Annex IV
Minimum technical requirements declaration

I, the undersigned, being the authorised signatory (including all consortium members, in case of a consortium, and subcontractors) confirm that the present tender meets the following minimum technical requirements as set out in section 3.2 of the Technical Specifications[1]:

No.	Minimum technical requirement	YES	NO
1	Compliance with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU.	☐	☐
2	The working language of the Agency is English and the contractor must confirm that it will be able to communicate with the Agency in English for seamless implementation and execution of all the services covered within the scope of the contract, including responsibilities resulting from regulatory requirements such as Health and Safety and Data Protection, as well as for the efficient and timely response in respect to contract management	☐	☐
3	Processing of personal data in connection with this service must comply with EU data protection legislation and in particular, Regulation (EU) 679/2016, the General Data Protection Regulation.	☐	☐
4	Technical Prerequisites: • The platform must be accessible via a standard web browser. • The platform must be compatible with the IT environment at the Agency (Windows 7 and 10, MS Office 2010 and 2016, Adobe Flash Player 28, Java 7, Internet Explorer 11).	☐ ☐	☐ ☐
5	Data: The **data** is required to be current, comprehensive, complete and frequently updated covering: • **Scientific information and adverse reaction reports on medicinal products and medical devices for humans at all stages of their lifecycle** development phase, clinical trials information, safety and efficacy, research, development and marketing data, therapeutic area, mechanism(s) of action, indications, formulations, routes of administration, INN and product names, (bio-)chemical class (cell and gene therapy, monoclonal antibody, recombinant DNA, etc), bibliographic references, orphan status, generics and biosimilars, regional location of main studies,	☐	☐

[1] Tenderers should note that a 'no' answer to any of these questions will result in the tender being automatically eliminated from further evaluation.

No.	Minimum technical requirement	YES	NO
	abstracted public adverse reaction reports. • **Business and commercial information** (e.g. company pipeline, market shares, company revenue, company deals, potential developments within specific therapeutic areas, revenue and sales, merging and acquisitions, licensing, patents (e.g. countries in which valid, expiration, litigations), CAGR (compound annual growth rate) related to human medicinal and medical device industry divided by major regional markets (EU, USA, Japan, BRIC). • Reference made should be accessible or at least abstracted	☐ ☐	☐ ☐
6	Language of the content: English	☐	☐
7	Searching, exporting, accounts and alerts: • Search facilities must include a **basic search function** (full text search) and a **filter or search function** to limit results by specified parameters as described in the data requirement section above and including language, time period, location, therapeutic areas, ATC code, indication, product identifier (INN, trade name), organisation, mechanism of action, development phase, orphan status, (bio-)chemical entity (e.g. new, generic, biosimilar, fixed combination) and (bio-)chemical class (cell and gene therapy, monoclonal antibody, recombinant DNA, etc.), revenue, market value, medical devices, adverse reaction, formulation, and route of administration. • The search results must be **printable** and **exportable** into MS Office applications. • The tendered database(s) must have individual and personalised user accounts with alerts function.	☐ ☐ ☐	☐ ☐ ☐
8	Administration, license: • A license based on IP recognition for an unlimited number of EMA staff and a period of 4 years. • Access to an administrative account for the EMA Information Centre's team to monitor the usage and to run regular usage reports and statistics. Alternatively this data must be provided by the tenderer as and when required by the Agency without further costs.	☐ ☐	☐ ☐
9	Customer Support: • (A) dedicated person(s) responsible for the overall management of the contract and for the communication with the Agency.	☐	☐
10	Customer Services:	☐	☐

No.	Minimum technical requirement	YES	NO
	Online and telephone support Mon-Fri 09h00 to 17h00 (CET), except on the Agency holidays and the public holidays at the Contractor's location. (Please see here for the Agency holidays: https://www.ema.europa.eu/about-us/contact/business-hours-holidays).		
11	Training: Provision of initial training on the use of the database free of charge. The tenderer may propose a remote training or provide online training material.	☐	☐

Date:

Signature of authorised representative:

(Print name):

Position in company:

Representing (name of tenderer):