Presentation Abstracts

Augustin Augier, ALIMA-ONG

Use of biometric devices for registration and follow-up of volunteers in a Phase II/III Ebola vaccine trial in Guinea.

In April 2015, NIH and INSERM asked Alima to implement a Phase III vaccine trial in Guinea comparing the efficacy of two vaccine candidates. We had three months between the decision to vaccinate and the forecast date of first vaccination. Given the low incidence of the Ebola virus disease (EVD), the trial had to include 150,000 volunteers. This posed two specific challenges – among many – that made us decide to use a biometric device. First, how do we make sure that all of the events are captured? Second, how do we prevent people from being enrolled more than once?

An individual follow-up at fixed dates for 150,000 individuals was not operationally feasible, so we decided to register volunteers biometrically and put recognition devices in every place where EVD cases could potentially been identified. We planned to deploy a total of 100 devices: in every health structure and Ebola Treatment Center (ETC), as well as with the outreach teams who were in charge of assessing community deaths. We contracted Morpho, a French-based company, to provide the devices and develop the necessary services. After 3 months of preparation, we were ready to start the vaccine trial. By this time, the incidence of EVD had become so low that we decided not to proceed with this study design and to switch to a phase II RCT, placebo controlled trial. This trial will start inclusions in July 2016 with the Morpho biometric devices being deployed.

ALIMA will present the design of this project, the specificities of the registration and confirmation processes, and the specifications of the biometric devices.

Sheana Bull, University of Colorado Denver

Engaging youth for health research and health promotion via Text and other Social Media: Challenges in a crowded and competitive environment

In a rapidly evolving technology environment, we have seen innovations in health promotion and disease prevention that use the Internet, text messaging, social media, and more recently, mobile applications or apps. While new technologies offer exciting potential for reaching populations at risk for HIV and impacting their health outcomes, they still fall short of fully realizing this potential. This talk will offer a brief history of the use of technologies for health promotion and disease prevention and consider how mobile technologies have been employed to impact youth sexual health behaviors, with an emphasis on “what works” to engage youth and ongoing challenges we face in impacting their risk for HIV.

Alix Dunn, The Engine Room

Beyond IRB: Responsible Data in Clinical Trials

This presentation will outline several processes and approaches for considering the responsible adoption of new tech/data in clinical trial management and research. The community of responsible data practitioners collaboratively defined responsible data as: The duty to ensure people’s rights to consent, privacy, security and ownership around the information processes of collection, analysis, storage, presentation and reuse of data, while respecting the values of transparency and openness. This means diverse things in different sectors, and the medical sector is very advanced in its thinking and consideration of the ethical and legal implications of how it collects and uses data. The engine room works across many sectors, and while we have supported medical organizations in the past. This presentation will introduce some concepts/processes that are useful to consider when designing projects that can push clinical testing practitioners to think beyond compliance and more actively advance their responsible use of data (in the same ways that they work to innovate and advance their use of data/tech) include: Responsible data red teaming, future proofing, Planning for the human element of best practices.

Janan Dietrich, Perinatal HIV Research Unit (PHRU)

Sexual and behavioral risk data collected via different platforms: phone-based surveys and in-clinic reporting in the HVTN 915 study

HVTN 915 is a prospective study evaluating the use of self-administered vaginal swabs for the detection of HIV-1 virions among 18 to 25 year-old women in South Africa. Study objectives are evaluating the feasibility of the self-administered swab regimen, and comparing behavioral data collected through text messaging versus in-clinic questionnaires. We will discuss the analyst's perspective on reconciling these data sources to address study objectives, including lessons learned and recommendations for questionnaire design and data management.

Jessica Haberer, Harvard University

Electronic devices and SMS for adherence measurement and intervention in developing settings

Dr. Haberer will describe the use of electronic devices (MEMS caps and Wisepill) and SMS text messaging for measuring and supporting adherence to PrEP, as well as ART. She will present data from studies conducted in Uganda, Kenya, and South Africa. She will review the pros and cons of each approach, with a focus on practical issues in developing settings.

Matt Johnston, US Military HIV Research Program (MHRP)

Paperless workflow in resource-constrained environments

The use of electronic technologies to streamline processes has proven beneficial across many industries. In clinical trials, those technologies have been utilized to improve the quality of data collection, refine operations and automate tasks. When introducing those systems in remote and/or resource constrained settings, one may encounter unanticipated challenges which could threaten a successful systems implementation and ultimately the success of a study. Our work focuses on the development and maintenance of a clinic paperless workflow system, used to identify, schedule and communicate with participants in clinical studies. This talk will aim to highlight some of the advantages and challenges faced since initial implementation of this application in support of RV144, and how the system has continued to evolve to accommodate the needs of our clinics and participants.

Anatoli Kamali, Medical Research Council Uganda and International AIDS Vaccine Initiative (IAVI)

Overview of IAVI Fingerprint projects, and use of fingerprinting in fishing communities in Uganda

Background: A robust cross-verification system is required in clinical trials to avoid potential challenges such as co-enrollment. IAVI-Africa research network has conducted a series of fingerprint (FP) projects in African countries to: i) assess acceptability of FP; ii) determine whether FPT could prevent co-enrollment; and iii) assess FP as a tool to track mobile populations as a 'virtual cohort'. In addition, FP is being used in a study of HIV prevalence, incidence, retention and migration in fishing communities in Uganda.

Lessons learnt: Over 3000 FP scans have been done across the research network. The scanners automatically register volunteer's fingerprint signature into an alphanumeric number using unique algorithm. The signature data are subsequently downloaded and managed on a centralized database. The fingerprint is acceptable with few refusals (<1%). The internet reliable devices are not a viable option in rural Africa with limited internet access. Improved technology and scanning 2 or more fingers can substantially reduce error rate. Preliminary data indicate that FPT could be useful tool for tracking hard-to-reach populations-virtual cohort.

Megan McBride, Janssen Pharmaceuticals at Johnson & Johnson

Tomorrow's Clinical Trials, Today

Learn about Janssen's pilot initiatives to modernize clinical trials and improve the patient experience. Megan will present pilot programs under the leadership of Janssen's RDO-Innovation department including patient communities, patient centered trial design and various mHealth approaches. Megan will focus on eConsent and share lessons learned to date on Janssen early eConsnet pilots.

Peter Simpson, iRespond

The landscape of current biometric technology and use in global health and clinical trials

An overview of current biometric identity tools and solutions that are being used to improve the quality of patient and clinical trial participant identity. The two most popular biometric modalities for clinical identity will be compared at a high-level on technical performance and field usability. The use of a common biometric identity hardware and software solution in two separate global health HIV projects in different areas of the world will be detailed.

Barbara Van Der Pol, University of Alabama Birmingham

Use of cell phones to collect daily diary data in studies of sexual behaviors

Dr. Van Der Pol will speak about the use of mobile phones to collect daily diaries regarding sexual behaviors. This information can be highly sensitive for study participants and the ability to use phones for web-based data entry has provided improved opportunities for data collection. However, there are also logistical and quality concerns related to mobile phone utilization, data completeness, and data reliability. The advantages and disadvantages of use of this technology will be discussed in this session.

Kristin Wall, Emory University

Use of electronic fingerprinting among female sex workers in Zambia

Longitudinal patient identification improves data accuracy and patient care but is an operational challenge in much of sub-Saharan Africa. When following patients in clinical trials and for service provision, misidentification can bias trial outcomes and affect patient care. Electronic fingerprinting is a proposed solution to identify patients longitudinally and link their health data across service sites. This simple, inexpensive technology overcomes challenges in resource-limited settings: it is user-friendly, cellular-based, and portable. Working with Biometrac, a US-based company, we deployed an electronic fingerprint-linked data capture system for use among female sex workers (FSWs) in Zambia. The technical feasibility (false fingerprint matching rate of 1/1000 and false rejection rate of <1/10,000) and acceptability (<2% refusals) of this system was confirmed in a pilot implementation phase. We now systematically electronically fingerprint all HIV-negative FSWs enrolled in a mock HIV vaccine trial at our research sites in Lusaka and Ndola. This system has allowed us to confirm the identity of enrolled participants longitudinally, as well as identify women attending follow-up visits who were not initially enrolled in the trial.

Christopher Whalen, Research Data and Communication Technologies

Protecting participant confidentiality on mobile devices: managing risks to participant privacy in clinical studies that use mobile phones and data networks

New mobile technologies offer significant opportunities for clinical studies to improve the quality, collection, and processing. However, solutions must integrate controls for the new risks posed to participant confidentiality. Vulnerabilities could violate aspects of the regulatory framework that governs clinical research. More significantly, the breach of confidentiality for some research carries the possibility of social stigma that can be life threatening to participants, their family, and their friends. Mobile phones, tablets, and other connected systems are and will be used in healthcare, therefore providing source data for clinical trials in new ways. The era of the Internet-of-things will create new vulnerabilities that can compromise or improve participant safety and confidentiality. This presentation will provide a review of some risks to participants from use of mobile technology and also examples of compensating controls. In addition, it will present some ongoing questions these technologies ask of the research community.