The need for multi-site Phase I studies is driven by a trend towards hybrid studies exploring drug effects in patients

celerion

Translating Scientific Ideas into Potential Medicines

Celerion is a premier global provider of early clinical drug development services to the pharmaceutical industry, and its track record spans both preventive and therapeutic vaccines, subunit, and conjugates, as well as antiviral agents and (passive) antibody therapies across all phases I-IV in more than 20 countries, 300 study centers and over 5000 subjects.

Zori Cheshmedzhieva is the **Vice President, Global Clinical Development** at Celerion. She is leading Celerion Global Clinical Development services across Europe and North America with direct line management of Operational team including Project management, Budgeting and Proposal preparation, Feasibility and start-up, Site management.

When was Celerion founded and what is its current market position like?
This year, Celerion is celebrating its 10th anniversary. When founded in 2010, the name Celerion was derived from the Latin word celeritas, meaning swiftness and speed, to reflect the high quality, speed, and efficiency of services that we provide. Our early clinical development and bio-analytical divisions are built upon the legacy of MDS Pharma Services and Harris Laboratories, and, thus, we can rely on more than 40 years of experience in this field. Today, Celerion is the leader in accelerating drug development for Phase I–IIb.

As one of the world's leading CROs in early clinical development, we offer clinical services ranging from First-in-Human studies to Proof-of-Concept and larger Phase II studies. These are exactly the stages of drug development during which our clients need to make critical go-no-go decisions on their investigational products. Any further investments in the candidate drugs are strongly driven by early signals of drug efficacy, in addition to favorable safety profiles. Celerion has a unique combination of competencies allowing it to extend exploration of drug effects from healthy volunteer studies to patient populations. We recruit healthy subjects in our internal clinics and through our network of external sites – but we also execute studies in patients at our in-house or partnering clinics.

What measures have you taken to stay one step ahead of your competition?
Well, irrespective of COVID-19, we have always been able to innovate our services over the years and optimally adapt to the needs of our clients. But 2020 is the year that COVID-19 changed the world, including the way trials can and should be conducted. So perhaps the way we adapted our services illustrates our ability to adapt our operations swiftly and remain a leading provider of early clinical research services.

In response to the pandemic, we immediately drew up Risk Mitigation Plans and incorporated novel working procedures and facility changes to accommodate COVID-19 concerns, all in line with regulatory guidelines and local public health regulations. We also implemented a broad package of protective measures for the safety of both study participants and staff and created more bed and lab space. Altogether, these measures enabled us to re-open our clinics and resume trial activities in May of this year.

Our bioanalytical labs, which have a long standing experience with vaccine-related analyses, have developed various assays in the context of COVID-19, ranging from PCR tests for SARS-CoV-2 to specific antibody assessments for IgG, IgM e.g. against the Spike protein – not only to enable in-

house screening for infection, but in particular to support the development of vaccines and anti-viral drugs targeting COVID-19.

Moreover, due to the impact of COVID-19 clinical trial conduct, a rapid expansion of virtual clinical trials was made. These trials take full advantage of virtual technologies (apps, monitoring devices, etc.) and online social engagement platforms to conduct aspects of each stage of the clinical trial from the comfort of the patients' home. This includes recruitment, informed consent, patient counselling, as well as measurements of clinical endpoints through deployment of wearables, ePRO and other tools/devices. We assist our clients in determining the most appropriate approach for their study, ranging from fully virtual to traditional trial execution.

How did the landscape of clinical trials change and how relevant was that for your role?
Celerion has always focused on the earlier stages of clinical drug development, in addition to bio-analytical services.

In the 10 years of its existence, the need for multi-site, exploratory studies has steadily increased. On the one hand, this reflects a trend towards hybrid studies, combining conventional safety and tolerability studies with early exploration of drug effects in patients.

On the other hand, vaccine trials do not necessarily need the highly specialized clinical research unit environment that many Phase I trials demand and may also recruit faster if multiple sites enroll participants.

With my solid background in clinical trial management organizations, I have been able to strengthen Celerion's global operations, expand the site networks and add efficiencies to the setup and conduct of trials. In particular, my expertise has been extremely useful in the seamless integration of in-house operations and external site management. With regard to trials evaluating vaccines and antiviral drugs, for instance, this is key when extending early studies in healthy volunteers to larger or special populations, such as elderly and health care workers.

One of our key approaches towards building relationships with potential clients is to showcase our scientific expertise and operational experience with the setup and conduct of exploratory Phase I and II trials. Although a personal interaction is our preferred way to connect with new customers, presentation of case studies at conferences often helps trigger the interest of its clients. With conferences going virtual because of the pandemic, we contributed to various discussions over the past months.

Being the world's leading provider of early clinical trial services, what makes Celerion so unique?
Over the years, our Phase I bed capacity has grown to the largest in the world, which in combination with complex methodologies, trial site networks, ECG Core Lab and bio-analytical lab services enables us to provide drug development services that accelerate the translation of scientific ideas into potential medicines.

Achieving clinical Proof-of-Concept is a critical milestone for drug candidates, and we help clients define what a successful clinical proof-of-concept study should entail. When a sponsor demonstrates that a drug works in humans as anticipated from preclinical data, their drug acquires real value.

For many drugs, such as antiviral agents, after initial evaluation in healthy subjects, Phase Ib and hybrid studies are conducted. These studies usually enroll patient cohorts to measure biomarkers that represent pathophysiological pathways that a drug is targeting. Thus, value is added by providing early signals of drug effects in the target population in the earliest stage of drug development.

For the development of prophylactic vaccines, Celerion has established innovative methods, for example to determine the percentage of functional antibody capable of producing a therapeutic effect, neutralizing a virus or toxin, or eliciting a specific immune cell response to enable, which can be applied to establish Proof of Concept in healthy volunteers.

Our innovative solutions set Celerion apart as a leading early-phase CRO, but we realize that ongoing advances are required to maintain that leadership position. Much of our strategy will focus on accelerating drug development up to Proof-of-Concept, by integrating early patient studies and biomarker development. The latter will encompass identification of biomarkers for new drug targets and method development featuring bio-analytical technologies like ELISpot and flow cytometry. Implementation of new technologies will contribute to virtual data management processes as well as to sophisticated sampling and detection methods to accelerate clinical conduct.

By using our expertise in biomarkers and clinical study design and conduct, we also believe that Celerion has an important role to play towards future modalities for curing diseases rather than treating symptoms, such as cell-based therapies and 3D-printed tissues or organs. We take pride in many of our clients referencing Celerion when presenting their clinical trial data at scientific conferences or when publishing in peer-reviewed journals.

With the volatile technological changes, what measures is the company taking to boost its growth?
It's absolutely true that technological advancements are a key driver of innovation in clinical trial conduct and in fact Celerion has always been an early adopter of

new technologies. For instance, we were at the forefront of highly automated electrocardiogram overread, and Celerion's laboratories were the first to move completely to electronic lab notebooks.

For Celerion, the implementation of virtual technologies have diminished the burden of in-house operations, especially during the COVID-19 pandemic requiring social distancing and stringent infection prevention measures, and have also facilitated the conduct of trials across multiple sites and geographies. As a result, we have been able to stabilise our in-house trial operations and grow our external trial capacity.

Apart from the shift to virtual trial conduct, at Celerion we have implemented the Veeva platform to achieve an interconnected and fully automated virtual environment for data management, with direct live access to study status and monitoring of data, trial files and documentation (eTMF) and direct access to sites data. This platform for instance allows straightforward tracking of study milestones and software integration enabling remote Source Data Verification and monitoring, thereby increasing efficiencies and data quality capture in any type of clinical trial – virtual, hybrid or traditional.