

## 2<sup>nd</sup> EMWA-ICR Joint Symposium

### Writing protocols: collaboration and compromise or conflict and confusion?

24<sup>th</sup> February 2009

London, UK

The process of designing, writing, and reviewing protocols is always challenging and is too often fraught with conflict and confusion. The aim of this second joint EMWA-ICR symposium is to bring together the different players involved in protocol writing and to provide a forum for them to discuss and debate their different points of view. Presenters and panelists will include experts representing the different facets of clinical research, including medical writing, monitoring, project management, ethics committees and the investigative site. We hope the outcome will be an agreement to collaborate and compromise—rather than open warfare—but you'd better come and find out for yourself!

PLACES LIMITED SO BOOK NOW!

Attendance fee: £225 ICR or EMWA members - £325 Non-members

See the EMWA website ([www.emwa.org](http://www.emwa.org)) or ICR website ([www.icr-global.org](http://www.icr-global.org))  
for the full programme and details of how to register.

#### Definitions box

### Orphan drugs

No pharmaceutical company wants to invest in a drug, the sales of which would never recoup its development costs. As a consequence, pharmaceutical companies are often unwilling to develop drugs for rare diseases. The Orphan Drug designation exists to encourage the development and commercialisation of drugs for the treatment of such rare conditions. An orphan drug designation, or more properly Orphan Medicinal Product designation, is a regulatory tool of European, American and Japanese regulators that gives regulatory protection to companies developing a medication for a rare disease. In the EU, a medicinal product is designated as an orphan medicinal product if: it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union at the time of submission of the designation application (prevalence criterion), or; it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and without incentives it is unlikely that expected sales of the medicinal product would cover the investment in its development, and; no satisfactory method of diagnosis, prevention or treatment of the condition concerned

is authorised, or, if such method exists, the medicinal product will be of significant benefit to those affected by the condition. The company has first to apply for orphan disease designation, which, when granted, means that the regulatory authority has approved that company to work on a rare disease. Once the new treatment is approved, orphan medicinal product status is given to the product in development. The company then has 10 years of protection in Europe and 7 years in the US. During that period no other company will be granted a licence for that product in the same indication. Companies with a product that has been granted orphan medicinal product designation benefit from incentives such as: protocol assistance (scientific advice during the product-development phase); marketing authorisation (10-year marketing exclusivity); financial incentives (fee reductions or exemptions); national incentives detailed in an inventory made available by the European Commission.

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For more information see:  
<http://www.emea.europa.eu/pdfs/human/comp/29007207en.pdf>