CALL FOR TENDER

CALL FOR TENDER TO DESIGN AND MAINTAIN A DIGITAL PLATFORM FOR PATIENT ENGAGEMENT

September 2022

1. Background Information

The European Patients' Forum (EPF) is a European patient umbrella organisation. Our members are the backbone of our work: their perspective brings an irreplaceable added value to our policy and advocacy activities. We currently represent 78 patient organisations, encompassing 19 countries and an estimated 150 million patients across Europe.

Our ambition is to become a reference point for the EU, European organisations and other stakeholders such as World Health Organisation (WHO) Europe, healthcare professionals and health minded organisations seeking to co-create better health policy with patients and patient organisations. With our updated Constitution, this aims to include work towards a Wider Europe as a geographical continent rather than as a purely political entity. Among other activities, EPF contributes to research initiatives, including EU-PEARL (EU Patient-Centric Clinical Trial Platforms).

Information about EU PEARL

EU-PEARL is a strategic partnership between the public and private sectors to shape the future of clinical trials. This innovative and challenging enterprise aims to create a framework for patient-centric integrated research platform (IRP) trials, through which novel techniques and treatments developed by multiple companies and organizations are tested in a platform trial.

To achieve this objective, EU-PEARL promotes cooperation amongst pharmaceutical companies, clinicians, patients and researchers and encourages knowledge sharing and open discussion amongst all stakeholders, including regulators.

This sustainable and reusable systematic approach to platform trials conceived to test multi-sourced compounds, is to be supported by a management structure designed by EU-PEARL which will be able to meet complex regulatory, ethical, legal, statistical, and data requirements.

EU-PEARL is also developing the specific IRP frameworks for platform trials ready to operate in four disease areas still facing high unmet needs:

- Major Depressive Disorder (MDD),
- Tuberculosis (TB),
- Non-Alcoholic Steatohepatitis (NASH), and
- Neurofibromatosis (NF).

Public and private alliances have formed around these four disease areas and are now ready to support innovative clinical drug research of new techniques and treatments. EU-PEARL is set to create trial-ready clinical networks in these four disease areas, so that platform trials can be initiated shortly after the project is completed and funding secured.

This project is funded by the Innovative Medicines Initiative (IMI) Joint Undertaking, under Grant Agreement no. 853966. IMI is a large, far-reaching public-private partnership integrated by the European Union and the pharmaceutical industry, represented by the European Federation of pharmaceutical Industries and Associations (EFPIA), to support research and innovation in life-science.

Why EU-PEARL matters to patients

- Adaptive platform trials have a potential to shorten the time needed for to develop innovative medicines—and subsequently, access—compared to standard clinical trials.
- Making clinical trials more efficient and patient centric can ensure that individuals find the clinical trial that matches their needs, that companies enrol enough patients, and eventually, that new treatments are evaluated comparatively through the use of multiple simultaneous treatment arms
- Enabling platform trials with one master protocol allows for easier participation in multiple trials, or to support patient engagement within PT's as a Patient Advocate

The role of EPF is to lead the workstream on Patient Engagement.

EPF contributes to the governance aspects and will deliver a framework for patient engagement and a platform with specific focus on patient engagement for platform trials. Through the Patient Advisory Group[1] and Work Package teams, we will inform the design of disease specific platforms. Our contribution will bring the patient perspective on aspects related to ethics, legal and non-technical aspects of the platform trials governance, sustainability, and multi-stakeholder collaboration.

More information about EU-PEARL is available here.

[1] The EU-PEARL Patient Advisory Group brings together Patient Advocates from different disease areas, who consult the project on aspects relevant to patients

2. Rationale, Purpose, and Nature of Services

The purpose of this call is to **invite tenders for the contract of web developer/service provider** that will **design and develop an on-line Patient Engagement Platform (herein after 'EU-PEARL PE Platform')**.

The **EU-PEARL PE Platform will provide information on ways of involving patients in Platform Trials as partners, and support all stakeholders (mainly investigators and funders, patient advisors, and patients) in these activities.** The **EU-PEARL PE Platform** will provide reusable educational information, and resources as well as tools, guidance, and standards developed by existing and in-development initiatives for the patient community and the stakeholders with whom they interact.

The **EU-PEARL PE Platform** will enable users (patients, industry, and investigators) to:

- **Identify and allow access to what training materials, educational content, tools, templates, guidance**, etc. are available **to increase their effectiveness** and **add value during their involvement in the Platform Trials from design till implementation.**
- Identify **synergies and opportunities for collaboration** with different stakeholders.
- **Provide resources and connections in an innovative, sustainable way** to enable wider and more effective engagement.

3. Methodology and Functionality

The content development of the materials and initial EU-PEARL PE Platform design requirements will be done by the EU-PEARL project partners and the project's Patient Advisory Group.

The services hired will work on:

1. **Designing attractive and easy to digest content,** while maintaining elements of the EU-PEARL project visual identity.
2. Develop the on-line **EU-PEARL Patient Engagement Platform infrastructure** ensuring full accessibility also for visually impaired visitors, and user-friendliness.
3. **Maintain the EU-PEARL PE Platform** and relevant content for a duration of at least five years since completion of the work.
4. Cover the costs related to the maintenance (including eventually modification of the content, domain name, technical adjustments) for the specific timing above.

The **EPF team will work with the web developer throughout the design and development phase to ensure all individual sections of the EU-PEARL PE Platform match all the requirements specified**. Strict quality checkpoints, including ethical review of the design of the system and its data management, will be enforced to ensure that pre-defined requirements are achieved. Also, strict monitoring for development timelines will be implemented by EPF, to ensure that the agreed development deadlines are accomplished.

Once a beta version of the platform is populated with content, **user testing will be conducted with volunteers from the EU-PEARL Consortium and EU-PEARL Patient Advisory Group**, to assess whether

the site meets the user requirements. Timely user testing will ensure that any remedial action can be taken with the developer to ensure that the requirements are met. After the completion of user testing, final adjustments will be made before delivery of the final version of the platform. The completed platform will be validated against the requirements (see section 4: Key Outcomes), including any changes that were made throughout the process.

4. Key outcomes

Main deliverable: to develop the EU-PEARL PE Platform, and design material for the content that will populate the platform. Materials should be as accessible as possible: visuals should at least be accompanied by alt-text, and videos with subtitles.

- Beta version to be ready by **31/12/2022**
- Validated version by **31/03/2023.**

For required materials, the winner of this tender is expected to:

- Design 2 infographics leaflets of approximately 1-page A4 (recto-verso) each by 4 November 2022
- Embed 3 repositories, with design interventions to ensure full and easy access to information by the end of November 2022
- Design 1 short (white board) video (<1 Minute) by the end of December 2022
- Design 1 long video (3-5 minutes) by the end of December 2022
- Design for interactive guidance document, to be transferred into pdf by the end of December
    - Preference will be given to any applicant who can provide a professional medical writer for this task
- Video editing of existing recorded material by the end of December 2022
- Upload any relevant additional material developed in the context of EU-PEARL or relevant to Platform Trials

A full list of content materials that will be hosted on the EU PEARL PE Platform is provided as annex 1. Note that content listed in the Annex, but not in section 4, will be developed by EPF and EU PEARL partners.

Altogether, EU-PEARL PE Platform and materials shall be finalised by 31/03/2023.

5. Participation in the Tender Procedure

5.1 TENDER PROCESS

EPF reserves the right to conduct the tender process and select the successful tender. EPF is not bound contractually or in any way to a bidder to this request for tender until EPF and the successful winner have entered into a written contract.

5.2 DOCUMENTS TO BE SUBMITTED

The tender proposal should include:

- An outline of the EU-PEARL PE platform approach to be undertaken to establishing and delivering the project (concept)
- Details of the individual(s) who will lead, manage and deliver the project and details of their experience
- Detailed breakdown of costs, with a maximum budget allocation of 45,000.00 EURO (all-in).
- Detailed timetable for delivery of the various designs and quality gates for the task
- Background material to demonstrate previous experience and range of work of the consultant(s) and/or of the specific personnel proposed for the work; This can include descriptions and examples of relevant previous work.
- Contact details of two referees;
- A completed Declaration of Interest (DOI) to ensure lack of any conflict of interest

Applications must be sent by 11/09/2022, 23:59 CEST to Hannes Jarke, at hannes.jarke@eu-patient.eu.

Please contact that email address if there are any queries regarding the call.

5.3 TENDER EVALUATION

Participation in this tendering procedure is open on equal terms to all natural and legal persons fulfilling the above-mentioned eligibility criteria and language requirements. EPF may, at its discretion, extend the closing date and time of the tender.

The selection procedure will be based on the principles of equal treatment, fairness, and transparency and on expertise. Applicants should explain any strategies to address platform accessibility issues for people living with disabilities (specifically those with visual and hearing impairments). Applicants should include which technological and security standards will be used in the platform.

All applicants will receive acknowledgment of receipt of their tender and will be informed of the outcomes of the selection process within 10 days following the deadline date. EPF is not obliged to provide reasons for its decision to shortlist; accept or reject any particular tender.

Offers to tender will be evaluated based on the following criteria:

Criteria	Weight
Credibility and expertise in the field	25%
Concept	35%
Project/Product planning	20%
Price	20%

5.4 EXCLUSION CRITERIA

Candidates shall be excluded from participation in this procurement procedure if:

- they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- they have been convicted of an offence concerning their professional conduct by a judgment which has the force of res judicata;

- they have been guilty of grave professional misconduct proven by any means which EPF can justify;
- they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the EPF or those of the country where the contract is to be performed;
- they have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Union's financial interests;
- following another procurement procedure or grant award procedure financed by the European Union's budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations.

5.5 SCHEDULE

The assignment shall start as from the date of signature of both contracting parties and shall be completed no later than **31/03/2023**.

Tender submission and schedule of the work are as follows:

Launch Tender	EPF	05/09/2022
Close of the Tender	Tenderer	11/09/2022
Selection of the tenderer	EPF	20/09/2022
Briefing meeting and signature	EPF - Tenderer	26/09/2022
Start of the assignment	Tenderer	30/09/2022
Delivery of beta version	Tenderer	09/01/2023
Finalisation of the platform	Tenderer	31/03/2023

6. Terms of payment

Prices must be fixed amounts in Euro and will not be subject to revision.

The amount of VAT should be shown separately on the invoice.

Costs incurred in preparing and submitting tenders are borne by the tenderers and cannot be reimbursed.

7. Quality issues

In delivering the service, the tenderer shall ensure the highest quality standards, of which EPF shall be the sole judge.

8. Confidentiality and conflict of interest

The Tenderer undertakes that they will not at any time, either before or after the termination of this service, use or disclose or communicate to any person confidential information relating to the affairs of EPF. This restriction shall continue to apply after the termination of the service without limit in point of time.

To ensure the independence of terms of their contract, the applicant tenderers will sign a DOI certifying that they have no conflict of interests in relation to the tasks to be undertaken and undertake to inform EPF's Project Coordinator, Hannes Jarke (contact details below and in section 5.2) should this status change.

9. Terms and conditions

EPF reserves the right to reject any and all proposals, in whole or in part, to advertise for new proposals, to abandon the need for services, and to cancel or amend this call for tender at any time prior to the execution of the written contract. EPF reserves the right to waive any formalities in the call for tender process. EPF may respond to questions or provide information from tenderers and is under no obligation to provide such responses or information to all other tenderers.

By submitting a proposal, the tenderer agrees that:

- EPF may copy the proposal for purposes of facilitating the evaluation of the proposal and agrees that such copying will not violate the rights of any third party.
- It will not bring any claim or have any cause of action against EPF based in any misunderstanding concerning the information provided or concerning EPF's failure, neglect or otherwise, to provide the bidder with pertinent information as intended by this call for tender.

The accomplishment of a tendering procedure imposes no obligation on the EPF to award the contract. Should the invitation to tender cover several items or lots, EPF reserves the right to award a contract for only some of them.

EPF shall not be liable for any compensation with respect to applicants whose tenders have not been accepted. Nor shall it be so liable if it decides not to award the contract.

The estimated date for the signature of the contract will be on **26/09/2022**.

10. Contact persons and contracting authority

10.1 CONTACT PERSONS

For more information, please contact:

Hannes Jarke, EPF Project Coordinator, Hannes.jarke@eu-patient.eu

Applications must be sent by 11/09/2022, 23:59 CEST

Please contact that email address if there are any queries regarding the call.

10.2 CONTRACTING AUTHORITY:

European Patients' Forum (EPF)
Chaussée d'Etterbeek, 180
1040 Brussels – Belgium
www.eu-patient.eu

This platform is funded under the EU-PEARL Project. EU-PEARL has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 853966. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and CHILDREN'S TUMOR FOUNDATION, GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT NON PROFIT ORGANISATION, SPRINGWORKS THERAPEUTICS INC

ANNEX 1:
NON EXHAUSTIVE LIST OF MATERIALS TO BE HOSTED AND/OR INTEGRATED IN THE EU-PEARL PATIENT ENGAGEMENT PLATFORM

	Material title	Aim/main content	Target Group	Action to be completed by EU-PEARL	Action to be completed by the tenderer	Integration in the PE platfom: technical requirements
1	**Leaflet with Infographics: Platform Trials**	Inform public about what platform trials are broadly	Trial Participants / Patients	Draft (End of August), send for review (early-mid September), adapt (October)	Graphics design	pdf to be downloaded and interactive resource (the latest TBC)
2	**Leaflet with Infographics: Patient Benefits**	Content based on the survey and PAG & WPs discussions	All, but geared towards patients/participants	Draft (End of August), send for review (early-mid September), adapt (October)	Graphics design	pdf to be downloaded and interactive resource (the latest TBC)
3	**Infovideo PT Short (<1 Minute)**	Gauge interest into PTs	Trial Participants / Patients	Develop Concept (early September), write script early October), hire video creator (early October), review and ask for edits (November)	Video development	Yes (video embedded)
4	**Infovideo PT "Long" (3-5 minutes)**	Inform and educate public about what platform trials are broadly	Trial Participants / Patients	Develop Concept (early September), write script early October), hire video creator (early October), review and ask for edits (November)	Video development	Yes (video embedded)

5	**Guidance document "how to integrate PE in the platform"**	Provide details in PE related to the "patient journey" within a Platform Trial informed consent, trial recruitment, tbd	All, but mainly researchers and sponsors	Discuss potential content with PAG and EAG (areas to be covered for recommendations)	Graphics Design	Yes, interactive platform representation and pdf to download
6	**Repository: Overview Document summarising/ guiding through existing materials**	Content based in T1.7 gap analysis	All		Build infrastructure for repository	Link tree to existing resources
7	**Repository: Previous Platform Trials**	Provide overview of existing PTs	Researchers and Patient Advisors	Consult with WP2 (September); consult with STAMPEDE and HEALY (September); Collect materials (September-October), Structure Materials and finalise looks (October), review (mid-Oct), finalise (mid-Nov)	Build infrastructure for repository	Link tree to existing resources
8	**Repository: existing matchmaking tools**			Identify (September), compile and format for platform (October)	Build infrastructure for repository	Link tree to existing resources
9	**Recording from PCE Day - Presentation: "What are platform trials?"**		All	Adjust visuals of the PCE Day recording	Video editing	Yes

10	**Recording from PCE Day - Panel "Discussions around informed consent"**		All	Adjust visuals of the PCE Day recording	Video editing	Yes
11	**Clinical Operations Tool**			Will be linked	N/A	Yes (links to the existing resources) and to newly created resources as listed here