

Contractual Agreement in Pharmacovigilance

The overview of all individual contractual agreements must be part of the pharmacovigilance system master file (PSMF). Any products specific information can be added or modified as an addendum to the existing agreements.

Types of Agreements

1

Technical agreements (TA)

Subcontracted PV work between MAH and service provider

2

Manufacturer's agreement:

any regulatory actions from manufacturer to be forwarded to MAH within 3 days

3

Safety data exchange agreements (SDEA):

co-licensing or co-marketing arrangements within the EEA

4

Distributors agreement/ simple PV agreement:

ADRs, complaints and regulatory enquiries

ELC Group provides a full range of support and advice for any third-party arrangements to be entered into by MAHs, and can help ensure full compliance across intergrated pharmacovigilance activities.



Concept to Safety

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