Table 1: Content of the simplified IMPD

Types of previous assessment	Quality data	Non-clinical data	Clinical data
The investigational medicinal product is authorised or has a marketing authorisation in an ICH country and is used in the clinical trial:			
— within the conditions of the SmPC	SmPC		
— outside the conditions of the SmPC	SmPC	If appropriate	If appropriate
— after modification (for example blinding)	P+A	SmPC	SmPC
Another pharmaceutical form or strength of the investigational medicinal product is authorised or has a marketing authorisation in an ICH country and the investigational medicinal product is supplied by the marketing authorisation holder	SmPC+P+A	Yes	Yes
The investigational medicinal product is not authorised and has no marketing authorisation in an ICH country but the active substance is contained in an authorised medicinal product, and			
— is supplied by the same manufacturer	SmPC+P+A	Yes	Yes
— is supplied by another manufacturer	SmPC+S+P+A	Yes	Yes
The investigational medicinal product was subject to a previous clinical trial application and authorised in the Member State concerned and has not been modified, and			
— no new data are available since last amendment to the clinical trial application,	Reference to previous submission		
— new data are available since last amendment to the clinical trial application,	New data	New data	New data
— is used under different conditions	If appropriate	If appropriate	If appropriate

(S: Data relating to the active substance; P: Data relating to the investigational medicinal product; A: Additional information on Facilities and Equipment, Adventitious Agents Safety Evaluation, Novel Excipients, and Solvents for Reconstitution and Diluents)