More Clinical Trials in China in the Future?

The China Food and Drug Administration (CFDA), which became a regulatory member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in June 2017, is now moving forward with the implementation of several ICH guidelines in order to further the development of innovative drugs and devices in China, and align with global regulatory standards in manufacturing and development.

China's implementation of the ICH guidelines will not only help ensure that global standards of quality and safety are met but can help reduce drag on pharmaceutical companies' timelines by streamlining various processes such as clinical trial application and approval. Additional reforms will likely increase the number of Chinese hospitals and research centers able to manage clinical trials without having to undergo an extensive certification process.

These ICH-driven reforms will likely provide US pharmaceutical companies with greater opportunities to include China in global clinical research as well as greater access to the Chinese markets. As a member of ICH, China will be expected to continue implementing regulatory requirements for the manufacture and testing of study drug products. We expect to see an uptick in the conduct of clinical trials once the controls are in place to ensure that quality, safety, and efficiency is consistent across the Chinese markets.

We at Contracts Associates are looking forward to the further integration of China's prominent researchers into our global clinical trials.