# BIOCLINICA®
## eCLINICAL SOLUTIONS

# FULL-SERVICE DATA MANAGEMENT & ENHANCED BIOMETRICS

**Bioclinica offers full-service data management and can create your clinical database more efficiently for site data entry, delivering clean, quality data for your analysis.**

## Our DATA MANAGEMENT services are flexible and we can perform the following functions on a study-by-study basis:

> Data management leadership – Lead data managers manage the entire data process from specification formation to database lock activities.

> Data Management Plans

> eCRF completion guidelines inside of Express and/or in accompanying documents

> eCRF design and edit check specification – Our SCDM certified specification analysts form the study database to accomplish protocol objectives while adhering to CDASH standards to deliver compliant SDTM domains.

> Data cleaning (manual review and query generation) to ensure that data is continuously being cleaned 24x6

> Dictionaries, coding and exception report approvals

> Reporting and metrics

> Standardized SAE and external vendor reconciliation

> Database lock activities

**Bioclinica's passion for data management and innovative spirit have given us the following unique BIOMETRIC OFFERINGS:**

1. Express is unique in that each page has its own URL address. Reports from the system contain hyperlinks directly to the Express eCRF page. These URL addresses can be sent via email, allowing the receiver to click the hyperlink and be present on the appropriate eCRF page. This is ideal when utilizing the quick and easily generated query report to move seamlessly from query to query to perform required review and closure. It eliminates the navigation from patient-to-patient, visit-to-visit or page-to-page required in other EDC systems. Query reports and data listings in Excel can be sent via email while the hyperlinking remains active.

2. Standard programmed output – External vendor reconciliation and data management overview listings are programmed and available quickly, with less validation. Our teams are familiar with the output, so there is reduced training and errors are minimized. A unique acronym tracking system prevents wasted effort reviewing the same issue again.

3. Clean Patient Tracker (CPT) – CPT is a simple spreadsheet providing one row per patient with specific yes/no or # status of each cleaning requirement. This typically includes all query status types, missing pages, SDV status, disposition date and reason, medical coding status, reconciliation status for each external vendor type, etc. This allows study teams to find areas of improvement in the data cleaning process early in the study and provides a way to powerfully direct resources to close the study efficiently.

4. Clean Patient Optics (CP Optics) – CP Optics gives visibility into the 'all-clean' timeline, the ability to target key areas to increase velocity, clarity around real-time status and the ability to mitigate risks and meeting milestones.