CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
KKR	UNITED STATES	12	SEP	1990	30 Years	Male	30.00 kg	12	JAN	2016	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Rash [Rash pruritic]
Cerebral Haemorrhage [Cerebral haemorrhage]

Case Description: This serious report from study report from the United States received on 06-SEP-2016 by an investigator describes the occurrence of Cerebral haemorrhage, and Death in a 25 year-old White male subject taking Rxstudy1 as a participant in the following clinical trial protocol: Rx Study 1: Clinical study double blinded for drug and vaccine

The past medical history for the subject included: Hypertension,

(Continued on Additional Information Page)

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☒ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Cipla US Tablet (P-COUMARIC ACID 100 g) Injection, 100 millimole {Lot # 12345; Exp.Dt. 01-SEP-2016}
#2) ALP VACCINE (PARACETAMOL 32 DF, HYDROCHLORIC ACID 56 **(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 50 mg, bid	#1) Oral
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Constipation (Constipation)
#2) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) JUL-2016 / 15-AUG-2016	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
05-AUG-2016 to Ongoing	Current Condition	Hyperaemia (Hyperaemia)
	The patient's currently suffering from "Hperaemia"	
01-JAN-2014 to 06-MAY-2014	Historical Condition	Abdominal pain (Abdominal pain)
	Patient suffered from "Abdominal Pain" in the past	

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Rxlogix
James M Potter
500 College Rd East, Suite 203
Princeton, New Jersey 08540 UNITED STATES
Phone: 223 910 1072 Extn: 1 609

26. REMARKS
Medically Confirmed: Yes

24b. MFR CONTROL NO.
16US001978

24c. DATE RECEIVED BY MANUFACTURER
06-SEP-2016

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☒ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
02-JUL-2018

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
Mr Chris
Dept: Pathology, Pathlab
REF: QA-89
21/6 Author Road
Trenton, New Jersey 1278
UNITED STATES