OPPTIMUM

Annotated CRF

Version 2.0

Does progesterone prophylaxis to prevent preterm labour improve outcome?

Isobel Docherty, Robertson Centre for Biostatistics

09 March 2013

Based on: eCRF (SDP Ref 146)

Contents

e-CRF Screen	Table Name (OPPTIMUM)	New/ Potential Participant	Screening	Randomisation visit	34 Weeks Gestation (End of Treatment)	Hospital Admissions	Outcome only
Participant Identification	webSubjects – if eligible webScreenExcl – if not eli ible						
Consent	webConsent OPPTIMUM_priv.dbo.webIdent						
Inclusion Criteria	webIncl						
Exclusion Criteria	webExcl						
Schedule fFN Test	webFibTestSch						
fFN Test Results	webFibTestRes						
Pregnancy Complications	webCompPreg						
Demographics	webDemog OPPTIMUM_priv.dbo.webPcode						
Medical History	webMedHistPreg webOthAbTest						
Prev Pregnancies	webPrevPreg						
Other Med History	webMedHistOth						
Contact Details	OPPTIMUM_priv.webContactDetails						
Randomisation	webRand						
Trial Treatment	webTrialTreatment						
Labour Hospital	webLabourHosp						
Labour	webLabour webAnalgesics						
Delivery	webDelivery webTransfer						
Postnatal Complications	webCompPostnatal						
Baby	webBaby2 OPPTIMUM_priv.dbo.webIdent						
Threatened Preterm Labour or PPROM	webHospAdmTPL webTransfer						
Antenatal Hospital Admission	webHospAdmOth webTransfer						

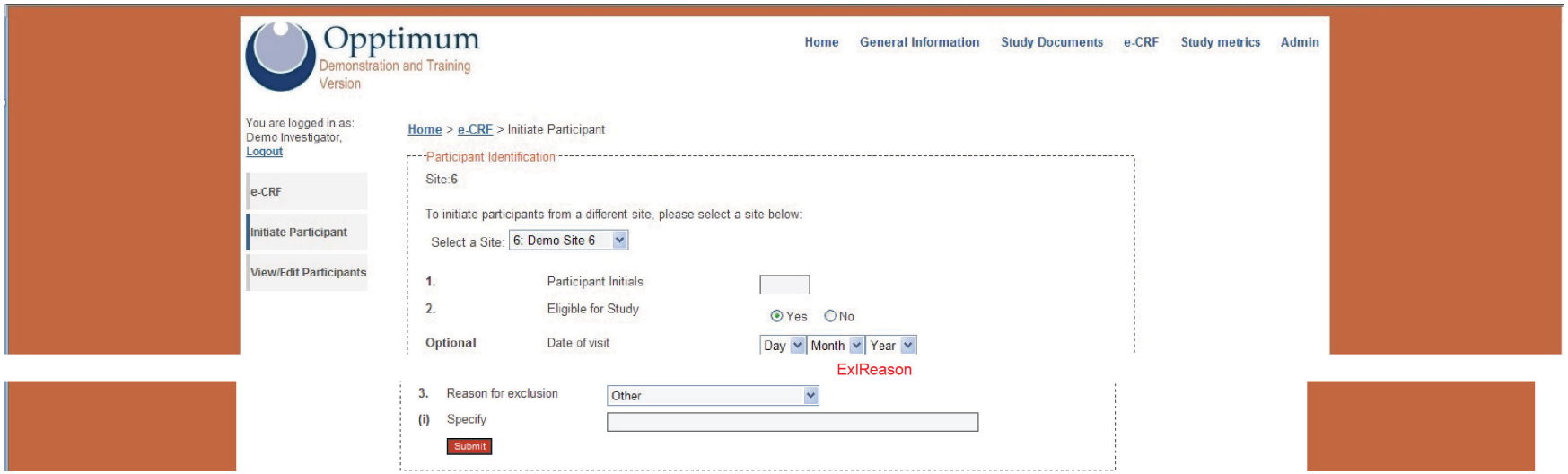
e-CRF Screen	Table Name (OPPTIMUM)	New/ Potential Participant	Screening	Randomisation visit	34 Weeks Gestation (End of Treatment)	Hospital Admissions	Outcome only
Neonatal Outcome	webNeoNatal2 webSurfactant webNeoDiag webTransfer						
Consent Withdrawal	webConsentWithdrawal						
End of Study	webTermination						
Protocol Violations	webProtViol						
Outcome only: Labour	webOoLabour						
Outcome only: Delivery	webOoDelivery						
Outcome only: Baby	webOoBaby						
Outcome only: Withdrawal	webOoWithdrawal						

Document history

Version	Date	Created by	Description
Version 1.0	27/04/2012	I. Docherty	Initial Creation
Version 2.0	09/04/2013		Incorporating changes to eCRF

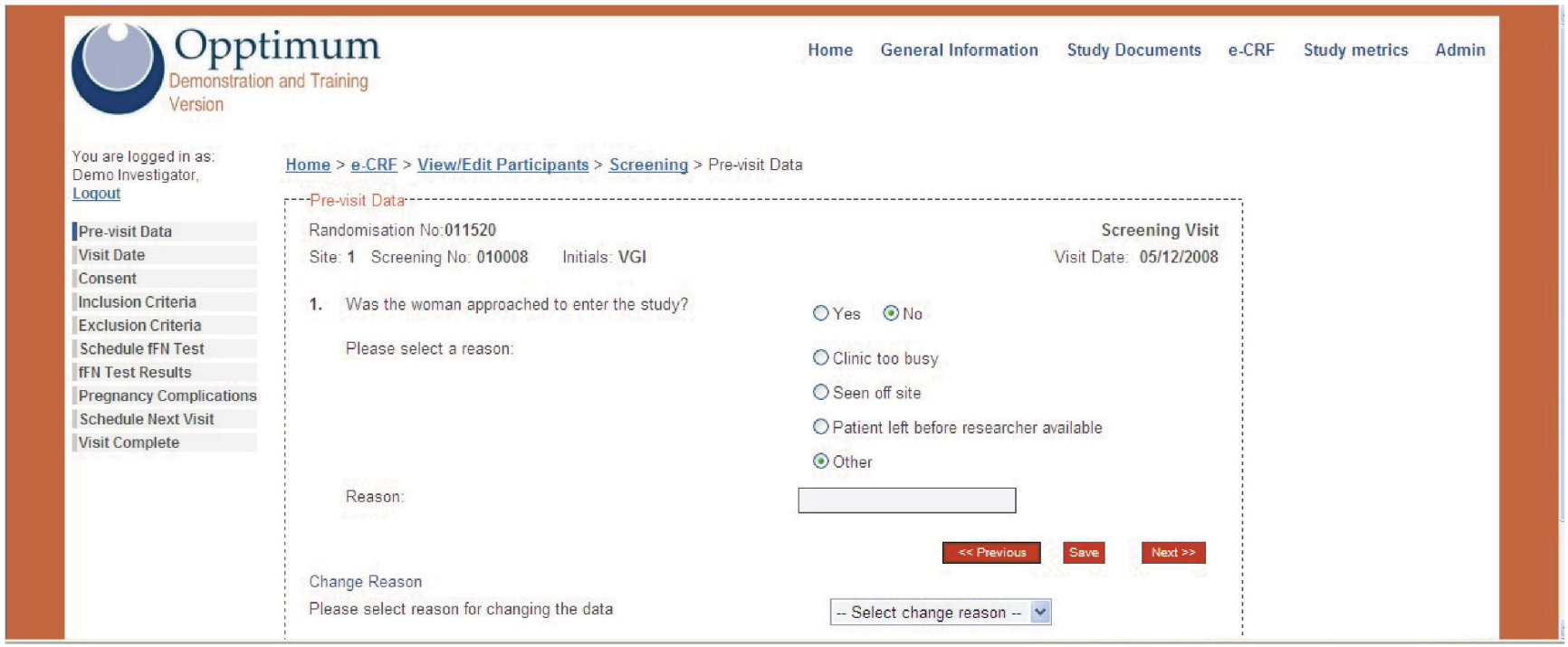
1. New/potential Participant –

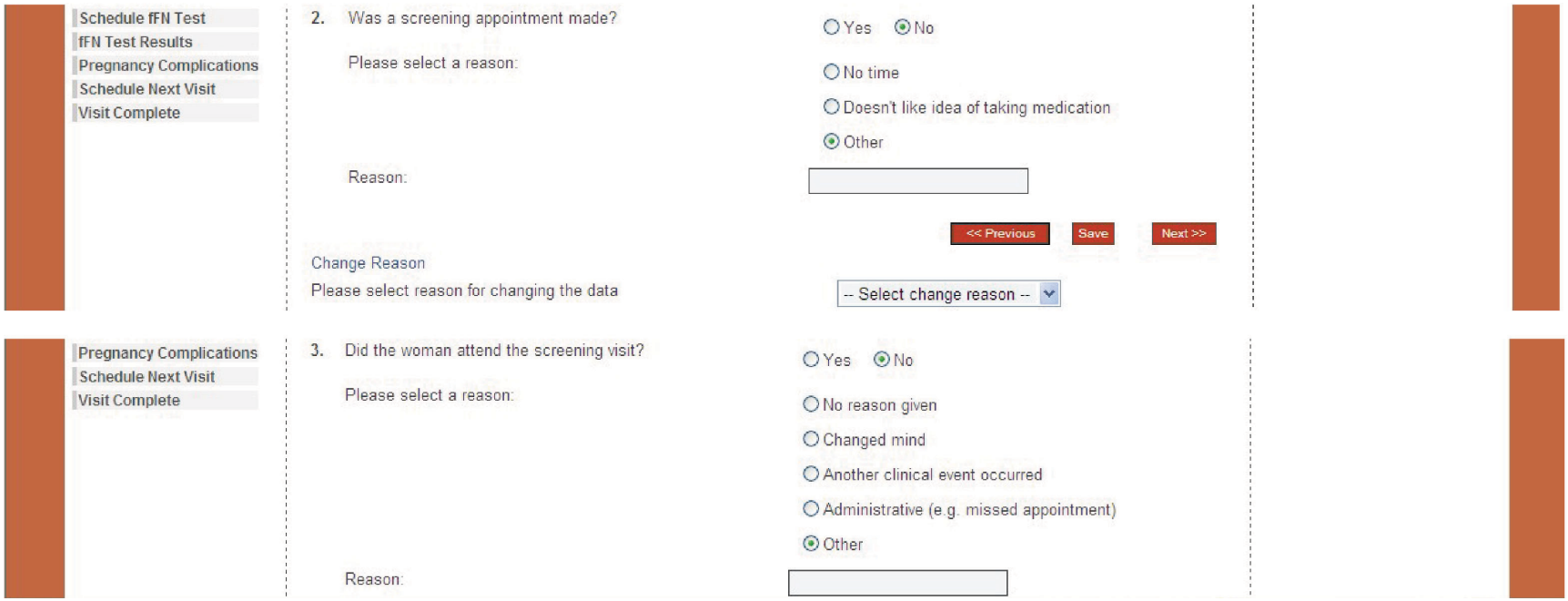
a. Initiate Participant



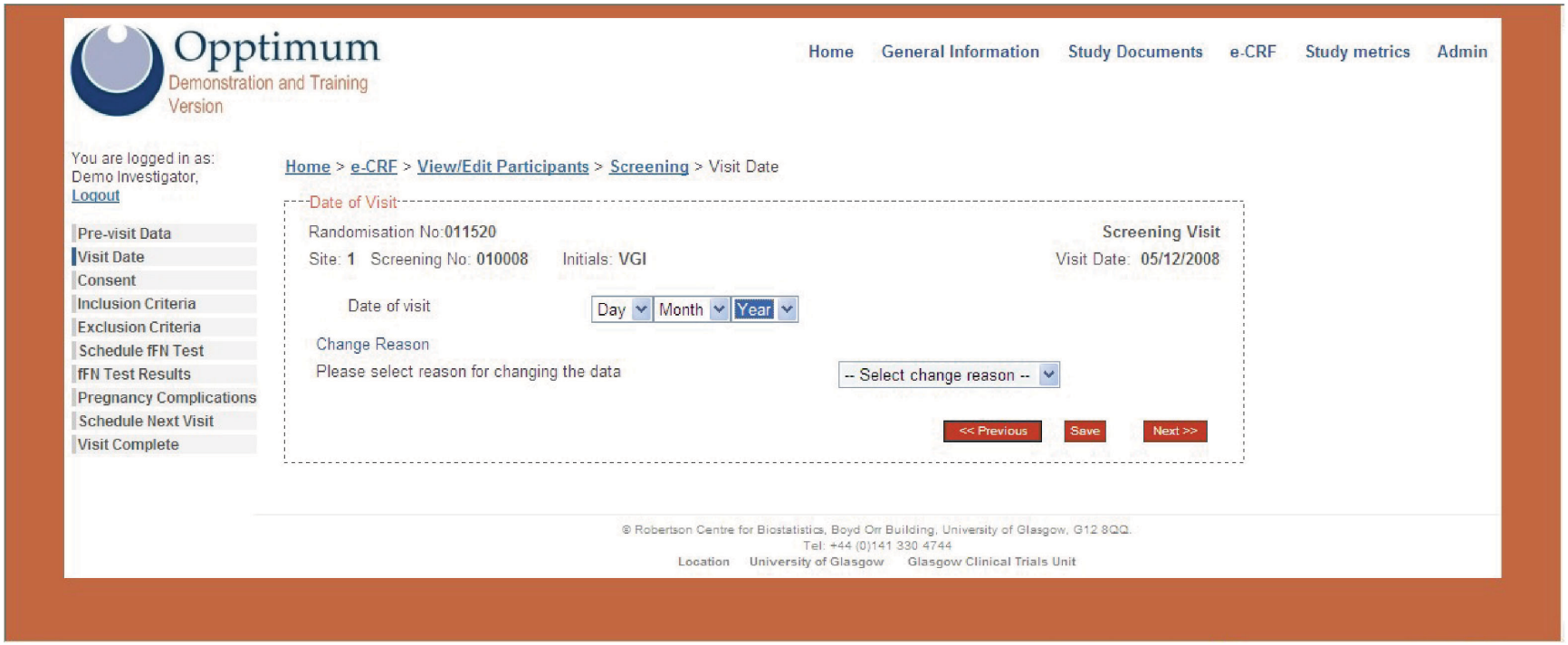
2. Screening Visit –

a. Pre-visit Data




Schedule fFN Test
fFN Test Results
Pregnancy Complications
Schedule Next Visit
Visit Complete
2. Was a screening appointment made?
Yes
No
Please select a reason:
No time
Doesn't like idea of taking medication
Other
Reason:
<< Previous
Save
Next >>
Change Reason
Please select reason for changing the data
-- Select change reason --
Pregnancy Complications
Schedule Next Visit
Visit Complete
3. Did the woman attend the screening visit?
Yes
No
Please select a reason:
No reason given
Changed mind
Another clinical event occurred
Administrative (e.g. missed appointment)
Other
Reason:

b. Visit Date


Opptimum
Demonstration and Training Version
Home
General Information
Study Documents
e-CRF
Study metrics
Admin
You are logged in as:
Demo Investigator,
Logout
Pre-visit Data
Visit Date
Consent
Inclusion Criteria
Exclusion Criteria
Schedule fFN Test
fFN Test Results
Pregnancy Complications
Schedule Next Visit
Visit Complete
Home > e-CRF > View/Edit Participants > Screening > Visit Date
Date of Visit
Randomisation No:011520
Screening Visit
Site: 1 Screening No: 010008 Initials: VGI
Visit Date: 05/12/2008
Date of visit
Day
Month
Year
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
Save
Next >>
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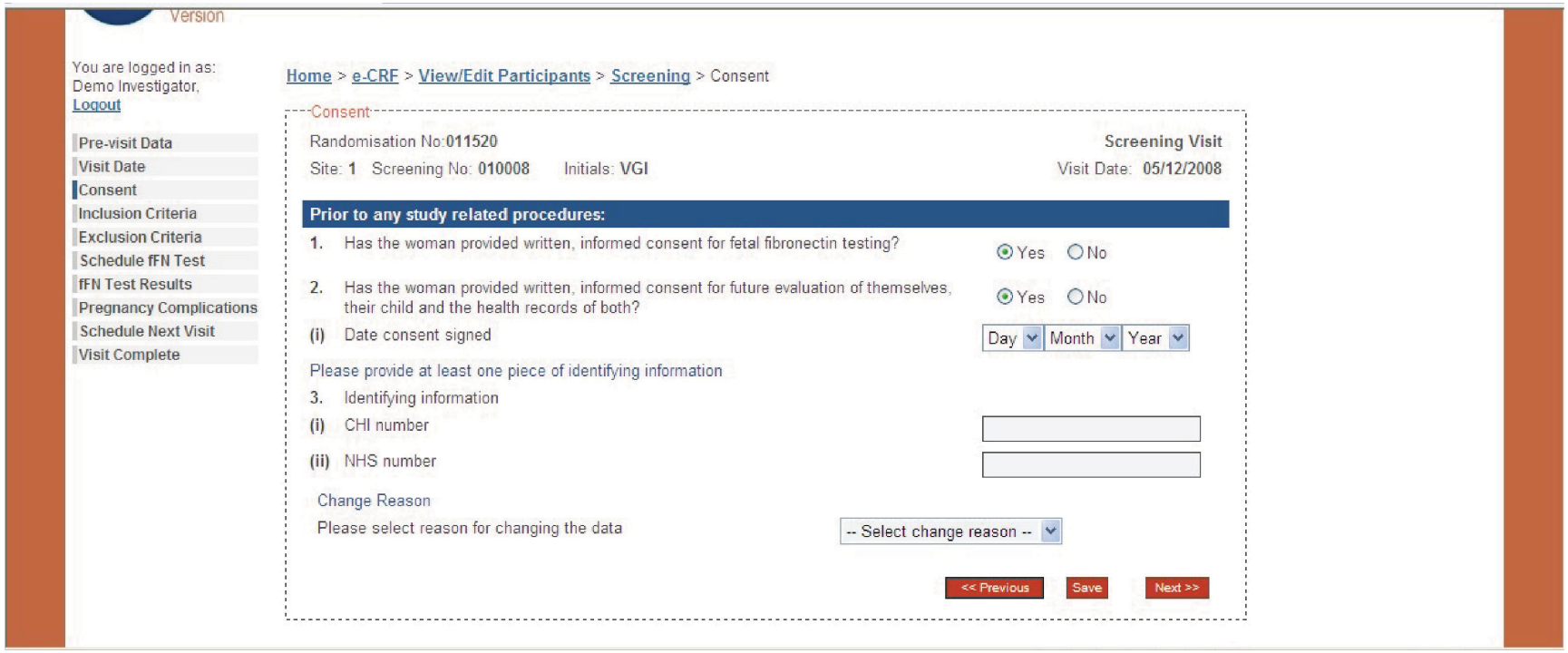
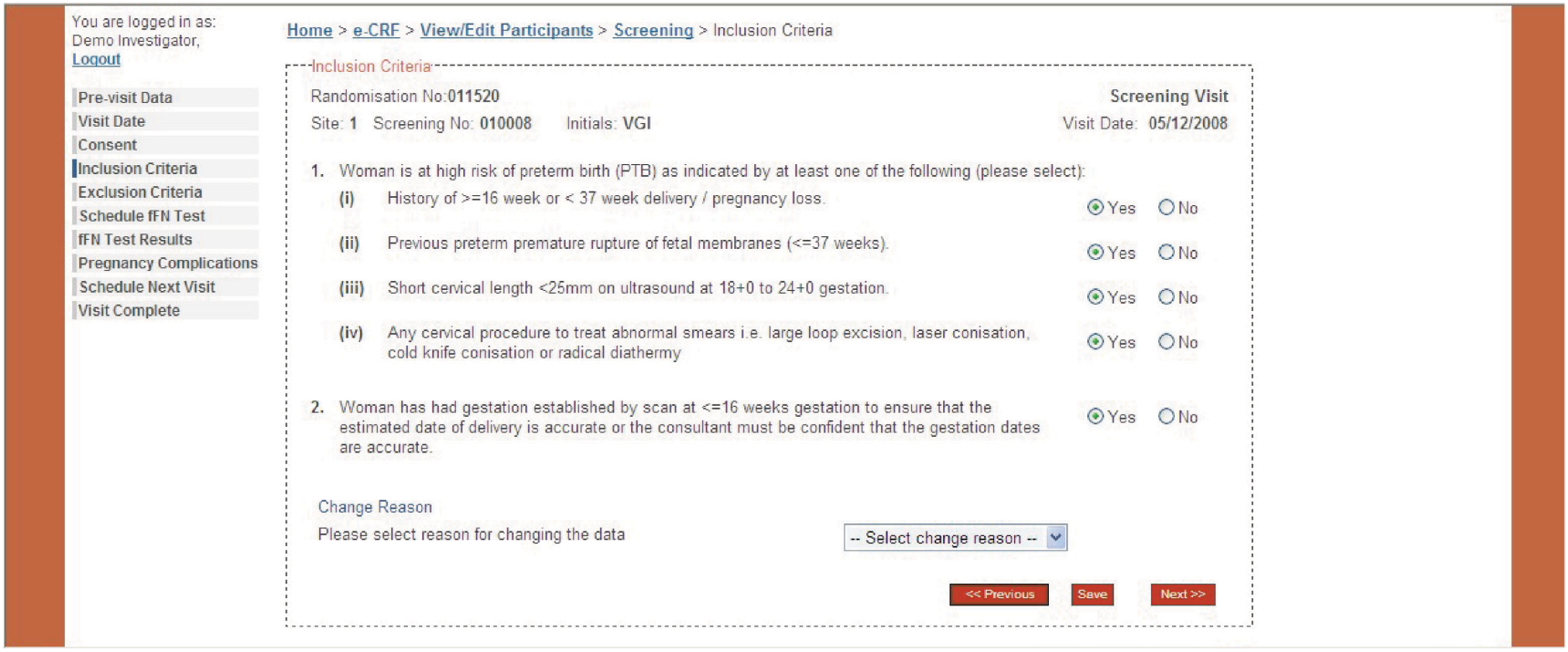
Tel: +44 (0)141 330 4744
Location University of Glasgow Glasgow Clinical Trials Unit

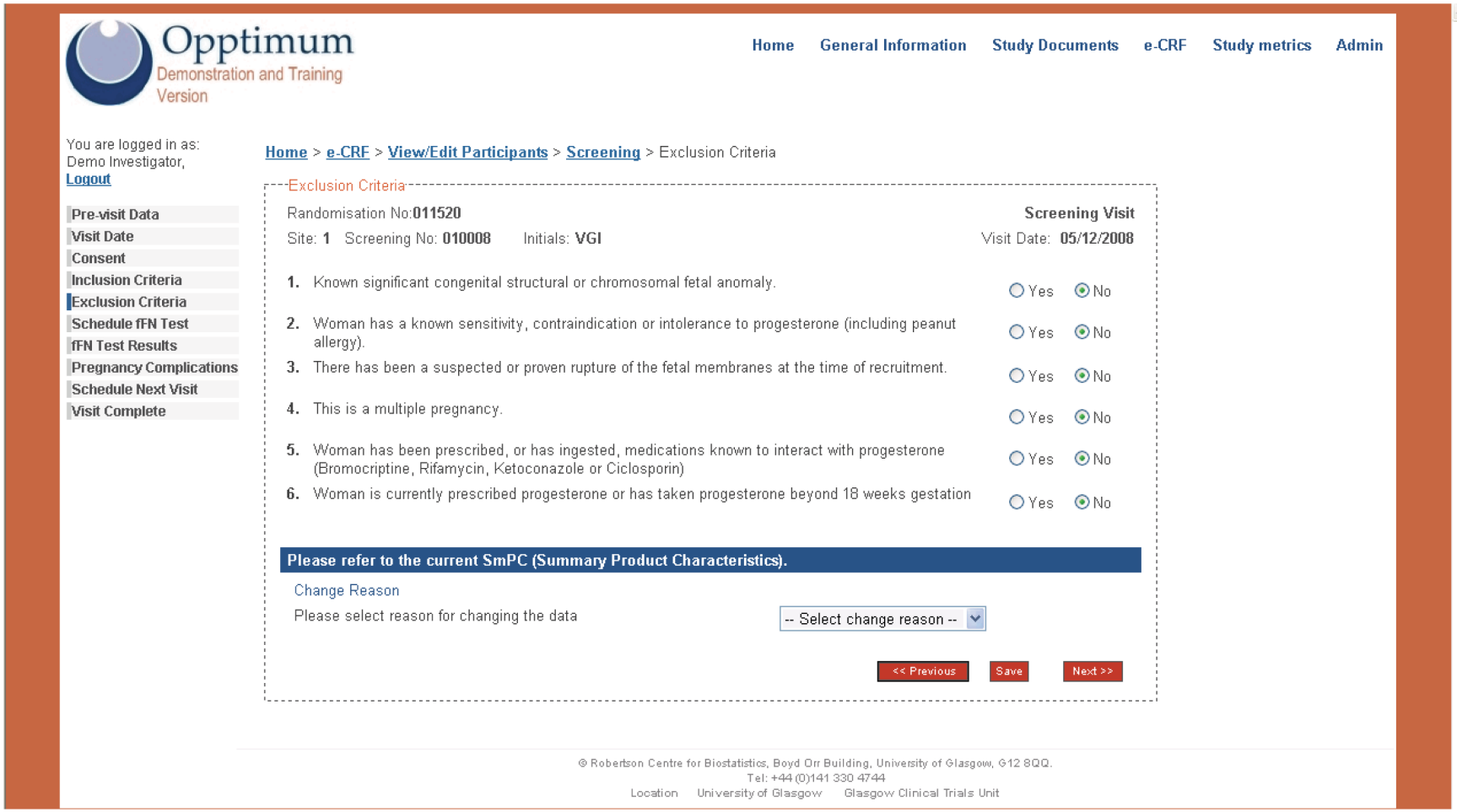
c. Consent


Version
You are logged in as:
Demo Investigator,
Logout
Pre-visit Data
Visit Date
Consent
Inclusion Criteria
Exclusion Criteria
Schedule fFN Test
fFN Test Results
Pregnancy Complications
Schedule Next Visit
Visit Complete
Home > e-CRF > View/Edit Participants > Screening > Consent
Consent
Randomisation No:011520
Screening Visit
Site: 1 Screening No: 010008 Initials: VGI
Visit Date: 05/12/2008
Prior to any study related procedures:
1. Has the woman provided written, informed consent for fetal fibronectin testing?
Yes No
2. Has the woman provided written, informed consent for future evaluation of themselves, their child and the health records of both?
Yes No
(i) Date consent signed
Day Month Year
Please provide at least one piece of identifying information
3. Identifying information
(i) CHI number
(ii) NHS number
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
Save
Next >>

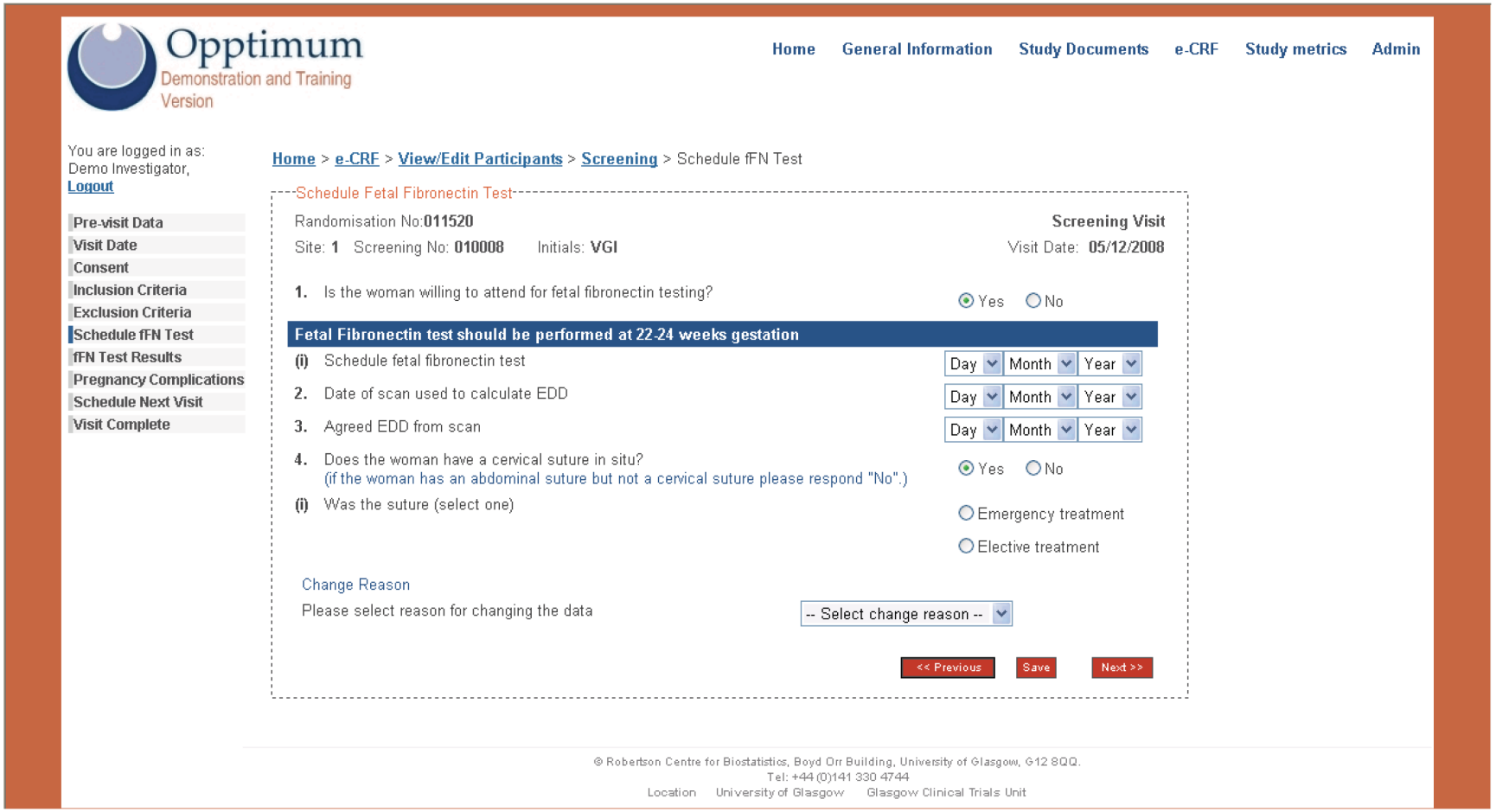
d. Inclusion Criteria



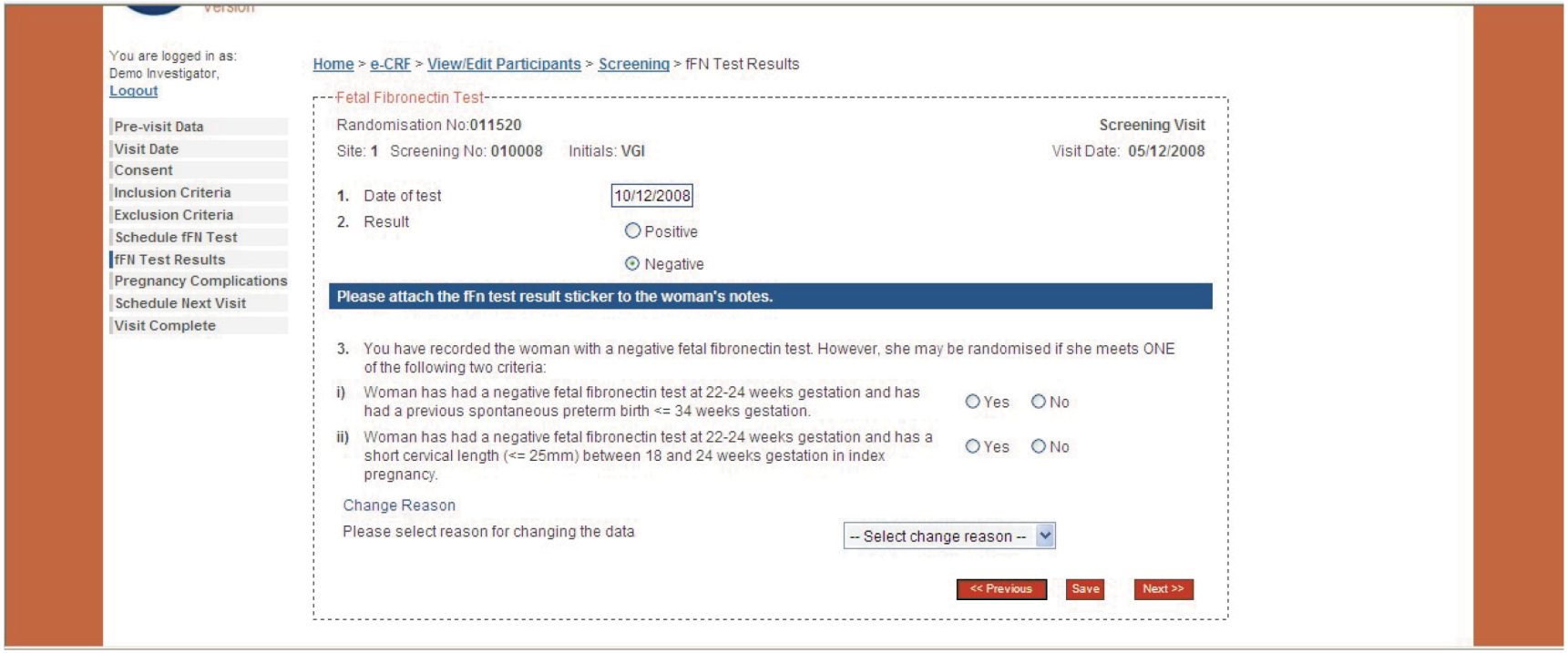
e. Exclusion Criteria



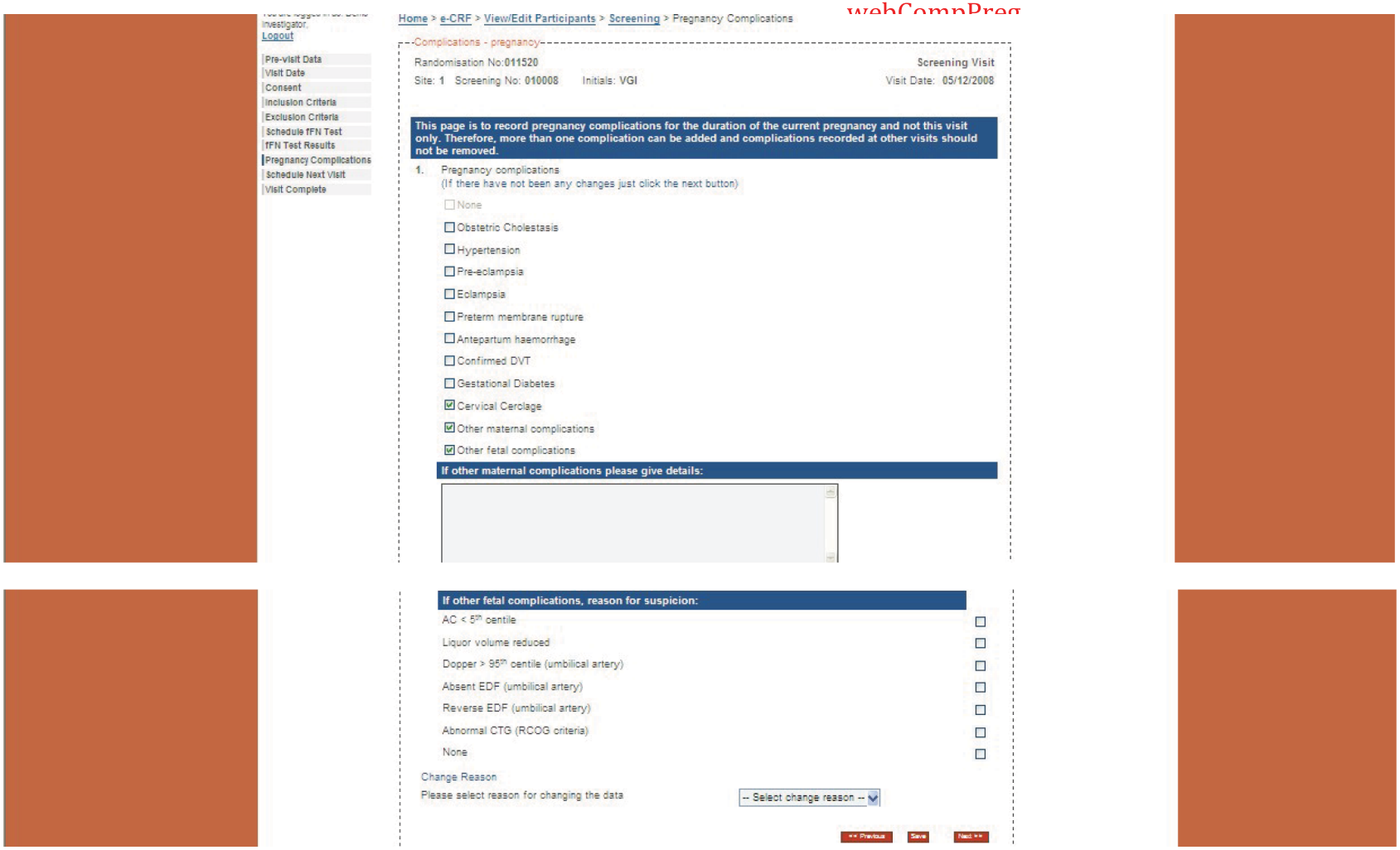
f. Schedule fFn Test



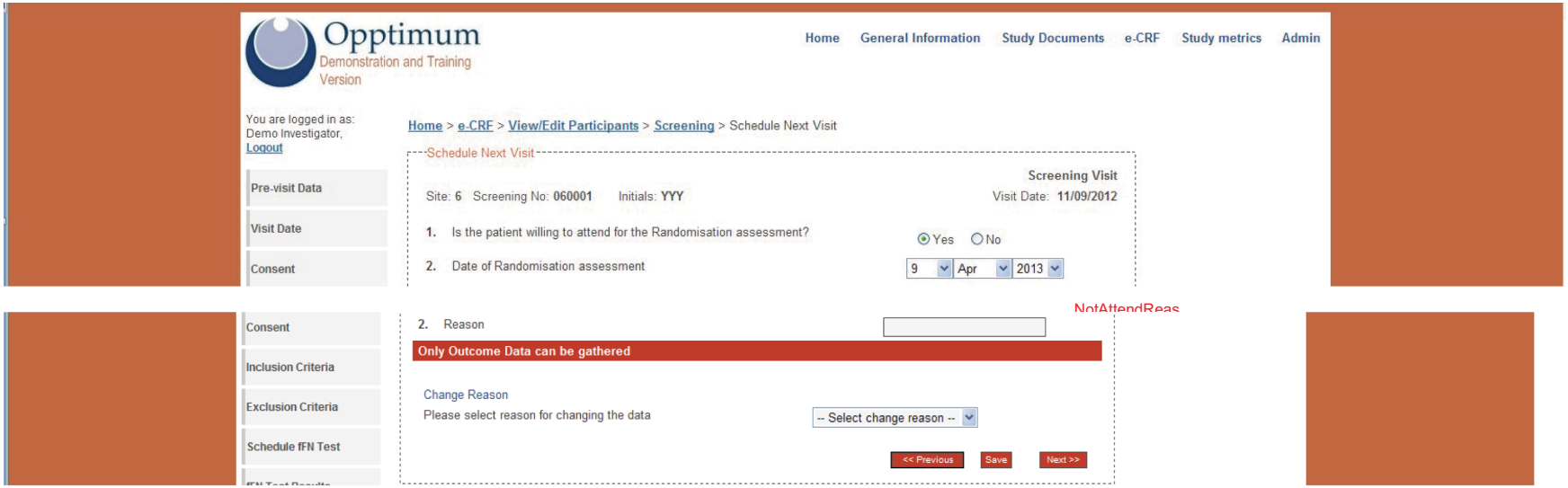
g. fFN Test Results



h. Pregnancy Complications



i. Schedule Next Visit

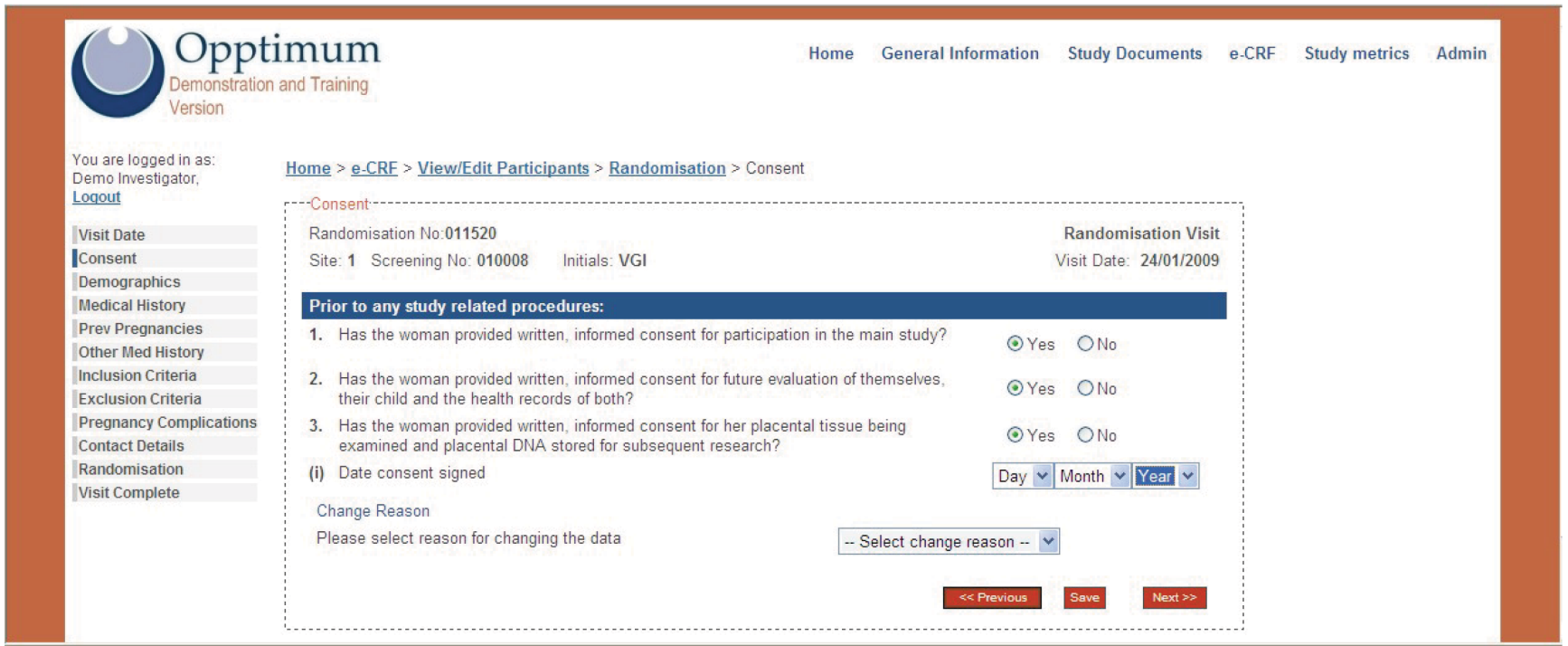


3. Randomisation Visit –

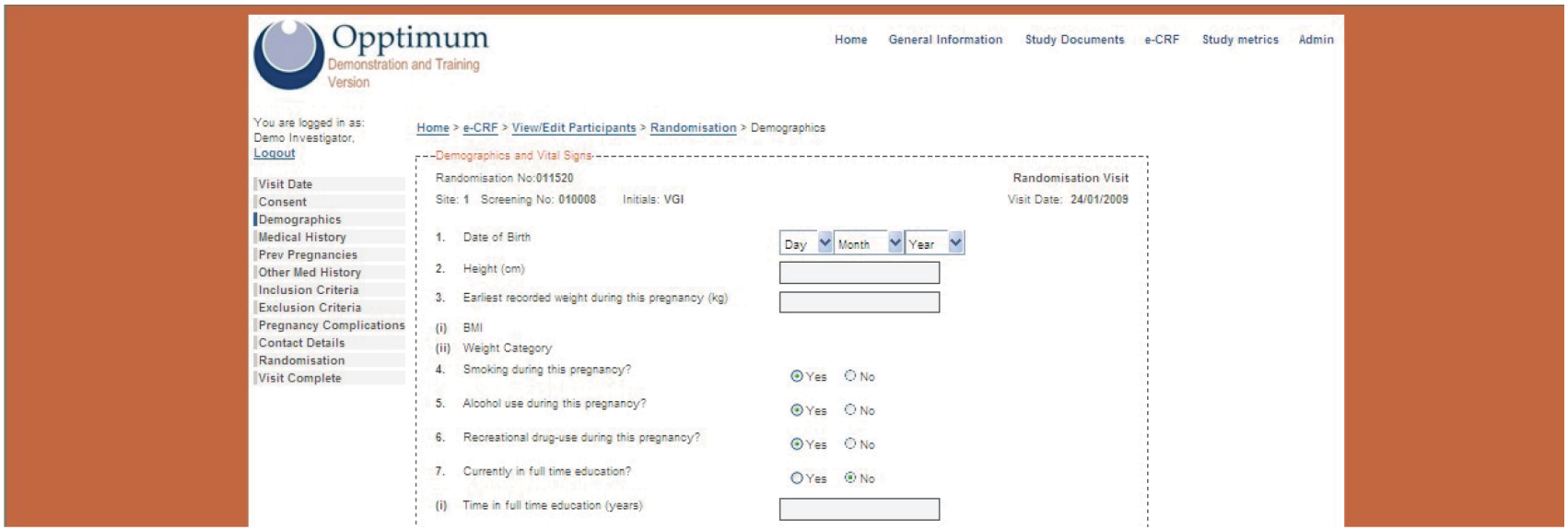
a. Visit Date – See Section 2 (b)

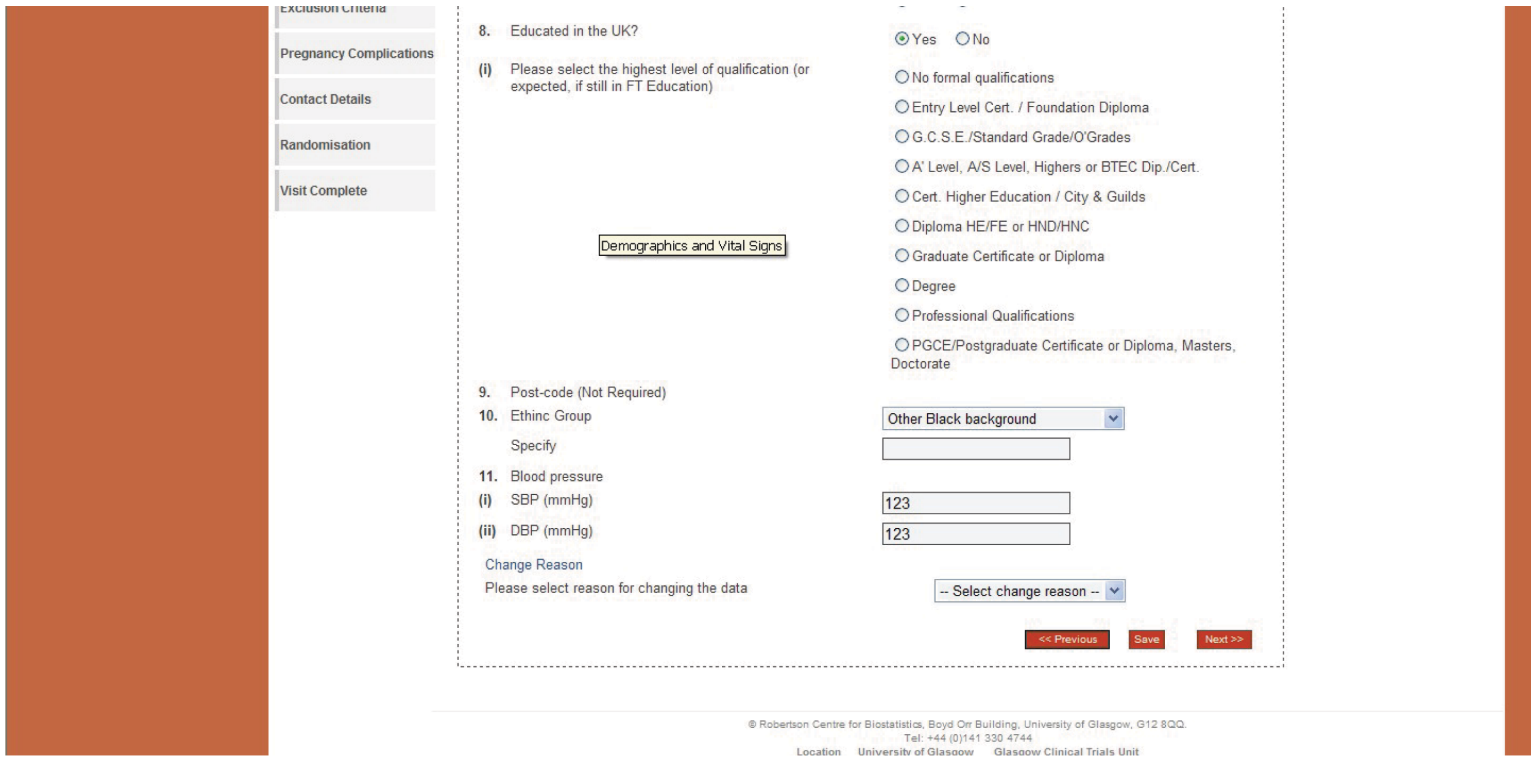
b. Pregnancy Complications – See Section 2 (h)

c. Consent


Opptimum
Demonstration and Training Version
Home
General Information
Study Documents
e-CRF
Study metrics
Admin
You are logged in as:
Demo Investigator,
Logout
Visit Date
Consent
Demographics
Medical History
Prev Pregnancies
Other Med History
Inclusion Criteria
Exclusion Criteria
Pregnancy Complications
Contact Details
Randomisation
Visit Complete
Home > e-CRF > View/Edit Participants > Randomisation > Consent
Consent
Randomisation No:011520
Randomisation Visit
Site: 1 Screening No: 010008 Initials: VGI
Visit Date: 24/01/2009
Prior to any study related procedures:
1. Has the woman provided written, informed consent for participation in the main study? Yes No
2. Has the woman provided written, informed consent for future evaluation of themselves, their child and the health records of both? Yes No
3. Has the woman provided written, informed consent for her placental tissue being examined and placental DNA stored for subsequent research? Yes No
(i) Date consent signed Day Month Year
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
Save
Next >>

d. Demographics




Exclusion Criteria
Pregnancy Complications
Contact Details
Randomisation
Visit Complete
8. Educated in the UK?
Yes
No
(i) Please select the highest level of qualification (or expected, if still in FT Education)
No formal qualifications
Entry Level Cert. / Foundation Diploma
G.C.S.E./Standard Grade/O'Grades
A' Level, A/S Level, Highers or BTEC Dip./Cert.
Cert. Higher Education / City & Guilds
Diploma HE/FE or HND/HNC
Graduate Certificate or Diploma
Degree
Professional Qualifications
PGCE/Postgraduate Certificate or Diploma, Masters, Doctorate
Demographics and Vital Signs
9. Post-code (Not Required)
10. Ethinc Group
Other Black background
Specify
11. Blood pressure
(i) SBP (mmHg)
123
(ii) DBP (mmHg)
123
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
Save
Next >>
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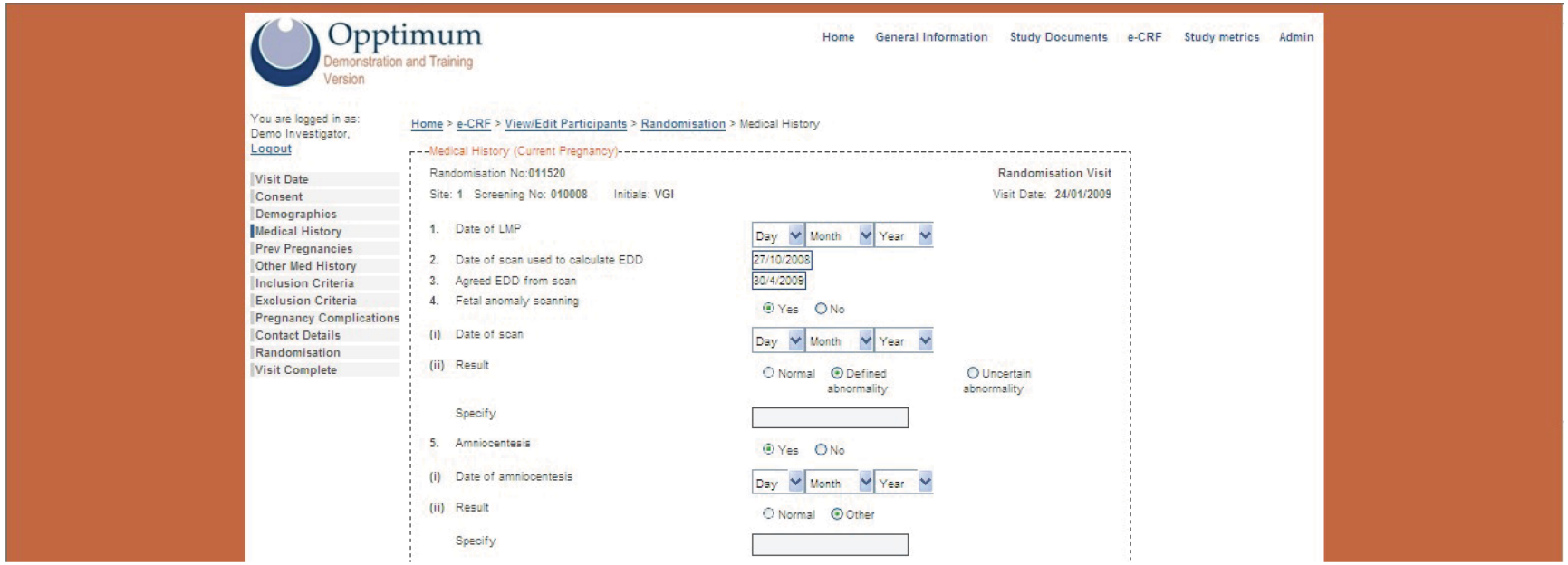
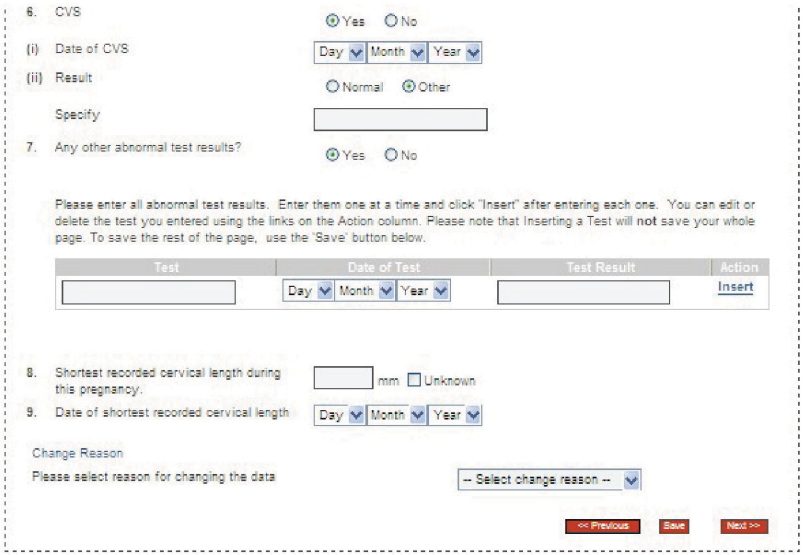
Tel: +44 (0)141 330 4744
Location University of Glasgow Glasgow Clinical Trials Unit

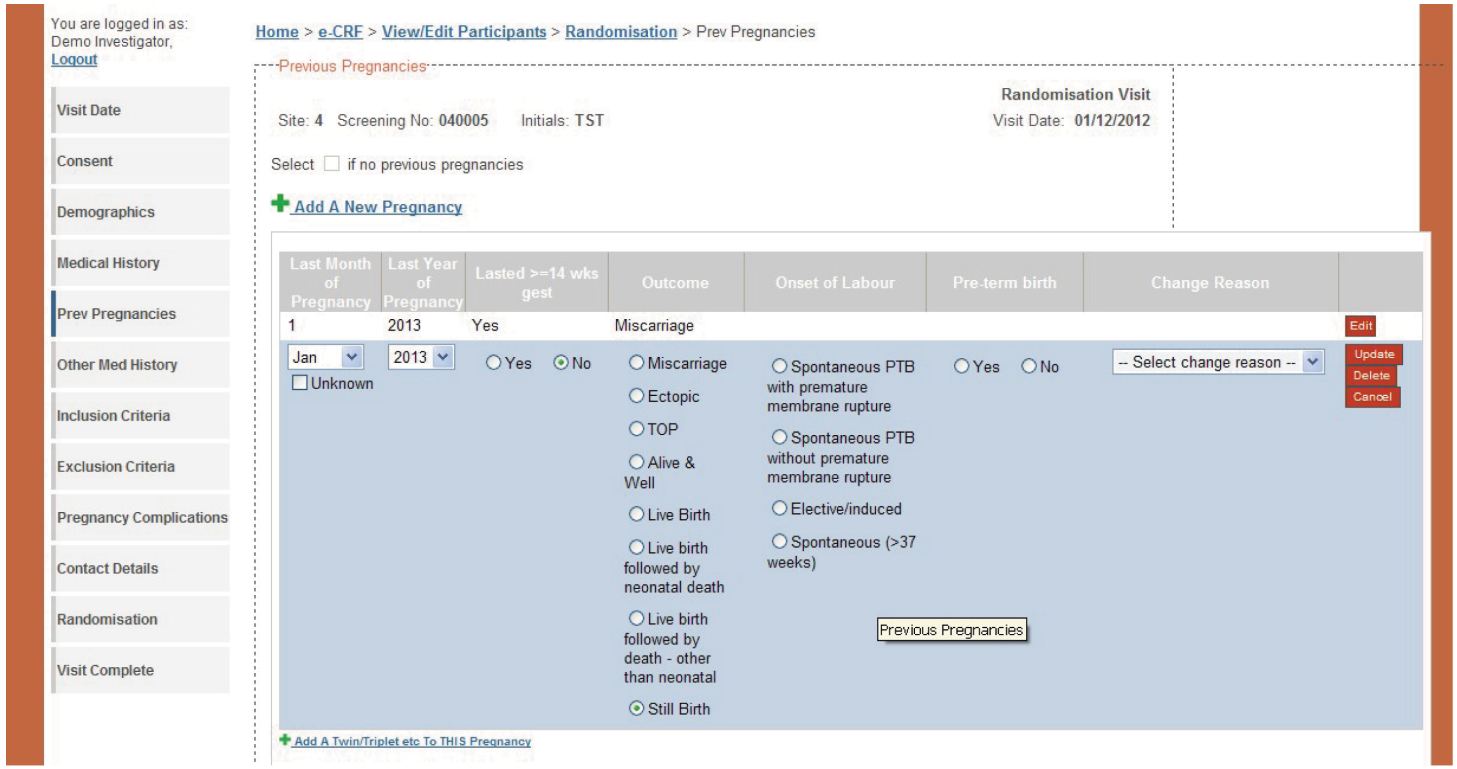
e. Medical History – Current pregnancy





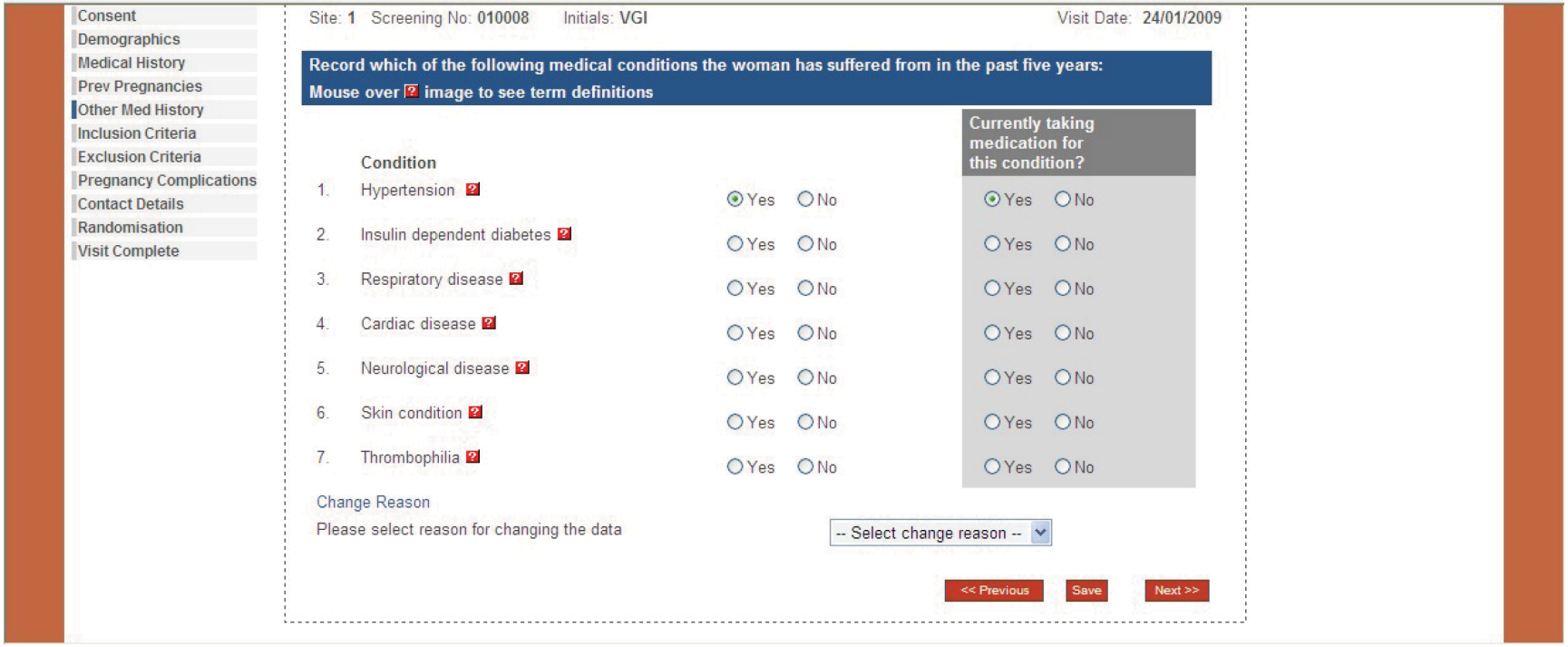
f. Previous Pregnancies

webPrevPreg

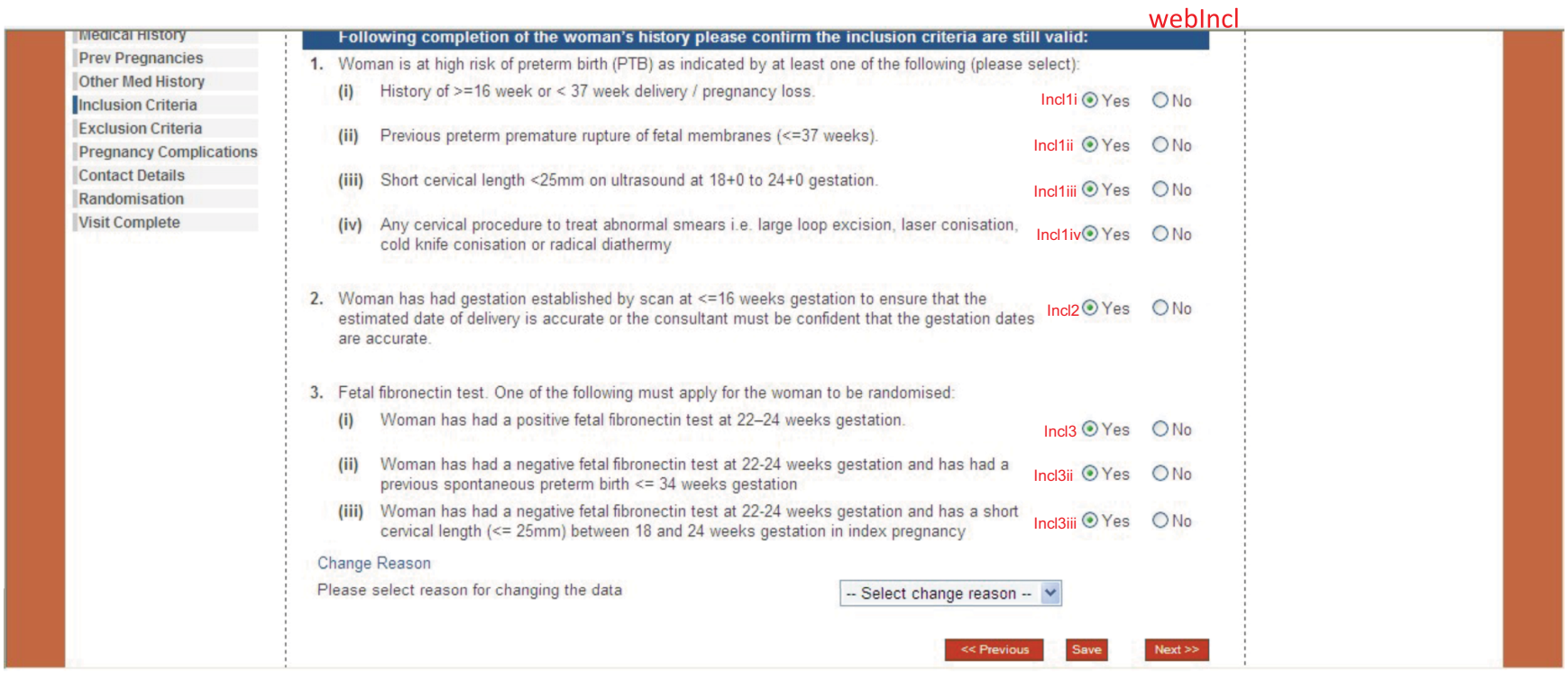


g. Other Med History

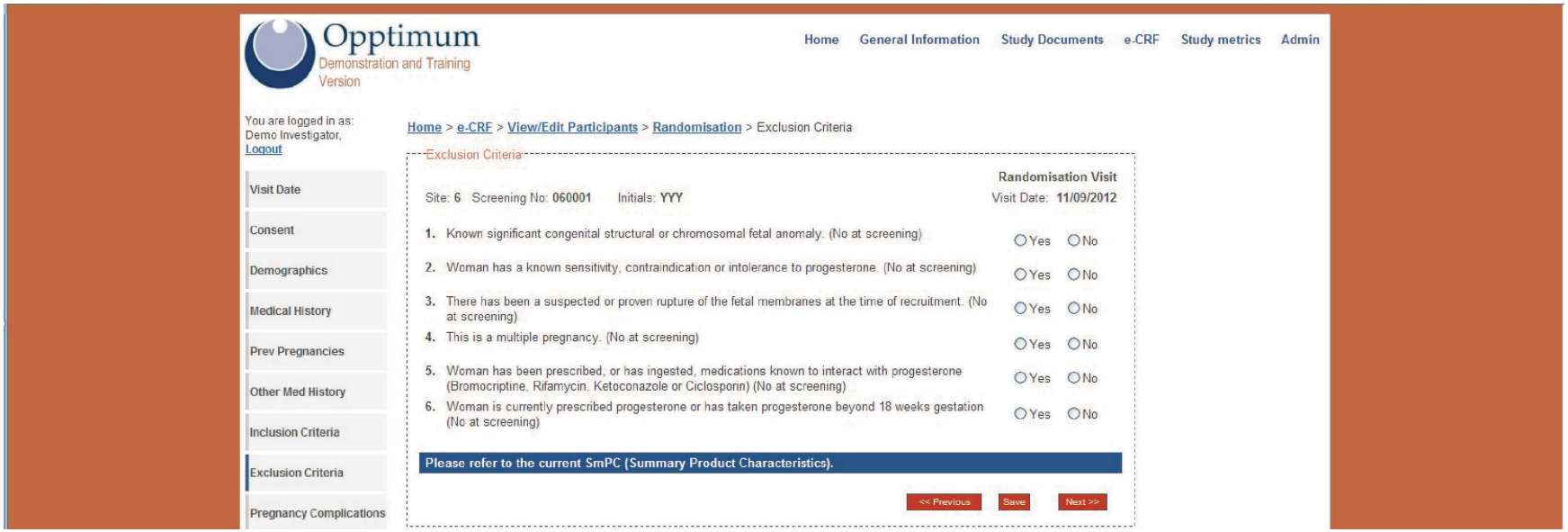
webMedHistOth



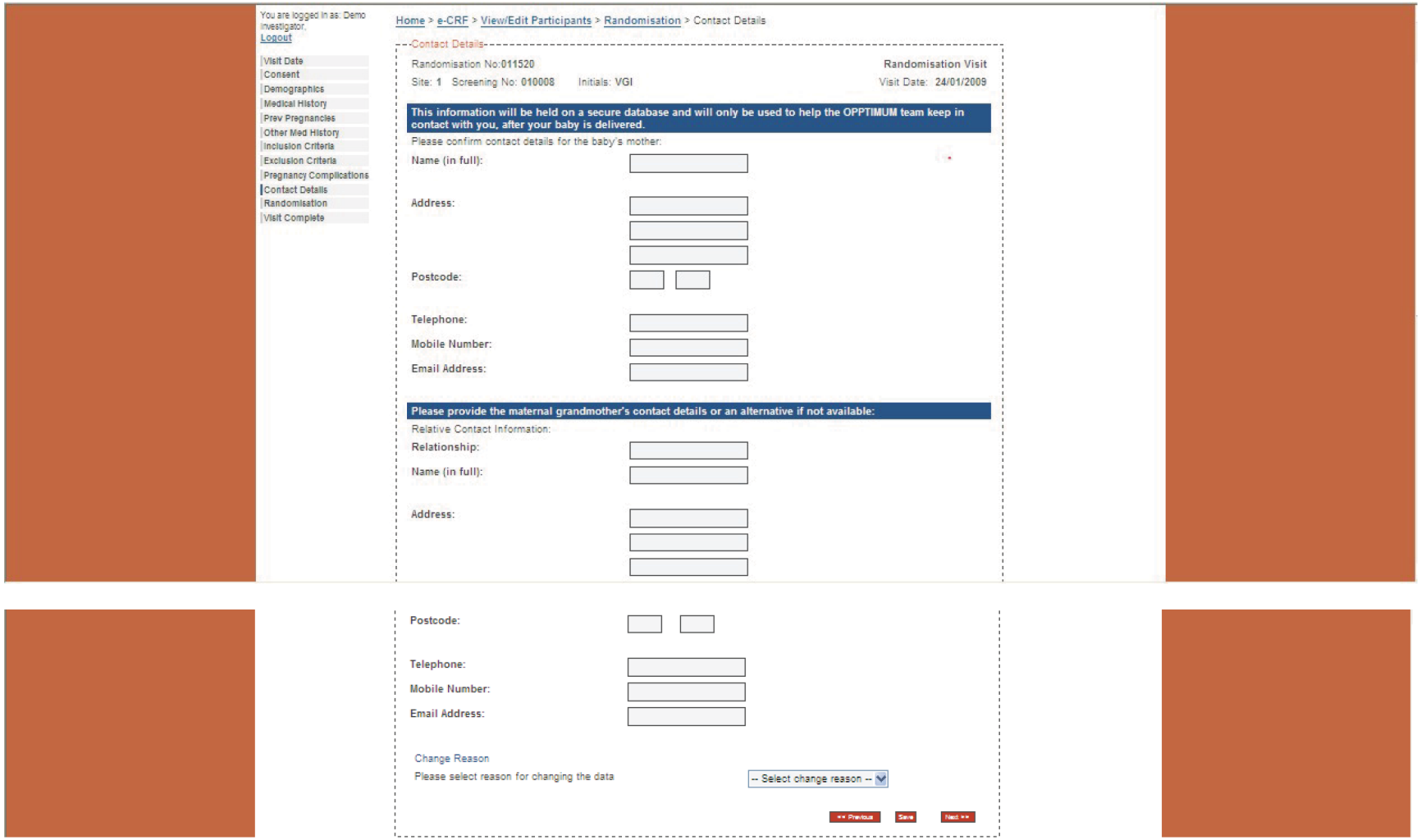
h. Inclusion Criteria

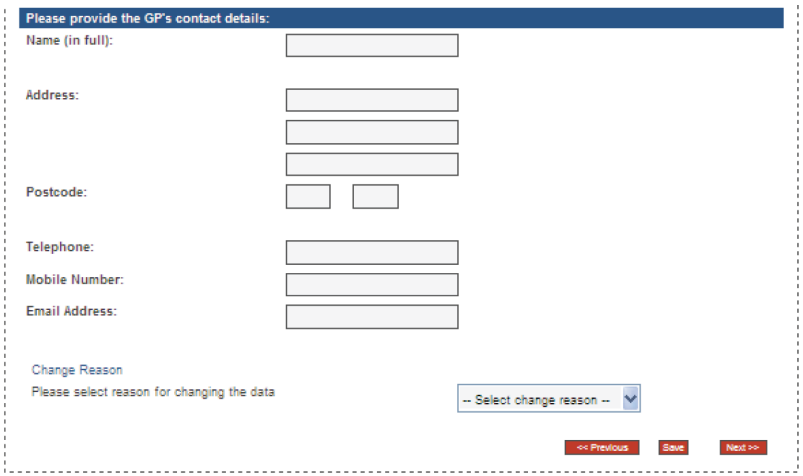


i. Exclusion Criteria

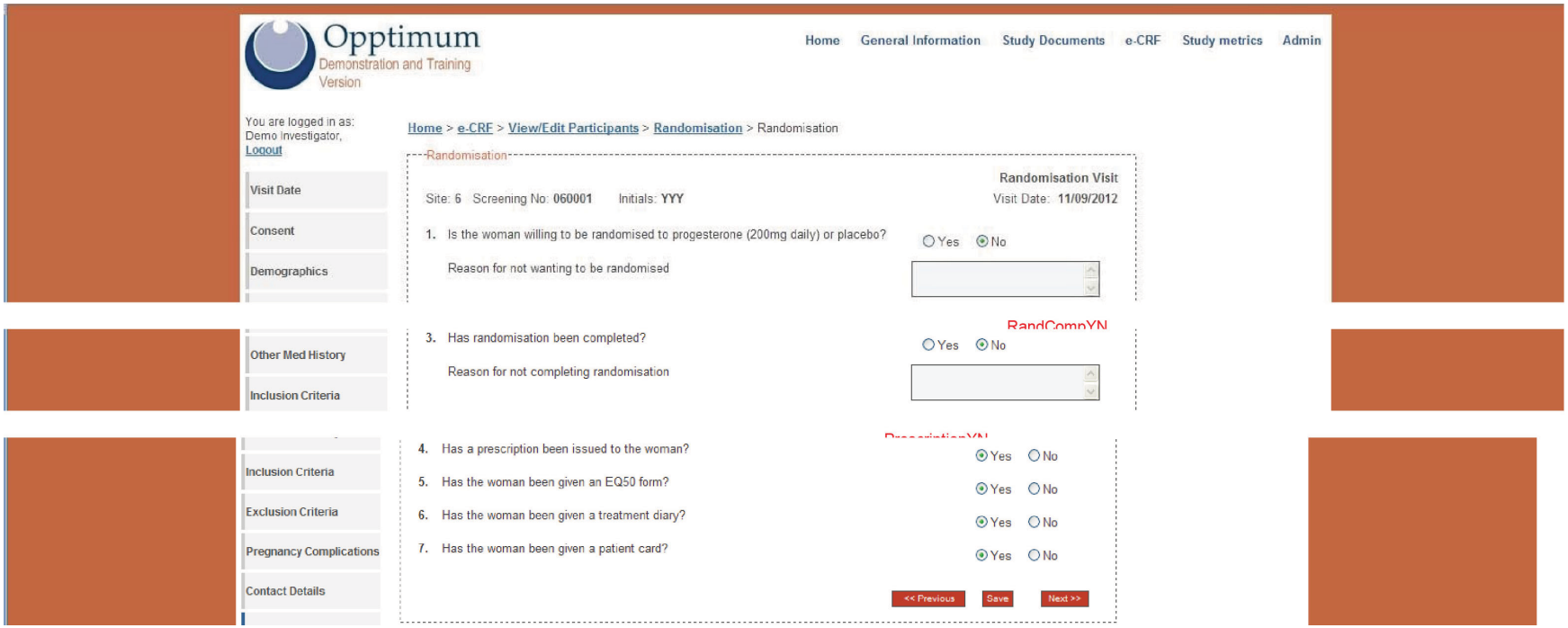


j. Contact Details




Please provide the GP's contact details:
Name (in full):
Address:
Postcode:
Telephone:
Mobile Number:
Email Address:
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
Save
Next >>

k. Randomisation



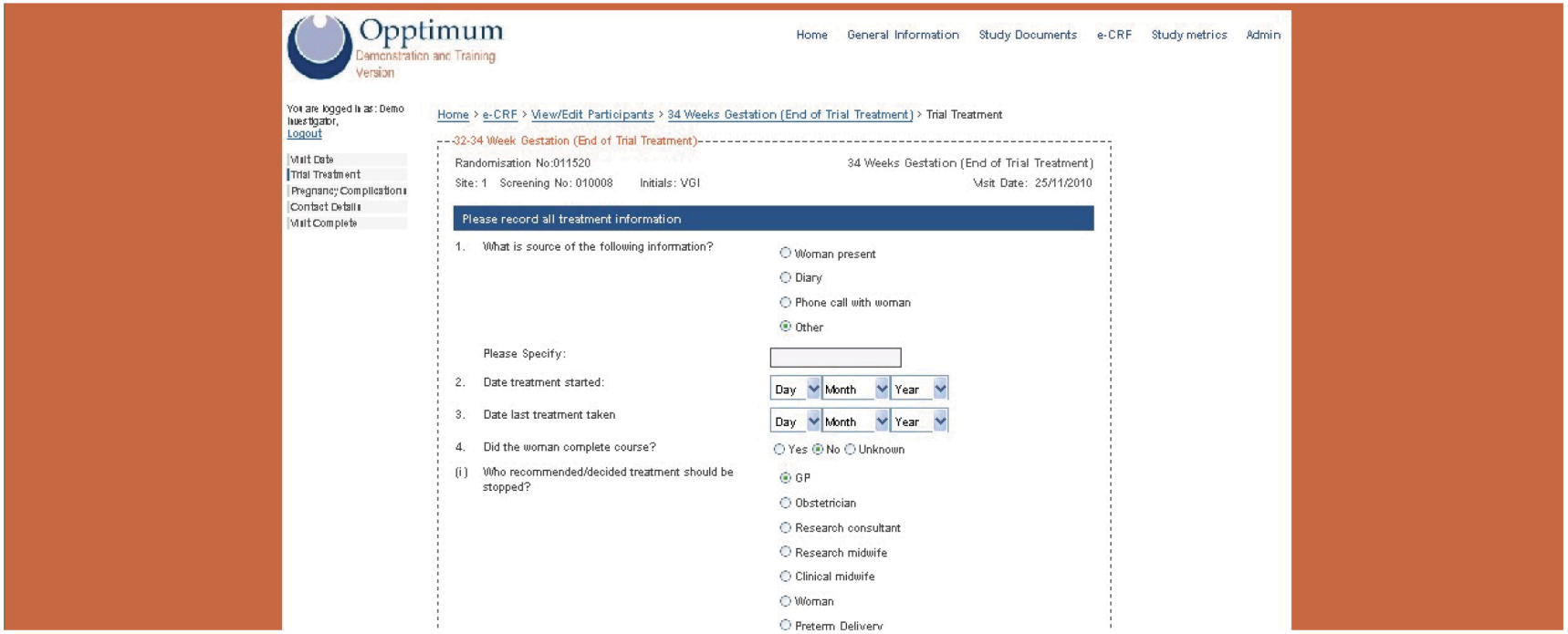
4. **34 Weeks Gestation (End of Trial Treatment) –**

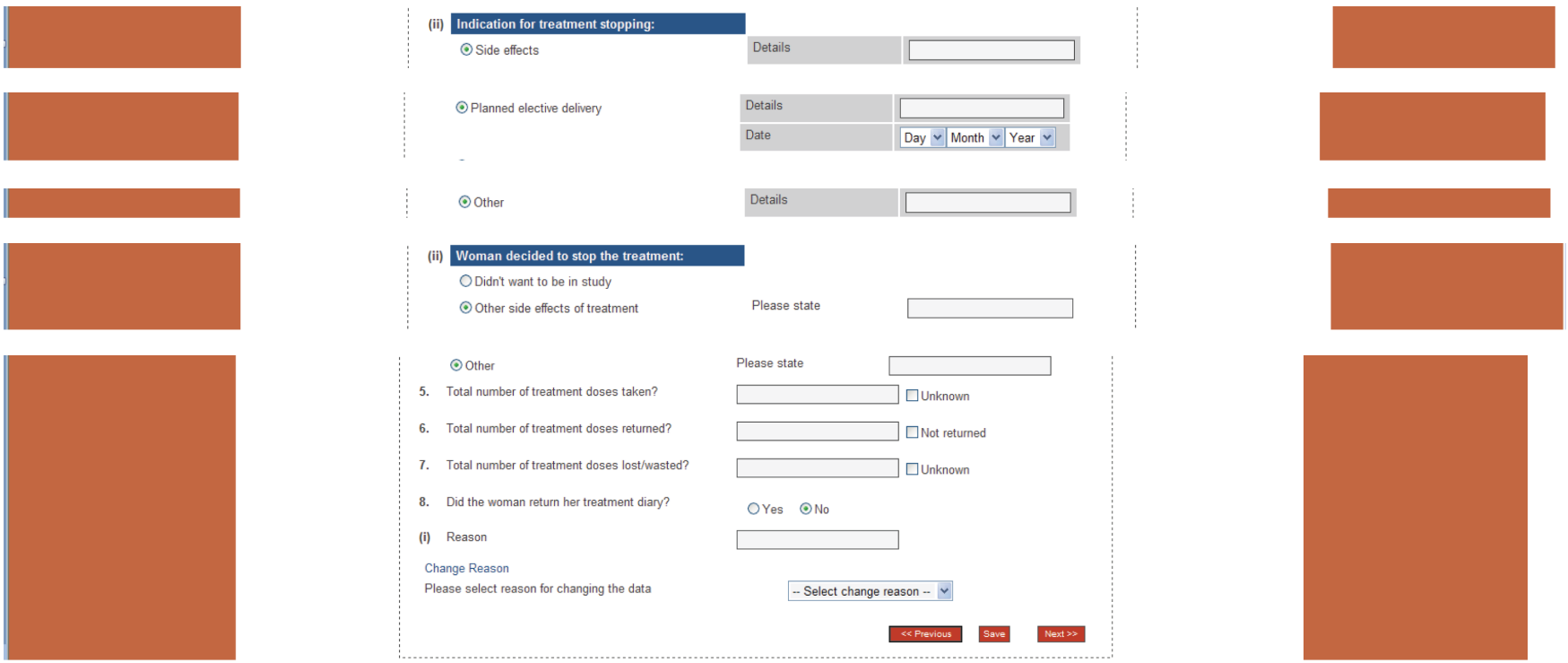
   a. **Visit Date – See Section 2 (b)**

   b. **Pregnancy Complications – See Section 2 (h)**

   c. **Contact Details – See Section 3 (j)**

d. Trial Treatment

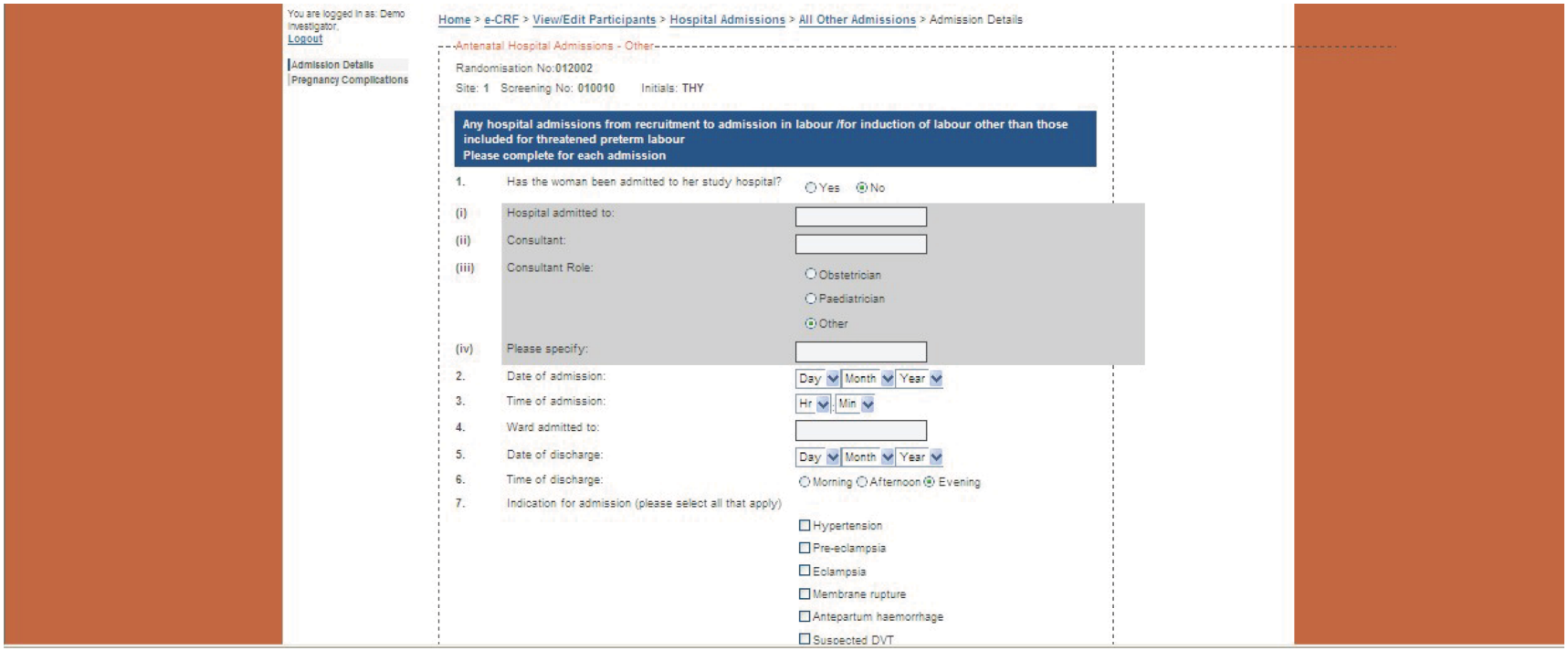



(ii) Indication for treatment stopping:
Side effects
Details
Planned elective delivery
Details
Date
Day
Month
Year
Other
Details
(ii) Woman decided to stop the treatment:
Didn't want to be in study
Other side effects of treatment
Please state
Other
Please state
5. Total number of treatment doses taken?
Unknown
6. Total number of treatment doses returned?
Not returned
7. Total number of treatment doses lost/wasted?
Unknown
8. Did the woman return her treatment diary?
Yes
No
(i) Reason
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
Save
Next >>

5. Hospital Admissions –

a. Pregnancy Complications – See Section 2 (h)

b. Admission Details – Antenatal Hospital Admissions



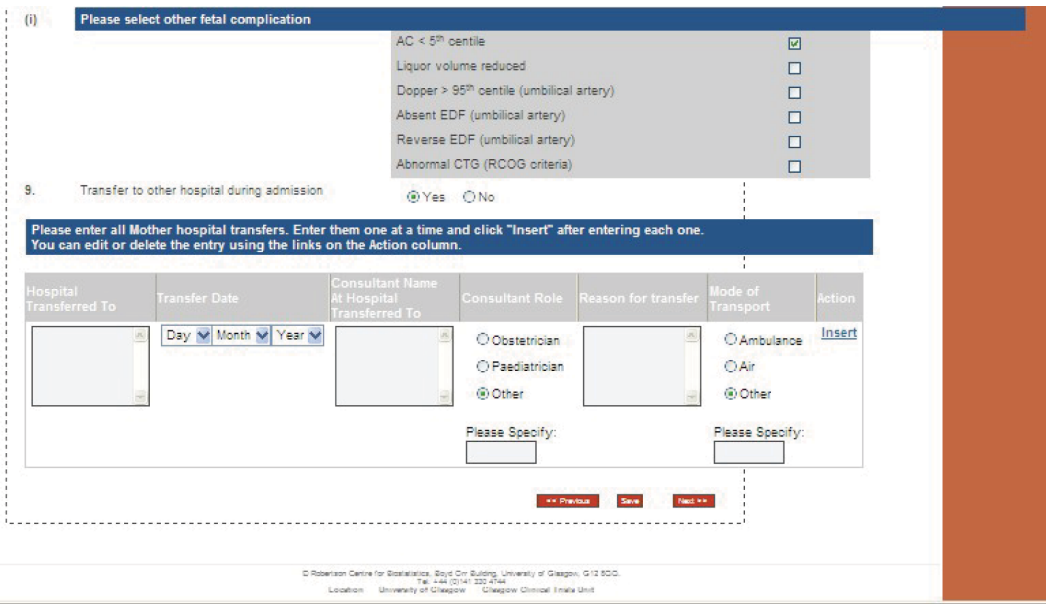
- ☐ Gestational diabetes
- ☐ Abdo pain
- ☐ Symphyseal pain
- ☑ Other maternal complication — Details
- ☑ Other fetal complication

(i) **Please select other fetal complication**

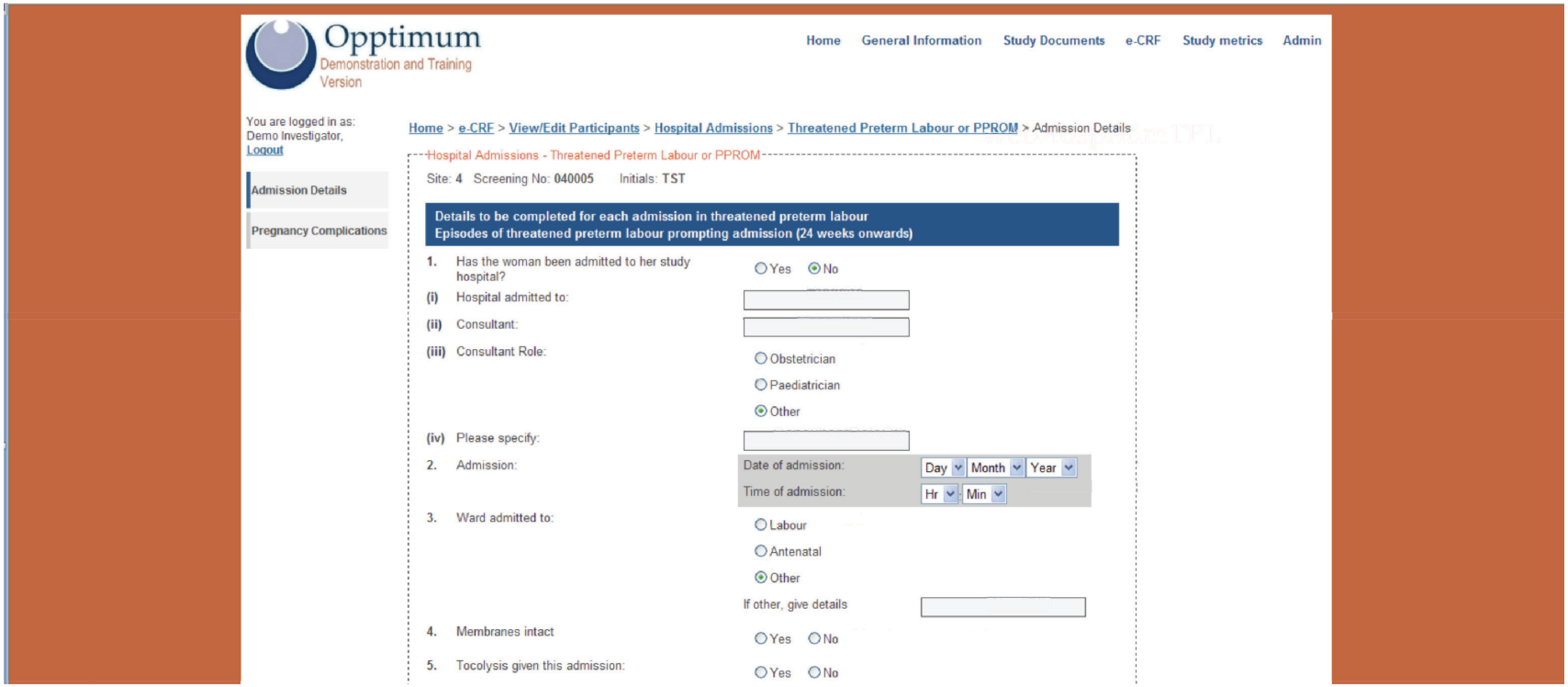
AC < 5th centile	☑
Liquor volume reduced	☐
Dopper > 95th centile (umbilical artery)	☐
Absent EDF (umbilical artery)	☐
Reverse EDF (umbilical artery)	☐
Abnormal CTG (RCOG criteria)	☐

8. Primary diagnosis on discharge:

- ☐ Hypertension
- ☐ Pre-eclampsia
- ☐ Eclampsia
- ☐ Membrane rupture
- ☐ Antepartum haemorrhage
- ☐ Suspected DVT
- ☐ Gestational diabetes
- ☐ Abdo pain
- ☐ Symphyseal pain
- ☑ Other maternal complication — Details
- ☑ Other fetal complication



C. Hospital Admissions – Threatened Preterm Labour or PPROM



(i) If yes, nature:

- ○ Nifedipine
- ○ Indomethacin
- ○ Atosiban
- ◉ Other

Max daily dose
Dose Unit: mg
Details

(ii) Date tocolysis treatment started: Day Month Year

(iii) Date tocolysis treatment stopped: Day Month Year

6. Steroid therapy given this admission: ◉ Yes ○ No

(i) Steroid therapy:

Date of first steroid dose: Day Month Year
Time of first steroid dose: Hr Min
Date of last steroid dose: Day Month Year
Time of last steroid dose: Hr Min

(ii) State drug and maximum dose given per day:

Drug
Dose
Dose Unit: mg

7. Date of hospital discharge: Day Month Year

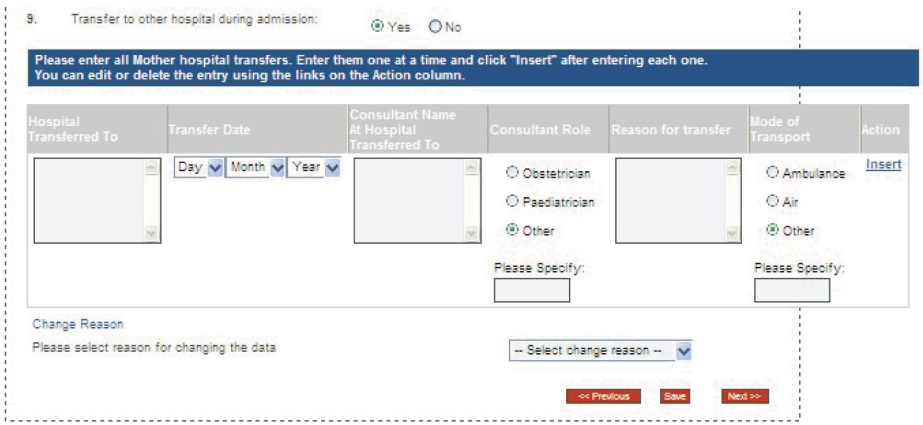
8. Other treatment given this admission:

- ☑ Antibiotics

If yes, name of antibiotic
Dose
Dose Unit: mg
Duration of treatment

- ☐ Cervical Suture
- ☑ Other

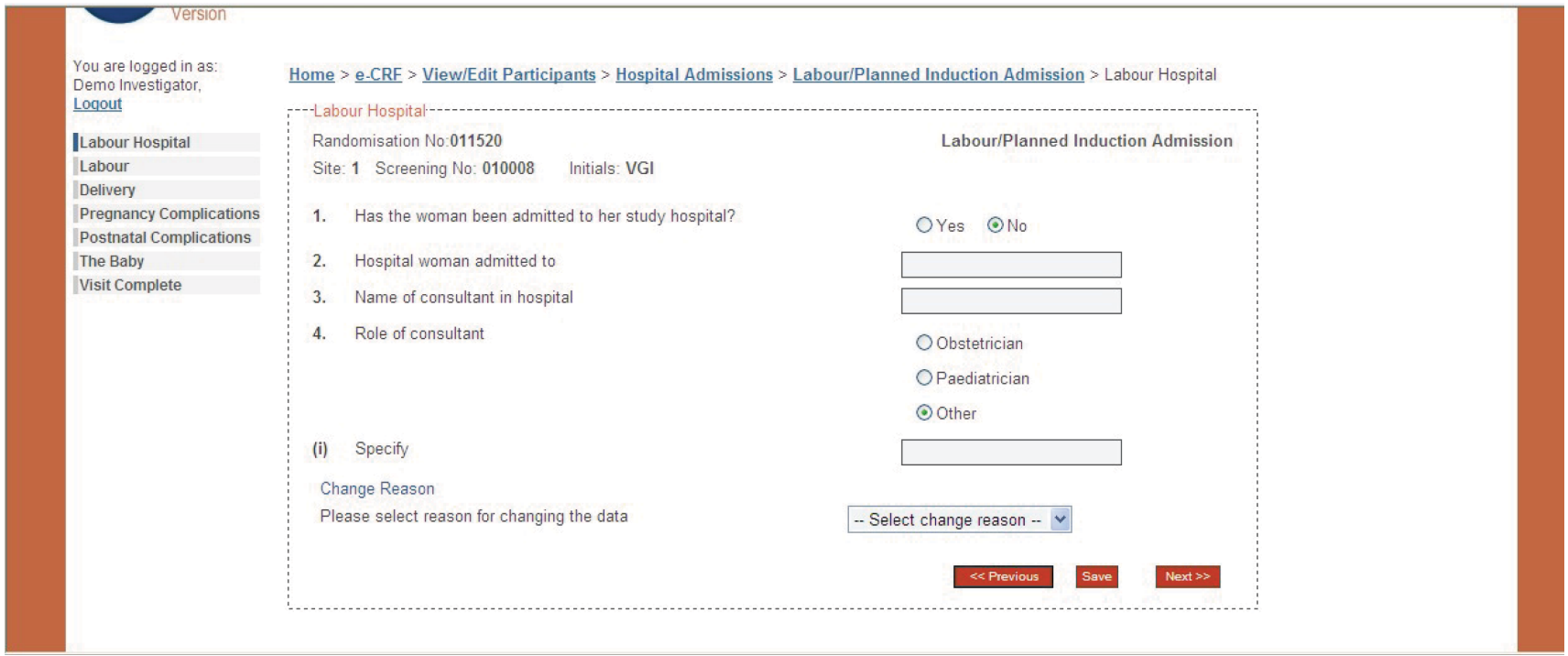
If other, give details


9. Transfer to other hospital during admission: Yes No
Please enter all Mother hospital transfers. Enter them one at a time and click "Insert" after entering each one.
You can edit or delete the entry using the links on the Action column.
Hospital Transferred To
Transfer Date
Day Month Year
Consultant Name At Hospital Transferred To
Consultant Role
Obstetrician
Paediatrician
Other
Please Specify:
Reason for transfer
Mode of Transport
Ambulance
Air
Other
Please Specify:
Action
Insert
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
Save
Next >>

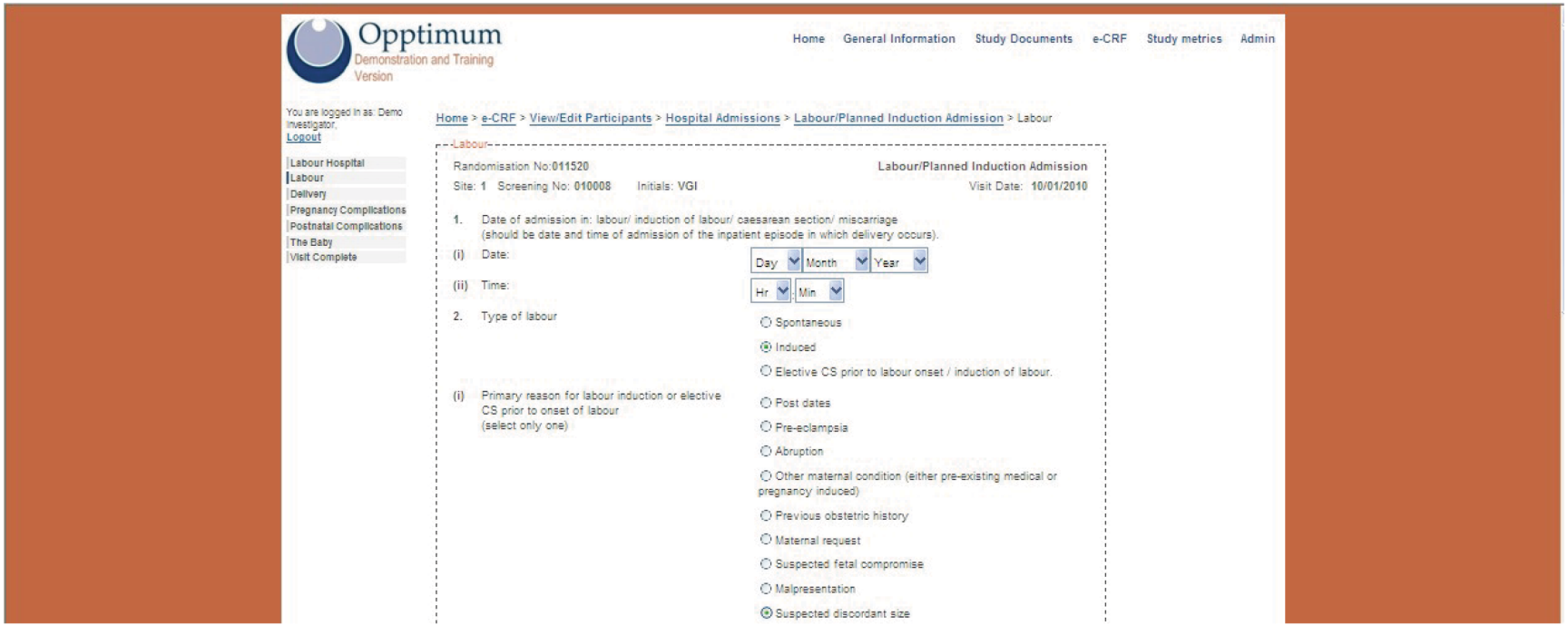
6. Labour/Planned Induction Admission

a. Pregnancy Complications – See Section 2 (h)

b. Labour Hospital



c. Labour


Opptimum
Demonstration and Training Version
Home
General Information
Study Documents
e-CRF
Study metrics
Admin
You are logged in as: Demo investigator.
Logout
Labour Hospital
Labour
Delivery
Pregnancy Complications
Postnatal Complications
The Baby
Visit Complete
Home > e-CRF > View/Edit Participants > Hospital Admissions > Labour/Planned Induction Admission > Labour
Labour
Randomisation No:011520
Labour/Planned Induction Admission
Site: 1 Screening No: 010008 Initials: VGI
Visit Date: 10/01/2010
1. Date of admission in: labour/ induction of labour/ caesarean section/ miscarriage
(should be date and time of admission of the inpatient episode in which delivery occurs).
(i) Date:
Day
Month
Year
(ii) Time:
Hr
Min
2. Type of labour
Spontaneous
Induced
Elective CS prior to labour onset / induction of labour.
(i) Primary reason for labour induction or elective CS prior to onset of labour
(select only one)
Post dates
Pre-eclampsia
Abruption
Other maternal condition (either pre-existing medical or pregnancy induced)
Previous obstetric history
Maternal request
Suspected fetal compromise
Malpresentation
Suspected discordant size

(ii) Duration of labour

	Hours	Minutes
1st Stage		
2nd Stage		
3rd Stage		

3. Rupture of Membranes — (•) Yes ( ) No

(i) Please specify
- ( ) Artificial
- ( ) Spontaneous

(ii) Date: Day / Month / Year

(iii) Time: Hr : Min

4. Were analgesic agents used during labour/delivery? — (•) Yes ( ) No

(select all that apply)
- [ ] General anaesthetic
- [ ] Epidural/spinal
- [ ] Opiates
- [ ] Entonox
- [x] Other

Please enter details of all other analgesics

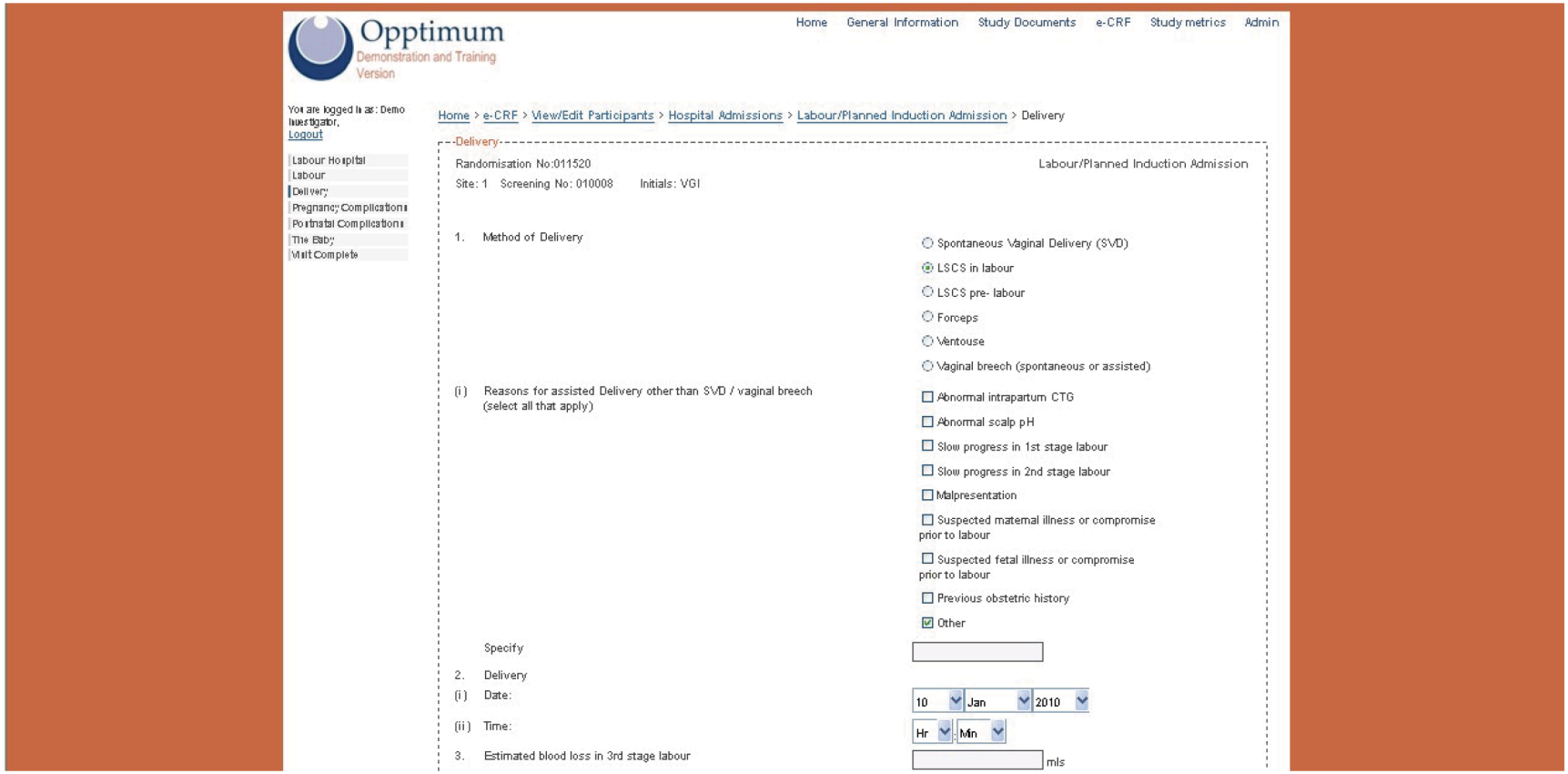
Name [ ] Add

5. Did the woman receive IV antibiotics during labour/delivery? — (•) Yes ( ) No

Change Reason

Please select reason for changing the data: -- Select change reason --

d. Delivery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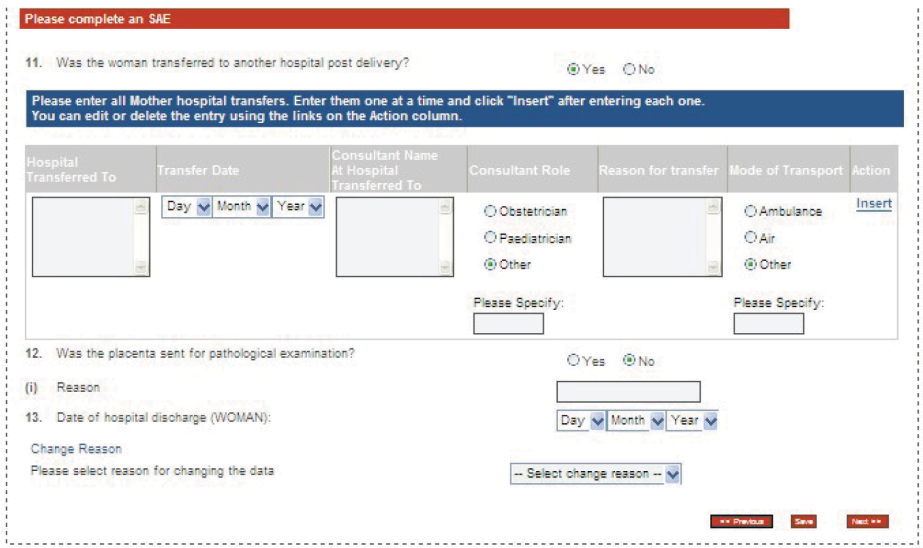
Labour Hospital
Labour
Delivery
Pregnancy Complications
Postnatal Complications
The Baby
Visit Complete
Home > e-CRF > View/Edit Participants > Hospital Admissions > Labour/Planned Induction Admission > Delivery
Delivery
Randomisation No:011520
Labour/Planned Induction Admission
Site: 1 Screening No: 010008 Initials: VGI
1. Method of Delivery
Spontaneous Vaginal Delivery (SVD)
LSCS in labour
LSCS pre- labour
Forceps
Ventouse
Vaginal breech (spontaneous or assisted)
(i) Reasons for assisted Delivery other than SVD / vaginal breech (select all that apply)
Abnormal intrapartum CTG
Abnormal scalp pH
Slow progress in 1st stage labour
Slow progress in 2nd stage labour
Malpresentation
Suspected maternal illness or compromise prior to labour
Suspected fetal illness or compromise prior to labour
Previous obstetric history
Other
Specify
2. Delivery
(i) Date:
10 Jan 2010
(ii) Time:
Hr Min
3. Estimated blood loss in 3rd stage labour
mls

4.	Was the woman sutured after delivery?	◉ Yes ○ No
(i)	Was the suturing as a result of (select all that apply	☐ Episiotomy ☐ First degree tear ☐ Second degree tear ☐ Third degree tear
5.	Did the woman receive a blood transfusion?	◉ Yes ○ No
6.	Did the woman receive antibiotics after delivery?	◉ Yes ○ No
7.	Were diagnostic imaging testing performed as a result of delivery or post delivery complication(s)?	◉ Yes ○ No
	Please specify & record the number of examinations	Number
(i)	Ultrasound	
(ii)	MRI	
(iii)	Other, please specify	
8.	Was a surgical procedure performed (other than minor suturing) as a result of a complication other than caesarean section?	◉ Yes ○ No
(i)	Manual removal of placenta (over and above that of CCT)	◉ Yes ○ No
(ii)	Other	◉ Yes ○ No
Is this surgical procedure considered an SAE? If so, please fill in an SAE form.		
9.	Was the woman transferred to a post-natal ward or area after delivery?	◉ Yes ○ No
(i)	Date of transfer:	Day Month Year
(ii)	Time of transfer:	Hr : Min
10.	Was the woman admitted to ICU (obstetric or main) in the delivery hospital prior to discharge or transfer?	◉ Yes ○ No


Please complete an SAE
11. Was the woman transferred to another hospital post delivery?
Yes
No
Please enter all Mother hospital transfers. Enter them one at a time and click "Insert" after entering each one.
You can edit or delete the entry using the links on the Action column.
Hospital Transferred To
Transfer Date
Consultant Name At Hospital Transferred To
Consultant Role
Reason for transfer
Mode of Transport
Action
Day
Month
Year
Obstetrician
Paediatrician
Other
Ambulance
Air
Other
Insert
Please Specify:
Please Specify:
12. Was the placenta sent for pathological examination?
Yes
No
(i) Reason
13. Date of hospital discharge (WOMAN):
Day
Month
Year
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
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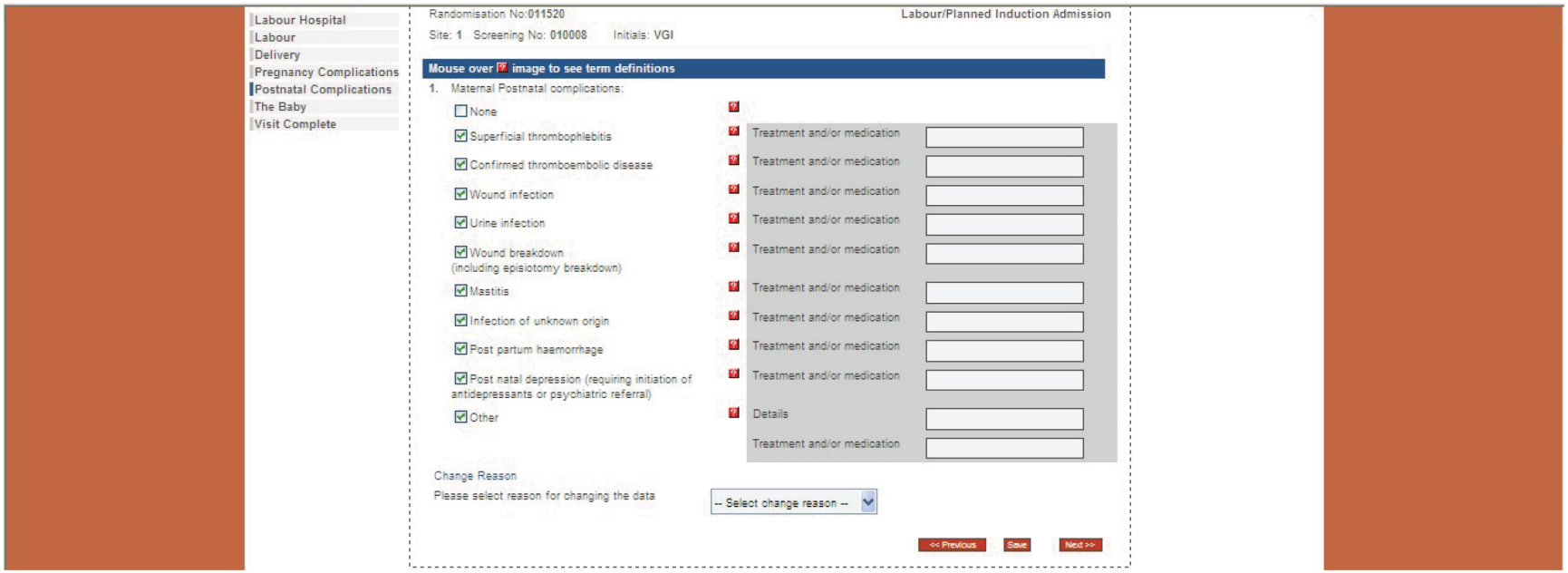
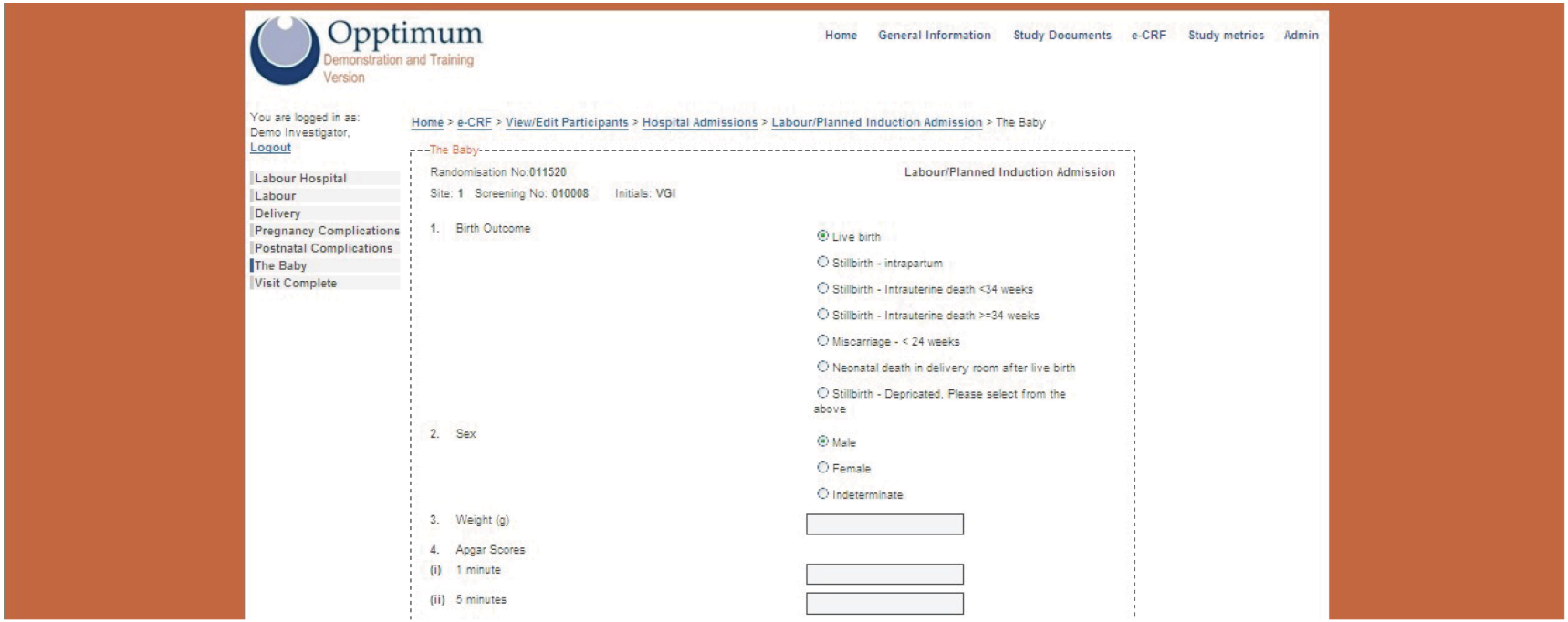
Next >>

e. Maternal Postnatal Complications



f. The Baby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Labour Hospital
Labour
Delivery
Pregnancy Complications
Postnatal Complications
The Baby
Visit Complete
Home > e-CRF > View/Edit Participants > Hospital Admissions > Labour/Planned Induction Admission > The Baby
The Baby
Randomisation No:011520
Labour/Planned Induction Admission
Site: 1 Screening No: 010008 Initials: VGI
1. Birth Outcome
Live birth
Stillbirth - intrapartum
Stillbirth - Intrauterine death <34 weeks
Stillbirth - Intrauterine death >=34 weeks
Miscarriage - < 24 weeks
Neonatal death in delivery room after live birth
Stillbirth - Depricated, Please select from the above
2. Sex
Male
Female
Indeterminate
3. Weight (g)
4. Apgar Scores
(i) 1 minute
(ii) 5 minutes

5. Highest level of care given in the delivery room

- (•) Minimal (none required or tactile stimulation)
- ( ) Suction
- ( ) Suction and facial 02 only
- ( ) Mask ventilation only
- ( ) Intubation
- ( ) Intubation plus chest compressions
- ( ) Intubation plus chest compressions and/or adrenaline

7. Care after delivery:

- ( ) Transferred to ward with mother
- (•) Transferred to neonatal unit

8. Did the baby have a neonatal screening examination prior to discharge: ( ) Yes (•) No

(i) Reason

(i) Were any abnormal findings recorded (•) Yes ( ) No

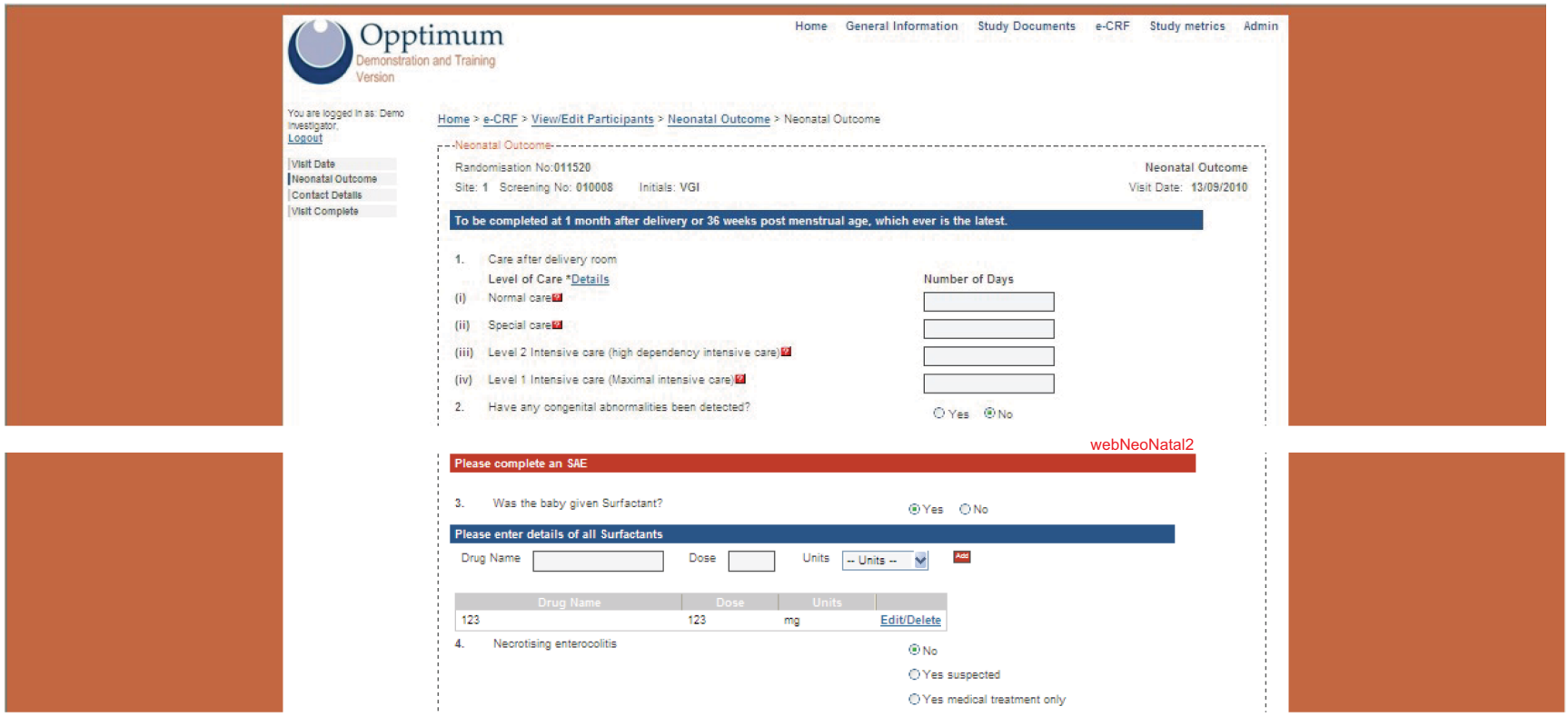
(ii) Specify

<< Previous | Save | Next >>

7. Neonatal Outcome

a. Contact Details – See Section 3 (j)

b. Neonatal Outcome



○ Yes required drain or laparotomy

5. Infection ◉ Yes ○ No

Episodes of infection:

(i) Number of discrete episodes with positive blood culture

(ii) Number of discrete episodes with positive CSF culture

6. Was surgery performed on the baby ○ Yes ◉ No

7. Has a cerebral ultrasound scan been carried out within the first month ○ Yes ◉ No

(i) Reason

(i) Date of scan Day Month Year

(ii) Scan findings

Other | Other | -- Ventricles --

Specify other (Haemorrhage)

Specify other (Parenchymal appearances)

8. Has the baby been diagnosed with severe chronic lung disease ◉ Yes ○ No

Please specify any other major neonatal complications

9. Patent arterial duct
◉ Yes - treated medically
○ Yes - treated medically & surgically
○ No

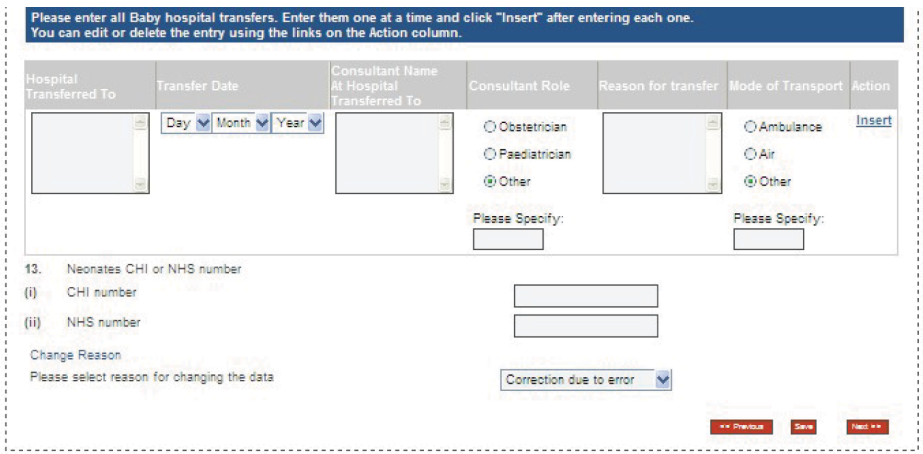
10. Any other principle diagnoses (e.g. retinopathy) ◉ Yes ○ No

Please record details of all other diagnoses

Name Add

11. Date of hospital discharge (BABY): 1 Feb 2011

12. Was the baby transferred to another hospital after birth? ○ Yes ◉ No


Please enter all Baby hospital transfers. Enter them one at a time and click "Insert" after entering each one.
You can edit or delete the entry using the links on the Action column.
Hospital Transferred To
Transfer Date
Day
Month
Year
Consultant Name At Hospital Transferred To
Consultant Role
Obstetrician
Paediatrician
Other
Please Specify:
Reason for transfer
Mode of Transport
Ambulance
Air
Other
Please Specify:
Action
Insert
13. Neonates CHI or NHS number
(i) CHI number
(ii) NHS number
Change Reason
Please select reason for changing the data
Correction due to error
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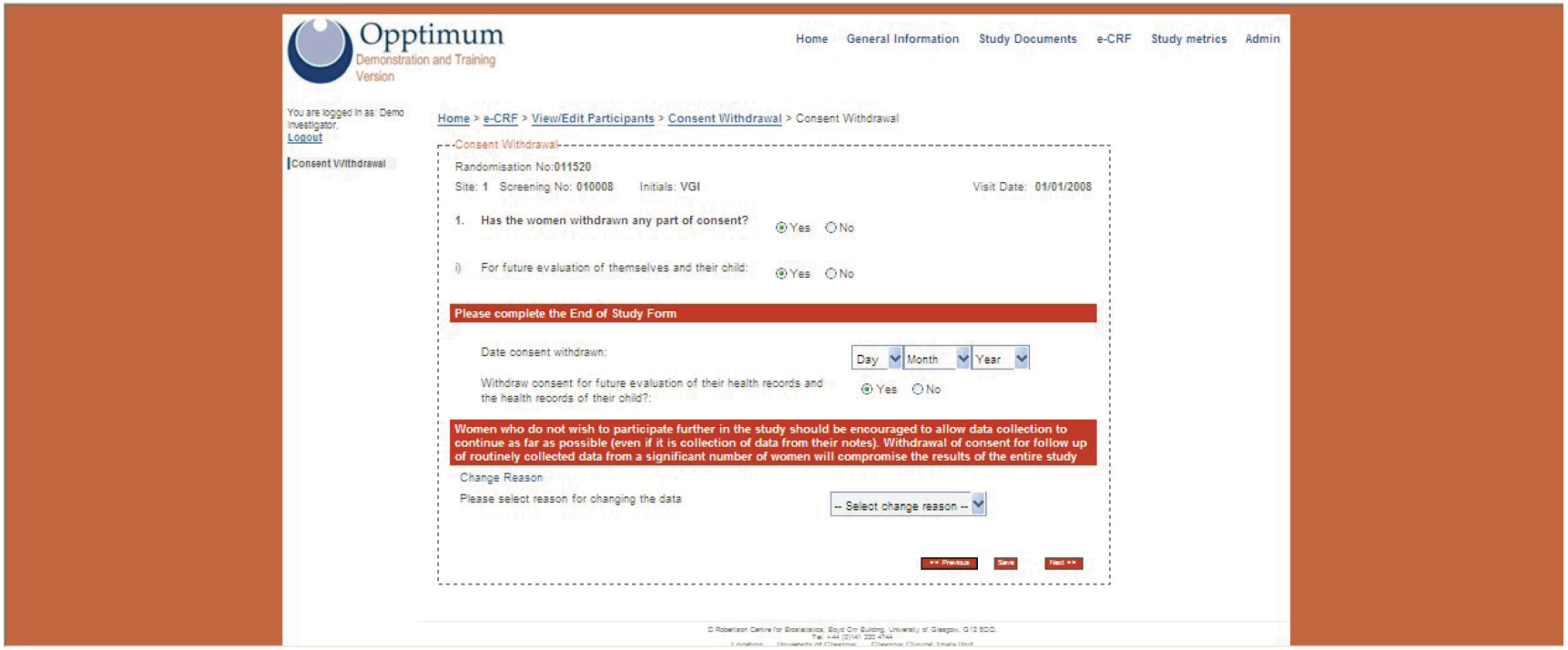
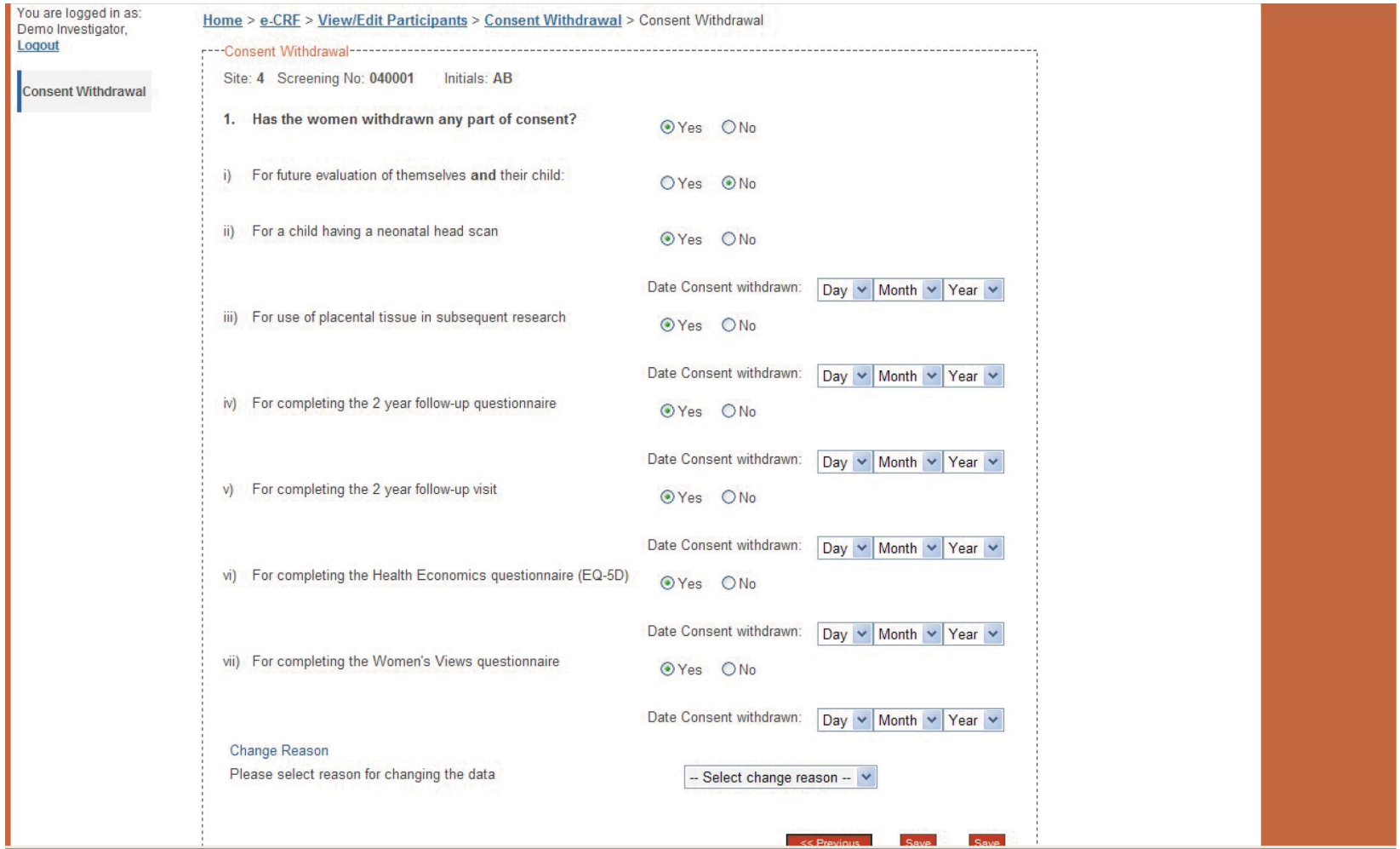
8. Consent Withdrawal

a. Consent Withdrawal

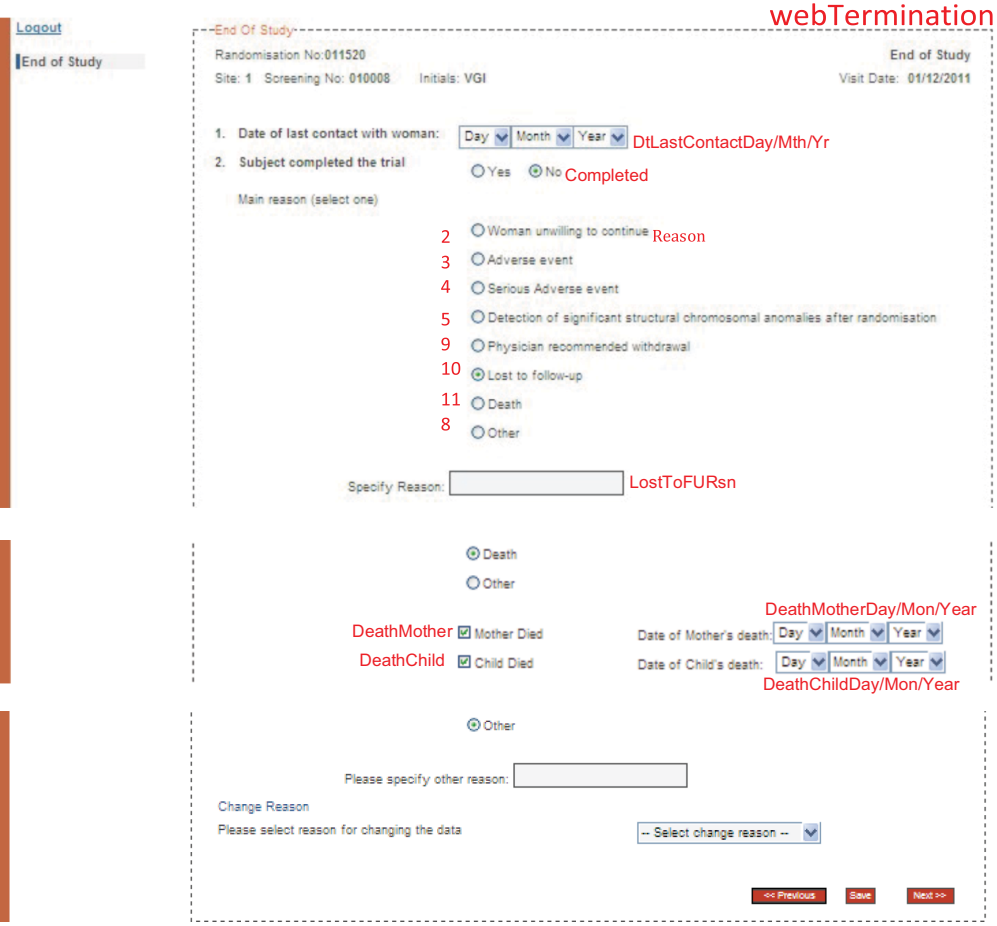



You are logged in as:
Demo Investigator,
Logout
Consent Withdrawal
Home > e-CRF > View/Edit Participants > Consent Withdrawal > Consent Withdrawal
Consent Withdrawal
Site: 4 Screening No: 040001 Initials: AB
1. Has the women withdrawn any part of consent?
Yes No
i) For future evaluation of themselves and their child:
Yes No
ii) For a child having a neonatal head scan
Yes No
Date Consent withdrawn: Day Month Year
iii) For use of placental tissue in subsequent research
Yes No
Date Consent withdrawn: Day Month Year
iv) For completing the 2 year follow-up questionnaire
Yes No
Date Consent withdrawn: Day Month Year
v) For completing the 2 year follow-up visit
Yes No
Date Consent withdrawn: Day Month Year
vi) For completing the Health Economics questionnaire (EQ-5D)
Yes No
Date Consent withdrawn: Day Month Year
vii) For completing the Women's Views questionnaire
Yes No
Date Consent withdrawn: Day Month Year
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
Save
Save

9. End of Study

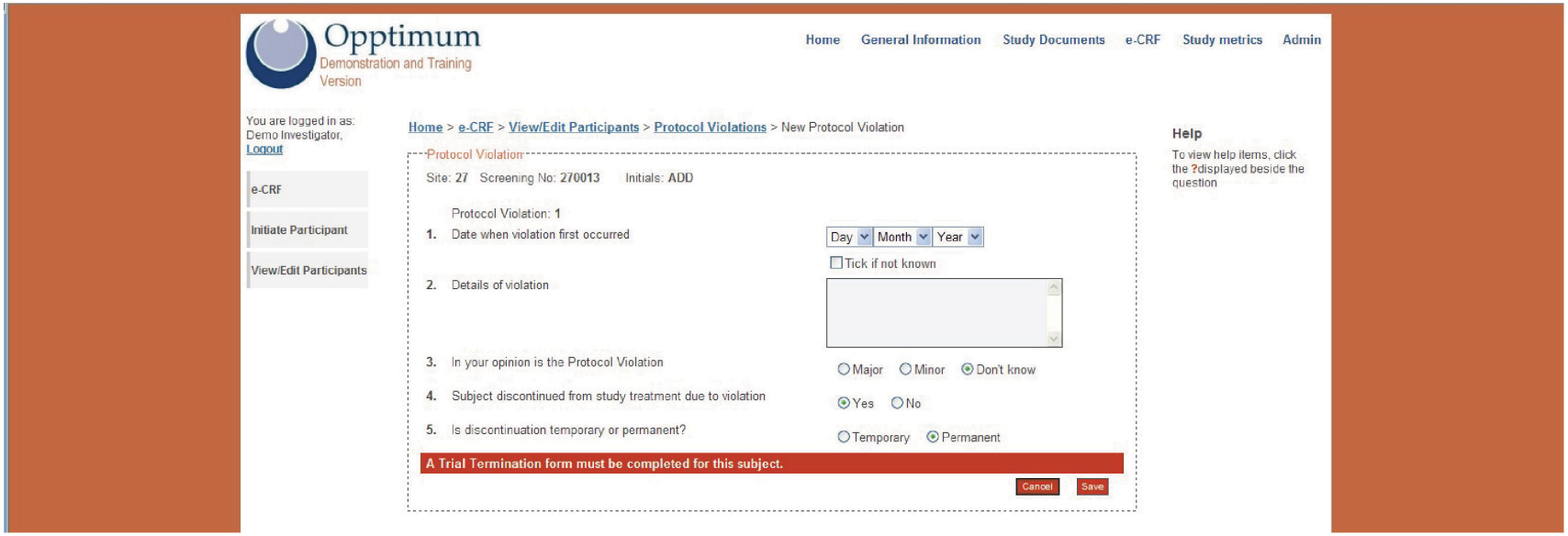
a. End of Study

webTermination



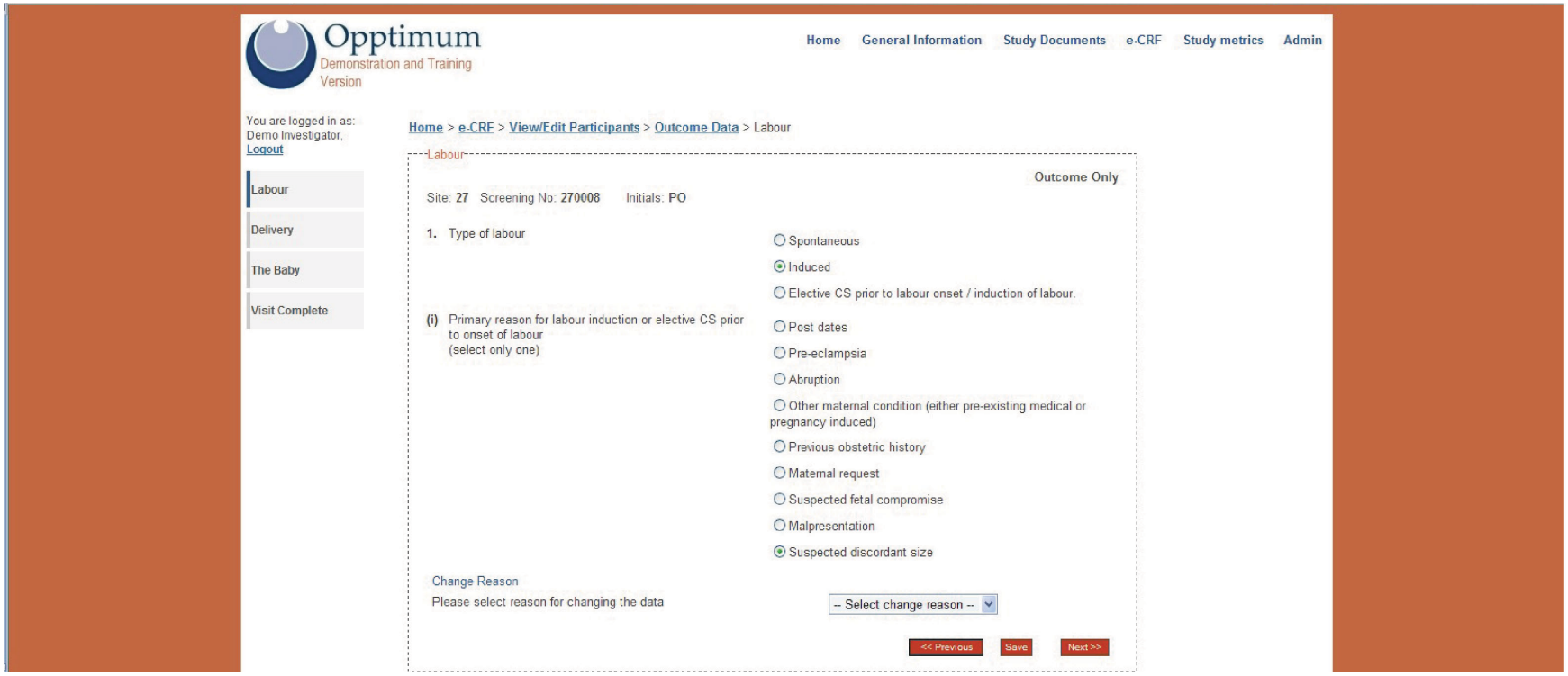
10. Protocol Violation

a. Protocol Violation

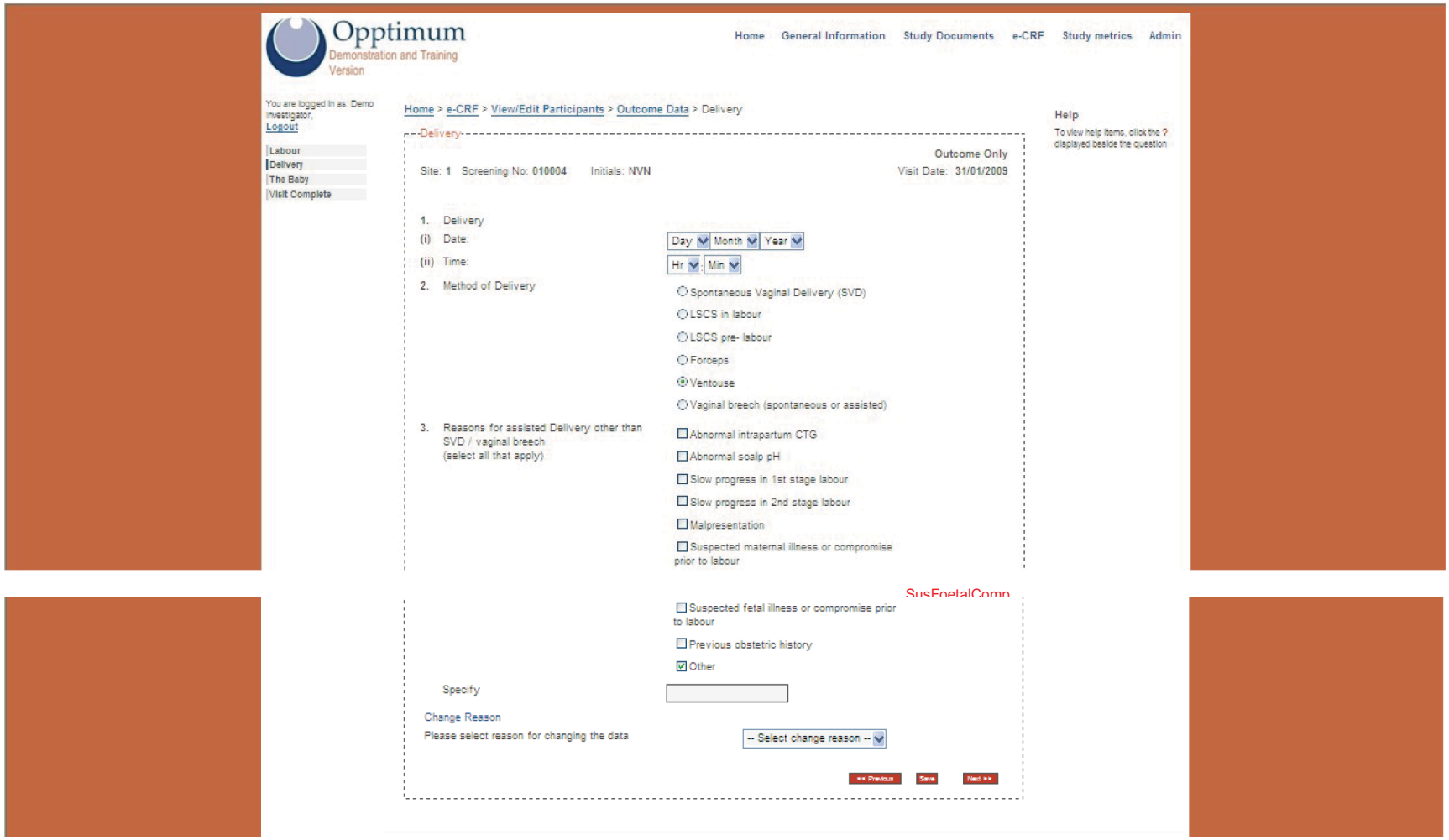


11. Outcome Data

a. Labour



b. Delivery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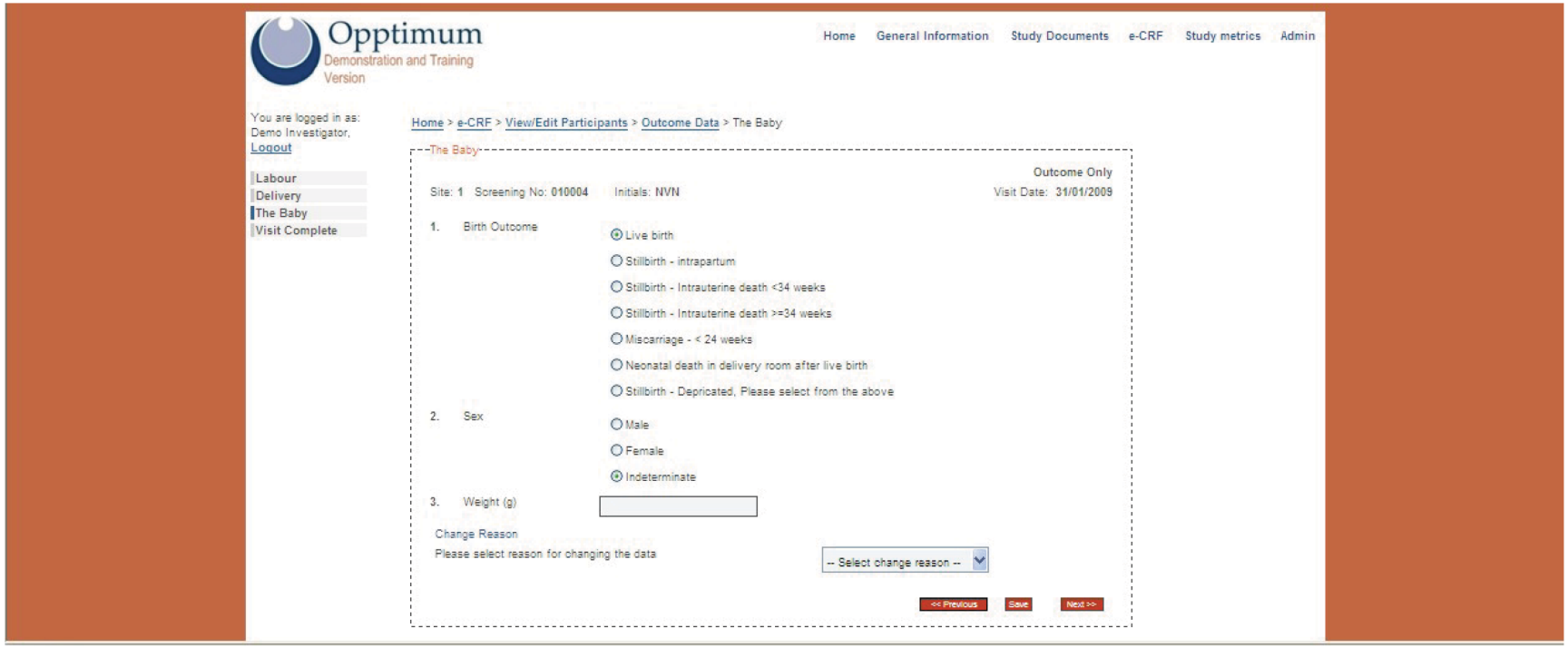
Labour
Delivery
The Baby
Visit Complete
Home > e-CRF > View/Edit Participants > Outcome Data > Delivery
Help
To view help items, click the ? displayed beside the question
Delivery
Outcome Only
Site: 1 Screening No: 010004 Initials: NVN
Visit Date: 31/01/2009
1. Delivery
(i) Date: Day Month Year
(ii) Time: Hr Min
2. Method of Delivery
Spontaneous Vaginal Delivery (SVD)
LSCS in labour
LSCS pre- labour
Forceps
Ventouse
Vaginal breech (spontaneous or assisted)
3. Reasons for assisted Delivery other than SVD / vaginal breech (select all that apply)
Abnormal intrapartum CTG
Abnormal scalp pH
Slow progress in 1st stage labour
Slow progress in 2nd stage labour
Malpresentation
Suspected maternal illness or compromise prior to labour
SusFoetalComp
Suspected fetal illness or compromise prior to labour
Previous obstetric history
Other
Specify
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
Save
Next >>

c. The Baby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Logout
Labour
Delivery
The Baby
Visit Complete
Home > e-CRF > View/Edit Participants > Outcome Data > The Baby
The Baby
Outcome Only
Site: 1 Screening No: 010004 Initials: NVN
Visit Date: 31/01/2009
1. Birth Outcome
Live birth
Stillbirth - intrapartum
Stillbirth - Intrauterine death <34 weeks
Stillbirth - Intrauterine death >=34 weeks
Miscarriage - < 24 weeks
Neonatal death in delivery room after live birth
Stillbirth - Depricated, Please select from the above
2. Sex
Male
Female
Indeterminate
3. Weight (g)
Change Reason
Please select reason for changing the data
-- Select change reason --
<< Previous
Save
Next >>

12. Obstetric Withdrawal

a. Withdrawal