Enclosure B: GP Brochure

**TOTEM Study: Multicentric randomized controlled clinical trial**
***between two follow up regimens***
***with different tests intensity***
***in endometrial cancer treated patients***

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Dear colleague,
we hereby inform you that Mrs. ... ... ... ... ... ... ... ... ... ... ... ... ... ...., became part of a study on the follow-up of endometrial cancer.

The study, carried out by a scientific committee and verified by an Ethics Committee, started in 2008 in Italy and seeks to ascertain the usefulness of clinical and instrumental post-operative examinations. The project, now active in several Italian hospitals, aims at analysis of 2300 patients. The study was approved and funded by ..
Over the next five years, your patient will be followed at our center according to the program marked with an X at the end of this paper.

At the end of primary treatment protocol asks the insertion of the patient in a group with low or high risk of relapse based on the characteristics of the tumor and then a randomization between two schemes of follow-up at different intensities is performed.
At the time of randomization (time 0), the staging of the patient must document the absence of residual disease and the following examinations must be negative: chest X-ray and abdominal CT performed within 20 days after full completion of primary treatment. If the doubt of a relapse onset, the patient will be subject to all necessary clinical investigations and will leave the trial.

The study design requires that additional tests planned by the general practitioner, are registered among data of the study. This way, after completion of the study, it will be possible to quantify the frequency of diagnostic procedures asked outside of those planned by the Centers participating in the study.

The purpose of this letter is to inform you of this initiative and give you the opportunity to contact colleagues at the hospital where your patient is followed for any further information.

You can contact the Centre Coordinator of the study through the following email: …….

We thank you for your attention

Yours sincere

**Minimalist scheme (ARM 1) low risk**

| PROCEDURE | Months from randomization | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 4 | 6 | 8 | 12 | 16 | 18 | 20 | 24 | 30 | 36 | 42 | 48 | 54 | 60 |
| Visit | * | | * | | * | | | | * | * | * | * | * | * | * |

**Intensive system (ARM 2) low risk**

| PROCEDURE | Months from randomization | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 4 | 6 | 8 | 12 | 16 | 18 | 20 | 24 | 30 | 36 | 42 | 48 | 54 | 60 |
| Visit | * | * | | * | * | * | | * | * | * | * | * | * | * | * |
| Pap Smear | | | | | * | | | | * | | * | | * | | * |
| TC chest, abdomen, pelvi | * | | | | * | | | | * | | | | | | |

**Minimalist scheme (ARM 1) high risk**

| PROCEDURE | Months from randomization | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 4 | 8 | 12 | 16 | 20 | 24 | 28 | 32 | 36 | 42 | 48 | 54 | 60 | |
| Visit | * | X | X | X | * | X | X | X | * | * | * | * | * | * | |
| TC chest, abdomen, pelvi | | | | X | | | X | | | X | | | | | |

**Intensive system (ARM 2) high risk**

| PROCEDURE | Months from randomization | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 4 | 8 | 12 | 16 | 20 | 24 | 28 | 32 | 36 | 42 | 48 | 54 | 60 | |
| Visit | * | * | X | * | * | * | X | * | * | * | * | * | * | * | |
| Ca125 | | X | X | X | X | X | X | X | X | X | X | X | X | X | |
| TV US and upper abdomen US | | * | * | | X | * | | * | X | | X | | X | | |
| Pap Smear | | | | * | | | * | | | * | | * | | * | |
| TC chest, abdomen, pelvi | | | | * | | | * | | | * | | * | | * | |