

*Lodz, June 17, 2022*

**Request for offer No. I /MRA/2022**

The purchase is planned in relation to the application that will be submitted by the Ordering Party within then call for proposals: „Call for enterprises on the financing of development, performance evaluation and clinical assessment of innovative medical devices” (call no: ABM/2022/2), organized by Medical Research Agency of Poland.

The general aim of the Project will be the clinical validation and development of a tool for monitoring the effectiveness of treatment and selecting the appropriate therapy of multiple sclerosis, that has been developed by the Ordering Party (Pixel Technology Ltd).

**NAME AND ADDRESS OF THE ORDERING PARTY:**

Pixel Technology Ltd  
Ul. Piękna 1  
93-558 Lodz, Poland  
VAT number: PL 7271010965

**Date of announcement of the request for offer:**

June 17, 2022

**Deadline for submitting offers:**

June 24, 2022 till the hour: 23:59 (Central European Summer Time-CEST)

**CPV CODE AND NAME:**

73100000-3 - research and experimental-development services

**SUBJECT OF THE ORDER, ITS DESCRIPTION:**

Role of the Subcontractor will be to carry out the following activities within the Project:

- Conduct a focus group with six Neuroimmunology and Neuroradiology experts about the clinical utility of the AI technology –minimum 12 hours
- Produce a focus group summary report on clinical utility including regulatory recommendations for the AI technology; this report may incorporate further feedback from the Neuroimmunology and Neuroradiology experts.
- Design a clinical validation, including producing a Study Protocol and Statistical Analysis Plan, to verify the accuracy of the AI technology in delineating multiple sclerosis lesions and brain regions (these regions include juxtacortical, periventricular, infratentorial, deep white matter, cortical gray matter, cerebral white matter, thalamus, lateral ventricles, third ventricle, hippocampus) on Brain MRI.
- Subcontractor will conduct clinical validation 3 more times using data developed in the previous task.
- Execute the clinical validation with ground truth annotations for 30 cases obtained from two Neuroradiology experts.
- Produce a clinical study report that documents the results of the clinical validation for the AI technology.
- Ensure the clinical validation is performed according to the relevant parts of Good Clinical Practice and the ISO 14155:2020 standard and relevant parts of ISO 13485:2016.
- The Subcontractor will prepare a Clinical Study Report that includes a statistical analysis of the clinical validation study. This analysis may include overall accuracy metrics and relevant subgroup analyses. Clinical study report elaborated by the Subcontractor is aimed at confirming that it has validated the performance and accuracy of the solution developed within the R&D Project
- The Subcontractor will propose at least 3 healthcare centers in which the product (result of the R&D Project) can be installed. These healthcare centers may serve as pilot sites for installation of the product.

All the documents elaborated by the Subcontractor within the completion of the order should be in English.

Total assumed number of months of engagements of the Subcontractor:

- Clinical and Regulatory Strategy including Study Design: 6 months
- Clinical Validation: 8 months

### **SCOPE OF EXCLUSION OF BIDDERS FROM THE PROCEDURE:**

1. In order to avoid conflicts of interest, the Ordering Party cannot award to a subcontractor that is related to it personally or by capital. A capital or personal relationship means a mutual relationship between the Ordering Party or persons authorized to incur liabilities on behalf of the Ordering Party, or persons performing activities related to the selection procedure of the subcontractor and a subcontractor, consisting in particular in:

- participating in the company as a partner in a civil partnership or partnership,
- holding at least 10% of shares or stocks,
- serving as a member of a supervisory or managing body, proxy or attorney,
- being married, in a relationship of kinship or affinity in direct line, kinship of second degree or affinity of second degree in collateral line, or in a relationship of adoption, custody or guardianship.

2. Public contracts may not be awarded to a subcontractor against whom the liquidation has been opened or bankruptcy announced.

3. The Bidder must not be in arrears with payment of taxes, fees or contributions for social or health insurance.

4. Participation in the proceedings is allowed for a Bidder, who has not been legally sentenced for a crime committed in connection with the proceedings for awarding the contract, crime of bribery, crime against business or other crime committed for financial gain; and a partner in a general partnership, partner or member of the management board of a partnership; a general partner of a limited partnership or a limited joint-stock partnership; a member of the governing body of a legal person has not been validly convicted of an offence committed in connection with a procurement procedure, an offence against bribery, an offence against business transactions, or any other offence committed for financial gain.

Verification of compliance with the conditions for exclusion from the procedure described above will be based on the submission by the Bidder of a signed declaration on the absence of personal / capital connections with the Ordering Party referring to the point 1 above and regarding situations excluding from the procedure described in the points 2, 3 and 4 above (a template of this declaration has been attached to this request for offer - Annex no 2 to this request for offer).

### **CONDITIONS OF PARTICIPATION IN THE PROCEDURE:**

Bidders who can participate in the procedure:

1. have the authority to perform specific activities or activities if the law imposes an obligation to have them
2. have the appropriate technical potential to carry out the order
3. have the appropriate personnel capable of carrying out the order. Minimal requirements related to personnel are the following:

#### ***Principal Investigator:***

- Higher medical education
- Higher research degree.
- Board-certified as a Neurologist by the American Board of Psychiatry and Neurology or by an equivalent institution.
- Clinical experience in neuroimmunology.
- 4 years of experience in AI technology development.
- 2 years of experience in AI technology clinical trials including regulatory body interaction.

#### ***Neuroimmunology / Neuroradiology experts for focus group and focus group summary report development (requirements for each person):***

- Number of Neuroimmunology / Neuroradiology experts needed to carry out subcontracting activities: 6
- Higher medical education.
- Board-certified as a Neurologist by the American Board of Psychiatry and Neurology or by an equivalent institution **or** Radiologist by the American Board of Radiology or by an equivalent institution.

- Undertaking or completed specialisation in Neuroimmunology or Neuroradiology.
- 3 experts with ≤5 years of experience in caring for patients and/or interpreting imaging for patients with multiple sclerosis.
- 3 experts with more than 5 years of experience in caring for patients and/or interpreting imaging for patients with multiple sclerosis.

***Neuroradiology experts for ground truth annotations (requirements for each person):***

- Number of Neuroradiology experts needed to carry out subcontracting activities:  
2
  - Higher medical education
  - Board-certified as a Neuroradiologist by the American Board of Radiology or by an equivalent institution
  - More than 5 years of experience in interpreting imaging for patients with multiple sclerosis.
4. are in an economic and financial situation ensuring the implementation of the public order

In case of conditions 1-4 verification of the aforementioned conditions will be based on the declaration of compliance with the conditions above (Annex no 1 to this request for offer).

**CONDITIONS FOR OFFERS:**

1. Offers must be submitted in writing. Offers can be signed either in the traditional way or with the use of qualified electronic signature.
2. Offers should be prepared either in Polish or in English.
3. Time of binding the offer - until the end of its validity period specified in the request for offer (offer should be valid at least till June 30, 2022).
4. The offer should be signed by people authorized to sign the offer in accordance with current registration documents or power of attorney granted. Incorrect

confirmation of the offer results in rejection and leaving the offer without consideration.

5. Offers must be submitted with the total net and gross price for carrying out the order, as well as VAT in Polish zlotys or in another currency. If an offer is submitted in another currency than Polish zlotys, the average exchange rate of the National Bank of Poland for foreign currency/Polish zlotys from the day of opening of offers will be used for price conversion.
6. The offer should contain the following elements:
  - Declaration of compliance with the conditions (Annex no 1 to the request for offer)
  - Declaration on the lack of personal and capital relationships with the Ordering Party and related to other situations excluding the Bidder from the procedure (Annex no 2 to the request for offer)
  - Offer form (Annex no. 3 to the request for offer) together with full identification of the Bidder as well as the date of preparation and validity of the offer (the offer should be valid at least until June 30, 2022)

#### **EVALUATION CRITERIA OF THE OFFER AND INFORMATION ON POINT WEIGHTS ASSIGNED TO INDIVIDUAL OFFER EVALUATION CRITERIA:**

The selection of the best offer will be based on the following criterium: total gross price - 100%.

#### **DESCRIPTION OF THE MODE OF AWARDING POINTS FOR MEETING GIVEN OFFER EVALUATION CRITERIA:**

The maximum number of points for meeting the criterium indicated in the point above is 100 points.

The number of points in the „total gross price" criterion will be awarded in accordance with the following formula:

$$N_p = P_{\text{MIN}}/P_o * 100 \text{ points} * 100\%$$

Where:

$N_p$  – number of points for the price criterion

$P_o$  - total gross price of a given offer

P<sub>MIN</sub> - the lowest total gross price of the offer that was submitted in response to the request for offer

The offer should refer to the evaluation criterium mentioned above. If the Bidder fails to provide information enabling the evaluation of this criterium, its offer may be considered invalid or it will be awarded 0 points.

The Ordering Party, after evaluating the submitted offers, will propose conclusion of the contract to the Bidder who will obtain the highest number of points.

**POSSIBILITY TO CANCEL THE PROCEDURE:**

The Ordering Party reserves the right to cancel the bidding procedure at any stage of its duration without giving reasons.

**POSSIBILITY OF SUBMITTING PARTIAL AND VARIANT OFFERS:**

The Ordering Party does not allow for submission of partial offers.

The Ordering Party does not allow for submission of variant offers.

**DATE AND WAY OF SUBMISSION OF OFFERS:**

Electronically (scan) to the following e-mail address: [unia@pixel.com.pl](mailto:unia@pixel.com.pl)

The deadline for submission of offers: **June 24, 2022, till the hour 23:59 (CEST).**

Offers submitted after the deadline indicated in this request for offer will not be taken into consideration.

Any additional questions regarding this request for offer should be sent to the following e-mail address: [unia@pixel.com.pl](mailto:unia@pixel.com.pl) by **June 21, 2022, till the hour 23:59 (CEST).**

**Annex no 1 to the request for offer no I/MRA/2022 of June 17, 2022**

....., .....

Place      Date

**Declaration of compliance with conditions**

In response to the request for offer no I/MRA/2022 of June 17, 2022, I/we declare that I/we meet the conditions for participating in the procedure listed below:

1. I/we have the authority to perform specific activities or activities if the law imposes an obligation to have them
2. I/we have the appropriate technical potential
3. I/we have personnel capable of carrying out the order that meets specific requirements described in the point 3 of the part „CONDITIONS OF PARTICIPATION IN THE PROCEDURE” of this Request for offer.
4. I am/we are in an economic and financial situation ensuring the implementation of the public order.

.....

(Signature of the authorized representative of the Bidder,  
stamp of the institution)



**Annex no 2 to the request for offer no. I/MRA/2022 of June 17, 2022**

....., .....,  
Place      Date

**Declaration on the absence of personal / capital relationships with the Ordering Party and regarding situations excluding from the procedure**

In response to the request for offer no. I/MRA/2022 of June 17, 2022, I/we declare that we are not related to the Ordering Party in terms of capital or personal relationships.

A capital or personal relationship means a mutual relationship between the Ordering Party or persons authorized to incur liabilities on behalf of the Ordering Party, or persons performing activities related to the selection procedure of the subcontractor and a subcontractor, consisting in particular in:

- participating in the company as a partner in a civil partnership or partnership,
- holding at least 10% of shares or stocks,
- serving as a member of a supervisory or managing body, proxy or attorney,
- being married, in a relationship of kinship or affinity in direct line, kinship of second degree or affinity of second degree in collateral line, or in a relationship of adoption, custody or guardianship.

In addition to this, we declare that situations excluding from the procedure described in points 2, 3 and 4 of the part SCOPE OF EXCLUSION OF BIDDERS FROM THE PROCEDURE of the request for offer, do not apply to us.

.....  
(Signature of the authorized representative of the Bidder,  
stamp of the institution)

**Annex no 3 to the request for offer no. I/MRA/2022 of June 17, 2022**

**OFFER FORM**

Bidder's full name: .....  
Registration No (e.g. National Court Register): .....  
Address:.....  
E-mail address:.....  
Phone number: .....

In response to the request for offer no. I/MRA/2022 of June 17, 2022, I/we present our offer:

<b>Total net price</b>	<b>VAT</b>	<b>Total gross price</b>

If an offer is submitted in a another currency than Polish zlotys, the average exchange rate of the National Bank of Poland for foreign currency/Polish zlotys from the day of opening of offers will be used for price conversion.

Date of preparation of the offer: .....

Offer validity date: .....

.....  
(signature of the person authorized to represent the Bidder)

.....  
(Bidder's stamp)