The acute impact of COVID-19 on the clinical trial market is dual

The acute impact of COVID-19 on the clinical trial market is dual. On one side the classic non-COVID trials are delayed, but a lot of COVID linked trials are initiated. The industry is adapting very fast and in the long term, the situation will recover. On the field, Bruno Speder of SGS assumes a shift in the development of anti-infectious drugs. In the last decades, the research and development of anti-infectious drugs were tremendously low. This will certainly change in the upcoming years.

For clinical trials started before the COVID-pandemic the recruitments slowed down promptly, so this means that the studies will take a longer time to include the necessary patient number. But in most cases, the studies are still running thanks to the development of remote follow-up, the logistic systems to provide the medicines and tests at the patient's home, and online date registering. But the system shows also growing problems, such as delays in the supply chain, the non-compliance of the patient, remote monitoring of data, and the incompleteness and quality of some datasets. In some cases, the sponsor decided to stop recruitment during COVID-19 which has led to critics certainly for orphan diseases, because there are no other therapeutic options.

At the same time, there is a huge intake of studies of COVID-studies focussed on vaccines and anti-viral drugs, with high urgency to bring them on the market. But strict rules on safety and lack of knowledge of potential disease enhancement are very important for the development and testing of potential vaccines. At this moment there is still little known about the reaction of the immune system on Sars-CoV-2. There is a reference to the data of SARS-1 in 2003, but differences occur. In the field of anti-viral drugs, we have to conclude that currently there are no broad-spectrum antiviral drugs available.

After the first wave of the pandemic, and after the deconfinement, we believe that most trials will continue because for most pharmaceutical companies the development of medicines is a lifeline. Once the hospitals are fully operational, trials will start in a new reality which will be a little bit more complex, which can lead to increasing costs. We expect that preventive measures for spreading the virus will be inserted and maybe also some adaptations on the including criteria: questions such as the in/exclusion of post-COVID-patients will certainly rise for some trials.

But certainly, I think we are facing interesting times. The interest of the public for vaccine trials and more broadly for the development of drugs is amazing. Besides the flexibility of people is enormous and I presume that in the long term the situation will turn back to normal.

Infectious diseases become a hot topic

A few years ago, following the 9/11 attacks, SGS collaborated in trials for an Anthrax-vaccine which was developed on request of the NIH for stockpiling by the American authorities. This example confronts us with the lack of priorities governments have set in the past and it refers also to the fact that the production of a vaccine takes time, even when you're already prepared. In an acute situation, anti-viral drugs are more effective and it is now remarkable that the focus lies on the development of a vaccine, which can take time and gives no direct solution.

I presume that the current pandemic will lead to a shift in the research and development of medicines for infectious diseases. In the last decades, there was little interest from the pharmaceutical industry to develop new anti-bacterial and anti-viral drugs, due to the very restricted use globally. Companies risked burning the return on invest principal. This pandemic will certainly lead to a shift, together with the necessary support of governments – probably at the EU-level – and can be a turning point in this evolution. At this point, the UK has a strong history of collaboration of industry and hospitals, and we can assume that they will probably take the lead.

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Point of View

Article written by: Prof.dr. Bruno SPEDER

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Bruno Speder is Head Regulatory Affairs & Consultancy and has played a pivotal role in the establishment of several CHIM models, and has led interactions with global regulators on their use. He is currently advising a broad range of organisations (non-profits, biotechs, large pharma) on the regulatory aspects of challenge studies and how they need to be implemented in development plans.

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