Central Committee on Research Involving Human Subjects

New directive makes use of Site Suitability Declaration (VGO) obligatory for research with a medicinal product as of 1 November 2021

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CCMO's directive on the assessment of the suitability of research centres (TGO) has been adopted and will apply to studies with medicinal products submitted for review from 1 November 2021 onwards. This directive replaces the current CCMO External Review Directive (RET 2012) for research with medicinal products.

The existing Research Declaration has been replaced in the TGO directive by a signed part A of the Site Suitability Declaration [Verklaring Geschiktheid Onderzoeksinstelling, VGO]. The VGO is part of the new procedure for local feasibility, drawn up by the Dutch Clinical Research Foundation (DCRF), in which the process of feasibility in the participating centres has already been started before the review committee (accredited MREC or CCMO) assesses the research file. By signing part A of the VGO, the executive board/management declares that its research centre is suitable to conduct the intended study.

The aim of the new local feasibility procedure is to ensure that clinical trials can be started more quickly, in accordance with the EU Clinical Trial Regulation (CTR).

The TGO directive will be applicable to research with a medicinal product only as of 1 November 2021. This means that use of the VGO will become obligatory for all new research with a medicinal product as of 1 November 2021. It will then no longer be possible to use the Research Declaration for these studies.

For other research subject to the Dutch Medical research involving human subjects Act (WMO), the TGO directive will become applicable in mid-2022. However, until then it is possible to use the VGO voluntarily for such research.