

Registering 100% of Clinical Trial Participants: How Memorial Sloan Kettering Ensures Registration Accountability

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1. Background

Clinical trial participant registration is a manual step performed by research coordinators into each recruiting site's registration system. The accountability and accuracy of this important step in clinical research participation is of utmost importance. Participant accrual reports are required quarterly to the NCI's Coordinating Center for Clinical Trials (CCCT) for all NCI-designated cancer center.

At Memorial Sloan Kettering (MSK), this process is being transformed as eConsent is implemented. eConsent is a web-based platform built by the Clinical Research Informatics & Technology (CRIT) team for electronic consenting, allowing for an automated data source, capturing real time consent data.

Given the ability to readily access the informed consent source data, we are reinventing how informed consent processes are systematically monitored and accounted for in the registration system, OnCore.

2. Goals

To achieve 100% registration compliance by accounting for all informed consent processes taken place via eConsent into the MSK registration system, OnCore.

3. Solutions and Methods

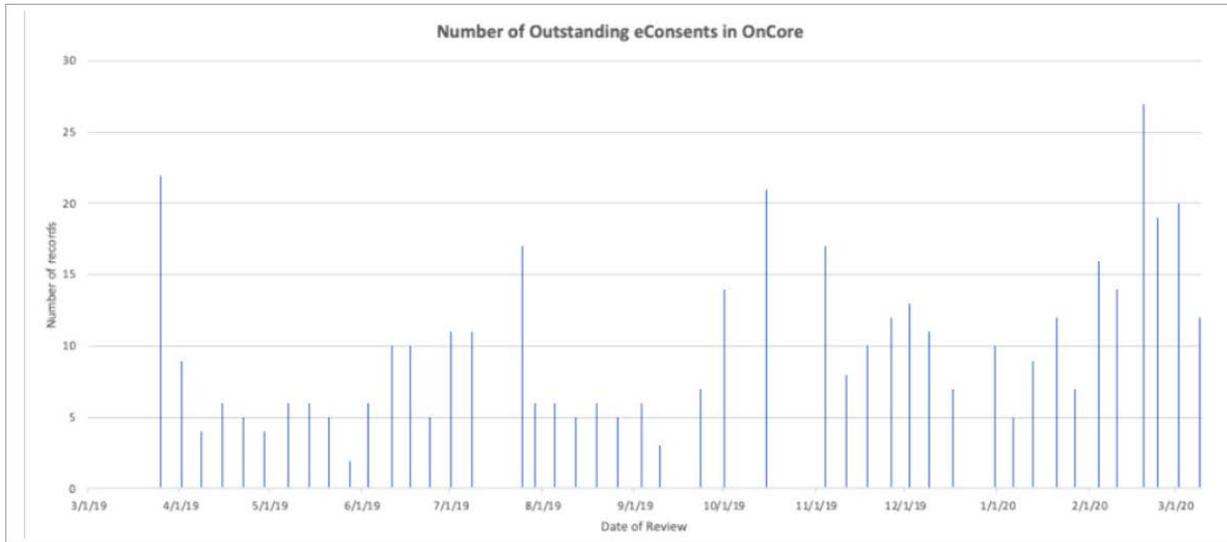
The MSK CRIT team has established a quality assurance process to review all informed consents for one institutional protocol in the eConsent platform, in comparison with the registrations in OnCore. The ability to cross-reference both databases allows MSK to ensure full registration accountability and accuracy. The proof-of-concept process focused on one institution-wide protocol, which recruits approximately 180 participants per week, 13% of the total number of subjects consented weekly at MSK. Consents processes occurring in eConsent between March - December 2019 were monitored.

During the consent process for this trial, a set of five questions are answered. They are entered in the eConsent platform and this data is stored in the MSK's Clinical Research Database (CRDB), the same system that is also integrated with OnCore and receives its registration data. Any discrepancies between the two data sources are identified daily in CRDB. Weekly reviews of this discrepant data are performed. The eConsent user is notified of the delinquency and asked to rectify immediately.

4. Outcomes

Since the beginning of the weekly reviews in March/2019, on average, 9 discrepant records are identified, with a standard deviation of 5. This equates to approximately 5% of this clinical trial's weekly registration, ranging from 2-22 records. When the outstanding registrations are identified, the users and their managers are contacted to register the consented subjects in OnCore immediately. At each weekly reconciliation, an average of 7 unique users are notified.

Category: Clinical Trial Operations – Work in Progress



5. Lessons Learned

The monitoring process initiated in 2019 was established as an initial effort to assess the number of outstanding consent processes that were not registered in OnCore. Once the rollout of eConsent is completed in 2020 for all protocols at MSK, the process can be scaled to all informed consents processes taken place in the MSK eConsent platform. This process will be automated with the implementation of the MSK Clinical Research Data Warehouse.

In the future, we foresee the ability to automate registrations by establishing an integration between eConsent and OnCore. This will effectively remove the need for manual data entry in OnCore, and significantly reduce clinical research coordinator’s administrative time and effort and eliminate inaccuracy.