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Καθ. Αθανάσιος Σκουτέλης

1ο Συνέδριο Ελληνικής Εταιρείας Φαρμακευτικής Ιατρικής, 30 Μαίου 2014

ΣΗΜΕΡΙΝΗ ΚΑΤΑΣΤΑΣΗ

- Νέος νόμος από το 2011
- Μεγάλες προσδοκίες
- Ανύπαρκτη υποδομή
- Ανύπαρκτες προσπάθειες
- Η θεωρία της ήσσονος προσπαθείας
- Προβλήματα για λύση (ακόμη): ΕΕΔ, πλαφόν αμοιβών, ενημέρωση νοσοκομείου....

Scientific development, however, suggests that future clinical trials will target more specific patient populations, such as subgroups identified through genomic information. In order to include a sufficient number of patients for such clinical trials it may be necessary to involve many, or all, Member States. The new procedures for the authorisation of clinical trials should stimulate the inclusion of as many Member States as possible. Therefore, in order to simplify the procedures for the submission of an application dossier for the authorisation of a clinical trial, the multiple submission of largely identical information should be avoided and replaced by the submission of one application dossier to all the Member States concerned through a single submission portal. Given that clinical trials carried out in a single Member State are equally important to European clinical research, the application dossier for such clinical trials should also be submitted through that single portal

Αυτή θα έπρεπε να είναι η νομοθεσία μιάς χώρας (όπως η Ελλάδα) **άν ήθελε** να προσελκύσει κλινικές μελέτες.

In order to avoid administrative delays for starting a clinical trial, the procedure to be used should be **flexible and efficient**, without compromising patient safety or public health.

(11) The risk to subject safety in a clinical trial mainly stems from two sources: the investigational medicinal product and the intervention. Many clinical trials, however, pose only a minimal additional risk to subject safety compared to normal clinical practice. This is particularly the case where **the investigational medicinal product is covered by a marketing authorisation,** that is the quality, safety and efficacy has already been assessed in the course of the marketing authorisation procedure" or, if that product is not used in accordance with the terms of the marketing authorisation, that use is evidence- based and supported by published scientific evidence on the safety and efficacy of that product, and **the intervention poses only very limited additional risk to the subject** compared to normal clinical practice. Those low-intervention clinical trials are often of crucial importance for assessing standard treatments and diagnoses, thereby optimising the use of medicinal products and thus contributing to a high level of public health. Those clinical trials should be subject to less stringent rules, as regards monitoring, requirements for the contents of the master file and traceability of investigational medicinal products. In order to ensure subject safety they should however be subject to the **same application procedure** as any other clinical trial

‘Low-intervention clinical trial’ means a clinical trial which fulfils all of the following conditions:

(a) the investigational medicinal products, excluding placebos, are authorised;

(b) (b) according to the protocol of the clinical trial, (i)the investigational medicinal products are used in accordance with the terms of the marketing authorisation; or (ii) the use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; and

(c) (c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned;

ΝΕΟΣ ΚΑΝΟΝΙΣΜΟΣ ΓΙΑ ΤΗΝ ΕΛΛΑΔΑ

- Ποιός φορέας θα αναλάβει να τον προσαρμόσει;
- Χρειάζεται νέα νομοθεσία;
- Εφαλτήριο για νέα αρχή;;
- «Εφιάλτης» ή «η καλή Νεράιδα;»