

To Whom It May Concern

Subject:	Request for Authorisation of Initial Clinical Trial Application pursuant to Articles 5 and 80 and Annex I of Regulation (EU) No 536/2014
Study title:	A Phase 2/3 Open-label Study Evaluating the Efficacy and Safety of Luveltamab Tazevibulin (STRO-002) versus Investigator's Choice (IC) Chemotherapy in Women with Relapsed Platinum-resistant Epithelial Ovarian Cancer (Including Fallopian Tube or Primary Peritoneal Cancers) Expressing Folate Receptor Alpha (FOLR1)
Protocol Number:	STRO-002-GM3
Protocol version and date	Protocol Version 3.0 dated 20 November 2023
EudraCT number:	2022-003843-82
Superseded EU CT number:	2023-506196-10-00
Newly created EU CT number:	2024-512477-27-00
Investigational Medicinal Product (IMP)	luveltamab tazevibulin (STRO-002)
Sponsor	Sutro Biopharma, Inc. 111 Oyster Point Boulevard South San Francisco CA 94080 United States
EU Legal Representative	Premier Research Group S.L.U

Dear Sir or Madam,

Premier Research, on behalf of the Sponsor Sutro Biopharma, Inc., would like to submit an application for a Clinical Trial Authorization for the above mentioned study in the following Member States concerned (MSC): Austria, Belgium, Czech Republic, Finland, Germany, Hungary, Ireland, Italy, Poland, Spain. This trial will be a multi-site, multi-regional study conducted in line with ICH E17 (Multi-Regional Clinical Trials) and ICH E6 (Good Clinical Practice).

The Sponsor respectfully requests the Spanish Competent Authority: [Spanish Agency of Medicines and Health Products](#) as the Reporting Member State for this clinical trial application.

During the preparation of the initial application, when most of the Part I and Part II documents were uploaded to CTIS, a few days before the planned submission date, the study has been unintentionally canceled from CTIS. It is probably happened accidentally by someone during working in the system. The EMA Service Desk was immediately contacted but unfortunately, they were not able to reinstate the study and the already uploaded documents. We were advised to create a new clinical trial application with new EU CT number. The new number is 2024-512477-27-00 however the previous number (2023-506196-10-00) still appears on the submitted study documents because it would have caused a significant delay in the submission if we change the EU CT number in all documents. We will update the EU CT number on applicable documents at the very earliest occasion to ensure that all documents contain the same and valid EU CT number 2024-512477-27-00. The previous EU CT number (2023-506196-10-00) is no longer functional therefore it will not cause potential confusion with another study.

The EU Representative for Sutro Biopharma Inc. is **Premier Research Group S.L.U.** with its registered office situated at Camino de la Zarzuela 19, 28023 Madrid, Spain.

Currently, this trial is being conducted in the United States under IND 134847, and also conducted in Australia, Canada, Israel, Singapore, South Korea, and the UK, furthermore may be conducted in Switzerland and New Zealand pending regulatory and ethics committee reviews.

A summary of the key features of the proposed clinical trial is provided below and other relevant information is included in the enclosed supporting documentation.

Scientific Advice

A request for EU Follow Up Scientific Advice was submitted on 05May2023 to discuss the design of the pivotal STRO-002-GM3 study. Scientific Advice has been received on 20Jul23.

Investigational Medicinal Product (IMP):

STRO-002 is being developed for the treatment of patients with relapsed platinum-resistant Epithelial Ovarian Cancer (Including Fallopian Tube or Primary Peritoneal Cancers), is the seventh most common cancer affecting women globally. STRO-002 is a novel FolR α -targeting single molecular species ADC containing an anti-FolR α aglycosylated human IgG1 antibody (SP8166) conjugated to a ibenzocyclooctyne(DBCO)-based cleavable 3-aminophenyl-hemiasterlin drug-linker (SC239), using site-specific conjugation technology to link 4 specifically positioned drugs per antibody molecule.

STRO-002 does not have marketing authorization in any country.



In parallel with this application, Premier Research, on behalf of the Sponsor Sutro Biopharma, Inc., will submit an IVD application as well. Study STRO-002-GM3 clinical efficacy results will provide the basis to evaluate the clinical performance of VENTANA FOLR1 (FOLR1-2.1) CDx Assay as an IVD device for luveltamab tazevibulin, in the target patient population. This Dx protocol is being conducted in support of Sutro Biopharma Study STRO-002-GM3 to identify the FOLR1 status of tumor specimens for patient selection and stratification.

Brief Summary of the Key Features of the Proposed Clinical Trial:

This is a randomized, multicenter, international, open-label, 2-part, Phase 2/3 study of STRO-002 to investigate the efficacy and safety of luveltamab tazevibulin compared to IC chemotherapy to treat subjects with relapsed, platinum-resistant epithelial ovarian cancer expressing FOLR1. Luveltamab tazevibulin targets FOLR1 which is expressed in recurrent ovarian cancers, and expression is maintained in metastatic foci and in recurrent carcinomas in patients and following chemotherapy treatment regimens.

The study has two parts:

- **Part 1:** Phase 2 study to select an optimized single dose regimen; consist of two dosing cohorts (Cohort A and Cohort B), with subjects randomized 1:1,
- **Part 2:** Once the optimized dosing regimen has been selected, the non-selected dosing arm will be closed to enrollment, and all subjects subsequently enrolled in Part 2 will be randomized 1:1 into the selected luveltamab tazevibulin arm or IC chemotherapy control arm.

To ensure continuity of enrollment between Part 1 and Part 2, subjects who are initially enrolled in Part 2 will be randomized 1: 1: 1 until adequate PK, safety and efficacy data are collected and analyzed to select the optimized dosing regimen. Subjects that will be enrolled in the currently submitted EU countries will not participate in Part 1 of the study.

The safety and preliminary efficacy of the two doses in Part 1 of the study have been evaluated in the Phase 1 STRO-002-GM1 clinical trial in advanced ovarian cancer, supporting their further investigation in STRO-002-GM3. The summary of safety and efficacy data from subjects treated with doses of 4.3 mg/kg and 5.2 mg/kg of STRO-002 is contained in the Investigator's Brochure, Edition 08. Preliminary efficacy demonstrates clinical activity at both doses in relapsed platinum-resistant epithelial ovarian cancer (including fallopian tube or primary peritoneal cancers) expressing FOLR1 that compares favorably to chemotherapy.

Taking into account the measures to minimize risk to subjects in STRO-002-GM3, combined with the Phase 1 safety and efficacy data in this population, Sutro considers it appropriate to continue enrollment of both dosing cohorts until the optimized dose is selected given the anticipated clinical benefit of both doses compared to standard chemotherapy for this unmet medical need population.

The study has the following periods:

- Screening period (up to 21 days)
- Cycles of treatment (each one is 21 days or 28 days for select chemotherapy agents)
- End of treatment visit (about 30 days after last dose of study drug)
- Long term follow-up (occurs every 3 months after last dose of study drug until death, withdrawal of consent, sponsor decision, or study end of study)

Approximately 600 subjects will be enrolled and treated.

The Reference Safety Information required for the assessment of whether an adverse reaction constitutes a Suspected Unexpected Adverse Reaction (SUSAR) can be found in section 7.0 of the Investigator’s Brochure edition 8.0 dated on the 20 November 2023

The Sponsor confirms that this clinical trial is not part of any agreed Paediatric Investigational Plan (PIP).

PCI Pharma Services Germany GmbH and PCI Pharma Services (previously Sherpa Clinical Packaging, LLC) USA, will be responsible for storage, packaging, labelling and distribution of IMPs in this study. A full IMPD is provided with this application including Manufacturing and Importation Authorizations, Certificates of Analysis and GMP certificates as Attachments.

The Sponsor recognizes that there is a need to assess the risk benefit ratio of any clinical study on an ongoing basis as well as the impact that COVID-19 outbreak might have in the clinical studies. Therefore, the Sponsor is committed to monitor any risk related to COVID-19 and to implement any necessary measures to ensure the safety of the patients and collaborators.

List of Documents Attached

Part I:

No.	Document	Version No.	Date
B	Cover letter		
B1	Cover letter – <i>version for publication and version not for publication</i>	N/A	07Mar2024
B1	Cover letter for Hungary (bilingual) – <i>version for publication and version not for publication</i>	N/A	07Mar2024
D	Protocol		
D1	Protocol version 3.0– <i>version for publication and version not for publication</i>	3.0	20Nov2023

D1	Protocol Synopsis English – <i>version for publication and version not for publication</i>	3.0	20Nov2023
D1	Protocol Synopsis - Spanish, Polish, Italian, Hungarian, German, French, Dutch, Czech, Finnish– <i>version for publication and version not for publication</i>	3.0	20Nov2023
D1	Short layman synopsis - English	N/A	07Mar2024
D2	Data Safety Monitoring Board Charter - <i>version for publication and version not for publication</i>	N/A	20Nov2023
D3	QLQ-OV28, screenshot– <i>version for publication and version not for publication</i> in English, German, Dutch, French, Spanish, Polish, Italian, Czech, Finish, Hungarian	N/A	As applicable per country
D3	QLQ-C30, screenshot– <i>version for publication and version not for publication</i> in English, German, Dutch, French, Spanish, Polish, Italian, Czech, Finish, Hungarian	N/A	As applicable per country
D3	EQ-5D-5L, screenshot - <i>version for publication and version not for publication</i> in English, German, Dutch, French, Spanish, Polish, Italian, Czech, Finish, Hungarian	N/A	As applicable per country
D3	FOSI-8, screenshot - <i>version for publication and version not for publication</i> in English, German, Dutch, Spanish, French, Polish, Italian, Czech, Finish, Hungarian	N/A	As applicable per country
D3	Questionnaires main menu, login screen, training screenshots - <i>version for publication and version not for publication</i> in English, German, Dutch, Spanish, French, Polish, Italian, Czech, Finish, Hungarian	N/A	As applicable per country
E	Investigator’s Brochure		
E1	Investigator’s Brochure – <i>version for publication and version not for publication</i>	8.0	20Nov2023
E2	Comparator SmPC – gemcitabine, paclitaxel, PLD, topotecan	N/A	N/A
E2	Auxiliary product - Pegfilgrastim	N/A	N/A
F	Documents GMP compliance		
F1	Manufacturer/Importer Authorization for Millmount Healthcare Limited, Ireland - <i>version for publication and version not for publication</i>	N/A	04Aug2021
F2	QP declaration - <i>version for publication and version not for publication</i> Millmount Healthcare Limited - A PCI Pharma Services Company, Ireland	N/A	15Feb2024

	Biotec Services International Ltd – A PCI Pharma Services Company, UK PCI Pharma Services Germany GmbH		16Feb2024 24Jan2024
F3	GMP certificates - <i>version for publication and version not for publication</i> PCI Pharma, Germany Piramal, USA Millipore Sigma, USA PCI (Sherpa), USA Sutro Biopharma, USA	N/A	16Apr2021 20Jan2022 10Feb2022 22Dec2022 12Dec2022
G	Investigational Medicinal Product Dossier (IMPD)		
G1	Investigational Medicinal Product Dossier (IMPD) – Quality for Active Substance and Placebo	7.0	December 2023
G1	Investigational Medicinal Product Dossier (IMPD) – Safety and Efficacy	Please refer to IB v8.0/20Nov2023 ; section 7.0 of IB and section 2.3 of protocol provides overall risk and benefit assessment	
H	Scientific Advice		
H1	EMA Scientific Advice - <i>version for publication and version not for publication</i>	N/A	20Jul23
I	Labelling		
I1	IMP Carton and Vial Label in local languages (AUS, BEL, CZ, FIN, GER, HU, IRE, ITA, ESP, POL) - <i>version for publication and version not for publication</i>	N/A	19Jan2024
J	Other		
J1	Proof of payment - <i>version for publication and version not for publication</i>	N/A	As applicable for the countries
J2	Sponsor's statement of data processing in compliance with union law on Data Protection – Regulation EU 2016/679 - <i>version for publication and version not for publication</i>	N/A	12Jan2024

Part II: AUSTRIA

Recruitment Arrangements			
1	K1 Recruitment and Informed consent procedure (English)	N/A	22Jan2024
Subject Information Sheet and Informed Consent Form			
1	L1 Main ICF (German) <i>version for publication and version not for publication</i>	1.0	06Mar2024
2	L1 Pre-screening ICF (German) <i>version for publication and version not for publication</i>	1.0	06Mar2024
3	L2 Patient Card (German)	2.0	29Nov2023
4	K2 GP letter (German)	3.0	24Jan2024
4	L2 Patient Reminder Card (German)	1.0	19Jul2023

5	L2 Patient Brochure (German)	2.0	26Oct2023
Suitability of the Investigators			
1	M1 CV PI Marth – <i>version for publication and version not for publication</i>	NA	05Feb2024
2	M3 GCP Training certificate PI Marth – <i>version for publication and version not for publication</i>	NA	22Aug2022
3	M2 Declaration of Interest PI Marth – <i>version for publication</i>	NA	07Feb2024
4	M1 CV SI Tsibulak – <i>version for publication and version not for publication</i>	NA	09Feb2024
5	M3 GCP Training certificate SI Tsibulak – <i>version for publication and version not for publication</i>	NA	08Feb2024
6	M2 Declaration of Interest SI Tsibulak – <i>version for publication</i>	NA	07Feb2024
7	M1 CV PI Polterauer – <i>version for publication and version not for publication</i>	NA	14Feb2024
8	M3 GCP Training certificate PI Polterauer – <i>version for publication and version not for publication</i>	NA	17Mar2023
9	M2 Declaration of Interest PI Polterauer – <i>version for publication and version not for publication</i>	NA	14Feb2024
10	M1 CV SI Grimm – <i>version for publication and version not for publication</i>	NA	08Jul2023
11	M3 GCP Training certificate SI Grimm – <i>version for publication and version not for publication</i>	NA	12Apr2023
12	M2 Declaration of Interest SI Grimm – <i>version for publication and version not for publication</i>	NA	14Feb2024
13	M1 CV PI Peters-Engl – <i>version for publication and version not for publication</i>	NA	01Feb2024
14	M3 GCP Training certificate PI Peters-Engl – <i>version for publication and version not for publication</i>	NA	02Feb2023
15	M2 Declaration of Interest PI Peters-Engl – <i>version for publication</i>	NA	02Feb2024
16	M1 CV SI Schramböck – <i>version for publication and version not for publication</i>	NA	02Feb2023
17	M3 GCP Training certificate SI Schramböck – <i>version for publication and version not for publication</i>	NA	02Feb2023
18	M2 Declaration of Interest SI Schramböck – <i>version for publication</i>	NA	05Feb2024
19	M1 CV PI Kolovetsiou-Kreiner – <i>version for publication and version not for publication</i>	NA	06Mar2024
20	M3 GCP Training certificate PI Kolovetsiou-Kreiner – <i>version for publication and version not for publication</i>	NA	03Oct2022

21	M2 Declaration of Interest PI Kolovetsiou-Kreiner – <i>version for publication and version not for publication</i>	NA	06Mar2024
22	M1 CV SI Trutnovsky – <i>version for publication and version not for publication</i>	NA	07Mar2024
23	M3 GCP Training certificate SI Trutnovsky – <i>version for publication and version not for publication</i>	NA	03Oct2022
24	M2 Declaration of Interest SI Trutnovsky – <i>version for publication and version not for publication</i>	NA	04Mar2024
Suitability of the Sites			
1	N1 Site suitability MU Innsbruck – <i>version for publication and version not for publication</i>	NA	08Feb2024
2	N1 Site suitability MU Wien – <i>version for publication and version not for publication</i>	NA	12Feb2024
3	N1 Site suitability K1 Hietzing – <i>version for publication and version not for publication</i>	NA	02Feb2024
4	N1 Site suitability UK Graz – <i>version for publication and version not for publication</i>	NA	07Mar2024
Insurance documents			
1	O1 Certificate – <i>version for publication and version not for publication</i>	NA	09Feb2024
2	O1 Policy – <i>version for publication and version not for publication</i>	NA	23Jan2024
3	O1 Policy Addendum – <i>version for publication and version not for publication</i>	NA	09Feb2024
Financial			
1	P1 Confirmation of financing the study	NA	pending
2	P1 Compensation site draft budget	NA	28Jun2023
3	P1 Compensation site draft contract	NA	28Feb2024
4	P2 Compensation trial participants	NA	22Jan2024
Compliance with national requirements for the data protection			
1	R1 Sponsor's statement of data processing in compliance with union law on Data Protection – Regulation EU 2016/679– <i>version for publication and version not for publication</i>	NA	12Jan2024
2	Sponsor's Compliance with Biological Samples	NA	29Jan2024

Part II: BELGIUM

Recruitment Arrangements			
1	Recruitment and Informed consent procedure (English)	N/A	22Jan2024
Subject Information Sheet and Informed Consent Form			
1	Main ICF (French; Dutch; German)	1.0	12Feb2024
2	Pre-screening ICF (French; Dutch; German)	1.0	12Feb2024
3	Patient Card (French; Dutch; German)	2.0	29Nov2023
4	Patient Reminder card (French; Dutch; German)	1.0	19July 2023
5	Patient Brochure (French; Dutch; German)	2.0	26Oct2023

6	GP Letter (French; Dutch; German)	3.0	24Jan2024
Suitability of the Investigators			
1	CV Dr Denys – <i>version for publication and version not for publication</i>	NA	20Mar2023
2	GCP Training certificate Dr Denys	NA	02Dec2022
3	Declaration of Interest Dr Denys – <i>version for publication and version not for publication</i>	NA	27Dec2023
4	CV Dr Kakkos – <i>version for publication and version not for publication</i>	NA	29Feb2024
5	GCP Training certificate Dr Kakkos	NA	15Jul2022
6	Declaration of Interest Dr Kakkos – <i>version for publication and version not for publication</i>	NA	29Feb2024
7	CV Dr Henry – <i>version for publication and version not for publication</i>	NA	09Dec2022
8	GCP Training certificate Dr Henry	NA	16May2022
9	Declaration of Interest Dr Henry – <i>version for publication and version not for publication</i>	NA	16Nov2023
10	CV Dr Van Nieuwenhuysen – <i>version for publication and version not for publication</i>	NA	29Mar2023
11	GCP Training certificate Dr Van Nieuwenhuysen	NA	29Mar2023
12	Declaration of Interest Dr Van Nieuwenhuysen – <i>version for publication and version not for publication</i>	NA	28Feb2024
13	CV Dr Vulsteke – <i>version for publication and version not for publication</i>	NA	06Jul2022
14	GCP Training certificate Dr Vulsteke	NA	05May2022
15	Declaration of Interest Dr Vulsteke – <i>version for publication and version not for publication</i>	NA	27Nov2023
Suitability of the Sites			
1	Site suitability AZ Maria Middelaes – <i>version for publication and version not for publication</i>	NA	01Feb2024
2	Site suitability CHU Namur – <i>version for publication and version not for publication</i>	NA	19Jan2024
3	Site suitability UZ Gent – <i>version for publication and version not for publication</i>	NA	22Jan2024
4	Site suitability UZ Leuven – <i>version for publication and version not for publication</i>	NA	23Feb2024
5	Site suitability – CHU Liege <i>version for publication and version not for publication</i>	NA	27Feb2024
Insurance documents			

1	Certificate – <i>version for publication and version not for publication</i>	NA	Exp Date: 16Jan2029
Financial			
1	Confirmation of financing the study	NA	27Feb2024
2	Belgium Local Budget	NA	28Feb2024
3	CTA Pharma be DENYS UZ Gent	Draft	13Feb2024
4	CTA Pharma be HENRY CHU Namur	Draft	13Feb2024
5	CTA Pharma be KAKKOS CHU Liege	Draft	13Feb2024
6	CTA Pharma be VAN NIEUWENHUYSEN UZ Leuven	Draft	13Feb2024
7	CTA Pharma be VULSTEKE Maria Middelaes	Draft	13Feb2024
Compliance with national requirements for the data protection			
1	Sponsor's statement of data processing in compliance with union law on Data Protection – Regulation EU 2016/679	NA	12Jan2024
2	Sponsor's Compliance with Biological Samples	NA	29Jan2024

Part II: CZECH REPUBLIC

No. / Č.	Document / <i>Dokument</i>	Version No. / <i>Verze č.</i>	Date / <i>Datum</i>
K. Recruitment Arrangements / <i>Způsob nábora</i>			
K1	Recruitment arrangements: Recruitment and Informed consent procedure template (Template No. 1) / <i>Způsob nábora: Nábor subjektů hodnocení a získávání Informovaného souhlasu (Šablona č. 1)</i> Language / <i>jazyk</i> : bilingvní / <i>bilingual</i>	1.0	26-Jan-2024
K2	Recruitment materials: Patient Leave Behind - Leaflet / <i>Náborové materiály: Informační leták pro pacienta</i> Language / <i>jazyk</i> : Czech / <i>čeština</i> Note: date and version not seen on the document itself, data was stated within the document electronic name / <i>Poznámka: datum a verze nejsou na samotném dokumentu vidět, údaje byly uvedeny v elektronickém názvu dokumentu</i>	2.0	26-Oct-2023
K3	GP Letter / <i>Dopis praktickému lékaři</i> Language / <i>jazyk</i> : Czech / <i>čeština</i>	3.0	24-Jan-2024
L. Subject Information, Informed Consent Form, other subject information material / <i>Informace pro subjekty a formulář informovaného souhlasu, další informační materiály pro subjekty</i>			
L1	Main ICF -Participant Information Sheet and Informed Consent Form / <i>Informace pro účastníka a formulář informovaného souhlasu</i> Language / <i>jazyk</i> : Czech / <i>čeština</i>	1.0	26-Jan-2024

	<i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i>		
L1	Pre-screening ICF- Participant Information Sheet and Informed Consent Form / <i>Informace pro účastníka a formulář informovaného souhlasu</i> Language / <i>jazyk</i> : Czech / <i>čeština</i> <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i>	1.0	15-Feb-2024
L1	GDPR ICF (Czech) - Information Concerning Data Protection / <i>Informace týkající se ochrany údajů</i> Language / <i>jazyk</i> : Czech / <i>čeština</i> <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i>	1.0	26-Jan-2024
L2	Other subject information material: Patient Card / <i>Další informační materiál pro subjekty: Karta pacienta</i> Language / <i>jazyk</i> : Czech / <i>čeština</i>	2.0	29-Nov-2023
L2	Other subject information material: Patient Reminder Tear Pad / <i>Další informační materiál pro subjekty: Připomínkový trhací blok pro pacienta</i> Language / <i>jazyk</i> : Czech / <i>čeština</i> Note: full date not seen on the document itself, data was stated within the document electronic name / <i>Poznámka: na dokumentu není vidět celé datum, údaj byl uveden v elektronickém názvu dokumentu</i>	1	19-Jul-2023
Questionnaires			
L2	Other subject information material: EORTC QLQ-OV28 questionnaire / <i>Další informační materiál pro subjekty: Dotazník EORTC QLQ-OV28</i> Language / <i>jazyk</i> : Czech / <i>čeština</i> <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i>	2.1	1997

	Note: version is not seen on the document itself, data was stated within the document electronic name / <i>Poznámka: na dokumentu není vidět verzi, údaj byl uveden v elektronickém názvu dokumentu</i>		
L2	Other subject information material: EORTC QLQ-C30 questionnaire / <i>Další informační materiál pro subjekty: Dotazník EORTC QLQ-C30</i> Language / <i>jazyk: Czech / čeština</i> <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i>	3.0	1995
L2	Other subject information material: EQ-5D-5L questionnaire / <i>Další informační materiál pro subjekty: Dotazník EQ-5D-5L</i> Language / <i>jazyk: Czech / čeština</i> <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i> Note: date is not seen on the document itself, data was stated within the document electronic name / <i>Poznámka: na dokumentu není vidět datum, údaj byl uveden v elektronickém názvu dokumentu</i>	1.1	2009
L2	Other subject information material: FOSI-8 questionnaire / <i>Další informační materiál pro subjekty: Dotazník FOSI-8</i> Language / <i>jazyk: Czech / čeština</i> <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i> Note: version is not seen on the document itself, data was stated within the document electronic name / <i>Poznámka: na dokumentu není vidět verzi, údaj byl uveden v elektronickém názvu dokumentu</i>	4.0	01-May-2019
L2	Other subject information material: EORTC QLQ-OV28 questionnaire - Screenshot / <i>Další informační materiál pro subjekty: Dotazník EORTC QLQ-OV28 - Snímek obrazovky</i> Language / <i>jazyk: Czech / čeština</i> <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i>	1.0	23-Feb-2024
L2	Other subject information material: EORTC QLQ-C30 questionnaire - Screenshot / <i>Další informační materiál pro subjekty: Dotazník EORTC QLQ-C30 - Snímek obrazovky</i>	1.0	23-Feb-2024

	<p>Language / jazyk: Czech / čeština <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>		
L2	<p>Other subject information material: EQ-5D-5L questionnaire - Screenshot / <i>Další informační materiál pro subjekty: Dotazník EQ-5D-5L - Snímek obrazovky</i></p> <p>Language / jazyk: Czech / čeština <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	1.0	14-Feb-2024
L2	<p>Other subject information material: FOSI-8 questionnaire – Screenshot / <i>Další informační materiál pro subjekty: Dotazník FOSI-8 – Snímek obrazovky</i></p> <p>Language / jazyk: Czech / čeština <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	1.0	23-Feb-2024
L2	<p>Other subject information material: Training Requirements – Screenshot / <i>Další informační materiál pro subjekty: Požadavky na školení – Snímek obrazovky</i></p> <p>Language / jazyk: Czech / čeština <i>version for publication / verze ke zveřejnění</i></p>	1.0	23-Feb-2024
L2	<p>Other subject information material: Main Menu - Screenshot / <i>Další informační materiál pro subjekty: Hlavní menu – Snímek obrazovky</i></p> <p>Language / jazyk: Czech / čeština <i>version for publication / verze ke zveřejnění</i></p>	1.0	01-Feb-2024

L2	Other subject information material: Login – Screenshot / <i>Další informační materiál pro subjekty: Přihlášení – Snímek obrazovky</i> Language / jazyk: Czech / čeština version for publication / verze ke zveřejnění	3.0	12-Aug-2022
M. Suitability of the Investigators / <i>Vhodnost zkoušejících</i>			
M1	CV PI (Template No. 2): Prof. David Cibula, MD, CSc / <i>CV hlavního zkoušejícího (Šablona č. 2): Prof. MUDr. David Cibula, Csc.</i> Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění	NA	05-Mar-2024
M1	CV PI (Template No. 2): Prof. Michal Zikán, MD, Ph.D. / <i>CV hlavního zkoušejícího (Šablona č. 2): Prof. MUDr. Michal Zikán, PhD.</i> Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění	NA	05-Mar-2024
M1	CV PI (Template No. 2): Vojtěch Tlustý, MD / <i>CV hlavního zkoušejícího (Šablona č. 2): MUDr. Vojtěch Tlustý</i> Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění	NA	05-Mar-2024
M1	CV PI (Template No. 2): Markéta Bednaříková, MD, PhD. / <i>CV hlavního zkoušejícího (Šablona č. 2): MUDr. Markéta Bednaříková, PhD.</i> Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění	NA	18-Jan-2024
M1	CV PI (Template No. 2): Prof. Lukáš Rob, MD, CSc. / <i>CV hlavního zkoušejícího (Šablona č. 2): Prof. MUDr. Lukáš Rob, CSc.</i> Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění	NA	05-Mar-2024

M1	<p>CV PI (Template No. 2): Ass. Prof. Jaroslav Klát, MD, PhD. / <i>CV hlavního zkoušejícího (Šablona č. 2): Doc.MUDr. Jaroslav Klát, PhD.</i></p> <p>Language / jazyk: bilingual / dvojjazyčný <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	NA	05-Mar-2024
M2	<p>Declaration of Investigator's Interests (Template No. 3): Prof. David Cibula, MD, CSc / <i>Prohlášení o střetu zájmů zkoušejícího (Šablona č. 3): Prof. MUDr. David Cibula, Csc.</i></p> <p>Language / jazyk: bilingual / dvojjazyčný <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	NA	05-Mar-2024
M2	<p>Declaration of Investigator's Interests (Template No. 3): Prof. Michal Zikán, MD, Ph.D. / <i>Prohlášení o střetu zájmů zkoušejícího (Šablona č. 3): Prof. MUDr. Michal Zikán, PhD.</i></p> <p>Language / jazyk: bilingual / dvojjazyčný <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	NA	05-Mar-2024
M2	<p>Declaration of Investigator's Interests (Template No. 3): Vojtěch Tlustý, MD / <i>Prohlášení o střetu zájmů zkoušejícího (Šablona č. 3): MUDr. Vojtěch Tlustý</i></p> <p>Language / jazyk: bilingual / dvojjazyčný <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	NA	05-Mar-2024
M2	<p>Declaration of Investigator's Interests (Template No. 3): Markéta Bednaříková, MD, PhD. / <i>Prohlášení o střetu zájmů zkoušejícího (Šablona č. 3): MUDr Markéta Bednaříková, PhD.</i></p> <p><i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	NA	18-Jan-2024
M2	<p>Declaration of Investigator's Interests (Template No. 3): Prof. Lukáš Rob, MD, CSc. /</p>	NA	05-Mar-2024

	<p><i>Prohlášení o střetu zájmů zkoušejícího (Šablona č. 3): MUDr. Prof. Lukáš Rob, CSc.</i></p> <p><i>Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>		
M2	<p><i>Declaration of Investigator's Interests (Template No. 3): Ass. Prof. Jaroslav Klát, MD, PhD. / Prohlášení o střetu zájmů zkoušejícího (Šablona č. 3): Doc.MUDr. Jaroslav Klát, PhD.</i></p> <p><i>Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	NA	05-Mar-2024
N. Suitability of the facilities / <i>Vhodnost zařízení</i>			
N1	<p><i>Site Suitability (Template No. 4): General University Hospital (VFN) / Vhodnost studijního centra (Šablona č. 4): Všeobecná fakultní nemocnice v Praze /VFN</i></p> <p><i>Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	NA	05-Mar-2024
N1	<p><i>Site Suitability (Template No. 4): Universitz Hospital na Bulovce / Vhodnost studijního centra (Šablona č. 4): Fakultní nemocnice Bulovka</i></p> <p><i>Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	NA	05-Mar-2024
N1	<p><i>Site Suitability (Template No. 4): Hospital AGEL Nový Jičín/ Vhodnost studijního centra (Šablona č. 4): Nemocnice AGEL Nový Jičín</i></p> <p><i>Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	NA	05-Mar-2024
N1	<p><i>Site Suitability (Template No. 4): University Hospital in Brno / Vhodnost studijního centra (Šablona č. 4): Fakultní nemocnice Brno</i></p> <p><i>Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i></p>	NA	18-Jan-2024
N1	<p><i>Site Suitability (Template No. 4): University Hospital Královské Vinohrady/</i></p>	NA	05-Mar-2024

	<p><i>Vhodnost studijního centra (Šablona č. 4): Fakultní nemocnice Královské Vinohrady</i></p> <p>Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</p>		
N1	<p>Site Suitability (Template No. 4): University Hospital in Ostrava / <i>Vhodnost studijního centra (Šablona č. 4): Fakultní nemocnice Ostrava</i></p> <p>Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</p>	NA	05-Mar-2024
N2	<p>Registration of non-state healthcare facility (change 1): Hospital AGEL Nový Jičín / <i>Registrace nestátního zdravotnického zařízení (změna 1): Nemocnice AGEL Nový Jičín</i></p> <p>Language / jazyk: Czech / čeština version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</p>	NA	07-Jun-2023
N2	<p>Registration of non-state healthcare facility: Hospital AGEL Nový Jičín / <i>Registrace nestátního zdravotnického zařízení: Nemocnice AGEL Nový Jičín</i></p> <p>Language / jazyk: Czech / čeština version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</p>	NA	13-Jun-2001
N3	<p>List of Sites in the Czech Republic / <i>Seznam center v České republice</i></p> <p>Language / jazyk: bilingual / dvojjazyčný version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</p>	1.0	24-Jan-2024
O. Proof of insurance cover or indemnification / Doklad o pojistném krytí nebo odškodnění			
O1	<p>Certificate of Clinical Trial Insurance, Insurance Policy No. MCICET23330 (B0180MCICLT2300) / <i>Potvrzení o pojištění klinického hodnocení, Pojistná smlouva č. MCICET23330 (B0180MCICLT2300)</i></p> <p>Language / jazyk: bilingual / dvojjazyčný</p>	NA	21-Feb-2024

	<i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i>		
O1	General Clinical Trial Insurance Conditions, CT GIC 01Jan2023 / <i>Všeobecné pojistné podmínky pojištění klinického hodnocení VPP KH 01Jan2023</i> Language / jazyk: Czech / čeština Note: CT GIC included in Policy document, not available as separate document. / <i>VPP KH je součástí dokumentu Pojistná smlouva, není k dispozici jako samostatný dokument.</i>	NA	01-Jan-2023
O1	Insurance Policy No. MCICET23330 (B0180MCICLT2300) / <i>Pojistná smlouva č. MCICET23330 (B0180MCICLT2300)</i> Language / jazyk: Czech / čeština <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i>	NA	28-Feb-2024
P. Financial and other arrangements / Finanční a jiná ujednání			
P1	Compensation for trial participants (Template No. 6) / <i>Kompenzace pro účastníky studie (Šablona č. 6)</i> Language / jazyk: bilingual / dvojjazyčný	1.0	02-Feb-2024
P2	Confirmation of financing study / <i>Potvrzení o financování studie</i> Language / jazyk: English / angličtina	NA	08-Feb-2024
P3	Invoice details / <i>Fakturační údaje</i> Language / jazyk: Czech / čeština	NA	02-Feb-2024
R. Compliance with national requirements on Data Protection / Soulad s národními požadavky na ochranu osobních údajů			
R1	Sponsor's statement of data processing in compliance with union law on Data Protection – Regulation EU 2016/679 / <i>Prohlášení zadavatele ke zpracování osobních údajů v daném klinickém hodnocení dle Nařízení EU 2016/679</i> Language / jazyk: English / angličtina <i>version for publication and version not for publication / verze ke zveřejnění a verze k nezveřejnění</i>	NA	12-Jan-2024
S. Compliance with use of biological samples / Soulad s použitím biologických vzorků			
S1	Compliance with Member State applicable rules for the collection, storage and future use of human biological samples (Template No. 7) / <i>Soulad s platnými pravidly členského státu pro odběr, skladování a budoucí použití lidských biologických vzorků (Šablona č. 7)</i>	1.0	02-Feb-2024

	Language / <i>jazyk</i> : bilingual / <i>dvojjazyčný</i>		
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Part II: FINLAND

Recruitment Arrangements			
1	Recruitment and Informed consent procedure (English)	N/A	22Jan2024
Subject Information Sheet and Informed Consent Form			
1	Main ICF (Finish)	1.0	19February 2024
2	Pre-screening ICF (Finish)	1.0	19February 2024
3	Patient Card (Finish)	1.0	29November 2023
Suitability of the Investigators			
1	CV Annika Auranen – <i>version for publication and version not for publication</i>	NA	27Feb2024
2	GCP Training certificate Annika Auranen	NA	02May2024
3	Declaration of Interest Annika Auranen – <i>version for publication and version not for publication</i>	NA	07Mar2024
4	CV Heini Lassus – <i>version for publication and version not for publication</i>	NA	06Mar2024
5	GCP Training certificate Heini Lassus	NA	01Nov2021
6	Declaration of Interest Heini Lassus – <i>version for publication and version not for publication</i>	NA	06Mar2024
7	CV Sakari Hietanen – <i>version for publication and version not for publication</i>	NA	04Mar2024
8	GCP Training certificate Sakari Hietanen	NA	25May2023
9	Declaration of Interest Sakari Hietanen – <i>version for publication and version not for publication</i>	NA	07Mar2024
Suitability of the Sites			
1	Site suitability HUS – <i>version for publication and version not for publication</i>	NA	06Mar2024
2	Site suitability TAYS – <i>version for publication and version not for publication</i>	NA	06Mar2024
3	Site suitability TYKS – <i>version for publication and version not for publication</i>	NA	07Mar2024
Insurance documents			
1	Certificate – <i>version for publication and version not for publication</i>	NA	09Feb2024
Financial			
1	Confirmation of financing the study	NA	22Jan2024

2	Compensation Investigator Site Contract draft	1.0	08Nov2022
3	Compensation Investigator Site budget draft	1.0	08Nov2022
Compliance with national requirements for the data protection			
1	Sponsor's statement of data processing in compliance with union law on Data Protection – Regulation EU 2016/679	NA	12Jan2024
2	Sponsor's Compliance with Biological Samples	NA	29Jan2024

Part II: GERMANY

Please consider that the study will be submitted to BfS for authorisation to use ionising radiation on humans for the purpose of medical research pursuant to Section 31 para. 1 StrlSchG.

The radiological examinations in this study deviate from the standard of care.

Recruitment Arrangements			
1	K1 Recruitment and Informed consent procedure (English)	N/A	22Jan2024
Subject Information Sheet and Informed Consent Form			
1	L1 Main ICF (German) <i>version for publication and version not for publication</i>	1.0	07Feb2024
2	L1 Pre-screening ICF (German) <i>version for publication and version not for publication</i>	1.0	07Feb2024
3	L2 Patient Card (German)	2.0	29Nov2023
4	L2 Patient Reminder Card (German)	1.0	19Jul2023
5	L2 Patient Brochure (German)	2.0	26Oct2023
Suitability of the Investigators			
1.	M1 CV PI Hemptenmacher – <i>version for publication and version not for publication</i>	NA	07Feb2024
2.	M2 Declaration of Interest PI Hemptenmacher – <i>version for publication and version not for publication</i>	NA	23Jan2024
3.	M3 GCP Training certificate PI Hemptenmacher - <i>version for publication and version not for publication</i>	NA	2022-2022
4.	M1 CV Hanker – <i>version for publication and version not for publication</i>	NA	07Feb2024
5.	M2 Declaration of Interest Hanker – <i>version for publication and version not for publication</i>	NA	02Feb2024
6.	M3 GCP Training certificate Hanker - <i>version for publication and version not for publication</i>	NA	2009-2022
7.	M1 CV PI Meyer-Wilmes– <i>version for publication and version not for publication</i>	NA	01Feb2024
8.	M2 Declaration of Interest PI Meyer-Wilmes– <i>version for publication and version not for publication</i>	NA	31Jan2024
9.	M3 GCP Training certificate PI Meyer-Wilmes- <i>version for publication and version not for publication</i>	NA	2017-2023
10.	M1 CV Stickeler – <i>version for publication and version not for publication</i>	NA	02Feb2024
11.	M2 Declaration of Interest Stickeler – <i>version for publication and version not for publication</i>	NA	31Jan2024

12.	M3 GCP Training certificate Stickeler - <i>version for publication and version not for publication</i>	NA	2017-2023
13.	M1 CV PI Wimberger– <i>version for publication and version not for publication</i>	NA	22Jan2024
14.	M2 Declaration of Interest PI Wimberger– <i>version for publication and version not for publication</i>	NA	22Jan2024
15.	M3 GCP Training certificate PI Wimberger- <i>version for publication and version not for publication</i>	NA	2010-2021
16.	M1 CV xxx – <i>version for publication and version not for publication</i>	NA	22Jan2024
17.	M2 Declaration of Interest xxx – <i>version for publication and version not for publication</i>	NA	22Jan2024
18.	M3 GCP Training certificate xxx - <i>version for publication and version not for publication</i>	NA	2009-2021
19.	M1 CV PI Lübbe– <i>version for publication and version not for publication</i>	NA	30Jan2024
20.	M2 Declaration of Interest PI Lübbe– <i>version for publication and version not for publication</i>	NA	30Jan2024
21.	M3 GCP Training certificate PI Lübbe- <i>version for publication and version not for publication</i>	NA	2008-2023
22.	M1 CV Tanasie – <i>version for publication and version not for publication</i>	NA	06Mar2024
23.	M2 Declaration of Interest Tanasie – <i>version for publication and version not for publication</i>	NA	06Mar2024
24.	M3 GCP Training certificate Tanasie - <i>version for publication and version not for publication</i>	NA	2020-2022
Suitability of the Sites			
1	N1 Site suitability Diakovere Hannover– <i>version for publication and version not for publication</i>	NA	31Jan2024
2	N1 Site suitability RWTH Aachen– <i>version for publication and version not for publication</i>	NA	16Feb2024
3	N1 Site suitability TU Dresden– <i>version for publication and version not for publication</i>	NA	26Feb2024
4	N1 Site suitability UKSH Lübeck– <i>version for publication and version not for publication</i>	NA	15Feb2024
Insurance documents			
1	O1 Certificate – <i>version for publication and version not for publication</i>	NA	19Jan2024
2	O1 Policy – <i>version for publication and version not for publication</i>	NA	19Jan2024
Financial			

1	P1 Cost Assumption Declaration	NA	19Feb2024
2	P1 Compensation investigator sites draft budget	3.0	28Feb2024
3	P1 Compensation Investigator sites draft contract	NA	28Nov2023
4	P2 Subject Compensation22Jan24	NA	22Jan2024
Compliance with national requirements for the data protection			
1	R1 Sponsor's statement of data processing in compliance with union law on Data Protection – Regulation EU 2016/679 <i>version for publication and version not for publication</i>	NA	12Jan2024
2	S1 Sponsor's Compliance with Biological Samples	NA	29Jan2024

Part II: HUNGARY

K. Recruitment Arrangements / <i>Toborzó anyagok</i>			
K1	Recruitment and Informed Consent Procedure – version for publication Language: English / <i>Toborzás és tájékoztatáson alapuló beleegyezési eljárás – közzétételre szánt verzió</i> <i>Nyelv: angol</i>	N/A	22Jan2024
K2	General Practitioner Letter – clean version for publication and tracked version not for publication Language: Hungarian / <i>Háziorvosi levél – végleges verzió közzétételre és változást követő verzió nem közzétételre</i> <i>Nyelv: magyar</i>	1.0	03Jan2024
K2	Patient Leave Behind	2.0	26Oct2023
L. Subject Information Sheet and Informed Consent Form / <i>Tájékoztatóson alapuló beleegyező nyilatkozat</i>			
L1	Main ICF – redacted version for publication and clean version not for publication, Language: Hungarian / <i>Fő tájékoztatóson alapuló beleegyező nyilatkozat – kitakart, közzétételre szánt verzió és tisztázott, nem közzétételre szánt verzió</i> <i>Nyelv: magyar</i>	1.0	14Feb2024
L1	Pre-screening ICF - redacted version for publication and clean version not for publication Language: Hungarian / <i>Tájékoztatóson alapuló beleegyező nyilatkozat Előszűréshez – kitakart, közzétételre szánt verzió és tisztázott, nem közzétételre szánt verzió</i> <i>Nyelv: magyar</i>	1.0	15Feb2024
L2	Patient Card – version for publication Language: Hungarian / <i>Betegkártya – közzétételre szánt verzió</i> <i>Nyelv: magyar</i>	1.0	15Jan2024
L2	QLQ-OV28 – version for publication and version not for publication in Hungarian QLQ-OV28 kérdőív – közzétételre és nem közzétételre szánt verzió magyarul	NA	1997
L2	QLQ-C30 – version for publication and version not for publication in Hungarian	3.0	1995

	QLQ-C30 kérdőív közzétételre és nem közzétételre szánt verzió		
L2	EQ-5D-5L - version for publication and version not for publication in Hungarian EQ-5D-5L kérdőív version for publication and version not for publication in Hungarian	1.1	NA
L2	FOSI-8 - version for publication and version not for publication in Hungarian FOSI-8 kérdőív version for publication and version not for publication in Hungarian	NA	25Jan2010
L2	QLQ-OV28, screenshot– version for publication and version not for publication in English QLQ-OV28 képernyőfotó közzétételre és nem közzétételre szánt verzió angolul	NA	13Dec2023
L2	QLQ-C30, screenshot– version for publication and version not for publication in English QLQ-C30 képernyőfotó közzétételre és nem közzétételre szánt verzió angolul	NA	05Dec2023
L2	EQ-5D-5L, screenshot - version for publication and version not for publication in English EQ-5D-5L képernyőfotó közzétételre és nem közzétételre szánt verzió angolul	NA	05Dec2023
L2	FOSI-8, screenshot - version for publication and version not for publication in English FOSI-8 képernyőfotó közzétételre és nem közzétételre szánt verzió angolul	NA	13Dec2023
L2	Questionnaires main menu, login screen, training screenshots - version for publication and version not for publication in English, Kérdőív fő menü, bejelentkező oldal, tréning képernyőfotó közzétételre és nem közzétételre szánt verzió angolul	NA	13Dec2023
L2	Patient Reminder Tear Pad	1.0	07/2023
M. Suitability of the Investigators / A vizsgáló megfelelősége			
M1	CV_Dr. Bagaméri – version for publication and version not for publication Önéletrajz_Dr. Bagaméri – közzétételre és nem közzétételre szánt verzió	NA	11Jan2024
M1	CV_Dr. Póka – version for publication and version not for publication Önéletrajz_Dr. Póka – közzétételre és nem közzétételre szánt verzió	NA	08Dec2023
M1	CV_Dr. Sipőcz – version for publication and version not for publication / Önéletrajz_Dr. Sipőcz – közzétételre és nem közzétételre szánt verzió	NA	25Jan2024
M2	Protocol v3.0 Acknowledgement of receipt_Dr. Bagaméri – version for publication and version not for publication /	3.0	11Jan2024

	<i>3.0 verziójú vizsgálati terv aláíró oldal_Dr. Bagaméri – közzétételre és nem közzétételre szánt verzió</i>		
M2	Protocol v3.0 Acknowledgement of receipt_Dr. Póka – version for publication and version not for publication / <i>3.0 verziójú vizsgálati terv aláíró oldal_Dr. Póka – közzétételre és nem közzétételre szánt verzió</i>	3.0	29Nov2023
M2	Protocol v3.0 Acknowledgement of receipt_Dr. Sipőcz – version for publication and version not for publication / <i>3.0 verziójú vizsgálati terv aláíró oldal_Dr. Sipőcz – közzétételre és nem közzétételre szánt verzió</i>	3.0	29Nov2023
M3	GCP Training certificate_Dr. Bagaméri – version for publication and version not for publication / <i>GCP képzési tanúsítvány_Dr. Bagaméri – közzétételre és nem közzétételre szánt verzió</i>	NA	08Apr2021
M3	GCP Training certificate of Dr. Póka – version for publication and version not for publication / <i>GCP képzési tanúsítvány_Dr. Póka – közzétételre és nem közzétételre szánt verzió</i>	NA	05Dec2020
M3	GCP Training certificate_Dr. Sipőcz – version for publication and version not for publication / <i>GCP képzési tanúsítvány_Dr. Sipőcz – közzétételre és nem közzétételre szánt verzió</i>	NA	27Mar2021
N. Suitability of the Sites / A vizsgálóhelyek megfelelése			
N1	Site suitability Template_Dr. Bagaméri version for publication and version not for publication / <i>A vizsgálóhely megfelelését igazoló nyomtatvány_Dr. Bagaméri – közzétételre és nem közzétételre szánt verzió</i>	NA	01Feb2024
N1	Site suitability Template_Dr. Póka version for publication and version not for publication / <i>A vizsgálóhely megfelelését igazoló nyomtatvány_Dr. Póka – közzétételre és nem közzétételre szánt verzió</i>	NA	15Jan2024
N1	Site suitability Template_Dr. Sipőcz version for publication and version not for publication / <i>A vizsgálóhely megfelelését igazoló nyomtatvány_Dr. Sipőcz – közzétételre és nem közzétételre szánt verzió</i>	NA	12Jan2024
N2	Site List – version for publication and version not for publication / <i>A vizsgálóhelyek listája – közzétételre és nem közzétételre szánt verzió</i>	1.0	22Jan2024
O. Proof of Insurance or indemnification / A biztosítási fedezet vagy kártalanítás igazolása			
O1	Certificate of Insurance (Hungary) – version for publication and version not for publication / <i>Biztosítási kötvény (Magyarország) – közzétételre és nem közzétételre szánt verzió</i>	NA	09Feb2024
P. Financial and other arrangements / Pénzügyi és egyéb megállapodások			
P1	Compensation investigator and trial site_Cost Division and Per Patient fee / <i>Vizsgálói és vizsgálóhelyi kompenzáció_Költségmegosztás és betegenkénti díj</i>	1.0	13Feb2024
R. Compliance with national requirements on Data Protection / A nemzeti adatvédelmi előírások betartása			

R1	Statement of compliance with Regulation (EU) 2016/679 (GDPR) – version for publication and version not for publication / <i>Nyilatkozat a 2016/679 (EU) rendeletnek (GDPR) való megfelelésről – közzétételre szánt verzió és nem közzétételre szánt verzió</i>	NA	12Jan2024
S. Compliance with use of Biological samples / A biológiai minták felhasználásának megfelelése			
S1	Compliance with Member State applicable rules for the collection, storage and future use of human biological samples – version for publication / <i>Nyilatkozat a 2016/679 (EU) rendeletnek (GDPR) való megfelelésről – közzétételre szánt verzió</i>	NA	29Jan2024

Part II: IRELAND

Recruitment Arrangements			
1	Recruitment and Informed consent procedure (English)	N/A	22Jan2024
Subject Information Sheet and Informed Consent Form			
1	Main ICF (english)	1.0	29Nov2023
2	Pre-screening ICF (english)	1.0	16Feb2024
3	Patient Card (english)	2.0	29Nov2023
4	GP Letter (English)	3.0	24Jan2024
5	Other Patient facing document: Patient leave behind (English)	2.0	26Oct2023
6	Other Patient facing document: Patient reminder tear pad (English)	1.0	19Jul2023
Suitability of the Investigators			
1	CV Dr Dearbhaile Collins – <i>version for publication and version not for publication</i>	NA	31Aug2022
2	Declaration of Interest Dr Dearbhaile Collins – <i>version for publication</i>	1.0	30Jan2024
5	CV Dr Geraldine O’Sullivan Coyne– <i>version for publication and version not for publication</i>	1.0	21Apr2023
6	Declaration of Interest Dr Geraldine O’Sullivan Coyne – <i>version for publication</i>	1.0	7Feb2024
7	CV Dr Karen Cadoo– <i>version for publication and version not for publication</i>	1.0	4Sep2023
8	Declaration of Interest Dr Karen Cadoo – <i>version for publication and version not for publication</i>	1.0	14Feb2024
9	CV Dr Michael McCarthy – <i>version for publication and version not for publication</i>	1.0	05Mar2024
10	Declaration of Interest Dr Michael McCarthy – <i>version for publication and version not for publication</i>	1.0	05Mar2024
Suitability of the Sites			

1	Site suitability CUH – <i>version for publication and version not for publication</i>	1.0	6Feb2024
3	Site suitability MMUH– <i>version for publication and version not for publication</i>	1.0	9Feb2024
4	Site suitability SJH– <i>version for publication and version not for publication</i>	1.0	14Feb2024
5	Site suitability UHG– <i>version for publication and version not for publication</i>	1.0	05Mar2024
Insurance documents			
1	Certificate – <i>version for publication and version not for publication</i>	NA	09Feb2024
2	Certificate-Title updated- <i>version for publication and version not for publication</i>	NA	09Feb2024
3	Policy – <i>version for publication and version not for publication</i>	NA	18Jan2024
Financial			
1	Payment compensation statement	NA	22Jan2024
2	Confirmation of financing the study	NA	19Feb2024
Compliance with national requirements for the data protection			
1	Sponsor's statement of data processing in compliance with union law on Data Protection – Regulation EU 2016/679 <i>Version for publication and version not for publication</i>	NA	12Jan2024
2	Sponsor's Compliance with Biological Samples	NA	29Jan2024

Part II: ITALY

The referent Italian Ethic Committee is: “Comitato Etico Territoriale Lombardia 1”.

We would like to confirm that the Patient's information sheets and Informed consent forms for Italy have been prepared following the Guidelines of National coordination centre (CCN) of ethics committees for clinical trials.

We declare that the Stamp Duty related to this application has been paid through F23 dated 02 February 2024.

Recruitment Arrangements			
1	Recruitment and Informed consent procedure (English)	N/A	22Jan2024
2	Patient Leave Language: Italian	2	26Oct2023
Subject Information Sheet and Informed Consent Form			
1	Main ICF Italian <i>version for publication and version not for publication</i>	1.0	23Jan2024
2	Pre-screening ICF Italian <i>version for publication and version not for publication</i>	1.0	16Feb2024
Suitability of the Investigators			
1	CV PI Dr. Germana Tognon – <i>version for publication and version not for publication</i>	NA	28Feb2024

2	Declaration of Interest Dr. Germana Tognon – <i>version for publication and version not for publication</i>	NA	29Feb2024
3	CV PI Dr. Federica Tomao – <i>version for publication and version not for publication</i>	NA	06Mar2024
4	Declaration of Interest Federica Tomao – <i>version for publication and version not for publication</i>	NA	06Mar2024
5	CV PI Dr. Federica Villa – <i>version for publication and version not for publication</i>	NA	06Feb2024
6	Declaration of Interest PI Dr. Federica Villa – <i>version for publication and version not for publication</i>	NA	06Feb2024
7	CV PI Prof. Domenica Lorusso – <i>version for publication and version not for publication</i>	NA	19Jan2024
8	Declaration of Interest PI Prof. Domenica Lorusso – <i>version for publication</i>	NA	19Jan2024
9	CV PI Prof. Gennaro Cormio – <i>version for publication and version not for publication</i>	NA	24Jan2024
10	Declaration of Interest PI Prof. Gennaro Cormio – <i>version for publication and version not for publication</i>	NA	24Jan2024
11	CV PI Prof. Giorgio Valabrega – <i>version for publication and version not for publication</i>	NA	29Jan2024
12	Declaration of Interest PI Prof. Giorgio Valabrega – <i>version for publication and version not for publication</i>	NA	05Feb2024
13	CV PI Dr. Carmine De Angelis – <i>version for publication and version not for publication</i>	NA	14Feb2024
14	Declaration of Interest PI Dr. Carmine De Angelis – <i>version for publication and version not for publication</i>	NA	14Feb2024
15	CV PI Dr. Vanda Salutari – <i>version for publication and version not for publication</i>	NA	06Mar2024
16	Declaration of Interest PI Dr. Vanda Salutari – <i>version for publication and version not for publication</i>	NA	29Feb2024
Suitability of the Sites			
1	Site suitability_Site PI Dr. Federica Villa – <i>version for publication and version not for publication</i>	NA	21Feb2024
2	Site suitability_Site PI Prof. Domenica Lorusso – <i>version for publication and version not for publication</i>	NA	22Jan2024
3	Site suitability_Site PI Prof. Gennaro Cormio – <i>version for publication and version not for publication</i>	NA	26Jan2024
4	Site suitability_Site PI Prof. Giorgio Valabrega – <i>version for publication and version not for publication</i>	NA	31Jan2024

5	Site suitability_Site PI Dr. Carmine De Angelis – <i>version for publication and version not for publication</i>	NA	16Feb2024
Insurance documents			
1	Certificate – <i>version for publication and version not for publication</i>	NA	09Feb2024
2	Certificate (Title update) – <i>version for publication and version not for publication</i>	NA	09Feb2024
3	Policy – <i>version for publication and version not for publication</i>	NA	19Jan2024
Financial			
1	Compensation for trial participants form on CCN template Language: English	NA	15Feb2024
2	Compensation investigators: National contract template Language: English and Italian	1	29Feb2024
3	Compensation investigators Budget draft for Italy Language: English	1	29Feb2024
Compliance with national requirements for the data protection			
1	Sponsor's statement of data processing in compliance with union law on Data Protection – Regulation EU 2016/679	NA	12Jan2024
2	Sponsor's Compliance with Biological Samples	NA	29Jan2024

Part II: POLAND

Recruitment Arrangements			
1	K1 Recruitment and Informed consent procedure (English, Polish)	N/A	05Feb2024
Subject Information Sheet and Informed Consent Form			
1	L1 Main ICF (Polish)	1.0	21Feb2024
2	L2 Pre-screening ICF (Polish)	1.0	23Feb2024
Suitability of the Investigators			
1	M1 CV Bidzinski – <i>version for publication and version not for publication</i>	NA	26Feb2024
2	M1 CV Mackowiak-Matejczyk – <i>version for publication and version not for publication</i>	NA	08Feb2024
3	M1 CV Mądry – <i>version for publication and version not for publication</i>	NA	12Feb2024
4	M1 CV Pikiel – <i>version for publication and version not for publication</i>	NA	30Jan2024
3	M2 Declaration of Interest Bidzinski – <i>version for publication and version not for publication</i>	NA	09Feb2024
4	M2 Declaration of Interest Mackowiak-Matejczyk – <i>version for publication and version not for publication</i>	NA	02Feb2024
5	M2 Declaration of Interest Mądry – <i>version for publication and version not for publication</i>	NA	12Feb2024

6	M2 Declaration of Interest Pikiel – <i>version for publication and version not for publication</i>	NA	30Jan2024
7	M3 Investigator suitability Bidzinski– <i>version for publication and version not for publication</i>	NA	09Feb2024
8	M3 Investigator suitability Mackowiak-Matejczyk – <i>version for publication and version not for publication</i>	NA	02Feb2024
9	M3 Investigator suitability Mądry – <i>version for publication and version not for publication</i>	NA	12Feb2024
10	M3 Investigator suitability Pikiel – <i>version for publication and version not for publication</i>	NA	30Jan2024
Suitability of the Sites			
1	N1 Site suitability Bidzinski– <i>version for publication and version not for publication</i>	NA	09Feb2024
2	N1 Site suitability Mackowiak-Matejczyk – <i>version for publication and version not for publication</i>	NA	21Feb2024
3	N1 Site suitability Mądry – <i>version for publication and version not for publication</i>	NA	21Feb2024
4	N1 Site suitability Pikiel – <i>version for publication and version not for publication</i>	NA	15Feb2024
5	N2 Site list with number of patients	NA	27Feb2024
Insurance documents			
1	O1 Policy with Endorsement 1– <i>version for publication and version not for publication</i>	NA	05Mar2024
2	O2 Proof of payment to Compensation Found	NA	19Feb2024
Financial			
1	P1_Compensation trial participants_investigator_funding and other arrangements	NA	22Jan2024
2	P2 Contract Template	NA	23Feb2024
3	P3_Budget Template	NA	12Feb2024
Compliance with national requirements for the data protection			
1	R1 Sponsor's statement of data processing in compliance with union law on Data Protection – Regulation EU 2016/679	NA	05Feb2024
2	S1 Sponsor's Compliance with Biological Samples	NA	29Jan2024

Part II: SPAIN- Please accept as an EC chosen for the study evaluation:
 Comitè Ètic de la Investigació
 Hospital Universitari de Bellvitge
 Antic Mòdul del Banc Santander
 Feixa Llarga, s/n

Recruitment Arrangements			
1	Recruitment and Informed consent procedure (English)	N/A	22JAN2024
Subject Information Sheet and Informed Consent Form			
1	Main ICF (Spanish) <i>version for publication and version not for publication</i>	1.0	29JAN2024
2	Pre-screening ICF (Spanish) <i>version for publication and version not for publication</i>	1.0	16FEB2024
Suitability of the Investigators			
1	CV Oaknin-H Vall d'Hebron – <i>version for publication and version not for publication</i>	NA	15JUN2023
2	CV Sanchez-CUN – <i>version for publication and version not for publication</i>	NA	23MAR2023
3	CV Guerra-H Ramón y Cajal – <i>version for publication and version not for publication</i>	NA	14DEC2023
4	CV Cueva-CHUS – <i>version for publication and version not for publication</i>	NA	23MAR2023
5	CV Romero-IVO – <i>version for publication and version not for publication</i>	NA	11JAN2024
6	CV Rubio-H Reina Sofia – <i>version for publication and version not for publication</i>	NA	31AUG2023
7	CV Alarcón-H Son Espases – <i>version for publication and version not for publication</i>	NA	15DEC2023
8	CV Gost-H Son Llatzer – <i>version for publication and version not for publication</i>	NA	03NOV2023
9	CV Castillo-H Virgen de las Nieves – <i>version for publication and version not for publication</i>	NA	04DEC2023
10	CV Robles-H Virgen de Valme – <i>version for publication and version not for publication</i>	NA	08NOV2023
11	CV Barretina-ICO Girona – <i>version for publication and version not for publication</i>	NA	27NOV2023
12	CV Pardo-ICO L'Hospitalet – <i>version for publication and version not for publication</i>	NA	26JAN2024
1	GCP Training certificate Oaknin-H Vall d'Hebron (Spanish) – <i>version for publication and version not for publication</i>	NA	14JUN2023
2	GCP Training certificate Sanchez-CUN (Spanish) – <i>version for publication and version not for publication</i>	NA	10OCT2022
3	GCP Training certificate Guerra-H Ramón y Cajal	NA	15NOV2023
4	GCP Training certificate Cueva-CHUS	NA	26APR2022
5	GCP Training certificate Romero-IVO	NA	06OCT2023
6	GCP Training certificate Rubio-H Reina Sofia	NA	24APR2023
7	GCP Training certificate Alarcón-H Son Espases	NA	02MAR2023
8	GCP Training certificate Gost-H Son Llatzer	NA	03MAR2023

9	GCP Training certificate Castillo-H Virgen de las Nieves	NA	21FEB2022
10	GCP Training certificate Robles-H Virgen de Valme	NA	02FEB2023
11	GCP Training certificate Barretina-ICO Girona	NA	16MAY2022
12	GCP Training certificate Pardo-ICO L'Hospitalet	NA	02FEB2024
1	Declaration of Interest Oaknin-H Vall d'Hebron – <i>version for publication and version not for publication</i>	NA	04DEC2023
2	Declaration of Interest Sanchez-CUN – <i>version for publication and version not for publication</i>	NA	18DEC2023
3	Declaration of Interest Guerra-H Ramón y Cajal – <i>version for publication and version not for publication</i>	NA	14DEC2023
4	Declaration of Interest Cueva-CHUS – <i>version for publication and version not for publication</i>	NA	11DEC2023
5	Declaration of Interest Romero-IVO – <i>version for publication and version not for publication</i>	NA	11JAN2024
6	Declaration of Interest Rubio-H Reina Sofia – <i>version for publication and version not for publication</i>	NA	28NOV2023
7	Declaration of Interest Alarcón-H Son Espases – <i>version for publication and version not for publication</i>	NA	15DEC2023
8	Declaration of Interest Gost-H Son Llatzer – <i>version for publication and version not for publication</i>	NA	10JAN2024
9	Declaration of Interest Castillo-H Virgen de las Nieves – <i>version for publication and version not for publication</i>	NA	04DEC2023
10	Declaration of Interest Robles-H Virgen de Valme – <i>version for publication and version not for publication</i>	NA	29NOV2023
11	Declaration of Interest Barretina-ICO Girona – <i>version for publication and version not for publication</i>	NA	27NOV2023
12	Declaration of Interest Pardo-ICO L'Hospitalet – <i>version for publication and version not for publication</i>	NA	20FEB2024
Suitability of the Sites			
1	Site suitability H Vall d'Hebron – <i>version for publication and version not for publication</i>	NA	01DEC2023
2	Site suitability CUN and a clarification form for this site– <i>version for publication and version not for publication</i>	NA	30NOV2023 and 04JAN2024
3	Site suitability H Ramón y Cajal – <i>version for publication and version not for publication</i>	NA	22DEC2023
4	Site suitability CHUS – <i>version for publication and version not for publication</i>	NA	19DEC2023
5	Site suitability IVO – <i>version for publication and version not for publication</i>	NA	11DEC2023

6	Site suitability H Reina Sofía de Córdoba – <i>version for publication and version not for publication</i>	NA	28NOV2023
7	Site suitability H Son Espases – <i>version for publication and version not for publication</i>	NA	04DEC2023
8	Site suitability H Son Llätzer – <i>version for publication and version not for publication</i>	NA	04DEC2023
9	Site suitability H Virgen de las Nieves – <i>version for publication and version not for publication</i>	NA	29NOV2023
10	Site suitability H Virgen de Valme – <i>version for publication and version not for publication</i>	NA	30NOV2023
11	Site suitability ICO Girona– <i>version for publication and version not for publication</i>	NA	13FEB2024
12	Site suitability ICO L’Hospitalet – <i>version for publication and version not for publication</i>	NA	21FEB2024
Insurance documents			
1	Certificates (Spanish) – <i>version for publication and version not for publication</i>	NA	09FEB2024
Financial			
1	Investigator & Subject Compensation (Budget) based on protocol version 3	NA	29FEB2024
2	Compensation for trial participants - Declaration Travel Reimbursement	NA	22JAN2024
Compliance with national requirements for the data protection			
1	Sponsor's statement of data processing in compliance with union law on Data Protection – Regulation EU 2016/679 - <i>version for publication and version not for publication</i>	NA	12JAN2024
2	Sponsor’s Compliance with Biological Samples - Version for Spain	NA	29JAN2024

I trust the information provided is adequate and complete, but should you have any queries about the submission content, please do not hesitate to contact me.

I look forward to receiving your response to this application.

Yours sincerely,

Zita Sinkovicz
Regulatory Start Up Manager
Premier Research Hungary Kft.
1036 Budapest
Lajos str. 74-76.
Hungary
Email : zita.sinkovicz@premier-research.com

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