

## IMP/NIMP

### **Example 1**

Trial Design:	An open label study in healthy volunteers to investigate the effects of rifampicin on the PK of RB0305
Purpose of Trial:	To investigate the effect of rifampicin on the PK of RB0305, a new agent for the treatment of TB acting by a novel mechanism
Products Administered:	RB0305 as an oral suspension Rifampicin as tablets
Key Parameters:	PK of RB0305 and of rifampicin
Product Classification:	RB0305      IMP Rifampicin    IMP
Rationale:	Since both products are used in the same indication and may be co-administered, this is a PK study of the interaction of two medicinal products. The rifampicin is considered as an IMP, not a probe

### **Example 2**

Trial Design:	An open label study in healthy volunteers to investigate the effects of rifampicin on the PK of T1B0308
Purpose of Trial:	To investigate the effect of rifampicin on the PK of T1B0308, a new lipid lowering agent
Products Administered:	T1B0308 as capsules Rifampicin as tablets
Key Parameters:	PK of T1B0308 and its effects on the PK of rifampicin
Product Classification:	T1B0308      IMP Rifampicin    NIMP
Rationale:	Since the products are used in the different indications, this is a PK study to investigate the role of CYP 3A4 in the metabolism of T1B0308. The rifampicin is considered as a probe, not as an IMP

### **Example 3**

Trial Design:	An open label study in healthy volunteers to investigate the effects of alcohol on the PD/PK of TW0907
Purpose of Trial:	To investigate the effect on PD and PK of TW0907, a novel anxiolytic which undergoes hepatic metabolism. The choice of alcohol is for two reasons – firstly because of its known physiological/ pharmacological effects including CNS effects and, secondly, because of its possible use in a social setting
Products Administered:	TW0907 as an oral suspension Alcohol as a commercial alcoholic beverage
Key Parameters:	PK of TW0907, PD of TW0907
Product Classification:	TW0907      IMP Alcohol      NIMP
Rationale:	TW-0907 is the medicinal product under clinical investigation therefore it is an IMP. Alcoholic beverages are not medicinal products hence the alcohol is a NIMP.

### **Example 4**

Trial Design:	An open label study in healthy volunteers to investigate the determine the PK/receptor occupancy of S1F0493
Purpose of Trial:	To investigate the PK, including receptor occupancy, of S1F0493, a novel antidepressant TW0907, a novel antidepressant.
Products Administered:	S1F0493 as a capsule [11C] AB1234 as an intravenous injection
Key Parameters:	PK of S1F0493, receptor occupancy by S1F0493
Product Classification:	S1F0493              IMP [11C] AB1234      NIMP
Rationale:	S1F0493 is the medicinal product under clinical investigation therefore it is an IMP. [11C] AB1234 intravenous injection is the PET ligand to enable receptor occupancy to be determined. Since it is not being developed as a medicinal product or as a diagnostic agent, it is not an IMP

### **Example 5**

Trial Design:	A study in healthy volunteers to validate the hand immersion in cold water model of pain
Purpose of Trial:	To investigate the variability of the pain producing effect of hand immersion in cold water on an inert and intra-subject basis
Products Administered:	None
Key Parameters:	The reproducibility of pain production both within and between subjects
Product Classification:	No medicinal products are administered
Rationale:	Since no medicinal products are being administered, this is not a clinical trial within the scope of the Clinical Trials Directive

### **Example 6**

Trial Design:	Administration of capsaicin and morphine to healthy volunteers
Purpose of Trial:	A method validation study using capsaicin as a pharmacological agent to induce pain and morphine as a positive control
Products Administered:	Capsaicin as a solution for injection Morphine sulphate as a solution for injection Naloxone as a solution for injection
Key Parameters:	To determine the extent, reproducibility and reversibility of the pain produced, using morphine sulphate as a positive control
Product Classification:	Capsaicin                      NIMP Morphine sulphate        NIMP Naloxone                      NIMP
Rationale:	This is a study to validate the pain inducing effect of capsaicin using a known analgesic as a positive control. The capsaicin is being used to induce pain by pharmacological means and is not an IMP. Since the morphine sulphate is being used as a positive control within the method validation, it is not regarded as an IMP for the purposes of the study. The naloxone is used to prevent unwanted opioid effects and is not an IMP. Since no investigational medicinal products are being administered, this is not a clinical trial within the scope of the Clinical Trials Directive

### **Example 7**

Trial Design:	Administration of capsaicin, morphine and T2B0308 to healthy volunteers	
Purpose of Trial:	A study to investigate the effect of T2B0308, a novel analgesic, in the capsaicin pain model	
Products Administered:	T2B0308 as a capsule Capsaicin as a solution for injection	
Key Parameters:	To determine the efficacy of T2B0308 in reducing the pain induced by capsaicin	
Product Classification:	T2B0308 Capsaicin	IMP NIMP
Rationale:	Since T2B0308 is a novel analgesic agent, it is an investigational medicinal product.. The capsaicin is being used to induce pain by pharmacological means and is not an IMP.	