

COLLABORATING TO IMPROVE MATERNAL OUTCOMES



Dear Collaborators,


WELL DONE for delivering the WOMAN-2 trial and contributing to the global understanding of postpartum haemorrhage in anaemic women! The trial results have been published in The Lancet journal along with a systematic review and IPD meta-analyses of data from over 54,000 women, including WOMAN-2 trial participants. Key findings from both studies are summarised below.




Although the main trial results are published, analyses of the high-quality data you collected is continuing to further inform global efforts to reduce maternal deaths. These analyses could help answer important questions such as why is there an increased risk of PPH and death in anaemic women; which women should receive TXA for the prevention of PPH; and how cost-effective would TXA be in this instance? We will share findings with you once they are available. In the meantime, thank you for being part of the WOMAN trials collaboration!

ENI ON BEHALF OF THE UK COORDINATING TEAM


KEY FINDINGS FROM THE WOMAN-2 TRIAL AND IPD META-ANALYSIS



Anaemia greatly increases the risk of poor outcomes during childbirth. As a woman's haemoglobin levels fall, the risk of her dying or suffering serious complications such as postpartum haemorrhage (PPH), antepartum haemorrhage, abruption and stillbirth increases. It is important to prevent and treat anaemia in women before they give birth.



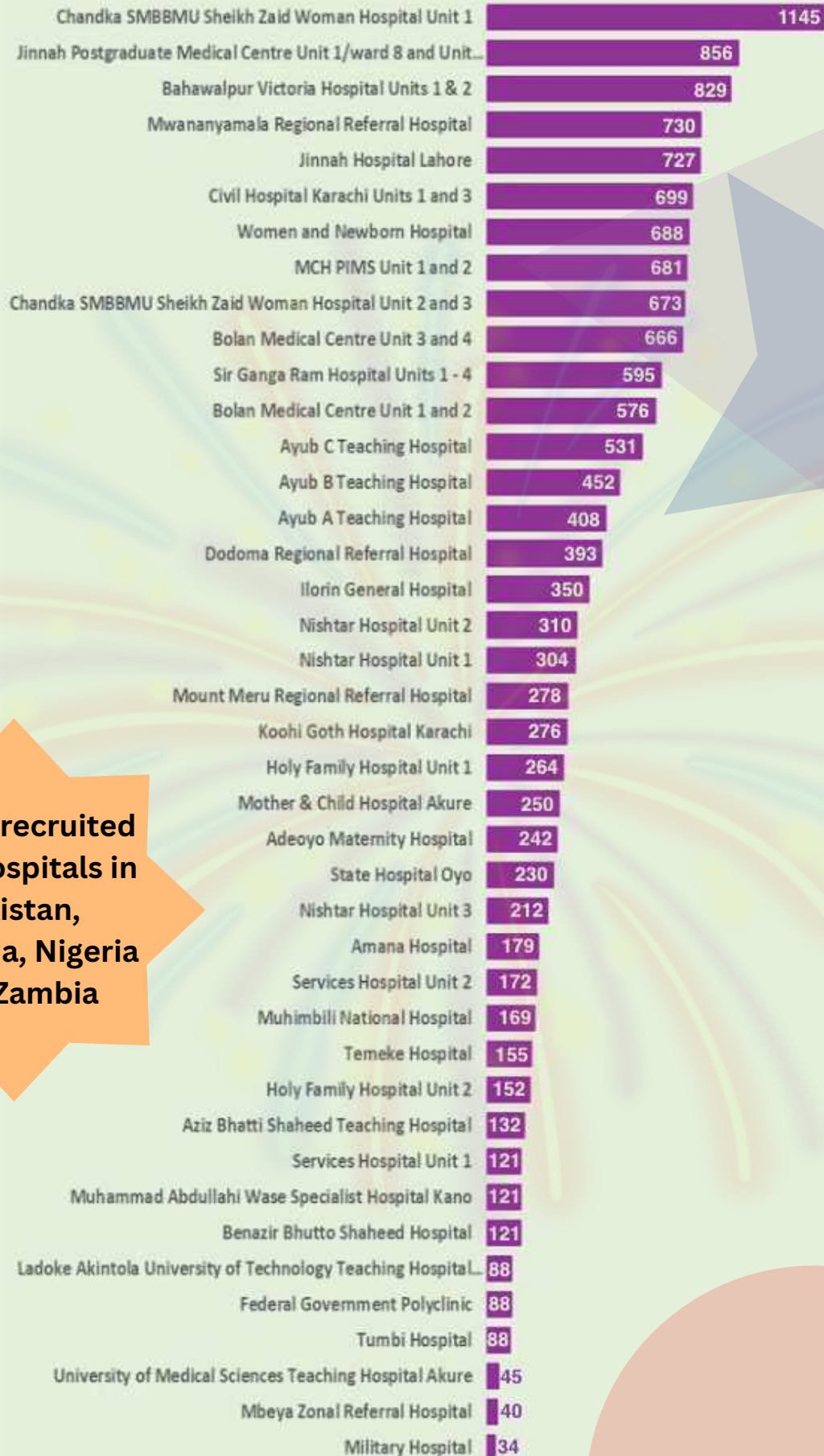
Giving tranexamic acid (TXA) within 15 minutes of cord clamping/cutting did not reduce the risk of clinically diagnosed PPH in women with moderate or severe anaemia. Earlier intervention may be necessary to prevent severe bleeding in many women, highlighting the need for trials on earlier treatment.



TXA reduced the risk of life-threatening bleeding after childbirth by nearly one quarter, regardless of the type of birth or haemoglobin levels. And no increase in thromboembolic or other adverse events was found with TXA use. So, clinicians should consider the use of TXA before a diagnosis of postpartum haemorrhage in women at high risk of death.

TEAMWORK MAKES THE DREAM WORK

THANK YOU to our Research Teams and Trial Participants for delivering WOMAN-2 with an amazing 99.9% follow up



**15,068 recruited
in 34 hospitals in
Pakistan,
Tanzania, Nigeria
and Zambia**

In this newsletter, our fantastic teams reflect on their WOMAN-2 journey over the past 5 years.

woman2 
TEAM PAKISTAN



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

The WOMAN-2 trial journey spanned several years, demanding constant adaptation to unforeseen challenges. Fluctuations in the patient enrollment, unexpected delays in obtaining approvals, and data collection complexities required trial teams in Pakistan to employ an ongoing problem-solving approach.

The COVID-19 pandemic had a major impact on the trial. In addition to dealing with extended approval timelines, collaborators in Pakistan had to strike a balance between ensuring the safety of research team members and participants and ensuring that patient enrollment and data collection could resume after recruitment stopped for several months at the height of the pandemic. The Coordinating Team adapted by carrying out virtual training and monitoring sessions to ensure that research teams in Pakistan received the support they needed. Post-COVID, we were confronted with an evolving clinical trials regulatory landscape in Pakistan, which resulted in delays in the approval process, that impacted on participant recruitment.

However, all these unforeseen challenges served to nurture our skills as researchers and to teach us the art of navigating rough waters. We express immense gratitude to our research teams for working tirelessly through all challenges. The journey of the WOMAN-2 Trial, from conception to completion embodies resilience, adaptability, and a steadfast commitment to advancing medical knowledge despite facing unforeseen challenges.

PAKISTAN COORDINATING TEAM



CHANDKA SMBBMU SHEIKH ZAID WOMAN HOSPITAL

**OUR #1
RECRUITING SITE**



Prof Shahida Magasi and team

Congratulations!



CHANDKA - UNIT 1

Participating in the WOMAN-2 trial has been a deeply rewarding experience. As the highest recruiter, I feel privileged to have contributed to this groundbreaking research aimed at improving outcomes for women experiencing postpartum haemorrhage.

At Sheikh Zaid Women's Hospital, Larkana, we often deal with complex cases in a resource-limited setting, and this trial has allowed us to bring evidence-based interventions to the forefront of maternal care.

The trial has not only enhanced our clinical knowledge but has also strengthened our teamwork and commitment to saving lives. It has been inspiring to see the impact of our efforts on mothers and their families, reaffirming the importance of advancing maternal health through research and collaboration.

PROF SHAHIDA MAGSI, PRINCIPAL INVESTIGATOR

CHANDKA - UNITS 2 & 3

We are very grateful to have participated in the WOMAN-2 trial. All the members of the team worked very hard in order to achieve the trial's target on time.

Thanks to the trial, we have learnt a lot; particularly on how to manage data efficiently for research purposes in developing countries.

THE TEAM AT CHANDKA UNIT 2&3, LARKANA



Prof Fouzia Kashif, Prof Shaista Hifaz Abro and team



AYUB TEACHING HOSPITAL, ABBOTTABAD

AYUB UNIT A



Prof Ruqqa Sultana and team

AYUB UNIT B



Prof Shehla Noor and team

AYUB UNIT C



Prof Ansa Islam and team

I have had a wonderful experience working with the WOMAN-2 trial team as a Research Fellow. Working on the trial from 2019 to 2023, initially at Unit A and then Unit C.

I still remember the day when I randomized the first patient at Gynae A unit - I was very excited. I learnt so many new things while working as RF for the WOMAN-2 trial. Initially it seemed difficult to manage as the anaemic patients load was enormous in our area but then with the passage of time I managed to streamline the problems under the guidance of the Coordinating team, especially Dr Aasia and Dr Kiran, who guided and helped a lot.

Zoom meetings with the London team, site visits by the Pakistan National Coordinating Centre, regulatory visits by the Drug Regulatory Authority of Pakistan, and the regular training courses were very interesting and it was enjoyable being part of trial team.

KUDOS! To the whole WOMAN-2 team for performing this trial with extreme dedication, honesty and hard work. I feel honoured to be a part of this dedicated team from the start till end.

DR SADIA BIBI, RESEARCH FELLOW

BAHAWALPUR VICTORIA HOSPITAL

The WOMAN-2 trial has been a remarkable journey for our team over the past 4 years. Our focus on enhancing patient monitoring and refining data collection processes has been a significant learning curve.

The collaboration and coordination within our team, along with the close bond formed with principal investigators, coordinators in Islamabad, and our patients, have been invaluable aspects of this journey.

Noteworthy moments include insightful discussions with Dr Aasia, Dr Kiran, Eni, Charlotte, and Professor Haleema. These interactions have not only enriched our understanding but also made the entire experience memorable.



Prof Shakila Yasmin, Prof Sohail Mahmood Chaudhary and team

THE TEAM AT BAHAWALPUR VICTORIA HOSPITAL



BOLAN MEDICAL COMPLEX, QUETTA



Prof Uzma Suhail Afridi and team

BMC Unit 1

We would like to thank you dear team members for all your incessant support, guidance and help throughout the trial. We want to extend our heartfelt gratitude to the coordinating team for providing the much-needed assistance which we always appreciated during this time period. We might have lost track of our work without your proper guidance. We appreciate the moral support which helped us to maintain our enthusiasm and passion.

Last but not least, we want to thank the entire team for this wonderful work. We feel so proud and honoured to work under the supervision of true professionals. It's nothing less than a privilege to be part of this incredible team. We look forward to working with you people again 😊

DR UZMA SOHAIL AFRIDI, PRINCIPAL INVESTIGATOR, DR NOSHEEN SIKANDAR & DR RAWAAL AMIN, RESEARCH FELLOWS

BMC Unit 2

Big thanks to LSHTM for the opportunity to work on the trial in Quetta, where such opportunities and exposures are not always available 🙌🙌

The trial was a journey full of learning, experiences, hardships and efforts. Sometimes it was fun 🥰 sometimes it was mentally and physically exhausting 😞...but we enjoyed every bit of it! We found that following up randomised patients for the timely completion of the data led to extra vigilance for PPH.

We faced the toughest time during COVID-19 😞...Aside from recruitment pausing, there was a myth in the post covid era that some poisonous injections are being given by health workers to patients to kill them. In such situations taking consent from women and defending the trial against a deeply seated myth was a great challenge, but the whole team worked hard to accomplish this goal and we are thankful to all our team members 🥰

DR REHANA KAMAL & DR YAMNA QAZI, RESEARCH FELLOWS



JINNAH HOSPITAL LAHORE UNIT 2



Prof Alia Bashir and team

It is a special honour being part of the WOMAN-2 Trial, as our little contribution will have had a huge impact!

We've had a great experience and the best things we learnt were the team work and enhanced communication - with the patients, our team and through emails and WhatsApp with the Pakistan & London Coordinating Teams. It was also great that some of our WOMAN-2 Trial patients shared with us when they were interviewed that they felt special because of the care they received and the colourful trial stickers documenting their care in their medical files!

It has been a long journey; the first patient was randomised at Jinnah Hospital in September 2019. We remember our excitement on that day and our whole team was present to deliver the patient.

Then there was a break due to COVID and there was uncertainty about everything. But that time passed, God was kind enough and life resumed again.

A few of our patients left against medical advice and it was interesting to note that this tended to be the severely anaemic women. It also seemed that the severely anaemic patients appeared to be those women with no antenatal care, uncooperative attendants and had a high probability of leaving against medical advice.

When we made mistakes along the way, we would contact Dr Aasia and she would say "Don't worry, it can happen" and reassure and give us advice. On the whole, it has been a great journey spanning 5 years with a hectic routine and enjoyable moments! 😊



JINNAH POSTGRADUATE MEDICAL CENTRE UNIT 1/WARD 8

JPMC Unit 1/ward 8

I'm thrilled to have contributed to the WOMAN-2 trial. My tenure as a research fellow proved immensely rewarding. It upscaled my attention to detail and vigilance in managing patients developing PPH. Witnessing the bond shared among mothers navigating maternal victories and setbacks due to anaemia was profound. In Pakistan, where resources are limited, the affordability of tranexamic acid emerges as both a blessing and the safest solution to prevent PPH in anaemic mothers.

Despite numerous trial challenges, the most notable was the mothers' lack of understanding regarding their reproductive health. The lack of awareness among pregnant women about anaemia led many to decline potentially life-saving blood transfusions, putting their lives at risk and leading to premature hospital departures. Conversely, educated mothers understood the importance of a nutritious diet, supplements, and blood transfusions, ensuring the birth of healthier children. Amidst the unexpected families rushing for discharge summaries without medical advice were notable, leaving me astonished.

THE TEAM AT JPMC UNIT 1



Prof Haleema Yasmin, Dr Saba Khan and team

JPMC Unit 2/Ward 9

The results of Woman 2 are amazing. We will try our level best to ensure that women in my country are not anaemic especially when they are pregnant and in labour. Tranexamic Acid is a wonder drug as it reduces life threatening bleeding after childbirth.

DR SABA KHAN, PRINCIPAL INVESTIGATOR

AZIZ BHATTI SHAHEED TEACHING HOSPITAL

It was a pleasure and a great honour to collaborate in this landmark research work. Any tiny contribution from our side which can help to save mothers is a source of pride for us.

DR SHAHIDA HUSAIN, PRINCIPAL INVESTIGATOR



Dr Shahida Husain Tarar and team



TEAM PAKISTAN

UNIT 1



Dr Syeda Ali and team

I have no words to explain my feelings because it was the biggest opportunity of my life. I was working with such a cooperative, committed, and hard-working team. When I joined the trial, it was a new experience for me, and I tried my best to understand the whole trial. Thanks to my colleagues, especially Dr Asma Akhtar, for helping me in this regard.

Special thanks to the Pakistan Coordinating Team for helping us achieve this task successfully. Now, we are able to differentiate between the quality of the data and the quantity of the data. We are aware of the protocol or standards regarding the collection of the data, and this will be helpful for us throughout our lives.

I also want to thank all the trial coordinating team members for supporting, guiding, and most importantly, providing all trial materials swiftly. We would be unable to accomplish this task without your support.

DR SYEDA ALI, PRINCIPAL INVESTIGATOR

NISHTAR HOSPITAL UNIT 2



Prof Mehnaz Khakwani and team

Exploring the complexities of anaemia in pregnancy and postpartum hemorrhage has been eye-opening. Also, collaborating with healthcare experts and collecting data firsthand has provided valuable insights and working with a renowned institution like the London School of Hygiene & Tropical Medicine is truly amazing!

I'm so glad that we had the opportunity to contribute to evidence-based approaches for the well-being of pregnant women. Working with an amazing team makes all the difference. I'm glad that we had such a positive experience and learned valuable practical knowledge. It's rare to find such a supportive and knowledgeable group. Kudos to all for successfully overcoming the challenges during the recruitment process - truly were an inspiration!

THE TEAM AT NISHTAR HOSPITAL UNIT 2



UNIT 3



Dr Saima Ashraf and team

Engaging in research on tranexamic acid in anaemic pregnant women was a profound learning experience.

Through collaboration with healthcare experts and hands-on data collection, we gained a deep understanding of the challenges faced by pregnant women dealing with anaemia and the associated risks.

The research experience enhanced our knowledge in the field and provided practical insights that can help provide better care for patients.

Working with a renowned institution like the London School of Hygiene & Tropical Medicine helped provide a rigorous scientific framework for addressing real-world health issues.

This learning journey has not only enriched our academic pursuits but has also fuelled a commitment to contributing to the well-being of pregnant women through evidence-based approaches.

Thank you for giving us this opportunity to be part of this wonderful research.

THE TEAM AT NISHTAR HOSPITAL UNIT 3





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

It has been a roller-coaster journey!

We obtained approvals for the trial in 2019 and then had to contend with the COVID-19 pandemic when recruitment started in Nigeria in 2020. Implementing the trial during the pandemic was an uncharted path but our collaborators proved their mettle and ensured that recruitment continued throughout the pandemic. Team Nigeria - WE APPRECIATE YOU!!!

We also had to contend with mild dramas getting approvals renewed and the ever recurrent industrial actions at trial sites. But eventually, we reached the finish line, which is a testimony of the grit, resilience and team work for a noble purpose shown by teams at all trial sites and the coordinating centre.

A massive THANK-YOU to all our Research Assistants - you are the MVPs! And also to all trial team members including pharmacists, nurses, doctors and record officers; we couldn't have reached here without you.

To our Principal Investigators, thank you for opting to participate and we look forward to working with you on disseminating the trial results and on future projects!

NIGERIA COORDINATING TEAM



ILORIN GENERAL HOSPITAL



Dr Mobolaji-Ojibara Mojisola and team



It's been amazing being part of WOMAN-2 Trial. I sincerely appreciate Prof Oladapo, my mentor, for considering our centre worthy, for believing in us and for support throughout the trial - we so much appreciate you! Also, we do not take for granted Mr 'Jide! Our wonderful supervisor, this trial wouldn't have been smooth if not for your unrelenting support, advice and patience - I say thank you!

To my ever ready, dynamic, loving and energetic GHI trial team, you guys are the best! To all other trial team members, we appreciate working with you and we have learnt so much.

On a lighter note, the most challenging part of the trial for me, were the numerous queries I received on a daily basis in my mailbox 😊 Many were to confirm or ascertain data uploaded, which further strengthened my faith in the data collected. A trying time for us was when recruitment paused briefly at our site so we could address local challenges. It was initially disheartening, however we came back to the trial stronger than ever! Kudos to all - Together we did it!

“Anaemia: A threat to Motherhood. Tranexamic acid: The Lifesaver”

DR MOBOLAJI-OJIBARA, PRINCIPAL INVESTIGATOR

UNIVERSITY OF MEDICAL SCIENCES TEACHING HOSPITAL, AKURE



Dr Theresa Irinyenikan and team

Postpartum haemorrhage is a major cause of maternal mortality, in women with moderate or severe anaemia. The effort put into designing the protocol, data collection, monitoring for data quality and evaluation of the data made the research excellent and has increased our curiosity about the issue. Attaining the recruitment milestone of 15,000 patients has made this research very robust.

We hope the findings of the trial will further help in producing guidelines that will help reduce maternal mortality and improve pregnancy outcomes for our women.

DR THERESA IRINYENIKAN, PRINCIPAL INVESTIGATOR

woman2 
TEAM TANZANIA



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

For us, the WOMAN-2 results have touched the tip of the iceberg on the challenges facing PPH management, particularly in low and middle-income countries where anaemic women form a substantial part of the female population. We ask ourselves if the standard first-line management of PPH works the same in the mainly anaemic women as in non-anaemic population.

PROFESSOR PROJESTINE MUGANYIZI, NATIONAL COORDINATOR



Dr Baya Kisiwa and team

We are very excited and proud of being part of the WOMAN 2 trial team, we hope our participation will contribute positive changes to science.

WOMAN 2 helped us to increase alertness in the management of pregnant women with anaemia during labour and delivery; no randomised trial has been done prior to WOMAN-2 in our hospital involving such anaemic patients, despite the higher prevalence of anaemia in our area.

DR BAYA KISSIWA, PRINCIPAL INVESTIGATOR



Dr Mwansa Ketty Lubeya (Principal Investigator) at Women and Newborn Hospital, Lusaka

WOMEN AND NEWBORN HOSPITAL, LUSAKA

Looking back on the five-year journey, filled with both challenges and milestones, we feel a profound gratitude for the opportunity to be part of a project with such significance. The WOMAN-2 trial is more than research; it symbolizes collaborative effort, a commitment to global health, and the pursuit of life-saving knowledge.

Esmart, a trial collaborator, shared her experience, emphasizing the need for detail-oriented teamwork and highlighting the enthusiastic women participating in the study. Collaboration with the CTU was impressive, resulting in high-quality data and a seamless transition from recruitment to closeout.

Chibesakunda, another dedicated collaborator, stressed the pivotal role of communication in the WOMAN-2 trial, and that collaborative communication among research assistants ensured accurate data collection. Maintaining open lines of communication with the PIs was vital for resolving queries, managing supplies, and ensuring smooth trial operations. Proper documentation, discipline, and unwavering dedication in the local team were fundamental to the trial's success. Additionally, according to Chibesakunda, a cooperative relationship with health workers in the labour ward improved efficiency and timely randomisation.





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Continued

Suwilanji, sharing his perspective as a collaborator, emphasized how firsthand experiences witnessing the deadly consequences of postpartum hemorrhage increased his empathy for maternal health. These experiences underscored the urgency in finding solutions to prevent PPH in anaemic women and ultimately save lives.



Members of the research team at Women and Newborn Hospital

During our journey with the WOMAN-2 trial, we've encountered many moments that have left an indelible mark on our hearts and minds. One such moment that stands out was when our team was acknowledged for uploading high-quality data to the database and responding to queries promptly. It was a testament to our team's dedication and efficiency.

Another memorable moment was when we had successfully randomized 600 participants following increased rates of recruitment. These moments, along with countless others, have made this journey unforgettable, and I'm proud to have been part of this incredible team.

In any long-term endeavor, unexpected occurrences are bound to happen, and the WOMAN-2 trial was no exception. We have sharpened our problem-solving skills and teamwork - locally and internationally and strengthened our resolve to see the trial through to its successful completion. We have learnt the importance of adaptability and resourcefulness in research.

This journey has been an extraordinary one, marked by dedication, resilience, and a shared commitment to improving maternal health worldwide. Our collaborative efforts have been nothing short of remarkable.

DR MWANSA KETTY LUBEYA, PRINCIPAL INVESTIGATOR





EXPRESSING OUR SINCERE GRATITUDE FOR THE
ENTIRE WOMAN-2 TRIAL TEAMS. YOUR
UNWAVERING COMMITMENT, DEDICATION, AND
PERSISTENCE THROUGHOUT THE COURSE OF THE
TRIAL HAS BEEN INSPIRATIONAL, AND YOUR
CONTRIBUTIONS HAVE BEEN INVALUABLE.

THANK YOU!

