QUINTILES COMMENTS

- Quintiles has seen a dramatic decrease in draft to executed contract time lines over the last 18 months or so, assisted by the generic review process and a better understanding of how sites in Scotland work. We are clearly seeing additional sites approving studies shortly after the CoC is released and there is clear evidence that the R&D Managers are more proactive in driving the process. The approval timelines (22 days for commercial) are not aligned to the real study start up time line recognised by industry.

- Once clarification of their key responsibilities is established, it might be helpful to have eligibility criteria as per any job description.

- The role of the R&D office (and manager) has changed considerably and they have taken on many responsibilities particularly around management of recruitment. If the responsibilities of the various roles within the new structure were clearly defined it would help identify the functions of the R&D office and these should broadly be the same for each Board.

- Available PI time was listed as a limiting factor to growth and expansion of the Quintiles Prime Site following the recent OPA. We have seen the immediate benefits of 'buying out' clinician time in GG&C and would encourage this where possible. As trials become more complex and risk based monitoring becomes more routine the role of the study co-ordinator and/or data manager will be key to study delivery and therefore any plans to manage resource should consider this too.

- It is clear that NRS is clearly focused on study delivery which is very positive. With respect to the new structure it would be helpful to have more clarity of who is responsible for what, in particular what responsibility will each of the roles have from feasibility to study close. Over the last year or so the NRS Industry Manager role has been instrumental in focusing Boards on delivery and being able to identify the key projects that need to be driven, facilitating how this is done at each Board and escalating as necessary. How will the Industry Manager role fit into the new structure for example? Efficient study delivery can be improved by careful study planning upfront and it would be good to know how this will be delivered through the new structure.

- Quintiles has not experienced delays for this reason for a long time. The local R&D offices may manage this very well in the background.

- Very positive.

- If developed in line with the PAGs, a trial register could be useful but the challenge is driving patients to the website in the first place. For this to work successfully, internet 'stations' within waiting rooms/clinics could be considered.

- As per previous section, bringing the internet into the hospital in an easy to access format would help. Currently when you enter a clinic there is nothing to inform patients that clinical research is taking place, what trials are currently running, if interested speak to the research nurse, etc. When the patient is in the clinic they are a captive audience and we probably don't use this enough. There is some evidence to show that patients respond to other patients who are already in a trial and can be used effectively in clinic areas. We are also seeing some evidence of the benefit of the right person within a study team having an informal chat with patients about research in general.

- There are private research organizations in Scotland which could be used in partnership with the NHS.

- Very positive - would recommend Q could add value from the global experience it has.