



PediCAP General Assembly Call #5

Date: 7th December 2020 09:00 – 12:00 GMT

Location: Teleconference

Chair: Mike Sharland – SGUL

Participants:

Francesca Viero – PENTA;

Mike Sharland, Julia Bielicki, Yasmine Yau, Tatiana Munera – SGUL;

David Moore, Ziyaad Dangor – WHC;

Paolo Denti, Roeland Wasmann, Lucy Cunnama, Susan Clearly – UCT;

Victor Musiime, Lawrence Kakooza – MU;

Hilda Mujuru, Kusum Nathoo – UZCHS;

Veronica Mulenga, Chishala Chabala – UNZA/SOM;

Nigel Klein, Mo Archary, Anne Derache, Leatitia Kampiire – AHRI;

Emily Dennis, Ben Spittle, Michelle Clements, Nisdha Naufal, Joe Standing – UCL;

Juan Pablo Rodriguez Ruiz, Xavier Britto, Tomislav Kostyanev – UA;

Gillian Levine – Swiss TPH;

Helena Wilcox, Trudie Lang – UOXF;

Sally Ellis – GARDP.

Apologies from:

Shabir Mahdi – WHC; Günther Fink – Swiss THP Surbhi Malhotra – UA.

TOPICS	DISCUSSION AND DECISIONS
1) Project Management and Finance (Francesca Viero)	<p><i>See Project Management slides</i></p> <ul style="list-style-type: none">• Overview of Project governance structure• Project coordination, milestones and deliverables: WP1 and WP2 are in line with the planned activities, whereas the other activities were delayed due to Covid-19 and changes of plans.• A Project Amendment will therefore be set up in January to align the Grant Agreement with the current situation.• It was reminded that the Grant Agreement is to be considered the key reference document of the Project.• First Periodic Report approval by EDCTP is still pending, PMT is chasing project officer for updates.



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<p>2) Trial setup and management (Ben Spittle)</p>	<p><i>See Trial Setup and Management slides</i></p> <ul style="list-style-type: none"> • Protocol, ethics and Regulatory <ul style="list-style-type: none"> - Introducing the clinical project manager – Ben Spittle - Next version of the protocol v3.0 finalised and circulated to sites, currently in various states of amendment submissions to EC and Regulatory authorities • Trial Setup <ul style="list-style-type: none"> - Database is now live. - PediCAP-A now open to recruitment, in Ugandan site opened on Friday, December 4th.
<p>3) IMP update (Julia Bielicki)</p>	<ul style="list-style-type: none"> • Using the SureScreen CRP test <i>See CRP testing slides</i> <ul style="list-style-type: none"> - Slides and short videos including instructions on preparing, setting up and using CRP tests were shared and explained in detail. - Capillary tubes: MOP and trainings were based on the assumption that capillary tubes would be used to collect the blood sample. However Julia and team tried them and found out that capillary tubes make it more difficult to collect the exact amount of blood needed. - It was therefore agreed that it would be better to use the pipettes provided with the test. <p>ACTION: MRC will update the MOP and training slides with regard to the use of pipettes instead of capillary tubes. ACTION: MRC will ask SureScreen to provide extra pipettes to sites (currently just 1 per test cassette is delivered). ACTION: Sites to review the process and provide any feedback to MRC.</p> • Dissolving IMP <ul style="list-style-type: none"> - A video prepared by the Ugandan team was shared, showing the dissolving of 5 tablets in 10mls of water. - The flavour is orange-y, but the texture is not smooth and has some bits, so need to encourage children not to chew on them. - Tablets can also be dissolved in milk.
<p>4) Site Updates</p>	<ul style="list-style-type: none"> • Uganda (Lawrence Kakooza) <i>See Site update for Uganda slides</i> <ul style="list-style-type: none"> - Site opened on December 4th and recruitment about to start. • Zambia (Veronica Mulenga) <i>See site update for Zambia slides</i> <ul style="list-style-type: none"> - Protocol v3.0 will be submitted starting next week. - Basic staff is in place and contracts are being prepared. - Contract with trial monitor is pending, guidance from MRC was requested. - SIV conducted on October 2nd and pharmacy staff trained, too. - Drug import permit obtained and drug shipment is in process. - FPFV expected in January.



	<ul style="list-style-type: none"> • Zimbabwe (Hilda Mujuru) <i>See site update for Zimbabwe slides</i> <ul style="list-style-type: none"> - Working on submission of Protocol v3.0. - Site waiting for IMP. - SIV planned for January. - FPFV expected in early 2021. • South Africa - Johannesburg (David Moore) <ul style="list-style-type: none"> - Working on Protocol v3.0 PIS/ICF. - Ethics requirements for site: submitted to ethics for review and submitted to SAPHRA. - Study personnel and study coordinator are on board; trial pharmacist was identified and have been in touch with MRC CTU re: IMP coordination. - Working with HR and recruitment for other study personnel, hope to have additional staff members in mid January. - SIV planned by end of January, aim to start in February 2021. • South Africa - Durban South Africa (Anne Derache) <i>See site update slides</i> <ul style="list-style-type: none"> - Working with Johannesburg on submissions. - Finalising agreement with ECF providing pharmacist. - Staff recruitment ongoing, team should be in place by January. - Monitoring contract pending.
<p>5) PK Substudy (Roeland Wasmann)</p>	<p><i>See WP3 - PK slides</i></p> <ul style="list-style-type: none"> • Question on PK sampling schedule: <ul style="list-style-type: none"> - for small children, 1 or 2 of the intermediate PK samples shall be omitted. There would not be any difference from the PK point of view, but sites suggested to give specific guidance to avoid confusion. - It was agreed to randomise patients to skipping the sample depending on the base of their study ID number. <p>ACTION: specific guidance on this point shall be included in the PK SOP by UCT.</p> • Question to sites: what is the expected proportion of enrolled children to participate in the PK substudy? <ul style="list-style-type: none"> - Different replies depending on the site (25-33%, most of them...). - DM noted that some children might need to stay in the hospital for supplemental oxygen, so not in all cases they would be kept in the hospital just for the PK study. <p>ACTION: UCT will reach out to PIs to set up a call on the practicalities of doing the PK in their site by the end of this week.</p>
<p>6) Microbiology (uan Pablo Rodriguez Ruiz)</p>	<p><i>See WP4 - Microbiology slides</i></p> <ul style="list-style-type: none"> • Overall update of next steps. • New start date estimated around April 2021.



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7) Health Economic analysis (Susan Cleary)	<i>See WP5 – Health Economics Slides</i>
8) TGHN (Helena Wilcox)	<i>See WP6 update slides</i> <ul style="list-style-type: none"> • Several training resources available of being set up and will be uploaded in the PediCAP hub within TGHN platform: pedicap.tghn.org • TGHN team will reach out to sites as teams are recruited.
9) Communication & Dissemination (Hilda Mujuru)	<i>See Communication and Dissemination slides</i> ACTION: HM to share Dissemination, Exploitation and Communication Strategy plan with Project Partners.
Next TC:	March 2021 – doodle will be circulated



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