STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

Amendments AM07 & AM08

STOP-COVID19

Amendments AM07 & AM08

- AM07 – 08-07-20, protocol up dated to version 5 03-07-20 – implement immediately
- AM08 – 08-07-20, Investigators Brochure up dated to V4 30-06-20 – **do not implement until MHRA approval received**

AM07: Protocol V5 03-07-2020 (1)

7.3 Informed Consent

- Updated in line with request from REC at AM05
- The Research Ethics Committee stipulated that a copy of the consent form **must** be kept and filed in the ISF.
- The ICF should either:
  - Be photographed and a copy printed, original should be given to participant
  - Be placed in a clean envelope and sealed for 7 days (or as per local infection control procedures) before filing, copy given to participant at this point (in person or posted to them)

AM07: Protocol V5 03-07-2020 (1)

8.7 Dosing schedules

- The day of first dose received will be deemed to be day 1 of the trial.

7.12 Storage and analysis of clinical samples

- Addition of Sheffield site to take research bloods.

Appendix 4

- Research samples to be taken at day 29 (Tayside and Sheffield only)

AM07: Participant Information Sheets V4 02-07-20

STOP-COVID19 Participant Information Sheet V4 02-07-20

STOP-COVID19 Participant Information Sheet Recovered Capacity V4 02-07-20.

STOP-COVID19 Participant Information Sheet Legal Representative V4 02-07-20

- Change of wording: *There are ~~no~~ only a couple of drugs at the moment which we know will definitely help people with COVID-19.*
- Wording removed: *In this trial we only include people who have a positive COVID-19 test (confirmed by a nose swab test). If your nose swab test was negative you will not be able to take part in this research trial.*

AM08: Investigators Brochure V4 30-06-20

New version of Investigators Brochure (IB)

- MHRA requested an updated IB at initial review.
- Insmend Ltd have confirmed that:
  - There are substantial changes, the addition of information from Willow Trial.
  - The benefit-risk remains the same, in fact the additional data reinforce the possibility of a positive benefit-risk.
- No change to Reference Safety Information, Section 6.6
  - There are no Serious Adverse Reactions (SARs) expected.
  - All SARs should be reported to Sponsor immediately as Serious Unexpected Adverse Reactions (SUSAR)

- Once approval for the IB has been given this will be provided to sites.
- IB **must** be signed and dated by PI and filed in ISF.