

Provision of a CTMS (Clinical Trial Management System) for the KCE Trials programme



Belgian Public Tender Bulletin

Publication of the Federal Service e-Procurement

SPF P&O - 51, rue de la Loi B-1040 Brussels



+32 27905200



e.proc@publicprocurement.be

www.publicprocurement.be

CONTRACT NOTICE

SECTION I: CONTRACTING AUTHORITY

I.1) NAME, ADDRESSES AND CONTACT POINT(S)

Official name: Belgian Health Care Knowledge Centre National ID:
Postal address: Boulevard du Jardin Botanique, 55 (10th floor)
Town: Brussels Postal code: 1000
Country: Belgium
Contact point(s): Petit Elisabeth Telephone: +32 22873380
 For the attention of:
Email: elisabeth.petit@kce.fgov.be Fax: +32 22873385

Internet address(es) (if applicable)

General address of the contracting authority (URL): www.kce.fgov.be

Address of the buyer profile (URL):

<https://enot.publicprocurement.be/enot-war/preViewNotice.do?noticeId=267709>

Electronic access to information (URL):

Electronic submission of tenders and requests to participate (URL): https://eten.publicprocurement.be/etendering/viewWorkspacesBasedOnExtUrl.do?wsName=KCE-2017_001_CTMS-F02

Further information can be obtained from

- ☒ The above mentioned contact point(s)
- ☐ Other: (please complete Annex A.I)

Specifications and additional documents (including documents for competitive dialogue and a dynamic purchasing system) can be obtained from

- ☒ The above mentioned contact point(s)
- ☐ Other: (please complete Annex A.II)

Tenders or requests to participate must be sent to

- ☒ The above mentioned contact point(s)
- ☐ Other: (please complete Annex A.III)

I.2) TYPE OF THE CONTRACTING AUTHORITY (in case of a notice published by a contracting authority)

- ☐ Ministry or any other national or federal authority, including their regional or local sub-divisions
- ☒ Body governed by public law
- ☐ National or federal agency/office
- ☐ European institution/agency or international organisation
- ☐ Regional or local authority
- ☐ Other: (please specify)
- ☐ Regional or local agency/office

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I.3) MAIN ACTIVITY *(in case of a notice published by a contracting authority)*

- | | |
|---|---|
| ☐ General public services | ☐ Housing and community amenities |
| ☐ Defence | ☐ Social protection |
| ☐ Public order and safety | ☐ Recreation, culture and religion |
| ☐ Environment | ☐ Education |
| ☐ Economic and financial affairs | ☐ Other: <i>(please specify)</i> |
| ☒ Health | |

I.4) CONTRACT AWARD ON BEHALF OF OTHER CONTRACTING AUTHORITIES

The contracting authority is purchasing on behalf of other contracting authorities: ☐ yes ☒ no
(if yes, information on those contracting authorities can be provided in Annex A)

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SECTION II: OBJECT OF THE CONTRACT

II.1) DESCRIPTION

II.1.1) Title attributed to the contract by the contracting authority

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II.1.2) Type of contract and location of works, place of delivery or of performance

(choose one category only – works, supplies or services – which corresponds most to the specific object of your contract or purchase(s))

☐ Works ☐ Execution ☐ Design and execution ☐ Realisation, by whatever means of work, corresponding to the requirements specified by the contracting authorities	☒ Supplies ☒ Purchase ☐ Lease ☐ Rental ☐ Hire purchase ☐ A combination of these	☐ Services Service category No: <i>Please see Annex C1 for service categories</i>
Main site or location of works, place of delivery or of performance:		
NUTS code: BE		

II.1.3) Information about a public contract, a framework agreement or a dynamic purchasing system (DPS)

- ☐ The notice involves a public contract
☐ The notice involves the setting up of a dynamic purchasing system (DPS)
☒ The notice involves the establishment of a framework agreement

II.1.4) Information on framework agreement (if applicable)

☐ Framework agreement with several operators Number <i>or (if applicable) maximum number of participants to the framework agreement envisaged</i>	☒ Framework agreement with a single operator
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Duration of the framework agreement

Duration in years: **8**

or in months:

Justification for a framework agreement, the duration of which exceeds four years:

The selected software will be potentially used (or accessible) in some 50 Belgian hospitals participating in one or more of the clinical studies funded by the KCE Trials programme. This deployment will be spread over 4 years. As the choice to install a CTMS in a hospital is a strategic decision requiring considerable investments with a profound technical and organizational impact, hospitals will have the possibility to choose, at the order of the software, a contract duration of 1, 2, 3 or 4 years. At the end of the first 4 years, no new orders will be placed, but the orders in progress will be honoured until the agreed term, which potentially brings the duration of this framework contract to 8 years.

Estimated total value of purchases for the entire duration of the framework agreement (if applicable, give figures only)	
Estimated value excluding VAT:	Currency:
or Range: between and	Currency:
Frequency and value of the contracts to be awarded: (if known)	

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II.1.5) Short description of the contract or purchase(s)

Provision of a CTMS (Clinical Trial Management System) software to manage clinical research as the sponsor of a study or as a participating site, and to oversee all studies in the KCE Trials programme as a funding body.

In 2016, KCE launched a programme to fund pragmatic clinical trials focusing on clinical practice: the KCE Trials programme. The plan is to fund 5 to 10 major multicentre studies per year (with a global budget of 5 million euro in 2016 and 2017 and 10 million euro from 2018). The KCE will select and fund the studies but will not lead them, since the role of clinical study sponsor will be taken by the organisation (often a university hospital) and the research team who have proposed the trial and drawn up the research protocol.

KCE is seeking a CTMS-type (Clinical Trial Management System) IT-program (as a Software as a Service) to monitor the studies included in the KCE Trials programme and to facilitate collaboration between the sites and the various stakeholders.

The type of monitoring will depend on who is using the software and for what purpose:

- for the local clinical research staff at a site participating in a study, it will facilitate the monitoring of the patient flows in that study (number of patients selected, randomised, who have finished the study or completed the study) and facilitate communication with the sponsor of the study including the possibility of uploading requested documents (e.g. training certificates, CVs, approvals, signature lists, etc.). If studies other than those financed by KCE Trials are entered into the system, it will provide a comprehensive overview of the progress of all clinical research in a hospital.

- for the project manager of the study sponsor (who may or may not belong to a participating site), it will provide an overview of the progress of the study in the various participating sites and will help to plan the monitoring visits and check patient recruitment. It will also provide an easy and clear way for the sponsor to provide the sites with the latest versions of the key documents for the study (protocol, ICF forms, guidelines, approvals, data analysis plan, etc.).

- for the KCE staff who manage the KCE Trials programme, it will provide access to real-time data on the status of all the KCE studies in progress and facilitate the production of status reports (Key Performance Indicators) for the programme. Only aggregated data on recruitment will be used for this purpose.

The software must comply with all the Belgian and European legal requirements on data protection. It has to allow to store patient identification codes, and these need to be accessible only to the person(s) who should have access to them e.g. the person(s) who have access to a particular study in a particular site (the clinical staff for a particular study at a study site).

In general, the IT solution must:

- be compatible with the structure and organisation of Belgian hospitals (some hospitals have several sites) and be able to function in a non-hospital setting (e.g. for doctors from private practice participating in a study).
- be efficient in terms of data collection and data standardisation (the data is entered into the software only once and is accessible to anyone involved in the study who needs it).
- facilitate the communication between the various stakeholders (funding bodies, sponsors and researchers at the site(s)) of key information on the trials (key study documents) by serving as an easily accessible document repository and communication forum.

- make it possible to distinguish between the studies in the KCE Trials programme and the other studies. In addition to managing the studies in the KCE Trials programme, the software may also be used by the site personnel to help manage their entire portfolio of commercial and non-commercial studies, as a sponsor and as a researcher at a participating site. The confidentiality of such studies must be respected by KCE: with the latter only receiving access to the aggregated data (and not the patient data) of the studies that are funded by the KCE Trials programme.

This procurement also covers the maintenance and support services, the training and the consultancy relating to this software.

In notices, the term 'hospital' is understood within the meaning of the coordinated law on hospitals and other healthcare institutions (Law of 10 July 2008), i.e. a hospital corresponds to an approval number and may include several geographically separate sites. The KCE imposes a pricing model per hospital (irrespective of the number of users in that hospital, "site licence"). The price may, however, depend on the volume of use of the software by the hospital. The KCE will cover the price of the "basic" license of the software (the one covering a low use of the software in terms of data volume).

The selected software will be used in around fifty Belgian hospitals which will be participating in one or more studies financed by the KCE Trials programme. This deployment will be spread over 4 years. This number of hospitals is provided for information only. The KCE gives no undertaking regarding the total number of hospitals in which the software will be in use at the end of 4 years.

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II.1.6) Common procurement vocabulary (CPV)

	Main vocabulary	Supplementary vocabulary (if applicable)
Main object	48000000	
Additional object(s)	48800000	

II.1.7) Contract covered by the Government Procurement Agreement (GPA)

☐ yes ☒ no

II.1.8) Division into lots (for information about lots, use Annex B as many times as there are lots)

☐ yes ☒ no

If yes, tenders should be submitted for (tick one box only)

☐ one lot only

☐ one or more lots

☐ all lots

II.1.9) Variants will be accepted

☐ yes ☒ no

II.2) QUANTITY OR SCOPE OF THE CONTRACT

II.2.1) Total quantity or scope (including all lots and options, if applicable)

(if applicable, give figures only) Value excluding VAT:		Currency:
or Range: between	and	Currency:

II.2.2) Information about options (if applicable)

Options ☐ yes ☒ no

(if yes) Description of these options:

(if known) Provisional timetable for recourse to these options:

in months: or in days: (from the award of the contract)

II.2.3) Information about renewals (if applicable)

This contract is subject to renewal ☐ yes ☐ no

Number of possible renewals: (if known) or Range: between and

(if known) In the case of renewable supplies or service contracts, estimated timeframe for subsequent contracts:

in months: or in days: (from the award of the contract)

II.3) DURATION OF THE CONTRACT OR TIME-LIMIT FOR COMPLETION

Duration in months:	or in days:	(from the award of the contract)
or Starting	(dd/mm/yyyy)	
Completion	(dd/mm/yyyy)	

Provision of a CTMS (Clinical Trial Management System) for the KCE Trials programme**SECTION III: LEGAL, ECONOMIC, FINANCIAL AND TECHNICAL INFORMATION****III.1) CONDITIONS RELATING TO THE CONTRACT****III.1.1) Deposits and guarantees required (if applicable)**

A global security deposit will be asked by the contracting authority after conclusion of the contract.

III.1.2) Main financing conditions and payment arrangements and/or reference to the relevant provisions regulating them**III.1.3) Legal form to be taken by the group of economic operators to whom the contract is to be awarded (if applicable)****III.1.4) Other particular conditions to which the performance of the contract is subject (if applicable)**

☐ yes ☐ no

If yes, description of particular conditions

III.2) CONDITIONS FOR PARTICIPATION**III.2.1) Personal situation of economic operators, including requirements relating to enrolment on professional or trade registers**

Information and formalities necessary for evaluating if requirements are met:

IMPLICIT SWORN STATEMENT

In submitting its bid application, the applicant of bidder declares that it does not fall into any of the exclusion situations appearing below.

The contracting authority will verify the accuracy of this implicit sworn statement in respect of the bidder whose bid is ranked highest.

The contracting authority itself will request the information or documents it is able to obtain free of charge by electronic means from the agencies responsible for such information or documents.

A bidder will be excluded from the contract if it appears, as a result of these checks, that the implicit sworn statement did not match the bidder's personal situation on the closing date for receipt of bids, since no subsequent rectification is possible.

A false declaration is a criminal offence.

1. First exclusion criterion: bankruptcy or conviction

An applicant of bidder may be excluded from the contract, at whatever stage of the procedure, if:

- it is in a state of bankruptcy, liquidation, cessation of activities, judicial reorganisation or any similar situation resulting from a procedure of a similar nature that exists in other national regulations;
- it has filed for bankruptcy or been the subject of a liquidation or judicial reorganisation procedure or any other procedure of a similar nature that exists in other national regulations;
- it has been convicted by a final judicial decision for an offence affecting its professional integrity;

For foreign companies or if, for a Belgian company, the requested information is not available via the electronic means at its disposal, the contracting authority will ask the bidder in question to provide police certificate or an equivalent document issued by a judicial or administrative authority in the country of origin or of provenance whereby its personal situation can be verified, before any decision to award the contract.

Where such a document or certificate is not issued in the country in question, it may be replaced by a sworn statement or a solemn declaration made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in the country of origin or of provenance.

2. Second exclusion criterion: Obligations relating to the payment of social security contributions

The applicant of bidder must be up to date with its obligations relating to the payment of social security contributions.

For Belgian companies, the contracting authority itself will request the necessary information from the ONSS [Office national de sécurité sociale – National Social Security Office] via the electronic means at its disposal.

For foreign companies, the contracting authority will request a certificate from the competent body demonstrating their compliance with the social legislation of their State.

3. Third exclusion criterion: Obligations relating to the payment of its taxes and duties

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The applicant of bidder must be up to date with its obligations relating to the payment of its taxes and duties in accordance with Belgian law or the law of the country in which it is established, in accordance with the provisions of Article 63 of the Royal Decree of 15 July 2011.

For foreign companies or if, for a Belgian company, the requested information is not available via the electronic means at its disposal, the contracting authority will ask the bidder in question to provide a certificate from the competent body demonstrating its compliance in respect of the payment of taxes and duties.

III.2.2) Economic and financial capacity

Information and formalities necessary for evaluating if requirements are met:	Minimum level(s) of standards possibly required (if applicable):
The applicant will give a declaration concerning his turnover for the furnitures and services requested covering the past 3 years.	The average annual turnover for the furnitures and services requested, calculated for the past 3 years, must be greater than €700 000,00
An applicant may assert the capabilities of other entities, whatever the legal nature of the links that exist between itself and those entities. In such cases, it must prove to the contracting authority that, for the execution of the contract, it will have the necessary means at its disposal by producing the undertaking given by those entities to place such means at the disposal of the supplier.	

III.2.3) Technical capacity

Information and formalities necessary for evaluating if requirements are met:	Minimum level(s) of standards possibly required (if applicable):
An applicant may assert the capabilities of other entities, whatever the legal nature of the links that exist between itself and those entities. In such cases, it must prove to the contracting authority that, for the execution of the contract, it will have the necessary means at its disposal by producing the undertaking given by those entities to place such means at the disposal of the supplier.	1° The applicant will provide 20 references, which must be consistent with the requested services.
----- The applicant :	----- 2° the number of people employed by the applicant who are responsible for the support and maintenance of the proposed solution, for Belgium, at the time the bid is submitted. This number must be greater than or equal to 2 people.
----- 1° will provide evidence that it has, during the past 3 years, given access to and configured the CTMS-type software in at least 20 organisations situated in Europe (an organisation may be a hospital, a funding body, a hospital network, a non-commercial sponsor, etc.). This software must be operational, and must currently manage at least 50 clinical studies in each of the organisations mentioned as references. For each reference, the bidder will mention o the name and address of the organisation, o the details of a contact person, o the implementation start date, o the number of clinical studies in the software for that organisation. If the contracting authority sees fit to contact these references, it will inform the bidder in advance.	----- 3° Those requirements are considered essential by the KCE in order to be able to submit a bid.: a. The IT solution is a "Software as a service" b. Data (and their back-ups) are stored in a data center located in a country of the European Union or, failing that, in a country that complies with European data protection legislation (GDPR 2016/679) c. Access to the software and the information contained in this software can be configured on the basis of the role of the user, the hospital (site) and the study. A user must first receive access to the data contained in the CTMS before they can modify / delete this data. d. The software has a complete audit trail, from each login of each user, for each change made to the data encoded in the software. This audit trail must be available to users with access rights to this data.
----- 2° will provide a declaration mentioning the average annual number of people employed by the applicant who are responsible for the support and maintenance of the proposed solution, for the past 3 years, at global level and in particular for Belgium.	

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3°

will provide a global description of its society and basic technical information about the software to prove that the minimum requirements for the solution are met.

III.2.4) Reserved contracts *(if applicable)*

- ☐ The contract is restricted to sheltered workshops
- ☐ The execution of the contract is restricted to the framework of sheltered employment programmes

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SECTION IV: PROCEDURE

IV.1) TYPE OF PROCEDURE

IV.1.1) Type of procedure

☐ Open	
☐ Restricted	
☐ Accelerated restricted	Justification for the choice of accelerated procedure:
☒ Negotiated	Candidates have already been selected ☐ yes ☒ no If yes, provide names and addresses of economic operators already selected under Section VI.3) <i>Additional information</i>
☐ Accelerated negotiated	Justification for the choice of accelerated procedure:
☐ Competitive dialogue	

IV.1.2) Limitations on the number of operators who will be invited to tender or to participate (*restricted and negotiated procedures, competitive dialogue*)

Envisaged number of operators
OR Envisaged minimum number and , <i>if applicable</i> , maximum number
Objective criteria for choosing the limited number of candidates:

IV.1.3) Reduction of the number of operators during the negotiation or dialogue (*negotiated procedure, competitive dialogue*)

Recourse to staged procedure to gradually reduce the number of solutions to be discussed or tenders to be negotiated

☒ yes ☐ no

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IV.2) AWARD CRITERIA

IV.2.1) Award criteria (please tick the relevant box(es))

☐ Lowest price

OR

☒ The most economically advantageous tender in terms of

☐ the criteria stated below (the award criteria should be given with their weighting or in descending order of importance where weighting is not possible for demonstrable reasons)

☒ the criteria stated in the specifications, in the invitation to tender or to negotiate or in the descriptive document

Criteria	Weighting	Criteria	Weighting
1.		6.	
2.		7.	
3.		8.	
4.		9.	
5.		10.	

IV.2.2) An electronic auction will be used

☐ yes ☒ no

If yes, additional information about electronic auction (if appropriate)

IV.3) ADMINISTRATIVE INFORMATION

IV.3.1) File reference number attributed by the contracting authority (if applicable)

KCE-2017_001_CTMS-F02_0

IV.3.2) Previous publication(s) concerning the same contract

☐ yes ☒ no

If yes,

☐ Prior information notice	☐ Notice on a buyer profile
Notice number in OJ:	of (dd/mm/yyyy)
☐ Other previous publications (if applicable)	

IV.3.3) Conditions for obtaining specifications and additional documents (except for a DPS) or descriptive document (in the case of a competitive dialogue)

Time limit for receipt of requests for documents or for accessing documents	
Date 16/06/2017 (dd/mm/yyyy)	Time 00:00
Payable documents	
☐ yes ☐ no	
If yes, price (give figures only):	Currency:
Terms and method of payment:	

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Date 19/06/2017 (dd/mm/yyyy) Time 13:00

IV.3.5) Date of dispatch of invitations to tender or to participate to selected candidates (if known) (in the case of restricted and negotiated procedures, and competitive dialogue)

Date (dd/mm/yyyy)

IV.3.6) LANGUAGE(S) IN WHICH TENDERS OR REQUESTS TO PARTICIPATE MAY BE DRAWN UP☐ Any EU official language☒ Official EU language(s)

ES	CS	DA	DE	ET	EL	EN	FR	IT	LV	LT	HU	MT	NL	PL	PT	SK	SL	FI	SV
☐	☐	☐	☐	☐	☐	☒	☒	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐	☐	☐

☐ Other:

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☐ yes ☒ no

If **yes**, estimated timing for further notices to be published:

VI.2) CONTRACT RELATED TO A PROJECT AND/OR PROGRAMME FINANCED BY EU FUNDS

☐ yes ☒ no

If **yes**, reference to project(s) and/or programme(s):

VI.3) ADDITIONAL INFORMATION *(if applicable)*

An application form can be downloaded from the website of KCE (www.kce.fov.be), in the 'Collaboration', 'Tenders' heading, OR from E-notification (<https://enot.publicprocurement.be>), in the heading 'Documents' from the tender notice.

The applications can electronically be submitted on the website e-tendering <https://eten.publicprocurement.be> OR per post on the adres mentioned under point I.1.

You can find more information on the website <http://www.publicprocurement.be> or by calling the helpdesk of e-procurement +32 (0)2 790 52 00

VI.4) PROCEDURES FOR APPEAL**VI.4.1) Body responsible for appeal procedures**

Official name: [Council of State](#)
Postal address: [Greffes de la section du contentieux administratif](#)
Town: [Brussels](#) Postal code: [1040](#)
Country: [Belgium](#) Telephone:
Email: Fax:
Internet address (URL): <http://www.raadvst-consetat.be>

Body responsible for mediation procedures *(if applicable)*

Official name:
Postal address:
Town: Postal code:
Country: Telephone:
Email: Fax:
Internet address (URL):

VI.4.2) Lodging of appeals *(please fill heading VI.4.2 OR if need be, heading VI.4.3)*

Precise information on deadline(s) for lodging appeals:

[15 jours en cas d'une demande en suspension en extrême urgence - 60 jours en cas d'un recours en annulation](#)

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VI.4.3) Service from which information about the lodging of appeals may be obtained

Official name:

Postal address:

Town:

Postal code:

Country:

Telephone:

Email:

Fax:

Internet address (URL):

VI.5) DATE OF DISPATCH OF THIS NOTICE:

11/05/2017 (dd/mm/yyyy)