

Information No 1 for Contractors to the Request for Bids No 11/WPD104/2020 announced on October 23, 2020 (announcement in the Competitiveness Base No. 2020-779-13537), as a part of the project entitled: *New approach to glioblastoma treatment addressing the critical unmet medical need*, under the contract No. POIR.01.02.00-00-0084/18-00, co-financed by the European Union under the *Smart Growth Operational Program 2014-2020, Priority I: Support for Research and Development work by Enterprises, Measure 1.2: Sectorial Research and Development Programs, Sectorial Program InnoNeuroPharm*

Awarding Entity's name and address:

WPD Pharmaceuticals sp. z o. o.
ul. Żwirki i Wigury 101, 02-089 Warszawa

entered in the Register of Entrepreneurs of the National Court Register kept by the District Court for the capital city of Warsaw in Warsaw, 12th Commercial Division of the National Court Register, under No. KRS 0000693186, initial capital of PLN 888 950,00 NIP: 5252721500

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Awarding Entity's authorized representative:

Mariusz Olejniczak – President of the Management Board

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Information for the Contractors, announced on November 10, 2020:

The Awarding Entity informs about changes incorporated to the Request for Bids No. 11/WPD104/2020:

- Within Section V – clarification of the Point 1.1 a)

The Awarding Entity requires Contractors to have at least **six (6)** years of experience in the provision of CRO services in the field of organization and conducting **commercial** clinical trials (**in accordance with article 37 of the Polish Pharmaceutical Law (Journal of Laws 2020, section 944 with the updates)**) (including basket trials and adaptive trial design) at the requests of Sponsors, according to GCP, including documented experience in conducting at least four (4) clinical trials in oncology (in advanced solid tumors) and (...). **The presented experience must result from services performed on the basis of contracts concluded directly with sponsors of commercial clinical trials in the scope above. The contractor should perform the above-mentioned works not as a subcontractor, in particular not as a subcontractor of another CRO.**

- Within Section V – clarification of the Point 1.1 c)

In terms of technical potential, the Awarding Entity requires that the Contractor has adequate experience in operating electronic systems dedicated for clinical trials management and conducting, as well as data collection (...). **The Awarding Entity also requires that, due to the planned start date of the clinical trials, the contractor has an open contract with a leading supplier of electronic systems eCRF (e.g. Medidata, Oracle or equivalent) and eTMF (e.g. Trial Interactive or equivalent) (...).**

The Ordering Party reserves the right to conduct a quality audit before signing the contract with the selected contractor in order to confirm the accuracy of the data provided by the Contractor in the Bid.