

To Interested parties – Market Consultation IPSCore Automated System

Dear Sir/Madam,

As preparation for the European public procurement procedure "IPSCore Automated System", Erasmus MC hereby invites you to participate in a market consultation.

About Erasmus MC

Erasmus MC is one of the seven University Medical Centers (UMCs) in the Netherlands and, with a turnover of over EUR 1.7 billion and approximately 15,000 employees, one of the largest and most versatile academic medical centers in the country.

"Our mission is a healthy population and excellent healthcare through research and education." Erasmus MC is committed to groundbreaking work, pushing boundaries and leading the way in research, education and patient care. Our professionals continuously strive to advance knowledge of disease and health, improve diagnostics and treatment, and innovate in order to provide the best possible care to patients and individuals with healthcare needs, while also supporting the health of the general population.

For more information about Erasmus MC, please visit: (<http://www.erasmusmc.nl/overerasmusmc>)

Scope of the Market Consultation

The potential applications of the iPS technology are immense and offer the Erasmus MC employees great opportunities to remain at the forefront of research into genetic diseases, therapy development, and regenerative applications. However, the predominantly manual process required to generate iPSC lines leads to variability between lines and significantly increases production costs. As a result, access to this technology remains limited for many researchers. For instance, the use of iPSC lines in cohort studies is currently not feasible due to these high costs. Additionally, high staff turnover poses a challenge due to the repetitive and demanding nature of cell culture work, including weekend shifts required.

To address these challenges, the Erasmus MC core facility, in collaboration with the Department of Developmental Biology and with financial support from the Erasmus MC Investment Committee, aims to fully automate the generation of iPS cells in a high throughput manner through a phased approach. Each phase will be tendered separately following successful setup and validation of the previous phase.

This tender concerns an automated platform is capable of expanding at least one batch of 42 newly generated iPS lines every three weeks, simultaneously, with each line cultured in a separate 12-well plate, and each plate containing 8 clones per line. The expansion of each batch of at least 42 iPS lines is called a cycle. After three cycles (each lasting approximately six weeks, with three cycles taking about three months) of expanding at least

42 lines according to the attached workflow, the platform will undergo a short maintenance period before processing the next three batches in a second term.

During the expansion process, the platform must be capable of:

- Determining Sendai virus clearance of the iPSCs that are passaged in the automated platform via RT-PCR.
- Expansion of four Sendai-negative clones per line for banking.
- Freezing the remaining clones for future use.
- Performing downstream quality control, including:
 - o Setting up trilineage differentiation assays.
 - o Conducting RT-PCR to assess expression of stem cell and pluripotency markers in newly generated lines.
 - o Collecting material for further analysis.

This automation effort will enhance reproducibility, reduce costs, and increase accessibility to iPS technology for researchers at Erasmus MC and beyond.

Objective of the Market Consultation

The objective of this market consultation is to assess whether it is feasible and market-conform to have the Liquid Handler (& Imager) fully supplied and integrated via a single system integrator. This is in view of a future procurement procedure in which the responsibility for integration is allocated as much as possible to one party.

Based on this consultation, Erasmus MC aims to explore whether a procurement structure with the following lot division would be appropriate:

Lot 1:

Integration of equipment, including supply, installation and integration of the Liquid Handler & Imager.

In addition, the market is explicitly invited to propose alternative lot structures, including combinations of equipment supply and system integration, where practical and feasible.

Background

Previous procurement procedures with a lot structure consisting of three separate lots were withdrawn due to limited market response and (excessively) high tender prices.

This market consultation therefore aims to gather market input on the feasibility, integration complexity and risks associated with supplying both devices via the system integrator, as well as to explore alternative lot structures.

The outcome of this consultation will form the basis for a procurement procedure with one lot or another proportional and market-conform structure.

Legal Context

Combining the supply of one or both devices through the system integrator may raise concerns regarding competition, as original equipment manufacturers may not be able to submit standalone bids for their devices.

Previous projects have shown that defining scope and responsibilities between multiple parties in complex system integrations can be challenging and may lead to differing interpretations, increased risk premiums and limited market participation.

This market consultation therefore serves as an objective dialogue with the market, in which all relevant stakeholders are invited to provide input on technical and organizational feasibility, allocation of responsibilities, associated risks and costs, and potential alternative lot structures.

By conducting this broad market consultation and documenting the responses received, Erasmus MC aims to substantiate whether any future choice for a (partial) combination of lots is technically feasible, operationally effective and proportionate within the framework of European public procurement regulations.

No preference for a specific lot structure has been determined at this stage. The market is explicitly invited to contribute ideas on the most efficient and feasible approach.

Questions for System Integrators

1. Functional and Technical Requirements

The functional and technical requirements for the Integrator, Liquid Handler and Imager are included in the attached Excel document.

Please base your responses on these requirements.

2. Technical Feasibility

2.1 Supply and Integration

Is your organization capable of supplying and integrating the Liquid Handler and/or Imager in accordance with the specified functional and technical requirements?

Please explain how such devices are typically integrated based on previous projects, including automation, software and workflow aspects.

2.2 System Integration

How is the integration of the Liquid Handler and/or Imager generally implemented within a total automation solution?

To what extent does this involve standardization versus customization?

3. Allocation of Responsibilities

3.1 Cooperation with Original Equipment Manufacturers

Are there elements of supply, installation, configuration or validation for which support from the original manufacturer is required?

If so, which activities are concerned?

3.2 Software and Workflow

How do you envisage the allocation of responsibilities between the integrator and the equipment supplier with regard to:

workflow programming;

implementation of software modules;

testing, validation and acceptance?

4. Capacity, Performance and Risks

Do you foresee technical, operational or logistical risks associated with supplying and integrating the equipment via the integrator?

How would these risks be managed or mitigated?

5. Costs and Planning

Do you anticipate additional costs or extended lead times resulting from supplying and integrating the Liquid Handler and/or Imager via the integrator?

If so, please explain the underlying causes.

6. Alternative Solutions and Lot Structure

Based on the functional and technical requirements, do you see opportunities to combine the supply of the Liquid Handler and/or Imager with the integration assignment, or to design a more efficient alternative lot structure?

Do you foresee advantages, risks or cost savings associated with such alternative structures?

Questions for Liquid Handler and Imager Suppliers

1. Functional and Technical Requirements

The functional and technical requirements for the Liquid Handler and Imager are included in the attached Excel document.

To what extent does your device comply with these requirements?

Are there any specific considerations or conditions related to delivery via a system integrator?

2. Supply via a System Integrator

Is it feasible for your organization to supply the device to a system integrator instead of directly to the end user?

Which conditions or agreements would you consider necessary (e.g. contractual, technical or organizational)?

3. Allocation of Responsibilities

3.1 Implementation and Workflow

For which implementation components (e.g. configuration, software modules, workflow development) is involvement of your organization required?

At what level of detail is your support necessary for workflow programming?

3.2 Troubleshooting and Support

How do you envisage a clear and workable allocation of responsibilities between integrator and supplier with regard to:

initial troubleshooting; resolution of software or hardware issues?

4. Cost Indication

Can you provide an indicative price for direct delivery of the device to a system integrator?

Are there additional costs associated with providing integration support?

Consultation Process

We kindly request you to:

Submit your participation and responses via TenderNed no later than 16 February.

After registration, Erasmus MC will contact participants regarding the next steps in this market consultation, such as an (optional) in-depth dialogue session or a written follow-up round.

Note

This market consultation is a separate process conducted prior to a formal procurement procedure. It does not constitute a call for competition and does not form part of a pre-qualification procedure. Information obtained through this consultation will be used solely to prepare a well-designed procurement process, increasing the likelihood of receiving suitable and competitive tenders.

For substantive questions, communication with Erasmus MC must take place exclusively via TenderNed. Telephone calls and direct emails will not be answered in order to ensure equal treatment of all parties.

Yours sincerely,

Esen Alatag

Buyer

Erasmus MC

Disclaimer

This market consultation is conducted separately and prior to a formal procurement procedure. Participation does not constitute an invitation to tender nor does it form part of any pre-qualification process. The information obtained through this consultation will be used to shape the follow-up process and procurement strategy.

All information provided to Erasmus MC through completed forms, one-to-one sessions or otherwise may be used by Erasmus MC for the purposes described above and will become the property of Erasmus MC. To ensure equal treatment, relevant information may be shared with other parties. Any information published will be anonymized and not traceable to individual respondents.

Participants are advised that they may provide commercially sensitive information or information subject to intellectual property rights. Erasmus MC cannot be held responsible for the disclosure of such information, taking the above into account.