

GOING LIVE With an e-Regulatory System: Lessons learned in managing the change process during an e-Regulatory rollout at a Comprehensive Cancer Center



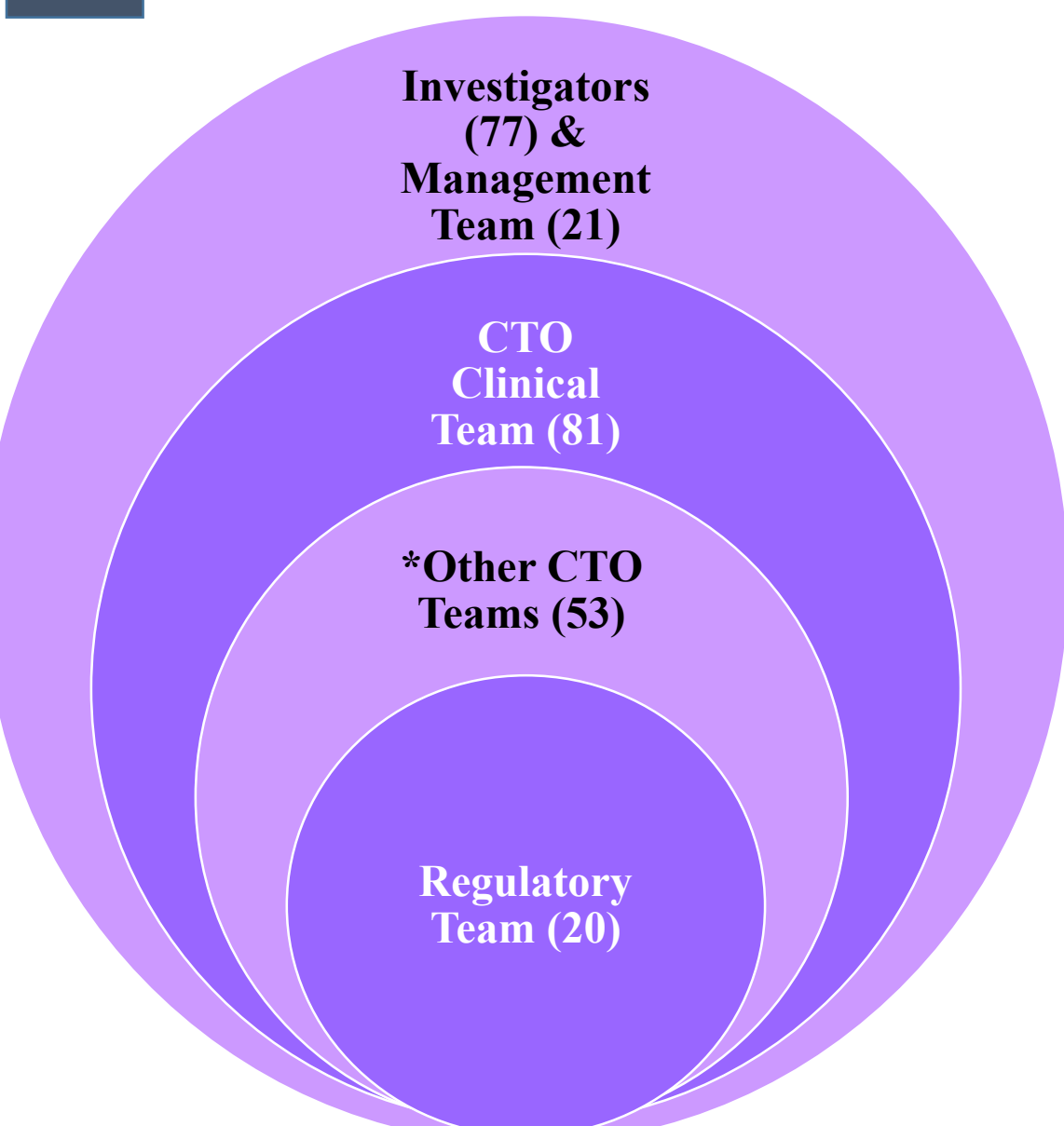
ROBERT H. LURIE
COMPREHENSIVE CANCER CENTER
OF NORTHWESTERN UNIVERSITY

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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



*Startup, PRMS, Finance, Pharmacy, Affiliate, Pathcore

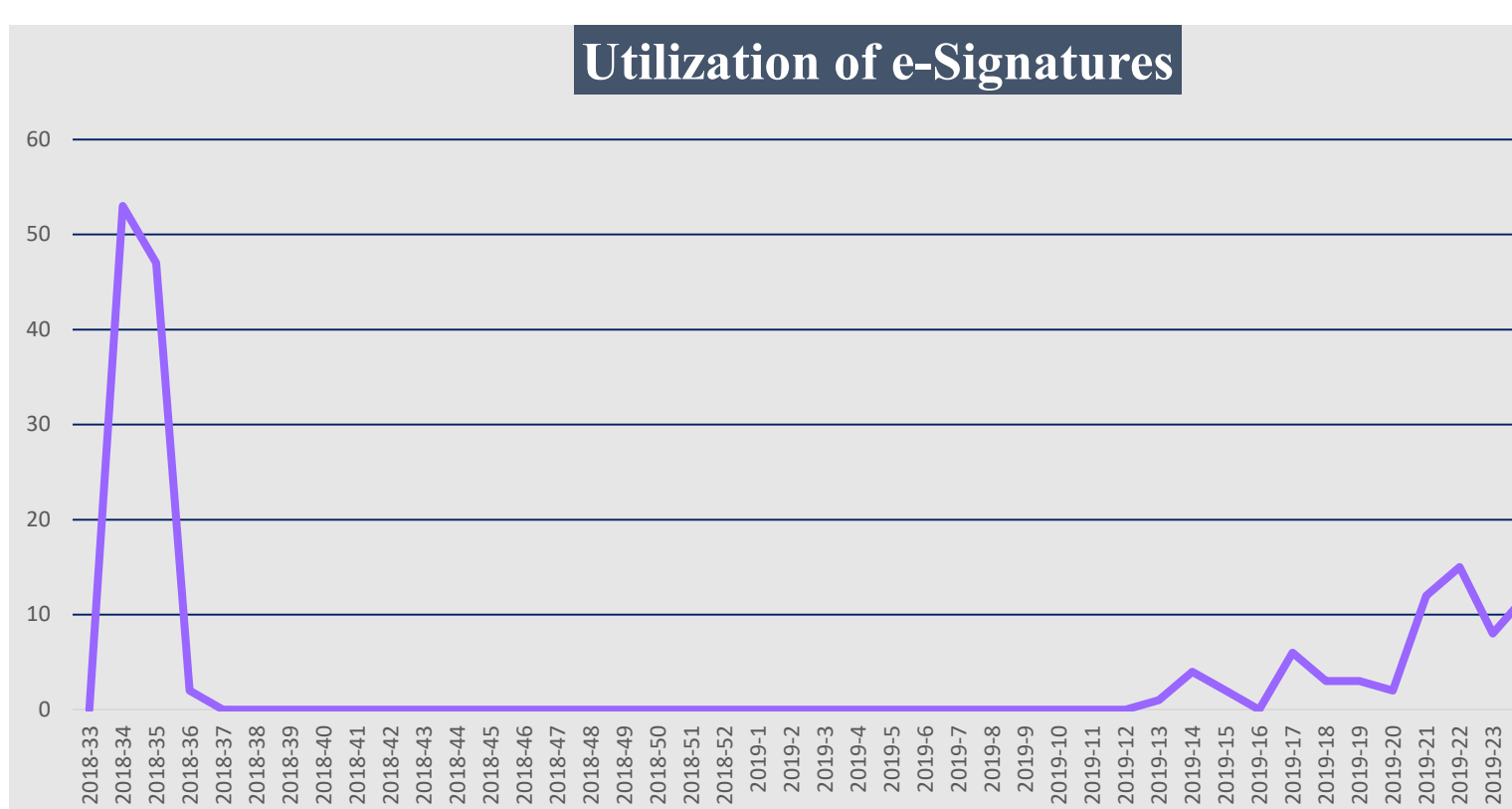
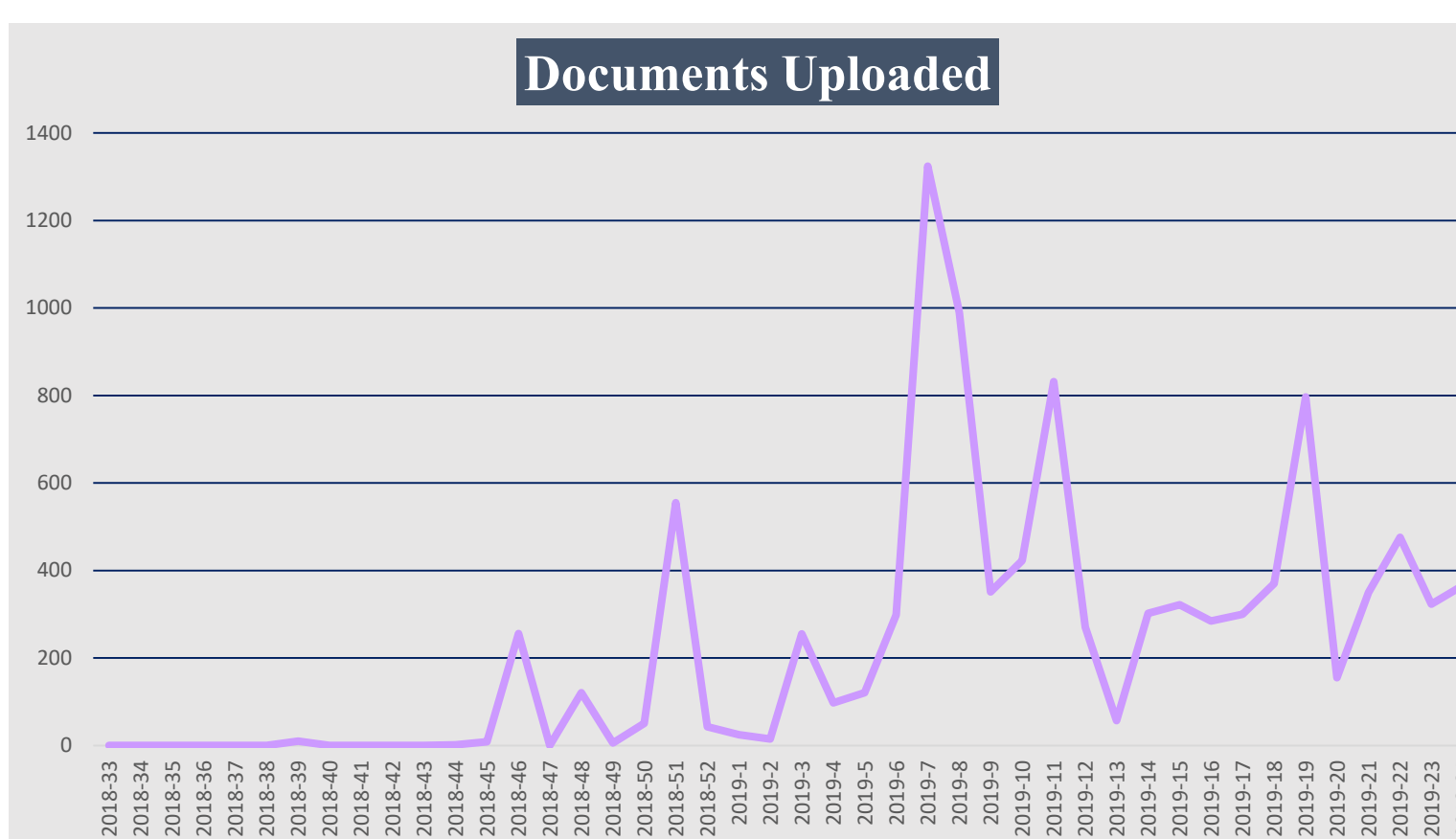
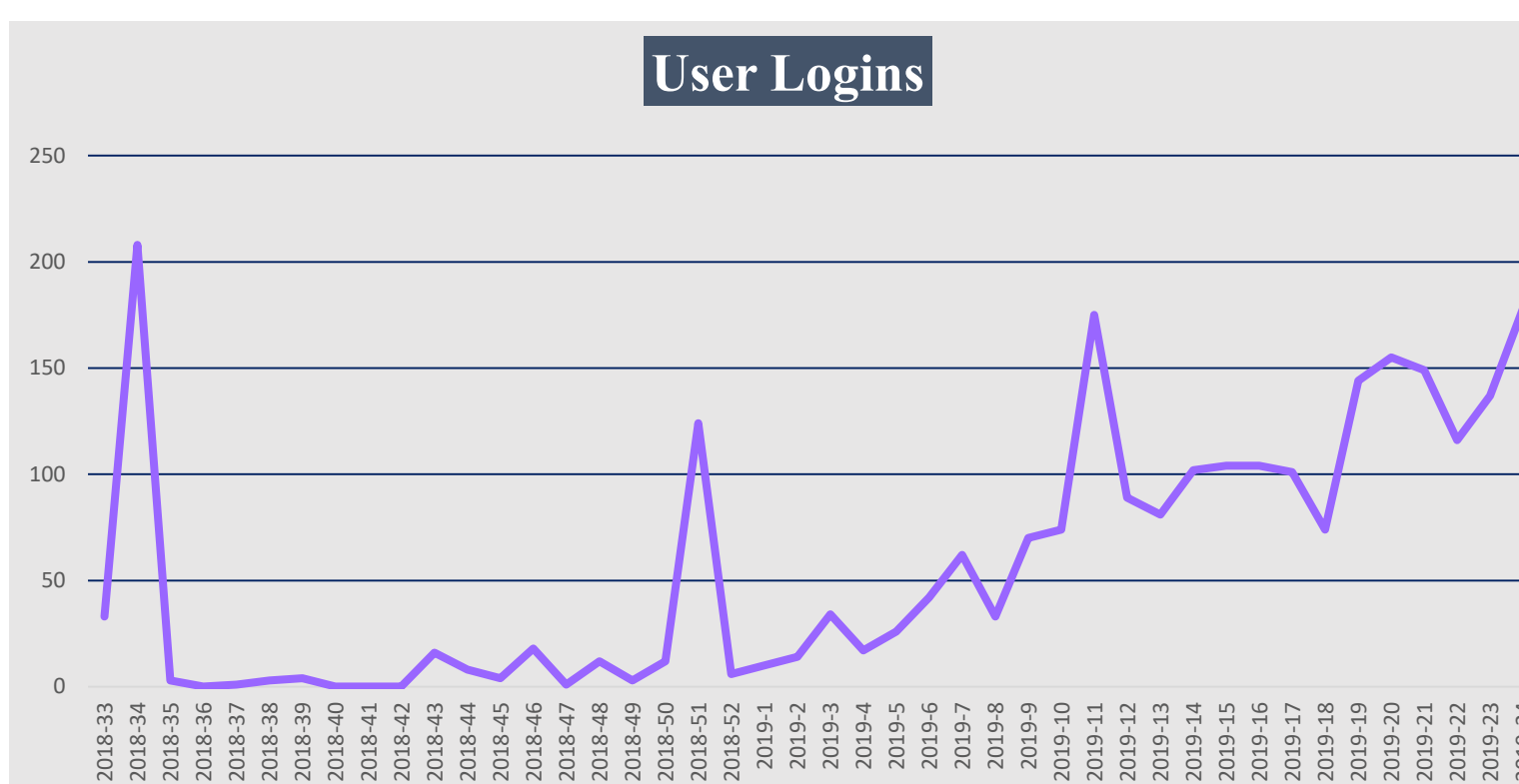
GOALS

- Examining the Approach**
Roll-out process and it's 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 and improved success at 6 and 12 months.



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

Effort

- 110 unique binders built
- Approx 1700 central binder documents filed
- 8 teams have started using the system

Outcome

- Improved IMVs, fewer questions
- Quicker turnaround times with signatures
- Decreased admin tasks associated with paper

Staff Survey Highlights (at 6 mos)

- Ease of **signing** and **approving** documents **electronically**.
- Centralized** and **well-organized version control**, eliminating confusion.
- Saved time** with less printing, scanning and shredding.
- Improved IMVs** – fewer interruptions to day.

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.

Comparative Team Size vs. System Input Effort

