

# Fast Trackガイダンス ISRコンセプトの申請 【Non-Clinical ISR編】

ブリストル・マイヤーズ スクイブ株式会社  
2017年10月作成



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‘ISR: Non-Clinical’をクリック

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Data Sharing

ISR: Clinical

ISR: Non-Clinical

Named Patient Program

ISR: RFPs

# \* 入力必須項目

1. Investigator & Institution Info 2. Request Details 3. Additional Request Details 4. Related Documents

## Investigator & Institution Info

### Enter the Investigator's Information

Check this box if you are the primary investigator.

**主任研究者が申請をする場合、チェック**

My Role\*

--select an item--

Primary Investigator First Name

Taro

Primary Investigator Last Name

Yamada

Primary Investigator Email

taro.yamada@example.com

### Enter the Institution Information

Institution Name\*

BMSKK

Institution Address Line 1\*

Shinjuku i-Land Tower, 5-1

Institution Address Line 2

Nishi-Shinjuku 6-chome

Institution City\*

Shinjuku-ku

Institution State / Province

13 - 東京都

**主任研究者以外が申請をする場合、申請者の役割をプルダウンより選択し、主任研究者の情報を入力ください**

My Role\*

- select an item--
- select an item--
- Co-Investigator
- Regulatory Document Coordinator
- Site Legal Contact
- Study Site Coordinator
- Sub-Investigator
- Other

Institution Postal Code\*

163-1327

Institution Country

Japan

Check this box if the shipping address is same as the address of the institution above.

**薬剤の送付先が医療機関の住所と同じ場合、チェック**

Shipping Address Line 1\*

Shipping Address Line 2

Shipping City\*

Shipping State / Province

Shipping Postal Code\*

\* - required

Save Next

**クリック**

\*入力必須項目

Bristol-Myers Squibb Takayori Ohno  
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Home Closed Requests

1. Investigator & Institution Info 2. Request Details 3. Additional Request Details 4. Related Documents

**Request Details**

Enter the Details of Your Request Below

Study Type  
Research Collaboration

Short Title\*  
[information]

Therapeutic Area\*  
Cardiovascular Disease

Disease Area\*  
Anticoagulation

Phase\*  
Phase N/A

Planned Start Date\*  
02/01/2018

Requested Resource\*  
Funding

Total Budget Requested\*  
5000000

Budget Currency\*  
JPY - Japanese Yen

Local BMS Contact Name  
Hanako Yamada

Primary Indication  
Anticoagulation

Primary Material

Primary Compound\*  
Apixaban

Quantity\*  
0

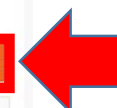
Unit\*  
0

Check this box to request additional compound.

\*- required

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**\*入力必須項目**

Bristol-Myers Squibb Takayori Ohno  
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Home Closed Requests

1. Investigator & Institution Info 2. Request Details 3. Additional Request Details 4. Related Documents

**Additional Request Details**

Enter the Details of Your Request Below

Study Rationale: Provide a brief description of the medical question and the rationale of how this trial addresses the question. Provide a rationale for the dose schedule outlined for all treatment arms. Reference any non-labeled indication.

\*

Primary Objective: Provide the main goal of the study and the study population. Provide a detailed definition that is directly linked to the primary objective. In some cases, the detailed description may be more appropriate in the statistical section.

\*

Primary Endpoint\*

Hypothesis\*

Study Assessments: Specify type and frequency of safety, efficacy, and outcome measures. Also indicate the method(s) used to assess measures.\*

Secondary Objective

Data and Statistical Plan: Describe the planned statistical analysis including timing of the primary and secondary measurements and sample size calculation. The range of sophistication will depend on a number of factors, including the size and complexity of the study.

\*

References: List references, studies, and sources that support the study design.

\*- required

Back

Save

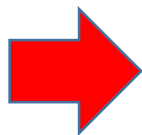
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**クリック**

‘Add File...’をクリックして、ファイルを選択



Bristol-Myers Squibb Tatsuya Iwasaki  
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Related Documents

Add Related Documents Below

Curriculum Vitae\* **Curriculum Vitae (必須)**  
Add File...

Other Curriculum Vitae **Other Curriculum Vitae**  
Add File...

References/Relevant Literature **References/Relevant Literature**  
Add File...

Supporting Document 1 **Supporting Document 1-4**  
Add File...

Supporting Document 2  
Add File...

Supporting Document 3  
Add File...

Supporting Document 4  
Add File...

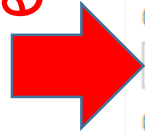
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名が表示される



Bristol-Myers Squibb Toru Nakao  
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Request Details 3. Additional Request Details 4. Planned Publication Information 5. Related Documents

Related Documents

Add Related Documents Below

Curriculum Vitae\*

✖ Dummy.pdf

Other Curriculum Vitae

✖ image.png

References/Relevant Literature

✖ Dummy.pdf

Supporting Document 1

✖ Dummy.pdf

Supporting Document 2

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Supporting Document 3

✖ image.png

Supporting Document 4

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### Request Submitted

✓ Your request has been successfully submitted and will be available here in a few minutes.

### Current Requests

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ファイル

メッセージ

McAfee E-mail Scan

ADOBE PDF



2017/04/26 (水) 13:51

BMS Admin &lt;mg-nrdg-support@bms.com&gt;

Your Concept REQ-0000019585 has been Submitted to Bristol-Myers Squibb.

宛先 ■ Nakao, Toru



申請後、システムより自動送信メール  
が送られますのでご確認ください

Dear Toru Nakao,

Your concept REQ-0000019585 has been successfully submitted for consideration by BMS. We look forward to reviewing your submission & strive to have a decision to you within 4 weeks unless the concept is submitted as part of a Competitive Research program or Alliance program.

Communications will be done within the FastTrack Portal and a formal email will be sent to you once a decision is rendered.

Should you have any concerns or questions, you may contact BMS Support by clicking [here](#).

Sincerely,  
Your BMS FastTrack Team

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bms.com



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FastTrack Access

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Japan

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toru.nakao@bms.com

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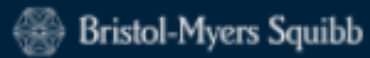
.....|

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Showing **All** Under Review

ACPA profile analysis [dummy information]

Type	Date of Request
ISR: Clinical	4/25/2017
Compound Name	Therapeutic Area
Abatacept	Immunoscience
Disease Area	BMS Protocol #
Rheumatoid Arthritis & R...	

Status: Under Review

[View](#)

申請した内容が表示されます