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Note

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Concerns: Clinical trials in Belgium

Note on electronic information and digital campaign about a specific clinical trial using websites and social media

Introduction

Pursuant to the Belgian Experiment Act of 7 May 2004 (art 11), and the royal decree implementing the Belgian Law about Clinical Trials of 7 May 2017 (art 32), the modalities for patient recruitment in clinical trials must be **reviewed and approved by Ethics Committees as part of their review of a clinical trial application**.

Purpose of the note

This note aims at proposing guidelines for the development of electronic information or digital campaign about a specific authorized clinical trial, and its dissemination via social media in order to facilitate patient recruitment. Social media is defined by a website or application that enable users to create and share content. Users can also participate in social networking. This note does not in any way imply that the recruitment materials can be used to promote a company or product. It is clear that recruitment materials can under no circumstances, either directly or indirectly contain any kind of promotional message, be of a promotional nature, or have a promotional purpose.

The purpose of this note is to provide guidance about the use of the social media to inform the public about a specific authorized clinical trial, not to interact with the public or to directly perform some online screening.

Scope of application of the note

These guidelines are applicable for interventional clinical trials with medicinal products

However, these guidelines are not applicable for clinical trials in healthy volunteers because they are not adapted to some specificities of these trials for which for instance other recommendations in terms of accepted content of the digital campaign would be applicable (e.g. compensation information).

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A website as a basis for the electronic information or digital campaign about an authorized clinical trial

Who should own this website?

- The website can be hosted by the sponsor or by a delegate (third party). However, in any case, the website should not made explicit reference to the name of the sponsor **other than for the purpose of the identification of the host of the website** (see hereunder). Sufficient measures must be taken to avoid that direct contact between the sponsor and the patients is possible ***in the context of the clinical trial***. A warning should be included to mention that trial specific questions must be directed to the clinical trials site(s) and not the host of the website when it is the sponsor.

- However, in line with Book XII "Law of the electronic economy of the Code of Economic Law, specific details about the website host must be mentioned to render certain identification and informative data easily, directly and permanently accessible to the recipients of the service and competent authorities:
    - its name or trade name;
    - the geographical address at which it is established;
    - further details which allow for rapid, direct and effective contact, including e-mail address (not in the context of the clinical trial but to respond to the legal obligation in the Law of the electronic economy)
    - its company register number;
    - if the activity is subject to an authorization scheme, the particulars of the relevant supervisory authority;
    - if he exercises a regulated profession:
        - any professional body or organization with which he is registered;
        - the professional title and the country where it was granted;
        - a reference to the applicable professional rules and the means of accessing them;
    - if he undertakes an activity that is subject to VAT, his VAT-number;
    - the codes of conduct by which he is bound, as well as the information on how these codes can be consulted online.

The creator and host of the website is responsible for the content of the website. Therefore, if the creation and hosting of the website is delegated to a third party, this must be done under an adequate agreement with the sponsor of the trial.

Content of the electronic information/digital campaign (website, social media content)

1/ Elements to be present (min to be present, not an exhaustive list (e.g. images and visuals in line with the trial indication, a link to more information about the patient rights in the context of trials can be added), to be read in conjunction with the list of not accepted elements)

- Contact details for the participant:
  - Name and address of the department/service/clinical site(s) in charge of the research project

    or
  - Details that allow for rapid, direct and effective contact for further information:
    - E-mail address
    - Individual telephone or call center number
- Details about the trial
  - Scope of the trial
  - Express indication that the concerned product is still an investigational medicinal product
  - Disease concerned
  - Research project (short title of the trial)
  - Short overview of the major inclusion and exclusion criteria in comprehensive, general language (not the specific medical criteria intended for HCPs only)
  - Estimated period of participation to the trial
  - Mention that participation will not generate any additional cost for the patients
  - Recommendation for the patient to consult his/her treating physician
- Information regarding the fact that personal information may be recorded and will be protected according to Belgian privacy law and the European Regulation on data privacy
- The authorities (incl. concerned ethics committee) that have approved the clinical trial, and the fact that this approval should not be seen as an incentive to participate in the trial.
- it is recommended to add a link to a database where the trial can be found: e.g. the Famhp database, the EU register website, the ClinicalTrials.gov website, as well as a link to the last

version of the Belgian law of 7 May 2004 on clinical experimentation, the Belgian law of 7 May 2017 on clinical trials, the Belgian law of 22 August 2002 on patient rights,…

Note: Each company decide for itself whether or not it wishes to mention the name of the product (Brand name, INN, or identifier for trial use) in its communication. However, it remains the company's responsibility to ensure that all legislation is respected, in particular legislation relating to the promotion of medicinal products, on the basis of a case-by-case assessment.

2/ Elements not accepted**:**

- Any explicit or indirect reference to the sponsor in the context of the clinical trial and other than the one needed for the identification purpose of the host of a website
- Marketing or promotional language and images, technical or overly complicated medical language that is not adapted to the general public's needs
- Terms such as "new treatment", "new medicinal product" without further indication that these medicinal products are experimental medicinal product
- Wording such as "free medicines", which could make the patient believe that *all* care-related costs will be compensated for by the sponsor, while *only* charges related to procedures *specific* to the trial, other than standard of care, are borne by the sponsor.
- Any form of financial inducement, promise of payment, or amount for compensation. Only wording related to the principle of fair compensation for the patient (*i.e.* no additional cost for the patient) is authorized
- Any information related to direct or exaggerated potential benefit, and especially to benefits superior to those described in the protocol and the informed consent
- Any statement making believe in a positive outcome
- Any (implicit or explicit) statement that the investigational medicinal product is safe and effective in the context of the trial objective, or any statement that downplays the potential risks
- Any (implicit or explicit) statement that the investigational product medicinal product is equivalent or superior to similar products on the market
- Any exemption or exoneration statement about the responsibility of the sponsor

3/ Which information should be submitted to the responsible ethics committee for review?

The content of the social media or the website as well as the information about the ownership/hosting of the website should be submitted to the ethics committee for review before any dissemination.

Passive and limited active dissemination of the digital campaign ((paid) social media, website) about the authorized clinical trials

1/ Passive (one-way) dissemination of the link to the website with the information about the clinical trial by the sponsor

- Off-line dissemination to patients:
  - Via posters, flyers containing a link to the website in pharmacies, hospitals setting, physician's cabinets.
- On-line dissemination to patients
  - Via banners containing a link to the website that pop up in Google. Keywords triggering the pop-up of the banner must be defined and submitted for approval by ECs. The keywords cannot be linked to the company sponsoring the trial, nor to a product name
  - Via a link on hospital websites when possible
  - Via videos (e.g. on a website, on you tube)
  - Via patient organizations (however, no direct financial support can be given to the patient organization by the sponsor for this dissemination, such as support for printing organization)

For both off-line and on-line dissemination, the information and images on the poster or on the banner must be in line with the general principles listed in previous section.

- On-line dissemination to healthcare professionals:
  - By mailing by the sponsor (medical department) of the link of the website to potentially concerned physicians in Belgium

2/ Limited active (two-way) dissemination via social media by the sponsor

The active dissemination under the scope of this guidance can be done via social media such as but not limited to Facebook, Twitter, Instagram,… However, blogs are not under the scope of this guidance.

Creation and ownership of the account:

The social media page or account,… could be owned and managed by the sponsor or its delegate (independent third party). In the latest case this should be done under the agreement of both the sponsor and the third party.

Content of the media

The content of the message should be strictly in line with the content of the message on the website or in social media that has been approved by the ethics committee (see above). It should be submitted to the ethics committee for review and approval.

Access:

When possible (depending on the type of the social media), the access should be controlled and clearly defined by the sponsor. A plan for the targeting of the population should be submitted for approval to an ethics committee before the start of the digital campaign, as well as for the potential use of the consultation data for fine tuning of the targeting of the population.

Comments and reactions

When possible (depending on the type of social media), the sponsor should set-up a mechanism to avoid inappropriate posting and comments from the viewers via the social media (e.g. it is possible upon request to Facebook to block the comments for a Facebook page). When comments and reaction cannot be blocked, and potential interaction between the viewer and the owner of the account cannot be avoided and hardly limited, the sponsor should prepare standard responses in advance that are systematically used in case of reaction/comment. The sponsor should put in place *ad hoc* mechanisms to monitor the comments and to avoid inappropriate reaction such as participants in the concerned trial using for instance the social media to incentivize others to join.

Pharmacovigilance

The sponsor should regularly screen the digital media under their management or responsibility (owned, paid for or controlled by the sponsor). The frequency of the screening should allow reporting of valid cases to the competent authorities within the appropriate reporting timeframe based on the date of posting the information on the social media. If the management of the social media is outsourced by the sponsor, contracts with external partners should include the pharmacovigilance obligations.

When the pharmaceutical company becomes aware of an adverse drug reaction via the screening of these social media, the adverse drug reaction observed during the screening should be reported as spontaneous report.

Education

Such a dissemination via the social media should be accompanied by educational information/initiatives towards the participants in the concerned trials in order to avoid as far as possible for instance participants revealing their experience in the concerned trials and using it and the information about the trial to incentivize other people to join the trial.

Literature references used for the preparation of this guidance:

1. Using Social Media as a Research Recruitment Tool: Ethical issues and Recommendations, L. Gelinas, R. Pierce, S. Winkler, I.G. Cohen, H. Fernadez Lynch, B. E. Bieber, *AM J Bioeth.* 2017 March; 17 (3): 3-14
2. Social Media and the Practicing Hematologist: Twitter 101 for the Busy Healthcare provider, M.A. Thompson, N.S. Majhail, W.A. Wood, M-A Perales, M. Chaboissier, *Curr Hematol Malig Rep.* 2015 December; 10 (4): 405-412
3. Practical Guidance: the Use of Social media in Oncology Practice, D.S. Dizon, D. Graham, M.A. Thompson, L.J. Johnson, C. Johnston, M.J. Fisch, R. Miller, Journal of Oncology Practice 2012 September; 8 (5): 114-122