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Recruitment to 'time and target' in clinical gastroenterology studies

Clinical gastroenterology research studies entered into the United Kingdom (UK) National Institute for Health Research (NIHR) portfolio are eligible for support provided by the UK Clinical Research Network (UKCRN).[1] The overarching aim of the UKCRN is to maximise clinical research delivery by providing infra-structure support, which includes, for example, protected Clinician research time and Research Nurse support at individual study sites in NHS institutions.

Individual study performance on the UKCRN Portfolio is closely monitored using several 'metrics', the principal one being study recruitment to 'time and target'. Each study is rated on a BRAG – black/red/amber/green system, with success (green) defined as greater than 80% recruitment according to each study's self-determined recruitment schedule.[2] One can immediately see that funding bodies such as NIHR and the research Charities might be very interested in the number of 'green' studies in the Gastroenterology Portfolio, as an indicator of the future ability of Gastroenterologists to deliver successful research projects, with which to make funding decisions. The same could be said of potential Pharma Trial Sponsors, which approach the UKCRN for identification of research sites for multi-centre studies.

It is, therefore, in the Gastroenterology research community's best interests to maximise the number of 'green' studies in the Portfolio. However, it appears that we are not currently performing very well (only 25% of open non-commercial studies were green compared with a Portfolio target of 80% [data accessed 21/2/2014]). There are obviously many reasons why research projects do not proceed to plan and participant recruitment is lower than expected, which may be beyond the Investigators' control. However, there are also several 'Investigator factors' that probably contribute to poor 'metric' performance and that can be addressed relatively easily by Gastroenterology researchers:

1. Investigators should carefully consider and state a realistic, achievable sample size target for their study, along with an appropriate start date and study duration, during the Integrated Research Application System (IRAS) application process for study approvals. Targets set during the approvals process directly populate the Portfolio entry. One might expect that basing the 'time and target' metric on the predictions of the Investigator would give a study the best possible opportunity to recruit to 'time and target'. However, many Investigators still underestimate the time taken to gain regulatory approvals during study set-up and over-estimate recruitment potential. Realistic targets compatible with the funding provided for a study are more likely to be achievable.
2. Investigators should realise that if unexpected delays are encountered, the above targets set in the UKCRN Portfolio may be altered in the Portfolio, in agreement with the study funder. This can make a huge difference to an individual study BRAG rating. The key action is to inform Portfolio staff through the Gastroenterology team (see below), who can then help the Investigator gain the necessary evidence of a study extension with which to affect change in the Portfolio.
3. Investigators need to update their study entry on the Portfolio on a regular basis. Portfolio data are updated every month and it is expected that each researcher will provide a monthly recruitment figure. This is, in fact, another 'metric' – so-called 'recruitment upload engagement' or the % number of occasions when monthly accrual data are reported (one

which we are rather better at [95% in February 2014] than recruitment to 'time and target'). One can easily imagine the effect of inaccurate recruitment data on individual study and overall Gastroenterology BRAG ratings.

One factor which has hampered the ability of Investigators to fully engage with UKCRN Portfolio performance has been the lack of a simple means by which to communicate with Portfolio staff in the UKCRN Coordinating Centre. Recently, this has changed with the appointment of a 60% FTE Gastroenterology Portfolio Co-ordinator, whose role is to ensure that individual non-commercial study data entries are as up-to-date and accurate as possible. We are convinced that the Gastroenterology BRAG rating will improve significantly if all Investigators respond in a timely and positive manner to requests from the Co-ordinator for information regarding individual studies that are supported by UKCRN infrastructure locally. The situation is slightly different regarding commercially sponsored studies, but the same strategy applies - maximal engagement with the UKCRN Commercial team will reap dividends for improved 'metric performance'. The Gastroenterology Portfolio Co-ordinator and Chair of the National Specialty Group can be contacted at gastro@nihr.ac.uk.

The UKCRN has recently undergone re-configuration such that Gastroenterology research takes place in 15 Local Clinical Research Networks (LCRNs).[3] Each LCRN has a Gastroenterology Lead, who is well-placed to help any Investigator communicate through the UKCRN Co-ordinating Centre to affect change in the Portfolio. If a Gastroenterologist is unclear who his or her regional Lead is, this can easily be determined by contacting the LCRN[4] or British Society of Gastroenterology[5].

In summary, we believe that the above simple measures based around improved communication with the Gastroenterology Portfolio Coordinator and more realistic targets can improve individual study and overall Gastroenterology BRAG 'metrics' with consequent benefits for Gastroenterology research in general by persuading funders of the feasibility of non-commercial Gastroenterology studies and attracting more commercially-sponsored Gastroenterology research.

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