



**Figure 1. Decision tree for determining the correct category for a modification.** This decision tree must be used alongside the tables in the *Examples of modifications* section of the Guidance accompanying the Medicines for Human Use (Clinical Trials) Regulations. Note that it is possible to include multiple modifications of different categories in a single application to the authorities. The sponsor must select the route of submission according to the modification in the application that requires the highest level of scrutiny by the authorities