



PediCAP General Assembly Call #2

Date: 7th May 2020

Location: Teleconference

Chair: Mike Sharland – SGUL

Participants:

Francesca Viero – PENTA; Mike Sharland, Yasmine Yau, Tatiana Munera – SGUL; David Moore, Ziyaad Dangor – WITS; Paolo Denti, Roeland Wasmann, Susan Cleary – UCT; Victor Musiime – MU; Hilda Mujuru – UZCHS; Veronica Mulenga – UNZA/SOM; Nigel Klein, Mo Archary, Anne Derache, Leatitia Kampiire – AHRI; Clare Shakeshaft, Emily Dennis, Nishdha Naufal, Michelle Clements, Joe Standing – UCL; Tomislav Kostyanev, Surbhi Malhotra, Juan Pablo Rodriguez Ruiz – UA; Günther Fink, Gillian Levine – Swiss TPH; Sally Ellis – GARDP.

Apologies from:

Julia Bielicki – SGUL; Shabir Mahdi – WITS; Sarah Walker – UCL; Trudie Lang – UOXF.

TOPICS	DISCUSSION AND DECISIONS
1) Protocol, Ethics and Regulatory submissions (CS)	<ul style="list-style-type: none">• See WP2 slides 1 to 6
2) Trial setup and management (CS, ED, Sites)	<ul style="list-style-type: none">• See WP2 slides 7 to 11 <p>Round of comment from sites on Covid-19 issues:</p> <ul style="list-style-type: none">• Zimbabwe/HM:<ul style="list-style-type: none">- Currently lockdown level 2: business has restarted and more people are going to work. People working in the clinical setting might face challenges to reach the workplace.- Parirenyatwa hospital is being partially rearranged to accommodate Covid-19 patients whereas Harare hospital is not.- At Harare hospital we normally admit 25-30 children (at least 15) a day, currently max 10. Probably patients are scared to get Covid if they come to the hospital and are also facing challenges to reach the hospital since public transportation was limited.- 1st level health facilities are opening for shorter hours and there is a shortage of staff. On the other hand some studies are finishing so we should have some staff available to be hired for PediCAP, only adding 1-2 additional people.- Cargos from South Africa (where shipments to Zimbabwe pass through) have been shut down so there could be issues with IMP importation.



PediCAP is part of the EDCTP2 programme supported by the European Union under Grant Agreement RIA2017MC - 2023.

EDCTP

	<ul style="list-style-type: none"> - In the current situation we would not be able to start enrolling, but we expect things to improve in the next few weeks and to be able to start by then. - We expect all approvals to be obtained in 4-6 weeks. <ul style="list-style-type: none"> • Uganda/VMusiime: <ul style="list-style-type: none"> - Lockdown situation is similar to Zimbabwe, it was recently partially lifted increasing the mobility. - Since beginning medical services categorized as essential (like hospitals) remained open. Staff moving on personal means of transportation can move to work; the ones usually moving with public transportation are not able to go to work since public transportation is still shut down. - We have staff available to start working on the trial. - Patients with pneumonia are still presenting to the hospital. - Cargo transportation by air or road is allowed into the country so IMP importation should be possible. - Local team waiting for NDA comments (should be received this week) and working on the required monitoring plan in the meantime, to be shared soon with the MRC. • South Africa, Durban/MA and AD: <ul style="list-style-type: none"> - We are experiencing a sensible decrease in admissions for respiratory diseases, probably due to the closing of schools and subsequent limited transmission, but still a fair number of admissions and the majority are linked to pneumonia. - Internal protocols and procedures are being created to limit patient contact and to manage them while waiting for the results of the testing that all of them shall be subjected to when presenting at the hospital. - Staff recruitment positive: Leatitia, the trial physician has been appointed and participating to the call and some further personnel was identified, some studies are finishing and the personnel will be reallocated to PediCAP. - King Edward Hospital's EC's activity was disrupted during the lockdown but is currently restarting. • South Africa, Johannesburg/DM: <ul style="list-style-type: none"> - This site is also experiencing a disruption of the expected numbers of respiratory cases in this season (instead of about 25 cases daily, max 10), probably due to the lockdown. This is being slowly lifted so we expect an increase in the next 2 weeks. - The ethics committee has issued a directive on March 23rd asking to scale back research activities in order to limit infections in participating staff and students. They recommended to suspend indefinitely observational studies and enrollment into ongoing studies. - IMP Importation: might be an issue because of limited air freight, this might impact our ability to procure IMP. • Zambia/VM: <ul style="list-style-type: none"> - Currently partial lockdown with restriction of non-essential services, but public service is running. Less patients with pneumonia are being admitted.
--	---



	<ul style="list-style-type: none"> - The team has already identified the staff to be enrolled in the trial and expects the ethics and regulatory submissions to proceed. • Agreed to try and move forward with the trial setup and implementation, keeping in mind the principle of safety for staff and patients. <p>ACTION: DM to share the directive and inquire about the new measures now that the lockdown is in a less strict phase.</p> <p>ACTION: All sites to inquire on importation limitations.</p>
3) IMP update (CS)	<ul style="list-style-type: none"> • <i>See WP2 slides 12-13</i>
4) Communication & Dissemination (HM)	<ul style="list-style-type: none"> • D7.3 Dissemination and communication strategy and D7.3 information sheet for stakeholders was drafted with SGUL and is now being revised. • CAGs: Uganda and Zamia are progressing in the constitution of CAGs but could not proceed due to the COVID-19 related restrictions. In Zimbabwe, the first meeting had been planned but was delayed for the same reason. South Africa will be involved shortly.
5) PK Study (RW)	<ul style="list-style-type: none"> • <i>See PK Slides</i> <p>ACTION: MS to link RW to UKBB to have access to Qazi's data on BD PK for amoxicillin.</p>
6) Microbiology (TK)	<ul style="list-style-type: none"> • <i>See Microbiology Slides</i> <p>ACTION: initial goal to sample the first 66 patients for the microbiology study should be postponed in SOPs and MOP not to overcharge sites with the related workload during the initial phase of the trial. MS and TK to follow up offline.</p>
7) Health Economics Analysis (GF)	<ul style="list-style-type: none"> • Swiss TPH/GL: the team is continuing the analyses of IQVIA datasets, looking at use and cost of different child-appropriate formulations of common antibiotics for pneumonia in children. These are being used to describe the current practices on consumption and costs and to model the potential effects of different scenarios of changing distribution of relative use of these antibiotics, as well as the potential costs associated with different pricing structures or a different distribution of use. • This work was to be presented at the European congress of clinical microbiology and infectious diseases, canceled because of COVID-19. • UCT/SC: the team has started a systematic review of economic evaluations for treatments of paediatric pulmonary diseases to inform health economics modeling methods of the cost effectiveness analysis and is currently at the data extraction stage.
8) Capacity Building (MS)	<ul style="list-style-type: none"> • Key activity will be the revision of trainings produced within WP 7 of trainings on pneumonia and study-specific modules, which will be circulated shortly to the Partners for comments (ACTION).



PediCAP is part of the EDCTP2 programme supported by the European Union under Grant Agreement RIA2017MC - 2023.

	<ul style="list-style-type: none"> • Work is being done on the idea of conducting trials remotely and trainings in adequate safety conditions, including SIVs online. <p>Round of comment from sites on remote SIVs: sites have different degrees of experience with this but are all open and available.</p>
9) Project Management (FV)	<ul style="list-style-type: none"> • <i>See Project Management Slides</i> • The Consortium Meeting 2020 is on hold and a longer call will take place instead on June, 17th AM. Key identified points to be discussed are: <ul style="list-style-type: none"> - Oral step-down - Clinical issues - Emerging data from HEA and PK studies - Conducting trials in the Covid era <p>ACTION: all Partners to inform FV of any communication or dissemination activity happened by March 2020.</p>
Next TC	Consortium Meeting TC on June, 17 th 2020 – AM



EDCTP



PediCAP is part of the EDCTP2 programme supported by the European Union under Grant Agreement RIA2017MC - 2023.