Dear Sir/Madam,
First of all, Solvay would like to express its appreciation for the opportunity to comment on the "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".

Solvay's main concern with regard to this list is, that it does not contain a time(line), nor a defined procedure for the collection, processing and publication of the various data elements, during the different stages of a clinical study from CTA submission to the submission of the final study summary. This may be of importance especially in early stages where for example the patent situation may not yet be fully clear.

The list of data fields as it is leaves still room for interpretation on the side of Health Authorities, medicinal product manufacturers and study sponsors. Clear guidance may be required in order to enhance data validity and integrity. Solvay acknowledges, however, the need for more transparency on clinical trial data and supports therefore this process, provided the appropriate procedures are put in place.

A communication from the EC on these timelines and procedures would be much appreciated. Clear guidance may also be required in order to enhance data validity and integrity as well as consistency with study descriptions that Solvay and others are registering already on sites like ClinicalTrials.gov.

As a technical suggestion we recommend to add the adaptive design under section E.8.1.
As a minor point we note that E.8.2.2 (use of placebo) appears to be redundant as it is almost identical to the information provided under D7.

Yours sincerely,
On behalf of
SOLVAY PHARMACEUTICALS
Gijsbert M. Slappendel
Solvay Biologicals (Solvay Biologicals is a daughter company of Solvay Pharmaceuticals)

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