Newsletter No. 2 – September 2021

NEWSLETTER #2

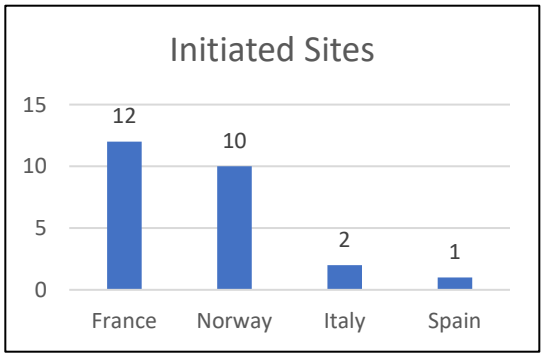
REMEMBER WE HAVE AN INTERNET PAGE: HTTPS://EU-RESPONSE.EU/EU-SOLIDACT/

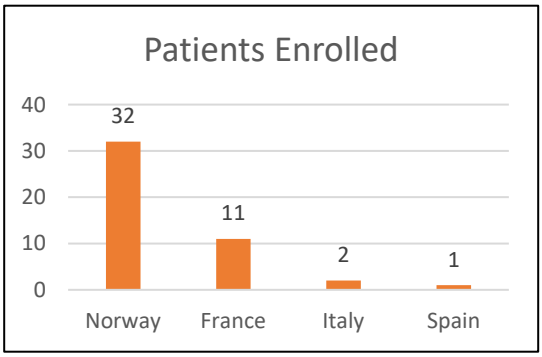
The webpage contains copies of protocols, procedures and training links, so make sure you check it out today!

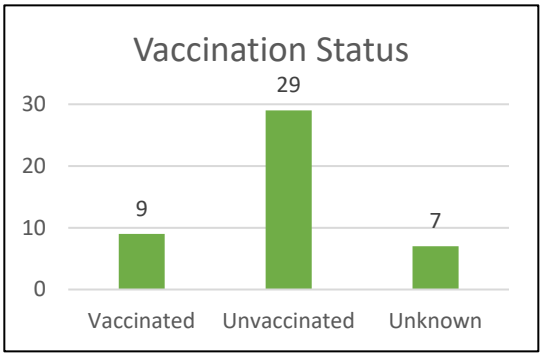
INTRODUCTION

EU SolidAct has now opened for inclusion in Norway, France, Italy, and Spain, and will hopefully give green light to the first site in Ireland this week. Inclusion rates have been slow due to few admitted patients during summer, but we plan to capture the fourth wave of the pandemic in as many countries as possible, aiming to open for inclusion in 10 countries by October. The logistics for biobanking is now ready, and we encourage biobanking in interested sites provided experience and facilities for biobanking.

STUDY UPDATE AS OF 8TH SEPTEMBER 2021







Part of EU-RESPONSE

EU SOLIDACT

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BARICITINIB IS BEING EVALUATED BY EMA

The Eli Lilly-sponsored COV Barrier trial was recently published, finding survival benefit by use of baricitinib, although the primary end point of disease progression was not met.

https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00331-3/fulltext

EMA is now reviewing the evidence of baricitinib for hospitalized patients, and randomization will continue in EU SolidAct until this evaluation has been concluded. Randomization to baricitinib is also ongoing in the RECOVERY trial, and if this trial comes out with a negative result, conclusive results from EU SolidAct will be important. Biobanking and the 90-day follow-up with patient reported outcomes are unique for EU SolidAct and will be of particular importance. We are currently planning new study arms for EU SolidAct and will come back with more information once this is concluded.

TRANSFER OF PATIENTS

A new procedure has been written on transferal of patients, both to another active study site and to a non-study site. The procedure can be found here, with the transfer form found here. It is important that the medication follows the patient, and that the access to the patient's eCRF is also transferred. When the patient is discharged, it is the original site's responsibility to follow-up and register the remaining data.

SCREENING OF PATIENTS

There will be no separate screening log in the trial. Therefore, all patients who have signed the informed consent MUST be entered into the eCRF. This applies even if they withdraw consent after 5 minutes or they are otherwise found non-eligible for other reasons. This is a GCP requirement. We also ask that all patients who fulfil all inclusion criteria except GI4 (informed consent) to be entered into the pre-screening log (found here).

COUNTRY CORNER

We would like to focus on the news from one country in each Newsletter. Would you like to share your news? Let us know if you'd like to be the first country in focus!

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