Workshop 1.3 Overview

W1.3: Using the PeRSEVERE guiding principles to prepare for and manage participation changes in clinical trials

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Participants' involvement in clinical trials can stop, change or reduce in various ways, and in various circumstances. It can be challenging for trialists to prepare for and manage this complexity in ways that maximise protection of both participants' rights and trial integrity, especially as existing regulatory and ethical sources mostly do not address this topic in a nuanced way. The PeRSEVERE project (PRincipleS for handling end-of-participation EVEnts in clinical trials REsearch), set up through the UKCRC Registered CTU Network, aimed to achieve wider agreement around a set of comprehensive guiding principles to give more clarity to all those involved in running or overseeing clinical trials.

This workshop will introduce the principles and then help attendees explore, through structured discussions and tasks, how they can be put into practice in clinical trials they work with. It will be a practical session aimed at individuals (including research professionals and patient contributors) with any current or future practical involvement in preparing for or managing participation changes in clinical trials. This includes activities such as protocol development, Case Report Form or database design, trial or data management, monitoring, trial recruitment or anyone who has direct contact with participants in trials.