

# Scientific Letters



Invited Lecture 1

## Conquering the hard road of entrepreneurship

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#### **Abstract**

**Background:** As a medical doctor and researcher, daily clinical challenges have always been a source of inspiration. One old problem was the delay in antimicrobial susceptibility testing (AST) results from clinical laboratories. In severe infections, biological samples are collected and sent for analysis, but traditional methods require 2-3 days to identify the pathogen and determine effective treatment options. In the meantime, empirical and often blind therapy must be initiated, although the risk of treatment failure increases significantly — by 4% in mortality per hour of delay. Due to rising antimicrobial resistance (AMR), initial therapies can fail in up to 40% of cases, with serious consequences for patient outcomes and public health. Objective: To develop a disruptive solution that delivers AST results within 2 hours using flow cytometry — a technology widely used in other laboratory fields but not yet applied to clinical microbiology. Methods: To bring this innovation to market, we secured multiple patents, founded a spin-off company from the University of Porto -FASTinov, applied for grants, attracted investors, and carried out extensive internal and external validations. Several FASTinov kits were developed for Gram-negative and Gram-positive bacteria, designed for use with pure colonies, positive blood cultures, and more recently, directly from urine samples. These kits incorporate antibiotic panels, fluorescent probes, and a multiparametric algorithm powered by artificial intelligence to classify bacterial strains as susceptible, resistant, or intermediate within two hours. Results: FASTinov kits are now CE-IVD certified and have begun penetrating the clinical diagnostics market. However, challenges remain, particularly in regulatory compliance and the need for automation - requiring full-time dedication to ensure continued progress and implementation. Conclusions: This journey transformed a clinician and researcher into an entrepreneur — not by choice, but by necessity. Without this personal commitment, advancing such a transformative solution would not have been possible.

Keywords: rapid antimicrobial susceptibility tests; sepsis; flow cytometry; FASTinov

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#### References

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