

TheraEDGE

An integrated platform enabling Theranostic applications at the Point of Primary Care *Pushing Point of Care Theranostics to the EDGE*

TheraEDGE is an industry-driven project to accelerate the adoption of theranostics applications in Primary Care, built around the high-incidence clinical case of early-diagnosing of lower respiratory tract infections. TheraEDGE will simultaneously test for different pathogens and their antibiotic resistance resulting in enhanced clinical outcomes, improved patient healthcare and reduced costs.

Objectives of the Project

Community-acquired Lower Respiratory Tract Infections (CA-LRTI) are a common cause of acute illness in the elderly. The spectrum of disease ranges from a mild mucosal infection, to acute bronchitis or acute exacerbation of chronic bronchitis or chronic obstructive pulmonary disease (COPD), infective exacerbation of asthma, to overwhelming parenchyma infection in patients with community-acquired pneumonia (CAP). CA-LRTI are the leading reason for seeking medical care. Yet, diagnosing CA-LRTI in primary care is very challenging being based primarily on medical history and physical examination as few patients undergo laboratory investigations. These diagnostic uncertainties have resulted in prescriptive misuse, which largely explains the escalating antibiotic resistance of common bacterial respiratory pathogens in the community.

TheraEDGE objectives are:

- **Achieve faster clinical turnaround**

by enabling clinical decision-making in less than 30 minutes from sample extraction to result delivery.

- **Improve analytical performance**

by employing single molecule detection techniques with higher specificity and sensitivity than alternative analytical techniques typically used at the Point of Care.

- **Improve usability and robustness**

by promoting the development of standard analytical and operational platforms.

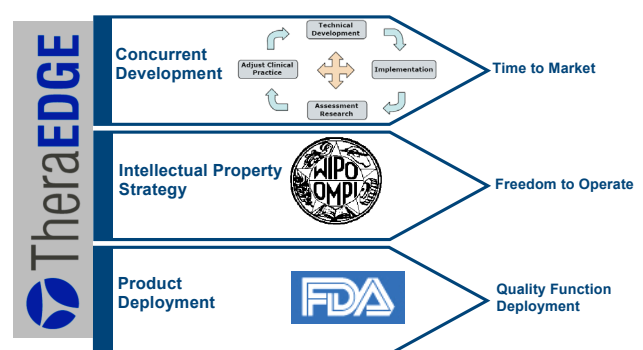
- **Provide economic systems**

by promoting therapeutic education and compliance to provide more efficient healthcare economics.

Project Description

TheraEDGE is built around the high-incidence clinical case of early-diagnosing lower respiratory tract infections in Primary Care. Simultaneous testing for different pathogens and their antibiotic resistance will have a huge European impact:

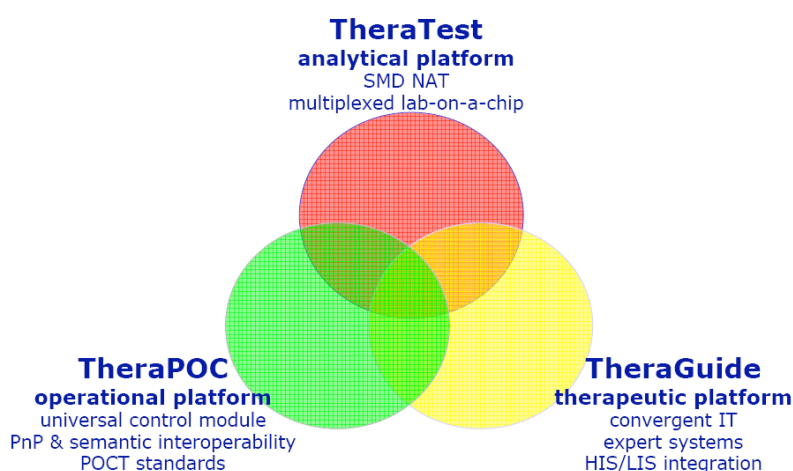
- better clinical outcomes and standards of care, more effective and timely diagnosis and treatment
- improved health economics, optimization of antibiotics prescription, infection control practices and reduction of clinical visits or hospital stays
- substantial business for the In Vitro Diagnostics industry through the standardisation and commercialization of innovative POCT products and systems.



TheraEDGE consists of three multidisciplinary platforms:

- **TheraTest**, a Lab-on-a-Chip supporting multi-marker assays using Single Molecule Detection (SMD). SMD removes the need for amplification and has the potential to become a key enabler for Nucleic Acid Testing at the Point of Care by providing less complex, faster, more sensitive and more specific assays

- **TheraPoc**, an architecture that provides Plug and Play semantic interoperability and creates opportunities for the standardisation of POCT instruments and information systems, offering radical usability, robustness and vendor interoperability improvements. Practitioners will be able to run out-of-the-box multiple compliant devices from one single PDA-based operator interface
- **TheraGuide**, a set of applications built on a convergent ICT platform that supports General Practitioners in their patient management and clinical decision-making, and provides therapeutic services for patient education and compliance monitoring in order to fight antibiotic misuse and abuse.



Expected Results & Impacts

TheraEDGE could in the next decade, **revolutionise molecular diagnostic point of care testing** by **providing clinicians with crucial information to allow targeted antibiotic treatment**. The technology being developed would have direct impact on the following areas.

- TheraEDGE will allow performing multiplexed assays in single reactions in less than 30 minutes to directly compete with today's nested PCR systems.
- TheraEDGE will be a multi-analyte platform to perform both genomic DNA and RNA detection.
- TheraEDGE will be a truly quantitative diagnostics platform that will allow distinguishing between colonization and infections.
- The fact that TheraEDGE is not based on amplification techniques greatly reduces the risks of cross-contamination issues of other genomic DNA detection methods.
- TheraEDGE will be developed to achieve usability characteristics and features capable to be used in primary care centers.

Furthermore, **TheraEDGE** will help drive leadership for the European IVD sector because it addresses the key market needs and drivers facing the sector such as molecular diagnostics technology, improved usability systems, enhanced connectivity standards, or new markers discovery.



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- Technical University of Dresden (Germany)
- Medical Device Consultancy (United Kingdom)
- Tekever (Portugal)
- Ridgeback (Italy)
- Clinic Hospital of Barcelona (Spain)
- University of Linköping (Sweden)
- Clinical Research Associates & Consultants (Slovakia)
- Systelab Technologies (Spain)
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Timetable: from March 2008 to February 2012

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Instrument: IP

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KEYWORDS

Lower Respiratory Tract Infections, Clinical applications, Personalized Health, Compliance, Single Molecule Detection