

# Accelerate Your Database Lock Using Clean Patient Optics

## A Bioclinica White Paper

Because a key step towards database lock is obtaining clean data for all patients, the ability to verify that data are clean early accelerates the ability to lock the clinical database. This ultimately shortens the overall study timeline while ensuring the quality of your data. However, this can be challenging when manually reviewing study data, particularly with larger studies.

### The Importance of Clean Patient Data

Data quality and completeness are important concerns for sponsors, contract research organizations (CROs) and regulatory agencies alike to ensure that the study has appropriately evaluated the efficacy and safety of the drug or device. Achieving clean patient data status is one component of ensuring data quality and requires the following:

- No open queries for the site to respond to or for the data manager (DM) or clinical research associate (CRA) to review and close
- No missing pages or visits
- Completed source data verification, as appropriate
- All terms medically coded, as appropriate
- All programmed DM data review listings completed
- All data reconciled that are external to the clinical data management system (CDMS) such as serious adverse events (SAEs), safety labs, ECGs, imaging and ePRO

The amount of data that you have to review and reconcile to achieve this status can be daunting, particularly when multiplied across all study sites and patients. **What if there was a better way to “see” into the study status at any point during the trial? *There is.***

Bioclinica offers a programmatic approach to tracking the status of your study using two integrated tools:

- **Clean Patient Tracker (CPT):** data aggregation from many study sources into one comprehensive source
- **Clean Patient Optics (CP Optics):** web-based visualization of the clean patient status, based on the aggregated data in the CPT

## Clean Patient Tracker

The CPT provides a single source of patient data from multiple sources, such as EDC, Safety Labs, ECGs, Pharmacokinetics, ePRO and more. The data in the CPT are compiled from separate files stored in a study-specific input folder. After the program is run, the resulting output delivers one record (row) per patient, with the status of each activity that requires completion for that study.

Based on their experience with clinical trials, the team at Bioclinica identified the following fields as paramount for clean patient tracking:

Data Elements Utilized for Clean Patient Tracking		
Study ID	Site ID	Patient ID
Next MV date	Clean patient group #	ICF date
End of treatment (EOT) reason	EOT date	End of study (EOS) reason
EOS date	Total open queries	Site open queries
DM open queries	CRA open queries	System open queries
# Pages not source data verified	# Missing pages	# Missing visits
Coded? (Y/N)	Overview? (Y/N)	Customer/study specific listings? (Y/N)
Serious adverse events reconciled? (Y/N)	Safety labs reconciled? (Y/N)	ECG reconciled? (Y/N)
ePRO reconciled? (Y/N)	Other external data reconciled? (Y/N)	# Open tasks
Clean? (Y/N)	Locked? (Y/N)	Signed? (Y/N)

## Clean Patient Optics

Once the CPT has been delivered, the activities that need to be completed before the patient can be marked as “clean” are easily identifiable. The clinical data manager uploads the CPT to the CP Optics product. Although this can be done at any time during the study, it is generally performed once or twice monthly and with increasing frequency closer to the end of the study when approaching database lock (DBL). Figure 1 shows the CP Optics Overview tab, which provides a high-level view of the study status.

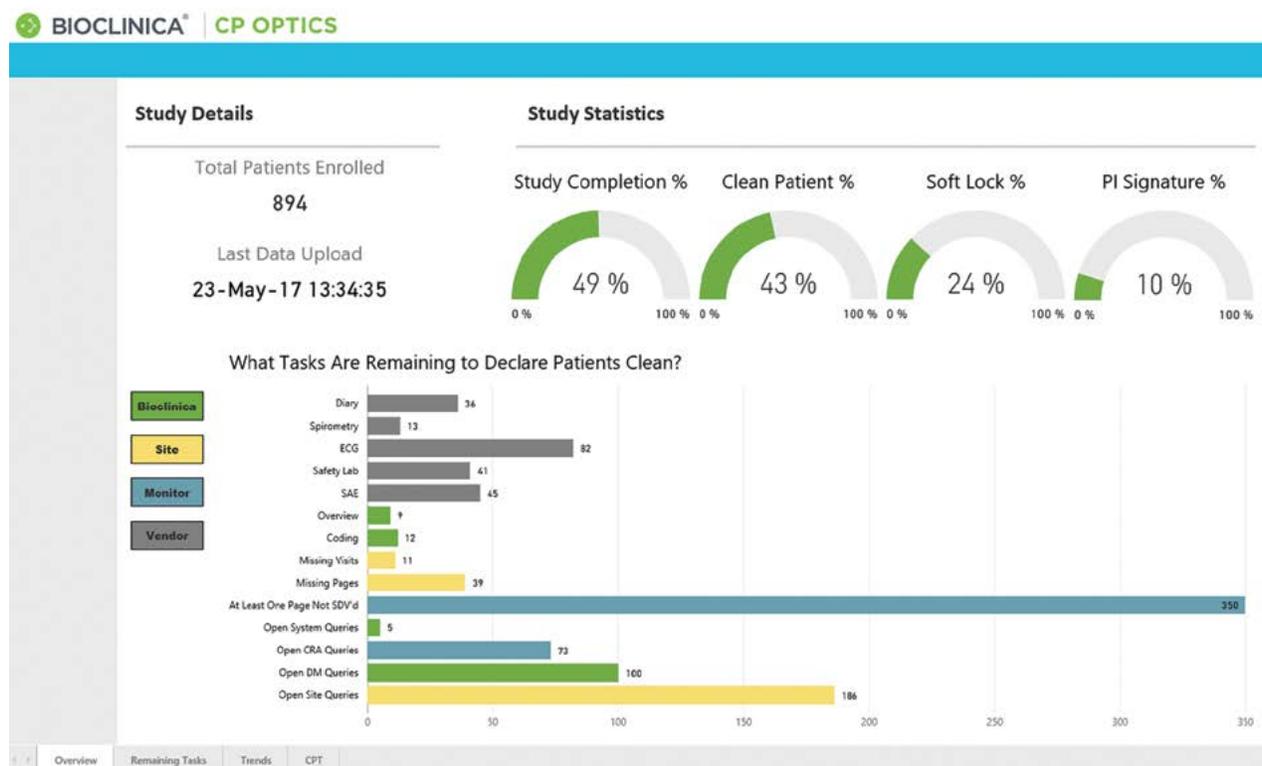


Figure 1. CP Optics Overview tab showing the study status and tasks needed to declare all patients “clean”

*Note: The data in the CPT, and therefore the CP Optics, are only as current as the data sources. For example, if a vendor only delivers their data every six weeks, the data for that vendor in the CPT will also only be updated every six weeks.*

All study data should be continuously and programmatically checked to detect “clean” data that become “unclean” because sites may make changes throughout the trial, sometimes unexpectedly. The priority is to check the data for patients that have completed the study.

With these tools, gone are the days of tedious data checks or waiting until the end of the trial to ensure data are clean for each activity and finding unexpected issues that delay DBL. Instead, using the CPT with the CP Optics product, you improve the efficiency in which you close out and lock your clinical database.

*Note: Because the CPT is built by data management, the visualization (CP Optics) is only currently possible with the use of data management services.*

## Focus Efforts

With the CP Optics product, the bottlenecks keeping patients from becoming “clean” are easily visible so you can stop wasting time and resources on the tasks that don’t help you get closer to your goal of “clean.” You are able to identify the areas with the greatest impact on accelerating the number of clean patients:

- Distinguish between external and system data, to determine where resources should be deployed
- Identify and determine situations that require further investigation, for example if vendors are not updating data as requested or sites are not submitting ECG tracings in a timely manner
- Filter by site, to identify those that require more monitoring or assistance in a specific area
- Identify and address the patients that have only one outstanding task first, to reduce the number of remaining patients to prepare for DBL (Figure 2)



**TRANSPARENCY,  
CLARITY,  
CONFIDENCE**

How Many Tasks Are Preventing Patients from Being Declared Clean?

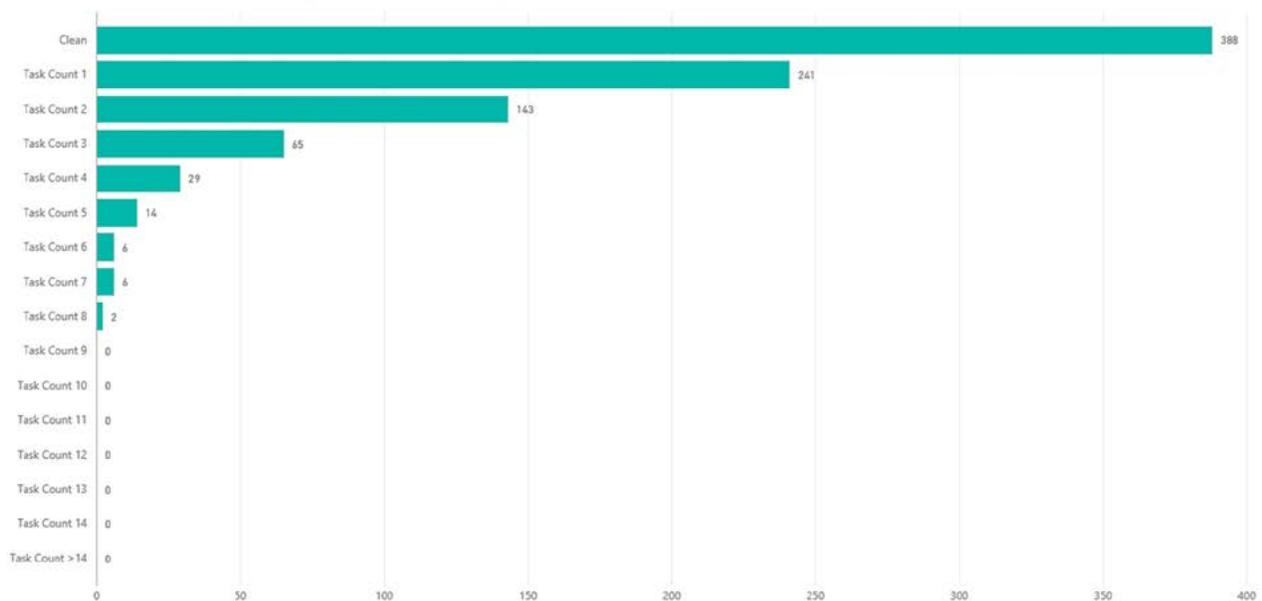


Figure 2. Representation of the outstanding number of tasks each patient needs to have resolved to be declared “clean”

The Bioclinica CP Optics Trends tab provides a graphical representation of the trends in key tasks required for DBL.

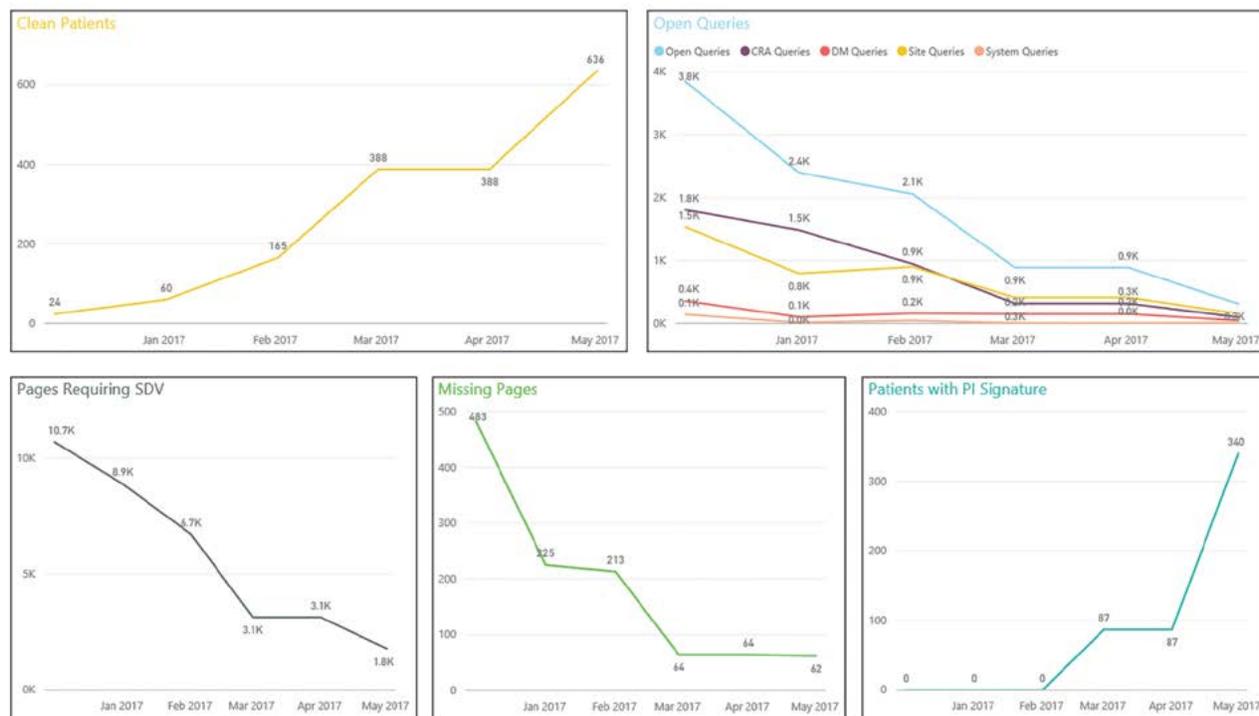
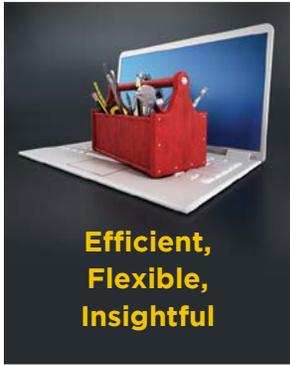


Figure 3. Graphical representation of the trends in study data, viewable on the CP Optics Trends tab

If needed, the data can be manipulated even further by exporting the data from the CPT tab in the CP Optics product to Excel (Figure 4). Activity details can be explored further and in almost any permutation.

Study	environ	Site	Patient	Next MV	CPG	ICF	EOT	EOS	EOS Status	Open Q	DM Q	CRA Q	Site Q	SYS Open	Not SDVd	Miss Pg	Miss	Coded	Overview	SAE
ABC-123	DEV	161	161-001	7-Jun-17	1	12-Oct-15	17-Oct-16	28-Oct-16	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-002	7-Jun-17	1	16-Oct-15	20-Oct-16	1-Nov-16	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-003	7-Jun-17	3	21-Oct-15	23-Oct-16	1-Nov-16	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-004	7-Jun-17	3	26-Oct-15	1-Nov-16	8-Nov-16	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-005	7-Jun-17	3	26-Oct-15	27-Oct-16	7-Nov-16	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-006	7-Jun-17	3	5-Nov-15	9-Nov-16	18-Nov-16	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-007	7-Jun-17	3	12-Nov-15	13-Nov-16	21-Nov-16	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-008	7-Jun-17	3	19-Nov-15	27-Nov-16	7-Dec-16	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-009	7-Jun-17	4	29-Jan-16	12-Feb-17	21-Feb-17	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-010	7-Jun-17	5	18-Feb-16	20-Feb-17	1-Mar-17	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-011	7-Jun-17	5	25-Feb-16	7-Mar-17	17-Mar-17	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-012	7-Jun-17	5	4-Mar-16	8-Mar-17	17-Mar-17	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-013	7-Jun-17	5	4-Mar-16	8-Mar-17	17-Mar-17	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-014	7-Jun-17	6	10-Mar-16	22-Mar-17	29-Mar-17	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-015	7-Jun-17	6	16-Mar-16	22-Mar-17	29-Mar-17	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-016	7-Jun-17	6	17-Mar-16	28-Mar-17	7-Apr-17	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-017	7-Jun-17	6	28-Mar-16	5-Apr-17	14-Apr-17	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-018	7-Jun-17	6	28-Mar-16	5-Apr-17	14-Apr-17	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-019	7-Jun-17	7	25-Apr-16	30-Apr-17			1	0	0	1	0	1	2	0	TRUE	TRUE	TRUE
ABC-123	DEV	161	161-020	7-Jun-17	7	26-Apr-16	30-Apr-17			2	0	0	2	0	1	2	0	TRUE	TRUE	TRUE
ABC-123	DEV	128	128-001	6-Jun-17	1	6-Oct-15	28-Jan-16	15-Jul-16	Lost To Follow Up	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	128	128-002	6-Jun-17	1	28-Oct-15	22-Feb-16	31-May-16	Lost To Follow Up	0	0	0	0	0	0	0	0	TRUE	TRUE	TRUE
ABC-123	DEV	128	128-003	6-Jun-17	2	2-Nov-15	22-Nov-16	6-Dec-16	Completed	0	0	0	0	0	0	0	0	TRUE	TRUE	FALSE

Figure 4. Data from the CPT exported from the CP Optics product to Excel for further manipulation



## Clean Patient Optics:

### The Perfect Addition to Your Study Management Toolbox

With CP Optics, you can:

- Easily visualize your data status
- Anticipate the ability to meet DBL milestones
- Share information across the entire study team
- Identify the bottlenecks preventing achieving the status of “clean”
- Be more efficient with your resources

**From technology architecture which supports large scale performance and integration requirements, to service offerings which ensure exceptional customer service, Bioclinica has the structure and experience to meet the needs of global pharmaceutical companies.**

To learn more, contact the Bioclinica eClinical Solutions division experts at [info@bioclinica.com](mailto:info@bioclinica.com) or visit [bioclinica.com](https://bioclinica.com).