

Title of research project:	Assessment of the prognostic impact of the published European Society of Gynecologic Oncology quality indicators for advanced ovarian cancer surgery
Sponsor and data controller:	EUROPEAN SOCIETY OF GYNAECOLOGICAL ONCOLOGY (ESGO) - C/o Kenes International, Rue François-Versonnex 7, P. O. BOX 6053, CH-1207 Genève – SWITZERLAND
Type of study:	Retrospective study based on secondary use of pseudonymised personal data

1. INFORMATION ABOUT THE PROJECT

This research project is an international retrospective multi-centre study. The main aim of the study is to assess the prognostic impact of ten published ESGO quality indicators for advanced ovarian cancer surgery. Its main objective is to evaluate the association between the quality indicators and time to recurrence of disease.

As part of the project, we will collect and register data from women treated for metastatic ovarian cancer in more than 100 hospitals world-wide. In your health care institution's database, patients who match the criteria of the research project will be identified. Since you match the criteria, we would like to collect your data. Data will be collected from your medical record and not directly from you. Therefore, this study does not involve any additional examinations or demands from you other than what is already carried out as part of your standard treatment. All data will be processed without names and personal identification numbers or other directly identifiable information (= pseudonymized data). A code links you to your data through a list. Only health-care professionals involved in your care (=local study personnel) are able to link the information used for the purposes of the project to your identity.

Possible advantages and disadvantages: The study does not involve any risk or constraint for you. If you do not object to processing of your data for research purposes, your personal data will be integrated in a REDCap database maintained by ESGO based on the secondary use of your clinical data. There are no direct advantages for you in participating in this project. The expected benefits of this study are collective benefits for the community of patients who suffer from Ovarian Cancer.

Voluntary participation and your rights: Participation in the project is voluntary. If you would like to participate, you do not have to take any action. If you object to participate in the study, please contact your treating gynaecologist at this hospital. You can also access to an objection form on the ESGO website (<https://esgo.org/>). You can withdraw from the project at any time without giving a reason. There will be no negative consequences for you or your treatment if you do not want to participate or if you choose to withdraw at a later stage. If you decide to object to the processing, your health data will not be used in any further research. You can request access to the data held on you, and this will be provided within 30 days. You can also exercise you rights to rectification, to restriction of processing and apply for your data in the project to be deleted. The right to have your data deleted or returned may not apply if the deletion of the data is likely to render impossible or seriously impair the achievement of the objectives of the project. Access may also be restricted if the data have been included in analyses already performed. If you want to withdraw at a later stage or have questions about the project, you can contact the project manager (see the contact details at the end of this document).

2. INFORMATION ABOUT THE PROCESSING OF YOUR PERSONAL DATA FOR THE PURPOSE OF THE PROJECT

The data necessary for the purpose of carrying out the research project are personal data within the meaning of the Regulation (UE) 2016/679 of the European Parliament and of the council of 27 April 2016 or General Data Protection Regulation (hereinafter "GDPR"). Your personal data are processed by ESGO, which has initiated this project and acts as the data controller. As such, ESGO undertakes to ensure that the processing of your personal data is implemented at all times in accordance with the requirements of the GDPR. The data processed is pseudonymized personal data concerning health related to you (height, weight, performance status), your diagnosis (tumor characteristics, extent of disease, laboratory tests), treatment (surgical and/or medical therapy at time of diagnosis and at recurrence if you have recurred) and follow-up.

Legal basis: The research project intends to contribute to the improvement of knowledge on ovarian cancer in accordance with the above objectives. Thus, the processing of your personal data is necessary for the purposes of the legitimate interests pursued by ESGO as a society of healthcare professionals. Your data is also necessary for reasons of public interest in the area of public health, i.e., ensuring high standards of quality of health care, through the performance of scientific research purposes (art. 9.2 (j) of the GDPR). Only personal data strictly necessary for the purpose of the project will be processed by ESGO.

Confidentiality: Your personal data are strictly confidential. The documents in which your full identity appears are intended exclusively for your gynaecologist and your medical file will remain confidential and can only be consulted under the responsibility of the latter. ESGO will not have access to your medical file. ESGO only has access to your data in a pseudonymised form, which means that ESGO will not be able to identify you in any way from the data that has been communicated to it. Moreover, ESGO implements appropriate technical and organisational measures to ensure a level of security appropriate to the risk of the data processing, in particular to ensure the ongoing confidentiality, integrity, availability and to avoid that data being distorted, damaged or accessed by unauthorised third parties.

Data retention: Your personal data will be processed in the framework of the project for its duration. However, you are hereby informed that your personal data will be then included in the ESGO database, the purpose of which is to carry out further scientific research projects in the field of gynaecological oncology, in accordance with the objectives of ESGO. It will then be archived in accordance with the regulations in force.

Recipients: Your personal data collected within the framework of the project is only intended for use by ESGO and its staff who must process them within the strict framework of their missions in relation to the research project. Your data included in the ESGO database will be collected and managed using REDCap (www.projectredcap.org), which is hosted in the cloud by Amazon Web Services (AWS) located in Germany (EU). AWS implements appropriate security measures to guarantee the confidentiality and integrity of your personal data. It does not have no right to use your personal data except for the purposes of carrying out the services entrusted to it by ESGO and under its control. Within the strict framework of their mission, the competent authorities, notably data protection supervisory authorities may have access to your data and the results of the project which do not contain directly identifying personal data about you.

Data sharing: Your personal data may be transferred outside the European Union or EEA. However, ESGO will make sure that the recipient country ensures an adequate level of protection or that appropriate safeguards are in place prior to any transfer of your data, in accordance with the regulatory requirements applicable. The code linking you to your personally identifiable information will not be disclosed.

ESGO has appointed a Data Protection Officer ("DPO") in order to implement its compliance with the applicable regulations. You can contact ESGO's DPO to exercise your rights at the following address gdpr@esgo.org, however this will lift the secrecy of your identity from the DPO. Therefore, if you wish to keep your identity secret, you can contact your gynaecologist to exercise your rights and your gynaecologist pass on the information to ESGO.

Further use of your personal data: Your data integrated in the ESGO database may be used subsequently for new research projects by ESGO teams and/or by teams from partners which may be public or private. All research projects must have the prior approval of ESGO council, which is composed of doctors and researchers with expertise in the field of gynaecological oncology. Information about research projects based on secondary use of data can be found on the ESGO website (<https://esgo.org/>). You may also object to the use of your data in such projects by contacting the DPO of the project leader/sponsor as described above.