

REQUEST FOR AUTHORISATION OF A CLINICAL TRIAL ON A MEDICINAL PRODUCT FOR HUMAN USE TO THE COMPETENT AUTHORITIES AND FOR OPINION OF THE ETHICS COMMITTEES IN THE COMMUNITY
--

To be filled in by the applicant

The questions in this form for the request for authorisation from the Competent Authority are also relevant for the opinion from an Ethics Committee (it represents module 1 of the form for applying to an ethics committee) and can be used as part of that application. Please indicate the relevant purpose in a box below.

REQUEST FOR AUTHORISATION TO THE COMPETENT AUTHORITY: Yes ●
REQUEST FOR OPINION OF THE ETHICS COMMITTEE: No ●

A. TRIAL IDENTIFICATION

A.1	Member State in which the submission is being made:	Netherlands - Competent Authority
A.2	EudraCT number:	2019-000831-26
A.3	Full title of the trial: English	A two-part parallel group study to assess the safety, tolerability and pharmacokinetic (PK) profile of multiple oral doses of RDN-929 in healthy older adults and subjects with early symptomatic Alzheimer's Disease
A.3.1	Title of the trial for lay people, in easily understood, i.e. non-technical, language: English	To assess the safety, tolerability, uptake and breakdown of multiple doses RDN-929 in healthy older adults and in adults with early symptomatic Alzheimer's Disease
A.3.2	Name or abbreviated title of the trial where available:	
A.4	Sponsor's protocol code number, version and date ¹ :	
A.4.1	Sponsor's protocol code number:	RDN-929-103
A.4.2	Sponsor's protocol version:	amendmt 2
A.4.3	Sponsor's protocol date:	2019-10-11
A.5	Additional international study identifiers (e.g. WHO, ISRCTN ² , US NCT Number ³) if available	
A.5.1	ISRCTN number:	
A.5.2	US NCT number:	
A.5.3	WHO Universal Trial Number (UTN):	
A.5.4	Other Identifier:	
A.6	Is this a resubmission? If 'Yes', indicate the resubmission letter ⁴ :	No ● First Submission
A.7	Is the trial part of an agreed Paediatric Investigation Plan?	No ●
A.8	EMA Decision number of Paediatric Investigation Plan:	

B. IDENTIFICATION OF THE SPONSOR RESPONSIBLE FOR THE REQUEST

B.1 SPONSOR		
B.1.1	Name of organisation:	Rodin Therapeutics, Inc.
B.1.2	Name of the person to contact:	
B.1.2.1	Given name	5.1.2.e
B.1.2.2	Middle name	
B.1.2.3	Family name	5.1.2.e
B.1.3	Address:	
B.1.3.1	Street address	300 Technology Square, 8th Floor
B.1.3.2	Town/city	Cambridge
B.1.3.3	Post code	MA02139
B.1.3.4	Country	United States
B.1.4	Telephone number:	+1 5.1.2.e
B.1.5	Fax number:	
B.1.6	E-mail:	5.1.2.e@rodintherapeutics.com
B.2 LEGAL REPRESENTATIVE⁵ OF THE SPONSOR IN THE COMMUNITY FOR THE PURPOSE OF THIS TRIAL (if different from the sponsor)		
B.2.1	Name of organisation:	QPS Netherlands B.V.
B.2.2	Name of person to contact:	
B.2.2.1	Given name	5.1.2.e
B.2.2.2	Middle name	
B.2.2.3	Family name	5.1.2.e
B.2.3	Address:	
B.2.3.1	Street address	Petrus Campersingel 123
B.2.3.2	Town/city	Groningen
B.2.3.3	Post code	9713AG
B.2.3.4	Country	Netherlands
B.2.4	Telephone number:	+31 50 304 5.1.2.e
B.2.5	Fax number:	+31 50 304 5.1.2.e
B.2.6	E-mail:	
B.3 STATUS OF THE SPONSOR:		
B.3.1	Commercial:	Yes •
B.3.2	Non commercial:	No •
B.4 Source(s) of Monetary or Material Support for the clinical trial (repeat as necessary):		
B.4.1	Name of organisation:	Rodin Therapeutics, Inc.
B.4.2	Country:	United States
B.5 Contact point⁶ designated by the sponsor for further information on the trial		
B.5.1	Name of organisation:	Rodin Therapeutics, Inc.
B.5.2	Functional name of contact point (e.g. "Clinical Trial Information Desk"):	5.1.2.e
B.5.3	Address:	
B.5.3.1	Street address	300 Technology Square, 8th Floor
B.5.3.2	Town/city	Cambridge
B.5.3.3	Post code	MA02139
B.5.3.4	Country	United States
B.5.4	Telephone number:	+1 5.1.2.e
B.5.5	Fax number:	
B.5.6	E-mail: (use a functional e-mail address rather than a personal one)	5.1.2.e@rodintherapeutics.com

C. APPLICANT IDENTIFICATION, (please tick the appropriate box)

C.1 REQUEST FOR THE COMPETENT AUTHORITY	
C.1.1	Sponsor
C.1.2	Legal representative of the sponsor
C.1.3	Person or organisation authorised by the sponsor to make the application Yes •
C.1.4	Complete the details of the applicant below even if they are provided elsewhere on the form:
C.1.4.1	Name of Organisation: QPS Netherlands B.V.
C.1.4.2	Name of contact person:
C.1.4.2.1	Given name 5.1.2.e
C.1.4.2.2	Middle name
C.1.4.2.3	Family name 5.1.2.e
C.1.4.3	Address:
C.1.4.3.1	Street address Petrus Campersingel 123
C.1.4.3.2	Town/city Groningen
C.1.4.3.3	Post code 9713 AG
C.1.4.3.4	Country Netherlands
C.1.4.4	Telephone number: +31 50 304 5.1.2.e
C.1.4.5	Fax number: +31 50 304 5.1.2.e
C.1.4.6	E-mail: 5.1.2.e @qps.com
C.1.5	Request to receive a copy of CTA data as XML:
C.1.5.1	Do you want a copy of the CTA form data saved on EudraCT as an XML file? No •
C.1.5.1.1	If Yes provide the e-mail address(es) to which it should be sent (up to 5 addresses):
C.1.5.1.2	Do you want to receive this via password protected link(s)?? No •
If you answer No to question C.1.5.1.2 the .xml file will be transmitted by less secure e-mail link(s)	

D. INFORMATION ON EACH IMP

Information on each 'bulk product' before trial-specific operations (blinding, trial specific packaging and labelling) should be provided in this section for each investigational medicinal product (IMP) being tested including each comparator and each placebo, if applicable. **For placebo go directly to D.8.** If the trial is performed with several products use extra pages and give each product a sequential number in D.1.1. If the product is a combination product, information should be given for each active substance.

D.1 IMP IDENTIFICATION		
Indicate which of the following is described below, then repeat as necessary for each of the numbered IMPs to be used in the trial (assign numbers from 1-n):		
D.1.1	This refers to the IMP number:	PR1
D.1.2	IMP being tested	Yes •
D.1.3	IMP used as a comparator	No •
D.2 STATUS OF THE IMP		
D.2.1	Has the IMP to be used in the trial a marketing authorisation? No • If the IMP has a marketing authorisation in the Member State concerned by this application, but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2.	
D.2.1.1	If 'Yes', specify the product to be used in the clinical trial:	
D.2.1.1.1	Trade name	
D.2.1.1.1.1	EV Product Code (where applicable)	
D.2.1.1.2	Name of the Marketing Authorisation Holder:	
D.2.1.1.3	Marketing Authorisation number (if Marketing Authorisation granted by a Member State):	
D.2.1.1.4	Is the IMP modified in relation to its Marketing Authorisation? No •	
D.2.1.1.4.1	If 'Yes', please specify:	
D.2.1.2	The country that granted the Marketing Authorisation	
D.2.1.2.1	Is this the Member State concerned with this application? No •	
D.2.2	Situations where an IMP to be used in the CT has a Marketing Authorisation in the Member State concerned, but the protocol allows that any brand of the IMP with a Marketing Authorisation in that Member State be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start	
D.2.2.1	In the protocol, is treatment defined only by active substance? No •	
D.2.2.1.1	If 'Yes', give active substance in D.3.8 or D.3.9	
D.2.2.2	In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS? No •	
D.2.2.2.1	If 'Yes', give active substance in D.3.8 or D.3.9	
D.2.2.3	The products to be administered as IMPs are defined as belonging to an ATC group ⁹ No •	
D.2.2.3.1	If 'Yes', give the ATC group of the applicable authorised codes in the ATC code field (level 3 or the level that can be defined) in D.3.3	
D.2.2.4	Other: No •	
D.2.2.4.1	If 'Yes', please specify:	
D.2.3	IMPD submitted:	
D.2.3.1	Full IMPD: Yes •	
D.2.3.2	Simplified IMPD: No •	
D.2.3.3	Summary of product characteristics (SmPC) only: No •	
D.2.4	Has the use of the IMP been previously authorised in a No •	

D.2.4.1	clinical trial conducted by the sponsor in the Community? If 'Yes' specify which Member States:	
D.2.5	Has the IMP been designated in this indication as an orphan drug in the Community?	No •
D.2.5.1	If 'Yes', give the orphan drug designation number ¹⁰ :	

D.2.6	Has the IMP been the subject of scientific advice related to this clinical trial?	No •
D.2.6.1	If 'Yes' to D.2.6, please indicate source of advice and provide a copy in the CTA request:	
D.2.6.1.1	CHMP ¹¹ ?	No •
D.2.6.1.2	National Competent Authority?	No •

D.3	DESCRIPTION OF THE IMP	
D.3.1	Product name where applicable ¹² :	
D.3.2	Product code where applicable ¹³ :	RDN-929
D.3.3	ATC codes, if officially registered ¹⁴ :	
D.3.4	Pharmaceutical form (use standard terms):	Capsule
D.3.4.1	Is this a specific paediatric formulation?	No •
D.3.5	Maximum duration of treatment of a subject according to the protocol: once daily for 28 days	
D.3.6	Dose allowed:	
D.3.6.1	For first trial only: Specify per day or total Specify total dose (number and unit): Route of administration (relevant to the first dose):	Not Answered •
D.3.6.2	For all trials Specify per day or total Specify total dose (number and unit): Route of administration (relevant to the maximum dose):	Total • 200 mg milligram(s) Oral use
D.3.7	Routes of administration (use standard terms):	Oral use

D.3.8	Name of each active substance (INN or proposed INN if available): N.Ap.	
D.3.9	Other available name for each active substance (provide all available):	
D.3.9.1	CAS ¹⁵ number	N.Ap.
D.3.9.2	Current sponsor code	RDN-929
D.3.9.3	Other descriptive name RDN-929 MALATE	
D.3.9.4	EV Substance code	SUB193800
D.3.9.5	Full Molecular formula C21H19F2N5O2	
D.3.9.6	Chemical/biological description of the Active Substance	
D.3.10	Strength (specify all strengths to be used):	
D.3.10.1	Concentration unit:	mg milligram(s)
D.3.10.2	Concentration type ("exact number", "range", "more than" or "up to"):	not less than
D.3.10.3	Concentration (number).	25

D.3.11	Type of IMP	
Does the IMP contain an active substance:		
D.3.11.1	Of chemical origin?	Yes •
D.3.11.2	Of biological / biotechnological origin (other than Advanced Therapy IMP (ATIMP))?	No •
Is this a:		

D.3.11.3	Advanced Therapy IMP (ATIMP)?	No ●
D.3.11.3.1	Somatic cell therapy medicinal product ¹⁶ ?	No ●
D.3.11.3.2	Gene therapy medicinal product ¹⁷ ?	No ●
D.3.11.3.3	Tissue Engineered Product ¹⁸ ?	No ●
D.3.11.3.4	Combination ATIMP (i.e. one involving a medical device ¹⁹)?	No ●
D.3.11.3.5	Has the Committee on Advanced Therapies issued a classification for this product?	No ●
D.3.11.3.5.1	If 'Yes' please provide that classification and its reference number:	
D.3.11.4	Combination product that includes a device, but does not involve an Advanced Therapy?	No ●
D.3.11.5	Radiopharmaceutical medicinal product?	No ●
D.3.11.6	Immunological medicinal product (such as vaccine, allergen, immune serum)?	No ●
D.3.11.7	Plasma derived medicinal product?	No ●
D.3.11.8	Extractive medicinal product?	No ●
D.3.11.9	Recombinant medicinal product?	No ●
D.3.11.10	Medicinal product containing genetically modified organisms?	No ●
D.3.11.10.1	Has the authorisation for contained use or release been granted?	No ●
D.3.11.10.2	Is it pending?	No ●
D.3.11.11	Herbal medicinal product?	No ●
D.3.11.12	Homeopathic medicinal product?	No ●
D.3.11.13	Another type of medicinal product?	No ●
D.3.11.13.1	If 'another type of medicinal product' specify the type of medicinal product:	
D.3.12	Mode of action (<i>free text</i> ²⁰)	
	5.1.1.c [REDACTED]	
D.3.13	Is it an IMP to be used in a first-in-human clinical trial?	No ●
D.3.13.1	If 'Yes', are there risk factors identified, according to the guidance FIH? ²¹	

D.4	SOMATIC CELL THERAPY INVESTIGATIONAL MEDICINAL PRODUCT (NO GENETIC MODIFICATION)	
D.4.1	Origin of cells	
D.4.1.1	Autologous	No ●
D.4.1.2	Allogeneic	No ●
D.4.1.3	Xenogeneic	No ●
D.4.1.3.1	If 'Yes', specify the species of origin:	
D.4.2	Type of cells	
D.4.2.1	Stem cells	No ●
D.4.2.2	Differentiated cells	No ●
D.4.2.2.1	If 'Yes', specify the type (e.g. keratinocytes, fibroblasts, chondrocytes...):	
D.4.2.3	Others:	No ●
D.4.2.3.1	If others, specify:	

D.5	GENE THERAPY INVESTIGATIONAL MEDICINAL PRODUCTS	
D.5.1	Gene(s) of interest:	
D.5.2	In vivo gene therapy:	No ●
D.5.3	Ex vivo gene therapy:	No ●
D.5.4	Type of gene transfer product	
D.5.4.1	Nucleic acid (e.g. plasmid):	No ●
	If 'Yes', specify if:	
D.5.4.1.1	Naked:	No ●
D.5.4.1.2	Complexed	No ●

D.5.4.2	Viral vector:	No •
D.5.4.2.1	If 'Yes', specify the type: adenovirus, retrovirus, AAV, ...:	
D.5.4.3	Others	No •
D.5.4.3.1	If others, specify:	
D.5.5	Genetically modified somatic cells:	No •
	If 'Yes', specify the origin of the cells:	
D.5.5.1	Autologous:	No •
D.5.5.2	Allogeneic:	No •
D.5.5.3	Xenogeneic:	No •
D.5.5.3.1	If 'Yes', specify the species of origin:	
D.5.5.4	Specify type of cells (hematopoietic stem cells...):	

D.6 TISSUE ENGINEERED PRODUCT		
The indication which determines that this is a Tissue Engineered Product as opposed to a Cell Therapy product is given in section E.1.1.		
D.6.1	Origin of cells	
D.6.1.1	Autologous	No •
D.6.1.2	Allogeneic	No •
D.6.1.3	Xenogeneic	No •
D.6.1.3.1	If 'Yes', specify the species of origin:	
D.6.2	Type of cells	
D.6.2.1	Stem cells	No •
D.6.2.2	Differentiated cells	No •
D.6.2.2.1	If 'Yes', specify the type of cells(e.g. keratinocytes, fibroblasts, chondrocytes, ...):	
D.6.2.3	Others:	No •
D.6.2.3.1	If others, specify:	

D.7 PRODUCTS CONTAINING DEVICES (i.e. MEDICAL DEVICES, SCAFFOLDS ETC.)		
D.7.1	Give a brief description of the device:	
D.7.2	What is the name of the device?	
D.7.3	Is the device implantable?	No •
D.7.4	Does this product contain:	
D.7.4.1	A medical device?	No •
D.7.4.1.1	Does this medical device have a CE mark?	No •
D.7.4.1.1.1	The notified body is:	
D.7.4.2	Bio-materials?	No •
D.7.4.3	Scaffolds?	No •
D.7.4.4	Matrices?	No •
D.7.4.5	Other?	No •
D.7.4.5.1	If other, specify:	

D.1 IMP IDENTIFICATION		
Indicate which of the following is described below, then repeat as necessary for each of the numbered IMPs to be used in the trial (assign numbers from 1-n):		
D.1.1	This refers to the IMP number:	PR2
D.1.2	IMP being tested	Yes •
D.1.3	IMP used as a comparator	No •

D.2 STATUS OF THE IMP		
------------------------------	--	--

D.2.1	Has the IMP to be used in the trial a marketing authorisation? No • If the IMP has a marketing authorisation in the Member State concerned by this application, but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2.
D.2.1.1	If 'Yes', specify the product to be used in the clinical trial:
D.2.1.1.1	Trade name
D.2.1.1.1.1	EV Product Code (where applicable)
D.2.1.1.2	Name of the Marketing Authorisation Holder:
D.2.1.1.3	Marketing Authorisation number (if Marketing Authorisation granted by a Member State):
D.2.1.1.4	Is the IMP modified in relation to its Marketing Authorisation? No •
D.2.1.1.4.1	If 'Yes', please specify:
D.2.1.2	The country that granted the Marketing Authorisation
D.2.1.2.1	Is this the Member State concerned with this application? No •

D.2.2	Situations where an IMP to be used in the CT has a Marketing Authorisation in the Member State concerned, but the protocol allows that any brand of the IMP with a Marketing Authorisation in that Member State be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start
D.2.2.1	In the protocol, is treatment defined only by active substance? No •
D.2.2.1.1	If 'Yes', give active substance in D.3.8 or D.3.9
D.2.2.2	In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS? No •
D.2.2.2.1	If 'Yes', give active substance in D.3.8 or D.3.9
D.2.2.3	The products to be administered as IMPs are defined as belonging to an ATC group ⁹ No •
D.2.2.3.1	If 'Yes', give the ATC group of the applicable authorised codes in the ATC code field (level 3 or the level that can be defined) in D.3.3
D.2.2.4	Other: No •
D.2.2.4.1	If 'Yes', please specify:

D.2.3	IMPD submitted:
D.2.3.1	Full IMPD: Yes •
D.2.3.2	Simplified IMPD: No •
D.2.3.3	Summary of product characteristics (SmPC) only: No •
D.2.4	Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community? No •
D.2.4.1	If 'Yes' specify which Member States:
D.2.5	Has the IMP been designated in this indication as an orphan drug in the Community? No •
D.2.5.1	If 'Yes', give the orphan drug designation number ¹⁰ :

D.2.6	Has the IMP been the subject of scientific advice related to this clinical trial? No •
D.2.6.1	If 'Yes' to D.2.6, please indicate source of advice and provide a copy in the CTA request:
D.2.6.1.1	CHMP ¹¹ ? No •
D.2.6.1.2	National Competent Authority? No •

D.3	DESCRIPTION OF THE IMP
D.3.1	Product name where applicable ¹² : Radioligand [11C]-UCB-J
D.3.2	Product code where applicable ¹³ : [11C]-UCB-J
D.3.3	ATC codes, if officially registered ¹⁴ :

D.3.4	Pharmaceutical form (use standard terms):	Solution for injection
D.3.4.1	Is this a specific paediatric formulation?	No •
D.3.5	Maximum duration of treatment of a subject according to the protocol: 1 minute	
D.3.6	Dose allowed:	
D.3.6.1	For first trial only: Specify per day or total Specify total dose (number and unit): Route of administration (relevant to the first dose):	Not Answered •
D.3.6.2	For all trials Specify per day or total Specify total dose (number and unit): Route of administration (relevant to the maximum dose):	Total • 740 MBq megabecquerel(s) Intravenous bolus use (Noncurrent)
D.3.7	Routes of administration (use standard terms):	Intravenous bolus use (Noncurrent)

D.3.8	Name of each active substance (INN or proposed INN if available):	
D.3.9	Other available name for each active substance (provide all available):	
D.3.9.1	CAS ¹⁵ number	
D.3.9.2	Current sponsor code	
D.3.9.3	Other descriptive name	
D.3.9.4	EV Substance code	
D.3.9.5	Full Molecular formula	
D.3.9.6	Chemical/biological description of the Active Substance	
D.3.10	Strength (specify all strengths to be used):	
D.3.10.1	Concentration unit:	
D.3.10.2	Concentration type ("exact number", "range", "more than" or "up to"):	
D.3.10.3	Concentration (number).	

D.3.11	Type of IMP	
Does the IMP contain an active substance:		
D.3.11.1	Of chemical origin?	Yes •
D.3.11.2	Of biological / biotechnological origin (other than Advanced Therapy IMP (ATIMP))?	No •
Is this a:		
D.3.11.3	Advanced Therapy IMP (ATIMP)?	No •
D.3.11.3.1	Somatic cell therapy medicinal product ¹⁶ ?	No •
D.3.11.3.2	Gene therapy medicinal product ¹⁷ ?	No •
D.3.11.3.3	Tissue Engineered Product ¹⁸ ?	No •
D.3.11.3.4	Combination ATIMP (i.e. one involving a medical device ¹⁹)?	No •
D.3.11.3.5	Has the Committee on Advanced Therapies issued a classification for this product?	No •
D.3.11.3.5.1	If 'Yes' please provide that classification and its reference number:	
D.3.11.4	Combination product that includes a device, but does not involve an Advanced Therapy?	No •
D.3.11.5	Radiopharmaceutical medicinal product?	Yes •
D.3.11.6	Immunological medicinal product (such as vaccine, allergen, immune serum)?	No •
D.3.11.7	Plasma derived medicinal product?	No •
D.3.11.8	Extractive medicinal product?	No •
D.3.11.9	Recombinant medicinal product?	No •
D.3.11.10	Medicinal product containing genetically modified organisms?	No •
D.3.11.10.1	Has the authorisation for contained use or release been granted?	No •
D.3.11.10.2	Is it pending?	No •

D.3.11.11	Herbal medicinal product?	No •
D.3.11.12	Homeopathic medicinal product?	No •
D.3.11.13	Another type of medicinal product?	No •
D.3.11.13.1	If 'another type of medicinal product' specify the type of medicinal product:	
D.3.12	Mode of action (<i>free text</i> ²⁰)	
D.3.13	Is it an IMP to be used in a first-in-human clinical trial?	No •
D.3.13.1	If 'Yes', are there risk factors identified, according to the guidance FIH? ²¹	

D.4	SOMATIC CELL THERAPY INVESTIGATIONAL MEDICINAL PRODUCT (NO GENETIC MODIFICATION)	
D.4.1	Origin of cells	
D.4.1.1	Autologous	No •
D.4.1.2	Allogeneic	No •
D.4.1.3	Xenogeneic	No •
D.4.1.3.1	If 'Yes', specify the species of origin:	
D.4.2	Type of cells	
D.4.2.1	Stem cells	No •
D.4.2.2	Differentiated cells	No •
D.4.2.2.1	If 'Yes', specify the type (e.g. keratinocytes, fibroblasts, chondrocytes...):	
D.4.2.3	Others:	No •
D.4.2.3.1	If others, specify:	

D.5	GENE THERAPY INVESTIGATIONAL MEDICINAL PRODUCTS	
D.5.1	Gene(s) of interest:	
D.5.2	In vivo gene therapy:	No •
D.5.3	Ex vivo gene therapy:	No •
D.5.4	Type of gene transfer product	
D.5.4.1	Nucleic acid (e.g. plasmid):	No •
	If 'Yes', specify if:	
D.5.4.1.1	Naked:	No •
D.5.4.1.2	Complexed	No •
D.5.4.2	Viral vector:	No •
D.5.4.2.1	If 'Yes', specify the type: adenovirus, retrovirus, AAV, ...:	
D.5.4.3	Others	No •
D.5.4.3.1	If others, specify:	
D.5.5	Genetically modified somatic cells:	No •
	If 'Yes', specify the origin of the cells:	
D.5.5.1	Autologous:	No •
D.5.5.2	Allogeneic:	No •
D.5.5.3	Xenogeneic:	No •
D.5.5.3.1	If 'Yes', specify the species of origin:	
D.5.5.4	Specify type of cells (hematopoietic stem cells...):	

D.6	TISSUE ENGINEERED PRODUCT	
The indication which determines that this is a Tissue Engineered Product as opposed to a Cell Therapy product is given in section E.1.1.		
D.6.1	Origin of cells	
D.6.1.1	Autologous	No •
D.6.1.2	Allogeneic	No •
D.6.1.3	Xenogeneic	No •
D.6.1.3.1	If 'Yes', specify the species of origin:	

D.6.2	Type of cells	
D.6.2.1	Stem cells	No •
D.6.2.2	Differentiated cells	No •
D.6.2.2.1	If 'Yes', specify the type of cells(e.g. keratinocytes, fibroblasts, chondrocytes, ...):	
D.6.2.3	Others:	No •
D.6.2.3.1	If others, specify:	

D.7	PRODUCTS CONTAINING DEVICES (i.e. MEDICAL DEVICES, SCAFFOLDS ETC.)	
D.7.1	Give a brief description of the device:	
D.7.2	What is the name of the device?	
D.7.3	Is the device implantable?	No •
D.7.4	Does this product contain:	
D.7.4.1	A medical device?	No •
D.7.4.1.1	Does this medical device have a CE mark?	No •
D.7.4.1.1.1	The notified body is:	
D.7.4.2	Bio-materials?	No •
D.7.4.3	Scaffolds?	No •
D.7.4.4	Matrices?	No •
D.7.4.5	Other?	No •
D.7.4.5.1	If other, specify:	

D.8 INFORMATION ON PLACEBO (if relevant; repeat as necessary)

D.8.1	Is there a placebo:	Yes •
D.8.2	This refers to placebo number:	PL1
D.8.3	Pharmaceutical form:	Capsule
D.8.4	Route of administration:	Oral use
D.8.5	Which IMP is it a placebo for? Specify IMP Number(s) from D.1.1	PR1
D.8.5.1	Composition, apart from the active substance(s):	
D.8.5.2	Is it otherwise identical to the IMP?	Yes •
D.8.5.2.1	If not, specify major ingredients:	

D.9 SITE(S) WHERE THE QUALIFIED PERSON CERTIFIES BATCH RELEASE²²

*This section is dedicated to **finished** IMPs, i.e. medicinal products randomised, packaged, labelled and certified for use in the clinical trial. If there is more than one site or more than one IMP is certified, use extra pages and give each IMP its number from section D.1.1 or D.8.2 In the case of multiple sites indicate the product certified by each site*

D.9.1	Do not fill in section D.9.2 for an IMP that: <i>Has a MA in the EU and Is sourced from the EU market and Is used in the trial without modification(e.g. not overencapsulated) and The packaging and labelling is carried out for local use only as per article 9.2. of the Directive 2005/28/EC (GCP Directive)</i> If all these conditions are met tick ?and list the number(s) of each IMP including placebo from sections D.1.1 and D.8.2 to which this applies
-------	--

D.9.2 Who is responsible in the Community for the certification of the finished IMPs?

This site is responsible for certification of (list the number(s) of each IMP including placebo from sections D.1.1 and D.8.2): **PR1**

please tick the appropriate box:

- | | | |
|-----------|--|--------------------|
| D.9.2.1 | Manufacturer | No • |
| D.9.2.2 | Importer | Yes • |
| D.9.2.3 | Name of the organisation: | 5.1.1.c [REDACTED] |
| D.9.2.4 | Address: | |
| D.9.2.4.1 | Street Address | 5.1.1.c [REDACTED] |
| D.9.2.4.2 | Town/City | 5.1.1.c [REDACTED] |
| D.9.2.4.3 | Post Code | 5.1.1.c [REDACTED] |
| D.9.2.4.4 | Country | 5.1.1.c [REDACTED] |
| D.9.2.5 | Give the manufacturing authorisation number: | 5.1.1.c [REDACTED] |
| D.9.2.5.1 | If No authorisation, give the reasons: | |

Where the product does not have a MA in the EU, but is supplied in bulk and final packaging and labelling for local use is carried out in accordance with article 9.2 of Directive 2005/28/EC (GCP Directive) then enter the site where the product was finally certified for release by the Qualified Person for use in the clinical trial at D.9.2 above.

D.9.2 Who is responsible in the Community for the certification of the finished IMPs?

This site is responsible for certification of (list the number(s) of each IMP including placebo from sections D.1.1 and D.8.2): **PR2**

please tick the appropriate box:

- | | | |
|-----------|--|--|
| D.9.2.1 | Manufacturer | Yes • |
| D.9.2.2 | Importer | No • |
| D.9.2.3 | Name of the organisation: | University Medical Center Groningen |
| D.9.2.4 | Address: | |
| D.9.2.4.1 | Street Address | Hanzeplein 1 |
| D.9.2.4.2 | Town/City | Groningen |
| D.9.2.4.3 | Post Code | 9713 AG |
| D.9.2.4.4 | Country | Netherlands |
| D.9.2.5 | Give the manufacturing authorisation number: | 108964 F |
| D.9.2.5.1 | If No authorisation, give the reasons: | |

Where the product does not have a MA in the EU, but is supplied in bulk and final packaging and labelling for local use is carried out in accordance with article 9.2 of Directive 2005/28/EC (GCP Directive) then enter the site where the product was finally certified for release by the Qualified Person for use in the clinical trial at D.9.2 above.

D.9.2 Who is responsible in the Community for the certification of the finished IMPs?

This site is responsible for certification of (list the number(s) of each IMP including placebo from sections D.1.1 and D.8.2): **PR2**

please tick the appropriate box:

- | | | |
|---------|---------------------------|----------------------|
| D.9.2.1 | Manufacturer | Yes • |
| D.9.2.2 | Importer | No • |
| D.9.2.3 | Name of the organisation: | Amsterdam UMC |
| D.9.2.4 | Address: | |

D.9.2.4.1	Street Address	De Boelelaan 1118
D.9.2.4.2	Town/City	Amsterdam
D.9.2.4.3	Post Code	1081 HZ
D.9.2.4.4	Country	Netherlands
D.9.2.5	Give the manufacturing authorisation number:	6682 F
D.9.2.5.1	If No authorisation, give the reasons:	

Where the product does not have a MA in the EU, but is supplied in bulk and final packaging and labelling for local use is carried out in accordance with article 9.2 of Directive 2005/28/EC (GCP Directive) then enter the site where the product was finally certified for release by the Qualified Person for use in the clinical trial at D.9.2 above.

E. GENERAL INFORMATION ON THE TRIAL

This section should be used to provide information about the aims, scope and design of the trial. When the protocol includes a sub-study in the MS concerned section E.2.3 should be completed providing information about the sub-study. To identify it check the sub-study box in the 'Objective of the trial' question below.

E.1 MEDICAL CONDITION OR DISEASE UNDER INVESTIGATION					
E.1.1	Specify the medical condition(s) to be investigated ²³ (free text): English neurodegenerative diseases with synaptic dysfunction				
E.1.1.1	Medical condition in easily understood language English Alzheimer's disease				
E.1.1.2	Therapeutic area Psychiatry and Psychology [F] - Mental Disorders [F03]				
E.1.2	MedDRA version, system organ class, level, term and classification code ²⁴ :				
	Version	System Organ Class	Classification Code	Term	Level
	21.1	10029205 - Nervous system disorders	10053643	Neurodegenerative disorder	PT
E.1.3	Is any of the conditions being studied a rare disease ²⁵ ?				No •
E.2 OBJECTIVE OF THE TRIAL					
E.2.1	Main objective: English Primary objective: To assess the safety and tolerability of multiple, once-daily oral doses of RDN-929 over 28 days in healthy older adult subjects and early symptomatic Alzheimer's Disease (AD) subjects.				
E.2.2	Secondary objectives: English Secondary: To assess the plasma and CSF pharmacokinetics (PK) of RDN-929 in healthy older adult subjects and early symptomatic AD subjects.				
	Exploratory: Part 1: To explore the pharmacodynamics (PD) of RDN-929 in blood through analysis of peripheral blood mononuclear cells (PBMC) as well as synaptic and neuronal biomarkers in plasma and CSF in healthy older adult subjects.				
	Part 2: To explore the pharmacodynamics (PD) of RDN-929 through analysis of synaptic and neuronal biomarkers in plasma and CSF in early symptomatic AD subjects. To explore the change from baseline in quantitative Electroencephalography (qEEG) in early symptomatic AD subjects. To assess the mean change from baseline in radioligand [11C]-UCB-J binding in pre-defined brain regions as measured by PET imaging in early symptomatic AD subjects.				
	Part 1 and 2: To explore the change from baseline in clinical measures of cognition in healthy older adult subjects and early symptomatic AD subjects.				
E.2.3	Is there a sub-study?				No •
E.2.3.1	If 'Yes', give the full title, date and version of each sub-study and their related objectives:				

E.3 PRINCIPAL INCLUSION CRITERIA (<i>list the most important</i>)	
English	<p>Adult males or postmenopausal or surgically sterile females age 55 – 85 years old for Part 1 and age 50 – 85 years old for Part 2, inclusive, at the time of informed consent.</p> <p>Body mass index (BMI) ≥ 18.0 kg/m², < 35.0 kg/m² . Further inclusion criteria can be found in the protocol section 8.5.1.</p>
E.4 PRINCIPAL EXCLUSION CRITERIA (<i>list the most important</i>)	
English	<p>History or current evidence of any clinically significant cardiovascular, endocrinologic, hematologic, hepatobiliary, immunologic, metabolic, urologic, pulmonary, neurologic (except for diagnosis of AD in Part 2), renal, or other major disease, as determined by the Investigator. Any conditions that, in the opinion of the Investigator, would make the subject unsuitable for enrollment or could interfere with the subject's participation in or completion of the study. Further exclusion criteria can be found in the protocol section 8.5.2</p>
E.5 END POINT(S):	
E.5.1	Primary End Point (repeat as necessary) ²⁶
English	Safety parameters include adverse events (AEs), serious adverse events (SAEs), physical and neurological examination, clinical laboratory values, vital signs, 12-lead ECG, and C-SSRS scores.
E.5.1.1	Timepoint(s) of evaluation of this end point
English	Throughout the study
E.5.2	Secondary End Point (repeat as necessary)
English	<p>Secondary Endpoints: Plasma PK and CSF parameters of RDN-929 such as Cmax and AUC as appropriate.</p> <p>Exploratory Endpoints: Part 1 and 2: PD parameters including selected biomarkers (within group changes and mean group differences).</p> <p>Part 1: PD parameters including PBMC post-translational modification (changes over time and mean group differences).</p> <p>Part 2: Quantitative Electroencephalography (qEEG), including resting state power spectral density (PSD), functional connectivity and Event Related Potential (ERP) acquired during neurocognitive tasks. Mean change in [11C]-UCB-J binding in pre-defined brain regions from baseline (Part 2 only) as measured by PET imaging.</p>
E.5.2.1	Timepoint(s) of evaluation of this end point
English	Throughout the study

E.6 SCOPE OF THE TRIAL – Tick all boxes where applicable		
E.6.1	Diagnosis	No ●
E.6.2	Prophylaxis	No ●
E.6.3	Therapy	No ●
E.6.4	Safety	Yes ●
E.6.5	Efficacy	No ●
E.6.6	Pharmacokinetic	Yes ●
E.6.7	Pharmacodynamic	Yes ●
E.6.8	Bioequivalence	No ●
E.6.9	Dose Response	No ●
E.6.10	Pharmacogenetic	No ●
E.6.11	Pharmacogenomic	No ●
E.6.12	Pharmacoeconomic	No ●
E.6.13	Others	Yes ●
E.6.13.1	If others, specify: English qEEG, radioligand binding	

E.7 TRIAL TYPE AND PHASE²⁷		
E.7.1	Human pharmacology (Phase I)	Yes ●
Is it:		
E.7.1.1	First administration to humans	No ●
E.7.1.2	Bioequivalence study	No ●
E.7.1.3	Other:	Yes ●
E.7.1.3.1	If other, please specify: English Pharmacokinetics	
E.7.2	Therapeutic exploratory (Phase II)	No ●
E.7.3	Therapeutic confirmatory (Phase III)	No ●
E.7.4	Therapeutic use(Phase IV)	No ●

E.8 DESIGN OF THE TRIAL		
E.8.1	Controlled	Yes ●
If 'Yes', specify:		
E.8.1.1	Randomised:	Yes ●
E.8.1.2	Open:	No ●
E.8.1.3	Single blind:	No ●
E.8.1.4	Double blind:	Yes ●
E.8.1.5	Parallel group:	Yes ●
E.8.1.6	Cross over:	No ●
E.8.1.7	Other:	Yes ●
E.8.1.7.1	If other specify: English Part 2: open design	
E.8.2	If controlled, specify the comparator:	
E.8.2.1	Other medicinal product(s)	No ●
E.8.2.2	Placebo	Yes ●
E.8.2.3	Other	No ●
E.8.2.3.1	If 'Yes' to other, specify :	
E.8.2.4	Number of treatment arms in the trial	4
E.8.3	Single site in the Member State concerned (see also section G):	No ●
E.8.4	Multiple sites in the Member State concerned(see also section G):	Yes ●
E.8.4.1	Number of sites anticipated in Member State concerned	3
E.8.5	Multiple Member States:	No ●
E.8.5.1	Number of sites anticipated in the EEA:	
E.8.6	Trial involving sites outside the EEA:	
E.8.6.1	Trial being conducted both within and outside the EEA:	No ●
E.8.6.2	Trial being conducted completely outside of the EEA:	No ●
E.8.6.3	If E.8.6.1 or E.8.6.2 are Yes, specify the regions in which trial sites are planned:	

E.8.6.4	If E.8.6.1 or E.8.6.2 are Yes, specify the number of sites anticipated outside of the EEA:	
E.8.7	Trial having an independent data monitoring committee:	No •
E.8.8	Definition of the end of trial: If it is the last visit of the last subject, please enter "LVLS". If it is not LVLS provide the definition: English LSLV	
E.8.9	Initial estimate of the duration of the trial ²⁸ (years, months and days)	
E.8.9.1	In the Member State concerned	years 9 months days
E.8.9.2	In all countries concerned by the trial	years months days
E.8.10	Proposed date of start of recruitment	
E.8.10.1	In the Member State concerned	2019-05-15
E.8.10.2	In any country	

F. POPULATION OF TRIAL SUBJECTS

F.1 AGE RANGE		
F.1.1	Are the trial subjects under 18? If 'Yes', specify the estimated number of subjects planned in each age range for the whole trial:	No •
	Approx. No. of patients ²⁹	
F.1.1.1	In utero	() No •
F.1.1.2	Preterm newborn infants (up to gestational age < 37 weeks)	() No •
F.1.1.3	Newborns (0-27 days)	() No •
F.1.1.4	Infants and toddlers (28 days - 23 months)	() No •
F.1.1.5	Children (2-11 years)	() No •
F.1.1.6	Adolescents (12-17 years)	() No •
F.1.2	Adults (18-64 years)	(15) Yes •
F.1.3	Elderly (>= 65 years)	(20) Yes •
F.2 GENDER		
F.2.1	Female	Yes •
F.2.2	Male	Yes •
F.3 GROUP OF TRIAL SUBJECTS		
F.3.1	Healthy volunteers	Yes •
F.3.2	Patients	Yes •
F.3.3	Specific vulnerable populations	No •
F.3.3.1	Women of child bearing potential not using contraception	No •
F.3.3.2	Women of child bearing potential using contraception	No •
F.3.3.3	Pregnant women	No •
F.3.3.4	Nursing women	No •
F.3.3.5	Emergency situation	No •
F.3.3.6	Subjects incapable of giving consent personally	No •
F.3.3.6.1	If 'Yes', specify:	
F.3.3.7	Others:	No •
F.3.3.7.1	If 'Yes', specify:	
F.4 PLANNED NUMBER OF SUBJECTS TO BE INCLUDED:		
F.4.1	In the member state	35
F.4.2	For a multinational trial:	
F.4.2.1	In the EEA	35
F.4.2.2	In the whole clinical trial	35
F.5 PLANS FOR TREATMENT OR CARE AFTER THE SUBJECT HAS ENDED HIS/HER PARTICIPATION IN THE TRIAL. please specify (free text):		
	English	None

G. CLINICAL TRIAL SITES/INVESTIGATORS IN THE MEMBER STATE CONCERNED BY THIS REQUEST

G.1	CO-ORDINATING INVESTIGATOR (for multicentre trial) and principal investigator (for single centre trial)	
G.1.1	Given name:	5.1.2.e
G.1.2	Middle name, if applicable:	
G.1.3	Family name:	5.1.2.e
G.1.4	Qualification (MD.....)	5.1.2.e
G.1.5	Professional address:	
G.1.5	Institution name	QPS Netherlands B.V.
G.1.5	Institution department	Clinical Pharmacology
G.1.5.1	Street address	Petrus Campersingel 123
G.1.5.2	Town/city	Groningen
G.1.5.3	Post code	9713 AG
G.1.5.4	Country	Netherlands
G.1.6	Telephone number:	+31 050 304 5.1.2.e
G.1.7	Fax number:	+31 050 304 5.1.2.e
G.1.8	E-mail:	5.1.2.e @qps.com

G.1	CO-ORDINATING INVESTIGATOR (for multicentre trial) and principal investigator (for single centre trial)	
G.1.1	Given name:	5.1.2.e
G.1.2	Middle name, if applicable:	
G.1.3	Family name:	5.1.2.e
G.1.4	Qualification (MD.....)	5.1.2.e
G.1.5	Professional address:	
G.1.5	Institution name	UMCG
G.1.5	Institution department	Alzheimer Center Groningen
G.1.5.1	Street address	Hanzeplein 1
G.1.5.2	Town/city	Groningen
G.1.5.3	Post code	9713 GZ
G.1.5.4	Country	Netherlands
G.1.6	Telephone number:	
G.1.7	Fax number:	
G.1.8	E-mail:	

G.1	CO-ORDINATING INVESTIGATOR (for multicentre trial) and principal investigator (for single centre trial)	
G.1.1	Given name:	5.1.2.e
G.1.2	Middle name, if applicable:	
G.1.3	Family name:	5.1.2.e
G.1.4	Qualification (MD.....)	
G.1.5	Professional address:	
G.1.5	Institution name	Amsterdam UMC
G.1.5	Institution department	Alzheimer Center Amsterdam
G.1.5.1	Street address	De Boelelaan 1118
G.1.5.2	Town/city	Amsterdam
G.1.5.3	Post code	1081 HZ
G.1.5.4	Country	Netherlands
G.1.6	Telephone number:	
G.1.7	Fax number:	
G.1.8	E-mail:	

G.1	CO-ORDINATING INVESTIGATOR (for multicentre trial) and principal investigator (for single centre trial)	
G.1.1	Given name:	5.1.2.e

G.1.2	Middle name, if applicable:	
G.1.3	Family name:	5.1.2.e
G.1.4	Qualification (MD.....)	
G.1.5	Professional address:	
G.1.5	Institution name	Brain Research Center BV
G.1.5	Institution department	
G.1.5.1	Street address	Cronenburg 2
G.1.5.2	Town/city	Amsterdam
G.1.5.3	Post code	1081 GN
G.1.5.4	Country	Netherlands
G.1.6	Telephone number:	
G.1.7	Fax number:	
G.1.8	E-mail:	

G.2	PRINCIPAL INVESTIGATORS (for multicentre trial ; where necessary, use additional forms)	
G.2.1	Given name:	
G.2.2	Middle name, if applicable:	
G.2.3	Family name:	
G.2.4	Qualification (MD.....)	
G.2.5	Professional address:	
G.2.5	Institution name	
G.2.5	Institution department	
G.2.5.1	Street address	
G.2.5.2	Town/city	
G.2.5.3	Post code	
G.2.5.4	Country	
G.2.6	Telephone number:	
G.2.7	Fax number:	
G.2.8	E-mail:	

G.3	CENTRAL TECHNICAL FACILITIES TO BE USED IN THE CONDUCT OF THE TRIAL	
	Laboratory or other technical facility, in which the measurement or assessment of the main evaluation criteria are centralised (repeat as needed for multiple organisations).	
G.3.1	Name of organisation:	5.1.1.c [REDACTED]
G.3.2	Department	5.1.1.c [REDACTED]
G.3.3	Name of contact person:	
G.3.3.1	Given name	5.1.2.e [REDACTED]
G.3.3.2	Middle name	
G.3.3.3	Family name	5.1.2.e [REDACTED]
G.3.4	Address:	
G.3.4.1	Street address	5.1.1.c [REDACTED]
G.3.4.2	Town/city	5.1.1.c [REDACTED]
G.3.4.3	Post code	5.1.1.c [REDACTED]
G.3.4.4	Country	5.1.1.c [REDACTED]
G.3.5	Telephone number:	5.1.2.e [REDACTED]
G.3.6	Fax number:	5.1.2.e [REDACTED]
G.3.7	E-mail:	5.1.2.e [REDACTED]
G.3.8	Enter the details of any duties subcontracted to this central technical facility in this trial	
G.3.8.1	Routine clinical pathology testing	No •
G.3.8.2	Clinical chemistry	Yes •
G.3.8.3	Clinical haematology	Yes •
G.3.8.4	Clinical microbiology	No •
G.3.8.5	Histopathology	No •
G.3.8.6	Serology/ endocrinology	Yes •
G.3.8.7	Analytical chemistry	Yes •
G.3.8.8	ECG analysis/ review	No •
G.3.8.9	Medical image analysis/ review - X-ray, MRI,	No •

	ultrasound, etc.	
G.3.8.10	Primary/ surrogate endpoint test	No ●
G.3.8.11	Other Duties subcontracted?	No ●
G.3.8.11.1	If 'Yes', specify the other duties	

G.3 CENTRAL TECHNICAL FACILITIES TO BE USED IN THE CONDUCT OF THE TRIAL		
Laboratory or other technical facility, in which the measurement or assessment of the main evaluation criteria are centralised (repeat as needed for multiple organisations).		
G.3.1	Name of organisation:	5.1.1.c
G.3.2	Department	5.1.1.c
G.3.3	Name of contact person:	
G.3.3.1	Given name	5.1.2.e
G.3.3.2	Middle name	
G.3.3.3	Family name	5.1.2.e
G.3.4	Address:	
G.3.4.1	Street address	5.1.1.c
G.3.4.2	Town/city	5.1.1.c
G.3.4.3	Post code	5.1.1.c
G.3.4.4	Country	5.1.1.c
G.3.5	Telephone number:	5.1.2.e
G.3.6	Fax number:	
G.3.7	E-mail:	
G.3.8	Enter the details of any duties subcontracted to this central technical facility in this trial	
G.3.8.1	Routine clinical pathology testing	No ●
G.3.8.2	Clinical chemistry	No ●
G.3.8.3	Clinical haematology	No ●
G.3.8.4	Clinical microbiology	No ●
G.3.8.5	Histopathology	No ●
G.3.8.6	Serology/ endocrinology	No ●
G.3.8.7	Analytical chemistry	No ●
G.3.8.8	ECG analysis/ review	No ●
G.3.8.9	Medical image analysis/ review - X-ray, MRI, ultrasound, etc.	No ●
G.3.8.10	Primary/ surrogate endpoint test	No ●
G.3.8.11	Other Duties subcontracted?	Yes ●
G.3.8.11.1	If 'Yes', specify the other duties	PK analysis

G.3 CENTRAL TECHNICAL FACILITIES TO BE USED IN THE CONDUCT OF THE TRIAL		
Laboratory or other technical facility, in which the measurement or assessment of the main evaluation criteria are centralised (repeat as needed for multiple organisations).		
G.3.1	Name of organisation:	UMCG
G.3.2	Department	Nuclear Medicine and Molecular Imaging
G.3.3	Name of contact person:	
G.3.3.1	Given name	
G.3.3.2	Middle name	
G.3.3.3	Family name	
G.3.4	Address:	
G.3.4.1	Street address	Hanzeplein 1
G.3.4.2	Town/city	Groningen
G.3.4.3	Post code	9713 GZ
G.3.4.4	Country	
G.3.5	Telephone number:	
G.3.6	Fax number:	
G.3.7	E-mail:	
G.3.8	Enter the details of any duties subcontracted to this central technical facility in this trial	
G.3.8.1	Routine clinical pathology testing	No ●
G.3.8.2	Clinical chemistry	No ●

G.3.8.3	Clinical haematology	No •
G.3.8.4	Clinical microbiology	No •
G.3.8.5	Histopathology	No •
G.3.8.6	Serology/ endocrinology	No •
G.3.8.7	Analytical chemistry	No •
G.3.8.8	ECG analysis/ review	No •
G.3.8.9	Medical image analysis/ review - X-ray, MRI, ultrasound, etc.	Yes •
G.3.8.10	Primary/ surrogate endpoint test	No •
G.3.8.11	Other Duties subcontracted?	No •
G.3.8.11.1	If 'Yes', specify the other duties	

G.3 CENTRAL TECHNICAL FACILITIES TO BE USED IN THE CONDUCT OF THE TRIAL

Laboratory or other technical facility, in which the measurement or assessment of the main evaluation criteria are centralised (repeat as needed for multiple organisations).

G.3.1	Name of organisation:	Amsterdam UMC
G.3.2	Department	Radiology and Nuclear Medicine
G.3.3	Name of contact person:	
G.3.3.1	Given name	
G.3.3.2	Middle name	
G.3.3.3	Family name	
G.3.4	Address:	
G.3.4.1	Street address	De Boelelaan 1117
G.3.4.2	Town/city	Amsterdam
G.3.4.3	Post code	1081 HV
G.3.4.4	Country	Netherlands
G.3.5	Telephone number:	
G.3.6	Fax number:	
G.3.7	E-mail:	
G.3.8	Enter the details of any duties subcontracted to this central technical facility in this trial	
G.3.8.1	Routine clinical pathology testing	No •
G.3.8.2	Clinical chemistry	No •
G.3.8.3	Clinical haematology	No •
G.3.8.4	Clinical microbiology	No •
G.3.8.5	Histopathology	No •
G.3.8.6	Serology/ endocrinology	No •
G.3.8.7	Analytical chemistry	No •
G.3.8.8	ECG analysis/ review	No •
G.3.8.9	Medical image analysis/ review - X-ray, MRI, ultrasound, etc.	Yes •
G.3.8.10	Primary/ surrogate endpoint test	No •
G.3.8.11	Other Duties subcontracted?	No •
G.3.8.11.1	If 'Yes', specify the other duties	

G.3 CENTRAL TECHNICAL FACILITIES TO BE USED IN THE CONDUCT OF THE TRIAL

Laboratory or other technical facility, in which the measurement or assessment of the main evaluation criteria are centralised (repeat as needed for multiple organisations).

G.3.1	Name of organisation:	QPS Netherlands B.V.
G.3.2	Department	Clinical Pharmacology Unit Leeuwarden
G.3.3	Name of contact person:	
G.3.3.1	Given name	
G.3.3.2	Middle name	
G.3.3.3	Family name	
G.3.4	Address:	
G.3.4.1	Street address	Henri Dunantweg 6
G.3.4.2	Town/city	Leeuwarden
G.3.4.3	Post code	8934 AD

G.3.4.4	Country	Netherlands
G.3.5	Telephone number:	
G.3.6	Fax number:	
G.3.7	E-mail:	
G.3.8	Enter the details of any duties subcontracted to this central technical facility in this trial	
G.3.8.1	Routine clinical pathology testing	No •
G.3.8.2	Clinical chemistry	No •
G.3.8.3	Clinical haematology	No •
G.3.8.4	Clinical microbiology	No •
G.3.8.5	Histopathology	No •
G.3.8.6	Serology/ endocrinology	No •
G.3.8.7	Analytical chemistry	No •
G.3.8.8	ECG analysis/ review	Yes •
G.3.8.9	Medical image analysis/ review - X-ray, MRI, ultrasound, etc.	No •
G.3.8.10	Primary/ surrogate endpoint test	No •
G.3.8.11	Other Duties subcontracted?	No •
G.3.8.11.1	If 'Yes', specify the other duties	

G.3	CENTRAL TECHNICAL FACILITIES TO BE USED IN THE CONDUCT OF THE TRIAL	
	Laboratory or other technical facility, in which the measurement or assessment of the main evaluation criteria are centralised (repeat as needed for multiple organisations).	
G.3.1	Name of organisation:	Brain Research Center BV
G.3.2	Department	
G.3.3	Name of contact person:	
G.3.3.1	Given name	
G.3.3.2	Middle name	
G.3.3.3	Family name	
G.3.4	Address:	
G.3.4.1	Street address	Cronenburg 2
G.3.4.2	Town/city	Amsterdam
G.3.4.3	Post code	1081 GN
G.3.4.4	Country	Netherlands
G.3.5	Telephone number:	
G.3.6	Fax number:	
G.3.7	E-mail:	
G.3.8	Enter the details of any duties subcontracted to this central technical facility in this trial	
G.3.8.1	Routine clinical pathology testing	No •
G.3.8.2	Clinical chemistry	No •
G.3.8.3	Clinical haematology	No •
G.3.8.4	Clinical microbiology	No •
G.3.8.5	Histopathology	No •
G.3.8.6	Serology/ endocrinology	No •
G.3.8.7	Analytical chemistry	No •
G.3.8.8	ECG analysis/ review	Yes •
G.3.8.9	Medical image analysis/ review - X-ray, MRI, ultrasound, etc.	No •
G.3.8.10	Primary/ surrogate endpoint test	No •
G.3.8.11	Other Duties subcontracted?	No •
G.3.8.11.1	If 'Yes', specify the other duties	

G.4	NETWORKS TO BE INVOLVED IN THE TRIAL (e.g. Paediatric Networks involved in the trial)	
G.4.1	Name of organisation:	
G.4.2	Name of contact person:	
G.4.2.1	Given name	
G.4.2.2	Middle name	
G.4.2.3	Family name	

G.4.3	Address:
G.4.3.1	Street address
G.4.3.2	Town/city
G.4.3.3	Post code
G.4.3.4	Country
G.4.4	Telephone number:
G.4.5	Fax number:
G.4.6	E-mail:
G.4.7	Activities carried out by the network:

G.5	ORGANISATIONS TO WHOM THE SPONSOR HAS TRANSFERRED TRIAL RELATED DUTIES AND FUNCTIONS
------------	---

G.5.1	Has the sponsor transferred any major or all the sponsor's trial related duties and functions to another organisation or third party?	Yes •
Repeat as necessary for multiple organisations:		
G.5.1.1	Organisation name:	QPS Netherlands B.V.
G.5.1.2	Organisation department	
G.5.1.3	Name of contact person :	
G.5.1.3.1	Given name	5.1.2.e
G.5.1.3.2	Middle name	
G.5.1.3.3	Family name	5.1.2.e
G.5.1.4	Address:	
G.5.1.4.1	Street address	Petrus Campersingel 123
G.5.1.4.2	Town/city	Groningen
G.5.1.4.3	Post code	9713 AG
G.5.1.4.4	Country	Netherlands
G.5.1.5	Telephone number:	+31 50 3045.1.2.e
G.5.1.6	Fax number:	
G.5.1.7	E-mail:	
G.5.1.8	All tasks of the sponsor	No •
G.5.1.9	Monitoring	Yes •
G.5.1.10	Regulatory (e.g. preparation of applications to CA and ethics committee)	Yes •
G.5.1.11	Investigator recruitment	No •
G.5.1.12	IVRS ³⁰ – treatment randomisation	No •
G.5.1.13	Data management	Yes •
G.5.1.14	E-data capture	No •
G.5.1.15	SUSAR reporting	No •
G.5.1.16	Quality assurance auditing	No •
G.5.1.17	Statistical analysis	Yes •
G.5.1.18	Medical writing	Yes •
G.5.1.19	Other duties subcontracted?	No •
G.5.1.19.1	If 'Yes' to other, please specify:	

G.5	ORGANISATIONS TO WHOM THE SPONSOR HAS TRANSFERRED TRIAL RELATED DUTIES AND FUNCTIONS
------------	---

G.5.1	Has the sponsor transferred any major or all the sponsor's trial related duties and functions to another organisation or third party?	Yes •
Repeat as necessary for multiple organisations:		
G.5.1.1	Organisation name:	5.1.1.c
G.5.1.2	Organisation department	
G.5.1.3	Name of contact person :	
G.5.1.3.1	Given name	
G.5.1.3.2	Middle name	
G.5.1.3.3	Family name	
G.5.1.4	Address:	
G.5.1.4.1	Street address	5.1.1.c
G.5.1.4.2	Town/city	5.1.1.c

G.5.1.4.3	Post code	5.1.1.c	
G.5.1.4.4	Country	5.1.1.c	
G.5.1.5	Telephone number:		
G.5.1.6	Fax number:		
G.5.1.7	E-mail:	5.1.2.e	
G.5.1.8	All tasks of the sponsor		No •
G.5.1.9	Monitoring		No •
G.5.1.10	Regulatory (e.g. preparation of applications to CA and ethics committee)		No •
G.5.1.11	Investigator recruitment		No •
G.5.1.12	IVRS ³⁰ – treatment randomisation		No •
G.5.1.13	Data management		No •
G.5.1.14	E-data capture		No •
G.5.1.15	SUSAR reporting		Yes •
G.5.1.16	Quality assurance auditing		No •
G.5.1.17	Statistical analysis		No •
G.5.1.18	Medical writing		No •
G.5.1.19	Other duties subcontracted?		No •
G.5.1.19.1	If 'Yes' to other, please specify:		

H. COMPETENT AUTHORITY / ETHICS COMMITTEE IN THE MEMBER STATE CONCERNED BY THIS REQUEST

H.1 TYPE OF APPLICATION		
If this application is addressed to the Competent Authority, please tick the Ethics Committee box and give information on the Ethics committee concerned. If this application is addressed to the Ethics Committee, please tick the Competent Authority box and give the information on the Competent Authority concerned.		
H.1.1	Competent Authority	No •
H.1.2	Ethics Committee	Yes •
H.2 INFORMATION ON ETHICS COMMITTEE		
H.2.1	Name:	Stichting Beoordeling Ethiek Biomedisch Onderzoek
H.2.2	Address	
H.2.2.1	Street address	Dr Nassaulaan 10
H.2.2.2	Town/city	Assen
H.2.2.3	Post code	9401 HK
H.2.2.4	Country	Netherlands
H.2.3	Date of submission:	2019-04-17
H.3 OPINION		
H.3.1	To be requested	Yes •
H.3.2	Pending	No •
H.3.3	Given	No •
	If 'Given', specify:	
H.3.3.1	Date of opinion:	
H.3.3.2	Opinion favourable	No •
H.3.3.3	Opinion not favourable	No •
	If not favourable, give:	
H.3.3.3.1	The reasons	
H.3.3.3.2	The eventual anticipated date of resubmission:	

I. SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

I.1 I hereby confirm that /confirm on behalf of the sponsor (delete which is not applicable) that:

- the information provided is complete;
- the attached documents contain an accurate account of the information available;
- the clinical trial will be conducted in accordance with the protocol; and
- the clinical trial will be conducted, and SUSARs and result-related information will be reported, in accordance with the applicable legislation.

I.2 APPLICANT OF THE REQUEST FOR THE COMPETENT AUTHORITY (as stated in section C.1):

I.2.1 Date: 11 October 2019

I.2.2 Signature³¹: [Redacted]

I.2.3 Print name: [Redacted]

5.1.2.e

I.3 APPLICANT OF THE REQUEST FOR THE ETHICS COMMITTEE (as stated in section C.2):

I.3.1 Date:

I.3.2 Signature³²:

I.3.3 Print name:

ENDNOTES

- ¹ Any translation of the protocol should be assigned the same date and version as those in the original document.
- ² International Standard Randomised Controlled Trial Number. Sponsors may wish to use an International Standardised Random Controlled Trial Number (ISRCTN) to identify their trial in addition to the EudraCT number; for instance if their trial is part of a multinational trial with sites outside the Community. They can obtain the number and guidance from the Current Controlled Trials website <http://www.controlled-trials.com/isrctn> to which there is a link from the EudraCT database website <http://eudract.ema.europa.eu>. When available they should provide it in Section A.6 of the application form.
- ³ US National Clinical Trial (NCT) Numbers required on the FDA clinical trial application form.
- ⁴ For a resubmission following previous withdrawal of an application or unfavourable opinion of an ethics committee, or previous withdrawal of an application or refusal of a request by the competent authority, enter a letter in the sequence, A for first resubmission, B for second, C for third et seq.
- ⁵ In accordance with Article 19 of Directive 2001/20/EC.
- ⁶ The contact point should give functional information rather than details of one "person", in order to avoid the need for update and maintenance of these contact details.
- ⁷ This requires a EudraLink account. (See <https://eudract.ema.europa.eu/document.html> for details)
- ⁸ According to national legislation.
- ⁹ Available from the Summary of Product Characteristics (SmPC)
- ¹⁰ According to the Community register on orphan medicinal products (Regulation (EC) n° 141/2000): <http://ec.europa.eu/enterprise/pharmaceuticals/register/index.htm>
- ¹¹ Committee for Medicinal Products for Human Use of the European Medicines Agency
- ¹² To be provided only when there is No trade name. This is the name routinely used by a sponsor to identify the IMP in the CT documentation (protocol, IB...).
- ¹³ To be provided only when there is No trade name. This is a code designated by the sponsor which represents the name routinely used by the sponsor to identify the product in the CT documentation. For example, a code may be used for combinations of drugs or drugs and devices.
- ¹⁴ Available from the Summary of Product Characteristics (SmPC).
- ¹⁵ Chemical Abstracts Service.
- ¹⁶ Complete also section D.4 Cell therapy as defined in Annex 1 part IV of Directive 2001/83/EC as amended.
- ¹⁷ Complete also section D.5 Gene Therapy as defined in Annex 1 part IV of Directive 2001/83/EC as amended.
- ¹⁸ Complete also section D.6 - Tissue Engineered Product as defined in Article 2(1)(b) of Regulation 1394/2007/EC.
- ¹⁹ Complete also section D.7
- ²⁰ The mode of action should briefly describe the chemical, biochemical, immunological or biological means the IMP uses to effect its pharmaceutical action.
- ²¹ Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products. EMEA/CHMP/SWP/28367/2007 19 July 2007
- ²² In accordance with paragraph 38 of Annex 13 of Volume 4 of the Rules Governing Medical Products in the European Union.
- ²³ In the case of healthy volunteer trials, the intended indication for the product under development should be provided.
- ²⁴ Applicants are encouraged to provide the MedDRA lower level term if applicable and classification code. These can be accessed from the EMEA EudraCT website (<http://eudract.ema.europa.eu/>).
- ²⁵ Points to consider on the calculation and reporting of the prevalence of a condition for Orphan drug designation: COM/436/01 (<http://www.ema.europa.eu/htmls/human/orphans/intro.htm>).
- ²⁶ The protocol will usually identify a single primary end point but there may be a co-primary end point in some cases and/or a number of secondary end points.
- ²⁷ The descriptions of the trial types provided are those recommended in preference to Phases. See page 5 of Community guideline CPMP/ICH/291/95. The development of a new indication after initial approval of a medicine should be considered as a new development plan.
- ²⁸ From the first inclusion until the last visit of the last subject.
- ²⁹ These numbers will be initial estimates. Applicants will not be required to update this information nor do they constitute an authorisation or restriction on the inclusion of these numbers of patients in the trial. The numbers of subjects whose inclusion is authorised are those set out in the authorised version of the protocol, or subsequent authorised amendments.
- ³⁰ Interactive Voice Response System: commonly used for randomisation of treatment and controlling the shipment of stock of product.
- ³¹ On an application to the Competent Authority only, the applicant to the Competent Authority needs to sign.

³² On an application to the Ethics Committee only, the applicant to the Ethics Committee needs to sign.