
STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use
(Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS
AND ETHICS COMMITTEE OPINION

Conclusion of clinical trial

27.—(1) Subject to paragraph (2), within 90 days of the conclusion of a clinical trial the sponsor shall notify the licensing authority and the relevant ethics committee in writing that the trial has ended.

(2) If a trial is terminated—

- (a) before the date for the conclusion of the trial specified in the protocol for that trial, or
- (b) before the event specified in the protocol as the event which indicates the end of the trial has occurred,

the sponsor shall notify the licensing authority and the relevant ethics committee in writing of the termination of the trial within 15 days of the date of termination.

(3) A notification made in accordance with paragraphs (1) or (2) shall contain the particulars specified in Part 4 of Schedule 3.

Changes to legislation:

There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Section 27.