



Creating Trust

Beyond Expectation, Beyond Borders

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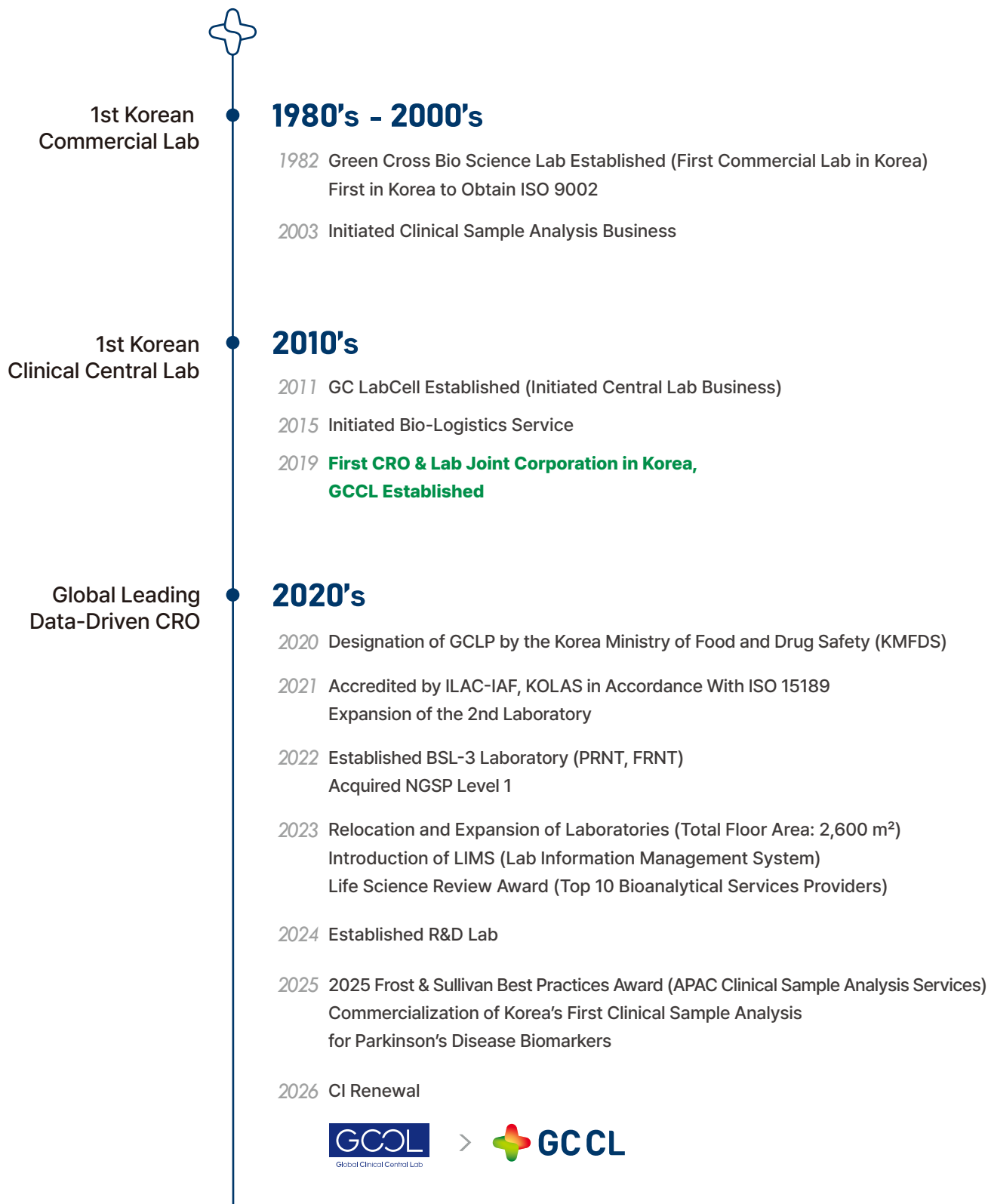
“Creating Trust”

Beyond Expectation, Beyond Borders

GCCL delivers **data-driven CRO** services
that enable successful clinical trials, built on high-quality bioanalytical expertise.



History

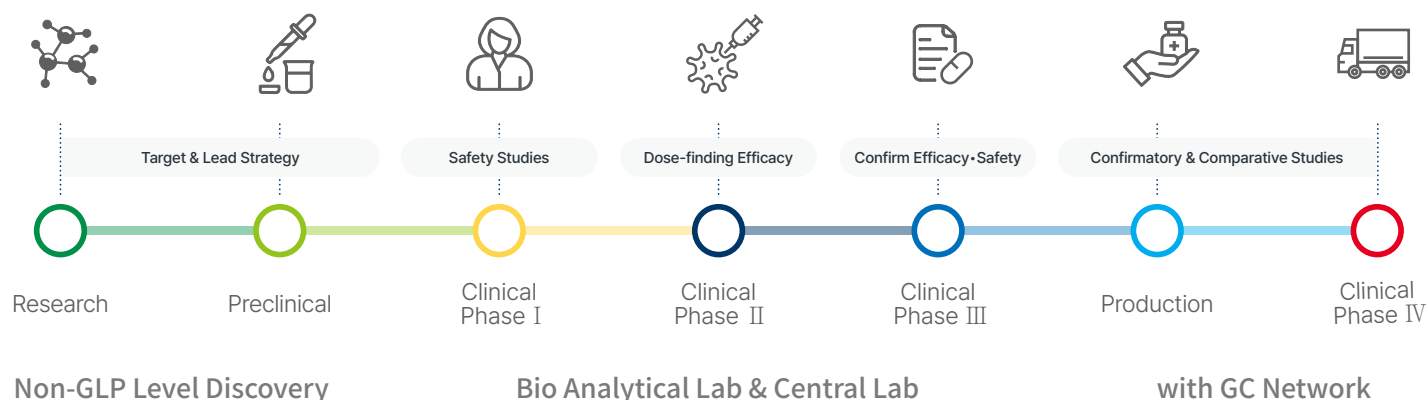


Key Facts & Figures



GCCL covers the **entire cycle** of new drug development

GCCL delivers end-to-end analytical solutions across the entire drug development lifecycle from early research to post-marketing Phase 4. Moving beyond fragmented service structures, GCCL provides integrated and customized analytical services built on its Bioanalytical and Central Lab expertise, while extending support to logistics and manufacturing through the GC Group network.



Accreditation & Award

• Accreditation



Good Clinical Laboratory Practice(GCLP) Accreditation



ISO-15189



EQA Proficiency testing Certificate



Intercomparison Programme Certificate



NGSP Level 1



CAP Certificate of Participation



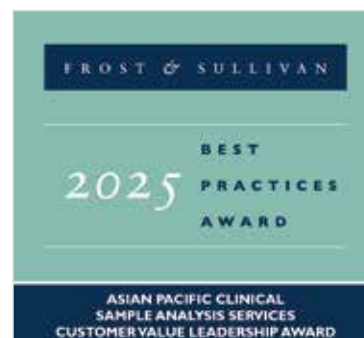
IBBL Certificate of Participation

• Award



Life Sciences Review

TOP 10 Bio-Analytical Services Providers in APAC 2023

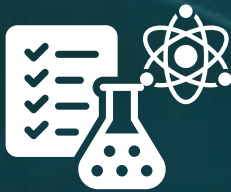
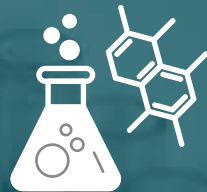


Frost & Sullivan

2025 Best Practices Customer Value Leadership Award in Asian Pacific Clinical Sample Analysis Services

Lab Service Scope

With an exclusive lab service available for its own logistics system and analyzing clinical trial samples that meet global quality standards, GCCL is building trust with over 350 worldwide partners by providing a sample analysis service spanning the entire cycle of clinical trials to meet customer demands.

 01.	 02.	 03.
R&D Lab • Method development & validation • Translational Research • Biomarker discovery • New technology evaluation	Bio Analytical Lab • Services -PK/PD • Biomarker Analysis -Neutralizing Antibody Assay with BL3 Facility -ADA Analysis • Platform -LBA(ELISA, MSD, Multiplex, SIMOA) -Flow Cytometry -ddPCR • qPCR -IHC(Immunohistochemistry) -Cell-based Bioassay -LC-MS/MS -ELISpot	Central Lab Analysis • 5,000+ tests -Immunology -Hematology -Pathology -Special Biochemistry -General Biochemistry -Microbiology -Molecular Genetics / Cytogenetics
 04.	 05.	 06.
Clinical Sample Management • Barcode system for sample management • Sample preprocessing and preparation (PBMC isolation, DNA/RNA extraction, etc.) • Biobank with RMS (Room temperature, refrigerated, frozen, cryogenic) • Temperature recording system when transporting samples • Establishment of sample storage environment and disposal procedure optimized for each project	Project Management • Review the clinical trial plan • Planning and reporting projects through G-HUB • Production and supply of lab kits according to protocol • Lab Instruction Manual • Central Lab Data Management • Sponsor / Site Communication • Bio Logistics Management	Bio Logistics • Offering overseas transportation service through outsourcing transport partners • Experienced in transporting samples overseas • Nationwide network bio-specialized cold chain transportation • Transport within 24 hours using the logistics network of 57 sales offices • Monitoring transport status through G-HUB

Facilities of GCCL's Laboratories

✦ Bio Analytical Lab | Central Lab | Storage Facilities



Bio Analytical Lab



LC-MS/MS Lab



MSD



Central Lab



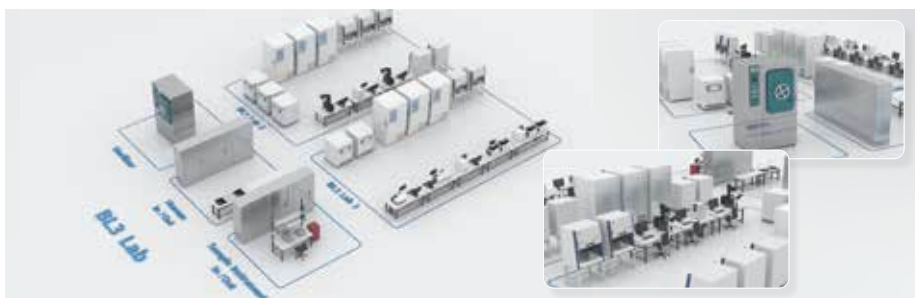
Storage Management



Lab Kit 제작실



Liquid Nitrogen



Bio-safety Level 3 Lab

R&D Lab

Biosimilar | Biologics | Biomarker

GCCL's R&D Lab was established to develop technologies for clinical sample analysis and conducts a wide range of R&D activities. In 2024, the lab successfully developed PK and immunogenicity assays for biosimilar drugs, analytical methods for key biomarkers related to CNS diseases, and stability studies for FACS sample analysis.



Services

- Method development & validation
- Translational research
- Biomarker discovery
- New technology evaluation



Features

- ✓ Reduce development risk
- ✓ Faster trial execution
- ✓ Accelerate clinical decisions
- ✓ Technological Advancement

+ Representative In-House R&D Lab Projects

Biosimilar

Proactively developed 6 analytical methods, including PK, ADA, and NAb, for blockbuster drugs like Keytruda, Yervoy, Perjeta, and Eylea.

■ Patent expiration



Spectral FACS

Spectral FACS technology allows simultaneous analysis of more biomarkers than traditional FACS, improving sensitivity and efficiency by collecting all signals on a single detector.

α-syn SAA

Developed a pathological blood biomarker analysis method for CNS diseases to detect α-synuclein, a key biomarker for Parkinson's disease, with high sensitivity.

NFL/GFAP Multiplex

Developed an in-house multiplex analysis method based on the MSD platform to simultaneously measure NFL and GFAP biomarkers.

Neurogranin

GCCL has developed a high-sensitivity analysis method using the MSD platform, enabling effective measurement of lower biomarker concentrations.

Multiplex ELISpot

The Multiplex ELISpot analysis method, which allows simultaneous measurement of multiple markers from a single PBMC, has reduced blood collection volume and costs in clinical trials while enabling the analysis of diverse immune responses.

Biomarkers



DNA Extraction for Shedding

The DNA Extraction for Shedding analysis method has achieved high efficiency even with challenging samples, such as saliva, and enables absolute quantification analysis through ddPCR technology, allowing flexible application in various clinical settings.

Cell-based Neutralization Assay

Leveraging years of experience in BL3 facilities, GCCL is developing neutralizing antibody assays for a wide range of viruses.

Stability of CD Markers in FACS

Through FACS analysis, we compared the stability of CD markers under various storage durations and methods.

Bio Analytical Lab

PK/PD | Immunogenicity | Biomarker | Method Development&Validation

01.

Method Development & Validation

- Consulting for test method development
- Development and validation of testing methods according to guidance by ICH M10, FDA, EMA, etc.
- ELISA, MSD, LC-MS/MS, qPCR, etc.



02.

Pharmacokinetics (PK)

- **LC-MS/MS**
Simultaneous metabolic analysis
Synthetic/improved new drugs, etc.
- **LBA**
Biologics, Antibody drugs, etc.
- **qPCR / ddPCR**
Cell & Gene therapy, etc.



03.

Immunogenicity (ADA / NAb)

- Screening and confirmatory tests, including Titer analysis, through method development and validation
- LBA-based analysis (ELISA, MSD) and application of cell-based assays (NAb)
- Applicable to biologics/antibody therapeutics and cell & gene therapies



04.

Pharmacodynamics (PD)

- Experience in analyzing over 250 PD markers
- **Blood**
Inflammation, Cytokine, Lipid, NGS, etc.
- **Tissue**
Multiplex IHC, NGS, etc.



05.

Biomarkers

- Comprehensive biomarker analysis services utilizing diverse analytical platforms
- **Singleplex** : ELISA, MSD, SIMOA
- **Multiplex** : Luminex, MSD, SIMOA
- FACS, qPCR / ddPCR, Sequencing, IHC, etc.



06.

Molecular Bioanalysis (qPCR / ddPCR)

- Quantitative nucleic acid-based analysis (DNA / RNA)
- **qPCR / ddPCR-based quantification**
VCN (Vector Copy Number), Shedding, Biodistribution, etc.
- Efficient nucleic acid extraction and analysis across various sample types, including DNA extraction for shedding



By Indication

Oncology

- Providing biomarker and PK analysis for CNS diseases such as Alzheimer's and Parkinson's
- Mass spectrometry and ultra-sensitive immunoassays
- In-house biomarker development
- Amyloid beta(1-40), GFAP, NF-light, Total TAU, pTAU-181, pTAU-231, BDNF, NSE, etc



Infectious Disease

- High-quality analytical platform and biosafety facilities (BL2/BL3) suitable for clinical trials of vaccines•therapeutics• in vitro diagnostic devices
- Established neutralizing antibody assays (PRNT/FRNT)
- Providing specialized bio-logistics services



Central Nervous System Disease (CNS)

- Most experienced including immuno-oncology and targeted therapy
- PK/PD analysis
- Biomarker analysis (RUO kit & LDT)
- Various platform (MSD, FACS, SIMOA, etc)



Platform



LC-MS/MS
TQ 6500+



FACS
FACSLyric BD



ELISPOT Reader
Eli.Scan Plus Reader



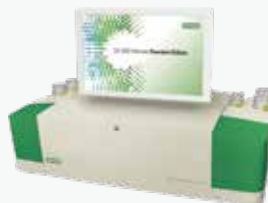
Multiplex
Luminex 200



Real-Time PCR
7500 Fast Real-Time PCR



DNA/RNA Extraction
King Fisher Flex



ddPCR
BIORAD QX One



Meso Scale Discovery
SQ120MN

Laboratory Information Management System

Purpose

To meet global standards by introducing LIMS (Laboratory Information Management System) used by the global pharmaceutical companies and CRO including USA FDA

Applicable Fields

- Development program for small molecule drug
-Pharmacokinetic Analysis
- Development program for large molecule drug
-Pharmacokinetic Analysis
-Immunogenetic Analysis

Characteristics

- Quick and accurate result confirmation
- Supporting systematic analysis history archiving and inquiry function
- Support for preparation of analytical method validation report/clinical test sample analysis result report required for global approval (meeting ICH M10 requirements)
- Reliable maintenance support (system improvement through data backup and periodic updates)

Introducing LIMS for the First Time in a Korean Lab CRO

Watson LIMS™, Thermo Fisher Scientific

Expected effects

- Supporting global approval (NDA/BLA)
- Guaranteed quality and reliability through systematic, efficient management of analysis result
- Reduction of the report production period

Central Lab

Safety & Efficacy

GCCL performs diagnostic, medical, and pathological tests required for clinical trials. We offer over 5,000 tests, ranging from general assays to specialized molecular genetic testing, providing analysis of safety and efficacy indicators in clinical trials.

01.

System Set-up for Study Initiation

- Lab Instruction Manual (LIM)
- Producing and providing sample collection kits
- Request for quotation form (RFQ)
- On-Site Training



Lab Instruction Manual



Sample Collection Kit

02.

System Set-up for Data Management

- Project-specific lab information system (LIS, G-HUB)
- Client portal service (result inquiry, application for lab kits, sample pick up)
- Electronic data transfer (EDT)



G-HUB



Sample Analysis Report

03.

Sample Biorepository & Disposal

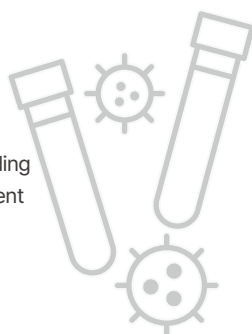
- Controlled ambient, refrigerated, frozen at -20°C , -70°C
- Liquid nitrogen at -150°C
- Temperature monitoring system (alarming on the problematic situation)
- Security surveillance system
- Sample disposal on specific date by medical waste specialized company



04.

Sample Preprocessing and Preparing Service

- Dedicated laboratory and team proceeding with sample preparation and management
- Sample preprocessing based on the client's protocol (Aliquoting, PBMC isolation, etc.)



05.

Sample Management and Shipment

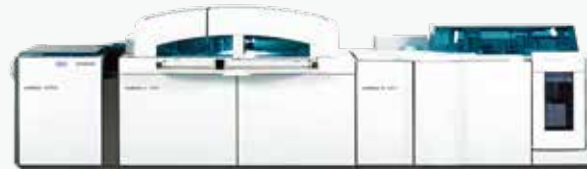
- Use of appropriate packaging for each sample and monitoring of the process for domestic and foreign transportation



Platform



FACS
FACSlyric™



Automated Chemistry / Immunology
Cobas 6000



Viral Marker
Architect i2000SR



Hematology
XN-1000

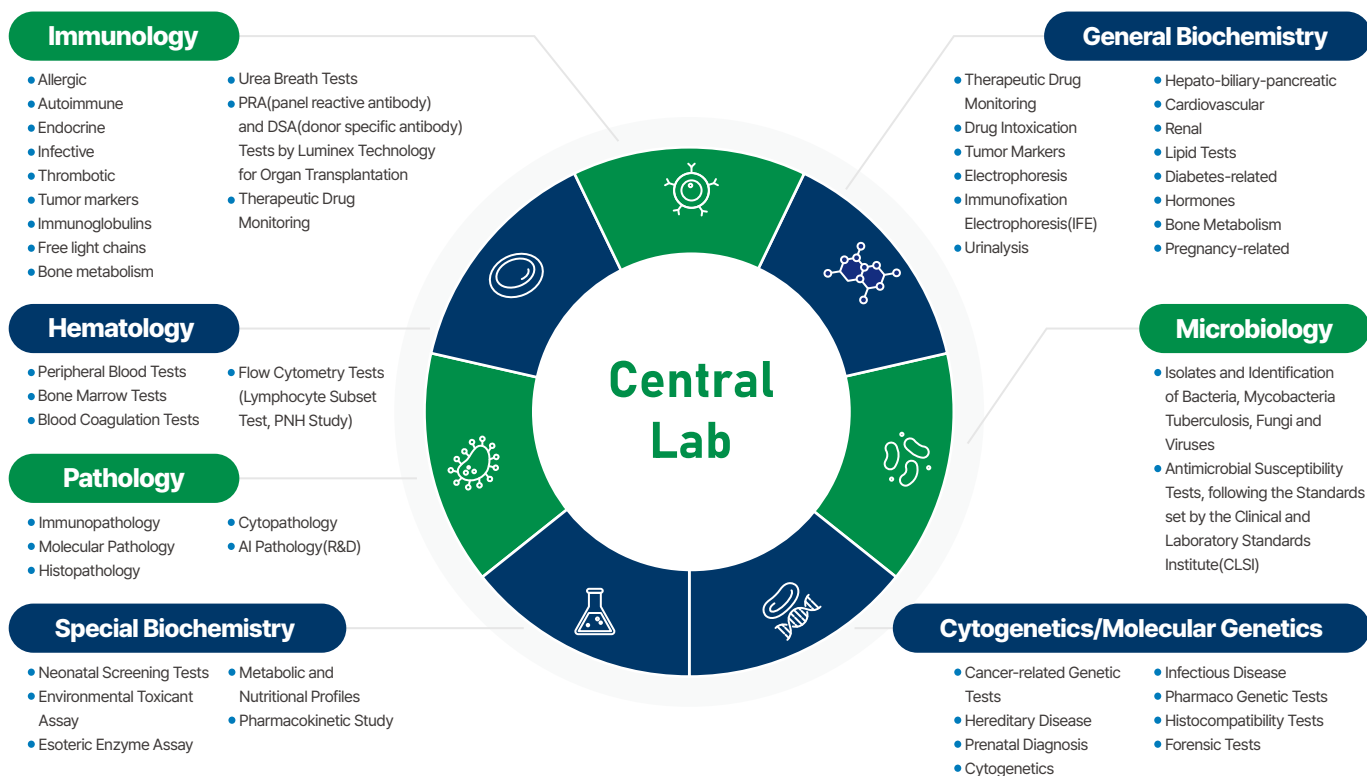


HbA1c Analysis
G11-HPLC



Urine Analysis
UC-3500

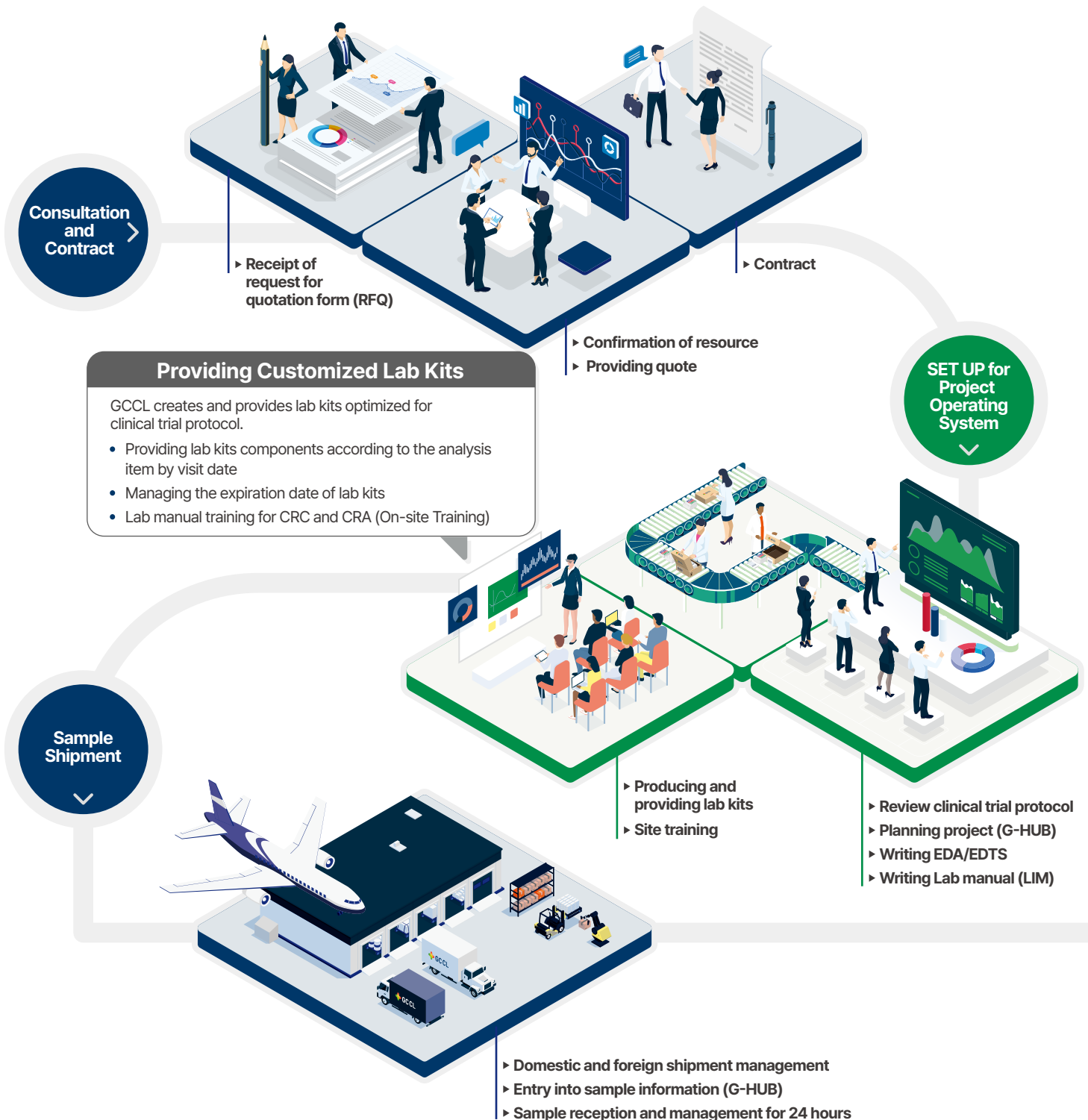
Central Laboratory Items

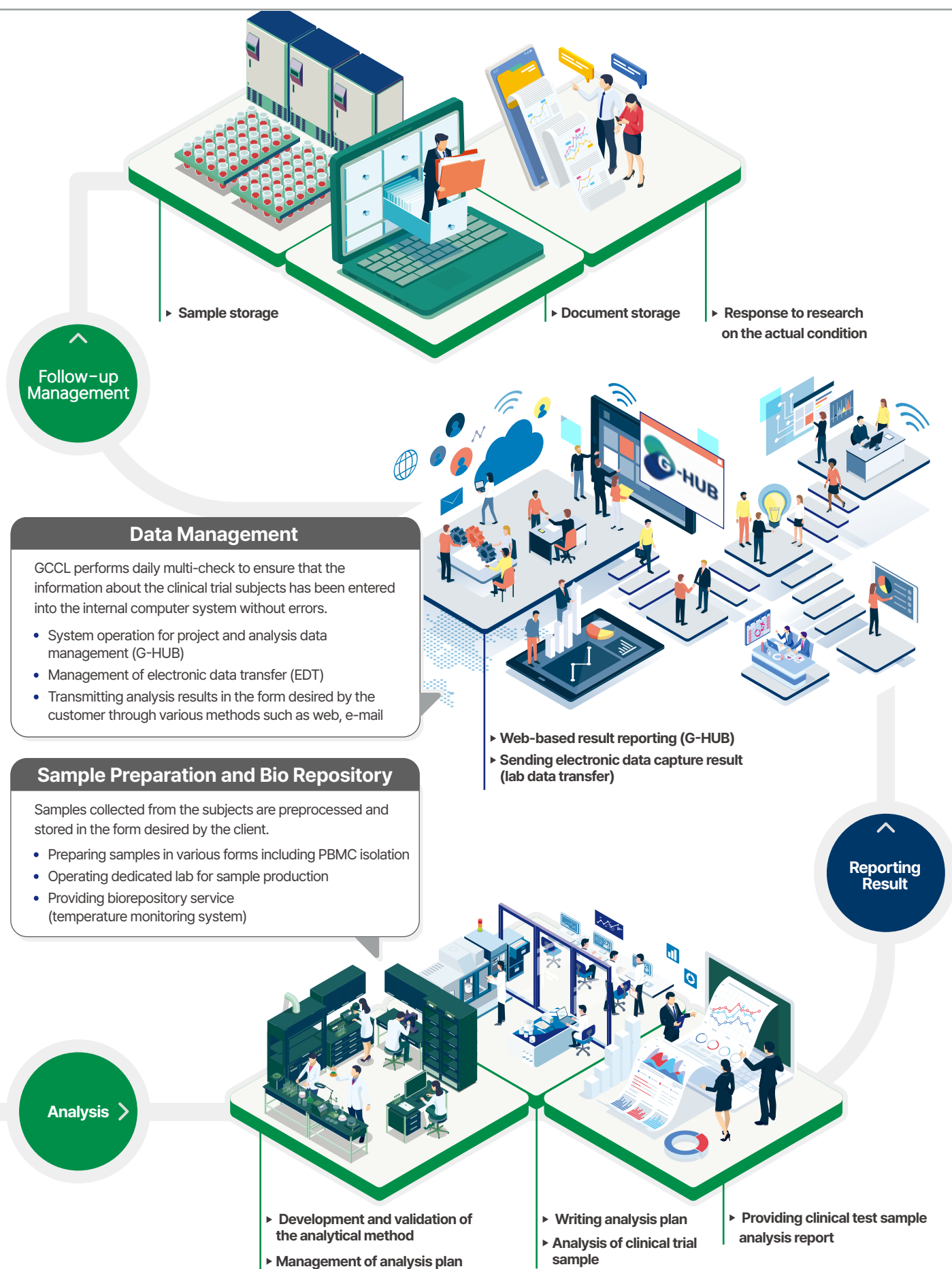


Project Management

Clinical Support Process

GCCL performs quality control throughout the entire process for efficient clinical trials and research analyses, and provides customized research support service for all projects.



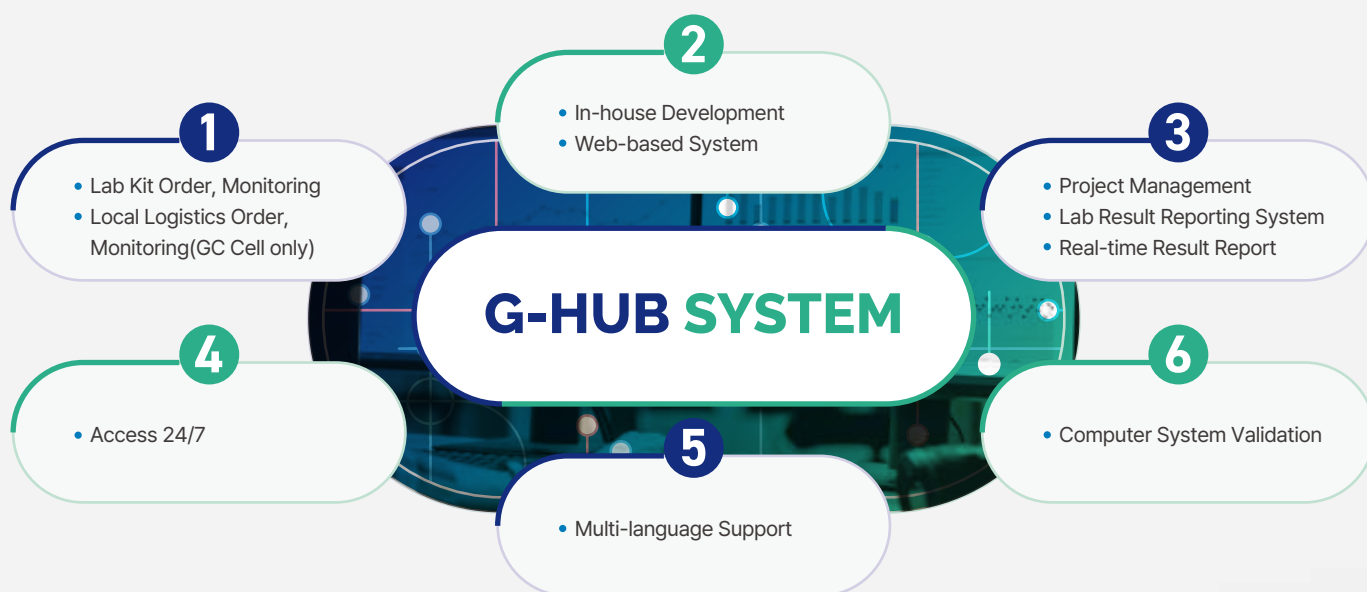




Client Portal for Integrated Supporting Services

G-HUB is an In-house developed on line platform of GCCL and manages client's projects and provides client portal service.

Features



Client Portal for Integrated Supporting Services

Analysis Result

- Downloading result report
- Processing data in Pdf, Excel format
- Compatible with various EDC programs

Lab Kits

- Ordering project-customized lab kits
- Receipt, expiry date, and inventory check available

Pick Up

- Domestic sample transportation pick-up service available
- Transportation history management



Bio Logistics

Clinical Trials • Bio Logistics | Global Forwarding

We professionally transport samples, blood, and sample collection kits(lab kits) that are sensitive to temperature and time.

Service

- A dedicated GCCL logistics specialist with proper training ensures an optimal logistics environment through appropriate packing and temperature control
- Overseas transportation management service provided through global courier
- Monitoring the entire process through the GCCL project manager
- Performing import and export business for sample, lab kits
- Providing solutions to reduce logistics costs and secure sample safety through local lab partners in each overseas region



Clinical Trial Logistics

- Clinical samples



Bio Logistics

- Shipment of infectious substances



Global Forwarding

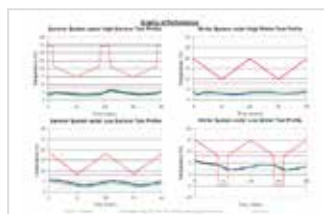
- Specimens and research samples, shipment of bio-related goods, etc.

Validated Packing Solution

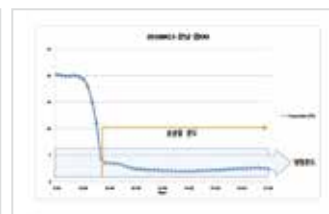


- Safe management of sample logistics through validated sample packing

Bio Logistics Monitoring System



Validation Report



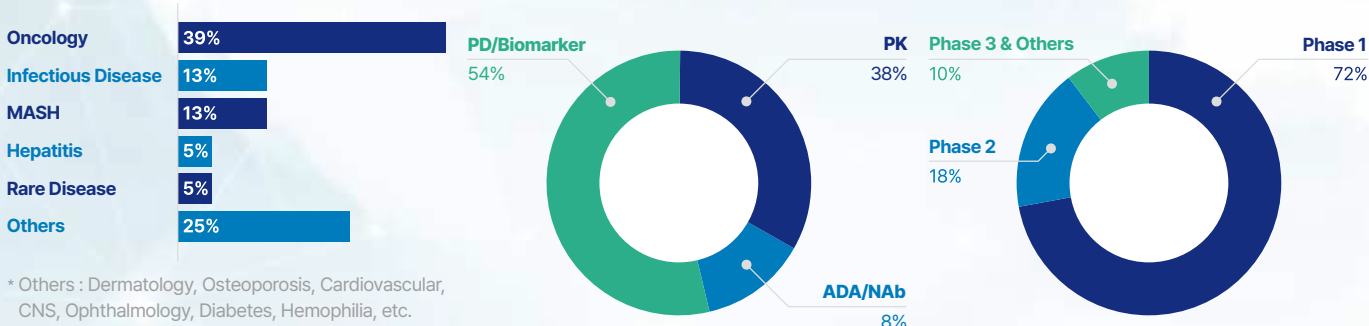
Temperature Log

- Monitoring transportation status through the project manager (tracking temperature and location in real-time)

Experiences

GCCL conducts various clinical trial analyses based on a state-of-the-art platforms and experienced staff.

Clinical Trial Experiences of Bio Analytical Lab



Global Compass



20+

Harmonization Labs



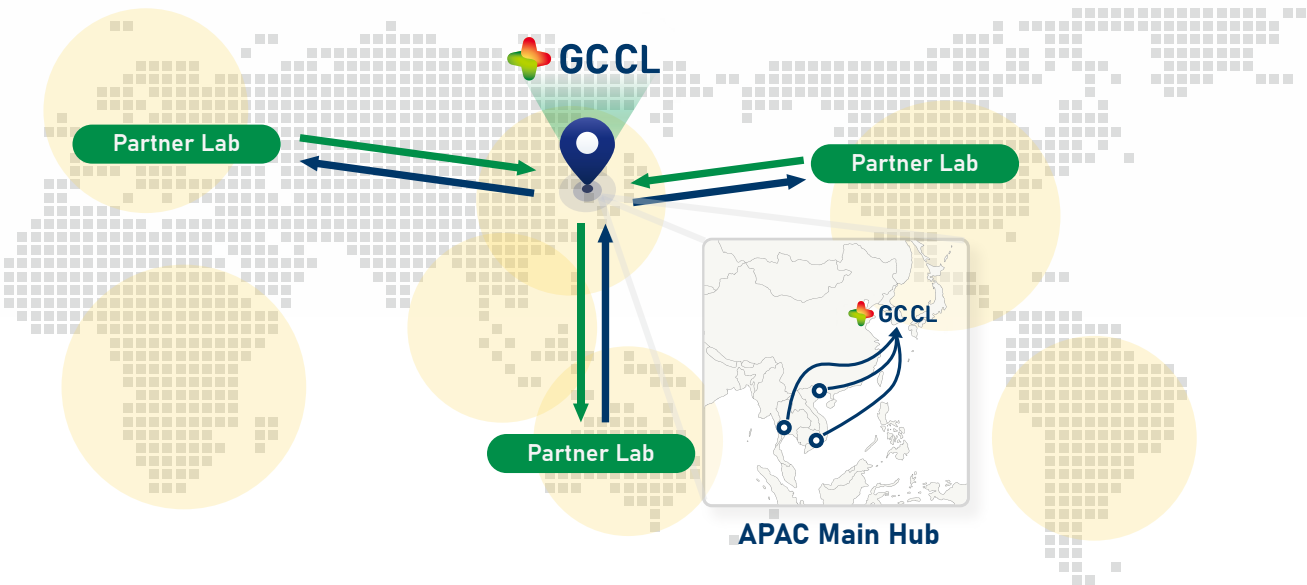
15+

Partner Labs



20+

Logistics Countries



● Experienced Site

Your Trusted Clinical Trial Laboratory Partner

Integrated bioanalytical and central lab solutions across every phase of clinical development.

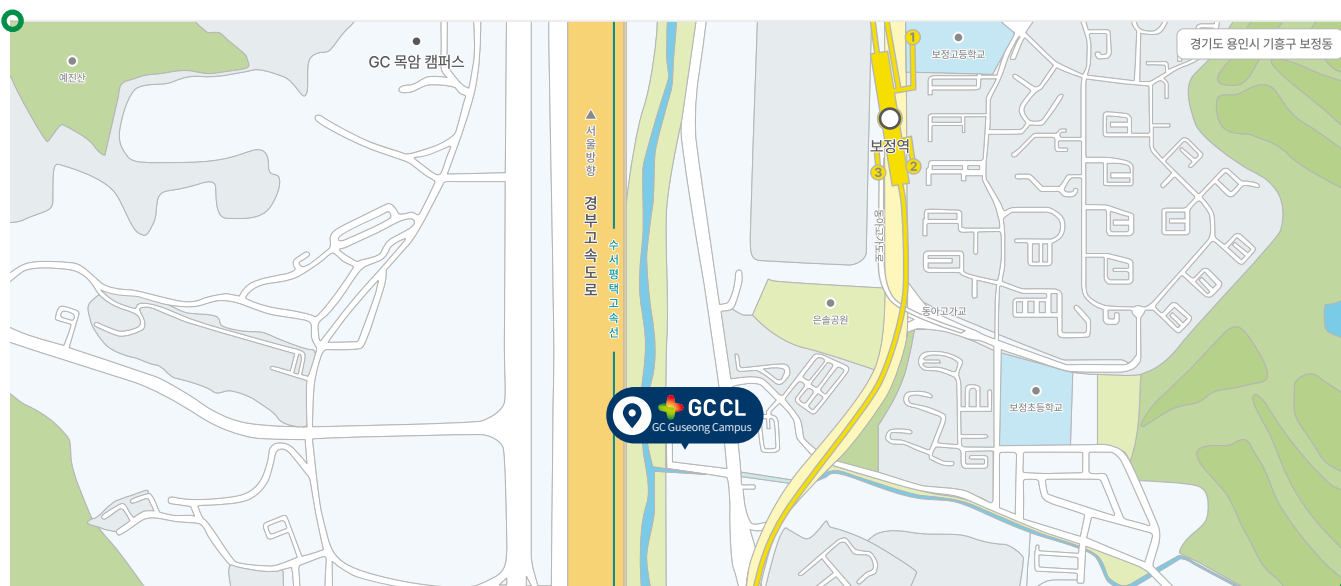


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