The expert system VALAB:
A knowledge-based intelligent system for the medical industry

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Introduction

This article presents the expert system VALAB (standing for "Validation Automatique en Laboratoire", French for Automatic Validation in a Laboratory), developed by the company EREMS (Flourens, France). This knowledge-based system performs automatic biological validation (or invalidation) of the medical analyses undertaken in a laboratory. VALAB intervenes in the last stage of the process before results are transmitted to clinicians, which used to be the only non-automated stage, therefore forming the bottleneck of the process. First, using VALAB decreases the time between arrival of the samples to be analysed and departure of the validated results. Secondly, it also increases the reliability of the biological validation because a smaller workload is imposed on the biologists, who can consequently focus their work on the validation of difficult cases only.

A first section describes the medical environment of use and its constraints. It explains the role of biological validation and the ways it is traditionally undertaken, with the associated problems and resulting needs. The expert system VALAB is then presented, with its approach of using qualitative reasoning for checking consistency between parameters and data from the analyses. Technical aspects of VALAB's implementation and integration in a laboratory's computer system follow. The performance of VALAB is objectively assessed by analysing independent studies that have evaluated some major characteristics of the system.

Medical analyses and biological validation

An analysis is the evaluation of a biological parameter measured in a blood sample. There are several dozens of parameters that can be measured. They can be grouped under categories such as haematology, biochemistry, coagulation, or gazometry. In hospitals, these different categories usually correspond to separate laboratories, in different units. On the other hand, private laboratories commonly perform analyses from several groups. Examples of analyses are, for the biochemistry group, the sodium, potassium, proteins, plasmatic magnesium, cholesterol, etc.

Before communicating results of analyses, two validation steps must be undertaken. The first step is the technical validation. This is performed as a global quality control, and can include an intra-laboratory validation and an inter-laboratories validation. For the former, a series of samples, bought from commercial sources or taken from the hospital's

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pool, is analysed and the results used for statistical checks. The inter-laboratories validation is a comparison of the results obtained by several laboratories from identical samples. The technical validation process can therefore notice problems resulting from analysers failures.

The second validation step is called the biological validation. It investigates individually the pertinence of each sample's results. It checks the coherence of the results within each patient's file. This process can notice types of faults that the technical validation cannot. For example, incoherence within a patient's file can occur from an error in a sample's labelling, which cannot be found through the technical validation. Other possible sources of errors include poor blood taking, sampling tubes swaps, etc.

The technical validation process is typically automated, as opposed to the biological validation. Traditionally, the biological validation is performed by a human expert. This physician, or this biologist pharmacologist, must examine the analyses results of every sample. Results can be edited and sent out only once they have been seen and validated by the expert.

The validation can be either positive, i.e. the patient's file is assessed to be coherent and the results will therefore be sent out, or negative, i.e. the patient's file presents some incoherence and the results will be kept until verification is performed, or further information is received, or until the results are definitely cancelled.

Most parts of the analyses process before the biological validation are automated, from labelling to performing the analyses and their technical validation. The intervention of the biologist or physician for the final signature constitutes therefore the bottleneck of the whole process. A request for analyses is typically processed within a few hours of its receipt by the laboratory, and then waits further hours, possibly until the next day, before the physician looks at the results and performs the biological validation. The presence of this bottleneck motivates automating the biological validation step.

The expert system VALAB

VALAB (standing for "Validation Automatique en Laboratoire", French for Automatic Validation in a Laboratory) is an expert system that undertakes automatically the biological validation phase.

The aim of VALAB is to undertake the automatic biological validation of medical analyses. Presented with a group of analyses results about one patient, VALAB must take the decision of validating the results or rejecting them. Validating the results means that they are medically coherent. This is therefore not a medical diagnostic function, since a set of results associated with a disease's diagnosis can be coherent and validated, or a set of results associated with no disease can be incoherent and rejected. Rejection is not actually equivalent to a signification of faulty analyses, but a signification that VALAB cannot validate them. This is the case when the values of some results are considered by VALAB to be incoherent, or when VALAB does not have the expertise for examining this set of results.

The consequences of validation or rejection are the following. Validation of a set of results by VALAB is equivalent to a signature/approval from a human biologist. The validated results can instantly be forwarded to the customer who ordered the analyses from the laboratory. Rejection is followed by the set of results being sent to the biologist for careful examination. The biologist makes the final decision of either validating the results and forwarding them to the customer, or rejecting them and ordering the analyses to be undertaken a second time.

Approach and method used

The expert system VALAB follows a knowledge-based rule-based approach. The rules are dealing with a set of biological variables, or analyses, for example protein, urea, creatininium, glucose, etc. Each analysis is associated with a couple of normal limits (upper and lower), in between which the result must be located for a positive validation. The expertise contained in VALAB adapts these normal limits from the initial value to a current value. Adapting these limits takes into account the age and sex of the subject, and the result of other analyses performed. When all the factors have been used, and therefore that the normal limits have been fixed, the result should be within these limits. If it is the case, then the validation is positive, otherwise it is negative.

The determination of the normal limits to the case at hand is only a part of VALAB's expertise. Other criteria are used by VALAB for analysing a set of results. The complete set of criteria is associated with the following parameters:

i- Extreme limits (limits outside which the values are unacceptable in all cases),

ii- Reference limits (limits of normality, adaptable to each case at hand),

iii- Maximum number of days since the date of previous results for them to be usable,

iv- Percentage above which the difference between the present and previous results is deemed significant,

v- Sensitivity for the anteriority (comparison with previous results) and correlation (comparison with current parameters and analyses) criteria,

vi- Origin of the request (laboratory),

vii- Clinical or therapeutic information,

viii- Other extra data.

Each biological variable is associated with these parameters. They allow multiple checks to be performed on the results of a group of analyses.

Technical implementation and integration in the laboratory's system

VALAB is connected with the LIS (Laboratory Information System). This connection can be set either as a serial connection (RS232-C) or as a network connection (Ethernet TCP/IP). The communication protocol is based on ASCII characters. It uses control characters (start of text, end of text, separators, etc.) and commands. Every command must be validated by the LIS , otherwise it is repeated until a customisable time-out. There are two configuration options:

- either the LIS always initiates the exchange with VALAB,
- or VALAB sends a request at regular intervals of time, in case no report has been received.

When a laboratory orders a VALAB system, an appointment is taken by our set-up technician with the system engineers in the laboratory. Our technician will usually spend two days on site for installing VALAB, performing initial parameter settings and training local users of VALAB. The system is protected by the use of a programmable dongle.

The daily use of the system is easy, since VALAB has been designed to be a user-friendly system. The interface includes several types of traces of VALAB's activity, with common-sense explanations of decision processes and statistical indicators. These

explanations and indicators are appreciated by the users, who are not computer scientists. They play an important role in the trust that the users need to have regarding the system.

Evaluation of performance

Independent groups of users have undertaken evaluations of VALAB. We refer in this section to two groups of users, as Group A [Fuentes-Arderiu *et al.*, 1997] and Group B [Marchand *et al.*, 1997]. Two major indicators of the system's performance are used: the characteristics of sensitivity and specificity.

The sensitivity represents the ability to recognise an incoherent report, and therefore not to validate incoherent reports. Group A's experiments resulted in a sensitivity of 100%, and Group B's around 98% (after tuning of the system). These figures obviously represent good results. Indeed, although 98% is not a perfect result, it is a significantly higher percentage that the ones reached by human biologists in the experiments of Group A (61.1%) and Group B (ranging from 62 to 91%, with a norm around 60%). This high sensitivity explains the trust that VALAB's users have in the system.

Specificity is the percentage of consistent reports which are validated. The specificity of the system is equal to or lower than the specificity of human biologists (respectively 95.7% against 99.1% for Group A, and 78% against 65 to 93% for Group B). This should be seen as a consequence of the will to make VALAB reach a high sensitivity. If a report is doubtful, it must not be validated by the system, so that it will be checked by a biologist, who will have to take the final decision. As this is the central principle of VALAB's function, it can be stated that a lower specificity than human biologists' specificity is a expectable characteristic of VALAB.

More statistical indicators can be studied for further evaluation of VALAB's performance. Please refer to the individual publications of Group A and Group B for the study of these further indicators. These statistical studies lead for both groups to a highly positive evaluation of VALAB's performance.

Advantages of using VALAB

The use of VALAB has three main consequences. Firstly, as explained above, it increases the sensitivity of the validation process. With specificity being such an important quality criterion for a biological laboratory, this consequence is very valuable.

Secondly, it betters the work conditions of the biologist who is responsible for the validation process, by decreasing the number of reports that need to be checked. This decrease corresponds to the percentage of reports which are automatically validated by VALAB. Typical figures are around 65% of validated reports. The validation work left to the biologist can then be undertaken with a higher quality, under less stressful time-constraints.

Thirdly, the overall time span between some analyses are ordered and the corresponding results are sent out is greatly reduced, since the validation, which used to be the speed bottleneck of the process, is now mainly automatic.

Conclusion

As illustrated by the two studies mentioned earlier, the system VALAB provides an efficient and sound service to many teams of professionals. Furthermore, it is worth noting that these medical professionals, in general, have only basic computing literacy. VALAB is therefore a successful application of artificial intelligence techniques to the needs of biological laboratories.

The system is currently installed on more than a hundred laboratories across Europe and the rest of the world. However, VALAB is still evolving, as upgrades are regularly implemented. Current trends of developments of the system's functionality include making the system's always more user-friendly, and increasing the amount of customisable features, so that VALAB can fit as closely as possible to the needs of each individual laboratory.

References

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