Trial Name	SOLVE	Participant ID	☐☐☐☐	Date of Report	dd-mmm-yyyy

SERIOUS ADVERSE EVENT (SAE) FORM
Cover sheet

This section is for completion by the BCTU trial management team ONLY for tracking purposes

BCTU SAE Reference number:	☐☐☐☐☐☐/☐☐				
Date received by BCTU	dd-mmm-yyyy		**Time received by BCTU (24 hrs)**	☐☐/☐☐	
Date acknowledged by BCTU	dd-mmm-yyyy		**Acknowledged by**		
Report Stage	**Initial** ☐	**Follow-up** ☐		**Follow-Up Number** ☐☐	
Assessment stage	**Causality assessment by PI or delegate complete** ☐	**Causality review by CI or delegate complete** ☐		**Expectedness review by CI or delegate complete** ☐	
Event category	**SAE** ☐				
	SAR ☐				
	SUSAR (Fatal or Life threatening) ☐		**Date reported to MHRA & REC**	dd-mmm-yyyy	
	SUSAR (Non-Fatal or Life threatening ☐		**Date reported to MHRA & REC**	dd-mmm-yyyy	
Does a Product Defect Form for DILPAPN-S need to be completed?				Yes ☐ No ☐	
Date Product Defect Form received by BCTU	dd-mmm-yyyy		**Date Product Defect Form acknowledged by BCTU**	dd-mmm-yyyy	
Acknowledged by			**Date Medicem informed if applicable**	dd-mmm-yyyy	

GUIDANCE FOR THE PERSON COMPLETING THIS FORM

- **Forms must be submitted to SOLVE within 24 hours of the site research team becoming aware of the SAE.**
- **Do not include personal identifiers (patient names, initials, dates of birth etc) on this form.**
- **Complete the form as far as possible. The form can be updated/signed and re-submitted as new information becomes available**
- **Any updates should be added to the original form – DO NOT create a new form for each update to this SAE.**
- **Forms must be submitted as a PDF via solve@trials.bham.ac.uk.**

Trial Name	SOLVE	Participant ID	☐☐☐☐	Date of Report	dd-mmm-yyyy

1. Report details			
Site Name:		Name of Principal Investigator (PI):	
Participant Age at randomisation:	☐☐	Participant Involved:	Mother ☐ **OR** Neonate ☐ *(if both are involved, please complete a separate form for each)*
Report type			
Initial Report	☐		
Follow-up Report	☐ Please insert Unique SAE number ☐☐☐☐☐☐ / ☐☐ Follow-Up Report number: ☐☐ Has the new information changed relatedness? Yes ☐ No ☐ *Please update the relevant sections of the form with new information only.*		

2. Event Information				
Signs and Symptoms				
Diagnosis				
Event Severity	☐ Mild	☐ Moderate	☐ Severe	
Seriousness Criteria *(tick all that apply)*	Yes	No	Details	
Death	☐	☐		
Life threatening event	☐	☐		
In-patient hospitalisation or prolongation of existing hospitalisation	☐	☐	Initial ☐ / Prolonged ☐	
Results in persistent or significant disability or incapacity	☐	☐		
Other medical reason for reporting?	☐	☐	If other please specify	
Date of Onset	dd-mmm-yyyy	Date became aware	dd-mmm-yyyy	

Trial Name	SOLVE	Participant ID	☐☐☐☐	Date of Report	dd-mmm-yyyy

3. Trial Intervention

Please list below details of all trial interventions delivered

Intervention	Total Dose Received	Intervention start date/time	Action taken 1=None 2=Intervention Stopped 3=Intervention Delayed 4=C-Section	Intervention end date/time
Propess (IMP) ☐	Series 1	Date: dd-mmm-yyyy Time: hh-mm	☐	Date: dd-mmm-yyyy Time: hh-mm
	Series 2 ..... Or N/A ☐	Date: dd-mmm-yyyy Time: hh-mm	☐	Date: dd-mmm-yyyy Time: hh-mm
	Series 3 ..... Or N/A ☐	Date: dd-mmm-yyyy Time: hh-mm	☐	Date: dd-mmm-yyyy Time: hh-mm
Dilapan-S (Device) ☐	Series 1	Date: dd-mmm-yyyy Time: hh-mm	☐	Date: dd-mmm-yyyy Time: hh-mm
	Series 2 ..... Or N/A ☐	Date: dd-mmm-yyyy Time: hh-mm	☐	Date: dd-mmm-yyyy Time: hh-mm
	Series 3 ..... Or N/A ☐	Date: dd-mmm-yyyy Time: hh-mm	☐	Date: dd-mmm-yyyy Time: hh-mm

Trial Name	SOLVE	Participant ID	☐☐☐☐	Date of Report	dd-mmm-yyyy

4. Concomittant Medications *Do not include therapy used to treat SAE*

Are there any relevant concomitant medications?	Yes ☐ *Provide details below*	No ☐ *Proceed to section 7*

Drug Name and Indication	Route of Administration 1 = Oral 2 = IV 3 = Subcutaneous 4 = IM 5=other (specify)	Dose (including units and frequency)	Start date	Ongoing?		End Date (if relevant)
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy
	☐		dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy

Trial Name	SOLVE	Participant ID	☐☐☐☐	Date of Report	dd-mmm-yyyy

5. Medical History

Is there any relevant medical history?				Yes ☐ *Provide details below*		No ☐ *Proceed to section 8*
Condition	Start date	Ongoing?		End date (if relevant)	Medication required?	
	dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy	Yes ☐	No ☐
	dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy	Yes ☐	No ☐
	dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy	Yes ☐	No ☐
	dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy	Yes ☐	No ☐
	dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy	Yes ☐	No ☐
	dd-mmm-yyyy	Yes ☐	No ☐	dd-mmm-yyyy	Yes ☐	No ☐

6. Relevant test/laboratory results *Include only the results relevant to the SAE diagnosis or course of SAE*

Are there any relevant tests/laboratory results?			Yes ☐ *Provide details below*		No ☐ *Proceed to section 9*
Test/laboratory finding	Unit	Date	Value	Date	Value
		dd-mmm-yyyy		dd-mmm-yyyy	
		dd-mmm-yyyy		dd-mmm-yyyy	
		dd-mmm-yyyy		dd-mmm-yyyy	
		dd-mmm-yyyy		dd-mmm-yyyy	
		dd-mmm-yyyy		dd-mmm-yyyy	
		dd-mmm-yyyy		dd-mmm-yyyy	
		dd-mmm-yyyy		dd-mmm-yyyy	
		dd-mmm-yyyy		dd-mmm-yyyy	

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7. Action Taken			
Action	Name of intervention	Date of Action	Initials & Date
Intervention permanently discontinued ☐		dd-mmm-yyyy	
No action taken ☐	N/A	N/A	

8. Outcome of SAE *Any follow-up information releant to this section can be added to existing (e.g.initial) information. DO NOT cross through or otherwise obscure exxisting information and do not use a new form.*		
Outcome of SAE	Additional Information	Initials & Date
Ongoing outcomes		
Condition still present and unchanged ☐		
Condition deteriorated ☐		
Condition Improving ☐		
Final outcomes		
Resolved no sequelae ☐	Date of resolution: dd-mmm-yyyy	
Resolved with sequelae ☐	Date of resolution: dd-mmm-yyyy Specific sequelae: _____	
Death ☐	Date of death: dd-mmm-yyyy Post mortem: Yes ☐ No ☐	

9. Details of persons reporting			
Name of person reporting	Job title of person reporting		Date reported
			dd-mmm-yyyy
Email		Telephone	
Signature of person reporting (must be on delegation log)		Date of signature	dd-mmm-yyyy

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Principal & Chief Investigator Review & Assessment

TO BE COMPLETED BY THE PRINCIPAL INVESTIGATOR (PI)OR NAMED DELEGATE			TO BE COMPLETED BY THE CHIEF INVESTIGATOR (CI) OR NAMED DELEGATE	
10. Review of Causality by PI or delegate			**11. Review of Causality by CI or delegate**	**12. Assessment of expectedness by CI or delegate**
If the event is unrelated, please provide details of an alternative explanation for the event:			*Please review causality assessment made by PI or delegate*	*This column should **only** be completed if causal relationship is classified as 3, 4 or 5 **(possibly, probably or definitely related)** The expectedness assessment **must** be made with reference to the reference safety information (RSI).* Version and/or date of IB or SmPC containing RSI to assess expectedness
Intervention	**Dose**	**Causality Assessment** 1 = Unrelated 2 = Unlikely to be related 3 = Possibly related 4 = Probably related 5 = Definitely related	**Review of Causality** 1 = Unrelated 2 = Unlikely to be related 3 = Possibly related 4 = Probably related 5 = Definitely related	**Assessment of Expectedness** 1 = Expected 2 = Unexpected
Propess ☐ or NA ☐	Series 1..... Series 2..... Series 3.....			
Dilapan-S ☐ or NA ☐	Series 1..... Series 2..... Series 3.....			
Name of PI or delegate			Name of CI or delegate	
Signature of PI or delegate			Signature of CI or delegate	
Date of Signature	☐☐ / ☐☐☐ / ☐☐☐☐		Date of Signature	☐☐ / ☐☐☐ / ☐☐☐☐