

Descriptive Document

European open tendering

QA-tool with secure data storage

Version 1.0

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Introduction

In front of you is the Descriptive Document belonging to the Tender QA-tool for the benefit of population screening for cervical cancer that the Stichting Bevolkingsonderzoek Nederland has started.

If you have not received the Descriptive Document in full or in good order, the Contracting Authority requests that you report this as soon as possible, but before 11 January 2023 via the TenderNed Procurement Platform, stating which documents are missing, incomplete or damaged.

In order for the assessment to run as smoothly as possible, you must follow the instructions described in this Descriptive Document. Section 4.5 of this Descriptive Document describes how to ask any questions you may have.



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1. Definitions

All words, written with a capital in this Descriptive Document and the Agreement, will have the meaning as set out below:

<u>Annex(s):</u>	Documents forming an integral part of this Descriptive Document and/or the Contract.
<u>Archiefwet</u>	The 'Archiefwet' is a Dutch law from 1995 that regulates the management and access of government archives.
<u>Award criteria:</u>	Evaluation criteria for the Tender.
<u>BD Onclarity assay</u>	BD Onclarity assay can detect the following hrHPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 en 68. Whereby six of these hrHPV types can be genotyped individually (HPV 16, 18, 31, 45, 51 and 52), and the others in three genotype groups (33/58, 35/39/68 and 56/59/66).
<u>BMHK23:</u>	The procurement project of the Contracting Authority in which Contracts on behalf of the Cervical Cancer screening are renewed on a project-by-project basis.
<u>BVO NL</u>	The Dutch Population Screening Foundation, Stichting Bevolkingsonderzoek Nederland
<u>Client</u>	Person who has received an invitation for the Cervical Cancer Population Screening.
<u>Consortium</u>	Tenderer can use Third Party(s) to jointly meet the Eligibility Requirements as a Consortium. A Consortium has joint and several liability. We are entitled to test whether the Consortium Member(s) and/or Third Party / Third Parties comply with the Suitability Minimum Requirements.
<u>Contract:</u>	The document including its Annexs in which the terms and conditions for the Services have been set out. The Contract is an Annex to this Descriptive Document.
<u>Contracting authority (after award: BVO NL):</u>	The contracting party, Bevolkingsonderzoek Nederland (hereafter: BVO NL) who is inviting suitable Tenderers to participate in this procurement process. BVO NL is responsible for the nationwide health screening for: breast screening, cervical screening and bowel cancer screening. These screenings are offered by the government and participation is free and voluntary. For the cervical cancer screening program quality assurance is established for the hrHPV and cytology screening analysis. BVO NL employs National Reference Officers for quality assurance of hrHPV and Cytology screening.
<u>Contractor:</u>	The Tenderer with which BVO NL enters into an Agreement for the QA-tool.
<u>Declaration exclusion grounds:</u>	The Declaration exclusion grounds is a European Single Procurement Document (Declaration exclusion grounds) completed by an economic operator to explain the capacity in which it is participating in a procurement procedure (independent trader, main Contractor, consortium member or subcontractor) and provide information on relevant grounds for exclusion, its financial and economic standing and other suitability Minimum requirements applied by the Contracting Authority.

<u>Descriptive document:</u>	This document and its Annexes.
<u>European Single Procurement Document (ESPD) :</u>	Declaration that you complete and sign with your Tender in accordance with the standard form as referred to in Commission Implementing Regulation (EU) 2016/7 of 5 January 2016.
<u>Exclusion Grounds :</u>	The mandatory and optional Exclusion Grounds from participation in the Tender as referred to in Articles 2.86 and 2.87 of the Public Procurement Act 2012, respectively.
<u>GDPR</u>	The General Data Protection Regulation (EU) (GDPR)
<u>hrHPV</u>	Human papillomavirus. More than 150 types of Human Papillomavirus are known, a limited number can cause cervical cancer or its precancerous stages. These types are referred to as high risk HPV (hrHPV). For the Dutch Cervical Cancer Screening Program, Samples are tested for the presence of a total of 14 hrHPV genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, and 66. The results of HPV16 and HPV18 are reported individually while the results of the other HPV genotypes are reported as a group: hrHPV-other..
<u>Information notice:</u>	The document containing anonymised questions asked by potential tenderers, together with the answers given by the Contracting authority. It includes any amendments/additions to this Discriptive Document, and forms an integral and binding part of it. The information notice with the most recent date prevails over an information notice of an earlier date.
<u>Minimum requirement:</u>	A Minimum requirement which Tenderer has to fulfil and/or meet in order to be eligible for award.
<u>Parties</u>	Contractor and BVO NL
<u>Public Procurement Act 2012:</u>	Act for the regulation of Public Procurement procedures in the Netherlands, applicable from 1 July 2016.
<u>QA-tool</u>	A software system including (IT) services that provides BVO NL real time insights and quality control in the hrHPV test performance in the cervical cancer screening laboratories The QA database provides the anonymous data for the queries and reports.
<u>QA database</u>	The QA database is a separate database used by the QA tool platform and based on anonymized dataset extracted from the Secure data storage.
<u>RIVM-CvB</u>	The Centre for Population Screening (CvB) of the National Institute for Public Health and the Environment (RIVM), which is responsible for directing the population screenings carried out by the government on behalf of the Ministry of Health, Welfare and Sport.
<u>Screening laboratory/laboratories:</u>	The Screening laboratories which analyze the specimen for the presence of hrHPV and possible cytological abnormalities at the behest of the Contracting authority.
<u>Secure data storage</u>	The Secure data storage is a separate database from the quality control part of the system and should not be accessible directly for the QA-reporting. It must be possible for authorized staff to perform maintenance procedures to manage the records in the secure data storage (remove and or anonymize records)
<u>Services</u>	All activities the Contractor fulfils for this Contract

<u>Subcontractor</u>	An Economic Operator who performs part of the Contract. The Subcontractor does this on the instructions and under the responsibility of the Contractor.
<u>Suitability Minimum requirements:</u>	Criteria a Tenderer must fulfil in order to qualify for contract award. The suitability Minimum requirements comprise of a) exclusion criteria and b) Minimum requirements as set out in Chapter 4
<u>Tender</u>	The bid(s) prepared and submitted by each Tenderer or consortium in response to the Descriptive Document. Chapter 4 of this Descriptive Document clarifies the ways in which a Registration may be submitted.
<u>Tendering Process</u>	This is the procurement procedure. We apply the 'open procedure'.
<u>Tenderer</u>	An economic operator (including consortia or joint venture arrangements) who submits a Tender to this Descriptive Document. An economic operator who independently submits a Tender can engage one or more Subcontractors for the execution of the Contract or to meet the set Eligibility Requirements. Tenderer may also be read for Tenderers where applicable.
<u>TenderNed</u>	The digital online procurement platform, which is used for the entire procurement procedure, from the notice to the award of the Contract as further described in this Descriptive Document.
<u>Terms and conditions</u>	The General Government conditions for IT agreements 2018 (ARBIT-2018) (Annex C)
<u>Third Party</u>	The entrepreneur that the Tenderer relies on to comply with the Eligibility Requirements.
<u>UDEC</u>	User Defined External Control
<u>V&V panel</u>	Release and Verification panel. Specific panel of control samples for, among other things, the verification of the HPV systems after maintenance and/or repair and during batch changes to release HPV kits in the within the HPV control program of the Cervical Cancer Population Screening.
<u>WGBO</u>	The 'Wet op de geneeskundige behandelingsovereenkomst' (WGBO), which regulates the right to inspect one's own medical file, based on the obligation to provide information and the consent requirement.
<u>WABVPZ</u>	The 'Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg' (WABVPZ) is a Dutch law that is an extension of the Wet algemene bepalingen burgerservicenummer (General Provisions for Citizen Service Number Act). This law regulates the processing of personal data in medical care, including the use of the citizen service number.

2. Contracting authority

2.1 Bevolkingsonderzoek Nederland (BVO NL)

The Dutch Cervical Cancer Population Screening is a preventive screening program that is offered by the government to women between the ages of 30 and 60. Smears have been made on a large scale in the Netherlands since 1970. Since 1996 there has been a nationally uniform Cervical Cancer Population Screening, based on Cytological screening of Pap smears. From that moment on, women aged 30 to 60 received an invitation every 5 years to participate in the Cervical Cancer Population Screening.

At the beginning of 2017, the Cervical Cancer Population Screening was renewed, whereby primary hrHPV screening was introduced with Cervical Cytology as Triage. In addition, a self-sampling kit has been introduced for women who find it difficult to have a Pap smear made.

The aim of the Cervical Cancer Population Screening is to reduce mortality and the burden of disease by detecting the precancerous stages of Cervical cancer at an early stage and thus preventing Cervical cancer from developing. Every year in the Netherlands approximately 800 women are diagnosed with cervical cancer, especially between the ages of 30 and 60. More than 200 women die of cervical cancer every year.

The Dutch Population Screening Foundation, (Stichting Bevolkingsonderzoek Nederland (BVO NL) has a dualistic governance model. The Board of Directors is responsible for the day-to-day management of the organization and a Supervisory Board supervises the Board of Directors.

BVO NL consists of a main establishment and branches, which are registered in the Chamber of Commerce. The geographical distribution of the sites (North, East, South, Mid-West and South-West) ensures national coverage for the performance of the Population Screening (figure 1).

More information on the screening of cervical cancer and BVO NL can be found at:
: <https://www.bevolkingsonderzoeknederland.nl/en/>

The end users of the QA-tool will be BVO NL and the three executive laboratories.

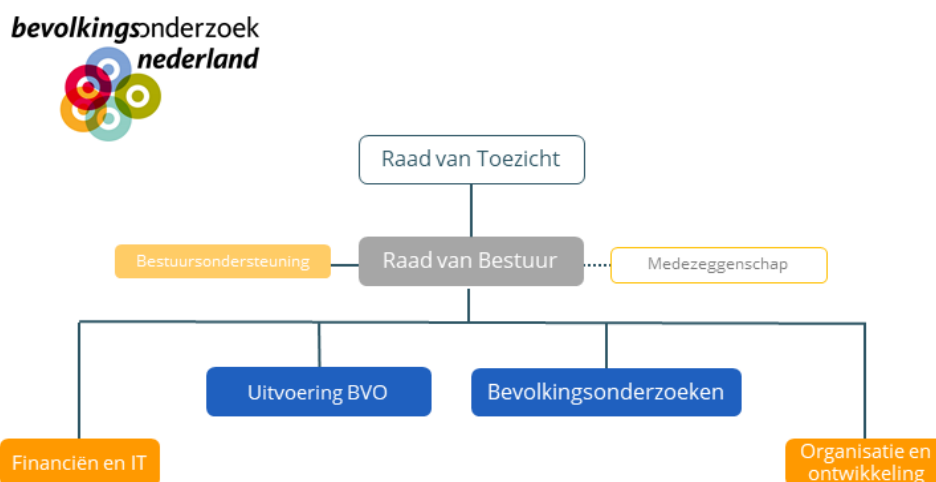


Figure 1: The organizational structure of BVO NL

2.1.1 Procurement support

BVO NL has instructed AevesBenefit, an independent consultancy firm for procurement, to execute this public procurement procedure.

3. Background, goals and scope of the tender

3.1 Reason and background of the tender

BMHK23

Since January 2017 the cytological screening for cervical cancer was replaced by primary hrHPV screening. The hrHPV screening is performed on cervical pap smears as well as on material collected with self-sampling devices.

In June 2023 a new contracting period for both the hrHPV assay and the selfsamples as well as the screening laboratories will start. From that moment the country wide hrHPV analysis will be performed in 3 laboratories (screening sites), each using the BD Onclarity assay on two separate BD COR systems (Becton Dickinson). The BD Onclarity assay can detect the following hrHPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 en 68. Whereby six of these hrHPV types can be genotyped individually (HPV 16, 18, 31, 45, 51 and 52), and the others in three genotype groups (33/58, 35/39/68 and 56/59/66). All laboratory procedures are completely standardized among the screening laboratories.

It is important to have access to the extended hrHPV results and detailed information from all BD-COR systems used in the screening program to be able to control the quality of the HPV analysis. The extended hrHPV results are also important for future developments and research purposes on Cervical Cancer screening.

With this tender BVO NL aims to implement a quality control program over the three separate sites and assure secure data storage of the extended hrHPV results for future purposes.

Quality control

Each of the laboratories is accredited according to the ISO 15189 standard. An integrated Quality Assurance program has been developed and is part of the screening activities of the laboratory. The quality assurance program for monitoring independently hrHPV test performance in cervical cancer screening laboratories is based on the following elements:

1. A program for acceptance testing of equipment upon installation and upon repair or major service.
2. A program to test and release (new lots of) critical reagents.
3. An assay control program based continuous monitoring of kit- control results with or without monitoring of results of a manufacturer-independent control included in a run.
4. A program for equipment monitoring of the performance of the HPV-systems.
5. External Quality Assessment to monitor inter-laboratory performances by participating in international inter-laboratory comparisons with proficiency panels.

To be able to fulfill the first two items of the above mentioned quality assurance program, a verification and release program is established. In short, according to protocols of the Quality Assurance program a ready to use HPV control panel (verification panel) will be used for acceptance of the systems upon (major) service or repair (H7- Landelijk protocol HPV systeemverificatie) and for the release of new lots of critical reagents prior to use (H6- Protocol ingangscontrole kritische reagentia). The verification panel consists of a set of samples containing various HPV types at different concentrations (high and low) and will also be tested before use (H5- Ingangscontrole en kalibratie vrijgifte en verificatie panel).

To perform the hrHPV test in the most uniform way as possible lots of critical reagents (for at least six months) are allocated by the supplier. Before these lots are released for the hrHPV test, an entry control is performed simultaneously by the three screening laboratories according to the protocol (H6- Protocol ingangscntrole kritische reagentia). The new lot will be accepted if the predefined acceptance criteria are met. In addition, any changes to the limits values, established during the acceptance test, must be adopted when using the new lot of critical reagents. It is thereby essential that the limit values belonging to the previous period will be maintained.

To gain and maintain insight into the variability and stability of the total laboratory setup for the hrHPV analysis of the three screening laboratories, an assay control program, based on monitoring different controls, is performed. During the initial months of the operational period of the BD onclarity assay, expecting to start in June 2023, an independent run control sample will be included in part of the runs. This independent run control, called User Defined External Control (UDEC), is used to monitor the (variation in) assay stability performance within and between the screening laboratories; it is certainly not aimed for acceptance of individual runs. For interlaboratory comparison the results of the laboratories will be compared with the national average. Furthermore, each laboratory needs to be able to monitor the possible variation between their two BD-COR systems.

In the same way that the UDEC is used to monitor the (variation in) assay stability performance within and between the screening laboratories, the kit controls of the BD Onclarity assay will also be used.

Equipment monitoring measures the technical performance of the HPV -systems. Errors are recorded and used for graphical and or tabulated display. Equipment monitoring needs to be provided both at laboratory and national level. In the equipment monitoring of the HPV-systems a distinction will be made in failed/invalid results at both run and sample level and errors like failed barcode reading.

In order to meet the above described quality assurance a software system including (IT) services is required. For clarification, some figures of the current program are included in Annex A.

Secure data storage

In addition to support on the quality assurance program, it is, in the interest of future scientific research, essential that this system is able to store the raw data (including the sample ID) collected from the BD-COR systems in a secure way. This data storage must be separate from extracted data to be used for quality control analyses. It must be possible for authorized staff to perform maintenance procedures to manage the records in the secure data storage (remove and or anonymize records).

Currently BVO NL has an agreement for software licenses, hosting and maintenance with a private service provider. In the execution of the Quality Control program described above, raw data files collected from the HPV systems (i.e. run files) are used. The raw data files are transferred to an external sftp-server. Upon data extraction and data analysis using a fixed set of queries, the results are graphically displayed in a data analysis software tool. A selection of the data can be exported to Excel for reporting purposes. Subsequently, periodic performance reports are manually prepared in Word, making use of the graphical display from Excel. The current software that covers only part of the quality assurance requirements, is called BMHK-laboratory quality monitoring software. The manual processing steps that are required for data selection, analysis of the quality assurance results and preparation of reports significantly complicates and delays the QA monitoring process both at the national level as well as within- and between laboratories. To fully support the Quality Control program using the raw data from the BD COR systems, including all hrHPV genotypes, a QA tool is required, that is able to execute all the steps described above, in an automatic way, such that the amount of manual operations/actions is minimized.

In order to fulfill the above described needs and the goals and results stated in paragraph 3.2 and 3.3, BVO NL publishes this Descriptive Document.

3.2 Tender goals and results

In the interest of a successful tender BVO NL defined the below described goals and Qualitative project effects of the Tender:

Goals of the Tender

1. Achieve the qualitative improvements, which are listed under 'qualitative project effects'.
2. Legality: procurement has been carried out within applicable regulations and procedures.
3. Efficiency: purchasing leads to value creation in money, efficiency and image;
4. Level playing field: tenderers are offered equal opportunities within the influence of BVO NL. BVO NL has made efforts to create a level playing field through the following:
 - To give as clear a picture as possible of the current and desired situation.

Qualitative project effects

1. Provide support to the integrated Quality Assurance program for monitoring independently hrHPV test performance in cervical cancer screening laboratories
2. Give insight in the stability of the assay and performance of the laboratory across samples, assay runs, instruments laboratory sites and/or personnel;
3. Store the raw data from the secure raw received data files of hrHPV testing for QA and QC purposes in a secure data storage;
4. Facilitate the procedures for carrying out of Clients legal rights according to (inter)national legal requirements from, among others, GDPR, Archiefwet, WGBB, WABVPZ.
5. Support all steps in the process for Quality Control (see Annex I) technically and graphically;
6. Facilitate all required steps in the process of Quality Control data analysis (see Annexes 1 and A) ;
7. Facilitate a Quality Control data analysis that is easy to perform with limited (technical or IT) knowledge.

3.3 Scope of the tender

The QA tool with secure data storage should receive raw data files from the separate BD COR systems that are installed in the laboratories that carry out the cervical cancer screening for BVO BMHK. The transfer method (currently secure FTP) must be determined by the tenderer, thereby taking into account the possibilities of BD and the laboratories-ICT department. The relevant data, that includes extended hrHPV genotyping from these files must be stored in a secure database. Access to this database must be managed by secure procedures for authorized personnel only.

Data used for the quality control program must be transferred from this secure data storage to a separate QA database, whereby the data must be anonymised.

To fully support the Quality Control program, a QA-tool, that is able to visually monitor assay stability and laboratory performance, is required. This QA-tool must be a single software platform that is able to monitor assay controls, external controls, instrument performance and Client samples on a daily basis, using the data that is stored in the QA database. (see figure 2).

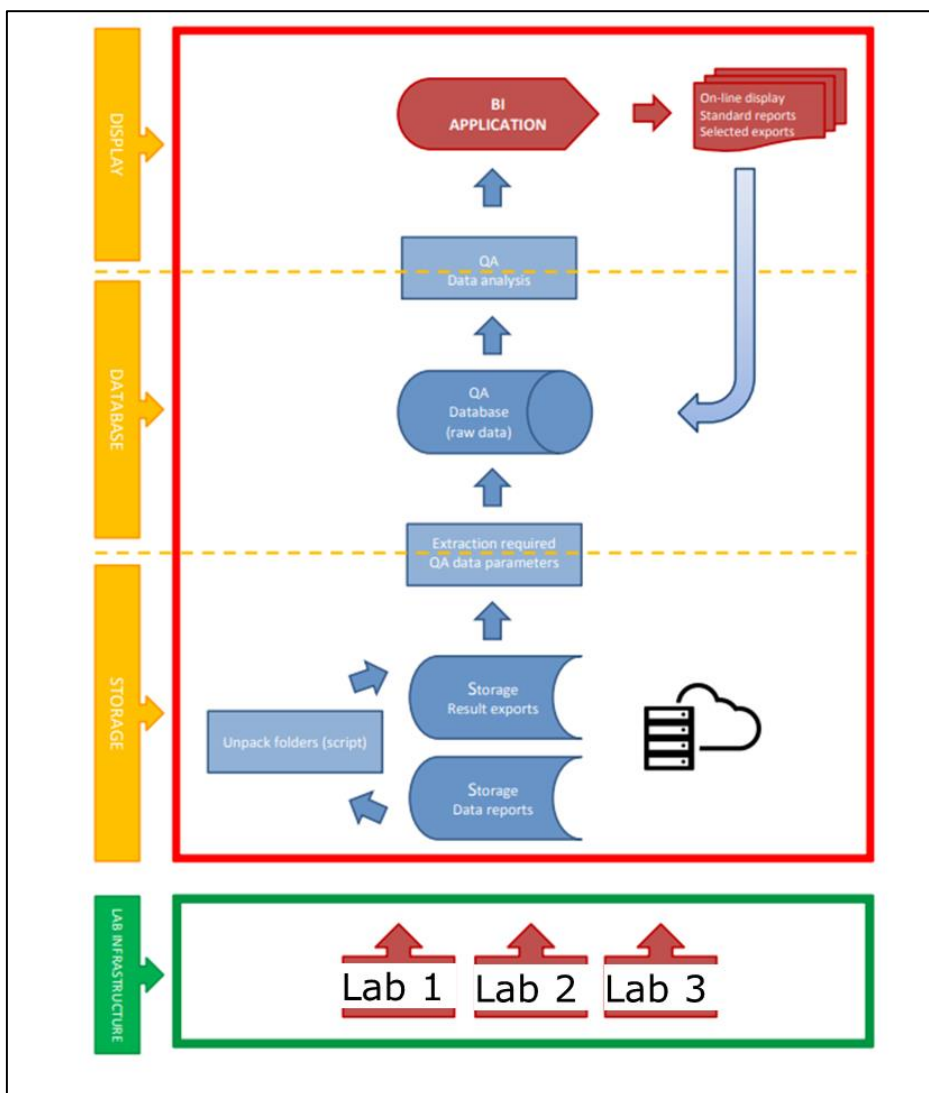


Figure 2: system overview of the QA-tool with secure data storage

Since the hrHPV test will be performed in 3 laboratories (screening sites), each using the BD Onclarity assay on two separate BD COR systems (Becton Dickinson) the application must be able to integrate the data from multiple systems and laboratory sites. For analyzing and reporting purposes it is necessary to

1. be able to run the analyses and reports on the site of the laboratories, using the data of that site, whether or not plotted/benchmarked in comparison to the total data of all sites,
2. as well as to run the analyses and reports on behalf of BVO NL, using the data of all participating laboratories.

For both groups of users it is important that the QA-tool has a user friendly and intuitive interface and that it is possible to view and analyze the actual data. Therefore it is necessary that the Secure data storage is able to receive raw data files (CSV and XML files) from the BD-COR systems at the three laboratory sites on an overnight basis, in such a way that the files are ready for QA-tool purposes the next day.

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

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 hoover 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.

Because of the importance for BVO NL to monitor the performance of the various systems on the three separate laboratories the QA-tool must be able to process results into machine errors graphs to visualize user and system failures.

Moreover it must be possible to implement changes in the QA-Tool as becomes necessary during the term of the contract. If further development is needed during the contract, it will be formally asked for by BVO NL.

In view of archiving of the (original raw) data files it is of utmost importance that the Tenderer provides a secure storage place. In addition Tenderer must provide a Secure, encrypted database with anonymous data built from a selection of parameters/data fields extracted from the raw data files delivered by the BD COR system. In addition, these raw data files will not contain personal information of the participants of the screening program, except the sample identification code

Award of the Contract will take place on the basis of the award criterion best price-quality ratio (see chapter 9).

Tenderer is invited to submit a Tender conform the conditions written down in this Descriptive Document.

The QA-tool and Secure data storage must be operational and in use on the 1st of June 2023.

3.4 Merging separate public contracts

BVO NL believes that the Contract concerns one public contract, because the various parts of the public contract as such fulfill one economic and one technical function. There is therefore no question of merging several public contracts within the meaning of Article 1.5 paragraph 1 of the Public Procurement Act.

3.5 Alteration of the Contract

BVO NL reserves the right to make the following (substantial) changes to the Contract during this tendering procedure and during the term of the Agreement on the basis of article 2.163c Public Procurement Act 2012:

- As part of the Scope of the Contract BVO NL asks the future Contractor to provide a secure database. BVO NL reserves the right to exclude this part of the Contract after the 4th year of the Agreement. This due internal policy regarding the secure database. It is therefore possible that in the 4th year (or any year after) BVO NL extends the Agreement as stated in paragraph 3.6 except for the secure database. For this reason the pricing of the secure database is mentioned separately in Annex 5 – Pricing sheet.

3.6 Contract

The purpose of this tender is to conclude an agreement with a Contractor. The contract duration of the Agreement is 4 (four) years. This Agreement may be extended by 4 (four) times with 1 year. The maximum duration of the Agreement is therefore 8 (eight) years (excluded implementation period).

BVO NL informs the Contractor in writing at the latest three (3) months before the end of the Agreement whether or not the Agreement will be extended.

BVO NL aims to have awarded the Contract on (finally). The Effective Date for the Agreement is set on the 1st of April 2023. A transition or implementation period of 2 months is provided for at the start and at the end of the term of the Agreement.

3.7 Service Level Agreement (SLA)

Following from this Tendering Procedure, the Tenderer who the Contracting Authority will sign the Agreement with will put together a Service Level Agreement in cooperation with the Contracting Authority during the implementation period. Annex 1, Annex A and Tenderers own submitted tender will be the basis for this Service Level Agreement.

This Service Level Agreement also contains measures to ensure the stated protection of personal data and continuity of data in paragraph 3.9.

3.8 Reserve Contractor Agreement

In addition to the Agreement, a Reserve Contractor Agreement (Annex E – Reserve Contractor Agreement) will be concluded that will only be used if the Tenderer with whom the Agreement has been concluded does not comply with the agreements according to the Agreement and additional agreements or otherwise performs poorly. This Reserve Contractor Agreement will be concluded with the Tenderer who has been assessed as the second most advantageous Tender (2nd in ranking).

During the period in which the Reserve Contractor Agreement is in force, the reserve contractor is not entitled to any compensation.

If termination of the Original Agreement takes place within one (1) year after 1st of April 2023, therefore by 1st of April 2024 at the latest, the Contracting Authority will invoke the reserve contractor.

3.9 Protection personal data, privacy statement

Large amounts of personal data are processed within the screening organisations, a significant part of which concerns special personal data. BVO NL must be able to maintain the level of information and privacy security that its Clients and stakeholders deem necessary at a sufficient level. It is essential to prove to these stakeholders (Clients, but also VWS/RIVM, chain partners, suppliers) that BVO NL has sufficient and appropriate information security measures in place. For this reason, BVO NL has set up a management system in order to manage, control and improve the measures taken, in accordance with the frameworks of ISO27001:2020 (hereinafter ISO27001) and NEN 7510-1_2017+A1_2020 (hereinafter NEN7510).

(Inter)national legal requirements from, among others, GDPR, Archiefwet, WGBO, WABVPZ are strictly complied with. The Contractor must contribute to the design and compliance with these frameworks.

For the present contract, this means that the information flows resulting from this tender must comply with a number of principles:

- All security frameworks from ISO27001 and/or NEN7510 are strictly adhered to, as well as the requirements set out in the WABVPZ, including NEN7512 and NEN7513+
- With regard to the exchange of personal data, the highest available level of security is always chosen,
- The existing information systems are used, results are sent directly to the ScreenIT system

The Tenderer with whom the Contracting Authority wishes to conclude an Agreement must complete and sign the 'Draft Data Processor Agreement' included in Appendix D at the request of the Contracting Authority after the award decision. By signing the Data Processor Agreement, the Tenderer agrees to the conditions contained herein regarding information security and the protection of personal data. The Data Processor Agreement will be included as an annex to the Agreement after signing. The tenderer can only use subcontractors after permission from the Contracting Authority and will therefore have to conclude the same processing agreement with any subcontractors to be used.

4. Tendering Process

4.1 European open procedure

BVO NL has opted for an open procedure. The underlying reason for this procedure is that as many interested parties as possible are given the opportunity to submit a Tender as stated in article 2.26 of the Public Procurement Act 2012. Please visit www.rijksoverheid.nl/onderwerpen/aanbesteden, for more information on European tendering.

4.2 Contact BVO NL

To provide a complete audit trail of communications, fair play, consistency for all, and to ensure certainty in document exchange All communication regarding this procurement procedure will exclusively be conducted via TenderNed. An economic operator which otherwise attempts to contact the Contracting Authority about this public procurement procedure may be excluded from participating in the Tendering Process.

When contacting BVO NL, the name of the tender procedure must always be mentioned.

4.3 Planning

The timetable below, provides an overview of the key stages and dates in this procurement.

The Contracting authority reserves the right to change these dates when necessary, although will try/seek to keep this to a minimum.

Activity	Data
Publication announcement and Descriptive Document on TenderNed	30 November 2022
First round of questions: Submit questions, suggest Contract conditions and report any inconsistencies in and/or objections to Tender documents	14 December 2022, untill 12:00 CET
Publication of Information Notice 1	23 December 2022
Second round of questions: Submit questions, suggest Contract conditions and report any inconsistencies in and/or objections to Tender documents*	11 January 2023, untill 12:00 CET
Publication of Information Notice 2	20 January 2023
Deadline Submit Tender	31 January 2023, untill 12:00 CET
Presentations	22 February 2023
Publish preliminary Award decision	3 March 2023
Verification of data in the European Single Procurement Document (ESPD)	From 3 March 2023
Suspensive period	23 March 2023, untill 23:59 CET

Definitive Award	24 March 2023
Contract signing	27 March 2023
Effective Contract date & start implementation period	1 April 2023
Start operational Contract	1 June 2023

* In the second round of questions only questions may be asked on the Answers given in the previous round of questions

TederNed contains a planning for this tender. The planning in TenderNed is leading. A number of planning moments have been mentioned in this document. Check if these moments are the same as in TenderNed.

Tenderers cannot derive any rights from this planning. BVO NL is entitled to unilaterally change the planning of the tender procedure. BVO NL will inform tenderers in good time of changes in the planning.

4.4 TenderNed

The tender is conducted digitally via TenderNed. This means that all tender documents are placed on TenderNed and all information between BVO NL and the Tenderers is exchanged via TenderNed. The Tenderer is responsible for reading the manuals for the correct use of TenderNed:

<https://www.tenderned.nl/cms/tenderned-voor-ondernemingen> (Dutch) or
<https://www.tenderned.nl/cms/english>.

The Contracting Authority is not liable for incorrect use of TenderNed. For help and support, please contact tenderned's Service Desk:

1. phone: 0800 836 33 76.
2. e-mail: servicedesk@tenderned.nl.

Please note: The Contracting Authority draws the attention of tenderers to the fact that TenderNed uses eHerkenning to be able to register and log in as an entrepreneur. You need at least eHerkenning with confidence level 2 for this. The Tenderer is responsible for the timely application of eHerkenning. The application for eHerkenning can take a few working days. The website <https://www.eherkenning.nl/> describes how the Tenderer can request eRecognition.

4.5 Information Notice

Questions about the Descriptive Document, its Annexes and the Tender Process must be submitted via TenderNed by the Tenderers no later than the date and time specified in the planning (see paragraph 4.3). The Tenderers are obliged to use TenderNed's tool for asking questions.

In principle, questions and proposed amendments received by BVO NL after this period, questions and proposed amendments that have not been submitted via TenderNed, and questions and proposed amendments that have not been submitted via TenderNed's tool for asking questions, will not be processed by the Contracting Authority.

No information will be provided by telephone or orally. If Tenderers nevertheless contact employees of BVO NL, no rights can be derived from statements made orally. In addition, they run the risk of being excluded from the Tender procedure.

After providing the first Information Notice, BVO NL will in principle answer no new questions, unless these questions could not have already been asked in the first round of questions.

All questions and proposals for changes submitted in a timely and correct manner will be answered anonymously. Both the anonymised questions and proposals for amendments and the answers are published on TenderNed by means of a Information Notice. Attached to the Information Note are the final Contracts concluded with the Tenderer to whom the Contract will be (definitively) awarded. The Agreements contains any changes to the Draft Agreements and the Terms and Conditions (ARBIT-2018). By submitting a Tender, a Tenderer declares unconditionally and without any reservation that he agrees to all the provisions of the final Agreements and the applicable Terms and Conditions.

The Information Notice should be considered an integral part of the Descriptive Document. In the event of conflict with the Descriptive Document, the Memorandum of Information shall prevail. Any Information Notice issued later shall take precedence over any previously issued Information Notice.

A Tenderer may request the Contracting Authority not to include certain information in the Information Notice if disclosure of this information would harm the legitimate economic interests of the Tenderer. In that case, the Contracting Authority can provide this Tenderer with individual information.

4.6 Submitting Tender

The Tender must be submitted via TenderNed no later than the date and time specified in the schedule (section 4.2).

After the date and time specified in the schedule, the Tenders will be opened digitally by two employees of the Contracting Authority using TenderNed's tender safe. The tender safe is then legally signed and the Tenderer receives an email confirmation via TenderNed.

Tenderers must take into account that the date and time in the planning form a strict deadline, after which it is - technically - no longer possible to submit a Tender via TenderNed. For this reason, BVO NL advises all Tenderers not to wait until the last minute to submit the Tender via TenderNed.

(Parts of) Tenders submitted after the date and time in the planning will not be considered and will be excluded from participation in the tendering procedure. The burden of proof for and the risk of timely submission of (all parts of) the Tender lies with the Tenderer.

For instructions the Contracting Authority refers to <https://www.tenderned.nl/cms/english>.

4.7 Content Tender

The Tender must consist of all documents that are included in the Tender checklist (appendix 1) and which are indicated to be submitted with the Tender.

The name of the Tenderer and the name of the Tender must be stated on all documents belonging to the Tender.

The prescribed annexes, declarations, forms, etc. may only be completed by the Tenderer and may not be substantively changed by the Tenderer. It is not permitted to make changes and/or deletions and/or additions to fixed texts of the annexes. Changing and/or removing fixed texts and/or adding text may lead to exclusion from the Tender.

Tenders that are not complete can be set aside as invalid by the Contracting Authority.

4.8 Tender costs

Each Tenderer shall bear their own costs of bidding. Contracting authority reserves its position as to whether or not to enter into contractual arrangements, and participation in the procurement is entirely at the Tenderer's risk. Contracting authority shall bear no liability whatsoever for the outcome of the procurement and shall not be liable for Tenderers costs, direct or indirect, relating to the preparation of detailed Services, fine-tuning, or any loss of profit or other economic loss whatsoever incurred by Tenderers as a result of this procedure (whether or not a contract is concluded with the Tenderer in question, another Tenderer or not at all).

Any expenditure, costs, liability, work or effort undertaken or incurred by the Tenderers in proceeding with and/or participating in this procedure is a matter solely for the commercial judgement of Tenderers. Contracting authority will not be liable to reimburse or compensate the Tenderers in respect of any of the Tenderer Costs, whether direct or indirect. Tenderers participate in this process and submit detailed Services in the knowledge and understanding that this is the case.

4.9 Variants

Submitting with variants is not allowed. These Tenders will be set aside as invalid

4.10 Conditional Tender

Submitting a Tender under conditions is not allowed. Tenders to which conditions are attached will be set aside as invalid.

General terms and conditions of the Tenderer are expressly not applicable. A Tenderer who declares its own general terms and conditions applicable, will be excluded from participation in the tender procedure. The Tender of this Tenderer is considered to be an invalid Tender subject to conditions.

4.11 Legally signing

If in this Descriptive Document the requirement is made that a document must be signed by an 'authorized representative', the Tenderer/the Partnership must be able to demonstrate that the signatory is authorized to represent the legal person concerned. This proof can usually be provided by submitting an extract from the Trade Register. If it is stated in the Trade Register that two or more persons are jointly authorized to represent, the documents must also be signed by all these persons. If restrictions on the power of attorney are formulated in the extract, this must be taken into account.

Is een specifieke schriftelijke volmacht voor ondertekening van de aanbestedingsstukken afgegeven door de bevoegde vertegenwoordiger van de inschrijvende rechtspersoon, dan moet deze volmacht bij de Inschrijving worden gevoegd.

4.12 Applicable law and dispute resolution

Dutch law applies to this Tender Procedure and to the Agreement to be concluded. All (then) current laws and regulations that relate to this Contract also apply. Changes in legislation and regulations or decisions by regulators or judicial institutions do not lead to changes in the prices or rates offered by the Tenderer during the term of the Agreement.

By submitting a Tender, a Tenderer declares that it fully and without reservation agrees to the application of the administrative, legal and other conditions mentioned in this Descriptive Document (including annexes).

Geschillen tussen de bij deze aanbesteding betrokkenen, die ontstaan naar aanleiding van deze aanbesteding, dienen te worden voorgelegd aan de bevoegde rechter in het arrondissement van de Rechtbank Den Haag.

4.13 Protection of rights

The communication of the preliminary award decision is an intention to award the contract. No rights can be derived from this communication by the Tenderers with regard to the actual award of the Contract.

If a Tenderer has objections to the preliminary award decision of the Contracting Authority, this Tenderer must lawsuit within a suspensive period (expiry period) of twenty (20) calendar days after the provisional award decision has been sent by filling a subpoena. This suspensive period ends on the date and time in the planning (see **paragraph 4.3**).

Tenderer must send this subpoena by email to the contact person as stated in **paragraph 4.2**.

Any requests for a further explanation of the provisional award decision and any explanation provided by the Contracting Authority do not affect this suspensive period. If, within the aforementioned suspensive period, a lawsuit has been brought by filling a subpoena, the Contracting Authority will comply with the provisional award decision before a judgment has been handed down in these interlocutory proceedings, unless a compelling interest opposes this. The judgment in the interlocutory proceedings then forms the basis for further decision-making on the award of the Contract.

The Contracting Authority shall inform the winning Tenderer when a lawsuit had been filled. The winning Tenderer must join or intervene in these interlocutory proceedings, on pain of forfeiture of the right to - afterwards - still be able to challenge a possible changed award intention of the Contracting Authority.

If a lawsuit has not actually been filled within the aforementioned suspensive period, Tenderers can no longer claim an award and have forfeited any rights in this respect. In that case, the Contracting Authority is therefore free to comply with the provisional award decision. In that case, the unsuccessful Tenderers also forfeited their rights to bring an action for damages in (substantive) court proceedings.

Please note: the suspensive period of twenty (20) calendar days included in this paragraph also applies to other decisions of the Contracting Authority, such as (but not limited to) a decision to temporarily suspend and withdraw the Tender procedure in whole or in part.

4.14 Language

The language of this procurement procedure is English. All communications and Tenders must be in the English language, except for official documents, which may be submitted in the original language. On first request by the Contracting authority, Tenderer will submit an official translation of the official document. The language after the Contract has been entered into, will be either English or Dutch.

During the Contract however documentation must also be provided in Dutch (See Annex 1).

4.15 Term of validity

The term for validation of the Tender is 120 calendar days after the day on which the Tender is submitted.

In the event a law suit has been instituted, the term of validity ends 30 calendar days after the day of the court ruling.

4.16 False statements

The Contracting Authority reserves the right to check all information provided for accuracy. The Contracting Authority expressly points out that statements that subsequently turn out to contain inaccuracies or contain promises that are not (or cannot) be fulfilled, are understood by the Contracting Authority as false statements within the meaning of Article 2.87 paragraph 1 sub h of the Public Procurement Act 2012. This may result in exclusion from all Tendering procedures of BVO NL. For this reason, the requested information must be provided very carefully.

The Contracting Authority reserves the right to check the soundness of all provided verify information (or have it verified), for example by means of a conversation, company visits, obtaining further information and / or gaining insight into the delivery products and services. The Tenderer is obliged to cooperate with this. This verification may also extend to the information provided in the preceding stages.

A verification (conversation) is made into a report that is part of the Agreement.

4.17 Ambiguities and irregularities

The Descriptive Document (including annexes) and the other tender documents have been compiled with care. Tenderers are therefore expected to adopt a proactive attitude. If the Tenderer nevertheless notices ambiguities, imperfections, errors and/or contradictions in one of the tender documents, he must inform the Contracting Authority of this via TenderNed before the latest date on which questions can be asked (see paragraph 4.3). If he does not do so, he has forfeited his right to challenge this in court.

4.18 Confidentiality

The information in this Descriptive Document is being made available by Contracting authority on condition that:

- Tenderers shall at all times treat the Information as confidential;
- Tenderers shall not (or allow anyone else to) disclose, copy, reproduce, distribute or pass on the Information to any other person at any time or allow any of these things to happen, unless this is done for the sole purpose of enabling Services or Solutions to be drawn up;
- Tenderers shall not use the Information for any purpose other than for the purpose of proposing (or deciding whether to propose) Services.

Tenderers shall not contact nor make any statement or pass comment to the media in relation to, this procurement or this Descriptive Document without the express approval of Contracting authority in writing. Tenderers shall not undertake (or permit) at any time, whether at this stage or after any contract award, any publicity activity with any section of the media in relation to this Descriptive Document and its outcomes, other than with the prior written agreement of Contracting authority. Such agreement shall extend to the content of any publicity. In this paragraph the word 'media' includes, without limitation, radio, television, other broadcast media, newspapers or other print media, trade and specialist press, the Internet and e-mail accessible by the public at large as well as the representatives of such media.

The Contracting authority may disclose detailed information relating to Services to its directors, officers, employees, agents, auditors or advisers. Contracting authority also reserves the right to disseminate information that is materially relevant to the Descriptive Document, even if the information has only been requested by one Tenderer, subject to the duty to protect any Tenderer's commercial confidence in its services. Contracting authority will act reasonably as regards the protection of commercially sensitive information relating to the Tenderer in the light of the latest published guidance in this area

4.19 Withdrawal or suspending Tendering procedure

The Contracting Authority reserves the right to temporarily suspend the Tendering procedure until the moment of final award and to withdraw it in whole or in part. The total or partial withdrawal of the Tendering procedure does not lead to any liability of the Contracting Authority towards the Tenderers/the Consortium. The Contracting Authority will therefore in principle not reimburse the costs incurred by the Tenderers and/or damage suffered, unless the Contracting Authority deems a contribution to the registration costs justified. In that case, the Contracting Authority determines the amount of the compensation.

The Contracting Authority reserves the right, in such situations, to fully outsource parts of the Contract, which are the subject of this tender, to a third party as part of an integral project, public-private partnership, DBFM-contract or similar construction, if such an integral approach is desirable in the opinion of the Contracting Authority. In such situations, the delivery in question falls outside the scope of the Agreement and the Contractor cannot claim the delivery or any compensation including lost turnover and/or profit or otherwise.

The Contracting Authority reserves the right to (continue to) perform (part of) the relevant work under its own management.

4.20 Complaints procedure for tender

For this Tendering procedure, the complaints procedure following from the Complaints Handling at Tendering (of 7 March 2013) applies as part of the Public Procurement Act 2012. A Tenderer or entrepreneur can make use of this complaints procedure, but is not obliged to do so. The right to fill in a lawsuit before the competent court by means of legal proceedings applies in full next to complaints procedure. If an entrepreneur has both filed a complaint and started legal proceedings, the handling of the complaint will be suspended until after the court's decision.

If an entrepreneur has both filed a complaint and started legal proceedings, the handling of the complaint will be suspended until after the court's decision.

A complaint submitted does not put a stop to this Tendering procedure. The Contracting Authority may, however, decide to suspend the Tendering procedure.

Complaints reporting point tendering (KMA)

Complaints in the context of this Tendering procedure can only be submitted digitally to the KMA via the following url: <https://klachtenmeldpuntaanbesteden.nl/leden/fsb/>.

Conditions for submitting a complaint

The Entrepreneur provides all information requested in the digital complaint form of the KMA, including:

1. the name and contact details (address, telephone and email) of the entrepreneur's company and of the contact person who submits the complaint on behalf of the entrepreneur;
2. the name and attribute/reference number of the Tender procedure;
3. a clear description of the complaint, the question number of the note of information in which the complaint may have been reported in the first instance and a proposal for a solution;
4. uploaded documents that are or may be relevant for the substantive assessment of the complaint, including in any case the tender document and the information notice;

The conditions regarding the admissibility of a complaint and the complaints procedure have been added to this document as Annex F.

5. Possibilities to submit a Tender

5.1 Introduction

This chapter sets out the various possibilities and conditions for with regard to the manner in which a Registration may be submitted.

You may participate in this Tendering Process once only: either as an independent Tenderer or as a Consortium Member. Economic Operators may decide to jointly participate in a Tendering Process. Reasons can include:

- they do not have sufficient individual capacity, experience and/or expertise;
- to spread risk: financial and/or dependence on one large client;
- they have no chance individually (SMEs).

The Contracting Authority may not prohibit Tenders being submitted by a Consortium or using one or more Third Parties. However, it may impose proportional conditions, such as joint and several liability, a single point of contact or the establishment of a legal entity after the Contract is awarded. Also see Articles 2.52 and 2.92 of the Public Procurement Act 2012.

You must complete the European Single Procurement Document (ESPD), as set out in Annex 6 – ESPD.

You may participate in this Tendering Process once only: either as an independent Tenderer or as a Consortium Member. If you do not comply with this rule, all your Tenders will be invalid and we will exclude all parties involved from further participation in the Tendering Process.

The three situations below are also prohibited in principle, unless you demonstrate that (i) the Tenders in question were drawn up separately, i.e. completely independently of each other, (ii) without knowledge of the relevant market behaviour of the other Tenderer/Consortium, and (iii) there is no threat to transparency and/or distortion of competition:

- You may not submit a Tender as an independent Tenderer or as a Consortium Member and also act as a Subcontractor for another Tenderer or Consortium;
- You may not act as a Subcontractor for more than one Tender;
- If you are part of a group, several subsidiaries or group companies of this group may not submit a Tender.

If we believe that one of these three situations applies, we will ask you to issue an anti-collusion statement. In the anti-collusion statement, you must declare that (i) your Tender has been drawn up separately, i.e. completely independently, (ii) without knowledge of the relevant market behaviour of any other Tenderer/Consortium, and (iii) there is no threat to transparency and/or distortion of competition between Tenderers/Consortiums. You must also specify the measures you have taken for this purpose. If you cannot demonstrate this, all your Tenders will be invalid and we will exclude all parties involved from further participation in the Tendering Process.

5.2 Independant Tenderer

An economic operator may, as an independent Tenderer, whether or not using a subcontractor, submit a Tender. The independent tenderer must complete the ESPD fully, unconditionally and without any reservation and legally sign it when registering (among other things).

5.3 Consortium

In the case of a joint venture (Consortium), all participants in the joint venture must complete and sign their own copy of the ESPD. This will be appended to the Tender. Under Part II A, Method of participation in the ESPD, they must give the names of all Consortium Members and their own role, also specifying which economic operator is in charge of the joint venture (Consortium) and acts as the authorised party ('coordinator') on behalf of the joint venture (Consortium) in dealings with the Contracting Authority.

The coordinator is therefore the economic operator who is duly authorised by each Consortium Member to enter into obligations on behalf of the joint venture for this Tendering Process, for which all individual participants in the joint venture are fully, jointly and severally liable towards the Contracting Authority.

By submitting a Tender, each Consortium Member declares that:

1. the information provided in the Tender and ESPDs is correct and legally valid;
2. they are each jointly and severally liable for the performance of the Contract and warrant the correct and timely fulfilment of all obligations under the Agreement.

After the period for submitting the Tender closes, the composition of the Consortium may not change without the Contracting Authority's consent.

5.4 Subcontractor(s)

A Tenderer is permitted to engage one or more subcontractors for the execution of the Contract. The Tenderer is fully liable for compliance with all obligations arising from the Agreement.

If a Tenderer involves subcontractors in the performance of the Contract, the Contract will only be awarded to this Tenderer if the subcontractor(s) do not fall under one or more of the grounds for exclusion (Chapter 6) stated.

If a Tenderer involves a subcontractor during the performance of the Assignment to which a ground for exclusion as referred to in Chapter 6 of this Descriptive Document applies, the Tenderer will ensure that this Subcontractor is replaced.

Please note: from the Tenderer to whom BVO NL intends to award the Contract, the following will be requested in the provisional award letter:

1. An extract from the Subcontractor's Trade Register, which at the time of the submission of the Tender must not be older than six (6) months.
2. The names of the legal representatives of the subcontractors associated with the execution of the Contract are involved.

The Contracting Authority requires the Tenderer to whom the Contracting Authority awards the Contract to notify the Contracting Authority of all changes to the aforementioned data of the subcontractor during the performance of the Contract.

If Tenderer has been awarded the Contract and would like to involve another party in performing the Contract after the Agreement has been concluded, ask BVO NL to give consent first and notify the Contracting Authority of the above mentioned information. As the Contractor, you will always remain responsible for performing the Contract as we have agreed.

5.5 Invoke Subcontractors (Third Party's) to meet the Eligibility Requirements

If you rely on a Third Party to meet the Eligibility Requirements, you must tick 'yes' in Part IIC of the ESPD. Third parties which a Tenderer relies on to meet the Eligibility Requirements must also submit their own copy of the ESPD with the information we request in Parts IIA, IIB and III.

A condition for relying on a Third Party to comply with the stated Eligibility Requirements is that the Tenderer must be able to demonstrate that he actually has access to the Third Party's resources needed for that Contract. This can be done, for example, with a statement from the Third Party that it is prepared to perform the relevant work.

If you rely on the technical and professional ability of a Third Party, you must be able to deploy the resources necessary for the performance of the Contract during the entire term of the Agreement.

By signing the UEA, this third party declares that the Tenderer or the Consortium may have access to the for the execution of the Contract necessary resources of this third party.

If the resources of a Third Party are called upon in the context of the Eligibility Requirement regarding the continuity paragraph (paragraph 7.2), this Third Party will be required to act as guarantor for the Tenderer. It must follow from this guarantee that, when the Contract is awarded to the Tenderer, the Third Party guarantees the fulfillment of all obligations arising from the Agreements to be concluded for the Contract, fully and without any reservations. If this Third Party is a company that belongs to the Tenderer's group, then the Tenderer can suffice by submitting a so-called 2:403 statement. A copy of the guarantee will be requested in the provisional award letter from the Tenderer to whom the Contracting Authority intends to award the Contract. The Tenderer must provide this evidence to the Contracting Authority within seven (7) calendar days after the intention to award has been sent.

If the resources of a Third Party are called upon in the context of the insurance requirement (Paragraph 7.3), then both the Tenderer and this Third Party are jointly and severally liable for the execution of the Contract.

If, within the scope of the Eligibility Requirements regarding technical competence and professional competence, if the resources of a Third Party are called upon, this Third Party must actually be deployed by the Tenderer for the performance of the Contract as a Subcontractor or member of the Consortium.

6. Exclusion Grounds

6.1 Exclusion Grounds

6.1.1 Exclusion grounds

In this chapter you can read about the Exclusion Grounds that we apply for the Tendering Process.

Using Annex 3 - European Single Procurement Document (ESPD), you indicate whether or not the Exclusion Grounds apply to you. You can read about how to submit a Tender with the ESPD in Chapter 5.

Part III of the ESPD lists the Exclusion Grounds that apply to this Tendering Process.

We divide the Exclusion Grounds into three different grounds:

- Part III.A: grounds relating to criminal convictions;
- Part III.B: grounds relating to the payment of taxes or social security contributions;
- Part III.C: grounds relating to insolvency, conflicts of interest or professional errors.

If an Exclusion Ground applies, we may decide not to declare your Tender invalid

In principle, your Tender is invalid if one of the Exclusion Grounds applies. We will then exclude you from further participation in the Tendering Process. We may decide not to declare your Tender invalid in these cases:

- if exclusion would be manifestly unreasonable (Article 2:86a of the Public Procurement Act);
- if you have taken sufficient measures to demonstrate your reliability (Article 2:87a of the Public Procurement Act);
- for imperative reasons of public interest (Article 2:88 of the Public Procurement Act);
- if, in our opinion, exclusion is not proportionate because of the time that has elapsed since the conviction and in view of the subject matter of the Contract (Article 2:88 of the Public Procurement Act).

If an Exclusion Ground as referred to in Part 2.3.5 of the Public Procurement Act 2012 applies to you, you can read about what you need to do in section 6.1.2.

Are you submitting a tender as a Consortium or with Third Parties to meet the Eligibility Requirements?

We will then test whether the Exclusion Grounds apply for each Consortium Member and each Third Party. You can read more about how you must submit your tender in paragraph 5.5.

6.1.2 How to complete and submit the ESPD

Instructions on how to complete the ESPD are provided below.

- The ESPD is added to the site of CTM, where you have to fill it in, in the required parts.
- The ESPD consists out of five parts. The Contracting Authority has already partially completed the ESPD. For each Tender Tenderers have to complete the rest of the ESPD. Tenderers must fill in every part of the ESPD except from part I, which is already completed by the Contracting Authority.

- After the ESPD is completed and signed a scan as a PDF file must be attached to the Tender as Appendix 1 and must be submitted.
- The ESPD is only valid if it has been signed by someone with sufficient authority.
- Every legal entity involved sends its own ESPD. See Chapter 5 for more information.

The ESPD consists of five parts

In Part II you enter the data of your own economic entity. Part III lists all Exclusion Grounds. We have ticked which Exclusion Grounds apply to this Tendering Process.

Each legal entity involved submits its own ESPD

If you submit your Tender as a Consortium or rely on Third Parties to meet an Eligibility Requirement, you must submit several ESPDs, one for each organisation involved. You can read more about this in Chapter 5.

With a signed ESPD, you declare that you are eligible for this Contract.

By ticking 'Yes' under α in Part IV of the ESPD ('Selection criteria') you declare that your undertaking complies with all the Eligibility Requirements set out in Chapter 7 of this Descriptive Document. The ESPD uses the term selection criteria. This refers to the Eligibility Requirements.

With a signed ESPD, you also declare that the Exclusion Grounds do not apply to your undertaking.

If an Exclusion Ground applies and you still submit a Tender, provide the information and/or measures requested in Part III of the ESPD (Exclusion grounds). The Tenderer must then demonstrate that it has compensated or has agreed to compensate for the damage resulting from convictions for criminal offenses (Article 2.86 Public Procurement Act 2012) or from errors/circumstances (Article 2.87 Public Procurement Act 2012), that it has contributed to the clarification of facts and circumstances by actively cooperate with the investigating authorities and that he has taken and implemented concrete technical, organizational and personnel measures that are suitable to prevent further criminal offenses or errors/circumstances. The Contracting Authority assesses the measures taken by the Tenderer taking into account the seriousness and the special circumstances of the criminal offenses and errors/circumstances. If the Contracting Authority considers the measures taken to be sufficient to demonstrate the reliability of the Tenderer, the Tenderer will not be excluded from participation in the tender procedure.

If something goes wrong while you are working with the ESPD, you will be given one more chance.

We do this because the ESPD might be unfamiliar to you and we understand that things can sometimes go wrong.

Tenderers can be excluded from a procedure or prosecuted if they make false declarations in the ESPD, withhold information or are unable to provide supporting documents.

6.1.3 Supporting documents exclusion grounds

The following means of evidence will be requested in the provisional award letter from the Tenderer to whom the Contracting Authority intends to award the Contract. With these means of evidence, the Tenderer must demonstrate within seven (7) calendar days after sending this intention to award, that the Tenderer (the members of the Partnership and/or subcontractor and/or third party) actually does not fall under one of the stated grounds for exclusion.

Exclusion ground	Supporting documents (verification)
Articles 2.86 under 2 and 3, and 2.87 under 1 sub c and d Public Procurement Act 2012	Certificate of Conduct for Procurement. Note: in view of the processing period, request the statement of conduct in good time. For more information, see: www.justis.nl/producten/gva/ . [*] Certificates of Conduct for Procurement must not be more than two years old, working back from the closing date of the Tender.
Article 2.87, sub b Public Procurement Act 2012	A current extract from the trade register of the Chamber of Commerce ('CoC extract'). By current, we mean a valid certificate of registration that is not more than six months old when the Tender is submitted (calculated from the closing date for submission of the Tender).
Articles 2.86 under 4 and 2.87 sub j Public Procurement Act 2012	Statement by the Tax and Customs Administration of their respective country that the Tenderer has paid its compulsory taxes and social security contributions. The statement must not be more than six months old when the Tender is submitted.

The Contracting Authority points out to the Tenderers that obtaining some means of evidence may take several weeks. Tenderers are advised to request the means of evidence at the earliest possible stage, so that they can be provided in good time – after a possible request by BVO NL. If the Tenderer – after being requested to do so by the Contracting Authority – does not submit the supporting documents in time, the Tenderer may be excluded from the Tendering Process.

The evidence will be requested from the Tenderer to whom the Contracting Authority intends to award the Contract. It must follow from these means of evidence that the Tenderer (members of the Partnership, subcontractor, third party) actually does not fall under the stated grounds for exclusion and that the Tenderer actually meets the set Eligibility Requirements.

If the Contracting Authority can obtain a means of evidence directly and free of charge by consulting a national database or already has this means of evidence, the Tenderer does not have to submit this means of evidence to the Contracting Authority. In the event that the Contracting Authority can obtain a means of evidence directly by consulting a national database, the Tenderer will provide the information in the ESPD (the internet address of the database and the identification data and, where applicable, the required statement of consent) that the Contracting Authority needs to access this information.

7. Eligibility Requirements

7.1 Introduction

We impose Eligibility Requirements on a Tenderer to determine whether it is suitable to perform the Contract.

Eligibility Requirements are requirements set for your technical and professional ability, professional qualifications and financial and economic standing.

You can read below which Eligibility Requirements apply to the Tendering Process. Your Tender will be invalid if you do not meet the Eligibility Requirements. We will then exclude you from further participation in the Tendering Process.

If you would like to submit a tender, but cannot meet the Eligibility Requirements, you can consider submitting a tender as a Consortium or using a Third Party to jointly meet the Eligibility Requirements.

We are entitled to test whether the Consortium Member(s) and/or Third Party / Third Parties comply with the Eligibility Requirements.

In this Tendering Process the following Eligibility Requirements are applicable:

1. Financial and economic standing;
2. Technical ability and professional ability;
3. Professional qualifications.

7.2 Financial and economic standing

Eligibility Requirement 1: Insurance

Tenderer is adequately insured (professional indemnity and/or civil liability insurance) for the performance of the Contract. If this Tendering Process will result in an Agreement, Tenderer must ensure that he remains adequately insured for the term of performance of the Contract.

Tenderer must possess a liability insurance policy according to article 29 ARBIT-2018 with a minimal cover of at least € 1,250,000 per claim and for a minimum annual payment of 200% of this amount.

This insurance must be taken out at least on the date of Tender and must be valid for the entire term of the Agreement concluded as a result of this tendering procedure.

In the event that a Consortium submits a Tender, this insurance must be taken out by the Consortium as a whole or by each of the members of the Consortium individually.

Supporting documents:

As proof that the Tenderer meets this requirement, it will suffice to submit the ESPD when submitting the Tender (tick Part IV, part α)

The means of proof from which the insurance cover follows will be requested from the Tenderer to whom the Contracting Authority intends to award the Contract in the provisional award letter. This means of proof can be, for example, a copy of the policy schedule or a statement from the insurance company. The Tenderer must provide this means of evidence to the Contracting Authority within seven (7) calendar days of sending the intention to award.

7.3 Technical ability and professional ability

As an Eligibility Requirement, you have the experience (core competencies) that we consider necessary to be able to perform the Contract.

The Tenderer must demonstrate by means of one or, if necessary, several references that the Tenderer has all the core competencies relevant to this Tender. For all core competencies, the services must be comparable in scope and type of services to those of the present Contract.

Core competences

1. QA-analyses experience
2. QA-analyses experience in a laboratory environment
3. Experience in setting up and managing of a secure data storage

The following Eligibility Requirements are set to test compliance with these core competencies.

Eligibility Requirement 2: References

1. QA-analyses experience related to the scope of the services

BVO NL wants to make sure that a service provider has the quantitative ability to provide the (IT) services as set out in Chapter 3.

Tenderer has experience in QA analyses for a client with the volume of at least 288.000 analyses per year and can prove this with a reference.

2. QA-analyses experience in a laboratory environment

The data that are collected by performing an HPV test in the lab are very specific and complex. In order to provide a software application that displays laboratory test results graphically and can detect deviations it is very helpful to have knowledge of laboratory procedures/tests.

Terms like positive control, standard deviation, PCR, reference set, plate layout, lot number, reagents, limit value, trend analysis etc. are easier to understand when one has work experience in a laboratory environment.

Tenderer has at least 1 full year of experience in QA analyses for a client in a laboratory environment and can prove this with a reference.

3. Experience in setting up and managing of a secure data storage

BVO NL wants to make sure that the service provider is able to store the raw data (including the sample ID) collected from the BD-COR systems in a secure way as set out in Chapter 3.

Tenderer has at least 1 full year of experience in setting up and managing of a secure data storage for a client and can prove this with a reference.

The reference(s) must have been carried out in the past three years prior to the date of the submitting of the Tender. References that have been terminated in the last three years prior to the date of

submitting fall within this period. References that are still in progress also fall within this period. However, these last reference assignments must have commenced at least one year prior to the date of submitting the Tender.

In addition, the reference(s) must have been performed to the satisfaction of the client of the reference and on time (including any postponement granted). Satisfaction means that the service has been performed in accordance with the requirements and wishes formulated in advance by the client*. In order to check whether the reference assignment has been carried out to the satisfaction of the client of the reference and on time (including any postponement granted), the Contracting Authority reserves the right to contact the client of the reference without the intervention of the Tenderer.

* By signing the reference statement, the client of the reference issues a statement of satisfaction regarding the quality of the performance of the reference. The client of the reference signs that all essential aspects of the performance of the agreement have been performed properly and in accordance with the agreement. This means that there was no structural non-compliance with one or more essential aspects of the service or delivery that formed part of the agreement

For the assessment on whether the experience requirement is met, only references that the Tenderer has carried out itself (i.e. without the intervention of a Subcontractor) will be taken into account. In the event that the Tenderer has carried out the reference assignment in a Consortium, only its share in the reference will be taken into account when assessing whether this experience requirement has been met. The experience of a subcontractor or member of a Consortium will only be taken into account by BVO NL if it is stated in the Tender that the experience of this third party is being called upon and the other conditions of paragraph 5.4 are met.

In the case of registration as a Consortium, it is required that the members of the Consortium can meet this experience requirement together.

The reference(s) must have taken place during the past period of no more than three years (to be calculated backwards from the closing date of the Tender). A prognosis does not count and can lead to exclusion.

Supporting documents:

As proof that the Tenderer meets this requirement, the Tenderer must submit the reference form (Annex 2) for each reference with its Tender, requesting the following information:

- Short description of the reference, which at least shows that the reference assignment meets the reference requirement (Core competence);
- Name and contact details of the client of the reference;
- Amount invoiced (annually in euros excluding VAT);
- Scope of the Contract in annual numbers of personnel supplied;
- Start and end date reference;
- If performed in a Collaboration: the percentage/share in the Collaboration.
- Nature and content of the own activities performed in Collaboration.

Please note: It is therefore not sufficient to submit the ESPD at the time of submitting the Tender as proof that the Tenderer meets this requirement.

Quality management (ISO 9001:2015 or equivalent)

Eligibility Requirement 3: Quality management

Tenderer shall have taken adequate measures in the field of quality assurance and shall demonstrate compliance with them in the following manner:

- a valid ISO 9001:2015 certified quality assurance system or comparable, whereby the certificate has been drawn up by a certification body that is recognized within the (inter) national accreditation structure; or
- a quality management system, proven by certificates issued by, recognized competence, official quality control institutes or agencies (e.g. ISO 9000);
- If you do not have a certificate and you are not in a certification process, it may be sufficient to submit your own quality manual. It must be an up-to-date and valid quality manual, containing the measures that your organization takes to guarantee and control quality, provided with a management policy statement showing that management endorses and monitors these measures (all you do is add a copy of a tailored quality manual index, a description and the policy statement). You must also include a description of why the measures included in your quality manual are equivalent to the set standard.

In the case of submitting as a Consortium, the indication of the measures taken to ensure quality shall be assessed for the whole Consortium.

If the Tenderer uses a Subcontractor for the performance of the Contract, then this Subcontractor must comply with the above requirement, under penalty of exclusion of the Tenderer from the tendering procedure.

Supporting documents:

As proof that the Tenderer meets this requirement, it will suffice to submit the ESPD when submitting the Tender (tick Part IV, part a) and the following supporting documents when submitting the Tender:

- A copy a valid ISO 9001:2015 certified quality assurance system or comparable, whereby the certificate has been drawn up by a certification body that is recognized within the (inter) national accreditation structure; or
- A copy off quality management system, proven by certificates issued by, recognized competence, official quality control institutes or agencies (e.g. ISO 9000);
- A description of a maximum of five A4 pages of another (own) quality management system that is equivalent to the NEN-EN-ISO 9001:2015 standard.

Information Security (ISO 27001 or NEN7510:2017)

Eligibility Requirement 4: Information Security

By submitting a tender, the tenderer declares that the organisation complies with the ISO 27001 Series of European standards series or an equivalent quality assurance system in the field of information security and provides prove thereof by submitting:

- A copy of the most recent, applicable quality certificate ISO 27001 indicating the year of introduction and expiration, issued by a certified body as referred to in Article 2.96 Aw 2012, or;
- a set of process descriptions based on NEN7510:2017

Supporting documents:

As proof that the Tenderer meets this requirement, it will suffice to submit the ESPD when submitting the Tender (tick Part IV, part α) and the following supporting documents when submitting the Tender:

- A copy of the most recent, applicable quality certificate ISO 27001 indicating the year of introduction and expiration, issued by a certified body as referred to in Article 2.96 Aw 2012, or;
- a set of process descriptions based on NEN7510:2017

7.4 Supporting documents Eligibility Requirements and Exclusion grounds

In the event that the Contracting Authority can obtain a means of evidence directly by consulting a national database, the Tenderer will provide the information (the internet address of the database and the identification data and, where applicable, the required declaration of consent) in the ESPD that is necessary to access this information.

If the Contracting Authority already has evidence, the Tenderer/the Collaboration refers in the ESPD to the information in the context of which Tendering Process the Contracting Authority has obtained this evidence.

8. Minimum Requirements

The Minimum Requirements (Annex 1) contain the minimum requirements that apply to the Contract. The Tenderer's Tender must meet all minimum requirements set out in this document. A Tenderer who does not meet one or more of the minimum requirements will be excluded from further participation in the tender procedure.

Signature of the documents to be submitted for the purpose of the Tender must be done by an official who is legally authorized to act on behalf of the Tenderer and, where appropriate, by the legally valid representative of the relevant members of the Consortium. See also the provisions in paragraph 5.3 with regard to the required signature if registration is made by a Consortium.

If during the term of the Agreement it appears that the Tenderer does not meet one or more minimum requirements, while the Tenderer has declared that it meets all the minimum requirements, this will be regarded as non-compliance with the Agreement. In that case, BVO NL is entitled to dissolve the Agreement.

9. Award criteria and assessment

9.1 The best price-quality ratio

All Tenders of the Tenderers that have not been excluded from the tender procedure and that have been found valid by BVO NL will be assessed on the basis of the award criterion: the economically most advantageous tender on basis of the best price-quality ratio.

The ranking (from high to low) in the total scores determines the most economically advantageous tender. The Contracting Authority considers itself free to award the Contract to the Tenderer who has submitted the Tender with the best price-quality ratio.

9.2 Award criteria

The award criteria consist of quality and price criteria. The qualitative criteria and the price criteria are valued differently. With the qualitative criteria, a total of 600 points can be obtained. A total of 400 points can be obtained with the price criteria. This means that the qualitative sub-award criteria together weigh for 60% in the assessment and the price criteria for 40%. The award criteria are set out in the table below:

Table 1			
Qualitative criteria:		Maximum score (points):	Minimum score needed (points):
AW1	Arguments for accomplishment	300	75
AW2	Risks	120	30
AW3	Presentation by Key personnel	180	45
		600	

Price criterion		Maximum score (points):	Weight
C1	Pricing	400	n.a.

* A Tenderer who scores below 25% on an award criterion will be excluded from further participation in the procurement procedure.

9.3 Qualitative award criteria

Based on the assessment of the sub-award criteria by the assessment team, points (according Table 1) are awarded to these sub-award criteria. whereby the criteria are rated according to the scores in Table 2.

For each Sub-Award Criterion, the Contracting Authority assesses the extent to which the elaboration gives the Contracting Authority confidence and the belief that the Tenderer is able to achieve the objective of the Sub-Award Criterion on a structural basis:

- Completeness: The Tenderer has fully elaborated the above subjects on all requested components.
- Specific: Subjects are attributed to the situation of the Contracting Authority and are in line with the texts from the Tender Documentation.
- Acceptable: The elaborations are so convincing that the Contracting Authority has the confidence that the Tenderer can and will guarantee the aforementioned subjects. The elaborations fall within the frameworks set by the Contracting Authority.
- Realistic: The elaborations are in line with practice and reality, such that the elaborations give the Contracting Authority the confidence that the objective of the Sub-Award Criterion will be structurally realized by the Contractor.

Table 2		
Score	Assessment	Percentage of points
Invalid: The answer to this award criterium does not fulfil the goals and results = Knock out	From the given answer it is clear that Tenderer has little or no understanding of an adequate execution of the Contract and the arguments do not have persuasiveness power.	0% knock out
Insufficient: The answer to this award criterium does partly meet the goals and results	From the given answer it is clear that Tenderer fails to understand the execution of the Contract since the arguments contains omissions and is unclear and the arguments have a limited persuasiveness power.	0%
Neutral/ no added value: The answer to this award criterium meet the goals and results	From the given answer it is clear that Tenderer understands and will be able to adequately execute the Contract and the arguments have a real and concrete persuasiveness power.	25%
Good/some added value: The answer to this award criterium meet the goals and results and add value.	From the given answer it is clear that Tenderer understands and will be able to execute the Contract with added value compared to the minimal requirements and the arguments have a good persuasiveness power	75%
Significant added value: The answer to this award criterium meet the goals and results and add significant value.	From the arguments it is clear that Tenderer understands and will be able to execute the Contract with significant added value compared to the minimal requirements and the arguments have superb persuasiveness power.	100%

9.3.1 AW1: Arguments for accomplishment

AW 1: Arguments for accomplishment

In the arguments for accomplishment, the Tenderer argues how he will meet the goals (see paragraph 3.2) within the Minimum requirements (Annex I and A) and attain the project effects (paragraph 3.2). The Tenderer must demonstrate that he fully understands the function of the QA-tool and the secure storage of the data, the importance and magnitude of the implementation and support, that he is aware of the possible risks, and that the solution offered in the tender is guaranteed to fulfill all

requirements and will meet the goals. As such, each argument must be well substantiated. The Tenderer describes:

A. Accomplishment:

The Tenderer must demonstrate by means of a description of max 2 A4 (Arial size 10) that the tenderer will achieve the described project objectives and will also meet the minimum requirements (of Annex 1 and Annex A). Additional graphs and figures may be added without limitations.

Important points that need to be covered in the description are:

- Description of the procedure in which the tenderer ensures that the data from the Clients is collected, transferred and stored in a secure way and that the Client rights are carried out according to (inter)national legal requirements.
- The way in which the secure Data store can be safely moved to a different hosting environment at the end of the contract period.
- The receiving of the datafiles and the automated storage in the secure Data store.
- The achievement of a secure, encrypted database (QA-database) with anonymous data built from a selection of parameters/data fields extracted from the secure data store.
- Description of the (user friendly) interface of the offered QA-tool and the feasibility to perform and graphically display (dashboard) the results of pre-defined queries (dashboard) and ad hoc queries. Besides an inventory of the possibilities to perform calculations and statistics on the data from the raw database and the potentiality to export these query results (graphs and reports).
- Specification and feasibility of the statistical interface module to achieve automatic alert functionalities upon deviations from pre-defined limits/criteria.
- Description of an implementation plan, which demonstrates how implementation of the tool and the Proof Of Concept (POC) is foreseen (based on the minimal requirements), which contributions the Contractor requires from BVO NL; and how Contractor will communicate and cooperate with BVO NL and with third parties like the screening laboratories and the provider of the hrHPV test (BD)
- Description how the Tenderer will achieve the requirements with regard to the user roles as defined in Annex A and Annex 1;
- Overview of possible expected developments in terms of personnel, planning, procedures, capacity and prioritization.
- Furthermore an indication of any relevant opportunity (added value) tenderer can offer. These must be relevant for the execution of the Contract, realistic and included in the TCO pricing.

B. Planning

The Tenderer submits a planning for implementation (format free, max 1 A4) thereby taking into account the starting date at 1st of April 2023 and the expected start of the operational face 1st of June 2023. Furthermore Tenderer has to include a Proof of Concept (POC) in their planning, to be scheduled 4 weeks before the Go Live of the QA-tool and the operational face.

The planning should at least contain the proposed:

- Activities;
- Milestones;
- Critical dates/periods in planning;
- Commitment and required availability of key personnel from all parties involved

The planning will be evaluated together with the arguments for accomplishment and is as such an integral part of this award criterion.

Assessment

Assessment of AW1 will be scored based on:

- To which extent all subjects have been covered;
- To which extent the tenderer has provided convincing and realistic arguments to demonstrate that the offered solution will fulfill the needs and requirements as describe in the tender document to support the quality assessment goals for hrHPV testing as part of the Dutch cervical cancer screening programme.

9.3.2 AW2: Risks and control measures

Contracting Authority asks tenderers to describe (in max 2 A4, Arial size 10) possible risks that might occur during the period of the contract together with a description how to mitigate the risks. Tenderers must thereby make a distinction between risks within and beyond their control and should rank te risks in order of relevance, both the risks, within and beyond control of the tenderer. In addition to this summary of risks with their mitigating measures also a description of the description of the effects of these measures e.g. by an example, is required.

The list of risks and control measures should result in controlled risks during the execution of the Contract. Risks that occur during the operational period and were not foreseen by any party, should be mitigated and discussed with the BVO NL and besides added to this list. It is obvious that Contractor is expected to prevent consequences in costs and planning as much as possible.

In the enumeration of the possible risks and associated mitigating measures the Contracting Authority expects the tenderer to address at least the following items:

- Client security and the protection of personal data;
- Unavailability of the QA-tool;
- Hacking with regards to hosting;
- Unavailability of the raw database;
- Shortage on personnel for the implementation, maintenance, support or subsequent queries/reports of the QA-tool.

Assessment

Assessment of AW2 will be scored based on:

1. To which extend the risks are realistic;
2. To which extend the division of risks and control measures fall within the right sphere of influence;
3. To which extend control measures are complete;
4. To which extent the offered software solution and services will meet the qualitative project results (paragraph 3.2);

9.3.3 AW3: Presentation by key personnel

A demonstration of the QA-tool design and functionalities (including the secure data base) should provide BVO NL good insight in the offered QA-tool and its functionalities and should provide confidence to BVO NL that the minimum requirements will be met and that the expectation that the

tool will meet these criteria at implementation is realistic. Furthermore it will provide BVO NL insight in the look and feel and user friendliness of the tool.

Note: Only Tenderers who scored 25% or more for Award Criterium AW1 and AW2 and are within reach of achieving (after the assessment of AW1 and AW2) the economic most advantageous tender will be invited to give a Presentation.

The demonstration should be carried out by key personnel of the Tenderer. On behalf of the Contracting Authority, it is expected that the following personnel will attend the presentation:

- IT specialist
- Security specialist
- Quality advisors laboratory
- Senior users

During the presentation and or demonstration at least the following topics need to be addressed:

1. The IT workflow from raw data to data ready for analysis (see Annex A);
2. The workflow for performing regular data analysis by BVO NL (national scale)
3. The workflow for performing regular data analysis by BVO NL (national scale)
4. The workflow for performing regular data analysis by a screening laboratory (benchmarking),
5. The look and feel of the QA-tool;
6. The dashboard functionality;
7. Demonstration of performance per time period (Ct values versus time period): trendanalysis
 1. Positive assay control (e.g HPV 16);
 2. Internal assay control (BG);
 3. Results of hrHPV positive samples from participants, for example but not limited to:
 - a. hrHPV per type;
 - b. BG;
 - c. GP sample vs Self sample;
8. Implementation of signaling system;
 - a. eg Westgard rules based on Ct values
 - b. equipment performance codes (eg clot detected, pipetting errors, aborted runs etc)
9. Demonstration to compare Results of 2 (or more) data points with regard to:
 1. Underlying parameters such as eg lotnumber of reagents, system ID, lab ID etc;
 2. Presentation, storage and export of this information;
10. The different user roles;

The presentation and or demonstration will take place on the date that is stated in the planning (paragraph 4.3) and will take a maximum of one hour. The members of the project team of BVO NL will ask questions about the software application and services for clarification.

All Tenderers will get the same questions. In addition, the assessment team can ask clarifying questions with regards to the presentation and the submitted AW1 and AW2 documents. Clarifying answers on AW1 and AW2 documents will not result in an alteration of the assessment of AW1 and AW2. The assessment will only result in scoring on AW3.

Assessment

Assessment of AW3 will be scored based on:

1. The extent to which all topics have been covered;
2. The extent to which the tenderer's arguments are realistic and give BVO NL sufficient confidence that the solution offered will meet all requirements described and set in the tender;

3. The extent to which the offered software solution and services will meet the qualitative project results as described in paragraph 3.2.

9.4 Pricing

Tenderer offers all cost of the QA-tool including possible future development, in accordance with the requirements of Chapter 8 and the wishes. This is therefore a TCO pricing criterium. The following components determine the pricing:

- A. Implementation costs (One-time costs)
- B. B1: User rights (licenses), hosting, support & maintenance (Per month)
B2: Secure database (see paragraph 3.6)
- C. Development (During the contract on the basis of hourly tariffs and on request of BVO NL)
- D. Training (One-time costs)

In the Pricing sheet (Annex 5) you will find a number of development hours for which you are to provide a price. These numbers are merely to evaluate the prices more easily. No rights can be derived from these numbers.

Please note: to complete the price sheet, see also section 9.6 of the Descriptive Document.

For the pricing criterium a tenderer can be awarded a maximum of 400 points. The tenderer must attach to his Tender the fully completed Pricing sheet (Annex 5). On the basis of this price sheet, fictitious total price is calculated. The Tenderer with the lowest fictitious total price gets the maximum amount of point (400 points).

For the award of points to the Tenderers who have offered a higher price, the following price formula is used:

$$\text{Points Tenderer} = \frac{\text{Price lowest Tenderer}}{\text{Price Tenderer}} \times 400 \text{ points}$$

The result is rounded to two decimal places after the decimal point.

9.5 Assessment

In order to submit an eligible award, the Tender must be complete and valid in the way as set out in this Tender document. This means that all documents as set out in the Checklist, must be handed in and comply with all Minimum requirements as set out in this document and its Annexes. This includes a duly signed document in those cases a duly signed document is required.

Should the Contracting Authority request Tenderer to repair an omission, the Tenderer must do so within the period of time set by the Contracting Authority. The Tender will be declared invalid in case the Tenderer does not comply with the request in a timely manner and/or fails to deliver the required information.

To guarantee objectivity, the price sub-award criteria and quality sub-award criteria are assessed by two different groups, which are multidisciplinary and supervised by the process leader of the present Tendering Process. Members of the assessment committee who assess the quality criteria have no

knowledge of (the ranking on) the price component (C1: Pricing) . The process leader does not play a substantive role in the assessment of the quality aspects.

Phase 1: Assessment qualitative award criteria (AW 1, AW 2 and AW 3)

The assessment takes place by means of an 'expert opinion' that is given by an expert assessment team, consisting of:

- IT/Security specialist
- 2 Quality advisors laboratory

The members of the assessment committee first form an individual opinion with regard to the qualitative award criteria. To this end, they first read through all Tenders for each qualitative sub-awarding criterion to obtain a general picture of the Tenders. Each Tender is assessed on its own merits. This does not alter the fact that the assessors can take into account what they have observed in other Tenders in their assessment. After all, this can partly determine the assessment framework/expectation pattern of an assessor.

After the individual assessment, the assessment team meets and the assessors exchange their findings and arguments. After the discussion, the assessment team will award one (joint) assessment per qualitative award criterion. (Members of) the assessment team can seek advice from other (external) experts for the purpose of assessing (parts of) the submitted information.

The **table in paragraph 9.1** shows which assessment method is used for each qualitative award criterion.

After the final score or assessment has been determined for each qualitative award criterion, the corresponding number of points will be awarded to the Tender for each qualitative award criterion.

Phase 2: Assessment award criterium C1 Pricing

After the assessment of the Tenders has taken place on the basis of the qualitative award criteria, the Tenders will be assessed on the basis of award criterion C1 Pricing using the formula **announced in paragraph 9.1**.

The Tenderer that has scored the most points on award criterion C1 Pricing and the qualitative award criteria together has submitted the Tender with the best price-quality ratio. The Contracting Authority intends to (provisionally) award the Contract to this Tenderer.

If two or more Tenders have been awarded the highest score after assessment, the Contracting Authority intends to (provisionally) award the Contract to the Tenderer that has achieved the highest score on award criterion AW1. If two or more Tenders have been awarded the highest score after that the Contracting Authority intends to (provisionally) award the Contract to the Tenderer that has achieved the highest score on award criterion AW3. If two or more Tenders have been awarded the highest score after that the Contracting Authority intends to (provisionally) award the Contract to the Tenderer that has achieved the highest score on award criterion AW2.

If two or more Tenders are the highest after assessment and these Tenders have achieved the same score on award criterion AW 1, 2 and 3, it will be determined by drawing lots to which Tenderer/ Collaboration the Contracting Authority will provisionally award the Contract.

If the Tender of the Tenderer that was ranked number 1 appears insufficient and cannot be definitively awarded after verification and this Tenderer had the lowest price, the points on the price award criterion will be recalculated in order to determine the ranking again.

9.6 Pricing sheet and anti-manipulation provision

When filling in Annex 5 - Pricing sheet and determining the prices to be offered, the Tenderer must take into account the following principles:

1. All prices must be rounded to two decimal places.
2. All prices are to be assumed in euros.
3. All prices must be quoted excluded turnover tax (VAT).
4. The Tenderer must indicate the other VAT percentages for all prices.
5. All prices include all possible costs, such as (but not limited to) travel and accommodation costs. This means that the Contracting Authority, on behalf of the rates quoted by the Tenderer, does not owe the Tenderer anything.
6. It is not allowed to specify 0 or negative prices (prices lower than EUR 0).
7. The Pricing sheet must be completed in full, under penalty of exclusion from the tender procedure. If the price form is not completed in full, the price forms are not mutually comparable and the Contracting Authority can exclude this Tenderer from participation in the Tender Procedure.
8. It is not allowed to make changes to the price list; only the indicated fields need to be filled in. Making changes to the price sheet can lead to exclusion from the Tender Procedure.
9. Under penalty of exclusion from the Tendering Procedure, the Tenderer is not permitted to offer the prices in any other way than by means of the prescribed price sheet in Annex 5.
10. The Tenderer is responsible for the correctness and completeness of the information entered.

Checklist Tender

The first part of the table below lists all documents that must be drawn up by the Tenderer at the time of submission of the Tender, under penalty of exclusion from the Tender procedure.

The second part of the table lists all documents that must be submitted by the Tenderer to whom the BVO NL intends to award the Contract within seven (7) calendar days of a request from BVO NL.

Submit with Tender:	
1	Minimal requirements
2	Reference Form(s)
3	European Single Procurement Document (ESPD)
4	Answers on Award criteria (AW1 & AW2)
5	Pricing sheet + Substantiation implementations costs
6	A current extract from the trade register of the Chamber of Commerce ('CoC extract')
7	A Quality Certificate, drawn up by an independent body, NEN ISO 9001:2015 or equivalent
8	A copy of the most recent, applicable quality certificate ISO 27001 indicating the year of introduction and expiration, issued by a certified body as referred to in Article 2.96 Aw 2012, or a set of process descriptions based on NEN7510:2017
To be submitted after the provisional award decision:	
1	Certificate of Conduct for Procurement
2	Statement by the Tax and Customs Administration
3	Supporting document Insurance

Annex 1

Minimum requirements

Separately published on TenderNed.

Annex 2

Reference form

Separately published on TenderNed.

Annex 3

European Single Procurement Document (ESPD)

Separately published on TenderNed.

Annex 4

Answers on Award criteria (AW1 & AW2)

The Tenderers own document.

Annex 5

Pricing sheet

Separately published on TenderNed.

Annex A

Further description QA-tool and minimum requirements

Separately published on TenderNed.

Annex B

Draft Agreement

Separately published on TenderNed.

Annex C

Terms and Conditions (ARBIT-2018)

Separately published on TenderNed.

Annex D Draft Data Processing Agreement

Separately published on TenderNed.

Annex E Reserve Contractor Agreement

Separately published on TenderNed.

Annex F

Procedure complaint handling (European) tendering

Conditions regarding the admissibility of a Complaint

The complaint is admissible and will only be dealt with substantively if the following conditions are met:

1. The complaint complies with all the conditions as mentioned in paragraph 4.20 for submitting a complaint.
2. The complaint relates to this Tendering Procedure
3. The complaint has been submitted in good time, i.e. within the shortest possible period after publication of the Information Notice if the complaint was initially discussed there, but in any case at the latest within the duration of this Tendering procedure.
4. The subject of the complaint falls within the scope of the Public Procurement Act 2012 or relates to an act or omission of the Contracting Authority in violation of the Public Procurement Act 2012 or the principle of transparency, non-discrimination, equal treatment and/or proportionality or in violation of another regulation that applies to this tender.
5. The complaint does not relate to the general procurement policy of the Contracting Authority
6. If the complaint originates from a subcontractor, there cannot be complained about the relationship between the main contractor (Tenderer) and subcontractor.
7. If the complaint was initially raised in a Information Notice or otherwise, the entrepreneur shows that the response of the Contracting Authority has not led to the desired result for the Entrepreneur.
8. The complaint was not made to abuse the complaints procedure. The Procurement Expert of the complaints handling point reserves the right to declare the complaint inadmissible if, in his/her opinion, it can be established on objective grounds that the Entrepreneur is making improper use or abuse of the complaints procedure.
9. The Contracting Authority advises to submit a complaint about the Entrepreneur in question to the Entrepreneur himself and then to the Committee of Procurement Experts in The Hague.

The complaint procedure

The complaint procedure follows according this steps:

1. The entrepreneur submits his complaint to the KMA via the following url:
www.klachtenmeldpunt.aanbesteden.nl/fsb
2. The KMA immediately confirms receipt of the complaint to the entrepreneur and to the Contracting Authority.
3. The complaint will be dealt with by one of the Kma's Procurement Experts or in consultation by the Contracting Authority itself. A Procurement Expert will only deal with the complaint if he/she guarantees his/her independence in relation to the Contracting Authority's tender and the entrepreneur who submitted the complaint.
4. The Procurement Expert assesses whether the complaint is admissible. If the inadmissibility can be restored, the entrepreneur will be given the opportunity to do so via the KMA. If the inadmissibility cannot be restored, the Procurement Expert will report this as soon as possible to the Contracting Authority via the KMA. The provisions of step 7 then apply.
5. If the complaint is admissible, it will be assessed expeditiously and within a period of **5 working days**, calculated from the moment of receipt of the complaint, by the Procurement Expert. Only in exceptional cases and depending on the nature and scope of the complaint can the treatment period be longer than 5 working days. For any additional information that the Procurement Expert needs, he/she will contact the Entrepreneur and/or the Contracting Authority directly, the handling

Procurement Expert may engage a second Procurement Expert for a second opinion. The handling of the complaint results in a motivated but not binding advice from the Procurement Expert to the Contracting Authority. The advice contains the name and contact details of the Procurement Expert who handled the complaint and, where applicable, the name of the second Procurement Expert who has given a second opinion.

6. Via the KMA, the advice of the Procurement Expert is send to the Contracting Authority.
7. Based on the advice of the Procurement Expert, the Contracting Authority will take a decision on the complaint as soon as possible which reads: - the complaint is justified; or - the complaint is not justified; or - the complaint is partly justified. Any decision of the complaint shall be duly reasoned. The Contracting Authority also indicates which conclusion he has drawn from the complaint and what corrective measures he may take. The Contracting Authority itself announces its decision on the complaint to the entrepreneur
8. If the decision on the complaint leads to corrective measures with regard to this tender, the Contracting Authority will not only inform the entrepreneur who submitted the complaint as soon as possible, but to all (potential) candidates or (potential) tenderers in such a way that the principle of equality is observed.
9. If the Contracting Authority has not taken a decision within a reasonable period of time or if the entrepreneur does not agree with the decision of the Contracting Authority, the entrepreneur can submit the complaint to the Committee of Procurement Experts in The Hague. The procedure that applies to this is not covered by the present complaints procedure.