

# Fuel science, feed the future



## Clinical trials: why participate while pregnant or breastfeeding?

Clinical studies are essential to developing innovative treatments. And for these drugs to be adaptable to pregnant and lactating women, their participation is crucial. Interview with Dr. Josué Mfopou Kunjom, Director of Clinical Operations at the Pfizer Clinical Research Unit (PCRU) in Brussels.

### Interview

#### Why do you specifically need pregnant and breastfeeding women to participate in clinical studies?

Dr. J.M.K.: "If a pregnant or lactating woman suffers from any condition, it is essential that a clinical study has shown that the medicine to treat her can be administered to her, without risk to her baby. Because the metabolism of pregnant women is different, drug concentrations on pregnant women should be evaluated. For breastfeeding women, the question above all is whether a treatment is present in their breast milk."

#### What types of clinical trials concerning breastfeeding women take place at the PCRU?

Dr. J.M.K.: "The last two projects at PCRU targeted COVID-19 and breast cancer. Other projects on other diseases will certainly come. Women who participate in our clinical trials are healthy."

#### Why don't they have to suffer from these pathologies to participate?

Dr. J.M.K.: "Because it is necessary to distinguish the different phases of a clinical trial. First, there is the preclinical phase, which occurs in the laboratory. This phase can last many years. Once enough data has been collected, the project can be moved to the clinical phase, which itself has four phases. Phase 1 is essentially what we do at the PCRU: the very first studies of a healthy human being. The objective is to assess the tolerability and safety of the new drug and its concentration in human blood. The following stages shall be carried out on patients suffering from the targeted disease."

## Are these trials risky for women or their babies?

Dr. J.M.K.: "The safety of the participants is our main objective, and everything to ensure this is done in this direction. Participants come to us in good health and must return in good health. The first line of safety is preclinical studies. In humans, doses 100 times lower than those tested in animals are used. Second, a clinical study always requires the approval from the competent authorities as well as an ethics committee. This approval is enforced by the European institutions, according to a precise protocol. The third line of safety is that a Phase 1 clinical research center must always be located in - or near - to a hospital. Finally, at the PCRU in Brussels, we have a medical and nursing team trained to take care of participants. In 32 years of existence, we have never encountered any problem threatening the health of our participants."

## How is the experience of pregnant or breastfeeding women at the PCRU?

Dr. J.M.K.: "Overall, their journey is the same as for the other participants. Anyone interested registers in our database. If the participant potentially meets the criteria of a study, we contact the participant, and the participant has the choice to register. A screening test is then conducted, which includes a medical questionnaire to determine the individual's background, and a series of medical examinations (Electrocardiogram, blood pressure, laboratory tests) to confirm that the individual is healthy and eligible for the study. If this is the case, she will be taken care of in our clinic for the administration of treatment and follow-up. The length of hospitalization may vary from three days to two weeks. **For women who are breastfeeding, everything is in place so that they can be welcomed with their baby: they are in a single room, with all the necessary equipment for the baby.**"



## Breastfeeding women make the difference in clinical research

### Who may participate?

Healthy breastfeeding women.

### Why participate?

Contribute to medical research by helping us better understand the transfer of breast milk in medicines.

### An experience designed for you.

A warm environment adapted to mothers and their babies. We provide you with a breastfeeding expert.

Visit website



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