



The project entitled: "Discovery and development of a new clinical drug candidate for the eradication of cancer stem cell in the treatment of hepatocellular carcinoma, through degradation of oncofetal transcription factor - Stage II". Financed by European Funds for Smart Economy 2021-2027 (FENG), SMART Track.

Appendix no. 2

Technical Specification: The bidder will provide medical dictionary software for coding and analyzing data for clinical trials, O at least the following functionalities:	
1.	Includes standardized naming of drug names (pharmaceutical form of the drug, active ingredients, trade names)
2.	Contains Drug Safety Information
3.	Is recommended by regulatory bodies FDA, EMA, WHO, compliant with ICH
4.	Allows monitoring the safety of pharmacotherapy
5.	Automatically update data resources in the database
6.	Standardized way of presenting data
7.	Compatibility with MEDdra (Medical Dictionary for Regulatory Activities) enabling full analysis of adverse reaction data.
8.	Compatibility with Electronic Adverse Event Reporting System (e.g. E2B-compatible systems).
9.	Compatibility with clinical trial database management tools (EDC, CTMS) dedicated to clinical trials.
10.	Ensures compliance with international reporting requirements, including WHO programs.
11.	Allows searching of information in the database by trade name, active substance, ATC code.
12.	Allows generation of reports for drug safety analysis.
13.	Possible to import and export data in XML, CSV formats.
14.	Compliance with European data protection regulations GDPR (General Data Protection Regulation).
15.	Software available in Polish or English



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By submitting an offer in the Proceeding LL/2/25, the Bidder declares, the compliance of the offered product with all requirements described in Appendix No. 2