ORPHANET JOURNAL OF RARE DISEASES

POSTER PRESENTATION Open Access

EU Clinical trial regulation in the environment of rare diseases: time for a change

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From 5th European Conference on Rare Diseases (ECRD 2010)
Krakow, Poland. 13-15 May 2010

The clinical trial directive 2001/20/EC is out for public consultation. This session will draw the attention of the challenges faced by Small and Medium Enterprises (SME) companies when developing new products for the rare diseases that affect a very limited number of patients and discuss possible options to overcome the challenges.

Indeed, with only a few patients in each country, clinical trials need to be conducted in many countries in order to enrol the number of patients required to demonstrate benefit/risk. The management of these clinical trials is associated with several issues that slow down the overall process of drug development: administrative hurdles associated with non harmonised regulatory authorisation process as well as cost pressure linked to the need to outsource local activities to several consultants to prepare and manage submission to health authorities and ethic committees.

Today, Europe must streamline its system and all stakeholders should raise their voice to propose specific approaches in order to facilitate the development of new drugs for orphan drugs in a timely manner.

Published: 19 October 2010

doi:10.1186/1750-1172-5-S1-P19
Cite this article as: Zimmermann: EU Clinical trial regulation in the environment of rare diseases: time for a change. *Orphanet Journal of Rare Diseases* 2010 **5**(Suppl 1):P19.

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