

PRINCIPLE Emergency Randomisation WI Appendix B – Instruction for Statisticians Team

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This document describe the process to conduct an emergency randomisation. The numbers are generated using simple randomisation method (i.e. with no stratification or block sizes).

1. Check if the generated random number on the form (Appendix A) matches the next random number on “K:\ID\PRINCIPLE\STATS\3. Randomisation\Emergency Randomisation\ERand_log.xlsx”. Go back to the sender if any discrepancy.
2. Check the Emergency Randomisation Form if the participant is eligible to be randomised to all or two of the three arms.
3. Obtain randomisation result based on the grid below:

	Usual Care	Azithromycin	Doxycycline
Eligible to all arms	0.xxx to 0.xxx	0.xxx to 1.xxx	0.xxx to 0.xxx
Not eligible to			
Doxycycline	0.xxx to 0.xxx	0.xxx to 1.xxx	
Azithromycin	0.xxx to 0.xxx		0.xxx to 1.xxx

Example (1): if a participant who is eligible to be randomised to all arms and the random number obtained from the emergency randomisation envelope is 0.xxx, then the allocated treatment would be Usual Care.

Example (2): if a participant who has a medical contraindications to Azithromycin, and the random number obtained from the emergency randomisation envelope is 0.xxx, then the allocated treatment would be Doxycycline.

4. Complete Part B of the Emergency Randomisation Form and send to a senior statistician for review.
5. Senior statistician to review the process and the allocation results, and sign off Part B of Emergency Randomisation Form if all correct.
6. Complete the information to “K:\ID\PRINCIPLE\STATS\3. Randomisation\Emergency Randomisation\ERand_log.xlsx”.

7. Send the Emergency Randomisation Form to the email address indicated on the bottom of the form.
8. Store the completed Emergency Randomisation Form to “K:\ID\PRINCIPLE\STATS\3. Randomisation\Emergency Randomisation\ER Forms\” folder.