SUBMISSION OF COMMENTS ON Draft list of fields contained in the 'EudraCT' clinical trials database to be included in the 'EudraPharm' database on medicinal products and made public , in accordance with Article 57(2) of Regulation (EC) No 726/2004
COMMENTS FROM (Schering-Plough, Lisette.vromans@spcorp.com and +31.(0)412.662755)
GENERAL COMMENTS
Our main concern regarding the availability of EudraPharm is that comparable information is already available via FDA/NIH. We would like to emphasize that the content information, especially regarding protocol and results sections, is the same on clinicaltrials.gov and in EudraPharm. EMEA should liaise with FDA/NIH to agree on how this is best achieved and maintained.

SPECIFIC COMMENTS concerning Protocol-related information		
Field number (e.g. D. 2.1.1.1)	**Comment and Rationale**	**Proposed change (if applicable)**
D	The information on the Investigational Medicinal Product is very detailed and very specialised (especially from section D.3.11 onward). As such, only experts in the field will be able to understand most of the terminology used. Furthermore, in an early stage of development some of the information may be part of the Intellectual Property. We wonder if publication of this information is really necessary in order to understand the essentials of the clinical trial.	

SPECIFIC COMMENTS clinical trial results information		
Topic name	**Comment and Rationale**	**Proposed change (if applicable)**
N Review by the Competent authority or Ethics Committee in the country(ies) concerned	We are concerned about the proposal to include a section on discussion and interpretation of study results. We believe that this is best avoided for the following reasons: Data from one single study can only be interpreted in the context of all other available data. An interpretation at a certain time-point on the basis of one study can therefore easily be overruled or contradicted by the results of the next study. If each single study will be accompanied by an interpretation, this potentially leads to a very confusing mixture of interpretations in the database on the same product. Furthermore, once a certain interpretation is published, it may start leading a life of its own, even after it may have been revised on the basis of new data.	