Dt&SanoMedics

The One Quality Needed for the Success of Your Clinical Trial

Dt&SanoMedics

www.dtnsm.co.kr

We Make
We Create
We Are Pioneers in CRO

We are CRO which is based on Korea and our experts are fully committed to providing you with the best plan & strategy for the whole process. From development stage to product approval, we can cover your every complex affair with regulatory capability and extensive experiences. We offer full coverage at all healthcare areas including pharmaceutical products, medical devices, and health functional foods. With one-stop service for every development stage.

Bio Technology

Dt&C BioGroup is providing unique convergence services for drug development from pre-clinical trial to RWE with IT technology.

Dt&C Bio GROUP

Domestic Corporation

Dt&CRO	Dt&SanoMedics	SAFESOFT	Huscience
Non-Clinical, Toxicity Test, Bioequivalence, Clinical (Phase 1)	Contract Research Organization	Software V&V and Development	Central Lab for Clinical Trial

HISTORY of Dt&SanoMedics

2021

- Mar Obtained ISO14155 Certificate by TÜV SÜD

2020

- Mar Signed MOU for promotion and development of the medical device industry with Korea University Medicine
- Jun Signed strategic alliance MOU with Korean Cancer Study Group for anti-cancer drugs clinical study development
- Sep Signed strategic alliance MOU with Ajou University Hospital

2017

- Oct Established Dt&SanoMedics Co., Ltd.
- Nov Signed license agreement with ABL Bio (NRDO)

2018

- Feb Signed strategic alliance with KoNECT for training
- Aug Signed co-development agreement with ABL Bio

2019

- Feb Signed strategic alliance partnership MOU for manpower training with Korea Biotechnology Industry Organization
- Feb Certified member of CDISC
- Aug Signed strategic alliance partnership MOU with CHA Bundang CTC
- Oct Signed strategic alliance partnership MOU with Korea University Hospital
- Dec Signed strategic alliance MOU with Chung-Ang University for new strain of infectious disease response

Service Overview

Full Service CRO

Medical Writing

- Study document development and review (IB, protocol, CRF, ICF, publications, abstracts)
- Literature summaries of safety/efficacy
- Support for preliminary meetings with Regulatory Authorities
- CSR Writing
- Publication
- Literature Writing
- Investigator Meeting

Pharmacovigilance

- Real World Evidence Study for Pharmacovigilance
- Regulatory PMS
- KIDS Reporting
- Medical Monitoring by Medical Doctor
- Pharmacovigilance supporting in accordance with regional regulatory requirements
- Safety management
- SAE processing
- SOP development and management
- PSUR(Periodic Safety Update Report) development
- DSUR(Development Safety Update Report) development
- Pharmacovigilance audit
- RMP(Risk Management Plan) development

Regulatory Services

› Application & Dossier Maintenance, Review for each CTD Section

- eCTD Writing and Registration
- SEND Pharmaceuticals / Biologicals / Cell therapy / Herbal medicines
- NCE (New chemical entity) / IMD (Incrementally modified drug) / Generic
- Safety & Efficacy review / S&TM (Specification & Test Method) review / GMP data review
- CMC Consulting
- Pharmacovigilance / RMP
- DMF (Drug Master File)

› Non-Clinical Management and Consulting

- Non-Clinical Strategy
- Study Lab Identification, Non-Clinical Study Set up, Study Monitoring
- Review and Writing of Non-Clinical Reports (Module 4)
- Gap Analysis for Non-Clinical trial results (with Global company)
- Writing of Module 2.4, and Module 2.6

› Drug Development & Strategic Consulting

- Product Pipeline Development and Consulting
- Registration & Pipeline Development Strategy
- Regulatory Scientific Advice and Consulting
- Agency Strategy and Interaction
- Pre-IND Consulting
- FDA/EMA Advisory Committee Meeting Support
- CTD Packaging and Full writing

Clinical Operations

- Site Feasibility Study/Pre-Study Visit
- Study Initiation Visit
- Study Monitoring Visit
- Site Management
- Study Close-Out Visit
- Source Document Review
- Regulatory Document Review
- Investigational Product Accountability
- Report Generation

Data Management

- Data Management Plan (DMP) writing and maintenance
- Data Validation Plan (DVP) establishment
- Design & Development of Case Report Form (CRF) / e-CRF & annotation
- Electronic Data Capture (EDC) applications setup across major EDC
- Platforms & EDC data management
- Medical Terminology Coding using MedDRA, WHOART, WHODD
- Reconciliation of Adverse Events and Serious Adverse Events
- External Data Management
- Database Quality Check
- Database Lock
- Study Data Transfer
- Full EDC integration & CDISC compliance
- Complete validated systems & environment (21 CRF Part 11, ICH compliance)
- CDISC SDTM database conversion programming

Biostatistics Analysis

- Consulting on clinical trial design and protocols, including statistical epidemiology and adaptive design studies
- Collaboration with medical team to ensure the consistency and quality of deliverables
- Sample size / Power Calculations
- Randomization services (IVRS/IWRS)
- Designing Statistical Analysis Plans (SAP)
- Full service or independent biostatistical and programming support
- Preparing Statistical Reports – Interim, Final and Clinical Study Reports, DSMB
- Provision of CDISC: ADaM compliant analysis datasets

Quality Assurance

› Project Audits

- Investigator files/site audits
- Trial Master File audits
- Database audits
- Statistical report audits
- Clinical Study Report audits
- Regulatory submission audits
- Process audits
- Vendor audits

› Additional Services

- Education & Training on GCP and clinical trial related regulations and guidelines
- SOP development and maintenance
- Support inspections by MFDS

Medical Device Clinical Trial

- Support for medical device clinical trial plan approval (IDE, Investigational Device Exemption)
- Medical device product approval (Manufacturing/Importing)
- Technical documentation review/documentation
- Safety & Efficacy data review/documentation

Dt&C BioGroup's One Stop CRO Service Scope

Dt&CRO

Discovery Period

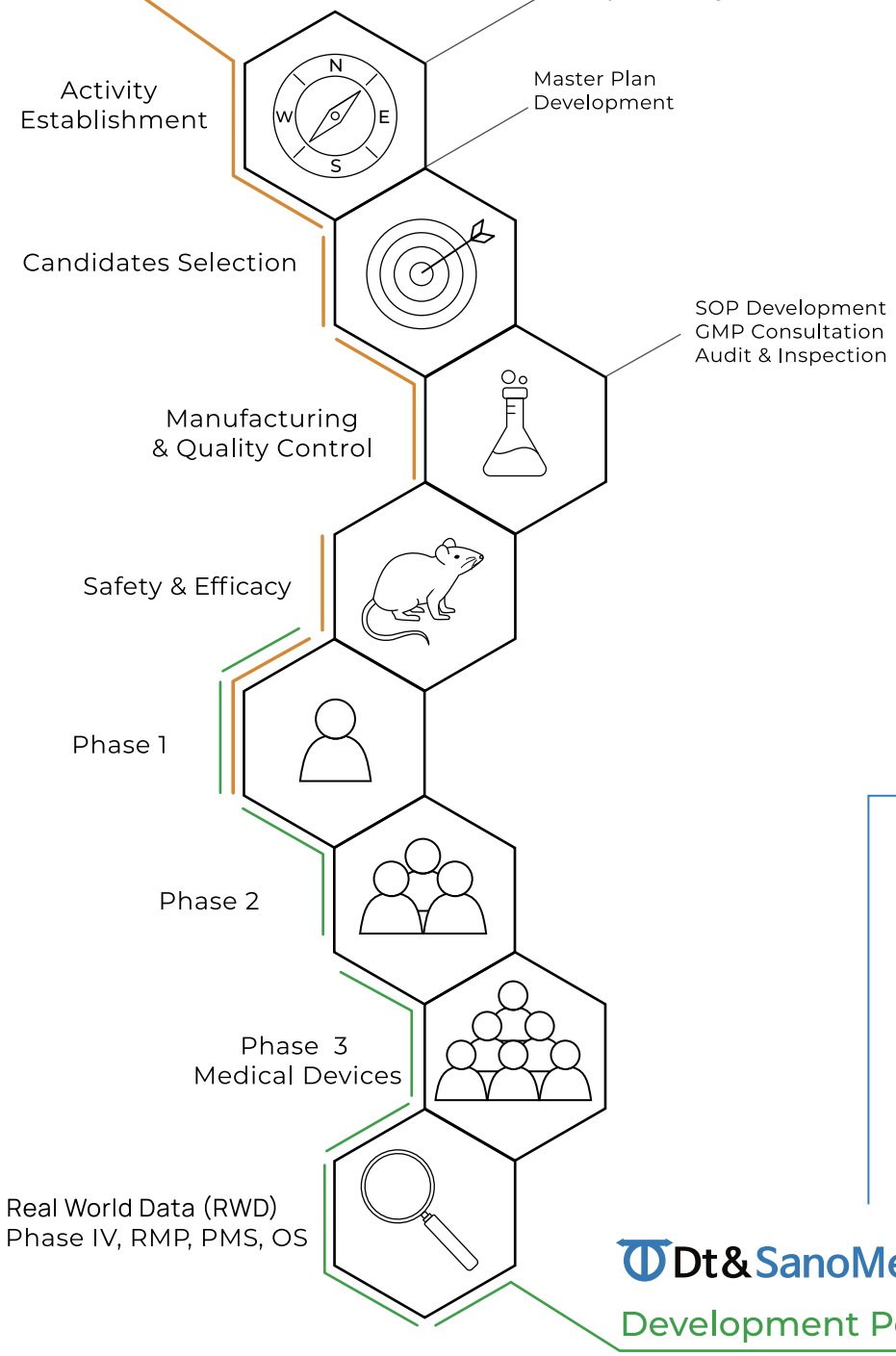
Analysis

- Clinical Trial Material Analysis
- Toxicokinetic Analysis
- Pharmacokinetic Analysis
- Protein Characterization

Pre-clinical trial consultation

Non-clinical Trial

- General Toxicity
- Genotoxicity
- Local/Immuno-toxicity
- Reproductive/ Developmental Toxicity
- Pathological Test



Dt&SanoMedics

Development Period

Huscience

Laboratory Testing

- Routine Analysis
- Advanced Diagnostics

Management for Clinical Trial

- Sample Management
- Data Management
- Investigator Support
- Bio-Logistics

STC (Smart Clinical Center)

SAFESOFT

Lab Software

- System Development for Clinical, Non-clinical Trial (LIMS/SEND/MoPS)

Medical/Trial Software

- System Development for Medical Lab, Trial Center, Non-Clinical Lab (eSOP/eLMS/ISO-MS)

Test Automation

- Test and Assessment Automation
- Unmanned System Development

Clinical Trial

- Regulatory Affairs
- CIP Development
- Site/Investigator Identification & Qualification
- Investigator Meeting
- Inspection / Audit
- Data Management
- Statistical Analysis
- Clinical Investigation Reporting
- Monitoring
- Project Management
- CRF Development
- Pharmacovigilance

Others

- License In/Out Service
- Global Partnering
- License Holding
- Contract Manufacturing Service
- SOP Review / Consulting

Regulatory/Medical Affairs Services

Non Clinical Trial and Early Phase

: We try to find out client's market access strategy like regions, licensing strategy, and so on.

- Non Clinical Trial Consulting
- Global Regulatory Consulting
- Licensing Out Strategy Consulting

Dt&SanoMedics & Dt&CRO Collaboration

Regulatory Affairs (with Dt&CRO Team and Global CRO)

- IND, IMPD, AUS IRB & Global Clinical Trial Application
- NDA, BLA, ANDA, 505b(2), MAAs, Generics, DMFs
- Dossier Review for special drug : Orphan Drug, Biosimilar, Fast Track, Breakthrough, Application & Dossier Maintenance, Review for each CTD Section
- eCTD Registration
- SEND

Non-Clinical Management & Consulting (with Dt&CRO Team)

- Non-Clinical Strategy
- Study Lab Identification, Non-Clinical Study Set up, Study Monitoring
- Review and Writing of Non-Clinical Reports (Module 4)
- Gap Analysis for Non-Clinical trial results (with Global company)
- Writing of Module 2.4, and Module 2.6
- IB Writing

Phase 2, 3,
Global Study, PMS

: We try to find out client's market access strategy like regions, licensing strategy, and so on.

Non Clinical Trial Consulting

Global Regulatory Consulting

Licensing Out Strategy Consulting

Global CRO Collaboration

Drug Development & Strategic Consulting

- Product Pipeline Development and Consulting
- Registration & Pipeline Development Strategy
- Regulatory Scientific Advice and Consulting
- Agency Strategy and Interaction
- Pre IND Consulting
- FDA/EMA Advisory Committee Meeting Support

Medical & Regulatory Writing Regulatory Publishing

- eCTD Submission
- CTD Packaging and Full writing
- CSR Writing for Publishing
- IB Writing
- DSUR/RMP/PSUR Writing
- Medical Monitoring Review Script
- Publication Manuscript
- Packaging Insert, Patient Information, Manuscript Writing

Our eTechnology

Anytime, Anywhere

eSOP

Electronic **S**tandard **O**perating **P**rocedure

Check and use of relevant SOP/RD before project initiation

Use of an electronic system to manage history such as SOP deviation and waiver, etc.

Digital Binder

Construction of SOP system based on web

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

Dt&SanoMedics provides 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.

eLMS

Electronic **L**earning **M**anagement **S**ystem

Anytime! Anywhere! Get access to the desired training system

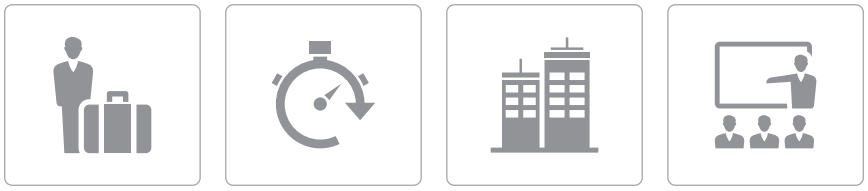
Database of curriculum vitae for clinical experience → Customized staff for each project

Qualification assurance by Job description

Training Record Review and curriculum vitae management

Digital Binder

Construction of LMS based on web



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

Dt&SanoMedics 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. Regardless of time and place, training is possible to progress, and LMS can improve your personal capability.

Our Special Feature

The First CRO in Korea with ISO14155 Certificate

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATE
No. Q4B 110244 0001 Rev. 00

Holder of Certificate: Dt&SanoMedics Co., Ltd.
15F, 126, Teheran-ro
Gangnam-gu, Seoul 06234
REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: Designing, planning and conducting clinical investigations with medical devices in compliance with the audited clinical quality management - Voluntary Clinical Certification Scheme Module B for the services provided by the Contract Research Organization (CRO)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a management system which meets the requirements of the listed standards. The results are documented in a report. For details see: www.tuvsud.com/ps-cert

Report No.: 713199140
Valid until: 2024-03-11

Date, 2021-03-12

(Zejian Yang)

Factory(ies): Dt&SanoMedics Co., Ltd.
15F, 126, Teheran-ro, Gangnam-gu, Seoul 06234, REPUBLIC OF KOREA

Applied Standard(s): ISO 14155:2020

TÜV®

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Design, Conduct, Report and Manage Clinical Trial in compliance with Global Standard

EU, USA, Canada, Brazil, Australia, Japan, China and Russia admit the medical device clinical trials according to ISO14155

Partnership

Global Partnership for Multinational Companies to conduct OS, PMS and NIS study

Global Partnership for Site Operation in Global Clinical Trials

Partnership for using EDC system suitable for study

Partnership to establish strategies for License In & Out and find new pipeline

Strategic Alliance Partners

Certified, Qualified Clinical Trial Centers

Medical Device One-stop Service

Electronic Certification, MFDS, CE, FDA 510 (k), TÜV

Drug Development One-stop Service

Drug Development Plan, Material Analysis,
Non-Clinical Trial (GLP), Clinical Trial (Local / MRCT)

Doctors	Beds	Patients
(+)2,210	(+)2,911	(+)12,000

Our strategic CTCs are specialized clinical trial units that can help to recruit patients and centrally coordinate clinical trials.

6 Hospitals (ISO 14155) Partners

중앙대학교병원 CHUNG-ANG UNIVERSITY HOSPITAL
Strategic Alliance MOU
Dec 2019

대한항암요법연구회 KOREAN CANCER STUDY GROUP
Strategic Alliance MOU
Jun 2020

아주대학교병원 Ajou University Hospital
Strategic Alliance MOU
Sep 2020

CHA UNIVERSITY BUNDANG WOMEN'S MEDICAL CENTER
Strategic Alliance MOU
Aug 2019

단국대학교병원 DANKOOK UNIVERSITY HOSPITAL
Strategic Alliance MOU
Oct 2019

KOREA UNIVERSITY ANAM HOSPITAL Korea Univ. Anam CTC
KOREA UNIVERSITY GURO HOSPITAL Korea Univ. Guro CTC
KOREA UNIVERSITY ANSAN HOSPITAL Korea Univ. Ansan CTC
Strategic Alliance MOU
Oct 2019

Dt&C Group

12 Companies , 6 Branch Offices in 6 Countries

Electrical Engineering Technology Service

Dt&C
KC / CE
Testing & Certification

DCJ
Software Verification & Validation (Japan corp.)

Dt&C VINA
Testing & Certification (Vietnam corp.)

Dt&C CHINA
Certification & Technology Consulting

LABT
ICT, Railway Specialized Testing & Certification

Dt&C Brazil
Certification & Technology Consulting

Dt&C Iran
Certification & Technology Consulting

Investment Service

Dt& Investment
Venture Capital

Dt&C BioGroup

Dt&SanoMedics

1 **Dt&SanoMedics Co., Ltd.**
IP, Device, OS, PMS, RWE
Contract Research Organization

Dt&CRO

2 **Dt&CRO Co., Ltd.**
Analysis Center, Non-Clinical Center
GLP/PK Analysis Facility

Huscience

3 **HuScience**
Central Lab for Clinical Trial

SAFESOFT

4 **SafeSoft**
Test Automation, Data Analysis, Data Control

The One Quality Needed for the Success of Your Clinical Trial

Electrical Engineering Technology Service

Dt&C
KC / CE
Testing & Certification

DCJ
Software Verification &
Validation (Japan corp.)

Dt&C VINA
Testing & Certification
(Vietnam corp.)

Dt&C CHINA
Certification &
Technology Consulting

LAB T
ICT, Railway Specialized
Testing & Certification

Dt&C Brazil
Certification &
Technology Consulting

Dt&C Iran
Certification &
Technology Consulting

Bio Technology Service

Dt&SanoMedics
Clinical Trial
Contract Research Organization

Dt&CRO
Analysis Center
Non-Clinical Trial Center

SAFESOFT
Software V&V and Development

Huscience
Central Lab
for Clinical Trial

Investment Service

Dt& Investment
Venture Capital

www.dtnsm.co.kr Linked in www.linkedin.com/company/dtnsm cdisc

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