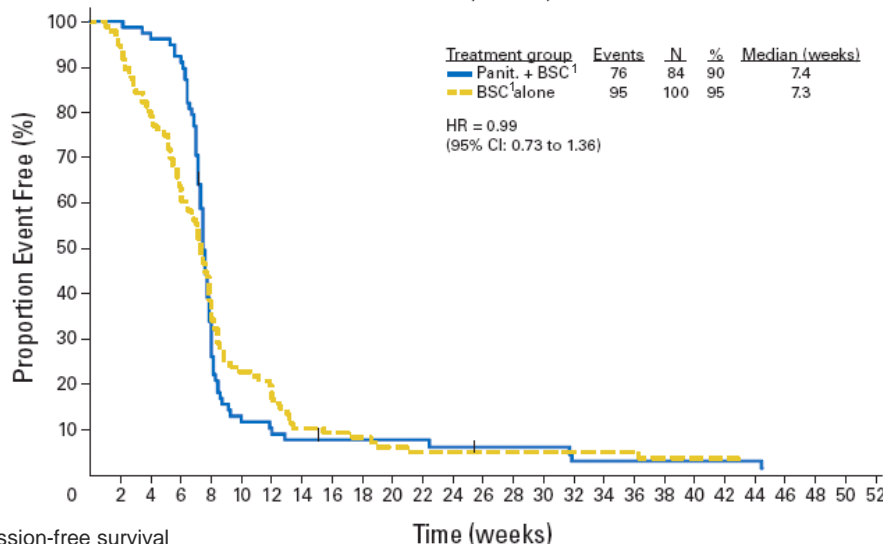
Commercial biomarkers - Example of KRAS mutation

Illustrative

Wild-type  
KRAS



Mutant  
KRAS



- Patients with mutant KRAS do not benefit from targeted therapy
- Survival without disease progression (PFS<sup>2</sup>) is significantly increased in wild-type KRAS group
- Side-effects in non-responders are avoided

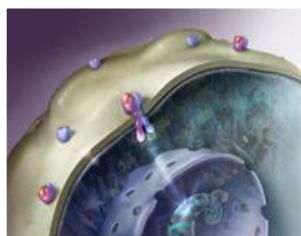
1) Best supportive care 2) Progression-free survival

Source: Amado RG et al.: Wild-Type KRAS is required for Panitumumab efficacy in patients with metastatic colorectal cancer, J Clin Oncol 2008; 26(10): 1626-1634

# Herceptin® has been a real success story for Roche – first example of a combined drug and "Companion" diagnostic kit commercialization

Commercial biomarkers – Herceptin® (trastuzumab) case

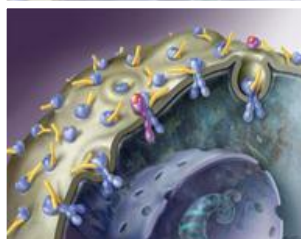
Illustrative



HER2<sup>1</sup> normally expressing cell

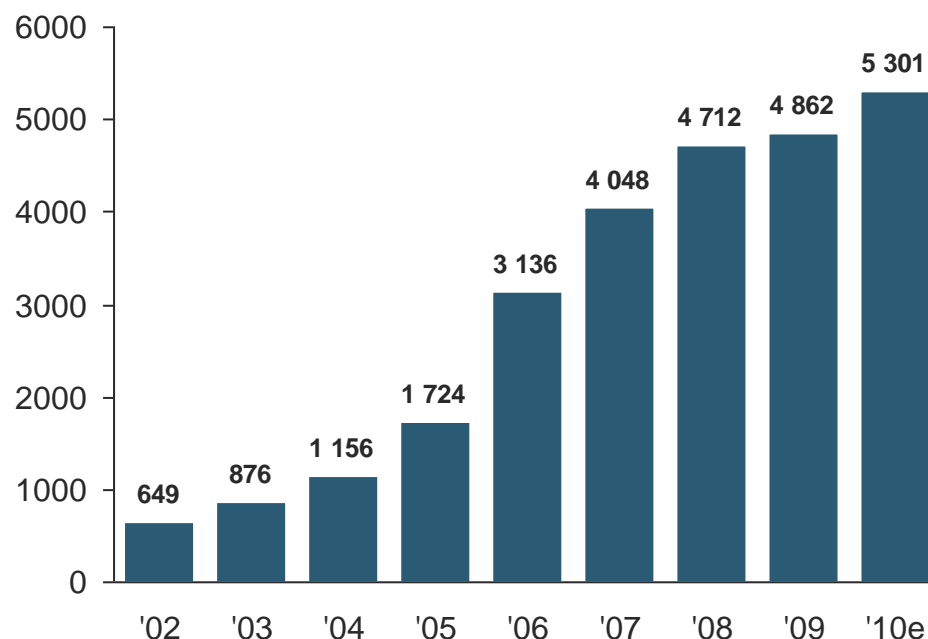


HER2 over-expression causing increased cell proliferation



HER2 antibodies binding to receptors thereby inhibiting tumor growth

## Herceptin® global sales [US\$m]



✓ **HER2+ is predictive of Herceptin® response**

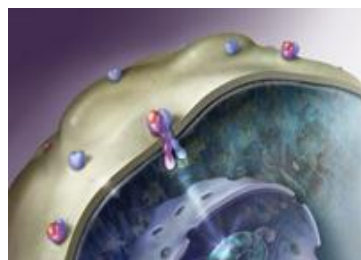
✓ **Testing for HER2 over-expression is mandatory**



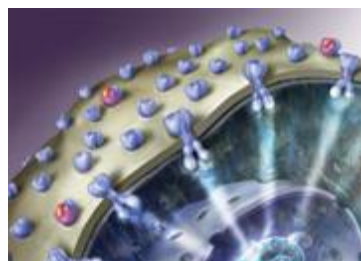
# Despite Roche's diagnostic capabilities, even for Herceptin® there are diagnostic tests from other providers

Commercial biomarkers – Herceptin® (trastuzumab) case

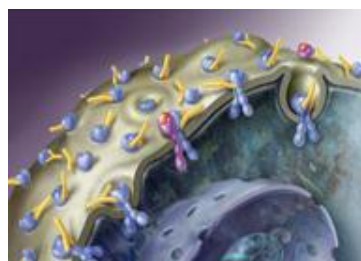
Examples



HER2<sup>1</sup> normal expression



HER2 over-expression



HER2 antibodies binding to receptors, inhibiting tumor growth

Drug Name	Company	CDx Name	Company	Indication	Reg. agency
<b>Selzentry®</b> Maraviroc	• Pfizer	• Trofile®	• Monogram Bioscience	• HIV	• FDA
<b>Ziagen®</b> Abacavir	• GSK	• HLA-B*5701	• Many LDTs <sup>2</sup>	• Infectious disease	• EMEA
<b>Erbitux®</b> Cetuximab	• Merck • BMS	• EGFR <sup>1</sup> pharmDx™	• <b>Dako</b>	• Colorectal cancer	• FDA • EMEA
		• TheraScreen® K-RAS	• Qiagen / Roche		
<b>Vectibix®</b> Panitumumab	• Amgen	• EGFR <sup>1</sup> pharmDx™	• <b>Dako</b>	• Colorectal cancer	• EMEA
		• TheraScreen® K-RAS	• Qiagen / Roche		
<b>Herceptin®</b> Trastuzumab	• <b>Roche</b>	• HercepTest™	• <b>Dako</b>	• Breast cancer	• FDA • EMEA
		• Pathway®	• <b>Roche</b>		
<b>Tykerb®/Tyverb®</b> Lapatinib	• GSK	• HercepTest™	• <b>Dako</b>	• Breast cancer	• EMEA
		• Pathway®	• Roche		
<b>Tarceva®</b> Erlotinib	• Roche	• EGFR <sup>1</sup> pharmDx™	• <b>Dako</b>	• NSCLC	• EMEA
<b>Iressa®</b> Gefitinib	• AZ • Teva	• EGFR <sup>1</sup> pharmDx™	• <b>Dako</b>	• NSCLC	• EMEA
<b>Epitol®/Tegretol®</b> Carbamazepine	• Novartis	• HLA-B*1502	• Many LDTs <sup>2</sup>	• Neuropsychiatric disorders	• EMEA

# Biomarkers may also be used to reduce overall treatment costs, as exemplified by MammaPrint® in stage I and II breast cancers

Commercial biomarkers – Cost effectiveness study example

## Description

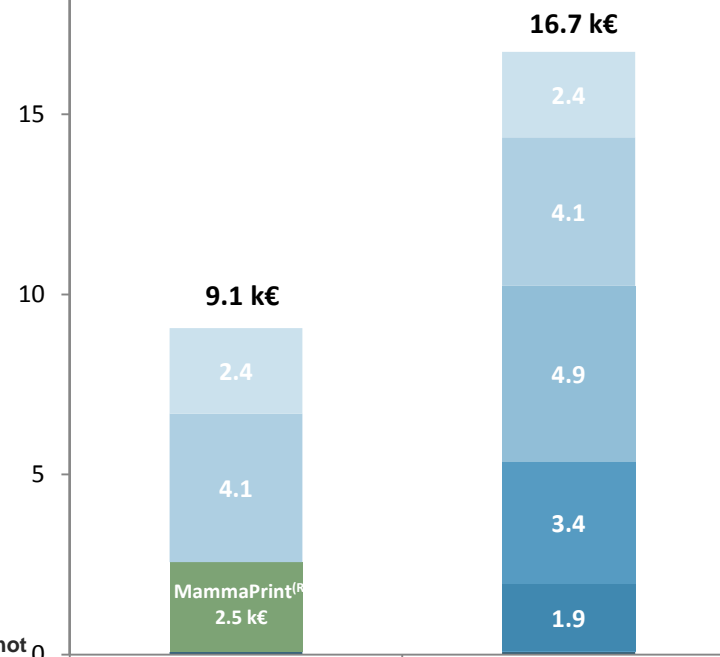
- Nucleic acid test determining the tumor's fingerprint by comparing a sample of the tumor with the 70-gene signature of breast cancers
- **Designed for Stages I & II**
- Performed before or during surgery determining whether hormone therapy will be enough to curb cancer
- Avoidance of ultrasound, biopsy and possibly usual treatment for stage I & II breast cancers

- **Better quality of life** during treatment and after treatment
- Cost effective if it avoids heavy treatments for **more than 15%** of stages I&II cancers

MammaPrint®'s result	Oncologist's assessment	
	HT <sup>1</sup> enough	HT not enough
HT enough	- 0.65 k€	+ 7.6 k€
HT not enough	Does not exist	- 0.65 k€

## Cost comparison of breast cancer treatment

Cost of tests, operations & exams  
in k€<sup>20</sup>



With MammaPrint®

Without MammaPrint®

- Post-treatment imaging exams
- Hormonal treatment
- MammaPrint®
- Mammography

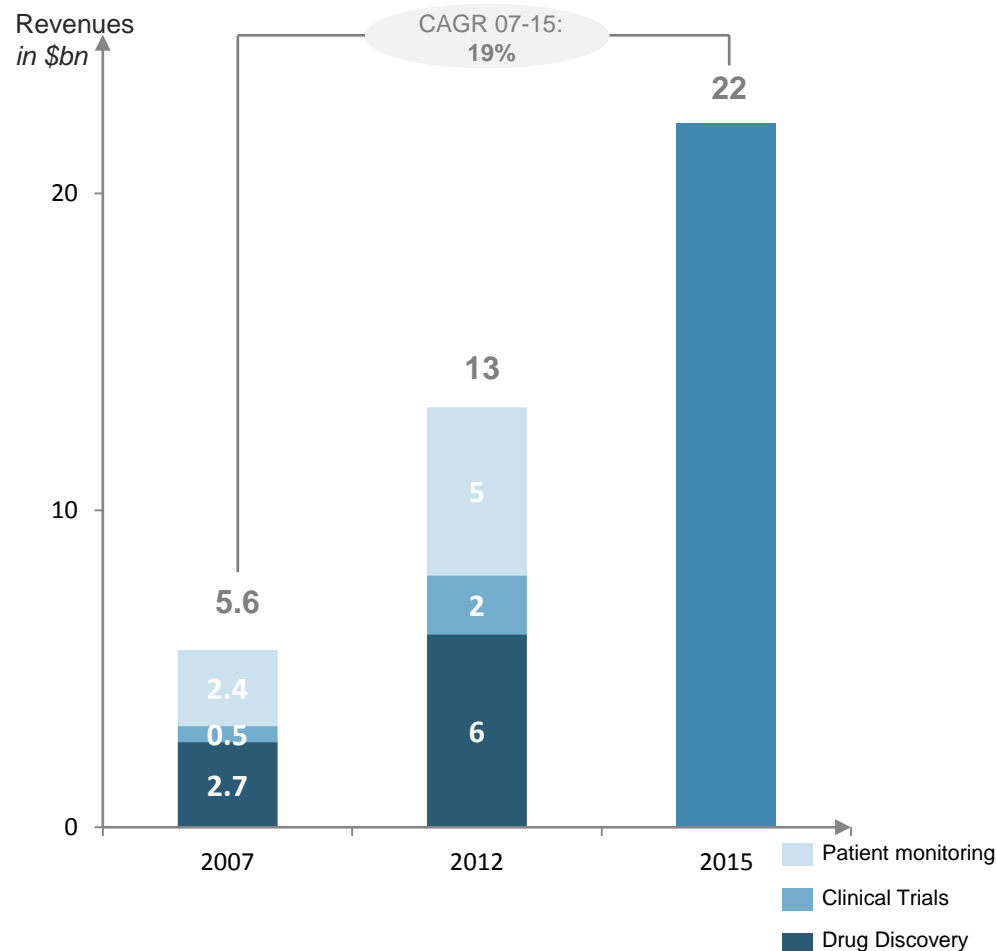
- Radiotherapy
- Lumpectomy
- Biopsy

1) Hormonal Therapy

Source: Agendia, Doctissimo, INCA, Bulletin du Cancer, MedCost, CEPTON analysis

# The biomarkers market is expected to increase sharply in the near future, driven by oncology and cardiology

Trend in biomarker sales, 2007-2015



Top 3 research fields

## Oncology

- hLAP *-protein-*: diagnosis, therapy management and monitoring of germ cell tumors
- P53 *-protein-*: cancer diagnosis
- ERCC1 and XPF *-proteins-*: prognosis of response to chemotherapy

## Cardiovascular diseases

- sPLA2 *-protein-*: diagnosis and prognosis of coronary disease and heart attack
- NT ProBNP *-protein-*: diagnosis of congestive heart failure, prognosis of 6-month-survival

## Neurology, Autoimmune diseases, Infectious diseases

- Sulfatide in cerebrospinal fluid *-lipid-*: AD diagnosis
- YKL-40 *-protein-*: diagnosis of rheumatoid arthritis
- CPS1 *-protein-*: diagnosis of sepsis disease

# Tomorrow, biomarkers will be everywhere in the healthcare value chain; however, the road is still long

Main barriers to the development of molecular diagnostics and biomarkers

## Challenges

## Impact on players

### More complex clinical trials

- More patient groups
- More complex monitoring
- More data to manage
- Need for co-development of diagnostic tools

Increased R&D costs and lead times

### Fragmented regulatory and HTA<sup>1</sup> processes

- Different requirements between EMEA and FDA
- HTA process managed at sub-national level in EU

Uncertainty about the future business model of molecular diagnostics

### Slow and uncertain reimbursement processes

- Based on decentralized HTA processes (2-5 years lead times)
- Little recognition by payors of the value of information provided by diagnostics

# Collaborations are the prevalent approach to develop and commercialize companion diagnostic tests

Strategies to approach companion diagnostics

Rx-Dx  
colla-  
boration



Collaboration with Genzyme genetics on BCR/ABL testing for CML drugs



Collaboration with Monogram Biosciences for HIV drugs  
Monogram's Trofile Assay is used to test CCR5 for Maraviroc



Collaborated with University of North Carolina for breast cancer studies on Gemzar



Partial control with limited Rx/Dx integration (Veridex and OrthoClinical Diagnostics)



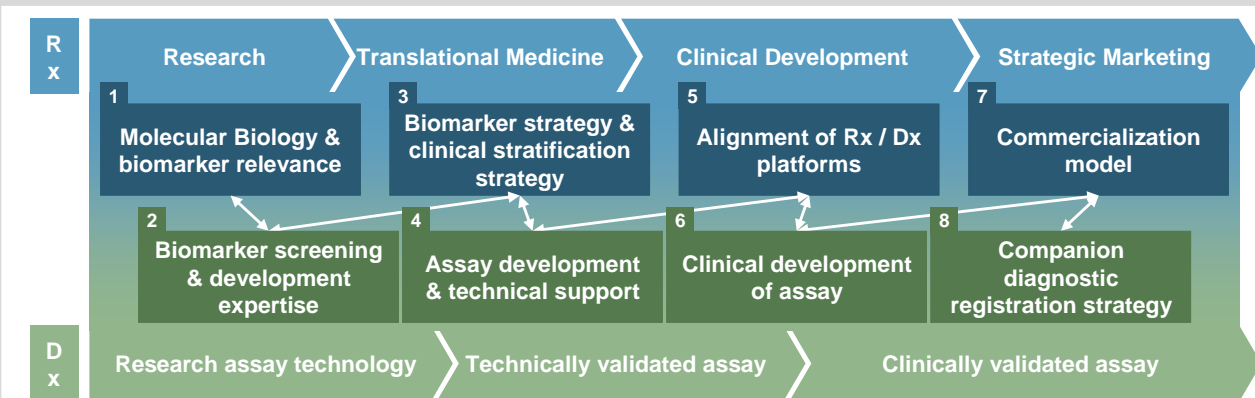
Most integrated Rx/Dx – close cooperation between Rx and Dx to validate novel Oncology markers for personalized medicine test



Partial control with limited Rx/Dx integration (Abbott Dx & Vysis)

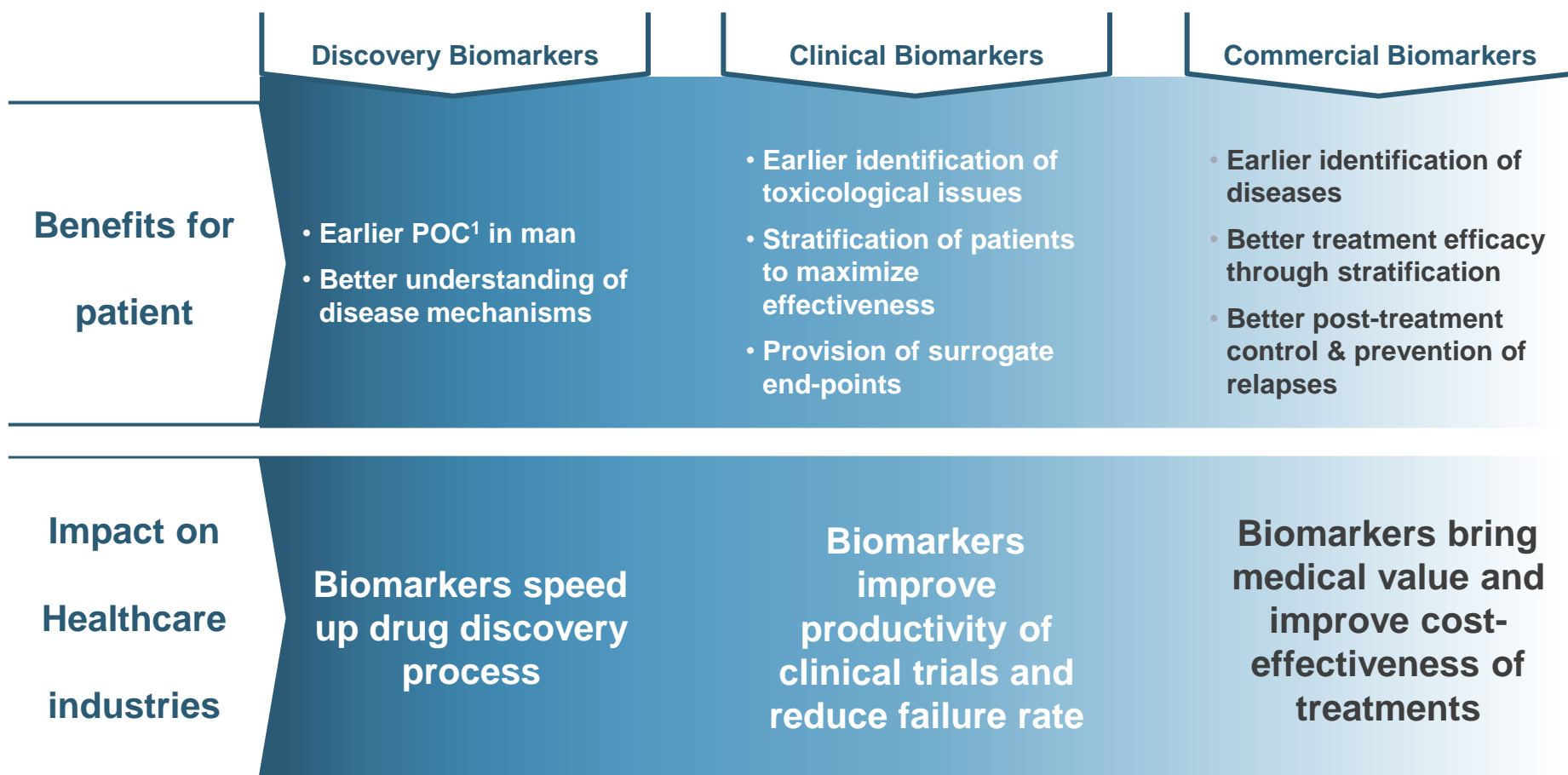
Integrated  
Rx & Dx  
divisions

## Roche model of Rx-Dx integration



# In the long term though, the impact of molecular diagnostics on pharma will be huge, both in scientific and economic terms

Biomarkers: benefits for patients and impact on healthcare industries

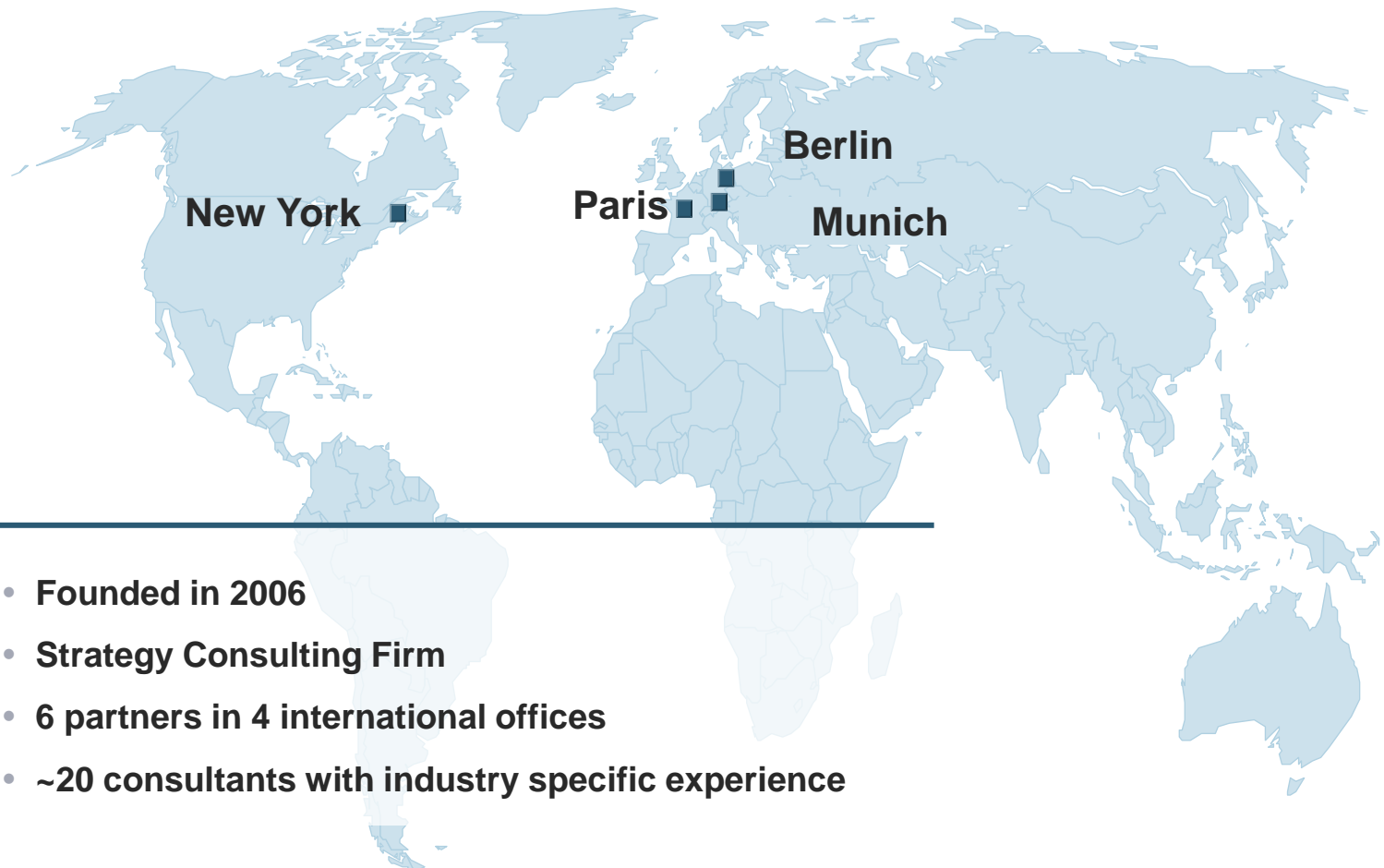


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**CEPTON is a Spin-Off of one of the most renowned global consulting firms operating from 4 locations with a team of ~20 permanent consultants**

CEPTON globally



- **Founded in 2006**
- **Strategy Consulting Firm**
- **6 partners in 4 international offices**
- **~20 consultants with industry specific experience**



## CEPTON - high value advice with small teams, senior team members and Partners dedicated to project work

- Small effective teams of **senior experts** and dedicated Partners
- CEPTON Managers and Partners all have **15+ years of experience** either in well-known Consulting firms or in the pharmaceutical Industry
- **Junior** consultants only on specific request – Partners and Managers are directly involved in projects
- Focus on **international** industry know-how and specifically adapted methods
- Integrating the client's organization and existing data by relying on proven **project management skills**
- Fostering **implementation** even as interim managers

# We focus on selected industries in which we have gathered long term relations and know-how

## Our Focus

	Strategy Consulting	Mediation & Senior Advice	Interim Management
Pharmaceuticals			
Medical Devices			
Biotechnology			
Healthcare			
Automotive			
Process Industries			

# Our offerings cover a spectrum of essential top executive questions and solutions

## CEPTON Offerings

Strategic Management	Performance
<ul style="list-style-type: none"> <li>• Corporate Strategy</li> <li>• Therapeutic Area Strategy</li> <li>• Regional Strategy</li> <li>• Portfolio-Management</li> </ul>	<ul style="list-style-type: none"> <li>• Launch Readiness (MAXXIMizing®)</li> <li>• Marketing &amp; Sales Force Effectiveness</li> <li>• Cost optimization</li> <li>• R&amp;D efficiency</li> <li>• Restructuring</li> </ul>
<ul style="list-style-type: none"> <li>• Reorganization</li> <li>• Post Merger Integration</li> <li>• Turnaround Management</li> <li>• Change Management</li> </ul>	<ul style="list-style-type: none"> <li>• Business Development support</li> <li>• Due Diligence (commercial)</li> <li>• Acquisition Screening &amp; Valuation</li> <li>• Carve Out Preparation</li> </ul>
Transformation	Transactions

Even since Cepton was founded early 2006 many interesting and fast growing clients have been served

Selected references of Cepton clients since 2006

celesio

PharmLog  
Pharma Logistik GmbH

Baxter

MERCK  
SERONO

NOVARTIS



sanofi aventis

IPSEN  
Innovation for patient care



THERAMEX

B | BRAUN  
SHARING EXPERTISE



JANSSEN-CILAG

Ethypharm  
Drug Delivery Solutions



DANONE

DAIMLER

STALLERGENES  
Allergen Vaccines Worldwide



IMERYS



basilea  
PHARMACEUTICA

BVMed  
Gesundheit gestalten.

gsk  
GlaxoSmithKline

exonhit  
therapeutics

Primmer  
NUTRICIA  
Advanced Medical Nutrition

AMGEN

NYCOMED

dna print  
genomics

# Jean Reboullet

## Managing Partner France

Year of birth: 1961      Nationality: French



### Professional experience

since 2006 CEPTON Founding Partner  
– Paris Office

2004-2005 Schlumberger Business  
Consulting: Director ECA  
area

1999-2004 Roland Berger Strategy  
Consultants: Partner then  
Senior Partner

1997-1999 AT Kearney: Principal

1990-1997 Arthur D. Little: Consultant  
then Associate Director  
since July 93

1987-1990 Touche Ross – Braxton  
Associates: Consultant

1985-1987 Aérospatiale – Design  
Engineer

### Key projects

- Optimization of R&D organizations in several mid-sized pharma
- Sales force optimization and marketing excellence in pharma
- Launch readiness for several pharma products : onco blockbuster, allergy tablet, antibiotic...
- Several Therapeutic Area strategy design
- Development strategy for Biotech start ups
- Several marketing optimization programs in chemical and process industry
- Strategic planning in process industry

### Industry competence

- Pharmaceuticals
- Process industry
- Oil & Gas
- Private Equity
- Automotive

### Education

- 1985      Sup'Aero (85) – Best French equivalent of a Master in Science in Aerospace

### Methodological competence

- Corporate strategy
- R&D optimization
- Strategic Marketing
- Post Merger integration
- Portfolio management
- Efficiency improvement
- Operations strategy

### Languages

- French
- English

# Marc-Olivier Bévierre

## Partner France

Year of birth: 1964      Nationality: French



### Professional experience

since Oct 2008 CEPTON Partner  
 1991-2008 16 years of experience in the Pharma Industry in different positions  
 2004-2008 Director of Strategy & Business Intelligence, J&J Pharma France  
 1997-2004 3 positions in Marketing & Sales management, both local and International (Novartis, J&J)  
 1991-1995 Medicinal Chemist in Drug Discovery (Novartis, Basel)

### Key projects

- 5-year Strategic Plan of a medical device and drug manufacturer with a special focus on the development of the Homecare business
- Reorganization of clinical trials management processes in a top 5 Pharma
- Design and financial assessment of strategic scenarios for relaunch of a major OTC brand in France, Italy and Germany
- Performance assessment and improvement of a major diabetes BU in Germany (350 reps)
- European launch of a new tablet product in allergy - Support in marketing, sales readiness and medico-marketing for product launch preparation
- Re-Launch of a Meningitis C vaccine in France: business case, marketing plan

### Industry competence

- Pharmaceuticals
- Animal Health pharmaceuticals
- Biotechnology

### Education

1996	MBA INSEAD
1991	Ph.D. Organic Chemistry
1988	Engineer Ecole Polytechnique

### Methodological competence

- |                                       |                                   |
|---------------------------------------|-----------------------------------|
| • Business case / Financial modelling | • Pharmaceutical R&D management   |
| • Sales & Marketing Management        | • Portfolio management            |
| • Strategic Marketing                 | • Due Diligence in Life Sciences  |
| • Market Research                     | • Business Planning & Forecasting |
| • Sales Force Effectiveness           | • Chemical Synthesis & Processes  |

### Languages

- French (mother tongue)
- English (fluent)
- German (fluent)
- Spanish (proficient)

# Francis Turina-Malard

## Partner

Year of birth: 1969      Nationality: French



### Professional experience

since 2008 CEPTON Partner  
 2007-2008 CEPTON Senior Manager  
 2004-2007 Microsoft – Program Manager Customer & Partner Satisfaction  
 2002-2004 Keyrus IT – Organization & HR Director, member of the Board  
 2000-2002 Keyrus IT - Founder of the Consulting Department  
 1998-2000 The Boston Consulting Group – Consultant  
 1994-1998 Aerospatiale (Space) – Project Manager

### Key projects

- Modeling of organizational scenarios and outsourcing strategy of DMPK teams - Pharma
- Set-up of a framework, governance & tools to improve productivity of Research – Pharma
- Business case on the evolution of the International clinical studies organization for the French affiliate of a big Pharma
- Diagnosis & definition of an action plan with medical & marketing teams to reach excellence in local medico-marketing studies
- Definition of a global IS Strategy to support Marketing & Sales Operations - Pharma player
- Several Mgmt seminars on Organization, growth & culture - different activity sectors
- Global change management program for the WW Leader of the Software Industry
- Corporate structuring, Organization and HR Strategy & Management of a Group during growth phase (150 to 1000p.)
- More than 4 years as Project Manager on International multi-cultural environment

### Industry competence

- Pharmaceuticals
- High-Tech + IT
- Automotive
- Process Industry

### Education

1993      Telecom Bretagne (French Engineering School – one of the top 2 schools in the Telecom field)

### Methodological competence

- Organization
- Change Management
- Corporate strategy
- Efficiency improvement
- Six Sigma (Green Belt)
- Project Management
- HR
- Post Merger integration

### Languages

- French (mother tongue)
- English (bilingual)
- German (good working knowledge)
- Spanish, Italian (basic)

# Dr. Michael C. Müller

## Managing Partner Germany



Year of birth: 1963      Nationality: German      **Founder Munich Office**

### Professional experience

since 2006    CEPTON Managing Partner  
 2004-2006    Managing Director Accenture  
 1996-2004    Roland Berger  
                  Strategy Consultants  
                  Partner & Head of Global  
                  Pharma practice group  
 1993-1995    Head of Marketing, Servier  
                  Munich  
 1992-1993    International Marketing  
                  Manager, Servier Paris  
 1990-1992    Clinical Research Director,  
                  Sanofi-Winthrop  
 1988-1990    Practicing as Medical Doctor

### Key projects

- MAXXIMizing® launch effectiveness for several products in EU and US for leading pharma companies
- Distribution strategy for global pharmaceutical companies
- Due Diligences of international pharma & biotech companies
- Various TA strategies for leading pharmaceutical companies
- Turnaround of a mid-size US-pharma
- Several M&A projects
- Diverse R&D programs
- Strategic Planning redesign for global TOP 3 company

### Industry competence

- Pharmaceuticals
- Medical Devices
- Consumer Products
- Healthcare Management
- Biotech
- Insurance

### Education

1990            Thesis  
 1982-1988    Medical Doctor  
                  University of Essen, Bochum  
                  and Bonn

### Methodological competence

- Corporate Strategy
- Marketing & Sales Excellence
- Corporate Organization
- Portfolio management
- Distribution strategy
- Cost containment/Restructuring

### Languages

- German (mother tongue)
- English (fluent)
- French (proficient)
- Italian (basic)



# Bertrand Kleinmann

## Partner France

Year of birth: 1960      Nationality: French



### Professional experience

As of 2010 CEPTON, Senior Partner  
2008- 2009 Invicem, Co-founder and Managing Partner  
2002-2008 Booz Allen Hamilton, Paris Managing Director & European Leader Automotive & Industrials Practice  
1992-2002 A.T.Kearney, Paris European Leader Communications & High Tech Practice  
1987-1992 Booz Allen Hamilton, Paris Senior Consultant Acquisition Services Practice  
1986-1987 SAGEM, Research engineer  
1984-1986 Massachusetts Institute of Technology, Visiting Scientist

### Key projects

- Alliance strategy between a Telco and a Transport operator
- European consolidation strategy in engineering
- Alliance strategy between a Technology Firm and a Utility followed by a Beauty Contest
- Organization redesign for a leading global supplier of high performance materials
- Enterprise transformation of a leading pan-European Automotive supplier including program profitability.
- Channel strategy design and implementation for a leading European telecom operator
- Numerous turnaround programs for industrial clients

### Industry competence

- Telecom, Media & Hi Tech
- Transportation
- Industrials: Automotive, Aerospace, other Capital Goods, Paper, Building Products

### Education

1984	Ecole normale superieure PhD in Atomic Physics
1982	Ecole Centrale Paris MsC

### Methodological competence

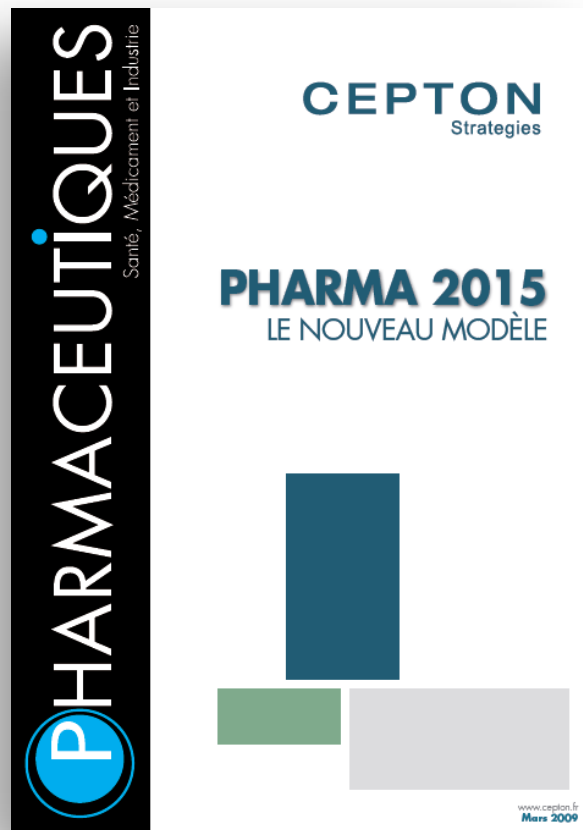
- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>• Corporate strategy</li> <li>• M&amp;A</li> <li>• Strategic alliances</li> <li>• Post merger integration</li> </ul> | <ul style="list-style-type: none"> <li>• Organization design</li> <li>• Turnaround programs</li> <li>• Operations strategy</li> <li>• Efficiency improvement</li> </ul> |
|---|---|

### Languages

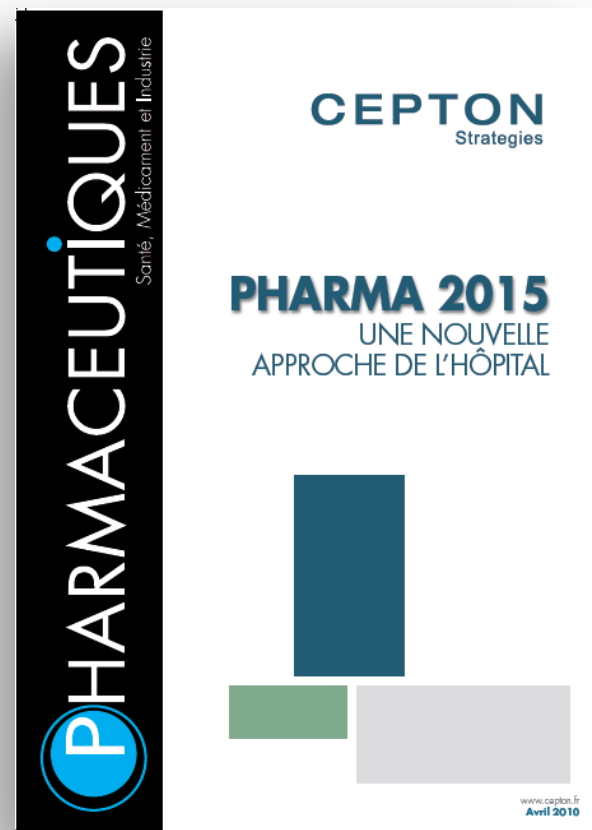
- French
- English

Recently, CEPTON released several publications on trends of the pharmaceutical industry in the specialized French press

"Pharmaceutiques"  
is the reference  
journal of the  
French  
Pharmaceutical  
industry



**March 2009**  
The future of Healthcare industries  
in France



**April 2010**  
The new organization of hospitals in  
France and its impact on healthcare  
industries

# CEPTON also regularly writes papers on the latest developments in the biotech industry

## February 2009 ("La Jaune et la Rouge")<sup>1)</sup>

A review of the latest developments of the biotech industry and its impact on the world economy



1) Review of the Alumni Association of Ecole Polytechnique, Paris.

## CEPTON also issues position papers on selected topics that have particular relevance for the pharmaceutical industry

Recent position papers of CEPTON

**CEPTON**  
Strategies

Strategic outsourcing  
across the  
Pharmaceuticals  
Value chain



**CEPTON**  
Strategies

The new Reality –  
Future needs for Marketing  
In the HealthCare Industry



A study on the impact of the HPST  
Act for pharma companies in  
France, performed in collaboration  
with a legal firm specialized in  
Healthcare



**CEPTON**  
Strategies

**Impacts de la loi « Hôpital, Patients, Santé,  
Territoires » pour les laboratoires  
pharmaceutiques**

**Jeudi 17 septembre 2009**

Une étude de J. Reboullet, M.O. Bévierre et O. Lantrès réalisée entre janvier  
et septembre 2009

# CEPTON released three renowned scientific studies on specific therapeutic areas or geographical regions

Examples of past research studies by CEPTON



# CEPTON's consulting approach is well received in the press





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