Trial Set-up and Management

Emily Dennis - MRC CTU at UCL

PediCAP Fourth General Assembly TC – 23rd September 2020

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

Protocol, ethics and regulatory

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Protocol

Protocol v3.0

- Submission of v3.0 postponed slightly.
- Uganda and Zambia to open on protocol v2.0.
- Aim to submit protocol v3.0 as a substantial amendment in Q4.
- Aim for South Africa and Zimbabwe to open on protocol v3.0.

Ethics and Regulatory Submissions

UK

- UCL REC approval received 13th August 2020.

Sites

- All ethics and regulatory approvals received at all sites.

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Timelines

- Pushing forward with opening two sites this year.
  - Uganda – remote SIV planned for 24th September 2020.
  - Zambia – remote SIV planned for 2nd October 2020.
- Plan to open the other three sites in January 2021.
- As previously decided, all sites will open initially to PediCAP-A.

- Point-of care CRP tests have been purchased and are currently being manufactured.
  - Estimated delivery to Uganda and Zambia by end of October 2020.
  - This means FPFV is likely to be end of October/beginning of November 2020.

MRC CTU at UCL Team

- New Clinical Project Manager – Ben Spittle. Will be taking over from Clare Shakeshaft.
- All still working from home due to COVID-19 and will be for the foreseeable future.
- COVID-19 has brought additional workload for many of the team. Data Management Services in particular have not been able to give us as much time as they may have in other circumstances.

Database Development

- Phase 1 of the database has been developed and is currently being tested.
- Phase 1 includes all forms except the substudy forms, and an Individual Visit Schedule Report.
- The substudy forms, validation checks and additional reports will be included in phase 2 and 3 of database development.
- Until phase 2 is released, manual checks on the data will be performed every 2 weeks by the Trial Statistician and queries will be added to the database manually by the Data Manager.
- Estimated go-live date for phase 1 is the beginning of October 2020.
- All site staff who will be entering forms on to the database will be required to complete additional data entry training to gain access to the live database. This will include adding dummy data to the test database. The Data Manager will contact sites individually after their SIV has taken place with details on this training.

Monitoring

- Following completion of the initial SIV's, we will finalise the monitoring documents and hold a separate training session for the local monitors.
- We will aim for the first monitoring visit at each site to take place after the first 5 patients have been randomised and preferably no later than 3 months after the first patient was randomised.
- Local monitor contracts will need to be finalised and signed prior to this visit taking place.

IMP

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- IIT Agreement between Penta and Sandoz has been finalised and signed.
- Uganda
  - Pharmacy induction completed 4th September 2020.
  - Received importation permit 8th September 2020.
  - Induction pack circulated and essential documents all completed and received.
  - Greenlight for shipment expected to be issued by the end of September 2020.
- Zambia
  - Applied for importation permit.
  - Induction pack circulated on 21st September.
  - Pharmacy induction scheduled for 25th September 2020.
- South Africa and Zimbabwe
  - Will be in contact within the next 2 months to start process.

Deliverables

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WP2 Deliverables Achieved

Previously achieved

- **2.1 Trial Protocol (UCL) – December 2019**
- **2.2 Ethics Advisor Report Year 1 (UCL) – March 2020**

Achieved since April 2020

- **2.3 Drug Procurement (PENTA) – October 2020**

  IIT agreement has been signed.

- **2.10 First study subject approvals package Approvals required for invitation/ enrolment of first subject in at least one clinical centre (UCL) – December 2020**

  This is complete and will be submitted with next set of deliverables.

Deliverables – Next Steps

- **2.4 CRFs and Database (UCL) Other – November 2020**

  CRFs have been designed and finalised. Phase 1 of the database has been developed and is currently being tested.

- **2.5 Incidental findings policy (UCL) – November 2020**

  This has been drafted and will be finalised prior to November 2020.

- **2.6 Statistical Analysis Plan (UCL) – November 2020**

  To be finalised prior to the first data review for the trial.

WP 2 Deliverables - Next Steps

- **2.7 TSC and DSMB Charters (UCL) – December 2020**

  Both charter have been finalised. TSC Charter has been signed. Awaiting final signature on DSMB charter.

- **2.8 Data management plan (UCL) – December 2020**

  First draft has been reviewed by MRC CTU's Quality Management Advisory Group. To make amendments and finalise before FPFV.

- **2.9 MTAs and import/export licenses for shipment of samples (UCL) – December 2020**

  MTAs to be finalised prior to first sample shipment.