

## REFLECTION PAPER - EFPIA Guiding Principles on Layperson Summary

### EU Clinical Trials Regulation 536/2014 – Annex V

EFPIA has welcomed the publication of the EU Clinical Trials Regulation 536/2014<sup>1</sup>. We fully support the provisions in the Regulation that allow EU citizens to have access to information about clinical trials as per Article 81(2). We consider that a significant benefit of the Regulation will be to enable patients and healthcare professionals to more quickly identify clinical trials and evaluate their relevance to an individual patient's condition. Access to information and enrolment in clinical trials should be key considerations, together with establishing the right balance between openness and the protection of personal and commercially confidential information (CCI).

Consistent with the EFPIA-PhRMA principles for responsible sharing of clinical trial data<sup>2</sup>, and our commitment to increasing patient centricity in drug development, EFPIA and its member companies are committed to enhancing public health through the responsible sharing of interventional clinical trial data in a manner that is consistent with the following principles:

- Safeguarding the privacy of patients
- Respecting the integrity of national regulatory systems
- Maintaining incentives for investment in biomedical research

Building upon the foundation of these imperatives, the research-based industry is committed to working with regulators, in order to adopt mechanisms for providing a summary of clinical trial results and make it available to research participants and public.

This Reflection Paper aims to provide high-level principles to help sponsors draft the summary of a clinical trial in lay language, in compliance with Annex V of the Regulation, "Content of the Summary of the Results of the Clinical Trial for Laypersons", which lists 10 requirements. The EFPIA key principles should guide sponsors to create a lay summary, taking into account patients' needs, by providing them with factual, meaningful and easy-to-understand content.

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<sup>1</sup> [REGULATION \(EU\) No 536/2014](#)

<sup>2</sup> [EFPIA-PHRMA Principles for Responsible Data Sharing](#)

Regardless of the format used for the layperson summary, a single summary per trial should be acceptable globally (in any country or region), regardless where the trial has been conducted.

Research sponsors are invited to consider the perspectives from patient organizations, academic groups and others with a vested interest in the layperson summary, including discussion about health literacy, and use the wealth of information listed in the reference section, as they deem appropriate.

### **What is the purpose of the layperson's summary of interventional clinical trial results?**

- To inform and educate research participants about the trial in which they participated;
- To honour the patient's voluntary contribution and recognise patients as partners in research;
- To enable patients, healthcare professionals and the public to identify clinical trials more quickly and evaluate their relevance to an individual patient's condition;
- To address patients, their families and the public's interest via the transparent dissemination of trial results;
- To comply with the EU Clinical Trial Regulation 536/2014 and its provisions allowing EU citizens to have access to information about clinical trials, as per Article 81(2) and Annex V of the Regulation.

### **What are the basic principles of the layperson's summary of interventional clinical trial results?**

The summary of clinical trial information communicated should:

- Respect patient privacy and confidentiality, and be delivered by employing methods that respect privacy concerns;
- Describe the factual summary of a specific single Phase I-IV clinical trial involving the use of an investigational medicinal product in research participants;
- Use language that is understandable to a layperson – i.e. adjusting it to from a six to eight grade reading comprehension level and utilising health literacy principles – and minimise the use of jargon, technical terms and acronyms. If complex terms are unavoidable, then provide easy-to-understand explanations;

- Provide a basic description of relevant findings from the trial, which should include, at a minimum, findings from the primary endpoint(s);
- Include references and links to further information.

**A. The information communicated should:**

- Include brief and factual statements describing the study objectives, design, conduct and study conclusion;
- Avoid interpretation or speculation as to the general meaning of results or the overall safety or efficacy of the medicinal product;
- Explain that the results presented reflect the results of only a single clinical trial;
- Offer notification that the information presented was accurate at the time of the review of study results by the sponsor and that the information may not reflect other research or approved prescribing information.

**B. Content of the layperson's summary of the results of the interventional clinical trial**

The summary of the results of clinical trials communicated to laypersons shall include the following information as identified in Annex V of the Clinical Trials Regulation 536/2014.

**1) Clinical trial identification<sup>3</sup>**

- a. Short title of the trial in lay language;
- b. Protocol number;
- c. Trial numbers (e.g. EU Clinical Trial Number and ClinicalTrial.Gov trial number) and other identifiers.

**2) Name and contact details of the sponsor**

**3) General information about the clinical trial**

- a. Rationale or reasons for conducting the trial
- b. Main objectives (describe the overall purpose) of the trial and an explanation of the reasons for conducting it
- c. Investigational medicinal products used

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<sup>3</sup> This and all clinical trial information (e.g. protocol number, contact information for public inquiry, etc.) should be consistent with the information included in the EU database.

- d. Key inclusion and exclusion criteria
- e. Where the clinical trial was conducted
- f. When the clinical trial was conducted (start/end dates)

**4) Brief description of research participants in the trial, per protocol and CSR**

- a. Number of research participants included in the trial (including, for the EU, the number of participants in each participating Member State of the Union, and in third countries).
- b. Gender and age group and their breakdown.

**5) Characteristics of the participants**

- a. Demographic characteristics of the participants, e.g. gender, age range, and any other characteristic of the research participants that is expected to influence the outcomes of the trial (e.g. prior treatment experience, co-morbidities)

**6) Overall summary of results of the trial**

- a. Overall results and factual conclusion of the clinical trial - to include at a minimum primary endpoint results
- b. Summary description of adverse reactions and their frequency
- c. Summary of possible follow-up trials, where they are foreseen

**7) Where additional information can be found**

Using the trial number, NCT or EU Clinical Trial Number, the study participant should be directed to the EU portal and/or to US ClinicalTrials.gov for additional information. The sponsor may also elect to provide additional information on the trial, if available, e.g. via a company's website.

**Additional guidance:**

CIRSP – the Center for Information and Study on Clinical Research Participation:  
<https://www.ciscrp.org/programs-events/trial-results/>

Duke, M. (2012). 'How to Write a Lay Summary'. DCC How-to Guides. Edinburgh: Digital Curation Centre. Available online: <http://www.dcc.ac.uk/resources/how-guides> -

EFPIA – PhRMA Principles for Responsible Clinical Trial Data Sharing: Our Commitment to Patients and Researchers. July 2013.  
<http://transparency.efpia.eu/uploads/Modules/Documents/data-sharing-prin-final.pdf>

EPF (EU Patient Forum) Position: Clinical Trial Results – communication of the lay summary  
<http://www.eu-patient.eu/globalassets/policy/clinicaltrials/epf-lay-summary-position-march-2015.pdf>

INVOLVE NHS Plain English Summaries in National Institute for Health Research (NIHR) Funded Research, 2013: <http://www.invo.org.uk/wp-content/uploads/2013/03/Improving-quality-of-plain-English-summaries-report-final.pdf>

Lay Language Glossary:  
[https://humansubjects.stanford.edu/new/docs/glossary\\_definitions/lay\\_language.pdf](https://humansubjects.stanford.edu/new/docs/glossary_definitions/lay_language.pdf)

MRCT Return of Results Guidance Document (version 1.0 - March 19, 2015):  
[http://mrct.globalhealth.harvard.edu/files/mrct/files/2015-03-19\\_mrct\\_ror\\_guidance\\_1.0.pdf](http://mrct.globalhealth.harvard.edu/files/mrct/files/2015-03-19_mrct_ror_guidance_1.0.pdf)