



*Newsletter No. 8 – 15 February 2023*

## **NEWSLETTER #8**

**REMEMBER WE HAVE AN INTERNET PAGE: [HTTPS://EU-RESPONSE.EU/EU-SOLIDACT/](https://eu-response.eu/eu-solidact/)**

The webpage contains copies of protocols, procedures, and training links, so make sure you check it out today!

### **INTRODUCTION**

First of all we would like to thank all sites for their continued support to the trial despite changing epidemiology and declining number of eligible patients. Due to slow inclusions in AXL SolidAct, a substantial amendment to the protocol will now allow for inclusion of nosocomial COVID pneumonia. We will use the next couple of months to assess how this will impact inclusion rates.

-- Marius Trøseid

### **STUDY UPDATE AS OF 14<sup>TH</sup> OF FEBRUARY 2023**

We continue to work with sites to get them up and running in the AXL-SolidAct trial. There are now 22 centres with bemcentinib on site.

As everyone already knows, the Bari-SolidAct arm has been halted, and centres are now wrapping up their work to complete their close-downs. If you haven't already been contacted by your monitoring team, you will likely hear from them shortly. The monitors will ensure that all required paperwork is in order, and help you prepare for archiving of your site's Bari-SolidAct information.

Version 3.1 of the Bari-SolidAct and master protocols were approved in all countries 30<sup>th</sup> of January. While this was too late to be implemented, this version needs to be archived in the site file. The monitors will make sure this version is archived.



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## AXL-SOLIDACT PROTOCOL UPDATE

The AXL-SolidAct protocol version 1.5 has been approved by all countries except Czechia and Spain. This means that for all sites outside those two countries, **the new protocol should now be implemented.**

The main changes to the protocol are:

- **SE-02:** updated to not exclude patients developing nosocomial pulmonary COVID-19 during hospitalisation.
- **SE-16:** Updated to specify that the “hospitalised > 4 days” exclusion criteria only applies if the hospitalisation is with COVID-19.
- The master protocol (v3.1) has been changed to be consistent with this protocol on the primary endpoint for phase 2 investigations.

Since it is not feasible to attach the protocols here due to their size, they will be transmitted to you by the CTU or monitoring team in your country.

**Please note that from an operational perspective, you should add the new protocol to folder 1 of your Investigator Site File (ISF), fill in the protocol change form, and move the v1.4 protocol into folder 1.3 (Previous protocols).** Monitors will check this part of your ISF, so make sure you do this before your monitoring visits flag this up as an error. **Please remember to sign and return the v1.5 Protocol Signature Page (attached to this email) to Thale and Inge as soon as possible!**

## BARI-SOLIDACT PUBLICATION

The Bari-SolidAct main paper has been published and attached to this newsletter. It can also be found here: <https://doi.org/10.1186/s13054-022-04205-8>



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## CTIS PUBLICATION

The publication on CTIS as mentioned in last newsletter has been updated and a formal preprint of the publication can be read at: <https://www.researchsquare.com/article/rs-2514582/v1>

## A REMINDER: MAKING CHANGES IN CTIS

Please remember that under the new regulations, changing a PI at a site and adding a new site within a previously approved country are now considered **SUBSTANTIAL AMENDMENTS**.

What this means: We can no longer process changes in P.I. at a site immediately. This must now be coordinated with other required changes since each time we submit a substantial amendment, we face a wait of up to 3-4 months for the change to be approved, as well as incurring very large fees from each affected country. Therefore, we want to ensure that we always put as many changes as possible into CTIS simultaneously to avoid unnecessary wasting of time and money.

While an amendment is being considered, the application is “locked”, and no other changes may be put into the system. Therefore, we really need your support in making sure that we get information as soon as possible after you’ve decided to make a change. We will put the request into the queue and apply it as soon as humanly possible, but this may not be immediate, so we ask for your patience as well.

**QUESTION & ANSWERS? SEE OUR INTERNET PAGE [EU-SOLIDACT - EU-RESPONSE](#)**