



Advanced Reporting Capabilities

Turning Data Into Actionable Intelligence

Transform your data into actionable information, expedite data review, and make better more informed decisions through our robust reporting engine.

With one click, your reports can be exported to Microsoft Excel and Adobe PDF. From the very simple to extremely complex, etrialS' reporting tools make it easy to extract meaningful information from your clinical data.

Standard Reports

The etrialS Trial Intelligence solution includes a number of valuable standard reports for fast and easy reporting. Available at your command, these standard reports allow for quick analysis and data review.

- 1. COMMENTS**—Listing of comments attached including information on site, subject, visit, page, date and author.
- 2. EDIT CHECKS**—Summary of the number of times each edit check has been triggered and % of total checks triggered. Report columns include page and field names.
- 3. FORM SUMMARY BY SUBJECT**—By subject provides total queries broken down by status as well as number of forms completed, monitored, frozen, etc.
- 4. FORM SUMMARY BY SUBJECT AND VISIT**— By subject and then further broken down by visit, provides total queries broken down by status as well as number of forms completed, monitored, frozen, etc.
- 5. DAYS QUERIES ANSWERED TO CLOSED**—Displays the number of days a query was in an answered status before being set to a closed status.
- 6. DAYS QUERIES OPEN**—Displays the number of days a query has been in an open status and is still open.
- 7. DAYS QUERIES OPEN TO ANSWERED**—Displays the number of days a query was in an open status before being set to an answered status.
- 8. DAYS QUERIES OPEN TO CLOSED**—Displays the number of days a query was in an answered status before being set to a closed status.
- 9. QUERIES PER PAGE**—Displays the total number of pages, manual queries, and system queries per site and the percentages of manual and system queries per page.
- 10. QUERY TOTALS**—Displays the total number of open queries, answered queries, and closed queries by site.
- 11. QUERIES BY CATEGORY**—Displays the total number of queries by type of query (manual or system) and the category and what the percentage of queries is compared to the other categories within the same type.
- 12. ROLE PERMISSIONS**—View role permissions by role IDs.
- 13. SDV REQUIRED**—Provides what questions still need SDV and what page it is on.
- 14. SDV COMPLETED**—Provides what question needed SDV and what the entered data was.
- 15. SITE METRICS**—Across sites, provides expected data and actual data for first and last visit, first randomization, and enrollment.
- 16. USER ACTIVITY LOG**—Track when users last logged in and when their last activity was.
- 17. USER REPORT**—By user ID, provides the name of the user, their role, and other information such as home site and password expiry date.

Report Builder

If there isn't a Standard Report that meets your needs, the Report Builder enables you to easily build your own. Reports may be created based on any of the clinical data points within the eCRF and can be run across visits, subjects, and sites. Once created, the report definition can be saved into that study's library of reports and can be run at any time without needing to recreate it. This can provide for standard review by all monitors or other study team members.

Advanced Reporting Options

Power Reports

When more sophisticated analytics are necessary, it's time to look at etrial's PowerReporting. In many instances, reports are required for information outside of the normal clinical data points.

With the PowerReports feature, users can easily create reports based on any information within the database-queries, audit trails, and statuses, and more.

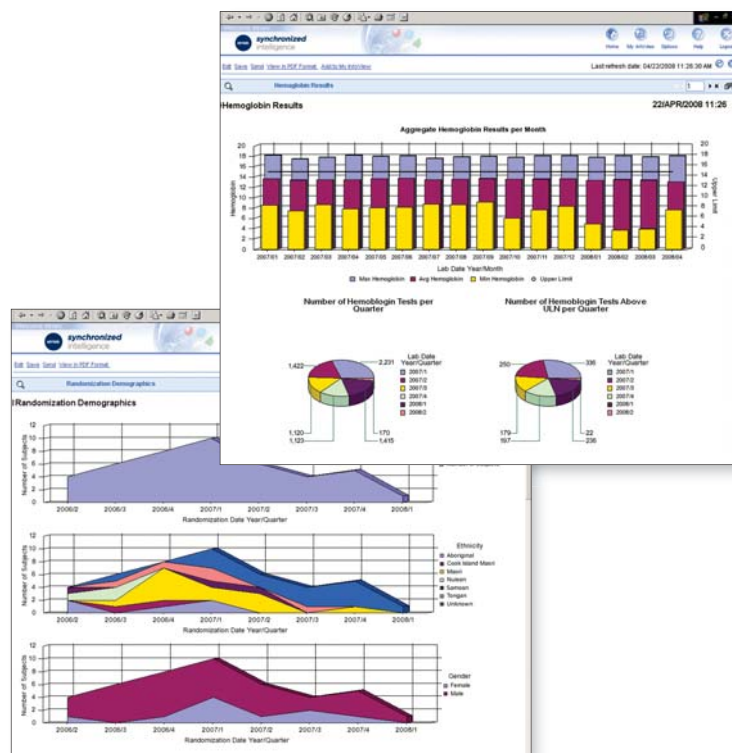
For a nominal set-up and licensing fee, easily create and customize reports by simply dragging and dropping what you need. You can even run reports based on multiple datapoints and set-up filters to further organize the data. And if that's not enough, PowerReports give you detailed formatting and graphical representation.

Custom Reports

We also offer an alternative for clients who need a different report outside of what is offered in our package or can even scale down the reporting functionality of the etrial's PowerReports. In these instances we offer custom reporting services.

etrial's custom reports can be created to meet any of your non-traditional reporting needs. Once created these custom reports can be run at any time within the Trial Intelligence solution, as well as be setup for automatic distribution based on your defined intervals, dates or data parameters.

Another feature custom reports is able to offer is change tracking which can be used to quickly and easily view what changes have been made since the last report. Access to these reports can be role- and group-based depending on your preferences for the study.



etrial's Adaptive Solutions for Trial Intelligence were developed in accordance with the requirements identified in the FDA's 21 CFR Part 11 and Guidance for Industry Computerized Systems Used in Clinical Trials. In addition, etrial ensures that it complies with ICH Good Clinical Practice guidelines. etrial's systems are validated per guidelines set for "Software Validation" provided by the FDA and through the SOPs in effect at etrial for software development. Validation of the systems includes verification of reliability, accuracy and consistency with defined user requirements.

To learn more about etrial's Adaptive Solutions for Trial Intelligence, please contact your sales representative and visit etrial.com/solutions.