

# The right combination

**Professor Umberto D'Alessandro** of the Institute of Tropical Medicine in Antwerp is also working as Theme Leader, Disease Control and Elimination, at the Medical Research Council unit in The Gambia. Here, he discusses some of the issues around his research into antimalarial treatment for African pregnant women



**How would you summarise the overall aims of PREGACT?**

The overall aim of PREGACT is to determine the safety and efficacy of the newly available antimalarial treatments, i.e. the artemisinin-based combination treatments, in pregnant women with malaria.

**One of your aims was to determine the safety of treatment by registering adverse events and grading, laboratory and vital signs evaluations. What have your preliminary results shown to date? Has the project been steered any differently as a result of any data you have gathered along the way?**

An independent safety and monitoring board, comprising four members, regularly reviews the data collected to ensure that they are of acceptable quality. It also reviews the safety data. As coordinating investigator, I am not allowed to run preliminary analysis on the individual treatments tested. Nevertheless, the board has not so far raised any concerns around safety.

**An open-label multicentre and randomised trial has been conducted that treats pregnant women with malaria with one of four Artemisinin Containing Therapies (ACT), followed up weekly until day 63 post-treatment and then monthly until four-six weeks and one year post-delivery. Could you describe the general trends that have arisen as a result?**

As coordinating investigator I do not have access to the results of the individual treatments. Until the end of trial, i.e. the end of the follow-up of pregnant women recruited, our main concern is to guarantee the quality of the data collected and make sure there are no signs of safety problems. So far, our safety and monitoring board has been satisfied and it has made the recommendation to continue the trial.

**What environmental factors may come into play that account for any anomalies in how well pregnant women with malaria and their unborn babies are faring whilst participating in the trials? To what extent does this complicate the drug discovery process?**

Malaria is a disease that is influenced by the environment, as it is a vector-borne disease. However, the fact that women are randomised to the different treatment arms – in other words, the assignment to a specific treatment is determined only by chance – should reduce the influence of such factors and make the different study groups before treatment comparable.

**To what extent is the approach undertaken by the European and Developing Countries Clinical Trial Partnership (EDCTP) in setting up and supporting projects a novel one?**

The EDCTP funds phase III clinical trials related to HIV, tuberculosis and malaria, promoting research in this field. It should be noted that

the EDCTP funding from the EU should be matched by an equal amount from EU Member States – not always an easy condition to fill.

**In the long term, are you aiming to forge links with pharmaceutical partners as a result of your work? How soon might the cycle from bench to bedside be completed?**

The PREGACT study is carried out with the collaboration of the pharmaceutical partners in the sense they provide the study treatments. This is extremely important because we must be absolutely certain of the quality of the treatment tested. It takes years before the cycle from the bench to the bedside is completed, and this is necessary to protect the patients. We need to be sure that new treatments, or vaccines, are safe and that the benefits outweigh any potential risks.

**What is your perspective on the nature of industry in the development of healthcare solutions? Can research that doesn't engage industry ever be truly successful?**

Research that does not engage industry can be successful because often industry, at least in the case of medicines, is mainly interested in registering a product. A trial such as PREGACT would have never been possible within the industry, mainly because we are trying to establish the pros and cons, as objectively as possible, of several antimalarial treatments given to pregnant women. Industry would be more interested in establishing the added benefit, if any, of a specific product against the currently available options; it is a different approach. Nevertheless, there are public-private partnerships in which industry plays a key role in the development of a product of public health interest. The issue here is not only about the funds available from industry, but also the specific expertise industry may have, which could be complementary to that available in academia.