

Informed consent form – Cover page

Study protocol No.	LEOPARD-II
EudraCT No.	2010-023427-18
Title	Definitive radiochemotherapy with 5-FU / cisplatin plus/minus cetuximab in unresectable locally advanced esophageal cancer: a phase II study
Study phase	II
Coordinating Investigator	Dirk Rades, MD (LKP according to §40 AMG) Department of Radiation Oncology
Sponsor	University Hospital Schleswig-Holstein, Campus Luebeck, Ratzeburger Allee 160, 23538 Luebeck
Date/Version	Version 2, 2012-08-06

Informed consent form

English version as requested by clinicaltrials.gov, for presentation at clinicaltrials.gov only

Center: University Hospital Schleswig-Holstein, Campus Lübeck
Department of Radiation Oncology, Ratzeburger Allee 160, 23538 Lübeck

Coordinating Investigator: Prof. Dr. med. Dirk Rades

EudraCT-number: 2010-023427-18

Study title: Definitive radiochemotherapy with 5-FU/cisplatin plus/minus cetuximab for unresectable locally advanced esophageal cancer: A phase II-study

Protocol code: LEOPARD-II

Patient: Full Name (block letters): _____

Date of birth: _____ Patient number: _____

Physician: Full Name: _____

I have been informed by the above mentioned physician in detail about the investigational drug and the comparative therapy, as well as about the nature, extent and significance of this study, including the study aim and duration, requirements and possible side effects, my rights and obligations, insurance coverage and voluntariness of participation.

I was assured that the informing was complete. I have read and understood the text of the patient information and the data protection declaration printed below. The questions I had with respect to these have been answered adequately and completely.

The following topics were discussed in addition to the written information:

I was given sufficient time to decide whether I would like to take part in this study or not.

I have been informed that I may withdraw my consent to participate in this clinical study at any time without giving any reasons (orally or in writing), without any negative consequences for me regarding my medical treatment.

Consent with respect to data protection:

I am aware that personal data collected during this clinical study, in particular medical findings, will be recorded, stored and evaluated. The use of my medical data will be in accordance with legal stipulations and requires my voluntary consent prior to my participation in the study. This means that without the following consent, I cannot take part in the clinical study.

- 1. I agree that personal data collected within this clinical study, in particular medical data, will be collected and stored both in paper form and on electronic data storage devices. If necessary, the data collected may be communicated in pseudonymous form (encoded):**
 - a) to the GSO mbH, the sponsor and a representative of the sponsor responsible for scientific evaluation (study management),**
 - b) in case of application for approval, to the applicant and the responsible regulatory authority, the Paul-Ehrlich Institute,**
 - c) in case of adverse events, to the GSO mbH, the sponsor, the responsible ethics committee and the responsible higher federal authority, the Paul-Ehrlich Institute, and from this authority to the European database, and**
 - d) to the manufacturer of the investigational drug (Merck Serono GmbH)**
- 2. In addition, I agree that persons authorized by the sponsor and subject to confidentiality, as well as the regulatory authorities, may access the personal data stored by the investigator, in particular medical data, if this is necessary to verify that the study is being conducted according to protocol. In this respect, I release the investigator from the confidentiality agreement.**
- 3. The consent to the storing and processing of my personal data, in particular my medical data, is irrevocable. I have already been informed that I may terminate my participation in the clinical study at any time. In the case that I withdraw my consent to participate in the clinical study, I agree that all data saved until that point may continue to be used if necessary in order to:**
 - a) evaluate the effects of the drug investigated.**
 - b) ensure that my legitimate interests are not affected.**
 - c) comply with the obligation to provide complete documents for approval.**
- 4. I agree to the condition that my data will be stored for at least 10 years after the end of the study or the termination of my participation therein, as stipulated by guidelines for the conduct of clinical studies. After this period, my personal data will be deleted, except if longer storage periods are required according due to other reasons.**
- 5. I have been informed about the following legal requirements: In case that I withdraw my consent to take part in the clinical study, all locations storing my personal data, in particular my medical data, must check whether the data stored for purposes given under 3 a) to c) are still required.**

Any data that is no longer required must be deleted without delay.

6. I agree that my general practitioner (GP)

.....
(Name, address)

will be informed of my participation in the clinical study and may transfer information about my health status to the investigator of this study (if not desired, please cross out).

I agree to participate on a voluntary basis in the clinical study mentioned above.

I have received one copy of the patient information plus the informed consent form and the conditions of the insurance. One copy remains at the study site.

Name of the patient (in block letters)

Date

Signature of the **Patient**

I hereby confirm that I have conducted the informed consent discussion and obtained the consent from the patient.

Name of the investigator (on block letters)

Date

Signature of the **Investigator** who obtained consent