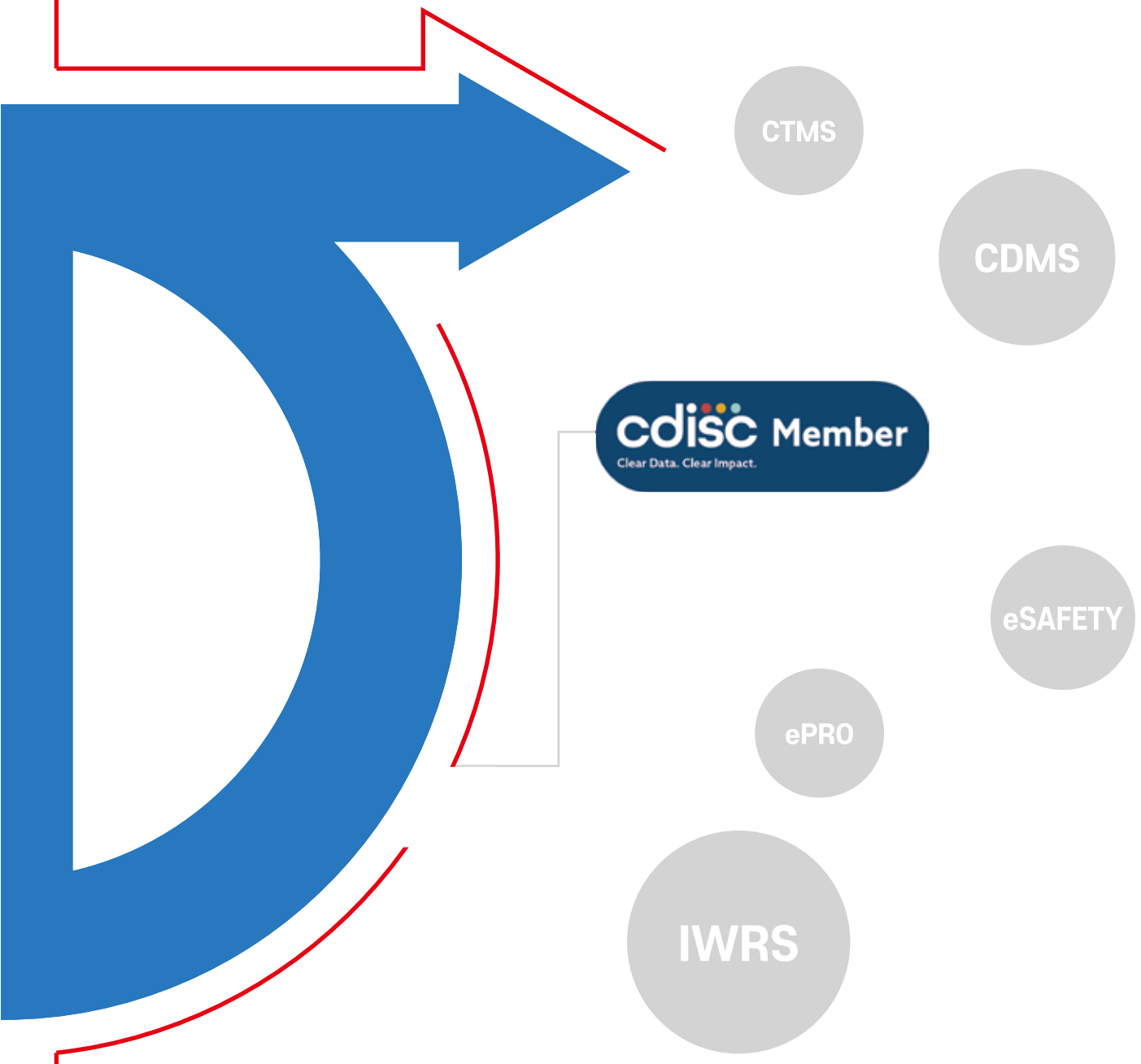
RedPine

Total Platform for Clinical Trials

(CDMS, CTMS, IWRS, ePRO, eSAFETY ...)



SAFESOFT

www.safesoft.co.kr

RedPine

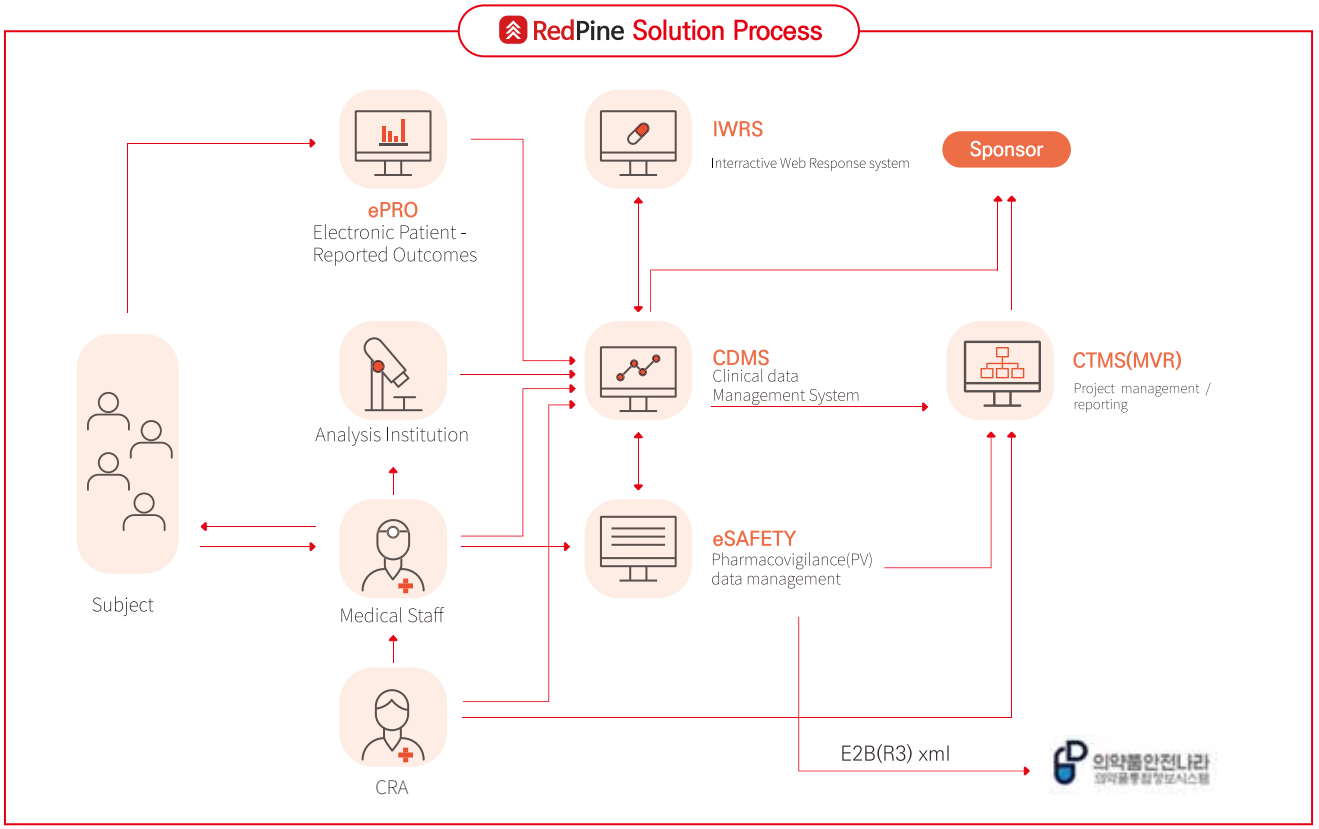
RedPine | Core of Clinical Trial Design and Data Management

CDMS / CTMS(MVR) / IWRS / eSAFETY / ePRO

· The core system of processing clinical trial data which is responsible for clinical trial protocols development, gathering data and reports of clinical trials. Accessing monitor of data and analysis result.

· **Replacing paper documents at a very rapid pace in clinical trials,** which is an essential solutions for **Digital Therapeutics(DTx) and Decentralized Clinical Trials(DCT)** studies.

· **Independent evaluation** capability enables clinical trials using images and videos, expanding the feature of CDMS.



Data Integrity

· Microsoft Cloud Azure Security Policy

· Microsoft Azure Backup

The World's **First** CDISC ODM Certified For Version 1.3.2

ODM PRODUCT CERTIFICATION

This is to certify that the ODM-capable product

Product: RedPine CDMS
Company: Safesoft
Product Version: 1.1.25
ODM Version: 1.3.2

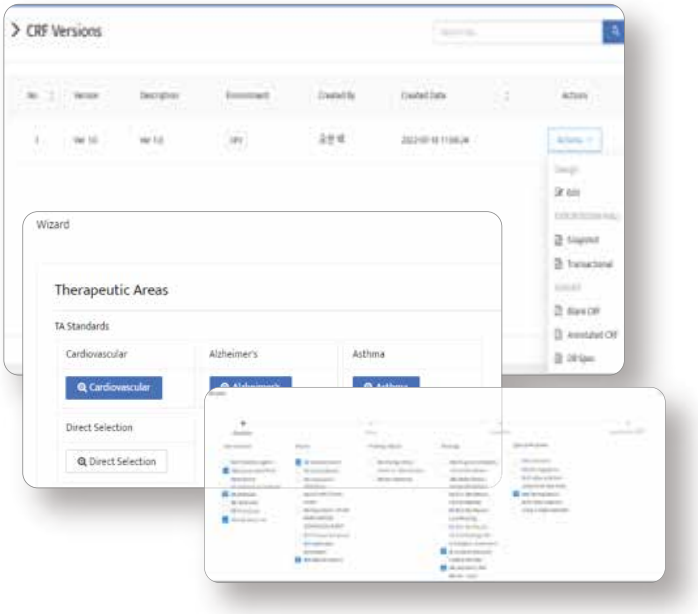
is able to process ODM files with a high level of conformity to the published specifications for the following use cases:

Metadata Export	✓
Metadata Import	✓
Metadata Interoperability	
Snapshot Data Export	✓
Snapshot Data Import	✓
Transactional Data Export	✓
Transactional Data Import	✓

6 November 2023

This certificate is valid for one year.

cdisc

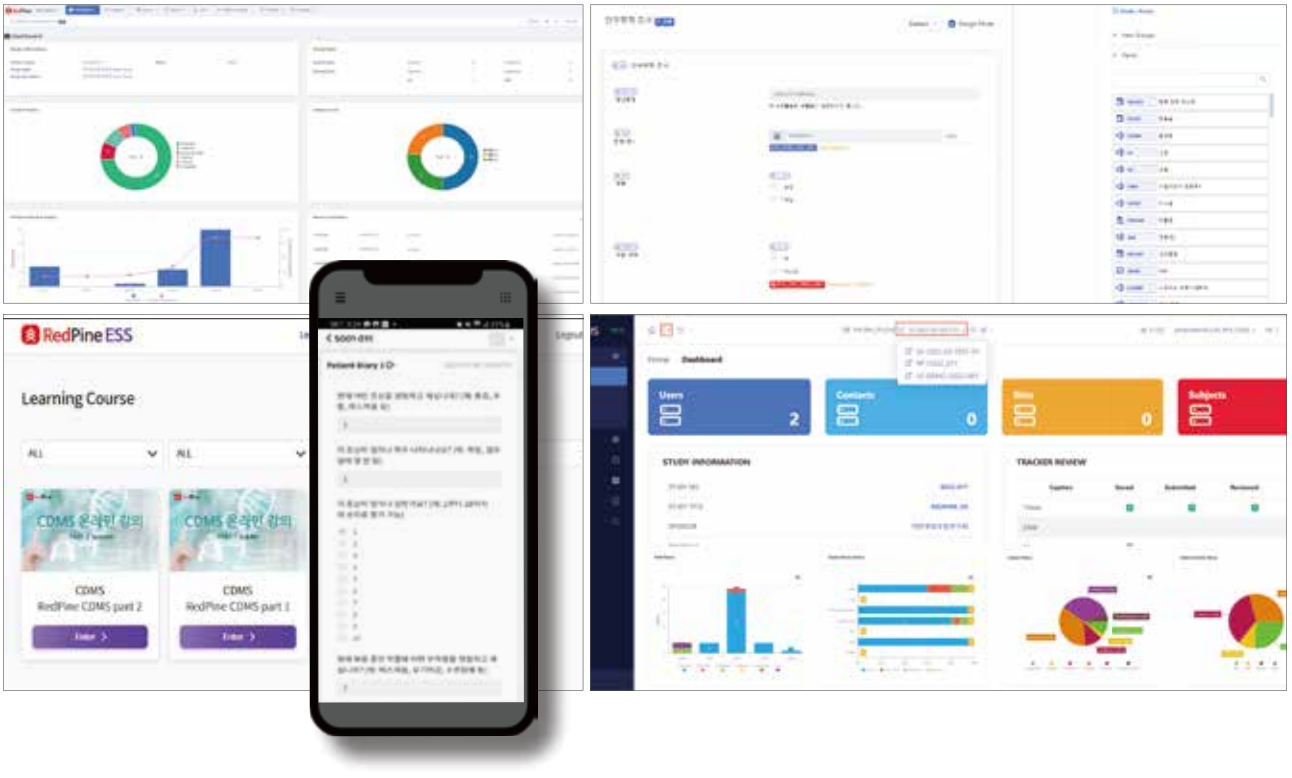


Standards and Compartibility

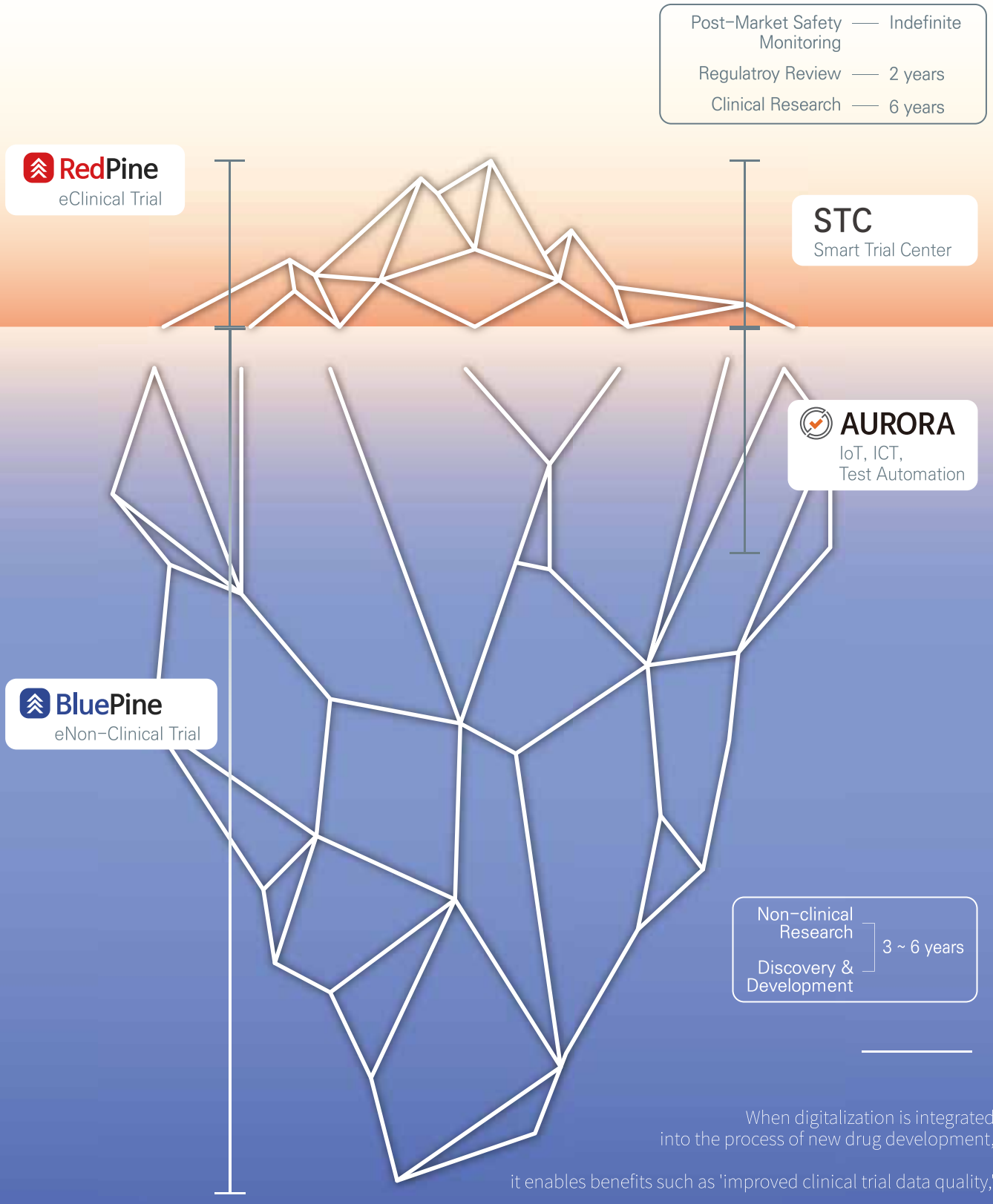
- Support for importing and exporting metadata as CDISC ODM (Operational Data Model) xml files
- Support for CDISC Library functionality (Therapeutic Areas Library).

Convenience

- Enable user-centric UI/UX implementation and convenience with the latest IT technology.
- Responsive program provides optimized usability across various devices, enabling convenient participation in clinical trials with **ePRO** solution.



Innovative new drug development is like an iceberg, appearing small on the surface but hiding a tremendous mass beneath the water. Similarly, in clinical trials, the journey begins with the exploration of candidate compounds, followed by non-clinical studies (animal /cell) and clinical trials (phases 1-3), leading to the regulatory approval for market sales. The success probability of this process is estimated to be around one out of 5,000 to 10,000.



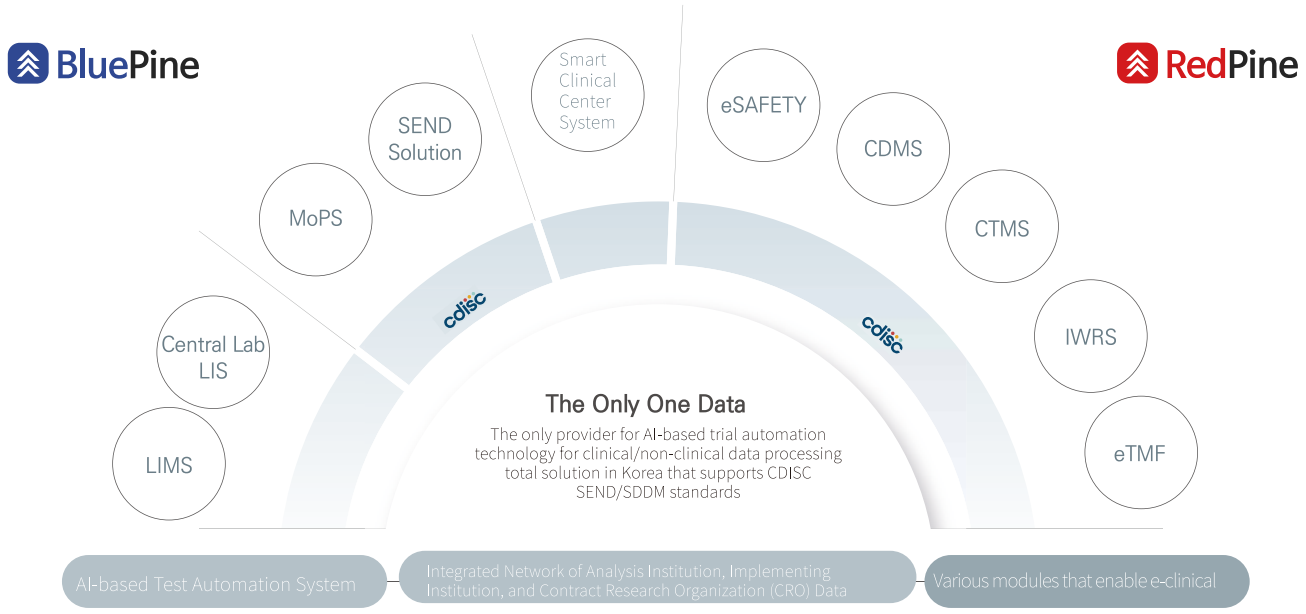
When digitalization is integrated
into the process of new drug development,

it enables benefits such as 'improved clinical trial data quality,'

'reduced duration of clinical trials,' and 'cost-effective'

Safesoft provides all the eClinical Trial Solutions supporting
Time-saving new drug development process

Company introduction



Safesoft is a clinical trial IT company that provides eClinical Trial Solutions encompassing the entire field of clinical trials, from non-clinical to pharmaceuticals/medical devices. Our solutions are built and serviced in accordance with CDISC standards . We have ISO certification in data quality and information security, ensuring impeccable data integrity. We strive to lead the new paradigm of clinical trials.

Through our eClinical Trial Solution, we have implemented AI, IoT, ICT, Blockchain, and Digital Transformation to achieve business automation , enabling synchronized data management between respective measurement devices and systems. This improvement applies not only to the emerging fields of Digital Therapeutics (DTx) and Decentralized (DCT) clinical trials, which have recently gained prominence, but also to the entire spectrum of clinical trials.

Quality Assessment

All quality systems at Safesoft are managed by certified professionals who hold qualifications from the International Software Testing Qualifications Board (ISTQB) and ISO 9001:2015 Lead Auditor Certification

SAFESOFT Guideline

- Compliance with ISO 27001:2013 Information Security Management Systems (ISMS)
- Compliance with ISO 9001:2015 Quality Management Systems (performing quality assurance activities through SOPs)

Local Guideline

- Guideline for the Electronic Clinical Trial Data Management and Processing (MFDS)
- Good Laboratory Practice (MFDS)

International Guideline

- We perform inspection activities through our SOP in accordance with 21 CFR Part 11 (US FDA), Electronic Records, and Electronic Signatures.

Corporate Identity

The only providor for IT solutions covering all areas of Non-Clinical/Clinical Trials in Korea.

Safesoft possesses and provides the only eClinical trial solutions in Korea that offers coverage across all areas, from analysis to Phase 3 clinical trials.

We possess a conversion tool that fully supports the Standard for Exchange of Nonclinical Data (SEND), which is the standard dataset for nonclinical data submission to the US FDA, making us the only provider in Korea with this capability.

BluePine

Non-clinical Trial Data Management Solution

- An integrated management system for analysis, nonclinical, and clinical trial implementing institutions, consisting of SEND-LIMS, MoPS, HSMS, eSOP-LMS, and more.
- STC (eCTS) system implementing Decentralized Clinical Trials (DCT)

RedPine

Clinical Trial Data Management Solution

- A comprehensive clinical trial data management solution comprised of CDMS, CTMS (MVR), IWRS, eSAFETY, ePRO, and more.

AURORA

RPA Testing Artificial Intelligence Solution

- Bulk control of all environments, providing a fully automatic unmanned environment
- An artificial intelligence solution to analyze and evaluate assessment results.
- Specialized in testing, development, and quality assessment stages.

STC

New Paradigm of Clinical Trials

- Smart Trial Center (SCT) System
- Realization of Decentralized Clinical Trials and Virtual Clinical Trials

Dt&C Bio Group

Dt&C Bio Group leverages its expertise in IT to develop a real-time system that allows for real-time explanation of clinical progress. As the first domestic CRO to disclose and provide visibility into the entire process of trials, we have established a differentiated business strategy. Based on this strategy, we offer comprehensive bio one-stop technical services for all stages of clinical trials.

Dt&CRO KOSDAQ 코스닥상장법인

Dt&CRO provides non-clinical GLP toxicity tests, PK tests, efficacy analysis, clinical trial and licensing consulting required for licensing pharmaceuticals, chemicals, health functional foods, cosmetics and medical devices.

Dt&SanoMedics

Dt&C SanoMedics is a bio-pharmaceutical Contract Research Organization (CRO) providing clinical trial services of clinical trial Phase 1-3, PMS, PV, etc. The provided services are clinical trial consulting, pharmaceutical and medical device approvals, medical writing, clinical trial monitoring, data management, statistical analysis, and quality assurance throughout the entire process of clinical trials.

Huscience

HuScience provides a new paradigm for clinical trials through its "Central Lab" for clinical trial specimen analysis and "Smart Trial Center" utilizing ICT (Information and Communication Technology).

Subsidiary

Dt&C KOSDAQ

Electrical and Electronic Testing and Certification
EMC, RF/SAR, Reliability, Failure Analysis,
IoT, and Interface Certification

Dt&C VINA

Testing, certification, and inspection in Vietnam
EMC, Safety, and testing services for home appliances,
LED lighting, and more.

LAB-T

Testing and certification in the railway and ICT sectors

EMC, RF/SAR, Safety etc

DCJ

Software evaluation, automated field testing in Japan
Software testing/evaluation and verification, field EMC

Dt&Investment

Venture capital investment specialist company
Start-up, Korean venture, and agriculture, forestry, and fisheries investment association formation and operational support, overseas investment, and consulting business

SAFESOFT
Location | 9F, UI Building 4-11, Yanhyeon-ro 405beon-gil, Jungwon-gu,Seongnam-si,Gyeonggi-do, Republic of KOREA
E-mail | safesoft@safesoft.co.kr

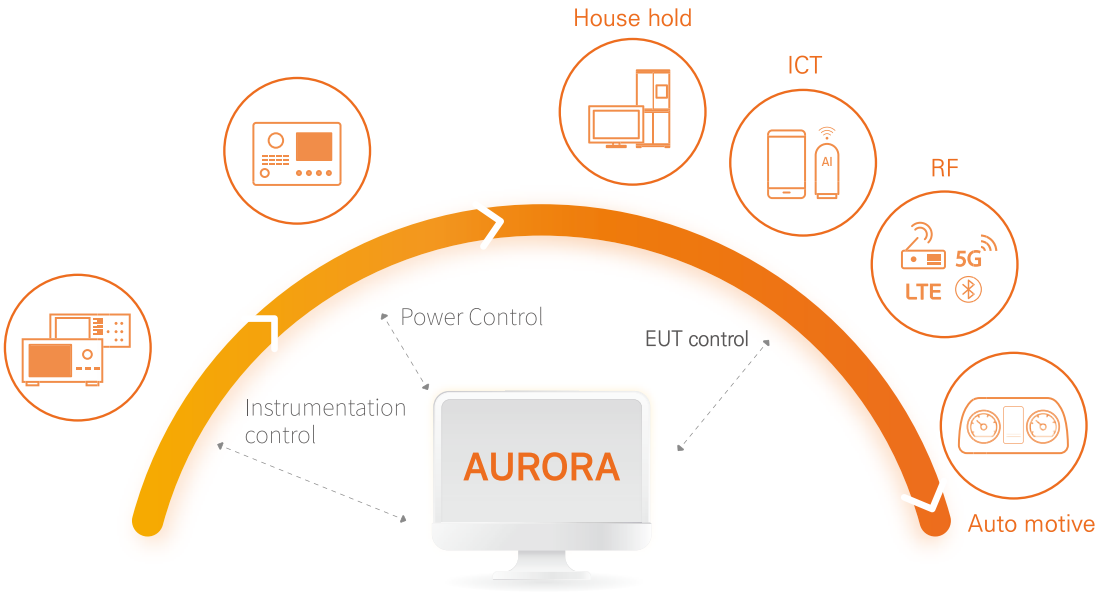
AURORA

AURORA I Unrivaled RPA Solution in the Smart Lab Field

Smart Lab Control Center - Aurora

Smart Lab Control Center provides an intelligent testing environment solution called AURORA,
which applies information and communication technology to the testing process.
It enables centralized control of all equipment and target devices (EUT),
offering an automated verification environment in both development and production lines.

AURORA based on the Smart Lab Diagram



Full automatic test / Script Test / Fail Recording / Auto Re-do function

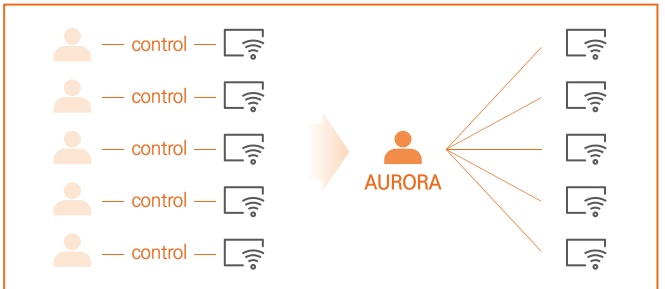
24-hour unmanned automated testing + Pass/Fail by AI-based automatic judgemt

The test recording feature allows issues encountered during testing to be reviewed through recorded videos

An astounding change in the environment

- Centralized control of all equipment
- 24/7 unmanned automated operation
- Android & Windows OS
- EUT mode control
- Re-do test / Ensuring reproducibility
- AI-based automatic judgment

A revolutionary transformation of the testing environment



AURORA smart lab Effect

- Over 40% efficiency increase
- Reduced product development time
- Providing clear testing quality standards
- Improved product quality through process implementation

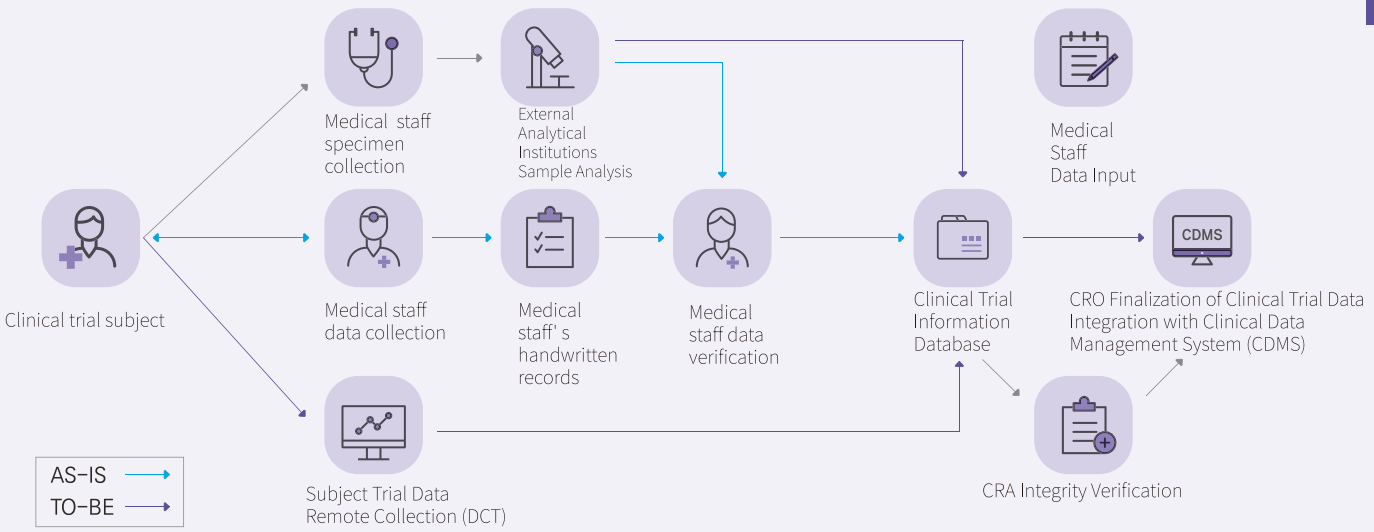
STC

STC I RedPine + eCTS + HSMS : Automation of clinical trials

Smart Trial Center System(STC : Smart Trial Center)

The entire process of clinical trials is transformed by utilizing a fully digital system that enables location tracking, electronic consent, individual identification, digital diagnostic equipment, and the movement and collection of sample analysis data, ensuring impeccable data integrity and significantly reducing the duration of clinical trials. It supports proactive autonomous **clinical trials, remote clinical trials, and decentralized clinical trials (DCT).**

Changes in Clinical Trial Data and Workflow Due to the Installation of STC Platform



Accuracy improvement | Time reduction | Cost savings

Data Integrity

- Attributable| It is possible to verify who and what device was used during all time using STC.
- Legible| The results from the STC are accessible to authorized individuals within e-CTS and CDMS.
- Contemporaneous| The results from the STC are automatically recorded and stored in real time.
- Original| The results from the STC are electronically recorded, with the first capture serving as the substantiating document
- Accurate| The entire process from evidence generation to record keeping is automatically saved, a nd any modifications or deletions can be tracked through audit trail.

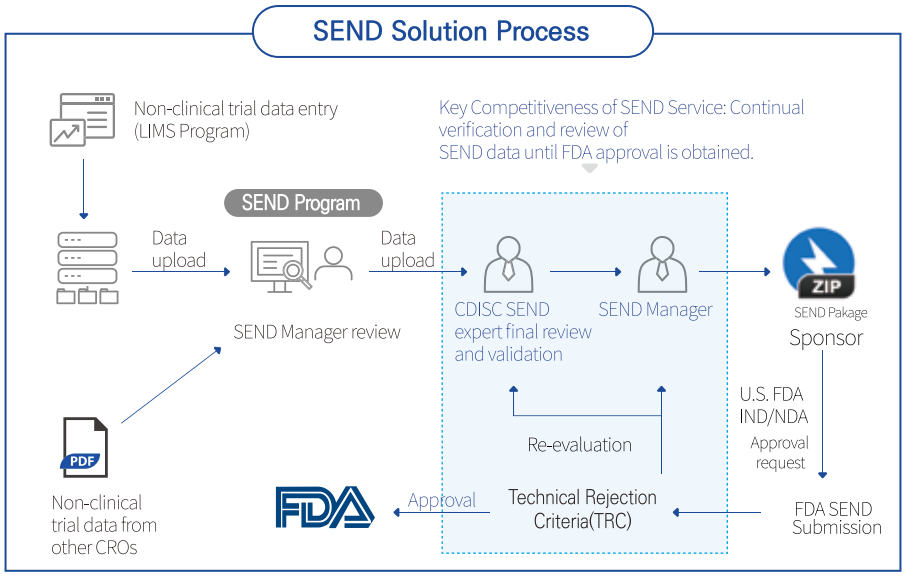
BluePine

BluePine | Non-clinical, specimen analysis data management solution

SEND-LIMS / MoPS / HSMS

The solution brand BluePine for non-clinical specimen analysis institutions is composed of the FDA eSubmission data solution, SEND(Standard Exchange of Nonclinical Data)solution, the trial schedule sharing solution, MoPS, the specimen analysis data processing solution, HSMS, and the eSOP-LMS capable of transitioning to a comprehensive Online SOP system

In particular, SEND solution is the only domestic automatic conversion solution that fully supports the **SEND Dataset, which is a mandatory requirement for non-clinical trial standard data, as required by the FDA.**



Unique SEND Solution

- Lifetime data storage within LIMS
- FDA submission SEND convertible on-demand
- Conversion of past legacy and other CRO data availabe
- Virtual non-clinical design services offered after data accumulation

BluePine Send Solution

- The only domestic developed proprietary solution
- The only commercial solution
- Continuous expansion of FDA application areas
- Strong competitiveness compared to foreign solutions

MoPS

HSMS

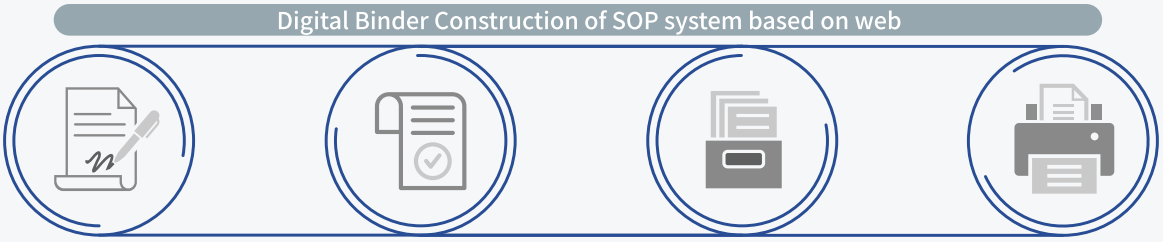
BluePine

eSOP / LMS

BluePine eSOP / LMS is system **that centralizes and integrates Standard Operating Procedures** managed within the organization, enabling conversion to a complete online SOP system, and **efficiently manages internal and external education and training activities** through the LMS function.

BluePine eSOP Solution

- Check and use relevant SOP/RD before project initiation
- Remote In-house SOP Training, Remote Audit
- Use of an electronic system to manage history such as SOP deviation and waiver, etc.

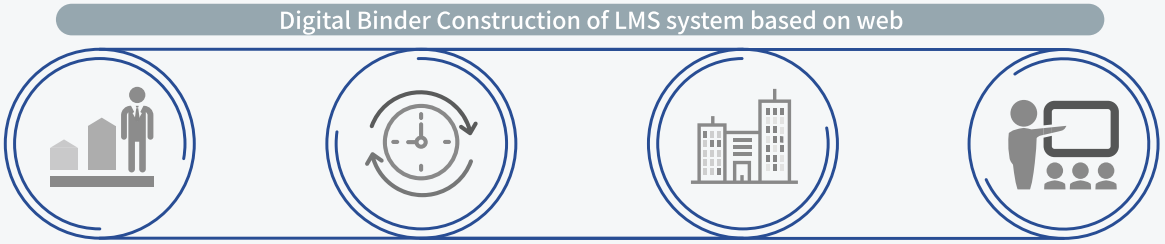


Improve inconvenience of writing and management for the existing Paper SOPs at once

SAFESOFT provider Electronic Standard Operating Procedure Development Service which corresponds to ICH-GCP and internal and external clinical trial guidelines. We improve the inconvenience of writing and managing of the existing Paper SOPs and increase the effectiveness of project performance and reduce the time of clinical trial.

BluePine eLMS Solution

- Anytime, Anywhere ! Get access to the desired training system
- Qualification assurance by Job description
- Training Record Review and CV management
- Database of CV for clinical experience Customized staff for each project



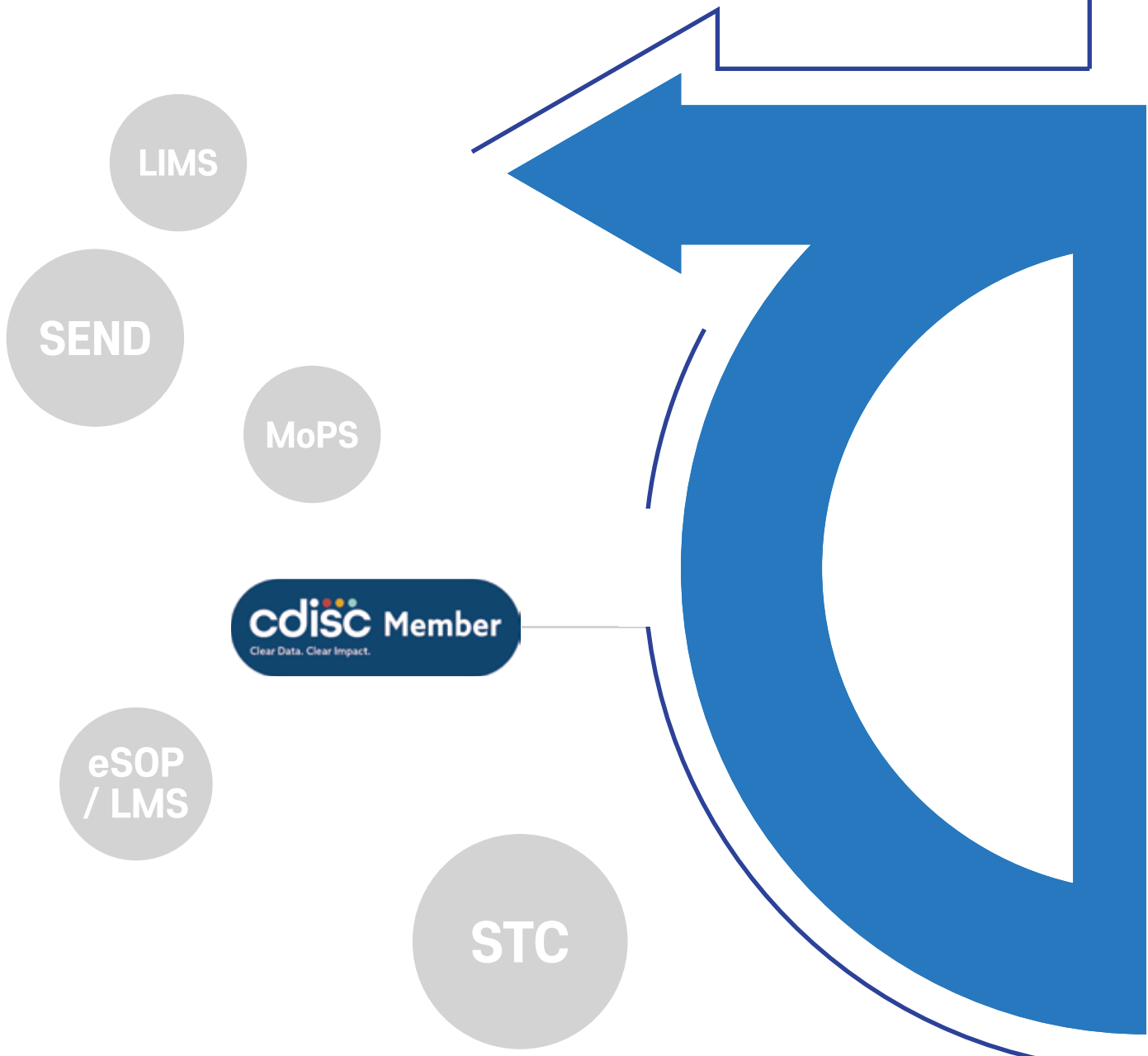
Improve training & seminar attendance for busy participants In the clinical trial industry

SAFESOFT developed an online training system for participants in the clinical trial industry who cannot physically participate in clinical trial training sessions and seminars. This system provides a variety of professional training opportunities to those who are interested in the field of clinical trials. Trainings can happen regardless of time and place to progress and LMS can improve personal capability of your employes

BluePine

Total Platform for Non-Clinical Trials

(CDISC SEND Dataset Transformation)



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