bevolkingsonderzoek
facilitaire samenwerking

Questionnaire Market Consultation

Laboratory QA software tool for hrHPV testing

Version: 1.0
Date: 27 July 2017

Introduction

Cervical cancer is an invasive malignancy of the mucosa on the transformation zone between the ectocervix to the endocervix. Cervical cancer is caused by high-risk types of the Human Papillomavirus (hrHPV). The malignant disease emerges from a longlasting pre-malignacy stage due to the emergence of lesions of cutaneous cells.

The Dutch Health Council advised the minister of health to replace Cytological screening for cervical cancer by hrHPV screening because of the higher sensitivity of the latter to detect pre-cancer lesions. Based on this advice the minister decided that as of January 2017 primary screening for cervical cancer should be based on hrHPV detection.

HPV screening is performed country wide in 5 Dutch Screeninglaboratories all using the Cobas 4800 HPV test. Each laboratory is equipped with an identical Cobas 4800 setup (including operating software) to perform the screening on cervical scrapes specifically collected as part of the national screening program. The laboratory procedures are completely standardized for the screening program. In each Cobas 4800 assay run, 93 cervical scrapes are tested along with a positive and a negative control and a kit-independent run control. During the course of this year a self sampling device for non-responders will be introduced and also processed with the Cobas 4800 HPV test.

Quality Control program

The laboratory activities for the Dutch hrHPV screening program are performed in 5 regionally distributed laboratories. Each of the laboratories is accredited according to the Dutch CCKL standard or 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 to independently monitor hrHPV test performance in cervical cancer screening laboratories is based on the following three elements:

1. A program for acceptance testing of equipment upon installation and upon repair or major service. In addition this programme is used to test and release (new lots of) critical reagents.
2. An run control programme with a manufacturer-independent control sample that is included in each hrHPV run.
3. External Quality Assessment to monitor inter-laboratory performances by participating in both international inter-laboratory comparisons with proficiency panels, and in national comparisons based on inter-laboratory exchange of clinical materials from the screening program.

QA software tool

A software tool is required in support of the above Quality Control program. Minimal functionality requirements for this tool are:

- On-line application with documented access control and authorization levels;
- Construction of a database with raw data, based on import of xml or csv based source files generated by the Cobas 4800 software to be retrieved with sFTP;
- Extract the required information / raw data from the database to perform structured and standardized data analysis, aiming to review laboratory and test performance over time, e.g inter-run, inter-lab and inter-lot comparisons based on quantitative (Ct-values) realtime PCR results for the independent run control sample and the kit controls;
- Graphical display of results and calculations in various charts; such as Levey-Jennings plots, bar graphs, scatter plots etc;
- Support for ad hoc queries on the raw data database using an intuitive user interface. The reporting should include graphical and tabulated display of the results;

- Intuitive) data mining option based on the graphical display, to allow parameter comparisons (e.g kit lot, equipment ID, etc) between a set of datapoints is desirable;
- Export of results to various formats (XLS, XML for aggregated results, graphical formats for charts).

The software tool should be operational for use end of Q1 2018. The estimated date for contracting after a (public) procurement procedure is 1 January 2018.

The customer will provide the Cobas 4800 source files (xml / csv) but has no IT infrastructure to run / host the application.

bevolkingsonderzoek
facilitaire samenwerking

Fill in attachment Questionnaire

If you need more space to answer the questions, you can use a separate sheet.

Nr.	Question	Answer
A.	*Functionalities*	
1.	What solution do you offer for the QA software tool as a whole or for the separate components? Indicate the components of the solution.	
2.	Which standard functionalitites are supported by the different components? Provide a summary per component.	
3.	Which additional functionalities are available with the software tool?	
4.	Is the solution specifically designed for QA and QC purposes, or does it support analysis and reporting of data in a more general way? Exemplify the type of data analysis and reporting options.	
5.	Is your solution specialized for laboratory usage or a generic tool? If specialized for laboratory practice, please give an overview of functions of your solution geared towards laboratory practice.	
6.	Has the solution previously been used for the processing, analysis and reporting of quantitative laboratory data? Give a brief description of the data processed in the context of the purpose of the analysis.	
7.	How will the software be hosted? • Local installation using the customer's IT infrastructure • Externally hosted: i.e. a solution provided by the supplier and offered by a third party through the Internet/VPN • Web based SaaS: i.e. a solution offered through internet/VPN by the supplier	
8.	What data security protocols / standards are in place to ensure save and secure data transmission, storage and access?	
9.	Does the software support a host- (multiple) client interaction, i.e would it be possible for laboratories to have (realtime) access to the data and reports from their own laboratory? Please explain.	

Nr.	Question	Answer
10.	How easy can extensions, adjustments and additions be made to your solution ? Can adjustments/additions be made by the supplier or also by the lead customer and / or individual laboratories?	
11.	What differentiates your solution from other software tools for this applicaton? Why is it more suitable for our screening program than other similar tools?	
12.	Provide some customers (references) where your software tool is used successfully. Exemplify per reference the application of the tool and indicate which person of the mentioned reference we can contact for more information.	
B.	*Support*	
13.	Which management activities like configuration, authorization, database management are provided and perfomed by the supplier?	
14.	Does your software tool use a generic Identity & Access Management (IAM) solution? How is authorization adjusted in your tool? Motivate your answer.	
15.	Do you have a Dutch speaking helpdesk and manuals in Dutch (or English as an alternative)?	
C.	*Implementation and costs*	
16.	What is your advise regarding the design and implementation of the QA software tool? What are the risks? What is the estimated duration of the design and implementation phase and what do you expect from the client/customer during this phase?	
17.	What can you tell us about the Total Cost of Ownership (based on a number of 10-15 users) of your solution for a QA software tool? What cost structure will be used; where are the greatest costs to be expected and where are possible savings to be achieved? Make a distinction between investment, design/ implementation, usage, and management costs.	

bevolkingsonderzoek
facilitaire samenwerking

D.	*Your organisation*	
18.	Describe your organisation: • How many developers do you have? • In what languages do they program? • What components in your QA software solution are open source? • Do you use a third party as implementation partner?	