



Irish Pharmaceutical Healthcare Association

IPHA wishes to clarify that there is no requirement for Standard Contractual Clauses (SCCs) to be included in any mCTA.

Data Transfer Within the EU

Where 1) an EU-based Sponsor (or a Sponsor located in another jurisdiction enjoying an EU adequacy decision) and 2) the Irish hospital site are involved in a study, EU SCCs are not included in the mCTA because the personal data transfer, under the study agreement, is between those two parties (the Sponsor and the Irish Hospital). Thus, the personal data remains within the EU and is governed by the General Data Protection Regulation (GDPR) which guarantees a high, uniform standard of data protection across all Member States. Clause 7 of the mCTA already legally covers the data transfer between the parties in the mCTA, which is akin to a data protection agreement.

Data Transfer Outside the EU

Any personal data transfer between the Sponsor company (including the local affiliate in Ireland) to the parent company (for example in the U.S.) is executed under intercompany agreements. Those agreements already include appropriate cross-border data transfer terms (such as SCCs).

With respect to vendors that offer enterprise applications that have their servers in the U.S., the Sponsor does not require the Irish hospital (or any other study site) to enter into SCCs with such vendors even though the site transfers data to these vendors. Rather, it is the Sponsor that enters into SCCs with such vendors. The transfer of the data from the Sponsor EU registered address to a third country will be governed by a separate agreement (SCCs etc) that the sites will not be a party to.