

# IRELAND - PROJECT MANAGEMENT SOFTWARE PACKAGE - ESTABLISHMENT OF A SINGLE OPERATOR FRAMEWORK AGREEMENT FOR AN ELECTRONIC TRIAL MASTER FILE (ETMF) AND ASSOCIATED SERVICES (GALW/CON1646/2023)

Contract or concession notice – standard regime

## 1. Buyer

### 1.1 Buyer

*Official name:* University of Galway (ID 1400)

*Legal type of the buyer:* Body governed by public law

*Activity of the contracting authority:* Education

## 2. Procedure

### 2.1 Procedure

*Title:* Establishment of a Single Operator Framework Agreement for an Electronic Trial Master File (eTMF) and Associated Services (GALW/CON1646/2023)

*Description:* The Clinical Trials Institute is looking to procure an electronic trial master file (eTMF) system and services for documentation and management of our clinical trials.

*Procedure identifier:* cde326e1-bf98-451f-a039-55c1ccac20df

*Type of procedure:* Open

*The procedure is accelerated:* No

#### 2.1.1 Purpose

*Nature of the contract:* Supplies

*Main classification (cpv):* 48331000 Project management software package

*Additional classification (cpv):* 48311000 Document management software package

*Additional classification (cpv):* 48170000 Compliance software package

*Additional classification (cpv):* 73110000 Research services

*Additional classification (cpv):* 73000000 Research and development services and related consultancy services

#### 2.1.2 Place of performance

*Country:* Ireland

Anywhere in the given country

#### 2.1.3 Value

*Estimated value excluding VAT:* 800,000 EUR

*Maximum value of the framework agreement:* 800,000 EUR

#### 2.1.4 General information

*Legal basis:*

Directive 2014/24/EU

#### 2.1.5 Terms of procurement

*Terms of submission:*

*Maximum number of lots for which one tenderer can submit tenders:* 0

### 2.1.6 Grounds for exclusion

Purely national exclusion grounds: Please refer to the Request for Tenders

## 5. Lot

### 5.1 Lot: LOT-0001

*Title:* Establishment of a Single Operator Framework Agreement for an Electronic Trial Master File (eTMF) and Associated Services (GALW/CON1646/2023)

*Description:* The Clinical Trials Institute is looking to procure an electronic trial master file (eTMF) system and services for documentation and management of our clinical trials.

*Internal identifier:* CON1646

#### 5.1.1 Purpose

*Nature of the contract:* Supplies

*Main classification (cpv):* 48331000 Project management software package

*Additional classification (cpv):* 48311000 Document management software package

*Additional classification (cpv):* 48170000 Compliance software package

*Additional classification (cpv):* 73110000 Research services

*Additional classification (cpv):* 73000000 Research and development services and related consultancy services

#### 5.1.5 Value

*Estimated value excluding VAT:* 800,000 EUR

*Maximum value of the framework agreement:* 800,000 EUR

#### 5.1.6 General information

*Reserved participation:* Participation is not reserved.

Procurement Project not financed with EU Funds.

*The procurement is covered by the Government Procurement Agreement (GPA)*

*This procurement is also suitable for small and medium-sized enterprises (SMEs)*

#### 5.1.9 Selection criteria

*Criterion:*

*Type:* Other

#### 5.1.11 Procurement documents

*Address of the procurement documents:* <https://www.etenders.gov.ie/epps/cft/listContractDocuments.do?resourceId=2889832>,

#### 5.1.12 Terms of procurement

*Terms of submission:*

*Electronic submission:* Required

*Address for submission:* <https://www.etenders.gov.ie/epps/eawarding/showTenderList.do?resourceId=2889832>

*Languages in which tenders or requests to participate may be submitted:* English

*Electronic catalogue:* Not allowed

*Tenderers may submit more than one tender*

*Deadline for receipt of tenders:* 2024-02-01Z 16:00:00Z

*Information about public opening:*

*Date/time:* 2024-02-01Z 16:30:00Z

*Place:* <https://www.etenders.gov.ie/epps/cft/prepareViewCfTWS.do?resourceId=2889832>

*Terms of contract:*

*The execution of the contract must be performed within the framework of sheltered employment programmes:* Not yet known

*Electronic invoicing:* Required

#### 5.1.15 Techniques

*Framework agreement:*

Framework agreement, without reopening of competition

*Maximum number of participants:* 1

*Justification for the duration of the framework agreement:* Required due to nature of system being bought.

*Information about the dynamic purchasing system*

No dynamic purchase system

*Electronic auction:*

#### 5.1.16 Further information, mediation and review

*Review organisation:* The High Court of Ireland

*Organisation providing offline access to the procurement documents:* University of Galway (ID 1400)

*Organisation receiving requests to participate:* University of Galway (ID 1400)

*Organisation processing tenders:* University of Galway (ID 1400)

## 8. Organisations

### 8.1 ORG-0001

*Official name:* University of Galway (ID 1400)

*Registration number:* 0022578J

*Postal address:* University Road, Galway

*Town:* Galway

*Postcode:* H91TK33

*Country:* Ireland

*Email:* [procure@universityofgalway.ie](mailto:procure@universityofgalway.ie)

*Telephone:* +35391493970

*Information exchange endpoint (URL):* <https://www.universityofgalway.ie/>

*Buyer profile:* <https://www.universityofgalway.ie/>

*Roles of this organisation:*

*Buyer*

*Organisation providing offline access to the procurement documents*

*Organisation receiving requests to participate*

*Organisation processing tenders*

### 8.1 ORG-0002

*Official name:* The High Court of Ireland

*Registration number:* The High Court of Ireland

*Department:* The High Court of Ireland  
*Postal address:* Four Courts, Inns Quay, Dublin 7  
*Town:* Dublin  
*Postcode:* D07 WDX8  
*Country:* Ireland  
*Email:* [HighCourtCentralOffice@courts.ie](mailto:HighCourtCentralOffice@courts.ie)  
*Telephone:* +353 1 8886000  
*Roles of this organisation:*  
*Review organisation*

#### 8.1 ORG-0003

*Official name:* European Dynamics S.A.  
*Registration number:* 002024901000  
*Department:* European Dynamics S.A.  
*Town:* Athens  
*Country:* Greece  
*Email:* [eproc-esender@eurodyn.com](mailto:eproc-esender@eurodyn.com)  
*Telephone:* +30 2108094500  
*Roles of this organisation:*  
*TED eSender*

## 11. Notice information

### 11.1 Notice information

*Notice identifier/version:* 3fe4e711-3a51-4e83-8758-10076cb7fc94 - 01  
*Form type:* Competition  
*Notice type:* Contract or concession notice – standard regime  
*Notice dispatch date:* 2023-12-21Z 14:50:27Z  
*Languages in which this notice is officially available:* English

### 11.2 Publication information