CORE Reference: Clarity and Openness in Reporting: E3-based

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Clarity and Openness in Reporting: E3-based
EMA Clinical Data Publication Policy

October, 2014
- EMA policy on publication of clinical data for medicinal products for human use (POLICY/0070)
- Q&A on the EMA policy on publication of clinical data for medicinal products for human use

January, 2015
- Coming into force

March, 2016
- External guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use
Область применения

- Initial marketing-authorisation applications
- Extension of indication
- Line extension

EMA will publish the reports **60 days after a decision on the application** has been taken. The publication of the first reports is foreseen for **mid-September 2016**.

**Clinical study report:**

- **Scientific review version**
  (full CSR text + all CSR appendices)
- **Redacted clinical report**
  (redacted CSR text + selected appendices)

Источник: EMA website
Example Title Page

CLINICAL STUDY REPORT
FULL VERSION FOR REGULATORY SUBMISSION/
REDACTED VERSION FOR PUBLIC DISCLOSURE

STUDY TITLE

Test Product: Drug name

(If not apparent from title, include brief description of development phase, indication studied, study design and type, duration, dose, and subject population.)

Sponsor’s Responsible Medical Officer name and qualifications
Sponsor name
Sponsor address

Comment [A20]: Can be prefixed with ‘abbreviated’ if the CSR is abbreviated.

Comment [A21]: Delete as applicable to the document version.

Note that CORE Reference makes content suggestions for the ‘primary use CSR’. Comments within CORE Reference indicate individual CSR text portions that may potentially impact the ‘secondary use CSR’, which will be publicly disclosed, and should therefore be considered for modification or redaction in the ‘secondary use CSR’.

Comment [A22]: Consider for PPD and CCI impact. Individual name and qualification will not be redacted in the ‘secondary use CSR’ for public disclosure. The address may be redacted if it is not an address of the Sponsor.
2. SYNOPSIS

A brief stand-alone synopsis without cross-reference to other sections of the CSR or other documents (usually limited to three pages, although longer is acceptable for more complex studies) that summarises the study should be provided. In addition to a brief description of the study design and critical methodological information (what was actually done), the synopsis should provide a summary of all relevant results (e.g. if there are multiple endpoints, consider limiting to primary and secondary) obtained during the study, as well as other critical information, including data on the study population, disposition of subjects, important protocol deviations and treatment compliance. The synopsis should include numerical data to illustrate results, not just text or p-values (consider presenting results as summary tables to reduce the amount of text in the synopsis). The conclusions should exactly match the overall conclusions in the body of the report. The use of a tabular format synopsis is not mandatory.

An example Synopsis follows.
CORE Reference

- Website: www.core-reference.org

- Review process:
  - Health Canada team
  - DIA Medical Writing Community
  - Academic and Principal investigator
  - Patient Advocate

- Publications:


Session Photograph 1
Session Photograph 2