Future Diagnostics – Finland Ideas for growth – April 2009

Dr Paul Mundill
Innostics Oy

Future Diagnostics-Finland Query 2009

- The aim was to assess the future directions and needs of the Finnish *in vitro* diagnostics industry and to collect foresights for future development
- The query was sent to 116 people, 47 responded(29 from Industry and 18 from Research)
- Questions were answered from mid December to mid February 2009
- Summary information circulated to participants in March 2009

Global Business environment (2007)

- 43 BUSD - Global IVD market
  - Growth at 6.7% (2007 to 2011 estimated) with molecular diagnostics the fastest growing at 15.4%
  - 90% of the market is in USA, Europe and Japan
  - 80% of the market is serviced by 10 companies
- Changes
  - From reagent pricing to result charging
  - Role of molecular diagnostics accelerating
  - Personalised medicine becoming realisable

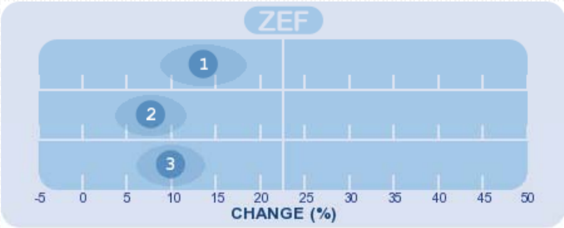
Finnish Business environment

- 100M€ - IVD market (11.8B€ total health care market)
- 30 companies employing 2000 experts with sales approaching 300M€
- Strong state funding (e.g. 5 to 6 M€ pa from Tekes)
- Strong innovation position on global indexes
- Above average technology competency and strong research and product development skills in all IVD component sectors

Changes in business metrics for IVD-sector in Finland (from 2008 to 2014)

- Industry expects growth in line with inflation
- Researchers are more optimistic anticipating higher sales and higher R&D spend
- Industry may well be organic and B2B focused, with partnerships and consolidation key

Industry

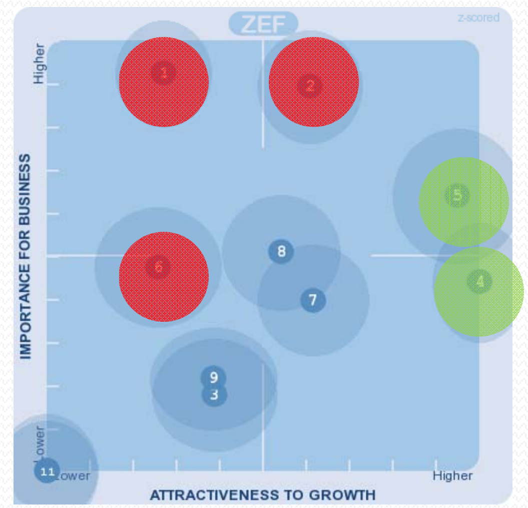


Research

1. Change in IVD-sales volume in the next 5 years
2. Change in the number of IVD-employees in the next 5 years
3. Change in R&D spending (IVD) in the next 5 years

Future sales growth opportunities

- Industry emphasis USA and particularly China with S America and Middle East of lowest interest
- Industry also see EU as important but low growth
- Researchers gave EU medium growth prospects



1. EU
2. North America
3. Central and South America
4. India
5. China
6. Japan
7. Asia
8. Russia
9. Brazil
10. South Africa
11. Middle East

Deloitte -Personalised Health - ROI

- "Personalized medicine is not a promise of the future; it is fast emerging as the current state in diagnostics and therapeutics," said Terry Hisey, vice chairman and U.S. industry leader for Deloitte LLP's Life Sciences industry group.
- Analysed the ROI for targeted breast caner treatment through
  - 2 scenarios -standard and companion therapy
  - stakeholders -- consumers, diagnostic companies, pharmaceutical and biotechnology companies and payers.
- Outcomes
  - Patient /customer always benefits, usually in 1st year
  - Payers get better tools, reimbursement issues
  - Diagnostic companies gain from multiple use exclusive tests, will need to use lean or virtual R&D strategies

www.deloitte.com

www.reuters.com/article/pressRelease/idUS144514+27-Jan-2009+PRN20090127

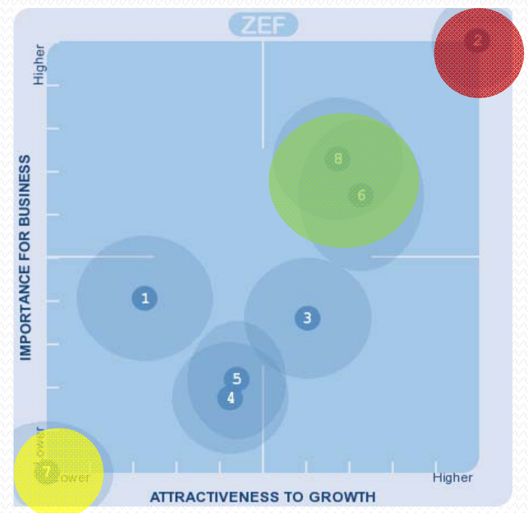
Growth in IVD (how much /where/what)

- 2 to 4 % growth (6 to 12M€)
- India and China (USA, Asia, Russia)
- Doctors office
- Diagnosis and health risk management
- Quantitative tests (Multiplexed and probe based microbiology)
  - Central lab – CVD and diabetes (Oncology & Metabolic syndrome)
  - Dr Office - CVD and diabetes (Metabolic syndrome & respiratory diseases)
  - Individual driven - CVD and diabetes (Metabolic syndrome & respiratory diseases)

Future biomarker types

- Quantitative platform was a clear priority.
- Microbiology – probe & Multiplexing key areas

(June 8th IVD Integrated platform meeting)



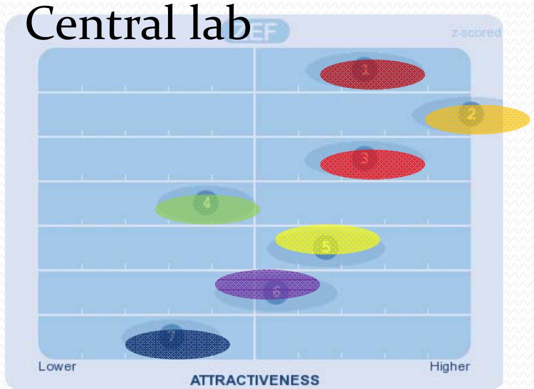
- Within the comments section disease profiling, virology and protein *invivo* modifications were suggested as possible areas

1. Qualitative – yes/no
2. Quantitative
3. Genetic risk
4. Proteomic based
5. Metabolomic based
6. Multiplexed
7. Microbiology – culture
8. Microbiology - probe

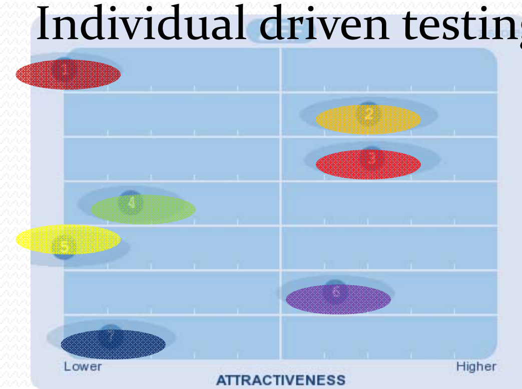
Future test segments

- CVD/Diabetes, Metaboloic and Asthma/respiratory seem to be prioritised for Individuals and Doctors offices
- In central labs oncology is highlighted

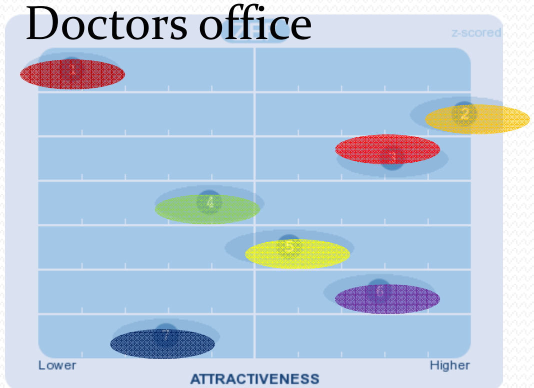
Central lab



Individual driven testing



Doctors office



1. Oncology
2. Cardiovascular and Diabetes risk
3. Metabolic syndrome risk
4. HIV and Hepatitis
5. Antibiotic resistance & susceptibility
6. Asthma and respiratory disease management
7. Osteoporosis

Growth in IVD (How/Whom)

- From understanding our current customers
- Success enabler
  - Test linked to specific therapies as
  - Health cost benefit demonstrated
  - Intelligent diagnostic platforms integrated with health data bases

- From established Finnish IVD-companies
- From start-ups & B2B partnerships
- From academic and government organizations

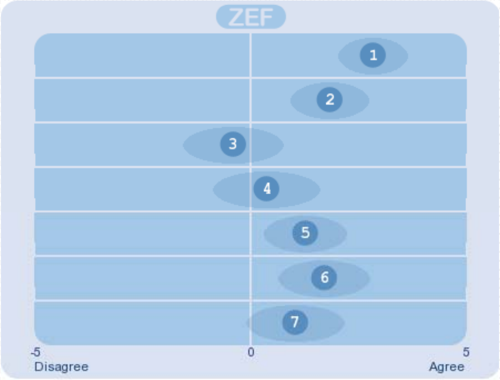
EU Innovation Scoreboard highlights

- Innovation Leaders - Sweden, Finland Denmark Germany and UK
  - Innovation Drivers 2nd
  - Knowledge creation 4th
  - Innovation & Entrepreneurship 7th
  - Applications 4th
  - Intellectual property 8th
- Biggest gap with USA is early stage finance , Finland one of the best EU countries for early stage finance.

www.proinno-europe.eu

Innovation: Understanding and realization

- Innovation is important
- Focus is unique products
- Processes appear to be in place
- Comment section indicated need to develop these processes



1. Innovation is essential to future growth
2. Innovation must deliver a unique product
3. Innovation always create new sales
4. Innovation is anything new which generates new profit
5. Our innovation process is understood by everybody in the company /unit
6. Our innovation actions are followed by the board or equivalent management group
7. Our innovation process has financial related metrics

Innovation enablers

- **Innovation is continuous and part of the business cycle**
- **Finance**
  - Stronger focus on the transfer from technology platform to product platform for both spin out, and start up companies.
  - Use of financial models is suggested

- **Network and communication**
  - Regular forum for industry and researchers to meet and exchange ideas and understanding Open innovation forum for IVD
  - A call to identify excellence and make it best practice, also to combine the best to make international break through work through cooperation.
  - Stronger, focussed collaborative projects needed in Finland, either under SHOK or other umbrella

- **Education**
  - Product design and test validation
  - R&D process improvements
  - How to enter new markets and regulatory/quality

Innovation- Finance & competitions

- Using public funding to explore new business ideas
  - MASI - Modeling and simulation (New financial models)
  - Liito - Innovative Business Competence and Management (new business models)
- Utilising the companies finance organisation/advisors to realise innovation
- Linking up with NGO – eg WHO, Bill and Melinda Gates Foundation

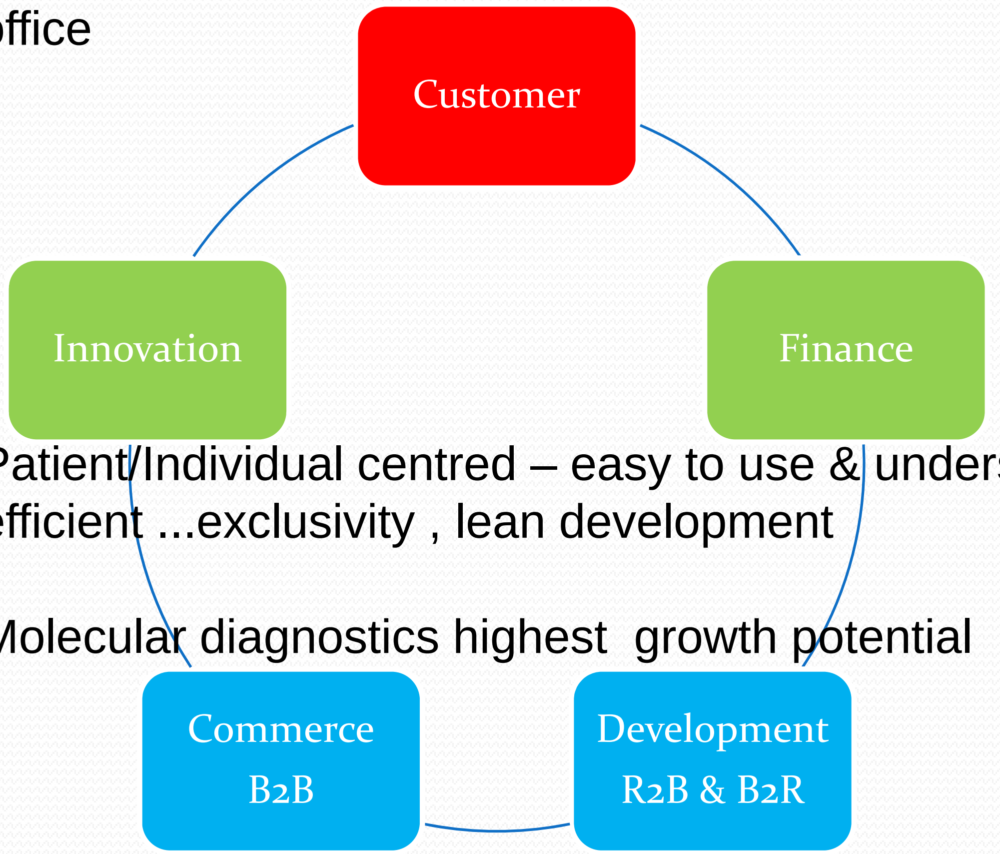
- Use of Open Innovation strategies and competitions
  - E.g. P&G - Female reproductive health and wellness, Kids' health and wellness , and Aging population health and wellness
    www.pgconnectdevelop.com
  - X Prize - TB diagnosis for the developing world – in development www.xprize.org

Growth Opportunities or Barriers

EU/USA doctors office
India/China

Business models
Completions
Open Innovation

Probe ,multi test & integrated IT formats



Patient/Individual centred – easy to use & understand, efficient ...exclusivity , lean development

Molecular diagnostics highest growth potential

Partnerships

Partnerships

CVD ,diabetes metabolic syndrome & respiratory diseases)