

**IVD toimialan tuloksia, kokemuksia ja näkymiä**  
**Results, experiences and outlook of the IVD-sector**

**FinnWell Seminar of April 29 , 2009**  
**Finlandia-talo, Helsinki**

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Chairman, Finnish In Vitro Diagnostics Industry Cluster FIVDIC

## Contents

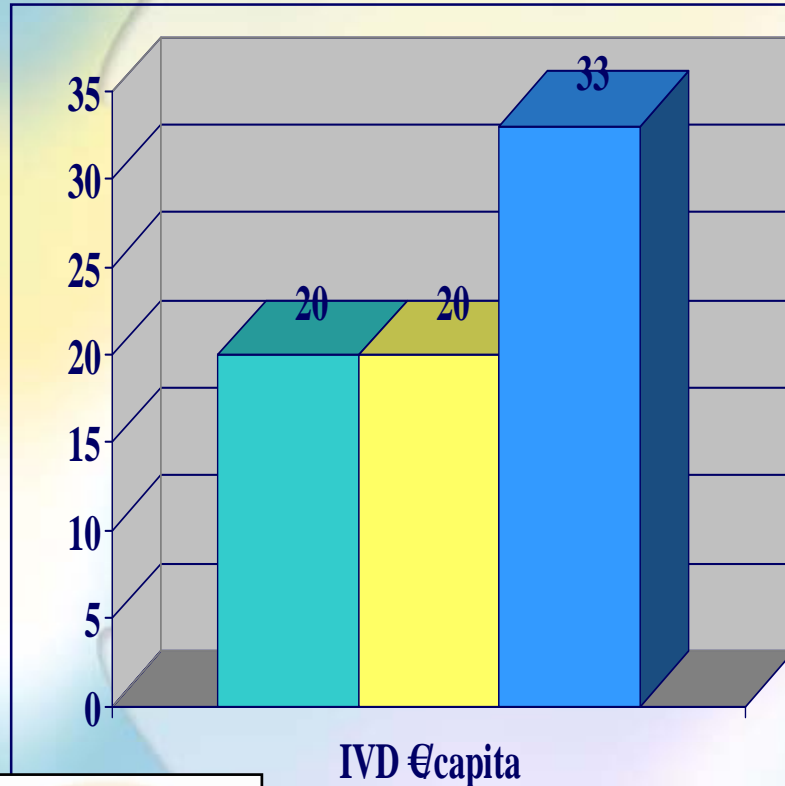
- Quick introduction of In Vitro Diagnostics (IVD) sector
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- IVD-related projects of the FinnWell-program
  - Some statistics, pros and cons for big vs focused programs
  - Example (Welfare - a public research project of FinnWell)
- Views of IVD industry
  - Attempts to balanced IVD-development
    - Next Generation Diagnostics, HealthBio, Tekes programs, EU, SCSTIs
- Strategic Center (SHOK) for Health and Well-being
  - Intelligent Monitoring of Health and Well-being – program
    - Work package areas to start with
- Conclusions

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## Global *In Vitro* Diagnostics (IVD) Revenues 2007 43 bUSD\*

“Diagnostic tests account for only less than 2 % of government healthcare expenditures worldwide, yet their finding influence 60-70% of healthcare decisions” Clinica 2008



Clinical chemistry	38%
Immunochemistry	36%
Bacteriology	9%
<b>Molecular Biology</b>	<b>7%</b>
Hematology	5%
Hemostasis	5%

Diabetes	24%
Infectious diseases	23%
Oncology	8%
Cardiology	6%
Hematology	5%
Other clinical chemistry	13%

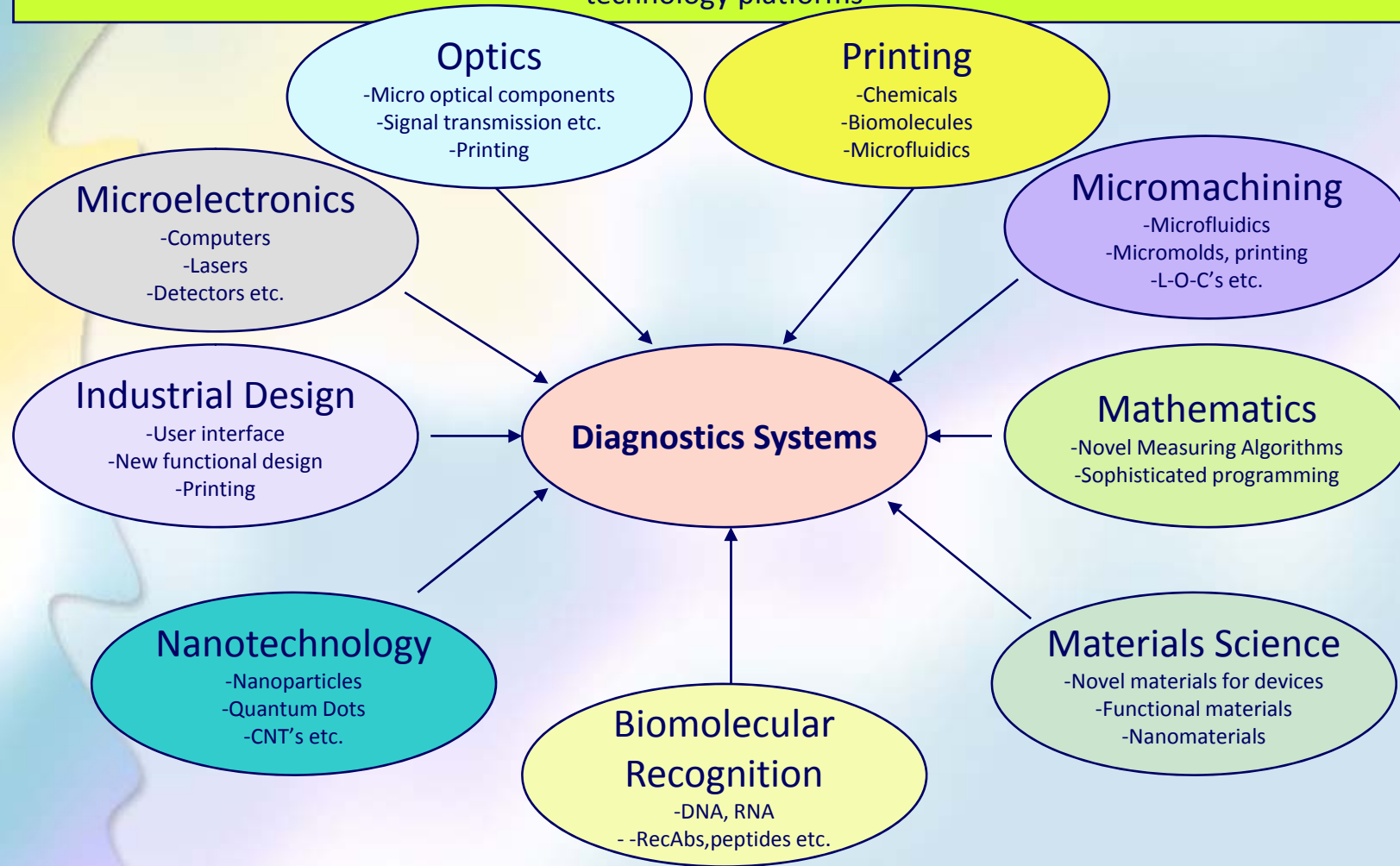
Centralized lab testing	63%
Decentralized glucose	22%
<b>Other Point-of-Care</b>	<b>15%</b>

Source: FIVDIC, Espicom 2006, BioMerieux 2006, Yole Development 2007, Kalorama 2008\*



# Diagnostics Technology Road Map

Technology convergence is creating new product innovations .Need to continue to invest in new broad technology platforms



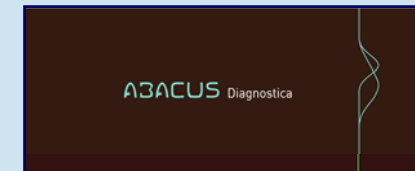
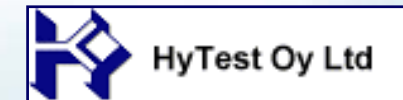
Diagnostics is the cross-road of advanced technologies

# Finnish In Vitro Diagnostics Industry Cluster FIVDIC

[www.fivdic.net](http://www.fivdic.net)



- Appr. 300 m€ sales
- Appr. 2000 jobs
- Appr. 30 companies



Future Diagnostics Finland, Query 2009  
Foresight Summary 2008 - 2014  
Views of Finnish IVD-experts (n=48/116)

- **IVD-sales** ; increase of 16% by 2014
- **Personnel**; increase of 8% by 2014
- **RD-investments**; increase of 12% by 2014
- **Growth opportunities**: China > USA > India > EU
- **User location**: DOC > PHC > Occupat. Health > Home
- **Future applications**: Therapy monitoring > Risk assessment > Self-testing > Screening
- **Biomarker types**: Quantitative tests > Microbial probes > Multiplexed testing > Genetic screening
- **Laboratory testing**: CVD > Cancer > MBO > Antibiotic resistance
- **Point-of-Care-testing**: CVD > MBO > Asthma > Antibiotic resistance
- **Self-testing**: MBO > CVD > Asthma > Osteoporosis
- **Future products originate**: Customer needs > Start-ups > B2B > IVD-companies
- **Success enablers**: Therapy-linked > Effect on health cost > Intelligent platforms data linked
- **Topics of interest**: Intelligent integrated platforms > Rapid microbiology > Intelligent Multiplexed biomarkers > Emerging markets

Source: Future Diagnostics Finland, Query 2009

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## Some statistics 2004-2008 (as of Jan 2009) FinnWell vs. IVD-related projects (I)

- **FinnWell program 2004-2009 , appr. total 177 m€ (381 projects)**
  - **FinnWell Funding: Tekes 92 m€, companies 85 m€**
  - **Processes of Healthcare (23%€) appr. 42 m€ (127 projects)**
    - 78 research projects vs. 49 company projects (61% research)
  - **HC IT Products & Services (34%€) appr. 61 m€ (168 projects)**
    - 55 research projects vs. 113 company projects (32% research)
  - **Technol for Diagn and Care (42%€) appr. 74 m€ (86 projects)**
    - 51 research projects vs. 35 company projects (60% research)
- **IVD-related projects (21%€) appr. 37 m€ ( 27 projects)**
  - 17 research projects vs 10 company projects (63 % research)
  - **IVD-related research projects (17) appr 8 m€**
    - Platform development (POC & DNA)
    - Biomarker discovery (mainly Type 1 Diabetes)
    - Printable diagnostic platforms (Immunosensors)
  - **IVD-related company projects (10) appr 29 m€**
    - Point-of-care platforms (immuno & DNA, metabolites)
    - Analyte discovery / Product concepts
    - Automated platforms

Some statistics 2004-2008 (as of Jan 2009)  
FinnWell vs. IVD-related projects (II)

**IVD-related “Technology for Diagnostics and Care” FinnWell projects  
(appr. total 37 m€ ,27 projects)**

- **21 %** of funding and **7%** of projects of **FinnWell**
- **50 %** of funding and **31%** of projects of **Techn for Diagn and Care**
- **21 %** of funding and **63 %** projects directed to IVD-research projects
- Tekes support: Public projects **67%**, Company projects **46%**  
(total Tekes support to IVD-related projects **52%**)

\*\*\*\*\*

- Pros; scale of funding (Tekes-support to IVD appr **3,8 m€/y**), increase in inter-field and multidisciplinary links
- Cons: little intra-field collaboration (within IVD-sector), a few company consortium projects, in research projects not enough input asked from companies in the planning stage



WELFARE , a public research project of FinnWell-program  
**(Low cost disposable sensor platform for home diagnostics  
and health care)**

**Background :**

- WELFARE ( DNo 40067/05) , WELFARE 2 (DNo 40378/06) and WELFARE 2.1 (DNo 1416/31/06).
- **Objectives and scope ( for Welfare 2.1 part)**
  - an integrated biosensor chip, where the biological recognition element, fluidistics and at least some of the optical functionalities are integrated. Demonstrator might need external sample handling, fluid pumps, external optical components and laboratory setup for light coupling and detection.
  - a camera based reader device that comprises the optical components that can not be integrated to the sensor chip itself and to verify the feasibility of the camera based platform
- **Duration:** 1.7.2005-30.6.2009 (total duration Welfare)
- **Total cost:** 1,3 m€
- **Parties:** VTT, Orion Diagnostica Oy, Nokia Oyj, Magnasense Oy, (Braggone Oy), (Comsol Oy)

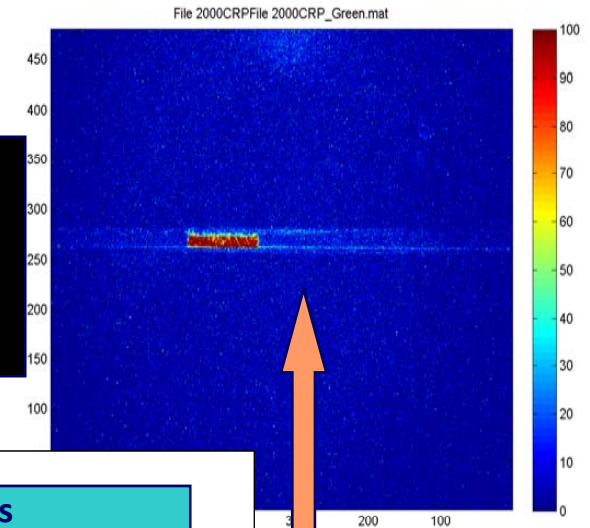
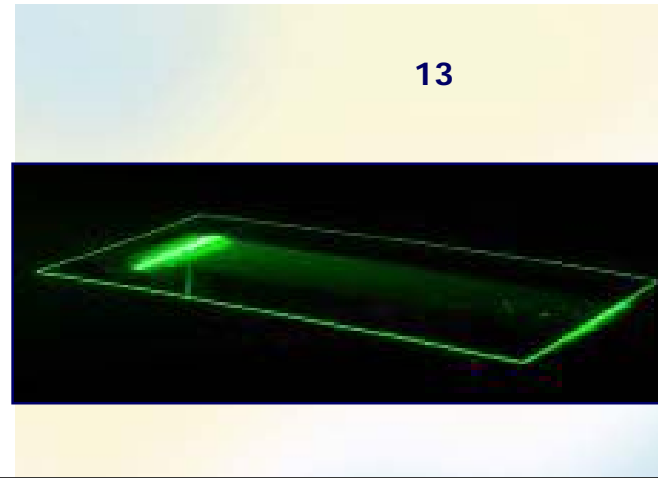
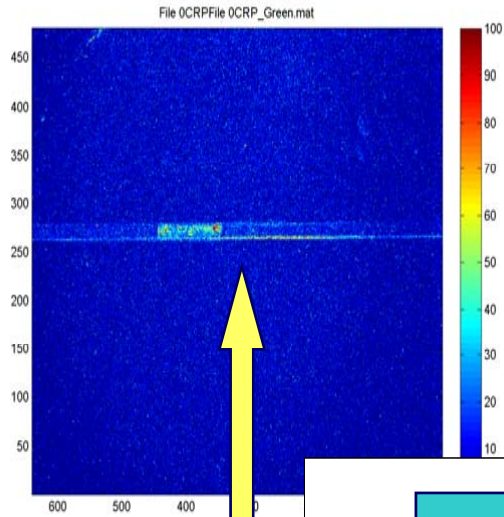
Expectations and assumed benefits (view of an industrial partner)  
Welfare-project 2005-2009

**Expectations**

- **Sensor-chip development:**
  - Roll-to-roll printable biosensor prototype and characterization report.
- **Reader device development:**
  - Design of the camera based reader device incl. signal processing software, prototype and demonstration results.
- **Biorecognition:**
  - Biocompatible ink and parameters for ink-jetting.
  - Printable biorecognition elements incorporated in the design of a quantitative assay.
  - Model analytes :CRP, NT-proANP and myoglobin (incl.validation of the measurement steps)

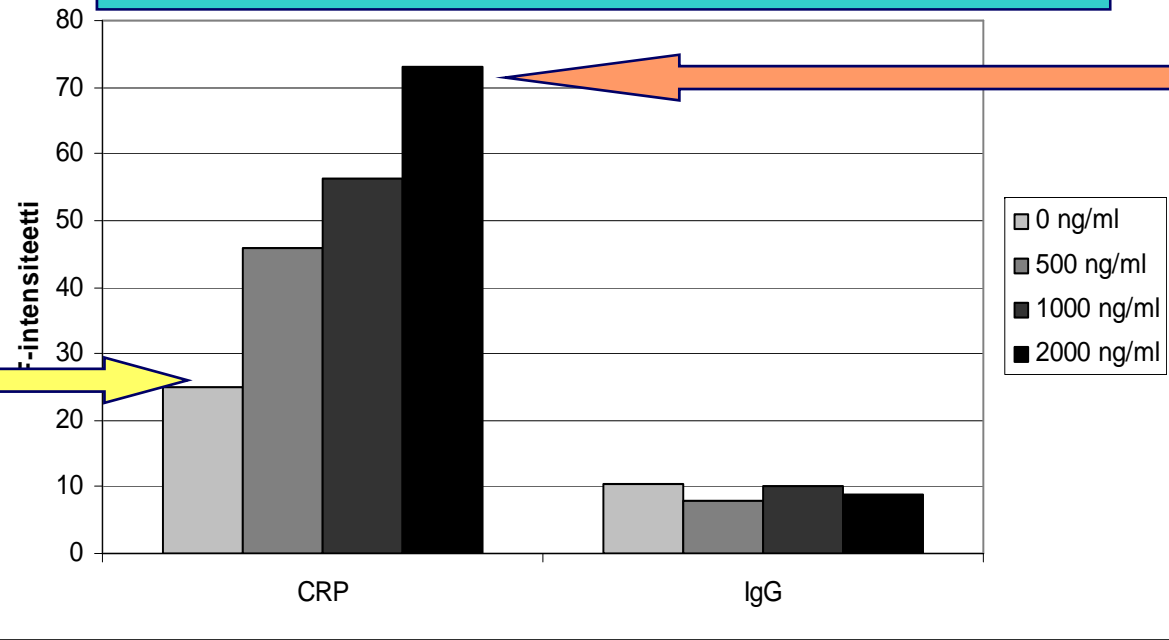
**Assumed benefits**

- Quantitative immunoassay constructed using low-cost printing technology suitable for POC and home testing > basis for future product realizations
- Use of Mabs is tested in printing environment and fluorescence labeling and fluorescence detection
- Defined period of negotiating rights to foregrounds of the program before they become open for all.



Preliminary CRP (C-reactive protein) results obtained by using printed sensor-chip and fluorescence detection

Typical CRP-levels to predict low risk of cardiac event

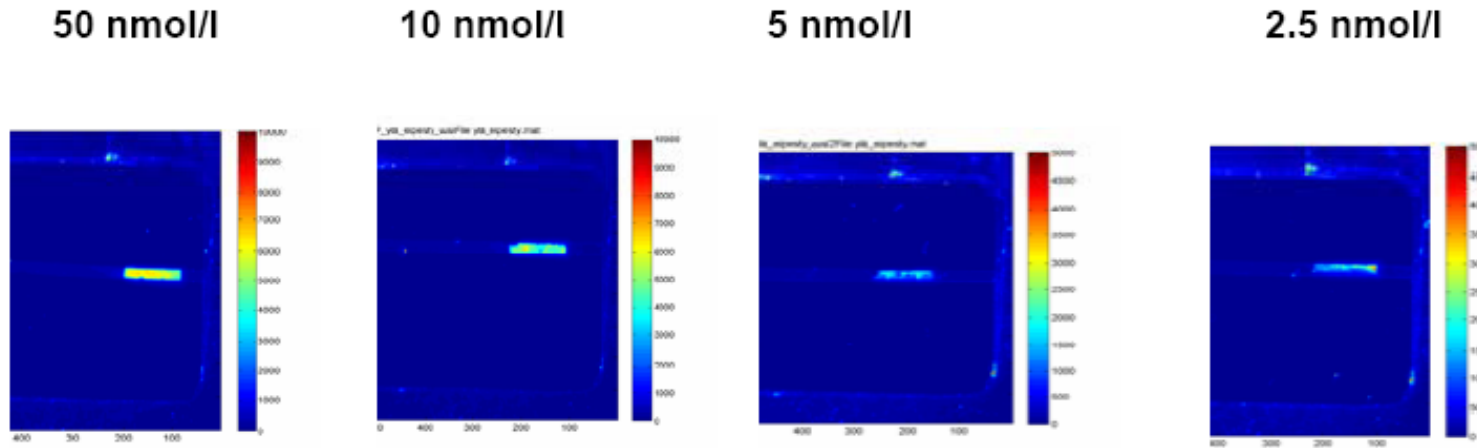


Typical CRP-levels to predict mildly elevated risk of cardiac event

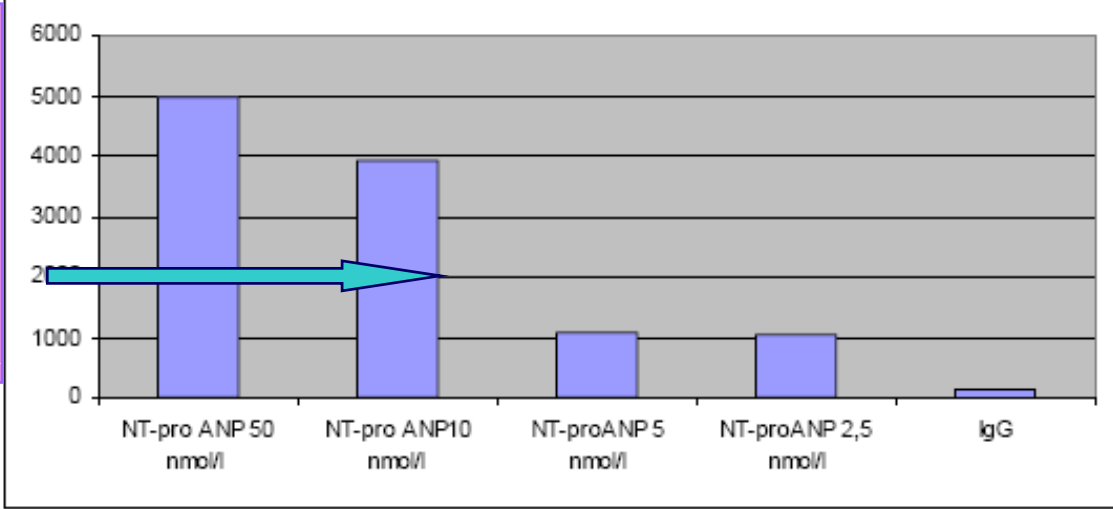
Source: derived from VTT, Hakalahti

# NT-proANP immunoassay in $\mu$ channels

(led illumination/camera detection)



Typical NT-proANP levels in patients with severe heart failure



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National Technology Programs and In Vitro Diagnostics (Finland)  
 (IVD-related projects comprising 5-8 % project share in big programs)

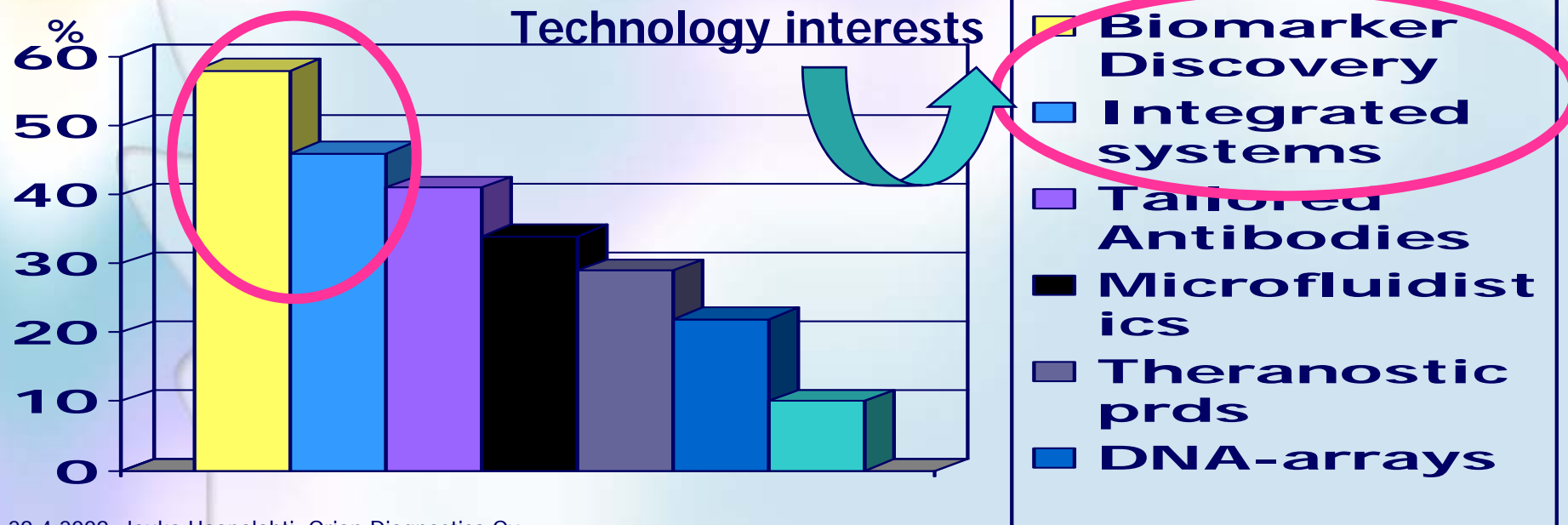


## Next Generation Diagnostics Quick Survey

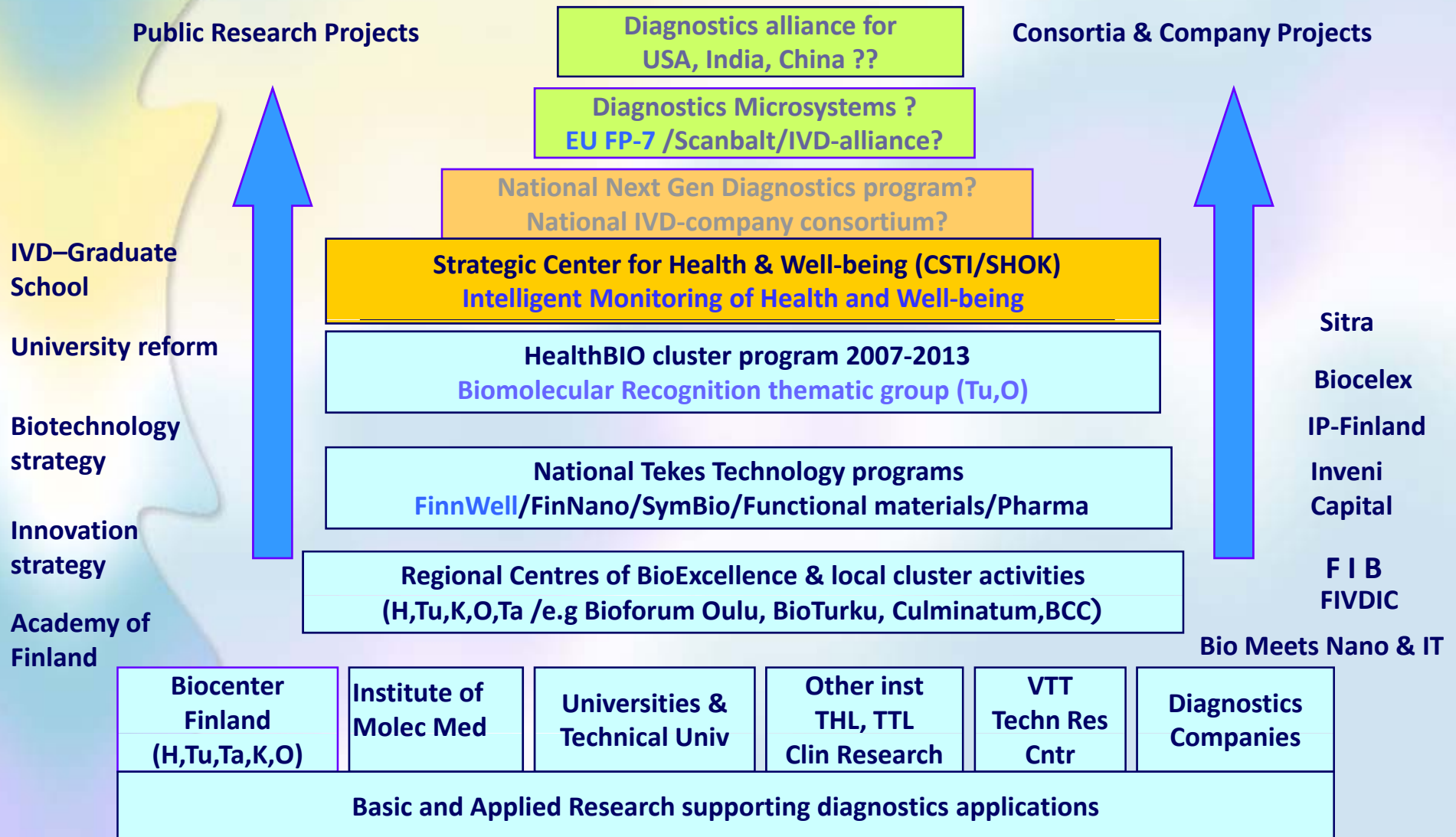
HealthBIO Strategy Seminar Helsinki, Nov 22, 2007\* ( 140 participants)

- High commitment to preparation of **Next Generation Diagnostics Technol program**
- Clear commitment to **Printable diagnostics & Biosensing** initiatives
- Value Chain strengthening in **detection systems development & assay prototyping**
- Highest technological interest in **Biomarker Discovery & Integrated systems**

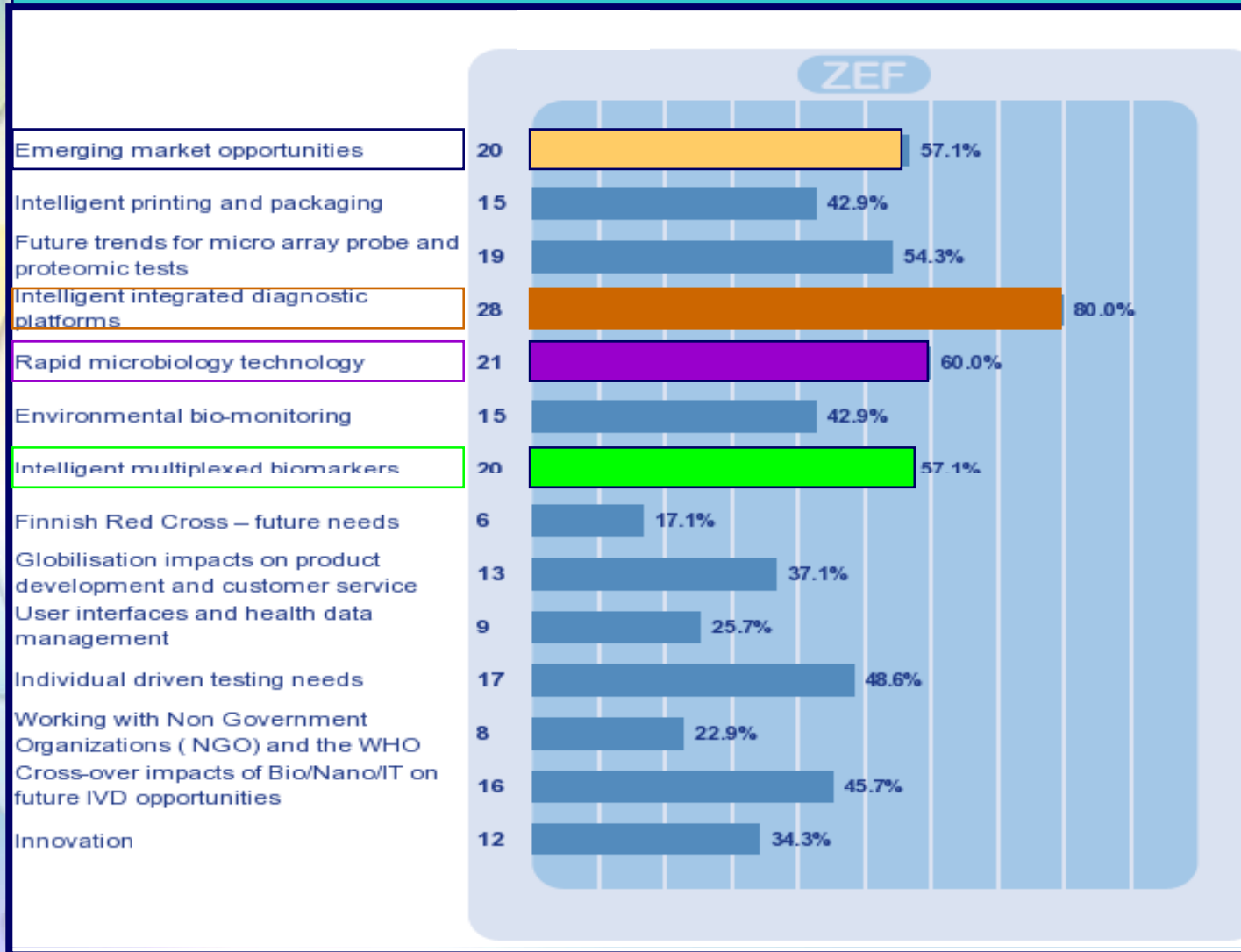
\* Results of seminar questionnaire (n=41)



## Towards Next Generation Diagnostics



## IVD-related interests, views of Finnish IVD-experts (n=48)



Source: Future Diagnostics Finland, Query 2009

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## Background of the “T&H SHOK”

- The goal of the Strategic Center (SHOK) for Health and Well-being is to develop products, services and practices to prevent and treat diseases with major public health and economic impact
- The diseases and conditions selected for SHOK focus are
  - i) Microbial infections and inflammation; ii) Metabolic syndrome; iii) Neurodegenerative diseases and iv) Malignant diseases, especially solid tumors
- SHOK has recognized the global trend of an individual becoming a more knowledgeable and demanding consumer of health and social care services. People are willing and capable of taking more responsibility of monitoring their health and actively contributing to it
- The P4 medicine (personalized, preventive, predictive and participatory) will change the entire health care structure posing high demands on solutions how to handle and understand the ever increasing magnitude of data
- The focus areas include advanced world class molecular and translational medicine, long pioneer position in preventive measures of type 2 diabetes, high quality brain research, traditions and innovations in the technology platforms for diagnostic applications, research of some cancers, nutrition and the strength in the ICT and telecommunications
- Finland has a uniform health care structure enabling new solutions to be studied for efficiency in selected “test-beds”
- Health and well-being related costs are increasing, challenging the economic situation of many communities. The population is aging rapidly, increasing service needs while a shortage of personnel both in social and health care is imminent

Source: Executive summary , SHOK Status Application

## “T&H SHOK Oy” Preliminary Shareholders\*

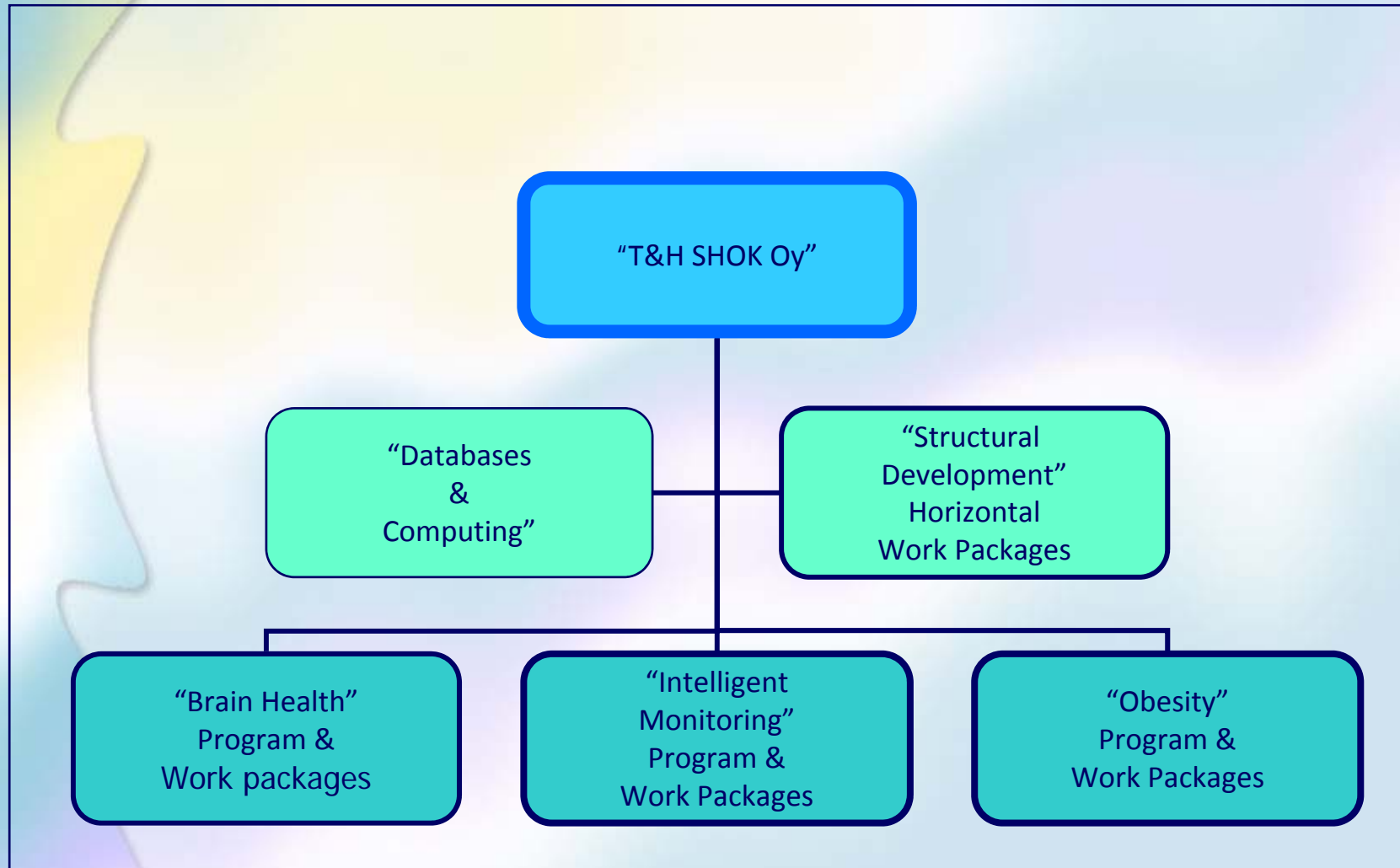
(companies shall have majority of shares)

- Electa Neuromag Oy
- GE Healthcare Finland Oy
- Orion Oyj
- Thermo Fisher Scientific Oy
- Tieto Healthcare & Welfare Oy
- Valio Oy
- BioTie Therapies Oy
- CSC – IT center for Science Ltd
- Finnzymes Oy
- Invalidiliiton Asumispalvelut Oy
- Kustannus Oy Duodecim
- Oy Medix Biochemica Ab
- Philips Oy
- Red Cross Finland Blood Service
- Mobidiag Oy
- NexStim Oy

- University of Helsinki (UHe)
- University of Jyväskylä (UJy)
- University of Kuopio (UKu)
- University of Oulu (UOu)
- University of Tampere (UTa)
- Tampere University of Technology (TUT)
- Helsinki University of Technology (HUT)
- Åbo Academy University (ÅA)
- Technical Research Center of Finland (VTT)
- UKK-Institute (UKK)
- Finnish Institute of Occupational Health (TTL)
- Agrifood Research Finland (MTT)

**\*) Non-binding Letter-of-Intent signed by March 27, 2009**  
**Source: T&H SHOK Status Application**

## “T&H SHOK Oy” Planned key areas of operation



## Intelligent Monitoring of Health and Well-being Program (I)

### Goals of the “Intelligent Monitoring” program

- Novel products, services and practices with significant commercial and health economical impact on testing and monitoring of health and diseases by individuals or healthcare professionals  
Solutions aim at improved management of microbial infections, inflammations, metabolic syndrome, neurodegenerative diseases and cancer
- The target will be reached by developing
  1. intelligent solutions\* for individual-driven monitoring of health and well-being
  2. validated tools for professional monitoring of disease conditions and personalized therapies

Intelligent biomarker combinations and integration of diagnostic platforms and bio-nano-IT-technologies will be the key to novel products and service concepts

\* *Intelligent solutions are affordable and easy-to-use monitoring systems, which through bi-directional connectivity enable computer-assisted interpretation of measurement results, long-term follow-up and links into background information and personal health records*

## Intelligent Monitoring of Health and Well-being Program (II)

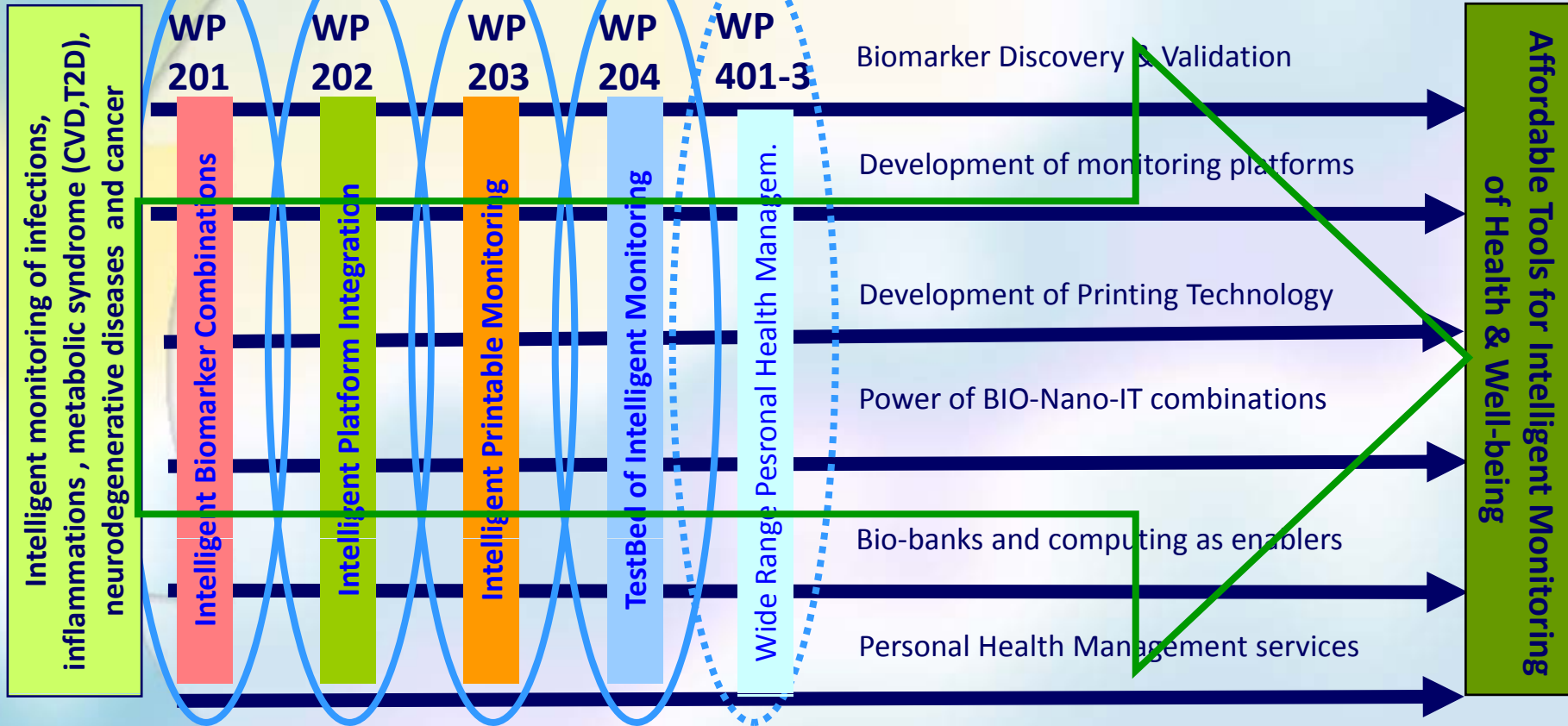
### Interim goals include development of :

- Discovery & validation of the most optimal biomarker combinations > WP201
- Novel technology platforms & affordable tests suitable for self-testing > WP202
- Novel ways to produce affordable intelligent monitoring through printing > WP203
- Means to motivate individuals to monitor health and to modify life styles > WP204
- Integration of tests and health information from large databases > WP204

### Work Packages (WP) of the “ Intelligent Monitoring”-program to start with;

- **WP201 (Intelligent Biomarker Combinations)**
- **WP202 (Intelligent Platform Integration)**
- **WP203 (Intelligent Printable Monitoring)**
- **WP204 (TestBed of Intelligent Monitoring) (linked with horizontal WPs 401-3)**

**“Intelligent Monitoring of Health and Well-being” Program  
” Intelligent Monitoring”**



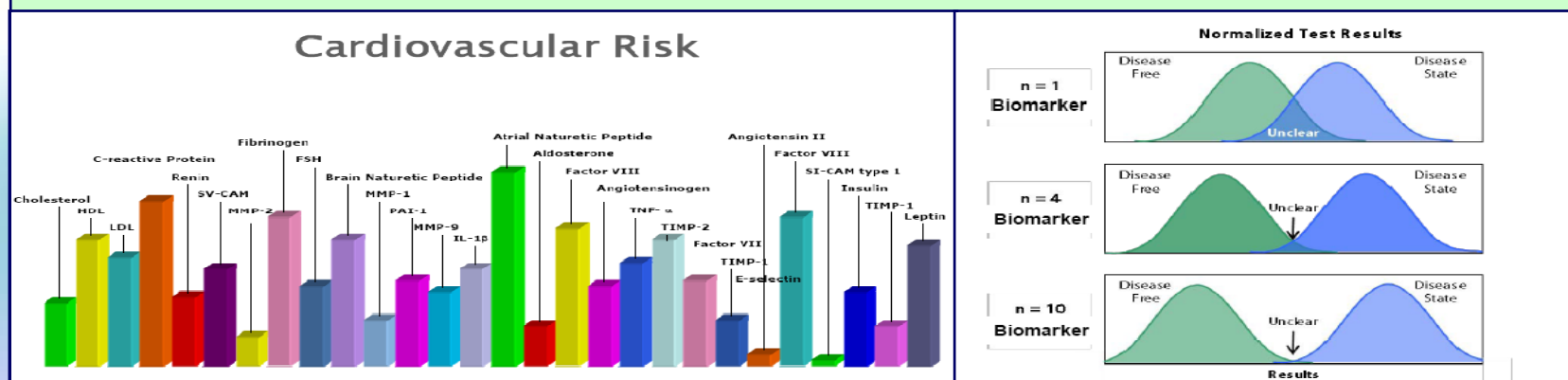
**Targets>Tools>Manufacture>Usability/Impacts**

Companies will define **WHAT TO DO**  
Companies, research institutes and universities will together define **HOW TO DO IT**

## WP201: Intelligent Biomarker Combinations

### Targets of WP 201:

- Clinically validated most efficient biomarker combinations which enable intelligent and affordable individual prediction and monitoring of conditions with metabolic syndrome, infections, inflammations, neurodegenerative diseases and cancer
- Markers may be chemical, enzymatic, immunological or nucleic acid based, known or novel outcome of genomic, proteomic or metabolomic biomarker discovery and based on use of large amount of samples, data mining and bio-computing



## WP202: Intelligent Platform Integration

### Targets of WP 202

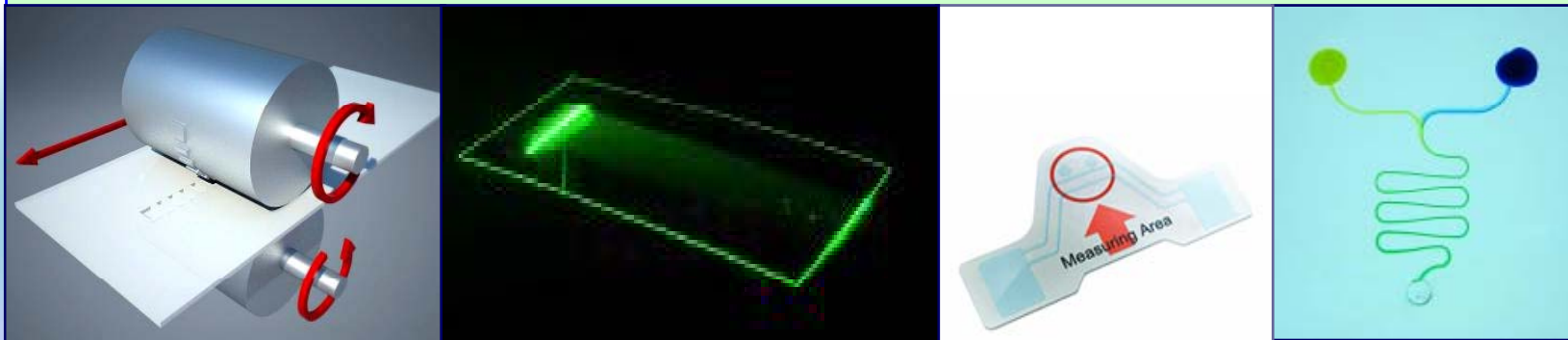
- Novel technology solutions to enable intelligent and cost-effective monitoring of microbial infections, inflammations, metabolic syndrome, neurodegenerative diseases and cancer by individuals themselves or by healthcare professionals
- New solutions may be combinations based on chemical, immunological or nucleic acid recognition, tailored bio-binders, sensors, micro-fluidistic and multiplexed structures, simplified detection methods, cost-effective reading, wireless data transfer and connectivity , printed intelligence and integration of bio-nano-information technologies



## WP203: Intelligent Printable Monitoring

### Targets of WP 203

- Basic concepts of novel printable monitoring, low-cost manufacturing processes and novel printable materials to enable integration of best biomarker combinations, optimal platforms of sample handling, multiplexed chemical, immunological and nucleic acid based methods, signal detection, wireless health information and decision support for personalized and individual driven health monitoring
- **Intelligent Monitoring by Affordable Test Arrays**

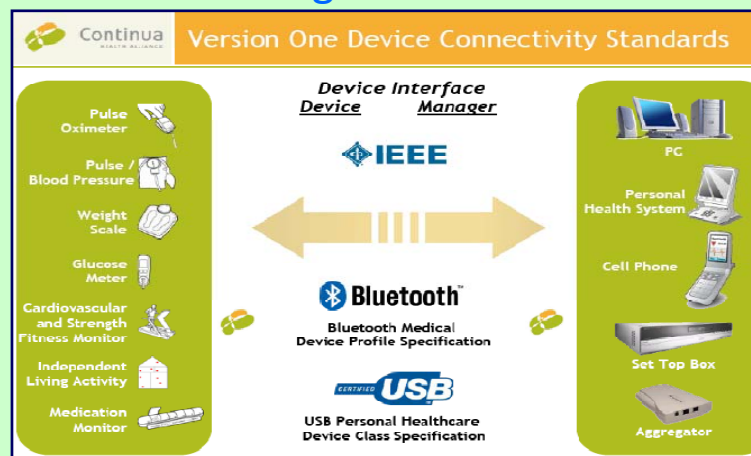


## WP204: Test Bed of Intelligent Monitoring

### WP401-3: Wide Range Personal Health Management

#### Targets of WP204

- Intelligent affordable monitoring products will create significant new international business activities
- TestBed-activities include bio-banks, clinical research, validation of products and services, wide use of bio-computing , scientific publications, dissemination of results of the program
- Linked with horizontal activities of the Structural Development-programs “Wide Range Personal Health Management” and “Databases and Computing”



**“Intelligent Monitoring” Program**  
**Examples for challenges in development of intelligent monitoring**

**Intelligent Biomarker Combinations**

- Panel for respiratory problems (POC)
- Panel of inflammatory markers (POC)
- Panel for microbial infections (POC)
- Panel of MBO-related CVD and T2D markers (POC)
- Panel for active surveillance of diagnosed prostate cancer (POC)

**WP201**

**Intelligent Platform Integration**

- Sample port and blood separation of microfluidistic device
- Multimodality (4-plex micro-device)
- Homogeneous fluorescence assays
- Engineered binders for POC and OTC
- Prototypes of intelligent low-cost LF- and Print-strip readers
- Sensors & select. electrodes /autom.

**WP202**

**Intelligent Printable Monitoring**

- Proof-of-Concept (PoC) of printed rapid microbial DNA POC detection
- PoC of multiplexed printed sensor chip
- PoC of printed sample handling
- PoC of printed quantitative immunological POC-tests
- Optimized process for sensor printing

**WP203**

**TestBed of Intelligent Monitoring & Structural Devel (IT/service-linked)**

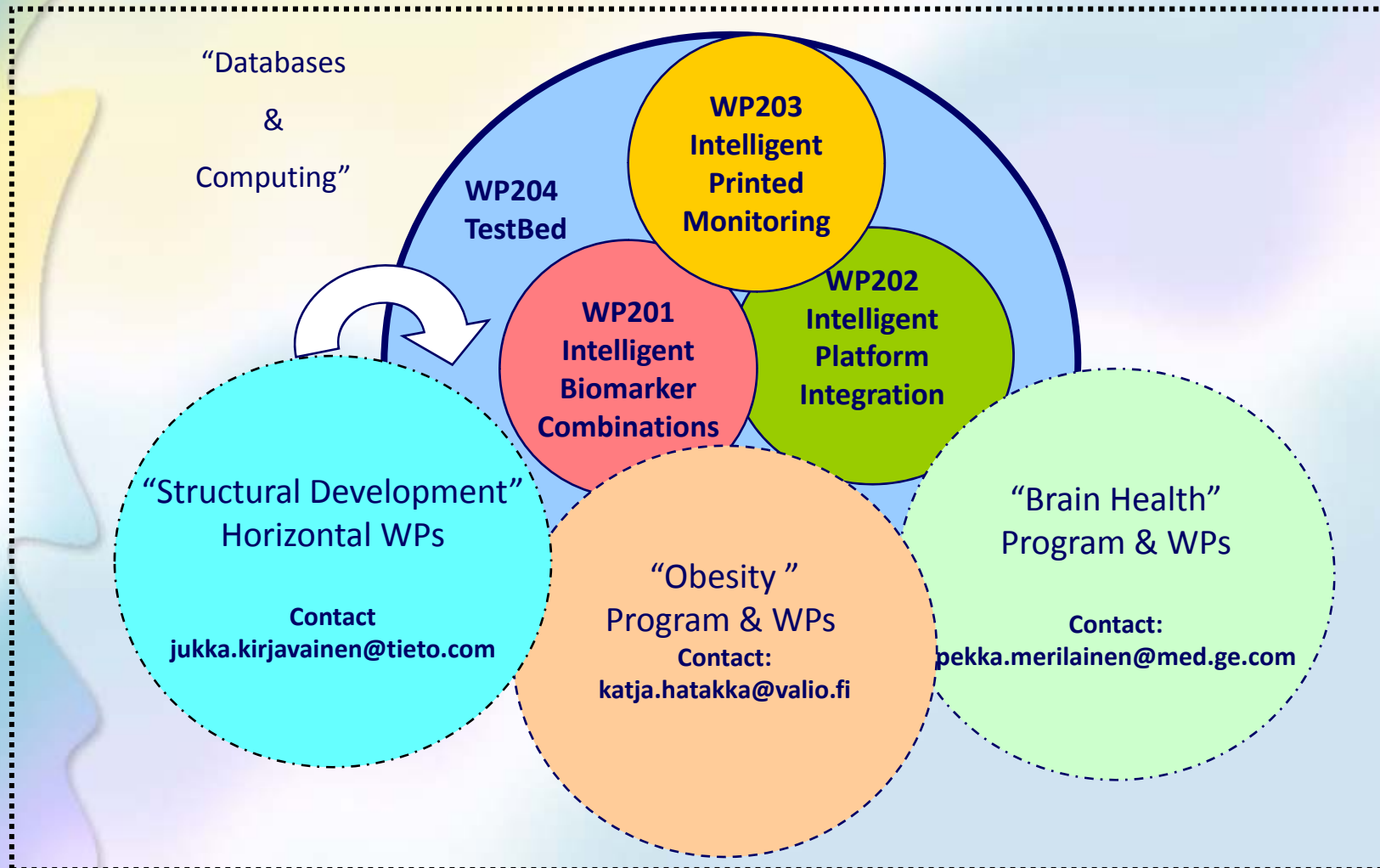
- Organized availability of clinical samples and health data for Dx-trials
- Evidence acquisition for purpose specific 4-plexed POC/OTC-tests
- 2-way IT-connectivity of Dx-devices
- “Virtual Doctor” vs Smart Monitoring
- Health economic impacts

**WP204/WP401-**

## “Intelligent Monitoring” Program & Work Packages

(contact: jouko.haapalahti@oriondiagnostica.fi)

Links with other “T&H SHOK”- Programs & Work Packages



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## Conclusions

- In vitro diagnostics sector (IVD) continues to offer possibilities for companies in Finland to be competitive and commercially successful
- Tekes technology and innovation programs are essential enablers
- Massive programs have increased multidisciplinary links but decreased unity between operators in the IVD field
- FinnWell-program significantly supported IVD-sector, mainly through company project funding
- Diagnostics sector is well placed in many health related national plans and activities
- Need to re-focus joint efforts towards “Next generation diagnostics” remains evident, especially in the integration of IVD-platforms to enable low-cost and easy-to-use analytical monitoring tools
- Strategic Center for Health and Well-being (T&H SHOK) will offer stream-lined continuation for IVD-related aims of FinnWell introducing company-driven programs, especially through program of “ Intelligent Monitoring of Health and Well-being”
  - projects under planning, aim to start 2010
  - contact: [jouko.haapalahti@oriondiagnostica.fi](mailto:jouko.haapalahti@oriondiagnostica.fi) (Intelligent Monitoring)

## Orion Diagnostica

- An in-vitro diagnostic company with emphasis on point-of-care testing



23.4.2009

## Key Figures in 2008

- Net sales MEUR 45.0 (+7.1%)
  - International sales were over 80% of net sales
  - Main market areas
    - Nordic countries
    - France, Germany, Italy, Spain
    - USA
    - Japan
    - China
- Personnel in 2008 was ca 300
  - Outside Finland ca 50
- Extensive collaboration with universities and research groups



23.4.2009

## Four business areas

### Point-of-Care tests



- QuikRead system
- Urinary tract infections
- Rota and adenovirus enteris

### Laboratory tests



- Clinical microbiology
- Clinical chemistry

### Dental tests



- Buffering capacity
- Mutans streptococci
- Lactobacilli
- Yeasts

### Hygiene tests



- Surface hygiene & microbial status in food and cosmetics industry
- Microbial status of industrial fluids



23.4.2009

## Quality in Partnerships

- Orion Diagnostica has earned a reputation as a service-oriented, high quality, reliable partner throughout the value-chain
- Orion Diagnostica partners with several of the top 20 diagnostics companies
- Orion Diagnostica is a well-recognized partner in research in Finland, and internationally. It will be one of the main contributors in the Strategic Centre for Science, Technology and Innovation in the Field of Health and Well-Being that will start its research programs in 2010



23.4.2009