

ARTIC PC EMERGENCY UNBLINDING INSTRUCTIONS FOR RECRUITING SITES (SEE EMERGENCY UNBLINDING STANDARD OPERATING PROCEDURE, v1.0,07/09/2016)

Clinical indications/emergency unblinding circumstances:

- there is a medical emergency and unblinding will influence the patient's treatment;
- the patient has suffered an Unexpected Serious Adverse Event or Suspected Unexpected Serious Adverse Reaction and the intervention must be made known;
- clinical deterioration means knowledge of treatment is required;
- requests for emergency unblinding can only be made by a healthcare professional with clinical responsibility for the patient's care. In most instances these requests are handled by Professor Paul Little or Professor Theo Verheij in the first instance prior to the request being sent to the company providing the unblinding A2
- other than in exceptional circumstances, requests to unblind should not be accepted from patients and relatives, but referred instead to the patient's GP.

1. Professor Paul Little or Professor Theo Verheij should be the first point of contact for clinicians:-

- When it is clinically necessary for the unblinding of an ARTIC PC patient, the clinician **must firstly attempt to put the request directly to Professor Paul Little/Theo Verheij (or his designate)**;
- In a medical emergency, please access the unblinding service on 0031 88 75 67999. The unblinding service is provided by A2 Antwoordservice B.V.,
- Contact details are additionally found in the Trial Site File, on the Trial Participation Card carried by the patient and on the ARTIC PC study website:-

In normal working hours (Monday to Friday, 9:00am to 5:00pm), please call Professor Little/Verheij on 0778 6126108 and quote the PID and MID numbers from the patient's Trial Participation Card.

- The Trial Participation Card should be carried by all trial participants for the duration of their involvement in the trial;
- All ARTIC PC recruiting sites will receive training on using the trial unblinding service before recruitment starts;

2. Clinicians must attempt to contact the trial team in the first instance

- When the clinician contacts the trial team with an unblinding request before the team contacts the relevant company, Professor Little or the Study Manager will:
 - Record the clinician's name and relevant PID on the **ARTIC PC Unblinding Accountability Log**;
 - Ensure the clinician has the PID and Medication ID numbers;
 - Professor Little (or his designate) will liaise between the site and A2 advising them that the request has been made.