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BLANTYRE HEALTH RESEARCH AND TRAINING TRUST (BHRTT)

**LIST OF FACILITATORS**

**NAME ADDRESS ORGANISATION**

1. Teresa Machai [Teresa.Machai@manhica.net](mailto:Teresa.Machai@manhica.net) CISM
2. Rodrigues Matcheve [rodrigues.matcheve@manhica.net](mailto:rodrigues.matcheve@manhica.net) CISM
3. Isaac Singini [SNGISA001@myuct.ac.za](mailto:SNGISA001@myuct.ac.za) BHRTT
4. J. Brew [joebrew@gmail.com](mailto:joebrew@gmail.com) ISGLOBAL
5. A.Nhacolo [Arsenio.Nhacolo@manhica.net](mailto:Arsenio.Nhacolo@manhica.net) CISM
6. Christine Toneatti [Christine.TONEATTI@ecrin.org](mailto:Christine.TONEATTI@ecrin.org) ECRIN
7. Rita Banzi (remote) rita.banzi@[marionegri.it](http://marionegri.it) …..
8. Rita Azevedo [**rita.azevedo@lygature.org**](mailto:rita.azevedo@lygature.org) ……..
9. Catarina Madeira [catarina.madeira@nms.unl.pt](mailto:catarina.madeira@nms.unl.pt) ECRIN
10. N. Kumwenda [nkumwend@icloud.com](mailto:nkumwend@icloud.com) BHRTT
11. Elizabeth Kampira [elkampira@yahoo.com](mailto:elkampira@yahoo.com) BHRTT
12. Treaser [treaseranderson@gmail.com](mailto:treaseranderson@gmail.com) BHRTT



**THE TESA DATA MANAGEMENT COURSE FACILITATORS’ BIOGRAPHIES**

**Christine Toneatti** MSc, MSc. She is the head of quality and information systems unit at ECRIN’s central Paris office, overseeing the quality system, managing risks and optimizing architecture, hosting, maintenance, access and security of ECRIN information systems. She has over 30 years of experience in biomedical research; initially as researcher and project manager in the field of infectious diseases, including involvement in drug and vaccine development programmes ranging from research and non-clinical development to clinical phases I to IV, and epidemiology. Since 2000, she provided leadership in the development and implementation of quality management systems in Good-X-Practice regulatory, research and ISO environments for various industrial companies (Wyeth, IPSEN, GSK) and academic organizations (ANRS, INSERM, Pasteur Institute). As international auditor, she coordinated and perform non-clinical, clinical, and information systems audits and hosted inspections by governmental agencies(EU, Japan). She has an MSc (Parasitology) and MSc, (Quality and Research Management, awarded) from Cranfield University, UK; she is ISO 27001:2013 certified and has got degrees in Statistics and Ethics.

** Isaac Singini BSc, MSC. He** is currently a PhD student at the University of Cape Town, South Africa. His research interests are in statistical modelling of longitudinal and survival data using new methods. He has over ten years’ experience managing data for multicenter clinical trials, he has also been involved in analyzing and reporting research data for multi-disciplinary studies. He has provided guidance in development of CRFs and SOPs for local studies. In 2009, he took up an honorary lecturing position at College of Medicine, University of Malawi and further in 2018 went on to lecture at University of the Western Cape and Stellenbosch University in biostatistics. In 2013 he, was accepted as a statistical intern at the Harvard School of Public Health, MA, USA under the supervision of Prof. Michael Hughes. He has an MSc (Medical Statistics) from the London School of Hygiene and Tropical Medicine, University of London, UK (2008) and a Bachelor of Science in Computer Science and Statistics from Chancellor College, University of Malawi.

 **Treaser Thomas BSC**. Treaser holds a BSC in Physics from Chancellor College, University of Malawi. She joined the Blantyre Health Research and Training Trust in 2017 and has been working on data management. She is currently also the Training Coordinator for the Trust and is the lead contact person for the Data Management Course.

 **Catarina Madeira PhD**: Catarina Madeira is the ECRIN European Correspondent for Portugal. She is focused on coordinating on-going multinational clinical trials in Portugal and providing support to national clinical investigators preparing clinical studies/projects for European funding. Catarina is also actively involved in the capacity building activities of ECRIN and the Portuguese scientific partner, PtCRIN. She is also involved in the organization of/participation in several training courses in clinical research, targeted to professionals involved in the implementation of clinical trials in Health Units and Clinical Trial Units (CTU). Previously Catarina worked in the Institute for Biotechnology and Bioengineering in Lisbon as a research associate in the field of regenerative medicine (RM). She supervised several post-graduation students (MA and PhD) and is (co)author of 30 scientific papers published in peer-reviewed journals. She has been a lecturer in PhD and MA programs in RM and other advanced courses in topics about clinical trials and advanced therapy medicinal products (ATMPs). Catarina received a BA in technological chemistry from Sciences Faculty, a MA and PhD in biotechnology from Instituto Superior Técnico, all from the University of Lisbon. She also did a post-graduation program in clinical trials and got a Project Management Professional (PMP) certification from the Project Management Institute (USA).

 **Rita Banzi PhD**: She is the head of the Center for Health Regulatory Policies at the Mario Negri Institute. Her main fields of expertise are drug regulatory policies, health research methodology and ethics, evidence synthesis, data sharing and transparency in research. Within the EU-funded CORBEL project, she was involved in the definition of standards for sharing individual-participant data from clinical trials. From 2010 to 2014 she was the European Correspondent for Italy of the European Clinical Research Infrastructure Network (ECRIN) and involved in the activities of its Scientific Board. She teaches in post-graduate training programs on clinical research methodology, systematic reviews and clinical guidelines at the University of Milan and Modena and Reggio Emilia. She is author of 65 scientific papers in international journals ([Medline/PubMed](https://www.ncbi.nlm.nih.gov/pubmed/?term=banzi+r%5Bau%5D)).Rita Banzi holds a doctoral degree in Pharmaceutical Sciences (University of Bologna, Italy) and a post-graduate specialization in Clinical Pharmacology (University of Milan, Italy).

 **Arsénio Nhacolo PhD:**  born in Zavala, Mozambique, got BSc degree in Mathematics in 2007 from the Eduardo Mondlane University, Maputo, where he worked afterwards as assistant lecturer for two years. In 2009 he joined the Manhiça Health Research Centre (CISM), Mozambique, where he worked as data manager and deputy head of the Data Centre Department. In September 2013 he left CISM to do a two-year MSc in Biostatistics at the Hasselt University, Belgium, after which he moved to Germany to do a PhD in Medical Statistics, at the University of Bremen. After finishing his PhD he re-joined CISM in November 2018, where he led the creation of the Data Management and Statistical Analysis Unit, of which he is the head. Publication (as first author):. Nhacolo, A., & Brannath, W. (2018). Interval and point estimation in adaptive Phase II trials with binary endpoint. Statistical Methods in Medical Research, 0962280218781411.

 **Newton Kumwenda PhD, MPH**. He is an Epidemiologist. He was the Director for the Johns Hopkins University Research Project working on HIV research in Malawi for several years. He is currently the Directory of the Blantyre Health Research and Training Trust and Site Principal Investigator (PI) for the EDCTP funded TESA II project. He is a WHO consultant on HIV/TB/Viral Hepatitis Strategic Information for East and Southern Africa Region. He ia also a GF consultant on Monitoring and Evaluation.

 **Elizabeth Kampira PhD.** She is Site Coordinator for Trial of Excellence in Southern Africa II (TESA) Project funded by the EDCTP. She obtained her PhD in Pharmacogenetics from the Department of Pathology at the University of Cape Town and MSc in Toxicology from the University of Surrey. She is a senior lecturer in the Department of Medical Laboratory Sciences in the faculty of Biomedical Sciences, College of Medicine, University of Malawi. She is also a co-investigator and PhD mentor on the AIBST research and training grant - on antibiotic drug resistance ‘ClinPHarAntibiotics Project in collaboration with the Federal Institute for Drugs and Medical Devices and BMG Global Health Programme (BfArm and BMG) in Zimbabwe, Zambia and Malawi. She is an Investigator of Records (IoR) at College of Medicine-Johns Hopkins Project on HIV/AIDS related research studies.

Her research interests include; pharmacovigilance and pharmacogenetic characteristics of the African population to understand drug metabolizing enzymes and transporter genes involved in susceptibility to diseases. Her current project is on investigating the Pharmacogenetics and Pharmacovigilance of HIV/AIDS antiretroviral therapy among Malawians.

Teresa Machai MBA, She holds an MBA from the University Pompeu Fabra of Barcelona, Spain and degree in agricultural engineering from the UEM, Mozambique. Actually is the Head of Education and Training UNIT at CISM, before was in charge of Training and Communications (2008-2016), Member of several international committees such as CUGH Sustaining Technical and Analytic Resources (STAR Project) Committee since 2018 November; Education Subcommittee for Capacity Building at Consortium of Universities in Global Health (CUGH) since October 2017, Training and education committee of ISGLOBAL since 2017, and at CISM training committee since 2012 ; a Council and management team member of eLearning national training group Since 2015, member of the Communications Group at PATH-MVI (2013-2016) and INDEPTH network (2010-2011),

Coordinator of capacity building activities through the supervision of personnel, development of training plans, and organization of courses of a UCSF Global Health Group, Malaria Elimination Initiative in the context of establishment long-term development in entomology ( 2017-2020)

Facilitator of Lusophone Management Development Institute –MDI, managed by NOVA Africa (Leadership and management training courses), 1st and 2nd edition in 2017 and 2018 respectively

She is the project Manager for Trials of Excellence in Southern Africa from 2010 until 2014, and actually since September 2017. From 2010-2011, International project coordinator of training and resources in research ethics evaluation for Africa- TRREE for Africa, Coordinated several Health Sciences Training Programs,

Accredited as Trainer the Trainer for Good Clinical Practices by TDR/WHO in 2016, and Train the Trainer in Implementation Science by School of Public Health, University of Ghana supported by TRD/WHO;

Before joining CISM working for International Organizations like World Food Program as monitor and at ActionAid International Mozambique as a Program Coordinator for six years.

**Teresa Eduarda Machai Eng. MBA:** She is Reponsavel de Farmaco at the Centro de Investigacao en Saude de Manhica (CISM).

**Rita Azevedo**

**Joe Brew**: e is a data scientist with a background in economics and epidemiology. He has previously worked in surveillance epidemiology for the Florida Department of Health (USA) and Chicago Department of Public Health (USA). His most recent projects include managing a TB case-finding project for Stony Brook University in rural Nepal, and running his company, DataBrew ([www.databrew.cc](http://www.databrew.cc/)). He did a dual MPH at Kobehavns Universitet (Denmark) and the Andalusian School of Public Health (Spain), an MA at the Institut Catholique de Paris (France), and a BA at Sewanee (USA). At some point in the 21st century, he'll finish his PhD (Universities of Barcelona and Vrije Universiteit Amsterdam). He likes data, open-source software, and pizza.

**INFORMATION NOTE**

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**9-12 July 2019, Blantyre Malawi**

**VENUE OF THE MEETING:**

**Physical Address: National Bank of Malawi, Learning and Growth Centre**

**Chikwawa Road**

**Blantyre**

**Phone: (265) 1 638 200 Fax: (265) 1 638 506**

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| **Meeting Organizer in Malawi - Logistics** | **Elizabeth Kampira** [**elkampira@yahoo.com**](mailto:elkampira@yahoo.com) **,Mobile:+265 888 858 470**  **Treaser Thomas** [t**reaser.t@bhrtt.org.mw**](mailto:treaser.t@bhrtt.org.mw)**, Mobile: +265 881 498 042** |
| **Working language** | Sessions throughout the meeting will be held in English |
| **Visa requirements** | **All holders of SADC passports will not require a visa to pass through.**  Participants from East Africa may require a VISA. As such, there will be a need to get copies of their passport details and write to Immigration -Permit counter Office requesting for visas. The charge is $75 cash to be paid at the airport. |
| **Health/Vaccinations** | Participants coming from outside the Southern African countries are required to have their yellow fever certificates. The risk of Malaria transmission is present throughout Malawi. Travelers may need to take medications for Malaria prophylaxis |
| **Travel for Participants** | All are expected to arrive on the July 9, 2019. All participantsare expected to depart by July 13, 2019. **Participants will cover their costs for accommodation**. **BHRTT** will cover the travel and accommodation costs for their respective participants to this meeting. |
| **Participation cost** | Training is free but participants are expected to meet their own cost for Travel, accommodation etc. |
| **Meals** | For any dietary requirements, kindly fill in the section on the **travel details** form provided to you and email to [treaser.t@bhrtt.org.mw](mailto:treaser.t@bhrtt.org.mw) |
| **Transportation** | BHRTT will offer transport to and from the airport. Taxis at the airport are not recommended. Participants are encouraged to provide flight details by filling in the section for arrival and departure times in the registration form provided. |
| **Accommodation** | A list of hotels is provided for participants to make their own reservations for accommodation in Blantyre. Participants requiring assistance for booking hotel accommodation should indicate on their registration form and send by email to [treaser.t@bhrtt.org.mw](mailto:treaser.t@bhrtt.org.mw)  **Training Venue:** **National Bank of Malawi, Learning and Growth Centre,** Room rate 50 US$ per night (limited no of rooms)  **OTHER Option 1 :** Leslie lodge, Malawi Sun Hotel. 64-75 US$; per night  **OTHER Option 2**: Mount Soche, Ryalls hotel Amaryllis hotels. 98-245 US$ |
| **Internet Connection** | Wi-Fi connection is available at the hotel and conferencing hall. Participants are encouraged to bring their own laptops. |
| **Currency**  **Foreign Exchange** | Local currency is KWACHA (MK) and TAMBALA (t), where one hundred Tambala equal to 1 Kwacha. One US Dollar will be equivalent to around K750. 00 and the rates do fluctuate on daily basis. Kwacha notes are different in size and color and come in denominations of K20, K50, K100, K500, K1000 and K2000. The use of foreign currencies, including US Dollars, is not allowed and participants are advised and encouraged to change any foreign currency from either the Bureau de change at the airport or make arrangements with the Logistics team to change at the local banks. |

**Program**

## DATA MANAGEMENT IN CLINICAL RESEARCH

**N.º HOURS:** 25H

**DATE**: 9-12th July 2019

**LOCATION:** Blantyre Health Research and Training Trust, BHRTT (Malawi)

**COORDINATION:** Blantyre Health Research and Training Trust, BHRTT (Malawi)

**SUPPORTING ORGANIZATIONS:** CISM, ISGLOBAL, ECRIN

## SCOPE OF THE TRAINING:

Data Management in clinical trials is critical to the success of providing evidence. The compliance with the recommendations provided in the Good Clinical Practice Guidelines (ICH-GCP – E6(R2)) assures the quality of the data collected throughout the clinical trial. To achieve the recommended levels of quality in the conduction of clinical trials, data management professionals should have training about all the strategies and procedures to comply with.

Clinical Trial Data management requires abilities in: data planning (creating data bases and data collection), data processing and analyzing, data management systems (hardware and software), data protection and storage (safety and secure), data transfer (ethics and regulations), data quality control and assurance.

The syllabus for this course was prepared according to the TESA members needs in Data Management, after filling a survey (December 2018-January 2019). In this survey the 28 respondents rated as Not relevant, Relevant or Very Relevant each of the topics covered in this course. All topics were rated by the majority as Relevant or Very Relevant. The topics with higher number of “Very Relevant” rating were chosen to be covered in more detail and with an extended practical approach.

## OBJECTIVES:

This short-term training course aims at promoting professional development and scientific leadership in clinical trials within TESA Network, specifically in data management, with a practical approach. With this course it is expected that the participants bring the knowledge and practical approaches to the respective institutions.

Therefore, at the end of this training course the students will be able to:

* Adapt and operate an existent CRF for clinical trial data collection
* Plan data management procedures for a clinical trial
* List the topics and concepts to be considered in a Statistic plan in a Clinical Trial Protocol
* Propose one or more clinical trial data archiving strategies
* Discuss the relevance of Data Sharing
* Recognize the need for Multimodal Data Management
* Support the development of a Data Management Center in the respective institution

**LEARNING AND EVALUATION METHODOLOGY:**

A certificate will be given to each student that attended to the course and participated in all the practical sessions. A short quiz will be given to the students at the end of each module to confirm that the main concepts were acquired.

**QUALITY OF THE TRAINING AND EVALUATION:**

At the end of the course a questionnaire will be given to each student to register their degree of satisfactions about the course.

## TARGET STUDENTS:

Professionals from organizations from all TESA members working in Projects involving Clinical Trials Data Management and/or Data Management Centers

**AGENDA**

**Coordination/Moderator: Elizabeth Kampira and Treaser Thomas**

**(BHRTT)**

Day 1: Tuesday, 9th July 2019

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| TIME | **Module** | **Institution** | **Responsible** |
| 8h-9h – Reception/ Registration of the Participants | |  |  |
| 9h-09h30 | Welcome to the participants and overview of the course | BHRTT  CISM | Newton Kumwenda  Teresa Machai  Dr Eucebio Macete |
| 09h30-10h30 | **Data Collection strategies**   * Planning data collection * Paper VS Electronic support * CRF design * Data Collection * Data Requirement specification * Data Hardware | BHRTT | Isaac Singini |
| **10h30-11h** | **BREAK** | | |
| 11h-12h30 | **Practical Session** | BHRTT | Isaac Singini |
| **12h30-13h30** | **LUNCH** | | |
| 13h30-15h00 | **Management of clinical trial data**   * Data management plan * Data entry * Data traceability | ISGLOBAL  CISM | Joe Brew  A. Nhacolo |
| 15h00-15h30 | Practical session | ISGLOBAL  CISM | Joe Brew -  A. Nhacolo - |
| **15h30-16h00** | **BREAK** | | |
| 16h00-17h00 | Practical session | ISGLOBAL  CISM | Joe Brew -  A. Nhacolo - |

**Day 2: Wednesday, 10 th July 2019**

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| **Time** | **Module** | **Institution** | **Responsible** |
| 08h-10h | **Management of clinical trial data**   * Managing data quality and validation * Data coding * Data Sharing | ISGLOBAL  CISM | J. Brew -  A. Nhacolo - |
| 10h-10h30 | **BREAK** |  |  |
| 10h30-12h30 | **Practical session** | ISGLOBAL  CISM | J. Brew  A. Nhacolo |
| **12h30-13h30** | **LUNCH** | | |
| 13H30-15-30 | ECRIN Data Management Center certification program   * ECRIN DM standards * Certification process * Achievements * Challenges to the auditors and auditees | ECRIN (Remote)  BHRTT | Christine Toneatti  Isaac Singini |
| **15h30-16h** | **BREAK** | | |
| 16h-17h | **Practical Session** | ECRIN (Remote)  BHRTT | Christine Toneatti  Isaac Singini |

**Day 3: Thursday, 11th July 2019**

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| **Time** | **Module** | **Institution** | **Responsible** |
| 08h-10h30 | **Data long term storage**   * Risk based archiving strategies * E-archiving challenges | ECRIN (remote)  BHRTT | Christine Toneatti  Isaac Singini |
| **10h30-11h** | **BREAK** | | |
| 11h-12h30 | PRACTICAL SESSION | ECRIN  remote  BHRTT | Christine Toneatti  Isaac Singini |
| **12h30-13h30** | **LUNCH** | | |
| 13h30-15h30 | **Data analysis**   * Data Requirements Specification * Study registration * Information in the Protocol * Statistics and Statistical plan (SAP) * Interim analysis * Publication * Data Processing * Data Cleaning * Statistical Analysis   + Descriptive Statistics   + Exploratory Data Analysis   + Confirmatory Data Analysis * Communication | ISGLOBAL  CISM | J. Brew  A. Nhacolo |
| **15h30-16h** | **BREAK** | | |
| 16h-17h | **Practical Session** | ISGLOBAL  CISM | **J**. Brew  A. Nhacolo |

**Day 4: Friday, 12th July 2019**

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| **Time** | **Module** | **Institution** | **Responsible** |
| 08h-09h | **Data sharing and reuse**   * What * Where * Why sharing data * Regulatory affairs |  | Rita Banzi |
| 09h-10h30 | **Multimodal data management**   * Clinical * Multiomics * Imaging |  | Rita Azevedo |
| 10h30-11 | **BREAK** |  |  |
| 11h-12h30 | **Conclusion of the course (final messages and certificate presentation)** |  |  |
| 12h30-13h30 | **LUNCH** | | |

THE END

LIST OF PARTICIPANTS (*Total is 20)*

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| --- | --- | --- | --- | --- | --- |
| **NAME** | **GENDER** | **POSITION** | **ORGANISATION** | **COUNTRY** | **EXPERIENCE WITH DATA MANAGEMENT** |
| Abel Nhama | M | Medical Doctor | CISM | Mozambique | No |
| Arlindo Malheia | M | Data Manager | CISM | Mozambique | Yes |
| Confidence Banda | M |  | COM | Malawi |  |
| Diana Kululanga | F | Student | COM | Malawi | Yes |
| Douglas Mhone | M | IT/M&E Officer | MOH | Malawi | no |
| Edmary Ipyana Ngosi | F | Student | Zomba Theological college | Malawi | yes |
| Eldo Elobolobo | M |  | CISM | Mozambique | Yes |
| Fabiao Louis | M | M&A and Health Systems Coordinator/ HMIS Investigator | CISM | Mozambique | No |
| Fainess Mwenelupembe | F |  | Mwaiwathu Private Hospital | Malawi | Yes |
| George Mangulenje | M | Senior Field Worker | MLW | Malawi | N/A |
| Inacio Manjate | M | Study Coordinator | CISM | Mozambique | No |
| Itumeleng Mosweu | F |  | Botswana Harvard Aids Institute Partnership | Botswana |  |
| Kenneth Machilinga | M |  | COPRED | Malawi |  |
| Lee Fonseca | M | Data Manager | CISM | Mozambique | Yes |
| Mailosi Inussa | M |  | COM | Malawi | Yes |
| Richard Luhanga | M | Lab Director | DREAM Malawi Program | Malawi | Yes |
| Simon Matchado | M | PV Database Officer | PMPB | Malawi | Yes |
| Teodimiro Matsena | M | Data Manager | CISM | Mozambique | Yes |
| Thandiwe Kehle | F |  | COM | Malawi | yes |
| Zefanias Nhamire | M |  | CISM | Mozambique | yes |