UK EORTC LIAISON OFFICE

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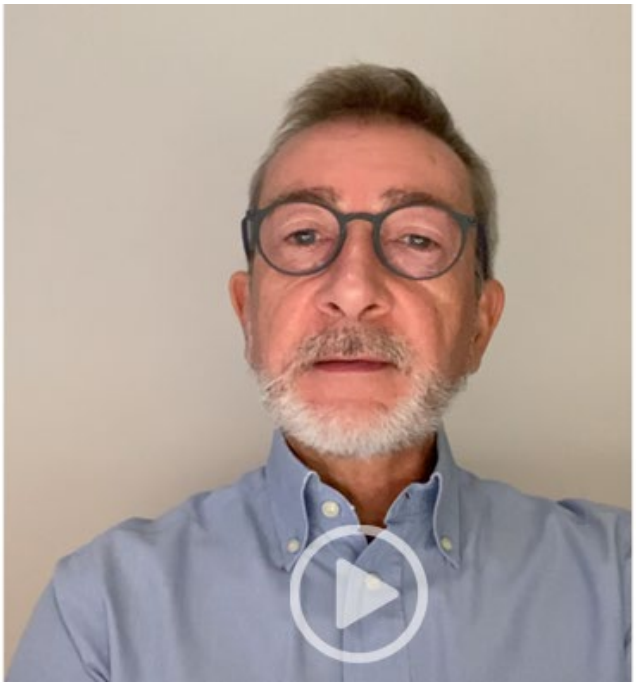


EORTC experts' views

Prof. Dr.Corinne Faivre-Finn, FRCR, MD, PhD
Honorary Consultant in Clinical Oncology,
The Christie NHS Foundation Trust
Professor of Thoracic Radiation Oncology,
Division of Molecular and Clinical Cancer Sciences,
The University of Manchester

Professor Corinne Faivre-Finn is an Honorary Consultant Oncologist and a Professor of Thoracic Radiation Oncology at The University of Manchester. She trained in Paris until 1998 and took a consultant post at The Christie in 2001. She was appointed as Professor of Thoracic Radiation Oncology at the University of Manchester in 2015.
Prof Faivre-Finn is recognized internationally as a leader and researcher in the field of lung cancer. She is an active member of several national and international research committees, among which the EORTC working group on the definition of NSCLC synchronous oligometastatic disease. She was the chair of Radiotherapy at EORTC Lung Group in years 2008 – 2014. Since 2015, she takes the chair's role of the EORTC Lung Group, NSCLC and Radiotherapy. Professor Faivre-Finn is also a member of the steering committee of the EORTC

Radiation Oncology Scientific Council (ROSC) and currently she is developing the PRIMALUNG trial (EORTC-1901-LCG).
She is the author or co-author of 221 scientific publications including publication of six practice changing clinical trials in the New England Journal of Medicine (2007,2018), the Lancet (2014, 2016), Lancet Oncology (2009, 2017). In 2019 the International Association for the study of Lung Cancer (IASLC) selected Professor Faivre-Finn as the recipient of the prestigious 2019 James D.Cox Lectureship Award for Radiation Oncology in recognition of her outstanding contribution in the field of radiation oncology.

Prof. Faivre-Finn has kindly agreed to share with us her opinion on below listed questions.

What challenges are you facing in conducting trials in your country?

During the peak of the COVID-19 pandemic most centres in the UK paused oncology clinical trials temporarily (in April 2020 the National Institute for Healthcare Research reported that 90% of its non-commercial research had been paused). This was due to staff capacity issues and also to the need to reduce the number of hospital attendances for patients. Since May 2020 most trials have reopened and the main challenge is to consider the risk-benefit ratio of patients taking part in clinical trials. Patients taking part in clinical trials may derive a benefit but on the other hand they will be attending the hospital more frequently for investigations, treatment or follow-up visits. This risk benefit ratio should therefore be discussed with patients when clinical trials are considered. Another challenge is that we are conducting a large proportion of follow-up consultations by telephone. As a result some investigations considered not essential are being postponed (e.g. per protocol bloods or CT scans) which could have an impact on clinical trial endpoints.

How can EORTC help to facilitate your clinical research?

The EORTC HQ team and Liaison Office have been very helpful in expediting the set-up of clinical trials. Cambridge are the lead site for the DYNAMIC trial looking at immunotherapy in OG cancer and cholangiocarcinoma, and the EORTC Liaison Office helped to complete trial documentation and regulatory submissions in good time. It is very efficient to have a team who is familiar with the regulatory landscape in the UK. EORTC HQ are very knowledgeable and friendly and always helped immediately with any queries from the Cambridge trials team or myself. In addition, setting up regular webinars with the study team is helpful for any questions that we might have during the trial. Overall, both HQ and the UK Liaison team make setting up and running the trial as stress free as possible.

How is clinical research going to change in the future? How will that affect your country?

In my view, it will take months to years for the oncology clinical research community to recover from this pandemic. Firstly, clinicians and patients may be reluctant to consider clinical trials for the reasons mentioned above. Secondly, funding for academic cancer clinical trials from the UK government and cancer charities will be reduced due to the impact of this pandemic on the economy. Thirdly, the clinical research focus and funding in the short and median term will be diverted towards COVID-19 research and trials. Lastly and sadly, some cancer clinical trials in the UK may not continue, particularly if the recruitment was slow prior to the pandemic.

UK EORTC Liaison office activity

Thank you!

A big thank you to all UK site teams and Chief Investigators for their valuable input in what has been a very challenging year! The emergence of the COVID-19 pandemic in early 2020 led to many EORTC studies being paused to recruitment and the set-up of new sites being delayed. However, whilst there was a rapid and significant reduction in NIHR research activity, the UK Liaison Office was still very busy submitting amendments related to the impact of COVID-19. We hope that recommendations such as the shipment of drugs to participants' homes will encourage participants to feel safe and reassured about the research process.

The NIHR Restart process is now underway. Whilst many EORTC studies continued to recruit globally, we are pleased to confirm that all EORTC studies are viable and that recruitment can recommence in the UK as soon as you are able. We are already seeing an increase in recruitment activity, which is promising.

Your help is crucial in getting our existing open studies up and running again and will enable us to open our new studies quickly and efficiently. More than ever, we appreciate your continued support.

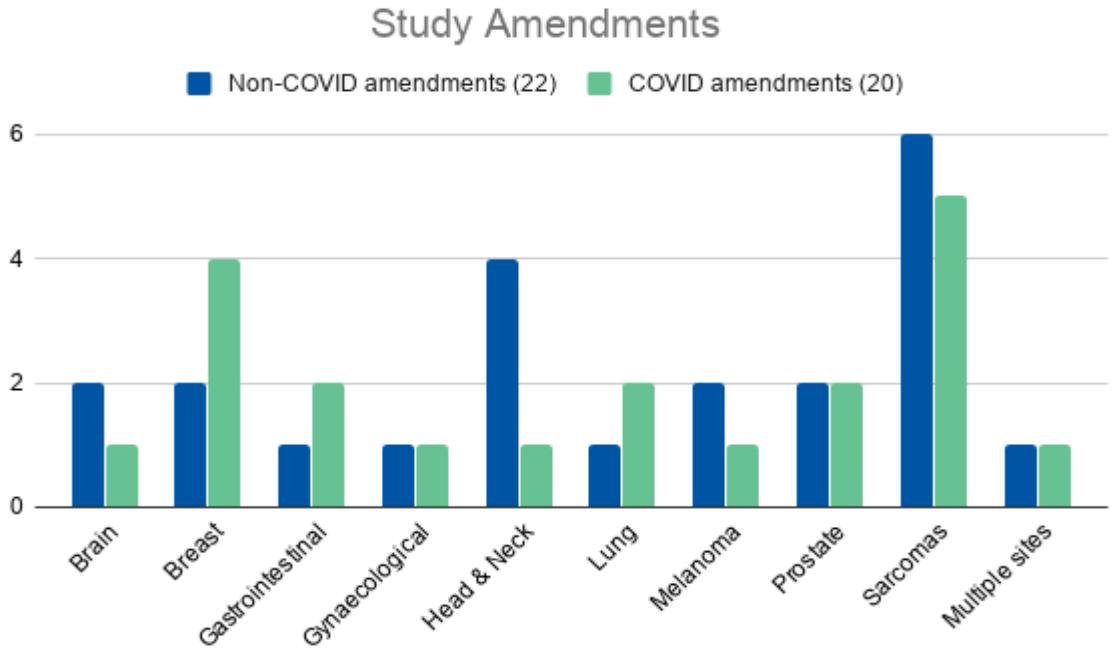
Studies recently opened in the UK or awaiting regulatory approval

Between November 2019 and 15 September 2020, 3 studies have opened to recruitment.
2 studies are still awaiting HRA and REC approval or have local approvals still pending.

Study number	Study title	Chief Investigator	Open to recruitment	Awaiting HRA/REC or local approvals
1607-GITCG	Open-label first line, single-arm phase II study of CisGem combined with pembrolizumab in patients with advanced or metastatic biliary tract cancer	**Dr Juan Valle,** The Christie NHS Foundation Trust	X	
1612-MG	Combination of targeted therapy (encorafenib and binimetinib) followed by combination of immunotherapy (ipilimumab and nivolumab) vs immediate combination of immunotherapy in patients with unresectable or metastatic melanoma with BRAF V600 mutation: an EORTC phase II randomized study (EBIN)	**Dr Heather Shaw,** East and North Hertfordshire NHS Trust	X	
1617-QLG-BCG	Follow-up in Early and Locally Advanced Breast Cancer Patients	**Dr Galina Velikova**, Leeds Teaching Hospitals NHS Trust		X
1635-BTG	IDH mutated 1p/19q intact lower grade glioma following resection: Wait Or Treat? IWOT - A phase III study	**Dr Sara Erridge**, NHS Lothian		X
1762-STBSG	Reduced dose-density of denosumab for maintenance therapy of unresectable giant cell tumor of bone: a multicenter phase II study "REDUCE"	**Dr Palma Dileo,** University College London Hospitals NHS Foundation Trust	X	

Study Amendments

A total of 42 study amendments were submitted and approved in the UK between November 2019 and 15 September 2020. This includes both substantial and non-substantial amendments. Changes and recommendations resulting from the COVID-19 pandemic were significant and account for approximately 50% of the amendments.



New studies planned for opening in 2021

Several new studies are planned for the UK in 2021. All are being prepared for regulatory submission in late 2020-early 2021.

Study number	Study title	Chief Investigator
1754-CLTF-REACH	Study to determine the aetiology of chlormethine gel induced-skin drug reaction in early stage mycosis fungoides cutaneous T cell lymphoma (MF-CTCL)	**Dr. Julia Scarisbrick**, University Hospitals Birmingham NHS Foundation Trust
1809-STBSG	A randomized phase III study of neoadjuvant chemotherapy followed by surgery versus surgery alone for patients with High Risk RetroPeritoneal Sarcoma (RPS) STRASS 2	**Dr Dirk Strauss**, The Royal Marsden NHS Foundation Trust
1811- E²-RADIatE	E²-RADIatE: EORTC-ESTRO RADiotherapy InfrAstrucTure for Europe	*To be confirmed*
1825-LCG	Activity of Lorlatinib based on ALK resistance mutations on blood in ALK positive NSCLC patients previously treated with 2nd generation ALK inhibitor ALKALINE	**Dr Fiona Blackhall**, The Christie NHS Foundation Trust

EORTC trials portfolio and recruitment status in the UK

List of studies under activation, recruiting or recently closed in the UK (cut-off date: 15/09/2020)

View table

Regulatory highlights and FAQs

What steps have been taken to ensure my study is COVID safe?

The NIHR wishes to restart paused and new research as soon as possible. To facilitate this all of our EORTC studies have implemented amendments that take into consideration the safety of our participants. Measures such as restricting the number of hospital visits have been introduced to reduce the risk of exposure to COVID-19.

We hope that these amendments will alleviate any concerns about COVID-19 that a participant may have. The UK Liaison Office is well-placed to provide guidance and support for any concerns you may have.

How can I ensure that my study is GDPR compliant?

The General Data Protection Regulation (GDPR) came into force on 25th May 2018. Since then, the UK Liaison Office and the Data Protection Office at the EORTC have been working closely together to develop our existing text regarding patient confidentiality to ensure that our studies are GDPR compliant. We will continue to develop this text where appropriate.

Who makes the regulatory submissions for EORTC member studies in the UK?

The Liaison Office is responsible, together with the UK CI, for making the UK regulatory submissions (with the exception of MHRA submissions that are managed by the EORTC study team) and is the main point of contact for any site-specific regulatory queries. Amendment submissions are also managed by the Liaison Office.
More information on UK LO's range of tasks and responsibilities as well as our contact details can be found on the EORTC UK LO webpage here.

What happens if an EORTC study requires an Amendment?

The Liaison Office is responsible for all amendment submissions in the UK. Please remember that with the exception of urgent safety measures, amendments cannot be implemented until all relevant approvals are in place and the EORTC team has given sites the green light.

Are EORTC studies eligible for the NIHR Portfolio?

EORTC member studies are not automatically eligible for inclusion on the Portfolio. The Liaison Office apply for inclusion and studies are assessed on a case-by-case basis. Whilst inclusion is not guaranteed, it is rare for EORTC studies to be rejected and indeed all submitted studies within the last seven years have been included. Sites will be informed of the study Portfolio status as soon as HRA Initial Assessment is provided.

Who provides the sites with documents in order to obtain NHS Permission?

The Liaison Office provides all documentation relating to regulatory submission in the UK. Additional documents required by the EORTC study team to activate sites to recruit will be provided/requested by the EORTC study team.

Should I ask the Liaison Office or the EORTC study team if I have any queries?

- The Liaison Office is best placed to answer UK-specific queries or any regulatory questions. However, the Liaison Office acts as a channel of communication and is happy to help with other queries or be copied into emails to aid correspondence.
- The EORTC study team should be preferably contacted in case of study-specific queries such as clinical/pharmacy questions or data queries and patient eligibility once the study is open.

Does my study require a SoECAT?

From 1st October 2018 a new process has been developed to support the cost attribution of study activities. The Schedule of Events Cost Attribution Tool (SoECAT) is a new template that captures and calculates the different activities and potential resource requirement associated with a study in a standardised way. This form should help funders, Sponsors and sites make a better assessment of the costs associated with their study and make it simpler for Excess Treatment Costs (ETCs) to be paid.
Under this new process, the Liaison Office will be responsible for completion of the SoECAT with assistance from the Local AcoRD Specialist. Further guidance can be found here.

EORTC membership

EORTC membership enables the active participation in EORTC clinical trials and EORTC groups' meetings, conferences and trainings. Candidates may apply directly through the Membership Committee, or through the structures of the research groups (chairman or secretary).

Related information can be found here. The application forms are available from the EORTC Membership Coordinator who should be contacted via the general e-mail: membership@eortc.org.

Fellowships for young investigators (physicians and statisticians)

EORTC always looks for young, active, talented people, who want to develop their skills under the supervision of EORTC. There are different opportunities available, the grants for
1 up to 3 years, when young people can design, construct and analyse different kind of data with the possibility to produce the final professional paper for publication or presentation at one of the world-famous scientific congresses. Everybody interested in the fellowship position at EORTC HQ is welcome. More information about fellowship program, current opportunities and selection process can be found here.

Agenda of events

The full calendar of virtual EORTC scientific meetings and conferences per category can be found here.

For direct access to information about the calendar of EORTC Research groups' virtual meetings click here.

SAVE the DATE!

We highly recommend the following key virtual conferences:

Free registration!

More information will be soon available on the conference website here.

Free registration!

More information will be soon available on the conference website here.

The Liaison Office contact details can be found on the EORTC UK Liaison Office home page