

Vaccine Clinical Trials

——Laboratory Solutions

Laboratory services for vaccine clinical trials

The development of innovative vaccines, represented by those targeting RSV, HPV, and COVID-19, has introduced new challenges for laboratories, particularly in the assessment of immunogenicity and clinical endpoint-based protective efficacy. As a result, laboratories have become one of the key determinants affecting clinical research.

KingMylab has more than 10 years' experience in infectious diseases, immunological experimental development and clinical trial testing. Our global lab network meets the professional testing needs of vaccine clinical development. We have accumulated extensive project management experience across diverse vaccine clinical study projects. With a commitment to a scientific and rigorous quality management system, a leading and comprehensive technical platform, and rapid, high-quality delivery, and by integrating real-world epidemiological data, we provide a one-stop clinical trial laboratory and data service platform, including central lab, bioanalysis, and translational medicine, to support vaccine study and contribute to a healthier future.



「Central lab + Bioanalysis」

One-stop vaccine clinical study lab solutions



Subject screening and enrollment

Service item:

Pathogenic microorganism testing, biochemical immunoassay, etc.

Technology platform:

Cobas, Yaneng BIO, Abbott, etc.

Sample type:

Blood, swabs



Protective efficacy/immunogenicity

Service item:

IgG, IgA, IgM; immunogenicity; Authentic/pseudo virus neutralizing antibodies

Technology platform:

BA, Elispot, Flow, etc.

Sample type:

Plasma, serum, blood cells



Pathogen identification

Service item:

Viral typing, loading determination, etc

Technology platform:

NGS, mNGS, qPCR, LBA, Sanger sequencing

Sample type:

Blood, swabs, etc.



Safety monitoring

Service item:

Safety biomarkers, etc.

Technology platform:

Hematology, Blood biochemistry, Urinalysis, etc.

Sample type:

Blood, urine



Pathological examination and diagnosis

Service item:

Histopathology, cytopathology

Technology platforms:

IHC, ISH, FISH

Sample type:

Tissue, cell samples



Biomarker

Service item:

Clinical endpoint biomarkers, exploratory biomarkers, infection microenvironment, etc.

Technology platforms:

Mass spectrometry, LBA, Olink, NGS, FCM, PCR, mIHC

Sample type:

Blood, body fluids, tissue, etc.

International high-quality standards central lab

Based on CAP and ISO 15189 standards, strictly complies with GLP/GCP and regulatory requirements from NMPA, FDA, EMA, etc.

- CAP and ISO 15189 certification for **15 consecutive years**.

- **Qualification certificates**



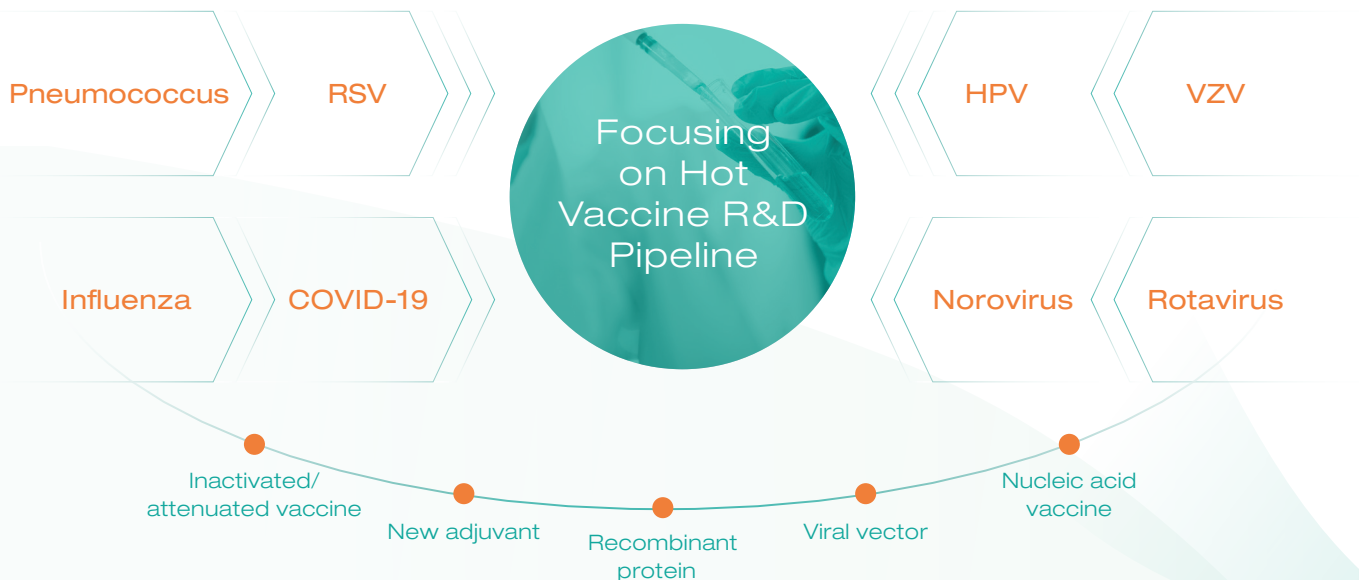
CAP certificate



ISO15189

Extensive experience in vaccine project service

KingMylab has accumulated extensive experience in the field of vaccine clinical trials. Since 2014, we have successively undertaken several clinical study projects such as HPV, COVID-19 vaccine and RSV at home and abroad. As of 2022, the Company has supported over 50% of domestic Phase III clinical trials for HPV vaccines and played a key role in the success of the first innovative multicenter clinical trial for HPV vaccines, which was approved for market launch in China's disease prevention and control system.



One of the **earliest** central laboratories for vaccine clinical trial in China.

One of the **most experienced** central laboratories in clinical trials of protective efficacy.

Laboratories in **Guangzhou, Shanghai and Hong Kong** cooperate to help global layout.

Meet the requirements of regulations, such as **NMPA, FDA and EMA**, etc.

Providing end to end project management

Experienced project management team

Project managers have been strictly trained and assessed, possessing excellent professional qualities and excellent organizational and coordination abilities. The team has successfully managed over 4,000 projects.

30%

Master degree or above

35%

More than 5 years of experience

65%

Experience in managing over 50 projects

50%

Experience in NMPA inspection

Digital empowerment

Lab-CTMS——Project operation management system

Project management:

Project operation protocol, visit plan and follow-up tracking, inspection item trigger rules, blind management rules, historical data comparison criteria, etc.

Data management:

Collaborating with the data management team to customize lab data process real-time logical audits based on clinical trial objectives, enabling remote data access and real-time data QC.

Sample management:

Sample life cycle management, backup sample classification management, etc.

Self-service:

Consumable kits application, logistics appointment, result reporting (alert value/critical value prompt, result trend), project data dashboards, etc.

KMCS

Central lab information system

Lab testing process management, from sample to data, minimizing manual recording errors.

Wason LIMS

Bioanalytical information system

Full process bioanalytical lab management.

Remote pathological system

Professional IRC service, whole process information management.

Based on risk management system

KPI management of central lab projects

RFP confirmation

Sample tracking

Assay development

Document traceability

Project design

Kit supply

CTMS system configuration

Deviation/Variation control

Quality control of first batch testing

Report/Data delivery



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



Accelerating drug development, advancing human health

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