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Management Strategies for Effective Clinical Research

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As an integral part of the strategic organisation of a hospital, clinical research in academic medicine has to serve diverse stakeholders and meet sometimes contradictory needs. Without doubt, the benefit and safety of patients are primary goals of clinical research. Other important drivers, such as economic aspects, reputation and quality should not be disregarded (Schilling et al. 2009). Thus, this article explains why clinical research should be understood as a business unit and should be integrated into the structure of the clinic or healthcare entity.

Management Tools in Clinical Research

Although economic teachings are subject to renewal and adaptation, for the development of sustainable clinical research, certain universal tools and methods are elaborated in the tool set offered below, which may be applied effectively in the future.

Business Plan

The efficiency of clinical research is dependent on its seamless integration into the strategy, processes and structure of the healthcare enterprise. A business plan can support this integration process in a goal-oriented way. First of all, a comprehensive plan for the clinical research business unit establishes trustworthiness, cost-effectiveness and the overall prospect for the planned programme to important stakeholders such as hospital management, clinical and industrial cooperation partners and potential capital providers. A business plan is a highly suitable tool for clinical research as it allows day-to-day control of operations by providing helpful and binding guidelines.

Traceable, Solid Structures Required

The complexity of clinical research requires traceable and solid structures. Everything from basic research and experimental surgery to clinical patient treatment and care should be incorporated seamlessly into every unit (Sarikouch et al. 2010) (see Figure 1). Each individual part of this network and its inherent hierarchies should be aligned with the general strategic focus of the clinical research programme. Information technology solutions should be built upon unified standards and networks across all units to provide integration at an operational level. For scientific success, complete and current data are as decisive as available medical technological infrastructure.

Five Golden Rules for Process Organisation

Healthcare providers must engage in active, multidisciplinary participation in clinical research. Demands on clinical employees are increasing (Rosta et al. 2007). To maximise the efficiency of these interactions, it is important to integrate clinical research into daily routine as efficiently as possible. I outline some possible 'golden rules' for this integrated, holistic approach, here:

- 1. Prior to patient admission, clinical and research personnel should begin a dialogue to help identify patients that are suitable for clinical trials.** By this means, any special diagnostics that are necessary can be prepared at an early stage.
- 2. Patient consent and briefing can be initiated with an adequate amount of lead time.** Effective selection of patients would reduce costs, save time and prevent loss of motivation of the staff by keeping up progress in the trial. The entire process should be evaluated regularly (see fig. 2).
- 3. Outpatient evaluation and aftercare should be carried out together with corresponding cooperation partners.**
- 4. Any required technical equipment should be prepared in advance in order for medical personnel to fulfill their tasks.**
- 5. Offering special trainings allows referring physicians in clinical trials to be facilitated.** Involving clinical cooperation partners such as referrers in this way can be financially beneficial for them. It embeds the partners in an integrated patient care model, while helping to ensure sources for future referrals and business for the healthcare entity.

Human Resources and Development

Student education in university hospitals should be involved in clinical research activities. Selected scientific questions sometimes offer innovative and interesting perspectives on healthcare. Furthermore, illustrated cases certainly abet the recruitment of doctoral candidates.

In addition, proactively training and educating staff for clinical research will result in the improvement of study processes and outcomes. As well as the self-evident, optimal clinical care, the specific tasks of a clinical study should be taken care of with maximum possible accuracy and discipline. In the department of cardiothoracic, transplantation and vascular surgery of Hannover Medical School, we strongly believe that every staff member is able to perform well and can focus on his or her core competencies if optimal working conditions are given. This fundamental principle requires ongoing training and certification initiatives, a sufficient size of staff and the availability of specialists for additional tasks, e.g. for professional project management or assistance for the publication of results (see figure 3).

Clear Definition of Roles & Tasks

The clear and adequate assignment of tasks and responsibilities according to individual qualifications offers a practical way to offset potential feelings of there being excessive demands made on the part of your personnel. Hospital managers can create and re-evaluate tasks with a sense of proportion and in regular staff appraisals. The traditionally established division between nursing and medical staff, including each having separate personnel managers, is still extensively common. The abolishment of this separation in our hospital led to a remarkable increase of options concerning the assignment of tasks and responsibilities.

Thus, nurses may be temporarily or permanently employed in the clinical research unit. The clinic regularly offers a qualification initiative to become a study nurse. Thus, employees who can no longer perform the physically challenging job of patient care due to health issues can still be employed in the hospital. The wide-ranging skills of such employees can be retained and employees' satisfaction increases.

A consequent treatment of the department of clinical research as a business unit also involves the optimal employment of an entrepreneurial leader as head of the department. Competencies like emotional intelligence, communication skills and creativity are already required by surgical unit leaders but are at least as important for the leadership of clinical research (Buchler et al. 2006).

Communication and Public Relations

Clinical research requires an especially sensitive integration of referrers, aftercare institutions and patients and their relatives each of whom are primarily interested in the excellent treatment of the disease. A priority task for the study centre is to prove that these demands are not controversial but rather complement one another. For continuous communication with stakeholders, a large number of tools are available: press releases, patient and further education trainings (Dierks et al. 2007), scientific publications, regular information media and the internet. In order to coordinate and implement these communication measures, a management-led staff unit was established in our hospital for corporate communications.

Financial Budgeting

The hospital's global budget should be coordinated by the management for the medical director. This includes the budget not only of the hospital but also of the department of research. It covers public funds, third-party funds, performance-oriented funds, outpatient and inpatient revenues as well as private liquidations. Due to this earmarking of funds for specific purposes, a transfer of funds or a subsidy is rarely possible. Nonetheless, synergies can be identified by the central coordination of budgets.

The clinical research unit is subject to the same principles of economic efficiency as all other units in the medical entity. Investments have to be profitable, and personnel and running costs have to be covered by the revenues accrued during the particular project period. At Hannover Medical School, the clinical management team supports the study directors in financial budgeting and controlling and serves as an interface to the central department of strategic control. The advantage is that by monitoring monthly records and analysing trends, unfavourable developments can be detected and counteracted at an early stage.

Quality Control

The entire clinical research unit undergoes regular evaluation. This evaluation is initiated by the medical director and supervised by the clinical management team.

Results

Reproducible and comparable data provide standards by which the achievement of objectives can be measured. These can be figures such as: The number of officially requested new diagnostic and treatment procedures or the number of clinical research projects and the number of publications. After having introduced a dedicated business unit of clinical research from 2008 on, we saw a significant increase for all three parameters (see Figure 4).

Discussion

For all stakeholders, clinical research is too important to be dealt with as a mere aside. Facing the demands between patient care, scientific and economic concerns as well as education, clinical research can sustainably exist only as a highly effective business unit.

Clinical research programme managers should consider establishing a central project management unit in order to professionalise the

organisation of research activities and to relieve the scientific staff of this duty. Tight organisation and seamless, structured integration of research in clinical processes assures realistic and successful project implementation. Structures and processes that are accepted similarly by staff and patients are key to this success. The results and thus the value of clinical research significantly depend on the medical and non-medical care of study patients. Staff shortages accompanied by excessive demands and resulting in employee's dissatisfaction endangers the reliable and timely handling of clinical research and thereby influences the reputation of the study centre among potential sponsors. Clinical research should be understood and treated as a revenue component at least in the academic context.

Existing results demonstrate this model's sustainability. A detailed evaluation of the results, of the stakeholders as well as the application of a corresponding balanced scorecard for personnel involved in clinical research is currently taking place.

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