Newsletter No. 7 – January 2023

NEWSLETTER #7

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

- Inclusion stopped in Bari-SolidAct
- Inclusion slow in AXL-SolidAct

INCLUSION STOPPED IN BARI-SOLIDACT

The inclusion has now been formally stopped in Bari-SolidAct, and it is no longer possible to randomise patients to this arm. The decision to stop inclusions was made unanimously in the Trial Steering Committee (TSC) meeting on the 16th of December. The trial will formally end when the last patient has reached the last visit. The last patient was included on the 19th of October so the last visit should be mid-January. Attached are the meeting minutes from the TSC meeting and a formal statement from the sponsor.

SLOW INCLUSION IN AXL-SOLIDACT

Since the start of the trial on 24th August 2022, there have been two inclusions in the AXL-SolidAct arm. The main reason for the slow recruitment is lack of subjects with pulmonary COVID-19. We are meeting this challenge by expanding the trial population to also include those with nosocomial infections. The amendment has been submitted via CTIS and we await approval, which should come by the end of January.

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WEBINAR - 31ST JANUARY 2023, 16:30-18:00

We welcome all investigators to an interesting webinar with the following agenda:

- Data from the baricitinib arm in EU-SolidAct. Discussion of safety of immunomodulators in fragile patients (15 min).
- Data from the Evusheld arm in DisCoVeRy. Discussion of antiviral Mabs vs direct acting antivirals for circulating variants and different patient groups (15 min).
- Data from the remdesivir systematic review and individual patient data meta-analysis of randomized trials (15 min)
- Current status of bemcentinib arm in EU-SolidAct in light of changing epidemiology and clinical presentation of COVID patients (10 min).

ARTICLE ON CTIS EXPERIENCES

The operational team has written an article titled "Experiences and challenges with the new European Clinical Trials Regulation" together with researchers from the MOSAIC study on the human mpox (monkeypox) virus disease. A preprint of the article can be found here: https://osf.io/2kdmh

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