Pedmed-NL **Standard Operating Procedure**	**SOP No: 002** **Version: 1.0** **Effective Date: 01 Jan 2021**

Title: Feasibility Process Pedmed-NL

Purpose	This SOP describes the standard operating procedure for determining the feasibility of scientific research involving humans within the Pedmed-NL network

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PURPOSE

To describe the procedures for determining the feasibility of scientific studies involving children and adolescents within The Netherlands, conducted via Pedmed-NL.
This standard operating procedure (SOP) describes the high-level steps for assessing the appropriateness and feasibility of implementing a protocol via Pedmed-NL (national hub of c4c).
The detailed steps of executing this process are described in the Work Instruction (WI) Feasibility process Pedmed-NL

A feasibility analysis prior to the start of the study can be used to estimate whether it is feasible to conduct the study within The Netherlands. The study protocol, the set time, the required quality standard, available resources and the proposed budget (amongst others) will be taken into account. In this way, a substantiated decision can be made whether or not to participate in or initiate a scientific study.

Pedmed-NL will collect the information of all sites and will communicate a single response to the applicant regarding the feasibility of the proposed study within The Netherlands. Herein, Pedmed-NL acts as a liaison.

APPLICATION

This SOP applies to all clinical trials involving children and adolescents performed in The Netherlands of which feasibility is performed via Pedmed-NL (e.g. feasibility requests from CRO's, pharmaceutical companies, academic trialists and funders).

ABBREVIATIONS AND DEFINITIONS

Abbreviations

BD	Business Days
c4c	conect4children
CDA	Confidentiality Disclosure Agreement
CRO	Contract Research Organization
PI	Principal Investigator
RC	Research Coordinator
SOP	Standard Operating Procedure
SPoC	Single Point of Contact
TSQ	Trial Specific Questionnaire
WI	Work Instruction

Definitions

Applicant	An academic group / Sponsor or industry Sponsor or an intermediary appointed by a Sponsor or funder submitting a request for feasibility assessment
c4c	collaborative Network for European clinical trials for children
CRO	A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions
Non-partner sites	Sites that not have signed the Pedmed-NL consortium agreement
Pedmed-NL	Dutch network for clinical trials in children
PI	Responsible leader of a team of individuals at the trial site where the clinical trial will be conducted
Site	Location where trial-related activities are actually conducted
SOP	Detailed, written instructions to achieve uniformity of the performance of a specific function
SPoC	The centralised electronic point of entry into c4c for sponsors/applicants, managed by the Network Infrastructure Office
Sponsor	An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial

METHODS

1. PROCESS OF FEASIBILITY

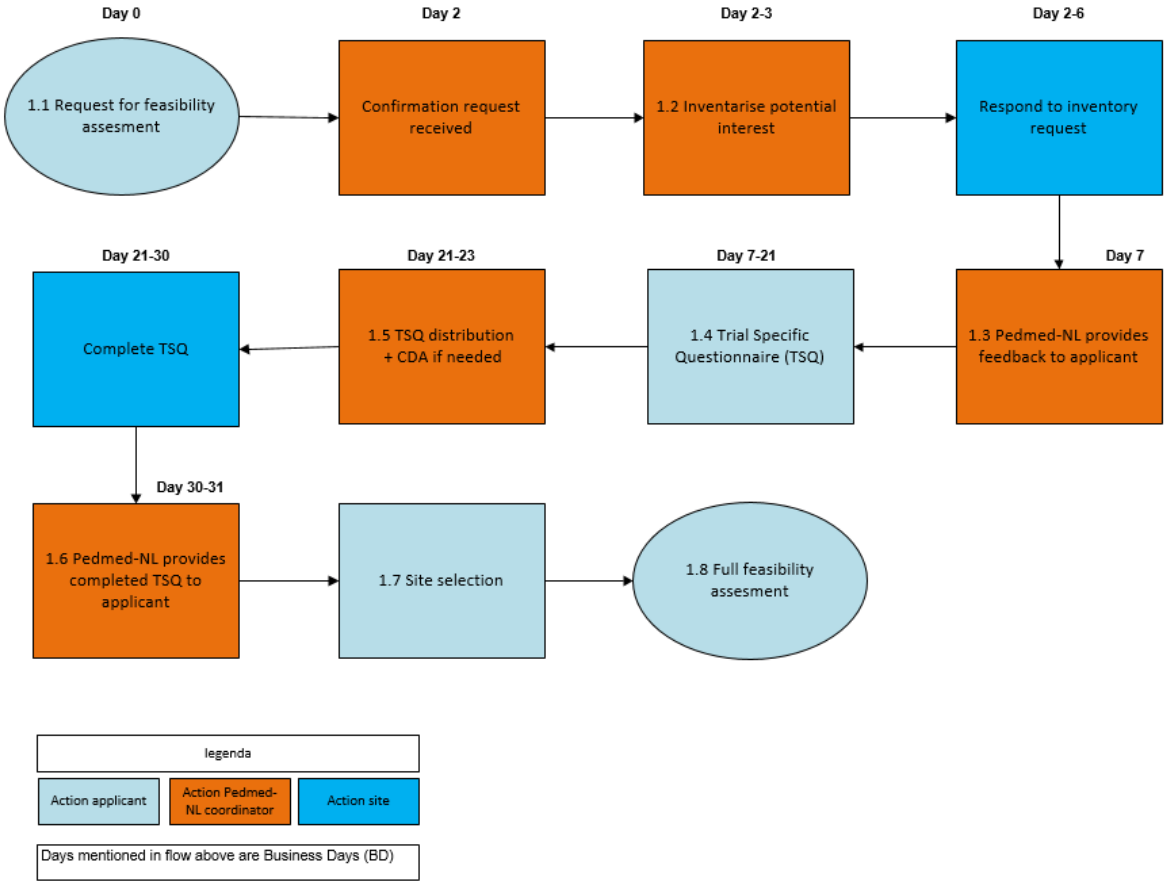

Figure 1. Flowchart process of feasibility

More detailed information on each step of the high-level process is described in the corresponding section below.
The detailed steps of executing this process are describe in the WI Feasibility process Pedmed-NL..

1.1. REQUEST FOR FEASIBILITY ASSESSMENT

Pedmed-NL receives a request for feasibility either from:

1.1.1 The applicant (e.g. CROs, pharmaceutical companies, academic researchers, funders). The applicant should complete the application form (under construction) containing minimal information to perform feasibility assessment (e.g. title, patient population, field of interest).
Or

1.1.2 The Single Point of Contact (SPoC) of c4c (Pedmed-NL is the national HUB within c4c on behalf of The Netherlands). During the course of the c4c IMI project (2018-2023), SPoC can contact Pedmed-NL with feasibility requests for potential Proof of Viability trials that will be running throughout the c4c project.

Pedmed-NL notifies the applicant (1.1.1) or SPoC (1.1.2.) that the request was well received and determines whether the request is feasible (e.g. timelines) and if any further information is needed. If needed, Pedmed-NL requests adaptation of the timelines and/or further information.
In some circumstances a CDA is already received in this step of the process (see 1.5) although this is an exception to the usual process.

1.2. INVENTORY FOR POTENTIAL INTEREST IN TRIAL PARTICIPATION

After receiving the request, Pedmed-NL determines the focus group to be contacted and notifies relevant contacts in Dutch centres about the trial. These contacts are asked if they are potentially interested in trial participation.
New contacts are asked to provide permission to be added to the Pedmed-NL database in order to further complete this database enable efficient communication in future requests.

Reactions from Dutch sites are collected and documented by Pedmed-NL. Based on these reactions, Pedmed-NL proceeds to move to the next steps of this procedure (if site is interested), or not (if site is not interested).

1.3. PEDMED-NL PROVIDES FEEDBACK REGARDING THE INTEREST OF DUTCH SITES TO THE APPLICANT / SPOC

All reactions are collected, an overview is made, and this overview is communicated (anonymized) to the applicant/SPoC by Pedmed-NL. Pedmed-NL provides the sponsor with one national answer regarding feedback received on the request. Names and contact details will not be communicated to commercial players at this point.

If the research proposal is not feasible within The Netherlands, Pedmed-NL will communicate this to the applicant. If possible, Pedmed-NL can provide advice regarding changes needed to allow the study to be carried out in The Netherlands (e.g. changes to study protocol).

1.4. TRIAL SPECIFIC QUESTIONNAIRE (TSQ)

The applicant/SPoC will send the TSQ to Pedmed-NL. If possible, Pedmed-NL will look at the TSQ and will prefill the questionnaire as far as possible, using data collected in the database so far.
Additionally, Pedmed-NL will distinguish the part that can be completed by a research nurse/trial

coordinator and the part to be completed by the clinician, if possible (not all digital questionnaires allow this, due to privacy regulations).

1.5. TSQ DISTRIBUTION

On behalf of Pedmed-NL the director or the Pedmed-NL project manager can sign the CDA for the consortium, including partner sites. For non-partner sites, Pedmed-NL will send the CDA to be signed. The TSQ will be distributed by Pedmed-NL to the sites that showed interest in potential participation in the trial, including a deadline for feedback.

1.6. PEDMED-NL COMPLETED TSQS TO APPLICANT/SPONSOR

Pedmed-NL collects completed TSQs, makes an overview of received reactions and provides feedback to the applicant/SPoC.

1.7. SITE SELECTION

Based on the TSQ, the applicant selects potential sites for the full feasibility assessment and informs Pedmed-NL which centres are selected. If requested, Pedmed-NL can provide advice regarding the most suitable sites, based on the study proposal. Pedmed-NL informs all sites whether they are selected, or not, if this information is provided by the requester. Pedmed-NL will connect the applicant/SPoC with the contact persons of the selected sites.

1.8. FULL FEASIBILITY ASSESSMENT

Pedmed-NL will support both parties, if needed, during full feasibility assessment. When possible, information will be pre-filled by Pedmed-NL, to be checked by the trial sites.

After receiving the signed CDA (if not received in an earlier stage, see 1.5), study documents can be shared with the sites and to determine feasibility to run the studies in the selected sites, operational and regulatory procedures within these sites will be assessed.

- Operational feasibility: Availability of patients with the disease under investigation. availability of personnel, timelines, facilities, potential conflicting studies in progress, contact details potential principal investigator and research coordinator if available, etc.
- Regulatory feasibility: Procedures regarding METC submission and potential problems when submitting to the METC.

Pedmed-NL collects the input from the potential trial sites within the set timelines.

During this process, Pedmed-NL can facilitate a teleconference between the interested Dutch Sites and the sponsor for discussion about possible questions, ambiguities or bottlenecks for this study.

The sponsor selects the centres based on the submitted feasibility criteria and provides feedback to Pedmed-NL. Pedmed-NL will inform the selected centres.