### Investigator Sponsored Research (ISR) General Research (GR) 申請ガイド

### 本申請システムは、以下のページで構成されています。

- Welcome page
- Introduction
- Content Information
- Organization Information
- Project Lead/Principal Investigator(PI)
- Study Details
- Budget Details
- Payee Information/Contracting organization
- Certifications

### 注:テキスト入力箇所は、全て英語で記入をお願いします。

# Welcome page

• 申請や申請者情報を編集するページです

**Pfizer** 

	EDIT PROFILE LOGOUT
Welcome, Yang Li!	メールアドレス(ID)やパスワード
The organization you are currently associated with is test organizati	
This site is intended for submitting an application for an <b>independent research grant</b> . This is a type of grant that s investigator or organization is the sponsor of the research and where Pfizer provides financial and/or non-financial specific and defined medical knowledge. If you have any questions please email <u>GlobalMedicalGrants@pfizer.com</u>	の修正が出来ます。

We recommend that you familiarize yourself with the online application before you begin. Please <u>click here</u> to preview the application. To create a new application, click the "Start a New Application" link at the bottom of this page. You may also save your applications now and return to work on them later. To continue work on an unsubmitted application, click the "Continue" link next to the application's Project Title. To view an application previously submitted to Pfizer, click the "View" link next to the appropriate Project Title.

Please note that all online application fields (and any uploaded documents associated with the initial application) must be completed in English.

If you have technical questions regarding this application, use the link located at the bottom of every page to contact the support team. For Grant Program Questions contact Global Medical Grants at <u>GlobalMedicalGrants@pfizer.com</u>.

#### Unsubmitted Requests

Action Project Title

Application Date Proposal Type 01/22/2021 Research Grant Application Amount \$0.00

#### Submit a Request

» START A NEW RESEARCH GRANT APPLICATION «



**Technical Questions** 

## Introduction

 申請する研究に対する、弊社のポリシーに合意いただく事を確認 するページです

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# **Contact Information**

• Contact Informationを確認するページです



# **Organization Information**

### • 申請施設の情報を入力するページです

2 Pfizer							
	Organization Information	Project Lead/Principal Investigator (PI)	Study Details	Budget Details	Informati	Payee on/Contracting çanization	LOGOUT
Organization Information							
						*	indicates required field
* Legal Entity Name Practice or Private Physician Office	Could your or an independe Please note th	ganization be classifi ent group of physician nat Pfizer cannot pro- ps which are not lega	ns not affiliated w vide grants to ind	ith a hospital,	academic in	stitution or profes	sional society)?
* Organization Type	Higher Educati	ion	~				
* Country							
	Japan		~				
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Address 2	(Optional)						
* City	dtdtdtdt						
Province							
* Zip/Postal Code	546454						
Website Address							
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	SAVE AND P	ROCEED	ions				

# Project Lead/ Principal Investigator (PI)-1

- Principal Investigatorの情報を入力するページです
- ・ (?)をクリックすると、その項目の説明が表示されます

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Welcome Page	Introduction	Contact Information	Organization Information	Project Lead/Principal Investigator (PI)	Study Details	Budget Details	Payee Information/Contracting Organization	Certification
Project Lead/	Principal Ir	nvestigator (P	?l)					
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		PI Middle Nan						
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# Project Lead/ Principal Investigator (PI)-2

PI Positions and Honors		
	(4000 character maximum)	11
PI Contributions to Science		
	(4000 character maximum)	_/_
Additional PI Information	Research Support and/or Scholastic Performance	
	(4000 character maximum)	11
	Co-Investigator Information	
Co-Pl First Name (?)		

Co-PI Middle Name	
Co-PI Last Name	
Co-PI Primary Degree	✓
Co-PI Email	
* PI Certification	I certify the information provided is accurate and complete.

SAVE AND PROCEED

Technical Questions

- 申請施設の情報を入力するページです
- (?)をクリックすると、その項目の説明が表示されます
- 後述(P.13)の「Budget details」のページの前に本ページの入力を 完了する必要があります

<b>Pfizer</b>	
	LOGOUT Drganization Lead/Principal Study Budget Payee Information Investigator Details Details Occupition
rage internation	(PI) (PI)
Study Details	
* Project Type	Classification Decision Matrix 1
* Caret Demost Ture	Investigator Sponsored Research: Pre-clinical/Clinical (Includes focus on a Pfizer Drug or Compound)
* Grant Request Type	Please select the items you are seeking within this request Funding
Pfizer Drug Of Interest	If your study has a focus on a Pfizer drug or compound, please select the drug or drugs from the list below. If your study does not focus on a Pfizer drug please return to the Project Type question and select a General Research option. If this is a compound request please select "Compound Request" below. Anti-PD-1 RN 888 (PF-06801591) apixaban: PF-06834635 avitimity azithromycin
* Primary Area of Interest	Please select the Pfizer Area of Interest that is most relevant to your research. This will ensure that the appropriate group at Pfizer reviews this request CVM - Blood Pressure/Hypertension
Secondary Area(s) of Interest (?)	Alopecia Areata Atopic Dermatitis Chronic Obstructive Pulmonary Disease (COPD) Crohn's Disease CVM - anti-coagulation (AFIB, VTE)
* Competitive Grant?	Is this in response to a Request for Proposal (RFP)? All active RFPs can be viewed <u>here.</u> No
* Pfizer-Sponsored Studies/Collaborations	Are you involved with any Pfizer sponsored studies and/or collaborations?
* Has your institution submitted this project for consideration to Pfizer previously?	No V
* Study Title	Enter a brief description as this will display on your Welcome page to help you identify your submission(s).
* Abstract	Please include an abstract summary of your proposal including the Rationale, overall goal, target population, methods and assessment. Please limit this to 500 words. <b>NOTE</b> : This should be the same text that is included in your Full Proposal document that you will upload later.           Test
	(2996 character(s) remaining)
* Protocol/Full Proposal	UPLOAD FILE Protocolを添付してください。 Protocolには、Version及び作成
	記入ください。

External Identification Number	Please note any External Identification Number assigned to the study by your institution
* Estimated Study Start Date	Please note that the start date must be at least 90 days post submission.
* Estimated Study End Date	MM/DD/YYYY
* Project/activity related to pain or opioids	Please indicate whether or not the project/activity for which you are seeking support from Pfizer is related to or includes discussions about pain or opioids.
	<b>NOTE:</b> To be eligible for funding, project/activity related to opioids must include components: 1) Aimed at increasing awareness of the risks of opioid addiction, abuse, and misuse; and 2) Detecting and preventing abuse, misuse, and diversion of opioids.
	✓
* Will any component of your activity/intervention offer continuing education credit?	No 🗸
* Research Setting	Please indicate if your study is a single-site or multi-site study. Multiple-Site 🗸
* Primary Country Site	If Multi Site, please specify the Country of Primary Site from the list of countries.           Japan <ul></ul>
Number of Sites	3
Additional Country <del>Site(s)</del>	Afghanistan ALand Islands Albania Algeria American Samoa
Study Type	Please indicate if your study is clinical or pre-clinical. Your answer to this question will impact the questions
	asked later in the application.
Clinical Study Type	What type of clinical study? Interventional 、 HAT STATES AND
Blinded Study?	Is your study blinded?
	No 🗸
Age Group(s) of Study Population	Indicate the age group(s) of the populations studied           Adult
Ethnicity of Study Population	Indicate the ethnicity of the populations studied. African Asian Caucasian Hispanic Open to All

Length of Enrollment	Please indicate the anticipated Length of enrollment. En	iter number of months.
	24	
Date of Estimated First Patient Enrollment	MM/DD/YYYY	
* Does your study involve genetics or genomics?	No 🗸	
Primary End Points: (i.e., what are you measuring?)	Test	
	(3996 character(s) remaining)	
Study Phases	Phase IV 🗸	
Study Design	Open Label 🗸	
Is the Study Randomized?	No 🗸	
Total Subject Enrollment	100	
Number of Arms	2 •	
1st Study Arm - Treatment Plan	Test	
	(3996 character(s) remaining)	
1st Study Arm - Pfizer Drug	adalimumab:PF-06410293 Anti-PD-1 RN 888 (PF-06801591) apixaban:PF-04652577 avelumab:PF-06834635 axitinib	A •
1st Study Arm - Non-Pfizer Drug	Please enter any non-Pfizer drugs being used in the stud	dy arm. Enter 'N/A' if not applicable.
	-	
1st Study Arm - Number of Human Subjects	10	

	2nd Study Arm - Treatment Plan	ac
		(3998 character(s) remaining)
	2nd Study Arm - Pfizer Drug	infliximab:CT-P13 (USA, Canada, Europe & Australia) infliximab:PF-06438179 (Japan & rest of world) inotuzumab ozogamicin:PF-05208773 Invited isavuconazole
	2nd Study Arm - Non-Pfizer Drug	Please enter any non-Pfizer drugs being used in the study arm. Enter 'N/A' if not applicable.           ABCDE
2nd Study	Arm - Number of Human Subjects	10 Planned Results
* Targe	et Date to Provide Results to Pfizer	MM/DD/YYYY 2nd Study Armにファイザー以外の
	* Publishing Results?	Do you plan to publish the results of this s Yes v Zind Study Arm-Pfizer Drug」で 「Invited」を選択し、
	Result Type	Abstract Final Report Manuscript Poster
	Target Conference or Journal	Please enter 'N/A' if not applicable Test
D	ate of First Anticipated Publication	10/30/2021
	Planned Results Notes	(4000 character maximum)
		SAVE AND PROCEED Technical Questions

# **Budget Details-1**

- 申請費用の情報を入力するページです
- (?)をクリックすると、その項目の説明が表示されます



# **Budget Details-2**

	Direc	t Labor Costs Subtotal	0.00	
1)	Direct Study/	/Project Costs Subtotal	Monitoring	
			One time fees	
			Participant reimbursement	
			Procedures/Tests/Assessments/Labs	
			Publication Costs	
			Statistics/ Biostatistics	
			Study Start up Costs	
			Supplies/Consumables	
			Travel	
		3 [	Other Fees	
			0.00 Total	
	4	Describe Other Fees		
	Institutional Ov	verhead Percentage (?)		
	Institutional	Overhead Subtotal (?)		L外の第三者からも支援を受け
	Total	Amount Calculated (?)	Pfizer. Other S	は「Yes」を選択し、「Specify Sources」の欄にその概要(支援
				援内容等)を記載してください。
	Requested /	Amount from Pfizer (?)	Enter the amount requested in your local currency. Enter number 🔊 🚓 🚜 🕂	、資金の支援を受ける場合は 記載してください。
			Total should match the Total Amount requested from Phzer (calc	記載してたこい。
				選択してください。
	Total Budget fo	or the Study/Project(?)		
	* Othe	er Sources of Support?	Will support (e.g. funding, drug, lab testing) be requested from sources other t	han Pfizer?
			Yes 🗸	
		Specify Other Sources	Specify the support and its source.	
			(4000 character maximum)	
		Budget Narrative (?)		
	2	Dudget Marrative (?)		
			(4000 character maximum)	

- 「Direct Study/Project Costs Subtotal」下の各項目(①)について、ご申請金額の適切性判断の 為に必要となりますので、各内訳を「Budget Narrative」(②)に具体的に記載ください。
- 「Direct Study/Project Costs Subtotal」(①)に関するFAQはこちら: FAQ
- 当てはまる予算が不明の場合は、「Other fees」(③)に金額をご記入の上、「Describe other fees」(④)に使途をご記入ください。
- 注:消費税法上、助成金は消費税の課税対象外とされていることより、ご申請いただいた金額に消費 税を上乗せしての支払いはできませんことにご留意ください。 消費税の課税対象となる物品購入や業務委託契約に対して、消費税を含めた支援を希望され

る場合は、消費税を加味した金額にて申請ください。

# Payee Information/ Contracting Organization

• 支払および契約施設の情報を確認するページです



## Certifications

 ISRに関するTerms and Conditionや有害事象報告について requirementの確認と承認をするページです

								LOGOUT
lcome 'age	Introduction	Contact Information	Organization Information	Project Lead/Principal Investigator (PI)	Study Details	Budget Details	Payee Information/Contracting Organization	Certifications
ificatic	ns							
	* Con	pliance Certification	Please read th	e following certificati	ion carefully. Yo	u must certify t	he following before you can su	ndicates required fie abmit your
			You certify tha		mployee of the	requesting orga	by clicking "I agree". anization, with the responsibili	ty and
				to apply for financial at you have no knowl			ement in the creation or devel	opment of this
			project.				port from Pfizer in all publicat	
			presentations	. When Pfizer suppor	t is "in-kind" the	e nature of the s	support must be disclosed to le	earners.
			project, as we enrollment re overdue, Pfize assist in resol	II as a Final Report at ports for clinical stud r reserves the right t ving the non-complia	the conclusion les involving hu o share your na nce. Further, yo	of your project. man subjects. II me with other r u acknowledge	y six months throughout the li You also agree to provide mo f any of these required reports representatives from your orga non-compliance of required rr ole for new grants from Pfizer.	nthly patient s becomes anization to
			comply with a U.S. Export Ac use goods and the CFSP - Tre	II applicable Global T Iministration Regulat d technology; Financi	rade Control La ions; the Interna al Sanctions Lav on; and the eco	ws. "Global Trac ational Traffic in vs and Restrictiv nomic sanctions	lated to an independent medi de Control Laws" include, but a 1 Arms Regulations; EU export ve Measures imposed within th s rules and regulations admini	re not limited to, controls on dual- ne framework of
			any pre-existing	ng or future business	relationship wi	th Pfizer; or (b)	e conditioned on or related, in any business or other decision ormulary status decisions).	
		Further you certify that you are authorized to submit an application and provide information in an application on behalf of the requesting organization and any partner organization(s), and you affirm that all responses and information provided in this application are truthful, accurate and complete. Your certification also represents that neither you nor your organization's directors, trustees, and/or anyone who will be involved in the project(s) that will be funded by this grant are on the OIG debarment list.						
		Please note, includes add	if the request is app itional terms and co	roved your org nditions as the	anization will by relate to the	be required to sign a contra- e grant.	ct which	
				the Com <mark>p</mark> liance Cert				
		For Investigat obtained from AE/SAEs to Pfi	n supplies on the mar	ch (ISR) studies ket and used as	where the prod per standard o	luct <u>under study</u> is sourced dir of care: the Grant Seeker is <u>reg</u>	ectly by Pfizer or <u>juired</u> to submit	
		Reporting Timeline: Pfizer requires the Grant Seeker to notify Pfizer within 24 hours of first awareness or secure email exchange any Adverse Event (AE) [serious and non-serious, as applicable] that occurs douring the reporting period in a study subject assigned to receive the Pfizer product. In addition, studies using a Pfizer device or Pfizer product packaged with a device, reportable events include not only AEs but also Device Incidents Malfunctions.						
		Reporting Forms: Principal investigator will report qualified adverse events using the applicable Pfizer ISR/CRC Adverse Event Report Form or approved local regulatory form (i.e. FDA MEDWATCH, CIOMS, etc.) with the AE/SAE Fax Cover Sheet provided by Pfizer, Grant Seeker may use the institution at Perport form provided it is preapproved by Pfizer Safety Leads. SAEs/AEs should be reported as soon as they are determined to meet the definition, even if complete information is not yet available.						
			Reporting Period: Reportable Events subject to this provision are those that occur from after the first does of the Pfizer product through at least 28 calendar days after discontinuation of the Pfizer product or longer as specified by the protocol. In addition, any AE/SAEs which occur after active reporting period and are considered related to study drug(s) by investigator should be reported to Pfizer.					
			Follow-up Inf		and/or Grant	Seeker will assis	t Pfizer in investigating any SA	E/AE and will
			Regulatory R	eporting: Reporting	a SAE/AE to Pfiz	er does not reli	eve the institution and/or prine authority, as required.	cipal investigator
		Final protoco	I: Safety language in ne Grant seeker/study	the Final Protoc	ol developed by	y the Grant seeker should alwa e written in contract to make s	ays be cross- sure these two	
		Special consideration for Multiple-site studies: For multi-site studies, lead institutions often use one single point of contact or data coordinating certer. This process may be acceptable by Pfizer provided the following terms are met and will be described in the contract with the sponsor:						
		<ul> <li>a. Study must be multi-national.</li> <li>b. All investigators from each site must report to a single, well established data coordinating center,</li> <li>c. Plizer must only receive AE/SAEs from this single and well-established data coordinating center,</li> <li>d. In such scenario, Plizer receipt date is the data on which the information is provided to the data coordinating center. Given such, the data coordinating center must document its receipt date on the approved adverse event report form.</li> <li>e. This single data coordinating center must be responsible for independently initiating and performing all follow-up activities with each individual investigator for missing and/or incomplete medical information for</li> </ul>						
			about th g. SAE info		v up with the inv Pfizer must not	estigator until		information
			Principal Invest documents fro	stigator agrees to the om the links below?	Pfizer Policy ter	rms listed above	e, and has downloaded the rel	evant
			~					

If you have any questions regarding your reporting requirements, please reach out to globalmedicalgrants@pfizer.com. Please note: You can return back to this request to access the SAE Reporting links above after submission.

SAVE AND PROCEED

Technical Questions

## Certifications

### 今まで入力した申請情報を確認、申請/保存するページです



#### **Review Your Application**

Please review your proposal information. If you are not ready to submit your proposal at this time, click the "Save Only" button. The proposal will then be available to edit from the Welcome page. Clicking the Submit button will immediately send the application to Pfizer and you will then be unable to perform further editing.

#### Introduction

\* Pfizer Policy on Submission of a Research Proposal I agree to the Pfizer Research Submission Policy

\* Financial Disclosure by Pfizer I agree to the Financial Disclosure Statement.

Note: Authorized Signatory Name Yang Li Authorized Signatory Email Yang Li6@Pfizer.com

Additional Authorized Signatory Name (Optional) Additional Authorized Signatory Email (Optional) Fully Executed Contract

#### **Contact Information**

- \* Salutation Mr
- \* First Name Yang
- \* Last Name Li
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- \* Email Address abcd@xxxx.ac.jp
  - \* Telephone 81312345678
    - \* Fax 81312345555

\* Legal Entity Name Pfizer Japan

#### Organization Information

\* Organization Type Medical & Science Organization \* Country Japan \* Address 1 3-22-7, Yoyou Address 2 \* City Tokyo Province \* Zip/Postal Code 1518599 Website Address Organization Mission Statement test

Project Lead/Principal Investigator (PI)

Primary Investigator Information

\* PI First Name Keiko

- PI Middle Name
- \* PI Last Name Ishii
  - \* PI Email keiko.ishii@pfizer.com

\* Principal Investigator (PI) is a US-licensed physician No

PI Current Position Title