



PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

CLINICAL TRIAL SERIOUS ADVERSE EVENTS (SAEs) REPORTS CAUSALITY ASSESSMENT FORM

Clinical trial ref no: CT149/2017

Period: August 2018

Title: IMPAACT 2010: Phase III Study of the Virologic Efficacy and Safety of Dolutegravir-Containing versus Efavirenz-Containing Antiretroviral Therapy Regimens in HIV-1-Infected Pregnant Women and their infants.

Principal Investigator: Dr. L. Stranix-Chibanda

Current Approved Protocol version: 1.0 dated 21 April 2016

Participant ID	MCAZ Ref #	SAE	Suspected Drug(s) (and dose)	Concomitant medicine(s) (Including start and stop date, and dose)	Clinical Findings/ Laboratory Values	SAE Management and Outcome	AE Listing in Summary of Product Characteristics	Evidence from Literature review	PI Causality Assessment	Recommended Causality classification
606 7531L	CT149 /2017	Meconium Aspiration Syndrome	DTG/FTC /TDF	None	<p>The mother of the infant was enrolled into the study in February 2018. The mother and the pregnancy progressed normally through the visits up until delivery via caesarian section on the 4th of August.</p> <p>During labour the membranes ruptured</p>	<p>The infant was put on amoxicillin 62.5mg bd and commenced on Nevirapine prophylaxis 15mg od.</p> <p>Outcome – Resolved as the infant was discharged from the neonatal unit on the 7th of August.</p>	None	None	Unlikely	Unlikely



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					and she was draining meconium stained liquor. She failed to progress and was sent to theatre. At birth the infant had recessive breathing.					
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Literature review

There is no literature that suggests that use of ART such as DTG/FTC/TDF causes meconium aspiration syndrome.

Evaluator's comments

The pregnancy was post-date and this likely resulted in the infant passing meconium in utero. The added stress of the attempt at vaginal birth which did not progress likely caused the baby to aspirate.

References

1st Reviewer	L. Mumbengegwi	Signature: 	Date: 21/08/2018
2nd Reviewer	A.T. Takaendesa	Signature: 	Date: 24/08/2018