**Potential Relevance and Impact:** With the ICH E6 (R2) 2016 guidelines advocating risk-based monitoring, more trials are now using site performance metrics to assess if a site visit is required. Trialists need to find out more about how site performance metrics normally behave. These forthcoming data will add to our knowledge and contribute to discussions of which metrics to use.

## P-34

### Assessing the quality of data collection in clinic; lessons from the Wound Healing in Surgical Trauma (WHiST) RCT

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**Introduction:** In 'closed' high-energy fractures associated with major trauma the surgical site infection (SSI) rate is an important outcome, as SSI involves prolonged antibiotic use, delayed rehabilitation and additional hospital admissions. To investigate the efficacy of interventions which might improve infection rates, robust methodology to assess the presence of deep SSI is required.
**Objective:** To compare wound healing complications that define a deep SSI on case report forms (CRFs) completed by patients and research nurses with information extracted from patients' medical notes.
**Methods:** This study was performed as part of the WHIST trial. Patients with a major trauma fracture requiring surgery were randomly assigned to standard or negative pressure wound dressings. The rate of deep SSI, defined by the Center for Disease Control criteria, was the primary outcome. CRFs were completed 30 days post-surgery by the participant and research nurse. An independent surgeon retrospectively reviewed a sample of participants' medical records (including all potentially infected and a random sample of non-infected cases), for pre-specified wound complications.
**Results:** 308 participants had their medical records checked. For the majority (83%), the CRFs and the routine medical record agreed on the presence or absence of a deep SSI. However, four participants with no deep SSI found on the CRFs, had a deep SSI according to their medical records. Conversely, 49 deep SSIs were indicated according to the CRFs, but not identified from the medical record. For nearly half of these latter participants (49%), at least one wound healing complication was identified in the audit. However, the remaining participants had no wound healing complications.
**Conclusions:** This study suggests that a review of the medical record alone is likely to lead to an underestimation of the rate of deep SSIs. This could have implications for the interpretation of reports of infection using routinely collected data.

## P-35

### Approaches to data cleaning in a pilot study: (EMmY) Effectiveness and acceptability of myo-inositol nutritional supplement in the prevention of gestational diabetes: a pilot placebo controlled double blind randomised trial

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**Background:** Pilot studies provide research teams with restricted time to demonstrate that the trial would be feasible at full-scale, as well as limited time to demonstrate that high quality outcome data can be collected for this study. This demand for clean and accurate data in a short time frame requires an efficient data cleaning process. Our objective is to assess an automated data cleaning approach versus a manual method.
**Methods:** The main method used for data cleaning within the EMmY study comprised of a post-entry validation tool. Rules were created in the database to detect discrepancies of interest, including missing fields, missing forms, and incongruent fields. Queries were then raised directly through the database to study sites, for site users to address and resolve electronically.
We compared this method against the manual approach used in previous studies within our unit. In this case, sites would receive a list of data discrepancies to complete manually and return them to the research team to update in the database.
Prior to final analysis, the study statistician raises further queries. To compare the two data cleaning approaches, we will examine the proportion of queries raised by the study statistician at the end of the study, as an indicator of the level of data quality reached.
**Timing of potential results:** The EMmY study completed follow-up in March 2019, and final data analysis will take place in May 2019. Therefore, the above comparison in data cleaning approaches will be made in August 2019.
**Potential relevance and impact:** While automated discrepancy rules are more labour-intensive upfront, they yield potentially valuable time savings, whilst also maintaining the high accuracy and quality required in the short timeframe of a pilot study. Our analysis will provide insight as to whether this upfront effort is warranted over a short study duration.

## P-36

### The Validity of Setting Error Rates in Clinical Trials

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**Introduction:** Data entry errors in clinical trial databases are inevitable due to the complexity of the information and the manual nature of the data collection process. The aim of this review was to evaluate the applicability of pre-setting acceptable error rates in clinical trials. As an indication of data quality, it is common practice to calculate error rates as part of the database audit process. Based on the error rate, decisions can be made if further data cleaning is required or if the database is ready to be locked.
**Methods:** An assessment of current literature was performed. Scientific publications, industry practices and standard operating procedures from clinical trials units were examined to determine the purpose and relevance of setting limits on error rates and how to apply them for specific clinical trials.
**Results and Discussion:** Error rates limits are influenced by such factors as industry standard, personal choice and historical precedent, with acceptable error rates ranging from 0.05% to 5%. They can also vary within a single trial, with one limit being set for critical primary outcome data and another less stringent limit for non-critical data. This review suggests that auditing and monitoring of data from early on in a trial leads to lower error rates and buys time for corrective and preventative procedures to be put in place for the remainder of the trial and for future trials. Also, in anticipation of more widespread data sharing being part of future clinical trials, publication of quality control measures such as error rates may become unavoidable.

## P-37

### Improving trial eligibility criteria: new methods to enhance fitness-for-purpose

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**Introduction:** Eligibility criteria (EC) are key in defining patient populations included in a trial. There are no widely used, detailed