construct
building the evidence

EudraCT Number: 2008-001968-36 **FAX : 01792 606599** **Email:** CONSTRUCTHelpdesk@swansea.ac.uk

Participant study ID: | | | | | | | |

PLEASE COMPLETE THIS FORM IF THE PARTICIPANT HAS ANY NEW SIGNS OR SYMPTOMS OR A COLECTOMY

Start date:	*d*	*d*	*m*	*m*	*y*	*y*	**Start time:**	*h*	*h*	*m*	*m*	***(or Duration):***		
End date:	*d*	*d*	*m*	*m*	*y*	*y*	**End time:**	*h*	*h*	*m*	*m*			

Event description ***(please give as much detail as possible):***

Severity:		**Outcome:**		
	Mild		Complete resolution	
	Moderate		Persisting problem	
	Severe		Irreversible consequences:	Surgery required
Trial drug:			*(please state which one)*	Death
	Remicade®			Other *(please specify)*
	Sandimmun®		Unknown	
	Neoral®		Other *(please specify)*	

QUESTIONS TO DETERMINE THE "EXPECTEDNESS" OF THE ADVERSE EVENT:

*"Yes" should only be ticked for **ONE** of the four questions below. As soon as a "Yes" has been ticked, complete the seriousness and causality categories overleaf.*

1) Is the symptom/problem a known, undesirable effect of the trial drug, *please check the Summary of Product Characteristics (SPC)*, in terms of its nature and severity?	☐ **Yes** ☐ **No**
If Yes, please turn over, if No go to Question 2	
2) Is the symptom/problem a stable symptom of a pre-existing condition? *NOTE: This question only concerns symptoms of medical conditions (other than UC) that were identified prior to the first treatment dose, and that have NOT significantly worsened since treatment commenced. If symptoms of a pre-existing symptom have worsened following trial treatment, select "No"*	☐ **Yes** ☐ **No**
If Yes, please turn over, if No go to Question 3	
3) Is the symptom/problem in keeping with an exacerbation or progression of the underlying disease (ulcerative colitis)? *NOTE: If the problem resulted in surgery/colectomy, please answer "No" and go to Question 4.*	☐ **Yes** ☐ **No**
If Yes, please turn over, if No go to Question 4	
4) Is the event a medical or surgical procedure e.g colectomy/colonoscopy?	☐ **Yes** ☐ **No**

Whether Yes or No, please turn over ***PTO for further instructions***

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If you have selected "Yes" for any of the earlier questions (1 – 4) *the adverse event is expected and, by definition, cannot be a SUSAR. Please complete the seriousness and causality categories below for the "expected" event, sign the form and fax to the CONSTRUCT Trial Office:*

Relation to trial drug (causality)

- ☐ Not related
- ☐ Unlikely to be related
- ☐ Possibly related
- ☐ Probably related
- ☐ Definitely related

Seriousness of event

- ☐ Resulted in death
- ☐ Is/was life threatening
- ☐ Resulted in disability / incapacity
- ☐ Required hospitalisation / prolonged hospital stay
- ☐ Resulted in congenital abnormality / birth defect
- ☐ Not serious (none of the above)

If you have selected "No" for all of the earlier questions (1 – 4) *the adverse event is unexpected and could be a SUSAR. Please complete the seriousness and causality categories below for the "unexpected" event:*

Relation to trial drug (causality)

- ☐ 1) Not related
- ☐ 2) Unlikely to be related
- ☐ **3) Possibly related**
- ☐ **4) Probably related**
- ☐ **5) Definitely related**

Seriousness of event

- ☐ **1) Resulted in death**
- ☐ **2) Is/was life threatening**
- ☐ **3) Resulted in disability / incapacity**
- ☐ **4) Required hospitalisation / prolonged hospital stay**
- ☐ **5) Resulted in congenital abnormality / birth defect**
- ☐ 6) Not serious (none of the above)

If causality = 3, 4 OR 5 AND seriousness = 1, 2, 3, 4 OR 5, the event is a **Suspected Unexpected Serious Adverse Reaction (SUSAR).**

You MUST now complete a SUSAR Report Form and send both the AE Screening and SUSAR Forms to the CONSTRUCT Trial Office within 24 hours of becoming aware of the event. Please refer to the Fieldwork Handbook for further instructions.

If the unexpected event is either not serious, not related or both, only fax the completed AE Screening Form as the event is not a SUSAR.

Name of person completing this form:		Signature:		Date form completed:	
Name of counter signatory:		Signature:		Date of countersignature:	

Once completed, please fax this form to the CONSTRUCT Trial Office on 01792 606599 as soon as possible.