IEO
Istituto Europeo di Oncologia

INFORMATIVE SHEET

InterNaTional rEgistry oN Sars-cov-2posItiVe nEuroendocrine neoplasm patients (INTENSIVE)

Dear Miss/Mister

We are asking you to participate in this study since the characteristics of your disease complies with the inclusion criteria.
In order to consciously decide whether or not participate to the study, you must have received adequate and comprehensive information: this process is called "Informed Consent". This document included information about the study, which we asking you to read carefully, or discussing it, if you wish, with trusty people. The doctor who proposed you to participate in the study is at your disposal to answer your questions and clarify your doubts. Once you are properly and thoroughly informed, you may or may not accept the proposal to participate in the study and, if you agree, you will be asked to sign the "Informed Consent Form", and you will receive a copy of it together with the Information Sheet.

WHY DO THIS STUDY
At the end of December 2019 in China, in the Hubei region, an infection caused by a new coronavirus, called SARS-CoV-2, come up. This infection has been associated with interstitial pneumonia which in many cases has resulted in acute respiratory distress syndrome. The epidemic quickly spread around the world and became a pandemic. At the time of the preparation of this study, the World Health Organization reports about 4 million confirmed cases of infection worldwide.

Patients who are currently on anticancer treatment, particularly those with chest cancers, are potentially at higher risk of contracting the infection and its complications. Having a neuroendocrine cancer falls into this category. However, neuroendocrine cancers are a very heterogeneous group of rare cancers, with a clinical behavior and response to cancer treatments that can be very different between several types. Therefore it is difficult to define an absolute and uniform risk in relation to SARS-CoV-2 for all people who, like you, have neuroendocrine cancer. Further, it is not known whether the SARS-CoV-2 infection or disease (also called coronavirus disease 19 - COVID-19) is more or less serious for patients with neuroendocrine cancer than for people who do not have a tumor or those who have a different type of cancer.
At the moment, therefore, it is impossible to give an absolute indication to doctors who treat patients with neuroendocrine malignancies in relation to SARS-CoV-2.

For this reason, considering the rarity and heterogeneity of neuroendocrine malignancies, only a uniformly structured and worldwide collection of information will be able to give reliable and reproducible data from which to draw guidances for physicians dealing with patients with neuroendocrine cancers.

STUDY OBJECTIVE
This study aims to collect information on patients with neuroendocrine cancer with COVID-19 infection through an international registry. This effort is aimed for sharing, across the scientific community, solid and reliable information about the management of patients with neuroendocrine cancer suffering from COVID-19.

DESCRIPTION OF THE STUDY
This is an international retrospective/observational prospective study. Centers around the world participating in the study will be asked to report a set of data of patients who have agreed to participate in the study and their illnesses on a specific case report form.
Information on the patient's age, gender, country of residence, comorbidity, characteristics of cancer disease and concomitant SARS-CoV-2 infection/disease will be recorded.

RISKS AND BENEFITS
Participating in this study, you do not take any additional risk for yourself because the study does not provide diagnostic-therapeutic items different from clinical practice. Data related to your medical history will be collected in RedCap a web application for building and managing online surveys and databases, specially created and universally accepted for this purpose.

VOLUNTARY PARTICIPATION AND THE RIGHT TO REFUSE
You participation in this study is entirely voluntary. If you don't want to participate to this study, this will not preclude you from receiving treatment that, in any way, you will continue to receive from your doctor.

POSSIBILITY OF RETIRING FROM THE STUDY
At any time, you may withdraw from the study, without providing any explanations, bearing in mind that this choice will never undermines in any way the relationship with the medical and nursing staff or the cure of your illness and your person. However, if you decide to retire from the study please provide your doctor with any information that may be requested.

STUDY COSTS
You will not have to pay any costs and will also not receive any compensation for the participation in the study.

DATA PROCESSING AND PRIVACY
The processing of your data will be carried out in accordance with Regulation (EU) 2016/679. Any information collected during the study, and in particular personal information, will be considered to be strictly confidential in nature. The anonymity of all data is guaranteed and consultation of such data will only be allowed to staff directly involved in the study, members of the Ethics Committee and Regulatory Authorities. Your name will never appear in any document, outside of personal records and medical records, kept confidential at the health care company that carried out the investigation.
If you wish to retire, please report it in writing to your doctor of the referral center. The data will be analyzed for research purposes only. None of the reports or publications resulting from this study will use your name or any other reference that may identify you. In the course of any audits, representatives of the promoter, health institutions and local Ethics Committees will have access to your medical record, but will be bound by the commitment to confidentiality.

STUDY APPROVAL
The study respects the "European Clinical Good Practice Standards" and is in accordance with the "Helsinki Declaration" for Human Rights, which guarantees respect for the individual.
The study protocol, patient information and informed consent form were approved by the Ethics Committee of the center, which aims to safeguard the rights of patients participating in the study.

PEOPLE TO CONTACT

We are available for all the questions that you want to discuss.
At any time, you can contact one of the study's investigators directly listed for further clarification regarding the study:

Dr. _____ phone_____

Dr. _____ phone_____

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INFORMED CONSENT MODULE

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PATIENT'S DECLARATION

I subscribed.....after receiving and reviewing the information for obtaining informed consent prepared for the study, I confirm that I have been given sufficient opportunity to discuss every aspect of the study I will be subjected to, with the doctor responsible, who has made himself available for any further information concerning the study to me, as well as, at my request, to the general practitioner, "external", of trust (family). I have been sufficiently informed about the purposes and methods of the trial and here I subscribe to my free and voluntary participation in this study and the processing of my data which will be carried out in accordance with the Legislative Decree 10 August 2018, No 101 "Dispositions for the adaptation of national legislation to the provisions of the General Regulation on the Protection of Personal Data (EU Regulation 2016/679)".

I have received a copy of the patient's information and informed consent form.

PATIENT'S SIGNATURE _____ Date _____

PATIENT'S NAME (printing) _____

RESEARCHER'S SIGNATURE _____ Date _____

RESEARCHER'S NAME (printing) _____

UNBIASED WITNESS SIGNING _____ Date_____

NAME OF IMPARTIAL WITNESS (in capital letters)_____

(only if the patient or his legally recognized representative is unable to read)