LeadTrial

WEB-based **Clinical Trial Platform**
for planning , design, data colleting, management,
and reporting of clinical research

All functions that you need can be operated in **one platform.**

LeadTrial is

a combination of the words 'Lead' which means leading IT field in Clinical trial and 'Clinical Trial'. It is web-based integrated Clinical Trial Platform that enables user to conduct a research easily and conveniently by electronicizing clinical trial execution and administration processes such as planning, design, data collection, management, and reporting of clinical research.

It enables to minimize the hassles of having to use multiple programs up to now. In addition, through integrated one platform combined with centralized database which can be accessed from any web-browser, it can easily access several applications including EDC(Electronic Data Capture).

Also, not only does it improve user satisfaction by providing intuitive and user friendly web-interface, but also using LeadTrial, we expect to improve data quality by real time edit check when data is input and on site monitoring, to reform existing inefficient work process. Thereby, successful clinical trial could be fulfilled.

Through LeadTrial, we will help you to conduct clinical trial on the basis of accuracy and reliability.

"Proven"

LeadTrial complies with below regulations.
- 21 CFR Part 11
  : Electronic Records / Electronic Signature

"Flexible"

- It is possible to set role/authorization for each project, so it is available to various research.
- It supports automatic email alarm function as well as provides a summary list of the tasks user has to perform according to the set role/authorization.
- By analyzing the collected data from various perspectives and providing it in real time, it supports user's task-oriented workflow.
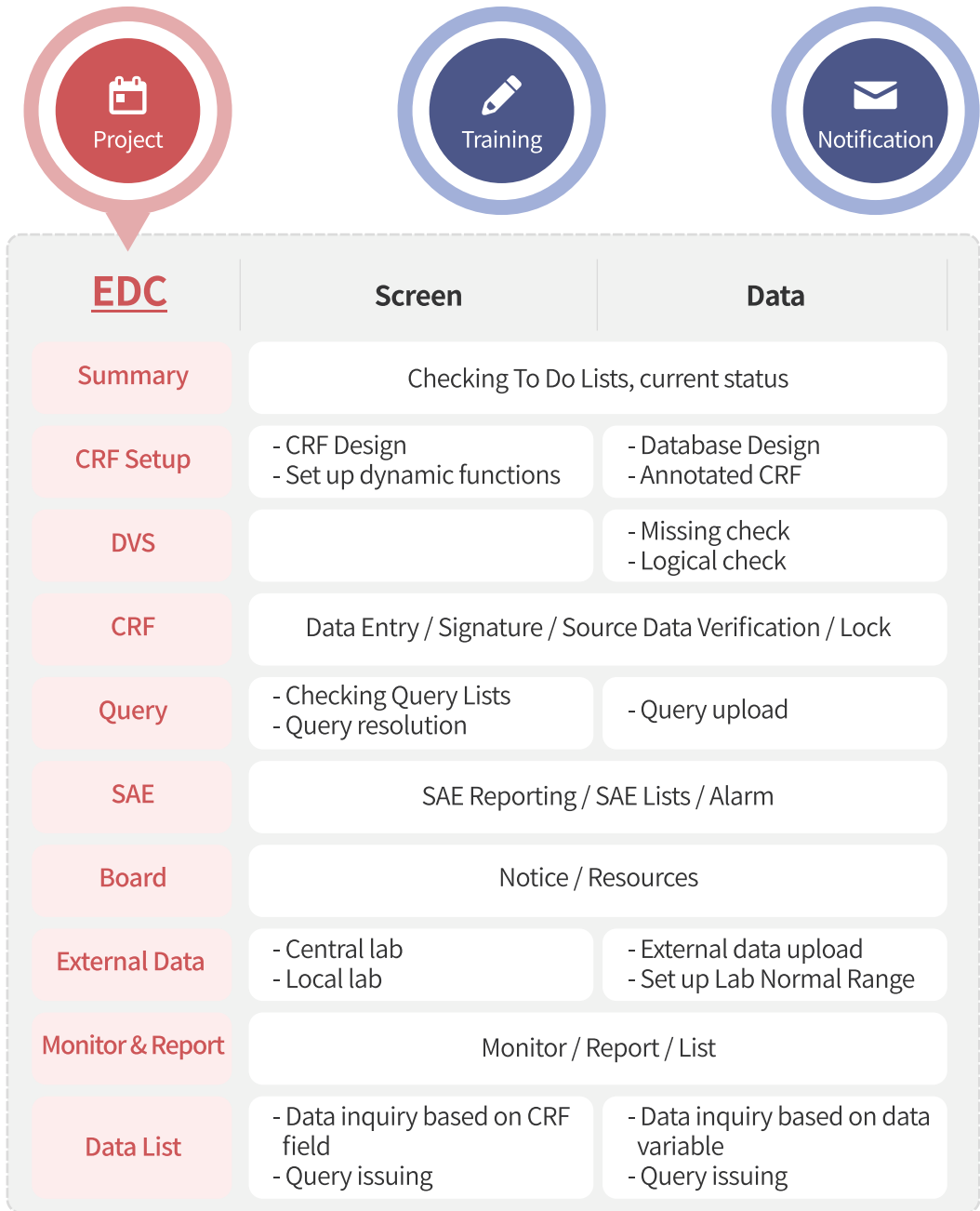
"Usability"

- It allows to proceed with the clinical trials efficiently without the help of a programmer.
- A variety of design tool and 'Drag and Drop' function in CRF setup could support user's easy and intuitive operation.
- It is possible to set up complicated logical checks using functions provided by system without additional program activities.
- It allows user to retrieve/download the data that meets their requirements if necessary.
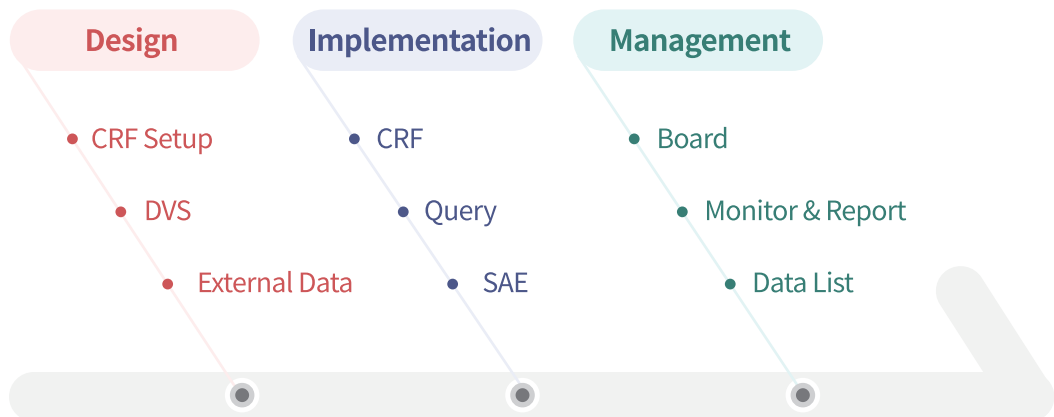
"Library"

- LeadTrial allows to save all of data including various types of external data as well as data collected via EDC during clinical trial.
- Through massive data accumulation, it is possible to improve the efficiency of the work for user by providing convenience of reuse, to provide an opportunity of new value creation for sponsor by interpretation of data.

Function

Project

Training

Notification

EDC	Screen	Data
Summary	Checking To Do Lists, current status	
CRF Setup	- CRF Design - Set up dynamic functions	- Database Design - Annotated CRF
DVS		- Missing check - Logical check
CRF	Data Entry / Signature / Source Data Verification / Lock	
Query	- Checking Query Lists - Query resolution	- Query upload
SAE	SAE Reporting / SAE Lists / Alarm	
Board	Notice / Resources	
External Data	- Central lab - Local lab	- External data upload - Set up Lab Normal Range
Monitor & Report	Monitor / Report / List	
Data List	- Data inquiry based on CRF field - Query issuing	- Data inquiry based on data variable - Query issuing

Composition

Design
- CRF Setup
- DVS
- External Data

Implementation
- CRF
- Query
- SAE

Management
- Board
- Monitor & Report
- Data List