Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 2

HUMAN MEDICINES

CHAPTER 1

[[F1]REGULATIONS: GENERAL**]**

5 Clinical trials

(1) Regulations under section 2(1) may make provision—

(a) corresponding or similar to provision in the EU Clinical Trials Regulation,

(b) about authorisations concerning clinical trials in the United Kingdom, including applications for an assessment of the ethics of a proposed clinical trial,

(c) about notification and reporting requirements in relation to clinical trials,

(d) about requirements that must be met before a clinical trial may be carried out, or

(e) relating to the conduct of clinical trials.

(2) In subsection (1)(a), "EU Clinical Trials Regulation" means Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Section 5.