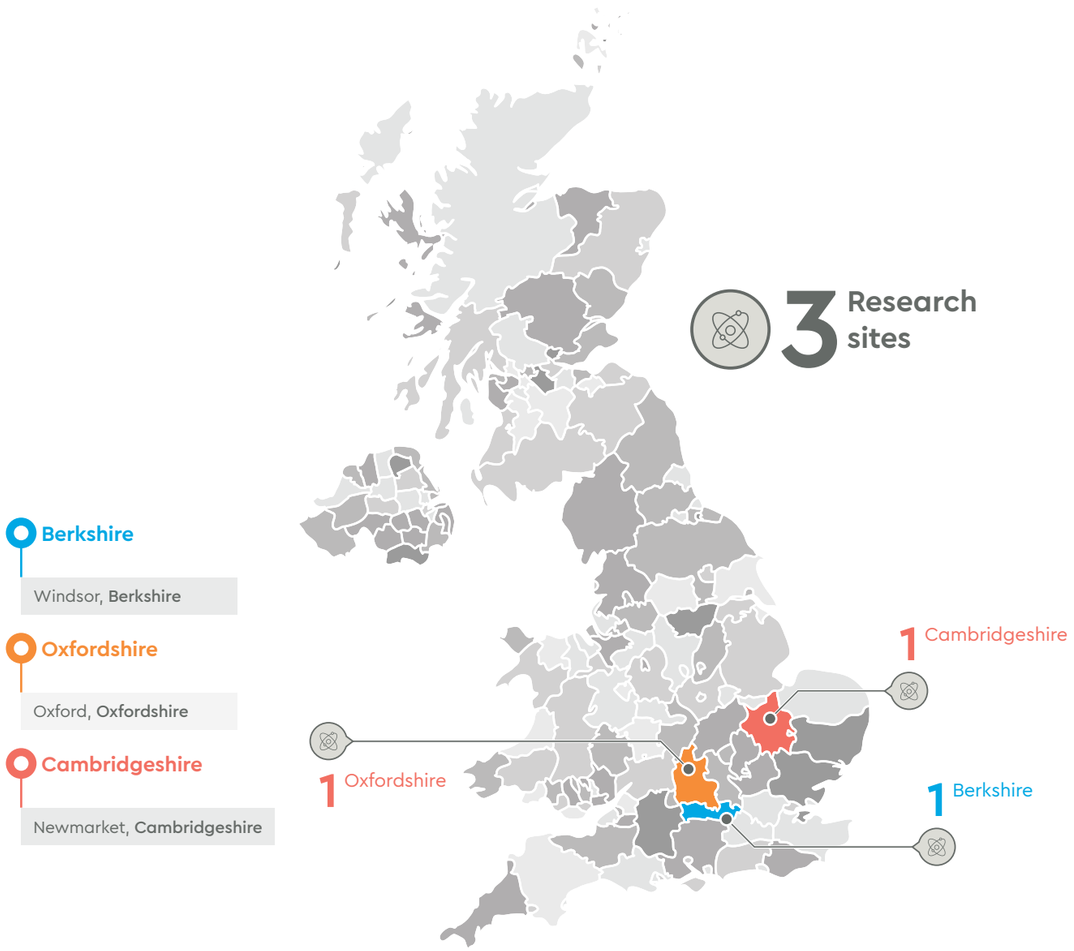
GenesisCare, UK

Active clinical trials	Total ongoing patients in trials	Top tumour types	Published articles	External sponsors	Number of sites	Number of research active PIs
6	14	Haematology Breast Prostate	3	5	3	8



Haemotology trials for patients – a foundation for more

From 2018, GenesisCare United Kingdom (UK) started to conduct clinical trials at its Oxford and Cambridge sites. Currently, the principal investigators and the research teams at these two sites have been engaging in haemotology trials; however, in 2020, aside from continuing its haemotology trials during the pandemic, the team worked hard to prepare GenesisCare Oxford for Medical Oncology studies and evaluating the potential of establishing Theranostics Research at GenesisCare Windsor (see Looking Beyond 2020 for more on GenesisCare Windsor's Theranostics Research).

Oncology research UK | **Trial feature**

TIDAL: Bringing new opportunities to patients with multiple-relapse lymphoma

Multiple-relapse, low-grade lymphoma is difficult to treat with no definitive therapeutic options routinely available. PI3K inhibitors are a class of drug with proven activity in follicular lymphoma, but they have quite high toxicity, and although approved for use in Europe, they are not reimbursed in UK. ME-401 is a new PI3K inhibitor which showed promising results in phase 1 trials. Unlike other PI3 kinase inhibitors, ME-401 is administered orally, resulting in a reduced side-effect profile.

At GenesisCare, Oxford, consultant haematologist Dr Graham Collins is principal investigator for the Mei Pharma, Phase II TIDAL study which investigates ME-401, a phosphoinositide 3-kinase (PI3K) inhibitor, in follicular lymphoma (FL) and marginal zone lymphoma (MZL) patients.

Dr Collins and the study team at GenesisCare, Oxford recruited six patients onto the study during 2020, exceeding the site target. The site is also the highest recruiter in the UK and 2nd in Europe. The trial has brought significant changes to lives of patients affected by the disease.

After not responding to standard treatments, one young patient improved to such an extent on MEI-401 that he was given the opportunity to receive a stem cell transplant. He commented:

“In 2020, I participated in a clinical trial for ME-401. At the time I began, I had just learned that my lymphoma (B-cell follicular) was resistant to chemotherapy. Since I had rather large tumours, I was extremely anxious to find some sort of treatment that might be able to help me. ME-401 worked very well and, over the course of 9 months, my lymphoma reduced to the point where I was able to receive a bone marrow transplant in early 2021. I am unbelievably grateful for the chance to participate in the trial, which probably saved my life. Dr Collins and the entire staff at Genesis[Care] were absolutely superb, during a year dominated by the Covid-19 pandemic. I am now, and will always be, very, very thankful to them for everything they have done for me and my family.”

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Trial highlight

ASSURE: A phase IIIb, multi-centre, open-label, single-arm study of acalabrutinib (ACP-196) in subjects with chronic lymphocytic leukemia

The research team at GenesisCare, Cambridge

Finding therapeutic options for chronic lymphocytic leukaemia (CLL) which are tolerable and can manage the disease long-term have been elusive. Acalabrutinib is a next generation Bruton's tyrosine kinase (BKT) inhibitor that can stem the production of B-lymphocytes at the receptor level with greater potency and molecular specificity than first-generation chemotherapeutic agents. The ASSURE clinical trial, sponsored by AstraZeneca, has provided an opportunity for patients with relapsed/refractory CLL to gain access to acalabrutinib.

Despite the challenges of delivering chemotherapy during pandemic restrictions and lockdown, principal investigator Professor Follows and the Cambridge research team, opened the trial as planned on 20 July 2020. Collaborating closely with the Cambridge centre, the research team achieved its recruitment target of four patients from August to October 2020. All have benefited from treatment with the first two patients set to reach 12 cycles of treatment in July 2021.

One patient describes their experience:

> I feel absurdly fortunate to be on the ASSURE trial. Only a year ago my NHS consultant had been through secondary treatment options for me and told me that sadly acalabrutinib would not be available through the NHS in time; and no NHS hospital was offering the trial. I was sad too as I had already read about its success rate in the USA. My JOY at finding I could be on a trial was enormous – and fully justified. A cancer patient on a trial needs expertise, compassion, reliability, safety and, as the icing on the cake, a calm healing environment. GenesisCare, Newmarket has all of these in spades! For me it has been a life-enhancing experience and I am hugely appreciative of the science and the care.

On 9 November 2020, acalabrutinib was approved in the European Union (EU) for the treatment of adult patients with chronic lymphocytic leukaemia.

Professor Follows with ASSURE trial patient

Professor Follows

> It is exciting to participate in this trial which aims to show acalabrutinib is safe and effective.

CC-220 Iberdomide: Oral ixazomib-dexamethasone versus oral pomalidomide-dexamethasone for lenalidomide-refractory, proteasome inhibitor-exposed multiple myeloma (MM) patients: A global, multicenter, randomized, open-label, phase II trial

Multiple myeloma (MM) makes up 12% of all haematological malignancies and often requires several lines of therapy with multiple drug combinations. It is common for patients to become refractory and patient age also affects tolerability. Therefore, developing convenient therapies, such as all-oral regimens, has been an area of high priority.

Iberdomide acts as an immunomodulator, binding selectively to cereblon – a protein coding gene – causing degradation of two proteins involved in lymphocytic differentiation. Used in combination with other agents, such as dexamethasone, its synergistic effects and increased tolerability makes it a promising prospect for MM patients.

Consultant haematologist Dr Karthik Ramasamy is principal investigator for an early clinical evaluation trial investigating Celgene Corp's CC-220, '-domide' class drug, in multiple myeloma patients.

Dr Karthik Ramasamy

> Myeloma patients do eventually become refractory to licensed therapies. The trial offers salvage agent iberdomide as a treatment option to both private and NHS patients at GenesisCare.