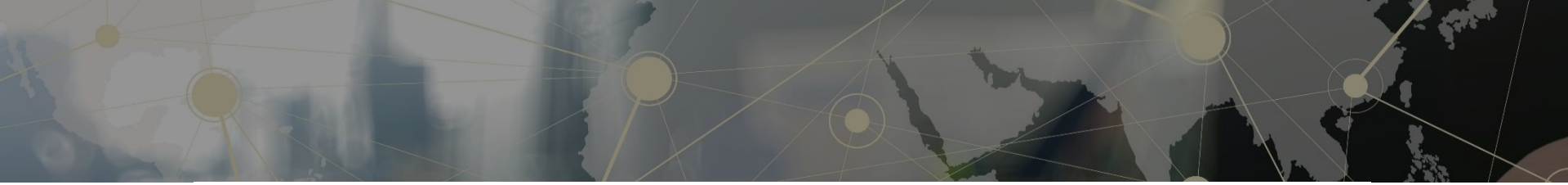
КЛИНИЧЕСКИЕ ИССЛЕДОВАНИЯ
В РОССИИ И ЗА РУБЕЖОМ

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

Евгения Радькова



CORE REFERENCE

EMWA EUROPEAN MEDICAL WRITERS ASSOCIATION

AMWA AMERICAN MEDICAL WRITERS ASSOCIATION
The Resource for Medical Communicators

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**

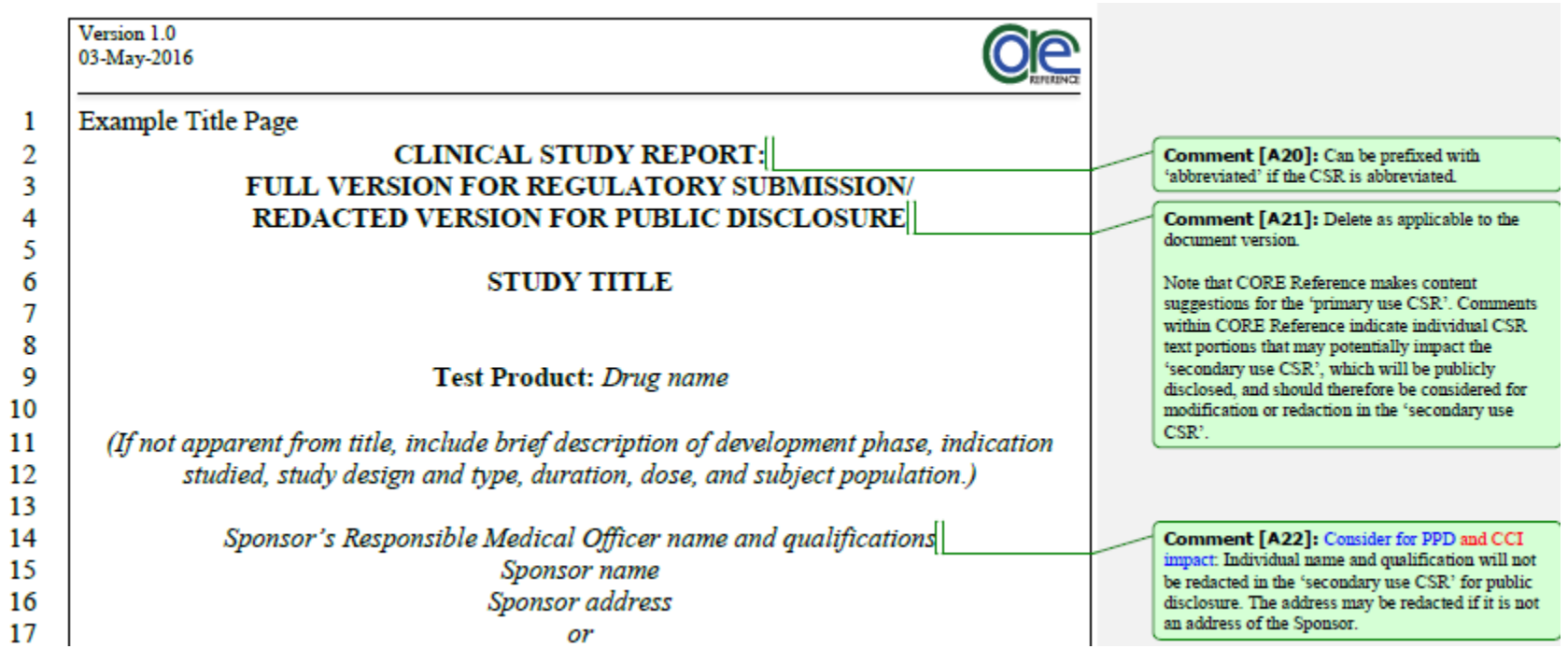
- EMA will publish the reports **60 days after a decision on the application** has been taken. The publication of the first reports is foreseen for **mid-September 2016.**

Clinical study report:

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

Источник: EMA website

CORE Reference



Version 1.0
03-May-2016

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
or

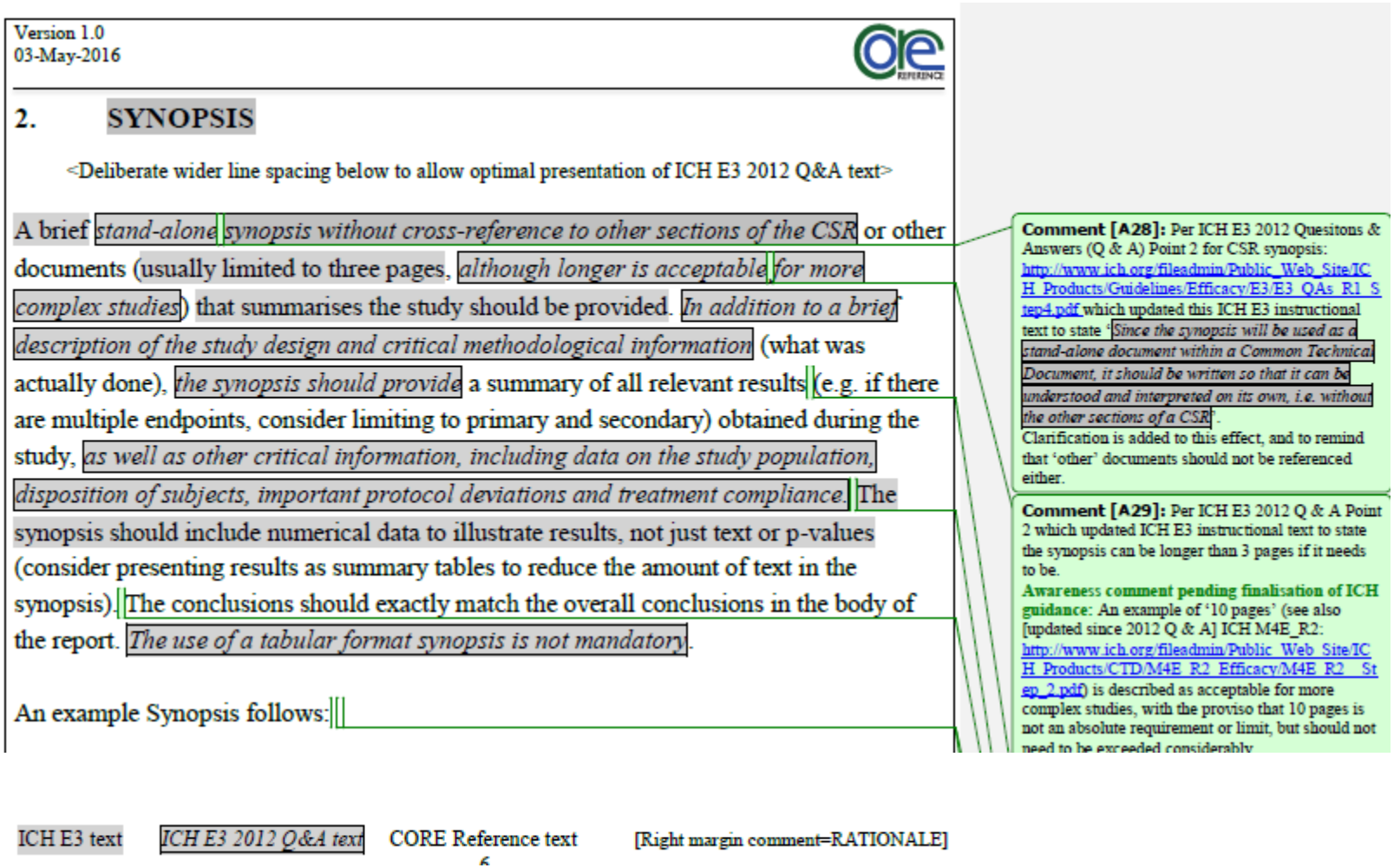
Comment [A20]: Can be prefixed with 'abbreviated' if the CSR is abbreviated.

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.

CORE Reference



Version 1.0
03-May-2016

2. SYNOPSIS

<Deliberate wider line spacing below to allow optimal presentation of ICH E3 2012 Q&A text>

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:

Comment [A28]: Per ICH E3 2012 Quesitons & Answers (Q & A) Point 2 for CSR synopsis: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/E3_QAs_R1_Step4.pdf which updated this ICH E3 instructional text to state '*Since the synopsis will be used as a stand-alone document within a Common Technical Document, it should be written so that it can be understood and interpreted on its own, i.e. without the other sections of a CSR*'.
Clarification is added to this effect, and to remind that 'other' documents should not be referenced either.

Comment [A29]: Per ICH E3 2012 Q & A Point 2 which updated ICH E3 instructional text to state the synopsis can be longer than 3 pages if it needs to be.
Awareness comment pending finalisation of ICH guidance: An example of '10 pages' (see also [updated since 2012 Q & A] ICH M4E_R2: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/CTD/M4E_R2_Efficacy/M4E_R2__Step_2.pdf) is described as acceptable for more complex studies, with the proviso that 10 pages is not an absolute requirement or limit, but should not need to be exceeded considerably

ICH E3 text | *ICH E3 2012 Q&A text* | CORE Reference text | [Right margin comment=RATIONALE]

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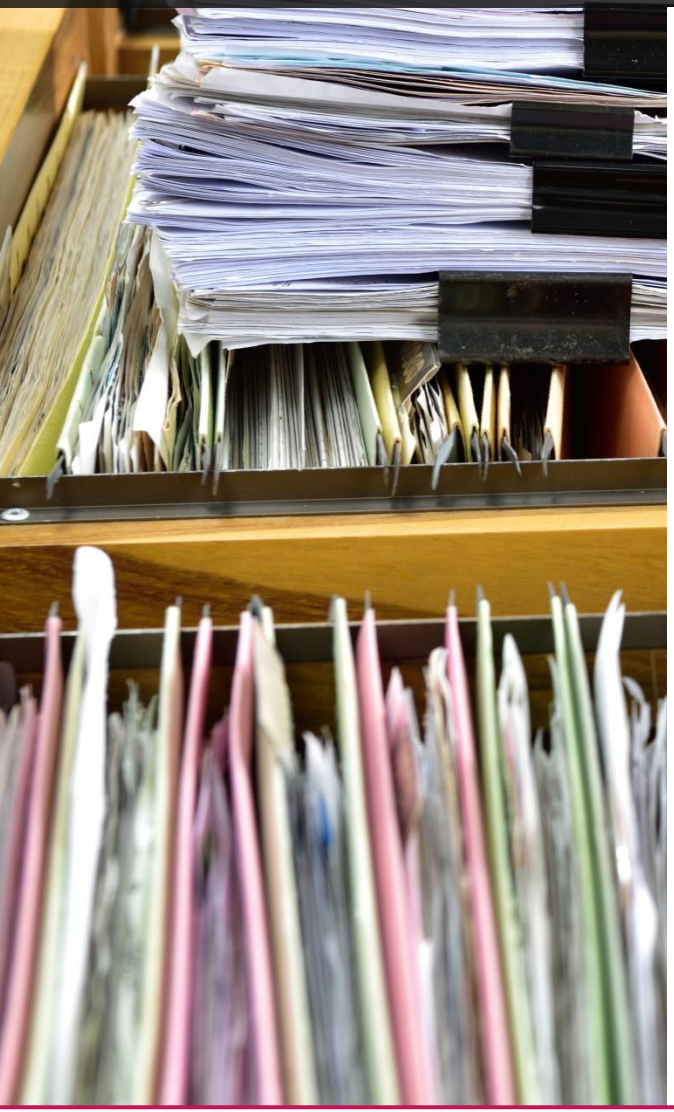
CORE Reference



- **Website: www.core-reference.org**
- **Review process**:
  - Health Canada team
  - DIA Medical Writing Community
  - Academic and Principal investigator
  - Patient Advocate
- **Publications**:

The EMWA Budapest Working Group: A 2-year collaboration to make recommendations for aligning the ICH E3 guidance with current practice and developing clinical study protocol guidance. Hamilton, S, Seiler W, Gertel A. Medical Writing 2014.

Hamilton S, Bernstein AB, Blakey G, Fagan V, Farrow T, Jordan D, Seiler W, Shannon A, Gertel A, ***Budapest Working Group: Developing the Clarity and Openness in Reporting: E3-based (CORE) Reference user manual for creation of clinical study reports in the era of clinical trials transparency.*** Research Integrity and Peer Review. 2016.

Session Photograph 1

Session Photograph 2