

The EMPOWER Study

Your physician has just given you a prescription for a hormone therapy. He or she has also provided you with information about the associated benefits, risks, and side effects. Information of this type is regularly evaluated and supplemented by knowledge gained from widespread routine use of such products. For this reason, a large-scale observational study of more than 10,000 women in Europe is now being started, in which you, too, have the opportunity to report your experience. It is supported by gynecologists and specialists in sexual medicine all over Europe and is being carried out by an independent institute. Your participation in the study will not influence your use of your medicine in any way. At any time, you may stop using the product or switch to another therapy.

What does your participation consist of?

Over a period of up to eight years, you will fill out a few questionnaires about your use of your medicine, your general condition and your state of health:

- First, the enclosed baseline questionnaire
- And then a short follow-up questionnaire every 6 months (or one year) with a few questions on your use of your medicine and any health problems/symptoms during that period. (We request that you fill out these questionnaires even if you permanently or temporarily stop taking the medicine or switch to another therapy.)

We will send you these subsequent questionnaires by mail with a pre-paid return envelope to ensure that you have no costs.

Your participation in this project is of course completely voluntary. ZEG — the Center for Epidemiology and Health Research, Berlin — and Medicys Ltd, the two organizations that are carrying out this study in Great Britain, comply fully with all privacy regulations. For more information, please read the enclosed "Declaration on Data Protection and Absolute Confidentiality".

Why do we need your address?

We need your address in order to send you the follow-up questionnaires. Your address will be saved in a separate file with special protection measures that is used solely for the purpose of printing out correspondence. We will only use your telephone number if we have questions about your responses on the questionnaire, or if we encounter difficulties in sending you the questionnaires by mail.

What will happen with your data?

The questionnaires do not contain your name or your address, but rather only a number for your physician which will later be supplemented by a number for you. The number printed on the follow-up questionnaires is solely for the purposes of keeping your information together. For more information on this topic, please see the "Declaration on Data Protection and Absolute Confidentiality".