

## Did you know?

The research, development and manufacture of life saving products require life science companies to conduct human clinical trials. Medical device manufacturers, pharmaceutical manufacturers and contract research organizations in particular are frequently involved in conducting such trials to determine whether new products, or new uses for existing products, are safe and effective.

Many life science insurance policies mandate, as a condition precedent to coverage for injuries resulting from the trial, that the policyholder provide the insurer with notice of the trial – or sometimes even a copy of the protocol - before the trial commences. This is a time consuming and burdensome task for a company planning to conduct many trials during the policy period. What if the policyholder fails to satisfy this notice requirement? No coverage would be afforded under the policy for any injuries resulting from that trial.



## How is LS Prime® different?

LS Prime® eliminates the human clinical trial reporting requirement that is included in most product liability policies. With LS Prime® clinical trials are covered on a blanket basis, so there is no need to schedule each trial separately. Additionally, LS Prime® has eliminated many clinical trial exclusions common in other life science policies. For example, there are no broad-based exclusions for minors; cognitively impaired individuals; pregnant women; prisoners; or new product indications.

## Who needs this coverage?

- ◆ Medical Device Manufacturers
- ◆ Biotech/Pharmaceutical Manufacturers
- ◆ Contract Research Organizations (CRO)



## How does this coverage work?

LS Prime® does not require the policyholder to provide prior notice of a human clinical it plans to start during the policy period. As long as the trial being conducted is an **approved clinical trial**, i.e., all required legal and regulatory filings have been made to, and authorizations received from, the Institutional Review Board, ethics committee or similar body, LS Prime® affords coverage for that clinical trial.

[See reverse side for Claims Examples](#)

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## Blanket Clinical Trials Claims Examples

**Drug or Device Trial:** A Phase I trial has been planned to test your product (device or drug). All the appropriate filings were made and authorizations obtained. Your insurance carrier, however, was not notified of the trial. The trial begins and, after a few weeks, a patient is injured. The patient makes a claim for damages. Since the carrier was not notified of the trial, there is no coverage. In contrast, with LS Prime<sup>®</sup>, coverage would be afforded since the trial was an **approved clinical trial** and there is no notice requirement.



**Pediatric Trial:** There have been several trials conducted as to the safety and efficacy of your product when used by adults. You believe that your product could also benefit children, so you begin a pediatric trial. The carrier is not notified of the pediatric trial. One of child participants is injured and the parent makes a claim for damages. Since the carrier was not notified of the trial, no coverage would be afforded. In contrast, LS Prime<sup>®</sup> would cover the claim. As long as the trial was an **approved clinical trial**, there is no need to report to Berkley Life Sciences that a pediatric trial is about to take place.

**New Indication Trial:** Trials have been conducted to test your product for one indication. It is discovered that your product can be beneficial in treating another indication, and a trial is commenced. During this new trial a patient is injured. The patient makes a claim for damages against the policyholder. The carrier denies the claim because the trial was not reported prior to its commencement. That is not the case with LS Prime<sup>®</sup>. As long as the trial was an **approved clinical trial**, meaning all the appropriate filings were made and authorizations obtained, LS Prime<sup>®</sup> affords coverage for the new indication trial.



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