

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)

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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 eligible						
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 PPRM	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


The screenshot shows the Opptimum web application interface. At the top left is the Opptimum logo with the text "Opptimum Demonstration and Training Version". To the right is a navigation menu with links: Home, General Information, Study Documents, e-CRF, Study metrics, and Admin. Below the logo, it says "You are logged in as: Demo Investigator, Logout". A sidebar on the left contains buttons for "e-CRF", "Initiate Participant" (which is highlighted), and "View/Edit Participants". The main content area has a breadcrumb trail: "Home > e-CRF > Initiate Participant". Below this is a dashed box titled "Participant Identification" containing the following form fields:

- Site: 6
- To initiate participants from a different site, please select a site below.
- Select a Site: 6: Demo Site 6 (dropdown menu)
- 1. Participant Initials (text input field)
- 2. Eligible for Study (radio buttons for Yes and No, with Yes selected)
- Optional Date of visit (Day, Month, Year dropdown menus)
- 3. Reason for exclusion (dropdown menu with "Other" selected)
- (i) Specify (text input field)
- Submit button

There is a red label "ExlReason" positioned above the "Reason for exclusion" dropdown menu.

2. Screening Visit –

a. Pre-visit Data



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](#) > Pre-visit Data

Pre-visit Data:

Randomisation No: 011520 **Screening Visit**
Site: 1 Screening No: 010008 Initials: VGI Visit Date: 05/12/2008

1. Was the woman approached to enter the study? Yes No

Please select a reason:

Clinic too busy
 Seen off site
 Patient left before researcher available
 Other

Reason:

Change Reason
Please select reason for changing the data

- Schedule fFN Test
- fFN Test Results
- Pregnancy Complications
- Schedule Next Visit
- Visit Complete

2. Was a screening appointment made?

Please select a reason:

Yes No

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?

Please select a reason:

Yes No

No reason given

Changed mind

Another clinical event occurred

Administrative (e.g. missed appointment)

Other

Reason:

b. Visit Date

The screenshot displays the Opptimum web application interface. At the top left is the Opptimum logo with the text "Opptimum Demonstration and Training Version". The top right navigation menu includes "Home", "General Information", "Study Documents", "e-CRF", "Study metrics", and "Admin". On the left side, a vertical menu lists various options: "Pre-visit Data", "Visit Date" (highlighted), "Consent", "Inclusion Criteria", "Exclusion Criteria", "Schedule fFN Test", "fFN Test Results", "Pregnancy Complications", "Schedule Next Visit", and "Visit Complete".

The main content area shows the user is logged in as "Demo Investigator" with a "Logout" link. The breadcrumb trail is "Home > e-CRF > View/Edit Participants > Screening > Visit Date". The central form, titled "Date of Visit", contains the following information:

- Randomisation No: 011520
- Site: 1 Screening No: 010008 Initials: VGI
- Visit type: Screening Visit
- Current Visit Date: 05/12/2008
- Form fields for "Date of visit" with dropdown menus for Day, Month, and Year.
- A "Change Reason" section with the text "Please select reason for changing the data" and a dropdown menu currently showing "-- Select change reason --".
- Navigation buttons: "<< Previous", "Save", and "Next >>".

At the bottom of the page, the footer contains the following text:

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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:
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[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-CRE](#) > [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

You are logged in as:
Demo Investigator,
[Logout](#)

- Pre-visit Data
- Visit Date
- Consent
- Inclusion Criteria**
- Exclusion Criteria
- Schedule IFN Test
- IFN Test Results
- Pregnancy Complications
- Schedule Next Visit
- Visit Complete

[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Screening](#) > Inclusion Criteria

Inclusion Criteria

Randomisation No:011520

Screening Visit

Site: 1 Screening No: 010008 Initials: VGI

Visit Date: 05/12/2008

1. Woman is at high risk of preterm birth (PTB) as indicated by at least one of the following (please select):

- (i) History of ≥ 16 week or < 37 week delivery / pregnancy loss. Yes No
- (ii) Previous preterm premature rupture of fetal membranes (≤ 37 weeks). Yes No
- (iii) Short cervical length < 25 mm on ultrasound at 18+0 to 24+0 gestation. Yes No
- (iv) Any cervical procedure to treat abnormal smears i.e. large loop excision, laser conisation, cold knife conisation or radical diathermy Yes No

2. Woman has had gestation established by scan at ≤ 16 weeks gestation to ensure that the estimated date of delivery is accurate or the consultant must be confident that the gestation dates are accurate. Yes No

Change Reason

Please select reason for changing the data

-- Select change reason --

<< Previous

Save

Next >>

e. Exclusion Criteria



You are logged in as:
Demo Investigator,
[Logout](#)

[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Screening](#) > Exclusion Criteria

- Pre-visit Data
- Visit Date
- Consent
- Inclusion Criteria
- Exclusion Criteria**
- Schedule fFN Test
- fFN Test Results
- Pregnancy Complications
- Schedule Next Visit
- Visit Complete

Exclusion Criteria

Randomisation No: **011520**

Site: **1** Screening No: **010008** Initials: **VGI**

Screening Visit

Visit Date: **05/12/2008**

- Known significant congenital structural or chromosomal fetal anomaly. Yes No
- Woman has a known sensitivity, contraindication or intolerance to progesterone (including peanut allergy). Yes No
- There has been a suspected or proven rupture of the fetal membranes at the time of recruitment. Yes No
- This is a multiple pregnancy. Yes No
- Woman has been prescribed, or has ingested, medications known to interact with progesterone (Bromocriptine, Rifamycin, Ketoconazole or Ciclosporin) Yes No
- Woman is currently prescribed progesterone or has taken progesterone beyond 18 weeks gestation Yes No

Please refer to the current SmPC (Summary Product Characteristics).

Change Reason

Please select reason for changing the data

-- Select change reason --

<< Previous

Save

Next >>

f. Schedule fFN Test



You are logged in as:
Demo Investigator,
[Logout](#)

[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Screening](#) > Schedule fFN Test

---Schedule Fetal Fibronectin Test---

Randomisation No: **011520**

Screening Visit

Site: **1** Screening No: **010008** Initials: **VGI**

Visit Date: **05/12/2008**

1. Is the woman willing to attend for fetal fibronectin testing? Yes No

Fetal Fibronectin test should be performed at 22-24 weeks gestation

(i) Schedule fetal fibronectin test

2. Date of scan used to calculate EDD

3. Agreed EDD from scan

4. Does the woman have a cervical suture in situ?
(if the woman has an abdominal suture but not a cervical suture please respond "No.") Yes No

(i) Was the suture (select one) Emergency treatment
 Elective treatment

[Change Reason](#)

Please select reason for changing the data

-- Select change reason --

<< Previous

Save

Next >>

g. fFN Test Results

version

You are logged in as:
Demo Investigator,
[Logout](#)

[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Screening](#) > fFN Test Results

Fetal Fibronectin Test

Randomisation No: 011520 Screening Visit
Site: 1 Screening No: 010008 Initials: VGI Visit Date: 05/12/2008

1. Date of test

2. Result Positive
 Negative

Please attach the fFN test result sticker to the woman's notes.

3. You have recorded the woman with a negative fetal fibronectin test. However, she may be randomised if she meets ONE of the following two criteria:

i) Woman has had a negative fetal fibronectin test at 22-24 weeks gestation and has had a previous spontaneous preterm birth <= 34 weeks gestation. Yes No

ii) Woman has had a negative fetal fibronectin test at 22-24 weeks gestation and has a short cervical length (<= 25mm) between 18 and 24 weeks gestation in index pregnancy. Yes No

Change Reason
Please select reason for changing the data

h. Pregnancy Complications

webComDrog

- 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 > Pregnancy Complications

Complications - pregnancy
Randomisation No: 011520
Site: 1 Screening No: 010008 Initials: VGI
Screening Visit
Visit Date: 05/12/2008

This page is to record pregnancy complications for the duration of the current pregnancy and not this visit only. Therefore, more than one complication can be added and complications recorded at other visits should not be removed.

1. Pregnancy complications
(If there have not been any changes just click the next button)
- None
 - Obstetric Cholestasis
 - Hypertension
 - Pre-eclampsia
 - Eclampsia
 - Preterm membrane rupture
 - Antepartum haemorrhage
 - Confirmed DVT
 - Gestational Diabetes
 - Cervical Cerclage
 - Other maternal complications
 - Other fetal complications

If other maternal complications please give details:

If other fetal complications, reason for suspicion:

- AC < 5th centile
- Liquor volume reduced
- Doppler > 95th centile (umbilical artery)
- Absent EDF (umbilical artery)
- Reverse EDF (umbilical artery)
- Abnormal CTG (RCOG criteria)
- None

Change Reason
Please select reason for changing the data

-- Select change reason --

<< Previous Save Next >>

i. Schedule Next Visit

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Home General Information Study Documents e-CRF Study metrics Admin

You are logged in as:
Demo Investigator,
[Logout](#)

Home > [e-CRF](#) > [View/Edit Participants](#) > [Screening](#) > Schedule Next Visit

---Schedule Next Visit---

Pre-visit Data
Visit Date
Consent

Site: 6 Screening No: 060001 Initials: YYY

Screening Visit
Visit Date: 11/09/2012

1. Is the patient willing to attend for the Randomisation assessment?
 Yes No

2. Date of Randomisation assessment
9 Apr 2013

2. Reason

Only Outcome Data can be gathered

Change Reason
Please select reason for changing the data
-- Select change reason --

NotAttendReas

<< Previous Save Next >>


Consent
Inclusion Criteria
Exclusion Criteria
Schedule IFN Test

3. Randomisation Visit –

a. Visit Date – See Section 2 (b)

b. Pregnancy Complications – See Section 2 (h)

C. Consent



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[Home](#) [General Information](#) [Study Documents](#) [e-CRF](#) [Study metrics](#) [Admin](#)

You are logged in as:
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[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

Change Reason
Please select reason for changing the data

d. Demographics

The screenshot displays the Optimum e-CRF interface. At the top left is the Optimum logo with the text "Optimum Demonstration and Training Version". The top right navigation bar includes links for Home, General Information, Study Documents, e-CRF, Study metrics, and Admin. On the left side, a sidebar menu lists various sections: Visit Date, Consent, Demographics (highlighted), Medical History, Prev Pregnancies, Other Med History, Inclusion Criteria, Exclusion Criteria, Pregnancy Complications, Contact Details, Randomisation, and Visit Complete. The main content area shows the breadcrumb path: Home > e-CRF > View/Edit Participants > Randomisation > Demographics. Below this, a dashed box encloses the "Demographics and Vital Signs" section. It includes the Randomisation No: 011520, Site: 1, Screening No: 010008, and Initials: VGI. The "Randomisation Visit" section shows a Visit Date of 24/01/2009. The form contains seven items: 1. Date of Birth (Day, Month, Year dropdowns); 2. Height (cm) (text input); 3. Earliest recorded weight during this pregnancy (kg) (text input); 4. Smoking during this pregnancy? (radio buttons for Yes and No, with Yes selected); 5. Alcohol use during this pregnancy? (radio buttons for Yes and No, with Yes selected); 6. Recreational drug-use during this pregnancy? (radio buttons for Yes and No, with Yes selected); 7. Currently in full time education? (radio buttons for Yes and No, with No selected). Below item 7 is item (i) Time in full time education (years) with a text input field.

- Exclusion Criteria
- Pregnancy Complications
- Contact Details
- Randomisation
- Visit Complete

Demographics and Vital Signs

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

9. Post-code (Not Required)

10. Ethinc Group

Other Black background ▼

Specify

11. Blood pressure

(i) SBP (mmHg)

(ii) DBP (mmHg)

Change Reason

Please select reason for changing the data

-- Select change reason -- ▼

<< Previous
Save
Next >>

e. Medical History – Current pregnancy

The screenshot displays the Opptimum e-CRF interface. At the top left is the Opptimum logo with the text "Opptimum Demonstration and Training Version". The top right navigation bar includes links for Home, General Information, Study Documents, e-CRF, Study metrics, and Admin. The user is logged in as a Demo Investigator, with a Logout link. The breadcrumb trail is Home > e-CRF > View/Edit Participants > Randomisation > Medical History. The main content area is titled "Medical History (Current Pregnancy)" and contains the following information:

Randomisation No: 011520
Site: 1 Screening No: 010008 Initials: VGI
Randomisation Visit
Visit Date: 24/01/2009

The form includes the following fields:

- 1. Date of LMP: Day, Month, Year dropdown menus.
- 2. Date of scan used to calculate EDD: Text input field containing 27/10/2008.
- 3. Agreed EDD from scan: Text input field containing 30/4/2009.
- 4. Fetal anomaly scanning: Radio buttons for Yes (checked) and No.
- (i) Date of scan: Day, Month, Year dropdown menus.
- (ii) Result: Radio buttons for Normal, Defined abnormality (checked), and Uncertain abnormality.
- Specify: Text input field.
- 5. Amniocentesis: Radio buttons for Yes (checked) and No.
- (i) Date of amniocentesis: Day, Month, Year dropdown menus.
- (ii) Result: Radio buttons for Normal and Other (checked).
- Specify: Text input field.

6. CVS Yes No
- (i) Date of CVS Day Month Year
- (ii) Result Normal Other
- Specify
7. Any other abnormal test results? Yes No

Please enter all abnormal test results. Enter them one at a time and click "Insert" after entering each one. You can edit or delete the test you entered using the links on the Action column. Please note that Inserting a Test will not save your whole page. To save the rest of the page, use the 'Save' button below.

Test	Date of Test	Test Result	Action
<input type="text"/>	<input type="text"/> Day <input type="text"/> Month <input type="text"/> Year	<input type="text"/>	Insert

8. Shortest recorded cervical length during this pregnancy. mm Unknown
9. Date of shortest recorded cervical length Day Month Year

Change Reason

Please select reason for changing the data

-- Select change reason --

[Previous](#) [Save](#) [Next](#)

f. Previous Pregnancies

webPrevPreg

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](#) > Prev Pregnancies

Previous Pregnancies:

Site: 4 Screening No: 040005 Initials: TST

Randomisation Visit

Visit Date: 01/12/2012

Select if no previous pregnancies

[+ Add A New Pregnancy](#)









Last Month of Pregnancy	Last Year of Pregnancy	Lasted >=14 wks gest	Outcome	Onset of Labour	Pre-term birth	Change Reason	
1	2013	Yes	Miscarriage				Edit
<input type="button" value="Jan"/> <input type="checkbox"/> Unknown	<input type="button" value="2013"/>	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Miscarriage <input type="radio"/> Ectopic <input type="radio"/> TOP <input type="radio"/> Alive & Well <input type="radio"/> Live Birth <input type="radio"/> Live birth followed by neonatal death <input type="radio"/> Live birth followed by death - other than neonatal <input checked="" type="radio"/> Still Birth	<input type="radio"/> Spontaneous PTB with premature membrane rupture <input type="radio"/> Spontaneous PTB without premature membrane rupture <input type="radio"/> Elective/induced <input type="radio"/> Spontaneous (>37 weeks)	<input type="radio"/> Yes <input type="radio"/> No	<input type="button" value="-- Select change reason --"/>	<input type="button" value="Update"/> <input type="button" value="Delete"/> <input type="button" value="Cancel"/>

[+ Add A Twin/Triplet etc To THIS Pregnancy](#)

Previous Pregnancies

g. Other Med History

webMedHistOth

Consent	Site: 1	Screening No: 010008	Initials: VGI	Visit Date: 24/01/2009
Demographics	Record which of the following medical conditions the woman has suffered from in the past five years: Mouse over  image to see term definitions			
Medical History	Condition		Currently taking medication for this condition?	
Prev Pregnancies	1. Hypertension 	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Other Med History	2. Insulin dependent diabetes 	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
Inclusion Criteria	3. Respiratory disease 	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
Exclusion Criteria	4. Cardiac disease 	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
Pregnancy Complications	5. Neurological disease 	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
Contact Details	6. Skin condition 	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
Randomisation	7. Thrombophilia 	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
Visit Complete	Change Reason Please select reason for changing the data	<input type="text" value="-- Select change reason --"/>		
		<input type="button" value=" << Previous"/>	<input type="button" value=" Save"/>	<input type="button" value=" Next >>"/>

h. Inclusion Criteria

webIncl

Medical History	Following completion of the woman's history please confirm the inclusion criteria are still valid:	
Prev Pregnancies	1. Woman is at high risk of preterm birth (PTB) as indicated by at least one of the following (please select):	
Other Med History	(i) History of ≥ 16 week or < 37 week delivery / pregnancy loss.	Incl1i <input checked="" type="radio"/> Yes <input type="radio"/> No
Inclusion Criteria	(ii) Previous preterm premature rupture of fetal membranes (≤ 37 weeks).	Incl1ii <input checked="" type="radio"/> Yes <input type="radio"/> No
Exclusion Criteria	(iii) Short cervical length < 25 mm on ultrasound at 18+0 to 24+0 gestation.	Incl1iii <input checked="" type="radio"/> Yes <input type="radio"/> No
Pregnancy Complications	(iv) Any cervical procedure to treat abnormal smears i.e. large loop excision, laser conisation, cold knife conisation or radical diathermy	Incl1iv <input checked="" type="radio"/> Yes <input type="radio"/> No
Contact Details	2. Woman has had gestation established by scan at ≤ 16 weeks gestation to ensure that the estimated date of delivery is accurate or the consultant must be confident that the gestation dates are accurate.	
Randomisation	Incl2 <input checked="" type="radio"/> Yes <input type="radio"/> No	
Visit Complete	3. Fetal fibronectin test. One of the following must apply for the woman to be randomised:	
	(i) Woman has had a positive fetal fibronectin test at 22–24 weeks gestation.	Incl3 <input checked="" type="radio"/> Yes <input type="radio"/> No
	(ii) Woman has had a negative fetal fibronectin test at 22-24 weeks gestation and has had a previous spontaneous preterm birth ≤ 34 weeks gestation	Incl3ii <input checked="" type="radio"/> Yes <input type="radio"/> No
	(iii) Woman has had a negative fetal fibronectin test at 22-24 weeks gestation and has a short cervical length (≤ 25 mm) between 18 and 24 weeks gestation in index pregnancy	Incl3iii <input checked="" type="radio"/> Yes <input type="radio"/> No
	Change Reason	
	Please select reason for changing the data	-- Select change reason --
		<< Previous Save Next >>

i. Exclusion Criteria

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[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Randomisation](#) > Exclusion Criteria

Exclusion Criteria

	Randomisation Visit
Site: 6 Screening No: 060001 Initials: YYY	Visit Date: 11/09/2012
1. Known significant congenital structural or chromosomal fetal anomaly. (No at screening)	<input type="radio"/> Yes <input type="radio"/> No
2. Woman has a known sensitivity, contraindication or intolerance to progesterone. (No at screening)	<input type="radio"/> Yes <input type="radio"/> No
3. There has been a suspected or proven rupture of the fetal membranes at the time of recruitment. (No at screening)	<input type="radio"/> Yes <input type="radio"/> No
4. This is a multiple pregnancy. (No at screening)	<input type="radio"/> Yes <input type="radio"/> No
5. Woman has been prescribed, or has ingested, medications known to interact with progesterone (Bromocriptine, Rifamycin, Ketoconazole or Ciclosporin) (No at screening)	<input type="radio"/> Yes <input type="radio"/> No
6. Woman is currently prescribed progesterone or has taken progesterone beyond 18 weeks gestation (No at screening)	<input type="radio"/> Yes <input type="radio"/> No

Please refer to the current SmPC (Summary Product Characteristics).

Visit Date
Consent
Demographics
Medical History
Prev Pregnancies
Other Med History
Inclusion Criteria
Exclusion Criteria
Pregnancy Complications

j. Contact Details

You are logged in as: Demo Investigator. [Logout](#)

[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Randomisation](#) > [Contact Details](#)

Contact Details

Randomisation No: 011520 Randomisation Visit
Site: 1 Screening No: 010008 Initials: VGI Visit Date: 24/01/2009

This information will be held on a secure database and will only be used to help the OPPTIMUM team keep in contact with you, after your baby is delivered.

Please confirm contact details for the baby's mother:

Name (in full):

Address:

Postcode:

Telephone:

Mobile Number:

Email Address:

Please provide the maternal grandmother's contact details or an alternative if not available:

Relative Contact Information:

Relationship:

Name (in full):

Address:

Postcode:

Telephone:

Mobile Number:

Email Address:

Change Reason
Please select reason for changing the data

[Previous](#) [Save](#) [Next](#)

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



Opptimum
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Home General Information Study Documents e-CRF Study metrics Admin

You are logged in as:
Demo Investigator,
[Logout](#)

[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Randomisation](#) > Randomisation

Randomisation Visit
Visit Date: 11/09/2012

Site: 6 Screening No: 060001 Initials: YYY

1. Is the woman willing to be randomised to progesterone (200mg daily) or placebo? Yes No

Reason for not wanting to be randomised

3. Has randomisation been completed? Yes No **RandComYN**

Reason for not completing randomisation

4. Has a prescription been issued to the woman? Yes No **PrescriptionYN**

5. Has the woman been given an EQ50 form? Yes No

6. Has the woman been given a treatment diary? Yes No

7. Has the woman been given a patient card? Yes No

<< Previous Save Next >>

Visit Date

Consent

Demographics

Other Med History

Inclusion Criteria

Inclusion Criteria

Exclusion Criteria

Pregnancy Complications

Contact Details

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

The screenshot displays the Opptimum e-CRF interface. At the top left is the Opptimum logo with the text 'Opptimum Demonstration and Training Version'. The top right navigation bar includes links for Home, General Information, Study Documents, e-CRF, Study metrics, and Admin. A user login bar on the left shows 'You are logged in as: Demo Investigator' with Logout, Visit Date, Trial Treatment, Pregnancy/Complications, Contact Details, and Visit Complete buttons. The main content area shows a breadcrumb trail: Home > e-CRF > View/Edit Participants > 34 Weeks Gestation (End of Trial Treatment) > Trial Treatment. Below this is a dashed box containing the form for '34 Weeks Gestation (End of Trial Treatment)'. The form includes fields for Randomisation No (011520), Site (1), Screening No (010008), Initials (VGI), and Visit Date (25/11/2010). A blue bar prompts the user to 'Please record all treatment information'. The first question asks for the source of information, with radio buttons for 'Woman present', 'Diary', 'Phone call with woman', and 'Other'. A 'Please Specify:' field is provided. Questions 2 and 3 are for 'Date treatment started' and 'Date last treatment taken', each with Day, Month, and Year dropdown menus. Question 4 asks if the woman completed the course, with radio buttons for 'Yes', 'No', and 'Unknown'. Question (i) asks who recommended/stopped treatment, with radio buttons for 'GP', 'Obstetrician', 'Research consultant', 'Research midwife', 'Clinical midwife', 'Woman', and 'Preterm Delivery'.

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Home General Information Study Documents e-CRF Study metrics Admin

You are logged in as: Demo Investigator
Logout
Visit Date
Trial Treatment
Pregnancy/Complications
Contact Details
Visit Complete

Home > e-CRF > View/Edit Participants > 34 Weeks Gestation (End of Trial Treatment) > Trial Treatment

--34 Weeks Gestation (End of Trial Treatment)--

Randomisation No: 011520 34 Weeks Gestation (End of Trial Treatment)
Site: 1 Screening No: 010008 Initials: VGI Visit Date: 25/11/2010

Please record all treatment information

1. What is source of the following information?

Woman present
 Diary
 Phone call with woman
 Other

Please Specify:

2. Date treatment started: Day Month Year

3. Date last treatment taken: Day Month Year

4. Did the woman complete course?
 Yes No Unknown

(i) Who recommended/decided treatment should be stopped?

GP
 Obstetrician
 Research consultant
 Research midwife
 Clinical midwife
 Woman
 Preterm Delivery

(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 --

5. Hospital Admissions –

a. Pregnancy Complications – See Section 2 (h)

b. Admission Details – Antenatal Hospital Admissions

You are logged in as: Demo Investigator. [Logout](#)

Admission Details
Pregnancy Complications

[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Hospital Admissions](#) > [All Other Admissions](#) > Admission Details

Antenatal Hospital Admissions - Other

Randomisation No: 012002
Site: 1 Screening No: 010010 Initials: THY

**Any hospital admissions from recruitment to admission in labour //for induction of labour other than those included for threatened preterm labour
Please complete for each admission**

1. Has the woman been admitted to her study hospital? Yes No

(i) Hospital admitted to:

(ii) Consultant:

(iii) Consultant Role:
 Obstetrician
 Paediatrician
 Other

(iv) Please specify:

2. Date of admission: Day Month Year

3. Time of admission: Hr Min

4. Ward admitted to:

5. Date of discharge: Day Month Year

6. Time of discharge: Morning Afternoon Evening

7. Indication for admission (please select all that apply)

- Hypertension
- Pre-eclampsia
- Eclampsia
- Membrane rupture
- Antepartum haemorrhage
- Suspected DVT

- Gestational diabetes
- Abdo pain
- Symphyseal pain
- Other maternal complication
- Other fetal complication

Details

(i) Please select other fetal complication

- AC < 5th centile
- Liquor volume reduced
- Doppler > 95th centile (umbilical artery)
- Absent EDF (umbilical artery)
- Reverse EDF (umbilical artery)
- Abnormal CTG (ROCG 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
- Other fetal complication

Details

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

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


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	Consultant Name At Hospital Transferred To	Consultant Role	Reason for transfer	Mode of Transport	Action
<input type="text"/>	Day <input type="text"/> Month <input type="text"/> Year <input type="text"/>	<input type="text"/>	<input type="radio"/> Obstetrician <input type="radio"/> Paediatrician <input checked="" type="radio"/> Other	<input type="text"/>	<input type="radio"/> Ambulance <input type="radio"/> Air <input checked="" type="radio"/> Other	Insert
			Please Specify: <input type="text"/>		Please Specify: <input type="text"/>	

[← Previous](#) [Save](#) [Next →](#)

C. Hospital Admissions – Threatened Preterm Labour or PPROM



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[Home](#) [General Information](#) [Study Documents](#) [e-CRF](#) [Study metrics](#) [Admin](#)

You are logged in as:
Demo Investigator,
[Logout](#)

[Admission Details](#)

[Pregnancy Complications](#)

[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Hospital Admissions](#) > [Threatened Preterm Labour or PPROM](#) > Admission Details

~~Hospital Admissions - Threatened Preterm Labour or PPROM~~

Site: 4 Screening No: 040005 Initials: TST

**Details to be completed for each admission in threatened preterm labour
Episodes of threatened preterm labour prompting admission (24 weeks onwards)**

1. Has the woman been admitted to her study hospital? Yes No

(i) Hospital admitted to:

(ii) Consultant:

(iii) Consultant Role:

Obstetrician

Paediatrician

Other

(iv) Please specify:

2. Admission: Date of admission: Day Month Year

Time of admission: Hr Min

3. Ward admitted to:

Labour

Antenatal

Other

If other, give details

4. Membranes intact Yes No

5. Tocolysis given this admission: Yes No

(i) If yes, nature:

- Nifedipine
- Indomethacin
- Atosiban
- Other

Max daily dose:
Dose Unit:
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:

7. Date of hospital discharge:

Day Month Year

8. Other treatment given this admission:

Antibiotics

If yes, name of antibiotic:
Dose:
Dose Unit:
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	Consultant Name At Hospital Transferred To	Consultant Role	Reason for transfer	Mode of Transport	Action
<input type="text"/>	Day <input type="text"/> Month <input type="text"/> Year <input type="text"/>	<input type="text"/>	<input type="radio"/> Obstetrician <input type="radio"/> Paediatrician <input checked="" type="radio"/> Other	<input type="text"/>	<input type="radio"/> Ambulance <input type="radio"/> Air <input checked="" type="radio"/> Other	Insert
			Please Specify: <input type="text"/>	Please Specify: <input type="text"/>		

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

Version

You are logged in as:
Demo Investigator,
[Logout](#)

[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Hospital Admissions](#) > [Labour/Planned Induction Admission](#) > Labour Hospital

Labour Hospital

Labour Hospital
Labour
Delivery
Pregnancy Complications
Postnatal Complications
The Baby
Visit Complete

Labour Hospital

Randomisation No: 011520
Site: 1 Screening No: 010008 Initials: VGI

Labour/Planned Induction Admission

1. Has the woman been admitted to her study hospital? Yes No

2. Hospital woman admitted to


3. Name of consultant in hospital

4. Role of consultant Obstetrician Paediatrician Other

(i) Specify

Change Reason
Please select reason for changing the data

C. Labour

 **Opptimum**
Demonstration and Training
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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	<input type="text"/>	<input type="text"/>
2nd Stage	<input type="text"/>	<input type="text"/>
3rd Stage	<input type="text"/>	<input type="text"/>

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?
(select all that apply)

Yes No

General anaesthetic

Epidural/spinal

Opiates

Entonox

Other

Please enter details of all other analgesics

Name


5. Did the woman receive IV antibiotics during labour/delivery?

Yes No

Change Reason

Please select reason for changing the data

d. Delivery

 **Opptimum**
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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 Ebb
Mitt 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:

(ii) Time:

3. Estimated blood loss in 3rd stage labour ml

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
<input type="text"/>	Day <input type="text"/> Month <input type="text"/> Year <input type="text"/>	<input type="text"/>	<input type="radio"/> Obstetrician <input type="radio"/> Paediatrician <input checked="" type="radio"/> Other	<input type="text"/>	<input type="radio"/> Ambulance <input type="radio"/> Air <input checked="" type="radio"/> Other	Insert
			Please Specify: <input type="text"/>		Please Specify: <input type="text"/>	

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](#) [Save](#) [Next](#)

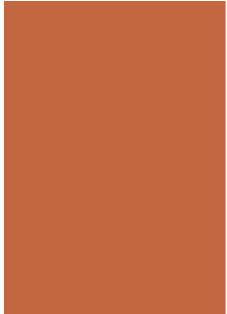
e. Maternal Postnatal Complications

<ul style="list-style-type: none"> Labour Hospital Labour Delivery Pregnancy Complications Postnatal Complications The Baby Visit Complete 	Randomisation No: 011520 Site: 1 Screening No: 010008 Initials: VGI	Labour/Planned Induction Admission																				
	Mouse over  image to see term definitions																					
1. Maternal Postnatal complications:																						
<input type="checkbox"/> None																						
<input checked="" type="checkbox"/> Superficial thrombophlebitis																						
<input checked="" type="checkbox"/> Confirmed thromboembolic disease																						
<input checked="" type="checkbox"/> Wound infection																						
<input checked="" type="checkbox"/> Urine infection																						
<input checked="" type="checkbox"/> Wound breakdown (including episiotomy breakdown)																						
<input checked="" type="checkbox"/> Mastitis																						
<input checked="" type="checkbox"/> Infection of unknown origin																						
<input checked="" type="checkbox"/> Post partum haemorrhage																						
<input checked="" type="checkbox"/> Post natal depression (requiring initiation of antidepressants or psychiatric referral)																						
<input checked="" type="checkbox"/> Other																						
Change Reason Please select reason for changing the data																						
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<input checked="" type="checkbox"/> Details	<input type="text"/>																					
<input type="checkbox"/> Treatment and/or medication	<input type="text"/>																					
<input type="button" value="Previous"/> <input type="button" value="Save"/> <input type="button" value="Next"/>																						

f. The Baby

The screenshot displays the Opptimum e-CRF interface. At the top left is the Opptimum logo with the text 'Opptimum Demonstration and Training Version'. The top right navigation bar includes links for Home, General Information, Study Documents, e-CRF, Study metrics, and Admin. On the left side, a sidebar menu lists various sections: Labour Hospital, Labour, Delivery, Pregnancy Complications, Postnatal Complications, The Baby (which is highlighted), and Visit Complete. The main content area shows the user is logged in as a Demo Investigator with a Logout link. The breadcrumb trail is: Home > e-CRF > View/Edit Participants > Hospital Admissions > Labour/Planned Induction Admission > The Baby. The form is titled 'The Baby' and contains the following fields:

- Randomisation No: 011520
- Site: 1 Screening No: 010008 Initials: VGI
- 1. Birth Outcome: Radio button options for Live birth (selected), Stillbirth - intrapartum, Stillbirth - Intrauterine death <34 weeks, Stillbirth - Intrauterine death >=34 weeks, Miscarriage - < 24 weeks, Neonatal death in delivery room after live birth, and Stillbirth - Deprecated, Please select from the above.
- 2. Sex: Radio button options for Male (selected), Female, and Indeterminate.
- 3. Weight (g): A text input field.
- 4. Apgar Scores: Sub-fields for (i) 1 minute and (ii) 5 minutes, each with a text input field.



5. Highest level of care given in the delivery room

- Minimal (none required or tactile stimulation)
- Suction
- Suction and facial O2 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

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7. Neonatal Outcome

a. Contact Details – See Section 3 (j)

b. Neonatal Outcome

Opptimum
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Home General Information Study Documents e-CRF Study metrics Admin

You are logged in as: Demo Investigator, [Logout](#)

Visit Date
Neonatal Outcome
Contact Details
Visit Complete

Home > e-CRF > View/Edit Participants > Neonatal Outcome > Neonatal Outcome

---Neonatal Outcome---

Randomisation No: 011520
Site: 1 Screening No: 010008 Initials: VGI

Neonatal Outcome
Visit Date: 13/09/2010

To be completed at 1 month after delivery or 36 weeks post menstrual age, which ever is the latest.

1. Care after delivery room
Level of Care *[Details](#)

	Number of Days
(i) Normal care <input checked="" type="checkbox"/>	<input type="text"/>
(ii) Special care <input checked="" type="checkbox"/>	<input type="text"/>
(iii) Level 2 Intensive care (high dependency intensive care) <input checked="" type="checkbox"/>	<input type="text"/>
(iv) Level 1 Intensive care (Maximal intensive care) <input checked="" type="checkbox"/>	<input type="text"/>

2. Have any congenital abnormalities been detected? Yes No

Please complete an SAE webNeoNatal2


3. Was the baby given Surfactant? Yes No

Please enter details of all Surfactants

Drug Name Dose Units -- Units --

Drug Name	Dose	Units	
123	123	mg	Edit/Delete

4. Necrotising enterocolitis No
 Yes suspected
 Yes medical treatment only

5. Infection 

Yes required drain or laparotomy

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 

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	Consultant Name At Hospital Transferred To	Consultant Role	Reason for transfer	Mode of Transport	Action
<input type="text"/>	Day <input type="text"/> Month <input type="text"/> Year <input type="text"/>	<input type="text"/>	<input type="radio"/> Obstetrician <input type="radio"/> Paediatrician <input checked="" type="radio"/> Other	<input type="text"/>	<input type="radio"/> Ambulance <input type="radio"/> Air <input checked="" type="radio"/> Other	Insert
			Please Specify: <input type="text"/>			
				Please Specify: <input type="text"/>		

13. Neonates CHI or NHS number

(i) CHI number

(ii) NHS number

Change Reason

Please select reason for changing the data

[Previous](#) [Save](#) [Next](#)

8. Consent Withdrawal

a. Consent Withdrawal

The screenshot displays the Opptimum e-CRF interface for a 'Consent Withdrawal' form. The header includes the Opptimum logo and navigation links: Home, General Information, Study Documents, e-CRF, Study metrics, and Admin. The user is logged in as 'Demo Investigator'. The breadcrumb trail is: Home > e-CRF > View/Edit Participants > Consent Withdrawal > Consent Withdrawal.

The form content is enclosed in a dashed box and includes the following fields and sections:

- Randomisation No: 011520
- Site: 1 Screening No: 010008 Initials: VGI Visit Date: 01/01/2008
- Question 1: "Has the women withdrawn any part of consent?" with radio buttons for Yes (selected) and No.
- Question 2: "For future evaluation of themselves and their child:" with radio buttons for Yes (selected) and No.
- A red banner: "Please complete the End of Study Form"
- Date consent withdrawn: A date picker with Day, Month, and Year dropdowns.
- Question: "Withdraw consent for future evaluation of their health records and the health records of their child?" with radio buttons for Yes (selected) and No.
- Another red banner: "Women who do not wish to participate further in the study should be encouraged to allow data collection to continue as far as possible (even if it is collection of data from their notes). Withdrawal of consent for follow up of routinely collected data from a significant number of women will compromise the results of the entire study"
- Change Reason: A dropdown menu with the text "-- Select change reason --".
- Navigation buttons: Previous, Save, and Next.

At the bottom of the page, there is a footer: "© Robertson Centre for Biostatistics, Boyd Orr Building, University of Glasgow, G12 8QQ. Tel: +44 (0)141 221 4744. E-mail: r.c.b@glasgow.ac.uk"

-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

Logout

End of Study

End Of Study

Randomisation No: 011520 End of Study
Site: 1 Screening No: 010008 Initials: VGI Visit Date: 01/12/2011

1. Date of last contact with woman: DtLastContactDay/Mth/Yr

2. Subject completed the trial Yes No Completed

Main reason (select one)

2 Woman unwilling to continue Reason
3 Adverse event
4 Serious Adverse event
5 Detection of significant structural chromosomal anomalies after randomisation
9 Physician recommended withdrawal
10 Lost to follow-up
11 Death
8 Other

Specify Reason: LostToFURsn

Death
 Other

DeathMother Mother Died Date of Mother's death: DeathMotherDay/Mon/Year
DeathChild Child Died Date of Child's death: DeathChildDay/Mon/Year

Other

Please specify other reason:

Change Reason
Please select reason for changing the data

10. Protocol Violation

a. Protocol Violation

The screenshot displays the Opptimum e-CRF interface for reporting a protocol violation. The header includes the Opptimum logo and navigation links: Home, General Information, Study Documents, e-CRF, Study metrics, and Admin. The user is logged in as a Demo Investigator. The breadcrumb trail is: Home > e-CRF > View/Edit Participants > Protocol Violations > New Protocol Violation.

The form is titled "Protocol Violation" and contains the following fields:

- Site: 27 Screening No: 270013 Initials: ADD
- Protocol Violation: 1
- 1. Date when violation first occurred: Day, Month, Year dropdown menus. Includes a checkbox for "Tick if not known".
- 2. Details of violation: A text area for describing the violation.
- 3. In your opinion is the Protocol Violation: Radio buttons for Major, Minor, and Don't know (selected).
- 4. Subject discontinued from study treatment due to violation: Radio buttons for Yes and No.
- 5. Is discontinuation temporary or permanent?: Radio buttons for Temporary and Permanent (selected).

A red warning message at the bottom states: "A Trial Termination form must be completed for this subject." Buttons for "Cancel" and "Save" are located at the bottom right of the form.


Help
To view help items, click the ? displayed beside the question

11. Outcome Data

a. Labour

The screenshot displays the Opptimum e-CRF interface for the 'Labour' outcome data. The page header includes the Opptimum logo (Demonstration and Training Version) and navigation links: Home, General Information, Study Documents, e-CRF, Study metrics, and Admin. The user is logged in as 'Demo Investigator' with a 'Logout' link. A left sidebar contains navigation tabs: Labour (selected), Delivery, The Baby, and Visit Complete. The main content area shows the breadcrumb 'Home > e-CRF > View/Edit Participants > Outcome Data > Labour' and a 'Labour' tab. The 'Outcome Only' section displays 'Site: 27 Screening No: 270008 Initials: PO'. The primary question is '1. Type of labour', with radio button options: Spontaneous, Induced (selected), and Elective CS prior to labour onset / induction of labour. A sub-question '(i) Primary reason for labour induction or elective CS prior to onset of labour (select only one)' has radio button options: Post dates, Pre-eclampsia, Abrupton, Other maternal condition (either pre-existing medical or pregnancy induced), Previous obstetric history, Maternal request, Suspected fetal compromise, Malpresentation, and Suspected discordant size (selected). A 'Change Reason' section prompts the user to 'Please select reason for changing the data' with a dropdown menu set to '-- Select change reason --'. At the bottom are buttons for '<< Previous', 'Save', and 'Next >>'.

b. Delivery



Home General Information Study Documents e-CRF Study metrics Admin

You are logged in as Demo Investigator. [Logout](#)

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--

Site: 1 Screening No: 010004 Initials: NVN Outcome Only 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

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

The screenshot shows the Opptimum e-CRF interface. The top navigation bar includes links for Home, General Information, Study Documents, e-CRF, Study metrics, and Admin. The user is logged in as a Demo Investigator, with a Logout link. A sidebar on the left lists menu items: Labour, Delivery, The Baby (selected), and Visit Complete. The main content area is titled 'The Baby' and contains the following information:

Site: 1 Screening No: 010004 Initials: NVN Outcome Only
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

Navigation buttons: << Previous, Save, Next >>

12. Obstetric Withdrawal

a. Withdrawal

You are logged in as:
Demo Investigator,
[Logout](#)

Obstetric Withdrawal

[Home](#) > [e-CRF](#) > [View/Edit Participants](#) > [Obstetric Withdrawal](#) > Obstetric Withdrawal

Obstetric Withdrawal
Visit Date: 01/05/2011

Site: 1 Screening No: 010001 Initials: SWR

1. Date of last contact with woman: 1 May 2011

2. Main reason for discontinuation (select one)

Withdrawal of consent for future evaluation of their health records and the health records of their child)

Lost to follow-up

Death

Other

Date consent withdrawn: Day Month Year

Lost to follow-up

Death

Other

Specify Reason:

deathmother

Mother

Date of Mother's death: Day Month Year

Child

Date of Child's death: Day Month Year other reason

Other

Please specify reason: