

## UKCRC Network of Clinical Trials Units

### Summary Response to MHRA Survey of Insurance Practice in Research

Fourteen organisations have responded to this survey and are listed at the end of the document; (12 universities, 1 government supported academic organisation and 1 charity).

The responding organisations hold policies which cover clinical trials activity of between 1 and over 50 trials live during that year. This unsurprisingly leads to a range of charges which is dependent upon the level of activity and the risk of that activity; the range over all organisations for annual premium being £10,000 to £108,000 with the aggregate cost over eight responding organisations totalling approximately £450,000 per annum (six organisations were unable to separate out their clinical trials premium from other insurance premiums and so are not included in this total). For the majority of organisations, (twelve) provided no-fault cover for all or a proportion of their clinical trials (this decision usually being based on the risk of the trial). From the responding group four report claims being made which total approximately £550,000; £500,000 was for one claim which was made in 2003. No other organisations report claims being made.

It is worthwhile noting that for many organisations the 'cost' and 'time' of negotiating and paying for insurance is in addition to that of the annual premium. The expertise and time required to understand and negotiate insurance requirements for individual trials, particularly those which fall outside of that organisation's standard policy e.g. for organisations wishing to move into conducting international trials and so face the complexity of understanding territory specific requirements and taking forward the related additional due diligence and contractual negotiations is sometimes seen as prohibitive and so has stopped some organisations from taking this work forward; this has been reported in a number of previous national and international consultations over the last few years. It was difficult for most organisations to quantify the increase in premium over the last ten years for a number of reasons including a change to the structure of policies and a change in the profile of risk or number of trials being conducted however of the seven organisations that were able to respond five indicated an increase of up to 51% with the remaining two reporting no overall increase.

Of the fourteen responding organisations twelve would likely participate in a national indemnification scheme if there was no related charge however a number of detailed technical questions in regard to how such a scheme might work have been forwarded directly to the MHRA for consideration included within the individual responses from each organisation.

#### Responding CTUs:

Bristol Randomised Trial Collaboration  
Imperial Clinical Trials Unit  
Intensive Care National Audit & Research Centre  
King's CTU at Kings Health Partners  
Leeds CTRU  
Liverpool Clinical Trials Collaborative  
London School of Hygiene & Tropical Medicine CTU  
MRC CTU  
NORTH CTU  
Peninsula Clinical Trials Unit  
CR UK & UCL Cancer Trials Centre  
University of Aberdeen/NHS Grampian [CHaRT CTU)  
University of Oxford on behalf of Oxford CTUs  
York CTU