What is PrEP?
Pre-Exposure Prophylaxis for HIV Prevention

Pre  before
Exposure  coming into contact with HIV
Prophylaxis  taking medication to prevent becoming HIV infected

• One of many paths in HIV prevention
• Others include vaccines, condoms, male circumcision, microbicides, treatment as prevention (ARVs)

PrEP and iPrEx

Partners PrEP:

• Phase III study of 4,758 HIV-discordant heterosexual couples enrolled at 9 clinical sites in Uganda and Kenya
• Three arms: placebo, tenofovir and Truvada
PrEP and iPrEx

iPrEx (Iniciativa Profilaxis Pre Exposicion):

• Phase III study of 2,499 HIV-negative sexually active men who have sex with men and transgendered women who have sex with men

• 11 sites in Brazil, Ecuador, Peru, South Africa, Thailand and the United States

• Two arms: placebo and Truvada

The PrEP Study World

• Partners PrEP
• iPrEx
• CAPRISA 004
• FEM-PrEP
• VOICE
• CDC Trials
PrEP and iPrEx: DataFax Success Stories in the HIV Prevention World

The PrEP Study World

• Partners PrEP (DF/Net – DataFax)
• iPrEx (DF/Net – DataFax)
• CAPRISA 004 (CAPRISA – DataFax)
• FEM-PrEP (FHI – Not DataFax)
• VOICE (SCHARP - DataFax)
• CDC Trials (CDC - overheard at a conference – “Should have used DataFax”)

Why was DataFax successful for these studies?

• DataFax is well suited for international research
DataFax is well suited for international research

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DataFax for international research

- Images of Africa are real, but the stereotypes are not
- I gave a talk at DFUG Snowbird in 1997 about my experience with DataFax in Uganda
- Focus was on building infrastructure to get data from there to here

Infrastructure is now in place

- Many things have changed since 1997….
  - Improved site facilities and excellent staffing
  - Better and dedicated infrastructure
  - Available and reliable Internet

- But many things have not
  - Time is still the most limited site resource
  - Increased regulatory scrutiny of sites
  - Simple solutions take less time
  - Simple solutions are more likely to work
DataFax has allowed clinical research in completely new areas

• To go from “the first clinical trial in Western Uganda since Adam and Eve”
  – Elioda Tumwesigye, Site P.I., Kabwohe

• To success!
  – Test fax from Kabwohe by Edna, Wana, and Stephen

Why was DataFax successful for these studies?

• DataFax works well for large Phase III trials (and small studies too)
• There’s no such thing as a small wedding
  - setting up any study takes work
• But there are big weddings
  - and DataFax manages big weddings well
Not all studies progress as planned

• iPrEx started with Peru and Ecuador, additional funding brought in US, Thailand, South Africa and Brazil
• PrEP started out with a bang and went even further from 3,600 to 4,758 couples
• Oh, and then there were all of the other studies at DF/Net, big and small
• DataFax allowed DF/Net to juggle chainsaws, bowling balls, and live parakeets and not drop any of them

Each study has its own concept of big

• And DataFax was able to manage them all
DataFax really did allow us to “scale” the studies

• “Scale” not only means to increase or reduce proportionately in size
• For PrEP and iPrEx, it felt more like the definition of “to climb up or over”
• Peak data flow from PrEP and iPrEx was 30,000 CRFs per week
• 700,000 CRFs in a six month period
Some days felt like a Seinfeld episode

"Because the mail never stops. It just keeps coming and coming and coming, there's never a let-up. It's relentless. Every day it piles up more and more and more! And you gotta get it out but the more you get it out the more it keeps coming in."

- Newman

DataFax scales at the site as well

• Efficient clinic flow is critical in large studies
DataFax scales at the site as well

- Participants may travel hours to get to the clinic, and visits are often long and complicated

DataFax scales at the site as well

- Sites have a lot going on…
- DataFax allowed them to focus on patient care and not on data management
DataFax can deal with complexity

• PrEP – The ever changing study
DataFax can deal with complexity

• As an example, PrEP:
  – 11 cycles, including Screening, HIV+, HIV-,
    Seroconverter, Post Study, Placebo Conversion,
    Post Study Seroconverter, and Babies
  – 93 conditional visits
  – 400 plate conditions
  – 11 languages across two countries

• 946 unique CRF combinations of plate, language, and versions

Things get even more complex when it works

New Vision
Uganda’s Leading Daily

THURSDAY JULY 18, 2019
Uganda’s Daily National Newspaper

CHOGM: IGG vows to pursue Bukyana, BUSINESSES: Six pages of tenders
See business page 9

Drug stops HIV infection by 73%
DataFax can deal with complexity

- All of the PrEP placebo participants had to be re-randomized to either tenofovir or Truvada (starting back at month “0”)
- And we could do all of this within the same DataFax study

Why was DataFax successful for these studies?

- DataFax was embraced by the study researchers as an everyday tool
- First with DFlite, now with iDataFax
"Seeing is believing" is the case for international research

The biggest advantage to me is the use of a paper source and being able to visualize that image. For me, this makes me feel I more directly know the site’s intent, I can view generations of the form, correction, etc. and there is more of a personal imprint (handwriting). Clearly paper doesn’t work for everyone and for every time. But, for me, having it has increased my confidence in the data.

- Dave Glidden, iPrEx Statistician

Why was DataFax successful for these studies?

• Time Magazine 2011 People Who Mattered

Together we have reached the next major milestone for iPrEx: the database on all 2,499 iPrEx participants has been cleaned and prepared for the next major review. This milestone was reached on time, and with the expected outstanding quality.

- Bob Grant, iPrEx P.I.
Bob Grant at the Investigator Meeting in Mexico City

With his cool iPrEx jacket!

Bob Grant at the Investigator Meeting in Mexico City

Or is it really his cool iDataFax jacket?
DataFax as a relevant solution for over 21 years

• Acceptance letter for a talk that I did for Wayne in July 1991:

DataFax as a relevant solution for over 21 years

• Just to put a little technical perspective on things at the time:

All rooms will be equipped with a 35 mm slide projector, an overhead projector, a blackboard, and a screen. No other audiovisual equipment will be available.

• I couldn’t find the PowerPoint slides because back in 1991 “slides” were real 35 mm slides!
   (but luckily the paper copy still existed)
In closing, DataFax has worked for us because...

- It’s nice to be able to reuse a slide from 21 years ago!

Thank you

- Lisa Ondrejcek and Darryl Pahl

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