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The Promise of Next-Generation Animal Management Systems

Pharmaceuticals, biotech, and device companies are searching for more robust next-gen animal management systems to help them enhance efficiencies, reduce costs and adhere to regulatory principles for humane animal care. Read on for an overview of existing systems, as well as the benefits, challenges, trends and technologies driving next-generation animal management systems.

Executive Summary

The use of animals across drug discovery, medical device and animal health research is not new to pharmaceutical, biotechnology, medical device and animal health companies. These companies have been relying on various animal management applications to support and track animal use in their research.

With a growing emphasis on exceeding financial, compliance, and administrative goals, these types of companies are looking for more evolved and robust systems to help them be fully compliant, and are easy to implement, use and maintain.

The changing IT landscape is driving the need for ideal animal management systems that cater to all of their requirements. This white paper will provide an overview of benefits and discuss gaps within existing animal management systems, as well as explore key challenges and trends driving next-generation animal management systems.

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ANIMAL USAGE IN DRUG DISCOVERY AND DEVELOPMENT

Model organisms have long played an important role in medical device, pharmaceutical biotechnology, and veterinary product research. They are used in drug discovery, preclinical studies, safety, efficacy and toxicology studies. Each industry utilizes different animals to have the most accurate models for their research. Pharmaceutical, biotech, and device companies use rats, mice, cats, dogs, pigs and primates. Veterinary product companies use horses, cattle, ferrets and cats depending on the products that they intend to manufacture. The use of invertebrate and lower vertebrate animal models like nematodes (*Caenorhabditis elegans*), fruit flies (*Drosophila*) and zebrafish (*Danio rerio*) have also gained importance—driven by the explosion of genomics and findings that not only genes but also pathways are conserved during evolution.

Animal models are used in basic research to understand physiological and disease pathways and develop new therapeutic strategies for treating human and animal diseases. These models are used extensively in drug discovery for target identification and validation, lead optimization, toxicity and safety screening. Preclinical studies continue the use of animal models for drug safety and efficacy tests. The data generated from the studies conducted using various animal species are extremely important to determine potential risks for humans in clinical trials. Approximately 70% of severe adverse effects are identified using animal models during the preclinical stage.

When developing medical devices, animal studies are used to provide initial evidence of the device's safety, its potential performance when used in a living system and the biological response a living system may have. The animal model safety data is used to complete an investigational device exemption (IDE) application or to demonstrate the safety of the device for a marketing application. Similarly, animals are used for safety, efficacy and effectiveness studies that help in Investigational New Animal Drug (INAD) and New Animal Drug Application (NADA) for veterinary and animal health products.

REGULATIONS FOR ANIMAL USAGE AND PROTECTION

The use of animals in testing is not only intended for pharma or biotech drugs, but also for medical devices, veterinary drugs and vaccines. Ultimately, these therapies improve the quality of human and animal patients' lives. Due to the importance of animal testing results, there are

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several international, national and regional laws and regulations that companies and institutions must adhere to:

- EU Directive on the Protection of Animals used for Scientific Purposes (2010/63/EU)

- European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (ETS 123) by the Council of Europe

- U.S. Animal Welfare Act and the U.S. Department of Agriculture's Animal Welfare Regulations

- Guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Guidelines)

Regardless of the regulatory agency, the main imperative for using animals in preclinical research is to follow the principles of the 3Rs– reduce, refine and replace:

- **Reduce** the number of animals to obtain statistical significance for the intended objective.

- **Refine** the experiments to minimize pain and/or suffering of the research subjects, or maximize animal welfare.

- **Replace** the use of animals with alternative techniques or avoid the use of animals altogether.

To meet regulatory guidelines, and to effectively monitor the principles of the 3Rs, many pharma, biotech, medical and animal health companies use animal management systems to capture and document end-to-end data on animals' activities during their active life span.

ANIMAL MANAGEMENT SYSTEMS OVERVIEW – MODULES, FUNCTIONALITIES AND KEY PLAYERS

There are a growing number of animal management systems currently available (see Figure 1) to address important functions like protocol management, animal operations and animal health management. These functions are supported either as individual applications or as modules within an application; they are custom built or commercial off-the-shelf (COTS) products. In either case, they depend on integration across the modules or Extract, Transform, and Load (ETL) scripts to load data from one application to another.

In the protocol management module, the Institutional Animal Care and Use Committee (IACUC) coordinators and researchers use the system compliance functions to create and track new protocol applications, annual review and three-year renewal applications, IACUC reviews, audit reports and related tasks. The system guides users through tasks, ensuring each step is completed thoroughly and according to compliance. This structure helps users comply with regulations by requiring all compliance-related fields to be filled out before submitting any forms.

For example, a researcher will not be able to submit a protocol application to the IACUC coordinators until all required information about his or her protocol is complete, which is facilitated by check-for-completeness functions. Similarly, when a protocol is within a few months of expiring, the protocol owner will be notified through email until it is resubmitted, cancelled or expired. Additionally, the system maintains the data for later access during annual and three-year reviews, audit reports and animal ordering. Once the IACUC determines that an application is compliant in the procurement module, the researchers can order the animals.

Performing Animal Operations to Comply with Protocol Information

Animal management systems also help users complete and maintain information about animal orders. Similar to completing a protocol application, it ensures that users enter all necessary animal order information completely. Also, the system will validate the orders using the approved protocol information to verify that the researcher is ordering the correct quantity and species available from the protocol management module. After the order is placed, researchers can track its status.

The system also facilitates the animal buyer's responsibilities including the financial aspects of animal orders. The system allows the animal buyer to review orders over a period of time, check if the orders were delivered correctly, pay the vendor and charge the appropriate research group by interacting with financial systems based

on SAP or Oracle financial applications software. Once animal orders are placed, the animal management system begins the process of tracking the new animals within the facility.

As animals are received, the order is verified by the animal receiving coordinator and any errors are documented and sent to the vendor and animal buyer. Upon entering the facility, animals are assigned a tracking method—usually a cage with a barcode or a radio frequency identification (RFID). These are used to conduct regular animal censuses and to track the movement of animals using tightly coupled RFID scanners/systems. Animal management systems are compatible with barcode or RFID scanners and efficiently manage all census data. During each census update, the system assists the census coordinator with the business processes for any updates or changes. For example, if animals are born in the facility, the census coordinator can note the increase in animals in a cage and the system will print a new cage card or update the data in the RFID.

Managing Colony Breeding Activities And Tracking Health Issues

In addition to ordering new animals for a facility, animal care personnel within the company can manage their own colony breeding activities using an animal management system. The management system can help breeders track the breed or type of animal they are working with and complete genetic studies. Other researchers within the company can access the information about the internally bred animals and order them

Popular Animal Management Vendors

COMPANY NAME	PRODUCT NAME
A-tune	Tick@Lab
Xybion	Pristima
Topaz Technologies (Cultura Technologies LLC)	Topaz Elements
Dynasys	Dynasys Animal care warehouse Management system
Lovelaceis	Lovelace intelligent systems
E-Z Systems/Euthanex/E-Z Anesthesia	EZ-track
Edstrom Industries, Inc.	Smartlab
Digital Paradigms	Animal Bioware Series II
NTM Consulting Services INC	eSirius 3G
ARMIS Limited	ARMIS
Huron Consulting Group	Click Portal
InfoEd Global	InfoEd Animal Facilities
NorayBio	Anibio
RayyCorp	Animal Inventory Management System
The Caplen company	Animal Information Management
Locus Technology	Facility and Labtracks
Virtual Chemistry	Mosaic Vivarium
Key solutions	Animal resource management software
IDEXX	DVMAX R

Figure 1

using the internal ordering system within the animal management software breeding module.

While maintaining animals in a facility, it is imperative to track not only the location of animals, but also their health. With an animal management system, veterinarians can track an individual animal's previous and current nutrition, health issues and medical treatments. By maintaining a comprehensive health record for each animal, researchers can better correlate health problems with a study the animal is participating in. Additionally, this information improves a facility's ability to prepare and respond to compliance audits. During health management of the animals, the system facilitates tracking of animals in study management systems, capturing body weight, feed and vitals of the animals, and requesting various diagnostic tests through external diagnostic systems.

The system captures the information across modules such as protocol management and animal ordering and helps in generating regulatory reports.
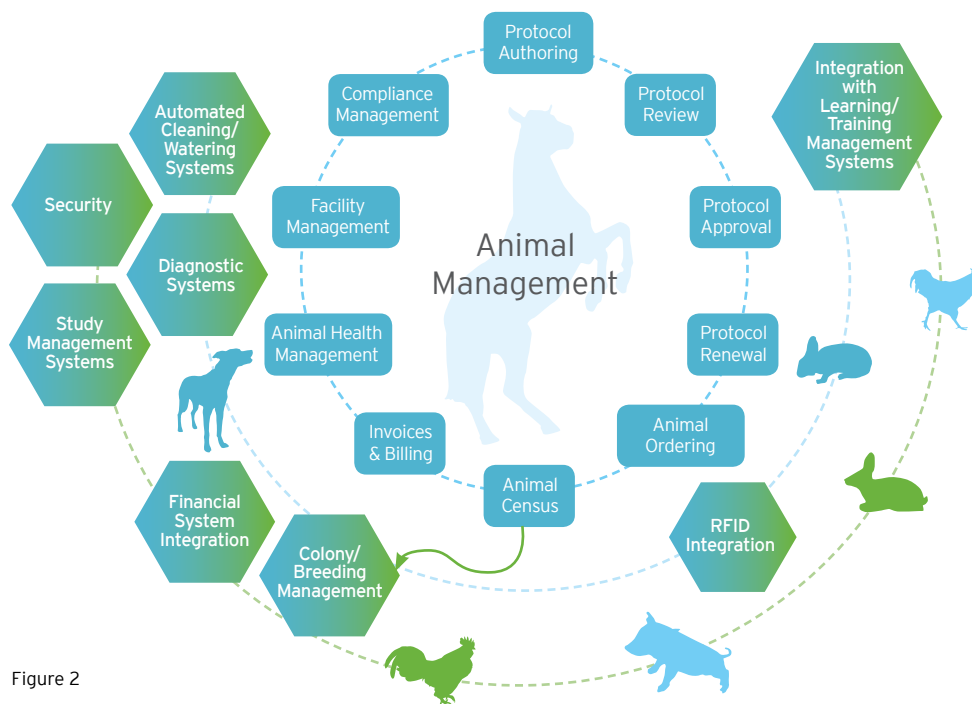
Key Components Of an Animal Management System

Figure 2

GAPS WITHIN EXISTING ANIMAL MANAGEMENT SOLUTIONS

There are significant gaps in current systems that spurred adoption and evolution of integrated or next-gen animal management systems—including rigidity of systems, outdated technologies, changing regulatory guidelines, reluctance to change, time constraints, costs and more.

Lack of Integrated Systems

Many organizations still use disjoined or independent systems and applications to cater to the core functionalities like protocol management, animal ordering, census and billing, health management, colony or breeding management. Some of these independent systems are still based on outdated technologies and sometimes involve using Excel spreadsheets to document and track data; that is because there is no integration with additional systems that support animal study management,

diagnostic systems, balances, environmental monitoring, financial management and training.

Incompatible Modules Across Animal Management Activities

While conducting preclinical research, health management professionals play many roles, such as regulatory committees, principal investigators, researchers, procurement staff and veterinarians. Each role has unique responsibilities that must accurately share information and communicate with one another across the modules. Because of the independent nature of these applications, user profiles are created in each system, which forces them to enter the base data multiple times, resulting in data inconsistency and duplication. Alternatively, organizations have also used ETL scripts to load the base data as a new protocol is created or new animals arrive. If one system is unable to deal with multiple functions and multiple user roles, then ETL's

shortcomings and data-related issues will make the use of these systems unreliable, time consuming and erroneous.

Manual Census & a Lack of RFID Technologies

One of the key aspects of the animal management module is performing animal census and real-time tracking of the animals for billing, room and facility capacity planning and study management. The census and movement of animals are still managed by the staff using manual counting and mapping despite the availability of RFID technologies. Some organizations either use barcoding and RFID technologies or different study management and tracking systems. In either case, the systems are not tightly coupled. This can lead to incorrect animal location data, erroneous room and facility capacity planning, a delay in study schedules because participating animals could not be identified quickly, and a heavy burden on facility personnel inputting and consolidating data from a manual census.

As regulatory norms get stricter, it becomes critical to monitor animals participating in various pharmacokinetic, pharmacodynamics and toxicology studies and report any health conditions that arise due to these studies. These tasks require requesting various diagnostic tests and importing the test results, or capturing vital signs and animal body weights from various external instruments. Research personnel and veterinary staff spend a huge amount of time manually performing the previously described tasks rather than spending time on the animals' environmental and general enrichment programs.

In addition to healthcare tasks, it takes some effort from protocol management personnel to track the eligibility and training status of the personnel handling the animals from external enterprise learning systems. Animal general and health maintenance charges have to be captured and

### A Summary of the Key Challenges and Issues with Current Animal Management Systems

KEY CHALLENGES	ISSUES
Lack of integrated systems	Logistical and time constraints in performing tasks related to animal health and facility management.
Incompatible modules across animal management activities	Data duplication and inconsistences, duplicate user profile management, and maintenance of ETL scripts for loading base data from one system to another.
Manual census and lack of using RFID technologies	Lack of real-time room and capacity overview, difficulties in finding animal location, leading to a delay in study schedules and an increased workload on the facility staff.
Varying regulatory requirements and increased costs	Increasing application support and maintenance costs and time constraints in generating regulatory reports.

Figure 3

billed to the research groups using these animals. These tasks highlight the complexities and logistical constraints involved in integrating disparate and incompatible systems like study management software's clinical pathology systems, training management systems and financial systems, and monitoring devices/weighing balances.

Varying Regulatory Requirements and Increased Costs

Many of the pharma, biotech and animal nutrition companies operate globally. With animal research spread across different geographies,
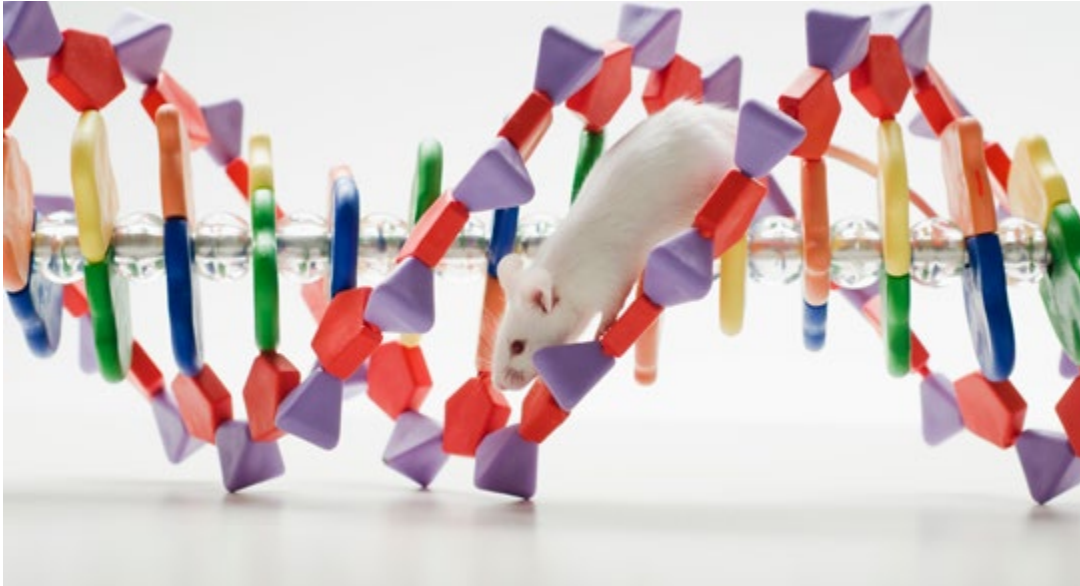
it is necessary to adhere to international and local guidelines for humanely caring for animals. Because of the different standards in countries, many organizations use a different animal management system for each compliance agency rather than a global system. This has led to increased application support and maintenance costs and substantial increases in time spent generating regulatory reports.

BENEFITS OF NEXT-GEN ANIMAL MANAGEMENT SYSTEMS

The potential benefits of using integrated or next-gen animal management systems to support animal research are:

• **Customizable to meet your business needs.** Not all organizations, institutions and research programs are alike. Animal management solutions provide comprehensive solutions with inherent configuration features allowing the client to tailor the application to the organization's business rules and processes.

• **Saves time and reduces costs**. These solutions help reduce time and costs by replacing

a variety of legacy systems that are expensive and difficult to maintain.

• **Uniform, consolidated data.** The system integrates processes and systems and manages activities and information with structured central data management.

• **Seamless data sharing.** A system will facilitate integration options with various enterprise systems through application programming interfaces (APIs) and web service interfaces and enable seamless data exchange between users, teams and modules by supporting easy integration with enterprise-wide directory services (Active Directory, LDAP) and single sign-on services.

• **Improves compliance.** The structure provided by these systems reduces the risk of non-compliance, provides better information to assist with audits and reduces the administrative burden placed on researchers and administrative staff.

• **Improves efficiency and effectiveness.** By enabling customized configuration and work-

flows for different levels in the organization and for different sites, the application provides a more efficient system. This enables rapid development of new forms and easy enhancement of existing forms without the need for any internal program or database changes.

- **Supports national and international compliance.** The applications cater to global and local needs to ensure compliance with national and international regulations, provide transparency regarding animal availability and usage and proactively support animal welfare and the 3Rs.

- **Reduced legal and operational risks.** Supported by these solutions, organizations can avoid legal and operational risks by standardizing and monitoring activities according to legal and company standards and regulations.

In conclusion, such well-defined solutions provide a better return on investment (ROI) by saving time, optimizing business processes and ensuring regulatory compliance.

KEY CHALLENGES & TRENDS DRIVING NEXT-GEN ANIMAL MANAGEMENT SYSTEMS

Challenges: Growing Need for SI Roles

There is a growing need for System Integrators (SI) roles in the animal management space. The SIs should primarily focus on three main points when supporting animal management systems—assessment, maintenance and improvements. By applying these three critical aspects, companies can expect an application that completely backs their business needs, improves their businesses' overall effectiveness, stays relevant and saves money and time.

When an SI team begins to support an animal management system, they conduct a thorough assessment of the client's needs and how the current system supports those needs. During this assessment, the team determines how well the current system meets regulatory guidelines, the animals' unique requirements and the scientists' research needs. They should able to employ a complete knowledge of animal management systems to provide the most effective, financially sound software or new system for the business.

After the new system is in place, the SI team continuously works with the vendor to ensure the application meets the client's changing needs. As a business grows, it may need to access different features within an application—such as multiple regulatory guidelines—and manage more highly regulated animals, or support new fields of research like breeding studies. The team anticipates and discusses these changes with the client and works with the vendor to make sure they are met.

Additionally, the SI team maintains an elevated knowledge of and evaluates new technology to determine its potential long-term success and if it will enhance the customer's existing system. Some of the key trends are shown in Figure 4.

Technology Trends

Modular/Workflow-Enabled Systems
Many customers are looking for a modular approach (plug and play) or workflow-driven systems that will enable workflows and functionalities for individual labs, users or locations, yet allow seamless data flows across modules/workflows. This gives customers more power without having to depend on vendors or IT supporting staff.

BI/Reporting
There is a continuous need to pull data and feed it into compliance reports that must be submitted to regulatory agencies and monitor the efficiency of 3R principle-based implementations. Customers need the ability to create ad-hoc reports themselves.

Key Trends Driving Next-Generation Animal Management Systems

Rank	Technology	
1	Modular/Workflow enablement	How well does the application allow me to activate modules and workflows to cater to site/location-specific requirements?
2	BI/Reporting	How do I generate new reports on the fly to meet compliance needs?
3	Mobile technologies	How efficiently I can use mobile technologies to perform, monitor and report animal operational and health activities?
4	Cloud computing	How do I scale globally (or reduce the costs of on-premises IT)?
5	Internet of Things	How do I monitor animal health in real time and plan my studies?

Figure 4

Mobile Devices

Mobile devices are being integrated into animal management systems as well. They are especially useful for census coordinators, veterinarians and animal receivers. RFID chips are inserted into the animals to store their unique information—such as name, protocol number and birth date. The animal receivers can user portable scanners connected to a smartphone to mark which animals have been received properly. The census coordinators can then use these portable scanners to scan the cages' barcodes and the RFID chips of the animals inside to track animals' location. Veterinarians use these scanners to complete their health checks by scanning the RFID chips to receive the animals' unique identifiers and accurately track the progress of health reports and required treatments. They also rely on iPad or mobile devices to capture animal health issues, upload images of diseased animals, and arrange or complete treatment plans.

Cloud Computing

Another promising innovation used in animal management is cloud computing-based applications. The cloud allows users to access the application on a third-party's server through the Internet, rather than having it installed on their computer. Using a third-party server eliminates all infrastructure maintenance for the client.

The cloud provider will update the hardware and complete all transitions as needed. Additionally, users will not have to track software updates or worry about downloading new versions of the application. Updates are done directly to the web application and are available to all users simultaneously. A cloud-based application makes the system available wherever it's most convenient for the user, who can access the application from any machine or anywhere they have Internet connectivity. This convenience allows the user to stay on top of animal management tasks no matter where they are and enjoy pay per use of the system.

The Internet of Things

One of the most promising technologies for animal management systems is the Internet of Things (IoT). This technology will allow researchers to access real-time data on the status of their study's animals whenever they want. In addition, automatic alerts and reminders based on the animals' changing condition can be sent to animal management roles to ensure that test subjects are treated according to the three Rs and that collected data's integrity is maintained.

These new technologies allow customers to work at peak productivity and efficiently use the animals for the intended purpose, adopt to and comply with changing regulatory needs and realize ROI.

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ABOUT COGNIZANT LIFE SCIENCES

Cognizant's Life Sciences business unit is committed to helping change millions of lives for the better by partnering with clients to build solutions to healthcare challenges, continually improve the way they do business, set the pace in clinical development, strengthen their regulatory infrastructure and increase competitiveness. Cognizant serves the top 30 global pharmaceutical companies, 9 of the top 10 biotech companies and 12 of the top 15 medical device companies. With a large team of dedicated professionals including doctors, pharmacologists, physicians, biomedical engineers, pharmacists, biostatisticians, medical writers and GxP consultants, the practice provides domain-aligned consulting, IT, business process, software and as-a-service solutions globally. Visit us at http://cognizant.com/life-sciences.

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