



Randomisation No. R /

Participant Initials

Serious Adverse Event Form

SAE details

Start date

d d m m y y y y

End date

d d m m y y y y

Procedure details

Treatment group RBL

HAL

Date of procedure

d d m m y y y y

Please choose and mark one of each below to rate the event:

Seriousness

- Death*
- Life threatening
- Inpatient hospitalisation**
- Prolongs hospitalisation
- Persistent or significant disability/incapacity
- Congenital abnormality /birth defect

Frequency

- Isolated
- Intermittent
- Continuous
- Unknown

Intensity

- Mild
- Moderate
- Severe

Outcome

- Recovered
- Improved
- Unchanged
- Deterioration
- Persisted
- Death*

*Date of death

d d m m y y y y

