

SOLVE Frequently Asked Questions

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Recruitment

Q. How can we encourage more Doctors to be involved in the study?

A. Explain the importance of GCP at Trust Induction to new Doctors and also the experienced Doctors within your local trust. Ensure that those identified on the delegation log have CV's and GCP Certificates up to date according to your local R&D trust policy. Keep the delegation log up to date as and when new Doctors are able to confirm eligibility.

Q. Do Doctors who fit Dilpan-S as part of everyday practice need to be on the delegation log?

A. No although you do need to ensure that the prescriber confirming eligibility is on the delegation log.

Q. Can a lady who has thrush still be fitted with Dilapan?

A. Yes, although the participant would still need treatment for thrush and be made aware that it may be a little bit more painful due to the infection

Q. Are ladies with vaginismus eligible for the trial?

A. Yes although you may need to counsel them as they may be unable to tolerate the treatment and need Propess.

Q. Can I recruit a lady with blood-borne infections?

A. Check with your local Principle Investigator although a point to note would be when ladies are fitted with Dilapan they can bleed and being taken back to a shared environment could pose a risk of infection.

Randomisation

Q. What do you do if a participant needs a different arm to that which she is randomised to?

A. Complete the Baseline & Birth CRF at Q2.3 series 1 and tick to confirm that 'intervention was not given' and tick received other form of pessary.

Q. What would happen if a participant did not go on to receive the treatment arm she had been randomised to?

A. *You will need to complete the Baseline & Birth CRF at Q2.3 series 1 and tick to confirm that intervention was not given and tick other documenting clearly why the treatment arm was not given.*

Q. Why are randomisation emails delayed or not received?

A. *This could be because you have not completely finished the call. You need to wait until you receive the response 'you may now end the call' and press the number to represent yes to end.*

Baseline & Birth CRF

Q. What do I do if there is a difference in the Bishops Score when transferring data onto the electronic CRF?

A. *This is a known problem. You should be aware that so long as the working out is the same the numbers may differ. The Clinical Trials Unit are in the process of compiling a file note to address this issue. A copy of the signed file note will be send out and you will just need to add a copy to your site file.*

Q. What happens when the hardcopy CRF information does not match against the database?

A. *This will come back to you as a data query in due course.*

Q. Baseline Birth Form (1.2 Indications for Induction). How do I add reduced fetal movement or fetus related issues under this section?

A. *Add details under 'other maternal disease'*

Maternal Satisfaction Questionnaires

Q. How do I encourage patients to complete the maternal satisfaction questionnaire prior to discharge?

A. *If possible try to encourage part completion during the induction process. Gently encourage partners to remind the participants to complete the questionnaire prior to discharge.*

Q. What can I do if I know I am not going to be around to collected the completed questionnaire prior to discharge?

A. *Utilise the Ward Clerks/Midwives on the delivery/postnatal wards by adding a SOLVE alert sheet to the front of the hospital notes around the time of discharge to remind them to ask the participant for the completed questionnaire. Arrange to leave a SOLVE collection box on reception so the Ward Clerks/Midwives can deposit them in the box and call the Research Midwife to collect the questionnaires.*

Treatment

Q. If an electronic prescribing system is used are study stickers still required?

A. *As long as all the information required on the study stickers can be accessed in the electronic records then this would be acceptable although a point to note would be if Dilapan is not recorded on the electronic system you would no longer have a signature record of the authorised prescriber. To overcome this issue you are advised to continue using the drug chart and stick the label on the back of the consent form and make sure the document is scanned in double sided and added to the electronic notes*