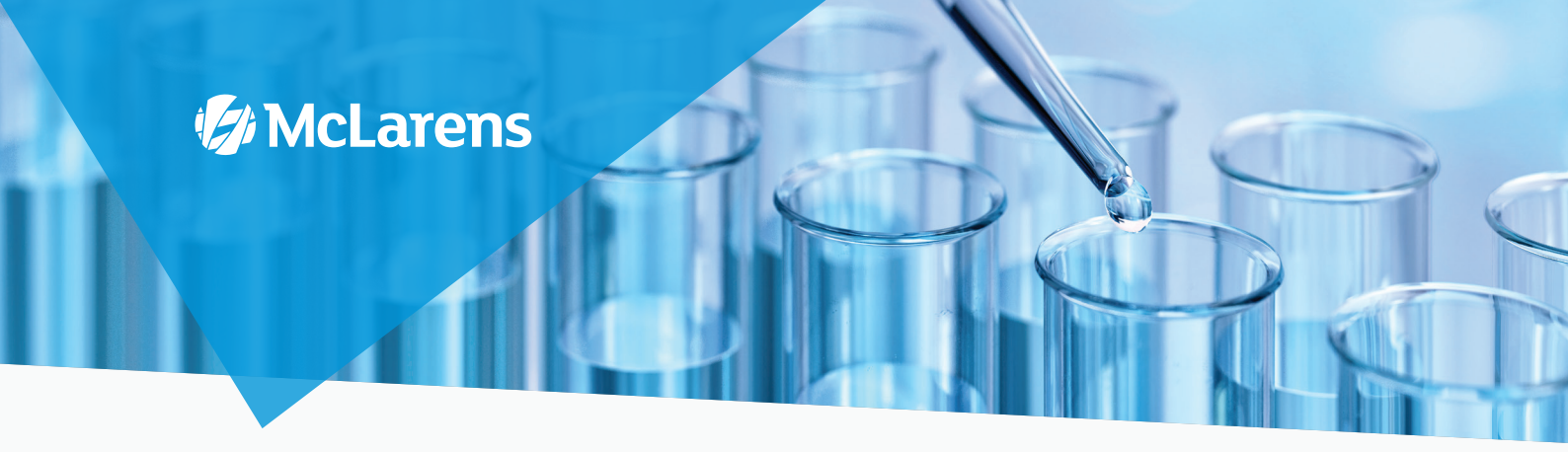

Life Sciences – Clinical Trials (CT)

Our Life Sciences Capability

McLarens has been a leading adjuster in the global Life Sciences sector for over 20 years.

We have managed a worldwide Captive led programme for a global pharmaceutical company as well as handling claims for an international chain of pharmacies, a research institution, and others.

Our global clients operate in industry sectors including:

- **Biotechnology**
- **Pharmaceuticals**
- **Biomedical Devices**
- **Cosmeceuticals**

Our UK clients also deliver:

Private healthcare; holistic and beauty treatments; care for the elderly, infirm and terminally ill.

Areas of expertise:

Product & Public Liability:

Bodily injury or property damage caused by defective medical devices, faulty diagnostics, pharmaceutical side effects or negligent treatments.

Professional indemnity claims:

Alleged negligence, errors in research, failure to meet professional standards, or advice given.

Product Recall & Tampering:

Financial losses following recall of products.

Clinical Trials (CT)

We have a presence in 80+ countries globally and have capability to handle CT claims in all these locations. We have previous experience of handling CT claims on all continents.

Our global clinical trials service is co-ordinated centrally from our London based 'hub' led by Helen Walker, Senior Executive Adjuster, who has been managing global Clinical Trials claims for over 15 years.

Clients can be confident that all reported matters are captured and managed in a coordinated way, which allows us to disseminate information to all stakeholders.

- Unique trial references and participant ID's (included in all communications)
- Robust data capture
- Clear reporting guidelines into our coordinating office

Insight into Global Clinical Trials

No matter the country, all clinical trials must legally comply with Good Clinical Practice (GCP) guidelines (specifically the internationally recognized ICH E6 (R3) standards). Key components include:

- **Informed Consent**
- **Participant Safety**
- **Data Integrity**

There may also be local legal, regulatory and compensatory frameworks in place. We work with our local affiliates and lawyers to identify and apply local regulations.

CASE STUDY

Local knowledge

The 'Informed Patient Consent' will usually define what is recoverable by a participant in the event of a Serious Adverse Event (SAE), typically limited to medical expenses associated with treatment to aid the patient's recovery from the SAE, where a causal link between the investigational product and the adverse event is confirmed. However, in a recent CT claim made in Australia, corrective surgeries were required and the individual was necessarily absent from work. We established that lost earnings could also be claimed in that instance and we negotiated settlement of the shortfall in earnings on behalf of the CT sponsor's insurer.

Insight into UK Clinical Trials

The UK has seen a rise in commercial clinical trial initiations over the past three years. In April 2026 the Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Authority introduced amended regulations. The aim is to support safe and trusted research in the UK by:

- protecting trial participants
- strengthening patient safety
- accelerating approvals and reducing unnecessary burdens

New legal requirements for clinical trials came into force on 28 April 2026, introducing new terminology, streamlined approvals, and, importantly from an insurance perspective, enhanced participant protections.

It is hoped that the changes will benefit patients, researchers, health professionals, and industry.

CASE STUDY

Claims and Risk Management

We investigated several claims for the same CT trial which were conducted at different locations. We identified that the wording of the Informed Patient Consent differed between study locations. Some participants were limited to recovering their medical expenses only where they did not make a full recovery.

Our claims handling delivered strong outcomes and flagged this risk management issue, which our clients were able to swiftly address.

Trending in Clinical Trials

- **Artificial Intelligence**
- **Regulatory Reform**
- **Strategies to Improve Patient Diversity**

If you would like to discuss your current requirements or to obtain further details of our services and range of expertise, then please contact:

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