

## Background

The Clinical Trials Office (CTO) is challenged to recruit, hire and retain experienced Clinical Research Coordinators (CRC) to the University of Kansas Cancer Center. The ongoing demand for CRCs did not slow during the COVID-19 pandemic and the need to fill vacant positions continues.

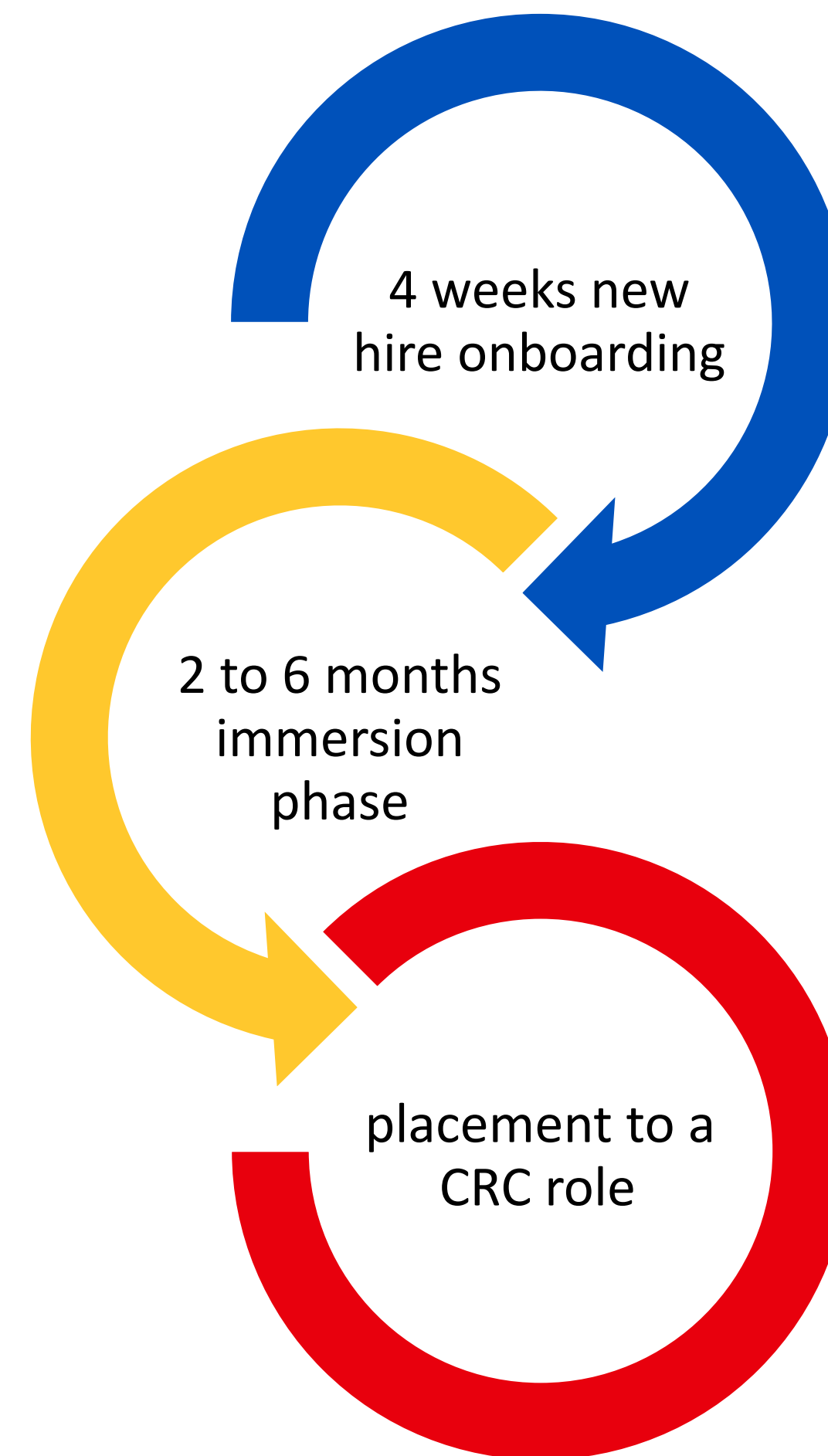
## Goals

Due to the ongoing demand for experienced CRCs the Clinical Operations team, Training Department and Human Resources leadership proactively implemented a program to develop candidates to fill open CRC positions. The goal is to hire individuals with little or no research experience as a Clinical Research Assistant (CRA) with a focus to train and provide cancer center research experience for a period of 6 months to 1 year with a plan to place them into a permanent CRC role.

## Solutions and Methods

- CTO leadership collaborated with HR to determine the number of CRA positions and develop the job description. Maximum of 3 CRA positions based on open positions.
- A Project Manager was hired to develop the CRA training curriculum and program and manage all CRAs during the training phase.
- The CTO training team onboards each CRA following the CRC training competency to ensure all new hires have the same baseline knowledge
- The CRA and Program Manager meet weekly for consent lab to practice how to consent, review documentation criteria and discuss methods to improve consenting style and efficiency. This role playing is conducted as if the CRA is consenting an actual participant using actual consents from a variety of disease, trial types and complexity levels
- Improvisation activities are practiced to prepare for the CRC role. These include:
  - ✓ How to effectively communicate with providers and sponsors, correction of errors, Good Clinical Practice documentation, completion of pill counts, drug diary preparation, and administration of quality-of-life questionnaires
- 4-week immersion training is rotated with a CRC from different disease working groups.

## Lifecycle of Training



## Immersion Phase Focused Activities



Informed consent process through enrollment



Observe scheduling, adverse event collection and serious adverse event submission, & drug accountability



Off study procedures and follow-up

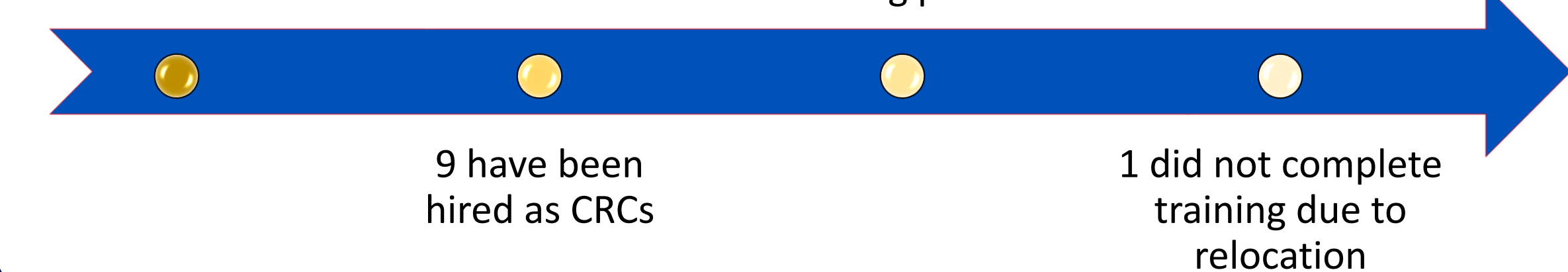
## Lessons Learned

- Initially the CRA was to complete their onboarding period, followed by an announcement to all staff of the new CRAs availability to shadow and assist CRCs and it was anticipated that CRCs would utilize the CRA for support and knowledge sharing. The need for focused immersion training was determined as the CRAs were not being called upon for actual coordination duties, rather only to complete administrative tasks such as redacting documents and sorting paperwork.
- The CRA Program Manager developed the 4-week immersion plan with an effort for all teams to mentor the learning of all CRC responsibilities. The immersion phase is a success as it creates a working bond with staff members, develops training and leadership skills for current CRCs and ensures the CRAs real time clinic exposure and trial coordination experience with actual CRCs.
- Daily check ins, bi-weekly one on one meetings, and administration of stay questions by the program manager allows the CRA to confirm their learning and request more training. This creates the opportunity to customize the training, or to provide the CRA additional training to reinforce their competency and escalate placement to a CRC position.
- The prediction of each CRAs success is subjective and continual open-ended questions and mentorship by many team members can assist in the successful, long-term placement of a CRA to the CRC role.
- Continuation of the CRA program is successful through consistent and frequent adjustment of the program to improve the experience through hands on learning.

## Outcomes

13 CRAs have been hired and trained

3 are pending completion of training period



## Future Directions

- Expand CRA immersion training to our various remote community sites for exposure to those locations.
- Develop a CRA program within other departments such as regulatory and data management.