

Trial Informatics

Data-driven analytics with clinical insights



*We are a Data Science Company for
"Reinventing Clinical Trial Data with
Digital Health Technologies".*

CONTENTS

ABOUT US	3
ORGANIZATION & NETWORK	3
Trial DataHub PLATFORM	4
Solutions in Trial DataHub	5
ImageTrial™	6
OncoTrial Board™	8
SERVICES	10
OUR STRENGTHS	14
REQUEST & CONTACT	15

ABOUT US

Trial Informatics is a spin-off company from Asan Medical Center. In-depth data analytics and clinical expertise are our core offering.

“ We maximize the utility of trial data with digital health technologies and data-driven analytics ”

Dr. Kyung Won Kim, CEO



“ Incorporating clinical insights and data analytics is the cornerstone of excellent research We provide clinical value to your pipelines with multidisciplinary clinical experts ”

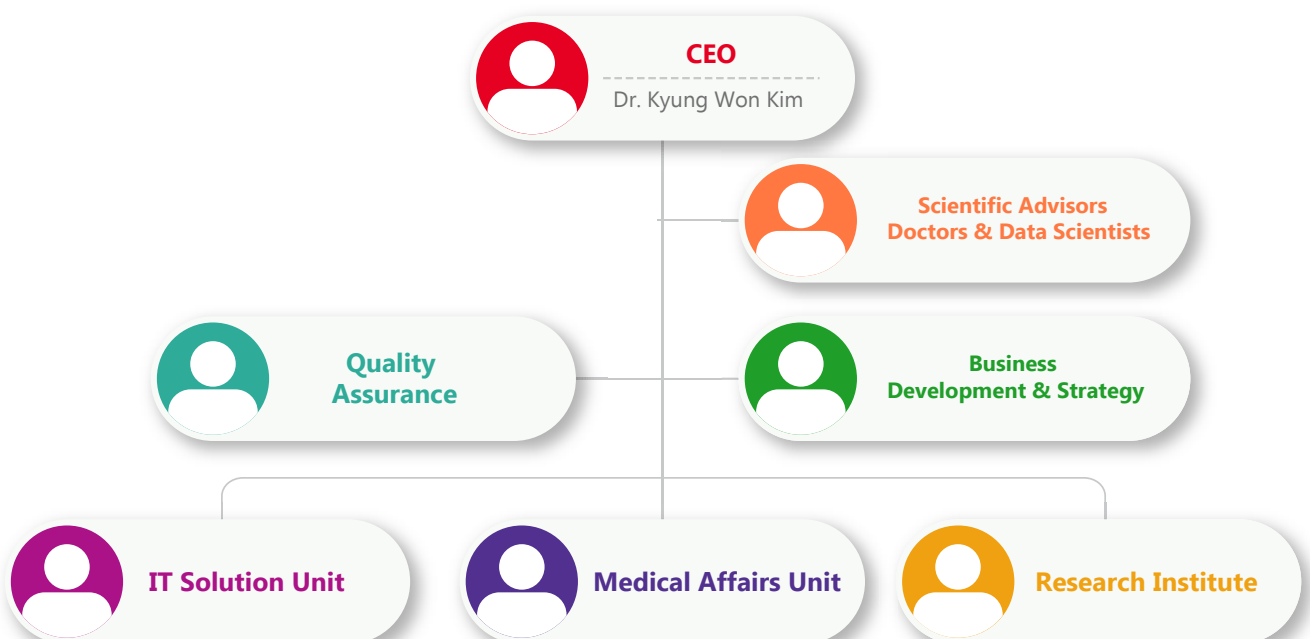
Dr. Bhumsuk Keam, Scientific Advisor

“ IT technologies empower high quality clinical trials We provide story health IT technologies for digital transformation of clinical trials ”

Jeongjin Lee, Ph.D. & M.B.A., Scientific Advisor

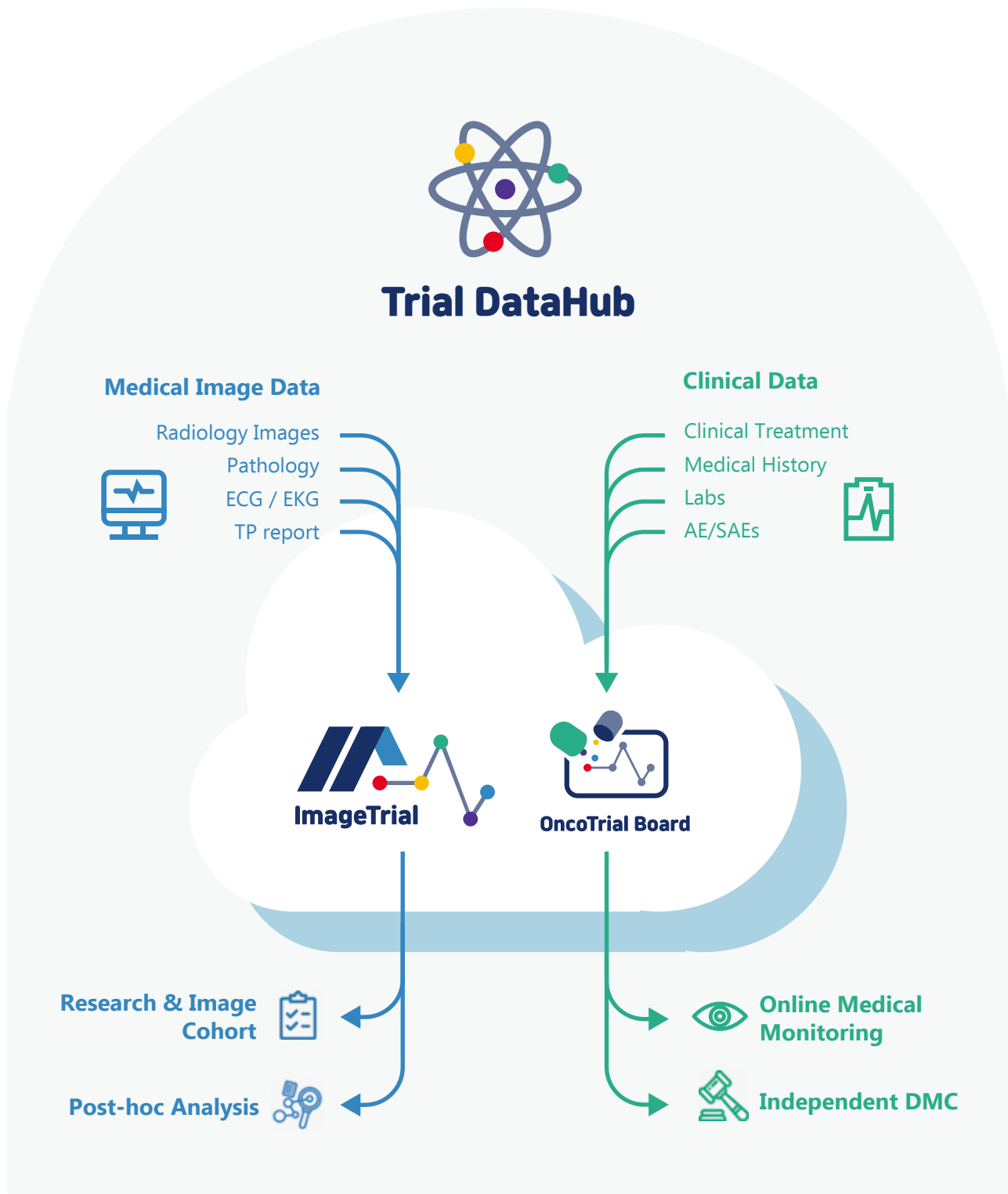


ORGANIZATION & NETWORK



Trial DataHub PLATFORM

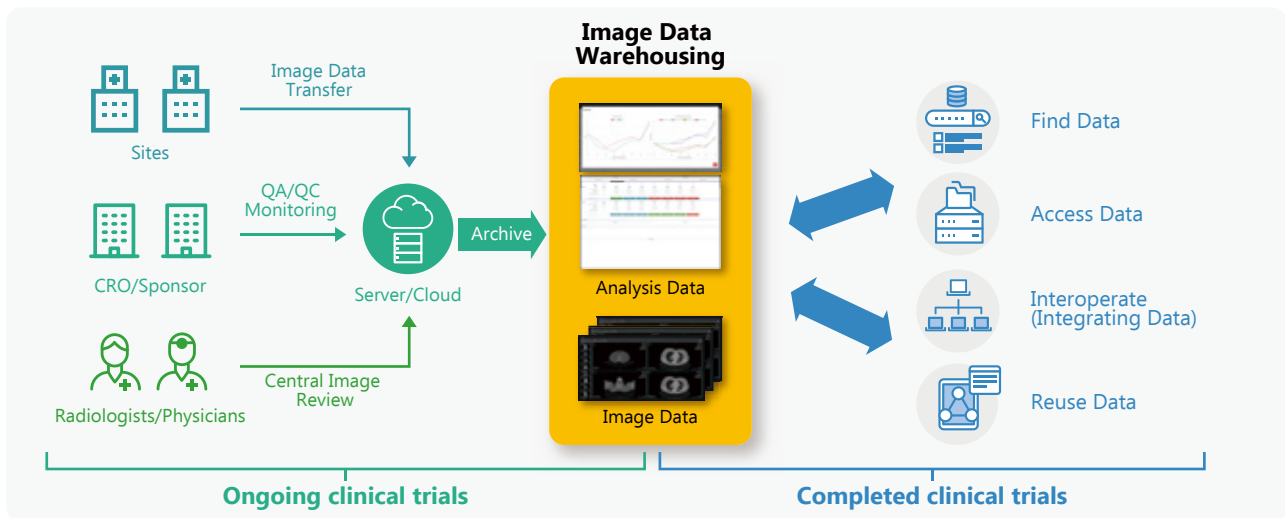
We empower clients with our platform for data-driven analytics and our extensive clinical experience and insights



Solutions in Trial DataHub

ImageTrial™

- Efficient image data management during clinical trial
- Data warehousing for accumulated data of completed trials



OncoTrial Board™

- Easy case review and medical monitoring during clinical trial
- Reutilizing accumulated data of completed trials



**End-to-end solution for digital data management
in both ongoing and completed trials**

ImageTrial™

Scope

- CloudPACS-based imaging platform for clinical trials
- Regulatory compliance: ICH, GCP, FDA, MFDS, etc
- Imaging data standardization: CDISC standards
- Post-trial data warehousing: archiving & utilize data



Functions

During clinical trial : from image data capture to reading

Image Upload



Web-Uploader
Anonymization
Automatic QC

Web-based image data transfer (No need to install program)
Automatic anonymization to ensure GCP compliance
Automatic image quality check (Predefined criteria & AI)


Image Archive



Archive
Audit trail
Security

Secure archiving of image data (SSL/TLS, triple backup, etc)
Audit trail (to track all steps of image workflow)
Data protection (Individual authorization setting, firewalls, etc)


Image View




Web & Mobile

View images through web-browsers (Chrome, Edge, etc)
Access any where any time (PC & Mobile)
Very fast and user-friendly

Image Reading



Structured Form
(RECIST, RANO, etc)



Customizable eCRF
CDISC format

Read the images through web-browsers by radiologists
Use structured forms (RECIST, RANO, LUGANO, etc)
Automatic conformity check to minimize human errors

After clinical trial : long-term archiving & data reutilization

Data Management

Automatic Source Data
Verification (SDV)

CDISC transformation

Search & Cohort


Semantic search
across trials

Generate new research
cohort

Image Analysis

Post-hoc analysis
Imaging biomarker
AI-based radiomics

Statistical Analysis



Exploratory
research

Real-time statistics
for image data

Main Features

WebPACS & Tele-radiology technology

- Access any time, any where, and any device
- No need to install any program & no need to worry about hospital firewalls
- Certified by MFDS medical device approval (Grade 2)



User friendly & CDISC-compliant reading form

- Standard eCRF forms for RECIST, RANO, LUGANO, etc
- CDISC-compliance: CDASH-based eCRF & automatic SDTM mapping
- Automatic conformity check: Reduce 90% of human errors
- Key images and graphs

		Date of PD				
		Reader1 2019-07-23	Reader2 2019-07-23			
TIMELINE		BL	TP1	TP2	TP3	TP4
Reader 1	#Time	2018-12-27	2019-03-04	2019-05-07	2019-06-05	2019-07-23
TL1 / LUNG, LEFT UPPER LOBE / CT SCAN		28.0mm (S.3, I.3)	24.0mm (S.3, I.3)	19.0mm (S.3, I.3)	22.0mm (S.3, I.3)	24.0mm (S.3, I.3)
Sum Measurement		28.00mm	24.00mm	19.00mm	22.00mm	24.00mm
BL / %Change_BL		BL	28.00mm / -14.29%	28.00mm / -32.14%	28.00mm / -21.43%	28.00mm / -14.29%
Nadir / %Change_Nadir		BL	24.00mm / 0.00%	19.00mm / 0.00%	19.00mm / 15.79%	19.00mm / 26.32%
Response(RECIST 1.1 / RECIST)		BL	SD / SD	PR / PR	PR / PR	PD / I/PD
Response(RECIST1.1 / RECIST)		BL	SD / SD	PR / PR	PR / PR	PD / I/PD
Reader 2	#Time	2018-12-27	2019-03-04	2019-05-07	2019-06-05	2019-07-23
TL1 / MEDIASTINUM / CT SCAN		27.0mm (S.3, I.3)	20.0mm (S.3, I.3)	18.0mm (S.2, I.3)	17.0mm (S.3, I.3)	21.0mm (S.2, I.3)
Sum Measurement		27.00mm	20.00mm	18.00mm	17.00mm	21.00mm
BL / %Change_BL		BL	27.00mm / -25.93%	27.00mm / -33.33%	27.00mm / -37.04%	27.00mm / -22.22%
Nadir / %Change_Nadir		BL	20.00mm / 0.00%	18.00mm / 0.00%	17.00mm / 0.00%	17.00mm / 23.53%
Response(RECIST 1.1 / RECIST)		BL	PR / PR	PR / PR	PR / PR	SD / SD
Response(RECIST1.1 / RECIST)		BL	PR / PR	PR / PR	PR / PR	SD / SD



OncoTrial Board™

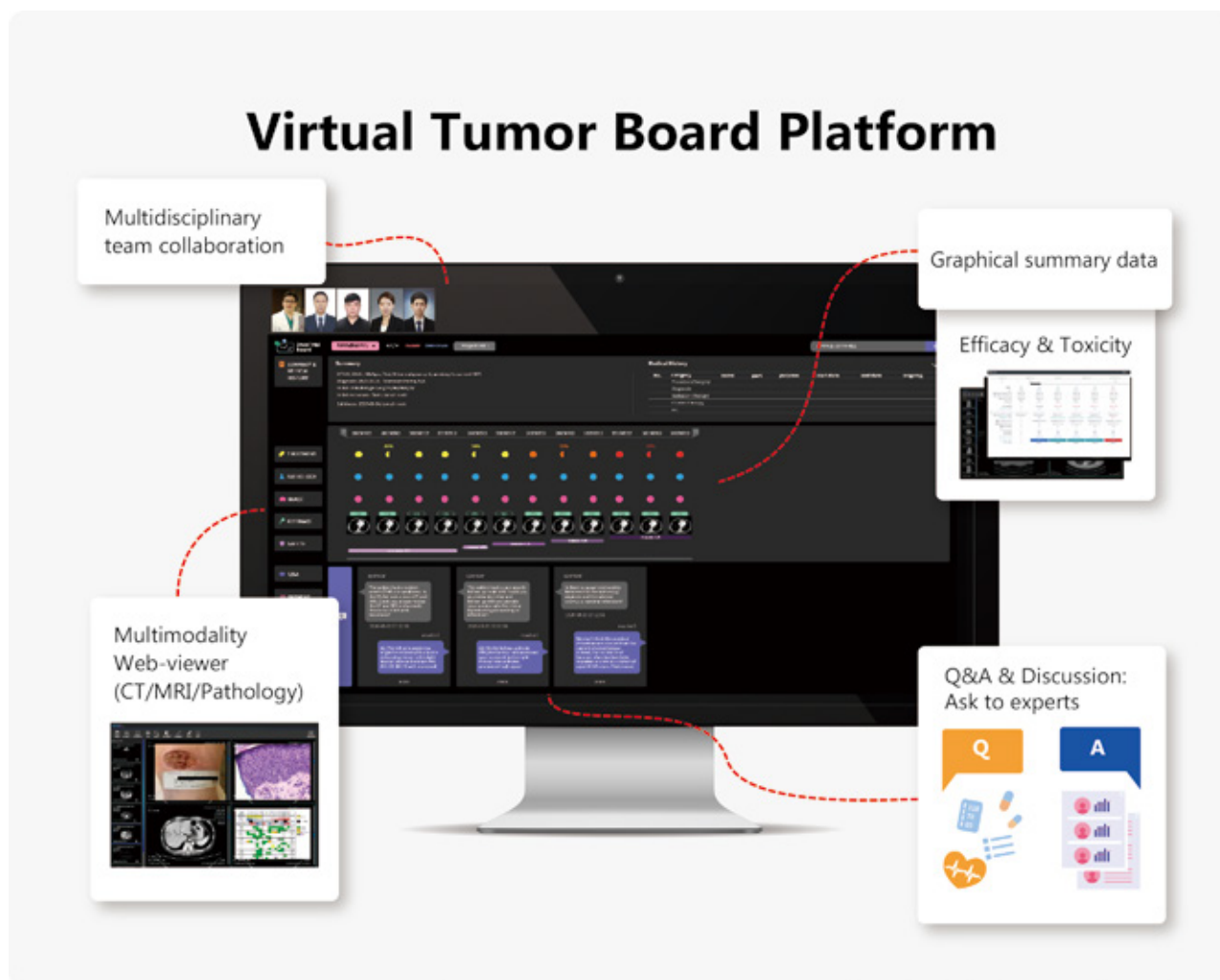
Scope

- A cloud-based platform for online medical monitoring and case discussion
- Graphical summary dashboard of cancer patients



OncoTrial Board

Functions

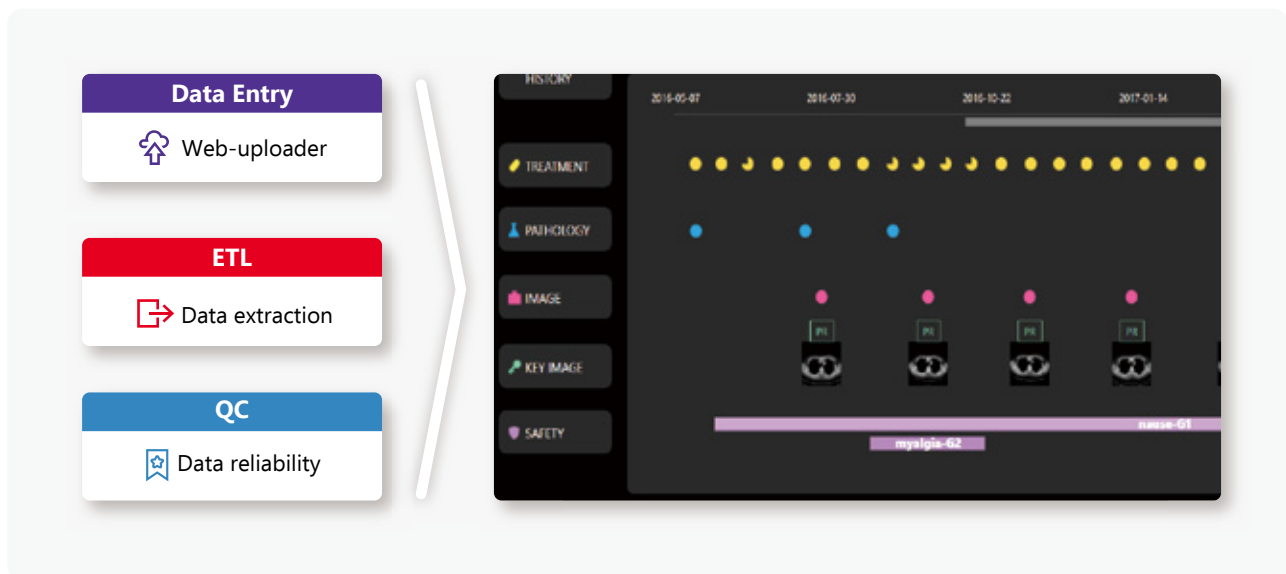


- Completely web-based solution: access any where, any time, and any device
- Collaboration among multidisciplinary experts: radiologists, oncologists, etc.
- Graphical summary of patient's history, treatment, adverse events, and treatment response in one dashboard
- Easily review the original image and pathology data through web-viewer
- Online real-time case discussion through online chat and tele-conference
- For completed clinical trials, Maximized reutilization of accumulated data for completed clinical trials

Main Features

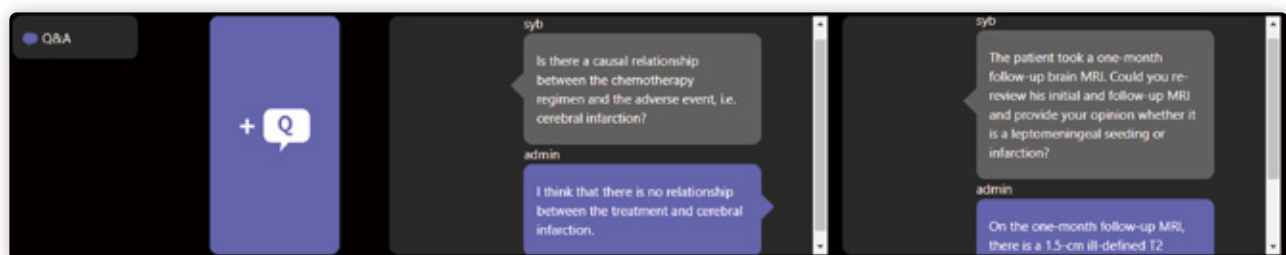
Process for graphical case summary

- External data entry: upload any types of clinical trial data with web-uploader
- Extract, transform, and load (ETL) function for automatic summary data generation
- Manual check process: data QC, data reconciliation
- Present summary data into the OncoTrial Board
- Access the summary data as well as raw data



Process for online multidisciplinary case discussion

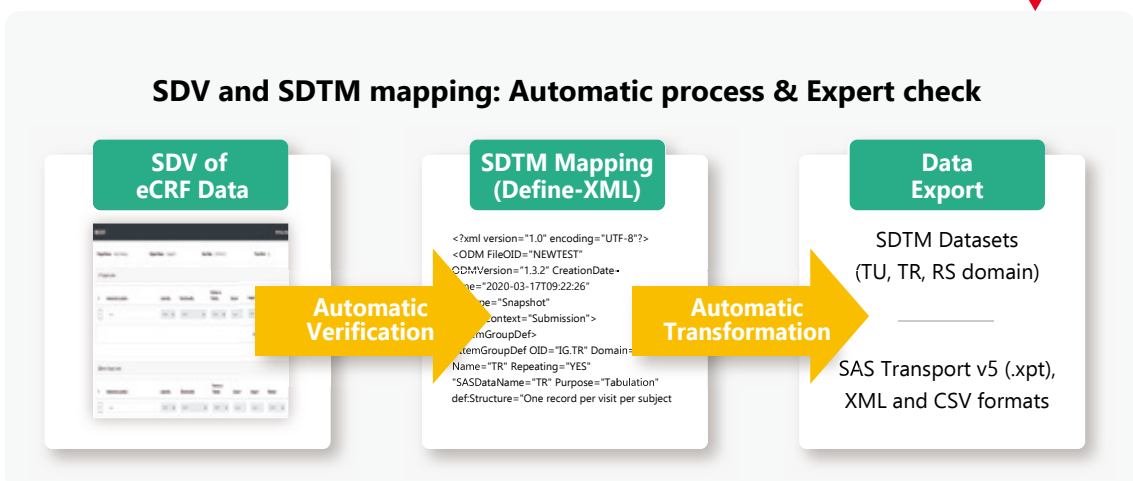
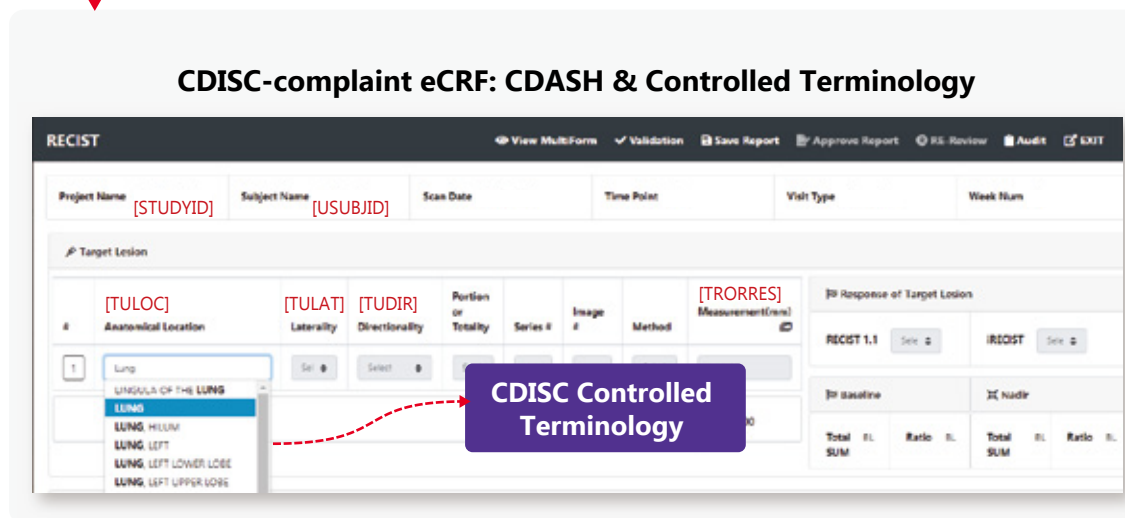
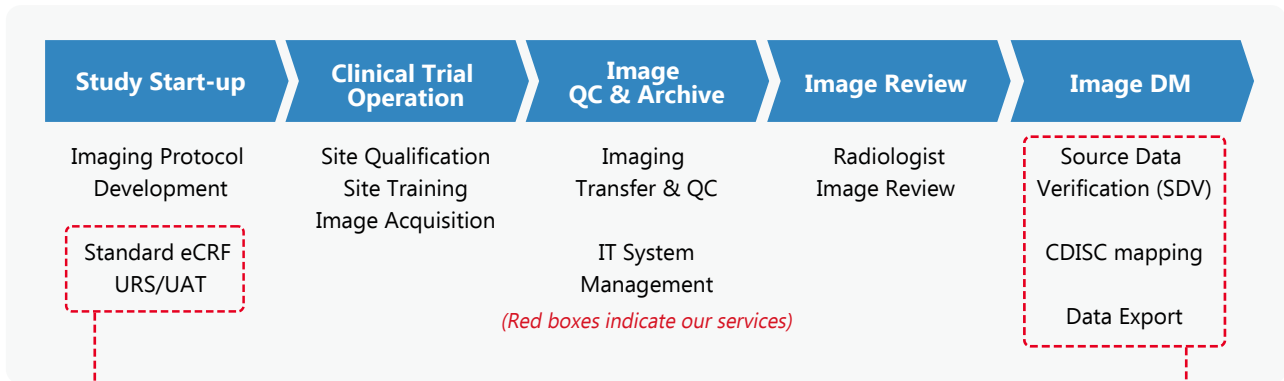
- Online chat mode
 - Sponsor or CROs can post questions and answers by users.
 - Answers can be issued with a report form
- Tele-meeting mode
 - Coordinate tele-meeting time and participants
 - Real-time discussion between sponsor/CROs and experts
 - Discussion can be issued with a report form



SERVICES

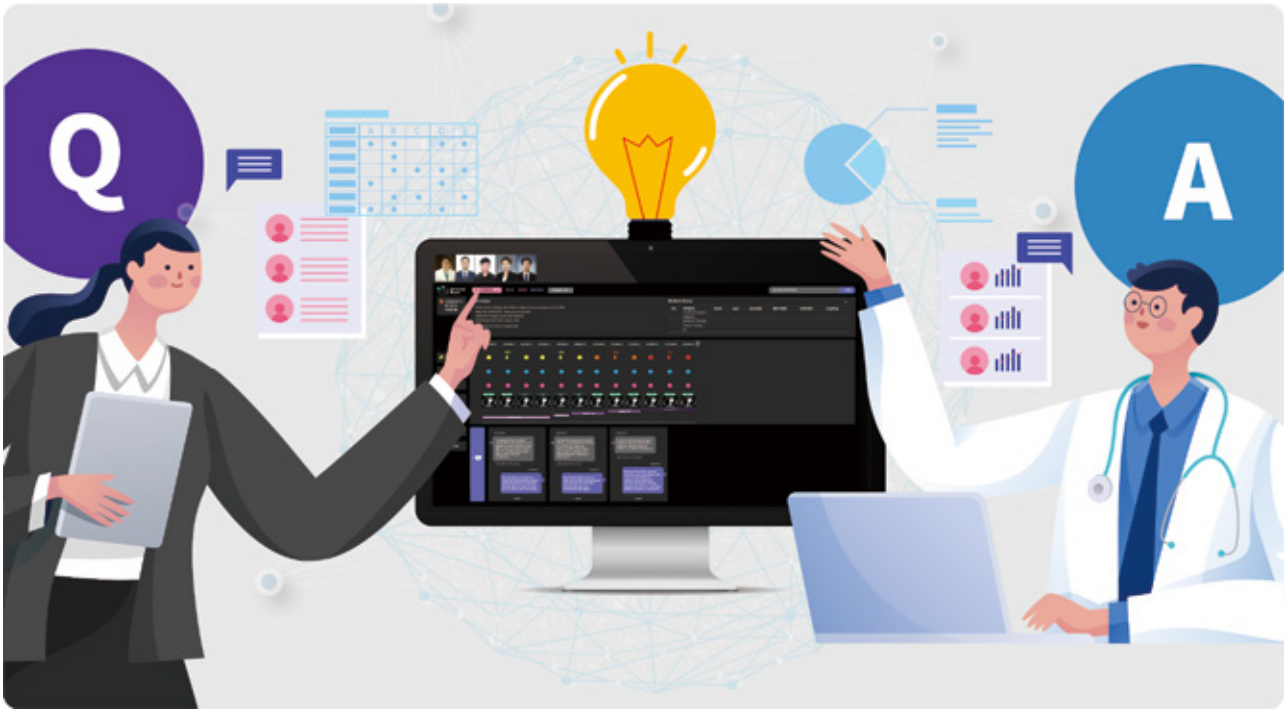
Imaging Data Management (DM)

- Using the ImageTrial™, we provide specialized expertise for imaging DM in the clinical trial process.
- Along with Asan Image Metrics (www.aim-aicro.com), we can provide the whole imaging processing in clinical trials.



Online Medical Monitoring & Consulting

- Using the OncoTrial Board™, we provide
 - Graphical summary of efficacy and toxicity data
 - Expert opinions: online Q&A, discussion, tele-meeting

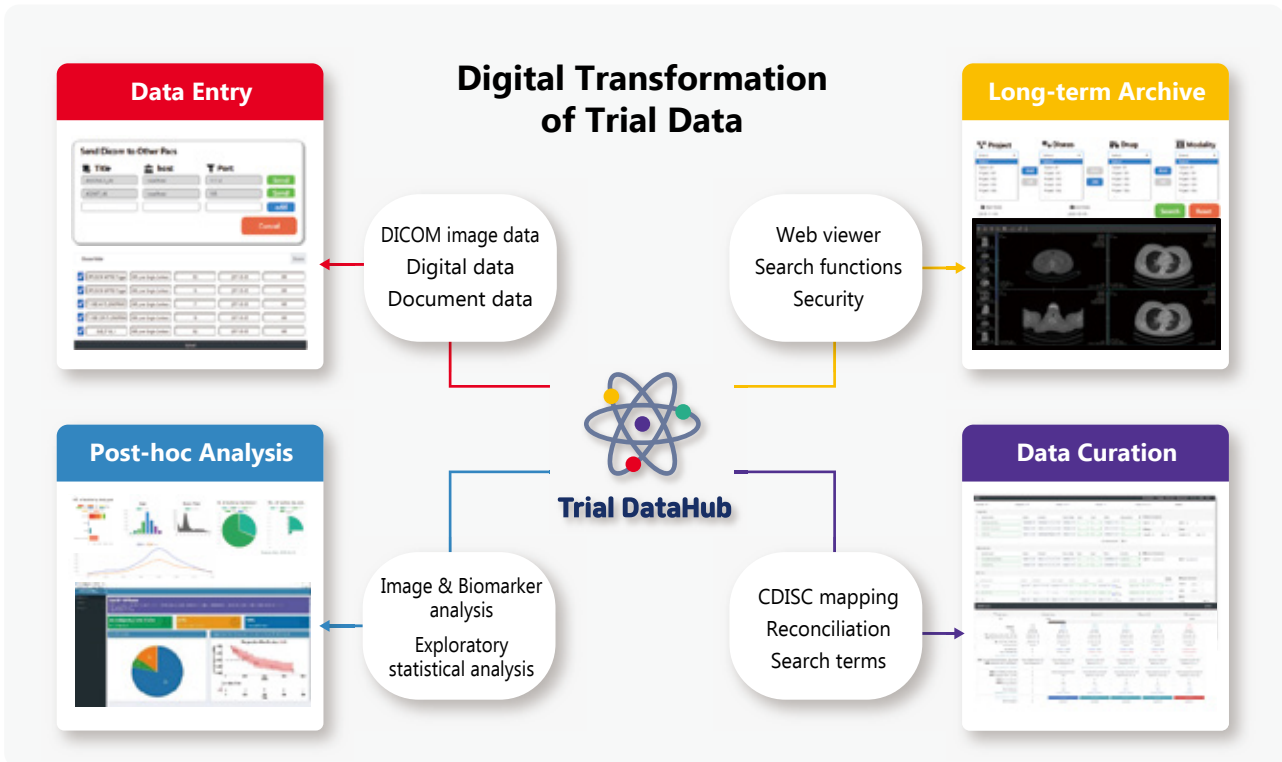


Independent Data Monitoring Committee (IDMC)

- IDMC service to ensure data integrity, scientific rigor and patient safety in clinical trials.
- We provide
 - IDMC member recruitment and management : doctors, data scientists, and statisticians
 - Protocol design or review
 - Data management and quality check for IDMC
 - Independent data review : safety and interim efficacy analyses
 - Secure data management using the Trial DataHub
 - Secure data transfer from all parties
 - Graphical case summary
 - Secure data sync and sharing with access rights

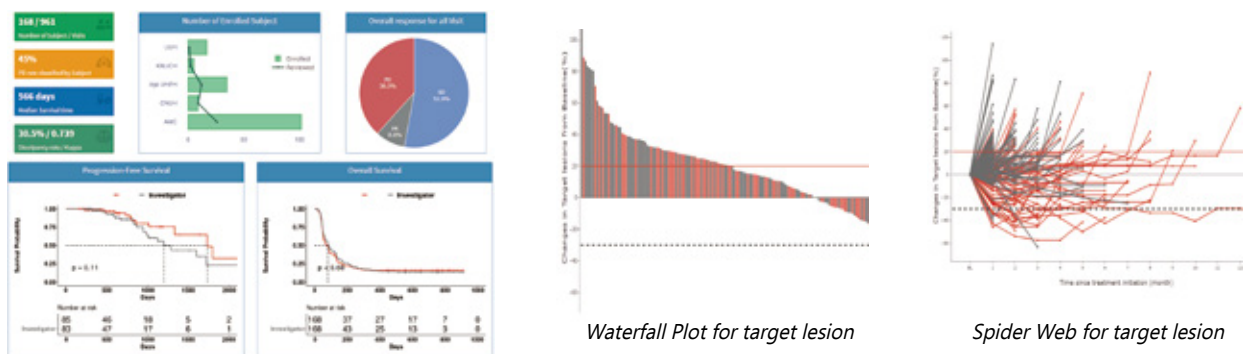
Clinical Trial Data Warehousing Service

- We implement Trial DataHub Platform for a pharma company either in the cloud or on-premise server.
- The main goals of Data Warehousing are as follows:
 - Long-term archiving clinical trial data
 - Organizing medical image, safety, and medical monitoring data efficiently
 - Access the data easily: any where, any time, and any device
 - Maximize reuse of accumulated data



Project Data Exploration Service

- Project overview & exploration of clinical trial data to find new information

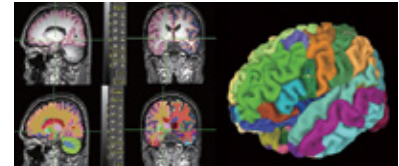


Medical Affairs for Clinical Trials

- Clinical development strategy consulting
 - Optimal clinical trial strategy based on target product profile
 - Indication, target diseases/patients, unmet medical needs
 - Designing key clinical trial protocol inputs
 - Clinical benefit-risk assessment
 - Competitiveness considering effectiveness, toxicity, dosing, etc.
 - Recommendation of CROs, key opinion leaders, and sites
- Data analysis: post-hoc analysis, exploratory statistical analysis
- Scientific publications
 - Research journal paper writing: drafting, critical revision, etc.
 - Conference abstract and scientific poster (ASCO, ESMO, etc.)
 - White papers for clinical value



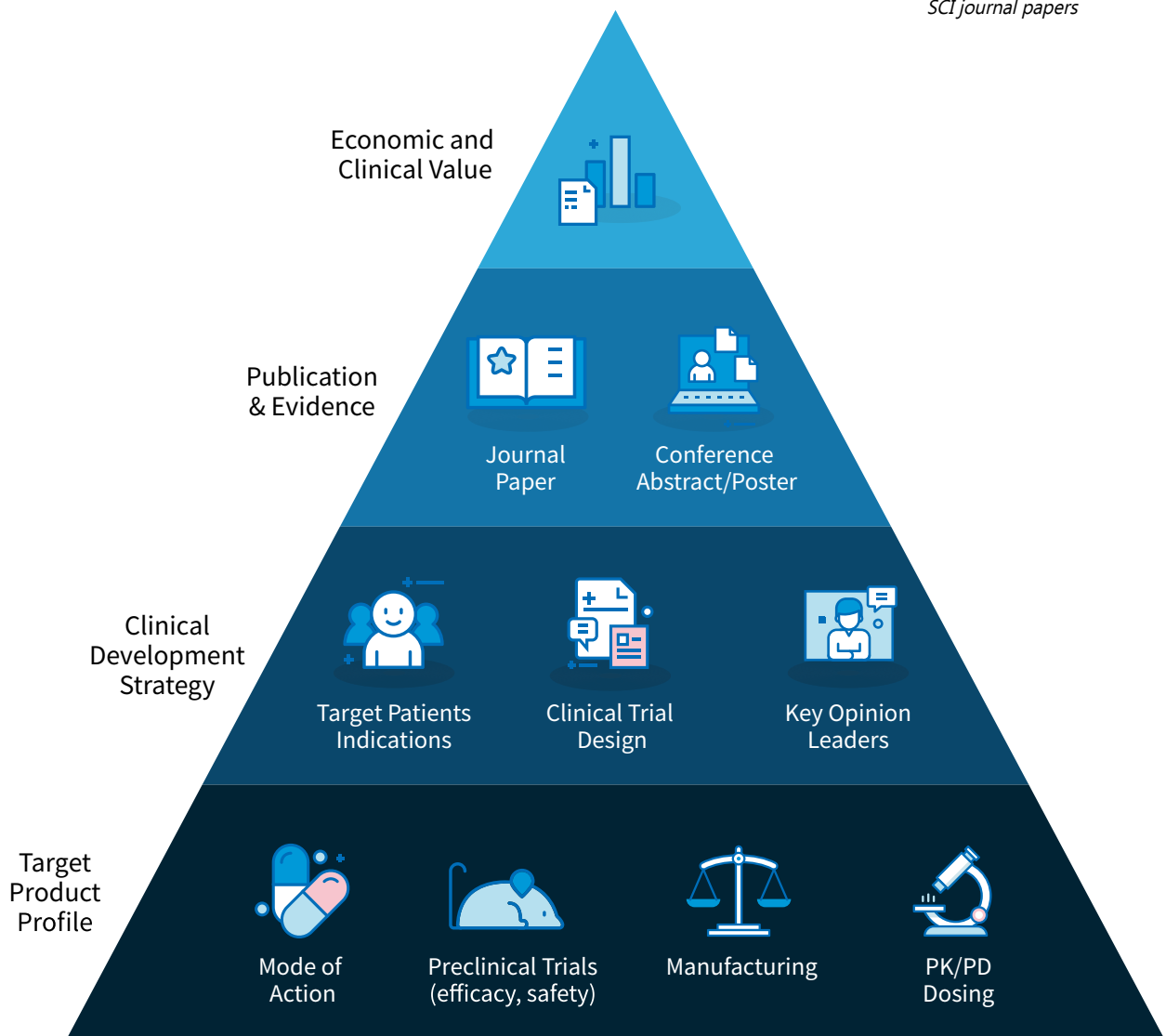
Medical Consulting



3D surface/volume mapping



SCI journal papers



OUR STRENGTHS

Scientific Expertise & Network

- Spin-off company from Asan Medical Center, grounded from:
 - Asan Image Research (<https://airres2020.wixsite.com/airres>)
 - Asan Image Metrics (www.aim-aicro.com)
- Collaboration with Deep Imaging Laboratory (www.gilab.co.kr)
- Related patents 13 , international publications > 100
- Top class engineers & data scientists



Youngbin Shin
Computer Science,
Ph.D.



Young Chul Cho
Biomed. Science,
Ph.D.



Yousun Ko
Convergence Science,
Ph.D.



Amy Junghyun Lee
Biomed. Science,
Ph.D. candidate



Mi-hyun Kim
Radiation Tech,
Ph.D. candidate



Jiwoo Lee
Solution Engineer

Highest Level of Medical Experts

- Top-class experts (radiologists, oncologists, pathologists) from:
 - Asan Medical Center, Seoul National University Hospital
 - Dana-Farber Cancer Institute, Harvard Medical School
- Collaboration with over 60+ the diverse clinical faculties from:
 - Other hospitals and research institutions



Dr. Kyung Won Kim
Radiology professor
Asan Medical Center
Publication 184
Patent 13

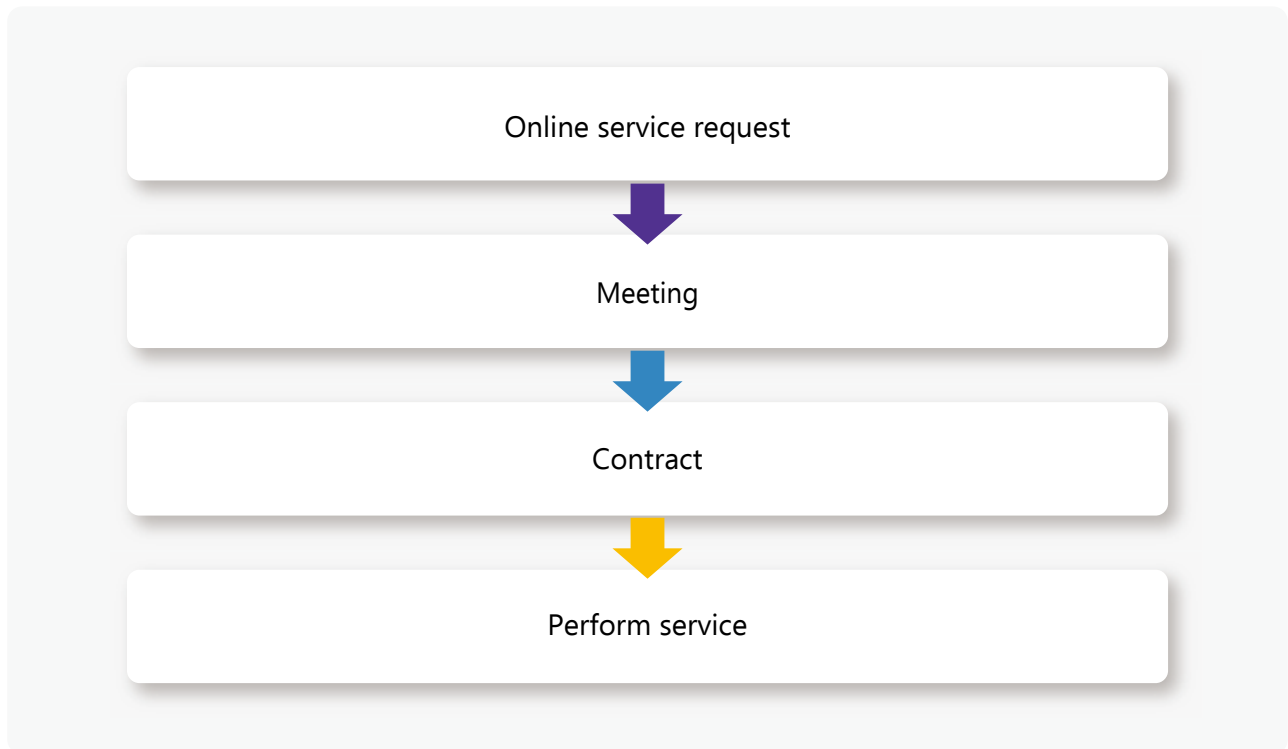


Dr. Bhumsuk Keam
Oncology professor
Seoul National
Univ. Hospital
Publication 200

Qualification

- Certified institution for global regulation compliance:
 - ISO 9001 certificate for Quality Management System
 - Good Software (GS) certificate (1st. level) from Korean government
 - Computer System Validation from CNR research
 - Multiple audits from CROs and pharmaceutical companies
- Quality Assurance System
 - We manage projects through regular project monitoring with QA Checklist.
 - We proceed projects based on precise SOPs and regulation.

REQUEST & CONTACT



www.trialinformatix.com

cs@trialinformatix.com





Trial Informatics



88, Olympic-ro 43-gil, Songpagu, Seoul
cs@trialinformatics.com
www.trialinformatics.com