PRODUCT / SERVICE TERMS

These Product/Service Terms apply to certain Products that you access through our platform(s), website(s) or are otherwise identified in your order form, statement of work or other ordering document (collectively "**Order**") and supplement the Clarivate Terms which apply to all of our products. If you have ordered or are accessing a product that is not listed below, then these Product/Service Terms not apply to your order. "**We**", "**our**" and "**Clarivate**" means the Clarivate entity identified in the order form; "**you**" and "**your**" means the Client entity identified in the order form. Any other terms not defined in these Product/Service terms have the meaning given to them in the Clarivate Terms.

Drug Safety Triager

1. Permitted Uses. You may use the Product to search, view, retrieve, display, download and print Data, including without limitation, to supply copies of individual items to national or international regulatory authorities (including without limitation for the purposes of regulatory approval of pharmaceutical products). You may use the Information Service and any information derived therefrom solely in support of your business and no other.
2. Regulations and Standards. Clarivate shall provide the Product according to the following regulations and standards: a) EU Good Pharmacovigilance Practices (GVP) Quality System guideline; b) EU GMP Vol 4 Annex 11: Computerized Systems; c) EU Medicinal Products for Human Use Volume 9 Pharmacovigilance; d) FDA Guideline: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment; e) FDA Guidance: Principles of Software Validation; f) 21 CFR Part 11 Electronic Records Electronic Signatures; g) 21 CFR 312.33 US-IND Annual Reporting and 314.80 Post-marketing Reporting of ADRs; h) 21CFR 820 (Medical Device) and 21 CFR 211 (Finished Pharmaceuticals) Personnel Regulatory Requirements; i) ICH Q10 Pharmaceutical Quality System
3. QMS Audits. You may, at your own expense, conduct a quality ("QMS") audit of the systems, personnel and records related to the Drug Safety Triager (DST). Such audit and review shall be conducted not more than one time every three years, with no less than ninety (90) days prior written notice to Clarivate. Such examinations (i) may be conducted by you or a nationally recognized independent accounting firm; (ii) will be limited to records related to the three-year period immediately preceding the notice of examination; (iii) will be conducted remotely and carried out only during Clarivate's normal business hours; (iv) will be in total a maximum of 2 days duration; and (v) will not unreasonably interfere with Clarivate's business operations. For any subsequent audit findings, Clarivate will provide corrective and preventative action responses in a timely fashion if required. If you request a QMS audit more than once every three years, in addition to the conditions specified in this paragraph, you will bear all Clarivate expenses for such audit(s), including without limitation any internal expenses incurred by Clarivate to support the audit or a fixed charge for Clarivate's expenses, to be agreed in writing by the parties in advance of the audit. Clarivate will provide a pre-audit SOP index upon request; other pre-audit and audit support activities are included in the QMS audit limits. Your self-service activities, such as data extracts, are out of scope for Clarivate's audit support.

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