REGULATION (EU) No 536/2014

To sponsors and contract research organizations conducting clinical trials in the European Union (EU)

The Canadian and Quebec requirements regarding *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 Text with EEA relevance* (the ***Regulation***), as concerns clinical trials.

Concluding a clinical trial agreement or other research agreement confirming that Quebec institutions and researchers will comply with the Regulation gives rise to contractual requirements applicable and enforceable against each of them.

However, such requirements should not apply to these institutions and researchers because they are located outside the EU, their activities are conducted only in Quebec and the participants recruited are from Quebec.

Given that the activities of these institutions and researchers do not fall within the scope of the Regulation, they should not be required to comply with the retention period imposed by that Regulation (see sections 1, 2 and 58 of the Regulation).

Public institutions that are part of Quebec's health and social services network and their researchers must comply with various legal requirements, particularly regarding document retention and destruction.

For example, these researchers and public institutions will follow the requirements set out in the *Food and Drug Regulations* (CRC, c 870) on the retention period for study records when they participate in clinical trials involving the use of an experimental drugs. These Regulations state that a "sponsor shall maintain all records referred to in this Division [clinical trial records] for a period of 15 years." These researchers and public institutions will also comply with their institutional policies, which confirm that records for clinical trials involving the use of an experimental drug will be retained for a period of 15 years, after which they will be destroyed.

To maximize sponsor compliance with the requirements set forth in the Regulation, a sponsor can decide to:

- retain the master trial file, which includes copies of all mandatory documents and the case report form including all de-identified study participants' data, for a period of 25 years; or
- secure a right to request, prior to the expiry of the 15-year period, that some documents part of the master trial file maintained by the Quebec institutions and their researchers be transferred to the sponsor. This transfer must be at the sponsor's expense, if any expenses are incurred, and cannot include source documents or any document containing identifiable information.

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