

# Implementing an Information Technology (IT) Infrastructure for HIV Vaccine Clinical Trials in Resource-Constrained Settings

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## Introduction

- The International AIDS Vaccine Initiative (IAVI) is conducting or preparing to conduct Phase I/II AIDS vaccine clinical trials in India, Kenya, Rwanda, South Africa, Uganda and Zambia, among others.
- Clinical sites utilize central databases that are located in Europe and North America. These databases are accessed on a daily and/or real-time basis in order to facilitate the tracking of participants and fulfillment of regulatory obligations.
- Each site needs have a suitable IT infrastructure that enables reliable and cost-effective communications with datacenters and assures data security and participant confidentiality.

### IAVI's Current Data Collection: The Numbers

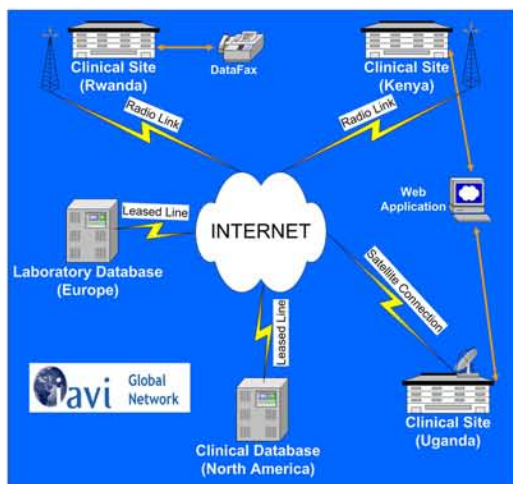
- 452 Phase I/II Trial Participants
- 52,000 Case Report Forms

### Critical Issues

- Clinical trial data is voluminous and mission-critical.
- In-country telecommunications infrastructure may be unreliable.
- Local Government may restrict or regulate certain methods of telecommunication.
- Electrical power may be unavailable or inconsistent.
- Trial participant data must be kept confidential.

### IAVI's Projected Data Collection: The Numbers

- 3,000 - 6,000 Trial Participants
- 1,000,000+ Case Report Forms



## Lessons Learned

- IT assessments must be done well in advance, preferably in person, especially where logistical or bureaucratic hurdles are anticipated.
- Early contact with the relevant communication authorities will reduce "lag time" for transmission licenses.
- Connectivity options, costs and service quality differ substantially across the developing world, so it is important to consider all methods of connectivity.

## Recommendations

**As IAVI plans for a multi-center, multi-country vaccine efficacy trial, considerable attention must be given to IT issues and challenges in order to provide real-time safety data.**

**Suitable IT infrastructure for IAVI's growing list of clinical sites throughout the developing world will only come through effective site assessments conducted well in-advance.**