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 Roche, October 15th 2008
GENERAL COMMENTS
The term 'public' should be defined which would indicate the level and type of information that should be made available. For example the level of information that is relevant to a patient versus the level of information that is relevant to a physician, or competitor should vary.
The level of information that is being proposed to be made public is extremely detailed and has commercial and intellectual property implications and is considered as commercially sensitive.

SPECIFIC COMMENTS concerning Protocol-related information		
Field number (e.g. D. 2.1.1.1)	**Comment and Rationale**	**Proposed change (if applicable)**
Section D	Sections D3 to D6 are of no value to patients (lay individuals) In addition, this information would provide unnecessary information to competitors with an advantage if made publicly available at such an early stage of development	Remove most of these points and make the section simple and clear. It might be simpler to have a single frame for comparator (or placebo or active. If active which active?)
Section E	Sections E1, E5 and E7 are acceptable to be made public. All other E fields are irrelevant or are covered by information in	Delete sections E2, E3, E4 and E8, and simplify.

	other sections. The level of detail is not likely to be of interest for the target users. Only the basic datasets should be made available.	
Section F	Section F should be limited to the population to be recruited i.e. whether both genders are eligible to enter the trial and the age range. The level of details made available should be limited to basics data.	Simplify
Section N	Ethics committee opinion should be clarified. In a global multicentre trial, the number of ethics committees is likely to be large.	

SPECIFIC COMMENTS clinical trial results information		
Topic name	**Comment and Rationale**	**Proposed change (if applicable)**
Draft list of paediatric fields (F1, and the general requirements in the outcomes section)	It is inappropriate to mandate publication of subgroup analyses. These could be misinterpreted and should only be considered a hypothesis generating tool	
Ancillary analysis	Any other analysis performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory, should be stated to address multiplicity	
Discussion and	Currently results are reported with no discussion or	Interpretation and discussion of individual trial data should be

Interpretation of Results	interpretation – interpretation could give rise to different opinions and interpretations –	avoided