

# Rule 4

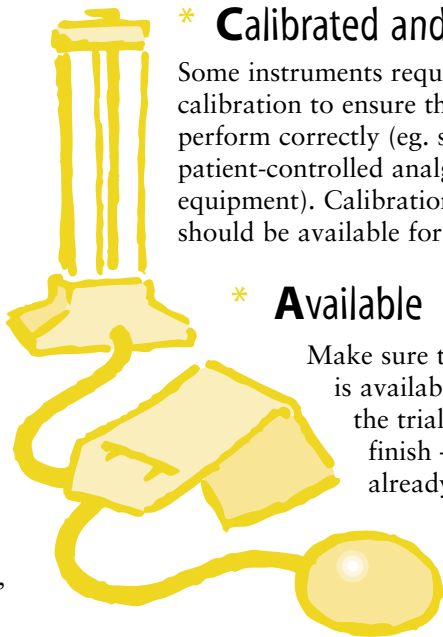
## Ensure Device and Study Equipment are Adequate

The study sponsor will verify that the study device is being used according to the instructions of use. For a new device the sponsor will provide written instructions and training. A proctor or instructor might be present during the first case(s).

The study monitor will make sure that any other equipment that needs to be used in the study (eg. fluoroscopy, Doppler or ultrasound equipment; spirometers; fridge) are adequate. The investigator can use the acronym 'SCAM' to check that the study equipment meets requirements.

### \* Suitable

Read the protocol to check that the correct equipment is being used.



### \* Calibrated and checked

Some instruments require regular calibration to ensure that they perform correctly (eg. spirometers, patient-controlled analgesia equipment). Calibration records should be available for inspection.

### \* Available

Make sure that equipment is available for use in the trial from start to finish – there may already be too great a demand for it!

### \* Maintained

All equipment should be regularly maintained. Records should be available for inspection by the monitor.



Do not assume that everyone knows how to use a piece of equipment correctly. Training should be given to ensure proper use in the trial.

## Summary of EN540 Requirements

An investigator brochure should be produced. This should describe the device, how it functions and its correct use (5.2.1.1).

The sponsor must ensure that the investigator receives adequate information on the use of the device and any other information requested by the investigator (5.4.8, 5.6.1).

The trial sponsor must ensure that the investigator is trained in the use of the device being studied and suitably experienced (5.4.1).

The trial monitor must check that the study site is suitable, and has appropriate facilities and staff to conduct the study 'safely and effectively'. The monitor should also check that the device is being used correctly (5.5).