

Study Title	Principle
EudraCT No	2020-001209-22
Version Number, Date	1.0, 07.11.20

Description of information needed	Label Text
Name, address and telephone number of the sponsor (the main contact for information on the product, clinical trial and emergency unblinding)	University of Oxford Joint Research Office 1st floor, Boundary Brook House Churchill Drive, Headington Oxford OX3 7GB Tel: +44 (0)1865572224 Fax: +44 (0)1865572228
Pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the name/identifier and strength/potency;	Budesonide (400mcg, Pulmicort turbohaler®) should take 2 puffs twice a day
Batch and/or code number to identify the contents and packaging operation;	
Trial reference code allowing identification of the <u>trial, site, investigator and sponsor</u> if not given elsewhere;	PRINCIPLE trial. University of Oxford Chief Investigator: Prof. Chris Butler
Trial subject identification number /treatment number and where relevant, the visit number;	
Kit/Pack number	
Investigator (if not included previously)	
Directions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product)	Take 2 puffs twice a day, for 14 days. Special instructions: To breathe in forcefully and deeply through the mouthpiece to ensure that an optimal dose is delivered to the lungs.
“For clinical trial use only” or similar wording;	For clinical trial use only
Storage conditions	Do not store above 30°C
Period of use (use-by date, expiry date or re-test date as applicable), in month/year format and in a manner that avoids any ambiguity	14 days Expiry date: month/year (MMM/YYYY) Shelf life: 24 months.
“keep out of reach of children” except when the product is for use in trials where the product is not taken home by subjects	Keep out of reach of children

