

Vaccine Development Services

Eurofins Clinical Trial Solutions is your trusted partner to support your Vaccine Development programs. With over 40 years of experience, Eurofins Clinical Trial Solutions provide comprehensive support throughout all stages of vaccine development – from pre-clinical to human pharmacology studies [phase I], therapeutics exploratory studies [phase II], clinical efficacy and safety studies [phase III] and post authorization surveillance [phase IV]. With a high volume of samples distributed across multiple global regions, maintaining specimen integrity, ensuring rapid turnaround times, and enabling global data access are vital to reliable outcomes.

Global Laboratory CRO to Support Multi-center, Multi-country Studies in over 85 Countries

- 6 dedicated testing facilities in USA, Europe and Asia
- 3 wholly owned Kit Packing and Distribution facilities
- Access to the broader Eurofins BioPharma Services global network of 85+ laboratories
- Global PBMC Processing services

Regulatory Compliance

- Non-clinical and GLP regulatory frameworks
- Applicable Good Clinical Laboratory Practice (GCLP) standards
- 21 CFR Part 11 where applicable
- CAP/CLIA

Assay development, validation and testing for the Moderna mRNA-1273 COVID-19 vaccine clinical trial

- Development of SARS-CoV-2 RT-PCR test, performed on all Phase II & III clinical trial samples
- Spike-gene sequencing assay (SARS-CoV-2 S gene NGS assay) and Whole Genome Sequencing (WGS) assay performed on nasal swabs to assess SARS-CoV-2 variants in the study population
- RT-qPCR assay designed by Eurofins Viracor, has also now been utilized world-wide to provide >20 million COVID-19 infection results

World Renowned Assay Development and Testing Capabilities

- Assay development, transfer, and fit-for-purpose validation
- Safety and Efficacy Testing
- Immunoassays including
 - ELISA
 - Luminex® Microbead arrays
 - MSD® electrochemiluminescence
 - ELISpot
 - Flow Cytometry including 25 Color NovoCyte® Quanteon™ and BD FACSymphony™ A5 (27 color)
- Immunogenicity, ADA and NAb Testing
- Biomarkers
- Molecular Testing including
 - qPCR, RT-qPCR, ddPCR
 - NGS and Sanger sequencing
 - Respiratory Pathogen Panels

Matrices

Tissue, Blood, Serum, Plasma, Saliva, Oral Mucosa, Nasal Swab, Nasal Lavage, Pulmonary Lavage, Urine, Stool, Occlusive Dressings, Surface Lesions, Anogenital Area

VACCINE TRIAL EXPERIENCE

EBV | CMV | HPV | ZIKA

CHIK | RSV | Influenza | SARS-CoV-2

BKV | HCV | HHV (6/7/8) | VZV | Denque

HTLV | JCV | HDV | HEV



Eurofins Kits Packing and Distribution

- 3 wholly-owned Kit Packing and Distribution facilities in USA, Europe and China
- Over 25 years of experience providing sample collection kits for Clinical Trials, Commercial DNA Testing, Clinical Monitoring Programs and Post Marketing Surveillance, both inside and outside the Eurofins network
- High quality specimen collection kits distributed worldwide to 85+ countries

Eurofins provided support to multiple SARS-CoV-2 mRNA vaccine protocols

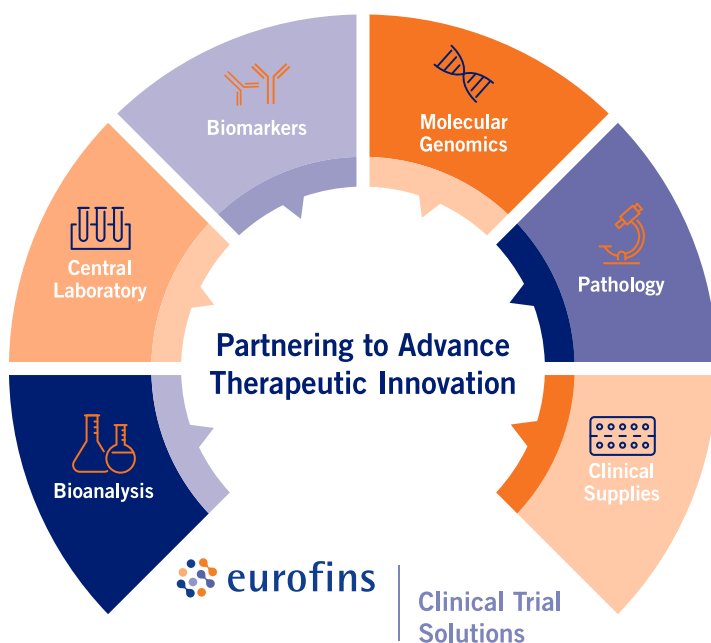
- One of the programs enrolled more than 40,000 healthy participants in multinational trials in Europe and Latin America
- Program included rapid study set-up and pre-planned wave-based distribution of specimen collections kits
- 100% paperless requisitioning for sample tracking from site through final analysis

For more information, please contact
clinicaltrialsolutions@bcl.eurofins.com



Global PBMC Processing

- Eurofins Clinical Trial Solutions harmonized laboratory locations worldwide
- Global service offers effective harvesting, processing, and cryopreservation of PMBCs
- Experience supporting different sponsor-defined processing protocols
- Specialized downstream testing services include immunophenotyping using Flow Cytometry, functional assays [ELISPOT], cytokine profiling using MSD, and ELISA, and molecular genomic analysis including qPCR and sequencing



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