

# Immune-Mediated Inflammatory Diseases (IMIDs)

—— Central Lab Solutions for Clinical Trials



# Since 2008 In China for global

KingMylab is one of the earliest labs of its kind in China and a leading provider of central laboratory services for clinical research. We are committed to delivering scientific, compliant, and comprehensive one-stop laboratory and data service solutions for clinical trial, supporting pharmaceutical and biotech partners both locally and globally. Founded in 2008 as the Clinical Trial Department of Guangzhou KingMed Diagnostics(ICL)—China's largest clinical diagnostics corporation—KingMylab became an independent entity in 2020, continuing its pioneering role in central lab services.

KingMylab strictly adheres to the highest quality industry standards, such as the GLP/GCP regulatory requirements of the NMPA, FDA, and EMA. Our labs have all been accredited by the CAP, CLIA, and ISO15189, building an integrative clinical trial laboratory service chain that covers central laboratory services, bioanalysis, translational medicine, etc., laying a foundation for a diverse portfolio of clinical trial CRO services.



4000+

Central Lab Testing Menu



600+

Global Clients



80+

Technical Platforms



4000+

Clinical Trials



70+

Innovative Drugs  
Supported



100+

NMPA/FDA/EMA  
Inspections

# One-Stop central lab service platform for IMIDs clinical trials

In immune-mediated inflammatory diseases (IMIDs), a specific signaling pathway may participate in multiple disease processes, making it possible to treat different diseases with the same treatment. However, the diversity and complexity of IMIDs also bring many challenges to the design of clinical trial.

On the one hand, IMIDs generally involve a variety of diseases, such as dermatology, rheumatology and immunology, therefore a multidisciplinary team (MDT) is required to provide more comprehensive treatment options. However, implementing such multidisciplinary cooperation remains challenging in clinical practice. On the other hand, ensuring the trial validity, representativeness and safety has become a key issue in clinical trials.

KingMylab has supported over 100 clinical trials of IMIDs across more than 15 indications. We have extensive project management experience and a complete technology platform for detection of clinical trial diagnosis, eligibility, pharmacodynamics (PD) and safety biomarkers in this disease field, fully enabling supports for IMIDs drug development.



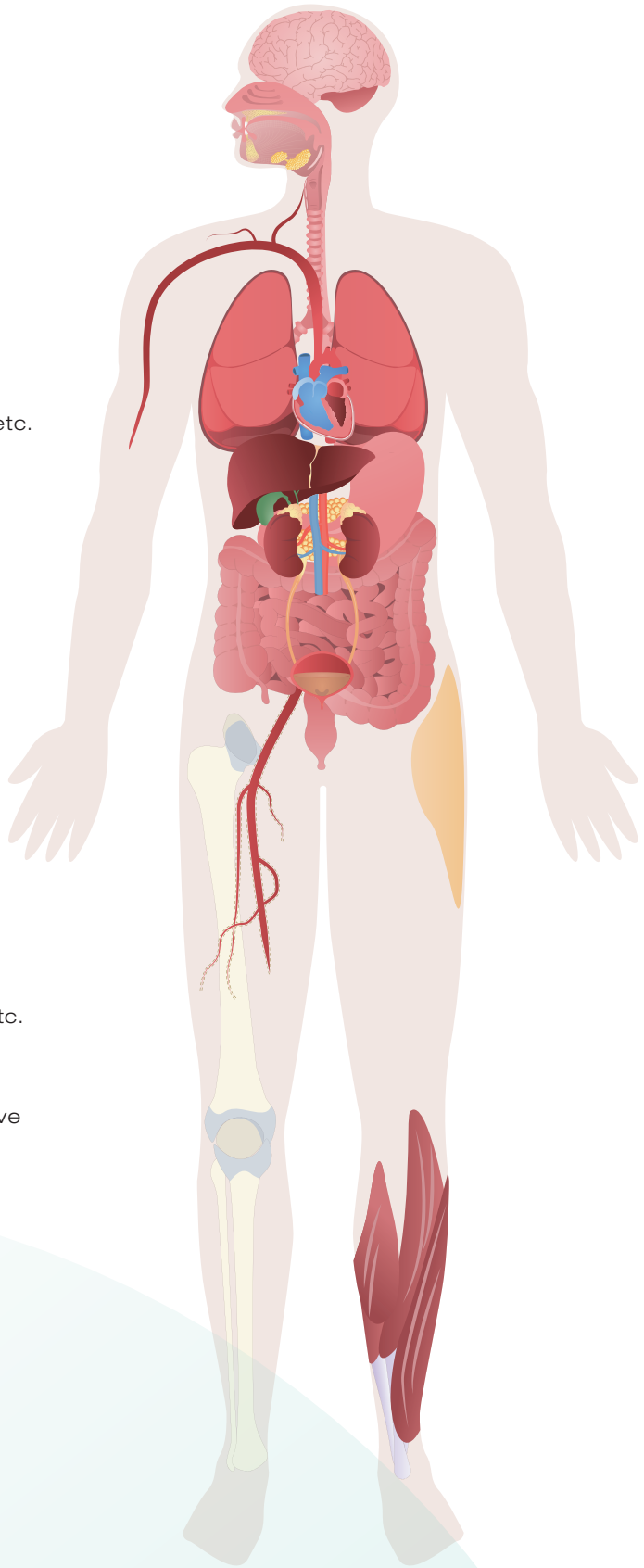
An experienced international team of scientific and management

17-Year proven compliant quality management system

Comprehensive and leading multi-omics platform integration

Rapid and high-quality delivery throughout the lifecycle

Multiple organs and systems



Rheumatic disease

• Systemic lupus erythematosus (SLE)

Eligibility/stratification tests:

ANA, anti-dsDNA antibody, anti-Smith antibody, antiphospholipid antibody, anti-RNP antibody, anti-SS-A antibody, anti-SS-B antibody, C3, C4, CH50, Coombs, etc.

PD tests:

SLEDAI-2K-related: C3, C4, CH50, anti-dsDNA antibody, and UPCR

BILAG-2004-related: anticardiolipin antibody, lupus anticoagulant, haptoglobin, and Coombs

Other immune markers: IgG, IgA, IgM, IgE, peripheral blood B-cell subsets, etc.

Inflammatory factors and cytokines: IL-6, IFN- $\gamma$ , etc.

Other biomarkers: based on MOA of the drugs

• Rheumatoid arthritis (RA)/Spondyloarthritis (SpA)

Eligibility/stratification tests:

RF, anti-CCP antibody, HLA-B27, hsCRP, HBV, HCV, HIV, TB, etc.

PD tests:

Disease activity: hsCRP

Exploratory markers: serum levels of IL-17A, IL-17F, IL-23, etc. (based on MOA of the drugs)

Neuromuscular disorders

• Multiple sclerosis

Eligibility/stratification tests:

CSF oligoclonal bands, peripheral blood B lymphocytes, HBV, HCV, HIV, TB, etc.

PD tests:

Lymphocytes: total lymphocyte count in peripheral blood, CD19/CD20 positive B lymphocyte count

Immunoglobulins: IgG, IgA, and IgM quantitation

Other biomarkers: PD markers (based on MOA of the drugs)

Inflammatory skin disorders

• Atopic dermatitis

Eligibility/stratification tests:

Total serum IgE, allergen-specific IgE, peripheral blood eosinophil count, HBV, HCV, HIV, TB, etc.

Exploratory PD markers:

Total serum IgE, allergen-specific IgE, peripheral blood eosinophil count, TARC/CCL17, hsCRP, LDH, IL-31, etc.

• Psoriasis

Eligibility tests:

HBV, HCV, HIV, TB, etc.

PD tests:

Disease activity: hsCRP

Exploratory markers: detection of skin biopsy tissue markers (FCM/mIHC/qPCR/NGS, etc.); serum levels of IL-17A, IL-17F, IL-22, etc., (based on MOA of the drugs)

Inflammatory bowel disease

• Ulcerative colitis (UC)/Crohn's disease (CD)

Eligibility tests:

HBV, HCV, HIV, TB, fecal culture, fecal *Clostridium difficile* test

PD tests:

Histological efficacy endpoints: endoscopic histology and evaluation

Efficacy-related markers: hsCRP, fecal calprotectin, HCT (calculated by CDAI)

Other biomarkers: T/B/NK lymphocyte subsets, C3, C4, cytokines, etc., (based on MOA of the drugs)

Inflammatory respiratory tract disease

• Asthma

Eligibility tests:

Peripheral blood eosinophil count, HBV, HCV, HIV, TB, etc.

PD tests:

Immunoglobulins: IgE, IgG, IgA, and IgM quantitation

Other biomarkers: peripheral blood eosinophil count, T/B/NK lymphocyte subsets, PD markers (based on MOA of the drugs)

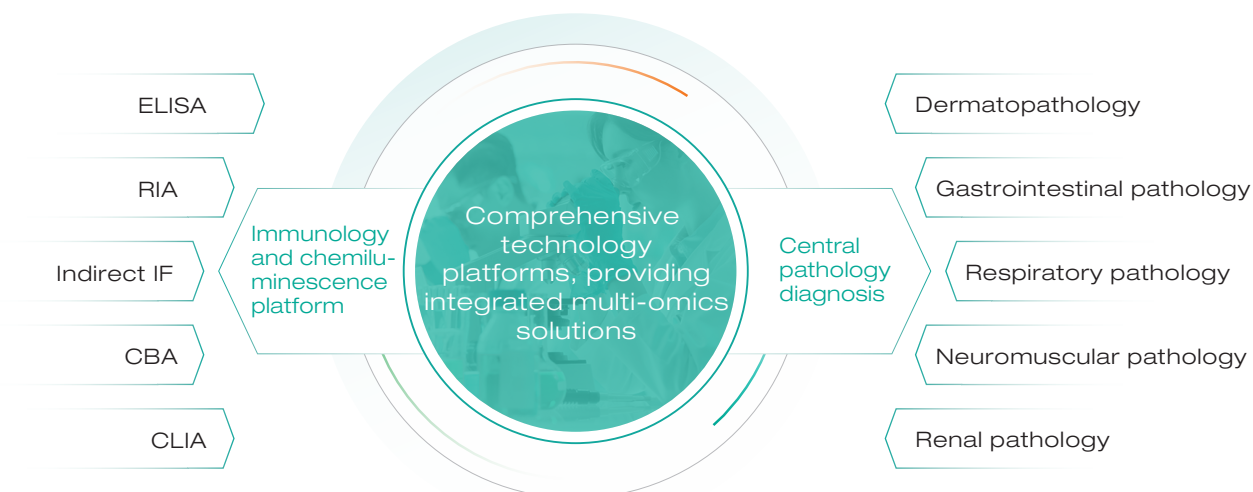
# International high-quality standards central lab

A quality management system based on international quality system standard CAP, CLIA, and ISO15189, which fully complies with clinical trial-related regulatory requirements such as GCP/GCLP regulations of NMPA, FDA and EMA.

Participated in and approved by CAP (College of American Pathologists) for **17 consecutive years**



**More than 10,000** clinical samples annually and a complete technology platform for detection of screening, eligibility, PD and safety biomarkers in clinical trials in specific disease area.



Chemiluminescence assay



Radioimmunoassay



ELISA



Transmission electron microscopy



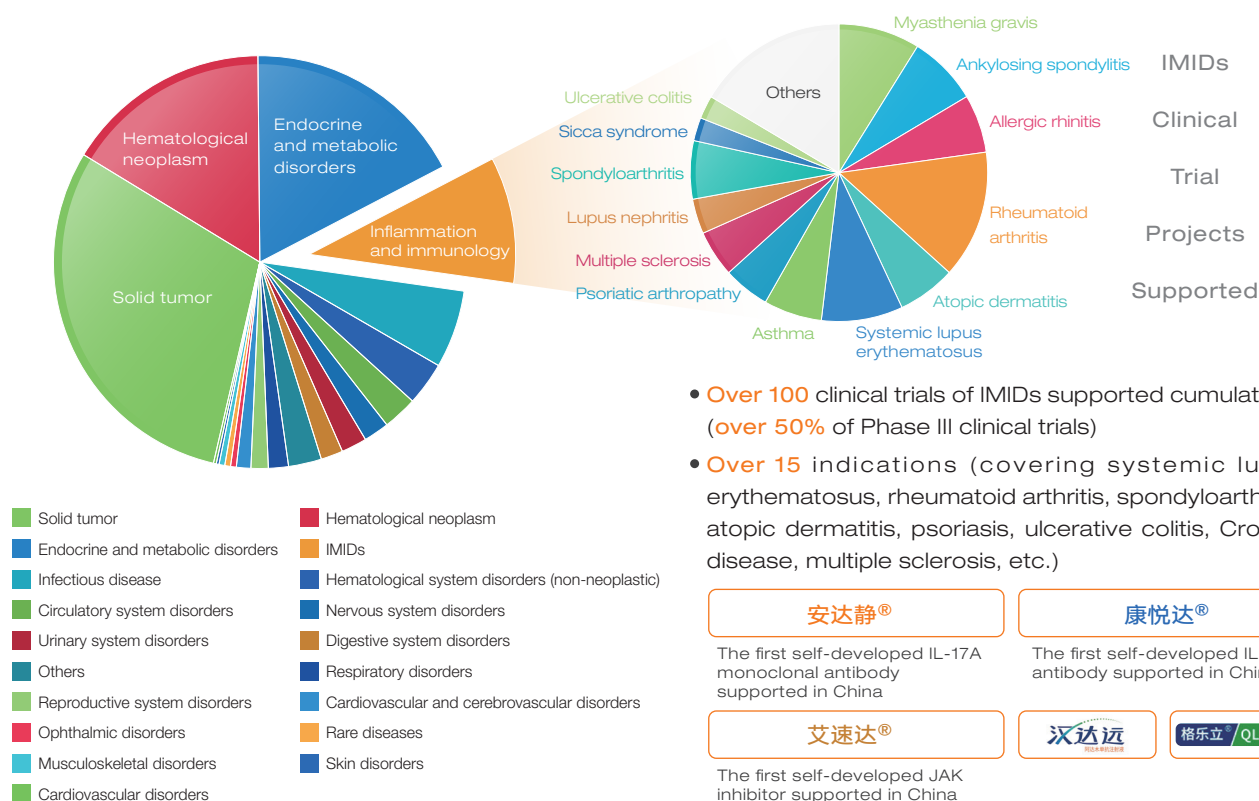
Scanning electron microscopy



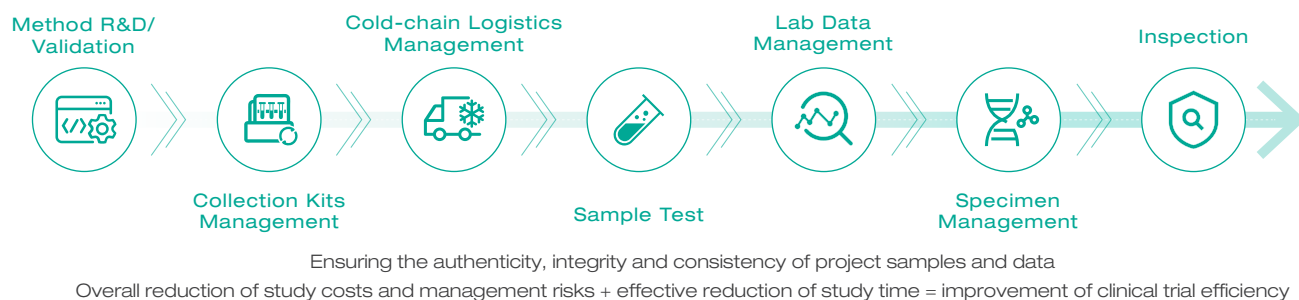
Central pathology diagnosis

# Rich IMIDs project experience accumulated to accelerate the development of innovative drugs

## 17 Years' Central Lab Service Experiences, 4,000+ Clinical Trials Supported



## Full lifecycle project management



## Digital empowerment



## Risk management system





Scientific, compliant, one-stop laboratory and  
data service platform for clinical trial



Accelerating drug development, advancing human health

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