# STRESS-L December Newsletter

## Seasons greetings from the STRESS-L Trial Team!

We have had a great end of the year, opening two new sites and recruiting four participants within the last week. We would like to thank you all for your continued support and hope that you have a brilliant Christmas break!

## Trial Update

The STRESS-L trial team has a had a busy and successful first year of recruitment. Our first sites, University Hospital Birmingham, Heartlands and UCL opened in March and since then we have opened a further 16 centres. We would like to thank you all for your hard work in helping us to deliver the study and for your contributions to screening and recruitment.

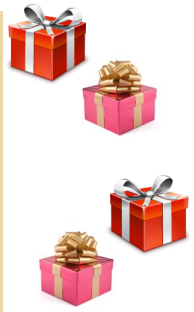
We greatly appreciate the interest in the trial from the critical care community and are looking forward to meeting further teams at our planned initiation visits over the coming months.


**Last IMP order date before Christmas: 17th December!**

Please let us know soon if you require re-stocking

## Milestones so far

- **18 sites open to recruitment**
- **19 participants recruited so far**
- **24 sites initiated to date**



## State of the Art Conference & Investigator's meeting

The STRESS-L trial team will be attending this year's SOA conference 10th - 12th December and look forward to meeting many of you in person.

Please feel free to visit our research stand and to attend our informal investigators meeting at 17:00 on the 11th in the Albert Room.

We will also organise a separate investigator's meeting in early Spring to discuss the trial in more depth. We will be in touch soon to finalise the details of this and look forward to hearing from you.

## Upcoming Protocol Amendment

A protocol amendment (v3.0) has been recently submitted and is pending approval. We will send out full guidance and a summary of the changes shortly. One notable change involves the extension of the 24 to 28 hour vasopressor inclusion window up to 72 hours which we hope will offer greater flexibility when screening. A relative's poster has also been created which can be displayed in public areas.

## Temporary Inotrope CRF

As you will have seen in our email dated 07th November, a temporary paper inotrope CRF has been created to capture essential SOFA score data which contributes to the trial's primary outcome.

We kindly ask that this paper form is completed for all patients whilst our database changes are pending and submitted to the coordinating team via email.

## Co-enrolment

We are working hard to finalise co-enrolment agreements with a number of compatible studies in order to facilitate recruitment. Agreements are upcoming with FLO-ELA and BLING III with more on the way. Co-enrolment is already permissible with ADAPT-Sepsis, REST and A-STOP.

## Christmas arrangements

Over the Christmas break the coordinating team will be out of the office from 21st December - 02nd January but we will be monitoring our trial email account for any urgent queries. Our CI, Dr Tony Whitehouse, will also be on hand for any clinical queries.

## IMP Delivery Clarification

Now that we have moved to ambient stock, our IMP release following delivery has changed. Initial IMP deliveries should be quarantined until recruitment green light is issued by WCTU. Subsequent resupply of IMP is fit for use immediately provided there are no issues raised on the Acknowledgement of Receipt. QP release will **not** be issued for the individual delivery.

## Lessons learnt

A number of sites have fed back about how they have benefited from holding internal training sessions to spread awareness of the study throughout the clinical teams and how this has contributed to increased screening.

This is also particularly vital in ensuring bedside nurses are comfortable in covering IMP administration over evenings and weekend.

Sites have used a diverse array of methods including recording podcasts to circulate, holding informal coffee mornings and discussing the study at departmental meetings. We have non-research team training slides, eligibility laminates and infusion protocols which we can provide to assist you but please let us know if there are any further materials which we can prepare.

## Consent clarification

Following TMG discussion about a consent query, it is felt that if a participant who has been consented to the trial by a professional legal representative passes away prior to ongoing consent being obtained from the patient's relatives, then it is likely to be inappropriate to approach the relatives and contribute further distress for this purpose. If you should experience this scenario and require any further guidance, please get in touch to discuss.

## Data completion

Just to remind you that the Eligibility, Participant and Baseline forms should be completed with 24 hours and on daily data within one week. Data queries will be submitted two weekly.