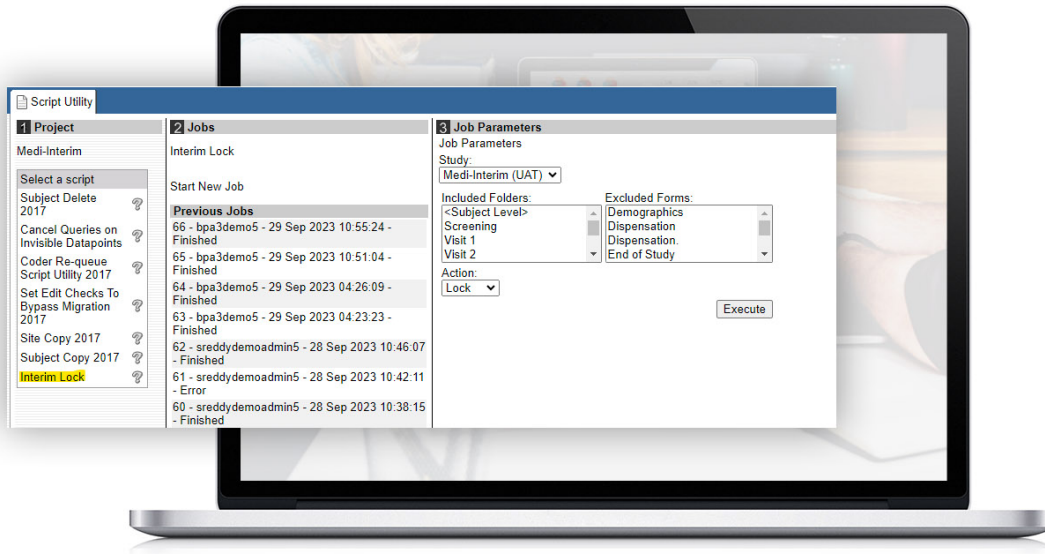**ⅮS MEDIDATA**

Medidata Interim Lock
Drive Automation and Efficiency in your Interim Lock Process

Medidata Interim Lock is tailored to drive automation and speed with your interim lock process. It provides the ability to lock and unlock the database of an ongoing clinical study by taking a 'data cut' at a particular time while the study is progressing. The temporary locking of the database allows for interim analysis, DMC/DMEC/Safety reviews, etc.

Medidata Interim Lock automates a very manual, labor-intensive process, replacing hours of work with just minutes. The Medidata difference is that this solution automates locking and unlocking selected forms while keeping log lines available for data collection. This capability allows for faster study execution, avoids significant cost increases, and eliminates site burden, as the study and data entry continues on during the lock.

Medidata Interim Lock Drives Significant Value and Operational Benefits

Faster Study Execution

250X faster than manual locking!!
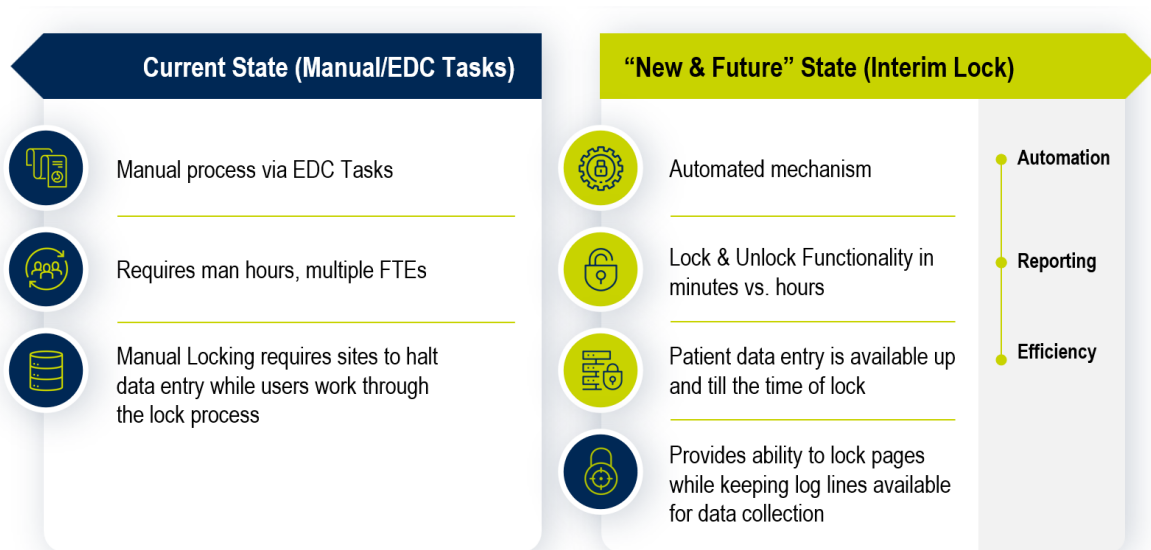
Lower Operational Costs

Reduce cost by 75+%

Reduced Site Burden

Allow close to 100% data entry in EDC with minimal disruption

*All metrics are based on Medidata's product calculations, conservative estimates compared to manual efforts, and average FTE hourly costs

Manual vs Automated Interim Lock

Current State (Manual/EDC Tasks)

- Manual process via EDC Tasks
- Requires man hours, multiple FTEs
- Manual Locking requires sites to halt data entry while users work through the lock process

"New & Future" State (Interim Lock)

- Automated mechanism
- Lock & Unlock Functionality in minutes vs. hours
- Patient data entry is available up and till the time of lock
- Provides ability to lock pages while keeping log lines available for data collection

- Automation
- Reporting
- Efficiency

Medidata Interim Lock Components

Rave EDC Internal Account - used to control:
- Which study(ies) are enabled to use Interim Lock
- Which role the Interim Lock uses for each study

Locking Engine - used to submit locking parameters. It can be used at any time. Parameters:
- Study
- Folders to be included in the locking
- Forms to be excluded in the locking
- Action (Lock, Unlock, or Cancel)

Interim Lock Reports - indicating lock status, and progress

The Medidata Advantage

Medidata Professional Services helps Life Sciences companies deliver innovative therapies to patients faster. With Interim Lock you can lock and analyze data without any downtime for your studies and patients. This automated process allows you to focus on moving your study forward and reduces the time of lock from hours to minutes.

Medidata Professional Services is the only technology partner with the expertise to power your success through a personalized approach through a trusted team. Navigate the evolving landscape of clinical trials and achieve optimal outcomes with our deep domain experience on the industry's leading clinical platform.