D3.6 Clinical Trial 2 EudraCT

WP3 Clinical Trial 2
Lead beneficiary: Nederlands Kanker Instituut – Antoni van Leeuwenhoek
Dissemination level: PUBLIC
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Project

Grant agreement number	635342
Acronym	MoTriColor
Full title	Molecularly guided trials with specific treatment strategies in patients with advanced newly molecular defined subtypes of colorectal cancer
Website	www.motricolor.eu
EU Project Officer	Jan-Willem VAN DE LOO

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Deliverable

Deliverable title	D3.6 Clinical Trial 2 EudraCT
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Publishable abstract

The EudraCT number for MoTriColor Clinical Trial 2: 2016-002364-13

Version log

Version	Issue Date	Author	Changes
0.1	27/05/2016	C. Vianen (NKI-AvL)	First draft
0.2	30/05/2016	Y. Groot (NKI-AvL), Sanne Huijberts (NKI-AvL)	Internal review
0.3	01/06/2016	E. Chavarria (VHIO)	Review and comments
0.4	02/06/2016	S. Schrauwen (EORTC)	Review and comments
1.0	02/06/2016	C. Vianen (NKI-AvL)	Final version

DEFINITIONS

- **Consortium**: all the MoTriColor partners.
- **Grant Agreement:** the agreement signed between the beneficiaries and the European Commission for the undertaking of the MOTRICOLOR project (635342).
- **Partners** (also named as beneficiaries) of the MoTriColor Consortium are referred to herein according to the following codes:
    - Vall d'Hebron Institute of Oncology – VHIO
    - Institut Catala d'oncologia - ICO
    - Agendia N.V. - AG
    - Stichting het Nederlands Kanker Instituut-Antoni van Leeuwenhoek Ziekenhuis – NKI
    - European Organisation for Research and Treatment Of Cancer AISBL - EORTC
    - ASST Grande Ospedale Metropolitano Niguarda – ONCG
    - Fundación para la Investigación del Hospital Clínico de la Comunitat Valenciana – INCLIVA
    - Seconda Università degli Studi di Napoli – UNINA2
    - Universita Degli Studi di Torino - UNITO
    - Katholieke Universiteit Leuven – KUL
- **Project:** the sum of all activities carried out in the framework of the Grant Agreement.

ABBREVIATIONS

CT2: Clinical Trial 2

CTIMP: Clinical Trials of Investigational Medicinal Products

EudraCT: European Union Drug Regulating Authorities Clinical Trials

1. Introduction: EudraCT

1.1. EudraCT database

All Clinical Trials of Investigational Medicinal Products (CTIMPs) must be registered on the EudraCT database as defined by Directive 2001/20/EC. The aims of this database are to support supervision of CTIMPs, to facilitate communication between competent authorities, and to link with other databases such as EudraVigilance and the EU Clinical Trials Register.

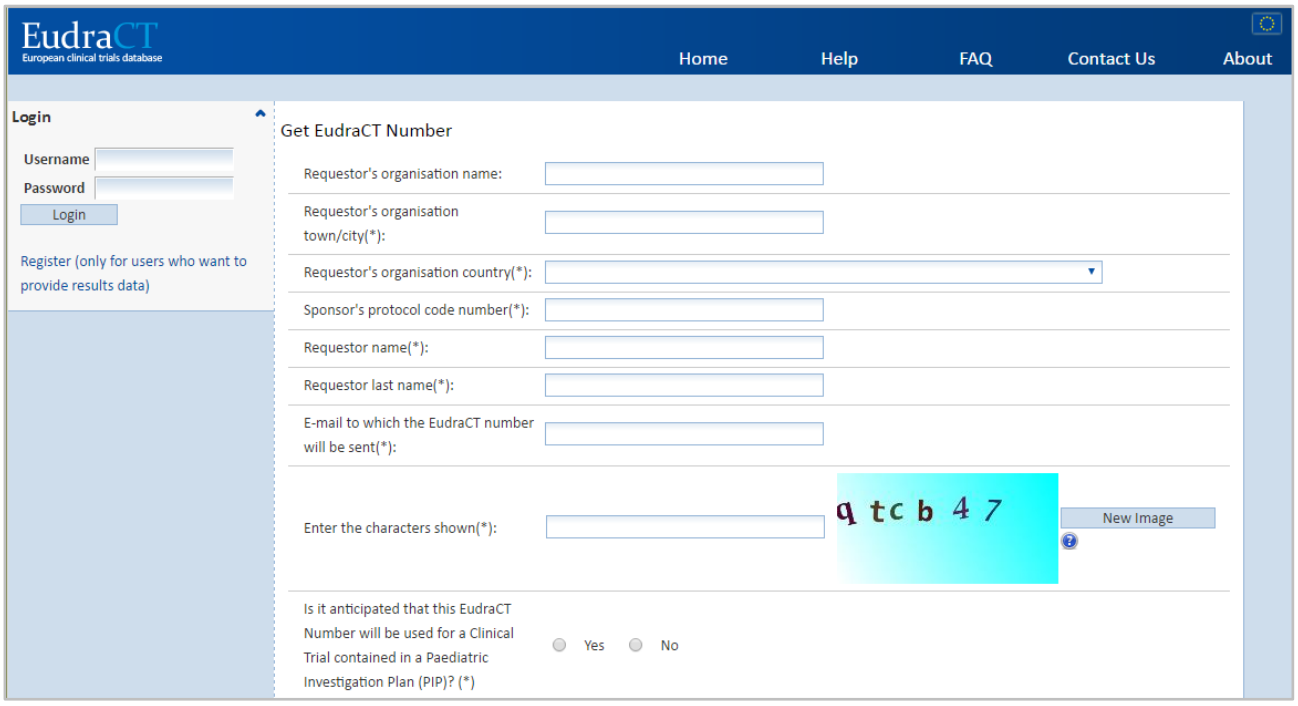
1.2. EudraCT number

According to the Directive 2001/20/EC, each trial must be issued with a unique EudraCT number. For this reason the MoTriColor consortium plans to request three different EudraCT numbers, one for each clinical trial (CT1, CT2, and CT3).

EudraCT number will be the main identifier for the trial. It should be included on all correspondence and documents regarding the protocol as for example protocol amendments and safety reports.

2. Applying for an EudraCT number

The application must be completed before submitting the clinical trial to any of the competent authorities where the trial will be running. In the case of MoTriColor, these countries are Belgium, Italy, Netherlands, and Spain. The application is made via the EudraCT website[1] by filling in the form shown in figure 1:



[1] https://eudract.ema.europa.eu/

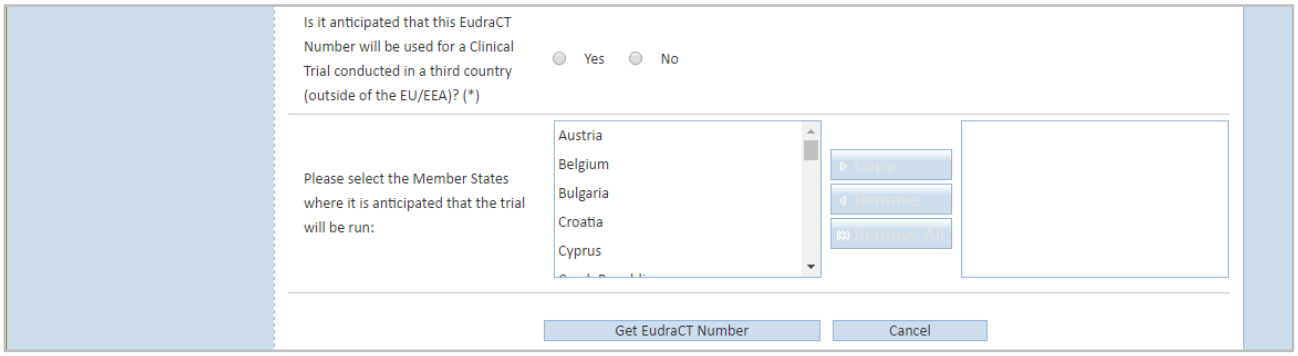


Fig. 1. "Create - EudraCT number" form

Once the form is submitted, a unique EudraCT number is generated with the format YYYY-NNNNNN-CC, where:

- YYYY is the year in which the number is issued
- NNNNNN is a six digit sequential number
- CC is a check digit.

An e-mail containing the EudraCT number (known as "EudraCT Receipt") is sent to the applicant. This email should be saved as PDF document and filed.

3. EudraCT for MoTriColor CT2

EudraCT number for MoTriColor CT2 has been requested by the Clinical Research Associate of the NKI-AvL. Figure 2 shows the EudraCT Receipt e-mail received by C. Vianen and confirming the EudraCT number.

From: noreply@eudract.ema.europa.eu
To: Carla Vianen
Subject: Application for EudraCT Number
Date: vrijdag 27 mei 2016 15:28:01

The EudraCT number 2016-002364-13 has been issued for your Sponsor's Protocol Code Number M16VIB.

THIS IS AN AUTOMATED EMAIL - PLEASE DO NOT REPLY AS EMAILS RECEIVED AT THIS ADDRESS WILL BE AUTOMATICALLY DELETED.

Fig. 2. e-mail "EudraCT Receipt"

To conclude, EudraCT number for Motricolor CT2 is:

EudraCT number 2016-002364-13