

Enclosure A: Patient Brochure

Please note that the questionnaires, which are delivered before some of the discussions with your doctor, must be delivered in a sealed envelope to doctor follows her to the hospital. Please complete carefully and follow the instructions accompanying the questionnaire.

The questionnaires will be given at enrollment, at the first visit and then once a year.

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TOTEM STUDY

“Multicentric randomized
controlled clinical trial
between two follow up
regimens with different tests
intensity in endometrial
cancer treated patients”



Dear Ms,

Your doctor asked you to participate in the "TOTEM study", a study comparing two different programs of visits after the therapy for your disease.

All of these controls is called "follow-up".

With this brochure we want to inform you quickly and easily about the purpose of the study and briefly anticipate the path that we set for the next 5 years.

Women who have had endometrial cancer, after surgery and medical treatment, are addressed to periodic clinical examinations and diagnostic tests for at least 5 years since unfortunately there is a possibility that the disease recurs. We discovered often you run different tests in different hospitals at different times; this happens because there is no agreement on how best to propose to our patients. It is not scientifically demonstrated which and how many tests are needed to effectively and quickly

find any recurrence. The doctors participating in the TOTEM study decided to remedy this deficiency by organizing a study in which two control programs (follow-up), set out to explore two different ways of thinking are compared directly. TOTEM study is set to involve 2,000 patients treated for your disease and get in touch very different reality in many hospitals throughout Europe. One important purpose of the study is to know your opinions, find out what are your expectations, fears and problems during the pathway of follow up visits. You will then be asked to fill out periodic questionnaires that have been created to gather your opinions and your experiences.

2. Reminder

TOTEM study involves two different schemes of follow-up : MINIMALIST (few examinations) and INTENSIVE (more examinations). If you decide to be part of this study will be assigned randomly and definitive, not influenced by doctors who follow you, to one of two sets of follow-up. Of course, all examinations as may

be necessary according to the clinical disease or in case of doubt will be performed at the discretion of the physician regardless of the type of follow-up that will be assigned.

Depending on your disease has been identified as "low" or "high" risk of relapse will be planned control visits every 4 to 6 months. Depending on the system of follow-up, your doctor will prescribe several blood tests or diagnostic examinations: you will be given a schedule of these visits and exams so that you know exactly this program.

Please note that it is important to carefully follow your doctor advises and remember that he will change the pattern of checks every time it will be necessary for your health. Please note that the medical examinations provided by TOTEM study are always performed in hospital while blood tests and diagnostic requirements will be done where you prefer. As for blood tests is important to always use the same laboratory for analysis for a better comparability of results