



PediCAP General Assembly Call #2

Date: 25th February 2020

Location: Teleconference

Chair: Mike Sharland – SGUL

Participants:

Francesca Viero – PENTA; Mike Sharland, Julia Bielicki, Yasmine Yau – SGUL; David Moore, Ziyaad Dangor – WITS; Roeland Wasmann, Susan Cleary – UCT; Victor Musiime – MU; Hilda Mujuru – UZCHS; Veronica Mulenga – UNZA/SOM; Nigel Klein, Mo Archary – AHRI; Sarah Walker, Clare Shakeshaft, Emily Dennis, Joe Standing – UCL; Tomislav Kostyanev, Surbhi Malhotra, Juan Pablo Rodriguez Ruiz, Christine Lammens – UA; Günther Fink, Gillian Levine – Swiss TPH; Sally Ellis – GARDP.

Apologies from:

Tatiana Munera – SGUL; Shabir Mahdi – WITS; Paolo Denti – UCT; Michelle Clements, Nisdha Naufal – UCL; Trudie Lang – UOXF.

TOPICS	DISCUSSION AND DECISIONS
1) Protocol, Ethics and Regulatory submissions (CS)	<ul style="list-style-type: none">• See MRC-CTU slides 1 to 5
2) IMP update (CS)	<ul style="list-style-type: none">• See MRC-CTU slides 6 to 7 <p>ACTION: MRC team to draft and explanation of why Sandoz is not providing Investigator’s Brochure for the resubmission to drug regulatory in Zambia.</p>
3) Trial setup and management (CS)	<ul style="list-style-type: none">• See MRC-CTU slides 6 to 7• Nishdha Naufal (Data Manager) and Emily Dennis (Trial Manager) are the two new members of the PediCAP team at MRC. <p>Round of comment from sites:</p> <ul style="list-style-type: none">• Zambia/VMulenga:<ul style="list-style-type: none">- Submission with Protocol v.2 to drug regulatory this or next week (once the IB clarification is received from MRC). Drug regulatory committee sits once in 3 months; once we have this approval we will submit to national ethics board Once we get drug regulatory we will submit to national ethics board (NHREB meets once a month).- Staff recruitment: planning to take staff from a finishing project, starting from April.• Zimbabwe/HM:



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

EDCTP

	<ul style="list-style-type: none"> - MCAZ should take 2-3 weeks to reply, then will submit to Research Council of Zimbabwe which should take about 4 weeks. - Staff recruitment: In our site this will be an inpatient study, so we are working on the logistics of this with the hospital. • South Africa/MA: <ul style="list-style-type: none"> - Staff recruitment – site is based at a hospital so convenient in terms of staffing and collaboration. - Waiting for site-specific ethics approval in Durban and will submit to committee after responses received. Regulatory submission to SAPRHA was done at the end of last year and feedback is pending. • South Africa/ZD: Ziyaad to send any additional comments via e-mail. • Uganda/VMusiime: Staff recruitment – planning to start by involving half-time the staff working on EMPIIRICAL (other EDCTP trial). • MS points out that some training should happen in June in occasion of the Consortium Meeting in Zimbabwe, so it would be beneficial for sites if they have identified a few of the staff members to involve in the trial by then.
4) Microbiology (TK)	<ul style="list-style-type: none"> • <i>See Microbiology Slides</i> • It was confirmed that the sample transfer from sites to Antwerp can't be incorporated in the Clinical Trial Agreement template and will need to be regulated separately by MTAs since each country requires specific templates and/or wording. • TK suggested that some wording on biobanking should be addressed to sites and asks to revise the CTA. FV pointed out that a legal review by UA would not be indicated since they will not be a party to the CTA. • MS pointed out that the deadline to choose 2 representative per site to attend to the Summer School is on March, 15th. This process will be supported by VMusiime. • 4 feasibility questionnaires completed and pending answers from two more sites. <p>ACTION: UA team to review ZA MTA template send by MRC.</p> <p>ACTION: MRC and PENTA to discuss on where to add the biobanking wording (CTA or MTA?)</p> <p>ACTION: VMusiime, MS and sites to agree on a participants' list by March, 15th.</p> <p>ACTION: Antwerp team to create a report and prepare summer school programme once received all feasibility questionnaires.</p>
5) PK Study (RW)	<ul style="list-style-type: none"> • Modelling is being finished, UCT team working with MRC (SW and MC) on a publication on the methods used. Plan is to finish by March and to discuss the results at the June meeting for practical inputs. • Sandoz has shared 10 datasets, 6 of which have been used in the modelling. The next steps will be adding the other 4 datasets, finding the co-variants such as food effects, and then combine the resulting models with JS's models on the IP for paediatric patients. • Currently starting to work on SOPs. • The next activity will be simulation.



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

6) Capacity Building (MS)	<ul style="list-style-type: none"> The next Deliverable for WP6 is 6.2 - Assessment of baseline research capacity at sites: once the study staff is hired they will be invited to fill in an online tool on TGHN portal to assess their capacity and training needs.
7) Health Economics Analysis (GF)	<ul style="list-style-type: none"> <i>See Health Economics Assessment slides.</i> <ul style="list-style-type: none"> Additional related activity: GL is using an ICUVIA database (pharmaceutical sales data) to work on an estimate on country and global levels of absolute and relative use of amox and co-amox for paediatric formulations. Some results will be ready for presentation and discussion at the June Consortium Meeting. SC pointed out that the HEA Substudy will also need approval at UCT. Protocol v.3 will be submitted there once it is approved at sites.
8) Communication & Dissemination (MS)	<ul style="list-style-type: none"> Community Advisory Groups: HM is putting together the group, liaising with VMulenga and VMusiime. The first meeting should take place timely by March (as set out in Milestone 7.1). Information sheet for stakeholders on the program (D7.4) is being finalized and will be sent to MS and then to other sites for review and finalisation by March. SGUL is coordinating the production of 3 training modules: <ol style="list-style-type: none"> Paediatric Pneumonia (built on PERCH training) to be ready by March; Study-specific training, by April; Antibiotic prescribing (rapid oral step-down & early rapid oral step-down, safety and absorption). Stakeholders engagement: MS having a conversation with MCA at WHO about how PediCAP results will inform the revision of their paediatric pneumonia guidance. This would then have an impact at MoH/national levels. A workshop is being organised in Harare for June, 19th on AMR, pneumonia and neonatal sepsis. This will be organised locally with Zim Paediatric Association and with the PENTA Education area, but PediCAP teams from other sites could also be involved as trainers. <p>ACTION: VMusiime to reply to HM on CAG.</p>
9) Project Management (FV)	<ul style="list-style-type: none"> <i>See Project Management Slides</i> SW reminded that when a Periodic Report is submitted to EDCTP any delay by any Partner will result in a delay in EDCTP's feedbacks and payments to all the Consortium, hence the need for responsiveness and timeliness. FV highlighted that the Scientific and Financial parts of the Periodic Report need to match (costs & activities) and that discrepancies with the original budget should be justified. <p>ACTION: Partners to confirm their bank details to FV asap for PENTA to proceed with Second Pre-Financing release.</p> <p>ACTION: PENTA to coordinate the Periodic Report drafting starting with instructions to be circulated by the end of March.</p>



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

<p>10) Consortium Meeting 2020 (MS)</p>	<ul style="list-style-type: none"> • Meeting will take place in June, 17th – 18th 2020 in Harare, Zimbabwe. • Venue: Cresta Lodge Harare • PENTA will take care of the logistics and their budget will cover major shared expenses (Consortium dinners, meeting rooms, ...) whereas each Partner will need to cover their delegates' travel and accommodation expenses (see Travel Expenses budget line under WP1). • Need to monitor the situation for travel in case of pandemic status. <p>ACTION: PMT will send e-mail with logistic information by March.</p>
<p>11)</p>	<ul style="list-style-type: none"> • Next Meeting: 3 months time, details to be confirmed.



EDCTP



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