WAZO GENI Patient Initials					Serial Number						Study number						
Case Record Form												W	G				



# CASE RECORD FORM

# The safety and efficacy of packed cord red blood cell transfusion in children with severe anaemia in a Kenyan hospital

KEMRI SSC No. 1215 LSTM REC No. 07.15 ISRCTN66687527

EVENT SUMMARY												
Event	Timing		Date		Ti	me						
		Day	Month	Year	Hour	Mins						
Transfusion start time												
Mid-transfusion bloods	Start +2 hrs											
Transfusion end time												
Post-transfusion assessment	End + 2 hrs											
Post-transfusion assessment	Start + 24 hrs											
Post-discharge follow-up	Start date + 28 days				Arrangeo discharge							

In the event of any queries regarding the completion of this form or the trial protocol, please feel free to contact us at *any* time:

Oliver Hassall	Principal Investigator	Ext. 221	Mob: 0723 495943
Johnstone Thitiri	Trial Co-ordinator	Ext. 501	Mob: 0722 408020

WAZO GENI	Pat	tient	Initi	als	Se	rial N	Num	ber		Stu	ıdy n	umb	er	
Case Record Form										W	G			

## **CONTENTS AND INSTRUCTIONS**

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## **General Instructions**

- Ensure you are familiar with the definitions of adverse and serious adverse events
- All fields should be completed
- Use a ball point pen and write clearly
- Print name, sign and date where indicated
- Errors ahould be crossed out with a single line. The correction should be made as close to the original as possible and initialled and dated.
- Ensure that adverse events/ serious adverse events are reported fully
- If you have any concerns, do not hesitate to contact Oliver Hassall (PI) or Johnstone Thitiri (Trial Co-ordinator)

WAZO GENI	Ра	tient	Initi	als	s	erial l	Num	ber			Stu	ıdy r	umt	ber	
Case Record Form											W	G			
							C	Check	( app	propri	ate b		-		LITY k (⊠)
Inclusion criteria These questions must bot 1. Is the child aged 12 yea			d YE	S for the	e child to	o be e	ligibl	e for	the s	study YES				<b>NO</b>	
<ol> <li>Does the child have seven if aged &lt; 3 monopole</li> <li>If aged &gt; 3 monopole</li> </ol>	onths, Hl	b ≤ 1(	)g/dL		sfusior	?							Inel	ligibl	e
Exclusion criteria	stions ar	e ans	swere	ed YES, a	the child	d is <b>nc</b>	ot eli	gible	for t	he st	udy				
1. Is the child in coma? • Blantyre Com	a Scale	score	e ≤ 2							YE	<b>S</b> ]		I	<b>0</b>	
<ul><li>2. Is the child prostrated?</li><li>If unable to sit</li><li>If able to sit w</li></ul>					enteral	feeds	(ng/	/oral)			ו				
3. Does the child have und	compens	sated	shoo	ck?							ו				
<ul> <li>4. Does the child have cor</li> <li>Capillary refill</li> <li>Temperature</li> </ul>	≥ 3s and	d/or	iock?	)							נ				
5. Does the child have res	piratory	distre	ess?	(Deep br	eathing	)					ו				
6. Does the child have nee	onatal ja	undic	e rec	quiring ar	ו excha	nge tr	ansf	usion	ı?		ן נ				
7. Is the child enrolled in a	inother <u>ii</u>	nterve	entio	<u>n</u> trial?							ונ				
8. Does the child have any enrolment in the study? (If					everity t	hat wo	ould	precl	ude		]				
<ul> <li>If YES, give b</li> <li></li> </ul>	elow: 								I 	nelig	jible				-
<b>Consent</b> Informed consent must be	given b	efore	the o	child can	be enr	olled ii	n the	e stuc	ly						
Has the child's parent or g enrol in the study and rece						or the d	child	to		YE [	<b>S</b> ]			NO D ligibl	e

I have assessed the patient, checked the inclusion/exclusion criteria and confirmed that informed consent has been given. The patient is eligible for the study.

Name	Sign	Date			Time (24	4hr)	
		0					
Investigator or nominee	Investigator or nominee	Day		Month	Year	Hour	Mins

WAZO GENI	Patient Initials					Serial Number					Study number						
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# **PRE-TRANSFUSION (0 hrs)**

# Clinical assessment prior to transfusion

Ad	miss	ion <b>t</b>	o Kl	DH								
Dat	te of	KDH admission Time (24hr)										
D	ay	Мо	nth	Ye	ear	Ho	our	Mi	ns			

PID Number												

	Current clinical problems		Antl	nrop	om	etric	: dat	ta			
1		Sex		Mal	e 🗆		Fe	ma	le 🗆		
2		Age		у			I	m			d
3		DOB		-			-				
4		Weight		kg	lf	pre-	tern	n in	fant:		
5		Length		cm	G	est.	Age	;		wee	eks
6		MUAC		cm							

Has the	e child rea	ceived a b	ood transfusion previously?	Yes	S 🗆	No 🗆					
If <b>yes</b> , o	on how m	nany occas	translusio								
Please gi	ive any deta	ails below									
	Date		Details of transfusion reaction	e if an	v						
Day	Month	Year	Details of transfusion reaction	5, 11 an	y						

Is the child currently receiving any treatment (e.g drug, fluid)?Yes □No □If yes, give details in the concomitant treatment sheet (Page 9)

Axillary	Pulse	Resp	O <sub>2</sub>	Air/	BP	BP	BP
Temp	Rate	Rate	Sats	O <sub>2</sub>	Systol	Diastol	Mean
℃	<i>bpm</i>	<i>bpm</i>	%	A/O	<i>mm Hg</i>	<i>mm Hg</i>	<i>mm Hg</i>

General Appe	earance									
Rigors/chills	Yes 🗆 No 🗆	Urticarial rash	Yes 🗆 No 🗆	Jaundice	Yes 🗆 No 🗆					
CVS										
Cap refill ≥ 3s	Yes 🗆 No 🗆	Temp gradient	Yes 🗆 No 🗆	Liver edge	cm bcm					
Chest										
Deep breathing	Yes 🗆 No 🗆	Basal creps	Yes 🗆 No 🗆	Wheeze	Yes 🗆 No 🗆					
CNS										
Prostration	Yes 🗆 No 🗆	BCS score	/ 5	Others (Record below)	Yes 🗆 No 🗆					

Additional finding	s of note					
Name	Sign	Date			Time (2	4hr)
Clinician	Clinician	Day	Month	Year	Hour	Mins

WAZO GENI	Patient Initials		Serial Number				Study number									
Case Record Form												W	G			

# **POST-TRANSFUSION (End transfusion + 2 hrs)**

# Clinical assessment (2 hours after end of transfusion)

Date of	assessm	Time (24hr)				
Dav	Month	Year	Hour	Mins		

#### **Physical examination**

	Axillary	Pulse	Resp	O <sub>2</sub>	Air/	BP	BP	BP
	Temp	Rate	Rate	Sats	O <sub>2</sub>	Systol	Diastol	Mean
	<i>°</i> C	<i>bpm</i>	<i>bpm</i>	%	A/O	<i>mm Hg</i>	<i>mm Hg</i>	<i>mm Hg</i>
ſ								

earance					
Yes 🗆 🛛	No 🗆	Urticarial rash	Yes 🗆 No 🗆	Jaundice	Yes 🗆 No 🗆
					·
Yes 🗆 🛚	No 🗆	Temp gradient	Yes 🗆 No 🗆	Liver edge	cm bcm
Yes 🗆 🛛	No 🗆	Basal creps	Yes 🗆 No 🗆	Wheeze	Yes 🗆 No 🗆
Yes 🗆 🛛	No 🗆	BCS score	/ 5	Others (Record below)	Yes 🗆 No 🗆
	Yes 🗆   Yes 🗆	Yes  No  Yes N	Yes □ No □ Urticarial rash Yes □ No □ Temp gradient Yes □ No □ Basal creps	Yes □       No □       Urticarial rash       Yes □       No □         Yes □       No □       Temp gradient       Yes □       No □         Yes □       No □       Basal creps       Yes □       No □	Yes □       No □       Urticarial rash       Yes □       No □       Jaundice         Yes □       No □       Temp gradient       Yes □       No □       Liver edge         Yes □       No □       Basal creps       Yes □       No □       Wheeze         Yes □       No □       BCS score       / 5       Others

Additional findings of note		

#### Adverse events

Has there been any evidence of a transfusion reaction?	Yes 🗆	No 🗆
If <b>yes</b> , ensure adverse event documentation completed (at end)		

Have there been any adverse events since the last assessment?	Yes 🗆	No 🗆
If yes, ensure adverse event documentation completed (at end)		

#### **Concomitant medication**

Has there been any change in the child's treatment since the last assessment?	Yes 🗆	No 🗆
Tick <b>yes</b> if new treatment started or current treatment ceased.		
If yes, give details on concomitant treatment sheet (Page 9)	ĺ	

#### Sign and date

Name	Sign	Date			Time (24hr)		
Clinician	Clinician	Day	Month	Year	Hour	Mins	

WAZO GENI	Patient Initials				Serial Number					Study number							
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# POST-TRANSFUSION (+24 hrs)

# Clinical assessment (24 hrs after start of transfusion)

Date of assessment							<b>Time</b> (24hr)					
Day		Мо	nth	Ye	ear	Н	bur	М	ins			

#### **Physical examination**

	Axillary	Pulse	Resp	O <sub>2</sub>	Air/	BP	BP	BP
	Temp	Rate	Rate	Sats	O <sub>2</sub>	Systol	Diastol	Mean
	<i>°</i> C	<i>bpm</i>	<i>bpm</i>	%	A/O	<i>mm Hg</i>	<i>mm Hg</i>	<i>mm Hg</i>
ſ								

General Appe	earance						
Rigors/chills	Yes 🗆 🛚	No 🗆	Urticarial rash	Yes 🗆	No 🗆	Jaundice	Yes 🗆 No 🗆
CVS	•						
Cap refill ≥ 3s	Yes 🗆 🛚	No 🗆	Temp gradient	Yes 🗆	No 🗆	Liver edge	cm bcm
Chest							
Deep breathing	Yes 🗆 🛛	No 🗆	Basal creps	Yes 🗆	No 🗆	Wheeze	Yes 🗆 No 🗆
CNS							
Prostration	Yes 🗆 🛚	No 🗆	BCS score	/	5	Others (Record below)	Yes 🗆 No 🗆
	•						

Additional findings of note		

#### Adverse events

Has there been any evidence of a transfusion reaction?	Yes 🗆	No 🗆
If yes, ensure adverse event documentation completed (at end)		

Have there been any adverse events since the last assessment?	Yes 🗆	No 🗆
If <b>yes</b> , ensure adverse event documentation completed (at end)		

#### **Concomitant medication**

Has there been any change in the child's treatment since the last assessment?	Yes 🗆	No 🗆
Tick yes if new treatment started or current treatment ceased.		
If <b>yes</b> , give details on concomitant treatment sheet (Page 9)		

#### Sign and date

Name	Sign	Date			Time (24hr)		
				0			
Clinician	Clinician	Day	Month	Year	Hour	Mins	

WAZO GENI	Patient Initials					Serial Number					Study number					
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# **POST-TRANSFUSION (Discharge)**

cm

# Clinical assessment (At discharge)

Date of	assessm	Time (24hr)					
Dav	Month	Year	Hour	Mins			

# Physical examination and symptom assessment

Is the child having fevers?	Yes 🗆	No 🗆		
			-	
Is the child jaundiced?	Yes 🗆	No 🗆		
	•			
Does the child have a rash?	Yes 🗆	No 🗆		
If yes, describe here. Include details of appearance, distribution and	associated sy	nptoms		
			1	
Does the child have an enlarged liver?	Yes 🗆	No 🗆	Liver edge	
If <b>yes</b> , note cm below costal margin				
			-	
Are there any other clinical findings of note?	Yes 🗆	No 🗆		
If <b>yes</b> , describe below				
			1	
Additional clinical findings of note			]	
Additional clinical findings of note				
Additional clinical findings of note				
Additional clinical findings of note				

#### Adverse events

Has there been any evidence of a transfusion reaction since last assessment?	Yes 🗆	No 🗆
If yes, ensure adverse event documentation completed (at end)		

Have there been any adverse events since the last assessment?	Yes 🗆	No 🗆
If yes, ensure adverse event documentation completed (at end)		

## Concomitant and discharge treatment

Has there been any change in the child's treatment since the last assessment?	Yes 🗆	No 🗆
Tick <b>yes</b> if new treatment started or current treatment ceased ( <b>Include DISCHARGE medication</b> ) If <b>yes</b> , give details on concomitant treatment sheet (Page 9)		

#### Discharge diagnoses

	Diagnosis
1	
2	

Name	Sign	Date			Time (24	4hr)
Clinician	Clinician	Day	Month	Year	Hour	Mins

WAZO GENI	Patient Initials				Serial Number						Study number					
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# POST-TRANSFUSION (28 days)

## Clinical assessment (KEMRI out-patients)

Date of	assessm	Time (2-	4hr)	
Dav	Month	Year	Hour	Mins

#### Physical examination and symptom assessment

Is the child reported to be having fevers?	Yes □	No 🗆		
			-	
Is the child jaundiced?	Yes 🗆	No 🗆		
Does the child have a rash?	Yes 🗆	No 🗆	7	
If yes, describe here. Include details of appearance, distributio				
		Jinptonio		
Does the child have an enlarged liver?	Yes 🗆	No 🗆	Liver edge	cm
If <b>yes</b> , note cm below costal margin	÷			
And there are other aliginal findings of pate 2			7	
Are there any other clinical findings of note?	Yes 🗆	No 🗆	_	
If <b>yes</b> , describe below				
Additional clinical findings of note			7	

#### Adverse events

Has there been any evidence of a transfusion reaction since last assessment?	Yes 🗆	No 🗆
If yes, ensure adverse event documentation completed (at end)		
Have there been any adverse events since the last assessment?	Yes 🗆	No 🗆
If yes, ensure adverse event documentation completed (at end)		

#### Concomitant treatment

Has there been any change in the child's treatment since the last assessment?	Yes 🗆	No 🗆
Tick <b>yes</b> if new treatment started or current treatment ceased.		
If <b>yes</b> , give details on concomitant treatment sheet (Page 9)		

#### Sign and date

Name	Sign	Date			Time (24	4hr)
Clinician	Clinician	Day	Month	Year	Hour	Mins

WAZO GENI	WAZO GENI Patient Initials				Serial Number						Study number					
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## **CONCOMITANT TREATMENT**

This sheet should provide a record of all treatment that the child has received in addition to a cord blood transfusion. It can help determine the cause of adverse and serious adverse events.

It should be updated, where necessary, at every clinical assessment

- Add current or new treatments and start dates
- Leave end date open if treatment still ongoing
- If treatments have ceased since the last assessment then fill in end date
- One-off treatments have the same start and end date

Tractment name (lies generic names for druce)	Route		Da	te star	t	Date stop				
Treatment name (Use generic names for drugs)	Route	Day Month			Year	Day	Month	Year		
				_						
								<u> </u>		
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#### Checked complete:

Name	Sign	Date			<b>Time</b> (24hr)		
				0			
Investigator or nominee	Investigator or nominee	Day	Month	Year	Hour	Mins	

WAZO GENI	Patient Initials			Serial Number				Study number									
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## **TRANSFUSION OBSERVATIONS**

#### Transfusion observations

To be completed by nursing staff after the post-transfusion observation period

How many cord blood units did the child receive?	1 🗆	2 🗆

Was frusemide prescribed?

Yes D No D

Unit 1

Donor	unit l	D		Expiry date			Blood group	Volume transfused			
			-					0			ml

		Date	Time		
	Day	Month	Year	Hour	Mins
Transfusion start time					
Transfusion end time					

Was the transfusion completed?	Yes 🗆	No 🗆

Was a transfusion reaction suspected?	Yes 🗆	No 🗆
If <b>yes</b> , ensure that MO/CO was informed and adverse event documentation completed		

Unit 2 Not applicable

Donor	unit ID		Ex	Expiry date			Blood group	Volume transfused		
		-					0			ml

		Date	Time		
	Day	Month	Year	Hour	Mins
Transfusion start time					
Transfusion end time					

Was the transfusion completed?	Yes 🗆	No 🗆

Was a transfusion reaction suspected?	Yes 🗆	No 🗆
If yes, ensure that MO/CO was informed and adverse event documentation completed		

Name	Sign	Date		Time (24hr)			
				0			
Nurse	Nurse	Day	Month	Year	Hour	Mins	

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# POST-TRANSFUSION (35 days)

# Follow-up at home

Dat	te of	visit			
D	ay	Мо	nth	Υe	ear

Was the child found at home?	Yes 🗆	No 🗆
If <b>no</b> , where was the child reported to be?		

If the child <b>was</b> found at home, was the child seen to be alive?	Yes 🗆	No 🗆	N/A 🗆
Give any details			

If the child <b>was not</b> found at home, was the child reported to be alive?	Yes 🗆	No 🗆	N/A 🗆
Give any details			

Name	Sign	Date		Time (24hr)			
Investigator or nominee	Investigator or nominee	Day	Month	Year	Hour	Mins	

WAZO GENI	Patient Initials	Serial Number	Study number
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		L	ABORATORY DATA (1)
Admission/ Pre-tran	sfusion		
Date	Time	ND= Not	Done
Day Month Year	Hour Mins	NR= No	Result
Haematology	Biochemist	try	
RBC   . _  _	GLU  _  _ .	рН	·
HGB       .	SOD  _  _	CAL	·
нст    .	POT  _ . _	Malar	ia microscopy
MCV	CRE    _		/ 100 WBC

Name	Sign	Date		Time (24hr)			
				0			
Investigator or nominee	Investigator or nominee	Day	Month	Year	Hour	Mins	

# Mid-transfusion (+ 2 Hours from start of transfusion)

Date	Date Time										Ν	D= Not Dor	۱e
											N	R= No Res	ult
Day	Мс	onth	Ye	ear	Но	our	М	ins			IN	IV- NO IVES	un
										1			
Bioch	emist	ry											
SOD	I		_	_		C	RE		_				
POT  _ . _  CAL  _ . _													

Name	Sign	Date		Time (24hr)				
				(	כ			
Investigator or nominee	Investigator or nominee	Day	Mont	h	Year	Ηοι	ır	Mins

WAZO GENI		Patient Initials						rial N	lum	ber		Study number						
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											L	ABC	RA	OR	ΥD	ΑΤΑ	A (2)	
Deat transfusion ()	04 Hours from start of transfusion)								<b>`</b>									

## Post-transfusion (+ 24 Hours from start of transfusion)

Date		Time	ND= Not Done
Day	Month Year	Hour Mins	- NR= No Result
Haema	atology	Bio	ochemistry
RBC	·	GLU  _	_     .    pH    .
HGB	·	SOD	_     CAL    .
нст	·	POT  _	Malaria microscopy
MCV		CRE	_      / 100 WBC
PLT		SBR	_      / 500 RBC

Name	Sign	Dat	e				Time	r)	
						0			
Investigator or nominee	Investigator or nominee	Da	эy	Мо	nth	Year	Hour		Mins

# Follow-up (28 days after transfusion)

Dat	te					Tin	ne		
Da	ay	Мо	nth	Υe	ear	Но	bur	Mi	ins

Haema	atology	
RBC	·	
HGB	·	
НСТ	·	Malaria microscopy
MCV		/ 100 WBC
PLT		/ 500 RBC

ND= Not Done

NR= No Result

Name	Sign	Dat	e				Time (24hr)			
						0				
Investigator or nominee	Investigator or nominee	Da	ay	Мог	nth	Year	Hour	Mins		

WAZO GENI	Pa	tient	Initi	ials	Sei	rial N	lum	ber		Stu	idy n	umb	er	
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## LABORATORY DATA (3)

## Blood bank data

Child's blood group

For children less than 4 months of age

Mother's blood group

N/A 🗆

How many cord blood units were cross-matched? 1 2 

#### Details of units cross-matched

Do	onor l	D		Exp	oiry c	late		Pack Weight	Cord Hb	Group	Volume issued
			-				0				

# Additional investigations of note

Investigation		Date		Result
Investigation	Day	Month	Year	Result
	_			
		_		

Name	Sign	Date				Time (2	4hr)
					0		
Investigator or nominee	Investigator or nominee	Day	Ма	onth	Year	Hour	Mins

WAZO GENI	Patient Initials						Serial Number						Study number						
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## **ADVERSE EVENTS- DEFINITIONS**

# Adverse event Any untoward medical occurrence which may or may not be related to cord blood transfusion Serious adverse event Any untoward medical occurrence which may or may not be related to cord blood transfusion, which: Is fatal Is life-threatening Is disabling or incapacitating Prolongs hospitalisation Results in hospitalisation The investigator considers a serious or significant hazard, contraindication, • precaution or side-effect Expected serious adverse events of cord blood transfusion are: 1. Related to blood transfusion in general Transfusion reaction 2. Related to cord blood transfusion in particular Citrate toxicity Hyperkalaemia In the event of ANY serious adverse event please contact the study team immediately **Intensity** (refers to the *maximum* intensity) Mild An event which is tolerated Moderate An event sufficiently discomforting to interfere with daily activity Severe An event which prevents normal daily activities Relationship to cord blood transfusion *Not related* The event is definitely not related to cord blood transfusion There are other more likely causes and cord blood transfusion is not Unlikely suspected as a cause (Reasonal possibility) A direct cause and effect relationship between cord Suspected blood transfusion and the event has not been demonstrated but is possible or likely Probable There probably is a direct cause and effect relationship between the event and cord blood transfusion

## Please ensure that all adverse events are fully documented

WAZO GENI	Patie	ent Init	ials	<b>u</b> ,	erial l	Num	ber		Stu	dy n	umb	er	
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# NON-SERIOUS ADVERSE EVENTS (1)

Tick (☑) where appropriate									
Adverse event		AE1							
	j	Date					Time		
Onset date and time					0				
End date and time					0				
Leave blank if ongoing	ļ	Day	Mor	th	Yea	nr	Hour		Mins
Outcome		Resolv	/ed		Ong	joing		0	Died
If died complete SAE form	ļ								
Maximum intensity		Milo	ł		Mod	erate		Se	evere
	ļ								
Action with regard		Non	е		Stop	oped	Ir		upted &
to cord blood		_			_	_		res	tarted
transfusion	ļ								
transfusion Relationship to cord		Not		Unlik	ely	Sust	pected	1	Probable
		Not related		Unlik	ely	Sus	pected	ł	Probable
Relationship to cord		related	es 🗌	Unlik	ely	Sus		10 [	Probable

Name	Sign	Date				Time (2-	4hr)
					0		
Investigator or nominee	Investigator or nominee	Day	Мо	onth	Year	Hour	Mins

Tick (	<u>الم</u> ا	where	an	nro	nriate
	œ)	WIICIC	ap	$\mu 0$	priate

Tick (⊠) where appropriate													
Adverse event	AE2												
	Date						Tim	ne					
Onset date and time					0								
End date and time					0								
Leave blank if ongoing	Day	М	ontl	h	Yea	r	Но	ır	Mins				
Outcome	Resolv	ed			Ong	oing			Died				
If died complete SAE form													
Maximum intensity	Mild				Mod	erate			Severe				
					Ľ								
Action with regard to cord blood	None	е			Stop	ped			terrupted &				
transfusion					Ľ				restarted				
Relationship to cord	Not		U	Unlikely		ly Suspe		ed	Probable				
blood transfusion	related												
Corrective therapy	Ye	es [						N	o 🗌				
concerve merapy	Record	det	Yes     No       Record details in concomitant treatment section										

Name	Sign	Dat	te					Tim	<b>1e</b> (24	ŧhr)
						0				
Investigator or nominee	Investigator or nominee	Di	ay	Мо	nth	Ye	ear	Но	our	Mins

WAZO GENI	Pati	ient	Initi	ials	Ser	ial N	luml	ber		Stu	dy n	umb	er	
Case Record Form										W	G			

# NON-SERIOUS ADVERSE EVENTS (2)

Tick (☑) where appropriate											
Adverse event		AE3									
		Date						Tim	е		
Onset date and time						0					
End date and time						0					
Leave blank if ongoing		Day	N	1ont	h	Yea	nr	Hou	r	Mins	;
Outcome		Resol	ved			Ong	joing			Died	
If died complete SAE form											
Maximum intensity		Mil	d			Mod	erate		5	Severe	
						Γ					
Action with regard to cord blood		Nor	ne	è		Stopped				iterrupted & restarted	
transfusion											
Relationship to cord		Not		U	Inlik	Inlikely		pecte	d	Probat	ole
blood transfusion		related	I								
Corrective therapy		Y	′es				No 🗌				
concourte morapy	Record details in concomitant treatment section									n	

Name	Sign	Dat	e					Tim	<b>e</b> (24	lhr)	
						0					
Investigator or nominee	Investigator or nominee	Da	аy	Мо	nth	Ye	ar	Но	ur	Min	າຣ

Tick (	<u>الم</u> ا	where	an	nro	nriate
	œ)	WIICIC	ap	$\mu 0$	priate

Tick (M) where appropriate		AE4									
Adverse event		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,									
		Date						Tim	е		
Onset date and time						0					
End date and time						0					
Leave blank if ongoing		Day	Мс	nti	h	Yea	r	Ηοι	ir	Mins	
Outcome		Resolv	/ed			Ong	oing			Died	
If died complete SAE form						Γ					
Maximum intensity		Mild	I			Moderate				Severe	
						Ľ					
Action with regard to cord blood		Non	е			Stop	pped		Interrupted 8		
transfusion									r	estarted	
Relationship to cord		Not		U	Inlike	ely	Sus	pecte	ed	Probable	
blood transfusion		related									
Corrective therapy		Ye	es [						No		
concentre merapy	Record details in concomitant treatment section										

Name	Sign	Date	e					Tim	<b>1e</b> (24	1hr)
						0				
Investigator or nominee	Investigator or nominee	Da	эy	Мо	nth	Ye	ear	На	bur	Mins

WAZO GENI	Pati	ient	Initi	ials	Ser	ial N	luml	ber		Stu	dy n	umb	er	
Case Record Form										W	G			

# NON-SERIOUS ADVERSE EVENTS (3)

Tick (☑) where appropriate										
Adverse event	AE5	i								
	Date	e					Time			
Onset date and time					0					
End date and time					0					
Leave blank if ongoing	Day		Mor	nth	Yea	nr	Hour		Mins	
Outcome	R	lesolv	/ed		Ong	joing		[	Died	
If died complete SAE form					Ľ					
Maximum intensity		Mild	I		Mod	erate		S	evere	
waximum mensity					Ľ					
Action with regard		Non	е		Stop	oped			rupted &	
Action with regard to cord blood transfusion		Non	e		Stop	oped	1		rupted & started	:
to cord blood	-	Not	_	Unlik			Dected	res	•	
to cord blood transfusion	-		_	Unlik				res	tarted	
to cord blood transfusion Relationship to cord	-	Not lated	_	Unlik			bected	res	tarted	

Name	Sign	Date				Time (2	4hr)
					0		
Investigator or nominee	Investigator or nominee	Day	М	onth	Year	Hour	Mins

Tick (	<u>الم</u> ا	where	an	nro	nriate
	œ)	WIICIC	ap	$\mu 0$	priate

Tick (M) where appropriate	AE6								
Adverse event									
	Date		Ļ				Tim	е	
Onset date and time					0				
End date and time					0				
Leave blank if ongoing	Day	Мс	nti	h	Yea	r	Ηοι	ır	Mins
Outcome	Resolv	/ed			Ong	oing			Died
If died complete SAE form									
Maximum intensity	Mild	I			Mode	erate			Severe
Maximum interisity									
Action with regard to cord blood	Non	е			Stop	oped			errupted &
transfusion					Ľ			1	restarted
Relationship to cord	Not		U	nlike	ely	Sus	pecte	ed	Probable
blood transfusion	related								
Corrective therapy	Ye	es [						N	⊃ 🗌
concentre merapy	Record	det	ails	in c	onco	mitan	t trea	tme	nt section

Name	Sign	Dat	te					Tim	<b>1e</b> (24	ŧhr)
						0				
Investigator or nominee	Investigator or nominee	Di	ay	Мо	nth	Ye	ear	Но	our	Mins

WAZO GENI	Pat	ient	Initi	als	Ser	ial N	luml	ber		Stu	dy n	umb	er	
Case Record Form										W	G			

# **SERIOUS ADVERSE EVENTS (1)**

Name and designation of person reporting SAE	
Name	Designation

Tick (☑) where appropriate									
Serious Adverse Event	SAE1	1							
	Date						Tim	e	
Onset date and time					0				
End date and time					0				
Leave blank if ongoing	Day	1	Mont	h	Yea	r	Hou	r	Mins
Outcome	Re	solve	t		Ong	oing			Died
If died, see below									
Marian interactor		Mild			Mode	erate		:	Severe
Maximum intensity									
Action with regard	1	None			Stop	ped			errupted &
to cord blood transfusion								re	estarted
Relationship to cord	N		U	Inlike	ely	Sus	pecte	d	Probable
blood transfusion	rela								
		Yes						No	
Corrective therapy									

Reason for considering this an SAE:
Fatal
Life-threatening
Disabling/ Incapacitating
Hospitalisation prolonged
Results in hospitalisation
Investigator considers serious or significant hazard, contraindication, precaution or side-effect
Assessment The SAE is probably associated with:
The study design or procedures (but not cord blood transfusion itself)

Another condition (e.g condition under study, intercurrent illness)

An intervention other than cord blood transfusion

Death certification

Not applicable

Date of death	Time of death	Place of death	
0			
		Sub-location or Health Institution	District
Immediate cause of death	Ante	acadent causes	Other significant conditions
Immediate cause of death	n Ante	ecedent causes	Other significant conditions
Immediate cause of death a)	h Ante b)	ecedent causes	Other significant conditions
		acedent causes	Other significant conditions

Name	Sign	Date	е					Tim	<b>ie</b> (24	4hr)	
						0					
Investigator	Investigator	Da	iy	Mor	nth	Ye	ear	Hc	our	Mi	ins

Now complete the SAE documentation

on the following

WAZO GENI	Pat	tient	Initi	als	Ser	ial N	lum	ber		Stu	ıdy n	umb	er	
Case Record Form										W	G			

# **SERIOUS ADVERSE EVENTS (2)**

Invoction		Dat	e					Value	Unit		Norma
nvestigation		Day		Mont	h	Yea	r	value	Unit		range
		·									
Remarks											
		u I. (									
Please provide a brief narrativ	e description of the SAE, a	ttaching ext	tra pa	ages if r	neces	ssary					
					· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·					
					· · · · · · · · · · · · · · · · · · ·						
Name	Sign				Da	te			Tim	e (24	4hr)
Name	Sign				Da	te		0		<b>e</b> (2-	4hr)
							Montl				
	Sign Investigator					te	Month				4hr) Mins
							Month				
Investigator	Investigator				D	Day	Monti		ar Ho	ur	Mins
Investigator						Day	Montl			ur	Mins
Name Investigator	Investigator				D	Day	Month		ar Ho	ur	Mins