Guidance Sheet 4: Randomisation

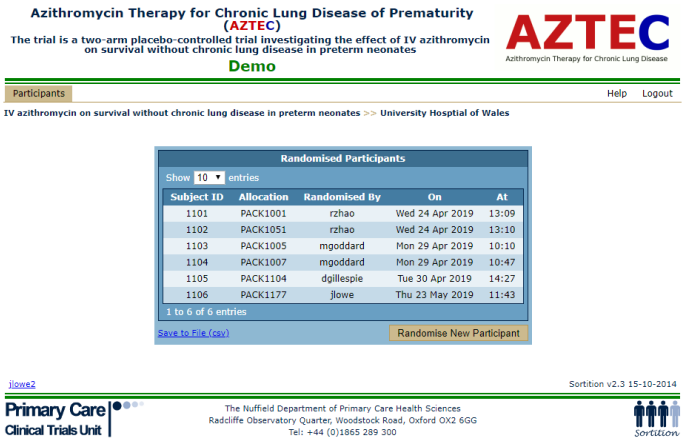
Randomisation must be carried out prior to administering the IMP

- Confirm that written informed consent from the parents has been taken by someone who has received suitable training and is named on the Delegation Log.
- Confirm the baby still meets all of the eligibility criteria and ensure a medically qualified person (who is delegated this duty on the Delegation Log) has documented clinical assessment of eligibility within the medical notes. The AZTEC eligibility sticker can used uses to support this (found in document box).

Steps to follow

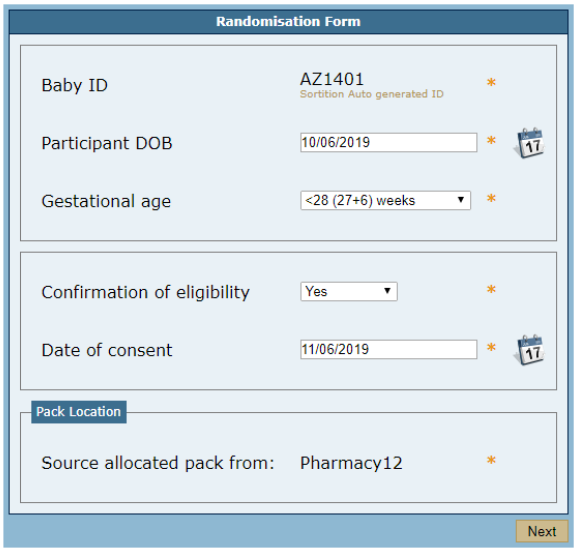
1. Access the study randomisation program (Sortition) at: https://ctu1.phc.ox.ac.uk/randomise/login
2. Log in using your individual credentials as assigned by the CTR team.

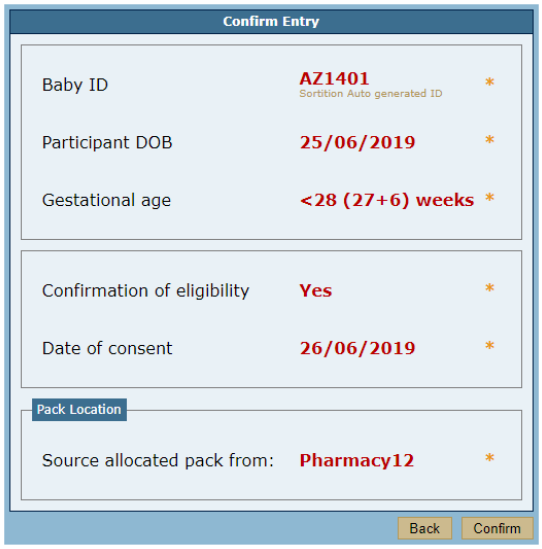
3. You will be taken directly to a randomisation page- note you should only be able to see a list of randomisations from your site



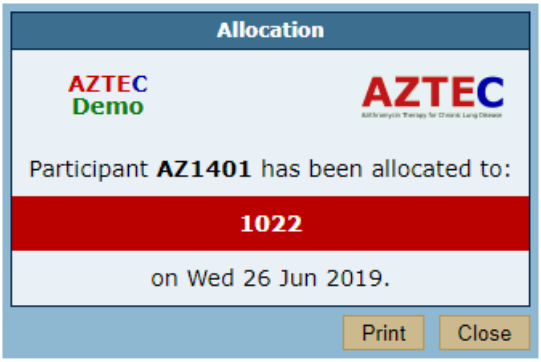
Guidance Sheet 4: Randomisation

4. Select 'Randomise new participant' from the menu and answer the inclusion/exclusion criteria to confirm eligibility. The baby is only recruited and randomised into the AZTEC trial when you confirm the data you entered is correct





5. The randomisation program will then confirm the baby's Study ID
   - Always starts with "AZ"
   - Then a 2-digit site identifier, which will always remain the same
   - Then a two-digit sequential number (i.e. "01" is first baby randomised)



6. The Baby is also allocated their IMP treatment **Pack ID**, a random 4-digit number

7. Before logging out print the randomisation details for the infant and place into the infant's clinical notes alongside the consent form. Allocations can be checked at any time by logging in to Sortition.

8. Check that the correct 'Pack ID' is available and unopened from the stock on the ward.

9. If the correct pack cannot be located, or the package is open, please report this to the trial manager urgently, LoweJ3@Cardiff.ac.uk, Tel 029 2068 7990

- Finally, please ensure the following:
    - Study ID recorded on the **Consent Form**
    - Study ID recorded on the **IMP pack label (outer box), and each vial label**
    - Pack ID recorded on the infant's drug chart or electronic prescribing system
    - **Screening Log** updated with the Study ID

- Put an **AZTEC Cot Card** on the infant's cot, and an **AZTEC Notes Sticker** (both documents located in the AZTEC document box) on the infant's clinical notes. Ensure that the neonatal team are aware that the infant is enrolled in AZTEC

Randomisation Backup

- If there are problems accessing the randomisation program during normal working hours (Monday-Friday 09:00-17:00), please contact the CTR data manager (029 2068 8105) or administrator (029 2068 7617) who are able to randomise on behalf of a site