EudraCT Safety Data Input Software Tool

# Introduction

The remit of the European Clinical Trials Data Base (EudraCT) is to provide open access to summaries of all registered clinical trial results; thus aiming to prevent non-reporting of negative results and provide open-access to results to inform future research. The amount of information required and the format of the results, however, imposes a large extra workload at the end of studies on clinical trials units. In particular, the adverse-event-reporting component requires entering:

* each unique combination of treatment group and safety event
* for every such event above, a further 4 pieces of information (body system, number of occurrences, number of subjects, number exposed) for non-serious events, plus an extra three pieces of data for serious adverse events (numbers of causally related events, deaths, causally related deaths).

# Methods

A project funded by the NIHR CTU funding call “Supporting efficient / innovative delivery of NIHR research” has developed tools using standard statistical software to:

* prepare the required statistics needed by EudraCT
* format them into the precise requirements to directly upload an XML file into the web portal, with no further data entry by hand.

# Timing of Potential Results

The project will be completed by October 2019, and we will present the tools, explain how they may be accessed and provide routes to further training.

# Potential Relevance and Impact

The tool should remove the workload on CTUs of manually entering a large amount of data points (e.g. over 1000 datum points for a recent oncology study) using the web-interface, which is expensive and error-prone. It should also prevent the alternative and lower quality practice of uploading pdf files with safety summaries, which are difficult to amalgamate with any other data sources, nor subject to any controls regarding content.