Overview: The Clinical Trials Office of the Robert H. Lurie Comprehensive Cancer Center has recently rolled-out an e-Regulatory system. Applying observations and lessons learned from the initial phase of roll-out may help foster improved adoption in later phases of implementation.

**PROBLEM / KEY ISSUES**
- **Team Characteristics**: Small teams, heavy-users vs. large teams, light-users
- **Workflow Transformation**: Paper and server-based document management to cloud-based eRegulatory
- **Staff Engagement**: Orienting and onboarding the teams. Continued utilization and adoption

**GOALS**
- **Examine the Approach**: Roll-out process and its effect on initial adoption. Team-targeted training for early vs. late users
- **Measuring the Impact**: Understanding changes to workflows – quantitatively and qualitatively. Unique issues & challenges.
- **Ensuring Success**: Evaluate lessons learned early and monitor for continued utilisation and adoption

**METHOD**
- **Team Stratification**: Early users: Regulatory and IT teams. Late users: Start-up, Study Coordinators, Investigators, etc.
- **Roll-out Phases**
  - **Early phase**: more hands-on training.
  - **Late phase**: basic intro to system and demonstration.
  - **Ongoing phase**: 1:1 with Investigators.

**OUTCOME**
- As expected, non-regulatory teams have taken longer to adopt. Roll-out is an ongoing process to promote awareness and build confidence, understanding, and trust.
- **Metrics**
  - **User Logins**
  - **Documents Uploaded**
  - **Utilization of e-Signatures**

**FUTURE DIRECTIONS**
- Oftentimes with major changes the focus is on the decision-making and building in phases. Roll-out may seem like a seamless end to the process, but in looking back there have been some lessons learned:
  - Create team-based user groups before roll-out.
  - To achieve buy-in, take the time to understand current workflows of different teams and consider how to demonstrate benefit to them.
  - Consider incentivizing the rollout process with prizes for teams with largest compliance.
  - Apply these lessons learned to other similar transformational initiatives (e.g. new CTMS).
  - Plan ahead how and when to measure and track adoption using appropriate metrics – for instance at roll-out, 6, 12 and 24 months.