
STATUTORY INSTRUMENTS

2012 No. 504

The Medicines (Products for Human
Use) (Fees) Regulations 2012

PART 11

Capital Fees For Application For Membership of Good Clinical
Practice Accreditation Scheme and for Certificate of Membership

Meaning of “good clinical practice accreditation scheme”

35. In this Part—

“good clinical practice accreditation scheme” means the non-statutory voluntary scheme of accreditation operated by the licensing authority in relation to Phase 1 trials which participants may join following satisfactory completion of a good clinical practice inspection; and

“Phase 1 trials” are clinical trials to study the pharmacology of a medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial.