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CTMS Software Summary Sheet

Clinical Trial Management Features

GENERAL
- Role-based security management
- Full audit trail accessible (via right click) on all fields
- Customizable and extendible document tracking and data collection feature for any entity in system (e.g., sites, study, protocols, monitoring visits)
- Central document management capabilities for tracking common work documents or storing work documents directly in database with version control
- Support for sponsor logo on study correspondence

SITE SELECTION/MANAGEMENT
- Global site and site personnel data
- Tracking of site personnel by roles
- Automatic emailing to site personnel by study role
- Manage site selection status
- Support for multiple addresses for sites/site personnel. Different addresses are automatically selected by system reports based on activity type

REMOTE SITE MONITORING
- Check out site to laptop for monitoring manually or via email
- Complete electronic regulatory monitoring forms and subject visit/CRF monitoring requirements at site
- Track issues and required actions for monitored items
- Capture notes for monitored items
- Check in monitoring issues/results once visit is complete

ENROLLMENT PROJECTIONS/TRACKING
- Record expected site enrollment performance
- Report on actual versus projected enrollment by site
- Forecast data entry volumes for actual and projected subjects

PAYMENT FORECASTING
- Record expected payment amount per CRF, expected percent CRFs completed and payment lag time
- Forecast expected payment expenditure by month for actual and projected subjects – based on visit schedule

INVESTIGATOR COMPENSATION
- Customizable rule-based investigator compensation system, including CRF and ad-hoc payments
- Payment History Reporting
- Check Request and Payment Letter generation
- Generate milestone payments or invoice-based payments

IRB/EC MANAGEMENT
- Track Site IRB/EC submissions
- Track multiple protocol submissions per study
- Use alerts to identify expiring IRB approvals
- Track approval and reapproval of protocol and informed consent

SUBJECT VISIT TRACKING
- Setup visit schedule per protocol
- Identify required and requested CRFs
- Define rules to identify missed visit or out of range protocol deviations
- Generate visit schedule letters
- Generate site subject visit status reports
- Visit schedule is combined with site enrollment projections for CRF workload forecasting and payment forecasting

SUBMISSION TRACKING
- Track protocol submissions to multiple regulatory authorities
- Track additional data requests
- Manage protocol start dates, enrollment count and study duration

DOCUMENT MANAGEMENT
- Check in/out documents into database
- Maintain document revision history

STUDY ALERTS
- Monitor data conditions and alert specified users (e.g., IRB expiry, adverse event or investigator termination)
- Support postponement of notification
- Simple or complex rules can be set up by end user

DEVICE/PRODUCT MANAGEMENT
- Support for Lot # with quantity or Serial # based product
- Product shipping screen to manage shipping
- Manual or automatic maintenance of product inventory
- Product Disposition reports
- Interface between CRF and product tracking automates inventory management to reflect product usage and allows for accurate status of site inventory

SUPPLEMENTAL FIELDS/CUSTOM SCREENS
- Extend data collected about any entity (e.g., site, study, protocol) with custom fields including document links, URLs, Custom Screens
- Create custom screens to collect CTMS specific data
- Can be set up by end users

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