

# Life sciences: clinical trials

## CLINICAL TRIALS

Clinical trials claims are similar in many respects to medical malpractice claims, but do have enough differences to require specialist handling.

The main differences surround the no-fault schemes that many of the trials are undertaken under and the respective insurance cover that is linked to these. There are specific industry guidelines for clinical trial compensation (such as the Association of British Pharmaceutical Industry Compensation Guidelines) and we regularly advise upon their applicability in individual clinical trial cases.

Even though no fault is required to be proven under these guidelines, cases can require extensive and expert investigation in relation to causation and the injuries themselves.

We have gained significant experience assisting those carrying out clinical trials, including universities, pharmaceutical companies, clinical research organisations (CROs) and their insurers. We have assisted on a range of such claims including those who have suffered life changing injuries and death, as a result of their participation in a clinical trial as well as those trials which are politically and emotionally sensitive.

Specific examples include:

- A participant who died some time subsequent to a trial of combination chemotherapy
- A participant who suffered permanent tinnitus following a trial within an MRI machine
- A participant who suffered permanent headaches following a trial which included a lumbar puncture
- A participant who suffered drug induced cholestatic hepatitis in a Phase 1 part-randomised, double-blind study to assess oral doses of a potential new drug.

## HOW CAPSTICKS CAN HELP

In clinical trials claims, we can:

- Review policy coverage issues and provide detailed policy coverage advice
- Undertake the necessary investigations including instructing
- Advise upon any industry specific guidelines that may be in place, such as the Association of British Pharmaceutical Compensation Guidelines, and their applicability in any particular claim
- Act in a group litigation

- Offer advice and assistance to your insureds on risk management and, for example, assist with re-wording of consent to participate forms / patient information leaflets to minimise the risk of future claims, or their impact.

Essentially, we are able to manage any complaints or claims from their early stages through all steps in the litigation process and offer advice on wider issues to reduce the risk of future claims being made against insureds.

## TAILORED TO MEET YOUR NEEDS

A central tenet of our service is that we will tailor the service to meet your requirements and have a small but dedicated and specialist team able to help. This means you will always know those lawyers assisting on any particular matter.

## OUR SPECIALISTS

Majid Hassan, Ed Mellor and Sarah Bryant are our principal senior insurance specialist lawyers. They are assisted by others across a range of qualifications to ensure work is passed to the appropriate level.

## CONTACT



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