



REMAP-CAP
JAPAN

EDCへの患者登録手順



Patients

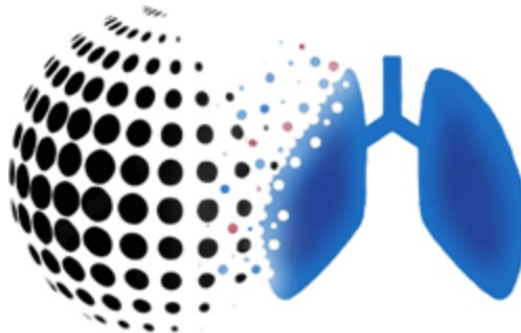
Resources

Manage

Monitoring

Reports

Polaris Infirmiry



Username/Email

Password

SIGN IN

① 登録している
メールアドレスとパスワードを入力

② “SIGN IN” をクリック

I forgot my username or password

Get in touch with us at Spiral if you would like to see more of
our software spinnaker@spiral.co.nz



すでに登録済みの患者一覧

+ Add patient

クリックして患者登録へ

Print site-specific eligibility checklist or blank CRF

Reveals pending

ID	ICU admission	Domains	Expires/Due
0899900028	18-Jul-2023 17:00	V	22-Jul-2023 18:16

29 Patients randomised at 999 - Polaris Infirmiry

Participant Study Number Find patient

Patient	Age	Sex	Day	Randomised
0899900029	43	Male	1	22-Jul-2023 S
0899900028	73	Male	5	18-Jul-2023 s
0899900027	73	Male	7	16-Jul-2023 S
0899900026	73	Male	8	15-Jul-2023 S
0899900025	45	Male	164	09-Feb-2023 S
0899900024	42	Male	327	30-Aug-2022 s

11th of July, 2023

The following changes have been released:

A read-only view of the eCRF is now available for select user groups including Regional Monitors. Prior to this release if your permissions included access to the monitoring view without the eCRF view you will now be able to switch between the eCRF data view and the monitoring view via the usual hyperlink located in the top right of the form page.

Thank you once again for your ongoing support of REMAP-CAP.

Alerts

Patient	ICU Admission	Alert
AXCGPZ	25-Feb-2022	Organ support questions need answering

[View all 4 alerts](#)

12028 Enrolments in the REMAP-CAP Trial

0 Enrolments at 08999 - Polaris Infirmiry

12000

患者の研究参加の適格性の評価（背景）



Patients

Resources

Manage

Monitoring

Reports

Polaris Infirmery



Patient list

Eligibility List

Transfers

Add patient



Eligibility

Demographics

Platform Incl/Excl 1

Platform Incl/Excl 2

Platform Incl/Excl 3

Domain Incl/Excl

Contraindications

Consent

Patient Interest

Result

Patient Eligibility

Test site only - Do Not enter real patient details

Polaris Infirmery is currently assessing eligibility for domains A, H, M, V

Patient Demographics

① Year of birth

yyyy

☐ Unknown at this time

② Sex at birth

Male

Female

③ Where is the patient physically located

If in ED must be accepted for hospital admission and specify location to which patient is accepted for admission. ICU includes repurposed ICU.

ICU

Not in ICU

④ Was the patient randomised in this study in the last 90 days

For a separate episode of severe community-acquired pneumonia

Yes

No

Next

or [Cancel](#)

① 生年月日（生まれた「年」のみの入力が良い）

② 性別（男性→“Male” 女性→“Female”）

③ 患者の入院先（ICUか非ICUか）

④ 過去90日以内に本研究（REMAP-CAP）に参入されたことがあるか

患者の研究参加の適格性の評価（プラットフォーム参入1）



Patients

Resources

Manage

Monitoring

Reports

Polaris Infirmary



Patient list

Eligibility List

Transfers

Add patient



Demographics

Platform Incl/Excl 1

Platform Incl/Excl 2

Platform Incl/Excl 3

Domain Incl/Excl

Contraindications

Consent

Patient Interest

Result

Platform inclusion/exclusion 1

① Is the patient a resident of a nursing home or long-term care facility ⓘ

A facility providing personal and nursing care

Yes

No

② Prior to this illness was the patient known to be an inpatient in any healthcare facility within the last 30 days ⓘ

Where one or more nights were spent at a healthcare facility where treatment/care was provided. A hospital transfer during this episode of CAP does not count as a prior inpatient admission

Yes

No

③ Does the patient have signs and/or symptoms that are consistent with lower respiratory tract infection ⓘ

Includes acute onset dyspnea (or acute increase in dyspnea), cough and pleuritic chest pain

Yes

No

④ Does the patient have radiological evidence of new onset infiltrate of infective origin ⓘ

In patients with pre-existing radiological changes, evidence of new infiltrate (consolidation)

Yes

No

⑤ Is community acquired respiratory tract infection (including due to COVID) the primary reason for this ICU admission ⓘ

The treating clinician believes that community-acquired respiratory tract infection, or complications of respiratory tract infection (e.g. septic shock, respiratory failure, acute kidney injury, multi-organ failure) is the primary reason for the patient's ICU admission

Yes

No

Next or [Cancel](#)

① 介護施設に入所中であったか？

② 本疾患発症の過去30日以内にあらゆる医療介護機関に入院していたか

③ 下気道感染症を示唆する徴候・症状を有しているか

④ 画像検査で感染症に伴うと判断される新規の浸潤影が認められるか

⑤ ICUへの入室する主な理由は市中肺炎（COVID-19を含む）であるか

患者の研究参加の適格性の評価（プラットフォーム参入2）



Patients

Resources

Manage

Monitoring

Reports

Polaris Infirmary



Patient list

Eligibility List

Transfers

Add patient



Demographics

Platform Incl/Excl 1

Platform Incl/Excl 2

Platform Incl/Excl 3

Domain Incl/Excl

Contraindications

Consent

Patient Interest

Result

Platform inclusion/exclusion 2 - ICU admission time window

- ① When did this hospitalisation start ⓘ
First presentation for this hospital admission for this illness
dd-MMM-yyyy : 24 Hour clock
- ② When did ICU admission start ⓘ
First ICU admission to any hospital during this hospitalisation
dd-MMM-yyyy : 24 Hour clock

Next

or [Cancel](#)

① 入院当日に、病院受診した日時（24時間表記）

* 転院症例の場合、最初の病院の受診時間

② ICUに入室した時間

* ①と②は少なくとも1時間開ける必要があります。

患者の研究参加の適格性の評価（プラットフォーム参入3）



Patients

Resources

Manage

Monitoring

Reports

Polaris Infirmary



Patient list

Eligibility List

Transfers

Add patient



Eligibility
ACHZHQ

Demographics

Platform Incl/Excl 1

Platform Incl/Excl 2

Platform Incl/Excl 3

Domain Incl/Excl

Contraindications

Consent

Patient Interest

Result

Platform inclusion/exclusion 3 - Organ support time-window

① Is the patient receiving a continuous vasopressor and/or inotrope infusion

At the time of completing this form

Yes

No

② Is the patient receiving high-flow oxygen delivered via nasal prongs or cannula

High-flow oxygen delivered by nasal prongs with FiO2 40% or higher and at a flow rate of at least 30 L/min.

Yes

No

③ Is the patient receiving non-invasive ventilation (NIV)

NIV includes positive inspiratory or expiratory pressure or both via a mask, helmet, or similar device

Yes

No

④ Is the patient receiving invasive mechanical ventilation

Any form of positive pressure ventilation via an orotracheal, nasotracheal or tracheostomy tube

Yes

No

* 人工呼吸器装着患者は追加で動脈血液ガスの追加項目あり

⑤ Is influenza infection suspected by the treating clinician or confirmed by microbiological testing

As part of the current illness

Yes

No

⑥ What is the number of days between first onset of symptoms of this acute illness and hospital admission

Symptoms may include coughing, sore throat, headache, nasal discharge/nasal congestion, feeling feverish or having chills, aches or pains of the muscles or joints, and fatigue

days

☐ Not recorded

⑦ Does the patient have clinically suspected or proven active pandemic infection

Clinically suspected means pandemic infection is considered likely. Active means that the patient has current signs and symptoms attributed to pandemic infection. Answer "no" for in-patients with incidental SARS-CoV-2 infection

Yes

No

⑧ Is death deemed imminent and inevitable during the next 24 hours AND either the patient, substitute decision maker or attending physician is not committed to active treatment

A clinical treatment or intensity of treatment that would otherwise be indicated is being withheld

Yes

No

①昇圧薬 / 強心薬の持続投与があるか

②HFNC (30L/min or 40% 以上)を使用しているか

③NIVを使用しているか

④人工呼吸器を使用しているか

⑤インフルエンザ感染が疑われるか確定している

⑥発症から入院までの日数

⑦パンデミック感染が疑われるか確定している

⑧24時間以内の死亡が想定され、かつ、本人、家族、あるいは臨床医が積極的治療を行わないと判断している

患者の研究参加の適格性の評価（ドメイン参加/除外）



Patients

Resources

Manage

Monitoring

Reports

Polaris Infirmery



Patient list

Eligibility List

Transfers

Add patient



Demographics

Platform Incl/Excl 1

Platform Incl/Excl 2

Platform Incl/Excl 3

Domain Incl/Excl

Contraindications

Consent

Patient Interest

Result

Domain incl/excl

- ① What was the date & time of the first known intravenous antibiotic administered for this illness ⓘ
Include an IV antibiotic given in the community if known. : ☐ None given
- ② Do you suspect methicillin-resistant Staphylococcus aureus (MRSA) infection ⓘ
An organism that is resistant to oxacillin or dicloxacillin or flucloxacillin
- ③ Is standard empiric antibiotic therapy for community-acquired pneumonia appropriate ⓘ
Bacterial infection is a strong possibility and standard empiric therapy is appropriate. Consider if therapy with alternative antibiotic(s) is indicated (e.g. colonisation with resistant organism, immunosuppression, known microbiological results). Note that bacterial co-infection with COVID-19 is uncommon; empiric antibiotic therapy is appropriate only if bacterial co-infection is strongly suspected.

or [Cancel](#)

① 最初の抗菌薬の投与日時(24時間表記)

② MRSA感染が疑われるか

③ 市中肺炎(CAP)としての抗菌薬治療が適切か

(耐性菌や免疫不全患者などで、市中肺炎の抗菌薬が不適切な場合は除外になる)

患者の研究参加の適格性の評価（禁忌薬）



Patients

Resources

Manage

Monitoring

Reports

Polaris Infirmary



Patient list

Eligibility List

Transfers

Add patient



Demographics

Platform Incl/Excl 1

Platform Incl/Excl 2

Platform Incl/Excl 3

Domain Incl/Excl

Contraindications

Consent

Patient Interest

Result

Contraindications

Does the patient have contraindications to any of the following

A clinical reason why a specific medication or intervention should not be administered. Please answer ALL questions

Penicillins

Including any history of anaphylaxis, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis with penicillin or any beta-lactam

Yes

No

Cephalosporins

Including any history of anaphylaxis, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis with cephalosporins or any beta-lactam

Yes

No

Quinolones

Known previous adverse drug reaction

Yes

No

Macrolides

Including risk of ventricular dysrhythmia sufficient to not prescribe a macrolide

Yes

No

Next


or [Cancel](#)

ペニシリン、セファロスポリン、キノロン、マクロライド

それぞれに禁忌がないか


（禁忌にはアナフィラキシー、スティーブン・ジョンソン症候群、中毒性表皮壊死症、心室性不整脈などを含む）

患者の研究参加の適格性の評価（患者の同意）



PatientsResourcesManageMonitoringReports

Patient listEligibility ListTransfersAdd patient



DemographicsPlatform Incl/Excl 1Platform Incl/Excl 2Platform Incl/Excl 3Domain Incl/ExclContraindicationsConsentPatient InterestResult

Current Assessment

Antibiotic Consent must be collected within 24 hours of ICU admission i.e. before 23-Jul-2023 13:30
Macrolide duration Consent must be collected within 24 hours of ICU admission i.e. before 23-Jul-2023 13:30

All remaining domains require prospective consent

Consent

① This patient was entered as being in ICU and receiving organ support. Is this still correct

YesNo

② Have you gained consent from the participant/legal representative or, in Germany, do you have permission to enrol the patient without prior consent into at least one domain

Select

③ Proceed with eligibility or Cancel

現時点で組み入れ可能なドメインが表示される

①本患者は現在もICUに入室し、臓器サポートを受けている状態であるかチェック

②患者あるいは、意思決定代替者からインフォームドコンセントを取得しているか

→「Yes」を選択すると、どの「ドメイン」のインフォームドコンセントを得たか選択する画面が出てくるので、それぞれチェック

③ “Proceed with eligibility” をクリック

患者の研究参加の適格性の評価（介入割り付け）



Patients

Resources

Manage

Monitoring

Reports

Polaris Infirmary



Patient list

Eligibility List

Transfers

Add patient



Demographics

Platform Incl/Excl 1

Platform Incl/Excl 2

Platform Incl/Excl 3

Domain Incl/Excl

Contraindications

Consent

Patient Interest

Result



Antibiotic domain

This patient is eligible for:

- IV Ceftriaxone + 3 days of IV Azithromycin
- IV Moxifloxacin
- IV Piperacillin-tazobactam + 3 days of IV Azithromycin
- IV Amoxicillin-clavulanate + 3 days of IV Azithromycin

← 組み入れ可能なドメイン

現時点で割り付け可能な介入が表示される

In the opinion of the treating clinician is allocation to any of the Antibiotic Domain options above appropriate for this patient

Yes

No



Macrolide duration domain

This patient is eligible for:

- Standard course IV Azithromycin (3 to 5 days)
- Extended course IV Azithromycin (14 days)

← 組み入れ可能なドメイン

現時点で割り付け可能な介入が表示される

In the opinion of the treating clinician is allocation to any of the Macrolide Duration Domain options above appropriate for this patient

Consideration should include risk of ventricular rhythm disturbance and QT prolongation

Yes


No

Confirm

or [Cancel](#)

各ドメイン内での割り付けられ得る介入が適切か確認
→問題なければ“Confirm”をクリック

患者の研究参加の適格性の評価（割り付け完了）



0899900030

Randomised 22-Jul-2023 17:59
Hospital ad. 22-Jul-2023 11:30
ICU ad. 22-Jul-2023 13:30

✓ Summary

✓ Eligibility

? Macrolide Reveal

? Domain V Reveal

✗ Baseline

✗ Microbiology

✗ Daily

✗ Medication

✗ Discharge


✗ Consent

✗ Day 90 - 20 Oct

✗ Day 180 - 18 Jan

Platform confirmed

Please PRINT this page and place it in an easily accessible place that bedside staff can view.

 Print this page

Patient 0899900030

Randomised 22-Jul-2023 17:59
age 63 has been enrolled in the REMAP-CAP Trial

← REMAP-CAP内での患者番号

Domain	Allocation Status
A Antibiotic Domain	IV Ceftriaxone + 3 days of IV Azithromycin 22-Jul-2023 17:59
M Macrolide Duration Domain	Reveal pending
V Ventilation Domain	Reveal pending

割り付けられた・今後割り付けられる可能性のあるドメイン

“Reveal pending”は現時点では明らかでないドメイン

This patient may be eligible for the Ventilation Domain

Check eligibility

What to do now ...

Antibiotic (A)

各ドメインの詳細が下に記載される

- Prescribe IV Ceftriaxone + 3 days of IV Azithromycin
- Next steps are outlined in the [Antibiotic Domain \(A\) Administration Guide \(pdf\)](#). Please print this and leave it at the bedside

Macrolide Duration (M)

作成者

第1版：吉田

第2版：2023/7/27 木庭

第3版：2023/8/07 木庭、吉田、一原