

COMISIA NATIONALA DE BIOETICA A  
MEDICAMENTULUI SI A DISPOZITIVELOR  
MEDICALE

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020125, Bucuresti , Romania

24 Apr. 2019

**Scrisoare de intentie pentru aprobarea textelor dedicate informarii generale a pacientilor, despre studiile clinice, prin intermediul unui website (www.studiiclinice.org/www.studiiclinice.ro) ce are ca scop informarea subiectilor si personalului medical**

Stimate Domnule Presedinte,

Va rog sa luati in considerare verificarea si aprobarea cadrului general al campaniilor pentru informarea pacientilor despre studiile clinice in diverse patologii, informatii care vor fi postate pe site-ul [www.studiiclinice.org/www.studiiclinice.ro](http://www.studiiclinice.org/www.studiiclinice.ro).

Pentru a veni in sprijinul demersului nostru, doresc sa fac urmatoarele precizari:

- In data de 17.07.2018 (Nr inregistrare 206 NP) CNBMDM a raspuns pozitiv cererii noastre de a realiza un website de informare in limba romana, despre studiile clinice, dedicat pacientilor si profesionistilor in domeniul sanatatii, inclusiv materialele dedicate pacientilor.
- Scopul website-ului este de a prezenta intr-o maniera nepromotionala si nepartinitoare, informatii publice generale legate de studiile clinice, de legislatia UE si internationala si de proiectele de cercetare in derulare in Romania.

Campaniile de informare ale pacientilor legate de studiile clinice in diverse patologii nu au un caracter promotional si au ca scop educarea pacientilor.

La aceste campanii participa medici si farmacisti.

Campaniile contin:

- Texte medicale adaotate pacientilor, provenite exclusiv din surse publice – unele sunt traduceri si adaptari ale materialelor similare de pe site-uri internationale de profil – cu acordul partenerilor din strainatate,
- Filmari testimoniale ale pacientilor participanti in studii clinice
- Interviu si aparitii in reviste de specialitate, televiziune, radio
- Minifilme informative pentru pacienti
- Numar de telefon dedicat informarii pacientilor
- Evenimente de tip workshop de educare a pacientilor
- Evenimente filmate cu raspunsuri la intrebarile pacientilor – raspunsuri furnizate de medici si farmacisti
- Informatii cu caracter general postate pe canale generale online

Materialele au fost gandite in bucati mici, pentru a putea fi citite repede si usor, intr-un limbaj simplu si nepretentios; conceptul prezentarii informatiilor a fost preluat de pe website-urile mari internationale

Tinem sa precizam ca toate informarile catre pacienti respecta normele GDPR, Protectiei Datelor cu Caracter Personal, 2016/679 in versiunea curenta OJ L 119, 04.05.2016.

Pe data de 19 Martie 2019, Scala Clinical Research a castigat premiul 'European Site Patient Recruitment Innovation Award' conferit de SCRS, Societatea Centrelor de Studii Clinice (societate ce reprezinta 9500 de centre medicale de studii clinice, in 47 de tari), pentru proiectul 'Navigatorul Pacientului in Studiile Clinice' materializat in Campania de Informare a pacientilor cu Colita Ulcerativa si Boala Crohn.

Va multumim inca o data

Cu sinceritate

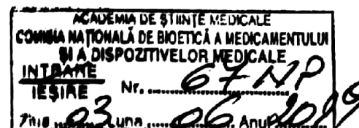
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ACADEMIA DE ȘTIINȚE MEDICALE  
Comisia Națională de Bioetică a Medicamentului și a  
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Către

Scala Clinical Research

În urmă studiului dosarului privind textele dedicate informării generale a pacienților despre studiile clinice prin intermediul website-ului [www.studiiclinice.org/www.studiiclinice.ro](http://www.studiiclinice.org/www.studiiclinice.ro), CNBMDM consideră că materialele prezentate îndeplinesc exigențele etice și pot fi utilizate.

Președinte CNBMDM  
Prof. Dr. Dinu Antonescu



NATIONAL BIOETHICS COMMITTEE OF  
MEDICINES AND MEDICAL DEVICES

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24 Apr. 2019

Cover letter for the approval of texts dedicated to general information for patients, on clinical trials, through a website ([www.studiiclinice.org/www.studiiclinice.ro](http://www.studiiclinice.org/www.studiiclinice.ro)) which aims to inform subjects and medical staff

Dear Mr. President,

Please consider reviewing and approving the general campaign framework to inform patients about clinical trials in various pathologies, which will be posted on [www.studiiclinice.org/www.studiiclinice.ro](http://www.studiiclinice.org/www.studiiclinice.ro).

In order to support our application, I would like to mention the following points:

- On 17<sup>th</sup> of July 2018 (Registration Nr. 206 NP) CNBMDM responded positively to our application to create an informational website in Romanian language about clinical trials, dedicated to patients and health care professionals, including patient-related materials.
- The purpose of the website is to present, in a non-promotional and impartial manner, general public information related to clinical trials, EU and international legislation and on-going research projects/clinical trials in Romania.
- Patient information campaigns related to clinical trials in various pathologies are not promotional and are aimed at educating patients.
- These campaigns are attended by doctors and pharmacists.

The campaigns contain:

- Medical texts adapted to patients, coming exclusively from public sources - some are translations and adaptations of similar materials from international sites - with the consent of foreign partners.
- (Video) testimonials of patients participating in clinical trials
- Interviews and appearances in specialized magazines, television, radio

- Short movies in informational purposes for patients
- Telephone number dedicated to patient information
- Patient education workshop events
- Filmed events with answers to patient questions - answers provided by doctors and pharmacists
- General information posted on general online channels

The materials have been thought of in small pieces, so they can be read quickly and easily, in simple and unpretentious language; the concept of information presentation has been taken from the major international websites Please note that all information to patients complies with GDPR, Personal Data Protection, 2016/679 in the current version OJ L 119, 04.05.2016.

On 19 March 2019, Scala Clinical Research won the European Patient Recruitment Innovation Prize, awarded by SCRS, the Society of Clinical Studies Centers (a society representing 9500 clinical medical centers in 47 countries) for the project 'Patient Navigator in Clinical Studies' materialized in the Patient Information Campaign with Ulcerative Colitis and Crohn's Disease.

Thank you once again.

Sincerely,

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ROMANIA

ACADEMY OF MEDICAL SCIENCES

Medical Bioethics Commission of Medicines and Medical Devices

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03.06.2019

To: SCALA CLINICAL RESEARCH

Following the examination of the file on the general patient information on clinical trials through the [www.studiiclinice.org/www.studiiclinice.ro](http://www.studiiclinice.org/www.studiiclinice.ro) website, CNBMDM considers that the presented materials meet the ethical requirements and can be used.

President of CNBMDM

Prof. Dr. Dinu Antonescu