Guidance Front Sheet Document on Reference Safety Information

**Study title** | PRIMUS 001
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**Version** | Version 7
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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 Jane Graham
4. **Reason for circulation:** To inform Investigators of the documents pharmacovigilance will be using to assess expectedness for SAE reports and the documents Reporting Investigators should refer to for the clinical management of PRIMUS 001 trial patients in the new 2020 – 2021 DSUR reporting year

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

- **Fluorouracil SmPC dated 24 Apr 2019** (produced by Accord Healthcare Limited)  
  (Section 4.8 acting as RSI)

- **Oxaliplatin SmPC dated 25 Oct 2019** (produced by Accord Healthcare Limited)  
  (Section 4.8 acting as RSI)

- **Gemcitabine SmPC dated 12 Jul 2019** (produced by Hospira) (Section 4.8 acting as RSI)

- **Folinic Acid (Sodiofolin) SmPC dated 27 Aug 2018** (produced by medac GmbH)  
  (Section 4.8 acting as RSI)

- **Nab-paclitaxel (Abraxane) SmPC dated 19 Nov 2019** (produced by Celgene Ltd)  
  (Section 4.8 acting as RSI)