Table of Contents

Foreword

I'm pleased to present the fourth report in the Compilation Report Series, the *Regulatory Compilation Report*, which focuses on GCP and methods used to ensure compliance with regulatory requirements that safeguard data integrity and human subject protection in clinical trials.

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:

- The number of warning letters issued to investigators has dropped in recent years, due to improved training and the incorporation of GCP requirements into operations; however, complaints received by the OSI have skyrocketed.
- 'Right to Try' laws, granting terminally ill patients access to investigational drugs, have been purported to make said access easier for patients than the FDA expanded access program. The movement continues to gain momentum as more breakthroughs occur in precision medicines that are targeted to receptors rather than diseases.
- The benefits and burdens of the Physician Payment Sunshine Act has pharmaceutical companies, investigators, sponsors and CROs buzzing as the process, though it has been in place for years, continues to be fraught with challenges and data errors.

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 *Regulatory Compilation Report* and gaining more insight about the multifaceted regulatory process as much as we have enjoyed the opportunity to report on it.

Joan A. Chambers
Chief Operating Officer