IRB market consolidating rapidly

Private equity driving a new commercial ethical review landscape

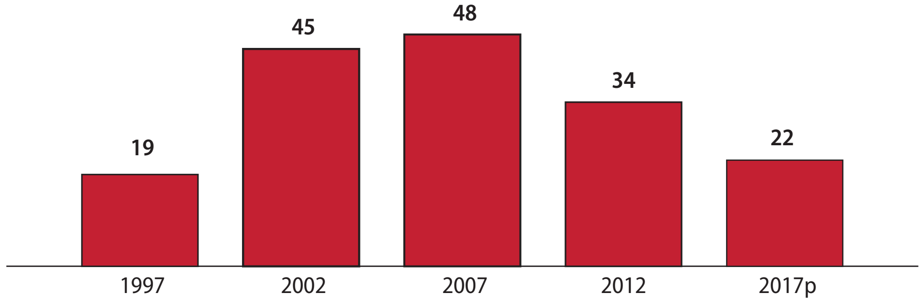
The commercial Institutional Review Board (IRB) landscape, historically dominated by small, owner-operated companies, has begun to rapidly consolidate over the past two years, signaling a different environment for ethical review and oversight of human subject projection in clinical trials going forward.

This marketplace, which now has about three dozen commercial IRBs, is widely expected to continue consolidating until only four or five major players are left.

Consolidation has been driven by the need for more economic efficiency in the review of research protocols and related materials, such as informed consent documents, to ensure the safety of human subjects in clinical trials. Regulatory demands on IRBs have increased, and studies have become more complex. Commercial IRBs also are merging to create economies of scale for providing more effective and streamlined oversight, as the industry moves toward central review models for multicenter trials.

"Bigger, private IRBs want to get rid of competitors who sometimes are taking away their business—particularly business from the pharmaceutical industry," said Arthur Caplan, Ph.D., head of the Division of Medical Ethics at New York University Langone Medical Center in New York, N.Y. "Some of it is just economy of scale. The big guys often are just more efficient. They can undercut the little guys in terms of price, they can do better quality control, they have better speed and they have the money to basically buy the small ones."

Number of commercial IRBs operating in the U.S.



Source: CenterWatch

While most sponsors and investigative sites haven't paid close attention to consolidation in the IRB landscape, much of which has been backed by private equity firms, the movement could have a profound impact on human subject protection review and oversight in the near future.

The effects of M&As

Mergers and acquisitions backed by private equity have significantly altered the commercial IRB landscape over the past two years. Nearly all commercial IRBs—also called independent IRBs—began as mom-and-pop companies in the 1980s or 1990s, with the landscape remaining highly fragmented and immature for the past three decades. Now, deals have begun to consolidate this landscape and allow companies to scale up and meet the growing demand for more efficient, higher quality ethical review services.

Two dominant players have emerged from the recent wave of acquisitions. The first formed when two of the largest IRBs—Western Institutional Review Board (WIRB) and Copernicus Group Institutional Review Board—were acquired by Arsenal Capital Partners in 2012 and combined to form the WIRB-Copernicus Group (WCG), although each IRB continues to operate separately. In June, two additional IRBs—Aspire IRB, located near San Diego, and Kansas City, Mo.-based Midlands IRB—joined WCG, expanding the group's presence in two major clinical research hubs. WCG also formed a new cancer-focused IRB, WCG Oncology, in June.

The second emerged last year when Chesapeake IRB, a 20-year-old, privately owned, commercial IRB, sold a majority stake to private equity firm Audax Group; Chesapeake IRB then