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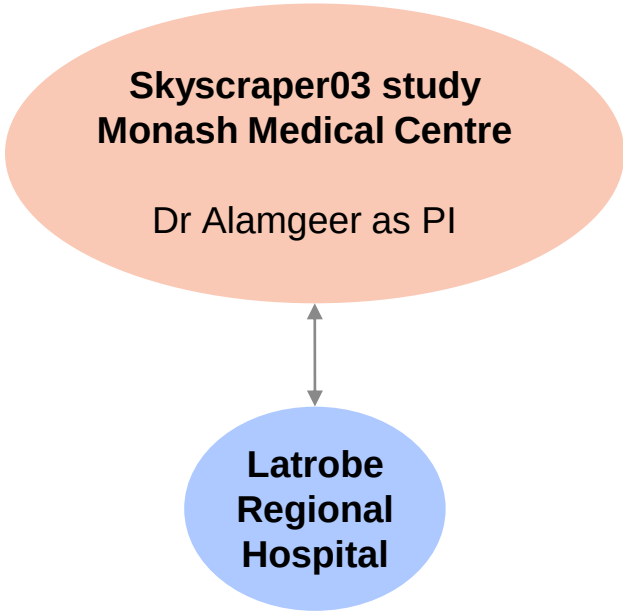
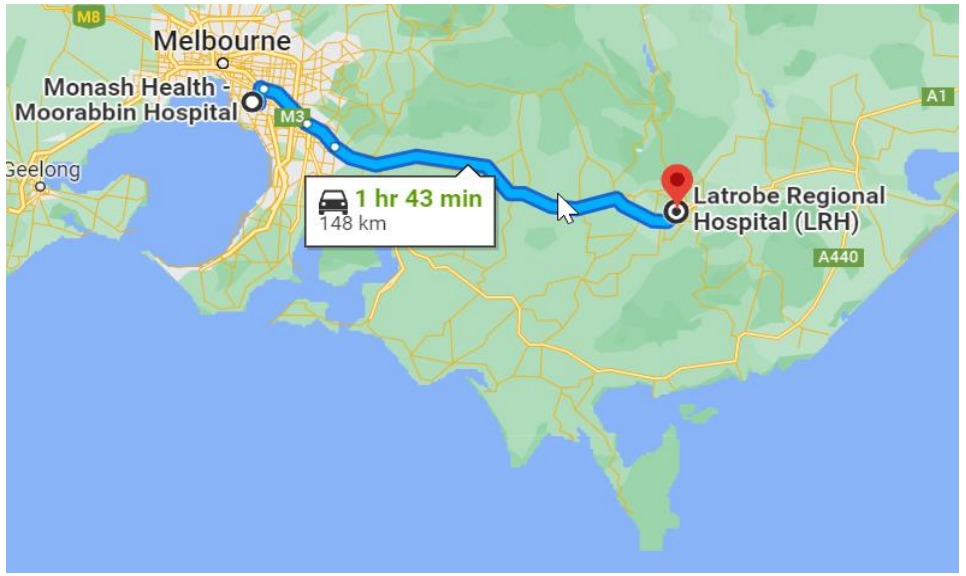
Why do we invest in teletrials at Roche *

- Improve diversity and inclusion in clinical trials
- Increasing access to new, innovative and life changing treatments to more patients
- Improve sustainability by bringing new business to the region
- Equal access to the best available treatment plan for all Australian patients
- Increase patient enrolment numbers

Case Study: Roche's first Victorian teletrial site

- **Skyscraper03 - NSCLC study**
  - Monash Health as primary site
  - Teletrial site: Latrobe Regional Hospital (LRH) –
  - Started discussions Oct 2021
  - LRH activated end July 2022
  - Study recruitment ended Nov 2022, no patients enrolled
- **Growth potential**
  - LRH now established with Roche, and has been selected as an independent site for a non-interventional study.
  - Potential to be selected as teletrial site in future
  - LRH can become independent site and have their own teletrial/ satellite sites.





Case study: Learnings on setting up a teletrials site

- Information on site capabilities and equipment is essential
  - Can the site run a clinical trial?
  - Site CV is important and saves time

- Collaboration between primary, teletrial sites and sponsor was beneficial
  - Completed the supervision plan together
  - Operation challenges could be addressed upfront (e.g. central lab kits shipped directly to teletrial site)

- Good communication/ relationship between sites is critical, not only during start up but also during the run of the study. Encourage the study coordinators across the sites to get to know each other in person if possible.

- Fit for purpose approach is needed for each study.

Case study: Positive outcomes

- New and flourishing relationship between Roche and LRH
- Site staff's exposure to setting up an oncology study
- Site staff (SCs) realised that they needed more training on theory and everyday running of a study. Able to access this training with Trialhub training facilities
- LRH can now operate as an independent site for a non-interventional Roche study.

Case study: Challenges and areas of improvement

Long timelines to teletrial site activation is the biggest challenge.

- Australia has a smaller and lower density population, therefore lower recruitment numbers
- Australian sites need to start up faster than other countries to maximise recruitment period

Potential ways to improve start up timelines:

- Identify primary sites per disease areas
- Set up template supervision plans
- Set up draft sub-contracts/ set expected payments

Share what your RGO's expects with the initial submission?

How to make teletrials attractive to a Sponsor*

The Sponsor has a duty of care to patients to ensure that the site is qualified and are confident the site can safety care for the patient on the trial and adhere to the protocol.

Teletrial site's need to get set up quickly and standard operations questions need to be addressed early so these don't cause delays.

- Pre- approved cost with departments and main site
- Sharing partnerships/connections to main or satellite sites per disease area (participating vs. teletrials)
- CTRA Sub-clauses; are these pre-approved by your legal teams and your main partner sites
- Facilities
  - ❖ Is there a room to do clinical trials
  - ❖ Is there knowledge of what standard equipment is needed and is it available at site
  - ❖ Theoretical knowledge of clinical trials*
  - ❖ Documentation of what training has been completed, beyond ICH GCP

Theoretical knowledge of clinical trials*

- Source notes (ALCOA)
- Quality and protocol compliance
- Data entry into an eCRF
- Safety reporting (SAEs/SUSARS)
- ICF best practices (contents and process)
- EC/ RGO requirements
- MA CTRA; understanding everyone's responsibility in the standard clauses
- IATA certificate
- Essential document and ISF
- Cost/Budget/Excel
- Study designs (blinded/unblended, multi-cohorts, washout periods, randomisation
- Continued eligibility and subject retention strategies
- Legal responsibilities
- Professionalism in communication
- Pharmacy accountability and IMP documentation
- IWRS and treatment assignment
- Temperature monitoring
- Audits

Training for clinical trial naive site/ department

- Traditional F2F training (mentoring) is not available in regional areas. What are the other options?
- What training on theory of clinical trial conduct is available?
- What training material is available to refer to when needed?
- Is the training consistent for all sites within each state and possible across the states?
- Will the ATP advise on where they can receive general clinical trial training?
- Can experienced sites share how they train new study coordinators.
- Have the regional sites compared their site to an established site?

Outstanding Sponsor questions for HREC/RGO *

- Will RGOs consider a pre-review of a draft supervision plan?
- Is there confidence for all RGOs to review a supervision plan? Is there sufficient education and training on the topic available to all RGOs? Is this national or local training?
- Are there plans for a consistent approach of the review process for HREC and RGOs in Victoria and nationally?
- Will there be a standard HRECs and RGO checklist with the same requirements?
- Can all items be listed in one supervision plan?
  - Evidence the satellite site Research Governance Office has been notified of the pending submission
  - Evidence the Principal Investigator (primary site) has endorsed the conduct of tele-trials at the satellite site
- Rationale RGO review of the following:
  - Master Supervision plan
  - Delegation log?

Outstanding Sponsor questions for HREC/RGO *

- How do we handle the ICF process where a patient is treated at 2 locations. Are they expected to sign the ICF form twice? How will this be recorded or Sponsor system (CTMS/eCRF)? What is the patient burden?
- Do they require separate teletrial ICF or just a section in main ICFs referring to teletrials?
- Would RGO or HREC be open to Sponsor's feedback on the design of the HREC / RGO checklist?

Questions

What information would you find valuable from Sponsors?

What support can we offer?

Doing now what patients need next