



**EUROPEAN
SOCIETY OF
CARDIOLOGY®**

Harmonisation of the definition of bleeding in clinical settings

ESC European Affairs Committee workshop

November 4, 2011

SUMMARY

- The aim of the workshop was to discuss issues relating to the harmonisation of the definition of bleeding in clinical settings that could be useful to the EMA in drafting future guidelines
- Bleeding has clinical impact and is an important safety endpoint in clinical trials. The problem is that at present a variety of different definitions are used and this makes it difficult to compare bleeding outcomes across trials and to assess a drug's risk:benefit
- The perception is that the industry tends to choose a bleeding definition that shows its drug in the best light
- The priority for the EMA is a simple definition that is stable, relevant to patient safety, and that will be used
- It was agreed that ideally one definition of major bleeding and minor bleeding would be used across all specialties, but that it might be necessary to have separate definitions for surgical and non-surgical settings. There could be a common minimum requirement, perhaps with different "branches" for different specialties
- There were mixed views on the new consensus definitions from the Bleeding Academic Research Consortium (BARC). These are not applicable to all specialties and are complex. However, they are similar to the definitions that cardiologists already use and were developed by an expert group, so it was suggested that it would be logical to work with these
- The group agreed on the need for standardised minimum data collection in phase III trials. This will allow analysis by multiple definitions if required
- Consistent reporting of trial data is also important, although space restrictions limit what can be included in manuscripts
- The importance of assessing minor bleeding in phase II trials to get an early signal of bleeding risk was highlighted
- In prophylaxis of VTE in orthopaedic surgery, efficacy is optimal and it is now important to focus on safety
- It was agreed that it would be useful to have a follow-up meeting to discuss proposals for one common definition or two definitions (surgical and non surgical) once EMA has progressed with drafting its new guideline on assessment of antithrombotic products for atrial fibrillation

To reduce the burden of cardiovascular disease in Europe

The European Heart House - 2035, Route des Colles - Les Templiers - BP 179 - 06903 Sophia Antipolis Cedex - France
Tel. +33-(0)4 92 94 76 00 - Fax. +33-(0)4 92 94 76 01 - Web Site: www.escardio.org

SOCIÉTÉ EUROPÉENNE DE CARDIOLOGIE Association loi 1901 - Déclaration du 08/04/1992 N° 1/10006 J.O. N° 18 du 29/04/1992 - Association agréée de tourisme n°AG.006.00.0002