



MeCRU Research Unit officially launched as the Paediatric COVID-19 VACCINE Trial Site



Mecru Clinical Research Unit (MeCRU), at SMU has been officially launched as the research site for Phase III Paediatric COVID-19 Vaccine study conducted by the Numolux Group and Sinovac on 10 September 2021. The very first child and the second one had the honour to receive their jabs which kick started the study.

In a hybrid ceremony of face to face and virtual sessions, messages of support and congratulations came as far as China and from a representative of the department of health on behalf of Dr Joe Phaahla, the Minister of Health. Prof Peter Mbatlana, the Vice-Chancellor also congratulated MeCRU for being identified as a site and wished everyone success in this noble campaign to stem the tide of the pandemic amongst young people.

The study is a multi-centre, randomized, double-blind, Placebo-controlled Phase III Clinical Trial to Evaluate the Efficacy, Immunogenicity and Safety of SINOVA Inactivated COVID-19 Vaccine (CoronaVac®) in children and adolescents aged 6 months to 17 years.

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The primary objective of the study is to evaluate the efficacy of two doses of CoronaVac® against confirmed symptomatic COVID-19 cases in children and adolescents aged 6 months to 17 years. Efficacy will also be evaluated against hospitalization and severe COVID-19 cases.

The worldwide study will enrol 14 000 children and adolescents in various paediatric age group cohorts across 5 countries (South Africa, Chile, Philippines, Malaysia and Kenya). MeCRU is one of the 7 clinical research sites across South Africa which will enrol 2000 participants from 6 months to 17 years.

Prof Maphoshane Nchabeleng, the Head of the Department of Microbiological Pathology, established MeCRU Research Unit, as a non-profit making research unit sustained by external funders for the clinical trial services.

The study timelines are 8-10 weeks from first participant enrolled. It's timelines for enrolment are up to mid- November to December 2021. The follow ups will continue until 12 months after the second vaccination. The study is expected to be completed by Dec 2022. c

The visits and milestones of the study are as follows: Visit 0 - screening visit with the parent/legal guardian. Visit 1- Enrolment/Vaccination visit: This is the first vaccination, and can be done up to 28 days from screening. Visit 2 - Follow up visit, done 7 days after vaccination. Visit 3 - Second vaccination, done 28 days after first vaccination. Visit 4 - follow up visit, done 7 days after second vaccination. Visit 5 - follow up visit after, 28 days after visit 3. Visit 6 - follow up visit, done 6 months after visit 3. Visit 7 - follow up visit, done 12 months after visit 3.

Follow up visits are conducted either on site or off site (contact by phone). Active follow up is when a participants comes on site to be seen. Participants are given contact numbers for site and study staff to contact them anytime if they experience problems. Participants are also contacted by study staff at least once a week to check on them for the first 2 months: thereafter they are contacted every 2 weeks. They are also encouraged to contact the site on the contact numbers given to them.

The contact numbers are 2 different landlines at the clinic, and 2 cell phones for the Principal Investigator (PI) and the Study Coordinator, which they can call anytime. Some Participants

have an option to have bloods drawn from them, which is 3ml at 4 different visits. They will be in a specific cohort, and they can choose to opt out.

Those participants who are on the cohort will be seen on site for blood draws. If they are not on a cohort, they can be contacted telephonically. Continuous monitoring of activities starts as soon as there are 10 participants and it becomes ongoing throughout the clinical trial. Any deviations from the protocol gets reported to the South African Health Products Regulatory Authority (SAHPRA) and to SMU Research and Ethics Committee (SMUREC). This will be included in the annual reports of the department of Microbiology which also include reports of activities of MeCRU research projects.

The investigator has been in contact the two participants with them and their parents.

They were contacted on the day they received their first jabs (10 September 2021) and they reported to be well with no local or systemic symptoms. They were contacted again on the weekend of (11 September 2021), still no symptoms. Their parents were also reminded to contact the site should there be any issues.

The two participants will report to MeCRU on 20 September 2021. They also have the contact numbers for calls, send an SMS or even WhatsApp should they experience any symptoms before their visit on site.

Vaccine pessimists spread lies about vaccines and undermine the COVID 19 vaccine campaigns, leading to the current slow uptake. It may even be worse for children. "To MeCRU Research Unit, the provision of basic information and education on the vaccines is very critical. We believe that when people are well informed, they are able to make informed decisions based on the information given. The community is being given ongoing education through Vaccine Discussion Groups (VDG) which can be done on site or in the communities," said Prof Nchabeleng.

The Community Advisory Group (CAG), Community Liaison Officer and the Community Educators, Recruitment and Retention Officers engage with the community and they address/clear the myths and beliefs about the clinical trials in general.



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SMU launches Golden Key International Honour Society



The SMU Chapter of the Golden Key International Honour Society (GKIHS) was launched recently at the Fire and Ice Hotel. GKIHS, the world's largest collegiate honour society for undergraduate and postgraduate students has a linkage with over 400 universities. The GKIHS is built on pillars of academic excellence, leadership, service and nurturing student leadership at campuses.

SMU's GKIHS Chapter launch was a hybrid event, in which Prof Eunice Seekoe, the Deputy Vice-Chancellor, Teaching, Learning and Community Engagement delivered an opening address which was attended by a captive audience of SMU Chapter members and those who joined the proceedings virtually.

"Congratulations to members for the successful launch. SMU GKIHS chapter is committed to honour excellence in the universe through academic achievements, grooming of young efficient leaders and to provide good community services, said Prof Seekoe.

"The chapter is a brain child of Mr Thulani Ramasehla. He approached me, in 2019, to discuss the feasibility of bringing this wonderful programme into existence, in the SMU community. We then took the initiative to contact Golden Key South Africa to enquire about the programme and what was required of us to be part of this wonderful society. The relationship was then established between my office and the

one of Golden Key South Africa," explained Prof Seekoe. "As GKIHS, we seek to become a benchmark of excellence for students in academia and in leadership for SMU Students. There is a need to remind the students to celebrate each achievement", said Mr Thulane Ramashehla in his remarks, as the President of SMU GKIHS.

Ms Natasha Maharaj, representing Golden Key South Africa, outlined the membership benefits. She said that as a member, one is due to receive academic recognition at an international level and access to financial rewards in the form of scholarships, grants and awards.

Mr Obriel Maphosa, the President of University of the North West University Golden Key, congratulated SMU Chapter for the launch. He added that membership benefits do not only accrue to individual members, but the university the individuals are enrolled with, will also reap benefits through grants and exchange programmes.

The membership of the SMU GKIHS Chapter was selected by schools and to qualify to be a member, one needs to be within the performing cohort of 15% in the class who obtain 65 percent pass mark in the final result. This membership makes them eligible for very attractive rewards, scholarships, travel, and overseas study opportunities in the final results. 627 students have qualified, in this way.



The executive committee of SMU GKIHS Chapter is as follows:

- Mr Thulani Ramasehla:** *President*
- Mr Tshiamo Sechogo:** *Vice-President*
- Mr Jabulani Nkosi:** *Secretary*
- Ms Kamogelo Mokhari:** *Community Outreach*
- Ms Courtney Cooper:** *Membership Recruitment Officer*
- Ms Tebogo Mojapelo:** *Public Relations Officer*
- Mr Thendo Tshingowe:** *Treasurer*

Left to right:
Ms A Malope, Ms C Cooper, Ms K Mokhari, Prof A Ramukumba, Prf E Seekoe, Ms T Tshingowe, Ms T Mojapelo, Mr J Nkosi and Dr T Tsebe

Squatting:
Mr T Ramasehla and Mr T Sechogo