METRODORA Multi-stakeholders' Meeting

Meaningful Engagement of Women in HIV Treatment Research

Priorities for Women in R & D: A Personal Experience

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Outline

- My Experience of being a Clinical Trial Participant
- Engaging Women
- Summary/Recommendations

My Experience of being a Clinical Trial Participant

Why join?

- Personal Reasons - need to change treatment due to side effects
- Clear Benefits – More monitoring, newer/better ARVs
- Wider reasons – Advocate for women's involvement in Clinical Trials

PIVOT

HIV

PIVOT Website

Protease Inhibitor monotherapy Versus Ongoing Triple-therapy in the long-term management of HIV infection

Is taking one drug (a protease inhibitor) as good as taking a combination of drugs in the treatment of people with HIV?

What is this study about?

PIVOT aims to compare the use of a single type of anti-HIV medication, protease inhibitors (PI), to the standard triple drug therapy by monitoring the effect on disease progression, drug resistance and death in HIV infected patients.

Currently a combination of three antiretroviral (ART) drugs is used to treat HIV. These drugs seem to be very effective and do not cause many side effects in the short term. However, as they are taken life long they may be associated with side effects after many years.

The results of PIVOT will help inform doctors if it is possible to simplify treatment to just one drug, a PI.

When is it taking place?

PIVOT opened to enrolment in November 2008. Participants will be followed to a common closing date five years after the first participant joined, which we anticipate will be November 2013.

Where is it taking place?

PIVOT is taking place at 43 sites in the UK.

Who is included?

587 patients have been included in the trial. All are HIV-infected adults on a stable ART regimen of two Nucleoside Reverse Transcriptase Inhibitor (NRTIs) and one Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) or PI. The patients included had CD4+ T-cell counts greater than 100 cells/μL and viral load (VL) less than 50 copies/ml for no less than 6 months before starting the PIVOT trial. Patients who had virological failure on any previous ART regimen, who had PI resistance mutations, or in whom PIs were contraindicated could not participate.

Treatment history

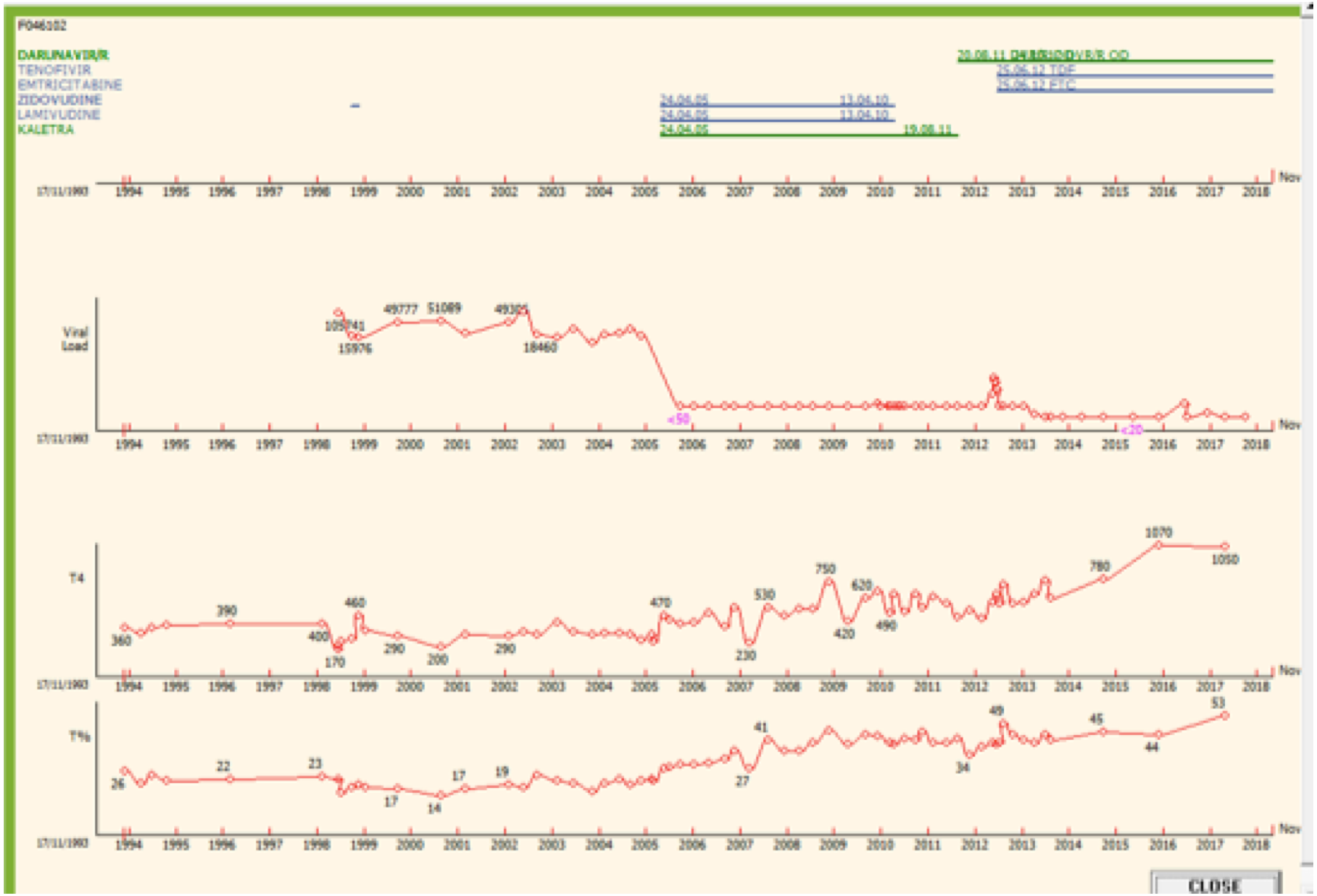
Pregnancy
25/9/98 – 30/11/98
AZT monotherapy

After delivery
24/4/05 – 13/4/10
Combivir & Kaletra

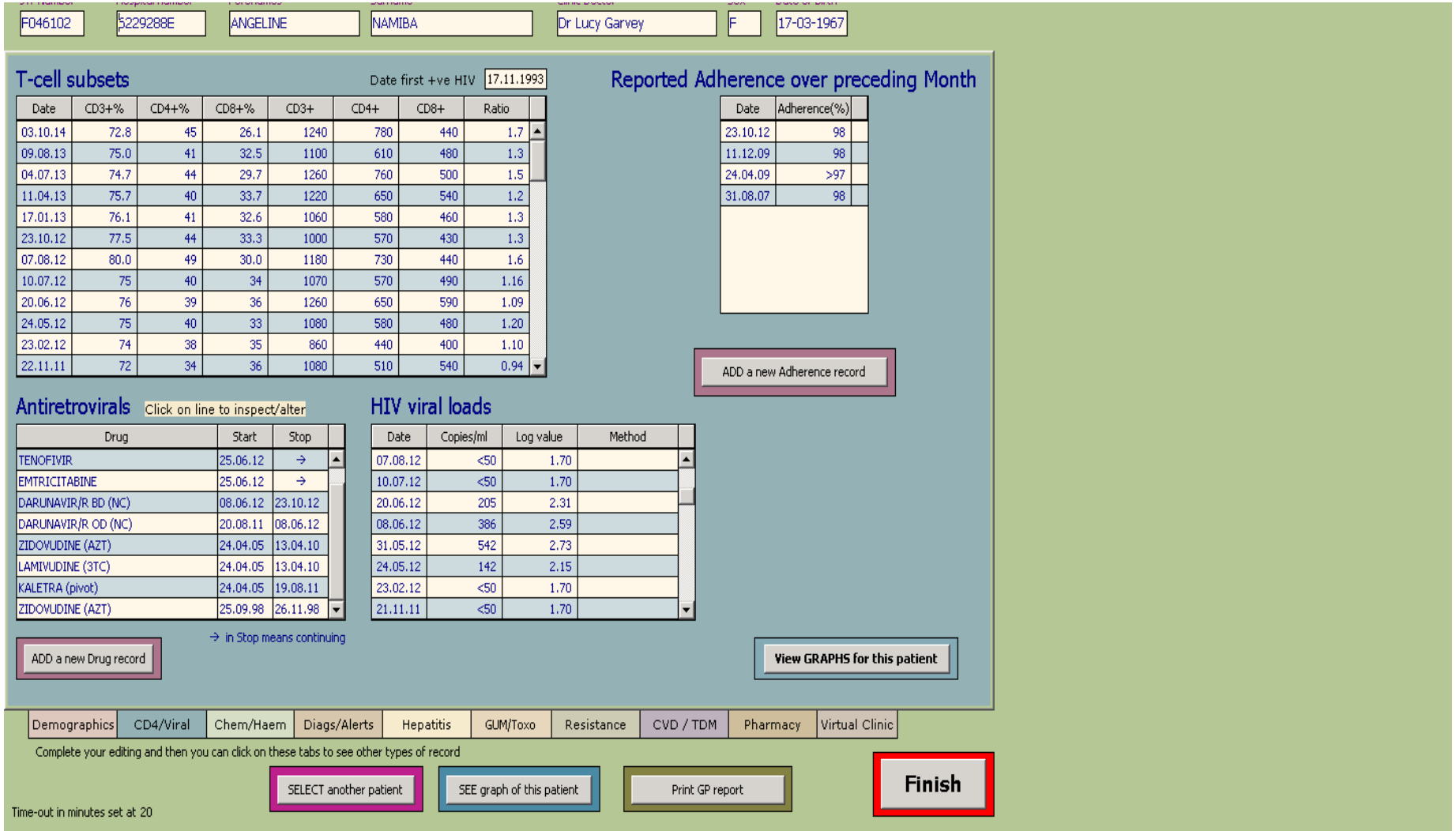
Joined Pivot Trial
13/4/10 – 20/8/11
Kaletra Monotherapy

20/8/11 – 8/6/12
Darunavir Monotherapy

8/6/12 to present switch:
Darunavir/r & Truvada



My Clinical Trial Journey



i-base

HTB

Viral load rebound rate of 35% using ritonavir-boosted PI monotherapy: results of five-year PIVOT study

24 March 2014. Related: Conference reports, Antiretrovirals, Treatment strategies, CROI 21 (Retrovirus) 2014.

Simon Collins, HIV i-Base

A long-term strategy study sponsored by the Medical Research Council (MRC) in the UK reported low rates of serious complications and the potential to reduce drug costs. However, more than a third of people on the ritonavir-boosted PI monotherapy group had viral load rebound compared to only 3% of people on standard combination therapy.

My thoughts on being a Clinical Trial Participant?

- A very positive experience
- Well monitored, well informed & my questions and concerns acted upon
- I felt really well treated.
- Direct experience enables me to be better placed to advocate for women
- Involvement ignited my interest in Clinical Trials & other social research in general
- Happy to be involved as part of trial team, or participant or as a peer researcher.

Why Engage Women?

- Significant social and medical differences between men and women
- Need for more gender specific data
- Women experience greater changes biologically & socially, bodies change dramatically from puberty; reproductive years to menopause.
- Women are still under represented in Clinical Trials

https://hivpolicyspeakup.wordpress.com/2015/11/08/women-living-with-hiv-and-research-mind-the-gap/

WHO 2017 SRHR Guideline : **6.2.1 Women living with HIV as equal partners in research**

Recommendations

Researchers

Proactively Address the lack of gender specific data and under-representation of women living with HIV

Caps on % of men in CTs to enable inclusion of more women

Women only spaces & women focused health

Community

Increase women's treatment and Clinical Trial Literacy & ability to work collaboratively with researchers in designing, implementing and evaluating research.

Encouraging Examples

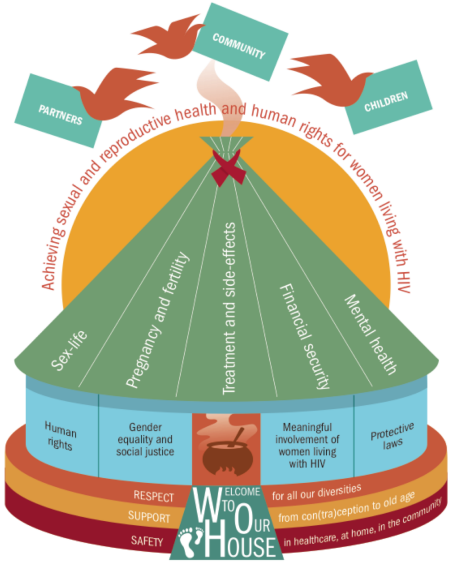
4M Project: My health my choice my child my life

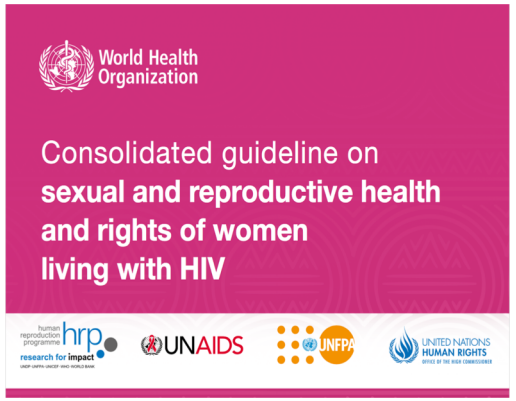
Women Living with HIV involved through the lifecycle

of the project: SG, Planning Development Delivery & Evaluation

WHO SRHR Values and Preferences Survey

- Research about, Conducted by and for women living with HIV.
- 945 respondents from 94 countries aged Between 15-72.
- Informed the WHO Consolidated guideline on SRHR .





Encouraging Examples

Strategies for Recruiting Women Living with Human Immunodeficiency Virus in Community-Based Research: Lessons from Canada

Kath Webster[1], Allison Carter[1,2], Karène Proulx-Boucher[4], Danièle Dubuc[4], Valerie Nicholson[1], Kerrigan Beaver[3], Claudine Gasingirwa[3], Brigitte Ménard[4], Nadia O'Brien[4,5], Kayla Mitchell[1], Micaela Pereira Bajard[1,7], Erin Ding[2], Alexandra de Pokomandy[4,5], Mona Loutfy[3,6], and Angela Kaida[1], on behalf of the CHIWOS Research Team

Progress in community health partnerships: Research, Education, and Action.
Volume 12, Issue 1, Spring 2018, pp 21-34 (article)

Facilitating and Enabling Engagement

- Narrative – **communicate** CT info in **clear concise** patient friendly language
- Ubuntu - **What's in it** for women and their communities
- **Involve** us in Early Clinical Development & through lifecycle of studies
- Design Studies that are appealing and of benefit to us
- **Continued community literacy** around Treatment & Clinical Trials and why it is important for us to participate
- **Family Friendly** clinic times, transport, childcare etc… where relevant

Thank you

- The **PIVOT** Trial Research Team at:
  Imperial College Healthcare NHS Trust. In particular,
  Dr Lucy Garvey & Scott Mullaley

- Dr Shema Tariq and
- Women Living with HIV, in all your diversities, who continue to inspire me.

Asante sana Zikomo Mille Grazie Twalumba Kea Leboha Enkosi Ya bonga Gracias Daalu Oshee Plangdes

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Questions?

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