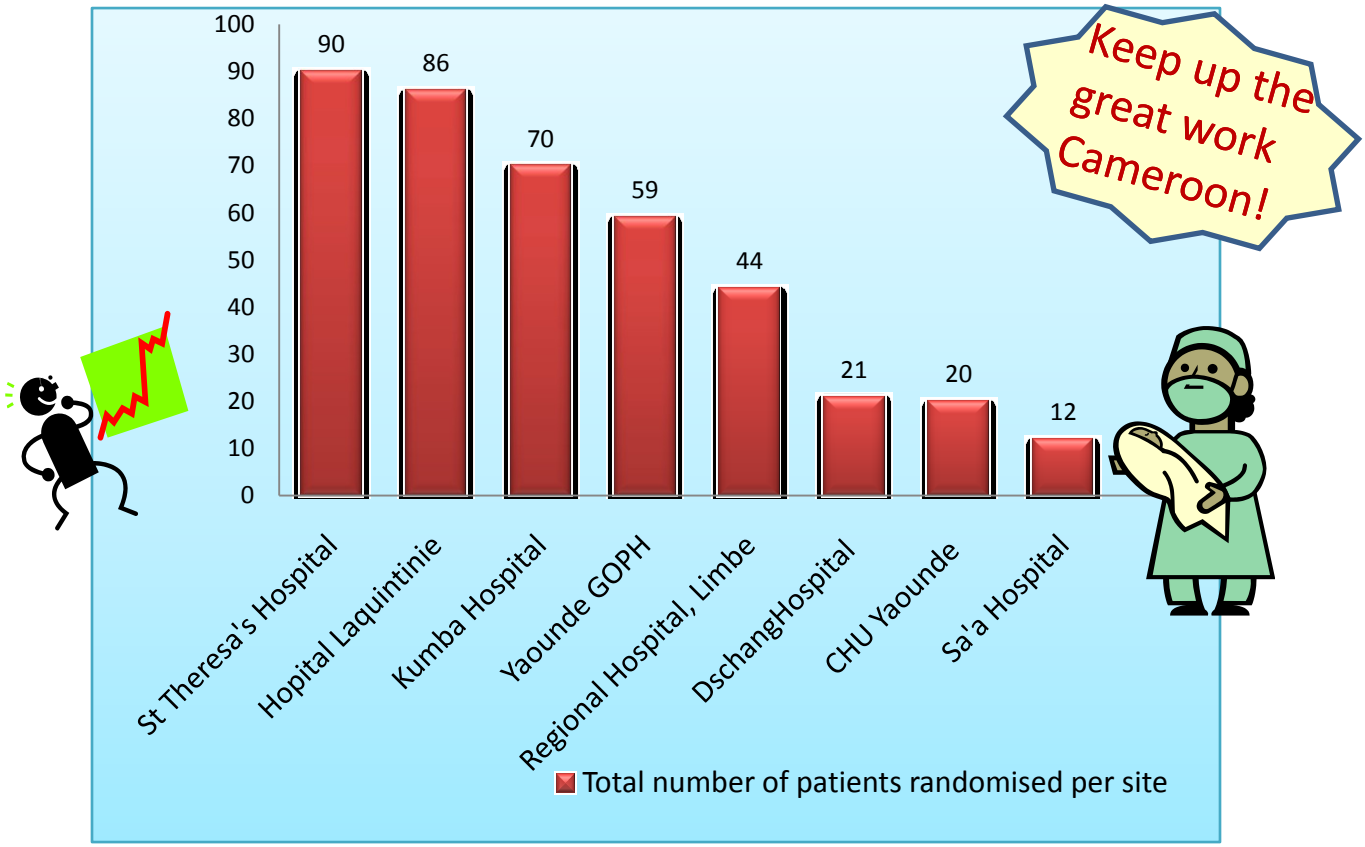
CAMEROON UPDATE FROM THE TCC

21 February 2012

402 PATIENTS RANDOMISED IN CAMEROON
2770 RANDOMISED WORLDWIDE



Congratulations Cameroon! A significant milestone has been achieved – over 400 patients randomised making Cameroon the second highest recruiting country in the world! This would not have been possible without the hard work and dedication of every single member of the WOMAN trial teams.
THANK YOU and MERCI from all the team at the TCC!

We are also pleased to announce that the WOMAN trial has received ethical clearance renewal from the Cameroon National Ethics Committee for another year. We hope to be adding Yaounde Central Hospital, Bamenda Regional Hospital and Banyo District Hospital to the recruiting sites very shortly.

Top Recruiters for December/ January
YGOPH – 12
St Theresa's – 10
Kumba – 8
Limbe – 7
Dschang – 4

As part of our ongoing responsibility as Sponsor of the WOMAN trial, some sites in Cameroon have recently undergone an audit. Special congratulations to Dr Venantius Mutsu Bumaha and all his team at St Theresa's for their hard work preparing for this and who have just finished the process, and Dr Tschele Mesack Tchana and all his team at Hôpital Laquintinie de Douala who completed their audit at the end of last year. As an audit may take extra time and effort, we may 'pause' the trial at the site so they can concentrate on the audit tasks. We look forward to both sites rejoining the trial!

What is a WAIVER of PRIOR WRITTEN Consent?

➢ Until consent has been obtained in **writing** with the patient or representative providing their dated signature (or thumbprint which MUST be witnessed by an independent person if patient/representative cannot read/write) then it is not Informed Consent, even if they have agreed to take part. In this instance, the patient may be entered on a WAIVER of prior **written** consent.

➢ If a Waiver is used, this must be clearly documented in the patient's medical records.

When can a waiver be used?

- The patient/relative has received all the information about the trial and has verbally agreed to take part but there hasn't been time to complete the consent form. Document in medical records that verbal agreement has been obtained and remember to obtain written consent as soon as possible.
- The patient is incapacitated and unable to provide consent, and there is no relative or representative present. In this scenario 2 clinicians (one independent of the trial) must agree to the enrolment of the patient. This must be fully documented in the patient's medical records.

REMEMBER – In all instances, each randomised patient requires written Informed Consent, but in certain situations this may be obtained AFTER randomisation (using the WAIVER process). Clearly document the consent process for each patient in her medical records and on the entry form.