

SEAM Tanzania

Quality Assurance: The Use of Personal Digital Assistants in Collecting Drug Inspection Data

R. Sangeda,¹ L. Mshana,² M. Ngemera,² R. Donna,³ H. Kraushaar,⁴ A. Speed,⁴ W. Mfuko,⁴ and P. Risha⁴

¹Faculty of Pharmacy, Muhimbili University College of Health Sciences ²Tanzania Food and Drugs Authority ³SATELLIFE ⁴Management Sciences for Health

Data Management Challenges

The collection and availability of correct and timely drug product inspectional and testing data are critical in drug regulation, allowing staff in the field monitoring the flow of pharmaceuticals to proceed more efficiently and enabling the larger governing body to identify and focus on trouble spots in the marketplace. To do their work, field inspectors must have ready access to the country's drug marketing authorization database and must be able to efficiently collect and submit inspectional data.

The data needed by inspectors for reference include a listing of approved products, manufacturers, and importers. Although the Tanzania Food and Drugs Authority (TFDA) now updates and revises this information frequently, distance, cost, and maintenance factors prevent the data from being readily available to inspectors in the field.



The data the inspectors need to collect include a wide range of product-specific and site-specific information elements. Prior to the implementation of the personal digital assistant (PDA) system, the information collected was handwritten by the inspectors on an inspection form. These paper inspection records are not only difficult to manage, but they must also be carefully and tediously entered into data files that can be used to summarize observations and prepare reports. Because of a shortage of staff, the pace of data compilation has been greatly limited and the data collected has not been made available in a timely fashion for use in making important public health decisions.

Implementing New Systems

To address the problems in the drug inspection data flow and preparation of reports, the TFDA, Management Sciences for Health (MSH), and SATELLIFE have adapted the existing inspection process to incorporate the use of PDAs by inspectors. The continuing increase in PDA capability has made their use a financially and technically reasonable option for addressing data collection and information sharing needs. Expected



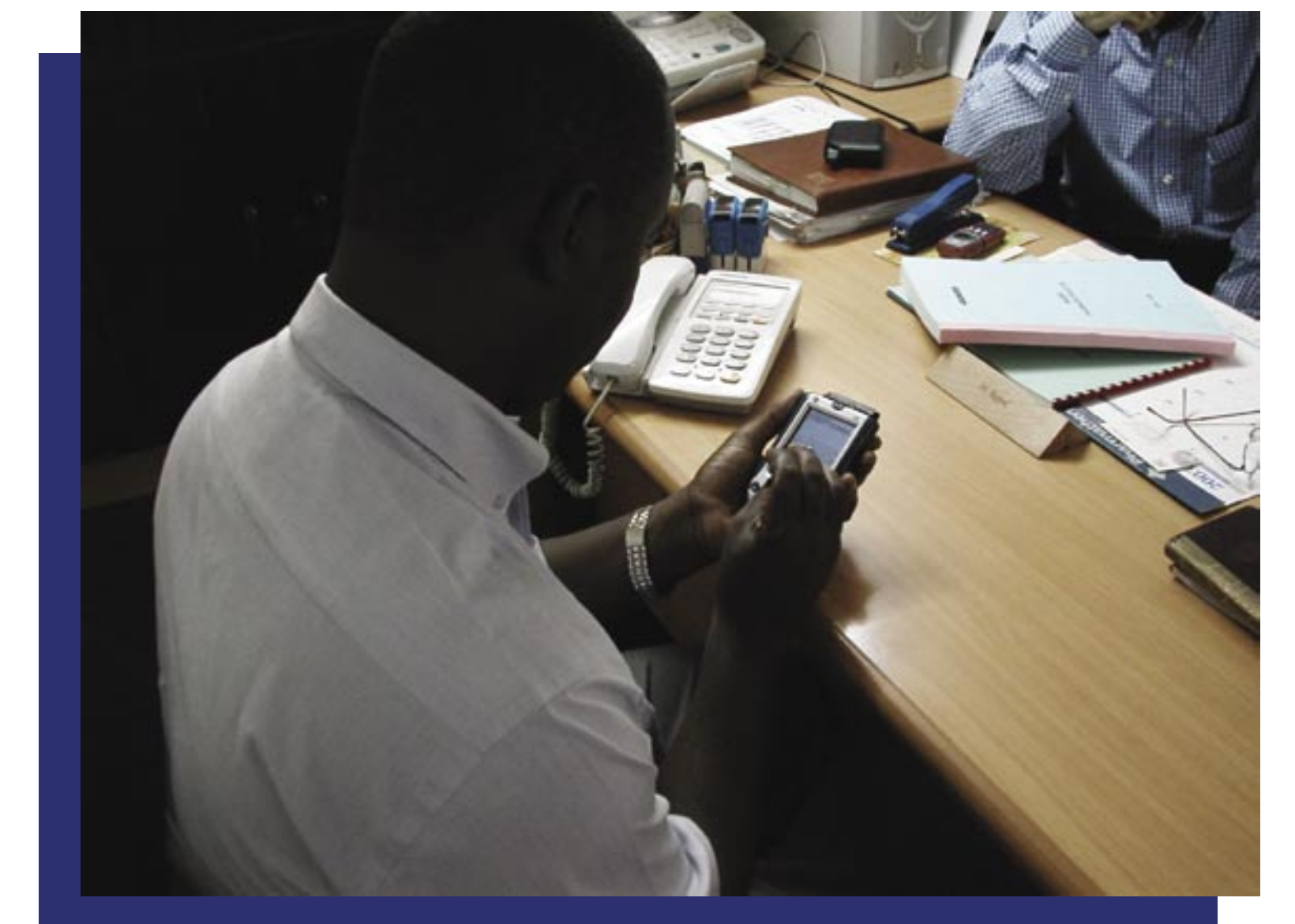
benefits of the fully implemented program include tighter regulatory control of the marketplace, reduced error in data collection and transfer, greater availability of lists of approved products and marketers, more timely access to needed information, and lower personnel costs.



As the first step in implementation, Pendragon Forms* software was selected for use with the Palm† m130 PDA to bring the paper-based inspection forms into an electronic medium. Next, the existing inspection forms were programmed onto Palm PDAs and beta-tested at MSH's office in Arlington, Virginia (USA). In September 2003, TFDA, MSH, and SATELLIFE conducted training in the use of PDAs and the converted inspection forms for a majority of the current drug inspectors. Once the training was completed, the inspectors field-tested the PDAs and the forms at various inspection points around Dar es Salaam, reporting errors and making adjustments to the forms and process based on their experiences.

Progress to Date

Because the data captured in the PDAs can be downloaded directly into a database, report writing will be streamlined and data retrievals will be much simpler to carry out. In addition, there will not be any transcription errors when transferring this inspectional data into TFDA databases.



Other expected benefits from the use of PDAs include the following—

- Reduction in the time necessary to conduct inspections
- Elimination of the need for inspectors to compose weekly reports
- Increase in time available for inspectors to devote to other job functions
- Elimination of the need for data entry into the central database
- Reduction in the need for data entry quality checks
- Updated reference tables of all approved products, manufacturers, and importers will exist on PDAs and be available for daily use by inspectors

* See www.pendragon-software.com

† See www.palm.com