DOI: 10.1002/ueg2.12320

NEWS

UNITED EUROPEAN GASTROENTEROLOGY ueg journal WILEY

Reducing bureaucracy in clinical trials

In the last few years, clinical trials have become more complex to carry out, mainly because of the increasing volume of needed bureaucratic documents. Therefore, the conduction of academic clinical trials is decelerated, with consequent limited access for patients to cutting-edge therapeutics.[1]

Moreover, the considerable bureaucratic workload limits the time that can be dedicated to patients, decreasing the quality of studies. Both scientific societies and patient associations advocate actions to decrease the bureaucratic burden of clinical trials, making them more practical and less expensive. The most relevant issues include: the safety reporting, as usually the description of suspected unexpected serious adverse reactions (SUSARs) need a burdensome requirement of documents; the informed consent, which is usually long and written with jargon-ridden terms; regulation and guidelines which are often written vaguely, leading to misinterpretation of rules, as, in examples, for general data protection regulation (GDPR) requirements. An advancement toward a leaner regulation has already been given by the Guidance on the Management of Clinical Trials during the COVID-19 pandemic, released by the European Commission in March 2020.[2] However, more comprehensive actions are needed to prevent the rarefaction of clinical research in Europe, including the revision of International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use guidelines on Good Clinical Practice (GCP), with the aim of reducing bureaucracy burden and make trials safe, more affordable and understandable by patients.

The BioMed Alliance, an organisation representing 36 leading biomedical societies in Europe, including the UEG, has gathered a multidisciplinary coalition of medical societies and patient advocates, to release a joint statement 'Reducing bureaucracy in clinical trials: now is the time!',[3] calling for urgent measures to reduce the bureaucracy of clinical trials and make them more efficient and patient-based, and less expensive, and developing practical recommendations, summarised below, concerning: (I) safety reporting; (II) informed consent; (III) regulatory guidelines; (IV) harmonisation of requirements across the EU.

HARMONISATION AND SIMPLIFICATION OF ADVERSE EVENTS REPORTING

The panel suggested that, ideally, investigators should focus only on the medical aspect of adverse events, and that a single harmonised investigator-friendly platform should be agreed by all sponsors (including academia and clinical research organisations [CROs]), using a simplified, paperless/electronic safety report form. Moreover, study protocols should be drafted with the aim of reducing the number of unnecessary safety reports.

INFORMED CONSENT

This Coalition advocates the clarity and the intelligibility of the informed consent, suggesting that: the consent form does not exceed 1000 words; it can be accompanied by images/audiovisual content to let the patient better understand the study; use appendices to shorten the body text and let it include only the relevant parts; grouping study procedures by frequency rather than listing them; providing electronic formats, with the possibility of electronic signatures; ensuring a role for laypersons and patients in ethics committees to check that the informed consent can be clearly understandable; provide a key information section (even with a text box).

REGULATORY GUIDELINES

The Coalition has released the following recommendations for the formulation of regulatory guidelines: they should focus on patient safety and the quality of collected data, and be draft with the aim of preventing overinterpretation; patients should play a key role in all stages of the clinical trial process, that is, to promote the identification of patient-focused endpoints; make the guidelines, and more specifically the requirements for safety reporting proportional to the risk profile of the study; formulate the text in a

clear manner, to limit room for misinterpretations; focus on mandatory requirements only, that is, those relevant for patient safety and for the quality of data; simplify the interplay with regulatory bodies and ethics committees; apply these principles to all trials (academic, non-academic, investigating drugs or devices, etc.); reduce regional differences, allow patient associations and medical societies to review study protocols; use the lessons learnt from the COVID-19 pandemic[4,5] to accelerate approval by ethical committees, implement remote training and monitoring, and use electronic signatures.

HARMONISATION OF REQUIREMENTS ACROSS THE EU

The panel believes that a harmonised interpretation and application of EU rules is necessary to reach the goal of a patient-centric, bureaucracy-lean management of clinical trials in Europe, and has released the following recommendations:

1) the European Commission should encourage aligned implementation of the Clinical Trials Regulation (CTR) across EU Member states;
2) the governance and implementation frameworks for the European Health Data Space should contribute to better clarity, avoidduplication, and homogenize interpretation of relevant requirements requirements; clarify the secondary use of data for health research; guarantee the participation of scientists, healthcare professionals and laypersons, as stakeholder of the trial development and review process.

The field of digestive diseases is wide and includes hot topics that are investigated by an increasing number of clinical trials.[6] The reduction of bureaucracy and the simplification of clinical trials regulations is expected to provide a benefit for research in gastroenterology and, consequently, for the care of patients with digestive diseases.

CONFLICT OF INTEREST

The author declares that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

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DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed in this study.

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REFERENCES

1. Rule S, LeGouill S. Bureaucracy is strangling clinical research. BMJ. 2019:l1097. https://doi.org/10.1136/bmj.l1097
2. European Commission. Guidance on the management of clinical trials during the COVID-19 (Coronavirus) pandemic. Version 3. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf. Accessed 30 May 2022.
3. https://bureaucracyincts.eu/statement/. Accessed 31 May 2022.
4. Magro F, Nuzzo A, Abreu C, Libânio D, Rodriguez-Lago I, Pawlak K, et al. COVID-19 in gastroenterology: where are we now? Current evidence on the impact of COVID-19 in gastroenterology. United Eur Gastroenterol J. 2021;9(7):750–65. Epub 2021 Jun 30. PMID: 34190413; PMCID: PMC8435247. https://doi.org/10.1002/ueg2.12115
5. Peck-Radosavljevic M, Burra P, Ferret MB, Fracasso P, Ricciardiello L, Seufferlein T, et al. COVID-19 and digestive health: implications for prevention, care and the use of COVID-19 vaccines in vulnerable patients. United Eur Gastroenterol J. 2021;9(9):1091–5. Epub 2021 Oct 30. PMID: 34716760; PMCID: PMC8598962. https://doi.org/10.1002/ueg2.12173
6. Michl P, Löhr M, Neoptolemos JP, Capurso G, Rebours V, Malats N, et al. UEG position paper on pancreatic cancer. Bringing pancreatic cancer to the 21st century: prevent, detect, and treat the disease earlier and better. United Eur Gastroenterol J. 2021;9(7):860–71. Epub 2021 Aug 25. PMID: 34431604; PMCID: PMC8435257. https://doi.org/10.1002/ueg2.12123