

Table of Contents

- 5 Foreword
- 6 Strategies for finding, eliminating sites' hidden costs
- 10 MSLs play growing role in patient care and clinical research
- 14 Will investigator certification improve site performance?
- 17 More private equity flowing to investigative sites
- 20 Strategies for success evolving in phase I space
- 24 Investigative sites' eye view of the clinical trials industry
- 28 Trials with in-home nurses poised to grow
- 31 AMCs vying to better compete for industry trials
- 35 Regulatory compliance an increasing burden on sites
- 39 Job satisfaction mixed as workload increases
- 45 Integrated research partnerships build momentum
- 51 Number of global clinical PIs remains a mystery
- 57 Insights from DCRI: Best-in-class ARO
- 60 A look at the evolving role of study brokers
- 64 CROs begin consolidating site landscape
- 69 The long wave goodbye to phantom PIs
- 73 Sites smothered by technology solutions
- 79 More attractive study conduct market invites competition

Table of Contents Continued

- 82 Introducing Site Optimization 3.0
- 85 Sites facing mixed operating conditions
- 91 Growing role for AMC clinical trial offices
- 94 Sites rate their relationships with IRBs
- 100 About CenterWatch

Foreword

I'm pleased to present the fifth report in the Compilation Report Series, the *Investigative Site Landscape Compilation Report*, which focuses on its strategic element, job satisfaction, financial exigencies, site consolidation and the evolution of the clinical trials landscape.

This report is a comprehensive compilation of archived CenterWatch articles based on in-depth interviews, investigative journalist reporting and original research and analysis.

Topics include:

- ▶ Concerns continue to mount about clinical trial costs, everything from investigator meetings, IRB submissions, source documents and the like—hidden costs—which are sites' number one financial concern and a prime factor as to why many sites still struggle financially.
- ▶ Despite a plethora of technological advancements, accurate data and greater efficiencies, site budgets are tighter and competition for studies has intensified. These advancements, combined with a 'doing more for less' approach has drawn mixed experiences as the industry continues to evolve.
- ▶ Many sites lack the cohesiveness and financial resources to improve efficiency and flexibility rendering regulatory compliance an ever-increasing burden on sites. Survey results indicate that sites cannot handle any increased burden in the regulatory process, and must handle existing burden better.
- ▶ Major trends in drug development are reshaping the global investigative site landscape. It will continue to consolidate as CROs purchase investigative sites or establish strategic partnerships with high-performing sites in order to have more involvement and control over site conduct.

For more than 20 years, CenterWatch has had the responsibility and privilege of dedicating its energies to objectively observing the clinical trials industry. CenterWatch has had a unique and unprecedented opportunity to serve as watchdog, educator and curator.

We hope you enjoy reading this *Investigative Site Landscape Compilation Report* and capturing the real-time issues investigative sites encounter, as much as we have enjoyed the opportunity to report on it.

Joan A. Chambers
Chief Operating Officer