Expand your clinical research word power with the new SOM Clinical Research Glossary!

Whether you are new to clinical research or an experienced member of the research team, mastering the highly specialized vocabulary of clinical research and using it effectively in scientific communication can be challenging.

Take a moment to test your word power with this imaginary scenario:

An IND for a phase 2, randomized, multisite, clinical trial is initiated to evaluate the safety and efficacy of a novel investigational drug for the treatment of hypertension. A commercial IRB is selected as the IRB of record and the study is approved. An SIV is conducted at which time the CRA meets with the PI and SC at one of the sites involved in the study. The site is approved to start after the local IRB approves the study.

Participants with essential hypertension are recruited based on the I/E criteria in the protocol. These participants are randomized into a treatment and a control group. During the trial, one of the participants in the treatment group develops a stroke. The IR does not describe the risk of stroke. The PI recognizes this as an SAE and immediately reports it to the sponsor. The SAE is also reported to the IRB as an UPIRSO because the investigator assesses the adverse event as both unexpected in nature and possibly related to the investigational agent. A CRC documents the SAE in the adverse event log and the CRF.

To facilitate clinical research communication in the SOM and beyond, the CRSO has created a comprehensive clinical research glossary that aligns with industry and regulatory standards and is clear, concise, and organized.

Click to Access the
SOM Clinical Research Glossary

Coming up!

The SOM Clinical Research Glossary is intended to be a living and interactive resource for UNC SOM clinical research teams. We are currently working on adding buckets of related words for each entry and other features to maximize utility of the glossary.
If you have suggestions for how to make the glossary work better, new terms, or clarifications that are key to your clinical research communications, please let us know.