UKCRC Registered Clinical Trials Units

Clinical Trials' Data Monitoring Committees (DMCs)/Data Safety Monitoring Boards (DSMBs): appropriate indemnification for committee members

UK Clinical Research Collaboration

igniting our potential

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Background

Any organisation wishing to Sponsor clinical research is required to have an appropriate infrastructure in place. In certain circumstances this will include the appointment and organisation of DMCs/DSMBs. These are not an independent legal identity; they comprise of academics and clinicians engaged due to their professional expertise (although not in the name of their employing institution) working to ensure, by reviewing ongoing data generated by the trial/study in combination with data from other sources, that the safety of the participants is not compromised. Members of DMCs/DSMBs may be appointed in a private capacity.

A paper commenting upon the DMC/DSMB role — DAMOCLES *[1]* recommends that members are not financially recompensed other than for travel and subsistence; in this sense the appointment to a DMC/DSMB is **not** analogous to a remunerated external consultancy.

It is ten years since a paper by Dr David DeMets *[2]* identified areas of concern and provided some proposals for the appropriate indemnification of those serving upon DMCs/DSMBs. Given the growth of a culture of increased litigiousness since then, it is perhaps surprising that the paper's conclusions regarding the provision of an appropriate indemnification have not been more-widely requested. They would appear to be a reasonable, cogent and practical means of addressing this question.

Summary of main considerations

- A DMC/DSMB does not have a distinct legal identity which could enable such a committee to obtain an indemnification through the mechanism of a standard commercial policy of legal liability insurance, which would then operate in respect of any claims arising from any acts or omissions amounting to negligence of that committee's members, or the committee itself with its members acting in concert.
- Even if it were possible for DMC/DSMB appointees to *individually* arrange their own professional liability insurance, how might that operate in the likely event of a collective decision, and not one driven by a single individual, or several identified individuals? Is it not likely to expose the DMC/DSMB chair to potential additional liabilities, making the appointment to these positions more difficult as concerns surrounding any lack of clarity on the indemnity question become more widely disseminated?
- How might a potential DMC/DSMB 'member to member' dispute be addressed, in the event of one member of the committee alleging that they have suffered a loss which could be quantified in a claim for damages, as a consequence of an act or omission of another member?

The conclusion of DeMets' paper — even at ten year's distance — appears an equitable solution:

> That the Sponsoring or Lead institution indemnifies DMC/DSMB members in respect of their ***negligence*** - and it needs to be borne in mind that as highly specialised experts in their field, the bar will be set very high — but ***not*** for any ***wilful breach, recklessness or attempt to defraud***.

At a practical level, this requires:-

A. An express agreement for each trial's DMC/DSMB that indemnification is provided, and with this provision built-in to the agreement between the Sponsor or Lead institution and the individual members.
B. Acceptance across the clinical research community conducting clinical trials/studies that this is an equitable approach which, where their insurance/indemnity arrangements permit, applicable institutions should adopt. Not to do so would leave academics serving upon a DMC/DSMB legally exposed. In making any appropriate representations to achieve the ratification of such an approach, it might be recognised that the Professional Liability/Negligence insurer or other indemnity provider of all Sponsor institutions should recognise that DSMBs/DMCs informing their institutions' Sponsored trials are essentially *'committees of the institution'* and insured within the main insurances as such. However, while the Sponsor should ensure that appropriate insurance /indemnity is in place to cover the members of these committees, it is recognised that the insurance /indemnity arrangements of some Sponsors will not enable cover to apply for committee members not employed by them. Therefore, while 1 might be expected to apply in many cases, it is recognised that some will need to adopt the position in 2 (below).

1. The Sponsor's insurance/indemnity arrangements provides cover for committee members while they are fulfilling this role.

2. The Sponsor is unable to provide insurance/indemnity cover and requires the committee member's employer to provide this. In such cases it is likely that where the sponsor is an NHS organisation in England, the Sponsor will seek indemnification from a committee member's employer.

If there are any doubts concerning the operation of these arrangements, the position should be checked with the insurer/indemnity provider.

Conclusions

UKCRC registered CTU members may wish to disseminate this paper as appropriate within their institution, thereby enabling their institution to consider whether indemnity and associated insurance arrangements are appropriate for their requirements, both as Sponsor institutions, with DSMBs/ DMCs under their aegis, and as institutions whose academics will serve upon others' DSMBs / DMCs.

While it will be for individual institutions to consider the position concerning their own insurance arrangements, from informal enquiries to a small number of insurers, and insurance brokers, it is not envisaged that this proposal will be problematic.

References

[1] Ellenberg SS, 2010

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[2] DeMets D, 2004

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