Targeted Good Clinical Practice (GCP) Training
Serious Adverse Event Assessment

Sugar or Salt trial:
Hyperosmolar therapy in traumatic brain injury

*This training should be completed by **non-GCP trained medically qualified physicians** who have been listed on the SOS Delegation Log to:*

SAE attribution assessment and sign off SAE form

Please document that you have completed this training by signing the Investigator Training log.

Good Clinical Practice (GCP)

GCP is an internationally agreed **ethical and scientific quality standard** for designing, conducting, recording and reporting trials that involve the participation of human subjects.

Working to GCP principles provides assurance that the **rights, safety and well-being of trial subjects are protected**, we are working ethically and in accordance with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial **data is credible**.

13 PRINCIPLES

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
   - A participant may withdraw from the trial at any time without giving a reason.
4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/ independent ethics committee (IEC) approval/favourable opinion.
7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
   - The causality of SAEs should be assessed by a medically qualified doctor.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
   - The reason for doing this training!
9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

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Principle 3: What is a Serious Adverse Event (SAE)?

An adverse event is considered to be serious if it fulfils one of the following criteria:

- **Results in death**
- **Is life-threatening**
- **Requires hospitalisation or prolongation of existing inpatients' hospitalisation**
- **Results in disability/incapacity**
- **Congenital abnormality/birth defect**
- **Requires important medical event/medical intervention**

Please inform your research team of any possible SAEs as these need to be reported to the trial coordinating centre **within 24 hours** of becoming aware of the event.

- **Serious Adverse Reaction (SAR) - Serious, and at least possibly related to IMP**
- **Suspected Unexpected Serious Adverse Reaction (SUSAR) - A SAR which is unexpected in nature, severity or frequency as documented in section 4.8 of Reference Safety Information (RSI)/Summary of Product Characteristics (SmPC) .**

What is causality?

A medical assessment of whether a SAE has a possible causal relationship to the administration of the Investigational Medicinal Product.

What should not be reported as a SAE for SOS?

- **Death**
- **Persistent or significant disability/incapacity**
- **Organ failure**
- **Any other events relating to the underlying illness/injury**