

Listing of LEO EudraCT: 2010-019602-16

Title: LEO EudraCT: 2010-019602-16

Number: A091876

Population: Safety

Subject ID	Onset Date	Type of Event	Description	Causality	Causality	Causality
				Lapatinib	Capecitabine	Oxaliplatin
LEO-01/1	2011-07-23	SAR	Gastrointestinal - diarrhoea & vomiting grade 2	Probably	Probably	Possibly
02/1	2012-05-17	SAR	Gastrointestinal & Pain Grade 2	Probably	Probably	Probably
05	2012-09-03	SAR	Dysphagia (grade2) & Dyspepia (Grade 3)	Unlikely	Possibly	Not Related
02/04	2012-11-02	NA	NOT AN SAE	NA	NA	NA
08	2013-01-14	SAR	Diarrhoea/Nausea/Vomiting	Probably	Probably	Possibly
02/09	2013-04-15	SUSAR	Anastomatic leak leading possibly to small bowel obstruction Grade 3	Possibly	Possibly	Possibly
02/10	2013-07-08	SUSAR	Anastomotic leak leading to chest infection and overwhelming sepsis Grade 5	Possibly	Possibly	Possibly