Guidance Front Sheet Document on Reference Safety Information

Study title	SCOT: Short Course Oncology Therapy – A Study of Adjuvant Chemotherapy in Colorectal Cancer
Prepared by	Lindsey Connery
Version	3
Date	03 Apr 2014

This document provides Investigators with advice on what trial documentation is to be referred to for the clinical management of SCOT patients. This document also includes what documentation will be used by Pharmacovigilance at the CR-UK Trials Unit Glasgow (CTU), to assess the expectedness of SAE reports for the SCOT trial, the Reference Safety Information (RSI).

1. **Study title: SCOT:** Short Course Oncology Therapy – A Study of Adjuvant Chemotherapy in Colorectal Cancer
2. **EudraCT number:** 2007-003957-10
3. **Chief Investigator:** Dr Tim Iveson
4. **Reason for circulation:** To update the documents to be referred to for the clinical management of SCOT patients and the documents which are acting as the RSI in the new DSUR reporting period

The following SmPCs are to be referred to by sites for the clinical management of trial patients and are available on the trial website:

Oxaliplatin SmPC from 10 Jul 2012 (produced by Accord)
Capecitabine SmPC from 23 Jan 2014 (produced by Roche)
5-Fluorouracil SmPC from 24 Aug 2011 (produced by Hospira)
Folinic Acid SmPC from 17 Oct 2012 (produced by Medac)

However section 4.8 undesirable effects of the following documentation will be used by CR-UK CTU as the RSI for assessing the expectedness of SAE reports:

Oxaliplatin SmPC from 10 Jul 2012 section (produced by Accord)
Capecitabine SmPC from 30 Jun 2011 (produced by Roche)
5-Fluorouracil SmPC from 24 Aug 2011 (produced by Hospira)
Folinic Acid SmPC from 17 Oct 2012 (produced by Medac)