STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 4

GOOD CLINICAL PRACTICE AND THE CONDUCT OF CLINICAL TRIALS

[F1Trial master file and archiving

31A.—(1) The sponsor shall keep a trial master file for a clinical trial.

(2) The sponsor shall ensure that the trial master file is readily available at all reasonable times for inspection by the licensing authority or any person appointed by the sponsor to audit the arrangements for the trial.

(3) The master file shall at all times contain the essential documents relating to that clinical trial.

(4) The essential documents relating to a clinical trial are those which—

(a) enable both the conduct of the clinical trial and the quality of the data produced to be evaluated; and

(b) show whether the trial is, or has been, conducted in accordance with the **[**F2relevant**]** requirements of **[**F3these Regulations**]**.

(5) The essential documents shall contain information specific to each phase of the trial.

(6) The sponsor shall ensure that any alteration to a document contained, or which has been contained, in the trial master file shall be traceable.

(7) The sponsor and the chief investigator shall ensure that the documents contained, or which have been contained, in the trial master file are retained for at least 5 years after the conclusion of the trial and that during that period are—

(a) readily available to the licensing authority on request; and

(b) complete and legible.

(8) The sponsor and chief investigator shall ensure that the medical files of trial subjects are retained for at least 5 years after the conclusion of the trial.

(9) The sponsor shall appoint named individuals within his organisation to be responsible for archiving the documents which are, or have been, contained in the trial master file and, subject to paragraph (2), access to those documents shall be restricted to those appointed individuals.

(10) If there is transfer of ownership of data or documents connected with the clinical trial—

(a) the sponsor shall record the transfer; and

(b) the new owner shall be responsible for data retention and archiving in accordance with paragraphs (2), (7) and (8).

(11) For the purposes of this regulation, an individual is an individual within the sponsor's organisation where—

(a) he is employed or engaged by the sponsor;

(b) he is acting under arrangements made with the sponsor for the purposes of managing or conducting the clinical trial;

(c) where the sponsor is an individual, he is the sponsor; or

(d) where the sponsor is a body of persons, he is—

(i) a member of the body, or

(ii) employed or engaged by such a member.**]**

Textual Amendments

F1 Reg. 31A inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **18**

F2 Word in reg. 31A(4)(b) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **13(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in reg. 31A(4)(b) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **13(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Section 31A.