ACT Government Health

ACT HEALTH VACATION STUDY PROGRAM

PROJECT SUMMARY

Project Title	**Simulation modelling to identify interventions to optimise clinical trials start-up times: a systems dynamics approach.**
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Lead discipline (please select one)	
☐ **Nursing**	☐ **Health Economics**
☐ **Allied Health**	☐ **Biostatistics**
☐ **Medicine**	**X Value-based Healthcare**
☐ **Pre-clinical**	☐ **Epidemiology**

Outline of the project

Start-up times for clinical trials at the Canberra Hospital are sub-optimal, with the current times being highly variable and generally taking longer than the *best-in-industry* standard. Hence, the Clinical Trials Unit wishes to apply systems dynamics thinking and system engineering techniques to determine systemic barriers to optimal start-up times and how to effectively intervene to overcome these barriers.

Proposed research methods

The Clinical Trials Unit has undertaken detailed process mapping of the clinical trials activities with the aim of identifying opportunities for optimization of start-up times. This project will build on the value-stream semi-quantitative models that have been created by the Clinical Trials Unit (Figure 1) by introducing computer simulation with the aim of optimising the clinical trials start-up process.

This action research project will use a system dynamics approach to identify high impact leverage points, and create a robust clinical trials model for the purpose of system optimization; commencing with the outcome of clinical trials start-up times. The required activities to address the project aims will include mapping of the clinical trials non-linear system using multiple causal feedback loops created through consultation with stakeholders (Figure 2); identification of systemic leverage points that can positively influence the trials start-up times; and creation of a simulation model for the purposes of identifying methods of system optimization. By mapping the non-linear system in detail *a priori*, potential limits or 'unintended consequences' of proposed interventions can be identified and potentially managed proactively during the post-project implementation.

Key	Heading	User	Process	Value adding Activity	Required Activity	Non-Value Adding Activity
Meaning	This is what the data is referring to.	This is stakeholder involved in the activitity	This relates to the different 'stages' in the process maps. Note that each process can have multiple activities associated to them	This relates to a step in the process that contributes to achieving customer requirements	This relates to a step in the process required by the business but does not contribute to achirving customer requirements	This relates to a step in the process that takes time or resources but does not contribute to achiving customer requirements (aka Wastes)

Process	Operations Manager					Co-ordinator					Principal Investigator				
	Activity	Notes	Duration (DAYS) MIN	MAX	AVERAGE	Activity	Notes	Duration (DAYS) MIN	MAX	AVERAGE	Activity	Notes	Duration (DAYS) MIN	MAX	AVERAGE
Sponsor contacts CHS CTU (0.0174,1.045,1.014)	Receive initial proposal from Sponsor		0.010417	1	1										
	Review initial proposal from Sponsor		0.003472	0.041666667	0.010417										
	Create folder in Email inbox regarding initial proposal		0.003472	0.003472	0.003472										
Refer to start-up Specialist / Co-ordinator (1,10,56)	Email co-ordinator and PIs to express interest		0.003472	1	1										
	Wait for response from coordinators/Pis		0.045139	7	49	Receive initial proposal from sponsor		0.010417	1	1	Receive initial proposal from sponsor		0.010417	7	49
						Review proposal from sponsor		0.041667	0.041666667	0.010417	Review proposal from sponsor		0.041667	0.04166667	0.010417
						Send email to express interest in study		0.003472	0.003472	0.003472	Send email to express interest in study		0.003472	0.003472	0.003472
	Collate EOIs from coordinators and Pis		0.003472	0.003472	0.003472										
	Send email to sponsor to request CDA and more information		0.003472	0.020833	0.04166667	Wait for more information from Op Manager		1.006944	2.024305	6.04513867	Wait for more information from Op Manager		1.006944	2.024305	6.045139
	Wait for more information from sponsor		1	2	6										

INITIATION
STAGE 1
STAGE 2
START UP

Figure 1: Clinical Trials Unit Value-Stream Mapping Exercise

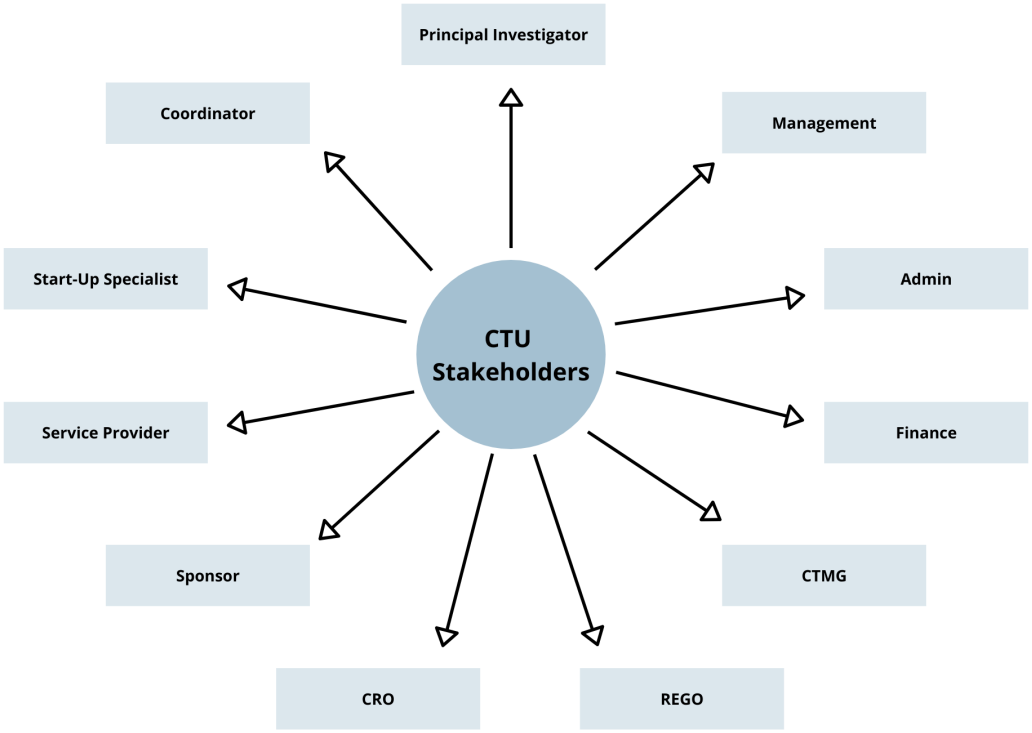

Figure 2: Clinical Trials Unit Stakeholders

Preferred study discipline being undertaken by the student

Systems Engineering in Healthcare

Potential benefits to the student and to the department

Although the benefits of using systems engineering techniques to improve quality of care and promote value-based healthcare are intuitively apparent, cross-sector collaborations between the two disciplines are rare and often not sustained in an extremely complex adaptive healthcare system. Because healthcare service delivery in clinical trials is largely protocol-driven, much of the complexity related to clinical decision-making is minimised, providing a unique opportunity for cross-sector collaboration between the Clinical Trials Unit and Systems Engineering.

Benefits to the student:

1. Gain experience to use system engineering techniques for the provision of value-based healthcare;
2. Increase skills in cross-sector collaborative action research;
3. Increase skills in simulation modelling and interpretation of outcomes;
4. Increase skills in preparing a manuscript for publication;
5. Co-authorship on a peer-reviewed publication.

Benefits to the department:

1. By increasing the efficiency of clinical trials conduct, we will increase the value of the clinical trials unit service to the organisation;
2. Improvement of start-up times will provide a competitive advantage for researchers in Canberra Health Services to successfully
    a. secure participation in highly sought-after industry-sponsored trials, which provide patient access to investigational products that improve quality of life and potentially a cure for diseases that is not currently available;
    b. complete investigator-led and collaborative trials within the timelines outlined *a priori* in the study grant.

Department within ACT Health Directorate / Canberra Health Services where the student will be based

Clinical Trials Unit

Please submit form to preclinical.research@act.gov.au