# 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 German Association of Research-Based Pharmaceutical Companies (VFA)**

| GENERAL COMMENTS |
|---|
| NA |

| SPECIFIC COMMENTS concerning Protocol-related information | | |
|---|---|---|
| **Field number (e.g. D. 2.1.1.1)** | **Comment and Rationale** | **Proposed change (if applicable)** |
| A 3.1 | It is not understandable why a second title for the trial should be created. Is "easily understood language" meant to be the national language? | |
| Sections D, E.6, E.7, E.8, and F | The proposed data fields to be made public appear to be acceptable given that they largely require information for 'classification' purposes and remain consistent with international initiatives relating to clinical trial registries for Phase II-IV trials as stated in the European Commission Communication.<br>Any additional fields would have to be agreed separately. | Clarification is required as to whether any data fields are considered not mandatory. e.g. Section D.6.6 |
| Section E.7 | With reference to the commission communication information on Phase I trials will not be made public however; it is not clear whether there is an expectation that FIH (first-in-human) studies in patients (as opposed to healthy volunteers) should be disclosed. | Clarification is required that both Phase 1 FIH studies in patients and in health volunteers do not fall within the scope of the guidance. |
| Section F.3.1 | In addition, field F.3.1 asks about healthy volunteers which does not seem to be consistent with the statement that Phase I trials are not made public | Suggest the removal of data field F.3.1 |

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| Section N. | The information on a trial has only to be released to the public when both EC and CA decision are positive. | Information should only be released to public when both CA authorisation and a positive opinion of the EC is given.<br>Ethics committee opinion (*positive*) |
| Section N. | It is not clear who will provide these data (e.g. recruitment status, date of the global end of the trial) | |

| **SPECIFIC COMMENTS concerning Clinical trial results information** | | |
|---|---|---|
| **Topic name** | **Comment and Rationale** | **Proposed change (if applicable)** |
| Trial Interruption | The sponsor is required to confirm whether the trial was interrupted and provide reasons for the interruption. There are many legitimate reasons why a trial may be interrupted, this is not considered valuable information to patients, their carers and healthcare professionals particularly when the reasons for trial interruption are remedied | Suggest section is removed. |
| Discussion and interpretation of study results | An electronic forum is not conducive to discussion and interpretation of study results. Discussion and interpretation of study results is best handled in a regulatory review setting involving the technical expertise of the regulatory authority, investigators and sponsor. This electronic forum does not lend itself to open discussions, clarifying questions, alternative interpretations and the like that is needed to properly interpret the data and draw appropriate conclusions. The public as a whole is not equipped to fully understand and judge the discussion that could ensue, which can lead to misunderstanding and confusion. | Clarification is required regarding interpretation of trial results provided by a) the sponsor and b) the competent authority. For example sponsor interpretations should reflect the conclusions made in the synopsis of the clinical study report, in a manner consistent with other registries. Competent authority interpretation of trial results should be provided following a formal scientific assessment of a MAA or post authorisation variation/follow up measure when all concerned competent authorities/ CHMP and the sponsor have had opportunity to comment and final assessment reports are available. |
| Discussion and interpretation of results | Sponsor should have the possibility to review the data (interpretation of CA) before release. | If applicable a link EPAR or relevant clinical trial results database in the internet should be possible to have consistent information. |