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The recommended artemisinin combination therapy (ACT) for treatment of uncomplicated malaria in
Tanzania is artemether-lumefantrine (AL). Although Artemisinin and its derivatives are generally thought to
be safe, there is currently little or no data on its safety among populations in Tanzania. In view of this INESS
established a phase IV study to

evaluate safety of AL through comprehensive pharmacovigilance in large populations with the aim of
documenting rare adverse drug reactions and to characterize known effects in ‘real-life’. The methodology
employed is cohort event monitoring which is observational, longitudinal and prospective. Patients with
diagnosis of malaria for whom AL was prescribed were recruited into the cohort from four health facilities
in each HDSS. Information on demographics, use of all medicines, mode of
diagnosis of malaria, presenting signs and symptoms, co-diagnoses, events suspected as adverse drug
reactions, reasons for stopping the drug and cause of death (if any) were collected using standardized
questionnaire. They were followed up on 7 to 10 days after AL was dispensed. This

report is on the number recruited so far and the challenges in getting the cohort going. 9028 patients were
recruited. 9016 (99.8%) completed follow-up on day 7, of which 668 (7.4%) were done by telephone calls.

12 (0.13%) were lost during follow-up. The main challenges encountered are getting enough trained staff to
recruit and follow up patients since CEM is quite labour intensive. 38 health providers and 10 field workers
were recruited and offered the relevant training in collaboration with regulatory authorities. This helped to
overcome the human resource challenge. Another challenge involved is the difficult to reach areas which
are cut off especially during the rainy season. Follow up by telephone

was adopted for these areas and this helped to reduce number of lost to follow-up. Setting up a cohort
event monitoring program takes time and is demanding in terms of human resource. Training is very
important in overcoming this. Involvement of all stakeholders and sponsors is a key to

success.