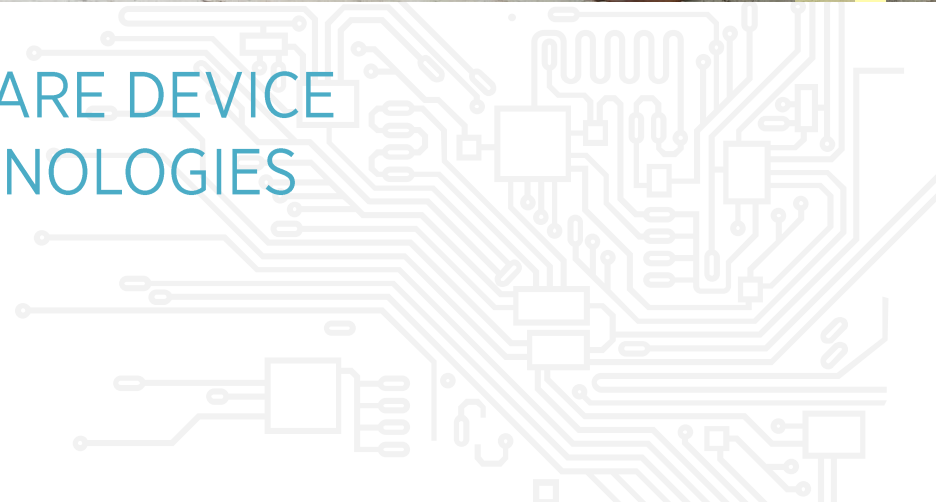




DEVELOPMENT OF A POINT-OF-CARE DEVICE WITH 2 NOVEL DIAGNOSTIC TECHNOLOGIES

CASE STUDY



INTEGRATION OF 2 NOVEL TECHNOLOGIES TO DEVELOP A POC IN-VITRO DIAGNOSTIC PLATFORM

Customer Challenges

Our client developed two novel clinically validated technologies for malaria and sickle cell disease diagnosis.

The customer was seeking a product engineering partner with proven R&D success in global markets, an established in-house infrastructure, supplier ecosystem, and extensive experience in market research, design, implementation, and manufacturing support to realize commercialization goals.

Scope

- Extensive market research to understand emerging markets
- Product requirements and specification identification
- Product design and engineering
- Packaging, branding, and visual content development
- Product software development
- Qt-based implementation for design, development, and validation
- Compliance testing and documentation as per the new EU-IVDR 2017/746 requirements



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Approach

Tata Elxsi carried out pan-India market research that included market sizing and user research to understand the product’s viability in the developing markets.

Tata Elxsi established a global engineering network with R&D and engineering centers in India and the US and a network of suppliers and vendors. Tata Elxsi team developed a proof-of-concept for battery-operated, easy-to-use, connected, and integrated malaria and sickle cell disease diagnostic platform and enhanced the technologies for real-world scenarios.

Tata Elxsi also undertook product commercialization complying with the regional regulatory requirements and set up a manufacturing vendor ecosystem in India.

Impact

- The customer launched the product in June 2020, and it is currently being sold in 12 countries
- The product offers 20X improvement in test time and sensitivity for malaria and sickle cell detection compared to conventional technologies
- The battery operated and portable device is designed to be used in rural settings, extending healthcare access in the remote areas
- The connected platform collects patient records, test results, and the GPS location of the tests providing insights for the interventions needed in the disease clusters



Patti White

Chief Executive Officer
Hemex Health



In our strategic mission to develop and launch a Lab-in-a-Box product, we are delighted to have the right partner in Tata Elxsi who understands the challenges of markets and possesses comprehensive capabilities from concept development to engineering and launch of medical products that meet regulatory standards.

