

APPENDIX 7

QUESTIONNAIRE RESPONSES – SUMMARISED

Some of the comments were common to several groups.

Q1 Current level of activity	As expected from the various groups and not listed here.
Q2 Current indemnity coverage	<ul style="list-style-type: none">• Lloyds in London via AON Annual renewal. \$10 million limit Excludes US and Canada All trials in the one basket• Per trial negotiation; no standard indemnity; not all trials covered.• Trial specific insurance; Gerling via Australian broker. Life of the trial policy; \$10,000 deductible. Premium \$30 – 50,000 per life of trial. Newline apparently provide near identical cover.• Annual renewal; cost up to \$80,000 per year. Cost of premium reducing over time. No deductible.• Trials all covered by the hospital. No knowledge of the deductible or premium• Umbrella policy for COSA Feb 2006 quote – Miller and associates \$90,000 to cover 45,000 patients. In addition \$25,000 administration costs in the first year. No other information provided.
Q3. Claims / incident experience	<p>7 different groups no claims or incidents</p> <p>One claim 61 y.o. with a recognised complication. Went to ICU and sought compensation for \$10,000 expenses. No legal issue.</p> <p>Overall more than 35,000 patients over many years without a claim.</p>

Q4. Who and how are claims handled	<p>Almost no experience with clinical trials in Australia. It is generally expected that they would be handle by any broker.</p> <p>There was some uncertainty about the best way to manage any out of pocket claims should they be sought.</p>
Q.5. What are the current concerns about indemnity	<ul style="list-style-type: none"> • Director and Officer indemnification – level, cover and need • Wide variety of hospitals participate but administration to ensure all the paper work is accurate is a concern. • Lack of experience with consulting studies in a relatively new group. • Corporate indemnity; concern that all collaborative group office-bearers are all volunteers – does this make them personally liable? • Over insurance; appears to be multiple layers of cover already in existence and yet there is still concern. • No sense of whether the premiums being charge are competitive or appropriate. • Uncertain how to mange a deductible; could the deductible to larger and premium smaller • Limited number of Australian broker interested in providing cover. • Paralysing research and seeming never ending in resolution. • Costly process to mange a very low risk situation. • CT patients better cared for and followed more intensively than most other patients. • Bureaucratic demands for any trials making their implementation arduous.
Q6. Personal fear and concerns	<ul style="list-style-type: none"> • Unable to conduct some trials as no CT insurance and will not be personally liable. • Pragmatic and commercial reality so no fear or concerns. • No personal concerns. • Unsure of MDO will cover me. • Covered by university • TMF arrangement in NSW stopping doctors getting involved and patients being recruited. • General unease in some NSW hospitals with treatment and status of patients in OP being treated as de facto private patients.

<p>Q7. management of cross-over issues – public, private and NGO</p>	<ul style="list-style-type: none"> • All covered by insurance. • No concerns or problems. • Many policies include both public and private patients. • All covered by university • NSW public/private patients a problem.
<p>Q8. Do you fear personal exposure</p>	<ul style="list-style-type: none"> • Directors and officers liability being sorted out. • No directors and Officer Insurance – in train. • Yes we do fear exposure as situation not clear and uncertain. • Directors and officer cover to a level of \$5 million. Very comprehensive system of trial management that satisfies the insurer. • Low-level nagging discomfort.
<p>Q 9. What is the actual risk of the CT work></p>	<ul style="list-style-type: none"> • Minimal risk with known treatment, all patients closely monitored. • Toxicity from trial protocols / costs of the trials/ financial insecurity of the groups/ office bearers' indemnity. • Never had a claim. All trials undergone scientific rigor. Excellent culture of rigor in COSA. Very large proportion of trials are part of large multi-centre international collaboratives. • Minimal risk.
<p>Q10. Are all trials covered by HREC</p>	<ul style="list-style-type: none"> • All are approved by HREC prior to commencement.

<p>Q11. How do you manage any surgical component of a CT</p>	<ul style="list-style-type: none"> • Minimal involvement. • All part of process; part of the general and specific consent. • Not usually an issue • Uncertain how to handle them as often a very small part of the trial. • Surgery muddies the water as out of the direct control of the oncologist or radio therapist.
<p>Q12. Other comments or concerns</p>	<p>Tissue bank – does it attract any liability? Does it need its own insurance?</p> <p>Healthy volunteers – not paid, just travel expenses. Are they covered? Part of prevention studies in healthy people. Treatment risk may be most significant.</p> <p>Desire umbrella cover for all CT</p> <p>Zero sum gain concept. Need to inform HREC and others that the CT does not increase the risk of the adverse event. The risk in a CT are not higher and quiet likely lower than usual care.</p> <p>NSW hospital insurance cover is different to Victoria and that causes confusion and concern.</p> <p>New Medicines Australia standard indemnity form (May 2007) refers to two attached schedules. Schedule 3 Form of Indemnity for Clinical trials (to be inserted by sponsor) .<i>The Sponsor agrees to execute and deliver to the institution, as necessary, an indemnity in the form of the Medicines Australia Standard Form of Indemnity for Clinical trials without amendment.</i> No such standard form is provided. Schedule 4 Insurance arrangements (to be inserted by Sponsor)</p> <p><i>Certificate of insurance</i></p> <p><i>For a study to be conducted in Victoria. The following details are mandatory;</i></p> <ul style="list-style-type: none"> • <i>Insurance provider</i> • <i>Insured entity</i> • <i>Additional insured</i> • <i>Protocol/ CTN number</i> • <i>Limits of liability in AUD/ per occurrence and annual aggregate</i> • <i>Excess/ deductible/ self insured risk.</i> • <i>Victorian managed Insurance Authority guidelines: wed site reference.</i>

	<p>There is no reference to any activity to be undertaken in any other state. Neither schedule appears to assist the investigator or cooperative group to any significant extent.</p>
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