

ESMO-CoCARE Patient Information Sheet

Sponsor Name & Address: Institute Curie, 26 rue d'Ulm, 75248 Paris cedex 05 – France (<https://institut-curie.org/>)

Principal Investigator: [to be filled in for each participating PI]
Consultant Medical Oncologist

Telephone no.: [to be filled in for each participating PI]

For questions about your rights or if you wish to make a complaint while taking part in this study, call the following:

Clinical Trials Office: [to be filled in for each participating hospital]

Telephone no.: [to be filled in for each participating hospital]

What is this Patient Information Leaflet about?

You are being invited to take part in a Registry Study. Registry studies are conducted to gather more information about the best way to manage patients' illnesses. This study is being conducted to collect information on the impact of COVID-19 on patients who are currently under treatment or have a history of treatment for cancer. Before you decide whether or not to take part in this study, it is important for you to understand why it is being done and what it would involve for you.

What is COVID-19

COVID-19 is the disease caused by the novel SARS-2 coronavirus. For patients with cancer across Ireland, the COVID-19 outbreak is a major cause for worry and concern. Cancer patients have been advised to cocoon due to the risk of severe COVID-19 infection. Their treatment is also being impacted. We want to understand how COVID-19 infection affects cancer patients.

What is ESMO-CoCARE?

The European Society of Medical Oncology (ESMO) has launched a COVID-19 Registry for patients with Cancer (ESMO-CoCARE) that aims to gather data on

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patients with cancer who develop COVID-19. Patients with cancer are at increased risk of infection as a direct result of both their cancer and their cancer treatment.

Who is organising the study?

This study is organised by the European Society of Medical Oncology (ESMO), which is a not-for-profit research organisation. ESMO's core mission is to improve the quality of cancer care, to educate on the best practices and latest advances in cancer care, and to promote equal access to optimal cancer care.

What is the purpose of this registry?

COVID-19 is a new virus and there is a lack of information on the management of patients with cancer who are either on active treatment or have had treatment for their cancer in the past. ESMO-CoCARE is a multinational and multicentre study which was developed to accelerate research to further the understanding of the impact of COVID-19 on cancer patients.

It aims to quickly gather and analyse data in order to publish evidence-based guidelines on the best course of treatment for patients like you.

Further information on the ESMO-CoCARE Registry may be found here:

<https://www.esmo.org/covid-19-and-cancer/collaborating-on-registries-studies-and-surveys/esmo-cocare-registry>

Do I have to take part in this study?

No, participation in this study is voluntary. If you decide against participating in this study, it will have no impact on the care you receive either now or in the future, and it will not impact the relationship you have with your doctors, nurses, or any other member of the team treating you at this hospital.

What will happen if I decide to take part in this study?

If you decide to take part medical staff will collect the following information from your medical charts:

- Personal information such as age, gender, health background
- Cancer Information such as the type of cancer that you have and what cancer treatment you are currently undertaking or have received in the past.
- COVID-19 information such as when and how you were diagnosed and what treatment you have had. It will also confirm if you remained at home and had your treatment at home or in hospital and the outcome of this treatment. Finally, it will confirm when you have recovered from COVID-19

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and whether there has been any significant additional impacts on your cancer care.

Your Name, Date of Birth, Hospital Number, Phone Number, Address, or any other identifiable information about you will not be collected for this study.

How is my information used?

The information collected from your medical chart will be entered on a secure web-based portal held by ESMO-CoCARE, which is based in Switzerland. The collected data from all participating patients over the world will be analysed and the results will provide management guidelines for doctors to treat COVID-infected cancer patients.

How is your privacy and confidentiality protected?

1. The registry will generate a unique number for your record and only your hospital can link your name to your record in the registry using this unique number.
2. Your personal data will be used in order to conduct research into patients with cancer who develop coronavirus infections.
3. Your data will be processed in accordance with General Data Protection Regulation (GDPR) legislation.
4. Only the ESMO-CoCARE staff will have access to your data but will not be able to identify you from the data collected on the database
5. Your data will be stored for a minimum of 10 years. This data may be accessed by the study researchers during this time.
6. Should you decide to withdraw from this study, you may request that any data collected prior to your withdrawal be erased.
7. You are entitled to request a copy of any/all data stored about you by this study under GPDR legislation. You have a right to have any inaccurate information about you corrected or deleted, unless your request would make it impossible or very difficult to conduct the study, e.g. if you do not want your data shared. In such instances, you would have the right to withdraw from the study and request that your data be erased.

What should I do if I want to discuss this study further before I decide?

We would encourage you to take some time to reflect on whether you would like to participate in this study. After reading this information, a staff member will discuss the study with you further and answer any questions you might have. We understand that you might not want to make a decision right away, and that you might want to discuss the study with your family or friends first.