ANNEX I

SYNOPSIS

Name of Sponsor/Company:	Individual Study Table Referring to Part of the Dossier	*(For National Authority Use only)*
Name of Finished Product:	Volume:	
Name of Active Ingredient:	Page:	
Title of Study:		
Investigators:		
Study centre(s):		
Publication (reference)		
Studied period (years): (date of first enrolment) (date of last completed)	Phase of development:	
Objectives:		
Methodology:		
Number of patients (planned and analysed):		
Diagnosis and main criteria for inclusion:		
Test product product, dose and mode of administration, batch number:		
Duration of treatment:		

Reference therapy, dose and mode of administration, batch number		
Name of Sponsor/Company:	Individual Study Table Referring to Part of the Dossier	*(For National Authority Use only)*
Name of Finished Product:	Volume:	
Name of Active Ingredient:	Page:	
Criteria for evaluation: Efficacy Safety		
Statistical methods:		
Summary - Conclusions **Efficacy Results:** **Safety Results:** **Conclusion** Date of report		