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| Study Title          | Principle      |
| EudraCT No           | 2020-001209-22 |
| Version Number, Date | 1.3 17.05.20   |

| Description of information needed                                                                                                                                  | Label Text                                                                                                                                                                                                                                                                                                |
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| <b>Name, address and telephone number of the sponsor</b><br>(the main contact for information on the product, clinical trial and emergency unblinding)             | University of Oxford<br>Joint Research Office<br>1st floor, Boundary Brook House<br>Churchill Drive,<br>Headington<br>Oxford<br>OX3 7GB<br>Tel: +44 (0)1865572224<br>Fax: +44 (0)1865572228                                                                                                               |
| <b>Pharmaceutical dosage form, route of administration, quantity of dosage units,</b> and in the case of open trials, the name/identifier and strength/potency;    | Azithromycin (250mg) capsules<br><br>The capsules are for oral administration.                                                                                                                                                                                                                            |
| <b>Batch and/or code number</b> to identify the contents and packaging operation;                                                                                  |                                                                                                                                                                                                                                                                                                           |
| <b>Trial reference code</b> allowing identification of the <u>trial, site, investigator and sponsor</u> if not given elsewhere;                                    | PRINCIPLE trial.<br>University of Oxford<br>Chief Investigator: Prof. Chris Butler                                                                                                                                                                                                                        |
| <b>Trial subject identification number</b> /treatment number and where relevant, the visit number;                                                                 |                                                                                                                                                                                                                                                                                                           |
| <b>Kit/Pack number</b>                                                                                                                                             |                                                                                                                                                                                                                                                                                                           |
| <b>Investigator</b> (if not included previously)                                                                                                                   |                                                                                                                                                                                                                                                                                                           |
| <b>Directions for use</b><br>(reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product) | Take two 250mg tablets (making 500mg in total) azithromycin once a day for 3 days by mouth (6 capsules in total)<br><br>Special instructions:<br>Azithromycin must be taken at least 1 hour before or 2 hours after antacids.<br>Azithromycin must be taken at least 1 hour before or 2 hours after food. |
| <b>“For clinical trial use only”</b> or similar wording;                                                                                                           | For clinical trial use only                                                                                                                                                                                                                                                                               |
| <b>Storage conditions</b>                                                                                                                                          | Store below 25°C                                                                                                                                                                                                                                                                                          |
| <b>Period of use</b><br>(use-by date, expiry date or re-test date as applicable), in month/year format and in a manner that avoids any ambiguity                   | 3 days<br><br>Expiry date: month/year<br><br>Shelf life is 36 months.                                                                                                                                                                                                                                     |
| <b>“keep out of reach of children”</b> except when the product is for use in trials                                                                                | Keep out of reach of children                                                                                                                                                                                                                                                                             |



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| where the product is not taken home by subjects |  |
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