Salvagene GROUP

Business Unit: SARS-CoV-2 Task Force
Keynote: #92

September 2021

Where are we now, almost two years into the pandemic? Nine months after the first vaccines for the prevention of Covid-19 were approved, are there any conclusions that can be reliably drawn? Since December 2020, 2.39 billion people worldwide have been vaccinated against Covid-19, with a total of 5.82 billion doses having been administered. Just under 30% of the world's population has thus been fully vaccinated, and in the United States that figure has now passed the 50% mark.

The raw data on how well the vaccines perform against infection with Covid-19 and on whether they provide sufficient protection are well known. Vaccinated individuals are less likely to become infected and, if they should nonetheless contract the virus, the course of the disease is generally much less severe. These statistics are enough to persuade most people, despite the acknowledged risk of vaccine side-effects. So, how

are we to weigh up the advantages of vaccination in preventing a disease that can cause long-term harm and even death against the possible side-effects? This is the dilemma in which a large proportion of the population find themselves, depending on age, pre-existing conditions and personal conviction.

In the current circumstances, it is difficult to find the objective middle ground, as there are many different perspectives on the matter. On the one hand, we are currently witnessing a mass clinical trial, in which all those who line up for vaccination are effectively test subjects, and the scientific community is on standby to respond to any side-effects that manifest themselves. These side-effects range from minor local reactions and discomfort after injection to fever, pain, nausea, swelling of the lymph nodes, sensory disturbances, autoimmune disorders and blood clotting. One of the most recent findings was an increased incidence of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the tissue that surrounds the heart) associated with a second dose of an mRNA vaccine, an occurrence more frequently observed in adolescent males. This again highlights the potential severity of such side-effects and also the importance of meticulously thorough monitoring.

On the other hand, we are approaching the point where the sheer number of vaccine doses and the thoroughness of monitoring make the detection of further rare diseases increasingly unlikely. Reliable data is available for the elderly who were vaccinated first in the USA, Europe and elsewhere. Nevertheless, there are always the “unknown unknowns”. In other words, vaccines against Covid-19 could theoretically set in motion internal processes that we could not have anticipated. For the moment, at least, the vaccines are safe and surprisingly effective, but what about three years further down the road? We cannot know today what the long-term results will be. The current crop of vaccines are based on an entirely new scientific principle which we are only just beginning to understand. So the question arises as to which groups of people should they be used on? It’s like this: if you are 60 years old, you won’t want to take the approximately

one percent risk of dying from corona. In the case of children or unborn fetuses who still have their whole life ahead of them, however, the possibility of long-term complications is a major consideration.

At Salvagene, we believe that this dilemma should be tackled by means of a specific strategy, with the key concept being “individualization”. The current aim of governments and of the World Health Organization is to vaccinate as many people as possible and thereby maximize protection against infection with SARS-CoV-2. Yet this is supposed to happen in a world where individuality counts for more than at any time in history. This issue, which is at the very least defined by differences in age, gender and ethnicity is largely ignored. A structured and finely-tuned individualization plan, such as the one we create at Salvagene, would not only identify risk groups and thus avoid vaccination side-effects, but would also have a positive effect on vaccination success and help to reassure those elements of society who are vehemently opposed. Our individualization plan comprises analysis of age, sex, medical history, risk factors and exposure, vaccine dose and immune status, as well as T-cell immunity and antibody titers against SARS-CoV-2.

A strategy of individualization has not yet been introduced on a broad scale, as the focus of the vaccination campaign is currently on the total number of doses administered rather than on the welfare of the individual. Which is not surprising, as there are limitations on the extent to which a policy of individualization can be implemented.

We were therefore delighted to learn last week that the BioNTech team have taken the first step towards individualization in their vaccination concept, specifically in terms of dose adjustment. BioNTech plans to apply for approval of its corona vaccine for children between the ages of five and eleven in the coming weeks. The data for this should be available by the end of September. The dose for this age group will be ten micrograms, which is one third of that given to adults. The data for even younger children (aged 6 months

to 4 years) should be available towards the end of the year. Here, too, they expect that the dose can be further lowered.

The study results are already available and must now be finalized for submission to the regulatory authorities. The European Medicines Agency (EMA) has stated that it cannot yet give a timeframe for possible approval. However, BioNTech is already preparing the production of the vaccine doses, so that the vaccination of children between five and eleven years of age could start as early as mid-October. Clinical trials are underway in the USA for both the Pfizer/BioNTech and Moderna vaccines. Previously, there had been delays because the FDA had required a greater number of child participants in the clinical trials being conducted by both BioNTech and Moderna.

According to immunologist Anthony Fauci, the vaccination of children in the States could begin in late autumn or early winter. For younger children, it may take a little longer, as the age groups six months to two years and two to five years are being tested separately. In late July, Israel became the first and so far only country to give the green light for BioNTech/Pfizer to be administered to children in the five to 11 age range who are at risk of serious health complications such as brain, heart or lung problems.

The Pfizer/BioNTech vaccine has been licensed for administration to children aged 12 and upwards since the end of May 2021, and the Moderna vaccine for the same age group since July 2021, but to date there is no vaccine specifically for children, particularly those in the 0-12 age group, which is why the dose adjustment announced now and further clinical research in the field is so important. Possible late complications of vaccination and undesirable side-effects in children can thus be counteracted.

In summary, we can say that we are looking forward to this development and will continue to follow it with great interest. It makes us all the more convinced of the importance and

benefits of our Salvagene individualization program, and we will continue to use this as the basis for our analyses and recommendations. If you have any further questions about our strategy and our individualization program, please do not hesitate to contact one of our Salvagene consultants.

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