



COMMENTS ON
**"CONSULTATION FOR DATA FIELDS FROM
EUDRACT TO BE MADE PUBLIC"**

**EUROPEAN CANCER PATIENT COALITION
14 October 2008**

The European Cancer Patient Coalition (ECPC) would like to respond to the public consultation on the data fields of the clinical trials database, EudraCT, to be included in 'EudraPharm' the European database on medicinal products for the public.

Clinical trials are helping patients fight against cancer and are one of the key steps in the long process of developing treatment and cures for cancer. Patients and society derive strong benefits from increased transparency of clinical trials and accessibility to information about available therapies. ECPC very much welcomes the European Commission's Guidelines on the data fields from EudraCT to be included in EuroPharm.

For the last four years, ECPC has been deeply involved in campaigning to make information on clinical trials publicly available. In May 2006, WHO unveiled the rules under which pharmaceutical companies and others conducting clinical research must **disclose 20 sets of data when they register clinical trials** before commencement of the study. This decision on disclosure rules came after two years of WHO consultations with representatives from the pharmaceutical, biotechnology and medical device industries, patient and consumer groups, governments, medical journal editors, ethics committees and academia.

ECPC strongly urges the Commission to follow all the WHO Guidelines requiring 20 key data sets to be published.

We have compared the proposed data fields of EudraCT to be made public in EudraPharm with those required by the WHO and would like to offer the following more detailed suggestions:

Early phase trials / Phase I trials

ECPC wishes that the EU Guidelines follow the WHO policy and include also Phase I trials. We see no reason why the EU should exclude Phase I trials from publication in EudraPharm.

According to the section 3 (Scope) of the EU Guidelines,

"...Information to be made available needs to be meaningful for the public, also by following agreed standards at international level. Moreover, phase I trials, certain details of the characterisation of the investigational medicinal products, certain details of the clinical trial design, information on batch release aspects, legal status of the sponsor, clinical trial sites and any personal related information are excluded from publication."

ECPC Office: Am Rothenanger 1b, 85521 Riemerling, Germany
Telephone: +49 89 62836807, Fax: +49 89 62836808, E-mail: info@ecpc-online.org
ECPC is registered in Utrecht (The Netherlands), Reg.-Nr. 30211815

ECPC Board: E. Adarska • L. Andreescu • S. Craine • S. Ene • J. Fox • L. Faulds Wood • J. Geißler • T. Hudson • H. Preuß

In line with WHO's findings, ECPC cannot see any reason why early exploratory trials (Phase I trials) should be excluded from EudraCT. During the two years of WHO's consultations, no robust concerns or examples of evidence were brought forward by the industry that disclosure of Phase I trials would bring competitive disadvantage, threaten innovation or stifle competition. **WHO's policy requires "that all interventional clinical trials be registered with a minimum data set of 20 items without any delay"¹. This includes Phase I trials.**

Trial sites

ECPC wishes that more precise information about the sites where trials take place is disclosed in the public database (Guideline section 3). It is of great benefit to cancer patients and patient advocates to find out which clinic/institution is conducting a certain clinical trial. In large metropolitan areas with a higher number of hospitals, it is often not sufficient just to know the city where a certain trial is being conducted, but patients and doctors need to be able to find out more easily at which institution they are conducted.

For example, in the US multi-centre trials on clinicaltrials.gov often list the US institution (and sometimes even the investigator's department) where the trial is being conducted, but for Europe, the same trial only lists the city (e.g. "Munich, Germany")². In metropolitan areas like Munich and London, there may be more than a dozen institutions conducting cancer trials of a certain type.

ECPC therefore thinks it is an unacceptable waste and loss of everyone's time – patients, their doctors or other patient advocates – to have to hunt for the information about the exact location of a trial. This may cost lives as such trials are often the only hope cancer patients have to survive.

We would like to suggest that in addition to a "contact point designated by the sponsor for further information on the trial" (as required in the draft list of fields, B.5) a research contact person / the investigator should be included.

In conclusion, ECPC recommends that details on the trial sites should be mandated in the Guidelines for EudraPharm along WHO policy lines³.

Ethics Review

We recommend that information about the review of research ethics is also included in EudraPharm along WHO data sets⁴ that require that such information is published.

Status of trial

ECPC recommends that the Commission's Guidelines also include the reasons for terminating a trial as this is of high relevance to the public (e.g. insufficient recruitment within a defined timeframe; withdrawal because of safety concerns; or trial completed as planned).

The Commission's current draft data set lists as options for the "recruitment status of the trial" the following:

"not commenced, active, ended. This status will be listed for each Member State with the relevant dates."

¹ WHO Bulletin, 16 June 2006 - <http://www.who.int/bulletin/volumes/84/6/news10606/en/index.html>

² Example: http://www.clinicaltrials.gov/ct2/show/NCT00519090?term=nilotinib&rank=22&show_locs=Y#locn

³ WHO's minimal registration data set, which requires publication of "responsible contact person" (WHO data set #7) and "research contact person" (WHO data set #8).

⁴ "Research ethics review", WHO data set #11

ECPC suggests that the Commission Guidelines use the same criteria as clinicaltrials.gov.

These are:

- **Not yet recruiting** (This study is not yet open for participant recruitment)
- **Recruiting** (This study is currently recruiting participants)
- **Active, not recruiting** (This study is ongoing, but not any longer recruiting participants)
- **Completed** (This study has been completed)
- **Available** (Expanded access is currently available for this treatment)
- **Withdrawn** (This study has been withdrawn prior to recruitment)
- **Terminated** (This study has been terminated, with reason given, e.g. due to insufficient enrolment)

Moreover, to adapt to the present drive for disclosure, ECPC would wish to see another category clearly formulated and added to increase transparency:

- **Results published** (The results of this study have been released to the public)

This would be in line with the current draft list of fields, section N ("Anticipated date of the availability of results, no more than end of trial date plus twelve months").

Appendix 1: "WHO minimal registration data set"

1. Unique trial number
2. Trial registration date.
3. Secondary IDs
4. Funding source(s) Name
5. Primary sponsor
6. Secondary sponsor(s)
7. Responsible contact person
8. Research contact person
9. Title of the study
10. Official scientific title of the study
11. Research ethics review
12. Condition
13. Intervention(s) The duration of the intervention(s) must be specified.
14. Key inclusion and exclusion criteria
15. Study type
16. Anticipated trial start date
17. Target sample size
18. Recruitment status
19. Primary outcome
20. Key secondary outcomes of measurement

Appendix 2: Suggested EudraPharm Information:

- EudraCT number for the clinical trial,
- sponsor's designation and protocol code number, (like WHO #5, #6)
- full title of the trial, (like WHO #9, #10)
- the International Randomised Standard Clinical Trial Number (IRISCTN) where available in EudraCT (like WHO #1) ,
- other international identifier(s) to be defined (like WHO #3) ,
- contact point(s) for further information (like WHO #7).
- name of the medicinal product ,
- active substance(s) (like WHO #13),

ECPC Office: Am Rothenanger 1b, 85521 Riemerling, Germany
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- route of administration (like WHO #13),
- therapeutic classification code,
- appropriate international identifiers.
- indication under study in the clinical trial and of orphan designation (like WHO #13):
- major objective (like WHO #19, 20),
- principal inclusion and exclusion criteria of the clinical trial (like WHO #14),
- phase of the clinical trial (like WHO #15),
- design (e.g. randomised, controlled) (like WHO #15),
- comparators (medicines/other treatments) if this is part of the clinical trial (like WHO #13),
- number of patients anticipated in the clinical trial (like WHO #17),
- age range(s) (like WHO #14),
- gender (like WHO #14).

ECPC Contact details



European Cancer Patient Coalition

Contact person:

Jan Geissler

ECPC Vice President

jan.geissler@ecpc-online.org

Hildrun Sundseth

Head of EU Policy

hildrun.sundseth@ecpc-online.org

ECPC Office: Am Rothenanger 1b, 85521 Riemerling, Germany
 Telephone: +49 89 62836807, Fax: +49 89 62836808, E-mail: info@ecpc-online.org
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