

GOING LIVE with an e-Regulatory System: Lessons Learned in Managing the Change Process During an e-Regulatory Rollout at a Comprehensive Cancer Center

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1. Background

Deciding to implement an eRegulatory system is one thing, but figuring out how to actually ‘go live’ when the time comes should be a thoughtful, step-wise process, taking into consideration all the teams that will be affected in order to successfully manage the change and ultimately foster adoption of the new system. This poster seeks to explore the Lurie Cancer Center’s rollout of Complion, delving into how it was organized and when different teams were engaged in the process. Key issues:

- Size and structure of the teams
- Shifting workflows from a paper and server-based system to a compliant eRegulatory system
- Engaging the teams throughout the change

2. Goals

By exploring the rollout phase of switching to an eRegulatory system, we will share our experiences and lessons learned, especially as the first of several departments within the institution. The goal is to provide insight into how to approach similar transformational initiatives. Key considerations:

- *Talking about* the change vs. *going live* with it
- Impact of going-live on each team’s workflows – quantitatively and qualitatively
- Targeted training for individual teams – When and How
- Common issues and unique challenges for various teams

3. Solutions and Methods

Our approach stratified research staff involved in roll-out as early users (regulatory, IT) or late users (study coordinators, finance, etc). The actual rollout took place in two main phases; early users participated in longer, more hands-on training. Having the Complion team on-site to provide hands-on troubleshooting and offer real-time solutions was critical for successful rollout. Roll-out with the investigators is still underway.

4. Outcomes and Future Directions

Within the first four months of roll-out:

- 110 binders built
- Approximately 1700 central binder documents filed
- Average of 8 different teams using the system daily, including personnel outside our clinical trials office from 5 of the 14 disease teams

Category: Regulatory – Work in Progress

As expected, we encountered somewhat slower adaptation from non-regulatory teams, as well as some degree of recoiling from others despite involvement prior to rollout. It is an on-going process to promote awareness and build confidence and trust in using the system.

Oftentimes when major changes are undertaken, there is a heavy focus on the decision-making and building phases. Final roll-out may seem like a seamless end to the process, but in looking back there have been some lessons learned:

- Involve the finance team earlier in planning the timing of roll-out.
- Create team-based user groups before roll-out.
- Heavy focus on regulatory may deter other teams from feeling as invested. Balance pros/cons of having an executive administrative team in charge of the design process as this takes ownership away from teams themselves.
- In order to achieve buy-in from other departments (especially those you do not oversee), take the time to understand their current workflows so you can demonstrate benefit to them.
- Plan for when and how to do roll-out with investigators – not too soon and not too late.
- Consider incentivizing the rollout process with prizes for teams with largest compliance.