

ORACLE HEALTH SCIENCES LABPAS

KEY BENEFITS

FLEXIBILITY, CONFIGURABILITY AND CONTROL FOR EARLY PHASE CLINIC AUTOMATION

Subject Recruitment

- Study volunteers are recruited quickly with an easy-to-use scripted data collection wizard and appointment scheduling tools
- Volunteers are automatically evaluated based on configurable inclusion and exclusion rules

Direct Data Capture

- Automation dramatically reduces the need for paper from your clinical trials
- Real-time study data collected and checked at the point of subject becomes an electronic source

Sample Management

- Barcode-driven sample management efficiently captures data and controls sample process
- Customizable edit checks and alerts reduce input and sample processing errors

Data Management

- Data visualization, data review/approval, metrics and query management allow effective qualification of electronic source
- Key decisions can be made earlier when real-time data is available to both investigators and sponsors

Reporting

- Data can be evaluated and easily transferred to the sponsor with flexible reporting capabilities

Oracle Health Sciences LabPas provides enterprise software tools to help recruit study volunteers quickly, directly capture data electronically, and streamline the clinical process. Oracle Health Sciences LabPas enables organizations to share real-time data with sponsors and investigators throughout a study and provides a flexible reporting structure that helps meet the specific sponsor data transfer requirements for each study.

Early Phase Clinic Automation

Oracle Health Sciences LabPas helps meet the demands of today's early phase clinical units by providing recruitment management, direct data capture, automated sample processing, data management, and flexible reporting capabilities. It can help to reduce errors and queries, allowing clinical staff to operate more efficiently while meeting critical timelines and improving overall data quality. Oracle Health Sciences LabPas provides time-saving process improvements for the early phase clinic, from recruiting to reporting.

- **Flexibility.** Early phase study protocols can change quickly, and with Oracle Health Sciences LabPas, last-minute setup, schedule and barcode label changes are easy to manage—even after a study has begun.
- **Configurability.** From setting up studies to defining sample processing requirements and configuring edit checks, Oracle Health Sciences LabPas can be used to define all the major elements of a study. The expansive reporting and data export structure allows organizations to decide how to best meet the specific data transfer needs of the study sponsor.
- **Control.** Oracle Health Sciences LabPas is designed to reduce errors and queries by using direct data capture and the automation of sample processing, combined with real-time edit checks and alerts.

Oracle Health Sciences LabPas Modules

Oracle Health Sciences LabPas Subject Recruitment Module provides essential functionality for automating the collection and tracking of all information involved in finding, screening, and scheduling subjects for an early phase study. With Oracle Health Sciences LabPas Subject Recruitment Module organizations can

- Access volunteer record management systems with ease and efficiency
- Search for volunteers based on specific demographics, medical history, and concomitant medications
- Define study-specific screening test panels and record volunteer screening test results
- Manage out bound communications to a specified volunteer list, by scheduling calls, sending emails, printing mailing labels, or exporting flexible comma separated value (CSV) files
- Provide staff with an easy-to-use, scripted interface for interviewing volunteers

KEY FEATURES

- Volunteer lookup based on demographics and medical history
- Volunteer screening, appointment scheduling and screening data entry
- Flexible study and data capture setup enables rapid configuration of study protocols
- Barcodes labels (subjects, dosing, tubes, instruments) improve workflow
- Define multiple clinics to enable global early phase deployment strategies
- Configurable security roles, electronic signatures, and a complete audit trail
- Sample storage temperature management

THE OWNERSHIP EXPERIENCE

Staffed by professionals with extensive pharmaceutical, biotechnology, development, and IT experience, Oracle Health Sciences provides one of the most robust cloud applications service offerings in the industry. It can scale to meet the demands of the smallest to the largest companies. With Oracle Health Sciences, clients enjoy lifecycle project management, study design and implementation, site and user provisioning, out-of-the-box integrations, hosting and application management, user training, and 24x7 global support. Clients looking to bring applications directly into their enterprise can also leverage Oracle Health Sciences' full range of mentoring programs, training offerings, and implementation services to transfer knowledge in-house.

- Automatically evaluate study volunteers based on configurable inclusion and exclusion requirements
- Schedule and manage screening appointments, by day, week, or month
- Track overall effectiveness of study advertising campaigns and outbound recruitment calls
- Seamlessly integrate data with Oracle Health Sciences LabPas Clinical Trial Module when a volunteer is accepted into a study

Oracle Health Sciences LabPas Clinical Trial Module automates the management of early phase clinical data, sample processing, and operational workflow. With Oracle Health Sciences LabPas Clinical Trial Module organizations can

- Set up a study in hours rather than days using adaptable data elements that can be used for multiple studies
- Capture data directly by deploying wireless tablet computers at point-of-subject to scan subject, dose, collection vessel, and instrument barcodes
- Capture real-time electronic data for collection times, comments, dosing, vital signs, and adverse events
- Manage adverse event observations and create electronic adverse event forms
- Set up configurable edit checks, cleaning data as it is entered
- Share real-time data with investigators and sponsors, using the Data Qualification Interface
- Raise and resolve data queries
- Report data via standardized reports, ad hoc reports and in Clinical Data Interchange Standards Consortium (CDISC) OpenDocument (ODM) format
- Enter on-site safety test results and import safety test results from external lab systems
- Capture data reviews and approvals and monitor data management metrics
- Incrementally lock and release data by group and period

Oracle Health Sciences LabPas Environmental Monitoring Module helps assure precise control of sample storage conditions to meet the quality and regulatory needs of life science companies. With Oracle Health Sciences LabPas Environmental Monitoring Module, organizations can

- Monitor storage devices via a single dashboard without leaving your desk
- Associate temperature readings with typical storage areas (refrigerators, freezers, rooms)
- View charts to quickly identify potential problems
- Capture data reviews and approvals and monitor data management metrics
- Set configurable alerts and notify staff by phone or pager

Contact Us

For more information about Oracle Health Sciences LabPas, visit oracle.com/healthsciences or call +1.800.ORACLE1 to speak to an Oracle representative.

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Hardware and Software, Engineered to Work Together