institutions and pharmaceutical and non-pharmaceutical industry is a promising strategic approach to promote sustainable clinical research capacity. The government vision is that beyond national boundaries, resource sharing and involvement of private players are key factors to mitigate the high burden of disease, nationally and regionally.

OC 8521 PRELIMINARY REPORT ON SAFETY OF CO-ADMINISTERED HUMAN HOOKWORM VACCINE CANDIDATES *NA*-APR-1 (M74)/ALHYDROGEL® AND *NA*-GST-1/ALHYDROGEL® IN GABONESE CHILDREN

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Background Human hookworm infection is a major public health issue in tropical low and middle-income countries with severe consequences. To date, improvement of water supply, sanitation, and hygiene is the major contributor to disease control, and additional control tools are needed. Here, we assess a phase I trial of a new hookworm vaccine candidate *Na*-APR-1 (M74)/Alhydrogel and *Na*-GST-1/Alhydrogel in Gabonese school-age children.

Methods A double-blind, randomised, controlled, dose-escalation phase I clinical trial that aims to evaluate safety, reactogenicity and immunogenicity of *Na*-APR-1 (M74)/Alhydrogel co-administered with *Na*-GST-1/Alhydrogel hookworm vaccines in children aged 6 to 10 years living in hookworm-endemic area of Lambaréné, compared to the hepatitis B vaccine (ENGERIX-B). Children received three doses of assigned vaccines, delivered intramuscularly (deltoid) on Days 0, 56, and 112 or 180. Safety is measured from Day 0 through Day 14 by the occurrence of solicited injection site and systemic reactogenicity events. Clinical laboratory evaluations were performed approximately 14 days after each immunisation. Unsolicited adverse events were collected from Day 0 through approximately 1 month after each vaccination.

Results A total of 135 children were screened, and 60, aged 6 to 10 years old, were randomised into 3 groups and received 10 µg, 30 µg or 100 µg of *Na*-APR-1 (M74)/Alhydrogel and *Na*-GST-1 Alhydrogel, respectively, compared to ENGERIX-B. At baseline, the mean age of the study population was 7.4 years and the sex ratio 1.3 (male: female). From Day 0 up to Day 14 after vaccination, the main solicited adverse events were pain and swelling at injection sites with 135 (26 of grade 2 and 1 of grade 3) and 9 events, respectively. Regarding systemic adverse events, 3 occurrences of grade 1 headache were recorded. Immunogenicity analyses are underway.

Conclusion The preliminary results confirm that co-administration of the two hookworm vaccine candidates is safe and well-tolerated in Gabonese children.

OC 8535 AN OVERVIEW OF RESEARCH ETHICS COMMITTEES OPERATING IN LUSOPHONE AFRICAN COUNTRIES

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Background In 2017, a North-South partnership was created, to strengthen Bioethics Committees in African Lusophone African countries (LAC), by joining the forces of National and Institutional Research Ethics Committees (REC) and Universities in Angola, Cape Verde, Mozambique and Portugal. This study is part of an EDCTP2-funded project and aims to describe key RECs operating in LAC, its establishment dates and further characteristics.

Methods Document analysis and interviews with REC representatives of five LAC were conducted in April 2018. Legal documents were obtained through official national sources.

Results We identified four National Ethics Committees, created between 2000 and 2008 by ministerial or governmental decree; only S. Tomé e Principe does not have an established REC. In Angola, the National REC was created in 2000, and since 2007, seven Institutional Committees were implemented at faculty level. National REC in Cape Verde and Guinee-Bissau (CNES) are unique and were founded in 2007 and 2009 respectively. In Mozambique, National REC (CNBS) dates to 2002, and since 2011, 8 Institutional Committees were formed; they functioned as a network under the umbrella of CNBS. Most National REC have representatives from health professional associations, lawyers, civil society and religious communities and have regular meetings (usually monthly). The number of members ranges between 6 (CNES) and 13 (CNBS). In 2007, around 200 protocols were reviewed by CNBS and 29 by CNES. Most of the National REC members attended training activities in bioethics but at different levels.

Conclusion Few publications described REC operating in LAC; this study fills this gap by reporting historical and functional characteristics of RECs in five Lusophone African countries. Additional tools based on quantitative and qualitative approaches are being developed to assess more in-depth REC operational characteristics and to identify their needs in order to target training and capacity building initiatives underlying our project.

OC 8546 SAFETY AND IMMUNOGENICITY OF THE MALARIA VACCINE CANDIDATE BK-SE36 IN YOUNG CHILDREN LIVING IN BURKINA FASO

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Background The malaria blood stage vaccine candidate SE-36 is based on the serine repeat antigen of *Plasmodium*