

The impact of COVID-19 on Dermatology clinical trials: An Australian perspective

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• Background:

- The unprecedented nature of COVID-19 has disrupted clinical trials research globally. Social distancing, travel restrictions, local government regulation and health advice relating to the containment of the coronavirus may have mitigated the transmission of spread. We wanted to investigate how COVID-19 has impacted clinical trials dermatology in an Australian context.

• Methods:

- A retrospective audit was undertaken of 26 dermatology clinical trial sites across Australia, between January to June, 2020. Data on the severity of impact, number of closures, patient termination and enrolment were collected. 6 Clinical trial sites that did not include randomised clinical trials were excluded from this audit and 1 site did not complete survey.

• Results:

- 26 sites were approached, 6 excluded and 1 declined, total 19 sites included.
- 8 patients from 19 sites reported early termination due to COVID-19
- At the Skin Hospital sites, 11% of visits were delayed due to COVID-19
- Changes in practice: remote & telehealth visits, PPE, pre-screening and temperature check on arrival, no family members, no site monitoring visits

State of surveyed sites

1 ACT, 7 NSW, 5 VIC, 1 SA, 3 QLD, 2 WA

Impact by COVID-19

11% (2/19) severely affected (closure of site), 42% (8/19) moderately affected (remote visits, early termination of patients), 47% (9/19) minimally affected (rescheduled visits)

Recruitment & Enrolment

37% (7/19) had no enrolment of new patients in clinical trials due to COVID-19

Change in practice

68% (13/19) reported change in practice due to COVID-19

Closure of site

5% (1/19) sites closed due to COVID-19

• Discussion:

- Our survey demonstrates the varying impact of the COVID-19 pandemic on the Australian Dermatology Clinical trial site. The impact ranged from minimal to severe across sites.
- All Victorian sites demonstrated moderate or severe effects, likely reflected in the longer, more intense lockdowns and public health orders that Victoria faced during 2020.
- 53% of dermatology clinical trial sites were moderately or severely affected by COVID-19, with patients terminating the trial early, having to run patient visits remotely over telehealth or having to close their site all together.
- Australia was impacted less than other countries in the COVID-19 pandemic. In the USA, in March-April 2020 1052 clinical trials in all specialities were suspended, with 905 citing COVID-19 pandemic as the reason.¹
- This study demonstrated changes to practice in Australian Dermatology clinical trial sites include remote visits, PPE, pre-screening and temperature check on arrival, no family members to attend and no site monitoring visits.
- Our study further demonstrates recruitment of patients was an issue.
- Other studies suggest primary concerns of clinical trial sites worldwide include; recruitment and enrolment, financial loss, patient safety, safety of staff, remote visits/telehealth, delivery of medication and need for COVID-19 screening.^{2,3}

• References:

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