

## Frequently Asked Questions about the Clinical Trials in South Africa

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### **NHLS – National Health Laboratory Service**

#### **TBDx – Signature Mapping TBDx**

**Question:** *Why is a clinical evaluation in South Africa required?*

**Answer:** The NHLS must follow good clinical laboratory practices; to justify a purchase decision the key scientific decision-makers must understand the overall performance of TBDx. This requires the NHLS to empirically validate TBDx's safety and efficacy compared to current sputum analysis standards. This is an important step in the validation procedure and will enable the NHLS to take advantage of all the technological improvements provided by TBDx.

**Question:** *Why did the clinical protocols change?*

**Answer:** After demonstrating the integrated slide automation with the performance results of computer-aided-detection, the TB experts realized the major impact TBDx could provide on the entirety of the South African screening program. Rather than methodically conducting analysis and testing serially, the South African TB experts decided that the clinical program should be expanded and accelerated to provide an enhanced understanding of the value of the technology and the impact on the South African program. The implications of the performance of TBDx under these expanded protocols have equally significant importance to the remainder of the highly burdened countries of the world.

**Question:** *When do you expect the expanded trial to resume?*

**Answer:** We would like to resume the trial "yesterday." Unfortunately, the expanded nature of the overall clinical program requires specific protocols to demonstrate proper scientific process. In addition, we are working under the constraints of NHLS personnel scheduling and the determination of an independent trial coordinator. All parties are working diligently to complete the protocols and recommence the trial. We indicated in the press release they would commence prior to July 17<sup>th</sup>.

**Question:** *When do you expect the expanded trial to be completed?*

**Answer:** Due to the newly announced HIV/TB screening program there is a heightened sense of urgency to complete the TBDx clinicals as soon as possible.

**Question:** *Who will be the likely independent observer validating the trial?*

**Answer:** At this time the individual/organization has not been identified to Guardian. NHLS and Aurum are discussing candidates with international credentials and no vested interest in the outcome of the trial. That individual should be known to us within the next week.

**Question:** *What impact will the expanded clinical trial have on business and revenues?*

The expanded trial won't directly affect revenues other than timing, but will directly affect business. The initial step in the introduction of any new medical technology is a demonstration of clinically acceptable results. Benchmarking improved performance by TBDx will position GDTI to make important product claims during the selling process. Publication of the detailed results in accepted medical journals will provide the important critical validation to support the overall adoption process worldwide. The independent validation further supports our development program to migrate our technology to the Ziehl-Neelsen staining process. Lastly, clinical feedback provides important information for future improvements and clinical adaptations.

**Question:** *Please explain the SA HIV/TB screening program and the perceived impact on the TBDx program in SA?*

**Answer:** The Health Counseling and Testing campaign launched in April 2010 is a widespread strategy and proactive approach by the government of South Africa to test 15 million people for HIV by June 2011. People who are infected with HIV are especially susceptible to developing active TB. TB is the leading cause of death among people living with HIV/AIDS and one of the most common opportunistic infections they experience. The prevalence of HIV infection among patients in TB clinical settings is high, up to 80 percent.

The opportunity for TBDx is increased revenue due to the increased volume of slides to be processed. Further, the increased volume puts added pressure on a laboratory system struggling with its current normal workload. This added pressure makes the deployment of TBDx that much more critical and adds to the momentum to complete the clinical trial as quickly as possible.

**Question:** *What is the South African government's procurement process?*

**Answer:** Like any other governmental bureaucracy there are processes that include the development of bid specifications, requests for proposals, bid reviews, and bid notifications followed by drafting and negotiating of contracts.

**Question:** *Is there a way to expedite the procurement process?*

**Answer:** Through discussions with the NHLS we have been able to negotiate an alternative contract vehicle that is centered on the concept of providing unique services rather than products. The services model works to expedite the procurement process by circumventing the formal procurement process - we are the sole source provider of the needed services. To accomplish this approach Aurum will need to provide the financing for the acquisition of all necessary hardware. While they have not completed negotiations on the terms of the financing, they have a verbal commitment from a large development bank to provide the necessary financing to purchase the hardware components, approximately \$15 million.

**Question:** *Do you intend to recognize a sale in South Africa this year?*

**Answer:** Absolutely. The only question to be answered is the final revenue recognition amount in 2010. The factors that will influence the final 2010 revenue number will be: (i) the rate at which the NHLS can absorb the new technology and develop workflow protocols, and (ii) the ability of the hardware equipment manufacturers to ramp-up production (specifically the 200-slide autoloader and stage navigator). Since the hardware being used in the autoloader solution is relatively new to the market, and not universally in use, production capability becomes the constraint.

**Question:** *Once the trial is completed, can the results be used to sell TBDx in other countries?*

**Answer:** There are two types of opportunities we expect to result from a successful clinical trial. First, any institution using auramine stained sputum slides will be an immediate sales prospect for TBDx, both in a production and research setting. Second, based on the South African clinical evaluation and the improved credibility and understanding of TBDx internationally, we expect new clinical partners to approach us and new avenues of grant funding to be available for expansion of TBDx capabilities, and for new application development.

**Question:** *After South Africa, who is the most likely customer for TBDx?*

**Answer:** Sub-Saharan Africa, which tends to follow the lead of South Africa, becomes the most likely next customers for TBDx. South Africa tends to be technology leader and early adopter of new medical technologies and products.

India should be the next major market for TBDx once the migration of the technology to the Ziehl-Nielsen (ZN) staining application is completed. ZN is the staining application used by most of the world.

**Question:** *Were there any other business developments that occurred during the trip to South Africa?*

**Answer:** We executed Reseller/Distributor Agreements for both healthcare and security products for the African continent.

Our Reseller/Distributor partners began financing negotiations with a regional development bank that when successful would provide the necessary financing to purchase all the hardware required for deployment of TBDx throughout all of South Africa, as well as, approximately \$1.1M in research and development funding to develop TBDx under alternate staining and lighting specifications.

We presented to the Airports Company South Africa (ACSA), a state owned company that oversees security and operations at nine airports throughout South Africa. We have reached preliminary agreement on a Pilot Program of Pinpoint at O.R. Tambo International Airport to commence after the conclusion of the World Cup Games.