Dear Friends

Welcome to the Sixth issue of the AIMS newsletter.

In this month’s issue hear all about how we are now randomising in all sites. Pakistan has joined the other sites in recruiting patients. Pakistan we are hoping to visit you soon!

The AIMS Team UK have recently returned from a visit to Tanzania...see the snaps on page 3. In the next newsletter hear all about our trip to Malawi.

The AIMS trial team UK continue to be amazed by the efforts that our team members go to ensure that the study is progressing well. This month hear about another team member that has gone above and beyond her call of duty for AIMS!
The AIMS Team
Welcome New Members

Ifakara Health Institute
Sister Halifa
Sister Makundi

Aga Khan University
Dr. Rabia Raheel
Dr. Reeta Vedwiyas
Dr. Momna Khan
Mr. Imran Ahmed
Mr. Najeeb Rahman

Randomisation Rankings

GOLD
Malawi 520

SILVER
Uganda 144

BRONZE
Pakistan 53

RUST
Tanzania 37

Sites Status Quo

Malawi are headlining with 520 randomisations. Great Work Dr Mhango, Theresa & Agatha

Uganda is following with 144 randomisation. Good work Dr Otim, James & Jane Francis

Our 3 sites in Pakistan have 53 randomisations. Thanks Dr Qureshi, Dr Iffat, Humera, Dr Rafiq, Dr Khan, Dr Rabia, Dr Noureen & Dr Reeta.

And finally our 2 sites in Tanzania have 37 randomisations...however, watch this space...exciting things are happening in Tanzania...watch out team, they will be hot on your heels soon! Thanks Dr Mbaruku, Dr Chibwana, Dr Ulimwengu, Beatus & Jimmy.

WATCH OUT FOR TANZANIA BIG THINGS ARE HAPPENING HERE!
A little birdie told me that Tanzania is moving one of its sites...is this true? Is the AIMS Trial going to be recruiting in the capital...Dar es Salaam? Wait and see in the next edition.....!
My name is Humera Ismail; I am the research Specialist for the AIMS Pakistan site. I have Seven years’ experience in research at Aga Khan University Hospital, Karachi, Pakistan. I was a part of many clinical trials and funded research projects conducted in AKUH. I did Masters in International Relation in 2008. I recently did my Master in Epidemiology and Biostatistics from Dow University of Health Sciences, Pakistan. I plan to do PhD Epidemiology in near future. I have organized seminars and also worked as a conference coordinator in National conference on Maternal and Child Health.


I am enthusiastic to be the part of the AIMS trial team. I find my job very challenging, exciting and rewarding because it’s been said that Research Specialist is the heart and soul of the research study and it’s us who carries forward the research goals, thereby playing a significant role in the success of the research study. As a Research Specialist I get to learn about the compounds being administered to the patients, I also get to know not only about the patient’s health but many other aspects of their lives. It makes the difference between a successful trial and a failure.

Its Dr. Sarah Rafiq. After graduation from Dow university of health sciences I started to learn German. I have successfully completed 3 levels (B1) of German language course from Goethe institute Pakistan.

During my graduation period, I had been working in the research project at Aga Khan University hospital voluntarily for 1.5 years. Now, working in AIMS trial as a Research Associate since October 2014. Besides AIMS, I am working on different departmental Research projects.

Apart from studies, I like to travel as much as possible to explore the beauty and different opportunities for my career.

Hello, this is Dr Rabia Raheel; I have recently joined the AIMS team at AKUH as a Research Associate. I did my MBBS from Dow University of Health Sciences, Karachi in year 2005. I have four years’ experience of working in different reputable hospitals of Karachi as a Research Medical officer, which has helped me better understand the process of patient recruitment and also achieving the goals and targets required to maintain study timelines. I did my CCRP (Certified Clinical Research Professional) training from Krigger Institute in 2012. I find my role as a research associate rewarding by playing a key part in improving the lives of thousands of people. This might be stressful at times and requires a lot of responsibility because we are dealing with people’s lives. AIMS trial has given me a tremendous opportunity in taking part in the process of seeing a seminal idea through to fruition, whatever form the final product takes. The process of taking part in this research study provides intellectual stimulation. I got an insider’s view of how knowledge gained from clinical studies could ultimately change the treatment for a condition.

I am Dr. Naureen Anjum. I did my MBBS from Bolan Medical College Quetta and then started my residency in Obstetrics and Gynaecology initially from Liaquat National Hospital for 1 year and then from Ziauddin university Hospital. I did FCPS in Obstetrics and Gynaecology from CPSP, Pakistan. My expertise apart from my clinical work is in research. I had completed a study on “Maternal and neonatal outcome in Obstetric Cholestatis–A comparison between early and late term deliveries”. I also worked as team leader on a quality project on “Prevention of Hospital Acquired MRSA infection in Nursery”. This project was selected for poster presentation on World Quality Day in AKU in Nov last year. Apart from these I am working on three other research papers that are: 1. Is meconium a risk factor for maternal postpartum infection? A prospective cohort study in low risk term pregnancy at secondary care hospital. 2. Pregnancy Outcomes of patients with ultrasound indicated and history indicated Mc Donald cervical cerclage. This trial will bring a major change in practices of gynaecologists who are prescribing antibiotics to every patient who undergoes for surgical evacuation of products of conception even when it is not needed. Moreover we have not seen any undesirable effect of this trial up till now in our patients.
Hello! I’m Agatha Chirwa, Clinical officer by professional, currently studying Bachelor of Science in Obstetrics and Gynecology at College of Medicine- University of Malawi.

A bit about me: I am a trusted, patient focused and experienced clinician with a long history of serving patients by successfully diagnosing, treating and also managing their illnesses and diseases.

I am easy going by nature and able to get along with other healthcare professionals and also senior managers. I have experience of working normal hours and also providing out of hours and weekend cover.

I am able to deal sympathetically with sensitive circumstances. I keep up to date with the latest treatments, medicines and surgical developments. I have a willingness to accept responsibility. I am experienced in working in a pressurized environment. I have excellent team leading and organizational skills. I have an ability to prioritize workloads during busy periods.

My thoughts on AIMS: I enjoy working in this research, because I acquire new knowledge every day, at the same time helping patients and building good relationship with them.

This is my first exposure to research field, I feel so lucky that it is in my field of Obstetrics and Gynecology.

It is my hope that this research will answer a long debate which has been there in medicine on the use of prophylactic antibiotics in miscarriages.

Thank you Agatha!
Q: ‘If I use only emergency randomizations will it be a problem?’
A: **YES**! This could create an imbalance in minimization between sites. **Please try to make sure emergency randomization is kept strictly for emergencies**

Q: ‘Should I file copies of the lab reports in the patient CRF folders?’
A: This is **not a requirement** for AIMS, however **many sites do** file them in the patient CRFs as there is not a system to trace such reports once the hospital notes are archived.

Q: ‘I have randomized a patient but no pack numbered has been given on the database’
A: Contact the trial coordinator. All of the remaining packs may have been allocated to the other arm of the trial. This usually occurs when only a few packs are remaining at the clinic store for randomization. More packs need to be added to the store and added on the database under the ‘transfer IMP’ tab, as available for randomization. Please inform Amie if this issue. See Flowchart 4a ‘IMP unavailable’ for guidance.

Q: ‘The patient does not have a phone or a personal phone number that I can call her on’
A: Is the patient able to provide a phone number of a relative or friend that she is in close communication with e.g. Sister or Neighbor

Q: ‘I want to practice using the database. Is this possible?’
A: **Yes** AIMS has a test database. You can enter as many pretend patients as you wish. [www.medscinet.net/AIMSTest/](http://www.medscinet.net/AIMSTest/)

The log in details are: User name: aimstest  Password: aims

Q: ‘A patient wants to take part in the trial but cannot return for the follow up appointment. Can she be included?’
A: No. It is essential that patients return for follow up. This is the only true way of assessing the primary outcome. Patients that do not return are classed as lost to follow up.’

Q: ‘When should I perform a white cell count?’
A: When one or more of the following symptoms is reported: UTERINE TENDERNESS, PURULENT VAGINAL DISCHARGE or if the patient has a temperature above 38.0 oC

Q: ‘If a white cell count has already been taken at a previous appointment and the patient has one or more symptom again should I repeat the white cell count?’
A: Yes. A white cell count should be taken at every appointment when the patient has one or more symptom. If the patient is an inpatient and has one or more symptoms daily, this will require daily white cell counts. A white cell count should be taken every day that the patient has one or more of the specified symptoms.

Q: ‘The patient did not return for follow up until 30 days after the surgery. Should I still complete her assessment?’
A: Yes. Although the participant will be classed as lost to follow up if she is assessed after day 28 post surgery, it is still important to conduct and record this assessment as this data will be analyzed in a further analysis.

Q: The participant declined to take the medication after being randomized. What should I do?’
A: The participant should be followed up as per protocol, as if the participant had taken the medication. Participants will be analyzed on an intention to treat basis so it is important that she is followed up as normal.

Q: ‘If a participant uses multiple methods of transport to get to the hospital, which method should I select on form 1?’
A: Select the method of transport that the participant used for the greatest amount of time during the journey.