Note: Text in *green* refers to the Site Suitability Template available at EudraLex - Volume 10 - Clinical trials guidelines

[EudraLex - Volume 10 (europa.eu)](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#:~:text=%EE%80%80EudraLex%20-%20Volume%2010%20-%20Clinical%20trials%20guidelines%EE%80%81,by%20the%20Clinical%20Trials%20Regulation%20%28EU%29%20No%20536%2F2014.)

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| **Protocol title** |  |
| **Protocol code** |  |
| **EU trial number** |  |
| **Sponsor** |  |
| **Trial site name and address** | **Universitätsklinik für XXX****A.ö. Landeskrankenhaus / Universitätskliniken Innsbruck****Anichstraße 35****6020 Innsbruck****ORG-ID: ORG-1000390925** |
| **Principal Investigator (Title, name, e-mail, telephone no.)** |  |

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| **Please provide a written statement on the suitability of the site adapted to the nature and use of the investigational medicinal product. *(Section 1 a)*** |
| Treatment focus of the trial site |  |
| Average number of patients treated per year in the trial indication: | ….. Patients/year |
| Planned number of subjects / patients for inclusion in the above-mentioned clinical trial: | ….. Patients in total….. Patients/year |
| Additional information if necessary: |

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| **Please describe the suitability of the facilities *(Section 1 b)*** |
| **Rooms and equipment** | Is there a dedicated space for IMP storage? | [ ]  Yes [ ]  No |
| Is there sufficient space to store the documentation available during and after the clinical trial (archiving)? | [ ]  Yes [ ]  No |
| **Clinical chemistry /Laboratory** | Which laboratories will be used (local/central)? |
| **Quality assurance** | Please confirm that SOPs are in place including process descriptions especially for investigator-specific tasks used at the trial site (recruitment, informed consent, documentation,… ):  [ ]  Yes [ ]  No |
| **Emergency care** | Emergency care over 24 hours/day ensured?[ ]  Department of Emergency Medicine[ ]  Other, please specify ….. |

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| **Please describe the suitability of the equipment *(Section 1 c)*** |

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| **Equipment** | Equipment at the trial site, as necessary and specific for the study to be indicated (e.g. ECG, X-ray/MRI equipment, temperature-controlled refrigerator/freezer, centrifuge, any other trial specific equipment[ ] Bone Scan[ ] PET/CT[ ] PET[ ] CT[ ] CT/MRI (Combined Scanner)[ ] X-Ray[ ] EEG[ ] ECG/EKG[ ] Dexa Scanner .[ ] ECHO[ ] ECHO/MUGA Scanning[ ] FDG-PET[ ] MRI[ ] On-site Lab[ ] Ultrasound[ ] Drug / Device storage[ ] Tumor Tissue Samples (Paraffin Blocks)[ ] Tumor Tissue Samples (Slides)[ ] -20° Freezer[ ] -70° Freezer[ ] Fridge[ ] Refrigerated Centrifuge[ ] Centrifuge[ ] Temperature controlled room temperature[ ] Personal computer (password protected), [ ] Scanner,[ ] Fax machines[ ] Rooms dedicated for study monitorings[ ] Other: |

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| **Please provide a description of all trial procedures which will take place at the Site *(Section 1 d)*** |
| Describe interventions, including blood sampling, ECG, X-ray, MRI, CT, Questionnaires, information about amount of blood, radiation exposure, time required for questionnaires,…. Do not forget unit (e.g. 20 ml) – Please describe only trial related interventions Add lines if necessary |
| Type of procedure | Amount/dose  | Time interval /duration | Total amount /dose |
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| **Please provide a description of Human Resources arrangements and expertise at the site *(Section 1 e)*** |
| **Description of the investigation team** |
| **Professional qualification** |
| **Principal Investigator (responsible for leading of the trial group)**  |
| Training in the principles of good clinical practice (GCP) and management of clinical trials. | The principal investigator(s) are adequately qualified according to the EU Regulation 536/2014 as well as nationally relevant legislation and principles of GCP. This includes detailed training with regard to ICH-GCP and CTR 536/2014[ ]  Other, specify:      The delegated study personnel are adequately qualified according to the principles of GCP. This includes detailed training with regard to ICH-GCP and CTR 536/2014[ ]  Other, specify:       |

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| The following documents /lists are provided: |
| Principal investigator (and deputy-investigator, if applicable):[ ]  Current (not older than 1 year), professional CV (1-2 pages) with the following information: Name, business address, current activity, professional career, specialist doctor, additional qualifications, date (signature optional). The use of the Investigator Curriculum Vitae template according to EudraLex - Volume 10 - Clinical trials guidelines is strongly encouraged.[ ]  Medical license/ ÖÄK (Österreichische Ärztekammer) number[ ]  Trial experience in the last five years (incl. indication, Type of trial, phase, own function, period of participation, EudraCT number, if applicable (only trials with medicinal products)[ ]  Evidence of training on general principles and rules of clinical trials, in particular EU Regulation 536/2014, AMG (Austrian Drug Law) and ICH-GCP guidelines[ ]  List of names of subinvestigators (physicians) within the trial |

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| List of names for PI (and deputy investigator, if applicable) and Medical license/ ÖÄK number  |
| Name | Function | Medical license/ÖÄK number | Licensed physician,specialist in … |
|  | PI |  |  |
|  | deputy PI |  |  |

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| Number of additional study personnel at the Trial Site |       Subinvestigators      Study nurses      Study coordinators      Lab personnel      ….      …. |
| Name of Subinvestigators, who will be delegated with medical activities in the clinical trial | Physicians Name/ MD | Specialist in…/ Resident |
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| **Confirmation and signature of principal investigator (signatures are accepted in wet ink, AES\* or QES\*\*)** |
| I confirm that I agree to conduct the above-mentioned clinical trial within my area of responsibility.I also confirm that the resources (number and qualification of staff, infrastructure, equipment, rooms) as well as the knowledge regarding the nature and the use of the investigational medicinal product are available for successful implementation. I also confirm that the recruitment of patients will not be jeopardised by competing trials.I further agree that the above-mentioned person will assume the function of the responsible **principal investigator** within the above-mentioned clinical trial. |
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| Name in block characters |  | Place, date |  | Signature **Principal investigator** |

\*AES: Advanced Electronic Signature; fortgeschrittene elektronische Signatur

\*\*QES: Qualified Electronic Signature; Qualifizierte Elektronische Signatur

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| **Statement and signature of the head the clinic/institution (usually medical director - verantwortlicher Leiter des ärztlichen Dienstes, ärztlicher Direktor der Krankenanstalt. .** For this signature section, please check the local requirements **(signatures are accepted in wet ink, AES or QES)** |
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| In authorizing this document, 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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| Medical Director |  | Innsbruck,  |  | Signature **(representative)** |