

## 13. Serious Adverse Events Flow

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- 1** When a Serious Adverse Event (SAE) has occurred - fill in the SAE form in endoACRO.
- 2** Save and sign the form.
- 3** After you have saved the SAE form, the SAE report will be created according to the Pfizer standard. The SAE report contains pooled patient data as reported in the SAE form and other relevant forms in endoACRO\*
  - \*e.g. relevant concomitant medication or medical history.
- 4** Open and print out the SAE report.
- 5** Check and sign the paper SAE report.
- 6** Send a copy (fax) of the SAE Report to your Pfizer Local Safety Department.
- 7** Paper original SAE Reports should be delivered to your Pfizer Local Safety Department, within 3 months.