EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Main principles for commercially confidential information (CCI) in the Clinical Trial Information System (CTIS)

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The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

Recital 67 of the CTR provides, amongst others:

" … The information in the EU database should be public, unless specific reasons require that a piece of information should not be published, in order to protect the right of the individual to private life and the right to the protection of personal data, recognised by Articles 7 and 8 of the Charter. Publicly available information contained in the EU database should contribute to protecting public health and fostering the innovation capacity of European medical research, while recognising the legitimate economic interests of sponsors."

Article 81(4) of the CTR provides:

"The EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the following grounds:

(a) protecting personal data in accordance with Regulation (EC) No 45/2001;

(b) protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product, unless there is an overriding public interest in disclosure;

(c) protecting confidential communication between Member States in relation to the preparation of the assessment report;

(d) ensuring effective supervision of the conduct of a clinical trial by Member States".

CTR and CCI

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- For the purpose of the guidance, CCI is defined as:

> *"any information contained in the clinical trial information submitted to the CTIS which is not in the public domain, or publicly available, and where disclosure may undermine the legitimate economic interest of the owner of the information"*

- Working definition based on "HMA/EMA recommendations on transparency approved in November 2010 - Recommendations on release of information with regard to new applications for medicinal products before and after opinion or decision on granting of a marketing authorisation (EMA/484118/2010)".

Information that may be considered CCI

General considerations

- Clinical and non-clinical information is not generally considered CCI.
- In specific circumstances, administrative, clinical and non-clinical documents may contain CCI.
- As the development plans advance, information which was initially considered confidential may cease to be confidential.

Information that may be considered CCI

- Names of manufacturers or suppliers of the active substance /excipients
- The quantitative composition of excipients of the investigational/authorised product
- Detailed information on the synthesis or manufacture of the active substance
- Detailed descriptions of the manufacturing and control processes
- Information related to future development plans
- New biomarkers or novel methodologies
- Detailed information concerning innovative analytical methods
- Detailed information on the facilities and equipment (sponsors and clinical sites)

Which information should NOT be considered CCI

- Information that is available in the public domain
- Information that does not bear any innovative features
- Examples of information that would not qualify as commercial commercially confidential include:
  - General or administrative information: CROs and vendors
  - Quality-related information: excipient
  - Non-Clinical information: well-known immunohistochemistry methods (e.g. ELISA/LC-MS)

Any questions?

Further information

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