

Editorial

Protocol-in-a-Day Workshop: A Lean Approach to Clinical Trial Development and Focus on Junior Faculty Development



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Introduction

Academic clinical trial development is complex and requires a variety of professional skill sets for successful implementation. Although most principal investigators who develop clinical trials are clinical research faculty, few are formally trained. The need for efficient development of clinical trialists is emphasized by the rapidly increasing number of trials, which rose from approximately 233,000 in 2017 to >290,000 in 2018¹ with a predicted global cost of \$64 billion by 2020.² Even at the largest cancer centers in the United States, facilitating the development of junior faculty to design and implement clinical trials can be challenging.

Implementing a prospective clinical protocol can take up to 18 months. Delays in opening new trials result in delays in clinical innovation and advances in clinical care. Faculty promotions may also be delayed when time is lost

to preparing rather than implementing a trial. Historically, faculty learn the lessons of successful trial implementation through an informal process of trial and error, which can be costly and frustrating given limitations in time, funding, staffing, and patient enrollment. In fact, poorly designed or failed trials can cost millions of dollars for these reasons, in addition to the loss to patients in potential clinical advancement.³

Protocol development may be complex because of the variety of treatment modalities, stakeholders, and regulatory processes involved. The industry practice of lean management is being adopted by health care management to integrate systems with the objective of eliminating inefficiencies while concurrently improving operations and outcome quality.⁴ Therefore, we developed a lean half-day program in which junior faculty present protocols to experts and clinical faculty and staff with the goals of optimizing mentorship opportunities, decreasing clinical trial activation time, and improving the overall quality and safety of clinical trial protocols.

Protocol-in-a-Day Concept and Operation

Our workshop was based on 6 key elements of trial design: (1) regulatory aspects; (2) institutional committee review (Clinical Research Council) and institutional review board; (3) research data coordination (including nursing); (4) statistics; (5) correlatives including imaging,

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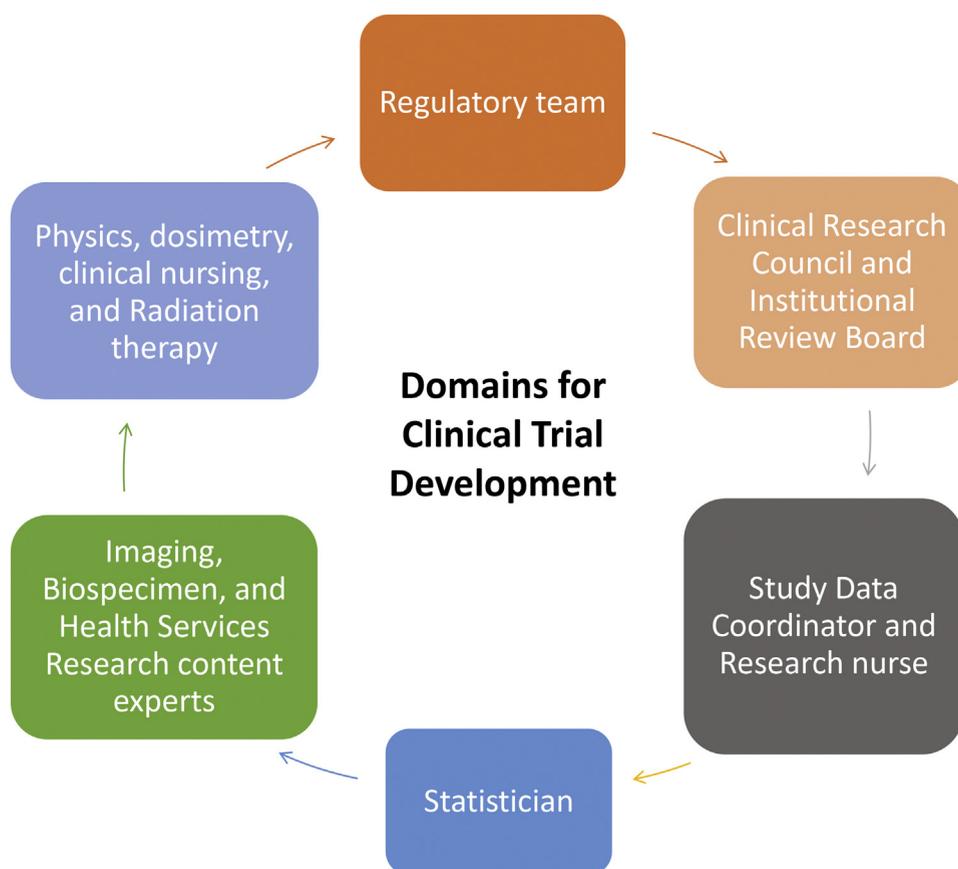


Figure 1 Clinical trial development domains.

biospecimens, and health services research/patient-reported outcomes; and (6) operations (Fig 1). With the exceptions of the institutional committee members and statisticians, individuals in each of these domains were members of the Division of Radiation Oncology, which includes the departments of Radiation Physics, Experimental Radiation Oncology, and Clinical Radiation Oncology. Content experts were senior faculty specializing in imaging, biospecimen development, and health services research. Clinical operations staff included physics faculty, dosimetrists, clinical nurses, and radiation therapists. Research administrative staff included trial regulatory/policy members, data coordinators, and study research nurses (Table 1).

Drafts of the protocols were provided a week in advance to all workshop participants, who were encouraged to provide feedback and share content that would improve protocol development. On the day of the workshop, junior faculty present a comprehensive overview of their proposal to all content experts, faculty, and staff. After the presentations, the junior faculty rotate individually through each of the 6 domain/topic stations every 30 minutes to obtain specific feedback.

Two protocols were included in the first phase of the workshop. The success of the workshop was assessed by

a Qualtrics survey and the time from protocol submission to Clinical Research Council and institutional review board approval. Between 2015 and 2018, the mean interval between institutional submission and approval was 258 days; the mean time for the 2 protocols that went through the Protocol-in-a-Day workshop was reduced to 135 days (Fig 2).

Mentoring Future Academic Clinical Trial Faculty

Clinical trials have a significant impact on advancements in the field of medicine, increasing the quality of clinical care, and improving patient outcomes. Protocol development has historically been taught informally or through trial and error. If not properly vetted by all stakeholders, including operational staff, a trial can waste clinical resources or, worse, put patients at risk. We implemented a program that provided direct input and mentoring from senior faculty members, clinical staff, and administrative clinical trial personnel, which resulted in a decrease of almost 4 months in the interval between protocol submission and acceptance by institutional oversight committees. As an example of lean

Table 1 Members of the clinical trial development domains

Regulatory team
Administrative director of protocol research
Manager of clinical protocol administration
Program coordinator
Consent editor
Clinical research council and institutional review board
Clinical research council chair
Manager of human research regulations
Associate director, human research registration protocol research
Institutional review board faculty member
Study data coordinators
Research nurse supervisor
Manager, study data coordinators
Statistics
Professor of biostatistics
Content experts
Faculty with joint appointments in health service research and radiation oncology
Biospecimens content expert (translational science faculty member)
Imaging research experts
Clinical trial operations
Faculty medical radiation physicist
Clinical supervisor of medical dosimetry
Clinical nurse (for feedback on feasibility of integration in clinic)
Radiation therapist

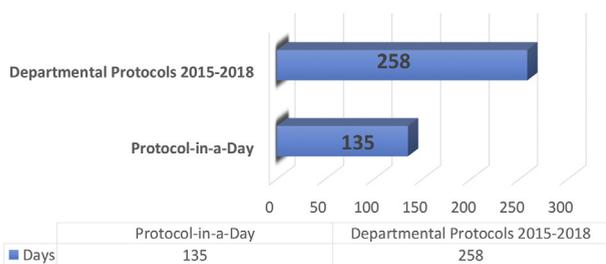


Figure 2 Average number of days from protocol submission to activation.

management, the program also provided an efficient means for protocol writers to have easier access to experts and for several content experts to provide focused input in 1 setting.⁴ We believe that this process has the potential to improve the quality and safety of submitted protocols while allowing increasingly complex trials to be developed and opened in a shorter timeframe.

Several national programs have been developed to train future clinical trialists, including the prestigious American Association for Cancer Research/American Society of Clinical Oncology VAIL Methods in Clinical Cancer Research Workshop, the Radiological Society of North America Clinical Trials Methodology Workshop, and European Society for Medical Oncology Methods in Clinical Cancer Research. These highly competitive international programs can accept 12 to 80 faculty members each year; thus, relatively few faculty members nationally will have the opportunity to participate. In addition, these

programs are limited to only 1 protocol, whereas the proposed program can be replicated with subsequent protocols that may require different subject matter experts and institution-specific policies. The efficient development of institutional-level, specialty-specific programs such as our Protocol-in-a-Day workshop may help bridge the gap in the pipeline of junior faculty who would like to develop 1 or more protocols in their departments.

The success of our Protocol-in-a-Day workshop highlights the need for effective faculty mentorship programs. Surveys of academic mentorship of junior faculty members showed that, although 62% of respondents reported receiving mentorship from peers, 56% reported difficulty in identifying role models, and less than half were satisfied with their formal mentorship programs.⁵ The role of mentored sponsorship or the direct provision of academic opportunities has also been explored. Models for successful sponsorship within academic medicine include programmatic themes with clear missions, explicit goals, robust processes for mentoring, and metrics for surveillance.⁶ Institutional investment in such programs can help improve academic advancement for all junior faculty, including improving the visibility gap for women and minorities.

Finally, the focus of mentorship is often on medical student and trainees, which results in a gap in the development of mentorship for faculty that can expand the pipeline of physician academicians. Systematic reviews of mentoring programs for physicians in academic medicine have identified frameworks for success.⁷ Faculty

programs dedicated to mentorship of junior academic faculty may improve the 5-year retention rates of those faculty by as much as 38% and offer added benefits for faculty advancement. Our program similarly contributes to the literature on successful mentorship and sponsorship of junior faculty in the development of clinical trials, which presumably will enhance the productivity of faculty and lead to a more efficient conduct of trials for the general benefit of patients.

We believe we were able to increase the efficiency of protocol development by compressing protocol design without compromising the quality of the protocols. Among the limitations of our program are its small number of participants and its recent development; therefore, long-term data on trial implementation and faculty career development are lacking. Our program simply serves as one model with which departments can encourage recruitment of junior faculty into clinical trial design and provide an infrastructure to foster mentorship.

Conclusions

The development of clinical protocols at academic medical centers can be made more efficient with the implementation of focused mentoring programs. Our goals at present are to expand this program to other departments at our institution and to encourage other institutions to borrow liberally from this model to increase the pipeline of junior faculty who can become clinical trialists.

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References

1. U.S. National Library of Medicine. Available from: www.clinicaltrials.gov. Accessed 2018.
2. Sonstein SA, Jones CT. Joint task force for clinical trial competency and clinical research professional workforce development. *Front Pharmacol*. 2018;9:1148.
3. Pretorius SG, Grignolo A. Phase III trial failures: Costly, but preventable. *Appl Clin Trials*. 2016;25.
4. Rotter T, Plishka C, Lawal A, et al. What is lean management in health care? Development of an operational definition for a Cochrane systematic review. *Eval Health Prof*. 2018; 163278718756992.
5. Lalani N, Griffith KA, Jones RD, Spratt DE, Croke J, Jagsi R. Mentorship experiences of early-career academic radiation oncologists in north America. *Int J Radiat Oncol Biol Phys*. 2018;101:732-740.
6. Gottlieb AS, Travis EL. Rationale and models for career advancement sponsorship in academic medicine: The time is here; the time is now. *Acad Med*. 2018;93:1620-1623.
7. Kashiwagi DT, Varkey P, Cook DA. Mentoring programs for physicians in academic medicine: A systematic review. *Acad Med*. 2013; 88:1029-1037.