Newsletter No. 6 – October 2022

NEWSLETTER #6

REMEMBER WE HAVE AN INTERNET PAGE: HTTPS://EU-RESPONSE.EU/EU-SOLIDACT/

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

Note also that the regulatory Clinical Trials Information System (CTIS) provides access to all the latest approved versions of trial documents such as informed consent forms (ICFs). If you are uncertain which version of the ICF has been approved, it could be downloaded from this page: https://euclinicaltrials.eu. A search for "SolidAct" will show both trials.

MAIN POINTS

- The new study arm AXL-SolidAct is now opened, with the first patient included September 27th. We aim to open as many sites as possible during October to have sites ready to include patients if a new wave if coming.
- Bari-SolidAct has stopped inclusion of immunocompetent patients due to external evidence from the RECOVERY trial. As our results suggested a potential safety signal in vaccinated participants, the results were immediately shared with EMA.
- Bari-SolidAct is still open for immunocompromised patients with signs of hyperinflammation. Although inclusions have been slow over summer, the arm will be kept open in case a new wave is coming.
- As the DisCoVeRy trial has ended inclusions, several DisCoVeRy sites have joined EU SolidAct. This is very welcome and important for future pan-European collaboration.

STUDY UPDATE AS OF 13TH OF OCTOBER 2022

As noted in the last newsletter (#5) Bari-SolidAct stopped inclusions for immunocompetent patients on 7th March 2022. Since this date, 4 immunocompromised patients have been included, making the total to 10 (8 randomised). In a trial steering committee meeting on the 23rd of September, it was decided to continue the trial to see if the next wave increases the inclusion rate in this important population. We have submitted a Substantial Amendment regarding this. The amendment counted 750 uploaded documents! We are writing a report to the European

Commission to inform them about our experiences with the new regulation, and the shear amount of documents required is one of the main points. We are also applying regulatory and ethical approval in Switzerland.

The AXL-SolidAct trial is now approved for inclusion of moderate pulmonary COVID-19 patients in Norway, France, Ireland, Belgium, Luxembourg, Spain, Greece, Slovakia, and Czechia. Italy will join shortly, while we are looking for appropriate sites in Portugal. Currently two sites in Norway are recruiting, and the first patient was included September 27th. We aim to open the rest of the sites during October to have the trial ready to include patients if a new wave if coming.

AXL-SOLIDACT PROTOCOL UPDATE

The AXL-SolidAct protocol version 1.4 has been approved by all countries within the study. This means that all sites within the AXL-SolidAct trial should now be using v1.4 on site.

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 tracking log and move the v1.3 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 v1.4 Protocol Signature Page to the sponsor team as soon as possible, see contact details below.

BARICITINIB PUBLICATION

Recently, a paper outlining the results of the Bari-SolidAct trial (prior to the database lock and change to immunocompromised patients only) was published as a pre-print. The paper has been accepted with the journal Critical Care and will be published soon. The pre-print of the paper (prior to updates and changes) may be viewed at:
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4172086

UPDATING SITE P.I.

We have noticed lately that some changes in P.I.s have not been communicated to the Sponsor team in a timely manner, and occasionally, not at all. We remind everyone that the Sponsor Office should be informed about changes to the P.I. or any other changes at a site (closing down,

temporarily halting inclusions, longer vacation times) as soon as possible so that we always have a good overview of what is happening within the trial. If you need help with any changes you need to make or if you have any questions at all, we are here to help you. Email us any time!

MAKING CHANGES IN CTIS

Please note that under the new regulations, changing a PI at a site or adding a new site is now considered a SUBSTANTIAL MODIFICATION.

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 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 in together as possible.

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.

UPDATED BIOBANKING INSTRUCTIONS

The new laboratory safety manuals are nearing completion, and with them will come the creation of the new biobanking kits for the AXL-SolidAct arm. If your site is a biobanking site, we will ship kits to your site at the same time as your first shipment of IMP.

DISCOVERY NEWS

Inclusions for the DisCoVeRy trial have now ended, and all the PIs from within that trial have been invited to join the EU-SolidAct trial. If you know an investigator who was working on the DisCoVeRy project and who may be interested in joining EU-SolidAct, or if you just know someone who might be interested in general, please do not hesitate to let them know that we are still open to recruiting new centres across Europe. Interested parties can reach us on the Sponsor Office group email: solidact@ous-hf.no.

QUESTION & ANSWERS? SEE OUR INTERNET PAGE EU-SOLIDACT - EU-RESPONSE