Clinical Trial Workflow and Document Management

Centralizing clinical study data, with document management and workflow tools helps trial sponsors to securely share blinded and unblinded interim analysis results, proactively protect study integrity and reduce potential for operational bias while streamlining communications and operational workflows – resulting in timeline reductions, increased security, and better compliance with regulatory standards and guidances.

The challenge is getting there quickly and cost effectively, without lengthy and risky implementation projects or costly, disruptive upgrades or downtime.

Cytel ACES® takes a fresh approach with a clinical development-specific workspace that will significantly impact how you facilitate interim analyses for safety and efficacy.

- If you are still managing interim analyses with large volumes of paper and delivery costs, ACES offers a cost-effective and proven solution to securely share electronic data and documents to be shared with all relevant parties such as Data Monitoring Committees, Data Safety Monitoring Boards, Independent Statistical Centers, CROs, drug supply and IRT providers.
- If you are still using disparate file sharing tools, complex security and firewall implementations, and e-mail to disseminate clinical information, ACES provides a validated, comprehensive, yet simple framework ensuring only the right individuals will have access to sensitive unblinded information, thereby restricting unintended sponsor access to all but eliminate the potential for operational bias. All access history is recorded in a 21 CFR Part 11 compliant audit trail.
- If your current processes and procedures seem complicated, cumbersome, and make external organization communications more difficult than need be, ACES can help you with an easily implemented, hosted solution to simplify how you communicate and share trial data and information.

ACES features and capabilities include:

Document Storage

- Centralized storage and access
- Role-based, audited access
- Consistent organization with user-defined categories

Workflow Automation

- Define planned interim analysis events
- Automated analyses improves efficiency
- SAS and R integration
- Event-based notifications

User Management

- Easily create user accounts
- User-defined roles
- Access visibility across clinical trials

Secure Firewalls

- Protect data and information
- Configurable role-based security
- Protect trial integrity by maintaining the blind and reducing biases

Global Access

- Supports all major browsers
- 128-bit SSL encryption
- SaaS hosted solution in certified and compliant data centers

Auditing

- 21 CFR Part 11 compliant audit trail
- System and trial level reporting of all access
- Guarantees “Who saw what and when?”