



# Giant PANDA

## Frequently Asked Questions

### **SECTION 1:**

#### ***Eligibility, screening, consent***

**Can women move from the trial to the observation study? For example women who are randomised but do not take their randomised medication.**

No, women who are randomised do not need to move from the randomised trial into the observational study if they do not take their randomised medication – this is all part of trial follow-up. If the woman does not start or if she stops taking the medication that has been prescribed following randomisation, this will be recorded on the database. The two-week survey is really important for women to complete, as it captures both their experience of the medication and their adherence.

Women can move (up until 34+6 weeks) from the observational study to the trial and be randomised.

**Do you accept paper consent forms? How do we update these to REDCap?**

Giant PANDA is a paperless study. The Giant PANDA e-consent forms are on the REDCap database. If there are problems with the consent process, please contact the trial team for support.

**When does recruitment to Giant PANDA finish/close?**

Once we reach our target of 2,300 women randomised.

### **SECTION 2:**

#### ***Medication/Prescriptions***

**Does the prescribing doctor need to be on the delegation log and/or take consent for the study?**

No, this is not necessary. Both Labetalol and Nifedipine are routinely prescribed in clinical practice and have been for many years. The prescribing doctor will need to:

- confirm that the woman can be safely prescribed either medication (confirm eligibility for the trial)

And then follow usual clinical practice as follows:

-write a prescription using the usual hospital process

-decide the starting dose

-document the medication in the woman's maternity notes

Members of the research team who are included on the Giant PANDA delegation log will take consent for the Giant PANDA trial or observational study. The person taking consent must discuss the points above with the prescribing doctor and enter their name and GMC number on the database. All GMC numbers can be found on this website: <https://www.gmc-uk.org/>

**Can a participating woman's antihypertensive medication be stopped, switched or additional antihypertensive added? And can she continue to take part in the study?**

Yes, this is a pragmatic study and like usual clinical care, antihypertensive medication can be stopped, switched, added to at any point in her pregnancy without discontinuing from the study. All changes will be captured on the REDCap database.

**Do we need to involve clinical trials pharmacy?**

No, local clinical pathways should be followed for prescribing antihypertensive medication, i.e. through the usual hospital pharmacy and/ or through GP prescribing, just as would usually happen in clinical care.

**Can a woman with diabetes or gestational diabetes take part in Giant PANDA?**

Yes. Currently, there is not enough evidence to suggest that women with diabetes should take one particular medication or another, so the research question is relevant to them.

**Can women from any ethnic background take part in the study?**

Yes, women from any ethnic background can take part. There is not enough evidence to support prescribing medication based on ethnicity in pregnancy (as noted in the NICE guidelines). The giant PANDA study will help us answer this question.

**Can women who are already on antihypertensive medication be offered participation in Giant PANDA?**

YES! If the woman is currently on a single medication and meets all the eligibility criteria and not any of the exclusion criteria, then she is eligible to participate. If the woman is on dual therapy, and **can** be safely switched to a single agent then she is also eligible for the trial.

It's only if the woman is on dual therapy can cannot be safely switched to a single agent (for example if she is on high doses of two agents), then she can be offered participation in the observational arm of the study. *Please see the newly developed study document - [Tips for recruiting with already on antihypertensive medication v1.0](#)*

**Do we need to write to a participating woman's GP?**

Follow local clinical pathways about communicating with their GP about antihypertensive medication changes or requesting repeat prescriptions. The GP can stop, switch, or add to a woman's antihypertensive medication at any point without her discontinuing from the study.

*Please see the newly developed study document - [Advice to healthcare professionals v1.0](#)*

**SECTION 3:**

**[Schedule of care](#)**

**Are there changes to the antenatal care for a woman participating in the giant PANDA trial?**

No, routine antenatal care for pregnant women with hypertension (NICE 2019

guidelines) should be followed.

### **Is there any postnatal follow-up?**

No. Outcomes are collected up until primary discharge or up to 28 days if mother or baby is still an inpatient (whichever is soonest)

## **SECTION 4:**

### ***Database queries***

#### **How do I get a REDCap login?**

Please send your CV and GPC certificate, along with an updated Delegation Log to Abbie Evans – [a.evans.10@bham.ac.uk](mailto:a.evans.10@bham.ac.uk)

#### **Where are data queries located in the database?**

Please navigate to the “Resolve Issues” section on the left hand navigation bar. This is where any, and all, outstanding queries are located.

#### **What do I do to resolve a data query?**

Please read and follow the instructions for each query individually. Please write your response within the query bubble outlining what you have done to rectify the query. Then select “Reply with response” and click “Response to query”. This query will then return to the trials team for review. Please **do not** close the query yourself as the trials team will need to review it first.

#### **When will I know if my site has outstanding data queries?**

We ask that sites regularly check their “Resolve Issues” section within REDCap. However, our Senior Data Manager will always email sites directly when new queries have been raised.

#### **I cannot answer a data query, what should I do?**

If you are struggling to answer any of the queries, please email our Senior Data Manager (Abbie Evans) and she can help guide you as to what to do next.

### ***Common query dilemmas***

**Waiting on a participant’s maternity notes** – If you are waiting for a woman’s maternity notes to answer a query, please do not respond to the query until you have the notes and are able to - this is fine.

**Data unobtainable** – If a query is asking for a piece of data that is not available, please respond to the query to say this is the case and the query will then be closed by the trials team. We also ask that you complete the Change in Study Status Form for any forms that will not be completed.

**The same query has appeared again** – If a query appears after you have answered it, please ensure the data was changed or inputted as requested. If a query has been sent back, it is most likely due to the trials team requiring further information/changes in order to resolve the data query.

## **SECTION 5:** *Study materials*

We have several study documents developed to support sites, these are listed below.

Please contact us ([Giant-PANDA@trials.bham.ac.uk](mailto:Giant-PANDA@trials.bham.ac.uk)) should you need a copy of any of the below:

### *Website*

<https://www.birmingham.ac.uk/research/bctu/trials/womens/giant-panda/index.aspx>

### *Documents*

- Quick reference sheet v1.1
- Study handbook v1.3 (new website link)
- Prompt card v1.2 (new website link)
- Memo for consultants + trainees v1.0
- Taking remote consent v1.0
- Tips for recruiting with already on antihypertensive medication v1.0
- Instructions for incomplete questionnaires v1.0
- Advice to healthcare professionals v1.0
- Poster PIS v0.8

### *Videos:*

- Giant PANDA study summary with Professor Lucy Chappell  
[https://youtu.be/5K7\\_Xaucj2w](https://youtu.be/5K7_Xaucj2w)
- A quick guide to the Giant PANDA study  
<https://www.youtube.com/watch?v=4lz80y4sWTY>
- Background and Rationale to giant PANDA with Professor Jenny Myers  
[https://youtu.be/z66lEwo\\_Ymc#](https://youtu.be/z66lEwo_Ymc#)
- Professor Lucy Chappell discusses approaching women to join the Giant PANDA study  
[https://youtu.be/O1\\_D4gBFtP0](https://youtu.be/O1_D4gBFtP0)
- Professor Jenny Myers approaching a woman to join the giant PANDA study  
<https://youtu.be/lx7ev5-EfHM>
- The Giant PANDA study database training RECORDED SESSION  
<https://youtu.be/vdeLJY7rXY0>