Guidance Front Sheet Document on Reference Safety Information

Study title	PRIMUS 001
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This document provides Investigators with advice on what trial documentation is to be referred to for the clinical management of PRIMUS 001 patients. This document also includes what documentation will be used by Pharmacovigilance at the CRUK Trials Unit Glasgow (CTU), to assess the expectedness of SAE reports for PRIMUS 001, the Reference Safety Information (RSI).

1. **Study title:** PRIMUS 001 A PRECISION PANC CLINICAL STUDY
   An adaptive phase II study of FOLFOX-A (FOLFOX and nab-paclitaxel) versus AG (nab-paclitaxel and gemcitabine) in patients with metastatic pancreatic cancer, with integrated biomarker evaluation (CTA: 24712/0042/001-0001) (REC 17/WS/0142)
2. **EudraCT number:** 2016-004155-67
3. **Chief Investigator:** Dr Janet Graham
4. **Reason for circulation:** To inform investigators which documents are to be referred to at the start of the trial, for clinical management of PRIMUS 001 trial patients and which documents Pharmacovigilance will be using as RSI to assess expectedness of serious adverse reactions

The following SmPCs are to be referred to for the clinical management of trial patients and are acting as the Reference Safety Information (RSI):

Fluorouracil SmPC dated 27 Apr 2016 (produced by Accord Healthcare Limited) (Section 4.8 acting as RSI)

Oxaliplatin SmPC dated 10 Jul 2012 (produced by Accord Healthcare Limited) (Section 4.8 acting as RSI)

Gemcitabine SmPC dated 01 Jul 2014 (produced by Eli Lilly and Company Limited) (Section 4.8 acting as RSI)

Folinic Acid SmPC dated 14 Aug 2014 (produced by medac GmbH) (Section 4.8 acting as RSI)

Abraxane SmPC dated 22 Nov 2016 (produced by Celgene Ltd) (Section 4.8 acting as RSI)