

# Your Unique Path to Vaccine Development

The diverse nature of the pathogens and diseases that are being targeted combined with the intricacies of the human immune response exponentially increases the complexities of vaccine development. At Celerion, we understand the importance of timing, experience and flexibility for the successful execution of a vaccine study. We provide access to experts and regulatory guidance throughout your drug development. We have the experience and expertise to provide counsel to your crucial early clinical development as well as pivotal efficacy and safety studies.

## Leaders in Vaccine

Celerion is a global leader in First in Human through Proof of Concept clinical research services. Our unique combination of medical expertise, clinical operations experience and scientific excellence gives you the confidence to make fast accurate decisions about your vaccine development program.

## **Clinical Operations**

- Our experienced teams ensure close coordination between all functional areas, sites and vendors to assure operational excellence.
- Our experienced staff can manage complex blood sample handling, storage and shipping logistics assuring safety and tolerability can be properly assessed.
- Our flexible solutions provide you with as much or as little assistance as you need including: medical or safety support, integrated data management, bioanalytical support, biostatistics and medical writing services.

## **Project Management**

- Our highly skilled project managers and streamlined processes will save you valuable time and budget, allowing you to focus on what you do best.
- Attentive team oversight ensures efficient communication across all divisions, allowing early risk/problem identification and implementation of mitigating or corrective actions.

#### **Clinical Monitoring**

- We precisely tailor a monitoring plan to your unique study. Celerion's proprietary CORE Monitoring approach is a compliance-oriented monitoring process, designed to accommodate the conditions of each study site. CORE is often complemented with risk-based monitoring.

## **Bioanalytical Sciences**

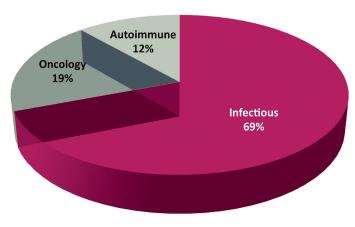
- Celerion's industry-leading bioanalytical sciences lab provides a unique resource to aid in the development of vaccines in an efficient and cost-effective manner. Our bioanalytical sciences team is skilled in developing innovative, precise, custom assays in collaboration with our clients.

> - We develop innovative methods to determine the percentage of functional antibody capable of producing a bactericidal effect, neutralizing a virus or toxin, or eliciting a specific immune cell response

## Clinical Development

Celerion has proven experience across a variety of vaccines including different routes of administration, and patient populations. Our track record spans both preventive and therapeutic vaccines, subunit and conjugates across all phases I-IV in more than 20 countries, 300 study centers and 4500 subjects.

## **Proven Vaccine Experience**



#### **Infectious Diseases**

- 206 sites - 3,935 subjects

## **Oncology Vaccines**

- 62 sites - 150 subjects

#### **Autoimmune Diseases**

- 73 sites - 765 subjects

### **Experience**

Infectious: Chikungunya Virus, Clostridium difficile, Japanese Encephalitis, Lyme borreliosis, Poliomyelitis,

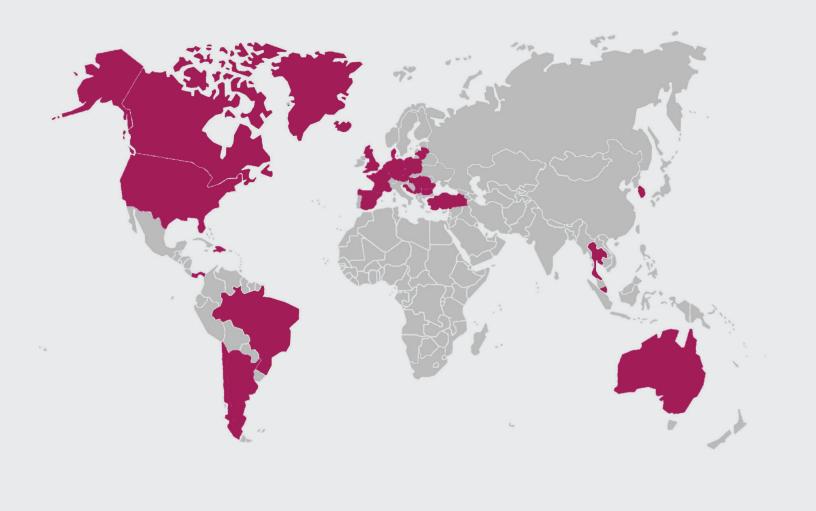
Pseudomonas aeruginosa, Togaviridae, Vaccine Enhancement Patch (Influenza Antigen), Zika

Virus

Autoimmune: Crohn's Disease, Rheumatoid Arthritis, Systemic Lupus Erythematosus



## Celerion's Vaccine Experience Around the World



## **COMMITMENT TO SERVICE EXCELLENCE**

Celerion is derived from the Latin celeritas meaning swiftness and speed. This word reflects one of our founding principles: to deliver services that enable you to get products to market faster.



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