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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADJUST</td>
<td>Antimalarial Dose Justification and Tolerability</td>
</tr>
<tr>
<td>AMARI</td>
<td>African Mental Health Research Initiative</td>
</tr>
<tr>
<td>ART</td>
<td>Anti-Retroviral Therapy</td>
</tr>
<tr>
<td>BMP</td>
<td>Blantyre Malaria Project</td>
</tr>
<tr>
<td>BDS</td>
<td>Births Defects Study</td>
</tr>
<tr>
<td>CCGP</td>
<td>Case Report Form Completion Guidelines</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and prevention</td>
</tr>
<tr>
<td>CEBHA+</td>
<td>Collaboration for Evidence Based Healthcare and Public Health in Africa</td>
</tr>
<tr>
<td>CHAIN</td>
<td>Childhood Acute Illness and Nutrition Network</td>
</tr>
<tr>
<td>COM</td>
<td>College of Medicine</td>
</tr>
<tr>
<td>CPD</td>
<td>Continuous Professional Development</td>
</tr>
<tr>
<td>COSYST-MNCH</td>
<td>Community Systems Strengthening for equitable Maternal Newborn and Child Health</td>
</tr>
<tr>
<td>CRF</td>
<td>Case Report Form</td>
</tr>
<tr>
<td>CTU</td>
<td>Clinical Trials Unit</td>
</tr>
<tr>
<td>DFID</td>
<td>Department for International Development</td>
</tr>
<tr>
<td>DMU</td>
<td>Data Management Unit</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>DP:</td>
<td>Dihydroartemisinin–Piperaquine</td>
</tr>
<tr>
<td>DREAMS:</td>
<td>Determined, Resilient, Empowered, AIDS-free, Mentored and Safe</td>
</tr>
<tr>
<td>DVS:</td>
<td>Data Validation Specifications</td>
</tr>
<tr>
<td>EDC:</td>
<td>Electronic Data Capture</td>
</tr>
<tr>
<td>EDCTP:</td>
<td>European and Developing Countries Clinical Trials Partnership</td>
</tr>
<tr>
<td>GCDMP:</td>
<td>Good Clinical Data Management Practice</td>
</tr>
<tr>
<td>GCP:</td>
<td>Good Clinical Practices</td>
</tr>
<tr>
<td>GIZ:</td>
<td>Gesellschaft fur international Zusammenarbeit</td>
</tr>
<tr>
<td>ICGHP:</td>
<td>International Conference on Harmonization of Good Clinical Practice</td>
</tr>
<tr>
<td>IMPROVE:</td>
<td>Improving Pregnancy Outcomes with Intermittent Preventative Treatment in Africa</td>
</tr>
<tr>
<td>IKMC:</td>
<td>Immediate Kangaroo Mother Care</td>
</tr>
<tr>
<td>INORMUS:</td>
<td>International Orthopaedic Multicentre Study in Fracture Care</td>
</tr>
<tr>
<td>IPTP:</td>
<td>Intermittent Preventive Treatment in Pregnancy</td>
</tr>
<tr>
<td>JHP:</td>
<td>Johns Hopkins Project</td>
</tr>
<tr>
<td>HBC:</td>
<td>Home Based Care</td>
</tr>
</tbody>
</table>
MAC: Malaria Alert Centre

MEIRU: Malawi Epidemiology and Intervention Research Unit

M-HIRST: Malawi HIV Implementation Research Scientist Training Program

MLW: Malawi Liverpool Wellcome Trust Clinical Research Program

NAC: National Aids Commission

NACCAP: Netherlands-African partnership for capacity development and clinical interventions against poverty-related diseases

NIH: National Institute of Health

NORAD: Norwegian Agency for Development Cooperation

PI: Principal Investigator

PMC: Post-discharge Malaria Chemoprevention

RDC: Research Dissemination Conference

RMU: Risk Management Unit

RSC: Research Support Centre

SARIMA: Southern African Research and Innovation Management Association (SARIMA)

SECURE: Strengthening Capacity to Use Research Evidence
SHARE: Sanitation and Hygiene Applied for Equity Survey of Health Ageing and Retirement

SOP: Standard Operating Procedure

SP: Sulfadoxine-Pyrimethamine

SUGARFACT: Sugar Requirements for African Children Trial

TSA: Technical Service Agreement

TRUE: Training and Research Unit of Excellence.

UNFPA: United Nations Population Fund

YRF: Young Researchers Forum
RESEARCH SUPPORT CENTRE’S PROFILE

College of Medicine’s Research Support Centre was established in 2006 through Netherlands-African partnership for Capacity development and Clinical interventions Against Poverty-related diseases (NACCAP) funding. Over the years, the Research Support Centre (RSC) has grown to several units namely Data Management, Training Coordination, Marketing and Communications, Clinical Trials, Risk Management and Grants Management. Grants Management Unit comprises the following sections: Grants Compliance, Grants Accounting, Human Resource Management and Procurement.

RSC is under the Dean of Postgraduate Studies and Research. The centre is located in the second floor of Chimutu Building at College of Medicine’s Mahatma Gandhi Campus in Blantyre, Malawi.

Vision and Mission Statement

The vision of RSC is to become a one-stop centre of excellence for grants management and research support to ensure conduct of world-class research. The centre’s mission is to create and maintain a stimulating environment at COM for generation of new knowledge and high impact research through research leadership development, delivery of research training and mentorship programmes, and provision of research support services.
Research Support Centre Staff

**Director**
Dr Cecilia Maliwichi-Nyirenda

**Administrative Assistant**
Chiku Sambo

**Grants Compliance Officer**
Palinji Mungoni

**Procurement Assistant**
Bright Msukwa

**Grants Management Intern**
Asante Makuta

**Office Assistant**
Martha Kayamba
Data Manager
Vincent Samuel

Assistant Marketing and Communications Officer
Sam Chikuni

Data Officer
Amos Msopera

Senior Clinical Research Associate
Atusaye Ngwira

Training Coordinator
Richard Mmadi

Human Resources Officer
Laura Kamanga
Data Management Intern
Joseph Misyenje

Data Management Intern
Cecilia Mdoka

Data Management Intern
Fred Maulidi

Data Management Intern
Miles Innussa
DIRECTOR’S REPORT

Major Strategic Thrusts

2018 was another successful year in the history of Research Support Centre. Finally, the centre launched its strategic plan and business plan. The launch took place alongside the 22nd Research Dissemination Conference of the College of Medicine on 23rd November 2018. The two plans define the pathway through which RSC will move in the next 5 years.

Some of the highlights in the two plans are as follows:

- Need for RSC to become a one-stop-centre in grants management and research support
- Improvement in operational effectiveness, efficiency and visibility of RSC
- Development of stakeholder engagement mechanisms
- Funding model for RSC

In addition, the vision and mission for the centre have been revised to align them to the stipulated mandate and roles. The new vision is “to become a one-stop centre of excellence for grants management and research support to ensure conduct of world-class research” while the new mission is as follows: “to create and maintain a stimulating environment at the CoM for generation of new knowledge and high impact research through development of research skills and leadership development”.

Over the years RSC has been operational, it did not have values. Through the development of the Business and Strategic Plans, the following values have been developed: efficiency, accountability and responsiveness, transparency, professionalism, Umunthu/humanity, commitment to service, teamwork and collegiality, integrity, passion, and excellence.

![Launch of RSC’s Strategic and Business Plans](image)

**Figure 1: Launch of RSC’s Strategic and Business Plans**

RSC continued providing support to upcoming researchers through the Young Researchers Forum (YRF). The centre continued to host and provide strategic guidance to YRF. In addition, RSC provided a platform to a young researcher through its 50th Research Seminar where the researcher made a presentation on how a young scientist can become relevant in Malawi.
Noting that there are few women researchers in the health sector, RSC made a decision to support Women in Infectious Diseases Health Research Network in Malawi (WIDREM), a grouping of women who have mobilised themselves to climb the research ladder. RSC opened its doors and provided office space to the network. In addition, RSC provided a platform to enable the women to tell their story through RSC’s 51st Research Seminar.

**Strengthening of RSC and research environment**

In its aspiration of ensuring efficient service provision to researchers at COM, research affiliates and beyond, RSC continued to strengthen itself. For the first time since its inception, RSC established Human Resource Section under Grants Compliance Unit. Services provided by the Human Resource section include facilitating recruitment of research staff, drafting and managing Technical Services Agreements (TSAs), and providing guidance to research staff with respect to human resource–related procedures, regulations and conditions of service.

RSC made advances in the development of the Electronic Grants Management System. In 2018, the system was showcased to different stakeholders including College of Medicine management. RSC is happy to report that management has finally approved the system. The system, which will be rolled out soon, has the following modules: contract management, administrative grant review, scientific review and human resource management. The system will go a long way in strengthening grants management as it will enable grant holders to know, in real-time, the financial status of their grants hence facilitate decision-making.
In the same vein of strengthening grants management, a strategic decision was made with respect to Grants Accounting function. In 2018, the Grants Compliance Officer assumed the role of providing direct supervision to grants accountants.

In the 2017 Annual Report of the RSC, we mentioned that we were planning to set up a Marketing and Communications Unit. We are happy to report that this unit is now functional. Consequently, RSC now has the ability to raise its visibility through various communication channels including social media.

2018 Grants Portfolio

In 2018, RSC managed 69 active grants valued at $55,538,260. Major funding sources for these grants were National Institutes of Health (NIH), European and Developing Countries Clinical Trials Partnership (EDCTP), World Health Organisation (WHO) and Glaxo Smith Kline (GSK). Of the 69 grants, 23 were awarded in 2018 alone.

Out of the new grants, Bill and Melinda Gates Foundation funded the highest number of grants (four). Medical Research Council (MRC) funded three grants while EDCTP, GIZ, GSK and NIH funded two grants each. Some of the funding organisations that funded the new grants included African Academy of Science, Africare, Children’s Investment Fund Foundation, Durham University, Scottish Government, Tampere University and University of British Columbia. These funded one grant each.
Research Dissemination Conference

RSC coordinated COM’s 22nd Research Dissemination Conference which was under the theme ‘Health Research for Preventing Illness and Improved Health Services in Malawi’. As usual, the conference comprised oral and poster presentations, John Chiphangwi Lecture, Science Cafe and Research Open Day.

The John Chiphangwi lecture was delivered by Professor John Kumwenda of COM’s Medicine Deanery. The 2018 Science Café was titled ‘Anti-microbial resistance: who is to blame’. The panellists at the café were Ms. Aggie Chitedze (Pharmacist at Mwaiwathu Private Hospital), Honourable Juliana Lunguzi (Chairperson for Parliamentary Committee on health), Dr Nick Feasy (Researcher at Malawi-Liverpool Wellcome Trust Clinical Research Program, and Dr Collins Mitambo (Ministry of Health).

The Conference was a huge success in different angles. In terms of abstracts, there was an increase of 50% in abstracts submitted in 2017. In addition, the number of oral presentations tripled since 2016. There were 19 parallel sessions in 2018 as compared to 16 for 2017. We also saw increased demand for sponsored sessions (4 in 2018 versus 1 in 2017). The conference was also attended by international researchers coming from Europe, USA and Australia.

Furthermore, there was overwhelming support from corporate world. These include First Capital Bank, TNM, Standard Bank, AMG Global, National Bank and Ernest & Young.
In line with COM’s effort of stimulating research culture among upcoming researchers, the conference had a stand-alone session and award category dedicated to Young Researchers Forum.

To ensure that delivery of the Research Dissemination Conferences is of high standard, RSC through partnership with University of Melbourne, engaged a Master of Public Health Student from University of Melbourne’s School of Population and Global Health who conducted an evaluation of the 2018 conference. The evaluation report contains useful insights that will improve delivery of upcoming conferences.

**Raising visibility of RSC**

In 2018, RSC had the opportunity to showcase its activities within Malawi and beyond. In the former, it made exhibitions at African Union summit, COM’s Research Dissemination Conference and TB Networking meeting. The summit and networking event took place in Lilongwe in November 2018. The centre also participated at the Southern African Research and Innovation Management Association (SARIMA) annual meeting where it shared its experiences with research management institutions in the region.

2018 was another exciting year because we continued to receive visitors who wanted to learn about RSC. One of the institutions that visited RSC included Lilongwe University of Agriculture and Natural Resources (LUANAR).
We were also privileged to receive Dr. Joann Schmidt (the first Director of RSC) on 19th of February 2018. She was impressed to see how RSC has grown from a small centre to a big centre with several units.
Prospects for 2019

Now that the long-awaited Business and Strategic Plans have been launched, RSC is confident that it will undertake its activities in a structured way. Consequently, the centre will begin to attain the strategic goals outlined in the two plans i.e. provide reliable and efficient technical and administrative research and consultancy support; raise visibility; and ensure effective and efficient governance and administration, and adequate and sustainable funding.

RSC anticipates to roll out the Electronic Grants Management System. This will undoubtedly strengthen grants management in the college.

RSC is planning to set up a manuscript writing unit. Through this unit, RSC will be providing biostatistics-related services to students, faculty and researchers within Malawi and beyond.

Appreciation

I am grateful to College of Medicine management, Dean for Postgraduate Studies and Prof Rob Moodie for the untiring support they provide to RSC. I am also thankful to COM faculty, research affiliates and RSC’s stakeholders for walking with RSC in 2018. Thanks very much for the insights provided and seeking our services.
I would also like to thank RSC staff for the commitment and hard work they have been providing. Without you, we would not have reached where we are today. Let me also thank COM’s Assistant Finance Officer 1 (Mr Samson Kalulu), COM’s Marketing and Communications Officer (Mrs Esther Masi) and COM’s Director for Resource Mobilisation and Investments (Mr George Namandwa) for always being there for RSC.

TRAINING COORDINATION UNIT

Research Support Center trainings

Over the years The Research Support Centre has been committed to making sure that its stakeholders receive relevant, up to date trainings related to health. The centre, through its Training Coordination Unit, provides trainings based on the Training Needs Assessments it has undertaken over the years. In addition, the centre delivers training courses as per requests received from the stakeholders.

In 2018, the Training Coordination Unit coordinated 24 courses including writing winning proposals, Good Clinical Laboratory Practices, Good Clinical Practices, Introduction to Biostatistics, Monitoring and Evaluation, Mentorship and Leadership, and Publishing Connect Authors work.
Furthermore, the unit in liaison with COM Deanery of Medicine and College of Medicine Education Training Office (COMETO) coordinated several Continuous Professional Development (CPD) courses such as Diabetes Management, Listeriosis and Reading Common Arrhythmias.

100 participants were trained of which 64% were females. The participants came from different organizations including College of Medicine, Malawi Liverpool Welcome Trust Clinical Research Programme, John Hopkins Project, Queen Elizabeth Central Hospital, Mzuzu University, Malawi University of Science and Technology, The Polytechnic, Dignitas International, Malawi Epidemiology and Intervention Research Unit, Baobab Trust, Malaria Alert Centre, as well as the Polytechnic.

**Research Seminars**

The Training Coordination Unit coordinates research seminars at least once each and every month on Wednesdays or Fridays. These seminars aim at providing researchers with a platform to disseminate research findings. The seminars also offer an opportunity to students and upcoming researchers to present their work and get feedback from renowned researchers. Primarily, the research seminars were established to cater for COM’s faculty, students and research affiliates. However, in
2018 we saw a rising interest from international researchers who presented at RSC’s seminars.

In 2018, the Training Coordination Unit facilitated ten research seminars, making the total number of seminars hosted by RSC 51. The 10 research seminars were as follows (Table 1).

Table 1: RSC Research Seminars held in 2018

<table>
<thead>
<tr>
<th>Date</th>
<th>Title of Seminar</th>
<th>Name of Speaker</th>
<th>Speaker’s Institution</th>
<th>Number of Attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td>9th Feb 2018</td>
<td>Translation science in tuberculosis and HIV Infections</td>
<td>Professor David Russell</td>
<td>Cornell University, USA</td>
<td>45</td>
</tr>
<tr>
<td>17th April 2018</td>
<td>35 Years of HIV History: An update on advances and future directions in prevention and treatment</td>
<td>Professor Jay Levy</td>
<td>University of California, San Francisco</td>
<td>200</td>
</tr>
<tr>
<td>20th April 2018</td>
<td>EPCR binding PfEMP1 are linked to brain swelling in Malawian children with cerebral malaria</td>
<td>Dr Annie Kessler</td>
<td>New York University</td>
<td>50</td>
</tr>
<tr>
<td>11th May 2018</td>
<td>Understanding the importance of academic; why do we need to publish</td>
<td>Miss Hoglah Dasari</td>
<td>Elsevier</td>
<td>40</td>
</tr>
<tr>
<td>1st June 2018</td>
<td>The validation of the PHQ-9 in non-</td>
<td>Mr Michael Udedi</td>
<td>College of Medicine</td>
<td>45</td>
</tr>
<tr>
<td>Date</td>
<td>Title</td>
<td>Presenter</td>
<td>Institution</td>
<td>Page</td>
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</tr>
<tr>
<td>29th June 2018</td>
<td>The quality research agenda</td>
<td>Dr. Andrew Likaka</td>
<td>Quality Management Department, Ministry of Health</td>
<td>55</td>
</tr>
<tr>
<td>14th September 2018</td>
<td>Understanding Molecular Mechanisms underlying Mycobacterium tuberculosis persistence</td>
<td>Mr Victor Ndlovu</td>
<td>Malawi Liverpool Wellcome Trust</td>
<td>40</td>
</tr>
<tr>
<td>21st September 2018,</td>
<td>The complexities of M. tuberculosis infection revealed in non-human primate models</td>
<td>Dr JoAnne L. Flynn</td>
<td>University of Pittsburgh School of Medicine Pittsburgh, Pennsylvania, USA</td>
<td>50</td>
</tr>
<tr>
<td>28th November 2018</td>
<td>How can a young science minded person become relevant in Malawi?</td>
<td>Dr. Titus Divala</td>
<td>College of Medicine</td>
<td>100</td>
</tr>
<tr>
<td>5th December, 2018</td>
<td>Advancing women in health research in Malawi; a national platform</td>
<td>Dr. Atupele Kapito Tembo</td>
<td>College of Medicine</td>
<td>65</td>
</tr>
</tbody>
</table>
Translation Services

RSC provides translation services in Chichewa, English, Sena, Tumbuka and Yao languages. The unit, in liaison with RSC’s Marketing and Communications unit, provided translation services to four studies.

Additional Services

The unit continued to provide administrative support to the Malawi HIV Implementation Research Scientist Training Program (M-HIRST) which is focusing on increasing the capacity of young researchers in HIV Implementation Research. The Unit is also part of the COM/MLW training committee hence it works closely with MLW’s Training Coordination office.

Plans for 2019

The unit plans to increase the number of courses by at least 20%. To achieve this, the unit will develop a comprehensive marketing plan in liaison with the office of the Assistant Marketing and Communications Officer.

The unit further intends to continue with its efforts to get the RSC courses accredited by relevant bodies.
RSC’s Marketing and Communications Unit is responsible for raising the visibility of College of Medicine’s research enterprise including Research Support Centre. The Unit is expected to raise RSC’s portfolio through the centre’s website (www.rsc.medcol.mw), newsletter and use of social media. Below are some of the activities the unit has been involved in the year 2018.

**Newsletters**

The Marketing and Communications Unit is responsible for coming up with quarterly newsletters which showcase research-related activities of the college and RSC-specific activities, upcoming research activities and funding opportunities. Electronic copies of newsletters are posted on RSC’s website and are also sent through email to RSC’s contacts. Hard copies are shared with strategic offices within the college.

**Website**

In 2018, a few changes were made to the website. A new tab which outlines products and services offered by RSC was introduced. This tab is titled ‘RSC Services’. Another tab ‘Subscribe to our newsletter’ was also introduced. This tab allows visitors to subscribe and receive our quarterly newsletters through email. Social media usernames were also added under *Contact Us.*
Social Media

In 2018, the unit revamped social media accounts for RSC (Facebook, LinkedIn, Twitter and Instagram) through constant updates and engaging the social media audiences. As at now, RSC Facebook page has 858 followers, LinkedIn has 878 connections, Twitter has 136 followers and Instagram has 51.

The following are the usernames for the social media pages:

Facebook: Research Support Centre
Twitter: @com_rsc
Instagram: com_research_support_centre
LinkedIn: https://www.linkedin.com/in/researchsupportcentre/

Funding and Training Opportunities

The unit is responsible for identifying and sending out funding opportunities. A total of 60 funding opportunities were sent out. 90% of these were extracted from the National Institute of Health research links.

Plans for the Year 2019

The unit plans to undertake several marketing activities in order to increase the visibility of Research Support Centre and College of Medicine.
Some of the plans are:

(a) Re-designing of the RSC website

(b) Explore possibility of having an RSC open day.

(c) Intensify use of email marketing and social media boosting.

DATA MANAGEMENT UNIT

The Data Management Unit (DMU) is responsible for provision of data management services. DMU strives to maintain Good Clinical Data Management Practice (GCDMP) which is the industry standard to ensure implementation of high quality clinical data management processes. Additionally, DMU provides the following services: Case Report Form (CRF) design, development of CRF Completion Guidelines (CCGs); database development, development of Windows-based, web or Mobile Electronic Data Capture (EDC) system; data entry, data cleaning, data analysis, data integration.

The unit also provides the following training courses: Introduction to Biostatistics using Stata, Advanced course in statistical analysis, Clinical Research Data Management, Electronic Data Capturing Systems.
In 2018, the unit carried out the following activities:

**Short Course Trainings**

The unit offered the following short courses:

1. **Introduction to Data Analysis using Stata**

   This course aimed at equipping participants with a wide variety of statistical concepts that can be applied to a wide range of datasets. A number of concepts like descriptive statistics, statistical testing to statistical modelling were discussed. The course was attended by 17 participants.

2. **Introduction to Clinical Data Management**

   The aim of the training was to equip participants with skills that will help them manage clinical data effectively. This course tackled various concepts such as introduction to data management, how to design data collection tools, how to develop databases, data storage, data entry and audit.

**Provision of Data Management Services to Research Studies**
The unit provided data management to the following studies:

1. **Birth Defects Surveillance Study in Malawi, funded by Centres for Disease Control and Prevention (CDC) through Nation AIDS Commission (NAC)**

The overall purpose of the study is to: 1) implement a birth defects surveillance system in four hospitals in Malawi namely Bwaila Hospital (Lilongwe), Queen Elizabeth Central Hospital (Blantyre), Mangochi District Hospital (Mangochi) and Ntcheu District Hospital (Ntcheu) and 2) to conduct a nested case-control study to examine the association of maternal use of antiretroviral treatment (ART) and birth defects.

The Data Management Unit was responsible for designing of the data collection tools, development of the data management system, data management, cleaning and analysis.

2. **Sugar Requirements in Febrile African Children Trial (SugarFACT), funded by Karolinska Institutet, Sweden**

The main objective of the study is to compare the difference in outcomes for children admitted to hospital due to an acute infection with low-glycaemia who are treated (intervention) and not treated (control) with dextrose and to describe the determinants of low-glycaemia.
The Data Management Unit designed the data collection tools, provided training on data management concepts, undertook data collection, developed the data management system, managed the data, and cleaned and prepared the datasets for analysis.

3. Gender Equality and Reproductive Health Improvement (GERHI) Study, funded by World Health Organization, UNFPA and Johns Hopkins University

The objective of this study is to develop instruments that assess gender norms about relationships in the Malawi context while enabling comparison and interpretation across the different cultural settings of the other nine GEAS sites around the world.

The Data Management Unit was responsible for design of the data collection tools, training on data management concepts such as standard operating procedures, data collection, development of the data management system, data management, cleaning and preparing the datasets for analysis.

4. Determined, Resilient, Empowered, AIDS-free, Mentored and Safe initiative Women (DREAMS) Implementation Science Survey

The overall study goal is to assess individual and community risk factors for HIV infection among Adolescent Girls and Young Women (AGYW) and the impact of the DREAMS initiative in reducing the risk factors.
The Data Management Unit provided the following services: design of the data collection tools, training on data management concepts such as standard operating procedures, data collection, development of the data management system, data management, cleaning and preparing the datasets for analysis.

5. Sanitation and Hygiene Applied Research for Equity (SHARE) Project

The main objective of the study is to measure the relative impact of WASH and food hygiene interventions on diarrhoeal disease in children under 5 in Chikwawa District in Southern Malawi.

The Data Management Unit was responsible for design of the data collection tools, training on data management concepts such as standard operating procedures, data collection, development of the data management system, data management, cleaning and prepare the datasets for analysis.

6. Accuracy and Reliability of XRapid Digital Malaria Microscopy For Efficient and Effective Management of Malaria (XRapid Study)

The purpose of the study is to facilitate the introduction of xRapid, a revolutionary malaria test, in Malawi. It is expected that the project will enable accurate diagnosis of Malaria in pregnant women and under-five children thereby promoting effective case management and reducing malaria related morbidity and mortality.

Since xRapid uses real time data, it will also enable the health management team from the targeted health facilities to monitor cases of Malaria versus the utilisation of malaria related drugs and supplies. Also, the project will help restore the trust of
patients/guardian/ people towards the case management systems for Malaria thereby promoting the adherence and completion of Malaria dosage for the patients.

Data Management Unit provided the following services to the study: designing of the data collection tools, training on data management concepts such as standard operating procedures, data collection, development of the data management system, data management, cleaning and preparing the datasets for analysis.

7. Immediate Kangaroo Mother Care (iKMC) Study

The aim of this trial is to evaluate the safety and efficacy of continuous Kangaroo Mother Care (KMC) initiated immediately after birth for neonates with birth weight from 1.0 to <1.8 kg compared to the current recommendation of initiating continuous KMC after stabilization.

The Data Management Unit was responsible for designing of the data collection tools, training on data management concepts such as standard operating procedures, data collection, development of the data management system, data management, cleaning and prepare the datasets for analysis. However, the preparation of the dataset is yet to take place as the study is still in progress.
8. Improving Pregnancy Outcomes with Intermittent Preventive Treatment in Africa (IMPROVE) Study

The overall aim of the study is to provide WHO with definitive evidence to determine whether Intermittent Preventive Treatment in pregnancy (IPTp) with Dihydroartemisinin-Piperaquine (DP), alone or combined with Azithromycin (AZ), is a viable alternative to the current strategy of IPTp with Sulfadoxine-Pyrimethamine (SP) in order to improve the outcome of pregnancies in areas with high levels of parasite resistance to SP and moderate to high malaria transmission and prevalence of STIs/RTIs in East and Southern Africa.

The Data Management Unit is responsible for design of the data collection tools, training on data management concepts such as standard operating procedures, data collection, development of the data management system, data management, cleaning and prepare the datasets for analysis. Preparation of the dataset is yet to take place as the study is still in progress.

9. Evaluation of RTS,S/AS01 Malaria Vaccine Implementation Program (MVIP) through the routine health systems in Malawi.

The evaluation will assess the vaccine’s impact on mortality, vaccine’s safety and the programmatic feasibility of delivering RTS,S/AS01 with new immunization contacts, including fourth dose in the second year of life.
The Data Management Unit was responsible for provision of advice in terms of sample size calculation, data collection tools, and data management system to be employed in the study.

10. Decreasing Dehydration Risk from Diarrhea in Kids in Malawi (DRINK Malawi)

The overall objective of this study is to determine if treatment of children 6 months to 5 years of age with mild and moderate dehydration treated with the test ORS produces equivalent or better health outcomes and economic benefits than those treated with the WHO recommended ORS.

The Data Management Unit designed the data collection tools, provided training on data management concepts, undertook data collection, developed the data management system, managed the data, and cleaned and prepared the datasets for analysis. Preparation of the dataset is yet to take place as the study is still in progress.

Other services provided

1. Research Clinics

In 2018, the unit assisted faculty members, undergraduate and postgraduate students during proposal writing stage. Emphasis was on methodology, data management, and data analysis.
## 2. Maintenance of Research Directory for the College of Medicine

The unit continued to maintain College of Medicine research directory (researchdirectory.medcol.mw/). The directory unveils research expertise available in the college and its research affiliates.

### CLINICAL TRIALS UNIT

Clinical Trials Unit (CTU) facilitates quality and high standard by providing Clinical Trial/ Study monitoring services within Malawi, Southern African countries and beyond. The unit provides the following services: Good Clinical Practice training, Archiving of Essential study documents, and clinical trial pharmacy monitoring (in partnership with the Department of Pharmacy within the College of Medicine).

In 2018, CTU provided the following services:
Pre Site and Site Initiation Monitoring Visits

Clinical Trials Unit provided the tailor-made service to the following studies:

1. IPTp with dihydroartemisinin-piperaquine and azithromycin for malaria, sexually transmitted and reproductive tract infections in pregnancy in high sulphadoxine-pyrimethamine resistance areas in Kenya, Malawi and Tanzania: an international multi-centre 3-arm placebo-controlled trial - IMPROVE study.

The sites were Zomba Central Hospital, and Madziabango Health Centre, and Mpemba Health Centre in Blantyre.

2. Randomized controlled trial of the Effect of intraVenous iron on Anaemia in Malawian Pregnant women REVAMP study.

The sites were Zomba Central Hospital and Limbe Health Centre (Blantyre).

3. Aggressive Antipyretics In Central Nervous System Malaria: A Randomized-Controlled Trial Assessing Antipyretic Efficacy And Parasite Clearance (FEVER study)

The site was Queen Elizabeth Central Hospital (Blantyre).

Interim Monitoring Visits

The unit conducted interim monitoring visits for the following studies:

1. IPTp with dihydroartemisinin-piperaquine and azithromycin for malaria, sexually transmitted and reproductive tract infections in pregnancy in high sulphadoxine-pyrimethamine resistance areas in Kenya, Malawi and Tanzania: an international multi-centre 3-arm placebo-controlled trial -
IMPROVE study.

The sites were Mangochi District Hospital and Chikwawa District Hospital.

2. Investigating the determinants of low-glycaemia and evaluating the impact of treating low-glycaemia in children admitted to hospital with an infection in Malawi (SugarRFACt study)

Zomba Central Hospital and Queen Elizabeth Central Hospital (Blantyre) were the sites.

3. Treating Brain swelling Study (TBS study)

The site for the study was Queen Elizabeth Central Hospital (Blantyre).

4. Building the evidence base for acutely ill, undernourished children in limited resource settings – a prospective cohort study (CHAIN study)

The site was Queen Elizabeth Central Hospital.

Close Out Monitoring Visits

1. Malaria Chemoprevention with monthly treatment with dihydroartemisinin-piperaquine for the post-discharge management of severe anaemia in children aged less than 5 years in Malawi: A 3-year, single site, parallel-group, five arm cluster randomized trial of community versus health facility-based delivery mechanisms with or without mobile phone sms reminder.

The site was Zomba Central Hospital.
2. A Prospective Randomized Open-Label Study on the Efficacy and Safety of Intermittent Preventive Treatment in Pregnancy (IPTp) with Dihydroartemisinin-Piperaquine (DP) versus IPTp with Sulfadoxine-Pyrimethamine (SP) in Malawi.

The monitoring site was Machinga District Hospital.

Archiving services

RSC established an archive in 2018. To date, studies are utilizing the archive.

Clinical Trial Pharmacy Monitoring services

RSC works hand in hand with College of Medicine’s Pharmacy Department in the management of Clinical Trial Pharmacy. Specifically, RSC provides an oversight monitoring service. In 2018, RSC, in conjunction with Pharmacy Department, provided Clinical Trial Pharmacy Monitoring Services to IMPROVE Study.

Facilitation of ICH GCP training

Clinical Trials Unit delivered GCP e training to study nurses, researchers, clinicians, investigators, drivers and cleaners, and members of College of Medicine Research Ethics Committee and Pharmacy Medicines and Poisons Board. A total of 89 people were trained.
One-on-one consultation from study members and other potential clients

Ten Principal Investigators, 8 Study Coordinators and 5 students visited the Clinical Trials Unit. Services that were sought included Investigator Site File organization, Essential Document review and filing, Standard Operating Procedures review and planning review for Clinical Trial Site set up and management.

All in all, Clinical Trials Unit was able to provide services to clients to their satisfactory and most of them are willing to bring in more and new studies in future. As a result, the number of studies requesting clinical trial monitoring services has increased. We also registered request to monitor clinical trial in Lusaka, Zambia. Furthermore, the number of registrants to our GCP courses increased.

HUMAN RESOURCES UNIT

Research Support Centre’s Human Resources unit is responsible for recruitment and induction of staff, managing the issuing and termination of employment contracts, records Management, managing remuneration and rewards, managing staff training and development and all human resource-related activities. The focus is on Project staff at College of Medicine. The unit provides these services in liaison with the Human Resources Department of the college.
The unit is also responsible for coordinating Performance Management in RSC. To achieve this, the unit works hand in hand with Human Resources Department and college’s Business Partners.

In 2018, the unit provided the following services:

**Staff Recruitment**

The unit facilitated recruitment of staff in 23 projects. In total, 39 staff were recruited.

These were in different categories as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Staff hired</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Officers</td>
<td>6</td>
</tr>
<tr>
<td>Data Managers</td>
<td>1</td>
</tr>
<tr>
<td>Field Workers</td>
<td>9</td>
</tr>
<tr>
<td>Insectary Technicians</td>
<td>1</td>
</tr>
<tr>
<td>Research Nurses</td>
<td>9</td>
</tr>
<tr>
<td>Study Administrators</td>
<td>5</td>
</tr>
<tr>
<td>Study Physicians</td>
<td>0</td>
</tr>
<tr>
<td>Project Coordinators</td>
<td>4</td>
</tr>
<tr>
<td>Laboratory Technician</td>
<td>1</td>
</tr>
<tr>
<td>Scientific Administrator</td>
<td>1</td>
</tr>
<tr>
<td>Surveillance and Monitoring</td>
<td>1</td>
</tr>
<tr>
<td>Finance and Administration</td>
<td>1</td>
</tr>
</tbody>
</table>
Technical Services Agreements

The Unit facilitated the setting up of Technical Services Agreements (TSAs) for 14 studies. In total, 68 TSAs were set up.

All in all, the establishment of Human Resource Unit in RSC has helped in fast-tracking project-related recruitment process. In addition, the existence of the unit has made the setting up of TSAs efficient.
CONTACTS

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To get a copy of RSC’s Training Calendar, visit: http://www.rsc.medcol.mw/

To access COM’s Research Directory, visit us on:

http://researchdirectory.medcol.mw/

To access archiving services, send email to: rscarchiving@medcol.mw

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