Best Practice

ClinicalTrials.gov Organizational Outreach and Education

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Purpose

The ClinicalTrials.gov Protocol Registration and Results System (PRS) can be difficult to navigate, in particular for those who do not utilize the system on a regular basis. Outreach and Education for new users is instrumental to help ensure compliance with federal requirements of study registration and results reporting.

There are multiple education and outreach approaches, for both in-person and virtual settings.

Best Practice

Consider every contact an opportunity to educate study teams.

- Create helpful Institution-specific reference documents for study teams (Note: reference Federal agency resources where relevant and helpful):
    - FAQ documents
    - Detailed procedures and guidance for Investigators, Research and Statistical Support personnel
    - Institutional website for Institutional ClinicalTrials.gov Policies and Resources
- Provide links to useful resources in your email signature, such as ‘register.clinicaltrials.gov’ (PRS), internal websites and help documents, or Institutional ClinicalTrials.gov Guidance.

- Offer information when a study team member requests a PRS user account:
    - Use this opportunity to encourage a 1 to1 consultation meeting. An hour-long consult can be enough time to start and complete a registration record, providing a very effective orientation to the PRS and registration requirements, resulting in a record more likely to pass ClinicalTrials.gov Quality Control (QC) review.
        - Forward a link to the PRS Registration Review Criteria in advance of 1 to1 consultation.
        - Ask the study team member to log into the PRS at the start of the consultation, share their screen (virtual setting) and walk the new user through each section of the record.
    - Attach any Institutional ClinicalTrials.gov resources in response to request for user account.

- Directly define ClinicalTrials.gov-specific terms for e.g., “study completion date (generally the last participant’s last visit)” when communicating via email with study teams. This enables study teams to learn and remember new concepts as they edit their records.

- Contribute to Institutional Newsletters to communicate ClinicalTrials.gov requirements and evolving policy or reporting on noncompliance. If your Institution sends out newsletters to your research community, offer to provide a short article, e.g., describing services provided by your office, tips on common errors, or important developments.

- Email PRS users periodically in lieu of or in addition to newsletter contributions.

- Conduct “Lunch and Learn” meetings that focus on Registration, Record Maintenance, and Results Reporting. Virtual Lunch and Learns can have higher attendance rates than in-person meetings.

- Offer to present ClinicalTrials.gov workflows and to review requirements at Departmental meetings to raise awareness and get study teams more involved, particularly for departments struggling to maintain compliant records. Include discussion about the impact of noncompliance on the ClinicalTrials.gov public site, on public perception, how to navigate the PRS, review regulatory and policy requirements, and orient them to your services and resources.

- Recruit the assistance of research leadership who can (and should) help get the word out regarding the importance of ClinicalTrials.gov, and where to go for help.
- Identify individuals within departments that can act as a liaison to researchers and teams, to reinforce messages regarding needed action and to help disseminate important information.
- Develop curriculum and deliver formal training to faculty and staff in a classroom setting.
- Develop recorded training material and post on your intranet site.

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