

ERA-NET NEURON

RESEARCH PROJECTS ON SYNAPTIC DYSFUNCTION IN DISORDERS OF THE CENTRAL NERVOUS SYSTEM Joint Transnational Call 2017

Impact Report

by

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Abbreviations

AKA - Academy of Finland

ANR - French National Research Agency

BMBF - Federal Ministry of Education and Research

CSO-MOH - Chief Scientist Office, Ministry of Health

ECR - Early Career Researcher

ERA-NETs - European Research Area NETWORKS

FNRS - Fonds de la Recherche Scientifique,

FRQS - Fonds de recherche du Québec-Santé

FWF - Austrian Science Fund,

FWO - Research Foundation Flanders,

HFSP - Human Frontier Science Program

ISCIII - National Institute of Health Carlos III

JCS - Joint Call Secretariats

JTC - Joint Transnational Calls

MINECO - Ministry of Economy and Competitiveness

MOH - Ministry of Health

NCBR - National Centre for Research and Development

NOW - Netherlands Organisation for Scientific Research

RCN - The Research Council of Norway

SAS - Slovak Academy of Sciences

SNSF - Swiss National Science Foundation

TUBITAK - The Scientific and Technological Research Council of Türkiye

UEFISCDI - Executive Agency for Higher Education, Research, Development and Innovation Funding

VIAA - State Education Development Agency

WHO - World Health Organisation

WoS - Web of Sciences

I. Introduction

1. ERA-NET NEURON

Public health is a central priority for individuals and governments globally. Brain and nervous system conditions affecting their growth, structure and/or function are responsible for a wide variety of congenital, neurodevelopmental and neurological dysfunctions. The World Health Organisation ([WHO](#)) estimates that one in three people will develop a neurological disorder at some point in their life, making neurological disorders the leading cause of disability and the second leading cause of death worldwide. In particular, defective synaptic function has been identified as a pathophysiological mechanism underlying a wide variety of disorders such as autism, epilepsy and other neurodevelopmental diseases; as well as sensory disorders and neurodegenerative diseases. In 2017, the ERA-NET NEURON launched a call addressing disease-related synaptic dysfunction with approaches ranging from understanding the basic mechanisms of disease to clinical studies aiming to develop therapies in humans.

The European community includes a vast pool of scientific and medical expertise. In order to coordinate research objectives and promote European research collaborations, the European Commission developed European Research Area NETWORKS (ERA-NETs). These ERA-NETs aim to support and encourage cross-border collaboration in various fields of research by supporting joint activities. The Network of European Funding for Neuroscience Research (NEURON; www.neuron-eranet.eu) was initiated in 2003 as a pilot Specific Support Action. It was developed into an ERA-NET in 2007 and has been funded by the European Commission in four phases: NEURON I (2007 – 2011), NEURON II (2012 – 2015), NEURON Cofund (2016-2020) and NEURON Cofund2 (2021-2026). The overarching aim of NEURON is to support the translation of results from fundamental brain research into improved prevention, diagnosis, therapy and rehabilitation for patients, their families, and carers.

Joint Transnational Calls (JTC) for research proposals are the centrepiece of NEURON's transnational activities. On behalf of national ministries and funding organizations, NEURON coordinates an annual launch of a JTC in the field of disease-related neuroscience, addressing important issues in fundamental neuroscience, neurology, or psychiatry (see call topics Table 1). These funding calls aim to advance research in strategically identified areas by encouraging transnational and cross-disciplinary projects. The main activity of NEURON is therefore the coordinated, transnational funding of basic, clinical and translational research on the nervous system. The NEURON initiative today is the result of the coordinated efforts of 35 funding organisations across 30 countries, engaging in a joint effort to promote excellent research in disease-oriented neuroscience.

Year	Topic	Impact Report
2008	Neurodegeneration	Published
2009	Method and Technology Development	Published
2010	Mental Disorders	Published
2011	Cerebrovascular Diseases	Published
2012	Method and Technology Development II	Published
2013	Mental Disorders II	Published
2014	Neuroinflammation	Published
2015	Neurodevelopmental Disorders	Published
2016	External Insults to the Nervous System	Published
2017	Synaptic Dysfunction	Current
2018	Mental Disorders III	Projects Ongoing
2019	Biomarkers	Projects Ongoing
2020	Sensory Disorders	Projects Ongoing
2021	Neurodevelopmental Disorders	Projects Ongoing
2022	Cerebrovascular Diseases	Projects Ongoing
2023	Vulnerability and Resilience in Mental Health	Projects Ongoing
2024	Bidirectional Brain-body interactions	Closed
2025	Neuroscience of pain	Launched

Table 1: JTCs launched under ERA-NET NEURON

II. Joint Transnational Call 2017 “Research projects on synaptic dysfunction in disorders of the central nervous system”

1. Participants of the call

For the 10th NEURON JTC, 20 funding organisations from 17 countries launched a Joint Transnational Call for Research Proposals on ‘Synaptic dysfunction in disorders of the central nervous system’ (Table 2), resulting in a total of ~12.2 M€ in funding for 12 successful projects (Table 3). Defective synaptic communication is at the origin of numerous neurological and mental disorders – synaptopathies - such as epilepsies, migraine, autism spectrum disorders, schizophrenia, mood disorders and others. JTC 2017 invited projects including research from basic disease mechanisms to proof-of-concept clinical studies covering either a) Fundamental research on the pathogenesis and/or aetiology of synaptopathies. This may include the development of innovative or shared resources and new technologies for prevention, diagnosis or therapy of disease and/or b) Clinical research, including the exploitation of existing clinical data sets, to develop new strategies for prevention, diagnosis, and therapy for diseases in which synaptic dysfunction plays a key role.

Partner Countries	Funding Agencies
Austria	Austrian Science Fund, FWF
Belgium	Fonds de la Recherche Scientifique, FNRS
Belgium	Research Foundation Flanders, FWO
Canada	Fonds de recherche du Québec-Santé FRQS
Finland	Academy of Finland, AKA
France	French National Research Agency, ANR
Germany	Federal Ministry of Education and Research, BMBF
Israel	Chief Scientist Office, Ministry of Health, CSO-MOH
Israel	The National Technological Innovation Authority
Italy	Ministry of Health, MOH
Latvia	State Education Development Agency, VIAA
Norway	The Research Council of Norway, RCN
Poland	National Centre for Research and Development, NCBR
Romania	Executive Agency for Higher Education, Research, Development and Innovation Funding, UEFISCDI
Slovakia	Slovak Academy of Sciences, SAS
Spain	National Institute of Health Carlos III, ISCIII
Spain	Ministry of Economy and Competitiveness, MINECO
Switzerland	Swiss National Science Foundation, SNSF
The Netherlands	Netherlands Organisation for Scientific Research, NWO
Türkiye	The Scientific and Technological Research Council of Türkiye, TUBITAK

Table 2: Funding organisations participating in JTC 2017

2. Evaluation of the projects

The selection of research projects was completed in two peer-reviewed stages by a pool of 37 international experts. For the first step, 92 consortia submitted eligible pre-proposals that were evaluated by 3 expert reviewers per pre-proposal (except for 2 with only 2 experts). Of these, 43 consortia were invited to present a full proposal, which was again evaluated by expert reviewers before the final ranking was made by a 20-member peer-review panel.

Projects were evaluated using the following criteria:

1. Excellence

- Scientific quality of the approach and methodology
- Novelty of the scientific concept/hypotheses
- Competence and experience of participating research partners in the field(s) of the proposal (previous work in the field, specific technical expertise)

2. Impact

- Potential impact of the expected results on clinical and other health related applications
- Added-value of transnational collaboration

3. Quality and efficiency of the implementation

- Feasibility of the project
- Coherence and effectiveness of the work plan, including appropriateness of the allocation of tasks, resources, time-frame and related risk analysis
- Quality and added-value of collaborative and multi-disciplinary interactions within the consortium
- Appropriateness of the management structures and procedures

3. Funded projects

The 12 successful projects included 59 research groups, with funding provided by 14 national agencies in 13 countries. As expected, the projects dealt with a wide variety of conditions such as epilepsy (2), autism spectrum disorders and intellectual disability (2); stroke (1), schizophrenia (3), addiction (2) and mood disorders (3). Selected projects addressed the study of the pathophysiology and/or the development of therapeutic approaches mainly at the preclinical level (Table 3).

The projects used a large variety of human data and experimental models including iPSCs, cell lines, human biopsies, transgenic rodent models, zebrafish and non-human primates. The methodologies used spanned from molecular/cellular biology, imaging, advanced electrophysiological measurements, viral vectors, nanobodies, *omics* approaches, immunology to clinical assessments and more.

Acronym	Title	Consortium PIs	Country (Agency)	Agency	Disease Focus
TREAT-SNGAP	Synaptic Dysfunction in Intellectual Disability Caused by SYNGAP1. Translational Research to Develop Human Models and Advance Pharmacological Treatments.	Àlex Bayés	Spain	ISCIII	Intellectual disability / Autism spectrum disorders
		Oliver Brüstle	Germany	BMBF	
		Daniel Choquet	France	ANR	
		Jacques Michaud	Canada	FRQS	
		Barbara Treutlein	Germany	BMBF	
topdownPTSD	Mapping and interrogating top-down control of the memory engram of the posttraumatic stress disorder	Mazahir Hasan	Spain	MINECO	PTSD
		Stefano Puglisi-Allegra	Italy	MOH	
		Agnès Gruart i Massó	Spain	MINECO	
		Philipp Böhm-Sturm	Germany	BMBF	
		Stephanie Le Hellard	Norway	RCN	
		Ewa Oglodek	Poland	NCBR	
MAGNOLIA	Amygdala synaptic neuromodulatory mechanisms and role of mGlu4 in Autism Spectrum Disorders	Cyril GOUDET	France	ANR	Autism spectrum disorders
		Ingrid EHRlich	Germany	BMBF	
		Julie LE MERRER	France	ANR	
		Amadeu LLEBARIA	Spain	MINECO	
IPS&BRAIN	A functional dissection of human nicotinic receptor polymorphisms linked to addiction and schizophrenia	Uwe MASKOS	France	ANR	Addiction / Schizophrenia
		Huib MANSVELDER	The Netherlands	NWO	
		Petra SCHOLZE	Austria	FWF	
SleepLess	Imaging synaptic	David Elmenhorst	Germany	BMBF	Depression

	plasticity in therapeutic sleep deprivation for major depression	Jeroen Verhaeghe	Belgium	FWO	
		Pedro Rosa-Neto	Canada	FRQS	
MISST	Multi-scale investigation of synaptic dysfunction after stroke	Valentin U. Nägerl	France	ANR	Stroke
		Nikolaus Plesnila	Germany	BMBF	
		Jérôme Badaut	France	ANR	
		Leszek Kaczmarek	Poland	NCBR	
		Javier Defelipe	Spain	MINECO	
		Baiba Jansone	Latvia	VIAA	
ADIKHUMICE	VGLUT3 rare mutant and vulnerability to addiction	Salah El Mestikawy	Canada	FRQS	Addiction / Eating disorders
		Stephane Jamain	France	ANR	
		Florence Vorspan	France	ANR	
		Rafael Maldonado	Spain	MINECO	
		Christian Rosenmund	Germany	BMBF	
NMDAR-PSY	Understanding psychosis, cognitive impairment and motor symptoms induced by NMDA receptor dysfunction: from mechanisms to prevention and therapy	Dragos Inta	Germany	BMBF	Schizophrenia
		Hannah Monyer	Germany	BMBF	
		Stefan Borgwardt	Switzerland	SNSF	
		Uriel Heresco-Levy	Israel	CSO-MOH	
		Ole Andreassen	Norway	RCN	
		Raul Muresan	Romania	UEFISCDI	
KARTLE	Targeting aberrant KAinate Receptors in Temporal Lobe Epilepsy	Christophe Mulle	France	ANR	Epilepsy
		Valérie Crepel	France	ANR	
		Dirk Grimm	Germany	BMBF	
		Bernard Pirotte	Belgium	FNRS	
SNAREopathy	Mechanisms of neuropsychiatric genetic diseases of	Ruud Toonen	The Netherlands	NWO	Epilepsy
		Federico Zara	Italy	MOH	
		Holger Lerche	Germany	BMBF	

	the SNARE complex: towards therapeutic intervention	Christian Freund	Germany	BMBF	
		Camila Esguerra	Norway	RCN	
MicroSynDep	Microglial control of synaptic function in stress response and vulnerability to depression	Marie-Eve Tremblay	Canada	FRQS	Depression
		Igor Branchi	Italy	MOH	
		Martin Fuhrmann	Germany	BMBF	
		Naguib Mechawar	Canada	Other	
		Maciej Lalowski	Finland	AKA	
		Valeria Mondelli	other	Other	
		Bozena Kaminska	Poland	NCBR	
SYNSCHIZ	Linking synaptic dysfunction to disease mechanisms in schizophrenia - a multi-level investigation	Ole Andreassen	Norway	RCN	Schizophrenia
		Marcella Rietschel	Germany	BMBF	
		Stefan Borgwardt	Switzerland	SNSF	
		Marja-Leena Linne	Finland	AKA	
		Dirk Schubert	The Netherlands	NWO	
		Magdalena Budisteanu	Romania	UEFISCDI	

Table 3: JTC 2017 Funded Projects and Consortia. Bold indicates coordinator of the consortium

4. Key Performance Indicators

As part of the final report for each project, researchers were asked to fill out a questionnaire to measure the key performance indicators set by NEURON (Table 4). A summary of the different aspects evaluated by this questionnaire is described below and organised according to ERA-NET NEURON's overarching objectives.

Objective of the Funding Programme	Key performance indicators	Measures (i.e. items in the questionnaire)
1. Enhance excellent cooperation between scientists working in the field of neuroscience	Communication of results	List of publications and communications - level of co publication, bibliometric indicators. (Question 1.2)
	NEURON JTC as starter of new collaborations	Have the partners participating in the NEURON project collaborated before applying for the NEURON JTC2017? (Question 3.1)
	New research groups from other countries joining the consortium	During the life time of the project has the consortium established collaboration(s) with other teams (not already participating in the JTC 2017 project)? (Question 3.2)
	Sustainability of the collaboration (obtaining further funding for the same consortium)	Have the results led to new initiatives in other types of funding programmes? (Question 3.3)
	Intensity of collaboration, early researcher participation (mobility)	List of meetings, young researchers involved in the project, lab visits/exchange of researchers, and training within the consortium (Question 3.4)
2. Promote multi-disciplinary consortia and encourage translational research proposals (from bench to bedside)	Consortium Composition	List of research groups
	Patient Involvement	Analysis of full proposals and final reports
	Patents and other outcomes with public health impacts	Patents and other outcomes with impact to health (Question 2)
3. Support the development of innovative or shared resources and new technologies	Evaluation of the development and the use of new resources	Has the consortium created a new or further developed an existing transnational patient registry, database or biobank? Have the consortium partners exchanged biomaterials (DNA, tissues, cells, animals)? (Questions 4)
4. Support research to develop new strategies for prevention, diagnosis, therapy, and rehabilitation procedures	Evaluation of the development of new strategies for diagnosis, therapy, and rehabilitation procedures for conditions associated to synaptic dysfunction.	Have the results of the NEURON research projects allowed the development of new strategies for: diagnosis, therapy (preparation of clinical trials), and rehabilitation procedures for disorders related to synaptic dysfunctions, prevention or anything else? (Question 5.1)
	Major achievements	Please list the major achievements of the consortium. (Question 5.2)

Table 4: Key performance indicators in relation to the objectives of the funding programme (The number of the respective question in the questionnaire is given in brackets)

A summary of the major achievements expressed as percentage from the total number of consortia funded can be found in Table 5. These results are further detailed in the sections below.

Objective of the Funding Programme	Key performance indicators	Results (percent of funded consortia, if not specified).
1. Enhance cooperation between European scientists working in the field of neuroscience	NEURON JTC as starter of new collaboration	→ ~16.7% were fully newly formed consortia → ~83.3% partially pre-existing consortia (selected PIs collaborated before)
	New research groups from other countries joining the consortium	→ 33.3% used widening process → 66.6% acquired new collaborations during the life time of the project
	Sustainability of the collaboration (obtaining further funding for the same consortium)	→ 50% (6 projects) had at least 2 PIs applying jointly for further funding
	Intensity of collaboration (meetings, mobility, joint publications)	→ 95.8% attended the mid-term symposium → On average each consortium held 4 meetings; 61.5% of the meetings were attended by all partners → 15.3% of the articles (of all publications) were published jointly in peer-reviewed journals
	Level of excellence of the funded research	→ 66.7% published at least one research article in a peer-reviewed journal with an Impact Factor above 10 (36 articles of which 2 were reviews)
2. Promote multidisciplinary consortia and to encourage translational research proposals (from bench to bedside)	Composition of the consortium	→ In 25%, the coordinator was a medical doctor. → In 67%, at least one PI was a medical doctor. → PIs worked in basic (54.2% of PIs) and clinical (17% of PIs) research labs and in hospitals (13.6% of PIs)
	Involvement of patients	→ Patients were involved in 33.3% of the projects.
	Patents and other outcomes with impact on health	→ 16.7% developed outcomes with impact on health comprising links with biotech industries, clinical protocols and international platforms for clinical research.
3. Support development of innovative or shared resources and technologies	Development and the use of new resources	→ 91.7% exchanged biomaterials and data (DNA: 83.3%, tissues: 66.7%, cells: 66.7%, animals: 58.3%, clinical data: 25%)

4. Support research to develop new strategies for diagnosis, therapy, and rehabilitation procedures	Development of new strategies	→ 0% developed new strategies for prevention → 0% developed new strategies for diagnosis → 41.67% developed new strategies for therapy → 0% developed new strategies for rehabilitation
	Major achievements (in humans/and or animals)	→ The major achievements that were most frequently reported include: development of innovative therapies (50%), screening system (25%), identification of molecular factors (33.3%) and biomarkers (25%)

Table 5: Summary of major achievements in the frame of key performance indicators

III. Objectives of the Funding Programme

1. Enhance excellent cooperation between scientists working in neuroscience

1.1 Communication of funded research results

Consortium partners were asked to report the dissemination channels of project results. This included peer-reviewed publications (journal articles, reviews, and books or book chapters), PhD dissertations, presentations (written and oral) to scientific congresses, and articles dedicated to the general public. Peer-reviewed articles and reviews were included only if NEURON support was acknowledged. Table 6 presents a summary of the different communications produced by the funded consortia.

Type of publication	Total	Consortia (total)
Peer reviewed articles (including reviews)	163	12
Reviews	17	8
General public papers	8	3
Books or book chapters	4	3
Communications in scientific congresses	169	12
PhD Dissertations	20	6

Table 6: Total publications resulting from projects funded through JTC 2017

All the consortia declared mainly peer reviewed publications at the end of the projects at a rate corresponding to a mean value of ~14 articles per consortia. Around 86 percent of the publications (including books) were authored by a single consortium member; and 8 consortia published articles authored by at least 2 consortium members (Fig. 1a). Further publications are expected in the years to come since at least 19 new publications were in preparation by 10 consortia at the time of the final report. **All the projects experienced delays and/or workplan modifications associated to the Covid-19 pandemics mainly at the level of patient recruitments, material or personnel exchange, availability of infrastructures, animal availability, mobility of staff, and funding shortage due to**

project duration extensions. Frequent solutions included the use of previously existing data from clinical studies, and change or reduction of experiments.

Eight consortia out of 12 published joint peer-reviewed articles with at least 2 authors from the consortium. This makes up for 16% of the total publications of this call (Figure 1a).

Web of Sciences (WoS) was used to categorise the publications generated by this call according to their scientific domains.

The top domains of publication were Neurosciences, Psychiatry and Multidisciplinary sciences (Figure 1b). This means that the publications were disseminated not only in the domain of Neuroscience, as was expected, but to broader journals covering more domains and interests, therefore with potential impact on a larger range of scientists.

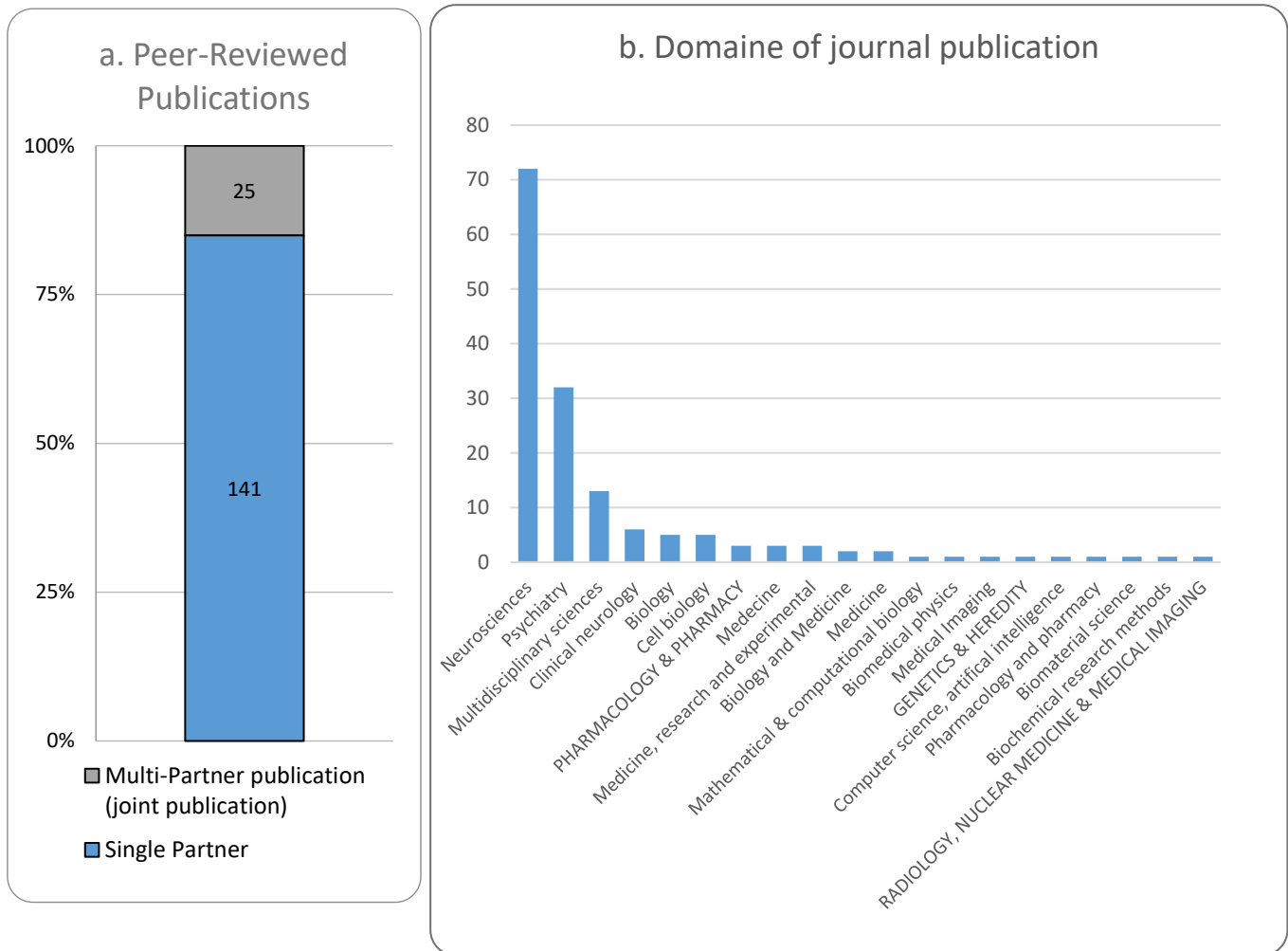


Figure 1: a. A Proportion of multi and single-partner peer-reviewed articles published by the 12 funded consortia. b. Peer-reviewed publications' main scientific domain. The histogram depicts the main disciplines to which the publications produced by consortia funded in JTC 2017 contributed.

The journals were also of high quality. An analysis was performed using “quartiles”. Quartiles indicate where a journal’s ranking lies within a particular subject category, using the citation level and impact factors. They are ranked from least referenced (Q4) to most referenced (Q1) in the domain. The quartile of each journal where the articles of this call’s projects were published was gathered on the “Web of Science” website and analysed. They are represented in Figure 2.

The vast majority (68%) of this call’s peer-reviewed articles were published in Q1 journals, highlighting the high quality of the scientific production of NEURON-funded consortia. The top domains of the Q1 journals were again Neurosciences (46 articles), Psychiatry (19 articles), and Multidisciplinary Sciences (12 articles) (Figure 2). The overall quality of the articles published by the JTC 2017 is extremely robust, with about 90% of the peer-reviewed articles being available in at least Q2 journals. It demonstrates the large impact of this call's research on the neuroscience community and beyond.

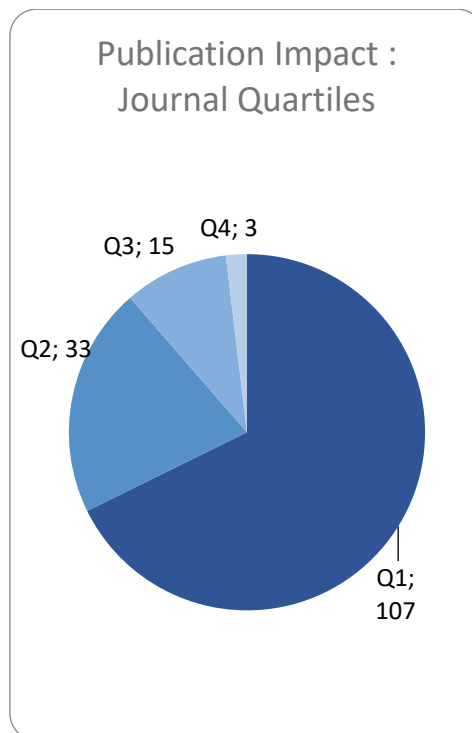


Figure 2: Peer-reviewed publications: Distribution of peer-reviewed publications by quartile rank indexed in relevant disciplines associated with the neurosciences in the WoS (Q).

1.2 NEURON JTC as a starter of new collaborations

The questionnaire contained a series of questions on the structure of the consortia, including whether the partners had previously collaborated on a research project and whether new collaborations arose or will continue during and after the funding period. The results are summarised below.

Ten out of the twelve funded consortia included members with a history of collaboration previous to this ERA-NET NEURON project. In general, the coordinator had collaborated with at least one partner. Moreover, other partners had previously collaborated in five consortia. The consortia then grew with the addition of new partners. In particular, between the two evaluation steps, 3 new partners from Poland, Latvia and Romania joined 3 consortia invited to submit a full proposal which were eventually funded. The addition of these new partners occurred through the widening procedure in which the inclusion of researchers from these national communities was particularly encouraged. None of the funded consortia had worked together as a full group before the present call and two were completely newly formed.

1.3 New research groups from other countries joining the consortium

Eight consortia reported a total of seventeen new collaborations established with international research groups. These new collaborations, mostly with European research groups, were in general established to further explore aspects related to the initial project. Additionally, two consortia created a firm or a start-up to help advance their research. Specifically, the SNAREopathy consortium created the VU Spin-out company Neurospector that provides novel screening assays in human neurons and the KARTLE consortium created Corlieve Therapeutics in October 2019 for the treatment of epilepsy with gene

therapy. The latter is not directly related to the outcomes of the KARTLE project per se, but falls within the same general topic.

1.4 Sustainability of the collaboration

Researchers were asked to report follow-on collaborations including further funding applications by consortia members. This measure indicates the impact of consortium development within the NEURON programme on continuing scientific advancement beyond the ERA-NET funding period, and on seeding sustainable academic collaborations.

Members of seven funded consortia applied for and were granted a total of 14 grants (8 in a national context and 6 international grants). The international grants include 3 subsequent ERA-NET NEURON grants, one ERC Consolidator Grant, one Human Frontier Science Program (HFSP) Research Grant and one JPND grant.

1.5 Intensity of Collaboration

Consortia are encouraged to organise regular in-person or virtual meetings as well as staff exchanges to fully capitalise on the range of expertise of project partners and to develop the skillsets of individual lab members. All the consortia organised between 1 and 9 meetings (mean of 4; total 52). 32 meetings were attended by the whole consortium and 20 by only part of the consortium members. These meetings were considered fruitful, as they fostered the exchange of scientific ideas and plans for funded and future work.

A total of 22 lab members involved in eleven projects; mainly early career researchers (ECRs) -master and PhD students or postdocs- visited the partner labs to learn new techniques and exchange experience. The role of the ECRs was frequently highlighted in the final reports for having played particularly important roles in the development of the project.

A Midterm Symposium was organised by NEURON in Lisbon in September 2019. It was a joint midterm with [the 2017 ELSA call](#). A consortium member, the coordinator in general, gave a presentation on the consortium's work progress and ECRs presented posters. Two former reviewers evaluated the progress and the coordinators received feedback. Two main aspects were evaluated, scientific progress (outcomes produced/advancement of the work plan) and collaboration between the partners. In general, the evaluations were satisfactory since the projects were considered properly advanced and some projects started publishing their results. The event facilitated interactions between researchers (including ECRs) on common topics of interest such as aspects associated to multicentre trials and scientific highlights in the field as well as interactions with national funders. Multiple collaborations were established among funded projects as a direct consequence of this symposium. Three round tables were organised, with the following topics: "What's up in health neuroscience", "SO WHAT? Neuroethics on Health neuroscience" and "TO DO. The role of the Ethics in the definition of the New Field". Special workshops with a focus on good ethical practices and "How to write a good ethics proposal" as well as one workshop specially dedicated to ECRs were organised by the ERA-NET NEURON and attended by all the researchers.

Summary

The present analysis shows that ERANET NEURON funding resulted in a high number of interactions between research groups in several countries. Most of these interactions were established for the first time within the consortia and were extended towards new research groups throughout the lifetime of the project. As a highlight, the midterm symposium organised by ERANET NEURON resulted in collaborations among the consortia and was considered instrumental for the longer-lasting structure of the field of synaptic dysfunction in disorders of the central nervous system in Europe, as reported by the attending researchers.

Most of the collaborations will outlast the period of funding by ERANET NEURON as evidenced by the report of 19 publications still in preparation at the end of the project. Ongoing follow-up work was reported, which is at the origin of national and international applications for funding. NEURON was instrumental in getting the research started and building long-lasting collaboration between international scientists. NEURON was used as a building block to structure the research ecosystem in the field. This structuring effect was highlighted by the high level of publications and joint publication, in the field of Neuroscience but also in more general domains, expanding the impact of this JTC 2017 research to a broader community.

2. Promoting multi-disciplinary consortia and translational research proposals (from bench to bedside)

2.1 Consortium composition

ERA-NET NEURON aims to promote interdisciplinary collaboration to solve unmet medical needs in the field of nervous system disorders, through the development of translational research projects. As such it is expected that the consortia include expertise from fundamental science but also any other expertise needed to pave the way towards solutions for the consequences of synaptic dysfunction of the central nervous system. Out of the 59 researchers funded by the call, 17 were medical doctors (from 8 out of the 12 funded consortia). Furthermore, 3 of these medical doctors acted as coordinators of the consortium.

The large majority of the researchers involved in the projects worked in basic research laboratories (43 researchers, in all of the consortia) and collaborated with researchers working in clinical research laboratories (10 researchers, in 7 consortia) and researchers working at hospitals (6 researchers, in 4 consortia).

This synergy between basic and clinical researchers generated new experimental paradigms ensuring a realistic approach to the disease being studied and facilitated the validation of results in both preclinical and clinical contexts. Moreover, this interaction enabled the development of tools with proven clinical value and the improved design of clinical trials. Finally, informal interactions among clinicians in different countries were beneficial, e.g., in the discussion of special clinical cases.

In addition to the principal investigators having applied for ERA-NET NEURON funding, the projects also included 97 members of the laboratories where the work was developed. Postdoctoral researchers and master, medical or PhD students, some of them funded through the ERA-NET NEURON, represent the main category of staff in the projects (21 and 60, respectively). Some other members such as technicians, associated researchers, medical doctors or engineers (respectively 8, 4, 2 and 2) were also reported as being involved in the projects (Figure 3).

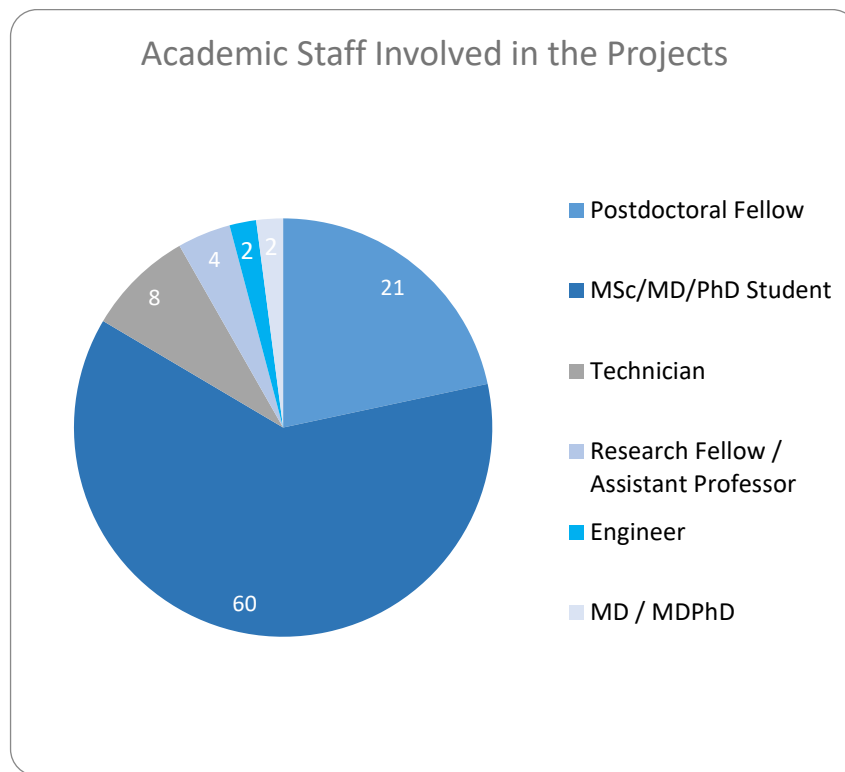


Figure 3: Lab members participating in the funded projects

2.2 Patient Involvement

In agreement with the call objectives, almost half of the projects used patient cohort data from various origins, either pre-existing or accessible through collaborations established with ongoing clinical trials as well as data from direct patient recruitment. Some projects required patient-derived material as well.

Researchers were asked to report the involvement of patients or patient groups as active members of the project. This includes involvement in the design, coordination (as part of a committee or advisory board), analysis or interpretation of research data, or in the dissemination of results. Four of the projects involved patients. In three of them, patients participated at the level of dissemination of results and in one project, patients spread awareness about available clinical slots. One project reported that patients were consulted before the creation of the consortium. Others specify working in fundamental science and therefore have not consulted with the patient community yet. The call text did not particularly encourage the participation of patients in the projects and this practice has since evolved in the more recent editions of NEURON calls.

The projects' outcomes were disseminated to a large public through specific publications, press releases, on the radio, podcasts, videos, social media, lay conferences, and dedicated events targeting healthcare professionals, patients, and family communities.

2.3 Patents and other outcomes with public health impacts

The JTC 2017 produced numerous outcomes, including some with public health impact (Figure 4).

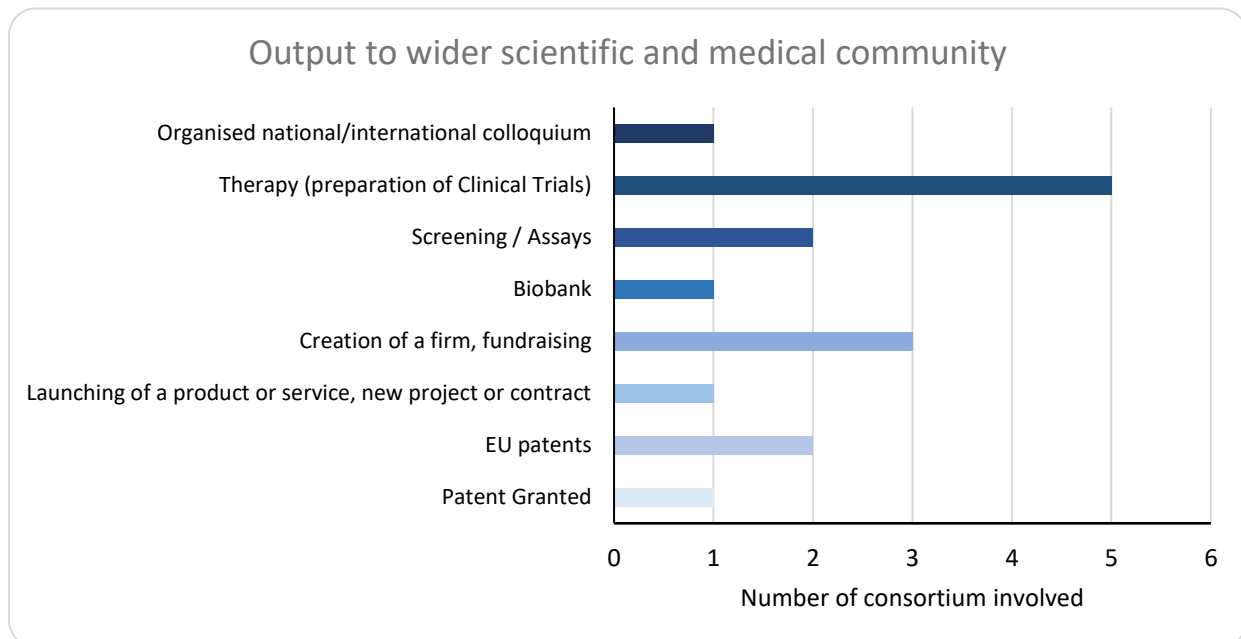


Figure 4: Output to wider scientific and medical community

The call was particularly successful in terms of innovation and company creation, as illustrated below.

- The SNAREopathy project was granted an EU patent for Nucleic acid molecules for compensation for STXBP1 haploinsufficiency and their use in the treatment of STXBP1-related disorders (PCT/EP2022/059354). This patent involves two partners of the consortium. They raised some funds through the Million Dollar Bike Ride event, and created a VU Amsterdam spin-off company, Neurospector, providing novel screening assays in human neurons. In addition, they created the STXBP1 Syndrome Database/Biobank by compiling existing national sources. The patients were recruited via an existing network of clinicians. They were also in contact with patient groups and clinician centres to expand the number of patients and patient skin biopsies. Although the biobank is not open access due to patient info being classified, iPSC lines obtained from patient skin biopsies are available for research use upon request and after MTA/CDA registration.
- The MAGNOLIA consortium submitted a patent for “Methods for treating autism spectrum disorders” (EP 21 194 699).
- The KARTLE consortium created Corlieve Therapeutics in October 2019, for the treatment of epilepsy with gene therapy. The company was acquired by uniQure, a leading gene therapy company advancing transformative therapies for patients with severe medical needs.

In addition, this year’s call was also particularly successful in terms of therapy development. Five consortia reported their research being in a clinical trial or in the preparation phase of a clinical trial.

- The ADIKHUMICE consortium opened the way for the development of a potential treatment (donepezil/Aricept) for addictive disorders, after identifying an unforeseen underlying neuronal mechanism.
- The NMDAR-PSY consortium did a preclinical assessment in mice of D-serine as an alternative antipsychotic.
- The SNAREopathy consortium developed novel genetic therapies based on increasing protein expression from the wildtype allele in heterozygote SNAREopathy models (tested in zebrafish

and human neurons). These therapies have the potential to significantly alleviate symptoms and may help in curing disease in the near future.

- The KARTLE consortium initiated the process to patent the identification of hippocampus-selective viral capsids for the genetic treatment of diseases involving the dentate gyrus.
- Finally, the MAGNOLIA consortium submitted their aforementioned patent application about autism spectrum disorder and mGlu4 receptor activity.

Two consortia developed novel screening assays to either test compounds and validate treatments or to perform high-resolution longitudinal imaging of brain adaptations at the morphological and functional level in stroked animals.

Summary

ERA-NET NEURON encourages the research communities to fill the gap between basic and clinical research towards translation and to develop solutions with potential applications for the diagnosis and treatment of brain diseases. The consortia funded in the frame of JTC 2017 engaged in collaboration with basic researchers as well as medical doctors to further understand the synaptic dysfunction in disorders of the central nervous system and develop diagnostic and therapeutic approaches. Several outcomes with direct clinical value were developed, such as screening assays, new molecules for therapy as well as new disease models. The research was promoted through the creation of start-ups, the setting up of a biobank and patent applications for new therapy. Overall, the highly successful results of this call shed a light on the capacity of the ERA-Net NEURON to bring together great international scientists and enable them to develop innovative solution for the patients and their families.

3. Supporting the development of innovative or shared resources and technologies

3.1 Development and use of new resources

In addition to scientific publications, the projects also generated a series of research resources shared among the partners of a project or open to broader scientific, clinical, and other relevant communities.

The success of the projects required the exchange of material among the laboratories including DNA, tissue, cells and other reagents such as viral vectors mainly, but also experimental animal models and data, as depicted in Figure 5. All consortia but one shared material. Common protocols and practices were developed and harmonised between sites.

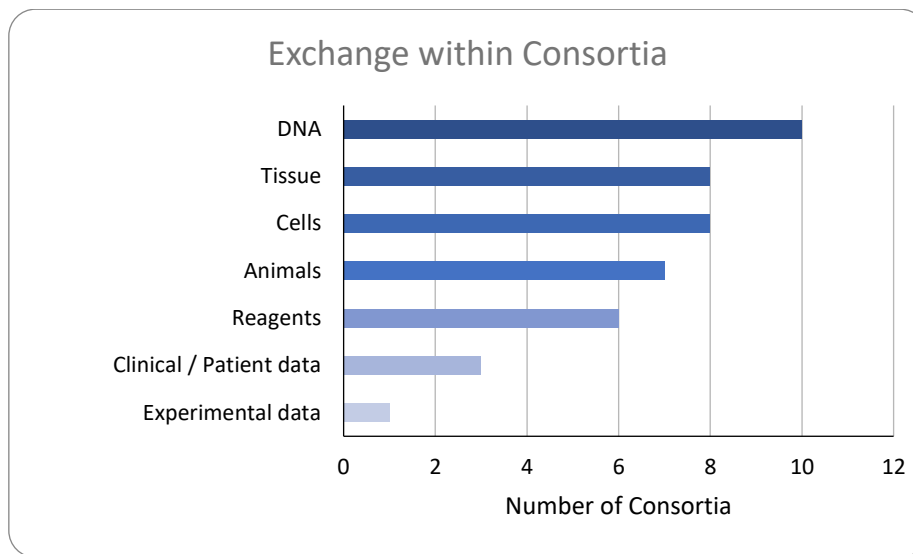


Figure 5: Exchange of resources among consortia members

Summary

ERA-NET NEURON aims to support the development of new tools and resources available to the research and clinical community at large. As such, the consortia generated protocols and experimental or clinical data which were exchanged between the participating laboratories. The resources generated within ERA-NET NEURON funding are expected to be further exploited to produce new knowledge in the brain disease field.

4. Supporting research to develop new strategies for diagnosis, therapy, and rehabilitation

4.1 Development of new strategies for diagnosis, therapy, and rehabilitation procedures

New clinical strategies were derived from the work of the funded consortia (Figure 6).

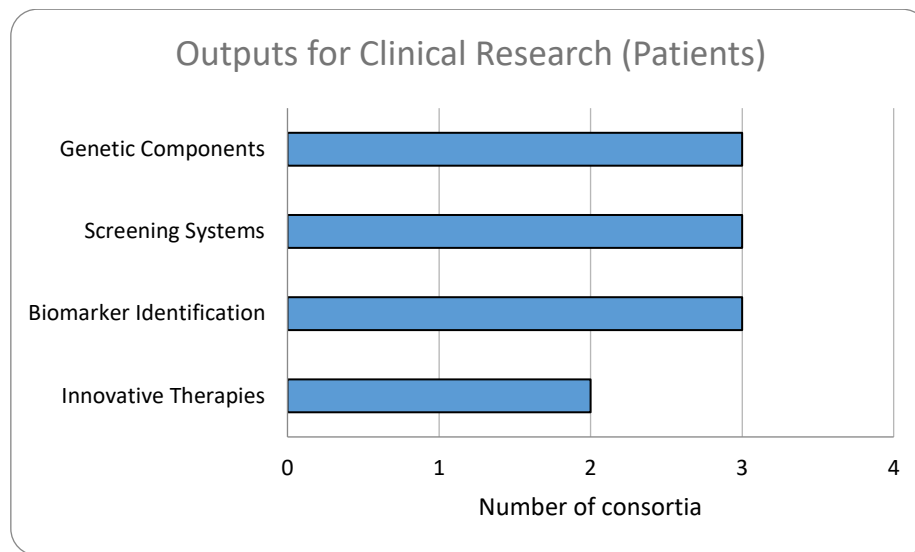


Figure 6: Output contributions for further clinical research by consortia

In particular, three consortia identified genetic components at the patient level:

- The ADIKHUMICE consortium looked for new patients with severe addiction to cocaine with a p.T8I mutation of the gene *VGLUT3*. In total, they identified 8 heterozygous subjects with this mutation out of the 514 affected subjects who have been genotyped. These 8 subjects presented with more severe psychotic symptoms, hallucinations and delusions than the general population of subjects with severe addictions. T8I carriers also demonstrated less alcohol dependency.
- The SNAREopathy consortium conducted proteomic and transcriptomic analysis on STXBP1 mutated-patient-derived neurons, thus yielding new insights into the protein/RNA landscape. The regulated genes/gene products are potential drug targets in the treatment of this disorder. They are currently researching this aspect further.
- The SYNSCHIZ consortium identified genes underlying functional brain networks and schizophrenia pointing at synaptic pathways.

Three consortia developed screening systems:

- The IPS&BRAIN consortium developed human iPSC lacking the gene *CHRFAM7A* which allows screening of alpha7 specific ligands, and *CHRFAM7A* specific ligands in a human context.
- The SNAREopathy consortium developed a novel screening assay for secretion defects in zebrafish, mouse models and iPSC-derived neurons. These assays provide High Throughputs Screening possibilities to screen for compounds (on-going) and to validate potential therapeutic strategies.
- The MISST consortium developed a method for high-resolution longitudinal imaging of brain adaptations at the morphological and functional level in stroked animals.

Three consortia identified or characterised biomarkers:

- The ADIKHUMICE consortium identified an asymmetric domain transmission in the dorsal striatum leading to the identification of morphological alteration of dorsal striatum in addiction.

- The SNAREopathy consortium identified several new potential biomarkers from their proteomic screens. They are currently being validated. There are currently no existing biomarkers for SNAREopathies. With their new leads, they will contribute clinical output measures for current phase 1/3 trials.
- The MISST consortium identified structural and functional parameters that correlate/predict the time course of recovery post-stroke.

Two consortia developed or found innovative therapies:

- The ADIKHUMICE consortium's findings suggest that donepezil (also named Aricept) could be useful in treating human patients with severe psychiatric disorders.
- The MicroSynDep consortium demonstrated the relevance of the interaction between the quality of the environment and the administration of anti-inflammatory drugs on depressive like-phenotype.

New strategies developed for basic and translational research were also well featured within this call (Figure 7), with the development of new model systems (animal and cellular) in 8 consortia. The development of therapeutic agents and methods at the preclinical stage was also featured in 6 consortia.

- The SNAREopathy consortium generated several new disease models in rodents, zebrafish and in human iPSC-derived neurons and designed novel screening assays to test compounds and validate therapeutic treatments. These assays not only contribute to further our understanding of disease mechanisms but are also in high demand from industry.
- The ADIKHUMICE consortium generated a new mouse line expressing the p.T8I variant (VGLUT3T8I/T8I mice). They observed that donepezil powerfully decreased self-starvation behaviours of these mice.
- The iPS&BRAIN consortium developed human iPSCs lacking CHRFAM7A, and specific re-expression lines (for further use in biomedical research).
- The NMDAR-PSY consortium generated mice with inducible ablation of NMDA receptors in cells expressing erbB4 in order to investigate the cell-specific role of NMDA receptor hypofunction and involvement in brain functions and psychiatric disorders. They also did a preclinical assessment of an alternative antipsychotic leading to possible improvement of therapy of schizophrenia and cognitive disorders.

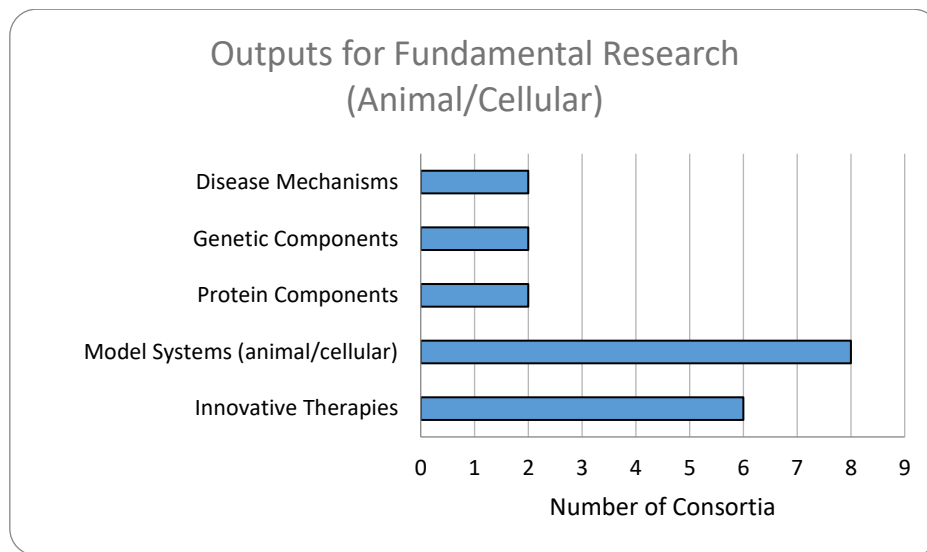


Figure 7: Output contributions for further fundamental research by consortia

4.2 Major achievements of the research consortia

As detailed in previous sections and in agreement with the general objectives of this call, the project outcomes were concentrated on the study of disease mechanisms and the development of diagnostic, prognostic and therapeutic approaches for brain diseases.

Multinational collaborations initiated in the context of this funding initiative continued after the end of the projects, emphasizing the long-lasting seeding effect of NEURON on the neuroscience community.

Moreover, the networking initiated through the midterm symposium of ERANET NEURON increased the collaborations among consortia and contributed to a stronger structuration of this research community. An important number of papers are still in preparation at the timepoint of the final report and the joint applications for funding evidence the long-lasting collaboration established among the funded groups.

The KARTLE consortium was particularly successful and obtained three prizes:

- Prize for Innovation of the Académie des Sciences et Belles Lettres of Bordeaux. V. Crépel and Christophe Mulle (March 2022). Award received for the foreseen treatment of TLE with gene therapy.
- Prize “Passerelle Recherche-Innovation” – Aquitaine Science Transfert. C. Mulle (September 2022). Award received for the foreseen treatment of TLE with gene therapy, and for being scientific co-funder of the Company Corlieve Therapeutics.
- iPrix de l’Innovation Inserm. V Crépel (December 2022). Award received for the foreseen treatment of TLE with gene therapy, and for being scientific co-funder of the Company Corlieve Therapeutics.

Poster prizes and travel grants were also obtained, for example for the MicroSynDep consortium:

- Poster prize during the midterm symposium on Synaptic Dysfunction, for “Microglia responses to a mild, chronic stress in the prefrontal cortex and hippocampus in a murine model of depression”.

- FENS-IBRO/PERC Travel Grant to attend the 13th FENS Forum, Paris, 9-13 July 2022. “Minocycline treatment increases cognitive performance and neural plasticity in a preclinical model of depression”.

Indeed, the ERANET NEURON played a key role in capacity building, through different workshops and opportunities to share the ECRs’ work, through the Midterm symposium and open science workshops, as well as EPNA awards. ECRs were able to establish collaborations with more experienced fellows through networking events. In more recent calls, ECRs were given more focus: their participation in consortia is now encouraged, as evidenced by the addition of a dedicated evaluation criteria.

Of key importance, some consortia brought their research to the level of future clinical trials and established robust links with industrial partners. These outcomes perfectly align with the overarching ERA-NET NEURON aim to pave the way for new or improved routes for diagnosis and therapy.

Overall, this call was particularly successful and the major achievements of the JTC2017 are depicted in Figure 8.

Summary

The 2017 call was very successful and gained a lot of visibility through the different networking events, and prizes received. It built a solid foundation for further funding, creation of start-ups and clinical developments. The different prizes won by the participants of the call are proof that the NEURON initiative steers its recipient toward innovation and pushes the research further in the field of brain diseases.

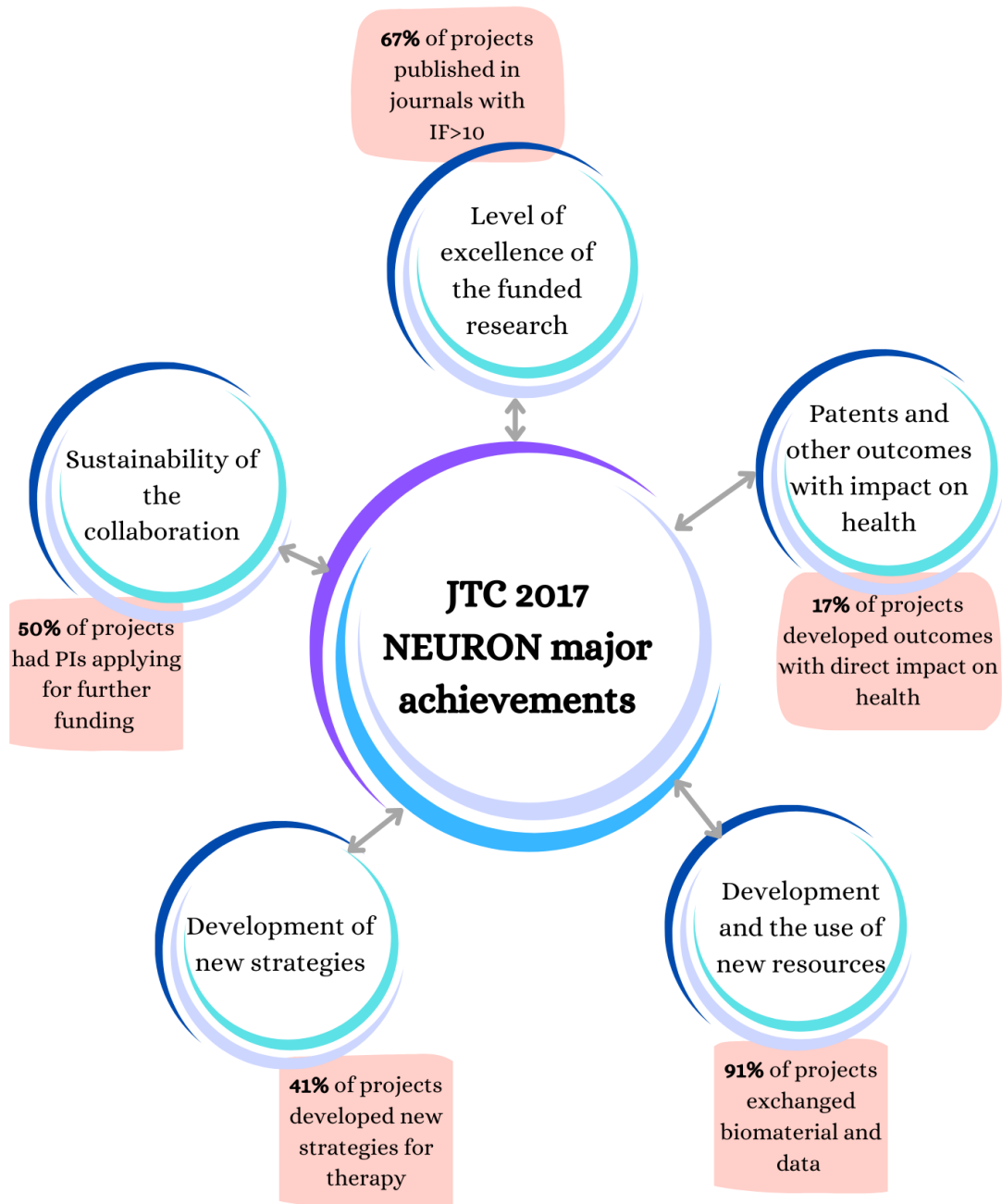


Figure 8: Major achievements of the JTC2017 call

IV. Outstanding projects

All the projects funded in this call reported good quality outcomes. This section aims at highlighting the diversity of projects. The paragraphs below describe examples of consortia which resulted in particularly relevant scientific and clinical outcomes and/or career advancement.

1. SYNSCHIZ

The objective of this project was to study synaptic dysfunction leading to Schizophrenia at various levels from genes to neuron cells to brain networks using state-of-the-art methodology. The project was extremely successful with 59 peer-reviewed publications in various high-impact factor journals. One of the partners identified genes underlying functional brain networks and schizophrenia pointing at synaptic pathways. Another established hiPSC-derived excitatory/inhibitory co-culture as a model system to study complex neuronal networks in vitro. The consortium is coordinated by a professor of Medicine from the University of Oslo, Norway, working in collaboration with partners from Romania, The Netherlands, Finland, Switzerland and Germany.

2. SNAREopathy

The consortium focused on a group of difficult-to-treat, severe epilepsies caused by mutations in genes coding proteins that mediate the communication between nerve cells (STXBP1, STX1 and PRRT2). They generated novel disease models in rodents, zebrafish, and human neurons reprogrammed from skin biopsies to identify the molecular mechanisms leading to epilepsy, leading to the creation of a dedicated biobank. They were granted a patent on Nucleic acid molecules for compensation of STXBP1 haploinsufficiency and their use in the treatment of STXBP1-related disorders. Their research led to the creation of a company called Neurospector. The project is coordinated by a PI in the Netherlands, with partners from Germany, Italy and Norway.

3. KARTLE

The consortium focused on the predominant form of epilepsy called temporal lobe epilepsy or TLE. Unfortunately, forty per cent of all TLE patients do not respond well to current pharmaceutical drugs. The project aimed to fill in this critical gap, by expanding on previous data that a certain type of cell surface molecules (aberrant synaptic kainate receptors, KARs) markedly contribute to epileptiform activity in TLE patients within a specific region of the brain. The central goal of the project was therefore to design and validate two parallel strategies to target aberrant synaptic KARs, in order to inhibit their activity and thereby alleviate the disease symptoms in TLE patients. The project was very successful as proved by the three prizes for innovation won by the PIs from prestigious institutions. They created a firm with 2 PIs being co-founders named Corlieve Therapeutics, aiming for the treatment of epilepsy with gene therapy. The collaboration carried on between the coordinator and one PI of the consortium with joint application for a grant of the national French agency (ANR). The project is coordinated by a PI from France, with additional partners from France, Germany and Belgium.

4. ADIKHUMICE

The major objective of the ADIKHUMICE consortium was to decipher if and how the *VGLUT3*-p.T81 mutation could cause addiction. They have previously discovered that cholinergic interneurons, located in the striatum, a region of the brain which plays an important role in addiction, express the atypical vesicular glutamate transporter (*VGLUT3*). They have also shown that the p.T81 mutation of *VGLUT3* was more frequent in patients with severe addiction. They were able to show the clinical impact of the

mutation in multiple severe psychiatric disorders (addiction, eating disorders and schizophrenia). A unique mouse model expressing the mutated form of VGLUT3 was established and used to finely dissect neuronal consequences of the p.T8I mutation. These investigations led to the discovery of an unforeseen neuronal mechanism underlying the compulsive use of drugs. The consortium discovery led to a clinical trial preparation for the drug donepezil. The project led to new collaboration bridging clinical and fundamental aspects of neuroscience. The project is coordinated by a PI from Canada, with additional partners from France, Spain and Germany.

V. Conclusion

The projects funded within JTC 2017 produced outstanding results at the scientific, clinical and career advancement levels. Multiple therapeutic approaches for synaptic dysfunction of the central nervous system were developed at the preclinical and clinical levels and will be instrumental in the development of new clinical practice in the near future.

As highlighted by the patent applications and company creation resulting from the research, this call provided the opportunity to bridge silos, from academia towards clinical innovation.

The collaboration between the consortia members was of high quality, as shown by the numerous meetings and further joint funding applications. The ERA-NET NEURON provided them with opportunities to network and foster further collaborations, which particularly benefited ECRs in their career advancement.

The still-ongoing collaboration and research will further structure the community of synaptic dysfunction in the nervous system, which will in turn greatly benefit young researchers in the field.

Results of the JTC 2017 funded consortia embody what the ERANET NEURON initiative strives to provide to the scientific community in terms of clinical advancement, translational innovation and outstanding communication and dissemination.

Annexe I Excerpt call text

You can access the call text through the link below:

[2017 "Synaptic Disorders" - ERA-NET NEURON](#)

Annexe II Questionnaire / Impact of the Project

Below is the questionnaire that was filled by the consortia members as a foundation for this impact report.

IV. Questionnaire / Impact of the Project

This section will be used by ERA-NET NEURON partner organisations to analyse the joint call results. Information from this questionnaire **may be published** for reporting the call output.

Q.1 Publications and communications

Please indicate the number of publications and communications in which **NEURON support was acknowledged**. Publications in preparation or submitted must be indicated.

Do not include:

- **articles published before the project start date**
- **articles that do not acknowledge NEURON funding**

Q.1.1 Publications and communications

Type of publication	Total N°
Peer Reviewed Research Articles (acknowledging NEURON support)	
Peer Reviewed Review Articles (acknowledging NEURON support)	
Books or Book Chapters	
Dissemination Articles (to lay audiences, news articles, press releases etc.)	
Communications in Scientific Meetings	
Dissertations	
Others (letters to the editor, comments, responses, etc.)	

Add lines as appropriate

Q.1.2 List of publications and communications

A. List the publications resulting from the funded project.

Highlight the name of the NEURON partners and indicate the partner number according to the numbering designation in section I (e.g. partner 1 or P1). Please only add publications that acknowledge NEURON support and **provide a snapshot of the relevant acknowledgment section** for each of the listed publications.

No.	Publication Type (Article, Book)	Publication (authors, title, journal, year, issue, pp.)	PMID	DOI	Partner(s)	Impact factor	Open access (Y/N)
1							
PASTE ACKNOWLEDGMENT SNAPSHOT HERE							
2							
PASTE ACKNOWLEDGMENT SNAPSHOT HERE							
3							
PASTE ACKNOWLEDGMENT SNAPSHOT HERE							
4							
SUBMITTED / IN PREPARATION							

Add lines as appropriate

B. List of other communications of NEURON funded project

List presentations to scientific congress (oral and poster), institutional lectures, seminars, workshops, summer schools, etc.

Presentation Number	Presentation Type (Oral, poster)	Venue (congress/meeting, date and location)	Partner(s)	Invited (Y/N)
1				
2				
3				
4				

Add lines as appropriate

Q.1.3 Has the consortium communicated “negative results” as an outcome of the project?

YES NO

► If YES, please (i) indicate the publication numbers concerned (table above) (ii) specify the nature of those negative results (e.g. a murine transgenic model without phenotype):

...

Q.2 Prizes and awards

Q.2.1 Have any prizes or awards been received for the work funded in this project?

YES NO

► **If YES**, please detail **(i)** the name of the award and organisation that conferred it, **(ii)** the individual who received it, and **(ii)** the work for which it was conferred:

...

Q.3 Patents and other outputs with impact to health

Q.3.1 List of patents/licences

Please indicate if details regarding the listed patents need to be treated confidentially

Please indicate the project partners involved using the numbering designation in section I (e.g. partner 1 or P1)

Patent/licence description (patent no., name, description)	Stage (deposited/granted)	Main partner	Partner(s) involved

Add lines as appropriate

Q.3.2 List of other outputs with impact to health

Please list below:

Category	Description	Partner(s) involved
Software or Prototype		
Launching a product or service		
Creation of a platform available to a community		

Creation of an enterprise (Startup/SME)		
fundraising		
Other (please specify)		

Q.3.3 Data management

Has a Data Management Plan been produced? YES NO

If yes, do you intend to publish this plan? YES NO

► **If YES**, please provide the link:

From JTC2019 onward the default is that NEURON will publish the final DMPs after termination of the projects.

Please list below how the consortium stored, treated and gave access to the data generated

Category	Description	Accessible by whom?	Partner(s) involved
Database or Registry			
Data Repository or Storage			
Data harmonization or simplification for international standards			
Other (please specify)			

Q.4 Consortium collaboration and sustainability

Please tick when applicable

Q.4.1 Have the partners participating in the NEURON project collaborated before applying to this NEURON call? YES NO

► **If YES**, please indicate which partners collaborated (e.g. partner 1 with partner 2, partner 3 with partner 5):

...

C. Training and mobility between partners

Please indicate the nature and duration of personal exchanges between consortium partners, based on NEURON funding.

Partners involved (from X to Y)	Position (PhD Student, Technician, Postdoc, PI, etc.)	Purpose of the exchange

Q.5 Development of innovative or shared resources and technologies

Q.5.1 Has the consortium created a new or further developed an existing transnational...

Patient registry Patient database Biobank N/A ?

► **If YES, please complete** (repeat this section as many times as necessary):

- Name of the registry/database/biobank: ...
- How was the registry/database/biobank created?
 - Totally new set-up
 - By compiling existing national sources
- How were new patients recruited?
 - Via existing network of clinicians
 - Through the development of NEW networks of clinicians
- Please specify how the registry/database/biobank will be maintained/financed after the end of this project: ...
- Is the the registry/database/biobank in open acces?

Q.5.2 Have the consortium partners exchanged resources?

Biological samples (DNA, RNA, tissue samples, cell lines, etc.)

Viral vectors

Reagents (indicators, chemical compounds, etc.)

Animals

Clinical data

N/A

► **If YES, please specify:**

- Have the shared samples allowed common studies? YES NO
- Did the number of samples suffice to reach the goal? YES NO
- Are data / materials made openly accessible (beyond the consortium) YES NO
If yes, please specify: ...

Q.6 Potential health impact / achievements

Please list the major achievements of the consortium.

Achievements		Brief description of achievement	Expected (research, policy, etc.)	impact treatment,
Identification of new genes	<input type="checkbox"/>			
Development of innovative screening systems	<input type="checkbox"/>			
Identification and characterisation of biomarkers	<input type="checkbox"/>			
Validation of biomarkers	<input type="checkbox"/>			
Generation of novel model systems (animal or cellular)	<input type="checkbox"/>			
Development of innovative therapies	<input type="checkbox"/>			
New medical treatments	<input type="checkbox"/>			
New medical devices	<input type="checkbox"/>			
Neurosurgical innovation	<input type="checkbox"/>			
Rehabilitation procedures	<input type="checkbox"/>			
Prevention	<input type="checkbox"/>			
Other (please specify)	<input type="checkbox"/>			

Add lines as appropriate

Q. 7 Patient engagement

Were patients/patient representatives involved in planning and/or conducting the research project?

YES NO

► If YES, please specify:

- designing the research project
- conducting / coordinating the research project (e.g. patient committee / advisory board)
- analysing / interpreting research data
- dissemination of results

► Please briefly describe the patient engagement:

...

► If NO, please explain why patients were not involved:

...