Dt&CRO

GLP/GCLP Certified

One CRO. All Solutions.

From Lab to Life



Dt&CRO

www.dtncro.com

Your Full-Service **CRO**

From Non-Clinical to Clinical

Dt&CRO is a leading Korean **Full-Service CRO** providing fully integrated, end-to-end solutions throughout the entire development lifecycle.

Our services include Non-Clinical efficacy studies, GLP-compliant toxicology studies, Pharmacokinetics (PK), Bioequivalence (BE), Clinical trials, and Regulatory consulting to support the approval of Pharmaceuticals, Chemicals, Dietary Supplements, Cosmetics, and Medical Devices.

As Korea's only end-to-end research partner, we deliver tailored solutions and differentiated expertise to accelerate your path to successful development.

- Efficacy Studies
- Safety Studies
- Bioanalysis
- Bioequivalence
- Clinical Trials
- Central Lab



History

Building the **CRO of Tomorrow**

Driven by Innovation and Challenges

2025	Oct 2025	MOU Signed with IDD, Japan
	Mar 2025	Established the PK/PD Center
2024	Mar 2024	MOU Signed with Radyus Research, USA
	Dec 2023	MOU Signed with Clinix, Thailand
	Nov 2023	Clinical Trial Education Agreement with Korea University Medical Center
	Jun 2023	MOU Signed with AVANCE Clinical, Australia
	May 2023	Construction of the PK/PD Center Commenced
2023	Apr 2023	Relocation and Expansion of the Efficacy Evaluation Center
	Nov 2022	Listed on KOSDAQ
2022	May 2022	Launched the Smart Clinical Trial Center (STC)
	Jul 2021	Established the Efficacy Evaluation Center
	Apr 2021	First in Korea to Introduce the Triple Quad 7500 LC-MS/MS
2021	Jan 2021	Merged with EBO Co., Ltd., an Efficacy Evaluation Provider
	Aug 2020	Commenced GLP Toxicology Services for Veterinary Drugs
	May 2020	Commenced Non-Clinical SEND Services for U.S. FDA Submissions
	Mar 2020	Commenced GLP Testing Services for Medical Devices
2020	Jan 2020	Commenced GLP Testing Services for Chemicals and Agrochemicals
2019	Sep 2019	Commenced GLP Toxicology Services for Pharmaceuticals
	Oct 2018	Completed the Non-Clinical Research Center
	Jun 2018	Launched MoPS (Trial Quality Management Program)
	May 2018	Designated as a Corporate Affiliated Research Institute
	Mar 2018	Designated as a GLP-Certified Testing Institution
	Feb 2018	Launched Protein Characterization Services
2018	Jan 2018	Established the Bioanalysis Center for Biologics and Gene Therapy
2017	Apr 2017	Established Clinical Trial Services
		Established Dt&CRO



01 Efficacy Evaluation Center

02 Safety Evaluation Center

03 Analysis Center

04 Clinical Trial Operations Center

05 Central Lab

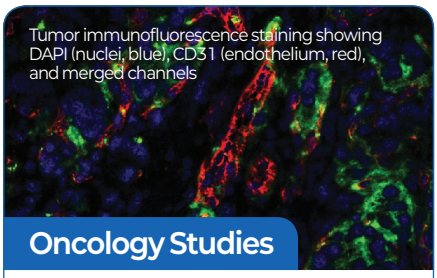
Dt&CRO



Efficacy Evaluation Center

Dt&CRO's Efficacy Evaluation Center delivers tailored Non-Clinical efficacy evaluation services for pharmaceuticals, nutraceuticals, and medical devices, leveraging a diverse range of disease-specific cell and animal models.

Specialized Study Areas



Oncology Studies

Xenograft, orthotopic, metastatic, syngeneic, and humanized mouse models



Ophthalmic Studies

Wet and dry age-related macular degeneration, dry eye, glaucoma, and related ocular disease models



Large Animal Studies (Beagle & Minipig)

Medical devices (RF, HIFU), osteoarthritis, implants, transplantation models, and more

Efficacy Evaluation for Nutraceuticals

- Evaluation services aligned with MFDS guidelines for health functional foods
- Evaluation studies supporting functional labeling for health functional foods
- Efficacy studies for natural products and functional ingredients
- Studies conducted using cell-based assays and disease animal models
- Consultation available for manuscript preparation and journal submission based on study results

Cosmetic Efficacy Evaluation

1. Cell-based efficacy studies for cosmetic ingredients
2. Cytotoxicity assessment (MTT Assay)
3. Studies for whitening, wrinkle improvement, skin elasticity, moisturization, and hair growth promotion

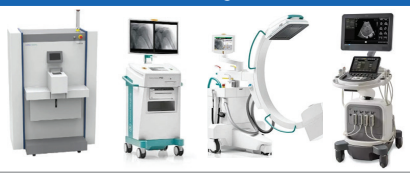
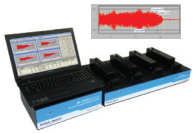
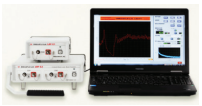
Efficacy Evaluation Test Items

Category	Indication	Study Model / Method
CNS & Behavioral Disorders	Cognitive Function, Memory	· Scopolamine-induced cognitive impairment and memory deficit model
	Parkinson's Disease	· 6-OHDA-induced model · α-Synuclein-induced model · MPTP-induced model
	Alzheimer's Disease	· Amyloid-β-induced Alzheimer's disease model
	Social Behavior Deficit	· Valproic acid-induced autism spectrum disorder model
	Attention Deficit	· SHR model
	Stress Relief, Relaxation	· Restraint and water-immersion stress model
	Sleep	· Caffeine-induced sleep disturbance model · Pentobarbital-induced sleep improvement model
	Pain	· Hot plate pain model
Ophthalmology	Retinal Disorders	· Laser-induced CNV wet AMD model · $NaIO_3$-induced dry AMD model · MNU-induced dry AMD model · STZ-induced diabetic retinopathy model
	Dry Eye	· Lacrimal gland excision model · BAC-induced dry eye model (Rabbit)
	Optic Nerve Disorders	· Dexamethasone-induced glaucoma model (Rabbit)
Oral & Dental	Periodontitis	· First molar ligation model
	Xerostomia	· Radiation-induced xerostomia model · 4-DAMP-induced xerostomia model
Respiratory	Allergic Rhinitis	· OVA-induced model
	Expectorant Activity	· Phenol red secretion assay
	Asthma	· OVA-induced model
	Chronic Obstructive pulmonary Disease (COPD)	· LPS-induced model · Elastase-induced model
	Pulmonary Fibrosis	· Bleomycin-induced model
Cardiovascular & Hematology	Hypertension	· SHR Rat model
	Thrombosis	· $FeCl_3$-induced thrombosis model · Platelet aggregation assay · Blood coagulation time assay
Hepatic	Hepatitis	· Acetaminophen-induced acute liver injury model · D-Galactosamine-induced acute hepatitis model
	Fatty Liver	· Alcohol diet-induced alcoholic fatty liver model · High-fat diet-induced non-alcoholic fatty liver model
	Non-Alcoholic Steatohepatitis (NASH)	· Choline-deficient diet model · Western diet model
	Liver Fibrosis	· Thioacetamide (TAA)-induced liver fibrosis model
Gastrointestinal (Stomach)	Gastritis	· Ethanol-induced gastritis model · Indomethacin-induced gastritis model · Restraint and water-immersion stress model
Gastrointestinal (Colon)	Constipation	· Loperamide-induced model
	Colitis	· DSS-induced model · DNBS-induced model
	Irritable Bowel Syndrome (IBS)	· Acetic acid-induced model · Loperamide plus restraint stress model
	Colon Cancer	· AOM/DSS-induced colon cancer model



Category	Indication	Study Model / Method
Prostate Health	Benign Prostatic Hyperplasia (BPH)	· Testosterone-induced model
Renal	Chronic Kidney Disease (CKD)	· Animal model using oral and dietary adenine administration
	Hyperuricemia, Gout	· Potassium oxonate-induced hyperuricemia model
Bone & Skeletal Health	Menopause, Osteoporosis	· Ovariectomized model
	Children's Growth	· Growth plate growth assessment
	Periodontal Disease	· Alveolar bone regeneration model (Beagle)
Endocrinology & Hormonal Health	Growth Hormone Evaluation	· Growth suppression model by hypophysectomy
	Sexual Maturation	· OECD TG 440, 441
Muscle & Soft Tissue	Sarcopenia	· Dexamethasone-induced model · Aged model
	Achilles Tendon Rupture	· Rabbit Achilles tendon injury model
	Rotator Cuff Tear	· Rat rotator cuff tear model
	Fatigue Improvement	· Antioxidant model for fatigue relief
	Muscle Regeneration	· Abdominal wall defect model
Joint & Cartilage	Osteoarthritis	· Intra-articular MIA-induced model
	Rheumatoid Arthritis	· Collagen-induced model
Metabolic Disorders	Obesity	· HFD-induced model · Ob/Ob mouse model
	Diabetes	· STZ-induced Type 1 diabetes model · STZ + HFD-induced Type 2 diabetes model · db/db mouse model
	Hypercholesterolemia	· HCD-induced model
Immunology & Inflammation	Immune Enhancement	· Cyclophosphamide-induced immunosuppression model
	Atopic Dermatitis	· DNCB-induced model · MC903-induced model · House dust mite-induced model
	Psoriasis	· IMQ-induced model
	Allergenicity	· Allergy induction assessment using Brown Norway rats
	Multiple Sclerosis	· MOG-induced experimental autoimmune encephalomyelitis (EAE) model
	Anti-Inflammatory Activity	· Carrageenan-induced paw edema model
Dermatology	Wound Healing	· Incision, burn, and pressure-injured skin models
	Wrinkle Improvement	· Photoaging model
Fatigue & Endurance	Fatigue Improvement	· Forced swimming and Treadmill analysis
Oncology	Xenograft & Syngeneic Model	· Tumor size measurement
	Orthotopic & Metastasis Model	· Tumor measurement using IVIS imaging system
Biodistribution & Excretion	Stem Cell, T Cell, Virus, Plasmid, Micro-organism	· Real-time PCR
Immunogenicity (ADA, nAb)	Screening	· In vivo antibody analysis using ELISA
	Confirmatory	
	Titration Assays	
PK, PD Biomarker Analysisof Bio-drugs		· ELISA, PCR, Flow cytometry
Medical Devices	Device Evaluation	· Large animal-based medical device evaluation · Dermal filler biodegradation assessment
Others	Hangover Relief	· Blood analysis after ethanol administration
	Topical Product Equivalence Test	
	Transgenic Mouse Breeding And Maintenance	· Animal breeding support using genotyping

Core Equipment of the Efficacy Evaluation Center

Equipment	Applications	Available Systems
Micro-CT **C-arm** **Ultrasonic device**	· Osteoarthritis · Bone growth · COPD · Periodontal disease · Medical device assessment · Osteoporosis · IPF · Emphysema	
X-ray (DEXA)	· Osteoporosis · Menopause · Obesity	
***In vivo* imaging system** (IVIS)	· *In vivo* tumor imaging (bioluminescence) - Allo- and xenograft tumor - Orthotopic tumor - Brain tumor - Tumor metastasis · *In vivo* tracking of target substances (fluorescence)	
Flow cytometry (FACS) **Cell separator**	· T cell subset analysis - CD4 : CD8 ratio · Cytokine analysis · Immune cell profiling - NK cells, dendritic cells (DC), macrophages, and other immune cells · Isolation of specific immune cell populations	 
Plethysmography **Pulmonary function tester**	· Rhinitis · Asthma · Emphysema · IPF · COPD	 
Blood pressure tester	· Hypertension-related disorders	
Blood flowmeter	· Vascular disorders - Blood circulation improvement - Thrombosis	
Retinal imaging microscope with laser ERG	· Dry Age-Related Macular Degeneration (Dry AMD) · Wet Age-Related Macular Degeneration (Wet AMD)	
Morris water maze **Passive avoidance, Elevated plus maze** **Treadmill** **Grip strength meter** **Open field** **Gait analysis** **Staircase test**	· Animal behavioral tests · Cognitive function and memory · Neuropsychiatric disorders · Parkinson's disease · Gait analysis · Motor function assessment	
PRIMOS^{CR}	· Wrinkle improvement · Dermal filler biodegradation evaluation	



Safety Evaluation Center

Dt&CRO provides GLP-compliant Non-Clinical safety studies to support the regulatory approval of pharmaceuticals, chemicals, dietary supplements, and medical devices, backed by extensive expertise in toxicology.

Safety Evaluation Study Areas

Safety Evaluation Studies

Test Materials:
Synthetic pharmaceuticals, biologics, plant-derived materials, chemical substances, ADCs, and combination products

- General toxicity
- Genotoxicity
- Carcinogenicity
- Immunotoxicity
- Reproductive and developmental toxicity
- Safety pharmacology
- TK/PK

Registration & Evaluation of Chemical Substances

Scope:
Industrial chemicals and biocides

- Acute toxicity
- Repeated-dose toxicity
- Genotoxicity
- Carcinogenicity
- Immunotoxicity
- Reproductive and developmental toxicity
- Endocrine disruptor assessment
- Eye irritation (corrosion/irritation)
- Skin irritation and corrosion
- pH determination
- n-Octanol/Water partition coefficient

Medical Devices

Examples:
Fillers, implants (including bone grafts), intraocular lenses, and other implantable devices

- Cytotoxicity
- Sensitization
- Pyrogenicity
- Genotoxicity
- Implantation study
- Irritation or intracutaneous reactivity
- Electrical safety (acute and repeated exposure)
- Acute systemic toxicity

Ministry of Food and Drug Safety



National Institute of Environmental Research

Safety Study

General Toxicity Study

1. Single Dose Toxicity Study
2. Repeated Dose Toxicity Study
3. Tumorigenicity Study

Genotoxicity Study

1. AMES Test
2. *In Vitro* Chromosomal Aberration Test
3. *In Vivo* Micronucleus Test
4. Mouse Lymphoma Assay
   MLA
5. Comet Assay
6. *In Vitro* Micronucleus Test

Local Toxicity Study

1. Skin Irritation Test
2. Cumulative Skin Irritation Test
3. Eye Irritation Test

Additional Safety Studies

- Oral mucosal irritation test
- Local tolerance test
- Vaginal and rectal mucosal irritation test



Immunotoxicity Study

1 **Skin Sensitization Test**

2 **Photosensitization Test**

3 **Active Systemic Anaphylaxis**

4 **Passive Cutaneous Anaphylaxis**

Reproductive and Developmental Toxicity Study

1 **Fertility and Early Embryonic Development Study** (Seg I)

2 **Embryo-Fetal Development Study** (Seg II)

3 **Pre-and Postnatal Development Including Maternal Function Study** (Seg III)

4 **Reproductive and developmental toxicity studies in accordance with OECD Test Guidelines**

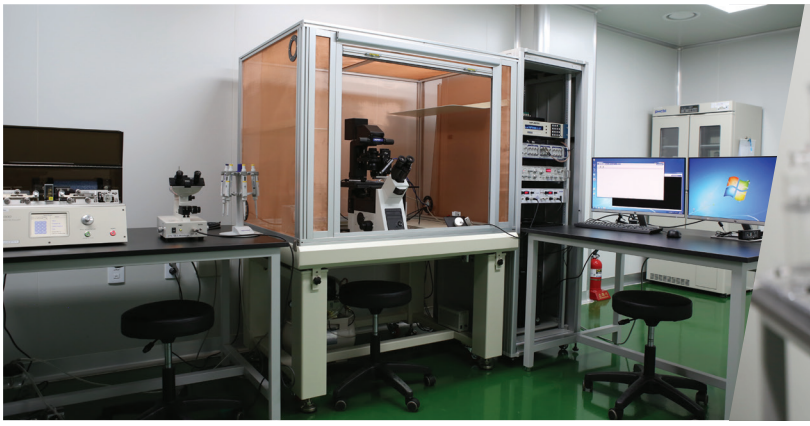
- Reproductive and developmental screening study (TG 421)
- Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (TG 422)
- Prenatal Developmental Toxicity Test
  Reproduction/Developmental Toxicity Screening Test (TG 414)

Safety Pharmacology

1 **Core Battery Study**

- Central Nervous System (FOB test, Irwin test)
- Respiratory System
- Cardiovascular System
  - Telemetry (*in vivo*)
  - hERG assay (*in vitro*)

2 **Nav1.5/Cav1.2 assay**





Pathology



1 **Necropsy**

2 **Clinical Pathology**

3 **Histopathology**

Clinical Pathology

Hematology	Clinical Chemistry	Urinalysis	Hormone Analysis
▸ Hematology ▸ Coagulation	▸ Chemistry	▸ Urinalysis	

Histopathology

Necropsy	Slide Preparation (Paraffin/Frozen)	Stain	Histopathology
▸ Rodent · Rat · Mouse ▸ Non-Rodent · Rabbit · Beagle · Minipig		· Hematoxylin & Eosin · Special Stain · IHC	· Microscopic Examination · Peer Review **Digital Pathology** · WSI (Whole Slide Image) · Image Analysis

TK/PK

1 **Toxicokinetic Analysis**

2 **Pharmacokinetic Analysis**

Medical Device

1. Cytotoxicity
2. Skin Sensitivity
3. Irritation
4. Pyrogenicity
5. Systemic Toxicity
6. Genotoxicity

Alternatives to Animal Testing

1. LLNA: BrdU-ELISA
2. Reconstructed Human Epidermis, RhE test
3. Reconstructed Human Epidermis, RhE Test
4. Reconstructed Human Cornea-Like Epidermis, RhCE Test/Short Time Exposure, STE
5. Reactive Oxygen Species (ROS)

Environmental Toxicity Study

1. Daphnia sp. Acute Immobilization Test
2. Daphnia Magna Reproduction Test
3. Fish, Acute Toxicity Test
4. Freshwater Alga and Cyanobacteria, Growth Inhibition Test
5. Ready Biodegradability OECD TG 301C
6. Analysis of Test Solutions
   - UHPLC I Ultra High Performance Liquid Chromatography
   - GC I Gas Chromatography
   - ICP-OES I Inductively Coupled Plasma Optical Emission Spectroscopy
7. n-Octanol-Water Partition Coefficient Test OECD TG 107, 117
8. Hydrolysis as a Function of pH, OECD TG 111



Analysis Center

Dt&CRO provides integrated analytical services to support drug development, including *in vitro* ADME/DMPK studies, pharmacokinetic (PK) analysis, PBPK modeling, toxicokinetic (TK) analysis, protein and ASO characterization, and impurity evaluation.



*Certified as a GLP bioanalytical testing institution for quantitative analysis of drug concentrations and biomarkers.

Comprehensive End-to-End Analytical Capabilities

GLP/GCLP-Certified Institution
Supporting IND/NDA submissions in Korea and overseas

End-to-End Analytical Support
In vitro → Non-Clinical → clinical phases → Full analytical support for BE/NDDS programs

PD Biomarker & ELISA Platform
Ensuring quantitative accuracy and analytical reliability

Advanced Analytical Equipment
SCIEX 7500, Waters Xevo TQ-Absolute, ICP-MS, MSD, ELISA, etc.

Extensive Clinical Sample Analysis Experience
Bioanalysis for multiple pharmacokinetic (PK) studies and BE projects

Flexible Protocol Design
Sponsor-tailored method development and validation

Responsive Communication
Dedicated PM and analytical experts assigned with consistent timeline management

Core Equipment at the Analysis Center

Equipment	Analytical Technology	Key Applications
SCIEX Triple Quad 7500	LC-MS/MS (Triple Quad)	· Ultra-sensitive bioanalysis of biological samples · Clinical and Non-Clinical PK analysis and drug concentration quantification · Quantification of generic and new drug compounds · Trace-level biomolecule and pharmaceutical quantification · High-sensitivity clinical and Non-Clinical analysis · Quantitative analysis
SCIEX Triple Quad 6500+		
SCIEX Triple Quad 5500+		
SCIEX Triple Quad 5500		
Waters Xevo TQ-Absolut		
Waters Xevo TQ-XS		
Waters Xevo TQ-S		
SCIEX Triple TOF 5600+	LC-MS/MS (Q-TOF)	· Qualitative analysis (Metabolomics, Proteomics) · Metabolite analysis
Waters Xevo MRT		
Agilent ICP-MS	ICP-MS	· Elemental analysis (heavy metals and trace elements)
Molecular Devices Microplate Reader	Plate Reader	· Cell viability assays, Enzyme activity assays, ELISA-based quantitative analysis
Waters HPLC with UV, RI, ELSD	HPLC	· Quantitative analysis, Excipient and impurity analysis, Lipid analysis
Waters UPLC with PDA	UPLC	· Rapid quantitative and qualitative analysis, Purity assessment
Shimadzu UHPLC with FL, PDA		· Analysis of fluorescent compounds and impurities
GC-FID	GC	· Residual solvents, VDCs, Fatty acid, etc.


Sample Preparation Room


Sample Storage Room


Instrument Room


Document Archive Room

Bioanalysis Center Service Scope

We provide GLP/GCLP-based quantitative analysis and characterization services from Non-Clinical studies to clinical trials.

Category	Service Details	Analytical Scope & Technology
In vitro ADME	Drug substances and metabolites	· Plasma/Microsomal/hepatocyte stability
		· Phase I, Phase II and non-CYP metabolism assay (Phenotyping/Inhibition/Induction)
		· Transporter assay (P-gp, BCRP, OAT, OCT, OATP, MATE, etc.)
		· Plasma, tissue binding (Brain, whole blood, etc.)
PK/PD Bioanalysis	Quantification of drugs and PD biomarkers in biological samples	· LC-MS/MS-based quantitative analysis (plasma, tissues, etc.)
		· GLP/GCLP-compliant analysis across the full Non-Clinical and Clinical development lifecycle
		· Pharmacokinetic analysis during Clinical Trials (PK sampling)
		· Quantitative analysis for bioequivalence (BE) studies
PBPK Modeling	Dose selection based on simulation	· PK-Sim®-based scenario modeling
		· Human exposure prediction, long-term exposure assessment, and DDI prediction
Toxicokinetics (TK)	Toxicokinetic and pharmacokinetic analysis	· PK analysis for GLP-compliant repeat-dose toxicity studies
		· DRF (Dose Range Finding) analysis for initial dose selection
		· Evaluation of key exposure levels and safety margins
		· Analytical support for dose optimization in the Non-Clinical stage
PD Biomarker	Drug efficacy quantification	· Mechanism-based PD biomarker analysis
		· Endogenous biomarkers related to inflammation, liver function, and metabolic indicators
		· Sample types: plasma, tissues, cerebrospinal fluid (CSF), etc.
		· Analytical platforms: LC-MS/MS, ELISA/Multiplex
Biologics/ASO	Biologics analysis	· Quantification of peptides, LNPs, siRNA, ASO, and oligonucleotides
		· Ligand-binding and hybrid LC-MS/MS analysis
		· Characterization analysis: aggregation, peptide mapping, etc.
ELISA & ECL Assay	Biomarker analysis based on enzyme immunoassays	· High-sensitivity multiplex analysis based on sandwich ELISA and competitive ELISA-MSD-ECL
		· Analytical validation and use of reference standards
Impurity/E&L	Impurity and extractables analysis	· Extractables & Leachables analysis based on nitrosamines, GTIs, and ISO 10993-18
		· Simultaneous multi-component analysis using GC-FID, LC-MS, and ICP-MS
Clinical sample analysis	Certified multi-analyte sample analysis	· Analysis of post-marketing surveillance (PMS) and clinical trials samples
		· Operation in compliance with MFDS certification standards
		· Method development and validation in accordance with ICH guidelines

Consulting Service for MFDS/FDA/EMA

PM Consultation

Target Clients

- Companies at the pre-IND stage preparing for clinical trial applications
- Companies experiencing difficulties in identifying appropriate Non-Clinical study requirements

Consulting Scope

- Review regulatory classification of the study drug/substance
- Identify required Non-Clinical study items through regulatory precedent review
- Review key checkpoints for clinical trial approval
- Provide Non-Clinical study design consulting for IND applications to MFDS and the U.S. FDA

Consulting Process

Inquiry	Information Review	Assessment	Strategy Development	Study Initiation
• Client requests consulting	• Project overview and material information review	• Material information and regulatory precedent review	• Regulatory classification and Non-Clinical study plan proposal	• Non-Clinical study agreement and project initiation



FDA Consulting

FTSR Service

FTSR provides a comprehensive review of existing toxicology data and Non-Clinical study design to assess compliance with key regulatory requirements, including those of the U.S. FDA, and recommends optimized strategies to strengthen the scientific rationale.

Scope of Work

1. Study Design & Regulatory Review
   - Gap analysis of study methods, data quality, and report integrity
   - Regulatory compliance review (FDA, Australia, Europe, and Asia)
   - GLP compliance evaluation, where applicable
   - Assessment of regulatory acceptability
   - Evaluation of statistical methodologies used in study design and analysis
2. Scientific & Data Review
   - Adequacy review of study data and comparison with reference data
   - Safety margin assessment based on anticipated human exposure
   - Benchmarking against competitor data
3. Risk Assessment & Strategy
   - Recommendations for additional studies or study design improvements
   - Identification of potential risks and mitigation strategies
   - Strategic recommendations to support regulatory review readiness

Dt&CRO + FDA Tox Expert

Study Type	Review Scope	Deliverables
Toxicology Studies	· Dose Range-Finding Study · GLP Repeat-Dose Toxicology Study	· Comprehensive Study Review Report · Risk Assessment and Optimized Strategy · Regulatory Compliance Recommendations
Safety Pharmacology Studies	· hERG (Cardiac Safety) Assay · CNS Safety · Respiratory Safety · Telemetry Study	
Genotoxicity Studies	· Ames Test · Chromosomal Aberration Test · *In vivo* Micronucleus Assay	
Bioanalysis & ADME Studies	· Pharmacokinetics (PK) & Toxicokinetics (TK) · Biodistribution (For Cell & Gene Therapies)	

Estimated Timeline Average 2–4 weeks per study type / Parallel execution available

Optional Services 1. Reproductive & Developmental Toxicity Studies | 2. Carcinogenicity Study

FTSR: FDA Toxicology Study Review

FTSC Service

FTSC provides strategic guidance during the toxicology study planning stage and supports the development of customized Non-Clinical study protocols aligned with key regulatory requirements, including those of the U.S. FDA.

Scope of Work

1. Study Design & Regulatory Strategy
   - FDA-aligned toxicology study design
   - Regulatory consultation during IND preparation, if required
   - Dose selection strategy and route of administration planning
   - Comparator/control study selection
   - Time point determination for data collection and analysis
2. Data Analysis & Scientific Interpretation
   - Scientific interpretation of study data
   - Sample size estimation and statistical analysis strategy
3. Risk Management & Regulatory Strategy
   - Support for regulatory pre-submission meetings
   - Integrated review of key CMC regulatory requirements
4. Study Execution Support
   - Interim review during study execution and issue resolution support

FDA Tox Expert

Study Type	Review Scope	Deliverables
Toxicology Studies	· Dose Range-Finding Study · GLP Repeat-Dose Toxicology Study	· FDA-aligned customized study design · Estimated study cost and budget planning
Safety Pharmacology Studies	· hERG (Cardiac Safety) Assay · CNS Safety · Respiratory Safety · Telemetry Study	
Genotoxicity Studies, Bioanalysis & ADME Studies	· Ames Test · Chromosomal Aberration Test · *In vivo* Micronucleus Assay · Pharmacokinetics (PK) & Toxicokinetics (TK) · Biodistribution Study	

Estimated Timeline Average 6–8 weeks per study type / Parallel execution is available

Optional Services 1. Reproductive & Developmental Toxicity Studies | 2. Carcinogenicity Study

FTSC: FDA Toxicology Study Consulting

FIND Service

FIND provides optimized strategies for FDA IND entry while reducing development time and cost.

Service Structure		Support Scope	Key Components
Early Development Plan		Development of FDA-aligned TPP and PDP, technical risk assessment, and regulatory gap analysis to establish early-stage development strategies.	• Drug Development Strategy Planning - Regulatory gap analysis - Technical risk assessment - Product Development Plan (PDP) - Target Product Profile (TPP)
			• Development Strategy Planning - Establishment of key development priorities
			• Non-Clinical (Non-GLP) Study Protocol Development[1]
			• Project Management for Study Execution
			• Regulatory Strategy Development - Support for Pre-RFD or RFD submission - Preparation and response support for INTERACT meetings[2]
Pre-IND Plan	Pre-IND Preparation Plan	Identify the key data required for the Pre-IND meeting and establish a regulatory strategy aligned with FDA expectations.	• Drug development and FDA regulatory strategy planning - Regulatory pathway analysis and Pre-IND strategy development
			• Non-Clinical (Non-GLP) study protocol development[3]
			• Project management for study execution
	Pre-IND Meeting Plan	Organize the FDA meeting document package and support meeting strategy development, including preparation and follow-up activities.	• Regulatory Strategy - Preparation of Pre-IND meeting documents and meeting support[4]
			• CMC / Manufacturing Strategy[5] - CMC quality document development - Analytical method development and validation - Formulation development[6] - Quality control and testing
IND Approval Plan		Provide strategic support from submission preparation through the IND submission process based on an integrated CMC and clinical development strategy.	• Project management for study execution
			• CMC / Manufacturing Strategy - GMP scale-up synthesis of clinical drug substance (API) - Drug product formulation development - GMP manufacturing of drug product - Validation activities (manufacturing process and analytical method validation)
			• Clinical Strategy - Clinical study protocol development (Phase 1 and Phase 2a) - Clinical site selection and operational strategy
			• Regulatory Strategy - IND preparation and submission support[7]
			• Drug Development Strategy - Development planning for IND submission
			• Development of GLP-based Non-Clinical study protocols[8]

1) Includes *In vitro* protocols related to target validation, efficacy screening, binding affinity, solubility, permeability, CYP450 inhibition, metabolite identification and stability, microsomal stability, cytotoxicity, cardiotoxicity, transporter inhibition, plasma protein binding, and DDI studies.
2) One revision included.
3) Includes study protocol design related to *in vivo* pharmacology, safety, route of administration, dose range, and *in vivo* efficacy studies.
4) Includes preparation of development data packages, GLP-based IND-enabling study planning, clinical strategy, CMC/manufacturing strategy, IND document preparation and revision, submission support, and meeting reports.
5) 505(b)(2)'s trend lower, biologics trend higher.
6) Typically includes consideration of absorption, bioavailability, composition/dissociation, stability, etc.
7) Includes development strategy consulting, CMC/manufacturing strategy, Non-Clinical study design and execution support, document preparation, and IND submission support.
8) Includes design and revision of IND-enabling study plans for FDA IND submission after the Pre-IND meeting (e.g., DRF, MTD, TK, PK, biodistribution, *in vivo* ADME, toxicity studies; up to two study types if required).

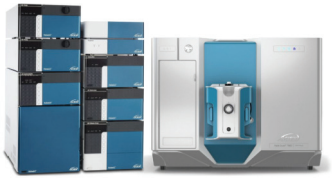
FIND: FDA IND Strategy Consulting

Clinical Trial Operations Center

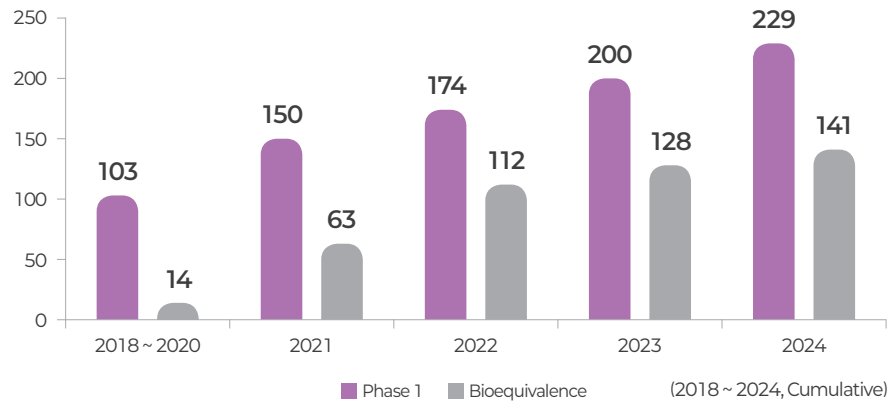
Bioequivalence Study

Analytical Instrumentation

- **Leveraging state-of-the-art high-resolution mass spectrometry systems and a team of experienced scientists, we provide comprehensive services including method development, validation, and sample analysis.**
- **GCLP/Non-GLP Bioanalysis: LC-MS/MS Total 16**
  AB SCIEX 7500 (1), 6500 (1), 5500 (12), Waters LC-MS/MS (2)
- **GLP Non-Clinical: Total 24**
  Waters LC-MS/MS (6), AB SCIEX 7500 (1), 6500 (1), 5500 (5), Waters UPLC (4), HPLC (3), Shimadzu HPLC (2), ToF (1), ICP (1)


Clinical Trial Experience



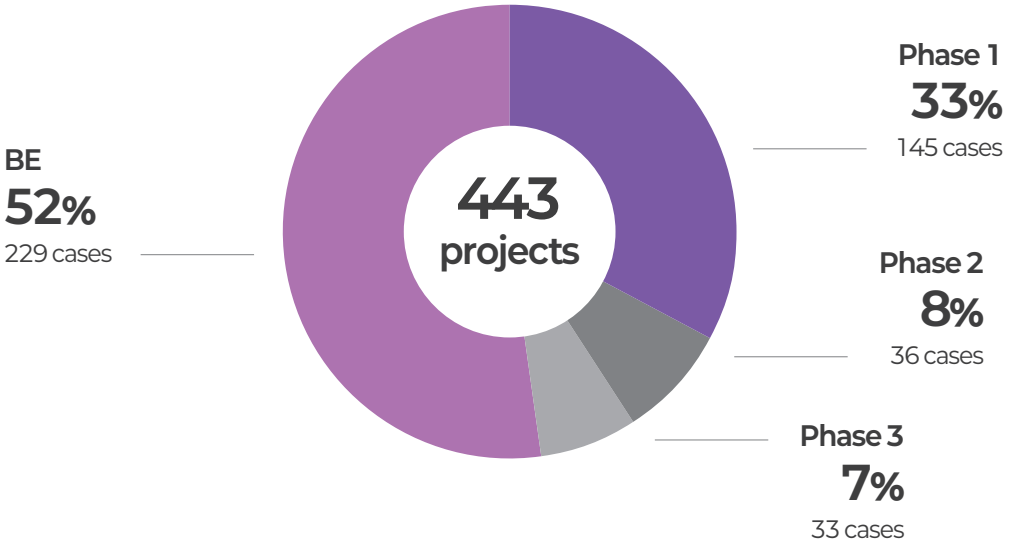
Equivalence Rate:
79.5%

ISR Compliance Rate:
99.3%

- Since 2017, we have performed over 300 bioequivalence studies and Phase I clinical sample analyses.
- Out of 229 bioequivalence studies, 182 demonstrated bioequivalence.
- **ISR compliance 99.3% (n=370)**, ensuring robust reproducibility and data reliability.

Early Phase Study

Dt&CRO Project Experience & Expertise



- Out of 443 approved clinical trials, we have successfully conducted over 374 approved clinical trials, including 229 bioequivalence (BE) studies and 145 Phase I trials.
- Leveraging strong collaboration with our Non-Clinical division, we partner with biotech companies in early drug development, supporting programs from clinical entry strategy consulting to early Non-Clinical and Phase I studies.
- Our team includes highly experienced professionals with extensive expertise in managing approved clinical trials.
- Our operational excellence is demonstrated through 74 sponsor audits and 6 MFDS inspections (2018-2024).
- Based on a specialized SAD/MAD operational framework, we provide optimized early-phase clinical execution, including cohort management, safety review meetings, and SRC operations.
- To enhance data reliability, double programming is applied to key statistical analysis variables.



Late Phase Study

Successful post-marketing clinical trials require study design, execution, and outcomes aligned with research objectives

Real-World Study Expertise

- PMS / Registry / Observational studies
- Optimized data collection for real-world settings
- Extensive experience across approximately 110 general hospitals & 200 clinics hospitals
- Nationwide clinical site coverage across Korea
- **Proven experience in large-scale post-marketing studies**

Efficient Study Operations

- Real-world aligned protocols
- **Reduced operational burden for sites**
- Reliable and high-quality data generation

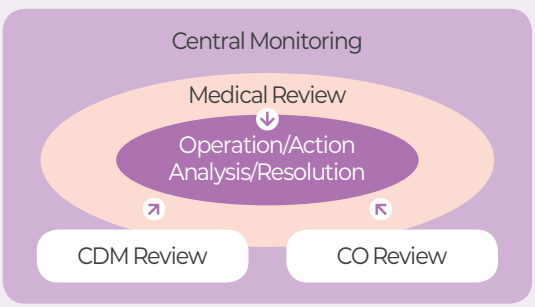
CP Compliance & Transparency

- Full compliance with CP (Compliance Program) regulations
- Transparent investigator engagement
- Strict adherence to rebate regulations (Pharmaceutical Affairs Act)

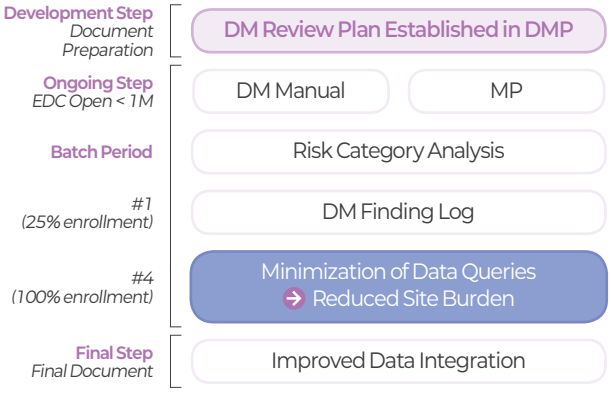
Risk Category–Based In-House Site Management

- **Budget Optimization:** proactive query analysis and efficient in-house monitoring
- **Early High-Risk Data Detection:** identification of missing data, outliers, and inconsistencies with clear data entry guidance
- **Data Quality Assurance:** ensuring data accuracy, completeness, and consistency

Dt&CRO Risk Category Management



Dt&CRO DM Review Process



Medical Device

ISO 14155–Based Global Standard Full-Scope Service

As the first ISO 14155–certified CRO in Korea, Dt&CRO supports the entire lifecycle of medical device development, from early market entry to post-market lifecycle management, in compliance with global regulatory requirements.

- Development of SOPs and RD* capabilities aligned with ISO 14155 international guidelines
- Clinical study design support optimized for medical device regulatory approvals (CE, MFDS)

CERTIFICATE ◇ CERTIFICATE

CERTIFICATE

No. Q4B 110244 0001 Rev. 01

Holder of Certificate:
Dt&CRO Ltd.
72-2. Baumoe-ro 41-Gil
Seocho-gu, Seoul 67741
REPUBLIC OF KOREA

Certification Mark:

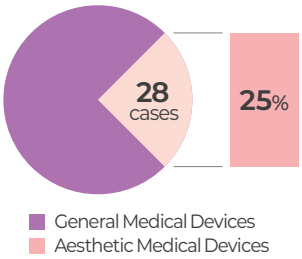
*RD: Relevant Document

Standardized Independent Evaluation Process

Independent Evaluators → Standardized Evaluation System → Reliable Data

- **Independent evaluation system** for scientifically objective results
- **Standardized procedures ensuring** data integrity and reliability
- Improved operational efficiency through system implementation
- **Evaluation manuals aligned** with **FDA and EMA regulatory requirements**

Medical Device Clinical Trial Experience



- Dt&CRO has conducted over 112 medical device clinical projects, including 25% in aesthetic medical devices, reflecting our strong expertise in this sector.
- Leveraging extensive project experience and a specialized team in aesthetic medical devices, we provide clinical strategies optimized for each product's characteristics.

Medical Device Consulting

- Dt&CRO delivers comprehensive clinical trials support through a team of medical device specialists with global regulatory expertise across the entire approval process.
- With proven experience in CE MDR certification, we provide science-based regulatory guidance throughout the product lifecycle, enabling efficient and effective regulatory execution.

Pharmacovigilance

Pharmacovigilance Services

Dt&CRO PV Team – Independent and Integrated PV Solutions

- Independent PV Organization
- End-to-End PV Solution
- Aligned with MFDS RMP Regulatory Trends
- In-Depth PV Partnership

1 Independent PV Organization

Dt&CRO operates an independent pharmacovigilance (PV) team, providing PV strategies optimized for regulatory requirements.

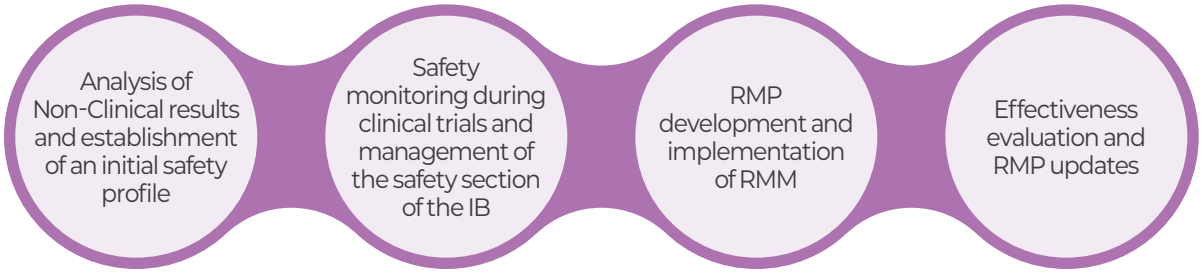
2 End-to-End PV Solution

We provide full-lifecycle PV services, covering both pharmaceuticals and medical devices.

Area	Key Services
Case Management	Full case processing from case intake to regulatory reporting
Clinical PV Activities	SMP development and maintenance, operation of Safety Review committees
Aggregate Reports	Preparation of DSUR, PSUR/PBRER, and RMP reports
Signal & Risk Management	Signal monitoring and RMP development and maintenance of safety databases
PV System Development	Development of PV SOPs, safety database development and maintenance, literature monitoring, PV audit and inspection support

3 Reflecting MFDS RMP Regulatory Trends

We provide lifecycle risk management strategies aligned with strengthened RMP regulations.



4 In-Depth PV Partnership

Dt&CRO provides customized PV training programs tailored to sponsors' product characteristics and country-specific regulatory requirements.

We also provide on-site pharmacovigilance training, PV SOP consulting, and strategic communication to build a long-term PV partnership.

Global Study

Dt&CRO's Worldwide Partners



Global Reach, Local Expertise

- 24/7 Project Management
- Multilingual Support
- Real-Time Communication
- Cost-Effective

- Fast and cost-efficient communication with global sites
- Seamless multi-country trial execution

Regulatory Affairs Consulting

Compliance & Quality Assurance

- ISO 14155 certified with annual audits
- Specialized in CE MDR
- Proven MFDS negotiation capability
- Compliance sensitivity

RA Consulting → Negotiation → Clinical Trial → Approval

Laboratory Information Management System | LIMS

We have implemented a Laboratory Information Management System (LIMS) to efficiently collect, analyze, and manage study data, enhancing the reliability of test results.
The system is also being developed to enable automatic linkage to SEND (Standard for Exchange of Non-Clinical Data) for U.S. FDA submissions.

LIMS System

Animal Facility Management System

1. Clinical Pathology
2. Reproductive Toxicity
3. Genotoxicity
4. Histopathology
5. Immunotoxicity
6. Safety Pharmacology
7. General Toxicity
8. Local Toxicity
9. Environmental Toxicity

Standard for Exchange of Non-Clinical Data | SEND

SEND (Standard for Exchange of Non-Clinical Data) is an FDA-required data standard for Non-Clinical study submissions supporting drug approval.
It standardizes key study data such as clinical observations, body weight, and pathology findings, and requires submission of SEND datasets, Define.xml, and the nSDRG.
Dt&CRO provides SEND conversion services using a proprietary conversion program, supporting both internally generated Non-Clinical data and data from external institutions.

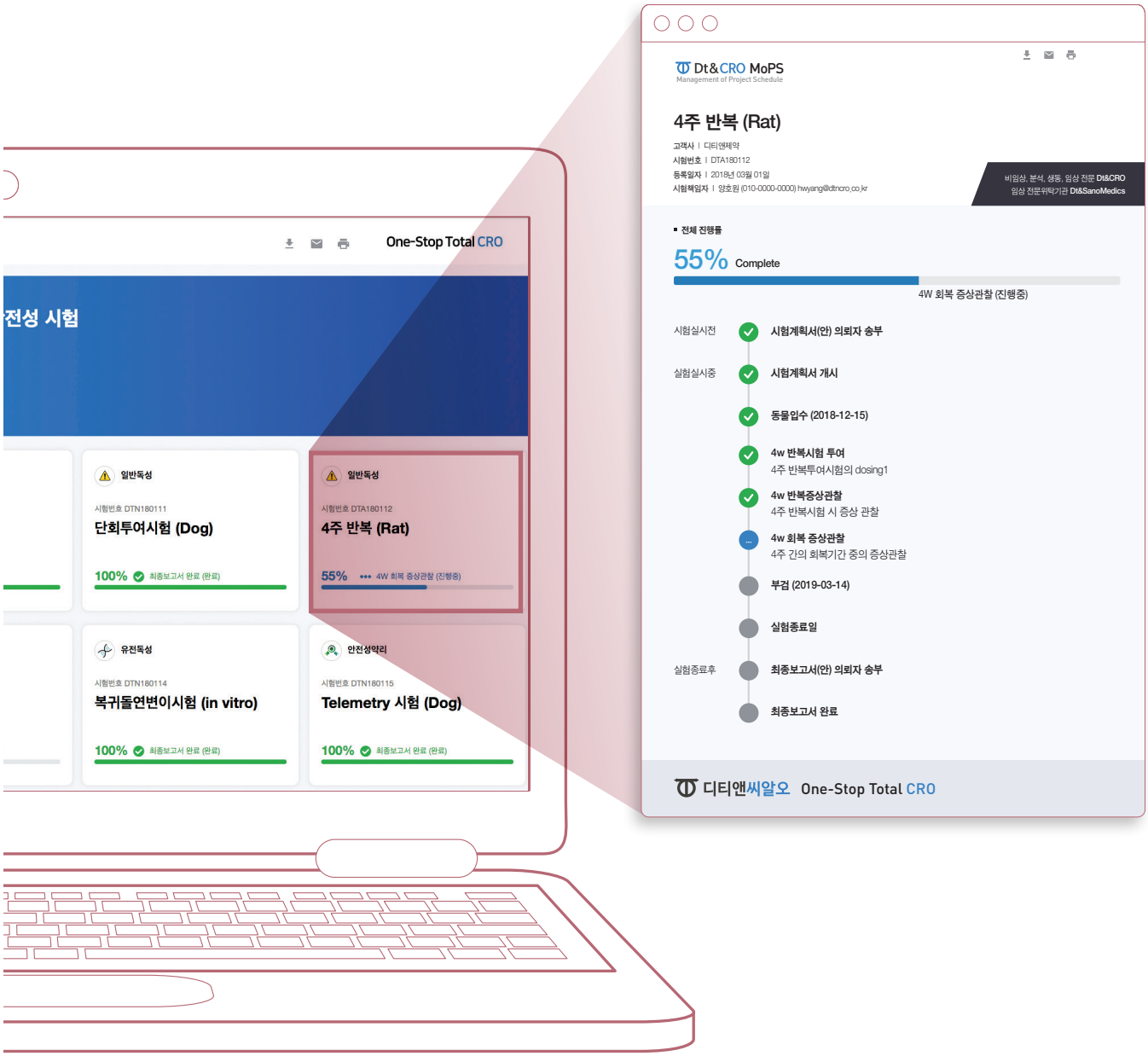


Management of Project Schedule | MoPS

Real-Time Project Schedule Management System

MoPS is a client communication platform that provides real-time updates on project progress and enables sponsors to track milestone completion.
The system automatically sends email notifications with access links whenever major study stages are completed, allowing sponsors to easily review project status and share information internally.

Detailed Study Progress by Test Item



Central Lab × Huscience

Huscience supports drug development through clinical trials sample analysis, along with assay setup, lab kit manufacturing, global biospecimen logistics, and data management services.

By operating customized services and internationally compliant quality management systems, we provide reliable and high-quality analytical results.

Global Certifications

- GCLP-certified clinical trials sample analysis laboratory
- ISO 17025 / CAP certifications

Specialized Analytical Expertise

- Clinical trials sample analysis services
- Academic research support for R&D projects (Companion sample analysis services available)

Standardized Procedures

- Clinical trials sample analysis services
- Academic research support for R&D projects (Companion sample analysis services available)

Certifications



CAP



ISBER
(PBMC, DNA, RNA)



ISO 17025



MFDS-GCLP

Analytical Services for Phase I-IV Clinical Trials

Bioanalytical Analysis

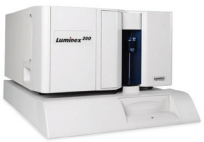
- PK&PD (In-House/Commercial)
- ADA/Nab
- Immunoassay (ELISA, MSD, Luminex)
- Cell analysis (Cell phenotyping, Cell cycle, etc.)
- PBMC isolation & cryopreservation



Microplate Reader



MSD



Luminex



CyTOF

Safety Analysis

- Clinical panel & infectious disease serology
- Hematology and coagulation assay
- Urinalysis
- Glycated hemoglobin assay



Roche Cobas 8000 series



TOSOH G11



Sysmex UC-3500

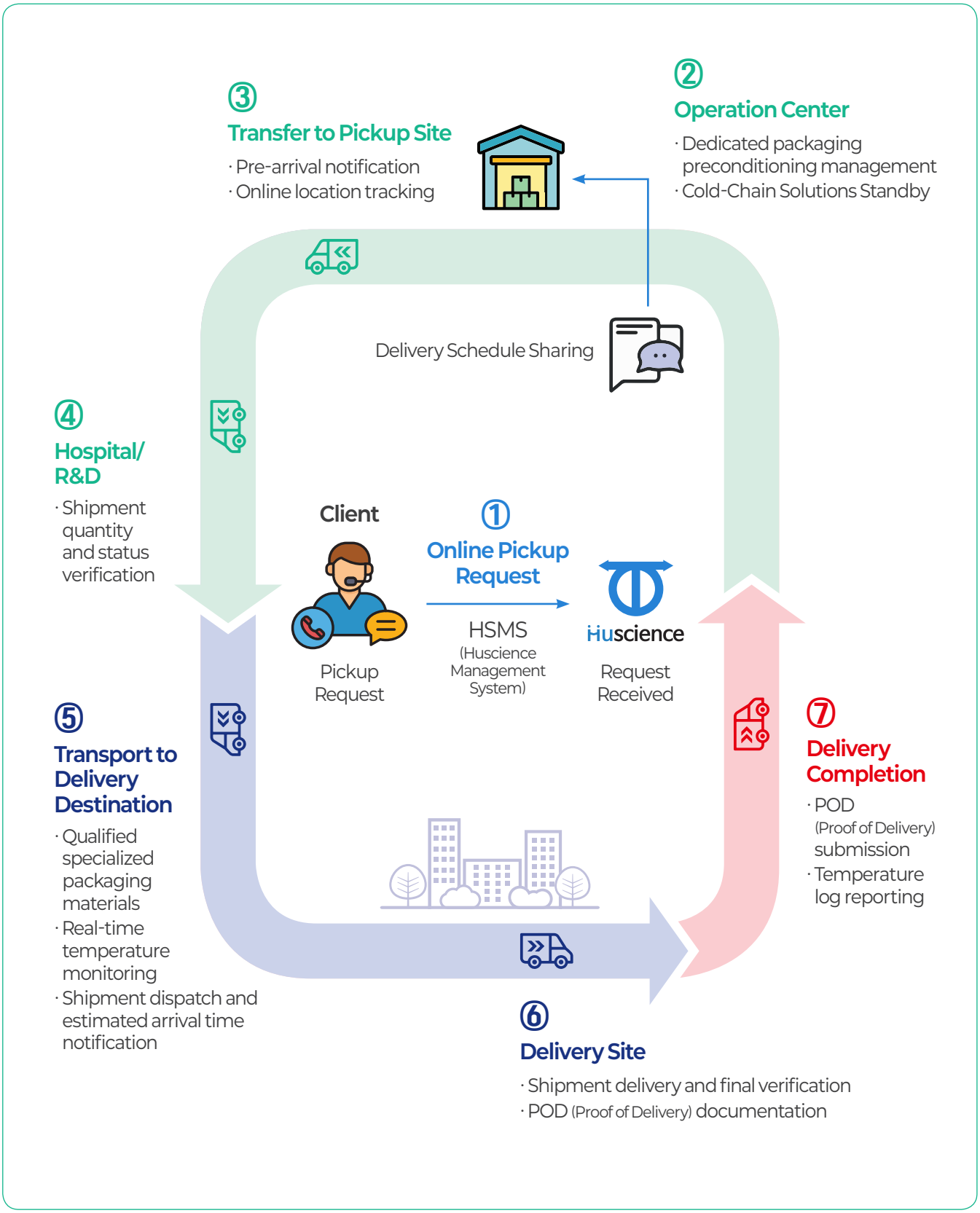


Sysmex CS-1600



Sysmex XN-3100

We deliver high-quality logistics services in partnership with specialized cold-chain logistics providers, ensuring full compliance with international regulations such as ISTA 7D, IATA, UN, ADR, and WHO guidelines.



Dt&CRO

Location

Efficacy Evaluation Center	I	17042 27, Baengnyeong-ro 20, Cheoin-gu, Yongin-si, Gyeonggi-do
Safety Evaluation Center	I	17042 46, Yurim-ro 154, Cheoin-gu, Yongin-si, Gyeonggi-do
Analysis Center	I	17042 28, Baengnyeong-ro 20, Cheoin-gu, Yongin-si, Gyeonggi-do
PKPD Center	I	17042 24, Yurim-ro 154, Cheoin-gu, Yongin-si, Gyeonggi-do
Clinical Trial Operations Center	I	06741 72-2, Baumoe-ro 41-gil, Seocho-gu, Seoul

Non-Clinical 031-322-2400 I Clinical 070-4916-7924

info@dtncro.co.kr https://www.dtncro.com

Dt&C Group

Bio Technology Services

Dt&CRO

Full-service CRO

Non-Clinical efficacy and GLP toxicology studies, Bioanalysis, formulation development, and Pharmacokinetics, Clinical trials (Phase I/II/III), Post-marketing studies (PMS, OS, IITs)

Huscience

Central Lab

Assay development & validation, Clinical trials sample analysis, Clinical project management & services, Data management, Global biospecimen cold-chain logistics

14322 190 Soha-ro, Gwangmyeong-si, Gyeonggi-do

070-8806-8240

BD@huscience.net

Electrical & Electronic Technology Services

Dt&C

KOSDAQ – listed company

Electronic device testing and certification services including:

EMC, RF/SAR, Reliability testing, Environmental testing, IoT and interface certification, etc.



SAFESOFT

Software certification, verification & validation and development

IT solutions for Non-Clinical and Clinical research

Software testing, certification, and evaluation services

Dt&C VINA

Testing, certification, and inspection services in Vietnam for:

EMC/Safety/RF testing for Mobile & Home Appliances, etc.

DCJ JAPAN

Testing and certification services in Japan

Software evaluation and automotive testing, Software testing & verification, Automotive EMC testing

Dt&C CHINA

Testing and certification services in China

Financial Services

Dt& Investment

Venture Capital Firm

VC Funding, Formation of Investment Associations, Local and Overseas Investment Consulting

DTCR-BR-202604-V5-001