NEXT-GENERATION INTEGRATED PLATFORM FOR INSTANT PROTEIN DIAGNOSTICS

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- Consortium and Aim
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NEXTDX

- **Philips (NL)**. Coordinator. Cardiac care & biosensing
- **Imec (BE)**. Optical integration technologies
- **PolyAn (DE)**. Molecular surface engineering
- **TU/e (NL)**. Protein engineering & Molecular biophysics
- **HyTest (FI)**. Biotech reagents
- **UBremen (DE)**. Optical particle characterization

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**NEXTDX**

- **Highly sensitive blood tests**
  - For protein diagnostics
  - Directly in blood plasma

- **Instant diagnostics**
  - Near the patient
  - To support on-the-spot decisions

- **Fully integrated system**
  - Cost-effective miniaturized plastic cartridge
  - Technology for a compact analyzer
INTEGRATED TECHNOLOGY FOR ON-THE-SPOT DECISIONS
UNIQUE VALUES FOR THE MEDICAL DOCTOR AND THE PATIENT

- Analytical performance
  - As in the central laboratory

- Time to result
  - Minute timescale, matching the doctor-patient or nurse-patient interaction or use in the home environment

- Ease of use
  - Small sample volume, for finger prick
  - System suited for less-specialized personnel or even patients themselves
COLLECTING USER NEEDS

- **NextDx Project**
  - Advisory Board, set up at project start
  - Start project with requirements document and incorporate input from Advisory Board
  - Yearly updates with Advisory Board

- **Existing business within Philips**
  - User need specialists
  - Dedicated Advisory Boards

- **Existing research activities within Philips**
  - E.g. national collaborations including clinical partners
NEXTDX ADVISORY BOARD

Stakeholders from various disciplines:

- Patient organization
- Clinician
- Clinical chemist
- Health insurance specialist
- Government regulatory expert
NEXTDX EXPLOITATION

- Philips (IND)
- IMEC (RES INST)
- Hytest (SME)
- PolyAn (SME)
NEXTDX EXPLOITATION

- Philips (IND)
  - Has established a Handheld Diagnostics business group (www.philips.com/magnotech), which is the main outlet for the project results, fitting with the users targeted by the NextDx project.

- IMEC (RES INST)
  - Is interested in direct technology transfer to the industrial partners in the project, by patent application (possibly shared with the industrial partners) and licensing, and in creating spin-off activities.
NEXTDX EXPLOITATION

- Hytest (SME)
  - Aims to develop knowledge on antibody requirements for point-of-care biosensing and magnetic particle assays, in order to expand the product portfolio

- PolyAn (SME)
  - High performance surfaces for coupling of antibodies that achieve a higher signal-to-noise ratio are in the core of the business interest
STEPS TO MARKET – DX SYSTEM

- Proof of separate principles
- Proof of principle for integrated prototype
  - Targeted status at the end of NextDx
- Business plan and commitment
- Development of integrated system and manufacturing
- System verification
- System validation
  - Performance evaluation in targeted use environment for registration with authorities
STEPS TO MARKET – DX SYSTEM

- Expertise required on
  - End-user needs and usability
  - Diagnostic system development
  - Diagnostic system manufacturing
  - Clinical testing
  - Regulatory aspects
  - Business and marketing knowledge

- Philips dedicated business group has required expertise in-house
SUMMARY

- Multidisciplinary project focused on technology integration and demonstration on real samples (blood plasma). Balanced academic-industrial efforts.
- Appropriate Advisory Board and early-on definition of Requirements safeguard future compatibility of prototype with User Needs.
- Coordinator is a large healthcare industrial party. Strong experience and infrastructure in the development and manufacturing of diagnostic platforms, including end-user insights, clinical contacts and regulatory and business knowledge.
- SME’s and research institute provide additional exploitation routes aimed at specific users.
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