

Collaboration proves crucial to recruitment success

For industry one of the biggest benefits of working with a Topic-specific Clinical Research Network is being able to tap into the expertise and support offered by Clinical Studies Groups (CSGs). One such CSG recently played an important role in the performance of an AstraZeneca sponsored study supported by the National Cancer Research Network (NCRN). As a result, the study overcame unforeseen obstacles and led the world in terms of recruitment.

A Clinical Studies Group is a UK-wide body of expert clinicians, scientists and consumer representatives who analyse the research landscape - in the UK and internationally - and decide which studies are needed to address the needs of their patients. CSGs then develop proposals for research studies to meet those needs and seek funding opportunities to finance them. Equally, CSGs consider studies that are proposed by other clinicians or by pharmaceutical, biotech or medical device companies and provide advice about their feasibility and how they may maximise their chance of success. CSGs also play an important role in running studies accepted onto the Clinical Research Network Portfolio.

NCRN works closely with the National Cancer Research Institute (NCRI) and both organisations share 22 CSGs. The Melanoma CSG recently played a significant role in study NCRN063 to ensure it met and eventually exceeded recruitment targets in the UK.

NCRN063 is a global, multi-site study looking at the safety and effectiveness of

an experimental drug for treating malignant melanoma. The drug is aimed at a minority of melanoma patients with particular characteristics in their tumour samples. Six UK sites participated in the study, with an overall recruitment target of 10 patients.

When NCRN063 opened in July 2009 it was expected that between 25-50% of patients screened would have the appropriate tumour type to be eligible for the study. By January 2010 study teams had screened 47 patients yet had only recruited four of the 10 patients required. With the successful screening rate running at only one in 12, there was a real chance that research staff could become disillusioned with the study. Jenny Gray, NCRN Industry Lead, explains:

“Recruitment was due to close, in all countries, in March 2010. To recruit to time and target we had to sustain a high screening rate and the key to this was keeping the study at the forefront of people’s minds. We achieved this with the help of Network managers, who maintained the profile of the study at recruitment sites, and by ensuring communications activities

were coordinated with AstraZeneca. But crucially, the study profile also benefitted from the influence of the Melanoma CSG. The Chair, Dr Paul Lorigan, and the chief investigator for NCRN063 in the UK, Professor Mark Middleton, communicated directly with principal investigators to support the study.”

Thanks to the concerted efforts of the Melanoma CSG, AstraZeneca and NCRN, screening remained high throughout all six UK sites. In the last two months of the study, the successful screening rate picked up markedly and study teams recruited 12 more patients. Ultimately this meant the UK led the world for recruitment, screening 69 patients and enrolling 16. This achievement is more significant given that a second commercial melanoma study, in the same patient population (NCRN058), was running at the same time and also delivered to time and target.

NCRN063 was one of the first AstraZeneca studies adopted on to the Clinical Research Network Portfolio. Ruth Coy, AstraZeneca Clinical Project Lead for the study, is clear about the benefits of working with NCRN:

“NCRN provided a coordinated process for admissions and approval. For NCRN063, this shortened set-up time meant that approvals were received only six days after full ethics approval. Sites were then able to get local approvals more quickly.

“The Network can also provide us with information about similar studies. If we found some of the sites were working on a study with a similar population, this could make the recruitment of patients more challenging. A positive aspect of Network



Dr Paul Lorigan chairs the Melanoma CSG

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support is that they have access to a list of sites, with particular expertise, who are interested in taking part in clinical research. That kind of knowledge and support is extremely useful.”

CSGs are part of that support network and for Dr Lorigan, the expansion of the National Cancer Research Network is having a positive impact on the influence of the Melanoma CSG:

“Because the NCRN is increasing in strength, we are at a point where we can provide better geographical coverage of the UK, and maintain the profile and activity of studies in an increasingly competitive environment, guaranteeing timely delivery of good quality data.”

Professor Middleton sees the cohesiveness of the melanoma clinical research community and expansion of NCRN as key industry selling points:

“The CSG creates a forum in which clinicians across England can share information, which provides a coherent, nationwide approach. The effect is that studies have a Network-wide profile and we can recruit to studies across the UK. If you look at the sites in NCRN063, they all screened at least nine patients. In other countries, recruitment was much patchier because some centres succeeded and others didn't. All the centres in England contributed and our system is seen as more efficient as a result.

“This is vital in engagement with industry as we can use it as a selling point. We can say, ‘You get a coherent response to your trial from the UK.’ We police ourselves and if it's not going well within a centre the chief investigator will address any problems that arise.”

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Dr Lorigan agrees that melanoma studies benefit from a collaborative approach that unites the Melanoma CSG and the wider clinical research community:

“The reason why the Melanoma CSG is having a positive impact on the set-up and delivery of studies is down to the ability, enthusiasm and reputation of members, coupled with their willingness to collaborate and work as a team. It's similar to a top football team in many ways: it's all good and well having talented players, but if they fail to work together, with a common aim, they will not succeed.

“The same can be said for the wider research community in that the Melanoma CSG, NCRN and NCRI have a shared ethos: we all want to give nationwide access to new drugs. The reason why the Melanoma CSG works hard to adopt commercial studies such as NCRN063 onto the Clinical Research Network Portfolio is because Network involvement brings studies in line with this ethos, as it gives more melanoma patients in England the opportunity to take part in clinical research.”

The results of NCRN063 are eagerly awaited. It is generally agreed that developing several types of such targeted therapies – so that treatments can be matched to specific individual patients – will be an important step forward. However, Dr Lorigan feels the research community needs to find smarter ways of working and a more effective way of acknowledging the amount of work that

goes into recruiting patients to targeted therapy studies such as NCRN063:

“What needs to be recognised is that conducting studies into targeted therapies involves a great deal of time and commitment, which is not reflected in terms of recruitment figures. While only 16 of 69 patients screened were eligible for NCRN063, all 69 had to be seen, consented, screened, and then advised on other options if they were not eligible. This involves many hours of work for all of the team that is not subsequently acknowledged as research activity. A standard chemotherapy study with no patient selection based on molecular testing would have recruited most of the patients and these numbers would have been recognised as an example of high performance.

“Of course, we need to find smart ways around this and that's exactly what we are doing. In 2011 we will have studies that are appropriate for a limited number of patients conducted alongside studies that are applicable to a much higher number of patients. This is an excellent example of key investigators collaborating to resolve a problem, securing access to novel therapies and maximising opportunities for patients to be involved in clinical trials.”

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