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Review

Project management: importance for diagnostic laboratories

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ABSTRACT

Background: The need for diagnostic laboratories to improve both quality and productivity alongside personnel shortages incite laboratory managers to constantly optimize laboratory workflows, organization, and technology. These continuous modifications of the laboratories should be conducted using efficient project and change management approaches to maximize the opportunities for successful completion of the project.
Aim: This review aims at presenting a general overview of project management with an emphasis on selected critical aspects.
Sources: Conventional project management tools and models, such as HERMES, described in the literature, associated personal experience, and educational courses on management have been used to illustrate this review.
Content: This review presents general guidelines of project management and highlights their importance for microbiology diagnostic laboratories. As an example, some critical aspects of project management will be illustrated with a project of automation, as experienced at the laboratories of bacteriology and hygiene of the University Hospital of Lausanne. It is important to define clearly beforehand the objective of a project, its perimeter, its costs, and its time frame including precise duration estimates of each step. Then, a project management plan including explanations and descriptions on how to manage, execute, and control the project is necessary to continuously monitor the progression of a project to achieve its defined goals. Moreover, a thorough risk analysis with contingency and mitigation measures should be performed at each phase of a project to minimize the impact of project failures.
Implications: The increasing complexities of modern laboratories mean clinical microbiologists must use several management tools including project and change management to improve the outcome of major projects and activities. **A. Croxatto, Clin Microbiol Infect 2017;■:1**
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Introduction

The constant need for diagnostic laboratories to improve quality and productivity while reducing turn-around-time (TAT), alongside constraints of personnel shortages and limited funding, implies that lab managers must constantly rethink the laboratory workflow and technology to optimize the laboratory organization and performance. The approach of project management provides a methodology to face the requirement to evolve and adapt diagnostic laboratories to the market and system constraints in a more and more complex diagnostic environment. Project management offers a rigorous approach organized in multiple phases for achievement of defined goals while reaching success criteria and respecting the budget, allocated human resources, time frame, and quality. However, as outlined by Munns and Bjeirmi, there are clear distinctions among project, project management, and project outcomes [1]. They defined the project as being the achievement of a specific objective, whereas project management is the process of controlling achievement of the project objectives. Thus, in the worst case, a project can be successfully achieved even with a management failure, and vice versa [1]. A project is carried out by a team under the supervision of a project leader, whose goal is to transform ideas and thoughts into a completed project characterized by three main characteristics: quality, costs, and time limit. To be useful for diagnostic microbiology laboratories, this review is illustrated by a project of automation in bacteriology to discuss practical steps of project management, including the importance of communication,

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reporting, and change management. Automating a diagnostic laboratory is complex, disruptive, time-consuming, and labour-intensive, and requires appropriate and efficient project management to guarantee that the project does not result in suboptimal performance, exceeding costs and time delays. Thus, we present in this review the design of a project based on the HERMES 5 model [2], characterized by a phased management approach. Note that the present article does not focus on the specifics of project management, but rather shares the authors' experience in project management applied to a large automation project affecting a diagnostic laboratory.

Phases of the project

A project is usually delimited by several phases and milestones, which structure the project during its lifecycle. Depending on the phase model, a different number of phases corresponding to different aims, actions, tasks, and activities can be used. Moreover, the name and activities of each phase can be interpreted in multiple ways by different users. As an example, a phase model such as HERMES [2] consisting of four phases is presented in this review. The four phases, initiation (exploration), conception (planning, design, and choice), implementation (execution and construction), and deployment (up to completion) are regulated by several milestones that represent project decision nods (Fig. 1). The milestones represent gates to allow or not transition to the next phase, based on the project status, quality, feasibility, execution, and its compliance with the strategic objectives of the core organization following intermediate phase reports by the project manager. Each phase of a project is characterized by a given number of tasks that determine the action and the activities that must be accomplished to achieve the aim of a project, hereafter called 'results' (Fig. 1). The results can be technical, organizational, functional, managerial, product-orientated, descriptive, and educative. It is important for a project manager to monitor planning of the tasks, which can be done using a GANTT or PERT diagram. For example, the GANTT diagram illustrates a project schedule that monitors the start and finish date of the different tasks and/or activities composing a project. It is thus possible for the project manager to identify quickly the limiting actions, that is the components of the project that are delayed or must be started early and for which actions must be taken to ensure a constant progression of the project to reach the objectives on time.

In theory, a project can be terminated at any phase if the objectives cannot be achieved on time with the human, material, and financial resources allocated for this project. Usually, the decision to release a phase is made by the project and core organization (project steering committee). An example of project phases applied to laboratory automation is depicted in Fig. 1. Hereafter, we discuss several key aspects of project management listed in the four phases that we consider to be essential for the success of a large project such as laboratory automation. In addition, we discuss risk analysis, an additional key aspect of project management that must be considered throughout the entire project.

Initiation

During the initiation phase, an analysis of the situation is performed by defining general requirements, objectives, context, scope, and risks. Various options are proposed and one solution is chosen. A project charter and a project management plan are prepared and submitted for approval to the core organization. Upon

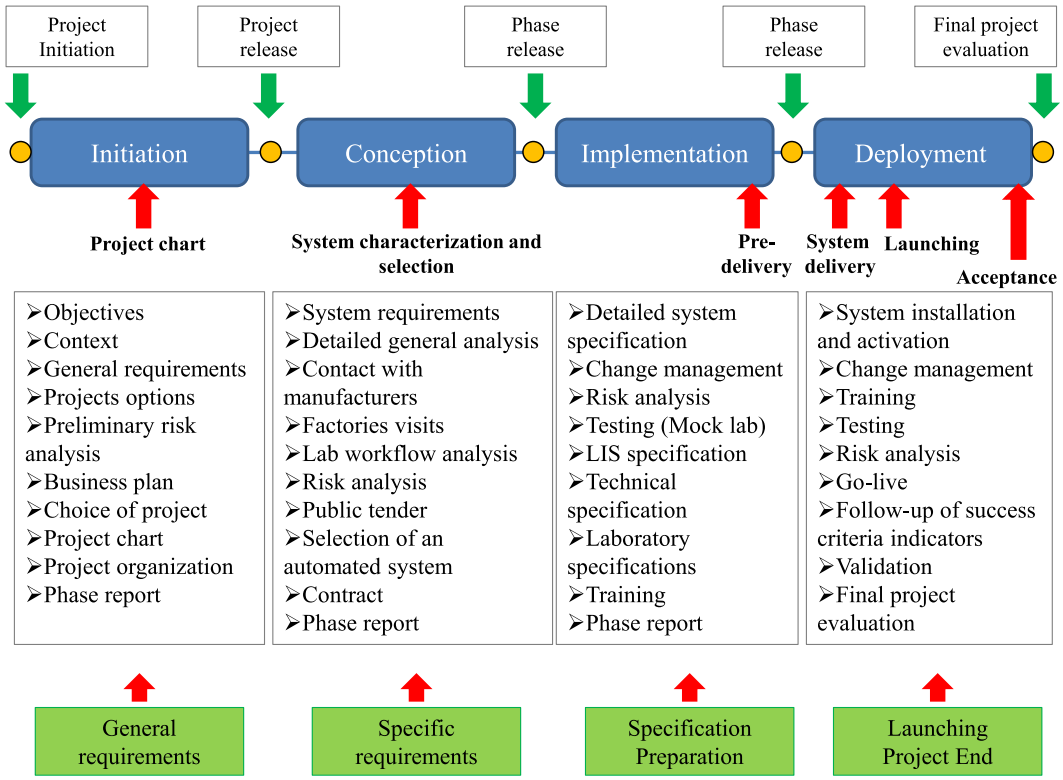

Fig. 1. Project phases with examples of tasks and activities that could be defined in a project of automation of a laboratory of bacteriology. Each phase is delimited by milestones representing security gates ensuring the appropriate progression of the project, allowing or not a phase release to the next phase based on phase reports of the project manager. However, additional multiple project status reports should be performed during each phase of the project from project management to the steering and the core organization. The project starts upon acceptance of a business plan by the core organization and ends with a final project evaluation. Adapted from HERMES 5 [2].

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acceptance by the core organization (that generally includes the project sponsor), the project is released to the next phase.

Project charter. A project charter must be established, usually during the initiation phase of a project, to determine the different parameters of a project (Table 1). Usually, a project includes (1) the name of the project, (2) a context describing the origin, the history, the meaning, and the reason for starting the project (see below), (3) the project scope describing the partners and the needs, (4) the objectives of the project including the expected overall final results and success criteria, (5) the phases of the project, which offer a stepwise description of the project evolution characterized by milestones of decision taking, (6) the time limit of the project, (7) a risk analysis, including mitigation and contingency measures, (8) a description of the project organization, (9) a description of human and material resources, (10) a budget, and (11) description of any other linked projects that may influence the outcome of the current project.

Table 1
Excerpt of a project charter of full lab automation

1. **Name of the project**	
Automation of the laboratory of bacteriology including inoculation, incubation and telebacteriology	
2. **Context (origin, history, signification, cause…)**	
• Sample increase of about 6% each year	
• Personal shortages	
• Recently introduced solutions (automated inoculation system and MALDI-TOF) and previous laboratory reorganization not enough to absorb the increasing number of samples.	
• Laboratory consolidation (bacteriology and hygiene)	
• New laboratory	
• ….	
3. **Project scope (partners and needs)**	
• Laboratory of bacteriology and hygiene	
• Laboratory department	
• Biomedical engineers	
• IT specialists (LIS)	
• Administration and general direction	
• Manufacturers	
• …..	
4. **Objectives of the project**	
Global final results	**Indicators of success criteria**
Functional automated system (inoculation, incubation and telebacteriology)	• ≥ 80% of samples inoculated automatically • ≥ 95% of plates read through telebacteriology • ≥ 98% reliability • …..
Results or gain of the project (quantitative and qualitative)	• Decreased TAT • Increased productivity • Increased quality • Decreased FTE • Increased security • ……..
5. **Phases of the project**	***See*** Fig. 1
Initiation, concept, implementation, and deployment	
6. **Time-limit of the project (estimation)**	
December 2017	
7. **Risks analysis**	***See*** Table 2
Identification, evaluation, processing, and management	
8. **Organization (hierarchy)**	***See*** Fig. 2
Core organization (executive board,…)	
Project organization	
• Steering (sponsor, project committee,…)	
• Management (project manager, project support, technical committee, subproject manager,…)	
• Execution (specialists: laboratory technicians, manufacturers,…)	
9. **Resources (human and material)**	
• Human	
• Material	
10. **Budget (estimation)**	
Not defined	
Other linked projects?	
• Construction of a new laboratory	
• Transfer of the activity to a new laboratory	
• Laboratory consolidation (bacteriology and hygiene)	

FTE, full-time equivalent; IT, information technology; LIS, laboratory information system; TAT, turn-around-time. The data provided in this table are given as examples based on our experience in the University Hospital of Lausanne.

The project charter represents a summary of the project proposal constituting the basis for an agreement among the project core organization, the sponsor, and the project manager. Upon approval of a project charter by the core organization and sponsors, the project manager must prepare a project management plan that describes how to achieve the project goals. A project management plan includes explanations and descriptions on how to manage, execute, and control the project including the different phases, tasks, activities, works, methods, human and financial resources, responsibilities, organization, project timelines, project milestones, and indicator measurements. The project plan represents a guide for all the partners involved in the project and is usually continuously updated and adapted throughout the evolution of the project.

We will focus below on some critical parameters that require special attention because of their importance throughout the project.

Context. The context must define the global current status of the diagnostic laboratory with a description including the environment, preliminary actions, link(s) with other projects, needs, opportunities, challenges, and partners. All these components of the laboratory will define the requirements of a significant evolution of the laboratory that may be achieved through various possible projects. The benefits and added value of the proposed project must be described. It is necessary to provide significant data on the laboratory activities to illustrate the magnitude of the problems requiring an evolution of the laboratory. The context will also represent the basis for development of a business plan, which is required to obtain funding for initiating a project. Some contextual information from the laboratories of bacteriology and hygiene of the University Hospital of Lausanne (CHUV) is provided below to illustrate the context of the automation project. As in many diagnostic laboratories, the laboratory of bacteriology of the CHUV is experiencing a significant increase in sample volumes (each year of about 5–10%) with a limited number of technicians. The laboratory reorganized its activities to optimize human resources and introduced a first level of automation with the acquisition of an automated inoculation system and a MALDI-TOF for microbial identification. However, despite the new tools and related reorganization, significant workload increase and constant stress were still observed because of increasing numbers of analysis per technician per day. Thus, increased productivity was further required, with the possible options being increasing the number of laboratory technicians, deeply modifying the laboratory organization and analytical portfolio, and/or introducing an automated solution allowing increased productivity with the same number of technicians. A laboratory workflow and activities analysis was performed. A reduction of 2.4 FTE (full-time equivalent) (16.5% of 14.5 FTE) or a significant potential for increased activity was estimated based on the expected gain in productivity conferred by laboratory automation [3]. In addition, the construction of a new laboratory, together with a planned consolidation of the laboratory of bacteriology and hygiene, represent an additional opportunity for laboratory automation which could represent a mutual platform allowing increased productivity for both laboratories. Finally, the project of full laboratory automation was fully in line with the general goals of the university hospital, which include increased quality, reduced TAT possibly shortening duration of hospitalization, and an increased activity (increased number of samples per year).

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Project scope. The project scope must define what and who belongs or not to the project. It lists the partners, the entities, and the area that will be part of the project, and describes their needs if they can be specified. A project of laboratory automation will include several partners and entities including the laboratories of bacteriology and hygiene (workflow analysis, users, description of needs), the laboratory department of the university hospital (sponsor, project committee), biomedical engineers (technical analysis of the proposed systems), information technology (IT) specialists from the diagnostic laboratory and from the manufacturers (laboratory information system (LIS) connection and parameterization), core organization (executive board, controlling and compliance bodies, project management competence centre, funding), and manufacturers (lab automation specialists).

Objectives. It is common to say that the goals of a project must be SMART—specific, measurable, assignable, realistic, and time-based [4]. However, the SMART acronym does not have one single specific meaning as different word definitions within the acronym have been used over time. The project must be well defined (specific), success criteria must be measurable with indicators (Table 1) to monitor the progression of the project and to find out when the goal will be achieved (measurable), people belonging to the project must be specified with a common agreement on the goal of a project (assignable, agreed upon), results that can be realistically achieved with the available human, financial, and material resources must be stated (realistic, reasonable), and time-based to specify when the results will be achieved (time-based, enough time to achieve the goal of a project but not too much time, which could alter the expected performance).

For instance, success criteria of the project on full automation of the laboratory of bacteriology and hygiene could include the following measurable indicators: percentage of total samples inoculated automatically, percentage of total plates read by telebacteriology [3], percentage of total antibiotic susceptibility testing processed by the system, reliability of the system, time to report identification as well as time to report antibiotic susceptibility testing and technician working time per sample (productivity). The objectives should also define the expected results (often named 'gain' of the project) that can be measurable. In case of a diagnostic laboratory, they could include several essential items such as decreased TAT, increased quality, increased productivity, and decreased full-time equivalent (Table 1).

Organization. The organization (hierarchy) involved in the project must be determined and should comprise the core organization, the structure to which the project sponsor and users are affiliated, and the project organization, which is a temporary organization existing only from project approval and closing. The project organization does not have to comply with the core organization hierarchy, but does have to describe the different roles involved in a project and its different tasks, responsibilities, and activities. As mentioned in change management, the project organization should encompass a powerful guiding coalition to achieve a project successfully. Moreover, the different partners involved in a project, and thus the project organization, may change throughout the project according to the different phases and tasks planned in the project. Based on the HERMES model, the project organization is divided into three layers: the steering, the management, and the execution [2]. The steering includes the sponsor and the project committee who control fulfilment of the project objectives and ensure that the different deadlines are met, the management includes the project manager, the technical committee, and if required the subproject manager, who are in charge of preparing, managing, and closing the project. The execution includes specialists who will take care of the tasks and their outcomes (Fig. 2). The project organization will also provide

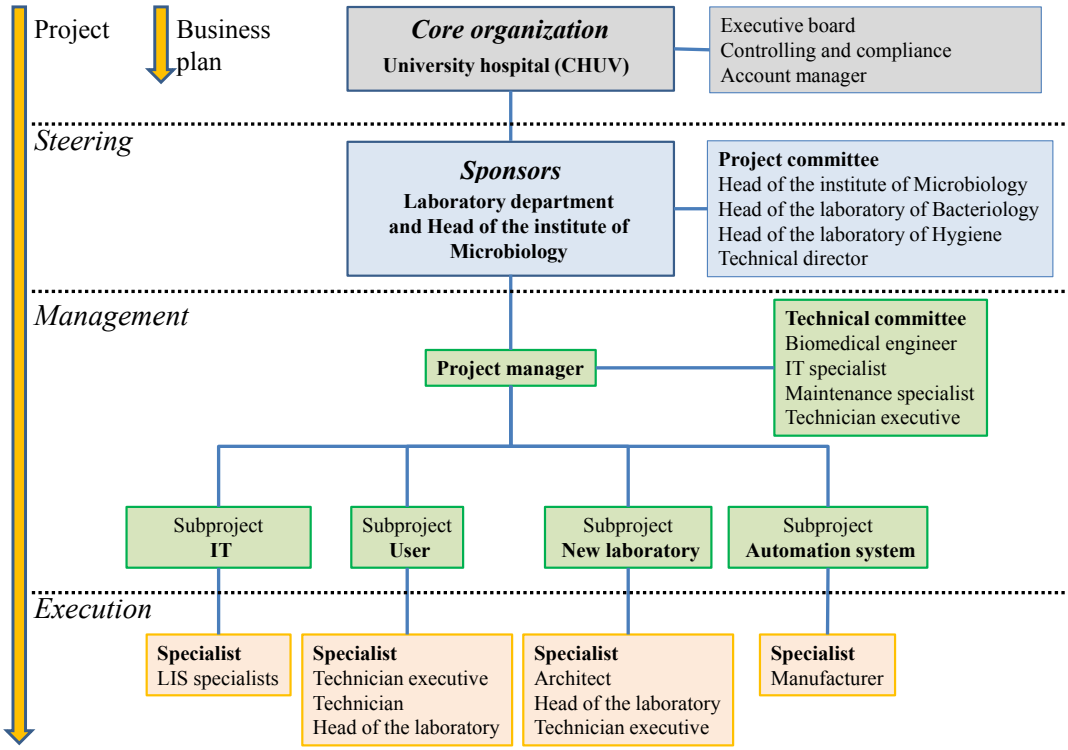

Fig. 2. Project organization of the automation of the laboratory of bacteriology and hygiene of the CHUV. The business plan acceptance includes only the core organization, whereas the project involves the core and project organizations. According to the HERMES 5 model [2], the project organization is characterized into three layers, the steering, the management, and the execution. The specialists (automation specialists, microbiologists, IT and LIS specialists, technicians, architects, manufacturers) will take care of the tasks and their outcomes. IT, information technology; LIS, laboratory information system.

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the basis to estimate the human resources required to achieve the project successfully.

Conception

The first major aspect is characterization of the laboratory needs based on a detailed analysis of its activity and organization. The activity must be defined with multiple parameters including inoculation and incubation protocols, sample/plate volumes and distribution (hourly, daily, and weekly), sample growth trends, FTEs, media, containers, and LIS specifications. Second, good knowledge on laboratory automation in bacteriology is required to understand the systems and better characterize their advantages, requirements, limits, and future evolutions [3,5–13]. This can be achieved through contact with manufacturers and with users, factories visits, literature, and congress attendance. All this information represents the backbone for a thorough analysis of manufacturer's propositions and a smart choice of an automated solution. These data will also assist the project manager and project steering committee in distinguishing between mandatory and optional needs, according to the budget of a project. Moreover, detailed analysis and good knowledge of the automated systems are essential to optimal risk analysis, as failure of the project may be caused by inadequate analysis of the laboratory activities (under- or overestimation of the laboratory needs) or by lack of knowledge of the automated systems (wrong expectations).

Implementation-deployment

The product is chosen and detailed system, technical, laboratory, and LIS specifications can be determined. Preparation for installation of an automated system in the laboratories must be conducted, including (1) identification and allocation of human resources, (2) architectural and technical adaptation of the premises, (3) planning of organization of the routine laboratory activities before, during, and after installation, which may require temporal recruitment of additional technicians, (4) specification of the connection of the automated system with the laboratory LIS (LIS interface development), (5) set-up of the configuration of the automated system and test of functionality at the factory facility, (6) training users via a workshop organized by the manufacturers, and (7) change management. The implementation phase represents the launch pad of the deployment, and the quality of the preparation will determine the success of the installation and the quality of the final product of the project. During the deployment phase, the automated system is installed and activated. The general functionality and configuration are tested. Then, the go-live of the system can be initiated with continuous improvement of the laboratory workflow through testing several validation processes. This task is performed in parallel to conventional approaches until most of the samples are processed automatically, thus introducing suboptimal working conditions with different sample analysis processes (manual versus automated) and reduced working areas. A follow-up of the success criteria indicators is performed and risks including system failures and staff commitment are carefully analysed. Thus, this phase can be time-consuming, stressing, and long-lasting, and careful change management should be followed by the project manager.

Change management. The success of a project is dependent on both the quality of the project and on the acceptance of the idea by all the individuals directly or indirectly involved in the project. The vision of a project must be shared with the entire staff of the laboratory. John P. Kotter identified eight errors that may cause project failure through inappropriate change management: (1) too much self-satisfaction, (2) failure to create a powerful guiding coalition, (3) underestimating the power of vision, (4) a lack of communication of the vision, (5) leaving obstacles blocking the new vision, (6) failure to obtain short-term wins, (7) shouting victory too early, and (8) neglecting to anchor the new approaches in the culture of the employees [14]. Thus, the project manager must communicate his/her vision of a project. Not knowing what is going to happen brings anxiety, fear of the future, and resistance. The project manager must convince all the partners or should modify the vision to create a guiding coalition that rallies every person involved in the project. To do so, the project manager relies on the line management, especially the project sponsor, who needs to provide strong support to the project manager by ensuring that resources and disciplinary commitments are provided by the entire organization. A regular and frequent communication program must be implemented to report the progression of the project including successes and difficulties encountered. It is also productive to involve the laboratory staff in the future reorganization of the laboratory activities following laboratory automation installation. Moreover, a complete training program of the staff prior to reception of the automated system will help to decrease any anxiety caused by inexperience using the new tool. The aim is clearly to arrange a transition from resistance to commitment to generate teamwork that maximizes the success of a project [15]. Poor change management may generate several counterproductive issues such as staff resistance, no adaptation to automation, productivity, and quality loss, staff escape, and conflict escalation. In the worst case, a significant project failure or interruption may be caused by poor change management.

Risk analysis

The risk is part of a project because a project is by definition introducing a notion of novelty, innovation not previously experienced. In addition, the size of the project with its level of complexity (technical, organizational, and human) will directly influence the risks. Thus a risk analysis must be conducted on all phases of a project. A methodology to analyse the risk must be implemented to identify, evaluate, address, and manage the risks. Failure mode and effects analysis (FMEA) methodology defines the risk index (RI) = probability (P) $\times$ severity (S) $\times$ detection (D) [16]. The probability describes the likelihood of occurrence of a failure, the severity characterizes the impact of a failure, and the detection describes how easy or difficult it is to identify a failure. Thus, the higher the risk index the more attention should be addressed to the activity impacted by the risk. Risk analysis tables can be used to identify, evaluate, and address the risks of a project (Table 2). It is recommended that measures are listed of mitigation to minimize or prevent the risk, or if the risk occurs, measures of contingency to manage and solve the problems. Moreover, the person in charge of risk management must be clearly identified. These measures should ensure that most problems that could affect the project are quickly and appropriately managed.

Conclusions

This review presented a general overview of project and change management with an emphasis on selected critical aspects. Structured project management conducted by an efficient project manager is required to achieve the goals and to meet the success criteria of complex projects such as laboratory automation. Such projects involving and impacting multiple partners and organizational entities require structured supervision and monitoring of all tasks and activities to achieve a project with optimal performance, cost control, and respect of time-limit. With the increasing complexities of modern laboratories, clinical microbiologists should use

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Table 2
Example of a risk table on a project of automation of the laboratory of bacteriology

Activity	Risk description/cause	P[a]	S[a]	D[a]	RI[a]	Mitigation[b]	Contingency[c]	Person/staff in charge[d]
Customers	Decrease or increase in sample volume	3	2	1	6	Marketing and good estimation of the growth trend	FTE recruitment/dismiss Externalization of some analyses	Lab manager/core organization
Core organization	Funding stopped after the initiation phase	1	3	2	6	Well designed business plan Proposition of a new variant	Laboratory reorganization Staff recruitment Externalization of some analyses	Project organization
Staff	Staff escape Active or passive resistance	2	3	2	12	Change management Communication Teamwork Training Reallocation of staff to added value tasks Involvement in R&D	Staff recruitment Modification of the lab organization	Project manager Lab manager
Manufacturer	Bankruptcy	1	3	2	6	Good knowledge of the manufacturers and market	None	Biomedical engineer Project manager
Technical	Failures	3	1–3	3	9–27	Good knowledge of the systems Preventive maintenance	Backup solution	Biomedical engineer
IT	Bad connectivity between the system and the LIS	3	3	2	18	Good knowledge of the IT Intensive testing before installation Good coordination between the manufacturer and the laboratory IT staff	Meeting crisis Troubleshooting LIS unconnected mode	IT specialist of the manufacturer, the LIS system and the laboratory
Project	Poor project management	2	3	2	12	Cautious recruitment of the project manager by the project committee Frequent reporting of the project progression Powerful guiding coalition	Recruitment of a new project manager and/or guiding coalition	Core and project organization

D, detection; FTE, full-time equivalent; IT, information technology; LIS, laboratory information system; P, probability; RI, risk index (RI = P × S × D); S, severity.
[a] (1) unlikely (P)/minor (S)/certain (D); (2) occasional (P)/moderate (S/D); (3) frequent (P)/critical (S)/low (D).
[b] Mitigation: measures to minimize the P and S.
[c] Contingency: measure to be taken if the risk occurs.
[d] Person or staff in charge of the management of the risks.

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current management tools to improve the outcome of their major projects, with project and change management being essential parts of their activities.

Transparency declaration

Dr Croxatto and Prof Greub have nothing to disclose. No external funding was received.

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