Impact of COVID-19 on cancer clinical trials in Victoria

Summary of survey findings, published December, 2020

Background

COVID-19 has had, and continues to have, a significant impact on the delivery of cancer clinical trials in Victoria; with many clinical trials being closed to recruitment or adapting workflow due to shortfalls in dedicated staff and resources, changes to health service, government and sponsor guidelines and changes to patient management and risk. This impact is especially concerning for patients who may have limited standard treatment options available outside of clinical trials.

To understand the scale and diversity of the COVID-19 impact, and to inform potential future advocacy and investments in the clinical trials sector, we collaborated with the Victorian Cancer Agency on a survey of cancer clinical trial units in Victoria.

The survey was distributed to (43) cancer clinical trial units involved in Cancer Council Victoria's annual clinical trial data collection process (the Cancer Trials Management Scheme) and remained open for one month in between Victoria's first and second wave of COVID-19 restrictions (Figure 1).

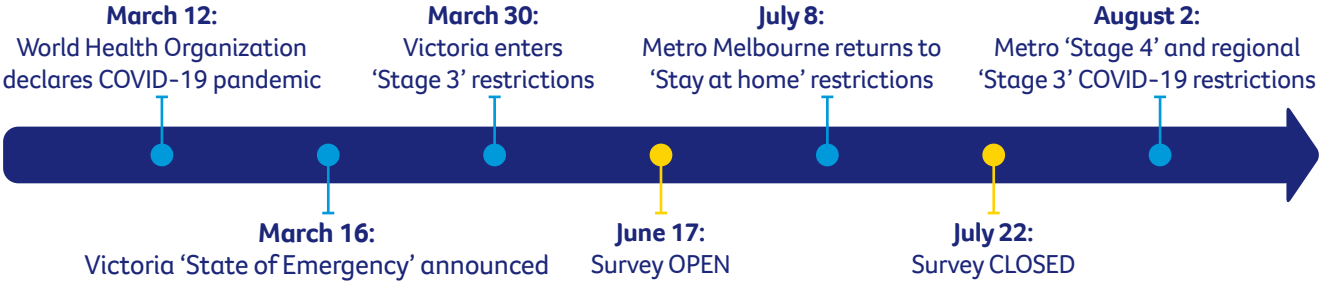

Figure 1. Survey distribution, in the context of COVID-19.

Results

Demographics

Forty-four individuals responded to the survey, representing a broad range of health services (Figure 2), clinical and non-clinical positions.

An equal number of clinical trial unit managers and clinical leads/clinicians responded, together accounting for over 60% of total respondents (n=30). Further responses were received from clinical trial research nurse coordinators (20%, n=9) and individuals in administrative or executive positions (11%, n=5).

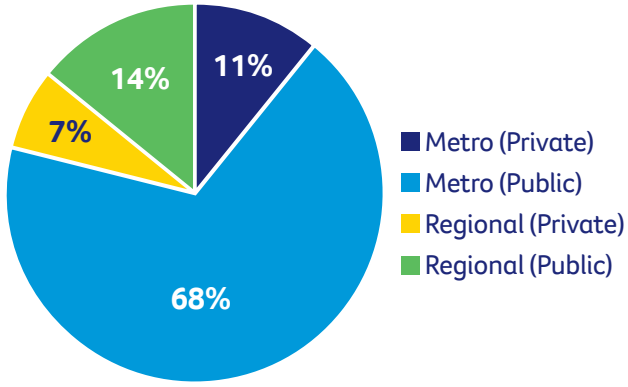

Figure 2. Respondents, by health service location and funding.

Impact

Over 50% of respondents reported having to close, place on hold or suspend recruitment for greater than 60% of their total clinical trial portfolio (n=23). For some (n=14) this impact was as high as 81-100% (Figure 3). When asked what guided this decision, a quarter of respondents (n=11) reported being guided by a combination of sponsor, organisation and unit-specific advice. Fourteen percent (n=6) reported a sponsor driven decision.

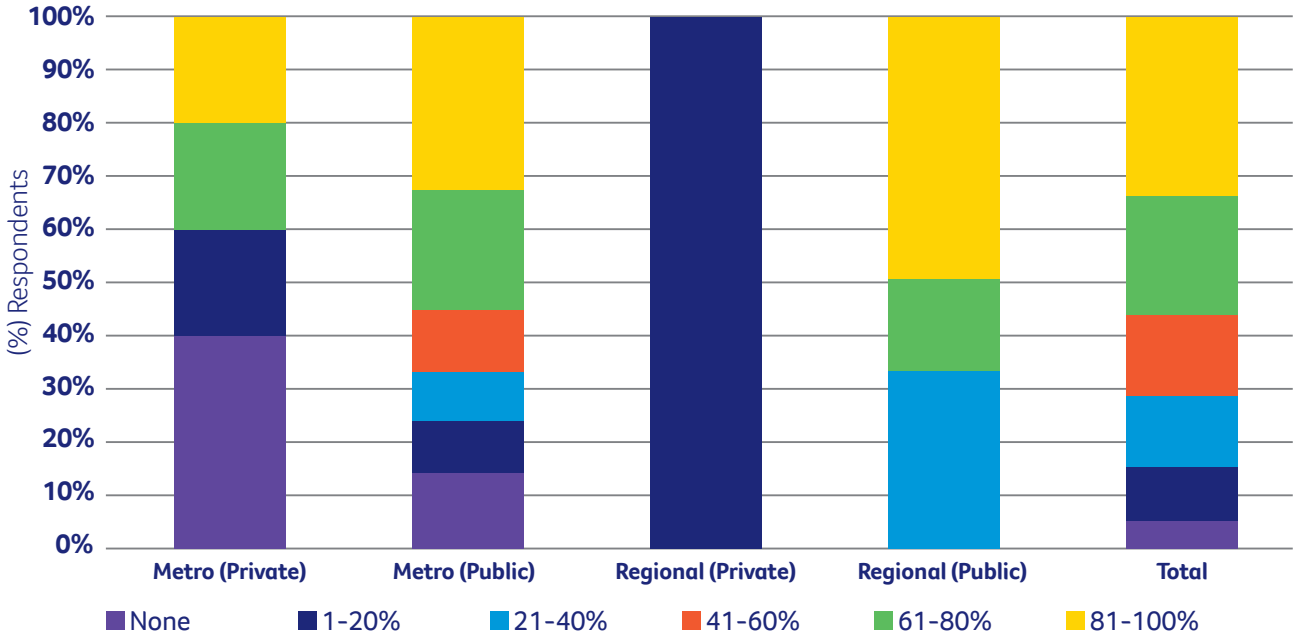

Figure 3. Proportion of trials suspended, placed on hold or closed to recruitment, by health service location and funding.

The majority of respondents reported a disruptive impact to clinical trials in Victoria, caused by COVID-19.

The areas most disrupted included workforce, protocol compliance and participant recruitment (Figure 4).

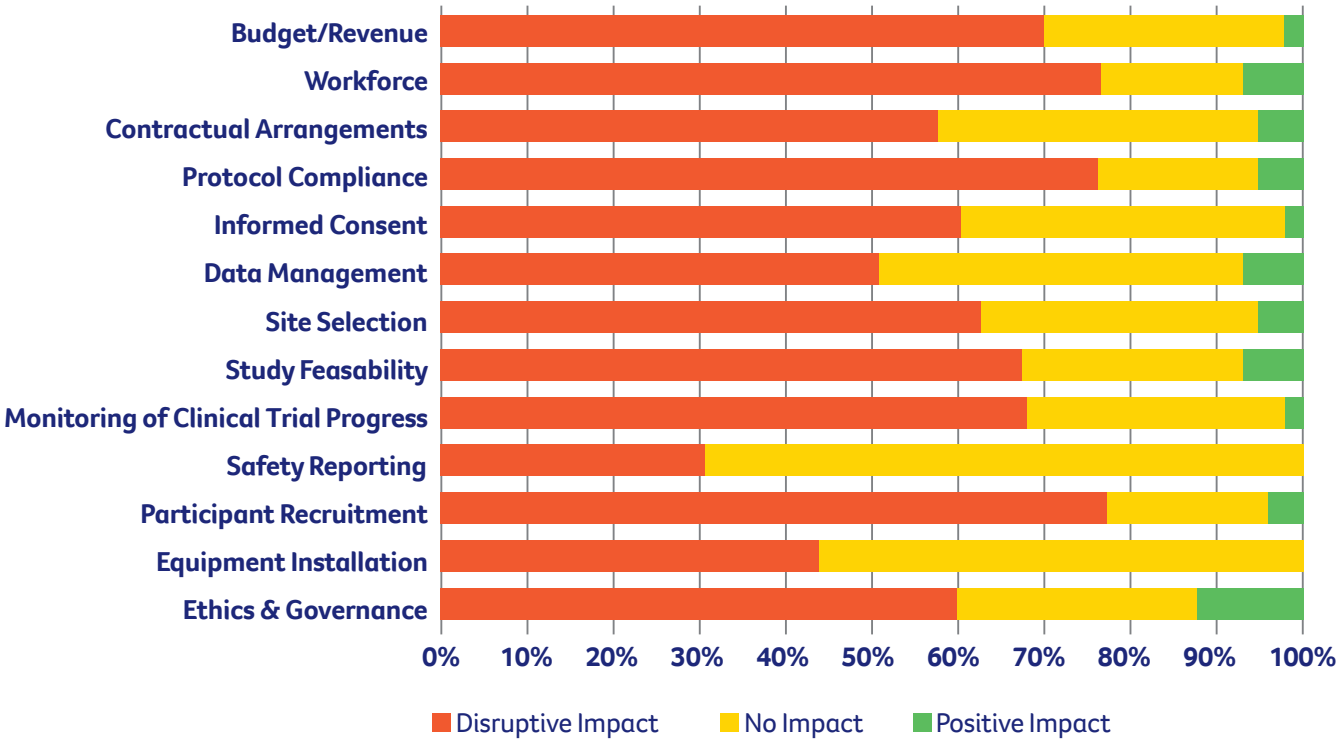

Figure 4. Areas impacted by COVID-19, rated as having disruptive impact, no impact or positive impact for clinical trial units in Victoria.

Just over 40% (n=18) expected COVID-19 to impact between 21-40% of their total annual budget/revenue; and a further 20% expected this impact to be as high as 60% (Figure 5).

When asked 'which type of research would be most impacted by COVID-19', a higher number of respondents (n=20) reported commercial clinical trials compared to non-commercial clinical trials (n=5).

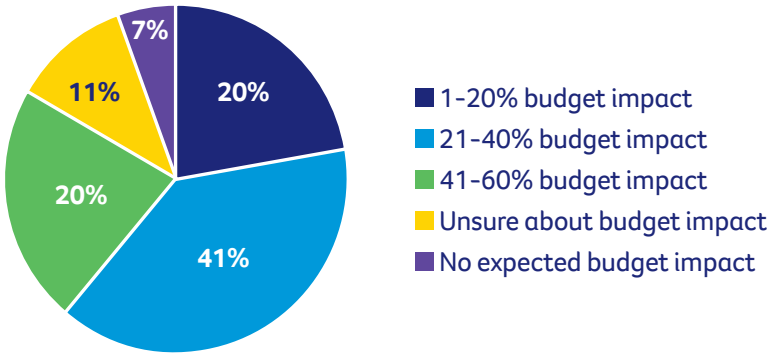

Figure 5. Estimated proportion of budget/revenue expected to be impacted by COVID-19

Change to practice

Various strategies have been implemented to support the continuation of clinical trials during COVID-19, with varying levels of preparedness. Most respondents felt prepared to transition to telehealth and to use local/community services to support blood tests and scans; but felt least prepared for remote clinical trial monitoring and e-signature/consent (Figure 6).

The majority of respondents (n=41, 93%) supported at least one of these strategies being integrated into standard practice following the COVID-19 pandemic. Just two reported 'none'. The strategies most frequently supported for integration were telehealth and remote monitoring.

> **“**
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> **Remote management of participants is real and opportune for broader trial participation**
> – Clinical Lead/Clinician, Metro (Public)

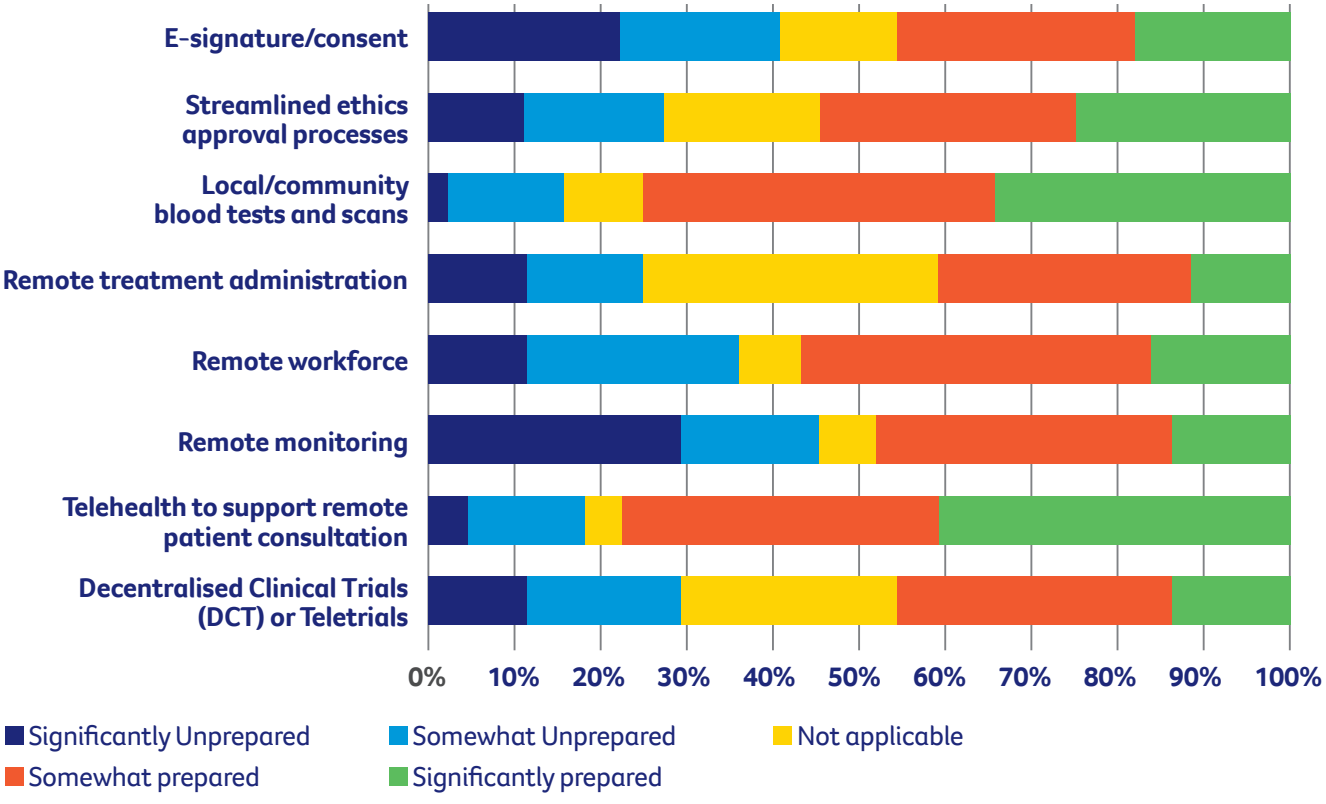

Figure 6. Level of preparedness to implement various strategies in response to COVID-19

Return to 'normal'

Just over 80% of respondents felt at least somewhat confident about a 'return to normal' operations following the COVID-19 pandemic (Figure 7). When asked to report on anticipated challenges for the return to normal operations, the three most frequently selected responses were budget (64%, n=28), patient recruitment (52%, n=23) and number of new studies approved (45%, n=20). 'Other' challenges included, but were not limited to, uncertainty around the COVID-19 pandemic and recurrent lockdown/physical distancing requirements imposed.

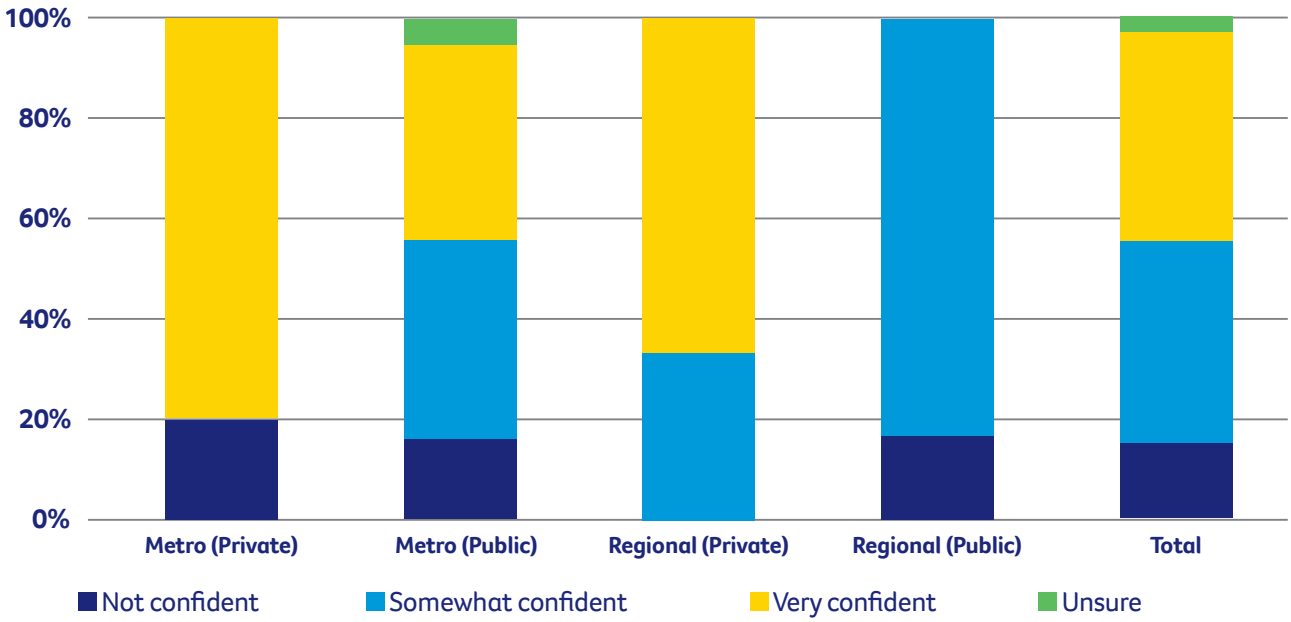

Figure 7. Confidence for return to 'normal operations'

Support

Respondents were also asked to comment on where support was most needed after the COVID-19 pandemic, to inform potential future advocacy and investment in the cancer clinical trials sector. Responses were broadly grouped into the following categories:

Education - and awareness raising for patients and health professionals about the significance and safety of clinical trials.

Funding - for loss in recruitment due to COVID-19, compensation for data requests and support for investigator-led research, including in disciplines other than medical oncology.

Harmonisation - state-wide coordination of clinical trials and related decisions.

Prioritisation - of research, backed by health service and government support.

Telehealth - funding and advocacy to support central teletrial, telehealth and regional clinical trial capacity building infrastructure to enable patient access closer to home.

Ethics & governance - review of ethics and governance procedures and timelines, and the setting of clear Key Performance Indicators (KPI) to ensure the Victorian sector remains competitive.

> **"Support regional trial units who can then help develop satellite centres at rural health services…The Regional Trials Network is a good example of funding going to a regional centre to support regional trials units..."**
>
> – Clinical Trial Unit Manager, Regional (Public)

> **"Funding for teletrials would be a huge benefit to the patients and give greater access to clinical trials for them, thus boosting recruitment and ensuring a quicker clinical trial process. It would be a win-win for everyone."**
>
> – Clinical Trial Unit Manager, Metro (Public)

> **"...Victoria needs to become more competitive with NSW and private research units in reviewing early phase studies through HREC... Hospital governance reviews are also very slow and there is no incentive or desire for this to improve at an organisation level…"**
>
> – Clinical Trial Unit Manager, Metro (Public)

Summary

COVID-19 has presented both challenges and opportunities for the cancer clinical trials sector in Victoria. The results of this survey highlight the potential impact to trial operations, recruitment and revenue, but also, potential advancements in how we deliver clinical care.

Although reports of disruptive impact were common, the rapid implementation of telehealth to support patient consultations, changes to ethics and governance procedures and remote monitoring all highlight advancements to current practice and are a catalyst to improve access and embed clinical trials in standard care, if appropriately resourced and supported in the long term. The need to embed reforms to help cancer patients and enable a more flexible and responsive health system has been recognised in the Victorian Cancer Plan 2020-2024.

This survey was distributed at a single point in time, in between the first and second wave of COVID-19 in Victoria. It does not capture the experiences of cancer clinical trial units during the second wave of COVID-19, which included higher rates of community transmission and restrictions to care. Continued consultation and surveys are needed to understand how further restrictions have impacted on the cancer clinical trials sector, particularly the opening and closing of clinical trials for people affected by cancer. Together with this additional evidence, the knowledge generated through this survey will strengthen the delivery of cancer clinical trials during the COVID-19 pandemic and prevent further interruptions to care. The results of this survey will be used to inform advocacy and investment in the clinical trials sector to support equitable access to clinical trials in Victoria.

This work, and the collection of annual clinical trial recruitment data, is supported by the Victorian Government.

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Cancer Council