Specific Terms

“Scientific literature monitoring” option

Option of RADAR Autonome, supplementing the Terms and Conditions

Reference	RAD-CP-LIT, version 1.1 of 06/11/2026
Status	Version approved by Rémy Moulin on 06/11/2026
Entry into force	On publication in the Tool; for each Customer, when the Option is activated or, if the Option is already active, on its acceptance by an administrator (Article 10)
Translation	Courtesy translation of the French version (RAD-CP-LIT v1.1), for information only. In case of discrepancy, the French version prevails
Publisher	AVADA-CONSULT (AVADA Consult), a French SARL with a share capital of €69,440, 205 Chemin du Mont, 69530 Orliénas, France; RCS Lyon 939 166 971
Contact	contact@avada-consult.fr; +33 6 84 09 05 87
Service	app.avada-consult.fr

The version enforceable against the Customer is the PDF of the French version published in the Tool on the date of its acceptance.

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Article 1. Purpose and relationship with the Terms and Conditions

These specific terms (the "Specific Terms") describe the paid option "Scientific literature monitoring" (the "Option") of RADAR Autonome. They supplement the general terms and conditions of sale of RADAR Autonome (the "Terms and Conditions"), whose definitions apply. In the event of conflict concerning the Option, the Specific Terms prevail; for all other matters, the Terms and Conditions apply.

Article 2. Definitions

- **Monitored Document**: a clinical evaluation report ("CER", Regulation (EU) 2017/745, Annex XIV) or a performance evaluation report ("PER", Regulation (EU) 2017/746, Annex XIII) of the Customer, existing or in preparation, for which the Option searches for new publications. The Monitored Document itself is never sent to AVADA Consult.
- **Strategy**: the search queries, filters and frequency of a Monitored Document, proposed by the AI and validated by an administrator of the Customer. Each validated version is kept.
- **Search**: the querying of the databases according to the validated Strategy, for a given period.
- **Possible Safety Signal**: an article or a Vigilance Item that the AI classifies as such under Articles 4.3 and 4.7. It is not a signal within the meaning of the vigilance regulations.
- **List of Monitored Devices** ("Devices to monitor" in the Tool): for a Monitored Document, the Customer's device and the equivalent or similar devices for which RADAR searches for recalls, incidents and safety notices. Each validated version is kept.
- **Vigilance Item**: a recall, an incident report, a safety notice, a marketing authorisation or a clinical trial, published by a source referred to in Article 4.7 and which mentions a device on the List of Monitored Devices.

Article 3. Access conditions

3.1 The Option is reserved for Organisations subscribed to RADAR Autonome, on a monthly or annual plan, and up to date with their payments. It cannot be activated during the free trial, except during a complimentary period offered by AVADA Consult (Article 7.3).

3.2 Only an administrator of the Organisation may activate the Option, add or stop a Monitored Document and validate a Strategy. Members view the results, take the decisions on articles, may propose a correction to the Strategy and may export.

Article 4. Description of the Option

4.1 **Strategy.** Based on the Customer's answers (indication, technology, equivalent or similar devices, medical condition, optional keywords) and on the description of the devices in its Profile, the AI proposes a Strategy. The Customer reviews it, corrects it if it so wishes and validates it. No Search takes place without a validated Strategy.

4.2 **Searches.** RADAR queries PubMed (National Library of Medicine, United States) and Europe PMC (EMBL-EBI) at the frequency chosen by the Customer, and on any fixed dates that the Customer adds. The first Search starts within one hour of the validation of the first Strategy; it goes back no more than twenty-four (24) months. The earlier period remains to be covered by the Customer. The date criterion is the date on which the article was entered into the database. Embase and the other subscription databases are not queried. Only the title, abstract and metadata of the articles are read.

4.3 **AI screening of articles.** Each new article is classified by the AI as "Possible safety signal", "Clinical performance" or "Not relevant", with a one-sentence reason. In case of doubt, the AI retains the highest class. Screening is an aid: it neither deletes nor hides any article, and every decision on an article rests with the Customer.

4.4 **Volume.** Where a Search contains more than two hundred (200) new articles, the Option keeps two hundred, Possible Safety Signals first, out of no more than one thousand (1,000) screened articles; the AI then proposes a

narrower Strategy, which the Customer validates or not. The articles not retained are counted and listed in the Excel export.

4.5 **Alerts.** The Possible Safety Signals of a Search, whether articles or Vigilance Items, give rise to a single email to all administrators of the Organisation and to the vigilance contact designated for the Monitored Document, followed by one reminder after five (5) Business Days if no one has acknowledged them in the Tool. No copy is sent to AVADA Consult.

4.6 **Monitoring log and export.** The Searches, the versions of the Strategy, the decisions (author, date, reason) and the follow-up given to alerts are recorded. The Customer exports, for the period of its choice, a Word file and an Excel file, dated and generated by the Tool, unsigned, which it approves within its own quality management system.

4.7 **Vigilance of equivalent devices.**

a) *List of Monitored Devices.* For each Monitored Document, RADAR proposes a List of Monitored Devices: the Customer's device, the equivalent devices it has cited, and no more than five similar devices known with certainty. The Customer corrects it; an administrator validates it. No vigilance source is queried until a List has been validated.

b) *Sources.* At each Search, RADAR queries the following public sources: FDA (recalls, MAUDE incident reports, 510(k) clearances and PMA approvals), ClinicalTrials.gov, MHRA (United Kingdom), ANSM (France), BfArM (Germany), Swissmedic (Switzerland) and Health Canada (recalls and notices, incidents). Notices published in PDF format by ANSM, BfArM and Swissmedic are read; other PDFs are flagged "not read by RADAR", with their link. A source that does not respond is shown as such ("did not respond") and is caught up at the next Search. A source that RADAR cannot read automatically (to date, the TGA, Australia) is shown as such at each Search: it remains to be consulted by the Customer. RADAR retains the items that mention a device on the List by its trade name; an item that refers to it in another way may not be retained.

c) *AI screening and grouping.* The AI summarises each Vigilance Item (device, manufacturer, problem, action), in the export language of the Monitored Document (Article 4.9), and classifies it as "Possible safety signal", "Useful information", "Recorded incident" or "Not relevant", with a one-sentence reason. In case of doubt, the AI retains the highest class. A marketing authorisation is never a signal. The AI groups the signals that reproduce the same failure mode, for one decision and one alert per group; each item in the group remains displayed. As for articles, nothing is deleted or hidden, and every decision rests with the Customer.

4.8 **Validation of screening.** The AI screening of articles and Vigilance Items has been validated by AVADA Consult on a reference dataset, in accordance with its quality management system (reports of 06/11/2026), for each output language offered. Any change to the AI model, to the screening instructions or to the output language gives rise to a new validation. The classes, summaries and proposals produced by the AI are identified as such in the Tool and in the exports.

4.9 **Language.** For each Monitored Document, an administrator chooses the language of the export (Word and Excel) and of the texts written by the AI (screening reasons, summaries of Vigilance Items, group titles, human-readable texts of the Strategy), from among the languages offered by the Tool. Only the output languages validated in accordance with Article 4.8 are offered; at the date of the Specific Terms, French and English. Articles and Vigilance Items (title, country, text) are displayed as collected by RADAR: they are not translated. A change of language applies to the subsequent responses of the AI; responses already stored are not translated. When the Monitored Document is created, the language is that of the Organisation's documents (Article 4.6 of the Terms and Conditions); any change is recorded.

Article 5. What the Option does not include

The Option is a self-service bibliographic monitoring service. It does not include the critical appraisal of articles, data extraction, the writing or updating of the CER or PER, the qualification of a vigilance signal, the reporting of an incident to the authorities, or any involvement of AVADA Consult in the content. There is no expert offer for the Option. The Customer remains solely responsible for its clinical evaluation or performance evaluation, its post-market surveillance and its vigilance obligations (Article 5 of the Terms and Conditions).

Article 6. AI and third-party services

6.1 **Anthropic.** The Strategy proposal, the proposal of the List of Monitored Devices, the screening and the grouping of signals go through the API of Anthropic (Claude), from the Tool's server, under Anthropic's commercial terms: content is not used to train the models. The following are sent: the type of Monitored Document, the Customer's answers, the description of the devices concerned, the List of Monitored Devices and, for screening, the title, abstract and metadata of the articles and the text of the Vigilance Items. The Organisation is identified by a number; no account data (name, email address) and no company name is sent. This processing supplements Article 6 of the Terms and Conditions and the "Anthropic" line of Annex 2 to the Terms and Conditions.

6.2 **Public databases and sources.** The Strategy queries, which may contain the name of the device, of its manufacturer or of equivalent devices, are sent to the National Library of Medicine (United States) and to EMBL-EBI (United Kingdom), publishers of these public databases, as with any search. Likewise, the names on the List of Monitored Devices and, where applicable, the FDA product code and the manufacturer, may be sent as search terms to the sources referred to in Article 4.7 b). A Customer who does not wish to send a name (for example, that of a device that is still confidential) removes it from the Strategy or from the List before validating it.

6.3 **Content of articles and notices.** Titles, abstracts and metadata belong to their authors and publishers; notices and reports, to their authors. They are displayed for the Customer's internal use as part of its monitoring. AVADA Consult does not guarantee their accuracy or their completeness, nor the availability of the databases and sources.

Article 7. Price and invoicing

7.1 The price is fifty euros (€50) excl. VAT per month per Monitored Document on the monthly plan, and five hundred and forty euros (€540) excl. VAT per year per Monitored Document on the annual plan. The Option activated without any Monitored Document costs nothing.

7.2 A Monitored Document is invoiced from the validation of its first Strategy, pro rata to the current subscription period, and charged immediately; it is then invoiced with the subscription on each renewal date. Articles 8 and 9 of the Terms and Conditions (price, payment, payment incident) apply.

7.3 **Complimentary period.** AVADA Consult may offer the Option for a duration and a number of Monitored Documents that it sets; the complimentary period and its end date are displayed in the Tool. It is not invoiced and **does not give rise to any automatic invoicing at its end**: the Searches for the complimentary Monitored Documents stop on the end date, except for those that the Customer has chosen, before that date, to continue under the paid Option, whose pro rata invoicing starts on the end date of the complimentary period. An email notifies the administrators seven (7) days before the end. The results, the monitoring log and the export remain available under the conditions of Article 8.

Article 8. Stopping a Monitored Document, cancellation and reversibility

8.1 An administrator may stop a Monitored Document at any time. The Searches stop at the end of the paid period (end of the month on the monthly plan, end of the paid year on the annual plan), with no refund for the current period. The stop may be withdrawn as long as that date has not passed.

8.2 The Option ends with the RADAR Autonome subscription. The results, the monitoring log and the export then remain available during the ninety (90) days of read-only access provided for in Article 13 of the Terms and Conditions, and are then deleted with the other data of the Organisation.

Article 9. Liability

Article 19 of the Terms and Conditions applies. In particular, AVADA Consult is not liable for an article that is absent from the databases queried, incorrectly indexed or outside the Strategy validated by the Customer; for a Vigilance Item that is not published by a source referred to in Article 4.7, that is published by a source that cannot be read automatically, or that does not mention a device on the validated List by its trade name; for an article or an Item classified by the AI in a class that the Customer would have judged differently; or for an email not received. The Tool permanently displays the Possible Safety Signals not yet addressed.

Article 10. Changes

AVADA Consult may change the Option and these Specific Terms under the conditions of Article 21 of the Terms and Conditions. A new version of the Specific Terms is subject to acceptance by an administrator.

Document history

Version	Date	Change
1.0	05/11/2026	Initial version
1.1	06/11/2026	Language of the AI responses and of the export, chosen by an administrator from among the validated languages (Articles 4.7 c, 4.8 and 4.9); Tool labels quoted (Articles 2 and 4.7 b); processing entrusted to Anthropic completed (Article 6.1); validation reports of 06/11/2026, French and English output (Article 4.8)