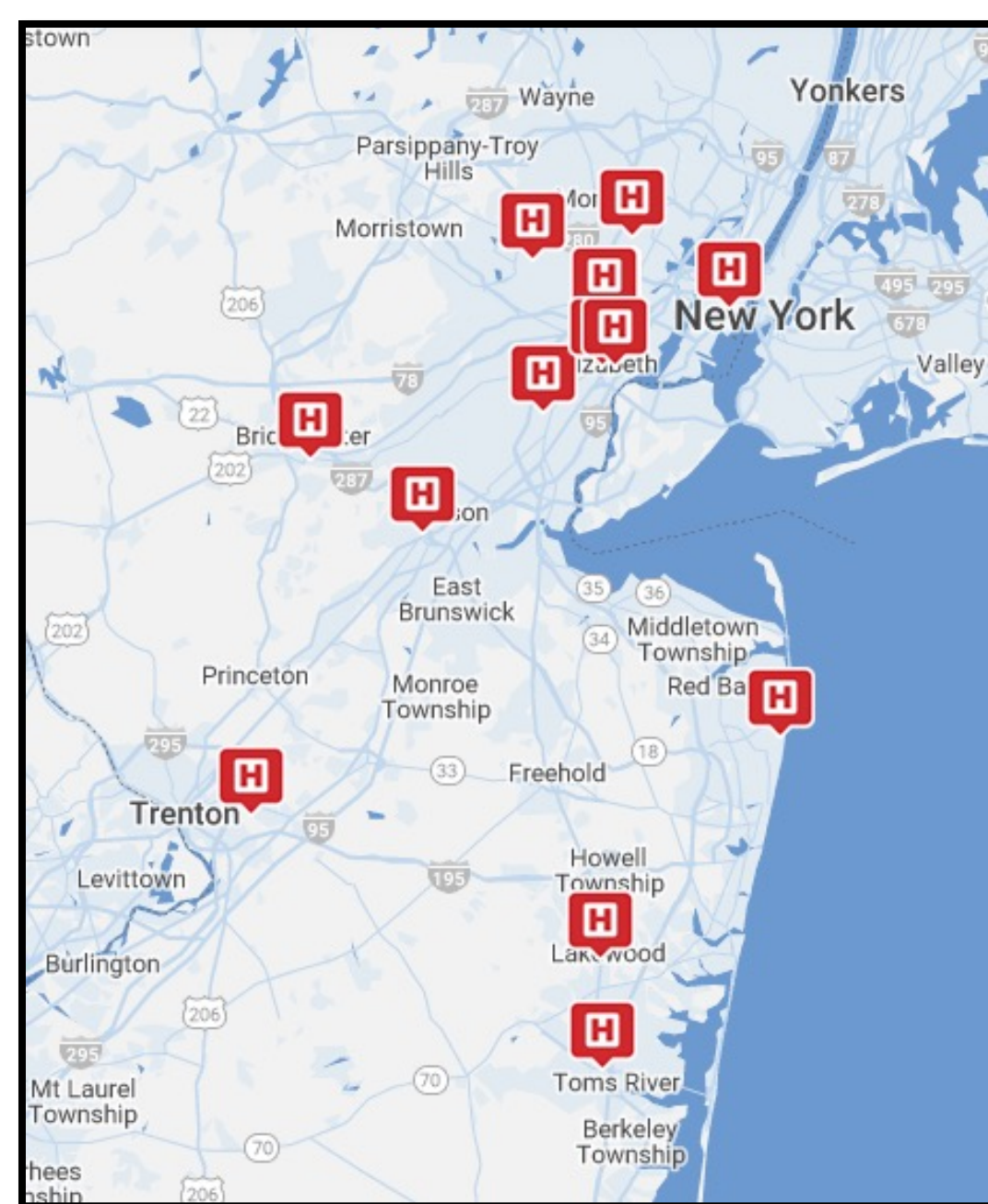


BACKGROUND

During the Covid-19 pandemic, the restrictions on external in-person visits presented a challenge because, per FDA requirements, sponsors require periodic external review of data, regulatory documentation, and drug accountability checks. Most importantly, in addition to routine monitoring visits, we wanted external audits to continue, since they are essential for assessing overall site performance standards and data quality.

GOALS & OBJECTIVES

To ensure adherence to FDA requirements, it was our goal to allow monitors/auditors to complete Source Data Verification (SDV) and review regulatory and pharmacy documentation remotely, for Rutgers Cancer Institute of New Jersey (RCINJ) and the state-wide academic health care system, from a single location.



SOLUTIONS & METHODS

Multifaceted approach to bridging the access gap. Key steps are listed below:

- Provision of remote Electronic Medical Record (EMR) and regulatory access to monitors/auditors by setting up EPIC-Carelink and Advarra e-Reg respectively, in collaboration with our informatics team.
- Microsoft TEAMS (CFR part 11 compliant) used for sharing additional paper-based documents not available in EPIC EMR system.
- TEAMS pages and channels created for each industry sponsor or cooperative group, and a folder organization with document naming convention in accordance with the rules for CFR part 11 compliance.
- Upon receiving patient lists for audits (4-6 weeks before visit), weekly audit-prep meetings scheduled to discuss data and source document upload status.
- The CINJ Quality Assurance (QA) group conducted an independent review of the patient cases.
- Monitors/auditors received EMR, TEAMS and regulatory access the day before the visit.
- Remote pharmacy visits held using Webex or Zoom to allow visual inspection via camera. Drug Administration Record Forms (DARFs) were uploaded to TEAMS.
- A single point person to liaise with the monitor/auditor via TEAMS messenger.
- The opening, close-out and PI meetings conducted via Webex or Zoom.



OUTCOMES

- The success of our remote monitoring/auditing program made it an ongoing practice despite the restrictions on in-person visits being lifted post Covid.
- Cutting down travel time to different partnering sites and having longer access to source beyond business hours, allows a comprehensive review of data, especially for studies monitored on a yearly basis.
- TEAMS continues to be our preferred mode of communication owing to its alert notifications every time there is activity on the messenger page, ensuring real-time remediation of issues raised by monitors/auditors.
- The availability of audit conversation transcripts in TEAMS makes the formulation of post-audit Corrective and Preventative Action plans (CAPA)s more efficient.
- We have conducted 30 audits and over 2300 monitoring visits since March 2020 that were either entirely remote or a hybrid consisting of in-person pharmacy visits.

LESSONS LEARNED AND FUTURE DIRECTIONS

Our initial success with remote monitoring and auditing, led us to implement EPIC EMR system across RCINJ and its academic health care systems, to ease patient access. We are also working on designating a single point person for data management across patients for all sites, to streamline study training and communication. We will continue to develop our onboarding and training programs for new staff based on monitoring/audit findings, as we continue with our collaborative ventures on an electronic platform and learn from our experience with our remote programs.

