**These questions were collated during a webinar, for more information, please access:**

VCCC teletrials toolkit: <https://www.viccompcancerctr.org/what-we-do/clinical-trials-expansion/teletrials/resources/>

VCCC Online Education Module: <https://www.viccompcancerctr.org/what-we-do/clinical-trials-expansion/teletrials/online-modules/>

COSA guidelines: <https://www.cosa.org.au/media/332325/cosa-teletrial-model-final-19sep16.pdf>

**What supports are provided to patients/families to get them up to speed on engaging with this medium? Whose responsibility does that fall to? Primary or satellite site?**

Both primary and satellite site responsible for providing information and support to patient. Ideally patient should go to nearest cancer centre or GP practice which facilitates the call.

In our experience the patients and satellite sites are enthusiastic in supporting this model and education the patient/carers.

**Our site in Canberra has the potential to be both a satellite site and primary site. What extra pressures and additional resourcing would be expected?**

Like any new process/model there is a learning curve. Just as you probably had experience in doing more telehealth consultations recently this is the same but doing trial related consultations/procedures. Administrative support is required but this can be done through your clinical trials team (who would receive trial specific payments according to the study agreement). Extra FTE for research nurses is ideal especially at outset. Extra patients recruited should also bring extra revenue to the trials unit.

**How do you plan to address the issues around blinding procedures for IMPs in a teletrial model? This will be particularly important when it comes to temperature monitoring and deviations.**

Blinding procedures are carried out through normal trial practices. Drug storage, dispensing, administration and accountability can occur at the remote site. Medicines Australia suggests shipping drug for storage at remote site. Temperature monitoring is no different to normal procedures.

**The Primary site receives Ethics Approval - is Ethics Approval also required at Satellite sites?**

Yes, as per normal Good Clinical Practice. The VCCC Teletrials Program hopes to collaborate with others to streamline these processes.

**Sabe, you and Ian have mentioned Phase 1 trials - is teletrials limited to Phase 1 (comparative effectiveness?) trials only -Phase 2 and 3 not currently included?**

Initially we thought it would be easier to focus on phase 2 and 3 trials while set up the system and to get the buy in. Most of the pilot 10 trials before COVID have been phase 3. but now the first phase 1 has been done, thus opening up the opportunity for all types of trials.

**Comment: Teletrials will definitely improve recruitment**

Yes, the recent experience in Victoria has been really positive with 3 trials open across 7 sites. A fourth trial to open this month and more in start-up. Some trials are metro to regional, regional to regional, regional to outreach site and recently Metro-metro interstate. More than 50 patients recruited across the 3 trials to date. Our baseline was only 100 patients in regional Victoria recruited to oncology trials in regional Victoria in 2017.

**How are satellite sites identified? Are they chosen in advance or only once an eligible patient from that specific area is enrolled?**

Satellite sites can be identified in advance through normal processes.

The VCCC teletrials program wants to developed streamlined cost-effective processes for rapid addition of new sites as patients identified. Eventually we hope to see state-wide or national trials whereby any appropriately credentialled sites can join as they identify a patient.

**If a site is FDA audited, will it be the PI and primary site that will be responsible for all documentation/compliance of the satellite site? If so, will there need to be a joint electronic medical record for monitoring?**

Yes, both sites could be audited. Responsibilities are covered in the site supervision plan.

Joint EMR is not required, most source data are collected at the central site. Source data collected at the satellite site can be de-identified and sent to the primary site much in the same way that cooperative groups now remotely monitor all sites. In theory remote monitoring may be cheaper and easier for trial sponsors.

**Thank you for a great presentation. Do you envisage any need for supportive care interventions for tele-trials participants? If so, how would you see these being assessed and met in regional areas?**

Thank you! Depending on the complexity of the intervention, teletrials are an ideal model to conduct supportive care trials.

**How do the technical issues such as we are experiencing now, impact on the ability to deliver Telehealth services to regional & remote Australians?**

One on one consultations are easier than webinars with 160+ participants!

Technical issues can be a problem at times and we continue to advocate for improvements. Tools now exists for supporting patients and administrative staff to setup telehealth consultations. Some patients do not have access to internet. Ideally patients should attend for consultations at the satellite site where calls can be facilitated.

**Does Kathleen feel there are rural / remote patients that decline trial participation based on the barriers she mentioned earlier (financial / isolation / mental health)?**

Whilst I do not have documented evidence with regards to this answer, after talking to other consumers and patients this is the case due to the cost and time away from family, friends and community. Also there is the possibility that it is all too hard for the patient and clinician.

We improve on treatment for cancer all the time, why not improve on delivery of treatment.

Research in Townsville and New Castle showed that if trials are offered closer to home, most patients will take part in it. Travel and cost of travel act as barriers in these studies.

**For staff training at the satellite sites, what is the realistic time-frame before capable of participating? How much is the primary site involved in this process?**

It depends on existing capabilities. Even the phase 1 between Alfred and Tasmania took only 4 weeks to get up and running. The training required is not onerous. The newly released VCCC teletrials toolkit has more information. For a specific protocol staff can participate in protocol specific training and start-up meeting by telehealth dialling into the primary site or a start-up meeting can be held at the primary site.

**Does the VCCC offer GCP training for regional sites in Victoria?**

GCP training is often available online through a contract research organization (CRO) or other training agencies. The VCCC does not offer GCP training. Regional sites can submit an EOI for financial support for training for regional Clinical Trial Units. For regional support enquiries please contact Chris Packer, Clinical Trials Workforce Manager, chris.packer@unimelb.edu.au.

**Statistics show that patients on trial do substantially better than someone not on trial, possibly due to increased screening, following-up and support. Do you think changing to the teletrial model may affect the amount of support provided to clinical trial participants by their research team?**

No, support still provided by telehealth. This model will allow more regional and remote patients to have access to the same level of support.

**What process are in place to protect patient privacy given that the data will be collected at multiple sites?**

The same processes are in place as to that provided by routine care.

**Hi all, in situations where investigational drug is being delivered at a satellite site, what is the advantage for sponsor to go this way rather than just setting up that site as a site in its own right? Just trying to pre-empt arguments from sponsors**

The main difference between a multi-site trial and a telehealth trial in this circumstance is that the patient is still recruited, consented, screened and has consults with the PI or CI at the primary site but the treatment is dispensed/administered at the satellite site, saving the patient many hours of travel. This is an ideal model for rare cancers. Common cancers can still be managed under usual multisite model. It may be that Teletrials are more cost efficient than opening multiple sites, but we are currently examining the costs associated to look at that.

**I am familiar with the teletrial model but not as much with telehealth. Are there site standardised processes for implementing telehealth in clinical trials (e.g. how remote consent should be performed and captured in a clinical trial, remote pt safety visits et).**

Yes, please refer to COSA Teletrials guidelines and VCCC toolkit. SOPs are in place to cover procedures done via teletrials model.

**Further information**

Please send any further questions to VCCC Teletrials Program Manager, Hannah Cross, hannah.cross@unimelb.edu.au

The VCCC Teletrials Program is supported by the Victorian Government.

