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## LabNovi: Preclinical Data Management System

### The scope:

LabNovi system intends to address the key goals of laboratory information management system adapted to preclinical *in vivo* studies or similar context where large volume of data is generated.

### The challenge:

In the drug development process, the use of computerized systems has increased domain knowledge by giving access to a **larger set of electronic raw data**, especially in the context of **preclinical *in vivo*** studies. In addition, information from previous research and development findings also needs to be collected and processed throughout the course of the study.

All this data thus available needs to be organized efficiently so that effort can shift from **managing large volume of data** generated during long term preclinical studies **to extracting its value** which is needed to drive the innovation and decision process. Having a **central solution** for study data as well as resources and workflow management has become essential in this context.

The goals for this central solution are:

- Central and secure storage of raw data & metadata as well as of data generated during analysis process for required retention period(s).
- Protection of raw data against loss, modification, unauthorized access and during transfer
- Easy access by authorized users for both processing and final reporting
- Upload/download of information from other sources (PK/PD, animal facility, imaging, *in silico* experiments, legacy systems, etc)
- Data retrieval at any point in time for further processing/reporting
- Data display and processing capabilities adapted to user types
- Seamless integration with labs' existing infrastructure (both hardware and software)
- Compliance with G(C)LPs & 21 CFR Part 11 requirements and adherence to GAMP© principles

Past years have seen the emergence of a broad spectrum of laboratory data management systems (LIMS). Despite the number of systems, very few address the preclinical study needs and constraints, especially for **large *in vivo*** data sets. For instance, key missing features are related to

- **Storage** and retrieval of **large volume** of data
- Standard **extraction** of data from **other origins & formats** to be used for further processing and reporting

This results in having each department developing its own solution or in using separate but sometimes overlapping applications for covering all needs. These constraints are often time consuming, costly, non scalable and also prevent seamless and efficient exchange of information in both cases.

### The solution:

The **LabNovi** solution supports the key preclinical data management system goals outlined above. It is designed to be accessed by study stakeholders **at all stages of the study, from project initiation till archiving**, thus removing the limitations existing with current preclinical LIMS systems.

**Central point receiving and distributing content**

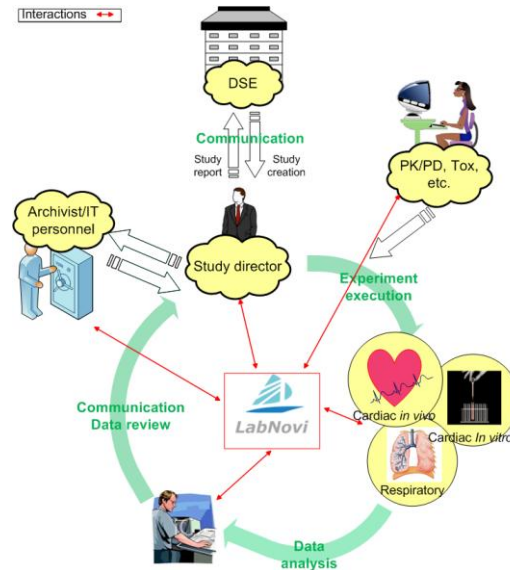
- Aggregation of data from multiple sources and formats
- Distribution of content to relevant authorized user(s)
- Secure communication between sites, systems and users connected to LabNovi
- Secure data transfer between sites, systems and users connected to LabNovi
- Updates of software versions installed in labs
- Notification as soon as new data is available
- Easy data retrieval at any point in time
- Collaboration between sites, applications, etc

**Digital content management system**

- Files versioning and relation management
- Not dependent on file type
- Access only to file information, not the file itself
- Integrates to industry standard Configuration Management Systems

**Web based solution**

- Access 24/7
- Data security & encryption
- Access from any (authorized) location
- Adapted to evolving technologies (portable devices, etc)
- Data review/validation, Report generation, data import/export, etc



**Open and scalable**

- Compatible with existing infrastructure & workflow
- Using OTS as well as custom components
- Can integrate with future focused tools, eg RFID for sample tracking integrity.
- Key components (eg database) can be replaced easily without discarding/re-designing previous work
- Scalable in cases of growing storage demands

**Benefits:**

- ✓ **Fit for preclinical *in vivo* (or similar) data type and volume**
- ✓ **Raw data integrity and security**
- ✓ **Access to information from other entities involved in drug assessment process**
- ✓ **Extraction of information from various origins and formats**
- ✓ **Simple global deployment due to entirely web based solution**
- ✓ **Unique platform to reduce complexity of laboratory SW architecture**
- ✓ **User focus on extracting value from all data rather than on managing its load**

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