Clinical Trials: Lessons Learned

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Background and operational challenges

In the U.S., the Federal Food, Drug, and Cosmetic Act requires that all investigational medical products be tested on human participants in the setting of clinical trials to demonstrate safety and efficacy prior to approval for marketing.¹ Sponsors, clinical investigators and institutional review boards (IRBs) that conduct or oversee these clinical trials are required to comply with U.S. FDA regulations based on adherence to the principles of good clinical practices (GCPs) and adequate participant protection.²

Increased regulatory oversight has led to better compliance with GCP requirements, more accurate documentation and a safer environment for patients.³,⁴ However, compliance with these requirements adds significant additional layers to the workload of the clinical staff conducting these trials.⁵,⁶ Therefore, an efficient system that permits consistent adherence with regulatory requirements during the trial along with quality patient care is highly desirable.

Strategies offering solutions

Multidisciplinary team approaches offer efficient and quality care, and prevent duplication of efforts through a complementary distribution of tasks based on each individual’s expertise and strengths.⁷,⁸ This poster describes tools developed to facilitate the functionality and maximize the efficiency of a patient-centered research-oriented team for the conduct of clinical trials in the division of hematology at a tertiary center. The primary aim of this coordinated team approach is to integrate treatment on clinical trials in a busy hematologic practice, while securing a seamless compliance with regulatory requirements.

In 2005, a coordinated team care approach was established with the goal of offering enrollment on investigational trials as an integral part of patient care. At the division level, the importance of team members’ geographic proximity led to the relocation of both clinical research staff and healthcare staff into one suite. To improve the functionality and maximize the efficiency of this team, tools were developed to address three key elements for the successful conduct of clinical trials: knowledge, documentation and communication (see Table 1).

Key take-away messages

This approach described in this poster can help integrate experimental treatment in the case of patients by providing a safety net for compliance with increasingly demanding regulatory requirements. This model can be easily applicable to any practice, tumor site and research center.

From a patient perspective, the multi-disciplinary approach was shown to be associated with improved patient adherence with treatment appointments and the treatment regimen,¹ reduced anxiety about care, enhanced quality of life, and improved outcomes of certain conditions.¹,¹²

The integration within the same team of the clinical and research staff was essential for both recruitment of subjects on trials and continuity of care.

Technology combined with a coordinated team approach can facilitate the integration of trials in clinical practice.

Table 1 Description of tools and roles of team members assigned for implementation

<table>
<thead>
<tr>
<th>Team member</th>
<th>Description</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapist</td>
<td>Includes the integration of standardized template to support referral processes and standardize counseling.php</td>
<td>To ensure a consistent approach to referrals and to facilitate clinic visits</td>
</tr>
<tr>
<td>Certification</td>
<td>Includes a standardized checklist to track appointment attendance and adherence to the treatment plan</td>
<td>To improve communication and expedite tasks</td>
</tr>
<tr>
<td>Financial</td>
<td>Creation of a centralized database to support trial-related activities and improve patient care</td>
<td>To ensure constant awareness by the team of progress and patient status</td>
</tr>
<tr>
<td>Data entry</td>
<td>Includes electronic data capture and analysis of clinical trial outcomes</td>
<td>To track patient enrollment and ensure compliance with regulatory requirements</td>
</tr>
<tr>
<td>Regulatory</td>
<td>Includes: application for study protocol; testing of clinical trial endpoints; and patient safety</td>
<td>To improve communication and expedite tasks</td>
</tr>
<tr>
<td>Treatment</td>
<td>Includes the integration of standardized protocol to support trial-related activities</td>
<td>To improve communication and expedite tasks</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Includes the integration of standardized protocol to support trial-related activities</td>
<td>To improve communication and expedite tasks</td>
</tr>
<tr>
<td>Communication</td>
<td>Includes the integration of standardized protocol to support trial-related activities</td>
<td>To improve communication and expedite tasks</td>
</tr>
<tr>
<td>Emergency</td>
<td>Includes the integration of standardized protocol to support trial-related activities</td>
<td>To improve communication and expedite tasks</td>
</tr>
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References