

# World-first clinical trial launches for advanced bowel cancer

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Patients with advanced bowel cancer are set to benefit from the launch of a revolutionary new clinical trial targeting treatments to their specific cancer type as well as rapidly adapting to include new drugs and new biomarkers as they become available.

The first trial of its kind in solid tumours, FOCUS4 will divide around 2,400 patients into different, smaller groups depending on specific biomarkers found in their tumour. These biomarkers will then be used to

predict the targeted treatments that patients are most likely to benefit from.

The trial is jointly funded by the National Institute for Health Research (NIHR) and Cancer Research UK, through its partnership with Stand up to Cancer and Channel 4.

Patients with advanced bowel cancer will first receive the standard four months of chemotherapy and have their cancer biopsy analysed for a number of biomarkers at the same time. Based on the test results, patients will be offered enrolment into a sub trial that will test a new drug targeted at their specific type of bowel cancer.

And for those who don't have any of these biomarkers, or if there are no open sub trials for their biomarkers, they will be offered a trial to see what difference extra chemotherapy could make.

Unlike a standard trial, each sub trial will be analysed at four stages to assess the activity and effectiveness of the drug. The flexible trial design allows researchers to stop testing treatments that are not working in enough patients and replace them with other targeted drugs, including new drugs as they become available.

This approach is also flexible enough so that new biomarkers can be added as and when there is strong evidence for them – having been developed within FOCUS4 or from other trials.

Chief investigator Professor Tim Maughan, of the University of Oxford and Oxford University Hospitals NHS Trust, said: "Research has shown that no two bowel cancers are identical, yet we treat them in the same way. FOCUS4 is a completely new approach to clinical trials for cancer – rather than focusing on an individual drug we are trying to find the best treatment for each of our patients.

"The trial takes advantage of the 'rest period' that patients with advanced bowel cancer have after being treated with four months of chemotherapy – they would normally be monitored until their cancer starts growing again and then offered more chemotherapy. In FOCUS4, they will receive the new treatments until the tumour starts growing.

"We hope this approach could be a game changing moment for the treatment of bowel cancer and for how we run clinical trials to tailor treatments to each individual."

Two of the sub trials are currently open and further ones are expected to open in 2015. Patients will be enrolled onto the trial from 132 centres across the UK, including the network of Experimental Cancer Medicine Centres (ECMCs), a jointly funded initiative supporting early phase cancer trials. Overall co-ordination of the trial will be through the Medical Research Council (MRC) Clinical Trial Unit at UCL, where the FOCUS4 design was developed.

Another important aspect of the trial is that all the samples will be tested at two central labs, in Cardiff and Leeds, rather than at each hospital. This will mean that it will be easier to test for new biomarkers as they become available.

Dame Sally Davies, Chief Medical Officer and Chief Scientific Adviser at the Department of Health, said: "That both the NIHR and Cancer Research UK are supporting this trial illustrates the huge leap forward it could represent in understanding how we can identify the most effective anti-cancer treatment for an individual, and the potential to make a real difference to people's lives."

Professor Richard Kaplan, FOCUS4 programme lead at the MRC Clinical Trials Unit at UCL, said: "The capability of handling multiple sub-types of bowel cancer, multiple drugs and multiple biomarkers

makes FOCUS4 potentially a far more efficient platform than conventional trial designs for speeding up identification of the best biomarker and drug combinations."

Kate Law, director of clinical research at Cancer Research UK, said: "The phenomenal pace of cancer research means that we are learning more about the disease every day. The flexibility of this trial will allow the researchers to respond to the latest findings and add in extra sub trials as new markers and drugs become available. This has the potential to answer many questions about bowel cancer in just one trial."

Provided by Cancer Research UK

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