Information No 2 for Contractors to the Request for Bids No 02/WPD104/2020 announced on the 29th April 2020 (announcement in the Competitiveness Base No. 1244028), 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, NIP: 5252721500
Tel: +48 515 262 381
www.wpdpharmaceuticals.com

Awarding Entity's authorized representative:
Mariusz Olejniczak – President of the Management Board

Contact person for the Request for Bids authorized by the Awarding Entity:
Mariusz Olejniczak
e-mail: oferty@wpdpharmaceuticals.com

The Awarding Entity informs about the change of the Request for Bids, in the Section V (Contract award procedure participation terms), Part 1, point 1), letter b):

Before: at least one (1) person with a specialized education (in medical sciences, pharmacy, biotechnology, veterinary medicine, chemistry or biological sciences or related fields) on the position of Clinical Research Associate (CRA), with at least six (6) years of experience in clinical trials monitoring including monitoring at least two (2) clinical trials in oncology; and at least one (1) oncology clinical trial in pediatric population;

After: at least one (1) person with a specialized education (in medical sciences, pharmacy, biotechnology, veterinary medicine, chemistry or biological sciences or related fields) on the position of Clinical Research Associate (CRA), with at least six (6) years of experience in clinical trials monitoring including monitoring at least two (2) clinical trials in oncology; and at least one (1) ~~oncology~~ clinical trial in pediatric population;

The Awarding Entity on the 18th May 2020 answer for question asked by the Contractors on the 15th May 2020:

Question No 1:
What you are referring to when requesting a "dedicated CRA" for the pediatric GBM study.

1. Is your expectation that the CRA would be fully allocated and dedicated to the pediatric GBM study? Meaning we would assign them as 1 FTE, with no availability to support other trials.

OR

2. Is your expectation that there would only be a single CRA (not multiple) assigned to the pediatric GBM study, at the appropriate FTE percentage? If they have additional availability they may be assigned to another study (WPD or other)

Answer No 1:
The Awarding Entity specifies that "dedicated CRA" means single CRA for the implementation of a clinical trial in the pediatric population, without fully assigning the CRA to only the one study.

Question No 2:
Is Docusign acceptable method for signature, or must it be wet ink?

Answer No 2:
The Awarding Entity allows for the signing of submitted documents with a qualified electronic signature.

Question No 3:
For Appendix 4 List of Services – can you please clarify what information is requested here? Are we to enter our oncology and GBM experience in this table?

Question No 3:
The Awarding Entity requests indication in Appendix No 4 of data confirming the compliance with the requirements indicated in the Section V of the RFP, point 1, letter 1a), regarding CRO`s experience in conducting clinical trials. In addition, the Awarding Entity requires indication of at least four (4) GCP inspections of the FDA or EMA or other regulatory authorities successfully completed by the Contractor in the last 5 years to confirm compliance with ICH GCP.

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