

SCHEDULE 2

Persons not required to comply with regulation 3 or 4

PART 2

Persons not required to comply with regulation 4

32.—(1) A person who—

(a) has travelled to the United Kingdom to—

(i) conduct a clinical trial within the meaning of “conducting a clinical trial” in regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004⁽¹⁾,

(ii) undertake such activities as are necessary or expedient to prepare for the conduct of a clinical trial, or

(iii) carry out any necessary compliance activity in relation to a clinical trial that cannot be conducted remotely,

(b) is a “qualified person” within the meaning of regulation 43 of those Regulations, where they have travelled to the United Kingdom in order to undertake activities in relation to their role as such a person, or

(c) is a “sponsor” within the meaning given in regulation 2(1) of those Regulations, or carries out the functions or duties of a sponsor, of a clinical trial and has travelled to the United Kingdom to undertake activities in relation to a clinical trial.

(2) For the purposes of sub-paragraph (1), “clinical trial” has the meaning given in regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004.

(1) [S.I. 2004/1031](#), to which there are amendments not relevant to these Regulations.