

TEEN-BESTrial – SAE Form

**1 Date of completion SAE form
(dd-mm-yyyy)**

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Completed by (name and function)

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2 Personal details of the participant with the SAE

Trial number:

TEEN-BEST

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Age

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 year

Sex

- male
 female

Randomisation

- RYGB
 SG

At which moment is the participant in the study (for example:
<30 days of surgery – 1 year FU – 5 Year FU) ?

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3 In which category does this report fit?

- An unexpected result of an expected serious complication
 A SAE related to a treatment specific for this study
 A SAE related to a medical device
 A SAE related to equipment failure
 Other, explain;

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4 Has this SAE (possible) consequences for the safety of the other trial participants in the TEEN-BESTrial?

- No
 Yes (which category fits best);

<input type="checkbox"/> Suspending the study (research 'on hold'); <input type="checkbox"/> Termination of the study; <input type="checkbox"/> Adjusting the trial participant information; _____ <input type="checkbox"/> Adjusting the dosing; _____ <input type="checkbox"/> Adjusting the in/exclusion criteria; _____ <input type="checkbox"/> Other; _____
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5 What was the date of the SAE
(dd-mm-yyyy)

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6 Date of hospital admission
(dd-mm-yyyy)

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7 Date of discharge
(dd-mm-yyyy)

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8 Describe the SAE

9 In which category falls this SAE?

- Death;
- Life threatening;
- (Prolonged) hospital stay;
- Congenital abnormality;
- Permanent disability or incapacity for work;
- Other; explain;

10 Did the participant recover?

- Yes – Date of recovery (dd-mm-yyyy) ____ - ____ - ____
- Still recovering
- No
- Recovered with residual symptoms – Date of recovery (dd-mm-yyyy) ____ - ____ - ____
- Passed away
- Unknown

11 Additional comments (other information, for example lab values or results of clinical tests that are important)