

Aanbesteding: QA-tool with secure data storage
Aanbestedende Dienst: Stichting Bevolkingsonderzoek Nederland
Referentie: 2022-005

Toelichting:

There are 2 additional questions and one clarification were the Contracting Authority decided to provide for an answer.

Ref.nr. **Onderwerp:**
1 Information Notice 1

Vraag:
Information Notice 1

Antwoord:
Since there have been no questions asked for the first Information Notice, BVO-NL gives the opportunity to ask questions until the 11th of January, 12:00 CET (Date of questions for second Information Notice).

BVO-NL appreciates if (pressing) questions are asked earlier than the above date.

Futhermore, questions for the second Information Notice may also include new questions.

Beantwoord op: 14-12-2022
Label: Proces

Ref.nr. **Onderwerp:**
2 Retrieve or receive data

Vraag:
Is the data sent from the laboratories to the QA tool or does the QA tool have to collect the data from the laboratories?

Antwoord:
Each lab is equipped with two BD-COR systems, the data from these two systems will be collected by Synapsis (Middle ware of BD). Per laboratory site the data will be sent from Synapsis to an sFTP database, that can subsequently forward the required dataset to the secure database which will be provided by the tenderer. That secure database will be the source of the anonymized data for the QA-tool.

Beantwoord op: 20-01-2023
Label: Inhoud

Ref.nr.
3

Onderwerp:
Technology for retrieving or receiving data

Vraag:
Which technique is used to retrieve the data or deliver it to the QA tool?

Antwoord:
The data will be sent using secure FTP.

Beantwoord op: 20-01-2023

Label: Inhoud

Ref.nr.
4

Onderwerp:
File / message format

Vraag:
In what file/message format is the data delivered to the QA tool?

Antwoord:
The data will be delivered as CSV files.

Beantwoord op: 20-01-2023

Label: Inhoud

Ref.nr.
5

Onderwerp:
File / message structure

Vraag:
What is the file/message structure of the data supplied to the QA tool? Can you provide an example file?

Antwoord:
The file format is CSV, attached are three example files that contain example data. The exact content of the file is still under development.

Beantwoord op: 20-01-2023

Label: Inhoud

Ref.nr.
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Onderwerp:
ARBIT article 17.5

Vraag:

Regardless of the nature and seriousness of the violation, a fine of € 50,000 is due as standard. The Tenderer understands the rationale behind attaching a fine to a breach of the duty of secrecy, but considers a standard amount of € 50,000 to be disproportionate. When determining the amount of the fine, account must be taken of whether or not there is intent, the seriousness of the violation and the consequences thereof. The Tenderer proposes to amend this provision as follows:

“The party that violates the secrecy obligation included in Article 17.1 owes the other party an immediately due and payable penalty of a maximum of € 50,000, taking into account whether or not there is intent, the seriousness of the violation and the consequences thereof, where a series of related events is seen as one event.”

Antwoord:

BVO-NL accepts an amendment to this article 17.5 ARBIT. The following amended article shall be added in Annex B - Draft Agreement:

Article 17.5 shall be deleted and replaced by: “The party that breaches the duty of secrecy provided for in article 17.1 will owe the other party a penalty of a maximum of €50,000, due and payable forthwith, for each infringement. When determining the amount of the penalty the other party will take into account whether or not there was intent, the seriousness of the violation and the consequences thereof. In addition, a series of related events is seen as one event and therefore will be seen as one infringement.”

Beantwoord op: 20-01-2023

Label: Contract

Ref.nr.

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Onderwerp:

ARBIT article 26.3

Vraag:

The Tenderer considers a liability of four times the amount of the Fee disproportionate. We request that you amend this article as follows: ""The liability referred to in Article 26.1 for damage other than that referred to in Article 26.2 is limited to an amount per event not exceeding twice the amount of the Fee due in the twelve months. prior to the event. Related events are thereby regarded as one event.

Antwoord:

BVO-NL accepts an amendment to this article 26.3 ARBIT. The following amended article shall be added in Annex B - Draft Agreement:

Article 26.3 shall be deleted and replaced by: "The liability referred to in article 26.1 for loss or damage other than that referred to in article 26.2 is limited per event to an amount not exceeding twice the amount of the Fee

due in the twelve months prior to the event. For this purpose, interrelated events will be treated as a single event."

Beantwoord op: 20-01-2023
Label: Contract

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Onderwerp:
ARBIT article 34

Vraag:

The Tenderer considers obligations of indefinite duration disproportionate and proposes to limit them in time. The Tenderer therefore proposes to add to Article 34:

"The obligations under this article apply for the duration of the Agreement as well as for a period of three years after its termination."

Antwoord:

BVO-NL accepts an amendment to this article 34 ARBIT. The following amended article shall be added in Annex B - Draft Agreement:

Termination of the Contract will not discharge the parties from obligations which, by their nature, are intended to continue in force thereafter. These obligations include in any event the provisions on indemnification for breaches of intellectual property rights and on guarantees, liability, the duty of secrecy, disputes and the applicable law. The obligations under this article apply for the duration of the Agreement as well as for a period of three years after its termination.

Beantwoord op: 20-01-2023
Label: Contract

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Onderwerp:
Annex 1 - 1.3

Vraag:

At Annex 1 item 1.3 you mention that data must be analyzed "on-site" of the lab. By this do you mean that the data may not leave the lab and thus cloud-based software is not possible?

Antwoord:

This requirement means that the lab can only analyze its own data in the QA tool, whether or not benchmarked against the total of the other (anonymized) sites.

This requirement does not concern the basis of the software (cloud based or

not).

Beantwoord op: 20-01-2023
Label: Inhoud

Ref.nr. **Onderwerp:**
10 BD COR system

Vraag:

Is it possible to send a test sample files of the BD COR system? What file format is this?

Antwoord:

See the answer on questions 4 and 5.

Beantwoord op: 20-01-2023
Label: Inhoud

Ref.nr. **Onderwerp:**
11 The report

Vraag:

Can you give an example of your expected report? What data should be exportable?

Antwoord:

In Annex A some figures, both tables and graphs, of the current program are depicted and explained. In these pictures the Ct values of the different control samples of the programm, both system controls and user defined controls, are plotted in relation to the date of test performance. These plots should be able to depict the results for a single lab for all labs, over a selected period of time. Similarly, such data should depicted for GP- versus self samples. We also want to periodically visualize system performance using graphs and figures. In general it should be possible to store and print all graphs, figures and other visualizations genarted by the QA-Tool. Annexed to this Information notice is an example of a monthly report for the laboratories. These are examples on de data BVO-NL wants to use for reporting, with or without additional analyses.

Beantwoord op: 20-01-2023
Label: Inhoud

Ref.nr. **Onderwerp:**
12 Ad-hoc queries

Vraag:

Question related to ad hoc queries: how far do you want to go in this: what kind of queries should we be able to support? Can this be a list of possibilities (clickable) or be able to run your own SQL statements?

Antwoord:

A list of (clickable) possibilities is sufficient.

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Onderwerp:

Annex 1 - 6.3

Vraag:

in connection with estimating translation costs, what kind of documents should we think of to translate into Dutch?

Antwoord:

All documents which will be used by the users of the system/QA-tool, such as user manuals, training documents etc need to be translated into Dutch.

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Onderwerp:

Annex 3 - ESPD

Vraag:

Something is going wrong with the Annex 3 document - ESPD. When opening it, an error message keeps coming up. Can you provide it to us in a more detailed way?

Antwoord:

On the basis of this question the ESPD document had been checked. This is a known problem. To solve this please search the document in your download folder, then save this document on your own drive. Then the document can be opened correctly.

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Onderwerp:

Deadline tender

Vraag:

The Tenderer considers the time between receiving the answers to the questions (January 20) and the deadline (January 31) to submit the tender very short. The Tenderer requests to extend the period to submit the tender by 2 weeks (until 7 February 2023).

Antwoord:

BVO-NL will accept the request of a 2 week extension of the deadline to submit the tender.

The new planning is the following:

Deadline Submit Tender: 14 February 2023, until 12:00 CET

Presentations: 1 March 2023

Publish preliminary Award decision: 10 March 2023

Verification of data in the European Single Procurement Document (ESPD):
From 10 March 2023

Suspensive period: 30 March 2023, until 23:59 CET

Definitive Award: 31 March 2023

Contract signing: 31 March 2023

Effective Contract date & start implementation period: 1 April 2023

Start operational Contract: 1 June 2023

Beantwoord op: 20-01-2023

Label: Proces

Ref.nr.
16

Onderwerp:
Annex 1

Vraag:

Please can you specify Annex 1 question 1.14 ?

Antwoord:

This requirement refers to the following text on page 14 of the Descriptive document:

“An automatic alert system (e.g. based on Westgard rules) for deviations from preset values based on calculations on the dataset must be supported by the QA-tool. Beside this automatic alert system the Descriptive Document QA-Tool With Secure Data Storage_1.0 Page 14 of 49 user needs to be able to detect potential deviations in the performance of the test and/or equipment in a timely manner, for example by (pre-defined) trend analysis. Both alert systems require that the tool must be able to perform calculations and generates tables and graphs automatically upon a selection of parameters thereby using a standardized dashboard functionality. Next to that it must be possible for the user to do additional queries (which are not defined yet). To

enable external (extended) data analysis (role/right) based it is essential that the QA-tool is provided with a display and export function. Moreover the QA- tool must contain a functionality to export results presented in tables, figures and results from ad hoc queries. (at least xls, doc, jpeg and pdf format).

To easily get more insight in the effect of specific data parameters on the quality of performance of the HPV assay by user defined (ad hoc) queries the QA-tool must contain a data mining option. Furthermore a hover functionality in which underlying information on relevant parameters is shown per datapoint in the graphical presentation of results is required.

For BVO NL/the laboratories it is required that the QA-tool is able to generate periodic and ad hoc reports based on specific selection criteria. One of these criteria the QA-tool needs to support is dedicated (standardized) analyses on a subset of the laboratory data, e.g. using the results from control samples (V&V panels and UDEC) (to be selected based on sample IDs). BVO NL will be involved in the design and acceptance of the output of these reports and in defining the acceptance criteria for these control samples.”

See also the given answer on question 12 Information Notice.

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Label: Inhoud

Ref.nr.
17

Onderwerp:
Annex 1

Vraag:
Please can you specify Annex 1 question 1.20 ?

Antwoord:
Question 1.20 refers to the following text of the Descriptive document (page 14):

“For BVO NL/the laboratories it is required that the QA-tool is able to generate periodic and ad hoc reports based on specific selection criteria. One of these criteria the QA-tool needs to support is dedicated (standardized) analyses on a subset of the laboratory data, e.g. using the results from control samples (V&V panels and UDEC) (to be selected based on sample IDs). BVO NL will be involved in the design and acceptance of the output of these reports and in defining the acceptance criteria for these control samples.”

It is important that the QA tool is able to generate reports for both BVO/NL and the laboratories on an ad hoc and on a periodic basis. The content and analyses and data presentations for these reports will be defined by BVO NL

Beantwoord op: 27-01-2023
Label: Inhoud

Ref.nr. 18
Onderwerp: Article 9.2 Annex B - Draft agreement

Vraag:
Clarification on behalf of the Contracting Authority

Antwoord:
On the basis of a question received by the Contracting Authority on user conditions in relation to article 9.2 Annex B – Draft agreement, the Contracting Authority hereby clarifies the following:

From Article 9.2 of the draft agreement it follows that the ARBIT-2018 conditions are in ranking above any user conditions, also for cloud based software.

Some ARBIT-2018 articles are written for Custom Software and not for cloud software platforms. However, this does not mean that provisions of the ARBIT-2018 are declared inapplicable in the Agreement. By definition Custom Software conditions do not all apply to Standard Software (see ARBIT-2018).

For users of all software of the future Counterparty, the user conditions are applicable insofar as these conditions do not conflict with the ARBIT-2018. This in accordance with article 9.2 ARBIT-2018.

Beantwoord op: 27-01-2023
Label: Juridisch