

Hello and welcome to the first DolPHIN 2 Newsletter!

Every three months, we will be producing an update on the progress of the project, key events and upcoming activities. We hope you find the information useful. Please get in touch with us at dolphin@liv.ac.uk should you have any questions about the project.

About the DolPHIN 2 Project

DolPHIN 2 is a multinational project led by the University of Liverpool which aims to reduce the rate of mother to child transmission (MTCT) of HIV by researching a new HIV drug called Dolutegravir.

The project will investigate whether dolutegravir is better than the current standard of care at preventing mother to child transmission (PMTCT) of HIV for women who begin HIV treatment in the third trimester of pregnancy. It will also develop ways to support the implementation of dolutegravir, should it prove superior to the standard of care.

The project involves:

- A multi-site clinical trial – taking place in Uganda and South Africa
- Qualitative studies - assessing the acceptability of dolutegravir and the reasons for late presentation in pregnancy
- A Pharmacoeconomic study – assessing the cost effectiveness of dolutegravir against the standard of care in South Africa and Uganda.

Meet the team

The DolPHIN 2 consortium is a multinational partnership comprising five research organisations and our funder, Unitaid.

University of Liverpool (UoL) is lead partner for the whole DolPHIN 2 project, responsible for overall programme management and implementation of the clinical trial, qualitative studies and pharmacoeconomic study. UoL is also the sponsor of the clinical trial.

Liverpool School of Tropical **Medicine (LSTM)** is responsible for both the management of the DolPHIN 2 clinical trial and lead partner for the qualitative studies within the programme

The Infectious Diseases Institute (IDI) is responsible for local co-ordination and implementation of the trial in Uganda as well as pharmacoeconomic research into the implementation of dolutegravir.

University of Cape Town (UCT) is responsible for recruitment, coordination and implementation of the clinical trial within South Africa.

Radboudumc (RU) is responsible for external monitoring of the clinical trial, ensuring that that it is carried out to a high quality standard, and in accordance with Good Clinical Practice (GCP) standards.



Key Activities Update

The DolPHIN 2 project commenced in December 2016, when the University of Liverpool executed our contract with our funders, Unitaid.

Since then, the team has been working hard on the project set-up phase, comprising the following key activities:

- Developing the protocol and processing all necessary ethical and regulatory approvals for the clinical trial
- Arranging the drug supply chain management for the clinical trial
- Establishing a qualitative research team who will investigate the challenges and identify effective strategies for implementing dolutegravir
- Developing and implementing a project communications plan, including the DolPHIN 2 website and social media channels. You can follow us on Twitter @UoLDolPHIN2

DolPHIN 1 Update

The DolPHIN 1 trial is a pilot study which will inform DolPHIN 2 on optimal dosing of dolutegravir. The trial commenced recruitment on 14th March 2017. 16 women have been recruited so far across both trial sites in Uganda and South Africa and the interim analysis of the trial is currently underway.

As well as informing dosing for DolPHIN 2, DolPHIN 1 has also enabled the trial teams to identify practical recruitment and retention strategies which will support DolPHIN 2



Key Events

The D2 consortium launched the project with our annual consortium meeting in Cape Town in March 2017 and the Programme Management team welcomed Unitaid to Liverpool in June. Both meetings have been essential to the development of the trial protocol and procedures, drug supply chain and qualitative studies



Upcoming Events and Public Engagement Activities

Members of the D2 consortium will attend both the **International AIDS Conference in Paris**, July 23 – 26 and the **ART Investigators meeting** on July 27. D2 Chief Investigator Prof Saye Khoo will attend the **European AIDS Clinical Society conference 2017** in Milan, October 25-27. This will be an opportunity to share an update on the progress of the project with ID clinicians and HIV civil society groups

Priorities for the Next Quarter

The key milestone for the team over the coming months is the recruitment of the first patient to the trial. The programme management team is therefore focussed on ensuring all contracts, approvals, policies and procedures are in place in order that we can commence recruitment by our target date of September 2017. Site Initiation Visits to both Uganda and South Africa will take place in early September.

In addition, a qualitative research associate will be recruited and inducted in the next quarter, when protocol development for qualitative studies in Uganda and South Africa will commence.