

## **FIND INITIATES FEASIBILITY STUDIES FOR RAPID, LOW-COST DIAGNOSTICS TO DISTINGUISH GONORRHOEA FROM CHLAMYDIA IN PRIMARY CARE CLINICS**

- **Axxin and QuantuMDx/Speedx will receive support for the development of molecular point-of-care gonorrhoea tests; DCN Diagnostics for the development of a rapid lateral flow assay for gonorrhoea**
- **Rapid, low-cost tests that can differentiate gonorrhoea from chlamydia in primary care settings are urgently needed to support stewardship of new and existing drugs, and curb the emergence of untreatable “super-gonorrhoea”**
- **Announcement follows the conclusion of a competitive request for proposal (RFP) process to accelerate development of technologies that could meet recently published target product profile (TPP) requirements**

Geneva, Switzerland – 7 November 2019 – The Foundation for Innovative New Diagnostics (FIND) announced today three awards to support the development rapid, low-cost diagnostic tests that can distinguish gonorrhoea from chlamydia infections in primary care settings. [Axxin](#) and a consortium comprising [QuantuMDx](#) and [Speedx](#) will each receive support for the development of molecular point-of-care tests for *Neisseria gonorrhoeae*. [DCN Diagnostics](#) Inc (DCN Dx) will receive support for the development of a rapid lateral flow assay for *N. gonorrhoeae*. In addition to funding, FIND is providing project support, including reference samples for rapid assay development and assessment, antibody reagents for capture and detection of *N. gonorrhoeae*, and technical expertise.

The three tests were selected following a competitive request for proposal (RFP) process, based on their likely ability to meet recently published target product profile (TPP) requirements. Assessment was conducted by an independent external review panel and the FIND Scientific Advisory Committee. The TPPs, recently developed by FIND and the World Health Organization (WHO), define urgently needed diagnostics that can address point-of-care diagnosis of gonorrhoea as well as susceptibility to existing antibiotics.<sup>1,2</sup> Diagnostics meeting these TPPs are part of a stewardship plan by WHO and GARDP for current as well as new drugs, such as zoliflodacin. Stewardship is needed to help guide correct treatment and protect the efficacy of treatments for as long as possible, in order to curb the emergence of untreatable “super-gonorrhoea” as part of the fight against antimicrobial resistance (AMR).

Globally, more than 1 million cases of curable sexually transmitted infections (STIs) – chlamydia, gonorrhoea, syphilis and trichomoniasis – occur every day. After chlamydia, gonorrhoea is the most common STI, with an estimated burden of 87 million cases worldwide.<sup>3</sup> Its complications disproportionately affect women, including pelvic inflammatory disease, ectopic pregnancy, and infertility, as well as increased transmission

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<sup>1</sup> FIND & World Health Organization. Target product profile for a test to identify susceptibility/resistance of gonorrhoea to antibiotics to facilitate antibiotic stewardship. [https://www.finddx.org/wp-content/uploads/2019/09/Comprehensive-NG-test-TPP\\_20190731\\_clean-who.pdf](https://www.finddx.org/wp-content/uploads/2019/09/Comprehensive-NG-test-TPP_20190731_clean-who.pdf) (accessed 29 October 2019)

<sup>2</sup> FIND & World Health Organization. Target product profile for a rapid, low-cost diagnostic to distinguish gonorrhoea from chlamydia infection at primary care. [https://www.finddx.org/wp-content/uploads/2019/09/NG\\_CT-Test-TPP\\_20190731\\_clean-who.pdf](https://www.finddx.org/wp-content/uploads/2019/09/NG_CT-Test-TPP_20190731_clean-who.pdf) (accessed 29 October 2019)

<sup>3</sup> World Health Organization. Report on global sexually transmitted infection surveillance, 2018. <https://apps.who.int/iris/bitstream/handle/10665/277258/9789241565691-eng.pdf?ua=1> (accessed 29 October 2019)

and acquisition of HIV. Moreover, gonorrhoea has progressively developed remarkable resistance to the majority of available antibiotics: the emergence of “super-gonorrhoea” raises grave concerns about the longevity of remaining and future therapies.

“Fast diagnosis and treatment is crucial to prevent transmission and consequences of gonorrhoea, but difficulties in differentiating gonorrhoea and chlamydia – especially in low-resource settings that lack appropriate tests – mean that the wrong treatment is easily prescribed. This is terrible for the patient and contributes to the spread of AMR,” said Catharina Boehme, CEO of FIND. “We must urgently close this gap and provide setting-appropriate, affordable diagnostics to the communities most in need.”

The feasibility studies are expected to be complete in 2020 and results will inform further test development in line with TPP characteristics.

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#### **About FIND**

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs). Since 2003, we have been instrumental in the delivery of 24 new diagnostic tools. Over 50 million FIND-supported products have been provided to 150 LMICs since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control and prevention. For more information, please visit [www.finddx.org](http://www.finddx.org)

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