# SUBJECT INFORMATION AND INFORMED CONSENT FORM

## IMART TRIAL

## IMPROVING TREATMENT OUTCOMES IN CHRONIC MYELOID LEUKAEMIA PATIENTS USING IMATINIB AND ARTESUNATE COMBINATION THERAPY.

**10th March, 2025**

**OBAFEMI AWOLOWO UNIVERSITY TEACHING HOSPITALS COMPLEX, ILE-IFE.**

**SUBJECT INFORMATION SHEET**

**Title of Study**: Improving treatment outcomes in chronic myeloid leukaemia patients using Imatinib and Artesunate combination therapy

**Principal Investigator**: Mrs. Oluwatoyin T. Famurewa Telephone No: +2348064695869
E-mail: toyinoyebanji42@gmail.com

**Institution/Department**: Department of Pharmaceutical Chemistry, Faculty of Pharmacy, OAU

**Co – Investigators**: Dr. Babatunde Adeagbo, Faculty of Pharmacy, OAU & Prof. Rahman A. Bolarinwa, Department of Haematology OAU/OAUTHC, Ile-Ife

**Sponsor** (If any): Self Sponsored

**General things to know about the study**

You are being asked to join a research study and your participation is optional. You may decide to leave the study at any time without being penalized. The aim of the study is to provide information on how your body handles imatinib, the first drug in the treatment of your blood cancer (CML). It is already part of your therapy. This study seeks to know if combining imatinib with artesunate (antimalaria drug) will improve the outcome of your CML treatment, for example, achieving major molecular remission (MMR) early and preventing the blood cancer (CML) from expanding.

**Procedures**

You will be assigned to one of the groups of the study and continue your imatinib medication irrespective of the group you are assigned to. Your drug will be taken at the study site on the day of sample collection and 2mls of blood sample will be withdrawn before you take the drug dose for the day (0-hour time point). Thereafter, 2ml of blood sample will be collected at least 5 times after taking the drug and the last blood collection will be taken between 6-8 hours from the time of taking your medication. The blood samples collected will be processed immediately to obtain plasma and stored at -20ºC until the time of analysis.

**Benefits and Costs of Participation**

The study may provide information on the benefit of imatinib-artesunate combination therapy and give information on safety of artesunate beyond the established antimalaria use. There is no direct cost to you for participating in the study.

**Risks and Compensation**

When taking your blood samples, minor pain and bleeding may occur from needle pricks, however, highly skilled professionals will be collecting your blood samples so that the risks of discomfort, bleeding or bruising will be very minimal. Also, protocols to ensure that both parties are protected from cross-infection will be ensured. You will not be paid for participation in this study and it will not cost you anything to participate.

**Confidentiality**

All research projects carry some risk that information about you may become known to people outside of the study. However, to minimize this risk of breach of confidentiality, the following measures will be taken: Data collected about you during screening for your medical fitness will only be made available to you and the investigators, blood samples and analysis will not be labelled with your real name, but a research code will be generated for each sample, and the link of each code to your personal information will be kept in a secure electronic database which only the investigators will have access to.

**Respondents' Rights**

You are under no pressure to participate in our research study, the decision is totally up to you. If you say no, it will not affect your participation in other studies you may be involved in, or your clinical treatment in any way. You can change your mind about being part of this study any time by contacting the contact above. They can then remove your sample and your data from the study.

**Conflict of Interest**

The study investigators have no financial or other relationships with any persons or organisations, including the manufacturers of the drug you are taking, that may affect the conduct of the study or the interpretation of its findings.

## For the Records

A copy of this document will be given to you for your records.

**OBAFEMI AWOLOWO UNIVERSITY TEACHING HOSPITALS COMPLEX, ILE-IFE.**

## Improving treatment outcomes in chronic myeloid leukaemia patients using Imatinib and Artesunate combination therapy.

**Subject's Agreement/Consent Form:**

I have read the information provided in the Subject Information Sheet, or it has been read to me.

I have had the opportunity to ask questions about the research and all questions I have asked have been answered to my satisfaction. I consent voluntarily to participate in this study and understand that blood samples will be collected from me at intervals, and I have the right to withdraw from the study at any time.

**Yes** ☐ **No** ☐

Signature/Thumb print of Research Respondent Date:

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If participants cannot read: Signature of Mother or Legal Guardian.

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Signature/thumb print of Person Obtaining Consent. Date:

Name of witness Signature Date

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Printed Name of Person Obtaining Consent: Pharm (Mrs) Oluwatoyin Famurewa

Phone Number: 08064695869