The ABCs of Vaccine Development

Whether a vaccine is being developed as part of a preventative or treatment measure, the regulatory, bioanalytical and clinical steps are similar. Preventative vaccines are given to avert future disease caused by an infectious agent such as Influenza virus and more recently for Coronaviruses. On the other hand, treatment vaccines are dosed as part of therapy for a disease that is already established in the body (e.g. cancer, autoimmune disease).

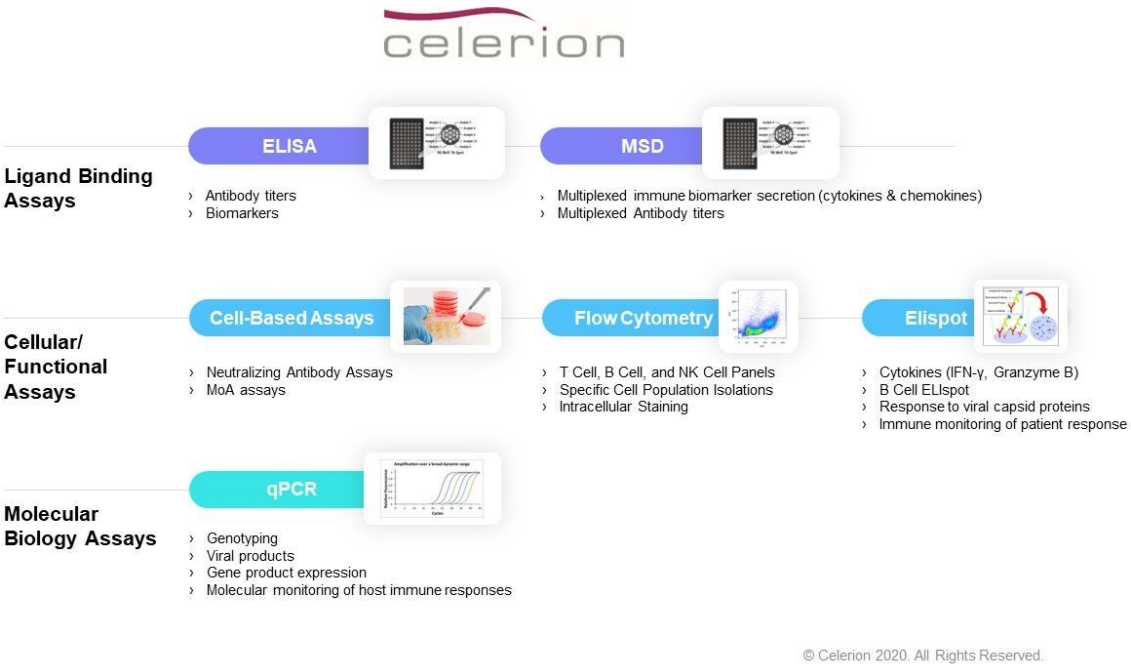
To establish adequate vaccination, an immunogenic agent or antigen is administered to elicit an immune response in which antibodies are created that recognize and bind to specific protein or genetic segments. Once the antibodies detect an antigen, this initiates cell-mediated signaling to sequester and clear a virus or bacteria from the body. The antigen can be part of a live attenuated or inactivated microorganism, produced synthetically, or created using recombinant RNA or DNA technology. In most situations, the immune system retains the ability to recognize and destroy future exposures to the specific antigenic site, however for some cases a booster vaccine is need to maintain immunization.

Celerion, a full service CRO, has successfully executed more than 30 vaccine trials within the past 5 years. With extensive experience and expertise, we apply an ***ABC*** approach to **vaccine development**.

➢ ***Advanced*** **technological assay platforms for antigen and antibody titer response.**

Celerion Bioanalytical Laboratories located in Lincoln NE and Zurich Switzerland offer an array of **assay technology** for vaccine development. Ligand binding methods are utilized for antibody titers both binding and neutralizing antibodies. Cell-based assays are required to confirm neutralizing activity of the assays, and qPCR for to measure viral load and production. Ligand binding assays and multiplex immunoassay platform such Meso Scale Platform can also be helpful to measure immune cytokine and chemokines, while immune cell populations can be monitoring via flow cytometry and ELISpot. In addition, we employ a regulatory compliant tiered approach for biomarker assay validation to satisfy a given context of use.

In some cases, it is important to measure adjuvant concentrations as well. Adjuvants such as aluminum salts or monophosphoryl lipids are chemicals that stimulate a more robust immune response. Celerion has state-of-the art LC-MS/MS capabilities to measure the adjuvant level in biological matrices.



- ***Building*** **upon our proven vaccine track-record.**

A good proportion of our vaccine experience lies with Phase I/II studies in healthy volunteers. The benefits of investigating an innovative or prophylactic vaccine in healthy participants prior to patient dosing are significant. These include confirming safety, immunogenicity, evaluating the need for booster vaccination, and optimizing the dose regiment. Furthermore, it may be important to access subjects that are naïve to the antigen or have low titer levels to evaluate safety and immunogenicity. In addition, a Phase I setting can efficiently explore the safety profile of vaccines with or without adjuvant or novel adjuvant formulations.

For certain indications such as influenza, a viral **challenge test study** in healthy subjects can provide valuable early insight into drug efficacy. Our Clinical Pharmacology Units pharmacies are equipped with specialized Bio-Safety Level (BSL-2) negative pressure cabinets and regulatory certifications to process live Class 2 and 3 biological products.

- ***Cohesive*** **transition from healthy volunteers to patient studies.**

Celerion has a global vaccine site network with access to patients in endemic locations for late stage clinical trials to evaluate treatment or establish extent of vaccine protection. Our multi-site clinical trials experience ranges from infectious disease to autoimmune and oncology vaccines. Our external sites include travel and outpatient clinics as well as hospitals with **intensive care units**. Connecting our Sponsor with Key Opinion Leaders in the disease area of interest early on during protocol development provides our clients with expert advice and solutions for difficult to recruit populations.

Our infectious disease vaccine experience includes: Chikungunya Virus, Clostridium difficile, Japanese Encephalitis, Lyme borreliosis, Poliomyelitis, Pseudomonas aeruginosa, Togaviridae, Vaccine Enhancement Patch (Influenza Antigen), Zika Virus, Yellow Fever.

In all, Celerion has streamlined the process of transitioning from healthy volunteers into patients, ensuring the highest quality data and bioanalytical support at every step while providing ***Global Access*** with ***Local Expertise***.

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Translating Science to Medicine

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