Site Suitability Template - Adopted in Hungary (v 2.1)

EU trial number:

Title of clinical trial:

Site name:

Site address:

Name of principal investigator:

Name of deputy principal investigator (optional)\*:

Planned number of trial participants at the site:

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| 1. Please provide a comprehensive written statement on the suitability of the site adapted to the nature and use of the investigational medicinal product. |
| Click or tap here to enter text. |
| 1. Please describe in detail the suitability of the facilities. |
| Click or tap here to enter text. |
| 1. Please describe accurately the suitability of the equipment. |
| Click or tap here to enter text. |
| 1. Please provide a detailed description of all trial procedures which will take place at the site. |
| Click or tap here to enter text. |
| 1. Please provide a detailed description of Human Resources arrangements and expertise at the site. |
| Click or tap here to enter text. |
| 1. Please provide a detailed description of how potential participants will be identified (e.g. patients of the investigators’ patient pool; patients appeared as a result of recruitment; patients referred by an other specialist). |
| Click or tap here to enter text. |
| 1. Please provide a detailed description of the medical attendance policy following the end of the trial (i.e. how the continous medical attendance of the participant is ensured). |
| Click or tap here to enter text. |
| 1. Please describe in detail how an urgent medical help is organised in an emergency situation. |
| Click or tap here to enter text. |

I confirm that the site has the facilities and equipment to be able to conduct the clinical trial and has suitable arrangements in place to ensure that all investigators and other individuals involved in conducting the trial have the suitable qualifications, expertise and training in relation to their role in the clinical trial, in compliance with EU Regulation 536/2014, and all conditions identified, which might influence the impartiality of any investigators, were addressed.

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Signature of Principal Investigator

or other responsible person Date

\*Approved deputy PI may take over the PI’s responsibilities in case the approved PI is unable to perform his/her role or leaves the site. Thus a seamless transition can be guaranteed.