ARE CURRENT US AND EUROPEAN SCIENTIFIC AND REGULATORY GUIDANCE ON THE CLINICAL REQUIREMENTS FOR BIOSIMILARS/FOLLOW ON BIOLOGICS APPROPRIATE FOR THE EVALUATION OF RISK:BENEFIT

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Biosimilars are complex molecules which may have the same overall structures as the originator reference protein yet activity differs because of minor chemical differences such as glycosylation or PEGylation.
Such small differences may have serious clinical consequences, introducing difficulties in characterising risk:benefit of biosimilars/follow on biologics in abridged clinical development programmes. European guidelines for the clinical development of biosimilar products request comparability data that demonstrates therapeutic equivalence in safety and efficacy to the originator product and case by case specific guidelines for individual products and therapeutic areas continue to be developed. Whether the rationale andspecifications of t such studies are sufficient is controversial. This debate looks at the scientific, ethical and legal issues including liabilities in negligence, consumer protection and intellectual property rights and this seminar will address these in respect of new treatments for chronic neurodegenerative disease, such as multiple sclerosis.