

# Military Drug Trials Group Eliminates Errors and Inefficiencies using Electronic Data Capture and Tablet PCs

*Infectious Disease Clinical Research Program (IDCRP) Uses Sahara Slate PC i500 Tablet PCs from TabletKiosk running Mi-Forms by Mi-Co, to improve efficiency and reduce errors in studies aimed at improving healthcare of military personnel overseas.*



## Background

Infectious Disease Clinical Research Program (IDCRP) is a worldwide network of Department of Defense (DoD) clinical and research centers that have collaborated to investigate infectious disease challenges facing the military. With a presence at the largest DoD medical centers, the IDCRP conducts research at 18 military medical facilities and collaborates with 12 military research sites across the world. The program is headquartered within the Department of Preventive Medicine and Biometrics at the Uniformed Services University in Bethesda, Maryland.

IDCRP is conducting ongoing clinical trials at deployed military bases located in Afghanistan, Kenya and Djibouti of an experimental single-dose antibiotic treatment that may increase the efficacy of treating acute infectious diarrhea (more commonly known as Travelers' Diarrhea or TD) that affects military readiness. The aim of the clinical study is to measure the effectiveness of this experimental treatment and evaluate the long term health of the infected military personnel returning from overseas.

The study consists of five scheduled clinical visits over a one-month period and personal interviews as well as multiple follow-up surveys conducted at per-determined intervals via e-mail.

## Challenge

Originally, the clinical data and surveys were to be recorded by hand onto multiple printed forms that were then transported back from the clinics and medical centers to a central office and scanned and e-mailed to IDCRP's Data Coordination Center in Bethesda, Maryland, and finally re-keyed by hand into a computer database. The process was cumbersome as the clinical researchers had to travel to medical centers and clinics with numerous stacks of questionnaires and other study forms, as close to 20,000 forms were required in order to record the responses from all stages of the study.

Besides the difficulty of transporting and storing (military bases have very limited storage for paper clinical records) all of the forms, there were additional challenges organizing them and then entering them into the

## EXECUTIVE SUMMARY

### IDCRP at-a-Glance

**Challenge:** IDCRP had a paper workflow that involved double-key data entry into EDC systems with resulting errors, scanning & mailing CRFs and almost 20,000 paper-forms for each study. This slowed trial completion & made the process time-consuming & inefficient.

**Solution:** Adoption of Mi-Forms Tablet-forms technology on a powerful Sahara Slate PC i500 Tablet PC to eliminate all paper-forms.

**Benefits:** A time savings of 50% was realized, with offline data-entry capabilities. Query resolution was immediate, rather than weeks or months and compliance by coordinators was increased. 80% of the coordinators report the solution as more efficient than paper.

"Our clinicians love this. We taught them to change the orientation of the tablet so they could fill the screen with the full height of the CRFs and now it's basically a perfect EDC system for research docs who are used to filling out paper forms on a clipboard. We don't have to spend hours training and re-training because of that simple intuitive feature."

— Josh Kumpf, IDCRCP

database. The process took a considerable amount of time to track and key the vast amount of paper case report forms and often resulted in keying errors and missing critical data fields which compromised data integrity.

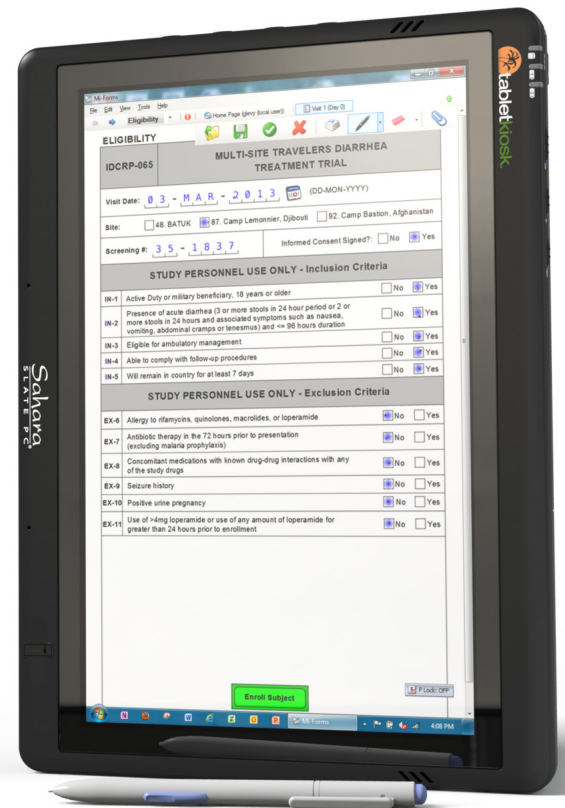
IDCRP previously used an electronic data capture (EDC) system that required an always-on Internet connection and was more suited for desktop PCs for studies based at military bases in the United States. This system was ill-suited for the challenges of a study involving deployed military bases with tenuous Internet connectivity, study researchers visiting multiple clinics to enroll subjects and capture patient data, and a distinct need for an intuitive, easy-to-learn user interface. Therefore, it was necessary that the IDCRP identify an EDC solution which could collect and retain data while offline and then transmit the results at a later time when Internet connectivity was available.

## Solution

Because the study involved so many different forms and questionnaires, it was crucial that whatever electronic solution was implemented would be able to closely replicate the myriad paper documents in a way that would not hinder clinicians' efficiency. It was therefore decided that the combination of Mi-Co's Mi-Forms software running on TabletKiosk's Sahara Slate PC i500 Tablet PCs was the most robust and efficient solution available.

Mi-Forms is an electronic forms (e-forms) software solution that runs on various mobile devices and allows for the creation, implementation, collection and processing of data driven forms that mimic the look of any paper form. The **Sahara Slate PC® i500** is a 12.1" slate Tablet PC—with a powerful Intel® Core™ i7 processor—that runs various desktop Windows® operating systems and features both a capacitive touch screen and an active digitizer (pen) panel for highly accurate handwriting input and recognition. In addition to its wireless networking capabilities, the Sahara Slate PC i500 also features a wired Gigabit Ethernet port for secure, high speed transfer of the data collected by the Mi-Forms application.

IDCRP digitized all of the forms required for the study using the **Mi-Forms Designer** and then loaded them onto the Sahara Slate PC i500 Tablet PCs that the clinicians took into the field. Because the tablets run Windows 7 Professional, they easily integrated themselves into the military's secure domains and allowed for the required two way communication the data servers used to collect the field data and populate the databases. In addition, because the Windows operating system was familiar to clinicians, they did not have to spend any unnecessary time or expense retraining to use the system. Lastly, the large 12.1" LCD on the Sahara Slate PC more closely mimics the dimensions of the traditional paper forms which made for easier reading and completion of the surveys.



## Benefits

Utilizing this new electronic data collection solution, IDCRP lowered their development costs while increasing their staff's efficiency as they discovered a time savings of nearly 50% for developing new report forms in Mi-Forms as compared to their previous EDC system. In addition, the following benefits were reported:

- ❖ 80% of IDCRP's clinical research coordinators reported that the Mi-Forms/Sahara Slate PC solution is more efficient and saved valuable time over the traditional paper forms and previous electronic data capture solutions.
- ❖ The new system allowed for faster and more reliable data collection as no double data entry was required after receiving the paper case forms at headquarters.
- ❖ IDCRP performed real-time data validation during data capture which led to significantly fewer mistakes in their data and the ability to query suspect data immediately, rather than weeks, months, or in some cases years after initial data capture. This often is the difference between resolving a query (even while the subject is still present) and accepting that a data issue is irresolvable.
- ❖ Much improved clinical research coordinator compliance due to the immediate availability of self-guided training materials and study manuals on the Tablet PCs. Previously, training materials could only be accessed by downloading files from the organization's intranet where network connectivity was available. The process took valuable time and effort and therefore lowered compliance among staff at clinical sites.

"Missing or incorrect data is by and large a thing of the past as we can now mandate entry of key information into digital forms. We couldn't direct attention, highlight blank fields, or ask CRCs to confirm suspect data on traditional paper forms, but we can in a robust computerized system like the one we have built around the Tablet PCs," said Joshua Kumpf, Data Configuration Specialist and lead Mi-Forms developer of IDCRP.

Improved efficiency and reliability of the new EDC system has garnered increased interest among other investigators and senior leadership at IDCRP. Citing ease of use, increased mobility and improved data accuracy; adoption of the Tablet PC solution by other clinical trials at IDCRP seems likely.

## About IDCRP

The IDCRP was formed in 2005 through an Inter-agency Agreement between the National Institute of Allergy and Infectious Diseases (NIAID) and the Uniformed Services University (USU) and is supported by the Henry M. Jackson Foundation for the Advancement of Military Medicine pursuant to a cooperative agreement.

The research described here is sponsored by the Uniformed Services University of the Health Sciences (USU), however, the information or content and conclusions do not necessarily represent the official position or policy of, nor should any official endorsement be inferred on the part of, USU, the Department of Defense, or the U.S. Government. For more information visit [www.idcrp.org](http://www.idcrp.org).

## About TabletKiosk

TabletKiosk, based in Torrance, CA, is a leader in providing enterprise Tablet PC computing solutions for business. TabletKiosk's signature Tablet PCs combine performance and familiarity of the full Microsoft® Windows® Pro operating system with powerful Intel® processors, an ecosystem of enterprise-based accessories, touch screen input, handwriting recognition, voice recognition, hot swappable batteries and a wide selection of mounting solutions.

TabletKiosk Tablet PCs are widely used in the Healthcare, Hospitality, Education, Control System and Government vertical markets both as TabletKiosk branded and OEM private label deployments. For more information, visit [www.tabletkiosk.com](http://www.tabletkiosk.com).

## About Mi-Co

Mi-Co is the developer of Mi-Forms, the market's leading Tablet e-Forms software platform. Mi-Co provides solutions for smart, flexible mobile e-Forms data collection in a variety of industries. Mi-Forms supports enterprise data capture using Windows 8 Tablets like the TabletKiosk Sahara Slate PC i500, the Digital Pen, iPads, Android Slates, and other mobile capture devices across diverse industries and has worked with customers like Eli Lilly, AT&T, Sutter Health and many others. For more information about Mi-Forms and the Mi-Co solution for mobile electronic data collection, please contact Mi-Co by visiting [www.mi-corporation.com](http://www.mi-corporation.com) or by emailing [info@mi-corporation.com](mailto:info@mi-corporation.com).