**FAQs - Synapse ICU**

**An international prospective observational StudY on iNtrAcranial PreSsurE in intensive care (ICU): Frequently Asked Questions**

**Q1: What is Synapse-ICU?**

It is Prospective, Observational, Cohort and multi-centric Study. The aim of the study is

- To evaluate the determinants (geographic area, ICU management, pathology) of practice variations in ICP monitoring in neurocritical care.

- To evaluate whether the interventions (measured as Therapy Intensity Level) and investigations (additional neuromonitoring and neuroimaging) are different in acute brain injured patients with/without ICP monitoring and in non-traumatic brain injury compared to TBI.

- To evaluate if having an ICP monitoring and an ICP driven therapy improves long term outcome, measured with the extended GOS.

**Q2: Why do we need National Representative (NR) and how I get involved?**

An NR facilitates the implementation of the trial at national level. The NR prepare the material for the ethic committee or IRB approval on national level (application might be needed locally) and he/she is the main contact for local investigators regarding ethical queries. The NR is requested to promote the trial at a national level using his/her network. We can provide you a certificate confirming you as a national representative for your country, if necessary.

Check on the website if your country has already an NR or not. If you are interested please send your request to Giuseppe Citerio and Cc research@esicm.org . As an NR, you need to register your site online.

You can find on the webpage the final version of the protocol in English and promotional material if necessary and any relevant information.

**Q3: Shall register my interest if I am not an NR? and How?**

You and your ICU are eligible to participate if you treat neurocritical care patients (traumatic brain injury, subarachnoid haemorrhage and intracerebral haemorrhage) with/without ICP monitoring.

We need all centers interested in participating to register themselves. Only one registration per site is necessary, we will take one referral per center. Do not forget to add your e-mail address to allow us to contact you and set up an account for the eCRF platform on due time.

If you have questions regarding the ethical procedures in your country, you can contact directly your NR (the list is regularly updated on the webpage). You can find on the webpage the protocol and other relevant information as well.

There is no financial compensation; the participation in the trial is completely voluntary.

**Q4: What is the duration of the trial? Does it depend on my IRB/ethical approval?**

Screening and recruitment: 12 weeks at each center starting from 1st March 2018. Follow-up: outcome measures will be collected at 3-6 months.

The planned enrolment phase might be postponed (until summer 2018) accordingly to the time required by the centers to obtain local Institutional Review Board approvals.

**Q5: What is the needed data collection this study?**

The eCRF collects anonymized, non-identifiable data:

- Screening log (inclusion/exclusion)
- For the recruited patients: demographics, past medical history, history of presenting event, details on ICP monitoring/alternative monitoring/no-ICP monitoring.
  A daily eCRF on Day 1, 3 and 7 of ICU admission (two types, one for ICP-monitored and one for non-ICP monitored patients): including single time-point vital parameters (8AM), blood results and summary of the 24h Therapy Intensity Levels.
- Discharge eCRF (GOSE at discharge from ICU/hospital) and Follow-Up eCRF (GOSE at 6 months assessed via phone interview).

**Q6: How will the data be managed?**

On due time, each involved center through its contact point (investigator) will receive credentials for the eCRF platform. The eCRF collects anonymized, non-identifiable data. The Principal investigator will have a daily manager appointed; the coordination will be done by ESICM office. Data will be inputted directly into the e-CRF by all investigators.

**Q7: What about data protection and security?**

The Clinfile platform will be an eCRF portal, all patient will be anonymized and will have a codified ID; the real ID patient from the hospital.

The eCRF platform is developed by CLINFILE©. The data management complies with the EU directive on data protection 95/46/EC. The data will be housed on the servers of Clinfile in France: 2 Rue Kellermann, 59100 Roubaix.

**Q8: Where the data is stored after the trial is closed?**

The data will be stored on a physical device such as USB key or CD-ROM at ESICM office in a locked room. This measure is taken to avoid hacking and the data is data is stored during a minimum of 5 years.

**Q9: What about authorship?**

All the participant centres will be granted in the group authorship. For each centre, a participant will be indicated in the group authorship list every 15 patients enrolled. Authorship of the main manuscript will follow the ICMJE recommendations that base authorship on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

- Drafting the work or revising it critically for important intellectual content; AND

- Final approval of the version to be published; AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

National coordinators will be authors if they will fulfil the ICMJE criteria and if they will promote the enrolment of at least 500 ABI patients in their country.

**Q10: Are there any plans for a similar study in children?**

At this stage we are not planning studying paediatric patients.

For more information visit the dedicated webpage using the following link: https://www.esicm.org/research/trials/trials-group-2/synapse-icu/

If you have further question you can contact your National Representative or contact ESICM office at research@esicm.org. For more technical/medical question please contact your NR or the Principal Investigator Giuseppe Citerio.