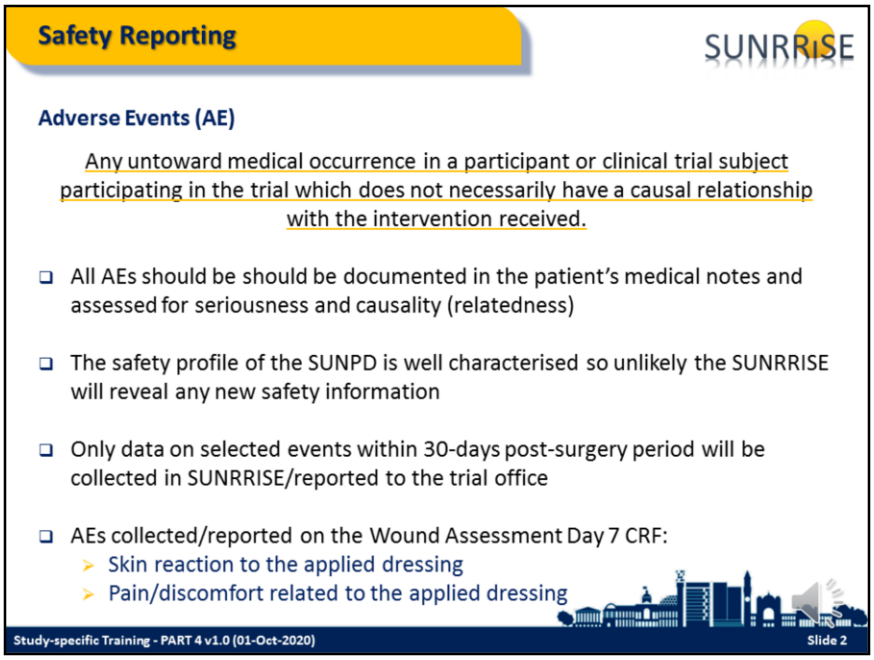
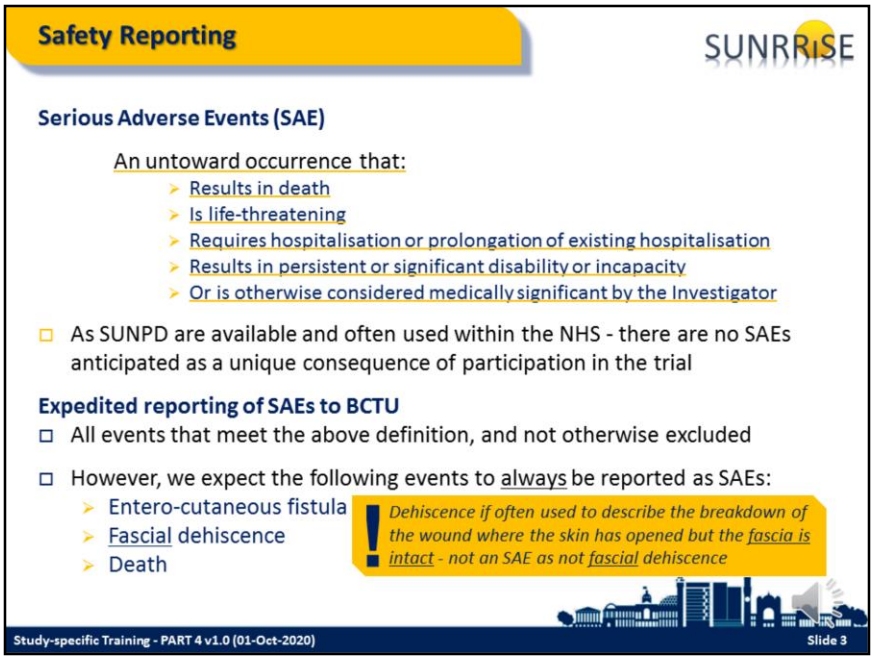
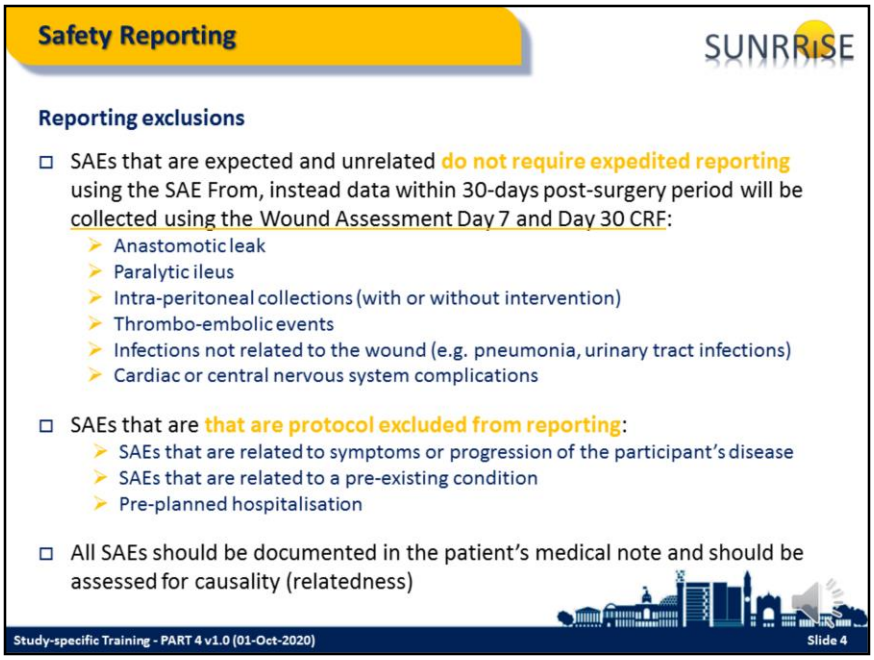
Welcome to study-specific training PART 4 for the SUNRRISE trial which covers safety reporting. Please do pause this video where necessary to allow yourself more time to review the content. A PDF version of this presentation can be downloaded from the training page of the SUNRRISE website.



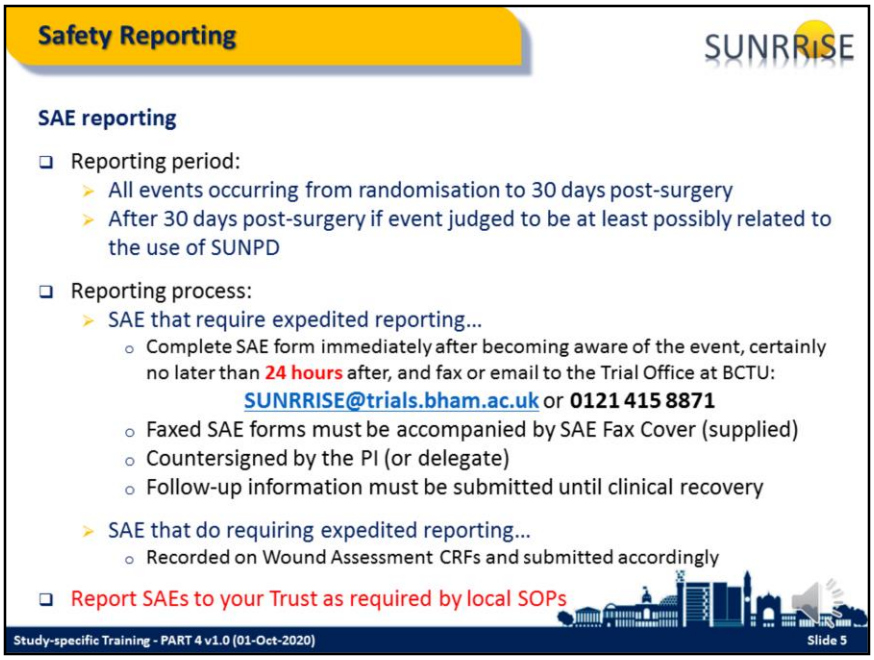
- An adverse event is any untoward medical occurrence experienced by trial participant, which does not necessarily have to be related to or caused the intervention or trial participation.
- All adverse events should be documented in the participant's medical notes and assessed for seriousness (i.e. is it a serious adverse event) and causality (i.e. is it related)
- The safety profile of PICO 7, which is the SUNPD used in SUNRRISE is well characterized, so it is unlikely that the trial will reveal any new information.
- Therefore, only selected events within the 30-day post-op period will be collected in SUNRRISE and reported to the trial office.
- In terms of adverse events, we are collecting skin reactions and pain and discomfort relating to the applied dressing, which are captured using the Wound Assessment Day 7 CRF.



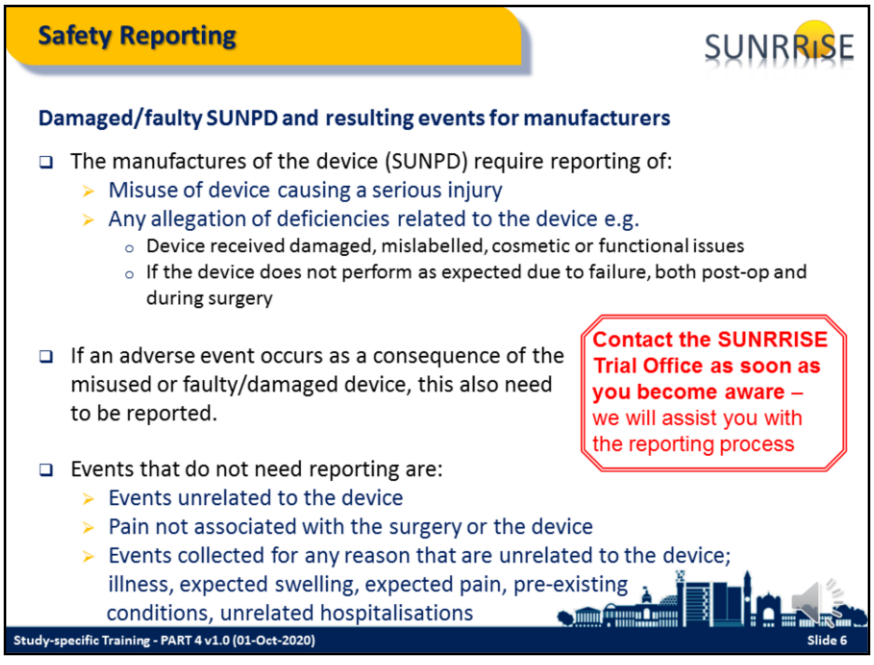
- Serious adverse events are adverse events that result in death, are life threatening, require hospitalisation or prolong an existing one, result in significant or persistent disability or incapacity, or are otherwise considered medically significant by the local investigators.
- SUNPDs, such as PICO 7, are widely used in the NHS and there are no anticipated SAEs as a unique consequence of trial participation.
- Expedited reporting of SAEs to BCTU means the completion and return of an SAE form. All events that meet the above destination of an SAE should be reported to the SUNRRISE trial office unless they are otherwise excluded, and we will cover what events *are* excluded and the types of exclusion later.
- We require some events, as shown, are to always be reported as SAE in the expedited manner, irrespective of whether it is classed as an AE or SAE.
- Please note that dehiscence is often used to describe the breakdown of the wound where the skin opens but the fascia remains intact. This superficial dehiscence does not need to be reported as an SAE and will be collected on the Wound Assessment CRFs. Only full thickness or deep dehiscence needs to be reported as an SAE.



- The SAE reporting exclusions in SUNRRISE fall into 2 groups.
- The first are SAEs that we are expected and unrelated, and as a consequence, they do not require expedited reporting using the SAE form, instead the data is collected on the wound assessments CRFs. The protocol defined list of events is as shown and they are expected potential complications of an emergency laparotomy.
- The second are SAEs that are excluded in the protocol from any reporting to the trial office. The protocol defined list of events is as shown.
- As mentioned, all adverse events, including serious ones, should be documented in the patient's medical notes and assessed causality, regardless of whether or not they are reported or require reporting to the Trial Office.



- When reporting SAEs the protocol defined reporting period show be considered. Any and all events that occur between randomisation and day 30 are to be reported, irrespective of whether or not they are related. After day 30, only events that are thought to potentially be related to the SUNPD or trial need to be reported.
- The process for reporting expedited SAEs is to complete the SAE form when you become aware of an event and send it to the trial office; either faxing or emailing it to the contact details shown. When faxing, cover sheets to accompany the form can be found in the investigator site file. SAE forms should be countersigned by the PI or delegate. However, please note that if countersignature cannot be readily obtained, the un-countersigned form should be sent straightway and then the countersigned form sent as soon as possible afterwards. Events will be followed up until the patient recovers, with interim updates submitted when appropriate.
- As mentioned, SAEs that do not require expedited reporting are collected on and reported using the wound assessment CRFs.
- Please note that you will need to report any SAEs that occurrence to your trust using your local processes and procedures.



- The PICO 7 manufacturers, Smith and Nephew, also have event reporting requirements.
- The events relate to the misuse of the devices causing serious injury or deficiencies with the device as shown.
- If an adverse event occurs as a consequence of these, this also needs to be reported.
- If you become aware of such events, please contact the trial office and we will assist you with the reporting process.
- Events that do not need reporting are as shown.

- Thank you for watching the SUNRRISE study-specific PART 4 training video on safety reporting.
- Please ensure you document the completion of this training. This can readily be done using our online training record tool which can be assessed using the link shown, which is also found on the training page of the SUNRRISE website, or by using the QR code shown. Alternatively, the paper training log found in your local investigator site file can be completed and a copy sent to the SUNRRISE Trial Office.
- If you have any queries, please get in touch.