**User Story - Audit trail - in Clinical trials**

I will be honest straight away that I am less interested in the reason for change, than I am in recording the user ID that updates a variable, the type of action (e.g. initial data entry, removal of data, updating data, adding a query etc.)

Example 1: a trial in which a new drug is tested in a vulnerable population (terminally ill patients). There is a high safety risk for the patients and it is absolutely crucial that the data is trustworthy and of high quality.

Detecting fraud / errors: Thanks to the audit trail showing everything that happens to a data point (initial data entry, updating of data, removal of data, adding queries, review, source document verification etc.) we can program a report showing us all data points that are updated at an odd time point. I am not so interested in data points that are updated within 15 minutes of initial data entry. But in these reports we also sometimes see data points being updated after > 1 week, which were not the result of a query raised by Data Management. These occurrences are critical to follow-up in high risk trials, as this could be a sign of fraud or data entry error. For such cases I will review the reason for change. I will also ask the monitoring team to double check the patient notes next monitoring visit to ensure the updated data is correct.

Example 2: a large study with low safety risk with over 10’000 patients.

There would not be much review of the reason for change involved. I would probably only run a report that double checks that any changes to the data after initial data entry, that are corrected within 15 minutes of initial data entry, have the reason for change ‘typo’ or ‘data entry error’ selected. I might review a random selection of the reasons for change for safety related questions that have been updated > 1 week after initial data entry. But in my experience, such studies don’t come with the most generous budget, so it is up to the Project Leader to decide where Data Management review should be focused on. And typically, reviewing the reason for change does not win.