Monitoring Patient Recruitment Campaigns for Compliance

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Agenda

• Background
• Do’s and Don’ts
• Acronyms
• Online Advertising and Social Media
Landscape

- Patient recruitment accounts for a quarter of the time spent conducting a typical clinical trial.
- Presently, nearly 86% of clinical trials conducted in the United States fail to meet established enrollment timelines.
Pop Quiz: Are These Statements Acceptable in Ads?

- Study participants will be helping doctors find out if symptoms return when patients stop taking medication.
- The drug used in this study has been approved by the Food and Drug Administration.
- You will be treated by a personal physician who is an expert in this disease.
- Are you suffering from this disease? We may be able to change that.
- You will be paid for your participation in this study.
What are the Rules?

- **FDA Information Sheet (1998)**
  - FDA considers direct advertising for study subjects to be the start of the informed consent and subject selection process.

- **21CFR312.7(a)**
  - An investigational new drug shall not be represented in a promotional context
  - Restricts promotional claims of safety and effectiveness of the drug to preclude commercialization of the drug before it is approved for commercial distribution

- **HIPAA**
Background: Types of Advertisements Used for Clinical Trial Recruitment

The types of advertisements include but are not limited to:

- Newspaper
- Radio
- Television
- Bulletin boards
- Posters
- Flyers
- Telephone recruiter scripts
- Internet (one exception – clinicaltrials.gov)
- Letters
- Receptionist Scripts
Study Recruitment Advertisements – Do’s:

- Mention that study is a research study – never downplay the investigational nature.
  - For example – “Conducting a research study with an investigational drug..”
  - This applies *even if the product is approved*, when studied in new indication, formulation, dosage, etc. (other than approved label)

- If there is a placebo arm, it is recommended that this be referenced.

- Information should include what prospective subjects need in order to determine if they are interested and/or eligible.

- Provide close oversight over any recruitment vendors. They are often unaware of many risks discussed and have a different focus: to efficiently recruit subjects (Recall the landscape).
Study Recruitment Advertisements – Do’s:

• When appropriately worded, materials can contain:
  • Name and address of the clinical investigator or research facility
  • The condition under study or the purpose of the research
  • A summary of the criteria used to determine eligibility for the study
  • A brief list of participation benefits, if any (e.g., a no-cost health examination)
  • Time or other commitment required of subjects
  • The person or office to contact for further information
Study Recruitment Don’ts
Advertisements Should Not Be:

Promotional / use branding

Avoid using information that may be deemed as promotional for the product:

• Branded name
• Generic name (in certain cases)
• Use of company-internal product code
• Terms used to describe the product that only one product would meet
  • Example – use of dosing strength that is very specific to a product
• “FDA-approved”
• Similar color schemes between product website and marketed product advertisements
• Tag lines
• Similar/same graphics
• Similar story lines
Ask Yourself…

• Are the materials completely distinct, in a perceptual sense, from the marketing campaign?

+ Quack =
Study Recruitment Advertisements Should Not:

Misrepresent the Facts by Including Statements About:

- a broadened or misleading indication
- special/personalized medical care or attention
- state that the product is FDA approved when it is approved for a different indication than the one under study
Do Not Be:

Unduly influential

- Does the advertisement state that the investigational product is known to be the equivalent or superior to any other drug, biological, or device?

- Is the word “benefit” used to describe receipt of study procedures?
  - If yes, it must contain mention of the risks.

- Does the advertisement use terms such as, “new treatment”, “new medication”, or “new drug”?
  - The term “new” should not be present in this context, as it indicates false promises (e.g., “receive new treatments” leads study subjects to believe that they will be getting improved products of proven worth).
Do Not Be:

**Unduly influential**

- Does it promise “free medical treatment”?

- Does it use language such as:
  - “Earn cash”
  - “You will be paid”
Do Not Use:

Coercive language

- “We need your help”
- “Call today”
Do Not Be:

**Overly reassuring**

- Does the ad contain comments that would make someone think that they will be healthier or cured if they participate?

- Does it state that the investigational product is safe or effective for the purposes under investigation?

- Does it state “FDA approved” or “approved”?
Study Recruitment Advertisements – Study Acronyms

Is an acronym associated with the study?

• Best Practice: Encourage study teams to speak with Compliance from the start.

• Upon the acronym’s first use, include the official title of the study or a brief explanation.
  • For example: The ADHD TEMPO Study - This clinical research study is gathering data to help doctors determine the best time of day to administer the investigational non-stimulant medication in order to best address children’s ADHD symptoms.
Internet advertising

• The industry has no specific guideline or regulatory agency recommendations on this topic (Reminder: GCP applies here as well).

  • FDA public hearing of November 2009 did not result in additional guidance

• Compliance should be continually involved in review of web-based advertising and providing recommendations on a case by case basis
Points to Consider

- 61% of Adults look online for medical help
- The various social media outlets account for a total of BILLIONS of people
To be as brave as the people we help
Points to Consider – Web-based advertising

Risks Involved:

1. Advertising versus Promotion

2. Posting on sites controlled by third parties – no control on where your ad ends up (eg. website reputation, other adjacent ads etc.)
Points to Consider – Web-based advertising

3. Adverse Event Monitoring and Reporting

4. Risk of Data Contamination

5. Confidentiality/Privacy Issues ("Scraping")

6. Accounting for Minors/Location of Subjects

Note: Not all disease trials are ideal for online recruitment. For example, chronic disease patients are mostly offline.
Example: Social Media Recruiting

Acute lower back pain (with associated leg pain within the last 30 days)

Irritable Bowel Syndrome (predominantly diarrhea)

When participating in a study, all study medications and relevant medical assessments are provided at no cost, subjects will be compensated for their time after being qualified for a study.

To see if you qualify for a study, please call 770-986-3885
OR - click on the following link:

Visit us online at http://piercrinc.com/PICR Clinic

If link does not open, copy and paste link into your browser.

Flu Vaccines available call about the H1N1 vaccine
We also have all children and Adult Vaccines available now

We also do Immigration Physicals
and D.O.T. physicals

CPR/AED/First-aid ClassesGiven

PICR Clinic
Perimeter Institute for Clinical Research
1745 Old Spring House Lane
Suite 420
Atlanta, GA 30338
770-986-3885
www.piercrinc.com

Location: Atlanta
Compensation: compensation of $40.00-$70.00 will be paid if qualified for the study.
This is a part-time job.
Principal only. Recruiter, please don't contact the job poster.
Please call about this job and do not contact the job poster about other services, products or commercial interests.

PostingID: 1805107238

Compensation of $40.00-$70.00 will be paid if qualified for the study.
This is a part-time job.

Shire
To be as brave as the people we help
“Has anyone ever participated in a clinical trial....? What was the financial compensation? Bad or good experience? Please share.”
To be as brave as the people we help
Why Consider Social Media?

Facebook Scale

Rapid

#1 Daily

#1 in Time Spent

500M Worldwide
120M US
50% return daily

Source: Compete.com, US 30 day active, Oct 09

Source: Nielsen, Jan 2010

To be as brave as the people we help
Advertising & Social Media

• If social media are used for trial ads, be aware:
• Agencies (eg. FDA) apply the same set of rules regardless of the media used (traditional vs. internet)
  • Sponsored or controlled sites provide for more opportunity to minimize or mitigate risk

• Bloggers can generally say anything about a company’s products, processes, standards
  • trying to correct wrong information – is it beneficial?
  • do you know who posts as a patient or HCP?

• How would that impact adverse event reporting and our responsibilities? What are our monitoring responsibilities?

Lack of awareness is never an excuse!
So What’s the Solution?

- Same criteria in place for content regardless of information venue
- Begin allowing one/few social media venue at a time, noting all ways that interactivity must be disabled
- Strict Criteria Regarding Settings and Approval Process (extra steps)
- Provide written guidance for instructions regarding settings necessary
- Close vendor oversight is required; the fewer vendors are used across the company, the better
- Emergency Takedown Procedures: ads must be immediately removable as necessary
Facebook Ads

- Standard ads only
- “Liking” still possible on non-standard ads = Connectivity
- No video, streaming, polling, etc.
- Hyperlinks may be included that direct potential study subjects to the study center’s landing page.
- Since Facebook does not have a test environment, Compliance must be notified as soon as the advertisement is posted and a confirmation review will be conducted.
- Interactivity will only be one way only from company/study center to individuals acting as an “information concierge” rather than full social media network.
- Ads targeted by age, gender, and keyword
- Can view traffic driving to recruitment website (assess)
• When posting a classified ad, you must first click – “post to classifieds” then click – “community”, then “volunteer”. 

*Ads may only be classified under the “volunteer” category.*
Craigslist Continued

- No interactivity is allowed i.e. “It's NOT ok to contact this poster with services or other commercial interests” must be selected.
- Hyperlinks may be included that direct potential study subjects to the study center’s landing page.
- Since Craigslist does not have a test environment, R&D Compliance must be notified as soon as the advertisement is posted and a confirmation review will be conducted.
Example of Requested Facebook Ad

• **Clinical Trials Research: Click Here**

• Adults 18-45 who don’t use tobacco, see if you qualify for a Research Study in a city near you.

• May be compensated up to $1,050 for time.

Should this ad be approved?
Recent News

- **FDA’s Bad Ad Program**
  - Run by DDMAC
  - Urges doctors to report ads and sales pitches that violate FDA rules
  - FDA will offer doctors training at medical conferences to help spot misleading ads

- **What’s next??**
Conclusion

- Know the rules
- Is the ad promotional?
- Don’t be:
  - Coercive,
  - Unduly influential
  - Overly reassuring
- Be cautious with study acronyms
- Develop social media policy and/or guidance
- Recall the landscape: weighing risk/benefit are key
- Keep abreast of guidance and regulations to come
To be as brave as the people we help