**Form Progress report**

*If the research has ended in the Netherlands, please fill in the form "Notification end of study"; In that case do not use the form "Progress report". Questions? Call Afdeling Toetsing Onderzoek (+31 88 7556376) or send an email to* *metc@nedmec.nl*

1. Sponsor of the trial/study: …………………………………………….…

Company/organisation: ……………………………………..……….

Department: ………………………………………………………….

Address: ………………………………………………………….…

ZIP code, city: ……………………………………………….

Name contact person: …………………………………………

Email contact person: ……………………………………

Telephone contact person: ………………………………………

1. Study title: ………………………………………………
2. Dossier number ToetsingOnline: NL…………………
3. On which date was the first study subject included in the study?

……………………..

1. How many study subjects have been included so far?

 Netherlands: ………………

 International: ……………….

1. How many study subjects should have been included according to planning?

Netherlands: ………………

 International: ……………….

1. What is the total number of study subjects what should have been included according to protocol?

Netherlands: ………………

International: ……………….

1. In case of multicenter research:

[ ]  not applicable

Number included subjects per approved participating centre in the Netherlands

Centre/number of subjects

…………………./……………….

…………………./……………….

…………………./……………….

…………………./……………….

…………………./……………….

1. How many study subjects in the Netherlands have completed the study according to protocol?

 ……………………………

1. How many study subjects stopped prematurely with the study?

 ……………………………….

1. How many study subjects stopped prematurely with the study for the following reasons?

[ ]  not applicable

[ ]  lack of efficacy: ……

[ ]  adverse effects: ……

[ ]  at own request: ……

[ ]  other, namely: ……

1. Were there serious adverse event/side effects?

[ ]  yes

[ ]  no

If yes, did you report these to the CCMO?

[ ]  yes

[ ]  no, please indicate why not?

………………………………………………………………………………

……………………………………………………………………………..

1. Are (were) there unexpected problems that prevent progress of the study?

[ ]  yes

[ ]  no

If yes, If yes, what kind of problems?

………………………………………………………………….

………………………………………………………………………

1. Is there a Data and Safety Monitoring Board, Monitoring Committee, Data Monitoring Committee appointed?

[ ]  yes

[ ]  no

If yes, did the committee give an advice?

[ ]  yes

[ ]  no

If yes, did the sponsor of the study follow this advice?

[ ]  yes

[ ]  no, for what reason: …………………………………………….

1. Were there amendments on the research protocol?

[ ]  yes

[ ]  no

If yes, how many? ………………………………

Were these reviewed by the CCMO?

[ ]  yes

[ ]  no

1. What is the expected end date of the study worldwide? ……………………….

Name (contact person sponsor):………………………………………….

Signature:…………………………. Date:………………