

OVER 50 PATIENTS

Lagos Island Maternity Hospital  
PI Aigbe Ohihoin



FMC Azare, PI Umar Ibrahim



Obafemi Awolowo UTH, PIA Babalola Adeyemi



Lagos State University Teaching Hospital, PI Oluwarotimi Ireti Akinola

Maiduguri UTH  
PI Audu Idrisa

FMC Makurdi  
PI Andrea Jogo



Maitama District Hospital, PI Frank Alu



FMC Birnin-Kebbi, PI Yusuf Tanko Sununu



LAUTECH Osogbo, PI Adetunji Oladeni Adeniji



Seventh Day Adventist Hospital, PI Owigho Peter O

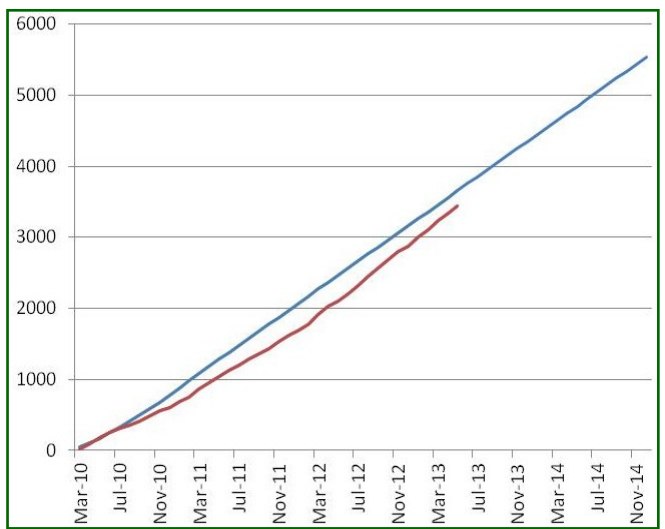


Jos University Teaching Hospital, PI Josiah Mutihir

Adeoyo Maternity Hospital  
PI Akintunde Ayinde

**Dear Collaborators,**  
We are well over the halfway mark with over 8,000 women randomised worldwide into the trial. As you can see from the graph overleaf, Nigeria leads the way with 3,700 women included to date. Well done to all the active sites – you are the reason why this trial is already the largest ever conducted in PPH and why we are halfway to finding out if TXA will help reduce the mortality burden from postpartum haemorrhage. Every single recruitment counts and your work is very important as the goal is to save lives. We appreciate your efforts even more knowing that you produce these excellent results despite local challenges ranging from security issues to staffing pressures. Last year we had a slight reduction in recruitment in Nigeria but we are pleased to report that recruitment is now back on track. There is still a small deficit to make up, but if recruitment continues at the current rate this should not be a problem. This is your trial – by recruiting, you are showing your commitment to improving the health of women worldwide. **Be proud of the work you have done so far and we look forward to a very successful trial.**  
*Haleema Shakur, on behalf of the London Coordinating Centre*

Recruitment is back on track in Nigeria!



WOMAN TRIAL IN NIGERIA

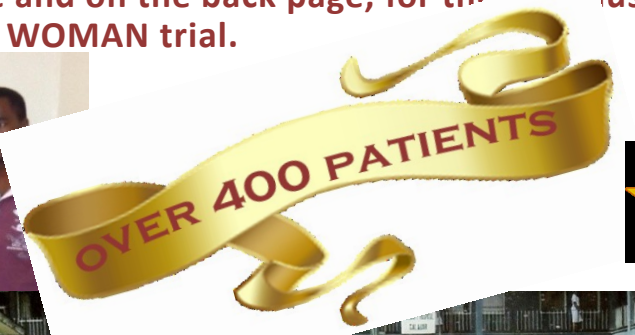


NIGERIA LEADS THE WAY – 3700 WOMEN RANDOMISED!

A huge thank you to the teams listed here and on the back page, for their enthusiasm and their outstanding contribution to the WOMAN trial.



Mother & Child Hospital Akure, PI Adesina Akintan



OVER 100 PATIENTS



University of Calabar Teaching Hospital, PI Saturday Job Etuk



FMC Katsina, PI Ibrahim Habib

Lagos UTH  
PI Omolulu Adegbola

8000 patients recruited worldwide



FMC Lokoja, PI Onile Temitope



University College Hospital Ibadan, PI Oladapo Olayemi



University of Ilorin Teaching Hospital, PI Abiodun Peter Aboyeji



FMC Owo, PI Olufemi Akinsanya



FMC Gusau, PI Kamil Shoretire



University of Abuja Teaching Hospital, PI Olatunde Onafowokan



Irrua Specialist Teaching Hospital, PI Felix Okogbo



Delta State UTH, PI Lawrence Omo-Aghoja



FMC Abeokuta, PI Moses Oluwafemi Alao



Nigeria continues to make significant contributions to the progress of the WOMAN trial. Most of the collaborating sites have maintained a steady pace of patient recruitment into the trial. Nigeria continues to play a leading role in the trial in terms of number of participating hospitals and participant recruitment. There are 38 sites in Nigeria. The enthusiasm of investigators and their team members is a positive indication that interest in the trial is still high.

The WOMAN trial is about the largest clinical trial to date in Nigeria. We consider this as an accomplishment for all investigators. It has afforded us a lot of opportunities to acquire experience in several aspects of clinical trials. Participation in WOMAN apparently has a positive impact on the quality of care for postpartum haemorrhage (PPH) in collaborating health facilities. Several investigators report that participation in the trial has heightened awareness about PPH among midwives and doctors in their hospitals with concomitant improvement in clinical management and outcomes for women. This is an accomplishment for the trial in Nigeria.

We are particularly delighted about the positive interactions with the National Agency for Food and Drug Administration and Control (NAFDAC) and National Health Research Ethics Committee (NHREC). We continue to enjoy the support of these agencies as they approve more sites for the trial. At the moment, two sites are awaiting approval while documents for six other sites are being processed.

NAFDAC has carried out inspection visits to some of our sites. Their positive comments attest to the quality and integrity of the trial in Nigeria.

We expect the trial to grow in Nigeria as we approach the last eighteen months. We look forward to more sites joining the collaboration. In the long term, we anticipate increased interest in clinical trials as a discipline and hope to see more clinical trials in maternal and perinatal health in particular, in Nigeria in future.

*Bukola Fawole, on behalf of the Nigeria Coordinating Centre*

### Recruitment at Nigerian sites in 2013 – target monthly randomisation ≥4 patients

SITE	Jan-13	Feb-13	Mar-13	Apr-13	May-13	Jun-13	TOTAL
Adeoyo Maternity Hospital	3	1	3	5	1	2	15
Ahmadu Bello UTH	0	1	0	0	0	0	1
Delta State UTH	5	4	5	3	1	6	24
Ekiti State UTH						7	7
FMC Abeokuta	3	2	6	5	7	3	26
FMC Azare	1	1	2	1	2	2	9
FMC Birnin-Kebbi	3	4	1	2	5	2	17
FMC Gusau	2	1	5	6	0	4	18
FMC Katsina	1	2	2	0	0	0	5
FMC Lokoja	5	10	3	2	3	9	32
FMC Makurdi	1	1	5	1	1	0	9
FMC Owerri	0	1	4	0	0	0	5
FMC Owo	10	4	5	5	6	4	34
Irrua Specialist TH	0	0	4	1	1	1	7
Jos UTH	2	4	4	4	0	3	17
LAUTECH Ogbomoso	1	0	1	2	2	0	6
LAUTECH Osogbo	3	5	4	6	1	2	21
Lagos State UTH	0	0	1	0	0	0	1
Lagos UTH	2	2	4	0	3	1	12
Maitama District Hospital	3	3	7	4	1	4	22
Mother & Child Hospital Akure	29	31	31	18	26	25	160
Nyanya General Hospital	5	0	2	2	6	8	23
Obafemi Awolowo UTH	3	1	0	2	2	0	8
Seventh Day Adventist Hospital	0	4	4	0	1	1	10
UCH Ibadan	4	9	5	11	3	9	41
University of Abuja TH	5	0	0	3	4	8	20
University of Calabar TH	21	12	13	17	18	17	98
University of Ilorin TH	7	1	4	3	2	2	19
University of Maiduguri TH	2	0	0	1	1	0	4
University of Uyo TH	0	0	0	4	7	3	14
Wesley Guild Hospital (OAUTH)	0	3	4	0	3	4	14
<b>NIGERIA</b>	<b>121</b>	<b>107</b>	<b>129</b>	<b>108</b>	<b>107</b>	<b>127</b>	<b>699</b>



Twelve Nigerian sites are among the top 20 recruiting hospitals in the WOMAN trial.

### More sites to start soon:

#### In progress – please send us all outstanding documents

- Murtala Mohammed Specialist Hospital
- Federal Medical Centre Umuahia
- Federal Medical Centre Gombe
- Federal Medical Centre Yenagoa
- University of Nigeria Teaching Hospital Enugu
- Braithwaite Memorial Specialist Hospital

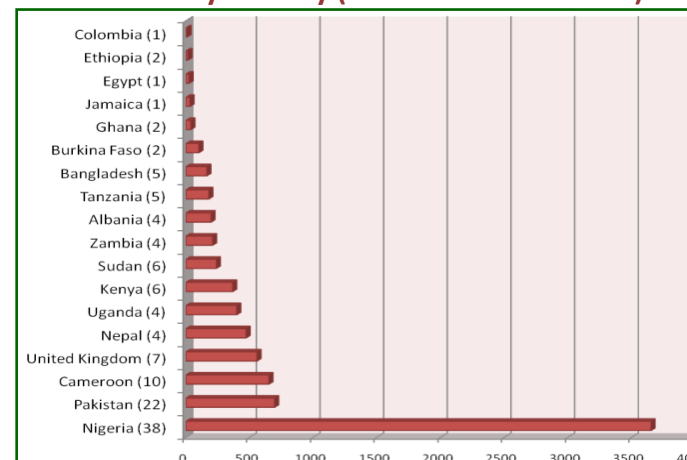
#### Documents complete

- awaiting NAFDAC and NHREC approval
- Aminu Kano Teaching Hospital

#### Materials on site

- expecting first patient recruitment!
- Federal Medical Centre Bida

### Recruitment by country (no of sites in brackets)



### TOP TIPS FOR MAKING THE TRIAL SUCCESSFUL AT YOUR HOSPITAL

1. Involvement of the PI
2. Support from hospital management
3. Putting in place a great trial team
4. Midwives should be part of the trial team
5. Trial pharmacist onboard
6. Keeping the Investigator Study File up to date

## THE NIGERIA WOMAN TRIAL FAMILY

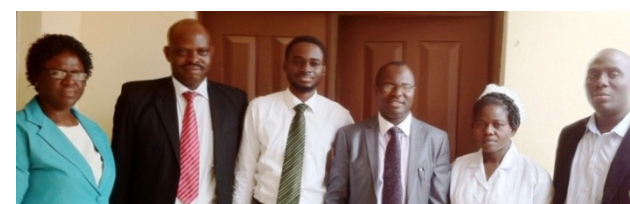
The first patient of the WOMAN trial was randomised in Nigeria in March 2010. Now, 38 hospitals in Nigeria have recruited 3700 patients, 45% of all trial patients to date.



LAUTECH Ogbomoso, PI Adetunji Oladeni Adeniji



FMC Bida, PI Ikemefuna Nwosu



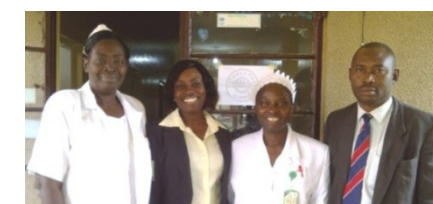
FMC Ido-Ekiti, PI Augustine Adebayo Adeniji



University of Uyo Teaching Hospital, PI Aniefiok Umoiyoho



Minna General Hospital, PI Mohammed Gana



Wesley Guild Hospital, PI Babalola Adeyemi



FMC Owerri, PI Emily Nzeribe



Nyanya General Hospital, PI Ola Nene Okike



Plateau State Specialist Hospital, PI William Nengak Golit