Memorial Sloan Kettering Cancer Center

Abstract # 12

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

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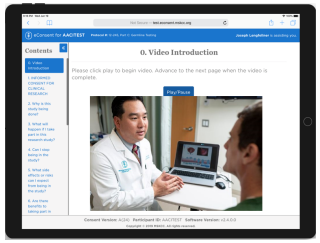
Background:

eConsent is a web-based platform built by MSK's Clinical Research Informatics & Technology (CRIT) for electronic consenting, allowing for an automated data source, capturing real time consent data.

eConsent digitalizes the consenting experience for patients through an educational engagement model.



eConsent platform has real time consent data stored in the MSK's Clinical Research Database (CRDB).

Patient registration is a manual process performed in OnCore by Clinical Research Staff, and is required entry within 2 business days of consent at MSK, as per internal SOP.

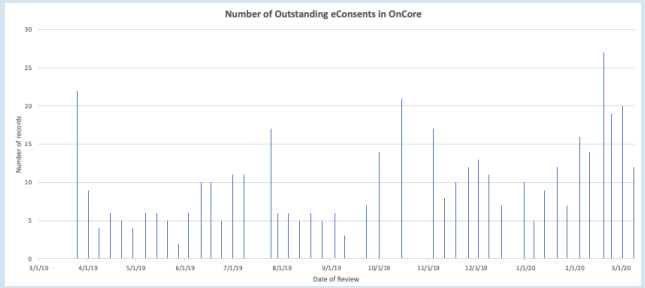
Goal:

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

Methods for Proof-of-Concept:

- Piloting with one institutional protocol live in the eConsent platform.
  - Recruits ~180 subjects/week (~13% MSK wide)
- Cross review of eConsents records and registrations completed in OnCore was performed weekly.
- eConsent user is notified of delinquent registration in OnCore if outside of 2 business day window, as per MSK SOP, and instructed to rectify immediately.

Results:

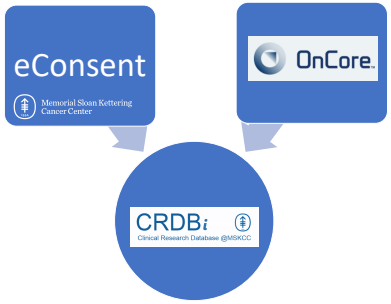


During Weekly Reviews:

- Average of 9 discrepant records found (SD: 5; 2-22)
- Average of 7 unique users are notified

Conclusions:

- Utilizing a monitoring effort between the eConsent platform and CTMS is valuable to enforce expected protocol patient registration requirements.
- Due to the positive results, once the rollout of eConsent is completed in 2020 for all MSK protocols, this process will be scaled to all informed consent processes occurring within the MSK eConsent platform



Future Directions:

- Automated process with implementation of the MSK Clinical Research Data Warehouse.
- Automate registrations by establishing an integration between eConsent and OnCore, removing the need for manual registration entry.