Digitally Enabling Life Sciences and Health Systems Companies to Bring New Products to Market Faster

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A New Digital World Realities For Life Sciences Companies

COVID-19 has put a sharp focus on digital transformation and the need to have the critical medicines and vaccines approved rapidly for treating patients

-The Need-

- Quickly translate ideas into innovations. Rapidly produce the designed molecules to start testing
- Rapidly ensure the safety of new drugs and vaccines
- Digitize and bring all processes together from drug discovery, research, preclinical trials, to clinical trials, while ensuring the full chain of custody of all samples, pharmaceuticals, supplies, and data to ensure full compliance
- Embed predictive compliance and quality and risk management in the process for full FDA Compliance
- Automate documentation of everything with full audit trails
- Assure health and safety of the employees.
- Utilize digital processes and cloud architectures to allow seamless work on-site and from remote locations

We Provide end-to-end, functional rich software for entire lab operations on a Low-Code SaaS Platform.

-Low capital investment...pay as you use model-

-Sample Clients

160+ Clients
100% of Top 20

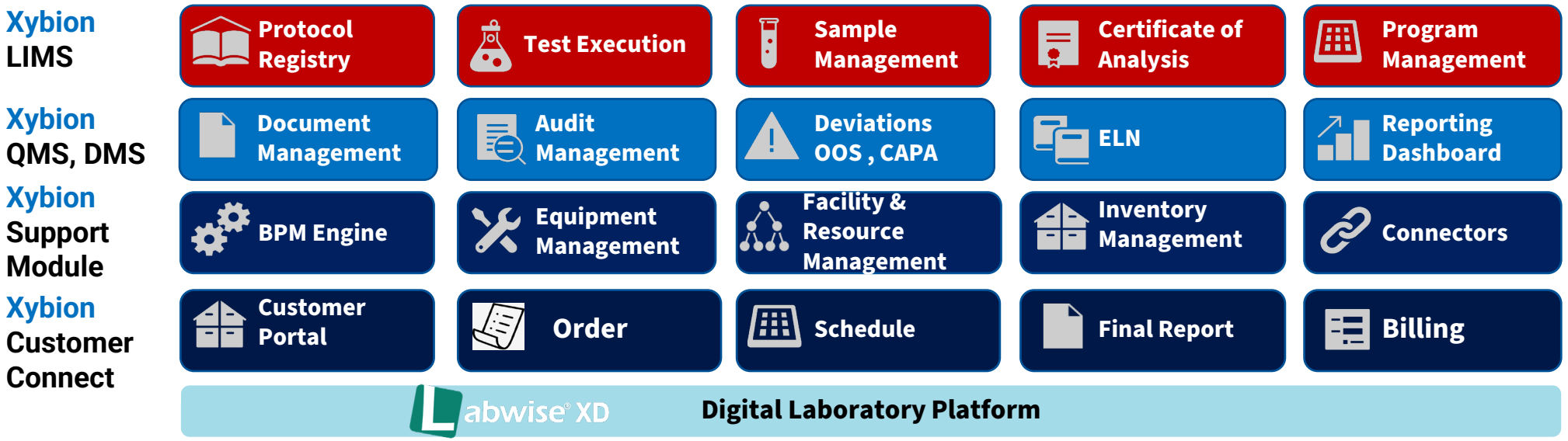
In 29 Countries

Offices in USA, Canada, Europe and India

Headquarters: Princeton, NJ

Early-stage life sciences organizations only need Xybion + Human Resource Management + Finance system to be fully operational and regulatory compliant.

-End-to-End digital process for Life sciences R&D and regulated labs.

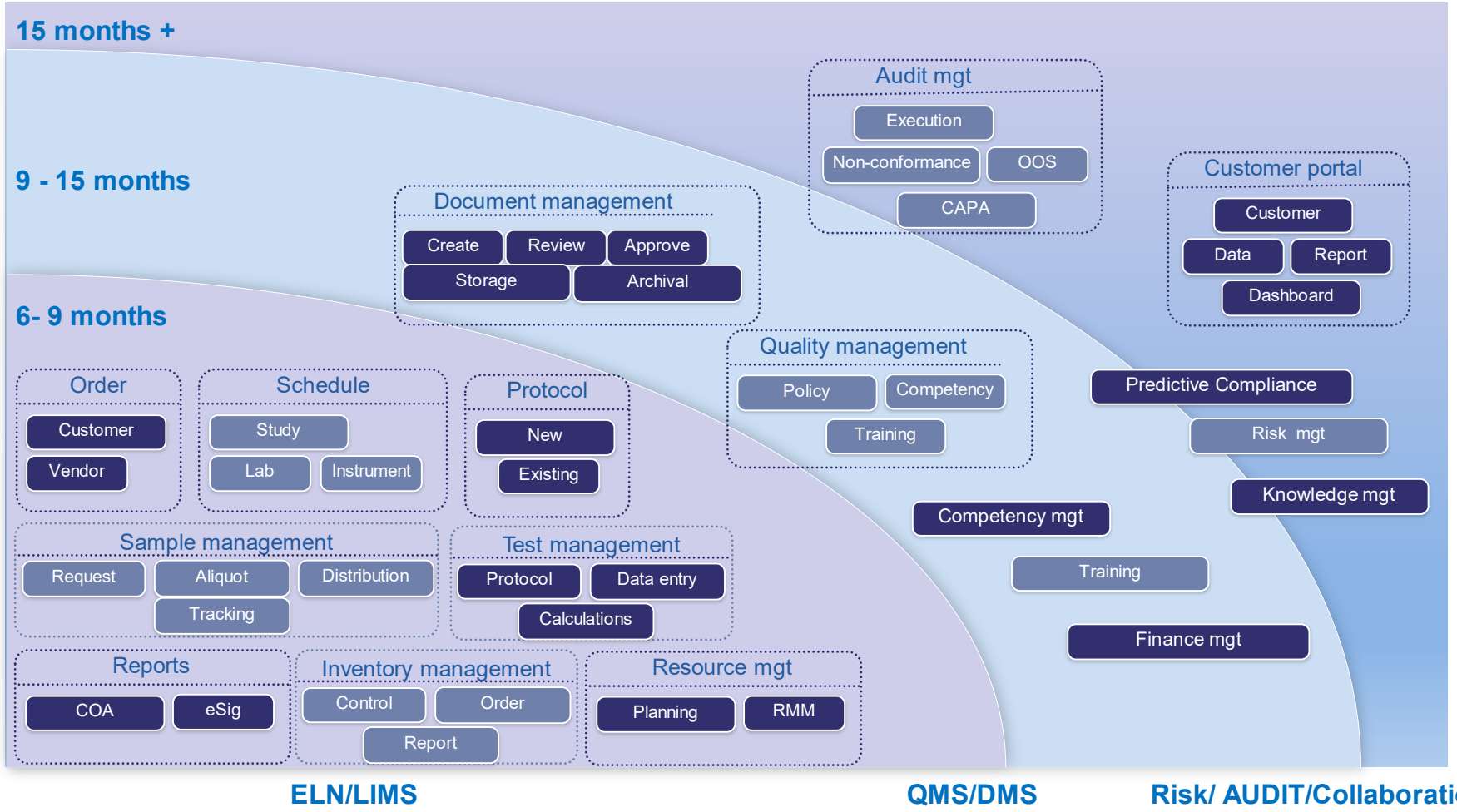


Segment specific bundled solutions for Gene Therapy, Diagnostic labs, Generic & Specialty Pharma. Companies, Enterprise Content and Protocol management, SOP and Competency Management, Facility, Instruments, Materials Compliance and Governance.

Digital Lab Execution system, a low CAPEX solution

Complete lab automation system using a simple platform-based architecture and a roadmap

- Unified solution, not traditional integration based
- Modular approach with an end goal and roadmap
- No IT infrastructure or investment needed



- End-to-end lab management on a single platform
- ELN
- Virus production & inventory mgt
- Protocol management
- QC
- Document management
- Project management
- Audit management
- Planning and cost mgt
- Invoicing
- Lab predictions, Training mgt

Client Successes

Case examples

World's Largest Pharmaceutical Company

Xybion's SaaS platform was rapidly configured to bring the internal scientific processes and their data into a single cloud to manage around 30,000 research protocols with role-based permissions and full security control for over 100,000 users worldwide.

Early Stage Biotechnology Company

This client utilizes Labwise XD for gene and immune therapies, sample management, all-in-one LIMS, quality management system, electronic lab notebook, and biopharma research-specific modules from Xybion. They can now manage their entire biotech business on a single cloud platform. The client is now fully operating with Xybion's Labwise XD covering all laboratory needs and a third party HRM and corporate finance system.

Northwell Health℠

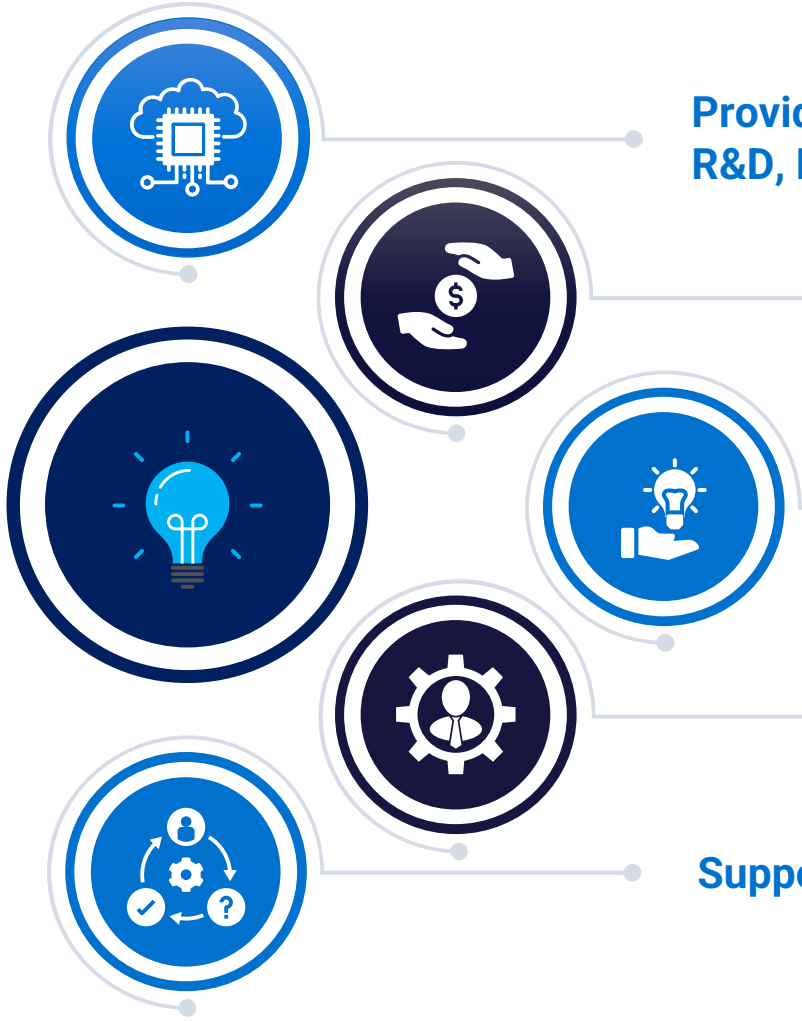
Northwell Health through rapid growth and multiple acquisitions has 23 hospitals with over 72,000 employees. Xybion's Emidence health and Safety module is used by Northwell Health of New York from the beginning of the pandemic to manage the safety of its entire workforce.

Boehringer Ingelheim

After selecting Xybion's Pristima XD for their preclinical R&D dept. and seeing our fully unified Quality and compliance software in the cloud, Boehringer Ingelheim Awarded us two more contract to replace its current QMS software vendor, a large company, by Xybion's fully unified CQRM XD module.

Why All Top 20 Biopharmaceutical Companies Choose Xybion

We Drive Growth in Regulated Environments.



Provide end-to-end Digital Cloud Platform as a service along with pre-built solutions for R&D, Labs, Health & Safety and Compliance RISKs for the Post COVID-19 World

Reduce Total Cost of Ownership

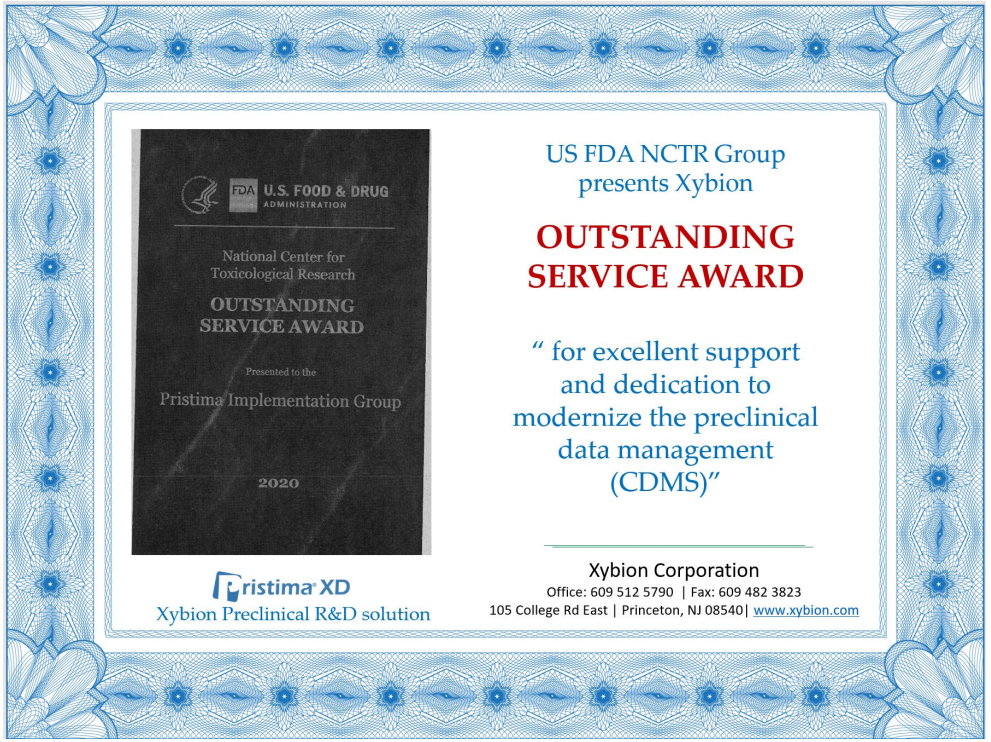
Replace multiple point solutions with a single platform

Provide Management Services and Focused Outsourcing

Support New All-Digital Global Business Models

Xybion Software and Services are Award Winning

Awarded By: FDA U.S. FOOD & DRUG ADMINISTRATION



pharma TECH OUTLOOK TOP 10 LIMS SOLUTION PROVIDERS

MarketWatch

Global Life Science Software Prominent Player

CIO Tech Solution Providers to Pharma and Life Sciences Industry

20 Most Promising Tech Solution Providers to Pharma and Life Sciences Industry

FROST & SULLIVAN

Customer Value Award for Enterprise Quality Management solution

REPORT CONSULTANT

Life Science Software Market Global Industry Players

10 BEST LIMS COMPANIES TO WATCH IN 2022 | CIOCoverage

Trusted by the Most Reputable Brands in the World

J&J · Pfizer · Roche · NOVARTIS · FDA · MERCK · AMGEN · Northwell Health

Xybion Digital – Your Total SaaS Solutions Partner for R&D and Laboratory Operations

- Avoid multiple siloed systems
- Avoid IT infrastructure and resources inhouse
- Reduce upfront CAPEX significantly
- Drive digitization to avoid data issues and huge migration work later
- Better manager data, operate in full compliance, even if you are not a GLP operation, yet
- Xybion consulting can help strategize and implement Xybion software to achieve these

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Thank You

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Xybion®

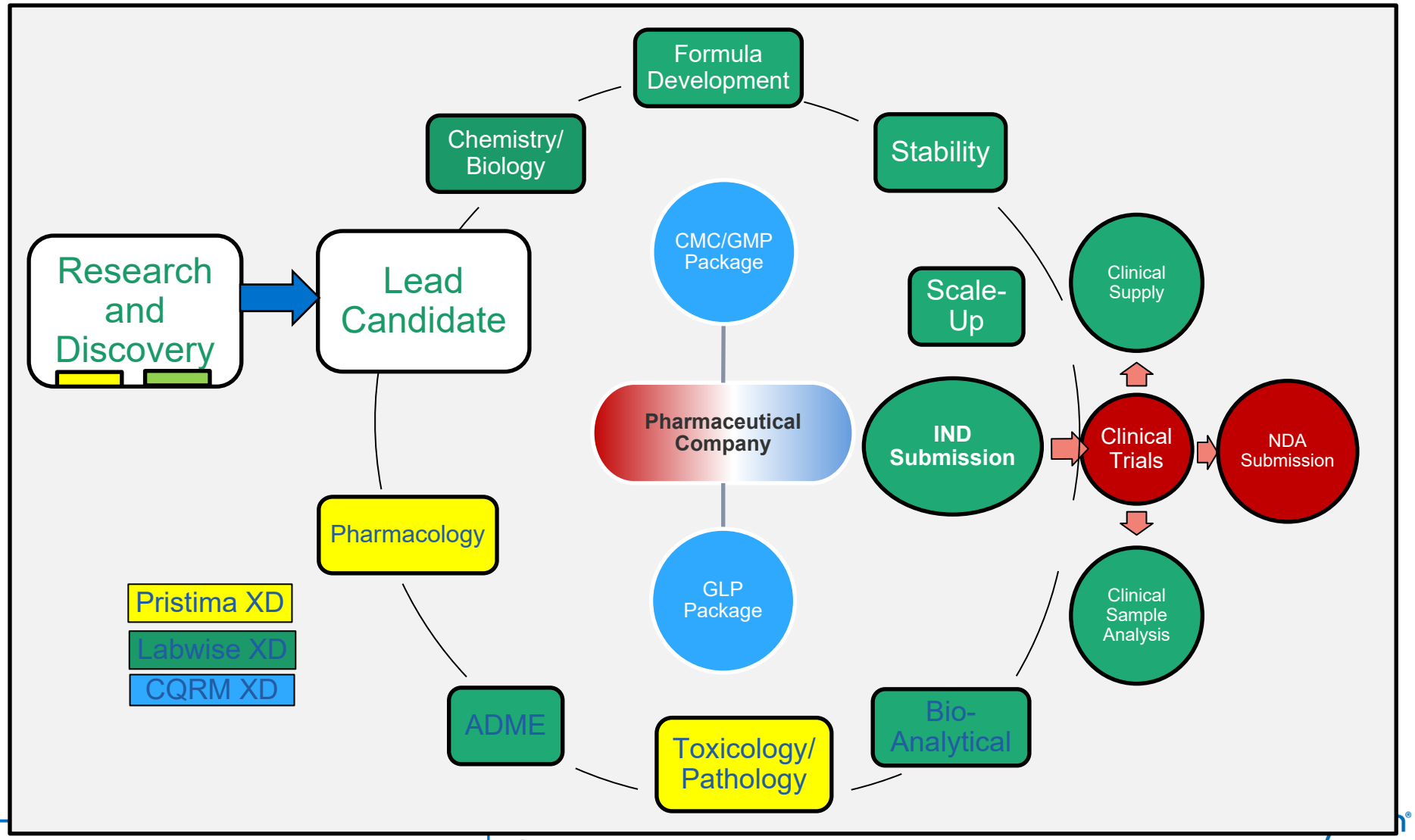
Appendix

Xybion Software and Solutions for Biotech

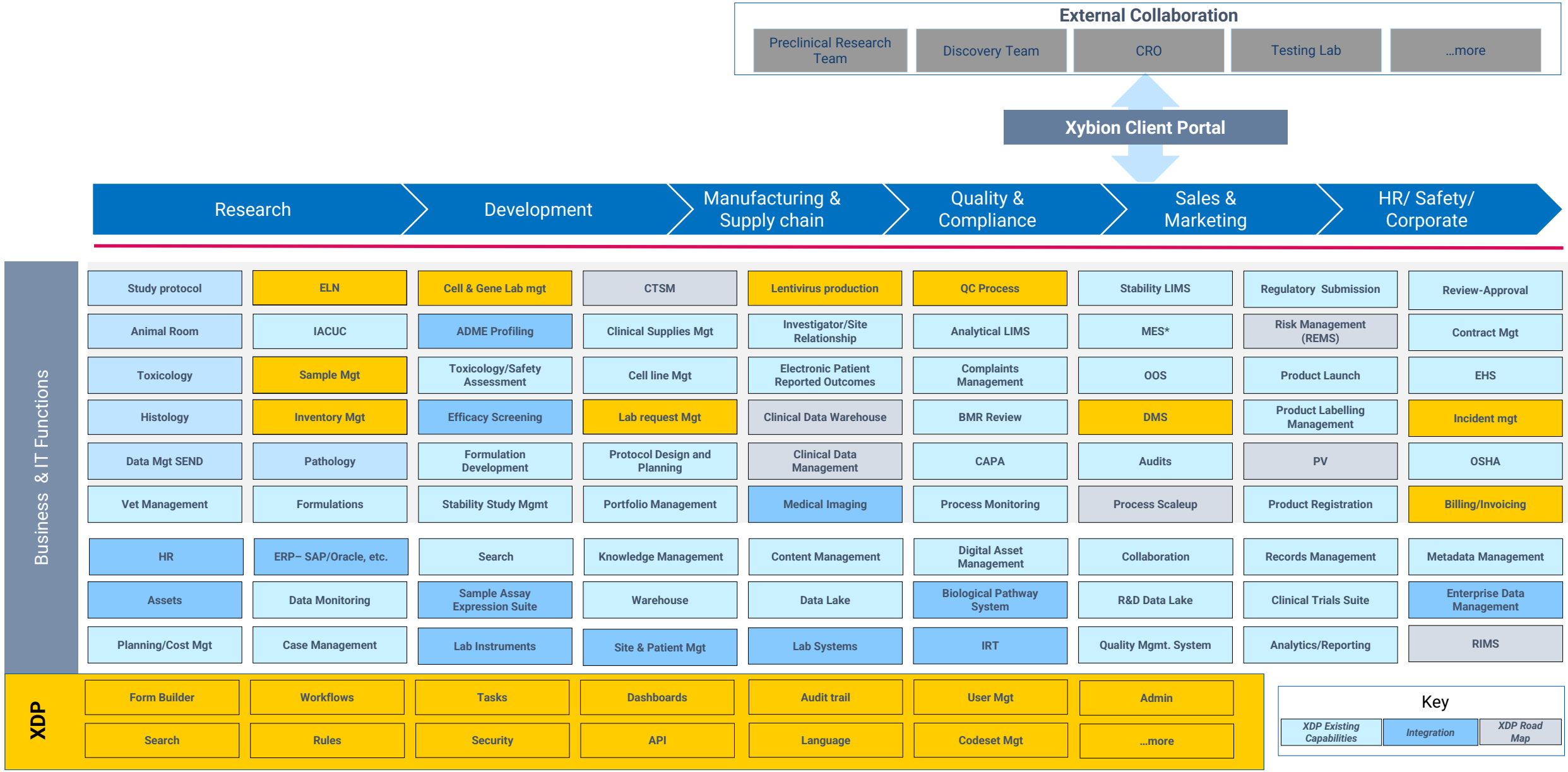
Our software cloud accelerates the conversion of inventions into approved medicines, saves lives, and helps keep employees safe.

How We Do It

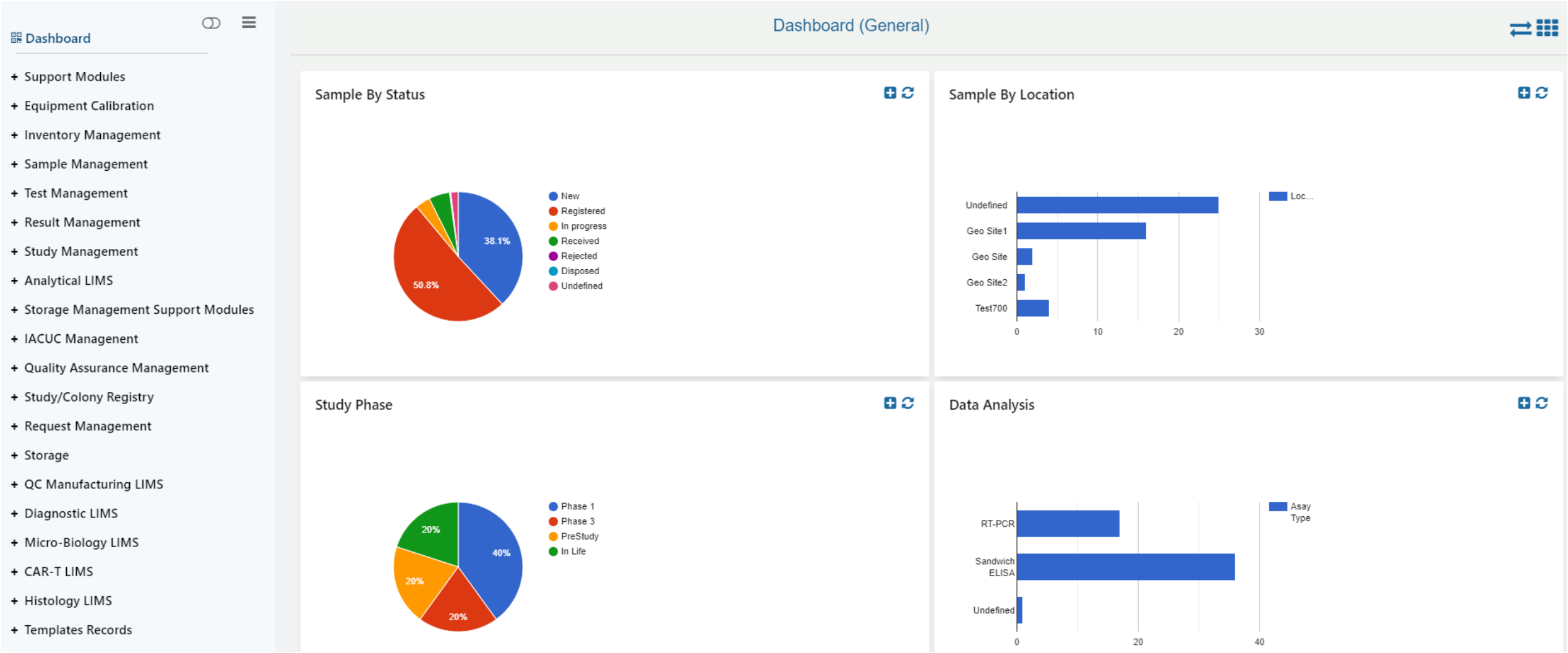
- Our software can address the entire non-clinical process as shown by the color mapping of our software modules
- Our clients typically need 6-12 different software and manual steps to get finish each of the process bubbles shown on the right.
- Now, a single Xybion platform can replace/displace 6-12 different software and provide improved compliance and reduce costs



Lab Platform as a Service for Biotech – Cell & Gene Therapy LIMS



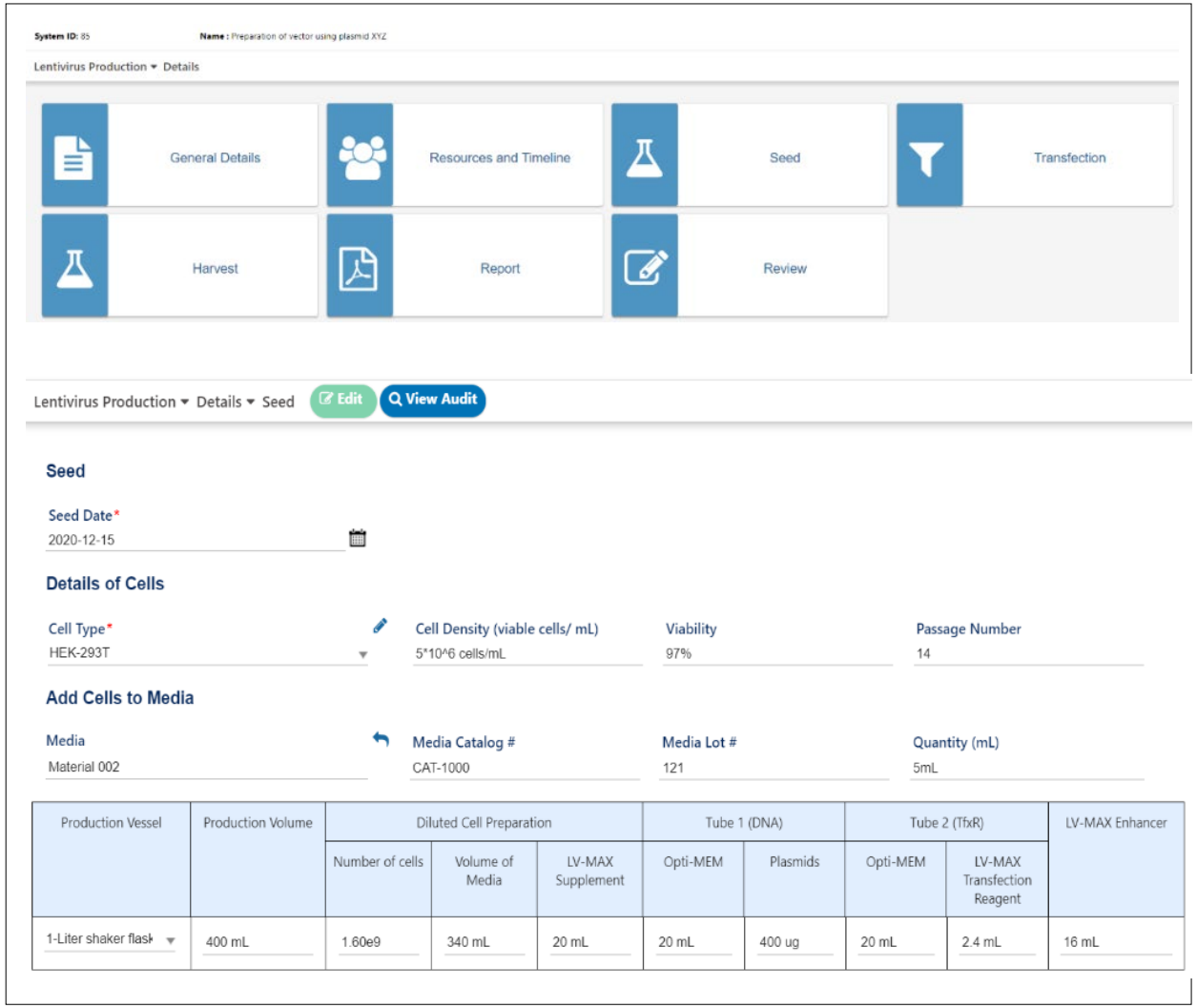
Xybion LIMS Software



Cell & Gene Therapy / Personalized Medicine Lab Management

The Cell and Gene Therapy module includes:

- Assay Protocol
  - Titre determination
- Workflow execution
- Master Batch Record
  - Virus Production
  - Car-T production
- Sample Management
  - Sample Registry
  - Sample Storage
  - Print Labels
  - End to End visibility of Sample Movement
- Store files of different formats across the process
- Generate Reports
- Reviews and Approvals
- E-Signatures
- Audit Trail

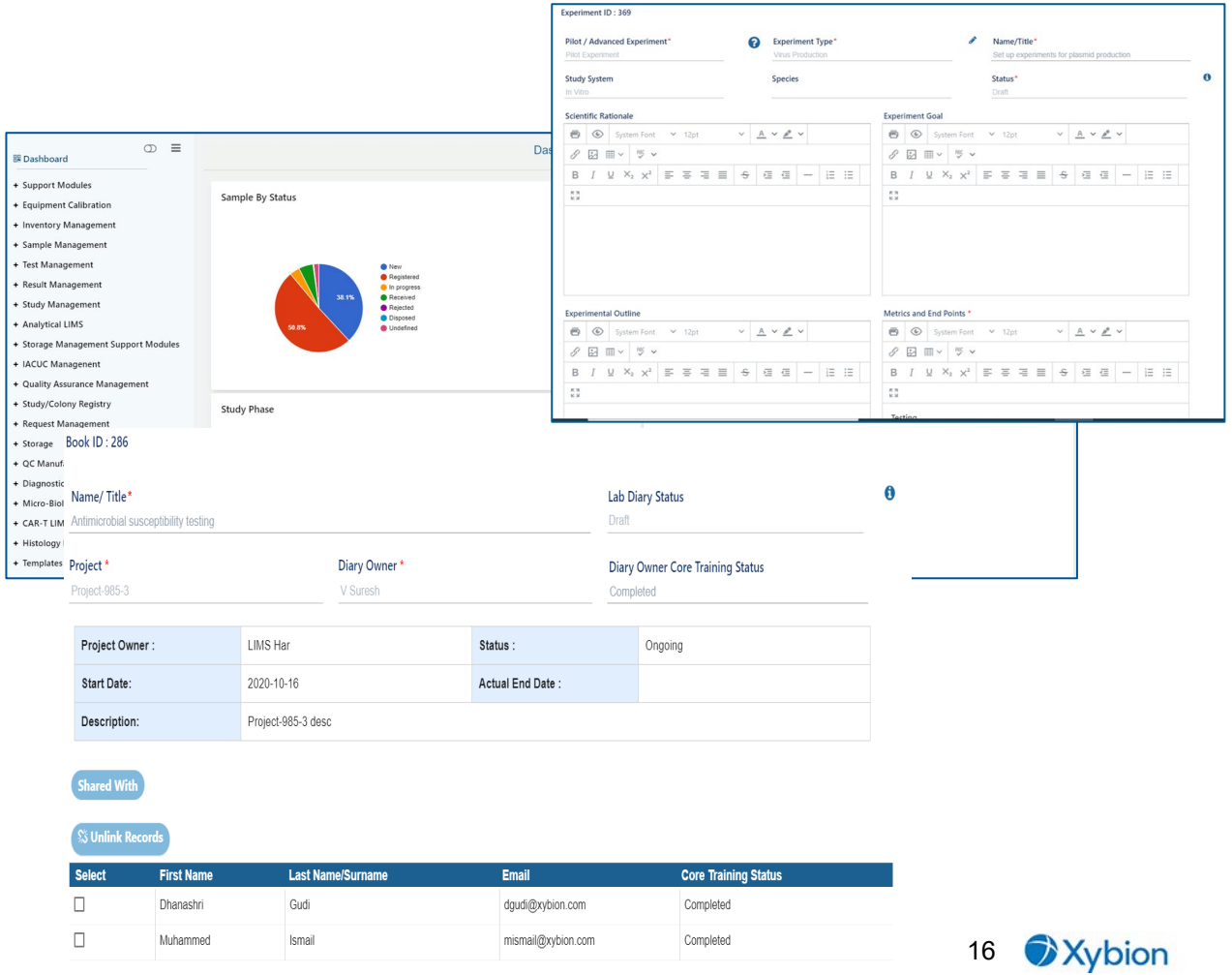


ELN - Electronic Lab Notebooks

Labwise® XD A modular, integrated, and inclusive end-to-end Business Process Management (BPM) platform that supports all workflows in the lab, including test methods, Laboratory Information Management Systems (LIMS), Electronic Laboratory Notebooks (ELN), Quality Management Systems (QMS), Electronic Communication Network (ECN) and client portal.

Lab Diary®, a cutting-edge ELN solution from Xybion® enables facile, intuitive, user-friendly electronic documentation system for data management, collaboration and integration with laboratory information management (LIMS).

- Manage multiple Experiments in a Lab Diary
- Share Lab Diary with a specific set of users and have secured Access to Lab Diary
- Competency Compliance Check to ensure only compliant users can conduct and manage experiments
- Add and manage multiple Notes to an experiment - Allows scientist to capture notes during experiment execution.
- Import instrument output and store data recording at the experiment level
- Able to view the step-by-step process in the protocol document while conducting experiments
- Ability to link a Lab Diary to a Project / Protocol execution - Easy access to Lab Diary data related to a Project/ Protocol execution
- Linking to Inventory, Equipment, Sample allows to capture and track the material/ equipment and sample usage in an experiment
- Data import and export
- Analysis and dashboard
- Option to store multiple documents of different format in Lab Diary
- Record Deviations at the Experiment Level
- Manage review and approvals of the Lab Diary and Experiments
- Generate Report for an Experiment and /or for Lab Diary
- E-Signature enabled
- Active Audit Trail of all activities in a Lab Diary



Labwise® XD Quality Control Management

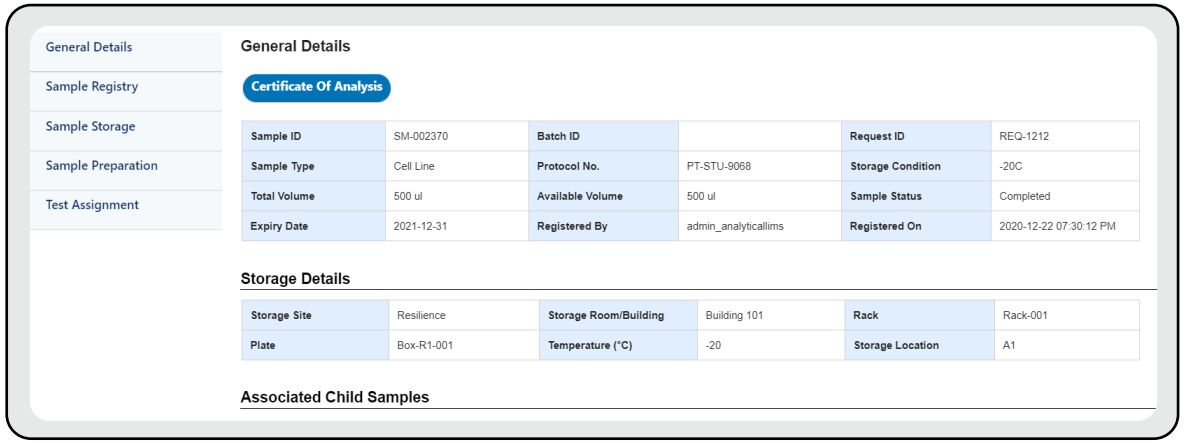
Labwise® XD is a QC LIMS with sample management, inventory management, test method management, certificate of analysis and client portal for internal and external collaboration.

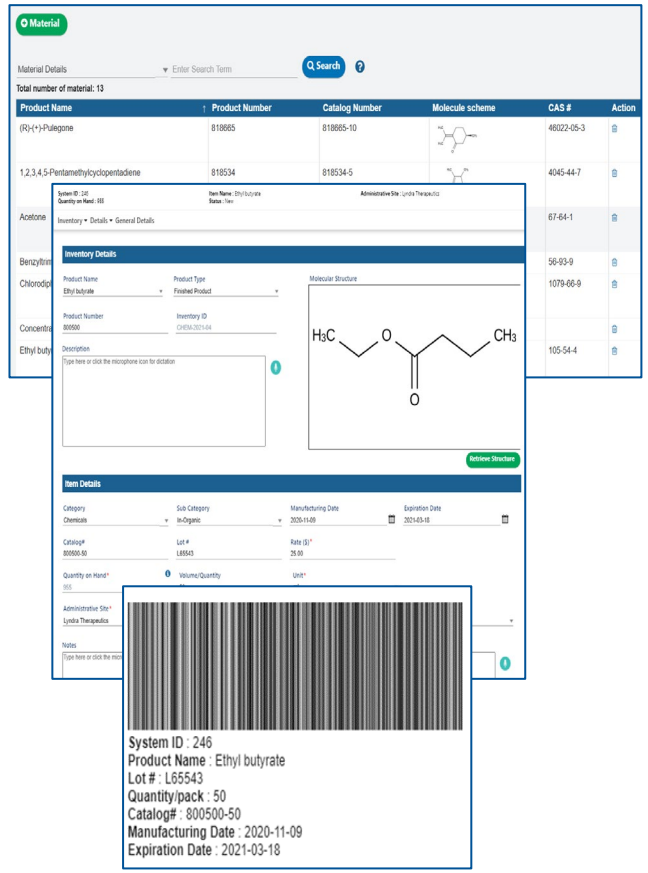
Test Method Management
- Test methods
- Product Management
- COA Mgt: USP/BP, etc.

Sample Management
- Sample Registry
- Sample Storage
- Print Labels
- End to End visibility of Sample Movement

QC Test
- Instrument calibration
- Test runs
- Final runs
- Test results
- Certificate of Analysis

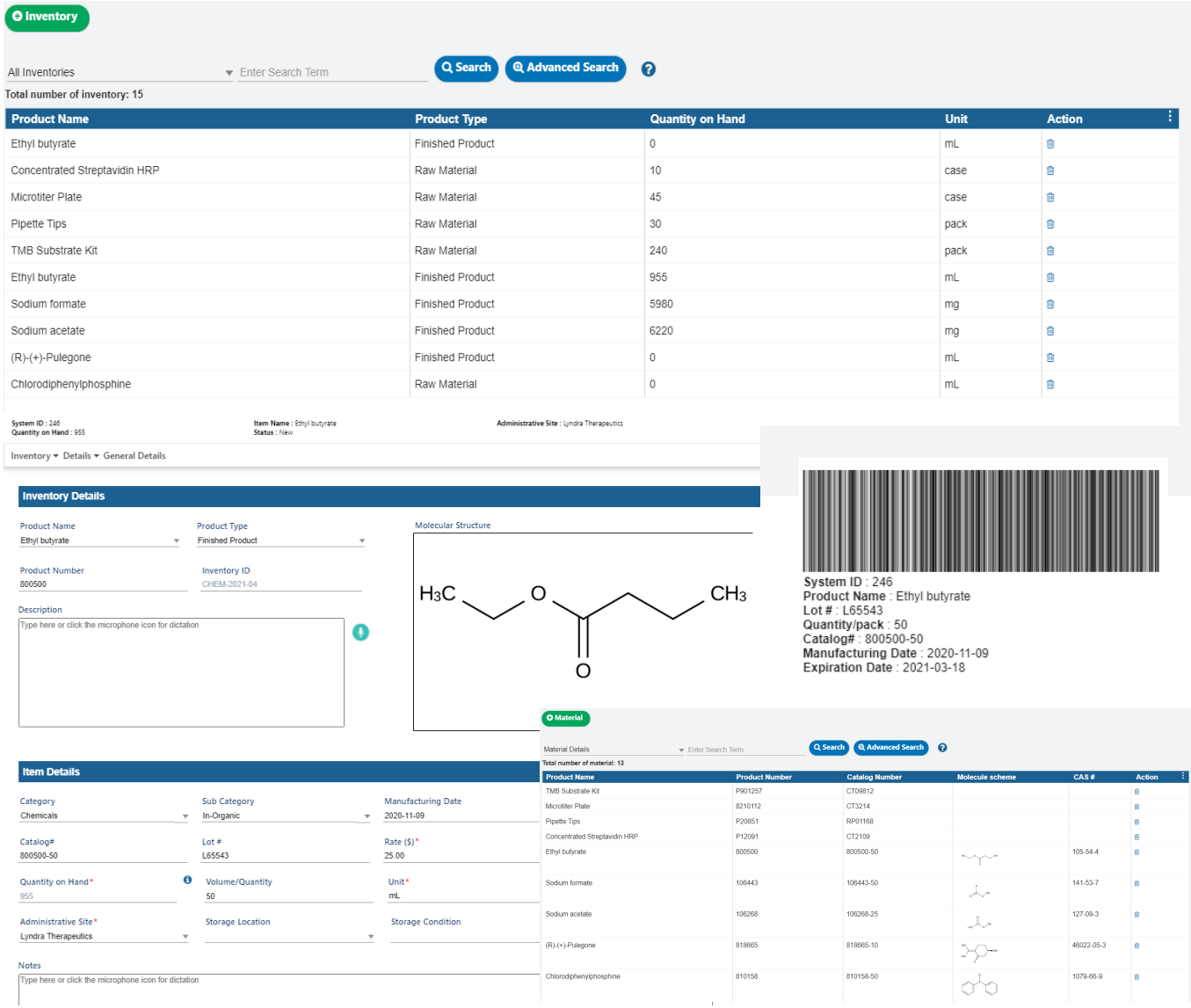
- Certificate of Analysis
- Integration with other systems such as ERP and MES
- Reviews and Approvals
- E-Signatures
- Audit Trail





Inventory Management

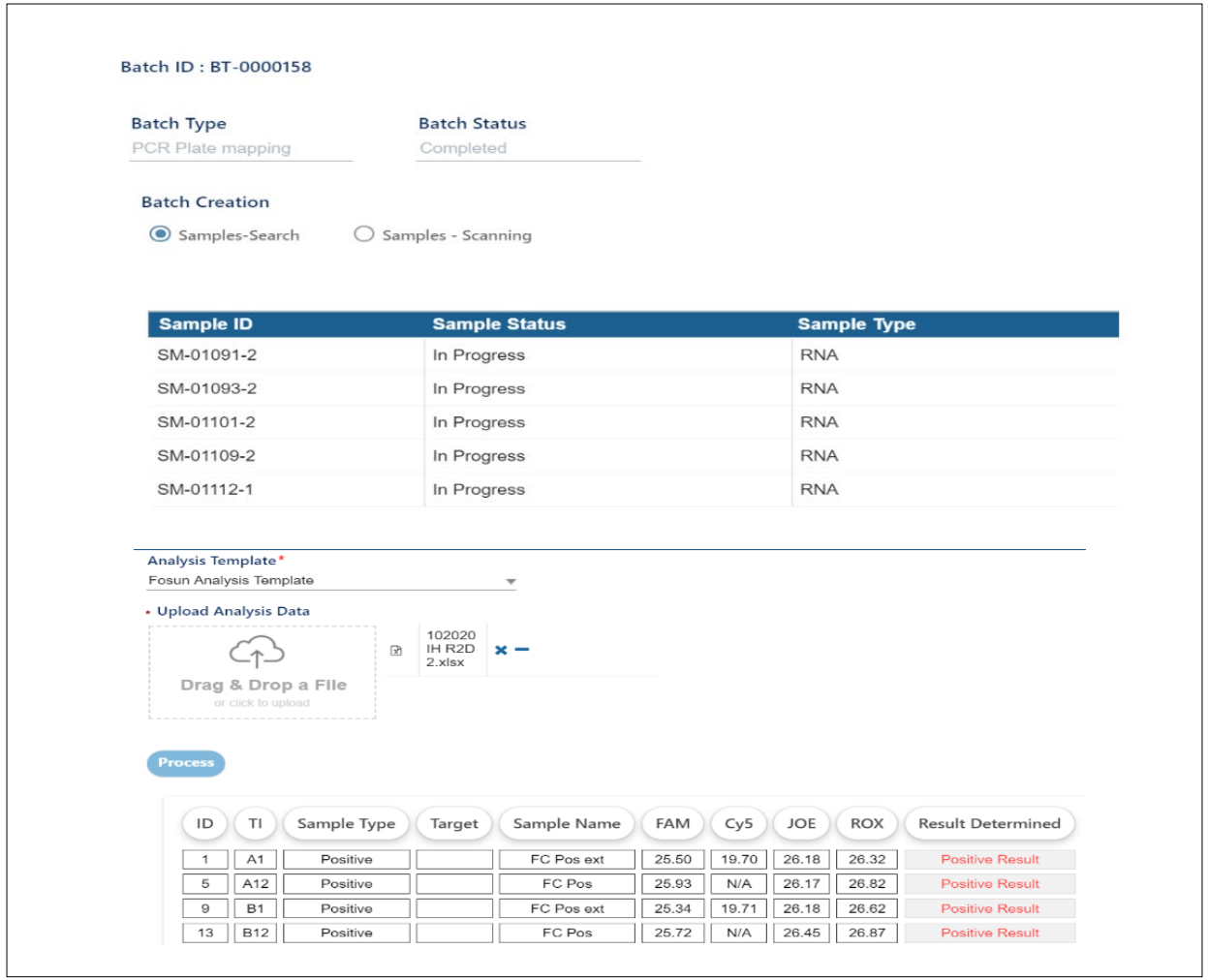
- Product Management
- Material Management
- Reagent preparation and management (inhouse)
- Material Reconciliation
- MSDS Management
- Automated Inventory updates
- Purchase Notification
- Order, receive and track inventory
- Search inventory using faceted search including chemical structure
- Track available, reserved, and consumed inventory
- Track date reserved, date used, and date created
- Be notified of any material that will expire within a specified number of days or of depleting inventory.
- Prevent usage of expired inventory in lab execution process
- Capture unit costs, ordering instructions, re-order amounts, and shipment details
- Automatically decrement inventory upon usage in lab execution process or upon fulfilling orders
- Audit Trail
- Review- Approval



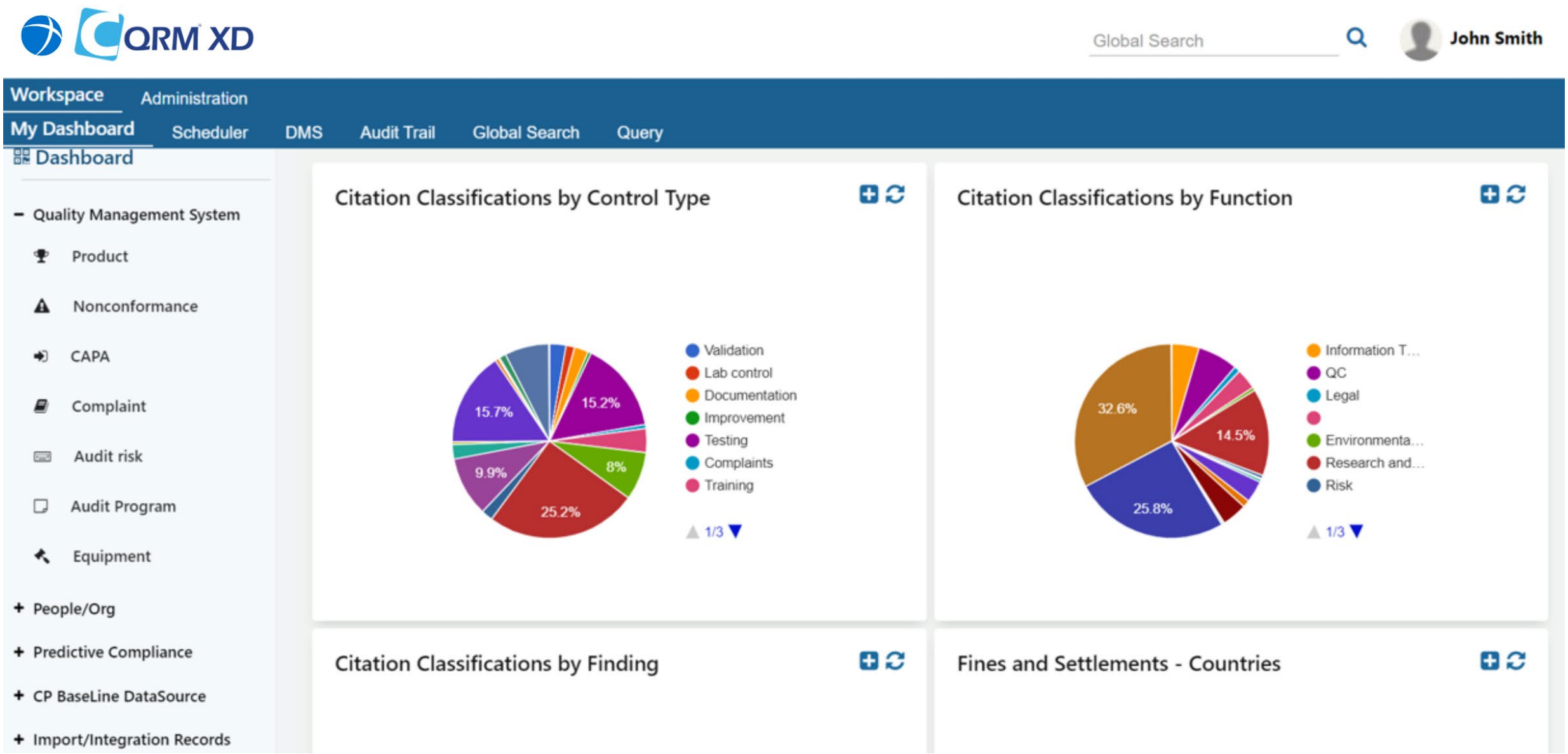
Patient Registration and Sample Management

The Diagnostic Lab module includes:

- Patient Registration
- Sample Collection and Submission
- Sample Registry
- Sample Processing
  - Batch creation
  - Plate mapping
- Instrument Integration
- Data Analysis
- QC Reviews
- Generate Reports
- Reviews and Approvals
- E-Signatures
- Audit Trail

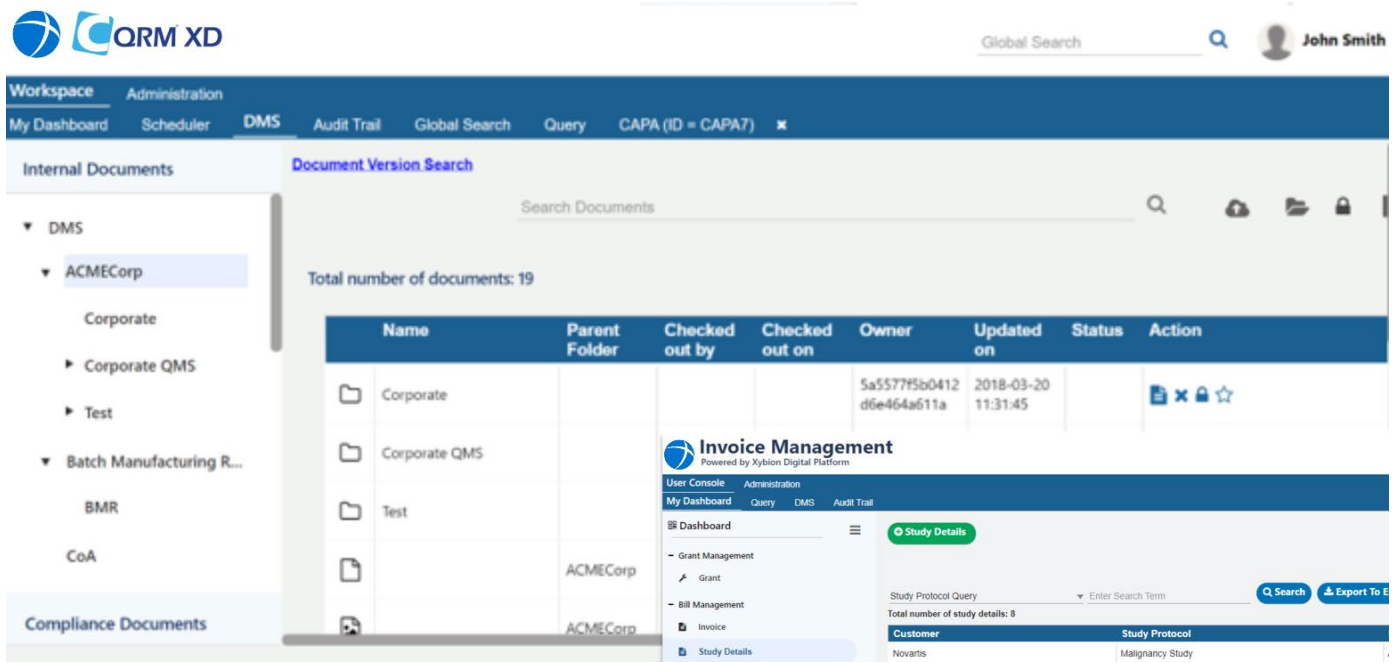


Quality Management & Compliance



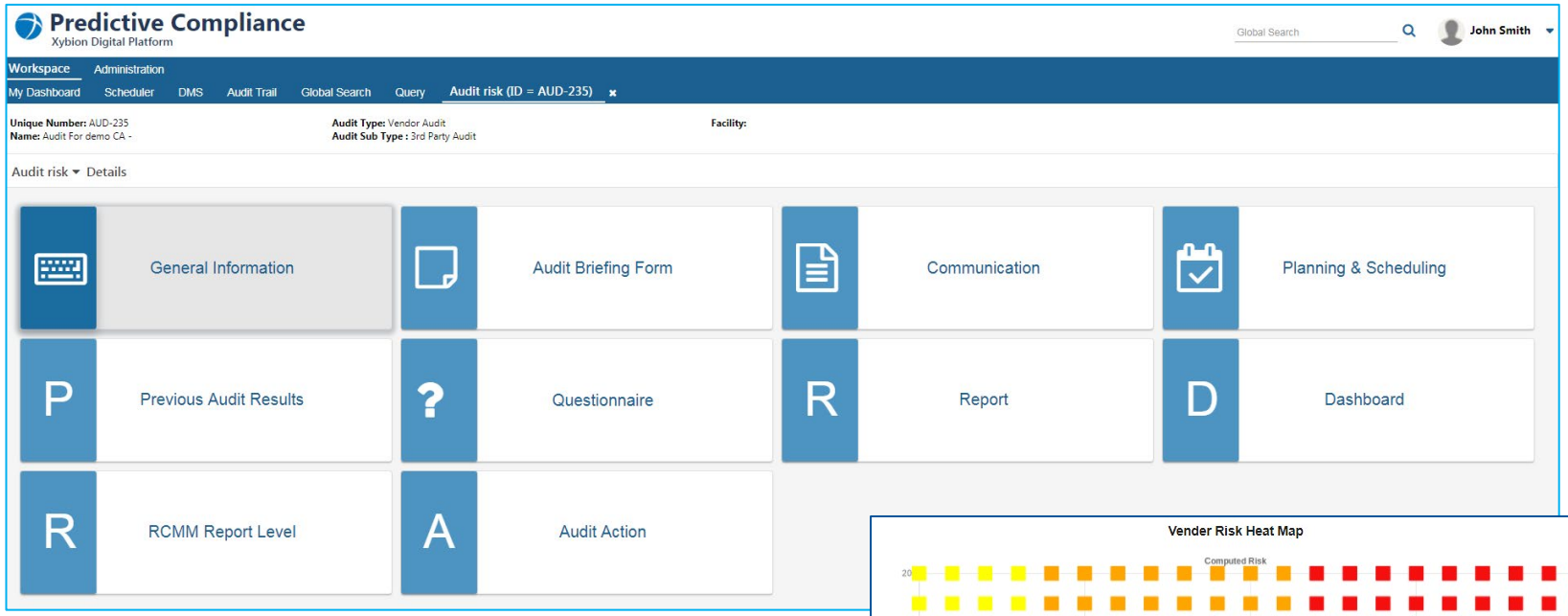
Document Management

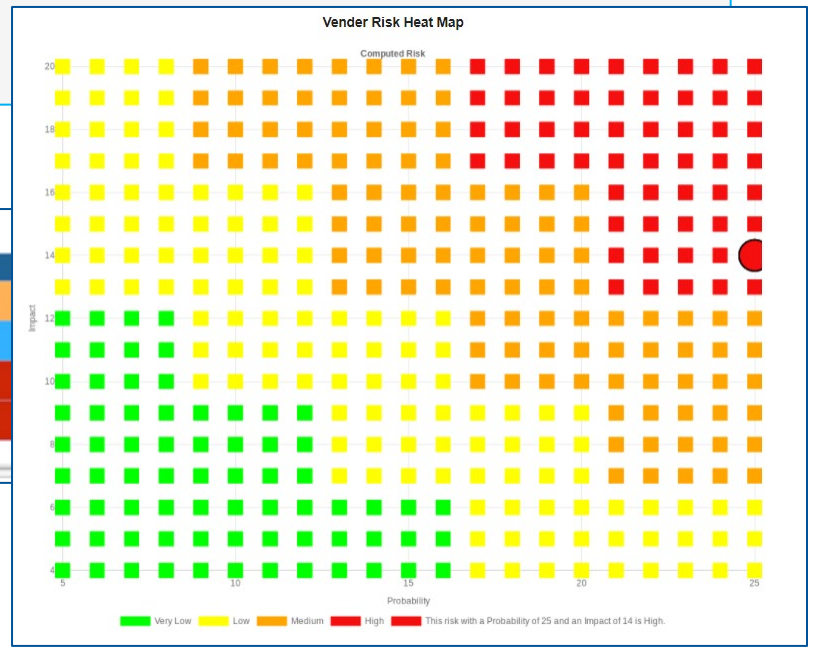
- Allows documents templates to be created and used as needed to be filed into a user-configurable hierarchical “folder” taxonomy.
- Document permissions
- Check-in/check-out, versioning, rendering, approval, search and expiring document tracking capabilities with full text search and retrieval
- Automatic PDF conversion for any document in the repository.
- Ability to receive documents in multiple formats
- Tagging on content, metadata, documents and records
- Document tasks are sent to a centralized workload engine and notifications of status and other events are distributed to the user’s e-mail to facilitate timely completion of critical document activities.
- Allows users to embed internal document hyperlinks to support key regulatory processes requiring internal document links.
- Allows users to specify if documents are controlled or uncontrolled for good corporate governance.
- Create, review and approve documents
- Receive documents through scanners
- Records management for regulatory audits
- 21 CFR Part 11 compliance



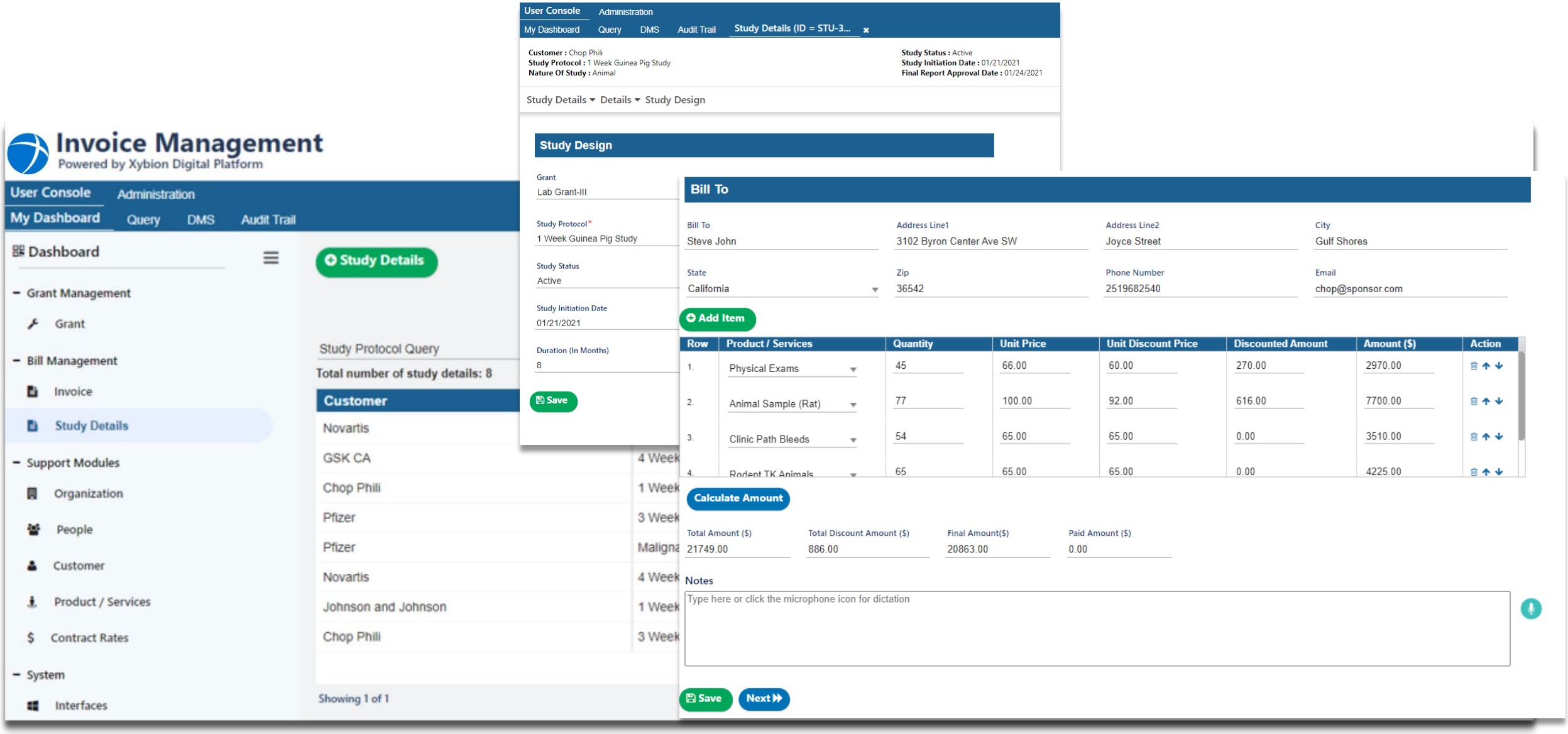
Internal and external audit and risk prediction

- Dashboard
- Communication
- Data analysis
- Data analysis
- Setup
- Audit Execution
- Report & Follow-ups
- NC & CAPA
- Closure





Cost and invoice management



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