Guidance Front Sheet Document on Reference Safety Information

Study title	PRIMUS 002
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Version	Version 6
Date	06 July 2020

This document provides Investigators with advice on what trial documentation is to be referred to for the clinical management of PRIMUS 002 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 002, the Reference Safety Information (RSI).

1. **Study title:** PRIMUS 002 A PRECISION PANC Study An umbrella phase II study examining two neo-adjuvant regimens (FOLFOX-A and AG) in resectable and borderline resectable Pancreatic Ductal AdenoCarcinoma (PDAC), focusing on biomarker and liquid biopsy development
2. **EudraCT number:** 2016-004156-29
3. **Chief Investigator:** Dr Derek Grose
4. **Reason for circulation: To inform investigators of the documents Pharmacovigilance will be using to assess expectedness of SAE reports and the documents sites should refer to for the clinical management of PRIMUS 002 patients in the new DSUR reporting year 2020 - 2021**

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 24 Apr 2019 (produced by Accord) (Section 4.8 acting as RSI)

Oxaliplatin SmPC dated 04 Apr 2019 (produced by Accord) (Section 4.8 acting as RSI)

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

Folinic Acid SmPC dated 27 Aug 2018 (produced by Medac GmbH) (Section 4.8 acting as RSI)

Abraxane SmPC dated 03-Apr-2019 (produced by Celgene Ltd) (Section 4.8 acting as RSI)

Capecitabine SmPC dated 25 Jul 2019 (produced by Roche Products Ltd) (Section 4.8 acting as RSI)