



MNBS 2014 – LAAS, Toulouse, 21&22 October

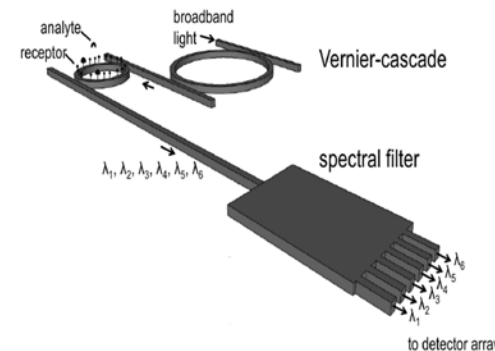
Prof. Dr. Mahavir Singh

LIONEX, Germany



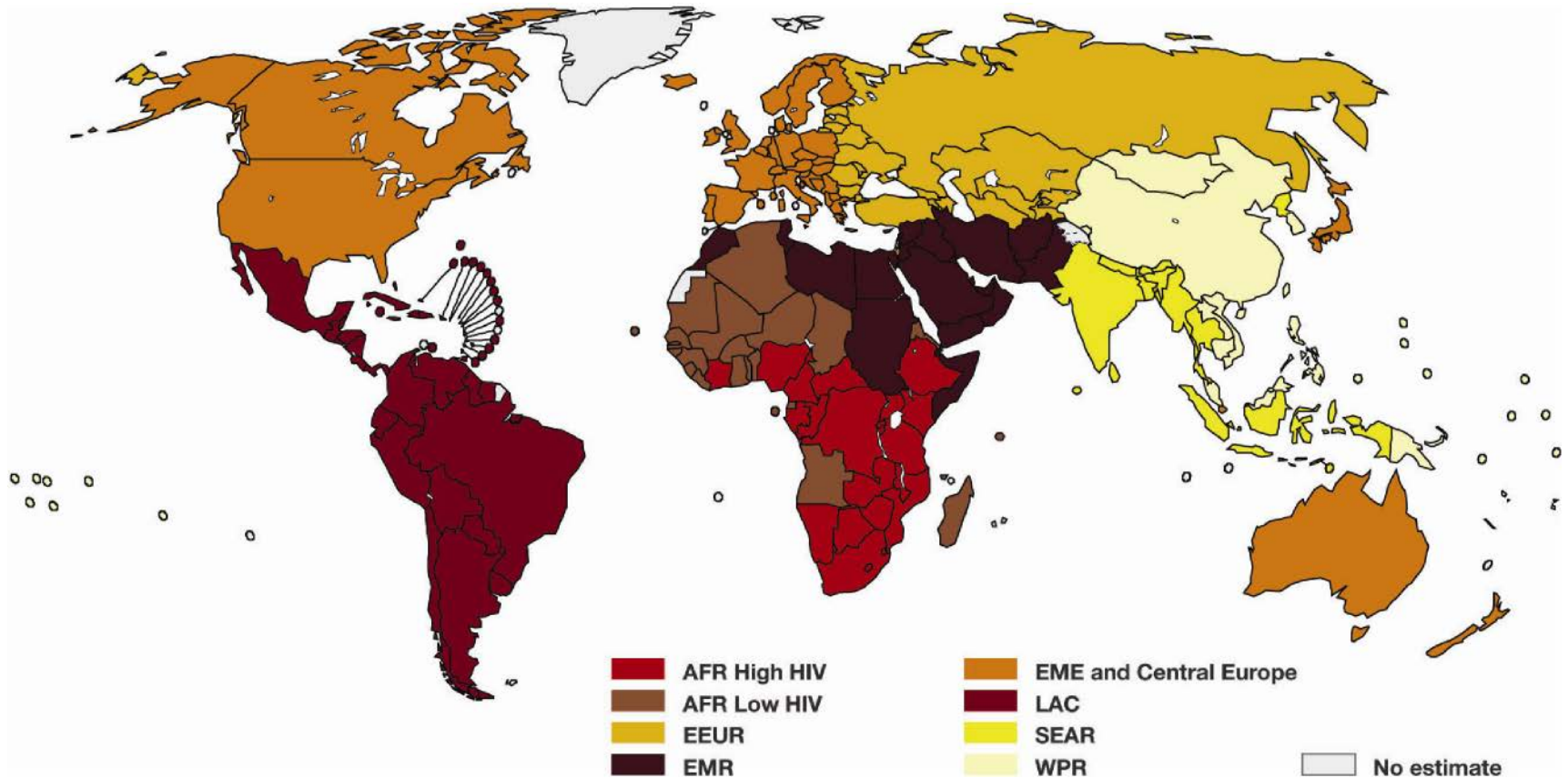
MNBS 2014 Projects-Innovation Session and user involvement

- **POCKET-GOAL : Development of a low-cost Point-Of-Care test for Tuberculosis detection**
- **CONSORTIUM**
 - **Coordinator:** Ghent University (BE): photonics transducer design
 - CIN2-CSIC Barcelona (SP): surface chemistry
 - Imec (BE): chip fabrication
 - LIONEX (DE): antibody and antigen development
 - microfluidic ChipShop (DE): microfluidic chip development
 - Trinean (BE): instrument design



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Users



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Users' Needs and Unique Value

- Users' needs: what are they? **Non-Invasive method of TB diagnosis**
- How do you know them? **Our own experience and long-term involvement in the area, WHO, FIND**
 - How do you validate them? **Constant contact and meetings with end users**
 - How do you contact and involve the users? **Telephone, Email, meetings and discussions**
 - How do you explain the potential advantage of your product to the users : specifications? Mock-ups?, Comics, videos?.... **Acurate description of the technology and product**
 - What position your users have in value chain (final, OEM, integrator)? **FINAL**
 - Why the technology under development has a unique value for the market users? **Rapid, Reliable and low-cost**
 - How do you know it? **30 years of experience in this area**
 - How the users' needs are addressed in the innovation process? **Considering each and every step of product development**

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Users' Needs and Unique Value

User survey for Pocket final product was done at start of the project

PART 1: INFORMATION ON YOUR INSTITUTE

PART 2: QUESTIONS ON THE CURRENT TB TEST METHOD

PART 3: REQUIREMENTS FOR A NEW TB TEST

25. Which of the following properties are important for you in a point-of-care setting?
(1: Not at all, 4: Very much)

	Do not know	1	2	3	4
Cost					<input type="radio"/>
Weight and portability					<input type="radio"/>
Ability to work on battery					<input type="radio"/>
Ease of use					<input type="radio"/>
Sensitivity					<input type="radio"/>

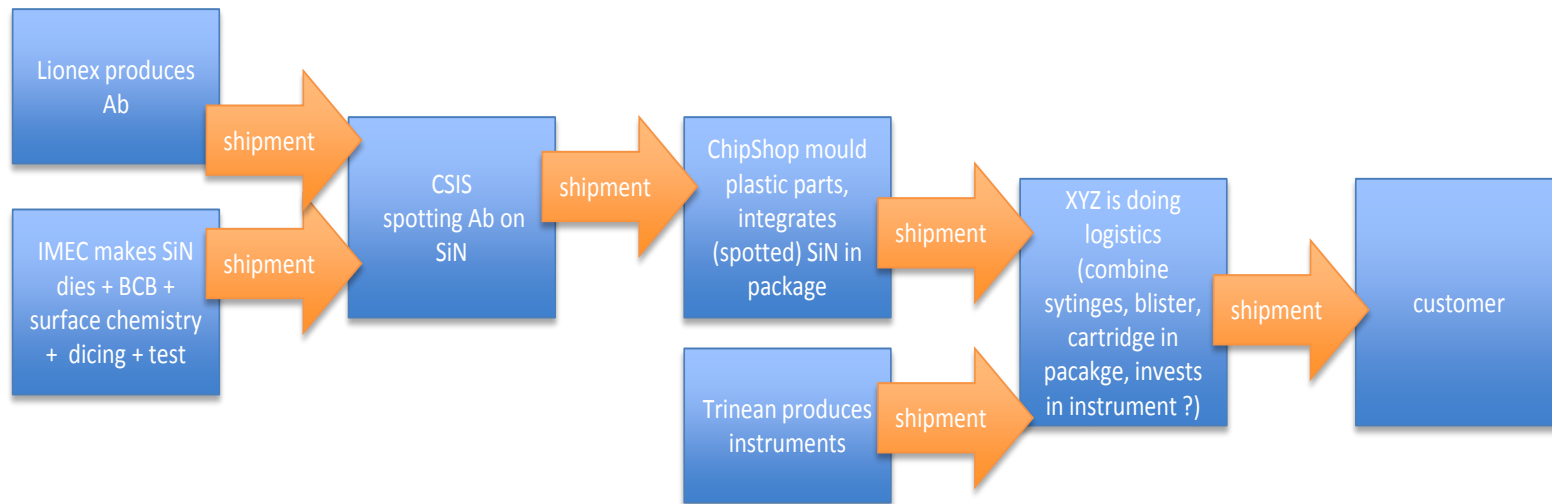
Parts of the users needs survey

The analyzed results were incorporated in the instrument specifications and marketing plan

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Innovation process and Road to exploitation

Direct Exploitation and Licensing based on users



Instrument production: partner Trinean has strong interest in producing the instrument and selling it to a 3rd party or directly to the end-user. This covers the instrument and the calibration and service tools required for validation and repair or recalibrate the instrument (if required). The production of the instrument is subject to regulatory obligations and must be done under ISO13485. Trinean is in the process of achieving this certification. It should be noted that in this project only the concepts are tested. The final product design has to start once the technology is proven, and that development will be done under the ISO13485 regulation.

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EXPLOITATION OF TECHNOLOGY IN OTHER APPLICATION DOMAINS

The technology developed in this project can be exploited in other domains:

1- BIOMARKER DETECTION FOR NON-TB APPLICATIONS

The Pocket platform is a unique system for highly-sensitive Ab detection in many types of fluids (urine, blood, blood serum, interstitial fluid etc). The system offers a simple workflow at customer site, and can be used for many other sensing applications.

2- OTHER APPLICATIONS FOR THE TECHNOLOGIES

Trinean will re-use the know-how in the upgrades of their current products for UV/vis spectroscopy. Imec will offer their SiN technology to third-parties similar to current services using Si.

Distance to the market

- How far you from the market is the project now and at the end.? **1-3 years**
- What it needs to be done after the project is finished to arrive to the market? **Manufacturing, validation, CE marking**
- How do you identify the non-technical steps needed to go to the market and its influence in the technical development? How do you manage it? **Marketing and distribution**
- How much money and time it will be needed. How do you know it? **3-4 years, experience**

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Commercialisation of any product requires freedom to operate: this means that the technologies used are not protected by patents (in the region of production or selling), and if this is the case, there is an agreement with the IP owner (such as licensing).

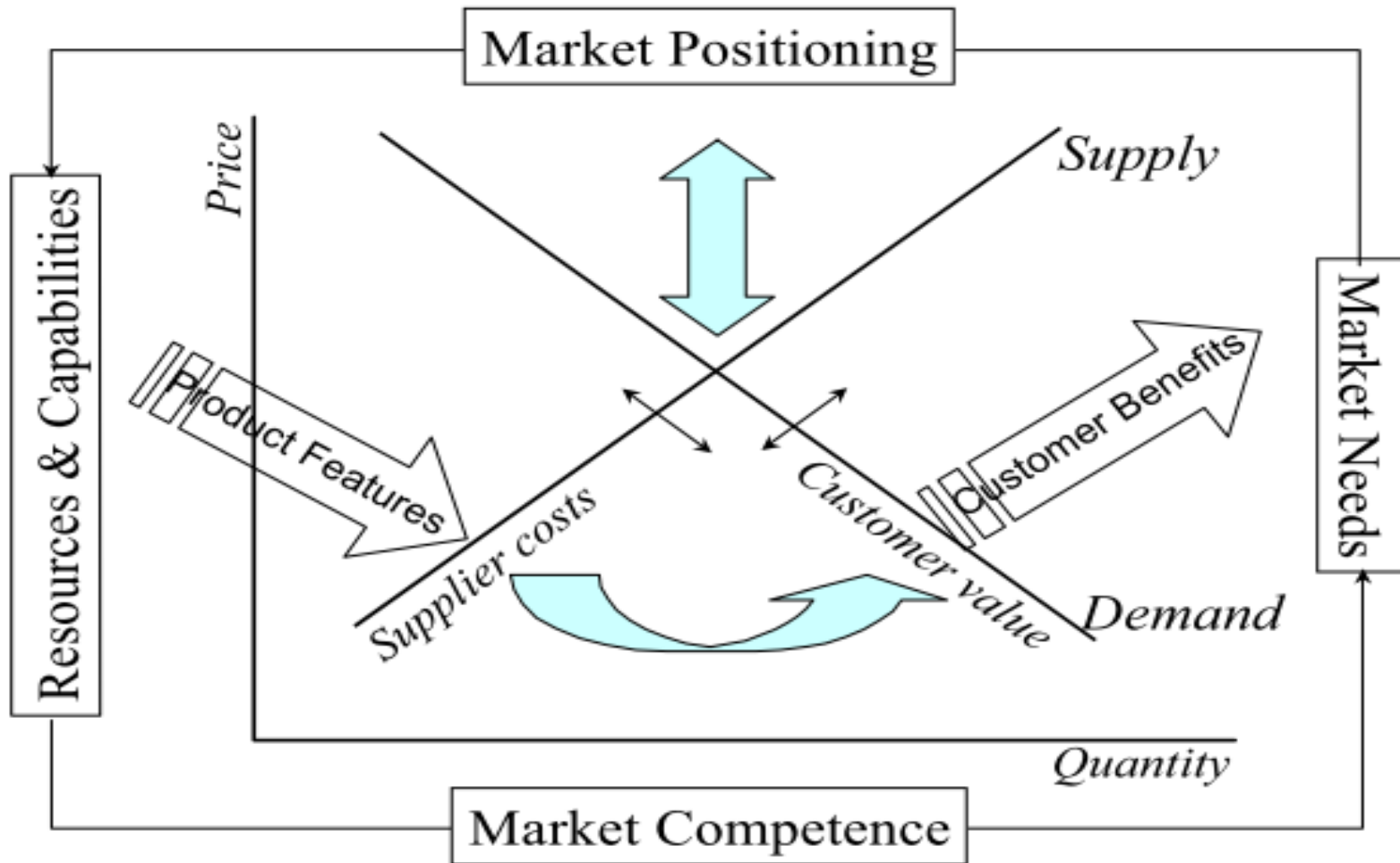
IP-ISSUES/ FREEDOM TO OPERATE

The partners own the rights on background IP which will not block the use of their results in the exploitation of the overall project results.

NO OBVIOUS OBSTACLE FROM THIRD PARTIES KNOWN

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Model of Pocket's market



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Access to the market

- Does any of the partners in the consortium has direct access to the intended market? **YES, LIONEX**
- **LIONEX (DE):** LIONEX Diagnostics & therapeutics GmbH, an ISO 13458 certified company), is exceptionally committed to the problems of tropical diseases such as TB, HIV, Malaria and Dengue. It is a partner of BioRegion, a highly active biotech region in Germany. LIONEX has excellent facilities and expertise in recombinant DNA technology, production of high quality recombinant proteins and monoclonal antibodies (mAbs) for research and diagnostics. In the last 15 years, more than 150 recombinant proteins of *M. tuberculosis* have been produced by LIONEX and are available in significant quantities. Corresponding mAbs are also available for a series of mycobacterial antigens. This fact shall be of considerable advantage for developing new diagnostic products (antigen and antibody detection) for TB. LIONEX is currently involved in a series of large international research projects developing and evaluating different platforms for rapid TB-diagnosis. LIONEX strength lies in the knowledge, decades of experience and in the proprietary pool of specific antigens and antibodies which can be used for various diagnostic platforms.

