Medicinal Products for Human Use - NETHERLANDS

Competent authority

Contact Details	**Contact Name 1** Central Committee for Research Involving Human Subjects/ Centrale Commissie Mensgebonden Onderzoek (CCMO) **Contact Name 2** F.a.o. Competent authority (CA) **Phone** + 31 70 340 6700 **Email General** ccmo@ccmo.nl **Email Department** bi@ccmo.nl **Address** PO Box 16302 **ZIP/City** 2500 BH The Hague **Country** Netherlands (NL) **Web address** http://www.ccmo-online.nl **Additional Information** NB! Email if CCMO acts as CA: bi@ccmo.nl
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s) **CA - Submission for authorisation mandatory for** Clinical IMP trials Clinical ATMP trials **CA - Registration/ notification without approval required for** – **CA - Submission required to** National CA **Specific Competent Authority for ATMP trials in place** Yes **Competent Authority for ATMP trials** Ministry of Health, Welfare and Sport (VWS)

National trial registry - Registration mandatory

Yes

National trial registry

The Nederlands Trial Register (NTR)

National legal framework in place

Yes

Applicable national legal framework/ Reference

Section 13i(5) WMO (en)

Additional Information

Clinical trials must be submitted to the relevant CA (CCMO or VWS) for a second extra marginal assessment (alongside the EC's review).

Concerned CA:
• CCMO: acting as CA for research with a MP that is reviewed by an accredited MREC.
• VWS: for research with a MP that is reviewed by the CCMO as reviewing EC

Submission of Application

Responsible for study submission

Sponsor
Legal representative domiciled in the EU/EEA

Entitled to study submission

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Prerequisites for submission

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Guidance on submission of application available

Yes

Guidance on submission of application

Further information on application procedure to CA is provided on the CCMO website in section: Home>Investigators>Research with a medicinal product & extra review competent authority>Primary submission to the competent authority

Additional Information

Information regarding ATMP and other involved authorities is provided on the CCMO website in section:
Home>Investigators>Types of research>Research on gene therapy/medicinal product with GMO.

Both reviews (EC and CA) can take place simultaneously

Submission Format

Format option(s)

Regular mail
Data carrier (USB key)

Preferred format

cd-rom (cd-r or cd+r) by post (in one package)

Standard application form - Additional information

The application dossier („the research file") to be submitted to the CA is the same as the file for submission to the reviewing committee.

Language of Submission	**Language(s) of application** Official national language English **Preferred language of application** – **English accepted** Partly, not for all documents **Documents mandatory to be in official national language** Information material, Documents and Forms intended for study participants and patient information **Additional Information**
Submission Fees	**Fees for trial submission mandatory** No **Fees** CCMO & VWS review is free of charge.
Timelines Authorisation	**General timespan (max nr days)** 14 **Mode of approval (General)** Explicit **ATMP/GMO trials (max nr days)** – **Mode of approval (ATMP/GMO trials)** – **External expert advice required (max nr days)** – **Xenogeneic cell therapy (max nr days)** – **Mode of approval (Xenogeneic cell therapy)** – **Timespan counted from** Date of submission of valid application **Applicable national legal framework/ Reference** Related information is provided on CCMO website in section Home>Investigators>Research with a medicinal product & extra review competent authority>Timelines competent authority **Additional Information** NB! No confirmation of receipt of application is sent by CA. In case of no motivated objections, the CA issues a ‘No grounds for non-acceptance’ by email to the applicant and the reviewing committee. The e-mail is sent to the registered user of the research file concerned in ToetsingOnline. Any motivated objections are made known by post.

Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** All clinical investigations requiring authorisation by CA **Responsible for submission of SA** Sponsor **Standard notification form available** Yes **Standard notification form** EudraCT Notification of Amendment Form (B5) + cover letter (A1) (Mandatory to use!) **Timeline for approval of SA (max nr days)** 35 **Guidance on submission of SA available** Yes **Guidance on submission of SA** Further information and templates for the mandatory notification form to be used (EudraCT Notification of Amendment Form (B5)) and the cover letter (A1) are provided on the CCMO website in section Home>Investigators>Research with a medicinal product & extra review competent authority >During and after the research & the competent authority **Additional Information** Submission format: by email (max 8 MB) or by cd-rom Timespan of approval counted from receipt of complete submission. NB: no confirmation of receipt is sent by CA! If the CA has no objections, a 'No grounds for non-acceptance' is issued per e-mail. The e-mail is sent to the registered user for the file concerned in ToetsingOnline.
Safety Reporting	**Responsible for AE reporting to CA** Sponsor Legal representative domiciled in the EU/EEA **Sponsor must declare reportable events to** – **Investigator/PI shall separately report any SAE /SADE to CA** No **Reportable AEs** SAE (Serious Adverse Event) SUSAR (Suspected Unexpected Serious Adverse Reaction) **SUSAR being life-thereatening or leading to death must be reported** Within a max of 7d upon first knowledge (+ 8d for additional information) **All other SUSARs** Within a max of 15d upon first knowledge **SAE /SADE must be reported** –

National standard reporting form available

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Reporting format - Options

(1) Online Portal for investigator initiated research: As of the 1st of January 2010 investigators are required to report serious effects and events (SUSARs and SAEs) via ToetsingOnline. (2) Other: by e-mail (maximum 8 MB) or by cd-rom

Preferred format

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Online Safety Reporting Portal

Toetsing Online (for investigator initiated research)

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA

Guidance on AE reporting procedure available

Yes

Guidance on AE reporting procedure

Related information and examples of completed SAE and SUSAR form fromToetsing Online are provided on the CCMO website in section: Home>Investigators>During and after the research>SAEs/SUSARs

National legal framework in place

Yes

Applicable national legal framework/ Reference

SAE reporting requirements on medicinal products are regulated by section o-q WMO (en)

Additional Information

General reporting obligations in the Netherlands:
SUSARs have to be reported to:
• the reviewing committee (MREC/METC or CCMO)
• the CA (CCMO or VWS)
• the Medicines Evaluation Board (MEB)

NB! Specific reporting obligations:
• Multi-national trials: SUSARs must be reported to the CA in other involved EU member states (depending on the country-specific reporting regulations). If the SUSAR has already been reported in the EudraVigilance database, then declaration to the national CA is not required. Note: SUSARs shall not be reported twice!
• Gene Therapy: SAEs and SUSARs which occur during a research on gene therapy must also be reported to the Gene Therapy Office.

Note: any reports to the CA must be submitted digitally. The CA does not send a confirmation of receipt.

Investigator shall report SAE to

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Reporting timeline

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End of Trial

End of trial declaration mandatory for

Multi-national trials (declaration of global end)

Responsible for End of trial declaration

Sponsor

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

–

Early/premature Termination - Declaration timespan (max nr days)

15

Reasons for early termination shall be clearly stated

Yes

Standard Declaration form available

Yes

Standard Declaration form

EudraCT-form End of Trial (B7)

Additional Information

Premature termination: shall be notified this within 15 days to the reviewing committee (MREC or CCMO) and, in case of a research with a medicinal product, also to the CA (CCMO or VWS) and CA of other member states stating the reason for termination.
National trials: Regular trial termination need not be notified to the CA.

Additional Information & Specifics

Additional Information

Research with a medicinal product must undergo an extra, marginal review carried out by the CA (CCMO or Ministry of Health, Welfare and Sport) alongside the review by the reviewing committee (dual reviewing system). Both reviews can take place simultaneously.

The Ministry of Health, Welfare and Sport published a comprehensive folder providing detailed guidance on how to conduct clinical reseach with medicines in the Netherlands in compliance with the regulatory requirements:
Clinical Research with medicinal products in the Netherlands - Instruction Manual.

National Portal: ToetsingOnline is an internet portal for the submission, review, registration and publication of medical research involving human subjects. The portal is only used for clinical research which falls under the scope of the WMO (en).

Ethics committee

Contact Details

Contact Name 1

Medical Research Ethics Committees MRECs/METCs

Web address

http://www.ccmo.nl/en/accredited-mrecs

Additional Information

Links to the 24 accredited MRECs/METCs and their contact data are provided on the CCMO website (see provided web address).

Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission to CA and EC to be performed in the following order** – **Additional Information** Clinical trials must be assessed by a reviewing EC based on the WMO (en). Reviewing EC: The law determines whether a research must be reviewed by the CCMO or an accredited MREC/METC. This is laid down in the Central Review Decree (Besluit Centrale Beoordeling, BCB). Both the accredited METCs and the CCMO are independent governmental bodies with a legal status that reach a legally binding decision on research protocols, and thus are not advisory boards. In practice, accredited MRECs/METCs review the vast majority of the research protocols. Most of them are linked to an institution such as an academic medical centre or a hospital. An accredited MREC/METC determines the region it covers with regards to reviewing research. However, in practice, the majority of MRECs review for the whole of the Netherlands. CCMO is the competent reviewing EC for: • Appeal aginst a negative desicion of a MREC/METC • Non-therapeutic interventional research with minors and incapacitated adults • Research with vaccines (only unauthorised vaccines since the 1st of November 2009) • Research in the field of cell therapy and gene therapy/medicinal products with GMO (genetically modified organisms), embryos and human gatemetocytes • Etc. • Further information on competence of MREC and CCMO is provided on CCMO website in section: Home>Investigators>Review procedure> Reviewing committee: MREC or CCMO **Regulatory and ethics bodies involved in approval process** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Accredited MREC/METC (regional EC) OR the CCMO (national EC) **Additional Information** Ethical approval from an accredited MREC/METC or the CCMO is required for single-centre trials. The type of reviewing EC depends on the type of research. In general, the accredited MREC/METC of the region where the chief investigator is located is designated the reviewing committee. But sponsors can in principle choose any accredited MREC/METC that meets the requirements. The approval of the board of directors of the participating center at which the MREC/METC is located is required.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Only one accredited MREC/METC or the CCMO (both acting as "Lead EC") **Submission of application required to** Lead EC (authorised to issue a single opinion)

Additional Information

Ethical approval from only one accredited MREC/METC or the CCMO is required for multi-centre trials.
The majority of the MRECs/METCs review multicentre research for all of the institutions in the Netherlands.

The type of reviewing EC depends on the type of research.
However, the approval („reserach declaration“) of the board of directors from each of the participating sites is required for execution of the study in its own institution.

Ethical Review procedure for multi-centre trials is specified on the CCMO website in section: Home>Investigators>Review procedure>Multicenter research

Submission of Application

Responsible for study submission

Sponsor
Legal representative domiciled in the EU/EEA

Entitled to study submission

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Prerequisites for submission / approval

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Guidance on study submission available

Yes

Guidance on study submission

The procedure for the submission and the content of the application dossier („research file“) are provided on the CCMO website in section: Home>Investigators >Primary submission or Home>Investigators >Standard Research file

National legal framework in place

Yes

Applicable national legal framework/ Reference

The requirements of the standard research file are based on WMO (en) and the Regulation for scientific research with medicinal products.

Additional Information

The research declaration(s) of participating centres shall be obtained by the sponsor and submitted within 14 days of the initial submission of the research file.

Radiation/Radiotherapy/antibiotics: Most METC/MREC will require a signed statement approving the study from the concerned hospital department.

Submission Format

Format option(s)

Data carrier (USB key)
Paper hardcopy

Preferred format

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Guidance on submission format available

Yes

Guidance on submission format

Detailed information on submission format is provided on the CCMO website in section Home>Investigators>Primary submission>Digital or hard copy

	Additional Information The required format depends on concerned reviewing committee (1) Accredited MREC: preferred format (hard copy or digitally) may differ between the competent ECs. (2) CCMO: Digitallly, as pdf-file in one package on a cd-rom. NB! The signed cover letter must be in hard copy for both the primary submission and the submission of substantial amendments to the reviewing committees (MRECs and the CCMO).
Language of Submission	**Language(s) of application** Dutch, English **Preferred language of application** – **English accepted** Partly, not for all documents **Documents mandatory to be in official national language** Information material, Documents and Forms intended for study participants and patient information **Additional Information** Clinical Trial Application may be written in English or Dutch.
Submission Fees	**Fees for Ethical review** CCMO review is free of charge. MREC/METCs charge varying reviewing fees for commercial and inverstigator driven/academic trials. There is no national agreement on the costs. Further information on respective fees of the accredited MRECs/METCs can be found on the CCMO websites in section: Home>MRECs>Accredited MRECs
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** max. 8 weeks, may be prolonged by another 8 weeks if METC needs more time **General timespan for multi-centre studies (max nr days)** max. 8 weeks, may be prolonged by another 8 weeks if METC needs more time **ATMP/GMO trials (max nr days)** 90 **External expert advice required: Timespan (max nr days)** – **Xenogeneic cell therapy: Timespan (max nr days)** No time limit **Clock-stop possible if complementary information requested** Yes **Timespan counted from** Date of submission of valid application

	Applicable national legal framework/ Reference Related information is provided on the CCMO website in section Home>Investigators>Primary submission to the reviewing committee>Timelines reviewing committee
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments **Responsible for notification of SA** Sponsor **Standard notification form available** Yes **Standard notification form** EudraCT Notification of Amendment Form (B5) NB: mandatory to be used **Timeline Ethical review of SA (max nr days)** 35 **Guidance on submission of SA** The templates for the forms and cover letter and related information is provided on the CCMO website in section Home>Investigators>During and after the research >Changes to the research file (amendments) **National legal framework in place** Yes **Applicable national legal framework/ Reference** Section 13(k) WMO (en) **Additional Information** Submission format: The signed cover letter must be in hard copy for the submission of substantial amendments to the reviewing committees (MRECs and the CCMO). All other documents which are part of a substantial amendment, are to be sent on cd-rom (together with the hard copy cover letter) Supplementary information is provided in the European CT-1-Guidance document: 'Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial'
Safety Reporting	**Reportable AEs** SAE (Serious Adverse Event) SUSAR (Suspected Unexpected Serious Adverse Reaction) **Investigator shall report SAE to** Sponsor **Reporting timeline** Immediately (without delay) **Responsible for AE reporting to relevant EC(s)** Sponsor **SUSAR being life-thereatening or leading to death must be reported** Within a max of 7d upon first knowledge

	All other SUSAR must be reported Within a max of 15d upon first knowledge **SAE/SADE must be reported** – **National Standard Reporting form available** Yes, electronic form of online portal 'Toetsing Online' **Reporting format - Options** Online portal **Preferred reporting format** Online portal **Online Safety Reporting Portal** Toetsing Online. SUSAR is then sent automatically to all involved parties **Guidance on AE reporting procedure available** Yes **Guidance on AE reporting procedure** Related information and examples of completed SAE and SUSAR form fromToetsing Online are provided on the CCMO website in section: Home>Investigators>During and after the research>SAEs/SUSARs **National legal framework in place** Yes **Applicable national legal framework/ Reference** SAE reporting requirements on medicinal products are regulated by section o-q WMO (en).
End of Trial	**End of trial Declaration mandatory** Yes **Responsible for End of trial Declaration** Sponsor **Regular Termination - Declaration timespan (max nr days)** 90 **Timespan counted from** – **Early/premature Termination - Declaration timespan (max nr days)** 15 **Reasons for early termination shall be clearly stated** Yes **Standard Declaration form available** Yes **Standard Declaration form** EudraCT-form End of Trial (B7)

Guidance on End of trial declaration

CCMO website in section Home>Investigators>During and after the research>End of study

Applicable national legal framework/ Reference

Section 13(l) WMO (en)

Additional Information

The date of the global end of trial shall be declared within 90 days to the reviewing committee (MREC or CCMO) and to the CA (CCMO or Ministry of Health, Welfare and Sport), using the EudraCT-form End of Trial (B7).

Submission Format:
CCMO (if reviewing committee) by post or digitally to tc@ccmo.nl
MREC/METC: variable

Additional Information & Specifics

Additional Information

National Portal: ToetsingOnline is an internet portal for the submission, review, registration and publication of medical research involving human subjects. The portal is only used for clinical research which falls under the scope of the WMO (en).

Study specific Requirements

Sponsor

Sponsor - Definition available in national law

Yes

Sponsor - Definition (pursuant to national law)

Sponsor - Definition according to section 1 WMO (en):
“The party who commissions the organisation or conduct of clinical trials; an individual, company, institution or organisation responsible for the initiation, management and/or financing of the clinical trial”.

Sponsorship mandatory - Additional information

The sponsor or legal representative of the sponsor must be established within the territory of the European community (pursuant to section 13d WMO (en).

Co-Sponsor - Definition available in national law

No

Co-sponsorship allowed

No

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Yes

Standard IC form (ICF)

Templates for the Dutch informed consent form, the Dutch Patient Information Form (PIF) and for other information material for research subjects are provided on the CCMO website in section Home>Investigators>Standard research file (E. Information for the research subjects)

IC is regulated by law

Yes

Informed Consent - Definition/ Requirements

“informed, written, dated and signed consent to take part in a clinical trial” (pursuant to Section 1(1.u) WMO (en))

Applicable national legal framework/ Reference

Special provisions regarding informed consent including consent obtained in vulnerable populations are specified in section 6 of WMO (en)

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Not specified

Specific provision

Clinical trials including minors are possible under special provisions according to the section 4, 6 and 13(e) of WMO (en)
The WMO applies the “no, unless” principle.

Related information and specific documents (“Non-therapeutic research on minors and incapacitated subjects: 'no, unless” and “Code of conduct involving minors”) are provided on the CCMO website in section: Home>Investigators>Types of research>Research with minors

Legal framework/Reference (Minors/Children)

Section 4, 6 and 13(e) of WMO (en)

Incapacitated persons - Studies allowed

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Specific provisions

Clinical trials including minors are possible under special provisions according to the section 4, 6 and 13(f) of WMO (en)
The WMO applies the “no, unless” principle.

Related information and specific documents (“Non-therapeutic research on minors and incapacitated subjects: 'no, unless”) are provided on the CCMO website in section: Home>Investigators>Types of research>Research with incapacitated adults

Legal framework / Reference (Incapacitated persons)

Section 4, 6 and 13(f) of WMO (en)

Emergency situations - Studies allowed

Witnessed oral consent

Specific provisions

Clincial trials in emergency situations are possible under special provisions specified in section 6(4) WMO (en)

Emergency situation without prior consent of patient or proxy - Studies allowed

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Conditions allowing trial participation in emergency setting without prior consent

„If the clinical trial can be conducted only in medical emergencies in which the consent required pursuant to subsection 1 cannot be given and if inclusion in the trial may benefit the person in urgent need of medical treatment, procedures to implement the trial may be undertaken without such consent for as long as circumstances continue to prevent the giving of consent.“

Legal framework / Reference (Emergency Situation)

Section 6(4) WMO (en)

Pregnant or breastfeeding women - Studies allowed

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Specific provisions

No legal reference

Study Participants - Compensation & Reimbursement

Reimbursement for study participants

Optional

Compensation is limited to/provided for

Inconvenience, Pain, Discomfort
Expenses arising from study participation (e.g. Travel)

Additional Information

Reimbursement of patients/ healthy subjects:
• Patients: travel expenses will be reimbursed.
• Healthy volunteers: Compensation is possible and depends on length and load (number of measurements and possible discomfort) of the study. The fee does not depend on the risk of research and is based on the minimum wage. The reviewing committee checks the level of compensation.

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

No

Approval/ authorisation required

No

Specific notification timelines before operations start

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Language of notification

–

Notification format

–

Data Protection Authority/ Agency - Contact Details

Dutch Data Protection Authority (DPA) / College Bescherming Persoonsgegevens (CBG)

Phone

(+31) - (0)70 - 888 85 00

Fax

(+31) - (0)70 - 888 85 01

Web address

http://www.cbpweb.nl./en/

Address

PO Box 93374

ZIP/City

2509 AJ The Hague

Country

Netherlands (NL)

Additional Information

Dutch Personal Data Protection Act (unofficial English translation) / Wet Bescherming Persoonsgegevens WBP lays down the main rules for handling and protecting personal data. It has been translated into a code of conduct known as the Use of Data in Health Research (Code Goed Gedrag)

The DPA is the supervisory body and monitors the compliance with the laws governing the use of personal data.
NB! There is a new law that enables the Dutch goverment to give (very, very high) penalties (in euros) if you break the law on this point.

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

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Insurance

Liability insurance or alternative arrangements for damages mandatory for

Investigator(s)
Sponsor
Study participants

Responsible for covering insurance

Sponsor

National legal framework in place

Yes

Applicable national legal framework/ Reference

Insurance Decree (Verzekeringsbesluit) - 1th of July 2015 &
Section 7 WMO (en)

Additional Information

The sponsor is responsible to insure study subjects against any potential damages incurred as a result of participating in the research and make provisions for insurance to cover the liability of the investigator and the sponsor.
The adapted Insurance Decree (Verzekeringsbesluit) came into force as of the 1th of July 2015 and applies to research issued a positive decision by an accredited MREC or the CCMO after the 1st of July 2015.
The Insurance Decree contains the rules for the obliged insurance for research subjects.
Amongst the changes is the new rule that the sponsor ensures that any potential damages for all participating human subjects of a research are covered and research subjects who participate in multicentre research in the Netherlands must be covered by a single research subject insurance.
Research applicants are also required to submit a Research subject insurance declaration.

Related details are provided on the CCMO website in section:
Home>Investigators>Standard research file (G. Insurance information) and Home>News archive>Consequences of the new Insurance Decree and CCMO Directive External Review as of 1st July 2015

Quality Assurance/ Quality Control (QA/QC)

Monitoring

Compulsory

Audit by sponsor

Optional

Standard Operating Procedures (SOPs)

Optional

Additional Information

NB! This depends on the risk classification of the study

National legislation

General Information: Applicable Legislation & Conventions

Official website providing relevant national legislation available

Yes

Official website providing relevant national legislation

http://www.ccmo.nl/en/national-legislation-dutch

Official governmental legal database available

Yes

Official governmental legal database

http://wetten.overheid.nl/

Additional Information

A list of applicable national legislation (in Dutch, some in English) is provided on the CCMO website in section: Home>Library>Legal framework>National legislation (Dutch).

Clinical Trials on IMPs in Humans

Applicable national regulations

Transposition of (CT) Directive 2001/20/EC
Transposition of (GCP) Directive 2005/28/EC

Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)

Medical Research Involving Human Subjects Act -Unoffical english translation: WMO (en)/ Wet medischwetenschappelijk onderzoek met mensen- WMO (Dutch) Transposition of Directive 2001/20/EC and 2005/28/EC, came into operation on 1 March 2006 Minor chang

Transposition of (GCP) Directive 2005/28/EC

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Other applicable regulations/ implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)

Regulation for scientific research with medicinal products:
covering the implementing rules for scientific research with medicinal products

Insurance:
Insurance Decree (Verzekeringsbesluit)
The adapted Decree came into force as of the 1th of July 2015 and applies to reserach issued a positive decision by an accredited MREC or the CCMO after the 1st of July 2015.

) CCMO External Review Directive 2012 (RET 2012)
The RET 2012 applies to all multicentre research that falls under the Medical Research Involving Human Subjects Act (WMO), whether it is research with a medicinal product or not.
NB! Update not available in English yet

Additional Information

WMO: Minor changes implemented in 2012 have not yet been translated to English.
NB! A recent amendment to WMO on reporting requirements of serious adverse events (SAEs) will come into force on October 1, 2015 (published in the Government Gazette in Dutch)

Gene Therapy	**Specific requirements** Yes **Applicable legal framework** Gene therapy trials are covered by WMO (en) **Additional Information** According to section 13 (c) it is prohibited to conduct gene therapy trials which are intended to result in modifications to the subject's germ line and genetic identity. Related information on specific requirements regarding clinical trials on gene therapy and ATMP are provided on the CCMO website in section: Home>Investigators>Types of research>Research on gene therapy/medicinal product with GMO
Data Protection	**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** – **National DP act** Dutch Personal Data Protection Act (unofficial English translation) / Wet Bescherming Persoonsgegevens WBP
Additional Information & Specifics	**Additional Information** Research involving embryos and gametes: Embryowet (Dutch)/Embryos Act (en)

Definition

IMP/IMP Study	**IMP - Definition available in national law** Yes **IMP - Definition** 'Any pharmaceutical form of an active substance or placebo which is being tested or used as a reference in a clinical trial, including any product which already has a marketing authorization but is used, assembled, formulated or packaged in a way different from the authorized form, or is used in the trial for an unauthorized indication or to gain further information about the authorized form.' Reference: Section 1(o) WMO (en) **IMP Study - Definition available in national law** Yes **IMP Study - Definition** 'An investigation intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of any investigational medicinal product, and/or to identify adverse reactions to any investigational medicinal product and/or to study the absorption, distribution, metabolism and excretion of any investigational medicinal product with the object of ascertaining its safety and/or efficacy.' Reference: Section 1(n) WMO (en)