



Independent Statistical Center Function

Experts and Systems to Fulfill Interim Analysis Requirements

Complying with Regulatory Guidance

Consistent with the latest FDA and EMA draft guidances on adaptive design, drug development sponsors are increasing their use of external independent Data Monitoring Committees (DMC's) for their adaptive designed Late Phase clinical trials. To carry out their mission, DMC's require timely and accurate statistical analyses and summaries of accumulating clinical trial data. Independent Statistical Centers (ISC's) provide these analyses to DMC's.

Eminently Qualified Personnel

Cytel has highly knowledgeable clinical trial statisticians, statistical programmers, and database managers with extensive ISC performance experience. They design, program, assemble, and validate interim analysis packages, including the tables, listings, and graphs summarizing trial results to date.

All work is strictly secured and conducted within the timelines to meet a DMC's objectives. We've served as the ISC across a wide range of therapeutic areas, including oncology, cardio-vascular, CNS, gastro-intestinal, and Diabetes treatment research.

Preserving Your Trial's Integrity

The regulatory guidances on adaptive design stress maintenance and documentation of the trials with regard to securing unblinded information to the DMC and the ISC, and keeping a "firewall" between them and the Sponsor.

Cytel's ACES system supports adaptive design implementation in a secure, audit-trailed environment. ACES facilitates sponsor-committee communications and interim data handling as prescribed by regulatory guidance and according to the study protocol and committee charter.



- Streamlines interim analyses
- Builds regulatory trust with audit trails
- Eliminates unsecure e-mailing and shipping
- Improves efficiency by automating reports
- Reduces potential for operational biases
- Generates supporting documents including statistical, operational reports
- Dashboards instantly displays key metrics: enrollment accruals, event occurrences, other KPIs

