Central Committee on Research Involving Human Subjects

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

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As of 1 November 2021, use of the Site Suitability Declaration [Verklaring Geschiktheid Onderzoeksinstelling, VGO] will become obligatory for research with a medicinal product.

The VGO is part of the new procedure for local feasibility which has been developed by the Dutch Clinical Research Foundation (DCRF) together with its affiliated partners and CCMO. This procedure ensures that the procedures for local feasibility in the participating centres start up before the review committee (accredited MREC or CCMO) assesses the research file.

Since 1 December 2020, sponsors are allowed to use the VGO for the assessment of the suitability of the participating centres. As of 1 November 2021, use of the VGO will become obligatory for research with a medicinal product. From then on, it will no longer be allowed to use the current Research Declaration [Onderzoeksverklaring] for research with a medicinal product. CCMO's External Review Directive (RET) will be amended accordingly.

In 2022, the obligation to use the VGO for other research subject to the Dutch Medical Research Involving Human Subjects Act [Wet medisch-wetenschappelijk onderzoek met mensen, WMO] will be phased in. However, until then it is possible to use the VGO voluntarily for such research.

The DCRF and CCMO will continue to monitor the procedure and use of the VGO for research with a medicinal product. An evaluation is planned for mid-2022.