2001/20/EC - A European Directive?

Major Regulatory Objectives for a Real Harmonisation in Europe

Everybody who has performed multi-center clinical trials knows that it is a real challenge to prepare a clinical trial application in different European countries. Frequently asked questions are: Which documents should be included into the submission package? Which timelines apply for the Competent Authority and Ethics Committee evaluation procedure? Are the Competent Authority and Ethics Committee procedures linked together or independent? Regarding the ten European Countries Austria, Belgium, Czech Republic, Germany, Italy, Slovenia, Spain, The Netherlands, Poland and UK your questions will be answered in this book. Beyond the answers to these questions short-, middle- and long-term measures are proposed in order to improve the harmonisation of the clinical trial authorisation procedures in the EU and finally to increase Europe's attractiveness for clinical research and to ensure global market competitiveness.

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"Die Arbeit ist ein Aufruf zu entsprechenden Schritten der Gesetzgeber, der sowohl an die Europäische Union als auch an die Mitgliedsstaaten gerichtet ist. Darüber hinaus ist sie eine wertvolle Hilfefür Unternehmendie von der derzeitigen Situation betroffen sind."

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