Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Mail to MyChart: Modernizing Dear Patient Letter Delivery in Clinical Trials

P. Warren, B. McGough, T. Imtiaz, E. Yepes, M. Dureja, A. Mesidor, R. Keller, S. Griglun, C. Infantino, H. He, J. Shirian, Z. Asif, N. Catti, M. Huber, A. Joshi, B. Pothuri, J. Mehnert

Laura and Isaac Perlmutter Cancer Center at NYU Langone Health

1. Background

The Perlmutter Cancer Center (PCC) at NYU Langone Health employs a Dear Patient Letter (DPL) to notify clinical trial participants in follow up, of significant new information via mail as part of our re-consent process. Managed by the Data Coordinating Unit (DCU), this process has become inefficient for larger studies due to challenges such as tracking hundreds of patients, non-responses, outdated EPIC addresses, and logistical issues in a hybrid work setup. As part of Epic Systems, PCC uses MyChart to facilitate patient-provider communication. The Institutional Review Board (IRB) permits MyChart use, though sponsor policies may require a standardized institutional process. We propose shifting the DPL process to electronic communication to reduce DCU workload, cut paper use, enhance patient engagement and improve efficiency.

2. Goals

The overarching goal is to establish a sustainable electronic communication process via MyChart to improve efficiency and patient engagement:

- Streamlining DPL distribution by transitioning to electronic communication and integrating tracking mechanisms.
- Ensuring regulatory compliance by incorporating MyChart verification into workflows and updating documentation for electronic tracking.
- Enhancing patient communication by developing clear confirmation instructions and follow-up strategies for non-responsive patients.
- Providing accessibility solutions by creating alternative methods for patients unable to use MyChart.
- Testing and refining the new process through pilot implementation in select studies.

3. Solutions and Methods

- In 2023, guidance was developed to standardize DCU training on MyChart DPLs. Qualitative assessments via RedCap surveys measured effectiveness. Collaboration with clinical stakeholders explored incorporating MyChart access verification into the Informed Consent Form (ICF) process, assessing troubleshooting challenges for staff. Stakeholders evaluated feasibility, and the Re-Consent Log was updated to document electronic DPL communications while ensuring regulatory compliance.
- Patient MyChart confirmation instructions were developed, and follow-up protocols for non-responsive patients were established. A tracker was designed to monitor DPL distribution and consolidated with RAU's system to improve efficiency and prevent duplication.
- In May 2024, a pilot study was launched to test MyChart-based DPL delivery in select trials. Ongoing assessments, including staff feedback and open-ended survey responses, refine the process by addressing barriers if a patient does not utilize MyChart, the process defaults to paper-based DPL delivery for accessibility.

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

4. Outcomes

- Presurvey results (n=25): 52 percent of respondents ranked themselves as "extremely" efficient, yet over 40 percent expressed slight to no satisfaction, with only 4 percent reporting extreme satisfaction. Confidence gaps included 52 percent not confident in MyChart activation and 40 percent not at all confident in MyChart Messaging. Key obstacles were addressing verification for patients, in-person requirements, and potential oversights, with digitization suggested as an improvement.
- Post-training results: Extreme satisfaction rose to 16 percent, while 8 percent remained completely unsatisfied, and 24 percent reserved judgment until after the pilot. Confidence in EPIC (beyond read-only) remained low (20 percent extremely comfortable).
- Early results after pilot (n=3) showed improving MyChart Activation confidence, stable MyChart Messaging, and overall fewer reported obstacles, suggesting workflow improvements.

5. Lessons Learned and Future Directions

Future efforts will focus on expanding MyChart-based DPL delivery across more clinical trials, refining patient follow-up strategies, and enhancing DCU orientation. Additional measures will address MyChart access barriers, optimize compliance tracking, and assess long-term effectiveness through stakeholder feedback.