

## Implementing a credentialing program to support pharmacy clinical trial competency in hospitals around Victoria

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### Background

Patients living in rural and remote areas have a willingness to participate in Clinical Trials (CT), however travelling to metropolitan hospitals to access trials has been reported as one of the main barriers to participation.<sup>1</sup>

Lack of pharmacy expertise to successfully manage CTs at regional hospitals can prevent the introduction of a CT service.

In order to expand CT capacity at regional sites, Alfred Health (AH), a large metropolitan hospital, which currently manages 300+ CTs, established a partnership with rural and regional hospitals to upskill pharmacists on the management of CTs. Creating an educational program requires a fine balance of incorporating expertise and valuable content, with structure and methods that engages learners and meets the needs of all types of learners. The construction and management of a credentialing program should be developed using key education principles for development and competency assessments.<sup>2,3,4</sup>

### Objective

To describe the development of a structured credentialing program for pharmacists and pharmacy sites in CT services.

### Method

The training and credentialing program was designed using evidence-based teaching methodology grounded in adult learning theory. Competency assessment criteria were established deductively from existing CT guidelines and refined via an iterative process by an expert CT pharmacy team (n=7). A prototype of the program was validated following completion by pharmacists new to CTs (n=2). The credentialing program utilises three learning principles: *Active Learning*, *Cognitive Apprenticeship* and *Communities of Practice* (see Figure 1).<sup>(2,3,4)</sup>

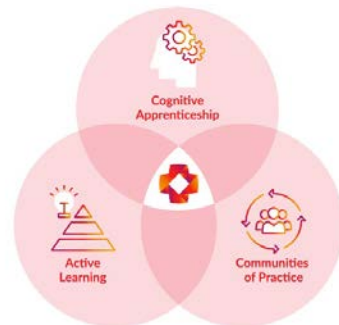


Figure 1. Alfred Health Learning Principles

**Active Learning:** Step-wise process of learning, from **knowledge activities** to final application of patient care.

**Cognitive Apprenticeship:** Encouraging critical thinking and reasoning by making the **thinking processes** of experts visible and providing **structured training**.

**Communities of practice:** Learning *from* and *with* others in a community of practice to establish **life-long learning**.

The program consists of three streams of credentialing (see Figure 2):

**1. Site credentialing:** the Alfred Health Clinical Trials expert and Pharmacy Education expert visit the site and conduct an initial site report. This report consists of observations and associated recommendations on best practice. Once the credentialing site has reviewed and implemented changes, based on the recommendations made, a follow up site visit facilitates full site credentialing.



Figure 2. Clinical Trials program credentialing streams.

### Method

**2. Pharmacist credentialing:** learning and competency are achieved using tools for *Activation*, *Exploration* and *Application* of knowledge (see Figure 3). The learners *activate* their knowledge by going through online eLearning content that sets clear learning objective and provides information through preparatory tasks with follow up knowledge activation questions. Learners then *explore* concepts of what they have already learnt through a structured on-site observation, with one-on-one coaching with feedback. *Application* of their knowledge and skills is then assessed through a final face-to-face Observed Structured Clinical Examination (OSCE).

**3. Trial Credentialing:** the final stage of credentialing. When a new trial is initiated, the Alfred Health CT expert reviews the site and pharmacist competencies, tailoring the assessment for management of the new trial.

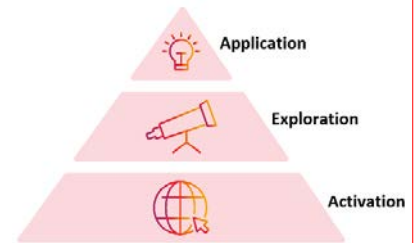


Figure 3: Three stages of learning and competency

### Evaluation

The training program was launched 2021 with three major regional hospitals and 10 regional site pharmacists participated in the credentialing program.

In the pharmacy site credentialing, an initial site visit was performed to assess current candidate site competency. Following implementation of recommended changes, a final site visit assessment was performed to establish provisional competency.

In the pharmacist credentialing, participants completed preparatory self-directed online learning and knowledge assessments. This was followed by experiential onsite training at the Alfred Health pharmacy CT department, during which a participant's provisional competency was assessed using a validated assessment tool and an observed structured clinical examination.

Following site and pharmacist credentialing, credentialing for individual CTs is undertaken. The candidate site notifies the Alfred Health about initiation of a new CT. The trial set-up and delivery is assessed to establish the candidate sites competency to independently manage the trial.

Feedback on the credentialing processes from sites and pharmacists who have undergone the program was received via an anonymous survey. All feedback was very positive. Pharmacists reported that their skills and knowledge in CT practice had improved and their professional network in CTs has expanded through completing the program.

### Discussion

Partnering with practicing pharmacist experts, with more established CT services, is a great way to increase capacity of CT services around Australia. Rural and regional sites wishing to progress CT pharmacy services should consider the adoption of this formalised credentialing program. Other sites wishing to expand and upskill their CT service could also consider participating in the CT pharmacy credentialing program.

### References

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