



*Newsletter No. 9 – 26 April 2023*

## **NEWSLETTER #9**

### **SUSPENSION OF THE AXL-SOLIDACT ARM**

Due to slow inclusions, the Trial Steering Committee today (Friday, 21<sup>st</sup> April 2023) decided to suspend the AXL-SolidAct trial until such time as the COVID rates pick up again. This was determined to be the best course of action for several reasons. First, the continuance of the trial as it is now is not in the best interest of the patients or their physicians. Second, due to the sluggish nature of the new CTIS system, which can now mean a delay of up to 6 months from conception to start-up of a new trial, it would not be feasible to completely close down the trial; if a new wave were to begin in December, and we were to be required to re-start our trial, we would not be able to begin including patients again until April or May at the earliest, likely missing the entire wave, as happened this time. Therefore, the TSC decided that the best, and quickest, course of action would be to suspend the trial pending an uptick in the number of cases due either to community-acquired infections or new strains of the virus that could pop up at any time. We believe that this is the most reasonable course to take.

We are aware that this process will entail some residual costs, and we ask that people consider those costs for their own country or centre, and communicate them to their National Coordinating Investigator, who will be able to collate your responses and send them on to the Sponsor for consideration. Further details on the process, the implications to the network and compensation of expenses incurred due to the suspension will follow.

Having said this, we would also like to re-assure everyone that we, as a consortium, are in no way “finished”! As we wait for a re-start opportunity, we are actively looking into new ways to keep our network alive, including looking at new paths to take while we await the next global pandemic, such as working on antibiotic-resistant superbugs. By keeping the network alive, we will ensure that we are well-placed to tackle the next pandemic as soon as it appears as well as benefitting from each others’ experience and expertise.

If you have any questions about what comes next, or you just need more information about any part of the trial or its administration, please feel free to contact Thale (solidact.thale [at] gmail.com) and Inge (i.c.olsen [at] medisin.uio.no) who will get you the information you need as soon as possible.

We look forward to working with everyone well into the future!

-- Marius Trøseid