NEWSLETTER AUGUST 2023

IT'S THE FINAL COUNTDOWN !!!

Over 14, 000 women randomised !!!!

Well done to WOMAN-2 sites in Nigeria, Pakistan, Tanzania and Zambia for your amazing efforts. Please continue the fantastic work you are doing to keep us on track to complete recruitment by September 2023. The sooner we finish the sooner the trial results can start making an impact!!!

Dear Collaborators,

By now, you will be aware that recruitment is going so well, it is not long before we reach our 15,000-participant target, hopefully no longer than 6 weeks away! Congratulations to you all and I am sure, like me, you can't wait for the results!

I would like to encourage you to keep recruiting every single eligible woman at your hospitals so we can reach our target of 15,000 women as quickly as possible. The earlier we do this, the more time we will have to clean and analyse the data and prepare for publication.

Getting to this point has been filled with struggles, drama, hard work but also a lot of positives, like the amazing people who have come together to form the Woman-2 team and the huge commitment of all the collaborators across 4 countries all working together to improve the wellbeing of women.

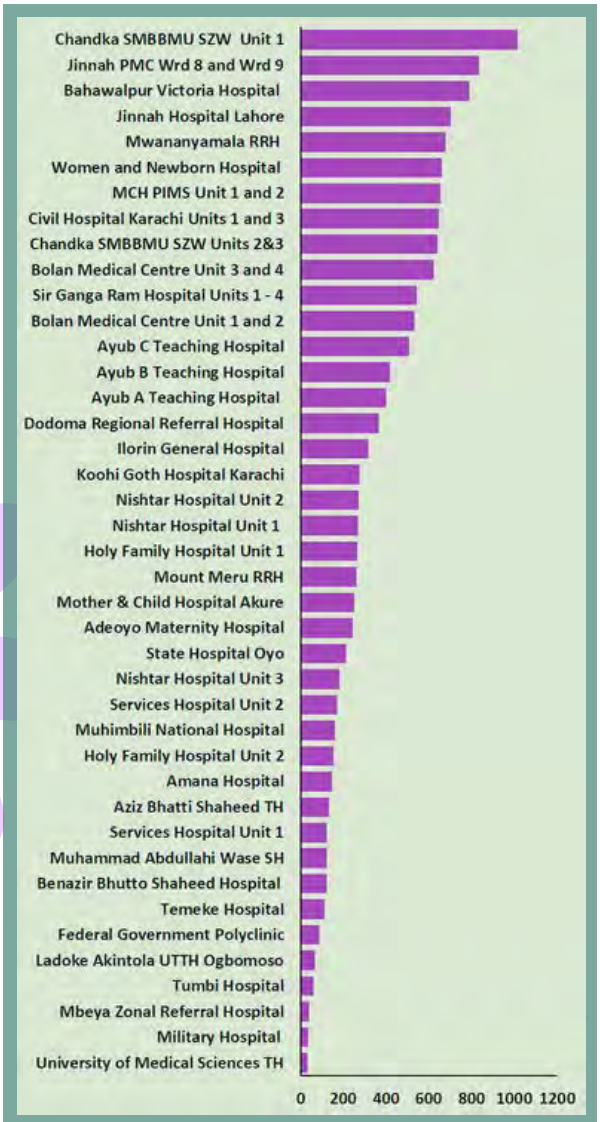
The Protocol development started back in 2017 with first patient recruited August 2019. Since then, we have seen the world changed by a pandemic and political upheaval, our teams changed through retirement, resignation and death. I am always amazed and humbled by the work and commitment which continues despite these setbacks.

As we await the results, I just want to say thank you and it has been a privilege working alongside you on the Woman-2 trial and as I always want to remind you - you are contributing to knowledge which will last beyond our lifetime.

Looking forward to recruitment completing and the excitement of having the results!

Haleema

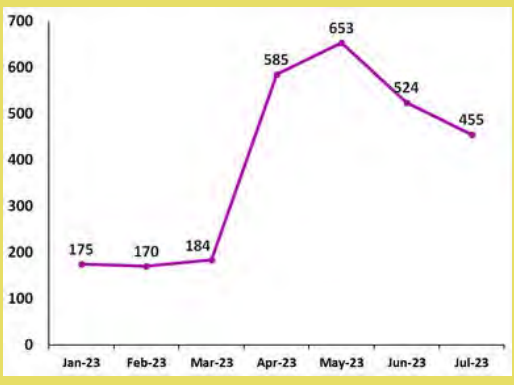
Fantastic work by Professor Shahida Magsi and her team at Chandka Medical Centre Unit 1, who are the No.1 recruiter with over 1000 women randomised



A massive THANK YOU TO to all WOMAN-2 Teams for the amazing work you are doing!

LET'S FINISH STRONG

We are very close to achieving our target of 15,000 women. However recruitment rate has dipped since June!
Please keep recruiting all eligble woman so we can complete recruitment by September 2023, so we can have results by next year!



Delivering woman2

TO IMPACT CLINICAL PRACTICE AND SAVE LIVES, OUR DATA MUST BE:

Accurate

Always take measurements with trial equipment and don't guess, round up, or estimate vitals signs and timings

Consistent

Keep data consistent across the trial by using the equipment provided and following the Trial Protocol and Procedures at all times.

Timely

Record data as it is collected, upload the entry and outcome forms to the trial database within 24 hrs of completing each form and respond to queries promptly.

Reliable

The data entered in the CRF and Trial Database should be verifiable from the woman's medical records, so help document the woman's care in hospital carefully.

Complete

All fields in the Clinical Record Form, CRF booklet and Trial Database. All the data is needed in the trial

We are only two months away from achieving the sample size of 15,000 participants, which will allow us to answer the important question of whether TXA can improve outcomes for women with moderate to severe anaemia that have PPH.

The data team have been working really hard to process all of the awesome data you are collecting and the Independent Data Monitoring Committee reviewed the data in June and were super impressed with the excellent work you have done so far.
WELL DONE !!!

So now, let's finish strong with high quality data to ensure that the trial results can be made available as quickly as possible so it can be adopted in treatment guidelines.

New evidence from woman2

SEVERE ANAEMIA IS LINKED TO A SEVEN-FOLD HIGHER RISK OF DEATH OR LIFE-THREATENING BLEEDS AFTER CHILDBIRTH

Even before reaching its target sample size of 15,000 women, the Woman-2 collaboration is changing PPH policy with high quality research data. A cohort analysis in over 10,500 women in the Woman-2 trial has shown that every 10g/L reduction in the pre-birth haemoglobin increases the chance of a life-threatening PPH by about 25%.

The findings were recently published in the journal The Lancet Global Health. Women with severe anaemia were seven times more likely to die or become dangerously ill than those with moderate forms of the condition.

Severe bleeding after childbirth kills one woman every six minutes and your data shows that anaemia greatly multiplies the risk of bleeding and death. World-wide, half a billion young women are anaemic and 20 million are severely anaemic. To date, anaemia prevention has been overlooked by the World Health Organization in its efforts to cut postpartum haemorrhage deaths. Based on these results we need urgent changes in policy and practice.

These early results point clearly to the importance of anaemia in the causation of PPH and pave the way for the Woman-2 trial results that should be published early next year. Congratulations to all.

Ian and Raoul

WOMAN-2 Site Spotlight

TIPS FROM TOP PERFORMING SITES

Ilorin General Hospital, Nigeria

An enthusiastic team who are constantly improving their processes to ensure the continued success of the trial at their hospital

"It's wonderful being part of the WOMAN-2 trial. We joined in September 2021 and it's been amazing since then! Team work, dedication, love and togetherness have been our driving force. ***Our watchword is No blame, No shame.***

I have a wonderful team at Ilorin starting from the Research Assistants, Pharmacists and my very energetic Assistants.
Let's keep the screening going!"

Dr Mobolaji-Ojibara (Principal Investigator)

Women and Newborn Hospital, Zambia

The WNH team work tirelessly to ensure that they collect high quality data, which is accurate and complete. They also upload the data to the trial database and respond to any queries promptly!

"I applaud the team at our Women and Newborn Hospital site for their outstanding contributions to maintaining high-quality data uploads and prompt query responses.

To replicate their success, consider these valuable tips: ***prioritise accurate and timely data submission, establish streamlined communication channels within the site, and foster a proactive approach to addressing queries.***

Commitment to these practices not only strengthens the trial's integrity but also paves the way for impactful research. We could learn from their dedication and work together to achieve excellence"

Dr Mwansa Ketty Lubeya (Principal Investigator)

Chankda Unit 1, Pakistan

The highest recruiting team in the trial with over 1,000 women randomised

"The driving force behind our success is our team of Research Fellows. *Their commitment, passion, capability, and their dedication to randomising all eligible women,* ***along with the incredible contribution and robust support of the Clinical Team*** *has been a boost to the trial.*

Clear communication at the start of every emergency day(twice weekly) with personalised meticulous supervision, scheduling regular interactions to discuss protocols, challenges, and professional development are (the) secrets of high randomisation at our site.

Pinpointing bottlenecks and looking for the solution is only possible when you selflessly work at prioritising to bring perfection. I assure our sustained cooperation for improving lives and shaping the future of research in our area"

Prof Shahida Magsi (Principal Investigator)

Dodoma Regional Referral Hospital, Tanzania

The Team communicate well with themselves and the Coordinating Centres in Dar es Salaam and London which helps ensure smooth running of the trial and less errors due to misunderstanding.

"Our site is constantly updated on various communication platforms utilised by the London Coordinating Center as well us our National Coordinating Center which helps us have open communications that are prompt and efficient and ensure little to no misunderstandings occur.

We have few sessions where the whole team sit together and discuss how the trial is proceeding. ***If there are challenges which have been encountered, we solve (them) together***

We advise other sites to set aside specific time where the whole team sit together and discuss challenges and to follow up on communications with the Coordinating Centers"

Dr Enid Chiwanga (Principal Investigator)

Meet Our Awesome woman2 Teams

TEAM PAKISTAN

With less than a 1000 participants left to be enrolled in the WOMAN-2 trial, we take this opportunity to express our gratitude and admiration for our trial teams working tirelessly. WOMAN-2's success would not be possible without you all. Your perseverance and hard work held the fort, and we are successfully sailing towards the conclusion of the trial.

Throughout the course of the trial, you all showed exemplary teamwork and set forth the highest standards of commitment and endurance.

Thank you for being with us and looking forward to finishing recruitment in the coming six weeks or even earlier!

Pakistan Coordinating Team:
Prof Rizwana Chaudhri, Dr Aasia Kayani
and Dr Kiran Javaid

TEAM PAKISTAN

Dr Shehla Noor and team at
Ayub B Teaching Hospital

Prof Ansa Islam and team at
Ayub C Teaching Hospital

Prof Shahida Magsi and team at
Chandka SMBBMU Sheikh Zaid Woman Hospital Unit 1

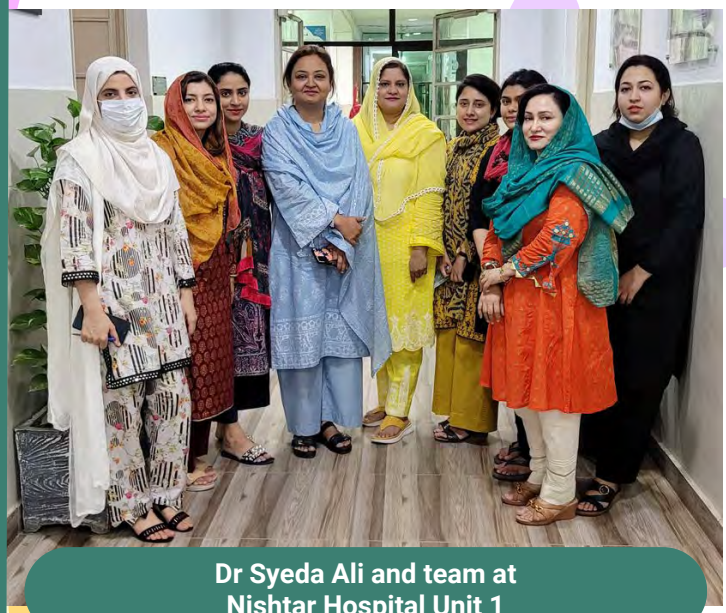
Prof Uzma Suhail Afridi and team at
Bolan Medical Centre Unit 1 and 2

Prof Haleema Yasmin and team at
Jinnah Postgraduate Medical Centre Unit 1/ward 8

Prof Riffat Jaleel, Prof Sarah Kazi and team at
Civil Hospital Karachi Units 1 and 3

TEAM PAKISTAN

Dr Musarrat Batool, Prof Sobia Luqman and team at Mother and Child, PIMS, Unit 1 and 2



Dr Syeda Ali and team at Nishtar Hospital Unit 1

Prof Mehnaz Khakwani and team at Nishtar Hospital Unit 2

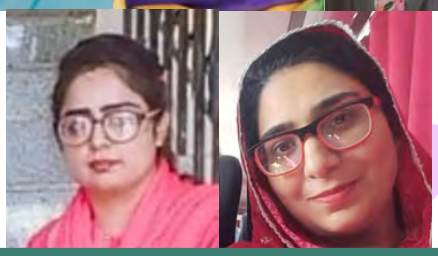
Dr Saima Ashraf and team at Nishtar Hospital Unit 3

Prof Alia Bashir and team at Jinnah Hospital Lahore Unit 2

Prof Fouzia Kashif, Prof Shaista Hifaz Abro and team at Chandka SMBBMU Sheikh Zaid Woman Hospital Unit 2 and Unit 3

TEAM PAKISTAN

Dr Najma Ghaffar and team at
Bolan Medical Centre Units 3 and 4



Prof Shakila Yasmin, Prof Sohail Mahmood Chaudhary and team at
Bahawalpur Victoria Hospital

Prof Aisha Malik and team at
Sir Ganga Ram Hospital - Unit 1

Prof Noreen Akmal and team at
Sir Ganga Ram Hospital - Unit 3

Prof Amna Zia Eusaph and team at
Sir Ganga Ram Hospital - Unit 2

Prof Shamila Ijaz Munir and team at
Sir Ganga Ram Hospital - Unit 4

Prof Ruqqia Sultana and team at
Ayub A Teaching Hospital

TEAM NIGERIA

As we approach the finishing line of the WOMAN-2 trial race, we cannot but thank you all for the efforts you have put into ensuring eligible patients are randomized into the study, and for doing this around the clock over the time each site has been in the study.

We wish to reiterate that, as onerous as some of the challenges we have faced and overcome might have been, what defines our contributions to the trial is the integrity of the data generated and the process of collecting the data.

In view of this, please ensure you follow the trial operating procedures in the performance of any trial tasks; make sure uploaded data is verifiable in hospital (primary) records and ask questions if not sure of what to do.

Our individual efforts are like a piece in a jigsaw puzzle without which the real picture is incomplete - and therefore imperfect. The degree of the integrity of the WOMAN-2 trials results lies in what YOU, as an individual, DO!

THANK YOU!!!



Nigeria Coordinating Team
Prof Oladapo Olayemi, Prof Folasade Nike Bello
and Mr Jide Okunade

TEAM NIGERIA

Dr Mobolaji-Ojibara Mojisola and team at Ilorin General Hospital

Prof Adewale Adeyemi and team at Ladoke Akintola University of Technology Teaching Hospital Ogbomoso

Dr Oyewole Tunde Aremu and team at State Hospital Oyo

Dr Theresa Irinyenikan and team at University of Medical Sciences Teaching Hospital, Akure

TEAM TANZANIA

We are proud that once again Tanzania has been granted a place in this Newsletter to share the progress that we have made so far in efforts to meet our target for the Woman-2 Clinical trial.

We are happy to report a randomization of over 1700 participants which is a significant improvement from the 460 we reported in the last Newsletter. This has been made possible through well-coordinated efforts to ensure continued randomization by all the seven study sites including the three newly added sites.

In March 2023, the Tanzania Medicines and Medical Devices Authority conducted its first routine site inspection for Good Clinical Practice. According to the preliminary report, the study was ongoing well except for some minor raised issues that have already been addressed.

I wish to congratulate all the working teams at our study sites and the assistance we continually receive from the London Coordinating Team . To all other countries, I call for more efforts as we climb our last steps towards the 15,000 global target!

Tanzania Coordinating Team:
Prof Projestine Muganyizi, Ms Rose Gerald Temba and Ms Alice Benito Kawala

TEAM TANZANIA

Dr Enid Simon Chiwanga and team at Dodoma Regional Referral Hospital

Dr Baya H Kissiwa and team at Amana Hospital

Dr Hudson August Manyanga and team at Temeke Hospital

Dr Vincent Timothy Tarimo and team at Muhimbili National Hospital

Dr Francis Ngimwichi Joseph and team at Mount Meru Regional Referral Hospital

Dr Luzango Evarist Maembe and team at Mwananyamala Regional Referral Hospital

Dr Alphonce Moyo and team at Tumbi Hospital

TEAM ZAMBIA

I am writing with immense pride and heartfelt appreciation for your exceptional contributions to our clinical trial. Your tireless efforts have propelled us forward, achieving remarkable milestones and potentially making a tangible difference in maternal health.

Your dedication shines brightly as we reflect on the significant strides we've taken. Having successfully randomized over 660 patients since the trial's inception is a testament to your unwavering resolve. The remarkable increase in the average number of monthly randomizations underscores your exceptional teamwork, efficiency, and enthusiasm.

Your work, however, transcends numbers. It directly impacts the lives of anaemic women, those who face the grave risk of postpartum haemorrhage. Your contributions hold the potential to reshape their outcomes, offering them a chance at a healthier and brighter future. Your steadfastness in collecting data, managing data, and pushing the boundaries of medical knowledge is inspiring and truly commendable.

As we continue this journey, I encourage you to sustain the same vigour that has brought us this far. Each day you spend working on this trial may be a step closer to making a lasting impact on the lives of women and families in Zambia and worldwide.

With gratitude,

Zambia National Coordinator
Professor Bellington Vwalika

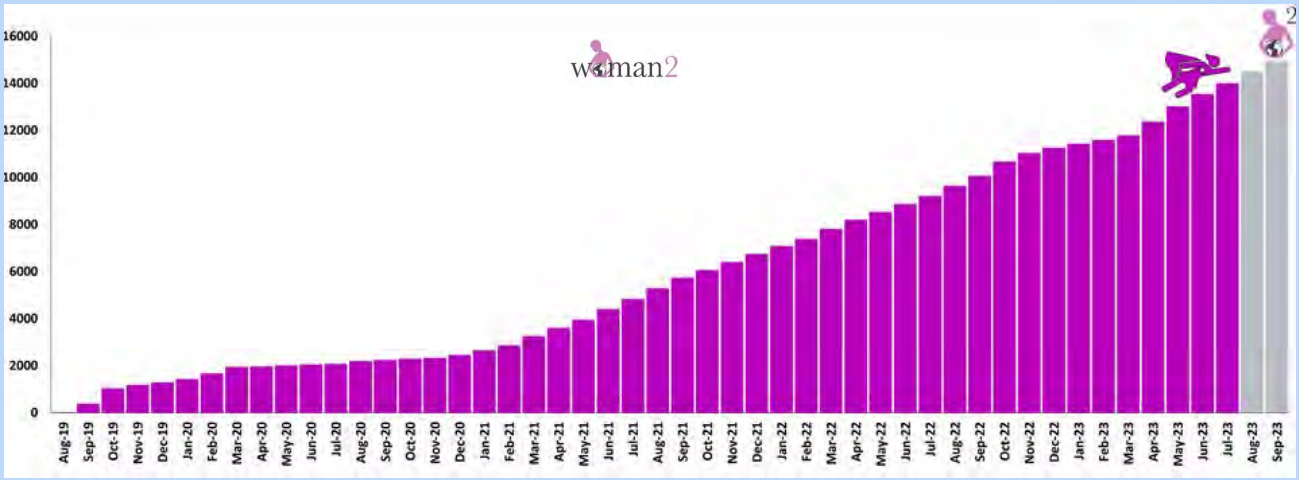
Dr Mwansa Ketty Lubeya, and team at Women and Newborn Hospital, Lusaka

We're nearly there!

LESS THAN A THOUSAND PARTICIPANTS LEFT TO RECRUIT - WOW

With just a few weeks of recruitment left, we are saying THANK YOU for your continued commitment to the trial. It has been awesome working with you and we are very excited to be close to answering the question of whether tranexamic acid can prevent PPH in women with moderate to severe anaemia.

KEEP UP THE EXCELLENT WORK



JUST A FEW REMINDERS:

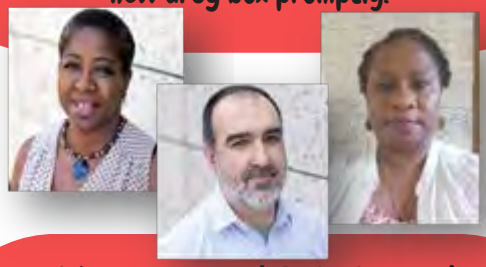
Review your data

To minimise queries, please carefully review your data before submission. Pay special attention to entering initials, dates, and timings accurately, and take the time to double-check your data to ensure accuracy and reduce errors.

Drug Accountability

Complete part 1 of the drug accountability log (DAL) and send it to the London Coordinating Centre, so we can activate your drug box, which will allow you to enter data for women that receive packs from the box into the trial database.

And send us part 2 of the DAL as soon as you have used up all packs in a drug box to ensure that we send you a new drug box promptly.



Notes section in the CRF Booklet

Add important information to the "Notes" section of the baseline and outcome forms on the Trial Database.

For example, if a woman develops PPH after randomisation but was not given tranexamic acid (TXA), please give a reason why she didn't get TXA in the "Notes" section.

Hb images and Data Upload

Post the anonymised baseline and outcome Hb images promptly in your site WhatsApp group within 24 hours of taking the pictures.

And upload baseline and outcomes data to the database within 24 hours of completing each form so we can verify your Hb images.