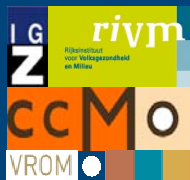


The central desk for Gene Therapy ...

Streamline assessment procedures

Harm Hermsen



Central desk for Gene Therapy

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The Netherlands

Assessment of scientific research that involves human beings



Environmental risk assessment

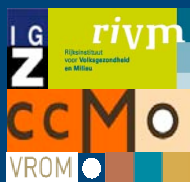


GMO office

Assessment of Batch safety of a gene therapy product that is based on immunological principles



Centre for Biological medicines and medical technology



Central desk for Gene Therapy

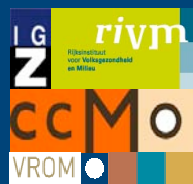
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**Central Desk
For
Gene Therapy**



Central desk for Gene Therapy

PO Box 1

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The Netherlands

Preliminary consultation

Application

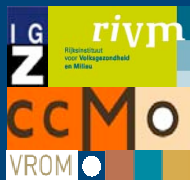
Tips

Amendments

Adverse events

Periodical communications

Contact



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GENERAL

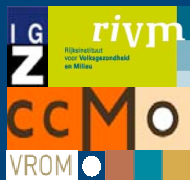
KPreceding the official application

KBased on a concept application

AIM AND STATUS

KAccelerate assessment procedures

KSeparate from official deadlines



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PREPARATION BY THE APPLICANT

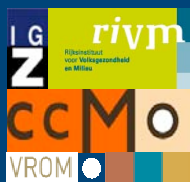
Submit a complete concept application

Submit questions at least 4 weeks prior to the preliminary consultation

ORGANISATION

Meeting is chaired by a member of the COGEM or the CCMO

Report of the meeting within 2 weeks after the meeting



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PROCEDURE

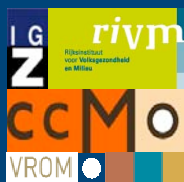
KApplication must be submitted to the Central desk for gene therapy by means of the joined application form and the necessary information

KThe application will be dispersed to the involved offices

KEvery application will be assigned to a case manager that is responsible for the particular assessment at one of the involved offices

KAnnouncement of decisions on an application via the Central desk for gene therapy

KDeadlines for assessment remain unchanged



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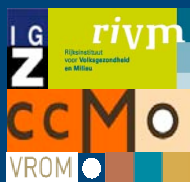
Use the possibility of a preliminary consultation

Try to avoid partial assessment procedures

In case a partial assessment is unavoidable try to start with the VROM application

It is suggested to allow the Central desk for gene therapy to share the information with all assessment offices

Use the possibility of a preliminary batch assessment (IGZ). A preliminary batch assessment can be started even in case not all QC data are available



Central desk for Gene Therapy

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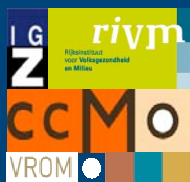
PROCEDURE

KAmendments must be submitted to the Central desk for gene therapy

KCentral desk for gene therapy informs all assessment offices

KSubmission guidance is provided in the “leidraad”

KAnnouncement of decisions via the Central desk for gene therapy



Central desk for Gene Therapy

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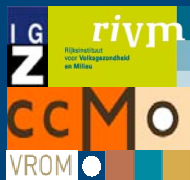
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Use the adverse effect notification form

Send notification in triplicate to the
Central desk for gene therapy

Announcement of decisions via the
Central desk for gene therapy



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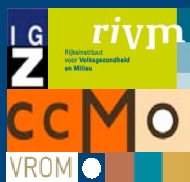
Progress report CCMO

Progress report VROM

These reports include:

- Number of included patients
- Number of dropped patients
- (Suspected) adverse events
- Safety of the patients
- Unsuspected environmental effects

Submit at the Central desk for gene therapy



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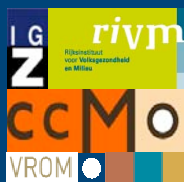
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Central desk for Gene Therapy

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