MODIFICARI DETERMINATE DE REGULAMENTUL EUROPEEAN PRIVIND STUDIILE CLINICE
CHANGES DETERMINED BY THE EUROPEAN CLINICAL TRIALS REGULATION

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ABSTRACT: *Doctors should do what is best for their patients, should not do any harm, and allow individuals to manage their own healthcare choices. These principles apply to medical research in tandem with clinical practice. How do we know the best treatment for a particular condition? How do we know that a new treatment (medicine) does not cause any harm? We could guess, "try and see what's going on," or we could design a clinical trial with defined endpoints, a statistical analysis, and monitoring adverse events to gain proof of benefit. Clinical studies provide some knowledge to practice medicine in an ethical manner.*

Are there regulations on clinical trials of medicinal products? What is the framework for authorization of clinical trials in the EU? The Regulation UE establishes a uniform framework for the authorization of clinical trials in all Member States through a single evaluation of the results, facilitating international cooperation in clinical trials, in the development of special treatments. Also, simplified experimentation rules are introduced which provide authorized medicines or used medicinal products based on scientific evidence published. A challenge for stakeholders is the complex processing procedures and shorter implementation times in comparison to the previously regulations, for the development of innovative medicines.

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