

Background

- Accurately adding staff to the Delegation of Task Log (DTL) and OnCore Clinical Trial Management System (CTMS), along with filing supporting credentials, is an important, and often time-consuming, task.
- Prior to 2022, Clinical Project Managers (PMs) emailed requests for Staff Additions (SAs) directly to the Regulatory Coordinators (RCs) assigned to the study. These requests were not standardized and often lacked complete information and credentials. This resulted in delays due to needed follow-up conducted by RCs.
- In 2022, the management of SAs shifted to a single Regulatory Staff Specialist who implemented a standardized Microsoft Word form, entitled the Staff Update Request Form (SURF).
- This form used a checklist to remind PMs to include supporting credentials in the submission packet.
- While this resulted in fewer incomplete submissions, credentials were still habitually omitted, and there was no clear way to delineate the differences between roles needed for OnCore and the DTLs.

Goals

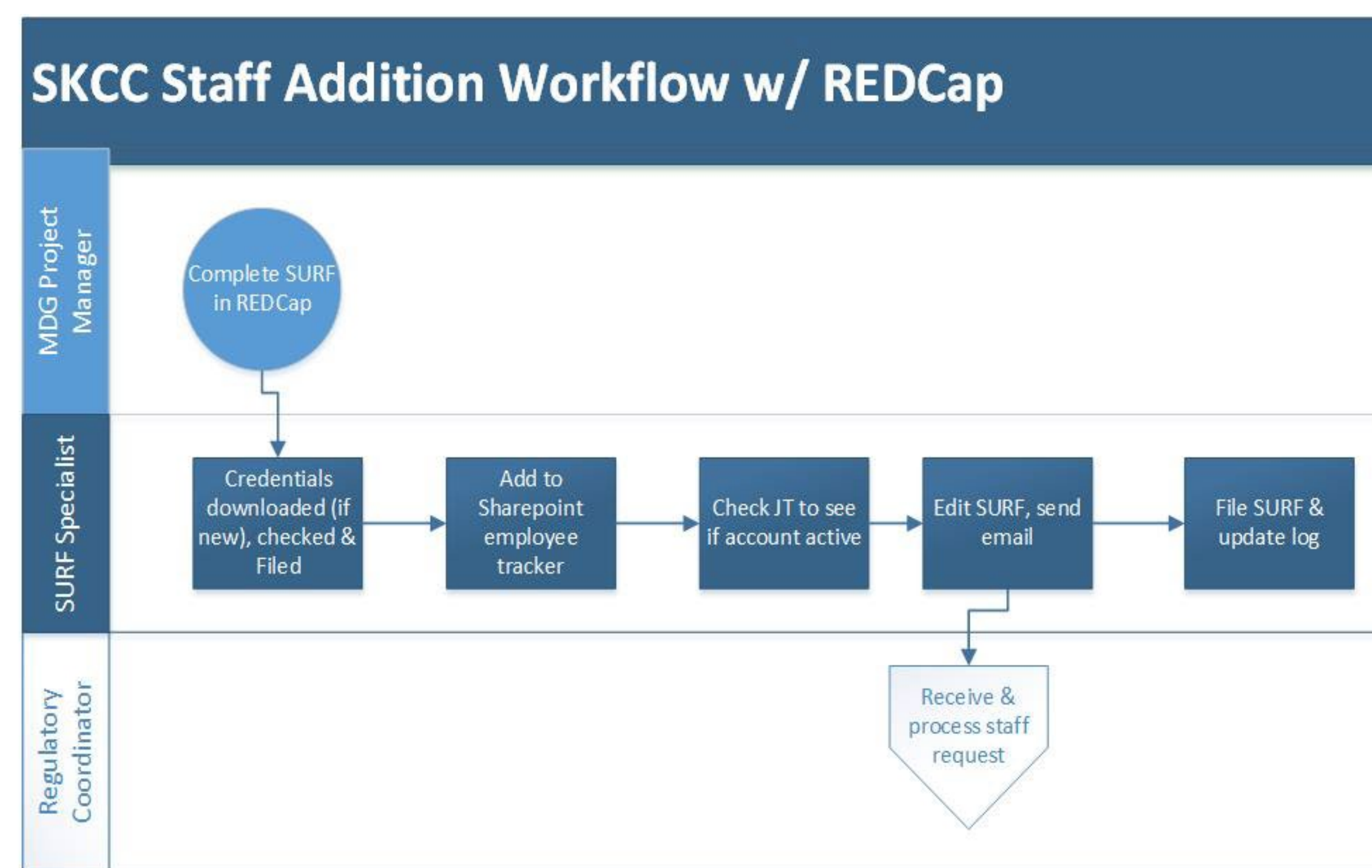
Regulatory Operations Leadership set out to **improve the SA process for both RCs and PMs by reducing the need for follow-up** by:

- (1) Ensuring the collection of credentials at time of SURF submission and
- (2) Reducing role confusion between OnCore and DTLs.

Solutions and Methods

- In 2023, an electronic SURF was created using REDCap, an electronic data capture system.
- Uploading credentials was mandatory for submission and prompted the user based on the role selected. For example, if a co-investigator is being added to a study, a request for a medical license appears.
- If “new to research” is checked, there is a prompt to upload CITI credentials. Using tools like dropdown menus and branching logic in REDCap, roles on studies were listed as prespecified options for both OnCore and DTLs.
- When the form is submitted, an email is automatically sent to the Regulatory Manager and the PM. A copy of the form is automatically stored in REDCap. PMs were consulted about the new design and seven were included in pilot testing.
- The electronic SURF was modified based on their feedback, a communication plan was developed, PMs were educated about the new SURF, and the process was implemented across all teams (Fig. 1).

Fig. 1



Outcomes

- The implementation of the electronic SURF has **reduced the administrative burden on RCs**.
- Since the electronic SURF was implemented, **supporting credentials were included 100% of the time**, reducing the need for follow-up emails and thereby increasing efficiency.
- PMs were also surveyed for feedback about the electronic SURF process, and **89% of PMs reported this saved them time**, primarily through having predefined fields to click on, making the completion of the form faster.

Future Directions

- Regulatory Operations Leadership learned the importance of including various stakeholders in the creation of the new process, including having PMs user test the form for additional feedback and buy-in.
- Using electronic data capture systems like REDCap to improve regulatory processes proved successful, and this will be implemented in process improvement moving forward.

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