

As CRO industry turns 30, a look back at modest beginnings

Phenomenal growth, strategic partnering highlight evolution of CROs

Some of the most well-known CROs—including Chiltern, Quintiles and Parexel—are marking their 30th anniversaries, highlighting the once uncertain road CROs traveled as they evolved from being a market trend to an integral piece of the drug development landscape.

The early years

In the early 1980s, the drug world was not thinking about outsourcing. The pharmaceutical arena was busy growing in response to the health issues of the decade and conducting groundbreaking research, but was plagued by secrecy, disorganization and a lack of transparency.

“Our veterans will tell you that back then, it may have taken six months to enter and analyze clinical data once the last patient in a trial was seen, and that was the norm,” said Phil Bridges, director of corporate communications for Quintiles.

Globalization of clinical trials and innovative ideas for expansion were not even on pharma companies’ radars, because the industry was “disorganized,” according to Josef von Rickenbach, Parexel’s founder, CEO and chairman. There were no standard regulations for clinical trials, so doctors wrote each protocol and tried new operating procedures with each trial.

Senior-level executives of large pharmas were unaware of what was

30 years of expanding services and outsourcing models

	Most commonly outsourced services	Prevailing outsourcing model used by sponsors
Late 1980s-1990s	Study monitoring Statistical analysis Dossier preparation Data management	Transactional
2000s	Study monitoring Statistical analysis Medical writing Data management Site selection Regulatory support	Transactional Preferred provider
2010s	Study monitoring Statistical analysis Medical writing Data management Site selection and management Patient recruitment Regulatory support	Transactional Preferred provider Functional service provider Multi-functional service provider Integrated alliance Embedded alliance

happening in R&D, and the privacy stigma attached to the industry made transparency of any kind completely nonexistent. Bridges said industry veterans have told him they remember when there was so much research going on, with no systems or standards in place, that “many pharma companies had reams of data sitting on the shelves, waiting for an analysis to be complete.”

Jamie Macdonald, CEO of INC Research, said that in the 1980s, CROs were all about covering the gaps in capacity. “At that time, they were not yet equipped to partner with biopharmaceutical organizations on a global scale to support their drug develop-

ment efforts,” he said.

The turning point: 1982, not only because now-major CROs including Quintiles and Parexel were established, but also because no one knew what might happen to this nascent industry.

Quintiles was founded as a biostatistics consulting firm in 1982 by Dennis Gillings, who had been consulting with pharmaceutical customers since 1974 as a professor at the University of North Carolina, Chapel Hill. Gillings wanted to focus on the core competency as a provider of statistical and management consulting services for drug sponsors.

Parexel also was born from intention, not from calculated planning or