



SAFEGUARDING SOLUTIONS IN RISKY TIMES

Under very challenging circumstances, insurance companies have provided essential support to the global medical community in its efforts to fight COVID-19. Since the beginning of the pandemic, Newline Group (Newline), the international casualty arm of Odyssey Group, immediately stepped up to facilitate potential solutions, ultimately insuring over 500 clinical trials investigating all stages of COVID-19 by the end of 2020. These trials include global studies in partnership with big pharma, universities and biotech companies, and range from diagnostic tools to identify the disease earlier to vaccine trials aimed to provide immunity across a population.

Based in London and led by Martin Hawkins, Newline's Clinical Trials team has been underwriting clinical trials for 18 years, so they were no stranger to epidemics and pandemics. "We underwrote through the SARS pandemic, MERS and more recently, were heavily involved with the Ebola virus in West Africa," explained Mr. Hawkins. "What's different with COVID-19 is the scale. Ebola, for example, was localized, while COVID-19 affected the global population. With worldwide demand, it was a different undertaking entirely, and clearly the biggest effort we have ever seen."

RISKY BUSINESS

The risk in any clinical trial boils down to patient indemnity. When individuals sign up to participate, they receive a consent form highlighting the risks that the medical profession believes are associated with the trial. While the benefits are usually worth the risk, there can be unexpected and unintended effects. "Clinical trials are really about protecting humans as they go through the process," said Mr. Hawkins. "It's not insuring whether the drug works; we insure in case of an adverse reaction in patients."

Since every client has different risks and needs, the coverage scenarios vary tremendously. Limits can range from less than

\$1 million for a small, low-risk trial, and go up to \$25 million for a large multi-territory study. Most countries have statutory requirements that govern the minimum limits for indemnity per patient and/or per trial. "For the larger limits, the market has to work together to respond, and the brokers work hard to put insurance coverage towers together, depending on the country and the size of the study," according to Mr. Hawkins.

While insuring clinical trials sounds like a complex and risky business, the key to success is having the depth of technical expertise. Mr. Hawkins added, "The range of difficulty varies by trial, so having experience and understanding the science behind the drug is critical. Once you have that, you can work out the risk factors and price the business accordingly."

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ADAPTING DURING A PANDEMIC

As the COVID-19 pandemic moved from east to west in early 2020, Newline began seeing a spike in coverage requests from its overseas offices. The global scientific community was operating at full capacity

to develop a vaccine, and Newline's team members worked around the clock to meet the demand.

The coverage requirements and necessary insurance documentation for each trial were unique in their own way. On top of this, the usual ways of doing business dramatically changed last year. With everyone working from



Martin Hawkins, Senior Underwriter, Liability



home, including the scientists sponsoring the trials, Newline adapted its coverage and how it provides service to meet the unique needs of these clinical trials, allowing this crucial work to continue within amended regulator-approved guidelines.

“Fortunately in recent years, we had become more digitized and invested more in technological infrastructure to handle clinical trials, so we could operate at the speed that is required to excel in this niche market. This enabled a smoother transition into a work from home environment,” said Carl Overy, CEO of Newline Group and head of Odyssey Group’s London Market Division.

RAPID RESPONSE

Many of the clients Newline insured for COVID-19 trials have been clients for several years. These close relationships were mutually beneficial as all parties were navigating through uncharted conditions and protocols. According to Mr. Overy, “We were already working with several clients prior to the pandemic, so we understood the building blocks they were using, and this familiarity allowed us to respond very quickly.”

Establishing close relationships can be years in the making, with the underwriting team regularly meeting with clients, visiting labs, and speaking with scientists and learning about and the science involved. “It’s critical that we understand what they’re doing so that we can actually look at the risk through true underwriting eyes,” said Mr. Overy. “Having strong relationships and a thorough understanding of our clients’ philosophy and approach, among other things, was certainly key during these challenging times.”

Newline also had new clients turn to them for insurance, particularly in therapeutics. These are drugs that the medical profession is using outside of its normal licensing (also known as off-label use) to help treat COVID-19 patients, particularly in the ICU. “Once again, our knowledge of these companies and the drugs in their current licensed applications enabled us to respond quickly,” added Mr. Hawkins.

THE NEXT PHASE

Thanks to many leading medical and research scientists from around the world, several vaccines were approved for emergency use and are being produced for the global population. This presented an opportunity for Newline’s Liability underwriting team to step in and provide product liability solutions



Carl Overy, CEO, Newline Group

to the primary vaccine manufacturers as well as coverage for in-country manufacturing facilities around the globe.

Mr. Overy remains optimistic about the future. He added, “Our experience from the past year and our multi-disciplinary, team-based model, which had scientists, researchers and underwriters working together, provides hope that we will continue to successfully find solutions to the most pressing life sciences and clinical trial challenges around the world.”

For additional information about Newline’s clinical trials business, visit [newlinegroup.com](https://www.newlinegroup.com).

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